Medical treatment in Poland
– analysis and models

Volume II: Cardiology

Edited by

Barbara Więckowska

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Medical treatment in Poland – analysis and models

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In this publication, the authors present their own views, supported by in-depth analyses and many years of experience. The publication cannot be considered an official position of state authorities and bodies. The authors and the editing team are not liable for the application of guidelines, examples, information and solutions presented in this publication to specific medical cases.

Contents:

Foreword

Barbara Więckowska

This document constitutes another volume on the use of quantitative methods in the analysis of health care system in Poland. In this volume we concentrate on cardiovascular diseases. The publication has been prepared by the team of experts working for the project "Improving the quality of management in health care by supporting the process of developing regional maps of health care needs as a tool streamlining the management processes in the health care system – training in estimating health care needs", managed by the Department of Analyses and Strategy of the Ministry of Health, co-financed with the European Union funds under the European Social Fund and is one of three publications documenting the work results of the team. An expert working group on cardiac diseases, composed of cardiologists, epidemiologists, experts in social policy, health economists, demographers, statisticians, econometrists, and big data analysts, performed an in-depth analysis of the Polish cardiac care system. The initial focus is on the recorded and projected number of cardiac patients.

The purpose of the publication is to present a systemic approach to analysis of data collected by the Polish heath care system in the area of cardiovascular diseases in a way that ensures reliable data and projections, which constitute the basis of maps of health care needs for individual voivodeships and Poland as a whole. This is the first such detailed publication on cardiovascular diseases that is complementary to the data collected in some registers (such as the register of acute coronary syndrome) and that describes treatment pathways registered in the datasets of the public payer (National Health Fund) and carried out under the universal health insurance in Poland.

Maps of health care needs have been developed by a number of countries such as Austria, Czech Republic, and France. They are an important tool that supports evidence-based management in the health care system, in terms of both ensuring robustness of actions (partial independence from the political process and making decisions based on objective analyses) and supporting the process of explaining social policy to citizens, which can be very difficult, especially in the area of health care policy. For this reason, projecting future health care needs

has been significantly supported by the European Commission through the introduction of the so-called ex ante requirements. According to the EU Regulation No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006 (OJ L 347, 20.12.2013, p. 320), disbursement of structural funds will depend on meeting the ex ante conditionality requirements, or ensuring fulfilment of specific entry conditions that allow efficient implementation of programmes co-financed with European funds. According to Annex XI to the above General Regulation, these requirements concern inter alia "The existence of a national or regional strategic policy framework for health within the limits of Article 168 TFEU ensuring economic sustainability" (conditionality 9.3).[1] *This framework should result from maps of health care needs.*

Regardless of European Union's requirements, Poland has planned its own system wide solutions for the development and use of maps of health care needs. The obligation to develop maps of health care needs in Poland was introduced by the Act of 22 July 2014 amending the Act on health care services financed with public funds and certain other acts (Journal of Laws of 2014, item 1138).[2] According to the Act, first maps of health care needs are to be developed by 1 April 2016 at the latest and will cover inpatient treatment.[3]

It does not mean, however, that the mechanism is new in Poland or that there had been no previous attempts to develop maps of health care needs. There were initiatives of this kind in previous years. In 1997, i.e. when regional health care funds were in place, Article 55a of the Act of 6 February 1997 on universal health insurance stipulated that local government bodies, having obtained the opinion of medical professional associations and in consultation with

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[1] Under thematic objective 9 of the Partnership Agreement (PA) – Promoting social inclusion, combating poverty and all forms of discrimination.

[2] The content of maps of health care needs is regulated by the Regulation of the Minister of Health of 26 March 2015 on the scope of contents of maps of health care needs (Journal of Laws of 2015, item 458).

[3] Pursuant to Article 19 of the Act, the first two editions of the maps will be developed by the minister competent for health. As to maps of health care needs beyond 2021, they will be developed by voivodes and by their Voivodeship Councils for Health Care Needs, with significant support from the National Institute of Public Health – National Institute of Hygiene.

the regional health care fund, shall develop a plan of securing outpatient health care.[4] Article 101 of the Act of 23 January 2003 on universal insurance in the National Health Fund (Journal of Laws of 2003, No 45, item 391, as amended) introduced the obligation of voivodeship authorities to develop voivodeship health care plans and the obligation of the Minister of National Defence, the Minister of Justice, and the minister responsible for internal affairs – to develop a plan of securing health care services for uniformed services5.

This publication is not a direct attempt at developing a map of health care needs for cardiovascular diseases *per se*. The purpose is to present data concerning a single but crucial area of cardiovascular diseases, namely incidence, i.e. to determine both current and projected levels of cardiovascular disease incidence, taking into consideration the allocation of patients into particular disease streams and the occurrence of the polypathology. Correct determination of current and historical values is the precondition for correct estimation of health care needs in the future.

It is possible to estimate the incidence of particular disease stream based on epidemiological studies or medical registers. Such studies are carried out in Poland and some medical registers already exist. However information gained from these sources is not sufficient to develop maps of health care needs. In the case of epidemiological studies the most detailed analysis in Poland was conducted in the area of myocardial infarctions, where the number of myocardial infarctions in Poland in years 2009–2012 was estimated on the basis of registered data, information on hospitalisation and information on deaths.[6] Myocardial infarctions, however, are only part of ischemic heart disease pathology, which in turn constitute about 30% of all cardiovascular diseases. Therefore such analysis is not sufficient for the predictive purposes, in particular due to the above-mentioned polypathology.

There are 3 medical registers in Poland for cardiovascular diseases: National Register of Acute Coronary Syndromes PL-ACS, National Register of Interventional Cardiology Procedures

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[4] The rules and conditions to be followed by a plan have been defined by Regulation of the Minister of Health of 10 October 2001 on the rules and conditions to be followed by a minimum plan of securing outpatient health care (Dz.U.01.121.1315).

[5] The rules and conditions to be followed by a plan have been defined by Regulation of the Minister of Health of 16 June 2003 on the conditions to be followed by voivodeship health care plans and on the scope of data necessary to develop such a plan (Dz.U.03.115.1087).

[6] AMI-PL Group (2014) Występowanie, leczenie i prewencja wtórna zawałów serca w Polsce Ocena na podstawie Narodowej Bazy Danych Zawałów Serca Raport AMI-PL 2009–2012.

(ORPKI) and National Register of Cardiac Surgeries (KROK). However, none of these registers is sufficiently complete to analyse the cardiovascular disease incidence rate and predict future values. The register of patients with acute coronary syndrome differs from the number of patients reported by the National Health Fund. The preliminary comparative analysis shows that the patients are not reported by all facilities. On the other hand, KROK is a register of cardiac surgeries and includes only one method of patient treatment. The third of these registers, ORPKI, again covers only a part of cardiovascular diseases and therefore cannot be used for designing a standardised method of analyses.

We have divided cardiovascular diseases into 15 sub-groups according to the 10th Revision of the International Statistical Classification of Diseases and Related Health Problems.[7] This publication focuses on cardiac diseases that form one of the main two streams of cardiovascular diseases[8]. To prepare a projection of incidence (the number of newly diagnosed cases of cardiac disease), it is necessary to: (i) define the forecasting methodology, in particular specifying the level of detail, and (ii) prepare the necessary historical data as the basis of estimation. As already mentioned, the results are to be used towards the development of maps of health care needs, in line with the Regulation, therefore the main objective of this publication is to determine the current incidence of heart disease in Poland, with the highest possible degree of precision, considering available data.

The publication is divided into two main parts: theoretical (Chapters I-II) and empirical (Chapters III-VIII). Chapter I by Ewa Kowalik presents the basic terminology used to talk about cardiovascular diseases. The author presents the wide range of causes, symptoms, and procedures of diagnosing and treating heart diseases. This chapter is a point of departure for further discussions. It emphasises the need for a more extensive analysis of co-existing cardiovascular diseases, because these diseases are usually chronic and, moreover, particular diseases are linked by cause-and-effect relationships.

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[7] Ischemic heart disease (I20, I21, I24, I25), heart failure (I50), atrial fibrillation and flutter (I48), other arrhythmia and atrioventricular blocks (I44-I47, I49), cardiomyopathies (I42, I43), congenital heart disease (Q20-Q26), acquired heart defects (I05-I09, I34-I37), pulmonary embolus (I26), endocarditis (I33, I38, I39), pericardium diseases (I30-I32), other diseases of pulmonary vessels (I27, I28), aortic aneurysm (I71), myocarditis (I40,I41), rheumatic heart disease (I00-I02), other heart diseases (not precise, not classified) (I51, I52).
[8] Peripheral vascular diseases will be covered by one of the future volumes in this series.

The second theoretical chapter by Jakub Witkowski covers a review of international experience in the methods of cardiovascular disease modelling. The author argues that regardless of the chosen study concept (statistical models vs. simulation models), it is of the utmost importance to apply scenario analyses at the same time to reduce projection uncertainty. At the same time the article deals with the problem of selection of decisive variables that are used in the cardiovascular diseases modelling and describes that in practice the key variables are determined by the type of model selected and by the scope of the available data.

Chapters III–VII contain empirical descriptive models for individual selected heart disease streams. In other words, they constitute the practical application of medical analysis and analytical models described in the theoretical part. Chapter III describes models for ischemic heart disease, Chapter IV – for acute coronary syndromes; the models for the arrhythmia and atrioventricular block are covered in Chapter V. Chapter VI deals with atrial fibrillation and flutter and the last chapter of this part, Chapter VII, concerns heart failure. The idea behind these chapters is to combine medical knowledge with statistical and IT knowledge. Therefore each chapter was written by a team of medical and analytical experts. Medical experts were Jacek Jagas – Chapter III, IV, Ewa Kowalik – Chapter V, VI, VII whilst the analysts were Beata Koń – Chapter III, Andrzej Tolarczyk – Chapter IV, Filip Urbański – Chapter V, VI, Janusz Dagiel – Chapter VII, Barbara Więckowska – Chapter IV, Chapter VI, Chapter VII. The content of each chapter is similar: discussion of medical aspects of diagnostics and treatment of a given disease stream is followed by a summary description of a treatment system in Poland, which will then be transferred on a decision tree pathway completed by empirical data recorded in 2013. The decision trees are the result of analysis performed by the expert working group for cardiology and were created on the basis of available foreign models, Polish treatment standards, and clinical expertise. The input data for the purposes of pathways was the number of new cardiovascular cases recorded in hospital treatment, however, articles include also cross-sectional data on predicted incidence estimated on the basis of reported services, regardless of the place of their provision (outpatient, emergency department or inpatient). Descriptive treatment models based on 2012 data form the final part of each chapter.

The last chapter of the book, co-authored by staff of the Department of Analyses and Strategy of the Ministry of Health, presents the projected cardiovascular disease incidence

in Poland for the years 2015–2025. The first part of this chapter presents the methodology for determining the number of new cases of a particular cardiovascular disease stream (15 disease streams were defined), using information reported to the NHF on services provided in outpatient, emergency department and inpatient settings for the period 2009–2014. It should be underlined that analyses differentiated between the types of provided services, because it was necessary to identify the patients, from the set under examination, who could have been registered in the public payer system for the first time since 2009, but who were not deemed to be newly diagnosed cases. On the basis of the analyses it was determined that in 2013 the incidence of cardiovascular disease events was about 745 thousand cases (with 367 thousand individual patients), and it will be gradually increasing to 857 thousand events (and 426 thousand patients) by 2025 (increase of about 15%). These results form a basis so that appropriate managerial decisions in the health care system can be made, taking into account an increase in the demand for health care services resulting from the increase in incidence.

We hope that the readers will find this publication inspiring and that it will contribute to greater understanding of quantitative methods used in the area of health management and thus that it will contribute to popularisation of those statistical tools of relevance for management. This is very important, since the development of health care system should be well-planned and based on thorough analyses of the current situation and on reliable forecasts, and not solely based on variable political decisions.

The authors would like to thank the reviewers of the publication, i.e. Professor Andrzej Wykrętowicz and Professor Bogumił Kamiński, for their valuable comments on the texts, which resulted in clarifying the topics discussed in individual chapters.

Characteristics of cardiovascular diseases – diversity of causes, symptoms and treatment methods

Ewa Kowalik

Introduction

Although heart diseases concern only one organ, they constitute a highly heterogeneous group of various conditions with different pathogenesis, including *inter alia* atherosclerotic cardiovascular diseases, congenital heart malformations, genetic cardiomyopathies or infectious diseases. The symptoms of heart disease are often non-specific (e.g. fatigue, dyspnoea, chest pain), thus it is often necessary to differentiate them from diseases of other systems. Each cardiovascular disease requires the application of different diagnostic and therapeutic algorithm. The treatment includes non-pharmaceutical measures, pharmacotherapy and procedures of interventional cardiology and cardiovascular surgery. The decisions concerning surgical treatment are made by a so-called heart team consisting of specialists in the field of *inter alia* interventional cardiology, cardiac imaging (echocardiography, radiology), electrophysiology, cardiovascular surgery and anaesthesiology, depending on the patient's condition and the type of procedure. The prognosis in patients depends to the large extent on the presence of coexisting conditions. The vast majority of patients require life-long cardiac care.

Since many cardiovascular risk factors can be modified (smoking, improper diet, insufficient physical activity, arterial hypertension, lipid and carbohydrate metabolism disorders, excess weight and obesity), the prevention is very important, i.e. identifying, evaluating and undertaking actions modifying or eliminating identified risk factors.

The cardiovascular conditions have particular characteristics, which differentiate them from diseases of other systems. It should be underlined that:

- heart diseases constitute a highly heterogeneous group, from very common civilisation diseases to those fulfilling the criteria of rare diseases;

- the symptoms of a disease are often preceded by a period without symptoms (e.g. asymptomatic left ventricular dysfunction, stenosis in coronary vessels without angina pectoris) and the first symptom of a disease might be sudden cardiac death;
- there are many causal relations between the particular conditions (e.g. patient after myocardial infarction may develop heart failure or ventricular cardiac arrhythmias), which sometimes may be bi-directional in nature (e.g. in the course of heart failure the significant secondary mitral regurgitation may appear, but also the primary mitral regurgitation may be the cause of heart failure);
- the vast majority of heart diseases are chronic (excluding uncomplicated myocarditis or pericarditis or heart failure caused by reversible factor) – patients require life-long cardiac care;
- in the course of cardiovascular disease potentially fatal conditions may occur, requiring urgent application of intensive treatment in hospital, including interventions (e.g. acute coronary syndrome).

In this chapter the epidemiology of heart disease and risk factors, with particular focus on the primary and secondary prevention are described. The diagnostic and therapeutic methods applied in this group of conditions are presented.

The basis for the classification and epidemiology of heart disease

Cardiac diseases are classified according to the International Statistical Classification of Diseases and Related Health Problems ICD-10 (WHO 2008). In practice this classification is used for epidemiological purposes (monitoring incidence rate, prevalence and mortality) and other objectives related to the health care system management (including e.g. reporting).

The heart diseases are listed in chapter IX (Diseases of the circulatory system, I00–I99) and include:

- acute rheumatic fever (I00–I02) and chronic rheumatic heart diseases (I05–I09)
- ischemic heart disease (I20–I25), including myocardial infarction,
- pulmonary heart disease and diseases of pulmonary circulation (I26–I28),
- other forms of heart disease (I30–I52) – this section includes heart valve disorders, cardiomyopathies, arrhythmias and atrioventricular blocks as well as diseases of endocardium and pericardium.

Congenital malformations of heart (Q20–Q26) are listed in the chapter XVII of the Classification (Congenital malformations, deformations and chromosomal abnormalities).

The epidemiological data concerning heart diseases are usually presented together with peripheral vascular diseases as diseases of the circulatory system / cardiovascular diseases. The specific data concerning *inter alia* incidence rate and prevalence of the most frequent cardiovascular diseases are presented in chapters dedicated to the selected cardiac diseases.

In Poland increase of mortality due to cardiovascular diseases was recorded in the 70s and 80s, followed by stabilisation in 1991, and then this trend was reversed (Wojtyniak 2003). The increase in the life expectancy registered since 1991 is due in 51% of women and 61% of men to the reduction of mortality rate due to cardiovascular conditions. However, the diseases of the circulatory system still constitute the most common cause of death in Poland – in 2010 40.8% of deaths among men and 51.8% among women were caused by cardiovascular conditions (Wojtyniak 2012). According to the National Health Survey WOBASZ and WOBASZ Senior in the period of 8 years (since 2012) mortality due to the diseases of the circulatory system accounted in the cohort of WOBASZ survey (people aged 20–74 years) for 38% of the total number of male deaths and 31% of female deaths. The ischemic heart disease and cerebrovascular diseases constituted the most common cause of death due to cardiovascular conditions in men (33% and 17%, respectively), whereas among women the most common were cerebrovascular diseases (31%) and second was ischemic heart disease (23%). In the older cohort of WOBASZ Senior survey the mortality due to cardiovascular diseases accounted for 48% of the total number of male deaths and 58% of female deaths (in the 5 year observation period). The most common cause of death was the ischemic heart disease (29% in men and 24% in women), followed by cerebrovascular diseases (16% and 21%, respectively) (Piotrowski 2015). These observations are confirmed by the data from the National Hygiene Institute (PZH), according to which the main cause of death in the whole Polish population aged over 64 years are diseases of the circulatory system and in the younger age group they are on the second place after external causes in case of men and neoplasms in case of women. The main cause of death among diseases of the circulatory system include: ischemic heart disease, including myocardial infarction (in 2010 45.8 thousand deaths, including myocardial infarction 17.8 thousand, i.e. 26% and 10% deaths due to cardiovascular conditions, respectively), cerebrovascular diseases (35.6 thousand deaths, 20% of the whole

group) as well as pulmonary heart disease and other forms of heart disease (51.5 thousand deaths, 30%) (Wojtyniak, 2012). The authors of the report point out that forms of heart disease other than ischemic heart disease have become more common cause of death in Poland. The mortality due to the pulmonary heart disease and the other forms of heart disease (I26-I51 according to ICD-10 classification) is significantly higher than the average mortality in the European Union (in general men die due to these diseases over two times more often and in the age group 25–64 years even three times, whereas in case of women this indicator is 67% higher overall and in the age group 25–64 years – 120%) (Wojtyniak, 2012).

In Poland the age standardised mortality rate due to diseases of the circulatory system is still 50% higher than the EU average (43% in women, 58% in men), whereas it is 14% lower in comparison to average standardised rate for the WHO European Region (Jankowski, 2014).

Ethiopathogenesis and pathophysiology of selected cardiac diseases

As already mentioned in the introduction, heart diseases are characterised by great diversity. Describing an etiopathogenesis of even few most common conditions goes beyond the scope of this paper, thus the information concerning only two of them: ischemic heart disease and heart failure have been presented.

The ischemic heart disease is a group of symptoms caused by the disproportionality of supply of the nutrients to the myocardium and its metabolic demand, which results in ischemia or hypoxia (Montalescot, 2013). The oxygen and nutrients are delivered to myocardium through the coronary arteries emerging directly from the ascending part of the aorta. The most common cause of ischemic heart disease is atherosclerosis of these vessels. The normal coronary arteries have flexible, smooth surface and can control the blood flow depending on needs (during physical activity the flow of blood through the coronary vessels can increase several times). The damage of inner membrane of arteries caused by increased cholesterol concentrations in the blood, constituents of tobacco smoke and arterial hypertension result in the development of atherosclerotic plaque in the wall of vessel, consisting of lipid molecules, blood platelets, fibrin and calcium salts. Such a structure directed inwards of the vessel lumen reduces its diameter and locally hinders the blood flow. Apart from the presence of atherosclerotic plaque in the etiopathogenesis of ischemic heart disease, the loss of

autoregulatory properties by the vascular endothelium, which prevents the vasoconstriction, also plays an important role (Beresewicz 2011). Finally, the reduction of blood flow in the coronary vessel gives clinical signs of myocardial ischaemia, i.e. exercise angina and angina at rest. The developed atherosclerotic plaque and the endothelial dysfunction promotes coagulation processes in the artery. The damaged atherosclerotic plaque accompanied by thrombosis may cause a complete arterial blockage and clinical symptoms of myocardial infarction, i.e. necrosis of myocardium supplied by closed vessel (Thygesen, 2012).

The heart failure is the result of the damage of myocardium, which is most frequently caused by ischemic heart disease, arterial hypertension and less frequently by heart defects, cardiomyopathies and other conditions. Irrespective of the origin of cardiac failure, the volumetric overload of the heart causing the increase of pressure on the heart walls and thereby increasing the need of myocardium for oxygen can be observed. In consequence the neurohormonal regulatory mechanisms in the organism are activated, including the activation of renin-angiotensin-aldosterone system and sympathetic system and excessive production/release of angiotensin II, noradrenaline and aldosterone (Beręsewicz, 2010). This phenomenon leads to further dysfunctions of the myocardium and its damage. The presented pathophysiological phenomena lead to a vicious circle resulting in the constant progression of the disease (Kuch, 2003).

The basic risk factors of cardiovascular diseases include modifiable factors (i.e. they can be influenced by modifying the lifestyle or therapy) and not modifiable factors (i.e. they cannot be effectively addressed). The knowledge of risk factors is crucial for prevention of heart diseases so that risk factors on which we can have impact can be evaluated, identified and modified or eliminated.

The cardiovascular risk factors, which can be modified, include:

- incorrect diet,
- smoking,
- too little physical activity,
- high blood pressure,
- lipid disorders (increased blood LDL-cholesterol concentration, low HDL-cholesterol concentration, elevated triglycerides),

– carbohydrate metabolism disorders (impaired glucose tolerance or diabetes),

– excess body weight (overweight or obesity).

Following factors cannot be modified:

– age (men ≥45 years, women ≥55 years),

– sex (greater risk in men than in women before menopause),

– family history of disease (early onset of the atherosclerotic cardiovascular diseases).

Furthermore, there are so-called new factors and markers, including inflammatory markers (hs-CRP, fibrinogen) and thrombotic biomarkers (homocysteine, lipoprotein-associated phospholipase A2), which are important for evaluating the cardiovascular risk

The presence and relevance of cardiovascular risk factors have been the subject of many large-scale surveys. Based on the results of the INTERHEART survey covering 52 countries worldwide, it was concluded that the risk of ischemic heart disease is influenced by nine independent factors, i.e. arterial hypertension, lipid disorders, abdominal obesity, diabetes, smoking, psycho-social factors, low physical activity, low consumption of fruit and vegetables and excessive alcohol consumption. This survey revealed that in total those factors are responsible for 90% of myocardial infarctions in men and 94% women (Yusuf, 2004).

The multi-factorial character of cardiovascular diseases risk is reflected in the tables, which aim to evaluate risk in the seemingly healthy people. The patients after clinical incident (e.g. after myocardial infarction and stroke) are automatically qualified for evaluation and intensive treatment of risk factors. The recommended SCORE scale evaluates 10-year risk of first fatal incident of atherosclerotic aetiology, i.e. myocardial infarction, stroke, aortic aneurysm or other episode based on age, sex, smoking, blood pressure and cholesterol concentration of a given person (Perk, 2012). A new version of the Systematic Coronary Risk Evaluation and SCORE tables for the population of Poland were created in 2015 (Zdrojewski, 2015).

The heart diseases may have a subclinical character for some time. The symptoms are often non-specific and it is necessary to differentiate them from diseases of other systems. Sometimes the first symptom of the heart disease may be sudden cardiac arrest. While interviewing a patient with suspected or diagnosed heart disease the cardiovascular risk factors should be taken into consideration, such as life style, consumption habits, smoking, coexisting diseases (diabetes, lipid disorders) and family history. The most frequently reported

symptoms include: decrease of exercise tolerance, dyspnoea at rest / exertional dyspnoea, pain in the chest, palpitation, syncopes. The angina in the chest is a sensation of pressure, squeezing, discomfort, heaviness in the retrosternal area. The pain may radiate to a jaw, neck or shoulder. The occurrence of pain, lasting usually a few minutes, is most often caused by a physical exertion (but can also be caused by a substantial meal, exposure to frost or wind, or emotions) and the symptoms subside after stopping physical activity or using nitroglycerin. The syncope is defined as a transient loss of consciousness caused by a reduction of cerebral perfusion characterized by a sudden onset, short duration and spontaneous recovery. A detailed medical history concerning the character of symptoms (e.g. pain in the chest) and the circumstances of their occurrence (e.g. syncope during exertion) facilitate accurate differential diagnosis.

During the physical examination in patients with cardiac diseases the edema (generalised edema), hepatomegaly and excess filling of jugular veins can be observed. The above-mentioned features occur in patients with heart failure. While performing the auscultation of patient's heart one should pay attention to: fast or irregular pulse rate (in arrhythmias, heart failure), improper accentuation of tones and presence of additional tones (in heart defects and in heart failure) pathological murmurs (in acquired and congenital heart defects and in case of infectious endocarditis), pericardial rub (in pericarditis) and the features of pulmonary circulation stagnation (in heart failure). The evaluation of heart rate, including frequency, regularity, amplitude, duration of the systole might be helpful in diagnosing *inter alia* heart defects, cardiac tamponade, arrhythmias, heart failure, shock and conditions of aorta. In some cases, e.g. in patients with stable coronary heart disease no abnormalities are found during the physical examination.

The screening and diagnosis of cardiac diseases

The cardiovascular diseases fulfil the criteria for mass screening in order to prevent their development because:

– they have a significant impact on the length and the quality of patients' life,
– their treatment methods are commonly available,

- they are characterised by the occurrence of sub-clinical period; diagnosing and treating a condition in this period significantly reduces the prevalence and mortality and the treatment result is better than when symptoms actually appear,
- the cost of screening is justified by the high incidence in the population.

The prevention programmes for the diseases of the circulatory system were developed at the European, national and regional level (Jorgensen, 2013). The European Heart Health Charter was developed by the European Society of Cardiology and the European Heart Network, with the support of the European Commission and the Regional Office of the World Health Organization and is designed to support the development and implementation of comprehensive health strategies, as well as undertakings and political actions at the European, national, regional and local level aimed at health promotion and prevention of cardiovascular diseases. The declaration was developed *inter alia* in order to place fighting cardiovascular diseases higher in the hierarchy of political objectives of the European Union and individual Member States.

The declaration signed by the European Parliament in 2007 and adopted by the majority of EU Member States included the characteristics associated with cardiovascular health constituting of following elements:

- no use of tobacco;
- adequate physical activity: at least 30 minutes 5 times a week
- healthy eating habits,
- normal weight,
- blood pressure <140/90 mm Hg,
- blood cholesterol <5 mmol/l (190 mg/dl),
- normal glucose metabolism,
- avoidance of excessive stress.

In 2009 this document was signed by the Minister of Health of Poland. Moreover the European Society of Cardiology together with other scientific societies for the fifth time published the updated guidelines concerning the prevention of cardiovascular diseases in the clinical practice (Perk, 2012). According to the guidelines an ideal outcome would be to include all adults in the evaluation of the risk of cardiovascular diseases, however in practice a decision about the cohort covered by screening is made by the individual countries. It is

recommended to consider performing the evaluation of risk factors, including lipid profile, among men aged over 40 years and women aged over 50 years or after menopause. The total risk shall be evaluated during a medical consultation, if:

- a person asks for it,
- one or more risk factors are present,
- the patient has a family history of premature cardiovascular disease or main risk factors,
- the symptoms indicating a disease of the circulatory system have appeared.

In 2011 the Working Party of Polish Forum for Prevention of Cardiovascular Diseases published the guidelines concerning the role of screening in the prevention of diseases of the circulatory system in Poland (Windak, 2011). The guidelines recommend:

- measuring the blood pressure among everyone not diagnosed with arterial hypertension, from the age of 3 at least once a year, and more frequent measurements among children with blood pressure values between 90 and 95 percentile and in adults with range 120–139/80–89 mm Hg,
- screening of total cholesterol concentration in healthy adults every five years, with first measurement at the age of 20,
- the complete diagnostics of lipid disorders in patients with high cardiovascular risk,
- diagnosis of lipid disorders among children over 2 years with family history of lipid disorders, other risk factors or unclear family history,
- fasting glucose level in all patients over 45 years performed every 3 years, aimed at early diagnosis of diabetes; and in case of impaired fasting glucose –oral glucose tolerance test (patients with high cardiovascular risk and pre-diabetes should undergo screening every 1–2 years regardless of patient's age).
- evaluating smoking in case of every patient aged 10 and more, and ensuring a minimal anti-smoking intervention for smokers in line with the scheme Ask-Advise-Evaluate-Help-Plan,
- determining the body mass index (BMI) and waist circumference in overweight every 2 years and ensuring that overweight (BMI >25 kg/m2) and obese (BMI >30 kg/m2) patients or patients with abdominal obesity have an individual education plan in terms of lifestyle and training of appropriate skills,

- all patients aged over 13 years should be asked about the amount and frequency of alcohol consumption and the number of days per week without alcohol,
- urinalysis in all patients over 55 years and in patients with high risk of kidney disease (diagnosed diseases of the circulatory system, diabetes, arterial hypertension, diagnosed chronic kidney disease among close relatives) – estimating the glomerular filtration rate.

The main preventive actions on the national level include the National Health Programme for years 2007–2015, where the first strategic objective is to reduce incidence and premature mortality due to cardiovascular diseases, including strokes (Kuszewski, 2007). The operational objectives of the Programme (concerning the risk factors and action in the field of health promotion) include:

- reduction in smoking,
- changing the structure of alcohol consumption and reducing alcohol-related health damages,
- improving the diet and the nutritional quality of food and reducing the obesity prevalence,
- increasing the physical activity of population.

Apart from recommended screenings, the examinations performed in the diagnosis of heart diseases include: electrocardiography and methods of prolonged ECG monitoring, blood tests, imaging procedures, functional and invasive tests.

The standard 12-lead electrocardiogram provides information about the frequency and type of heart rhythm, arrhythmias and atrioventricular blocks, occurrence of ischaemia, past myocardial infarction and other less common irregularities. In patients with suspected arrhythmia, which was not identified in standard electrocardiogram, more intensive and longer methods of ECG monitoring are used, i.e. Holter ECG monitoring (lasting from 24 hours to 7 days), registering and transferring the ECG recordings by phone, using devices activated automatically or by a patient, as well as external and implantable loop recorders.

In case of the laboratory testing the most frequently analysed parameters include:

- cardiac necrosis markers (preferably cardiac troponin I or T, which is characterised by nearly complete specificity for cardiomyocytes and high sensitivity), used primarily in

diagnosing of acute coronary syndromes. Higher concentration of cardiac troponins indicates also worse prognosis in acute coronary syndromes, heart failure and pulmonary embolism (Orzechowski 2007),

– natriuretic peptides (natriuretic peptide B [BNP] and N-terminal pro-B type natriuretic peptide [NT-proBNP]), hormones secreted by the cardiac tissue in response to the increased filling of any cardiac cavities The high negative diagnostic value of the test allows to exclude heart failure and differential diagnosis of dyspnoea; the measurement is also applied to evaluate the prognosis in monitoring the treatment of heart failure and evaluating the risk in acute coronary syndromes, pulmonary arterial hypertension and stenosis of aortic valve.

– D-dimer, the concentration of which increases in the serum in case of acute blood clot due to the simultaneous activation of coagulation and fibrinolysis.

In cardiology the most commonly used imaging technique is echocardiography. This method is characterized by the greatest accessibility, relatively low cost, not preparation required for the patient and there are practically no contraindications. The ultrasonic heart examination evaluates the cardiac cavities and the thickness of the left ventricular muscle, the total and segmental contractility of the left ventricle and the left ventricular diastolic function, morphology and function of heart valves, the estimated pressure in pulmonary circulation and the pericardium (Kasprzak, 2007). In the cardiac diagnosis, apart from the most frequently applied standard transthoracic examination, the stress echocardiographic study and transoesophageal examination are also used. Moreover imaging examinations in cardiology include computerised tomography and heart magnetic resonance imaging. A CT scan enables to evaluate coronary vessels in non-invasive way (calcifications and stenosis), large blood vessels (artery, veins and pulmonary arteries) and incorrect structures inside and outside myocardium. The CT involves the application of ionizing radiation and the administration of contrast media. The magnetic resonance imaging of heart enables to perform the morphological and functional evaluation of heart with the measurements of the volume and mass of ventricles, the analysis of blood flow and identifying abnormalities of the myocardium (necrosis, myocarditis). Unfortunately magnetic resonance is characterised by the lowest accessibility and cannot performed in patients with implanted metal devices with ferromagnetic properties (e.g. pacemaker or cardioverter-defibrillator).

Among the functional tests particular attention should be given to tests used in the diagnosis of ischemic heart disease: cardiac stress test and stress imaging, including echocardiography, perfusion scintigraphy of myocardium [single-photon emission computed tomography (SPECT) or positron emission tomography (PET)] and stress magnetic resonance imaging of heart (Montalescot, 2013). In case of patients with chronic heart failure the ergospirometry is applied (the stress test with the analysis of respiratory gas), which facilitates the determining of prognosis and indications for heart transplantation. In addition this test is used in patients with pulmonary arterial hypertension, congenital heart defects, in cardiac rehabilitation and sport cardiology (Stankala, 2008).

Finally, to diagnose some cardiac diseases it is necessary to perform invasive tests, including coronarography (the 'gold standard' in case of evaluating the coronary arteries), cardiac catheterization (including the pulmonary resistance evaluation in patients with pulmonary arterial hypertension or under the qualification for heart transplant) and electrophysiological study (recording intracardiac electrical signals performed to diagnose arrhythmias and less frequently atrioventricular blocks).

Baseline treatment of cardiac diseases

Guidelines concerning treatment regimens in heart diseases are developed by international groups of experts (recommendations of European Society of Cardiology) and based on scientific study results (evidence-based medicine, EBM). Treatment procedures include conservative methods (non-pharmacological and pharmacological treatment) as well as interventional procedures.

Due to a broad range of currently available therapeutic methods, decisions concerning surgical treatment (or the disqualification from such treatment) are often made by a so-called heart team consisting of a number of specialists in the field of *inter alia* interventional cardiology, cardiac imaging (echocardiography, radiology), electrophysiology, cardiovascular surgery and anaesthesiology, depending on the patient's condition and the type of procedure.

The main non-pharmacological interventions include actions aimed at changing lifestyle, i.e. quit smoking programmes, strict blood pressure monitoring, dietary consultations and body weight control, as well as encouraging physical exercise.

Pharmacotherapy in cardiology is divided into two main areas:

– pharmaceuticals administered in order to improve prognosis and reduce fatality rate (such as beta-adrenolytics, renin-angiotensin-aldosterone system (RAAS) inhibitors, antiplatelet and hypolipidemic drugs)
– drugs administered in order to reduce/eliminate disease symptoms (e.g. antianginal drugs in ischemic heart disease or diuretics in heart failure).

Invasive treatment in cardiology includes a broad range of procedures:

– revascularization in stable IHD and acute coronary syndromes (percutaneous transdermal angioplasty of coronary arteries, usually involving stent implant, including drug-eluting stents and bioresorbable stents, as well as coronary artery bypass surgery (CABG), optimally with inserting arterial bypasses),
– surgical correction of congenital heart defects (mainly surgical valvuloplasty involving for example insertion of rings/artificial chordae tendineae or mechanical/biological valve replacement, as well as percutaneous aortic or pulmonary valve implantation or repair of mitral regurgitation),
– insertion of implantable devices (artificial cardiac stimulation systems, cardioverter defibrillator, cardiac resynchronization therapy system),
– radiofrequency ablation (most frequently transvenuous, less frequently intraoperative) of arrhythmia,
– in extreme cases of heart failure - cardiac mechanical support and heart transplant.
–

Prognosis and monitoring of the patient after cardiac treatment

Long-term prognosis in patients with heart diseases is influenced by a number of factors. The most frequently listed ones include: age of a patient, comorbidity, intensification of clinical symptoms (cardiac stress, angina) as well as the advancement of cardiac disease and depression. Comorbid conditions that worsen prognosis in patients following myocardial infarction with ST elevation include disorders of carbohydrate metabolism and kidney disease. In patients with heart failure, also anemia and hyperuricemia have negative influence on prognosis. In patients with IHD and heart failure prognosis is worse in case of lower left ventricular ejection fraction. In case of IHD the image of lesions in vessels (location and size) also influence prognosis.

For some clinical situations dedicated prognostic scales have been developed (taking into account of patient's history, physical examination and clinical data), which estimate the risk of death within a defined period since the incident (Morrow and Antman scale, GRACE sale in acute coronary syndromes).

The majority of cardiac diseases are chronic and frequently require life-long integrated medical care (including permanent supervision by primary care physician, cardiologist as well as other highly specialized doctors, including cardiac rehabilitation).

Cardiac rehabilitation, patient education programme as well as strict monitoring of risk factors improve prognosis and quality of life of people suffering from cardiac diseases and belong to cost-effective medical interventions. It has been proven i.a. that a comprehensive cardiac rehabilitation of patients with heart failure decreases the risk of rehospitalization by 28% (Jankowski, 2013). Comprehensive cardiac rehabilitation programmes should be obligatory for patients after coronary artery bypass graft (or other cardiac surgery), patients with stable IHD (including following the planned coronary angioplasty), patients following acute coronary syndrome and patients with heart failure.

Cardiac rehabilitation is divided into early (stage I and II) and late (stage III) one. The model of rehabilitation programme depends on physical fitness of the patient and the estimated risk of adverse events. The first stage of cardiac rehabilitation should be started as early as possible during hospitalization, and should be continued until the patient is discharged from the hospital. The second stage of cardiac rehabilitation (from 4 to 12 weeks) may take place in cardiac rehabilitation centres (cardiac rehabilitation wards, cardiac rehabilitation hospitals and cardiac rehabilitation facilities located in destination spas) or at ambulatory cardiac rehabilitation centres or at home. The third stage (late cardiac rehabilitation) aims at sustaining the hitherto effects of therapy and rehabilitation and at minimising the risk of relapse and should be conducted life-long under the supervision of a specialized cardiac rehabilitation therapist, cardiologist or primary care physician (Smarż, 2008).

Following hospitalization due to heart failure (de novo or due to exacerbation of disease) patients require intensive ambulatory care, the aim of which is to educate patients (including to self-monitor their clinical condition and to possibly implement certain actions, avoid factors which result in disease exacerbation), to optimise pharmacological therapy and to provide

patient with psychological and social support. Regular check-ups enable early detection of worsening clinical condition and provision of required socio-psychological support. Patients with heart failure should be able to consult a specialist in a highly specialised cardiac clinic (Dickstein, 2008).

Patients with coronary heart disease, including patients following acute coronary syndrome, are obliged to regularly control modifiable risk factors. The frequency of check-ups depends on their exacerbation and clinical symptoms of angina pectoris - usually in the first year of treatment a patient should undergo regular check-ups at an ambulatory facility approx. every three months, and in the subsequent years (if the disease is stable) - every six months.

In patients with implanted pacemaker or cardioverter-defibrillator it is necessary to carry out regular check-up of the device operation. It is done at a facility that is equipped with a programmer, which reliably assesses the efficiency of the implanted device.

Patients with valve failures require cardiac examination with imaging (echocardiogram) in intervals ranging from 6 months to 3 years, depending on the advancement of failure and patient's clinical condition. Patients with implanted valves also require cardiac care for their lifetime; the frequency of imaging examinations in that case depends on the type of implanted valve and possible appearance of new symptoms (Vahanian, 2012). Patients with congenital heart defects require highly specialized care in reference centres, patients with severe defects should be consulted minimum once a year in order to detect, as early as possible, remote consequences and complications of previously conducted surgeries (Baumgartner, 2010).

Summary

Cardiac diseases are a very heterogeneous group of diseases and feature a number of specific characteristics that make them distinct among the diseases of other body systems. Cardiac diseases remain the main cause of death, especially in elderly people, and the statistics for Poland in this respect are very unfavourable as compared with the average for the EU Member States. Since many cardiovascular risk factors can be modified (smoking, wrong diet, insufficient physical activity, arterial hypertension, lipid and carbohydrate metabolism

disorders, excess weight and obesity), taking preventive actions is crucial for avoiding cardiac diseases.

Guidelines concerning treatment regimens in cardiovascular diseases are developed by international group of experts - members of European Society of Cardiology, and based on scientific study results. Treatment procedures include conservative methods (non-pharmacological and pharmacological treatment) as well as surgery. Due to a broad range of currently available therapeutic options, decisions concerning surgical treatment are made by a heart team consisting of a number of specialists.

Long-term prognosis in patients with heart diseases is influenced by a number of factors; the most frequently listed ones include: age of a patient, comorbidity, intensification of clinical symptoms as well as the advancement level of cardiac disease and the degree of heart muscle damage. The majority of cardiac diseases are chronic and frequently require life-long medical care (including permanent supervision by primary care physician, cardiologist as well as other highly specialized doctors, including cardiac rehabilitation). Cardiac rehabilitation, patient education programmes as well as strict monitoring of risk factors improve prognosis of patients suffering from cardiac diseases.

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Quantitative approach to modelling prevalence in cardiology – an overview of international research

Jakub Witkowski

Introduction

Cardiovascular diseases are one of the major causes of death. Every year 31% of deaths worldwide are estimated to be due to cardiovascular diseases (World Health Organization, 2015). This number may increase in the future; according to AHA (American Heart Association) estimations, by 2030 approx. 40.5% of the US population may suffer from some form of cardiac disease, and between 2010 and 2030 the costs of treating cardiac diseases are going to triple (cf. Heidenreich et al., 2011). Thus, quantitative modelling of cardiac diseases morbidity and development is vital, especially in the context of assessment of the corresponding intervention schemes as well as for the purpose of risk identification.

This publication aims at presenting quantitative approaches that are applied in studying prevalence processes in cardiology based on international study results. The modelling focuses on the following characteristic epidemiologic measures: incidence rate, prevalence and mortality. It is worth to point out that it is selected cardiac diseases which are subject to modelling rather than cardiac diseases in general. Incidence rate, prevalence and mortality are modelled for two purposes: prognostic (estimation of future values of previously mentioned variables, e.g. the number of people who will develop a given cardiac disease, which will enable the estimation of future costs of treating a given disease and the need for medical services) and explorative (studying the impact of exogenous variables on a selected endogenous variable, e.g. studying the impact of smoking on cardiac disease incidence rate, which will help assess to what extent the anti-smoking campaign will influence the cardiac diseases incidence rate). Various quantitative methods used for simulation or estimation statistics are applied to achieve those purposes. The methods have been described in the second part of this publication. The third part is dedicated to the role of scenario analysis, whereby various scenarios of future events development can be analysed for the purpose of

cardiac disease modelling. Part four of this publication describes decision variables that are used in modelling. Part five focuses on methods of estimating concrete models, and part six includes the summary of the overview.

Basic quantitative approaches in modelling the prevalence of cardiovascular diseases in international/foreign studies

The purpose of modelling the prevalence of cardiovascular diseases is to support decision makers in health-care system operation by identifying risk factors related with diseases, projecting prevalence (including incidence rate and mortality) and policy evaluation. The two basic approaches to the modelling of prevalence of cardiovascular diseases include estimation statistics and simulations.

Estimation statistics involves defining correlations between a variable under examination (e.g. mortality as a result of myocardial infarction) and exogenous variables (characteristics of a cohort or an individual), followed by estimation of impact indicators of each exogenous variable on the endogenous variable. Statistical modelling relies on data from various sources at various level of aggregation, depending on the assumed purpose of study.

Studies, the aim of which is to project future trends in mortality and incidence rate, usually make use of data originating from various sources, which is aggregated at the central (state) level (epidemiologic and demographic data). Frov, Capocaccio, Giampaoli, Verdecchia (1997) have used data from Italian offices of statistics and survival rate data collected under MONICA (*Multinational MONItoring of trends and determinants in CArdiovascular disease)* study programme (see: Luepker, 2011) in order to make projections of future trends of cardiovascular morbidity by means of APC (age-period-cohort) model. The APC model was also used for the purpose of projecting mortality due to ischemic heart disease in Sweden, based on data sourced from the Swedish office of statistics (Peltonen, Asplund, 1997). It has to be pointed out that the data concerning incidence rate and prevalence are often available only for certain areas of the country rather than for the whole country, this is why the results of such studies might not be representative for the whole cohort. An attempt at estimating incidence rate and prevalence for the whole cohort based on partial data is described by Giampaola, Palmieri, Capocaccio, Pilotto, Vanuzzo (2001). Alternatively Mathers, Loncar (2006) use macroeconomic

variables for estimating mortality due to cardiovascular diseases. It is worth mentioning that Bayesian inference is used for making projections of mortality due to coronary heart diseases (cf. Huovinen, Härkänen, Martelin, Koskinen, Aromaa, 2006).

Individual data, i.e. data concerning particular patients is usually used in studies which aim at identifying factors which impact a risk of a given cardiovascular disease occurrence. Such data can be collected as a result of follow-up studies during which patient's condition is checked in regular time intervals (e.g. every month). Pocock et al. (2006) make use of data pertaining to patients participating in CHARM programme (*The Candesartan in Heart Failure: Assessment of Reduction in Mortality and Morbidity*) which involved a follow-up examination within the period of 38 months. Based on that data statistical models are estimated, the purpose of which is to identify good variables, which enable making projections concerning deaths of patients suffering from chronic heart failure. Based on another follow-up study (Framingham Study), Kannel, Wolf, Benjamin, Levy (1998) identify factors which impact the risk of atrial fibrillation occurrence in patients. Follow-up studies may provide quality data, but they are usually very expensive and time-consuming. Apart from follow-up studies, case-control studies are also used for studying risk factors concerning cardiovascular disease development. During those studies, a sample of patients is compared with a sample of healthy cohort based on selected variables. Yusuf et al. (2004) presents results of that type of a study to identify factors which impact the risk of acute myocardial infarction. One has to remember that extrapolation of results of that type of studies onto a general case must be treated with a great degree of reservation (Weinstein, 2006). With each type of studies, data collection methods (and data quality) is crucial for making correct conclusions; this is why, if the data quality is disputed, the modelling results may turn out to be unreliable.

If statistical data quality is poor or if the data is unavailable (e.g. it cannot be collected in a short time), simulation models can be employed. Simulation methods are based on multiple repetition of a course of a given phenomenon that is described by means of mathematical equation systems (suggested by a scientist). Such a phenomenon may include e.g. a course of disease in a patient or change in health conditions of a certain social group. Based on simulation methods it is possible to make projections of future values of variables on which the scientists' interest is focused (e.g. incidence rate, prevalence or mortality) or to verify the

effects of intervention schemes (e.g. how big is the impact of the anti-smoking campaign on cardiac disease incidence).

State transition models are the first group of simulation models used in quantitative studies in cardiology. These models, based on Markov chains, simulate the transition of patient groups between the states that describe their health condition. Weinstein et al. (1987) described such a model, where the authors model coronary heart disease morbidity (the model is known in the literature as *Coronary Heart Disease Policy Model*). Based on this model, trends concerning incidence rate, prevalence and number of deaths due to coronary heart disease in the USA have been projected. The model contains three sub-models: demographic-epidemiologic, "bridge" sub-model and disease history sub-model. In an annual simulation cycle, the demographic-epidemiologic model groups of people aged over 35 who have never suffered from a coronary heart disease. Those people are assigned to one of 5400 patient groups (those groups are formed as a result of dividing a cohort of patients due to such features as: age, sex, smoking status, weight, blood pressure, cholesterol level), which feature a various probability of developing a coronary heart disease. If the coronary heart disease does occur, a patient concerned is moved to another sub-model (the "bridge" sub-model). And if the disease does not occur, the patient remains in the first sub-model until their death due to another cause. The period of time during which a patient remains in the "bridge" sub-model amounts to 30 days since the cardiac event. Depending on cardiac event type and patient's characteristics, the likelihood of the patient's death or survival is calculated. If the patient survives, he/she will be moved to the third sub-model: further living with coronary heart disease. In this part of the model patients are again divided into groups depending on their demographic characteristic, health condition and disease stage. The model parameters are estimated based on data from various sources (i.a. Health Interview Survey, Second Health and Nutrition Examination Survey), and then they are adjusted in a calibration process (cf. Weinstein, 2006). Examples of applying the *Coronary Heart Disease Policy Model* (or modifications thereof) include: estimating clinical morbidity due to ischemic heart disease and congestive heart failure in the Netherlands ((Bonneux, Barendregt, Meeter, Bonsel, Van der Maas, 1994), assessment of impact of cholesterol interventions (Goldman, Weinstein, Williams, 1989), expected gains in life expectancy from various coronary heart disease risk

factor modifications (Tsevat, Weinstein, Williams, Tosteson, Goldman, 1991). The RISC model described by Van Kempen et al. (2012) also is a state transition model.

Apart from models based on Markov chains, microsimulation models are a popular approach to modelling cardiac disease morbidity. They involve simulating the occurrence of disease events (e.g. coronary heart disease occurrence) in single cohort members (described by means of certain features which impact the probability of the event occurrence). Such a type of modelling is applied e.g. to trace treatment pathways for patients after cardiac event, which enables making estimations of future mortality due to those diseases (Cooper, Davies, Roderick, Chase, Raftery, 2002) or in order to assess the effect of prevention schemes (Babad, Sanderson, Naidoo, White, Wang, 2002).

When discussing simulation models it is also worth mentioning a PREVENT model which is used for assessing the effect of risk factor modification on cardiovascular disease incidence rate (Gunning-Schepers, 1988).

Although simulation models are very useful, especially for the assessment of actions taken towards risk factor modification, they also have some limitations. First of all, it must be remembered that the results of modelling depend strongly on the assumptions made (including on the equation system describing a given phenomenon), this is why it is so important to conduct sensitivity analysis, which is not always practiced, and to check if the model complies with empirical data (cf. Unal, Capewell, Critchley, 2006). Model quality assessment issues are also described in Kopec et al. (2010).

Both approaches to modelling cardiological disease prevalence have their strengths and weaknesses. The choice between them should depend on the goals of the analysis and on the data available. A comparison of strengths and weaknesses of estimation and simulation approaches is presented in Table 1.

Table 1. Comparison between estimation statistics and simulation methods
(source: own analysis).

	Statistical approach	Simulation approach
Weaknesses	- Making correct conclusions requires good quality data, which is difficult to obtain. - If data is available only for certain sub-cohorts, the results of the model application will not be representative for the whole cohort.	- Results are strongly dependent on the assumptions made with respect to a phenomenon under study. - Model quality is difficult to check.
Strengths	- Values of parameters calculated based on data map the reality. - It enables to analyse the impact of factors on values of endogenous variables.	- Many data sets may be used for building a simulation model. - The model reflects the whole process pathway. - It is possible to check how a process modification will impact the results obtained.
Recommendations for use	- Calculation of values of concrete parameters (e.g. effect of a given factor on the probability of developing a disease) - Projecting future values of endogenous variables.	- Analysis of impact of policy interventions on the process and values of endogenous variables. - Projecting future values of variables, which are subject to modelling.

The role of scenario analysis in international research on prevalence of cardiovascular diseases

Scenario analysis is a tool for projecting various possible future states of affairs. It involves considering a number of possible event scenarios and checking how prevalence will change depending on a given scenario. The scenarios may relate to introducing changes in health-care (e.g. increasing expenses on preventive actions or screening) or to changes in incidence rate trends (e.g. increased or decreased number of myocardial infarctions within a cohort). In

studies dedicated to health protection, scenario analysis is particularly important as it enables to assess the effectiveness of pro-health schemes and to estimate future costs of treatment, including prevalence based on an assumed change of disease spreading trends. A frequent approach used when developing scenarios to be applied in the subsequent analysis involves the development of at least 3 scenarios: pessimistic, baseline and optimistic one. A pessimistic scenario assumes trend worsening (e.g. increase of incidence rate due to a certain disease), the baseline scenario assumes a continuation of current trends, and the optimistic one - trend improvement. It is possible that some of those scenarios may seem unrealistic, however, their role is to indicate certain boundary values of variables studied. Scenarios drafted in this way may be widely used in statistical as well as simulation models.

In case of statistical models, scenario analysis involves forecasting future values of endogenous variable for different sets of values of exogenous variables. Many such scenarios are usually developed in order to check how the projection will change based on different realities. Such scenarios may be related to an uncertainty as to a future development of mortality trends due to a disease - e.g. Huovinen, Härkänen, Martelin, Koskinen, Aromaa, (2006) consider two scenarios assuming increase in mortality due to coronary heart disease or drop in the trend, respectively. Macro-economic situation may also be the subject of scenario analysis. Mathers, Loncar (2006) consider 3 scenarios, which assume different macroeconomic values (GDP, human capital) at various levels: baseline, optimistic and pessimistic one, which translates into various levels of cardiovascular incidence rate and prevalence.

In simulation models, scenario analysis involves modification of entry parameters and verification how the modification will influence the results obtained. A change in the number of smokers within a cohort or lowered average blood pressure in a certain cohort group may be examples of such a modification. Such scenarios are used for assessing intervention schemes in health-care service.

With the help of a simulation model based on Markov chains, Tsevat, Weinstein, Williams, Tosteson, Goldman (1991) verify, how the modification of factors such as cholesterol level, number of cigarettes smoked per day, weight or blood pressure relate to the increase of live expectancy. The study considers various levels of the parameters' modifications. Although the results obtained suggest that the impact of such modification at the cohort level is insignificant,

the model shows, however, that in case of individual patients, a modification in life expectancy may be quite significant. Based on the same type of model, Goldman, Weinstein, Williams (1989) compare two intervention schemes aimed at decreasing cholesterol level in blood: the first one is targeted at the whole population, and the other only at people whose cholesterol levels are too high. By comparison of the two scenarios of modifications of the cholesterol levels, future incidence rate of coronary heart disease is projected. Another example of analysis in which scenario analysis is used is the study by Bonneux, Barendregt, Meeter, Bonsel, Van der Maas (1994), in which three possible scenarios are assumed, in which the decrease in mortality due to cardiac diseases is explained in various degrees (low, medium and high) by a drop in the incidence rate. Another study, which is based on the *Coronary Heart Disease Policy Model,* is the study by Moran et al. (2010) in which scenarios serve for making projections concerning cardiovascular incidence rate and prevalence depending on risk factor trends (e.g. increase in BMI or the number of smokers are considered).

Decisive variables

The hitherto described models make use of a lot of decisive variables, i.e. exogenous variables that remain in a certain correlation (which is described by the model) with an endogenous variable, i.e. the variable studied. Since there are a lot of diseases that are of interest for cardiology, the sets of exogenous variables may be very different depending on a specific study. Variables may be divided into those which occur in almost every proposed model (e.g. demographic statistics such as age, sex, etc.) as well as those that appear only in a specific type of research (e.g. specific physical characteristics of individual patients). As the selection of variables is crucial for results obtained and for the quality of the model developed, it is important to carefully consider their use. Another important issue for the model quality is how a specific variable is going to be used in the model (e.g. patient's age may be taken account of as a continuous variable or discrete variable) and whether it is going to be subject to functional transformations (e.g. logarithmization). The decisions are crucial for the impact of exogenous variable on endogenous variable and should result from the expert knowledge on the subject.

Variables considered in international/foreign studies on prevalence of cardiovascular diseases, based on simulation models

In case of simulation models based on Markov chains (e.g. *Coronary Heart Disease Policy Model* and derivatives thereof, cf. Weinstein et al. 1987) endogenous variables are applied in order to divide cohorts into sub-cohorts (particular model cells). For people not suffering from coronary heart diseases (demographic-epidemiologic submodel) those variables include: age (as discrete variable, separate category for each value within the range 35-84 range), sex, smoking status (smoker/non-smoker), blood pressure (as discrete variable divided into 3 categories: below 95 mmHg, between 95-104 mmHg and above 105 mmHg), cholesterol level (below 250 mg/dL, between 250-299 mg/dL and above 299 mg/dL) and relative weight (below 110% of normal weight for a given person, between 110-129% and above 129% of normal weight). Grouping patients within the "bridge" sub-model is based on using age, sex and type of cardiac event that has occurred (the following are distinguished: angina, myocardial infarction, cardiac arrest and cardiac arrest accompanying myocardial infarction). The third sub-model (disease history) groups patients according to the following variables: type of cardiac event (state types depend on time which has elapsed since the first cardiac event), age and sex. Similar variables are used in the studies by Tsevat, Weinstein, Williams, Tosteson, Goldman (1991) and Goldman, Weinstein, Williams (1989).

Microsimulation models are also based on the above mentioned variables: sex, age, blood pressure, cholesterol level, smoking, e.g. in the study by Babad, Sanderson, Naidoo, White, Wang (2002). The authors point out that the set of variables could be extended to include physical activity, diabetes or alcohol consumption, but unfortunately it is impossible due to a lack of adequate data. In the study by Cooper, Davies, Roderick, Chase, Raftery (2002) variables also include patient's past history of diseases.

Variables considered in international/foreign studies on prevalence of cardiovascular diseases, based on estimation statistics

For a study in which estimation statistics are used, the selection of variables depends on a type of model and type of data to be used in the model.

In age-cohort-period models (APC cf. Frova, Capocaccia, Giampaoli, Verdecchia 1997; Peltonen, Asplund 1997) incidence rate or mortality projections are made using three types of effects: age, cohort (based on date of birth) and period (date of observation). Such models

usually assume logistic transformation of endogenous variable. An open question remains, how to measure age in such models, i.e. in what time intervals it should be measured. In the studies mentioned above, 5-year age intervals are used.

Authors of another study, which is based on a greater degree of data aggregations for projecting mortality due to cardiac diseases (Mathers, Loncar 2006), have made use of macroeconomic data, such as GCP per capita, human capital (measured by an average number of education years among adults) and time trend interpreted as a measure of technological progress in medicine. In addition, for certain diseases (including cardiac diseases) variables are used which describe the effect of smoking on mortality (measured as a percentage of deaths due to lung cancer resulting from smoking).

Studies that identify risk factors are based on individual data. Since such studies usually examine risk factors concerning a specific disease, sets of endogenous variables in such studies are extended to include factors specific for a given diseases. For example, in the study by Pocock et al. (2006), model estimations for patients with chronic heart failure have been based on variables which describe clinical characteristics: systolic and diastolic blood pressure, heart rate, symptoms of heart failure according to NYHA classification (discrete variable), ejection fraction and edema, apart from commonly used demographic-behavioural variables such as sex, age, smoker status - including a category of former smoker, weight and height). -Additionally, specific variables are used, which describe a patient's history of diseases (previous cardiac events, diabetes or cancer), aetiologies of heart failure, clinical proofs of cardiac diseases and data originating from ECG tests. In that study, some continuous variables (age, ejection fraction, BMI) have been categorized against their non-linear effect on endogenous variable. Kannel, Wolf, Benjamin, Levy (1998) study the effect of similar factor groups on atrial fibrillation (demographic, behavioural variables, disease history and ECG description variables). It should be noted that both studies consider different variables concerning ECG test. An extended set of demographic-behavioural variables is used for the purposes of some studies. For example, for estimating probability models concerning myocardial infarction based on case-control data, Yusuf et al. (2004) used variables concerning diet, physical activity or psychological characteristics of the subjects.

Methods of cardiovascular incidence rate and prevalence estimation applied in international/foreign research

The goal of estimation is to define values of parameters for a cohort based on data collected in a sample. What is characteristic for studies on cardiovascular diseases is that the investigators use many sources within one model and they make use of a number of various estimation methods simultaneously.

Coronary Heart Disease Model is the most important of all simulation models for modelling cardiac diseases (cf. e.g. Weinstein et al., 1987), i.e. the model of transition between states, based on Markov chains. This model is divided into three sub-models: demographic-epidemiologic, "bridge" and disease history. In the first sub-model, a cohort is divided according to demographic-behavioural variables into 5.4 thousand cells. For each cell estimation is made of the probability of transition to another state (transition to another cell due to change in demographic-behavioural factors or due to a cardiac event occurrence, which results in a patient's death or transition to another sub-model). These probabilities are estimated with the help of a risk function, which is an exponential approximation of a logistic function. Parameters of that function have been estimated based on data originating from a follow-up type of study (Framingham Study), and values of concrete probabilities have been estimated with the help of data from HANES (Health and Nutrition Examination Survey) study. In the second ("bridge") sub-model, a probability of patient's death within 30 days of cardiac event occurrence is estimated. Probabilities and treatment costs are estimated in each group based on data collected during statistical studies (i.a. Eisenberg, Bergner, Hallstrom 1979, Schaffer, Cobb 1975). The third sub-model deals with estimation of probabilities of occurrence of subsequent cardiac events in patients. Those estimations are based on variable sources of data, specific for particular cardiac events. Based on a model constructed in this way, estimations are made concerning future incidence rate in subsequent years (based on changes in the number of units in particular model cells) and prevalence in a given population.

In case of micro-stimulation modelling, distributions necessary to describe a frequency of cardiac events in patients (due to their characteristics) are estimated from various data sources. In the study by Babad, Sanderson, Naidoo, White, Wang (2002), distribution of event probabilities originate from the *Framingham Study*, and the data sourced from Health Survey

for England provides information on the cohort features. Other data sources are also used in the study for the purpose of parameter calibration and a subsequent model validation.

In case of studies which make use of statistical models for projections, the APC (age-period-cohort) model is frequently used. It has to be underlined that in case of projecting incidence rate, it is assumed that the disease cannot be cured (cf. Frova, Capocaccia, Giampaoli, Verdecchia 1997). In that model, the incidence rate is a polynomial function of age, period of study and a cohort. Parameters of that type of models are estimated from data at a cohort level while applying various methods (strict relation between particular model effects is a difficulty in estimation). For example, Frova, Capocaccia, Giampaoli, Verdecchia (1997) use the maximum likelihood method for their estimations. On the other hand, Wong, Cowling, Leung, Schooling (2013) estimate APC model (for mortality) by means of Bayesian inference. More information about APC model estimation methods can be found in the studies by Clayton, Schifflers (1987) or Holford (1983). Incidence rate and prevalence are also estimated by means of MIAMOD model (cf. Giampaoli, Palmieri, Capocaccia, Pilotto, Vanuzzo (2001)), which is an extension of the APC model.

In studies which examine the impact of risk factors on incidence rate or mortality due to a given cardiac disease, logistic regression is usually used, (Yusuf et al. (2004), Kannel, Wolf, Benjamin, Levy (1998)).

Summary

This review summarises state of the art in the field of modelling the prevalence of cardiovascular diseases. More specific information concerning the methods applied can be found in relevant references.

There are two main categories of methods used for quantitative modelling of prevalence of cardiovascular diseases: estimation statistics and simulation models. Both groups differ significantly from each other but their goals are similar: to make projections of incidence rate of selected cardiovascular diseases or to explore the impact of risk factors on incidence. Scenario analysis is the tool that enables effective use of both types of models. It enables making numerous possible projections. The scenarios can describe the development of future trends as well as evaluating the expected effects of social interventions. On such basis (which

is mainly the feature of simulation models) social schemes can be assessed. Variables used in the models are the basis for obtaining good quality estimations. A conclusion may be drawn from the above review that demographic-behavioural variables are most often used in simulation studies, while statistical studies (especially those based on clinical microdata) make use of a broader range of factors, including variables that describe patient's condition in detail. As regards simulation studies, a very popular model is the state transition model based on Markov chains, although microstimulation models that reflect behaviours of individuals are also developed. In case of statistical estimation methods, one frequently uses APC models to make incidence rate projections. It is worth pointing out that a lack of sufficiently big data sets is a very common problem in modelling the prevalence of cardiac diseases; very often a number of data sets are used for estimations of various parameters in the model.

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Treatment pathway model in ischemic heart disease

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Introduction

In Poland, cardiovascular diseases are the leading cause of death (46% of all deaths of Polish population in 2010), hospitalization and permanent or temporary inability to work (Wojtyniak et al., 2012) In 2011, 90,526 men and 79,346 women died due to cardiovascular diseases (of which 29,808 women and men died prematurely, i.e. before reaching the age of 65), which accounts for 40% and 51% of all deaths in Poland, respectively (Polcard, 2014). Cardiovascular diseases dominate among the most frequent causes of mortality in majority countries of European countries, and especially in Central and Eastern Europe. World Health Organization (WHO) forecasts that by 2030 cardiovascular diseases will remain the most frequent cause of death in the developed countries, with majority due to ischemic heart disease and cerebrovascular diseases (www.who.int/en). This chapter presents the main issues concerning ischemic heart disease.

The main goal of this chapter is to present a model pathway of treating ischemic heart disease in Poland. The first part of the chapter is dedicated to presenting the classification of ischemic heart disease. Then follows the description of its causes, clinical symptoms and the standard diagnostic and therapeutic procedures. The last part of the chapter describes a treatment pathway model in ischemic heart disease in Poland. National Health Fund statistics were used to determine annual ischemic heart disease incidence rate depending on sex, age group and residence (urban or rural areas). Frequency of invasive procedures used for the diagnosis and treatment of ischemic heart disease is presented, including coronarography, percutaneous coronary interventions and coronary artery bypass grafts (CABGs).

Definition and categorization of ischemic heart disease

Ischemic heart disease (hereinafter: IHD) by definition includes all the conditions of myocardial ischemia regardless of the underlying pathomechanism. Coronary heart disease in which myocardial ischemia is caused by lesions in coronary arteries is a particular example type of IHD (Pasierski et al., 2015).

According to the applicable guidelines of the European Society of Cardiology (ESC), coronary heart disease can be differentiated (simplified model) into stable coronary artery disease (chronic coronary heart disease) and acute coronary syndrome (ACS).   Stable coronary artery diseases include:

– stable angina,
– microvascular angina (so called cardiac syndrome X),
– myocardial bridge,
– coronary vessel spasm (variant angina, Prinzmetal angina)

Acute coronary syndromes include:

– ST-elevation myocardial infarction (STEMI heart attack),
– Non ST-segment elevation myocardial infarction (NSTEMI heart attack),
– unstable angina (UA) (ESC 2012, ESC 2013).
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Causes of ischemic heart disease

Over 98% IHD cases are directly related to atherosclerosis. Atherosclerosis is a chronic inflammation process occurring in internal elastic lamina of large and medium arteries (Undas et al., 2015). Factors predisposing to the disease can be divided into unmodifiable ones, such as age, sex, or genetic predispositions, and modifiable ones, such as excess weight and obesity, lack of physical activity, hyperlipidemia, high blood pressure, smoking or diabetes. From among those factors, it is cholesterol present in LDL lipoproteins that plays a critical role in the development of atherosclerosis (Frostegård J., 2013)

The presence of fatty streaks is observed during the autopsies of some children, which is a sign of a chronic character and early beginnings of atherosclerosis. Continuous accumulation of lipoproteins around atherosclerotic lesions leads to the development of so-called atherosclerotic plaque which narrows the lumen of the coronary artery, impairing

blood flow. Extracellular matrix (fibrous cap) around the plaque is exposed to stress resulting from pulsatile blood flow in the coronary artery, which usually causes ruptures and easement of thrombogenic material into the circulation. While in contact with the blood, this material induces thrombus formation in the lumen. Thrombus formation most often results in acute coronary syndrome because of partial or total blockade of blood flow through artery (Undas et al., 2015).

Other, less frequent mechanisms of IHD development (accounting for less than 2% of all IHD causes) include such conditions of coronary arteries as: coronary artery spasm (variant angina or Printzmetal's angina), coronary embolism, coronary arteritis, anatomical defects of coronary vessels, injured coronary arteries and all other pathophysiologic conditions involving insufficient oxygen supply in relation to myocardium needs (valve disease, myocardial hypertrophy, cardiac arrhythmia, carbon monoxide poisoning, anaemia, unbalanced hyperthyroidism, too low blood pressure, chronic low blood pressure, respiratory failure).

Chronic ischemic heart disease

Due to variable clinical picture of chronic ischemic disease it is difficult to assess its prevalence and incidence rate (Strong J.P. et al., 1999). Morbidity increases with age in both sexes and is estimated to affect 10-12% women aged 65-84 and approx. 12-14% men aged 65-84 (ESC, 2013).

In case of chronic ischemic heart disease one can observe reversible episodes of mismatch between oxygen supply to myocardium and myocardium needs. Those episodes are induced by excessive physical effort, stress or emotional states (or they occur independently), which can be accompanied by symptoms of discomfort in the chest (angina) (Morrow D.A. et al., 2007).

In stable IHD, the symptoms result from narrowed lumen in coronary artery(ies), and from the dysfunctional micro-vessels and coronary vessels' spasms.

IHD diagnosis is based largely on clinical interview of a patient... During such an interview attention is paid to angina-like symptoms described by patient, along with the presence of risk factors (obesity, smoking, family history of IHD, etc.). Apart from a detailed interview, blood tests also play a role in diagnosing IHD. Every patient suspected of suffering from IHD

should have the following tests done: complete blood count, lipid profile, creatinine blood test, electrolyte test, tests for diabetes and other metabolic disorders (e.g. hyperthyroidism). Diagnostic procedures should also include additional tests which help to assess the stage of the disease and define an appropriate treatment strategy (selected studies have been presented below) (ESC, 2013).

Electrocardiography (ECG) is a broadly accessible, cheap and non-invasive process of recording electrical activity of the heart; for stable IHD it features, however, low sensitivity and specificity. This means that IHD-characteristic changes (e.g. ST-T segment changes) may be absent from the ECG recording made when a patient does not have any angina. However, ECG should be performed in cases of all patients suspected of IHD, as it can point to other reasons for feeling chest discomfort (such as arrhythmia and atrioventricular block) or reveal an earlier episode of myocardial infarction (Dąbrowski A. et al., 2015).

For the purposes of diagnosing IHD one can perform a 48-hour 12-lead Holter monitoring, which is particularly useful in detecting the so-called silent ischemia.

Cardiac stress test done on a treadmill or an exercise bike involves ECG recording of patient who is in the process of doing a physical exercise according to a defined procedure. Physical effort increases myocardial need for oxygen, but atherosclerotic lesions, which are present in coronary arteries may reduce sufficient supply of oxygen, which results in myocardial ischemia visible in the ECG record. The stress test features better sensitivity and specificity as opposed to a classic ECG test, which is done when a patient is resting. Unfortunately, a large group of those suffering from IHD cannot, for various reasons, be subject to a stress test (e.g. due to osteoarthritis) (Dąbrowski et al., 2015).

Stress echocardiography test is also important. Echocardiography which involves physical effort (on a treadmill or on an exercise bike) or using pharmaceuticals, enables to detect impaired left myocardial contractility which is characteristics of myocardial ischemia, pointing to IHD (Senior R et al., 2009). Another procedure used for diagnosis is myocardial perfusion imaging by single-photon emission computed tomography (SPECT), which registers myocardial perfusions (Di Carli et al., 2007).

Dual source computed tomography (DSCT) belongs to minimally invasive methods of assessing anatomical lesions in coronary arteries and it can be performed without a contrast

medium (assessment of coronary artery calcification - Agatstone score) or with intravenous application of a radiological contrast (contrast enhanced CT coronary angiography) (Abbara et al., 2009).

Coronarography or angiography of coronary arteries is currently a so-called gold standard test for diagnosing IHD. A doctor qualifies patients for coronarography based on assessing the strength of symptoms, IHD risk factors present, results of non-invasive tests (ECG, stress test, ECHO, SPECT) and general condition of a patient. The test involves producing an x-ray-like image of coronary arteries after a contrast medium has been injected to them. Thanks to the procedure one can very precisely define the location and degree of arterial luminal narrowing. One has to pay attention to the fact that coronarography belongs to the so-called invasive tests which carry a risk of complications.

In order to better understand the difference between stable coronary artery disease and acute coronary syndrome and reasons why a specific medical procedure is elected, below follows a simplified classification which takes account of the degree of arterial luminal narrowing and the corresponding symptoms (ESC 2013). Anatomical arterial luminal narrowing can be classified as follows:

– non-significant narrowing - luminal diameter narrowing does not exceed 50%. Atherosclerotic plaque which causes such narrowing may cause ACS, but in stable condition it does not cause angina;

– significant narrowing (sub-critical narrowing) - myocardium functions correctly, but in case of increase demand for oxygen (e.g. during a physical effort), angina may occur. Such a degree of narrowing is often observed in stable coronary artery disease, but it can also cause ACS;

– critical narrowing - if luminal diameter narrowing exceeds 80%, angina may occur also at rest. There is a big risk of ACS.

Having collected such information a cardiologist may make a decision on further treatment strategy. Depending on the strength of atherosclerotic lesions, the number of coronary arteries featuring significant lesions and an overall clinical picture, the patient may be qualified to follow a given therapeutic pathway (conservative treatment or invasive treatment).

Clinical characteristics of stable coronary artery disease

Stable angina is a set of clinical symptoms that feature the presence of chest pain or its counterpart (e.g. dyspnoea), which are a result of myocardial ischemia. The symptoms usually appear during significant physical effort (e.g. going upstairs) or stress, when the myocardium need for oxygen is not satisfied (the flow of blood through coronary vessels is reduced because of plaque, which usually does not cause angina at rest) (Kośmicki, 2011). In stable coronary artery disease myocardial cells' death does not occur, but their metabolism is changed; as a result of hardening those cells "freeze".

A typical symptom of angina includes chest pain similar to tightness or suffocation. The pain may be located behind the sternum or radiate to the neck, lower jaw, left shoulder, epigastrium or interscapular area. It is most often caused by physical effort and it usually eases when the effort is given up or after administering nitroglycerin during 1-3 minutes. In case of some patients the disease manifestation is untypical. Instead of angina, other symptoms s may occur which mask real angina, such as effort-related dyspnoea (especially in the elderly people or in people suffering from diabetes), fatigue, abdominal pain or nausea. It is worth paying attention to the fact that as many as 50-80% episodes of myocardial ischemia do not cause any symptoms ("silent ischemia") (Pasierski et al., 2015).

Intensity of angina symptoms can be graded based on a 4-grade scale developed by Canadian Cardiovascular Society (CCS):

- – Class I - Angina only during strenuous or prolonged physical activity
- – Class II - Slight pain during usual activity. For example angina occurs during vigorous climbing the steps, to the 2nd floor and higher;
- – Class III - serious angina e.g. during slowly going upstairs to the first floor;
- – Class IV - serious angina during insignificant effort and angina at rest (Szczeklik A. et al 2011).

Microvascular angina is a type of angina with accompanying ST depression on ECG stress test record (ECG record in rest is usually normal) and a normal image of coronary arteries in a coronarography report. Previously such a type of angina was called cardiac syndrome X. Contrary to pain felt in case of stable angina, chest pain in microvascular angina is often untypical. It can be very strong and it usually accompanies effort, but it can also occur at

rest (in many patients it occurs between midnight and early morning); it usually persists for over 10 minutes (and even exceeds 30 minutes) after giving up the effort, the response to sublingually administered nitroglycerin being insufficient. Microvascular angina must always be differentiated from other causes of chest pain (classical angina, myocardial infarction or unstable angina, pericarditis, aortic dissection, pleuritic chest pain, neuralgia, gastro-oesophageal reflux disease, esophageal rupture, cholelithiasis, peptic ulcer, musculoskeletal pain, neurosis (Pasierski et al., 2015).

Another type of angina is angina related to myocardial bridges that form on top of coronary arteries. The symptoms result from the existence of an "additional" myocardial bridge (a band of heart muscle that lies on top of a coronary artery, most frequently above anterior interventricular branch), which causes coronary luminal narrowing during myocardial contraction. The symptom includes physical effort-related angina. Diagnosis is made based on coronarography (Stables et al., 1995).

Another type of angina is a coronary vessel spasm, which manifests with a chest pain caused by vasospasm. The typical form of coronary vessel spasm is characterised by a short-term ST elevation on ECG, usually not leading to a myocardial infarction. This type of angina is also called variant angina or Prinzmetal angina. The symptom is angina without a specific cause, often long-lasting, most frequently occurring between 24.00 and 6.00 a.m. at rest (however it can also occur after physical activity). The most intense symptoms occur within the first year from the beginning of the disease. The ailments are recurring, but the incidence rate of myocardial infarction is very low (<0.5% patients annually) (Tada et al., 1995).

Treating patients with stable coronary heart disease

In all patients with chronic coronary heart disease therapeutic measures aimed at reducing clinical symptoms and improving the prognosis should be used. The therapy covers *inter alia* the lifestyle modification, control of coronary heart disease risk factors, appropriate pharmacotherapy and health education.

According to the applicable standards of the European Society of Cardiology the treatment of stable coronary heart disease should cover:

- broadly understood primary prevention,
- treating diseases that negatively impact on angina (mainly anaemia, hyperthyroidism, some types of cardiac arrhythmias),
- increasing the physical activity (without causing angina),
- vaccination against influenza,
- using medications preventing cardiovascular incidents and death and reducing the symptoms of angina,
- invasive treatment (in selected cases) (ESC 2013).

The medications improving patient's prognosis (preventing cardiovascular incidents and reducing the risk of death) include *inter alia*:

- antiplatelet drugs,
- statins (hypolipidemic drugs),
- angiotensin-converting enzyme inhibitors or angiotensin receptor blockers in case of coexisting arterial hypertension, diabetes, heart failure or left ventricular systolic dysfunction.

The drugs reducing the symptoms of angina include:

- short-acting nitrates – causing short-term reduction of symptoms, may be applied preventively before planned physical activity,
- beta-blockers, calcium channel blockers or long-acting nitrates – prevent angina and increase the exercise tolerance.

Although the basic treatment of stable angina is optimal pharmacotherapy, some patients are qualified for invasive methods of coronary heart disease treatment. Invasive treatment includes myocardial revascularization (restoring the blood circulation), which could be performed during percutaneous coronary interventions (PCI) or by means of the coronary artery bypass graft (CABG) (ESC 2013). The development of PCI techniques means that nowadays these interventions are routine and safe procedures in patients with stable coronary heart disease and appropriate anatomy of lesions in coronary arteries. PCI techniques include percutaneous transluminal coronary angioplasty (PTCA), which in turn includes:

- angioplasty involving the implantation of bare metal stents (BMS), drug eluting stents (DES) and absorbable metal stents (AMS),

–   percutaneous old balloon angioplasty (POBA).

Surgical treatment in the chronic stable coronary heart disease reduces the symptoms of angina, the ischemia of myocardium and improves the quality of life.

Empirical model of ischemic heart disease treatment in Poland

Assessment of incidence and prevalence rate of ischemic heart disease

The basic element for the construction of empirical treatment model is estimating the number of new cases of ischemic heart disease. The incidence of this disease was estimated at 219.1 thousand cases in 2013 (569.2 cases per 100 thousand inhabitants).[9] It should be underlined that this estimate includes not only hospitalised patients, but also patients who first presented in the Specialist Outpatient Care (SOC), at Emergency Department (ED) or Hospital Admission Unit (HAU). Including these patients is justified by the fact that not every case of diagnosed ischemic heart disease is treated in a hospital. Among the newly diagnosed patients there were slightly more men (51%, incidence rate ratio 597.8 per 100 thousand of population, women 49%, incidence rate ratio 542.4 per 100 thousand of population).
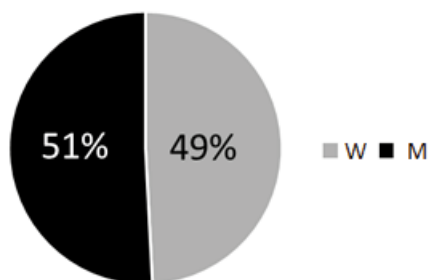
Figure 1. The structure of new patients with diagnosed ischemic heart disease in relation to sex in 2013 (source: DAiS analysis based on NHF data)

Another characteristic taken into account while analysing the incidence is the patient's age. In the analysis the following age groups were established: (0; 18), <18; 45), <45; 55), <55; 65), <65;75) <75;85) and 85+. The number of cases by age group, together with the incidence

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[9] For more information on the detailed methodology for estimating incidence see: *Cardiovascular diseases in Poland – the results of the predictive model for 2015–2025*

ratios per 100 thousand of population in each group, are presented in Table 1. The highest number of ischemic heart disease cases has been observed in the age group from 55 to 65 years (68.75 thousand cases) and the lowest number of cases in the group from 0 to 18 years – less than 170 cases. However, the highest incidence rate ratio was observed in the age group from 75 to 85 years (cf. Table 1).

Table 1. The incidence and incidence rate of ischemic heart disease in relation to age groups in 2013 (source: own study)

Age group	Number of cases (in thousands)	Ratio per 100 thousand of population
(0; 18)	0.17	2.4
<18; 45)	9.94	64.8
<45; 55)	25.87	524.5
<55; 65)	68.75	1237.2
<65; 75)	59.93	1970.0
<75; 85)	43.37	2161.2
85+	11.10	1780.0

Using reporting data from NHF, including the information about the patient's place of residence, enabled us to construct the incidence ratio by the patient's place of residence. 68% of new patients with a diagnosed ischemic heart disease came from the urban areas. Also in the relative terms the incidence rate of ischemic heart disease was higher among patients from the urban areas (city: 642.3 cases per 100 thousand of population, rural areas: 457.7 cases per 100 thousand of population – cf. Table 2).

Table 2. The incidence and incidence rate of ischemic heart disease in relation to place of residence (urban/rural area) in 2013 (source: own study)

	Number of cases (in thousands)	Ratio per 100 thousand of population
urban area	149.4	642.3
rural area	69.7	457.7

While making projections about the incidence of ischemic heart disease, the incidence rates by sex, age group and place of residence were used. The incidence and incidence rate ratios for each of these groups are presented in Tables 3 and 4.

Table 3. The incidence (in thousand) of ischemic heart disease in relation to all analysed profiles in 2013 (source: own study)

Sex	urban/rural area	Age group						
		(0; 18)	<18; 45)	<45; 55)	<55; 65)	<65; 75)	<75; 85)	85+
W	urban area	0.04	2.53	6.81	21.53	21.75	17.07	4.78
	rural area	0.04	1.21	3.49	8.74	9.02	8.18	2.59
M	urban area	0.04	3.98	9.91	26.03	20.31	12.15	2.47
	rural area	0.05	2.22	5.67	12.46	8.85	5.98	1.26

Table 4. Incidence rate of ischemic heart disease in relation to all analysed profiles in 2013 (source: own study)

Sex	urban/rural area	Age group						
		(0; 18)	<18; 45)	<45; 55)	<55; 65)	<65; 75)	<75; 85)	85+
W	urban area	2.2	55.3	446.5	1085.0	1867.2	2104.4	1737.1
	rural area	2.4	40.6	364.0	924.0	1572.0	1691.4	1413.3
M	urban area	2.1	86.6	706.5	1579.4	2405.7	2728.7	2454.6
	rural area	3.1	69.6	540.7	1272.0	1927.2	2239.1	1949.6

The previously made analysis of incidence rate ratios per 100 thousand of population only slightly differs in relation to sex (men – 597.8 per 100 thousand of population, women – 548.4 per 100 thousand of population) (cf. Figure 1). Nevertheless, it can be observed that, while specifying the analysis by successively adding new profiles, the observed difference in the incidence rate in relation to sex become more visible – e.g. the incidence rate of men in the last age group living in urban areas is 40% higher than women from the analogous group.

Empirical model of treatment

The presented innovative model illustrating the decision tree for IHD treatment involves the services provided in the hospital setting within the first year. The analysis is limited by the character of data reported to the National Health Fund by healthcare providers. Additionally,

in case of the cardiac diseases there is a possibility that patients are diagnosed and treated outside hospitals, as well as outside the public sector. Therefore the period from the first appointment in the framework of outpatient treatment and the first hospitalisation of a given patient can exceed one year. In the analysis such patient would be qualified to a group of patients who did not receive services included in the analysed procedures, which could lead to erroneous conclusions concerning the treatment process.

This analysis takes into account all procedures reported in the framework of hospitalisation for individual patients diagnosed according to the ICD-10 classification with the following diseases:

– I20 – Ischemic heart disease,

– I21 – Acute myocardial infarction,

– I24 – Other acute ischaemic heart diseases,

– I25 – Chronic ischaemic heart disease,

within 365 days (regardless of the main ICD-10 disease reported for the hospitalisation[10]) of the first appearance of patient in the inpatient system with the diagnosed ischemic heart disease. Some patients analysed in this chapter have been included in estimating of incidence rate in previous years – this concerns patients, who appeared in SOC, at ED/HAU, in the years 2009–2012 and were recorded in the inpatient system only in 2013. Finally, the study group consisted of over 170 thousand patients, who were recorded in the inpatient system in 2013 (and were not hospitalised due to ischemic heart disease in the years 2009–2012[11]).

The analysis focuses primarily on determining how many patients received particular type of therapy, i.e. in case of how many patients with ischemic heart disease the following invasive diagnostic and treatment procedures were recorded:

– coronarography,

– percutaneous coronary intervention (PCI),

– coronary artery bypass graft (CABG).

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[10] This means that, if patient after the hospitalisation due to ischemic heart disease was hospitalised, e.g. due to atrial fibrillation and flutter and during such hospitalisation performing of the coronarography has been reported, then this procedure will be taken into account in the following analysis.

[11] The lower time limit, i.e. the year 2009, is associated with the accessibility of NHF data.

On the basis of data reported to National Health Fund we conclude that 71.2 % of patients with IHD had undergone an invasive diagnostic procedure in the form of the coronarography. (cf. Table 5). It has also been shown that 43% of patients with ischemic heart disease undergo percutaneous coronary interventions (PCI) within one year of the appearance in the inpatient system and almost one in 10 patients undergoes the coronary artery bypass graft (CABG).

Table 5. Empirical model of ischemic heart disease treatment part 1 (source: own study)

Coronarography	Percutaneous coronary interventions	Coronary artery bypass grafts
71.2%	43.5%	7.6%

In order to draw comprehensive conclusions about the course of treatment of patients with ischemic heart disease it is necessary to analyse the frequency of performed procedures in appropriate combinations. The convenient and commonly applied format used to present this type of analysis are decision tree structures. This kind of tree of the ischemic heart disease treatment process, developed on the basis data reported to the National Health Fund, is presented in the Flowchart 1.

Was the coronarography performed?					Including: PCI?					Including: CABG?				
YES/NO	Number of patients	Share	Number of deaths	Share	YES/NO	Number of patients	Share	Number of deaths	Share	YES/NO	Number of patients	Share	Number of deaths	Share
NO	49 013	28,80%	6587	13,44%	NO	44 088	90,00%	6111	13,86%	NO	42 235	95,80%	5 971	14,14%
										YES	1 853	4,20%	140	7,56%
					YES	4 925	10,00%	476	9,66%	NO	4 801	97,50%	467	9,73%
										YES	124	2,50%	9	7,26%
YES	121 481	71,20%	9191	7,57%	NO	52 333	43,10%	2906	5,55%	NO	44 330	84,70%	2 420	5,46%
										YES	8 003	15,30%	486	6,07%
					YES	69 148	56,90%	6285	9,09%	NO	66 256	95,80%	6 147	9,28%
										YES	2 892	4,20%	138	4,77%

Flowchart 1. Empirical model of ischemic heart disease treatment part 2
(source: DAiS analysis based on NHF data)

On the basis of the graph analysis it has been concluded that in case of many patients who underwent PCI and CABG, performing of the coronarography, commonly used in diagnosing the ischemic heart disease, has not been reported. The coronarography is the basic test used to qualify patients for the percutaneous coronary interventions (PCI) and the coronary artery bypass graft (CABG). Therefore the tree presented in the Figure 1 has been adjusted by assuming that procedures related to PCI and CABG were preceded by the coronarography. The adjusted tree of the ischemic heart disease treatment process has been presented in the Flowchart 2.

Was the coronarography performed?					Including: PCI?					Including: CABG?				
YES/NO	Number of patients	Share	Number of deaths	Share	YES/NO	Number of patients	Share	Number of deaths	Share	YES/NO	Number of patients	Share	Number of deaths	Share
NO	42 235	28,80%	5971	14,14%	NO	42 235	100,00%	5971	14,14%	NO	42 235	100,00%	5 971	14,14%
										YES	0	0,00%	0	0,00%
					YES	0	0,00%	0	0,00%	NO	0	0,00%	0	0,00%
										YES	0	0,00%	0	0,00%
YES	128 259	75,20%	9807	7,65%	NO	54 186	42,20%	3046	5,62%	NO	44 330	81,80%	2 420	5,46%
										YES	9 856	18,20%	626	6,35%
					YES	74 073	57,80%	6761	9,13%	NO	71 057	95,90%	6 614	9,31%
										YES	3 016	4,10%	147	4,87%

Flowchart 2. Adjusted empirical model of ischemic heart disease treatment
(source: DAiS analysis based on NHF data)

In almost 30% patients treated in hospitals due to ischemic heart disease within a year of their appearance in the system neither coronarography, PCI nor CABG has been reported, which is illustrated by the upper branch of tree presented in the Figure 2. One should assume that these are the cases of stable coronary heart disease, in case of which the conservative treatment is predominant. Over 44,000 patients, who have undergone coronarography, but without subsequent recorded PCI and CABG can be included in the same group.

On the basis of the adjusted empirical treatment model it can be concluded that 75% of patients with ischemic heart disease underwent coronarography. There is a group of patients, who after the coronarography or the coronarography and the angioplasty of coronary arteries, are qualified for the coronary artery bypass graft (CABG). They are typically patients with significant stenosis of many coronary arteries and therefore, it is impossible to obtain improvement of the blood circulation of their myocardium through the angioplasty of coronary arteries. Among the patients who underwent coronarography, 57% of patients subsequently underwent PCI. 4.2% of patients with PCI underwent also the coronary artery bypass grafts. On the other hand, 15% of patients with coronarography and without performed percutaneous coronary interventions underwent the CABG.

The presented empirical model of treatment contains also information on deaths in each of the patients groups. The lowest proportion of deaths may be observed in the group of patients who underwent both PCI and CABG. In turn, the highest share of deaths has been observed regarding patients with ischemic heart disease who did not undergo the invasive diagnostics and treatment.

Summary

This chapter contains the definition of the ischemic heart disease and its classification. It also includes description of the characteristics of each of the presented forms of the disease. The guidelines concerning treatment regimes in ischemic heart disease, including the basic diagnostic tests and treatment methods, were also presented.

The ischemic heart disease empirical model of treatment developed on the basis of the analysis of data related to the hospital treatment reported to the National Health Fund constitutes a significant element of this chapter. The results of the analysis show that ischemic heart disease incidence rate is higher in case of men. It is observed that the incidence increases with age. It is also significantly higher in urban areas. The analysis shows that 3/4 of patients with ischemic heart disease undergo coronarography within a year from being recorded in the system. However, over 80% of these patients do not undergo any invasive treatment.

Despite many shortcomings related to the specificity of the data reported to the National Health Fund (e.g. reporting particularly on the procedures of the highest valuation that

determine settlement of a given homogeneous patients group), the presented original concept of the empirical model of treatment constitutes the attempt to fully analyse the events related to the treatment of ischemic heart disease in the hospital area. It constitutes a step towards the application of the so-called evidence based management in Polish health sector and its results may be the basis for the forecast of demand for particular hospital treatment pathways related to ischemic heart disease treatment.

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Treatment pathway model in acute coronary syndromes

Jacek Jagas, Beata Koń, Barbara Więckowska

Introduction

Acute coronary syndrome (ACS) is a clinical condition in which the sudden ischemia and necrosis of myocardium occur as a result of the occlusion or critical stenosis of the coronary artery. The symptom is, among others, acute chest pain, which is very often the cause of hospitalisation. The term *acute coronary syndrome* covers three disease entities: ST elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI) and unstable angina (UA). The ACS diagnosis is based on the clinical picture, electrocardiography tests (ECG), damage of myocardium, biochemical indicators of the myocardium damage (so-called biomarkers), mainly troponin, and image examinations such as echocardiography (ECHO). In the case of both STEMI and NSTEMI, the elevated concentration of the biomarkers is found, whereas the differentiating element constitutes the ECG image (in STEMI the presence of the ST elevation in ECG). In case of the unstable angina, no elevated level of biomarkers is observed, however, ST-segment changes may occur (in the form of its depression).

During the last twenty years Polish cardiology has made extensive progress, including ACS diagnosis and treatment. These actions resulted, among others, in the significant improvement of the prognosis and reduction in fatality rate among patients with ACS. In this respect, the allocation of significant funds for the construction and equipment of the interventional cardiology centres and training of the medical staff was the decisive factor. Currently Poland is one of the leaders among the European Union countries in the field of the invasive ACS treatment.

The aim of this chapter is to present ACS treatment pathway model in Poland. The first part of this work presents the pathomechanism, types and epidemiology of ACS. Another part of the chapter relates to the ACS diagnosis, treatment, as well as to the importance of the cardiac rehabilitation after the coronary incident. Then, the article sets out the empirical model of ACS treatment, which describes results of the quantitative analysis for the ACS

treatment in Poland in 2013. It is based on the reporting data of the National Health Fund (NHF) and presents the number of ACS cases and the number of the "first time" patients, as well as the frequency of the performance of key – from the perspective of the treatment of this disease – procedures: angioplasty of coronary arteries and coronary artery bypass graft.

Pathomechanism, types and epidemiology of ACS

The cause of ACS is a sudden insufficient oxygen supply to myocardium, which in consequence leads to its necrosis (irreversible process). From the pathological perspective, myocardial infarction is defined as a death of myocardium cells caused by the prolonged ischemia (on average approximately 20 minutes) (Jennings et al., 1974). In most cases the cause of the acute myocardial ischemia is the significant delimitation of perfusion or obstruction of the coronary artery caused by the rupture of atherosclerotic plaque with thrombus formation in its lumen (Arroyo et al., 1999). The damage of myocardium may be recognised by identification of the sensitive and specific biomarkers of this damage in the blood, such as cardiac troponin or creatine kinase isoenzyme, CKMB (Jaffe et al., 2006).

The preliminary diagnosis of ACS may be carried out on the basis of clinical picture (symptoms) and electrocardiographic changes (ECG).

Depending on the result of the electrocardiography test (ST-segment and T-wave change ECG), the acute coronary syndromes may be divided into ACS with ST elevation and ACS without ST elevation. However, taking into account the whole clinical picture, result of the preliminary electrocardiography test, biochemical indicators of the damage of myocardium (biomarkers) and imaging procedures (such as echocardiography), the acute coronary syndromes may be divided into:

– ST-elevation myocardial infarction (STEMI),
– non ST elevation myocardial infarction (NSTEMI),
– unstable angina (UA) (Thygesen et al., 2012).

The simplified concepts of the ACS types pathomechanisms (according to Steg et al., 2012; Thygesen et al., 2012) are presented below:

- ST-elevation myocardial infarction – usually the thrombus formation completely and suddenly closes the lumen of the coronary artery. The necrosis starts developing within 15–30 minutes after the blood flow has stopped and it advances from endocardium to epicardium layer. The time in which the necrosis is developed depends on the diameter of the closed vessel and on the presence of collateral circulation;

- non ST elevation myocardial infarction – is often a result of the unstable angina (continuum). The area covered by the infarction usually has well developed collateral circulation or it is relatively small (i.e. is supplied by further/final part of the coronary artery);

- unstable angina – usually occurs as a consequence of damage of eccentric atherosclerotic plaque; the thrombus formation limits the coronary blood flow but it does not block it completely.

Currently the decreased frequency of the occurrence of STEMI is observed, while at the same time the number of NSTEMI diagnosis slightly increases. In the period 1997–2005 the frequency of the occurrence of STEMI per 100,000 inhabitants decreased from 121 to 77 and the frequency of the occurrence of NSTEMI increased from 126 to 132 (Roger et al., 2012). The in-hospital fatality of patients with STEMI observed in national registers of individual member countries of ESC ranges from 6 to 14% (Mandelzweig et al., 2006) and shows the downward trend due to increasingly wide application of the reperfusional treatment and secondary prevention (Widimsky et al., 2010;McManus et al., 2011). However, it should be noted that further 12% of patients die within 6 months from the infarction (Fox et al., 2006).

According to AMI-PL data, the number of hospitalised patients with ACS in 2012 in Poland reached 79.4 thousand (62% of all admissions were men), of which 47.2% related to STEMI and 51.8% related to NSTEMI (1% of ACS type was not identified). Over 80% of patients underwent diagnostic or therapeutic invasive procedure. Among patients who were admitted to centres with the access to invasive diagnostics and therapy, the hospital fatality rate was 6% and was two times lower in comparison with patients treated in hospitals without interventional cardiology centres (AMI-PL Group, 2014).

The brief clinical characteristic of the above-mentioned ACS forms is presented below:

–   ST-elevation (STEMI) acute coronary syndrome may be manifested as the intense retrosternal pain, which radiates to arms, mandible, back. Duration of pain exceeds 20 minutes. Pain is accompanied by anxiety, sweating, paleness, nausea. Symptoms may be diffuse, they do not depend on the position and are not affected by the movements of the areas of body they are related to. The ECG test identifies characteristic changes such as ST elevation which can be accompanied by arrhythmia or atrioventricular blocks in the cardiac conduction system. According to serum tests the increase of biomarkers of myocardium damage was identified (Steg et al., 2012).

–   non ST-elevation (NSTEMI) acute coronary syndrome – frequently symptoms are similar to those in STEMI. On the other hand, ECG test shows the wide spectrum of changes (such as persistent or transient ST elevation or reversion of T-wave, flattening of T-wave, etc.) and there is no ST elevation in two adjacent leads. In the laboratory tests the concentration of biomarkers is significantly elevated (Hamm et al., 2011);

–   unstable angina (UA) – it is identified when clinical symptoms indicate ACS, duration of pain does not exceed 20 minutes, but the significant increase of biomarkers is not observed. Changes indicating ischemic heart disease during electrocardiography test may be present (Hamm et al., 2011).

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ACS diagnosis

Patient suspected of suffering from ACS should be diagnosed according to clearly defined algorithms included, among others, in the relevant recommendations of the European Society of Cardiology. Very detailed clinical approach to the patients with chest pain constitutes a rule. The basic methods allowing for identification of patients requiring hospitalisation include (apart from the interview and physical examination): electrocardiography (ECG) and biomarkers test (Thygesen et al., 2012). The literature data indicates that for 1/3 of patients with the acute chest pain the diagnosis is very difficult in the emergency department and preliminary tests that were carried out not always allow to diagnose the patient (Klimeczek et al., 2013). In such cases, the observation should be prolonged and additional tests should be carried out, including imaging procedures, such as transthoracic echocardiography or chest X-ray.

Difficulties with the proper risk assessment and diagnosis of the disease may lead to unnecessary admissions to the hospital and to implementation of expensive (and also often invasive) diagnostics, resulting in the costs for health care system or increasing the risk of complications (Hoffmann et al., 2009).

During the examination carried out in the emergency department, patients with the acute chest pain are generally divided into two groups:

- – patients with chest pain of a coronary nature (high probability of ACS),
- – patients with chest pain of a non-coronary nature (this category involves large group of patients with chest pain that is not caused by ACS, including lung and pleura disease, acute aortic dissection, ostealgia and arthralgia, etc.).

This initial division is essential because procedure models in the above-mentioned patients groups are completely different. The patients suspected of suffering from ACS should be immediately directed to the interventional cardiology centre (Jagas, 2014).

ACS treatment

Treatment of patients with the acute coronary syndrome is based on diagnostic and therapeutic algorithms, which are included, among others, in so-called recommendations of the European and Polish Society of Cardiology (Steg et al., 2012; Hamm et al., 2011).

In case of all patients with a preliminary diagnosis of ACS, the aim is to carry out an invasive test demonstrating coronary arteries – coronarography. The classic coronarography allows for the assessment of the stage of coronary heart disease and for choosing further therapy related to ACS (Klimeczek et al., 2013).

According to the data developed by the Association of Cardiovascular Interventions, 226,713 coronarographies were carried out in Poland in 2014 and the total number of percutaneous coronary interventions reached 126,241. The indications for coronarography included: stable ischemic heart disease (39.9%), STEMI (12.2%), NSTEMI (13.4%), unstable coronary heart disease (29.8%) and other indications (4.7%). Therefore, over 50% of indications for coronarography constituted different forms of ACS (Ochała et al., 2015).

According to the currently recommended standards of procedures, the patients after coronarography are qualified to one of the treatment methods (simplified division):

– conservative treatment of the coronary heart disease (treatment without the interventional cardiology or cardiac surgery procedures),

– one-stage or multi-stage percutaneous coronary intervention (PCI) – in case of the recognition of multivessel disease,

– cardiac surgery – qualification to the coronary artery bypass graft (CABG) (Steg et al., 2012; Thygesenet al., 2012).

Treatment of patients with ACS by percutaneous coronary interventions (PCI) methods has significantly contributed to the improvement of their prognosis in short- and long-term observations (Almeda et al., 2003, Brodie et al., 1994). Initially PCI was limited only to broaden the lumen of the narrow artery during plain old balloon angioplasty (POBA). Then the treatment methods were developed by introduction of the vascular prosthesis, i.e. stent, to the lumen of the coronary artery and this procedure was called angioplasty of coronary arteries involving the implantation of stent. Currently there are many different types of stents which generally can be divided into three groups (Iqbal et al., 2013):

– bare-metal stent (BMS),

– drug-eluting stent (DES),

– absorbable metallic stent (AMS).

Drug-eluting stent, i.e. DES, are currently used in most of patients with coronary heart disease. Their continuing technological development is observed and in the future they may be replaced by absorbable metallic stents, which after releasing an active substance (antiproliferative drug), are gradually dissolved (absorbed) and within a certain time their presence in coronary vessels is undetectable. The coronary artery recovers its reactivity to chemical stimuli and the lack of metallic staging enhances the security of patient and reduces the time of application of antiplatelet treatment (Ormiston et al., 2009).

In specialised ACS treatment the most important factor is the criterion of time from the appearance of coronary pain to the expansion of the balloon in the coronary vessel (time to open coronary vessel and restore physiological blood flow).

It should be mentioned that interventional treatment has already displaced the application of thrombolytic drugs from the clinical practice, which was a method of choice for treatment of patients with ACS in the so-called pre-PCI era (Poloński et al., 2011).

Patients with ACS are significantly different in terms of clinical, electrocardiographical features, biomarkers' concentrations and probability of complications and it is therefore very important to determine relevant strategy and to estimate the probability of death. To this end, the scales were created, such as GRACE (Global Registry of Acute Coronary Events) (Eagle et al., 2004) and TIMI Risk Score for patients with STEMI and NSTEMI (Morrow et al., 2000;Antman et al., 2000).

According to guidelines related to the treatment of patients with STEMI, within 12 hours from the appearance of symptoms, when ST segment is still elevated, the early mechanic reperfusion (PCI) or – if it is not available – pharmacological reperfusion (fibrinolysis) should be immediately carried out. Currently the treatment of choice is the percutaneous coronary interventions (Steg et al., 2012).

In case of patients with NSTEMI without contraindications to invasive treatment, the coronarography shall be carried out within 24–72h after their admission and depending on its result, a revascularization procedure (PCI or CABG) should be carried out. In some cases patients are qualified to conservative treatment or to revascularization procedure that is carried out at the deferred date (Hamm et al., 2011).

It should be noted that even 50% of patients with STEMI suffer from multivessel disease, which means that significant changes appeared in at least in two coronary arteries. Similar results are obtained among patients with NSTEMI. The multivessel disease has an influence not only on the choice of the strategy but also significantly changes prognosis of the patients. In case of presence of the multivessel disease, the interventional cardiologist and the treating team (i.e. Heart Team) often make a difficult decision on the type of intervention and its duration. The choice of the relevant strategy is influenced by many factors such as: left ventricular systolic dysfunction, patient's age and coexistence of accompanying diseases (diabetes, renal failure and others), number of changes in the coronary arteries, presence of the clinical symptoms and others (Wijns et al., 2014).

Surgical treatment of ACS

Together with the development of the interventional cardiology methods, the number of coronary artery bypass graft (CABG) performed has been significantly reduced. According to the AMI PL report, in 2009 the number of patients with myocardial infarction reached 75,054, of which 72.5% of patients underwent coronarography, 59.1% of patients underwent angioplasty and only 1.9% of patients underwent the coronary artery bypass graft during their first inpatient stay (AMI-PL Group, 2014). In Poland, in 2011, a total of 13,792 coronary artery bypass graft procedures were carried out, of which 6,059 without extracorporeal circulation. On the other hand, coronary procedures that use minimally-invasive techniques are carried out more often (KROK, 2012).

System of the interventional treatment of ACS in Poland

The ACS invasive treatment model provides for the fastest possible transfer of the patient with ACS (or suspected of suffering from ACS) to interventional cardiology centre specialised in ACS therapy. According to data from the Association of Cardiovascular Interventions of Polish Cardiac Society (AISN PTK), 155 interventional cardiology units (hemodynamic units) were registered in Poland in 2014, of which 92% were on 24-hour duty in case of infarction (Ochała et al., 2015). The number of units in Poland meets the requirements included in the current European guidelines on the treatment of ST-elevation myocardial infarction (STEMI). The interventional cardiology units are a component of cardiology departments. In accordance with the National Health Fund requirements, the structure of cardiology department also consists of the intensive cardiac care sub-department that complies with the standards of intensive cardiac care (24-hour monitoring of patient's vital parameters and regular nursing care and medical care). Hospital emergency departments (SOR) or admission room and emergency medical services system are an integral part of the whole health-care system for patients with ACS.. The emergency medical services have the possibility of ECG recording teletransmission directly to the hemodynamics unit from the place of incident, which is often even dozens of kilometres away from the targeted treating unit where the specialist in the interventional cardiology field is on duty. The National Health Fund's requirements strictly specify skills of the physician who is on the haemodynamic emergency duty (related to ACS treatment). According

to AISN PTK data, 571 individual operators of the interventional cardiology work currently in Poland, of which the majority is specialised in the field of cardiology (Ochała et al., 2015).

When compared to Europe, Poland has the most developed (in terms of density) network of ACS surgery treatment centres per number of inhabitants. In addition, in case of STEMI ACS treatment, Poland gained third position in the ranking of 37 European counties, taking into account the number of the initial PCIs carried out per 1 million of inhabitants (Kristensen et al., 2011).

Cardiac rehabilitation

Comprehensive cardiac rehabilitation is an integral part of the health-care system for patients with ACS. It has been proven that when such rehabilitation is carried out effectively, it reduces mortality caused by cardiovascular reasons and the mortality in general by 20–25%, it also reduces the number of sudden deaths within the first year after myocardium infarction by approximately 35%. In addition, the rehabilitation improves physical performance, reduces symptoms of myocardial ischemia and may delay further development of the atherosclerosis of coronary arteries, therefore, it is very important that as many patients with ACS as possible could be included in the rehabilitation programme (Ades et al., 1997; Ades et al., 2001). The cardiac rehabilitation is a complex and long-term process and its basic purpose is the complexity involving continuation of the basic disease treatment and physical mobilisation, as well as having influence on the mental condition and social conditions (Cybulska et al., 2005; Piotrowicz et al., 2004). This process can be divided into three main stages:

- – stage I – early period (covering hospital rehabilitation),
- – stage II – post-hospital rehabilitation,
- – stage III – late rehabilitation (covering secondary prevention and healthy life style).

Each stage of the cardiac rehabilitation is adjusted to the individual capacities of the patient. Stage II may be carried out in stationary or outpatient conditions (depending on the patents' state of health and distance between the patient's place of residence and the centre), while stage III may be carried out in outpatient or health-care conditions, as well as in the patient's place of residence (Piotrowicz et al., 2008).

In Poland cardiac rehabilitation for patients who overcame ACS may be carried out as a part of services financed by NHF or from the funds from ZUS (medical rehabilitation within the framework of Social Security ZUS early disability retirement prevention).

Empirical model of treatment of the acute coronary syndrome in Poland

The treatment models are based on actual historical data and they describe the patient's treatment path. They provide a way of determining the main treatment methods of a given disease. The identification of the group of patients whose treatment will be described by the model is the first element necessary to build the treatment model. This document presents separately treatment models for acute coronary syndromes treated in a given year and the model of treatment of the "first time" patients with diagnosed ACS. In order to identify the number of cases of the ACS, "first time" patients and their treatment paths, the data reported to the National Health Fund (NHF) were used, i.e. information on patients and their hospitalisation with diagnosed I20.0, I21 according to ICD-10.

The identification of the cases of ACS and "first time" patients with ACS stems from the fact that during calendar year one patient may several times suffer from ACS and thus the number of cases cannot be identified with the number of patients. If, in a given patient, the interval between hospitalisations and ACS diagnosis was longer than 28 days, it must be treated as a new ACS case. However, if the interval between one hospitalisation of a patient diagnosed with ACS and another was 2–28 days, the second incident must be interpreted as a re-infarction. Flowchart 1 presents a precise model describing the process for determining the number of ACS cases.

The methodology used allowed for the determination of the number of ACS cases in Poland. The NHF reporting data indicate that were 123,091 ACS cases in 2013. The largest group were cases with unstable angina (38% ACS, 47.4 thousand). STEMI accounted for 32% of ACS cases (39 thousand), while NSTEMI accounted for 30% of all ACS cases (36.6 thousand) (cf. Figure 1).
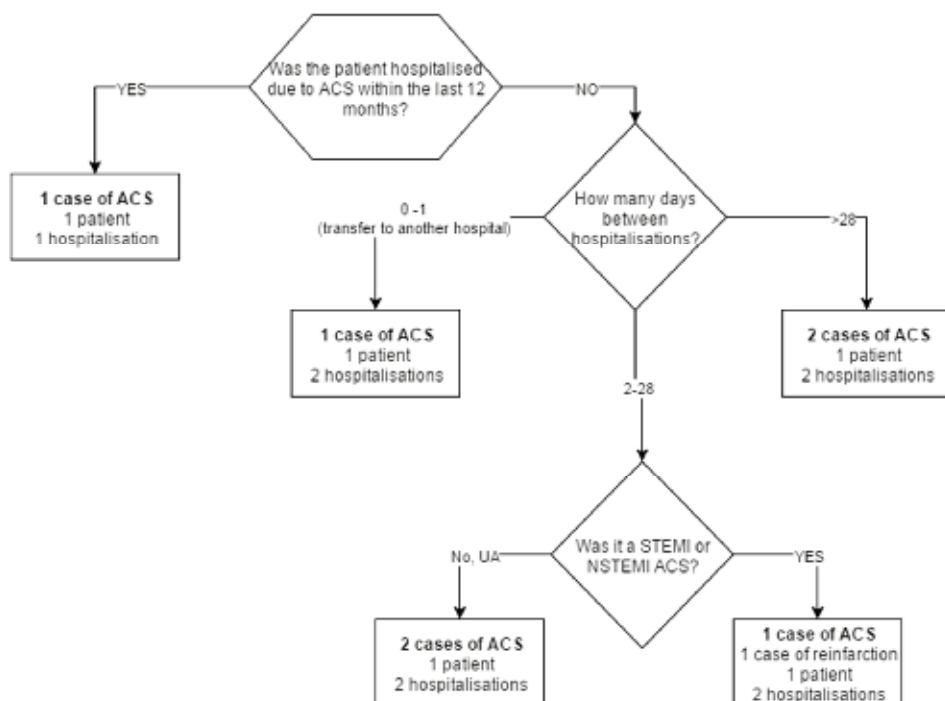
Flowchart 1. Model describing the methodology for determining the number of new ACS cases (source: DAiS analysis)
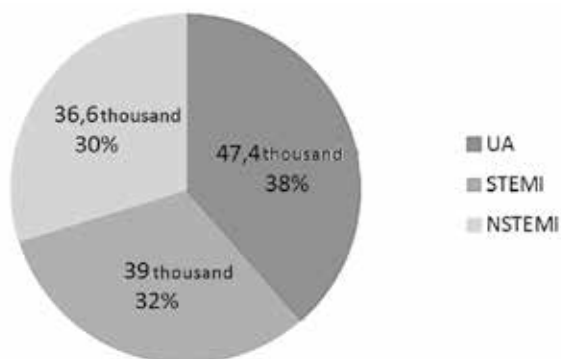
Figure 2. ACS structure in Poland (source: DAiS analysis based on NHF data)

The main methods of treatment of ACS cases include PCI and CABG. Table 1 shows information on the percentage of ACS cases treated with those methods. The table also contains information on the use of coronarography in invasive diagnostics of ACS. It should be emphasised that these data relate to the treatment of a given case. In the case of UA, one ACS case may be associated with one hospitalisation. In turn, in some cases of NSTEMI and STEMI, one ACS case is associated with two hospitalisations – this may be the case where the interval between hospitalisations is 0–1 day. If the interval between hospitalisations of NSTEMI or STEMI is longer than 1 day, these shall be taken into account as separate ACS cases, otherwise they will constitute the same ACS case.

The derived values indicate that on average 79 in 100 ACS cases were diagnosed using coronarography. On average 60 in 100 ACS cases were treated using interventional cardiology methods (PCI), while coronary artery bypass grafts (CABG) were rarely performed – on average in 4 ACS cases out of 100. PCI was performed most frequently in cases of STEMI events – 76%, and then in cases of NSTEMI events – 58%. PCI was performed least frequently in the case of UA (about 50%). For this category of ACS cases, CABG was performed most frequently (5.6%), however this procedure was performed least frequently in the case of STEMI (1.9%).

Table 3. Empirical model of ACS treatment and the use of coronarography in invasive diagnostics, part I (source: DAiS analysis based on NHF data)

ACS group	PCI	CABG	Coronarography
NSTEMI	58.4%	2.7%	77.7%
STEMI	75.8%	1.9%	82.2%
UA	49.7%	5.6%	76.5%
Total	**60.2%**	**3.6%**	**78.6%**

Values presented in Table 1 include the total use of PCI and CABG in treating individual ACS cases and do not take into account combined treatment methods. Flowchart 2 presents comprehensive conclusions on the course of treatment of ACS cases in 2013 and describes the treatment in individual cases determined in accordance with the model shown in Figure 1. To

ensure the transparency of presented results, no further division of the tree was performed, where the sample size in each branch (i.e. number of cases in each section) was smaller than 100 cases.

The treatment pattern for ACS cases shown in Flowchart 2 indicates that in 64% cases treatment using PCI or CABG was performed within one ACS incident (61% for NSTEMI, 77% for STEMI and 55% for UA). Additionally, the analysis of the graph indicates that ACS cases were rarely treated using both PCI and CABG. The largest group of ACS cases, in the treatment of which CABG was performed, were cases of UA without angioplasty.

Attention should be paid to ACS cases, in which the performance of angioplasty or CABG was reported without previously reporting the performance of coronarography. NHF reporting indicates that 6.6% angioplasty procedures were performed without previously reporting the performance of coronarography (7% in case of NSTEMI, 7.5% in case of STEMI and 4.8% in case of UA). In turn, CABG was reported without coronarography in 64% of cases (50% in case of NSTEMI, 49% in case of STEMI and 72% in case of UA).

ACS stream	number of patients	proportion of patients	Was the coronarography performed?			Of which: was angioplasty performed?			Of which: was CABG performed?		
			YES/NO	Number of patients	Share	YES/NO	Number of patients	Share	YES/NO	Number of patients	Share
NSTEMI	39006	31.69%	NO	8692	22.3%	NO	7181	82.6%	NO	6653	92.6%
									YES	528	7.4%
						YES	1511	17.4%	NO	1505	99.6%
									YES	6	0.4%
			YES	30314	77.7%	NO	9038	29.8%	NO	8577	94.9%
									YES	461	5.1%
						YES	21276	70.2%	NO	21211	99.7%
									YES	65	0.3%
STEMI	36641	29.77%	NO	6513	17.8%	NO	4583	70.4%	NO	4255	92.8%
									YES	328	7.2%
						YES	1930	29.6%	NO	1921	99.5%
									YES	9	0.5%
			YES	30128	82.2%	NO	4298	14.3%	NO	3991	92.9%
									YES	307	7.1%
						YES	25830	85.7%	NO	25791	99.8%
									YES	39	0.2%
UA	47444	38.54%	NO	11128	23.5%	NO	9648	86.7%	NO	7740	80.2%
									YES	1908	19.8%
						YES	1480	13.3%	NO	1457	98.4%
									YES	23	1.6%
			YES	36316	76.5%	NO	14200	39.1%	NO	13564	95.5%
									YES	636	4.5%
						YES	22116	60.9%	NO	22014	99.5%
									YES	102	0.5%

Flowchart 2. Empirical model of ACS treatment and the use of coronarography in invasive diagnostics, part II (source: DAiS analysis based on NHF data)

The tree presented in Flowchart 2 shows the model of treatment of a given ACS case and describes the treatment of a patient diagnosed with ACS as part of a single, so-called hospitalisation period; therefore, it relates to patients who were treated for ACS in a given calendar year. Another important information as regards the treatment pathway analysis is data on the treatment of patients who in a given year were diagnosed with ACS for the first

time. In this paper, the model of treatment of first-time patients concerns 2013, which means that it describes the treatment of patients who, according to NHF reporting data for the period 2009–2012, did not receive any services in relation to ICD10 I20.0 or I21 diagnosis. The model takes into account the 365-day treatment pathway for a patient.

As in the case of the model of treatment of ACS cases, the first key information is the number of patients whose treatment is described by the model. NHF reporting data suggest that in 2013 there were 98,509 new patients diagnosed with ACS (Diagram 3), of which 35.9 thousand were patients with UA (36% of all ACS cases), then patients with NSTEMI (31.4 thousand; 32% of ACS cases) and patients with STEMI (31.1 thousand; 32% of ACS cases).
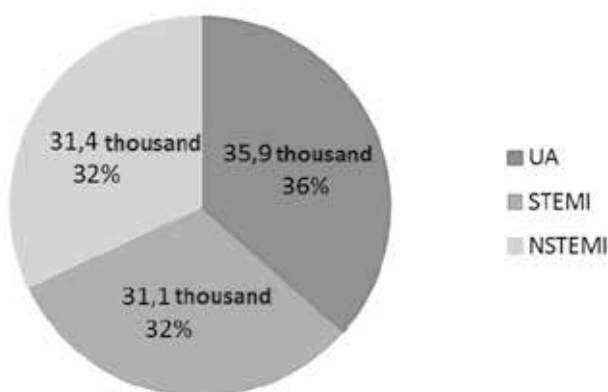
Figure 3. ACS structure in Poland (source: DAiS analysis based on NHF data)

Table 2 presents the percentage of first-time patients diagnosed with ACS, who were treated using PCI and CABG within 365 days of the first registration in the system. The vast majority of patients were diagnosed using coronarography (80%). PCI was used more frequently – 62% of first-time patients were treated by means of this method. Angioplasty was performed most frequently in patients with STEMI (almost 80%). Coronary artery bypass grafting (CABG) was performed in 4% of patients newly diagnosed with ACS – most frequently in the case of UA (6.7%) and least frequently in the case of STEMI (1.7%).

Table 4. Empirical model of treatment of first-time ACS patients and the use of coronarography in invasive diagnostics, part I (source: DAiS analysis based on NHF data)

ACS group	PCI	CABG	Coronarography
NSTEMI	60%	3%	79.2%
STEMI	79.9%	1.7%	84%
UA	49%	6.7%	78.4%
Total	**62.3%**	**4%**	**80.4%**

Flowchart 3 presents the combination of individual invasive treatment methods for patients who in 2013 were diagnosed with ACS for the first time. The results show that only 0.6% of patients were treated using both methods, i.e. CABG and angioplasty. Also, in the case of this treatment model, it may be noticed that for some patients, the performance of coronarography was not reported along with the performance of CABG or angioplasty (in 6% of patients in case of angioplasty, 41% of patients in case of CABG), despite the fact that this procedure is an integral part of revascularisation. It should be noted that 20% of patients (22% of patients with NSTEMI, 8% of patients with STEMI, 30% of patients with UA) after undergoing coronarography were qualified for conservative treatment, as the procedure did not show any hemodynamically significant constrictions in coronary vessels, or the nature, location and number of changes disqualified the patient from the currently available revascularisation methods. The majority of patients who belong to this group have lived through the period of 365 days – the mortality rate was 11%.

It was assumed that lack of coronarography before CABG or PCI is due to reporting errors. Flowchart 4 shows the model of treating first-time patients, in which it was assumed that the performance of CABG or PCI is associated with the performance of coronarography, thus this model does not lead to a situation in which there is a group of patients with the combination: no coronarography and angioplasty performed or no coronarography and CABG performed.

ACS stream	number of patients	proportion of patients	number of deaths	% of deaths	Was the coronarography performed? YES/NO	Number of patients	Share	number of deaths	% of deaths	Of which: was angioplasty performed? YES/NO	Number of patients	Share	number of deaths	% of deaths	Of which: was CABG performed? YES/NO	Number of patients	Share	number of deaths	% of deaths
NSTEMI	31422	31.90%	5250	16.7%	NO	6538	20.8%	2280	34.9%	NO	5347	81.8%	2135	39.9%	NO	5143	96.2%	2113	41.1%
															YES	204	3.8%	22	10.8%
										YES	1191	18.2%	145	12.2%	NO	1178	98.9%	144	12.2%
															YES	13	1.1%	1	7.7%
					YES	24884	79.2%	2970	11.9%	NO	7208	29.0%	1007	14.0%	NO	6660	92.4%	972	14.6%
															YES	548	7.6%	35	6.4%
										YES	17676	71.0%	1963	11.1%	NO	17488	98.9%	1952	11.2%
															YES	188	1.1%	11	5.8%
STEMI	31144	31.62%	5577	17.9%	NO	4984	16.0%	1886	37.8%	NO	3276	65.7%	1663	50.8%	NO	3208	97.9%	1654	51.6%
															YES	68	2.1%	9	13.2%
										YES	1708	34.3%	223	13.1%	NO	1702	99.6%	220	12.9%
															YES	6	0.4%	3	50.0%
					YES	26160	84.0%	3691	14.1%	NO	2969	11.4%	556	18.7%	NO	2618	88.2%	529	20.2%
															YES	351	11.8%	27	7.7%
										YES	23191	88.6%	3135	13.5%	NO	23073	99.5%	3132	13.6%
															YES	118	0.5%	3	2.5%
UA	35943	36.49%	2349	6.5%	NO	7751	21.6%	655	8.4%	NO	6751	87.1%	595	8.8%	NO	5485	81.2%	530	9.7%
															YES	1266	18.8%	65	5.1%
										YES	1000	12.9%	60	6.0%	NO	973	97.3%	59	6.1%
															YES	27	2.7%	1	3.7%
					YES	28192	78.4%	1694	6.0%	NO	11575	41.1%	686	5.9%	NO	10747	92.8%	628	5.8%
															YES	828	7.1%	58	7.0%
										YES	16617	58.9%	1008	6.1%	NO	16338	98.3%	991	6.1%
															YES	279	1.7%	17	6.1%

Flowchart 3. Empirical model of treatment of first-time ACS patients and the use of coronarography in invasive diagnostics, part II (source: DAiS analysis based on NHF data)

ACS stream	number of patients	proportion of patients	Was the coronarography performed?			Of which: was angioplasty performed?			Of which: was CABG performed?		
			YES/NO	Number of patients	Share	YES/NO	Number of patients	Share	YES/NO	Number of patients	Share
NSTEMI	31422	31.90%	NO	5347	17%	NO	5347	100%	NO	5347	100%
			YES	26075	83%	NO	7208	28%	NO	6456	90%
									YES	752	10%
						YES	18867	72%	NO	18666	99%
									YES	201	1%
STEMI	31144	31.62%	NO	3276	11%	NO	3276	100%	NO	3276	100%
			YES	27868	89%	NO	2969	11%	NO	2550	86%
									YES	419	14%
						YES	24899	89%	NO	24775	100%
									YES	124	0%
UA	35943	36.49%	NO	6751	19%	NO	6751	100%	NO	6751	100%
			YES	29192	81%	NO	11575	40%	NO	10747	93%
									YES	828	7%
						YES	17617	60%	NO	17311	98%
									YES	306	2%

Flowchart 4. Empirical model of treatment of first-time ACS patients and the use of coronarography in invasive diagnostics, part III (source: DAiS analysis based on NHF data)

The treatment model presented in Figure 4 takes into account the values adjusted by the values for invasive diagnostics performed (coronarography). This model shows a group of patients who were not treated with CABG or PCI, but also did not undergo coronarography. This is why in the next stage of the analysis it was verified whether this group of patients was not previously reported as having coronarography with diagnosis other than ACS. The results are presented in Table 3, which shows that coronarography with diagnosis other than ACS was performed only for a small percentage of patients (3%) prior to being diagnosed with ACS for the first time. These percentages were similar for STEMI, NSTEMI and UA.

Table 5. Percentage of patients who were subjected to coronarography prior to being diagnosed with ACS for the first time (source: DAiS analysis based on NHF data)

Was coronarography performed?	NSTEMI	STEMI	UA	Total
NO	96.9%	97.8%	95.9%	96.7%
YES	3.1%	2.2%	4.1%	3.3%

Those patients who had previous coronarography were most frequently diagnosed with I25.0, i.a. atherosclerotic cardiovascular disease, and accounted for almost 30% of ca. 400 patients who, before being hospitalised for ACS, underwent coronarography with another cardiological diagnosis (cf. Table 4).

The vast majority of patients diagnosed with ACS lived through the period of 365 days (87%). STEMI and NSTEMI were both characterised by the highest mortality rate, where out of 31.1 and 31.4 thousand patients diagnosed in 2013, 5.5 and 5.3 thousand had died. (cf. Table 6).

Table 6. Deaths of first-time patients diagnosed in 2013 with ACS within 365 days from the first occurrence of ACS.

ACS group	Number of cases	Number of deaths	Mortality rate
NSTEMI	31,422	5,250	17%
STEMI	31,144	5,577	18%
UA	35,943	2,349	7%
Total	**98,509**	**13,176**	**13%**

The treatment model took into account the use of revascularisation methods (PCI and CABG), which constitute the "gold standard" of conduct in the case of patients diagnosed with ACS. Another important issue in the process of treating patients with ACS is cardiac rehabilitation, which aims at improving the overall health of patients and reducing the risk of cardiovascular death. Flowchart 5 presents the use of cardiac rehabilitation in patients after the ACS. The tree describes the first instance of ACS for patients who in 2013 were

diagnosed with ACS for the first time and who lived through the period of 365 days from the date of diagnosis. The tree indicates whether a patient was provided cardiac rehabilitation benefit within 365 days from the date of ACS diagnosis. The NHF reporting data indicate that in 2013 cardiac rehabilitation was used in ca. 21.4% of patients with ACS, who were not diagnosed with ACS before 2013 and who lived through 365 days from the date of ACS diagnosis. Rehabilitation was most frequently performed in patients with STEMI (27.6%), then in patients with NSTEMI (21.4%) and UA (16.8%)[12].

Table 7. Use of cardiac rehabilitation in ACS, part I (source: DAiS analysis based on NHF data)

Was cardiac rehabilitation performed?	NSTEMI	STEMI	UA	Total
NO	78.6%	72.4%	83.2%	78.6%
YES	21.4%	27.6%	16.8%	21.4%

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[12] Empirical data also confirm the relation between cardiac rehabilitation and drop in mortality due to ACS. Specific information in this regard are presented in the publication *Świadczenia onkologiczne i kardiologiczne w Polsce – podejście ilościowe do oceny jakości leczenia i szacowania potrzeb*, which was prepared as a result of the project.

ACS stream	number of patients	proportion of patients	Was PCI performed?			Of which: was CABG performed?			Of which: was cardiac rehabilitation performed?		
			YES/NO	Number of patients	Share	YES/NO	Number of patients	Share	YES/NO	Number of patients	Share
NSTEMI	26172	30,7%	NO	9413	36%	NO	8718	93%	NO	7600	87%
									YES	1118	13%
						YES	695	7%	NO	255	37%
									YES	440	63%
			YES	16759	64%	NO	16570	99%	NO	12647	76%
									YES	3923	24%
						YES	189	1%	NO	65	34%
									YES	124	66%
STEMI	25567	30,0%	NO	4026	16%	NO	3643	100%	NO	3191	88%
									YES	452	12%
						YES	383	10%	NO	140	37%
									YES	243	63%
			YES	21541	84%	NO	21423	99%	NO	15137	71%
									YES	6286	29%
						YES	118	1%	NO	49	42%
									YES	69	58%
UA	33594	39,4%	NO	17045	51%	NO	15074	88%	NO	13530	90%
									YES	1544	10%
						YES	1971	12%	NO	793	40%
									YES	1178	60%
			YES	16549	49%	NO	16261	98%	NO	13538	83%
									YES	2723	17%
						YES	288	2%	NO	98	34%
									YES	190	66%

Flowchart 5. Use of cardiac rehabilitation in ACS, part II
(source: DAiS analysis based on NHF data)

Summary

This chapter presented the pathomechanism, breakdown and epidemiology of acute coronary syndromes together with the description of diagnosis and treatment. It also presented results of the analysis of the data of the public payer that allow for developing an empirical model of ACS treatment for Poland. In particular, the number of STEMI and NSTEMI events and unstable coronary heart disease cases was determined. For each of these diagnoses, the frequency of performed procedures reported by healthcare providers to the National Health Fund was analysed. The chapter also describes the treatment pathway for "first-time" patients belonging to the cohort of 2013.

It should be emphasised that the current treatment model for acute coronary syndromes is transparent, and significantly facilitates and speeds up the proper therapeutic qualification of a patient. The performance of diagnostic coronarography allows for qualifying the patient for percutaneous coronary angioplasty (PCI) or for full revascularisation of the myocardium by means of CABG, or for conservative treatment.

Poland has one of the highest number of invasive cardiology centres in Europe per 1 million inhabitants. In case of ACS treatment the time between occurrence of symptoms and taking up treatment is of relevance, and therefore not only the number of employees matters but also their optimal deployment, which will ensure proper safety for the patient. Analyses conducted in the process of creating regional map of health care needs, especially forecasts on the needs for medical procedures connected with the treatment of acute coronary syndrome, are a sound basis for adopting management decisions that should allow to address this issue.

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Treatment pathway model in arrhythmia and atrioventricular block

Ewa Kowalik, Filip Urbański

Introduction

Arrhythmia and atrioventricular block constitute a very wide set of diseases caused by irregular electrical activity of the heart. With regard to the pathomechanism and the treatment methods the following diseases are distinguished: supraventricular cardiac arrhythmia, ventricular cardiac arrhythmia, sudden cardiac arrest and sudden cardiac death as well as abnormal automaticity and atrioventricular block.

The supraventricular cardiac arrhythmias include additional supraventricular contractions and supraventricular tachycardia (atrioventricular nodal reentrant tachycardia, atrioventricular reentrant tachycardia and atrial tachycardia). This disease stream includes also atrial fibrillation and flutter. However due to the fact that this is the most common form of sustained arrhythmia causing heavy burden for the health care system, atrial fibrillation and flutter were excluded from this group and are described in a separate chapter of this publication.

Ventricular arrhythmias include: additional ventricular contractions (premature, mono- or polymorphic extrasystoles) non-sustained and sustained tachycardia (at least 3 subsequent ventricular contractions) and ventricular fibrillation and flutter. Electrical storm is defined as frequent (at least 3 during the day) episodes of ventricular tachycardia / ventricular fibrillation requiring intervention. Sudden cardiac arrest is defined as the discontinuation of mechanical activity of the heart together with the lack of pulse and respiration (alternatively agonal respiration), which may take place in the event of ventricular fibrillation/flutter, pulseless ventricular tachycardia and less frequently in the event of asystole (no electrical activity of the heart) or a pulseless electrical activity (the electrical activity is maintained but without the mechanical activity). Sudden cardiac death means death due to cardiac causes preceded by sudden loss of consciousness when the symptoms preceding the death occurred not earlier than an hour before. Cardiac causes of the death include: myocardial infarction (the most common cause), cardiomyopathies (including hypertrophic cardiomyopathy, arrhythmogenic

right ventricular cardiomyopathy) genetically conditioned electrical heart diseases (e.g. long QT syndrome, Brugada syndrome), heart defects (e.g. aortic stenosis), sick sinus syndrome and atrioventricular block, acute pulmonary embolism and aortic dissection.

The abnormal automaticity and atrioventricular block include: sinus node dysfunction, atrioventricular blocks (of first-, second- and third-degree) and intraventricular blocks.

Clinical symptoms of arrhythmia depend on the type of arrhythmia and its duration, the heart rate during the episode of arrhythmia as well as on the age of the patient and the underlying disease. Usually additional contractions do not cause relevant symptoms. In case of complex arrhythmias patients feel palpitations, fatigue, pain in the chest, dyspnoea. These kinds of arrhythmias may lead to the loss of consciousness and sudden cardiac arrest. Longer or more frequent cardiac arrhythmia may result in the development of the so-called tachycardia induced cardiomyopathy.

Signs of bradycardia are also characterised by a varied intensity – from the lack of signs of bradycardia in young people without other coexisting diseases through a decreased tolerance of effort, vertigo, the feeling of a risk of collapsing, to a syncope and sudden cardiac death.

The diagnosis of arrhythmia and atrioventricular block takes usually place on the basis of the resting electrocardiogram and/or longer electrocardiographic monitoring. The treatment is based on: implantation of an artificial pacemaker in patients with symptomatic/advanced atrioventricular blocks, secondary prevention of sudden cardiac death in patients who survived a sudden cardiac arrest (implantation of ICD), ablation and pharmacotherapy of ventricular and supraventricular cardiac arrhythmia and implantation of ICD in case of patients at risk of sudden cardiac death.

This article attempts to design a treatment structure model for arrhythmia and atrioventricular block (excluding atrial fibrillation and flutter) in Poland. The first part is dedicated to the epidemiological description on the basis of the international research review. The next part is dedicated to risk factors of the disease concerned and presents the way of diagnosing it. The third part concerns the decision-making models in treatment of arrhythmia and atrioventricular block as well as containing statistics on implantation of pacemakers and ICD in selected countries. The last part presents treatment structure model of these diseases in Poland. On the basis of the public payer database, a yearly incidence rate of arrhythmia

and atrioventricular block according to age, sex and the residence area (urban/rural area) has been established. This part concerns also the frequency of procedures performed with a key relevance from the point of view of the disease treatment: EPS based invasive diagnostics, ablation, implantation/replacement of ICD and its parts as well as implantation or replacement of the pacemaker. Also the frequency of implanting pacemakers and ICD was compared with the cited statistics.

Epidemiological analysis

Available epidemiological works assessing the occurrence of arrhythmia and atrioventricular block are characterised by significant differences resulting from the sample of the study population, considered cardiac arrhythmias and diagnostic methods used for diagnosis. In few cases the analyses included the non-selected population, most of analyses were narrowed to populations of patients particularly predisposed to cardiac arrhythmia (e.g. patients with coronary heart disease, hypertrophic cardiomyopathy) or atrioventricular block (e.g. patients after aortic valve replacement). Part of analyses was focused on the occurrence only of particular arrhythmia or atrioventricular block (this comment applies especially to epidemiological works analysing the frequency of sudden cardiac death but also to the pre-excitation syndrome). The analyses also included different methods of detecting cardiac arrhythmia: 12-lead ECG, Holter monitoring or monitoring cardiac arrhythmias during a stress test ECG. Table 1 shows results of studies which assess the frequency of arrhythmia or atrioventricular block occurrence in the broadest possible perspective, by a cohort studied and by a type of cardiac disorder.

Table 1. Frequency of arrhythmia and atrioventricular block occurrence in epidemiological studies (source: own study based on Manolio et al. 1994, Lok et al. 1997)

Country	Hong-Kong	USA
Cohort age	60–94	above 64
Cohort size	1,454 individuals	1,372 individuals
Selection of a cohort for the purpose of studies	members of cultural centres in 9 Hongkong districts were invited to participate voluntarily in a health-condition study.	systematic sampling with the use of social insurance number
Diagnostic method	ECG at rest	24-hour Holter ECG monitoring
Atrioventricular block	9.8% population, cases of total atrioventricular block were not recorded	women: 1.9% men: 5.6%[1] including total atrioventricular block: women: 0.0% men: 0.3%
Supraventricular arrhythmia	supraventricular extrasystoles in 2.3% of the cohort	supraventricular tachycardia (3 and more stimulations): women: 49.9% men: 47.7%[2] clear increase in the frequency of supraventricular arrhythmia with age in both sexes
Ventricular arrhythmia	ventricular extrasystoles in 1% of the cohort	ventricular tachycardia (3 and more stimulations): women: 4.3% men: 10.3%[3] (p=0.001)

The table above shows that the frequency of arrhythmia and atrioventricular block that were determined in particular studies differs significantly depending on the diagnostic method applied. Performing a 24-hour Holter ECG monitoring as opposed to a standard ECG increases the chances to record significant arrhythmias and atrioventricular blocks.

The specificity of studies presented in Table 1 does not enable analysing sudden cardiac death occurrence in the population. The risk of sudden cardiac death is higher in men and increases with age (which results from IHD occurring more frequently in old age groups). It ranges from 1.4/100 thousand patient-years for women to 6.668/100 thousand patient-years for men, and in younger age groups that indicator ranges from 0.46 to 3.7 cases/100 thousand patient-years (Priori et al., 2015).

Risk factors related with arrhythmia and atrioventricular block morbidity, diagnostic tests

Cardiovascular comorbidities, including first of all IHD, are the greatest risk factor related to arrhythmia. Ischemic heart disease, valve diseases and heart failure are the main causes of sudden cardiac deaths in older age groups (Priori et al., 2015). Certain percentage of arrhythmias are genetically conditioned. Chanellopathies and cardiomyopathies are the main causes of sudden cardiac deaths in younger age groups. Based on a Framingham study cohort analysis it was proven that the probability of a sudden cardiac death increases by approximately 50% in case of a positive family history of that disease (Friedlander et al., 1998).

Age related idiopathic fibrosis of electrical conduction system as well as IHD are among the main causes of atrioventricular block (Chow et al., 2012). Moreover, the causes of bradycardia include: cardiomyopaties, diseases affecting myocardium (sarcoidosis, amylosis, and haemochromatosis), connective tissue diseases (systemic lupus erythematosus, rheumatoid arthritis), infectious diseases (e.g. myocarditis, endocarditis, and Lyme disease), post-surgery damages and harms following intravesical interventions. Atrioventricular block can also occur as a consequence of increased stimulation of vagus nerve, electrolyte disorders (hypo- and hyperkalemia), metabolic disorders (hypothyroidism, hypothermia, anorexia nervosa) or neurologic disorders (increased intracranial pressure, brain tumours), obstructive sleep apnea or medicine or stimulants used (including beta-adrenolytics, verapamil and diltiazem, digitalis, class I antiarrhythmic agents, amiodarone, cocaine).

In case of persisting arrhythmia or bradycardia, diagnosis is made based on a standard 12-lead ECG. The diagnosis of transient bradycardia or paroxysmal arrhythmias requires, apart from ECG, a longer period ECG monitoring. Due to the frequency of symptoms' occurrence one applies: Holter method (telemetric monitoring in hospital conditions) if the symptoms appear every day, 48-72 hour Holter (or telemetric monitoring in hospital conditions) if symptoms occur every 2-3 days, 7-day Holter monitoring or external loop recorder if the symptoms appear once a week. If the symptoms appear less frequently it is recommended to apply external (symptoms appearing once a month) or implantable (symptoms appearing less frequently than once a month) loop recorder. A suspicion of unrecorded episodes of arrhythmia or bradycardia authorises doctors to conduct provocation tests (tilt test, carotid sinus massage, and stress test) or electrophysiology study (EPS).

Stress tests are indicated for patients who tend to faint during or shortly after physical effort or during the diagnostic procedure for IHD.

Imaging tests are also recommended (echocardiography as the most important one) in order to assess the left ventricle function and possible diagnosis of structural heart disease. Echocardiography is recommended in patients endangered with a high risk of serious ventricular arrhythmias or sudden cardiac death i.e. in patients suffering from hypertrophic or dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, following myocardial infarction and in patients' relatives with hereditary diseases related with sudden cardiac death.

Coronarography must be considered in order to confirm or exclude IHD with major coronary luminal narrowing in patients suffering from life threatening arrhythmia or following a cardiac arrest (with medium or high probability of IHD due to age and symptoms).

Decision-making models in arrhythmia and atrioventricular block treatment

As in case of other major diseases of cardiovascular system, guidelines concerning diagnosis and treatment of arrhythmia and atrioventricular block have been developed at the European level by the European Society of Cardiology. Guidelines applicable to the above mentioned group of diseases relate to the treatment of supraventricular cardiac arrhythmia (Blomström-Lundqvist et al., 2003), procedures followed in ventricular arrhythmia and prevention of sudden cardiac death (Priori et al., 2015) and those related to stimulation and resynchronization (Brignole et al., 2013). Thus, the differences in arrhythmia and atrioventricular block treatment procedures among the European countries result from a various extent of implementing the recommendations, especially those concerning the performance of ablations and implantation of implantable devices.   They can result from an insufficient number of the procedures performed, and from the performance of the procedure in patients who did not have such indications (e.g. to have a pacemaker implanted). The latter cases are far more difficult to detect in the records and analyses on the use of resources.

Treatment in case of arrhythmia should take account of excluding the reversible causes of arrhythmia, eliminating the triggering factors and treating the core disease. The aim of the treatment is to prevent sudden cardiac death and to improve life quality of the patients.

Arrhythmia is treated by means of procedures which increase vagus nerve stimulation, administration of antiarrhythmic agents and electrotherapy.

Treatments which increase vagus nerve stimulation (Valsalva manoeuvre, triggering emesis, immersion of face in cold water, carotid sinus massage) are applied in case of supraventricular cardiac arrhythmia.

Pharmacotherapy is used in treating ventricular and supraventricular cardiac arrhythmia. There are four classes of antiarrhythmic drugs (according to Vaughan-Williams classification): class I A (quinidine, procainamide, disopyramide), class I B (lidocaine, mexiletine); class I C - flecainide and propafenone; class II - β-blockers; class III - amiodarone, dronedarone, sotalol, bretylium, ibutilide; class IV - verapamil, diltiazem. Some of class I and III drugs are not available in Poland, and the ones used most frequently include beta-adrenolytics and amiodarone.

Electrotherapy includes radiofrequency ablation (less frequently - surgical one) and implantation of a cardioverter-defibrilator. Moreover, cardioversion is applied as an urgent procedure in case of hemodynamicaly unstable tachycardia, and defibrillation is performed in case of sudden cardiac arrest as a result of ventricualr fibrillation. Ablation is recommended in patients showing the symptoms of supraventricular tachycardia and in patients with sustained ventricular tachycardia or electric storm (related with the presence of myocardial scarring), as well as in patients with recurrent ICD breakdowns caused by sustained ventricular tachycardia. Ablation of the cause of arrhythmia should also be considered in patients with symptomatic ventricular extrasystoles or suffering from left ventricular dysfunction caused by arrhythmia.

Implantation of cardioverter defibrillator is recommended in patients with documented episodes of atrial fibrillation or hemodynamically unstable ventricular tachycardia in case of a lack of a reversible cause (or within 48 hours following a myocardial infarction) and an optimum chronic therapy. Implantation of cardioverter defibrillator is also considered in patients with recurrent sustained ventricular tachycardia without left ventricular dysfunction who are treated optimally. In both situations, the treatment is conditioned upon the expected survival in a good clinical condition exceeding 1 year.

Risk stratification of sudden cardiac death in certain diseases also enables to define indications for cardioverter-defibrillator implantation as a primary prevention scheme e.g.

in patients with hypertrophic cardiomyopathy, long QT syndrome or arryhythmogenic right ventricular cardiomyopathy.

Also, permanent cardiac electrostimulation is a basic treatment procedure in patients with symptomatic or advanced atrioventricular block. The stimulation system includes a pacemaker (detector and generator of electric impulse, with a battery) and electrodes connected with it intravenously or epicardially (much less often). Heart stimulation is indicated: (1) in patients suffering from sick sinus syndrome (SSS), where the symptoms can be assigned to bradycardia, (2) in patients with third degree atrioventricular block and type 2 second degree atrioventricular block, irrespective of the occurring symptoms, (3) in patients with syncope, bundle branch block and positive result of ECG and in (4) patients with variable bundle branch block regardless of whether symptoms are present.

Dual-chamber stimulation is the preferred one; in regard of patients with chronotropic incompetence, especially younger ones who are physically active, and in patients with sustained atrial fibrillation and single-chamber pacemakers one should consider stimulation with adapted frequency function. Artificial pacemaker is not indicated for patients with atrioventricular block resulting from reversible causes. Flowchart 1 presents a simplified treatment pathway model for arrhythmia and atrioventricular block.
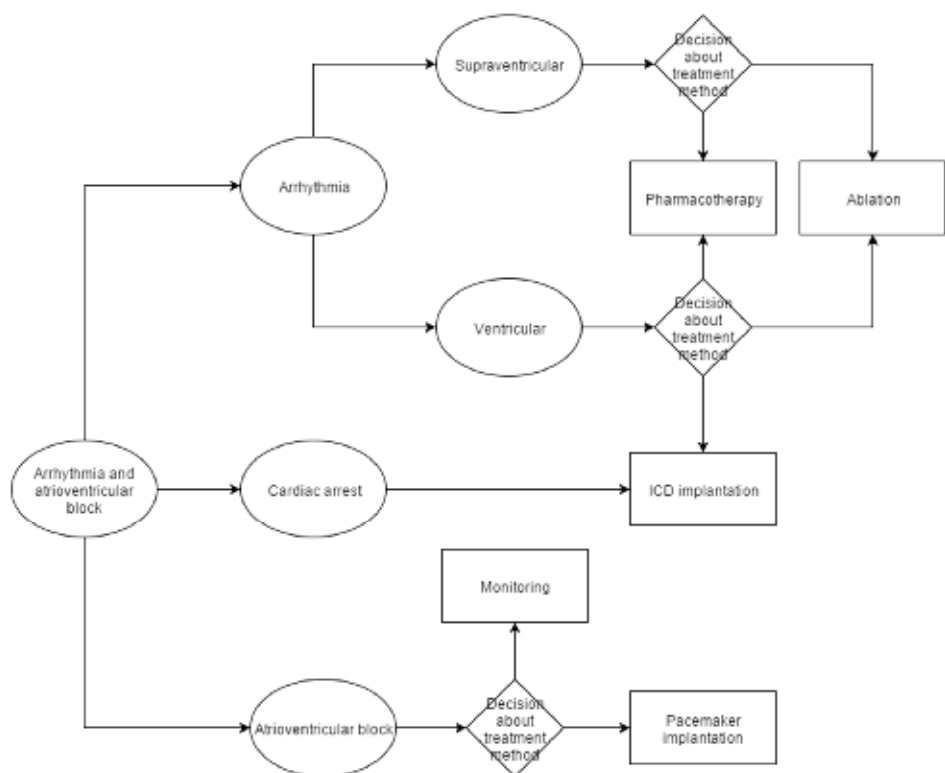
Flowchart 1. Treatment pathway model for arrhythmia and atrioventricular block (own study)

Apart from administering pharmacological antiarrhythmic agents and treating the core disease, the main method of treating arrhythmia and atrioventricular block includes an implantation of an artificial pacemaker and/or cardioverter-defibrillator as well as radiofrequency ablation of arrhythmia.

Based on the analysis of EUCOMED data on the number of implantable devices sold in Europe between 2004-2008, a moderate increase of implantable pacemakers was recorded (from 831/million inhabitants in 2004 to 907/million inhabitants in 2008 – cf. Figure (wykres) 1, Veldhuisen et al., 2009). The greatest number of the procedures were performed in Germany (1196/million of inhabitants in 2008), and the smallest number in Ireland (490/million of inhabitants in 2008). Within the same period the number of implantations of cardioverter-defibrillators increased in Europe (from 80/million inhabitants to 140/million inhabitants). As

in the case of artificial pacemakers, the greatest number of ICD implantations was performed in Germany (264/million inhabitants in 2008, cf. Figure 1).

Figure 1. Implantations of pacemakers and cardioverter-defibrillators
(per one million of inhabitants) in particular Western European countries in 2008
(source: own study based on Veldhuisen et al., 2009)

In the following years the EUCOMED data included also Poland[13]. In 2013, 787 pacemakers/ million inhabitants were implanted in Poland and 204 cardioverter-defibrillators/million of inhabitants, and the average for all the analysed European countries in the period under consideration amounted to 933/million and 176/million, respectively (cf. Figure 2).

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[13] http://www.eucomed.org/uploads/_medical_technology/facts_figures/CRM_Graphs_2015.pdf
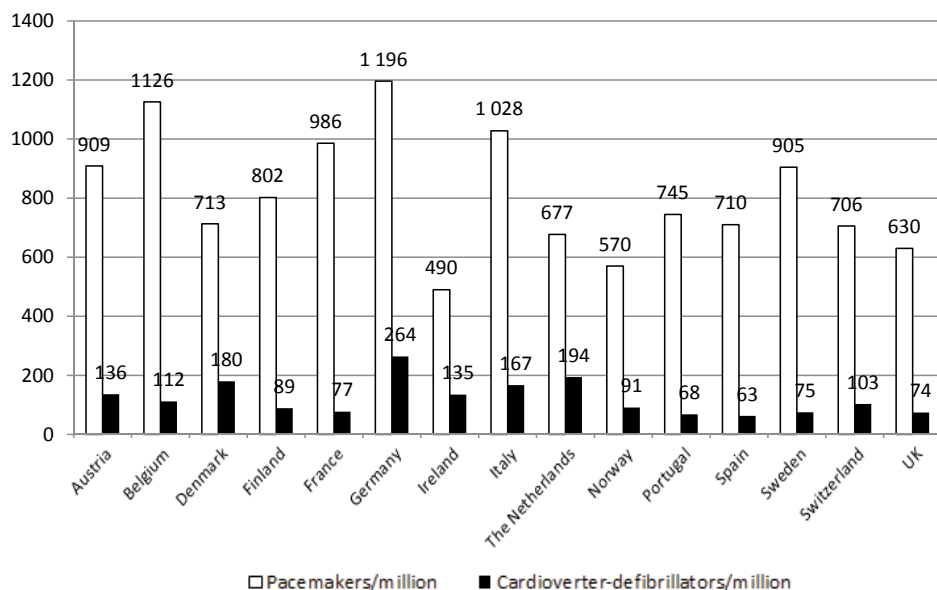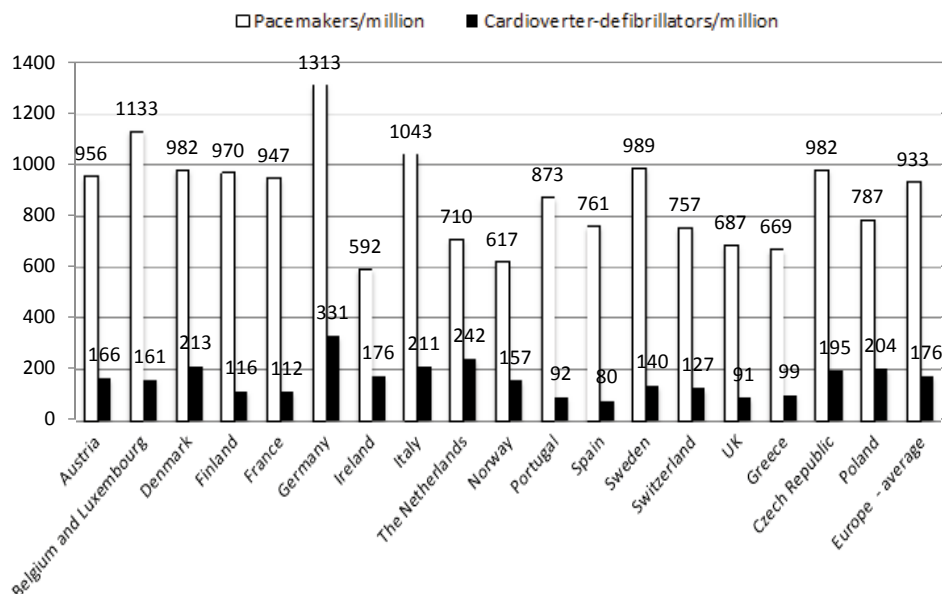
Figure 2. Implantations of pacemakers and cardioverter-defibrillators
(per one million of inhabitants) in particular Western European countries in 2013
(source: own study based on EUCOMED)

One has to draw attention to the fact that the EUCOMED data relate to the number of sold devices, i.e. potentially both first-time implantations and replacements of pacemakers and cardioverter-defibrillators, in all possible indications (e.g. in case of ICD also in patients with heart failure under sudden cardiac death primary prevention scheme).

The worldwide 2009 data (Mond et al., 2011) indicate that pacemaker replacement procedures accounted for up to approx. 30% of all procedures carried out (on average 26% of all analysed implantations, i.e. over 1 million pacemakers). The above mentioned study included 61 countries and 5.05 billion people (i.e. 74% of all the world population). The majority of first-time implantations of pacemakers were carried out in Germany (927/1 million of inhabitants), in France (782/1 million of inhabitants), USA (767/1 million of inhabitants) and in Italy (744/1 million of inhabitants). As far as cardioverters-defibrillators are concerned, the USA is the leader (434 new implantations per 1 million of inhabitants) followed by the Western European countries: Germany (290/1 million of inh.) The Netherlands (220/1 million of inh.) and Italy (174/1 million of inh.) - cf. Fig. 3.
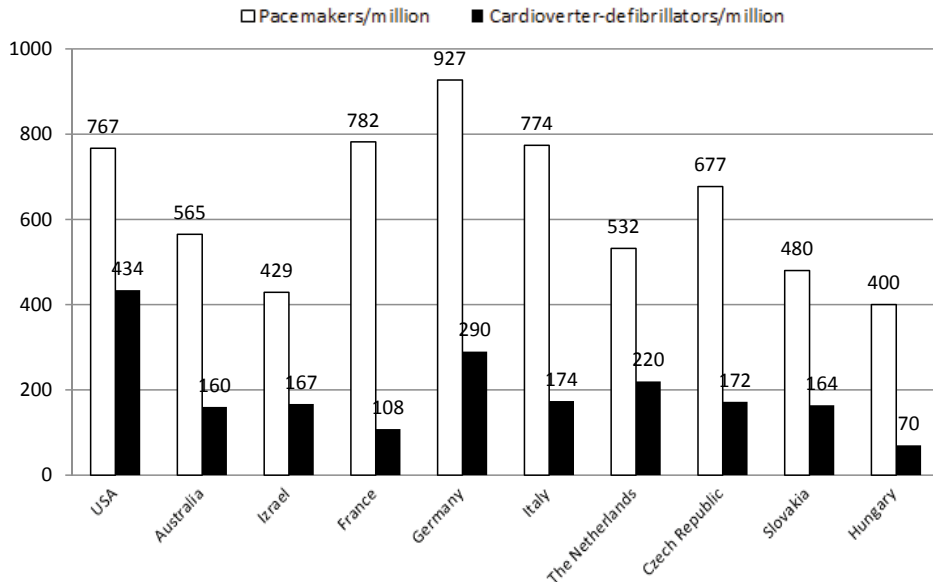
Figure 3. Data on the first-time implantations of pacemakers and cardioverters-defibrillators from selected European countries and worldwide in 2009 (source: Mond et al.. 2011).

The socio-economic differences may account for noticeable differences in the frequency of the outlined expensive medical procedures among the particular countries. A visible trend in the more frequent use of cardioverters-defibrillators, that may result not only from the growing availability of electrophysiology units and skilled operators, but also from an increased demand associated with unfavourable demographic developments (aging of the populations).

Information on the heart arrhythmia ablation procedures in Europe is published by the European Heart Rhythm Association (see Fig. 4). In Europe 251 heart arrhythmia ablation procedures per 1 million of inhabitants were carried out in 2011 with the majority of these procedures being provided in Germany (614/1 million); their number in Poland was almost three times less (214/1 million). It should be noted that these figures concern all clinical indications for the procedure, including atrial fibrillation. Ablation procedures due to atrial fibrillation amounted to as much as 30–50% of all treatments (Arribas et al., 2012).
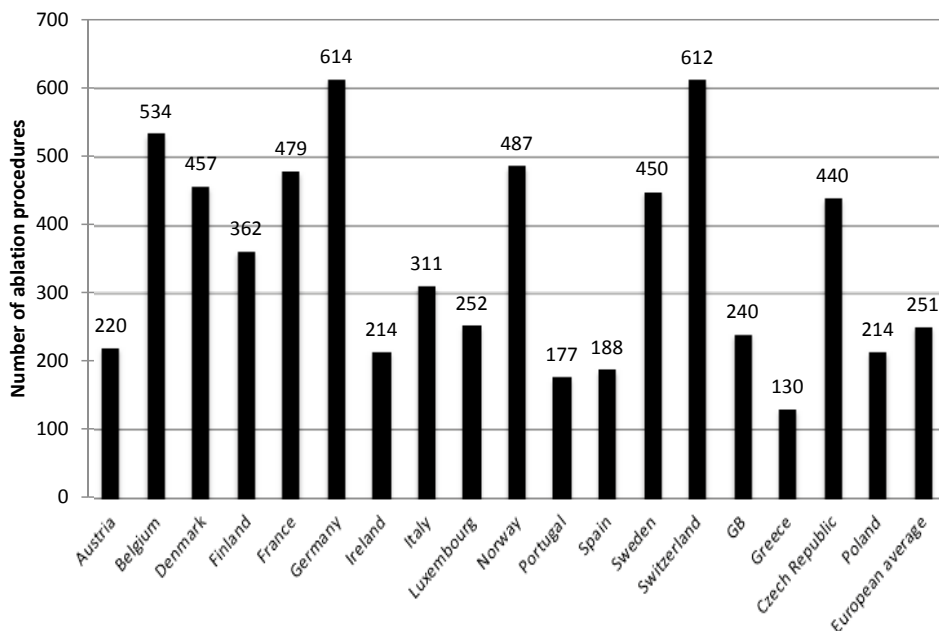
Figure 4. The number of ablation procedures in selected European countries in 2011 (source: own study based on Arribas et al., 2012).

Empirical models of arrhythmia and atrioventricular block in Poland

Determination of the crude incidence and incidence rate of arrhythmia and atrioventricular block in Poland

The first step in construction of an empirical model of arrhythmia and atrioventricular block treatment (excluding atrial fibrillation and atrial flutter) consist in defining the number of new cases of this ailment in the year under study. The incidence of this disease stream was estimated at 153.1 thousand cases in 2013 (397.69 cases per 100 thousand inhabitants). When determining the incidence the patients hospitalized and patients in contact with Secondary Out-patient Care (hereinafter referred to as SOC) or with Emergency Department/Admission Unit (hereinafter referred to as ED/AU). This approach has allowed to avoid serious underestimates since not all patients with arrhythmia and atrioventricular block are hospitalized - for example in the case of ventricular tachycardia the pharmacological cardioversion or self-recovery of sinus rhythm is possible without the need for inpatient hospital care. Among the newly

diagnosed patients there were slightly more men (60%, incidence rate ratio 460.97 per 100 thousand population, women 40%, incidence rate ratio 330.21 per 100 thousand population, cf. Figure 5).
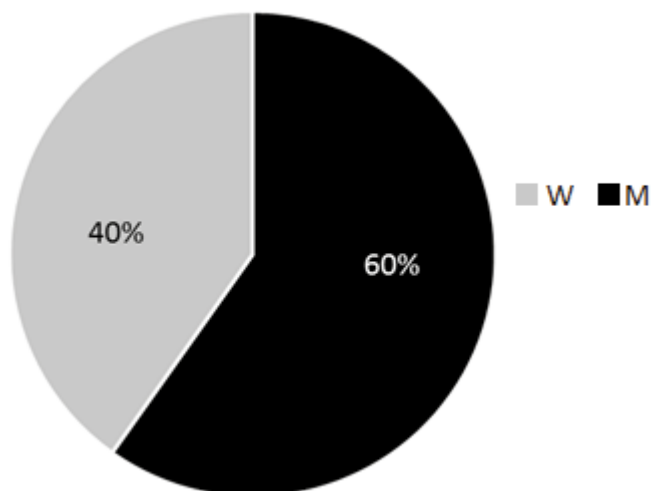
Figure 5. The structure of new patients with diagnosed arrhythmia and atrioventricular block in 2013 in relation to sex (source: DAiS analysis based on NHF data)

The incidence of arrhythmia and atrioventricular block was also determined in particular age groups, i.e. (0; 18), <18; 45), <45; 55), <55; 65), <65;75) <75;85) and 85+. Table 3 shows the number of new cases in the analysed age groups together with the relevant incidence rate ratios per 100 thousand persons. The highest number of arrhythmia and atrioventricular block cases has been observed in the age group of 18; 45 years (34.8 thousand cases) and the lowest number of cases in the last group (7,8 thousand). After the size of a given age group has been taken into account the incidence rate ratio grows with age and reaches the highest value for the group of 75–85 year old persons (cf. Table 3).

Table 3. Incidence and incidence rate of arrhythmia and atrioventricular block in relation to age groups in 2013 (source: DAiS analysis based on NHF data)

Age group	Number of cases (in thousand)	Ratio per 100 thousand of population
(0; 18)	8.6	123.2
<18; 45)	34.8	226.7
<45; 55)	17.5	354.6
<55; 65)	30.7	551.8
<65; 75)	28.4	934.0
<75; 85)	25.4	1264.9
85+	7.8	1244.4

The data set reported to the National Health Fund by the health care providers allowed to widen the analysis with incidence rate ratios in relation to the patient residence area. 71% of new patients with arrhythmia and atrioventricular block have originated from the urban areas. In relative terms, i.e. after the number of the rural and urban areas have been taken into account, a higher incidence rate has been observed among the urban patients (urban area: 467.0 cases per 100 thousand of population, rural area: 291.9 cases per 100 thousand of population – cf. Table 4).

Table 4. Incidence and incidence rate of arrhythmia and atrial flutter in relation to place of residence (urban/rural area) in 2013 (source: DAiS analysis based on NHF data)

	Number of cases (in thousand)	Ratio per 100 thousand of population
urban area	108.6	467.0
rural area	44.5	291.9

In order to obtain the most accurate results the incidence projection[14] was made with the use of incidence rate ratio for sex+age group+residence area profile. Tables 5–6 show the relevant ratios for these profiles.

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[14]To learn more on this subject see Chapter: *Cardiovascular diseases in Poland – the results of the predictive model for 2015–2025*

Table 5. The incidence (in thousand) of arrhythmia and atrioventricular block in relation to all analysed profiles in 2013 (source: DAiS analysis based on NHF data)

Sex	urban/rural area	Age group						
		(0; 18)	<18; 45)	<45; 55)	<55; 65)	<65; 75)	<75; 85)	85+
W	urban area	2.65	14.90	7.90	13.71	12.24	10.56	3.47
	rural area	1.52	7.36	3.41	4.45	3.93	4.03	1.44
M	urban area	2.99	8.21	4.07	8.91	9.00	7.88	2.10
	rural area	1.46	4.29	2.11	3.59	3.24	2.91	0.76

Table 6. Incidence rate of arrhythmia and atrioventricular block in relation to all analysed profiles in 2013 (source: DAiS analysis based on NHF data)

Sex	urban/rural area	Age group						
		(0; 18)	<18; 45)	<45; 55)	<55; 65)	<65; 75)	<75; 85)	85+
W	urban area	139.78	326.16	518.30	691.33	1051.17	1302.14	1260.46
	rural area	100.50	246.49	355.68	470.69	684.42	832.67	786.36
M	urban area	149.91	178.57	290.09	540.51	1066.59	1770.83	2083.20
	rural area	91.52	134.74	201.55	366.34	704.62	1091.04	1167.15

It was first reported that the incidence rate expressed as the number of cases per 100 thousand of population was considerably lower in the case of men (men – 557.58 per 100 thousand of population, women – 749.1 per 100 thousand women). However, taking into account the subsequent profiles (sex, age, residence area) even larger differences are observed - often as a reverse relation - e.g. for the last age group the incidence rate ratio among men from urban areas is by 60% higher that among women in the same group.

Treatment pathway model for arrhythmia and atrioventricular block (own analysis)

The inpatient care history was used to construct the empirical treatment pathway model - i.e. the outpatient care history in SOC or Emergency Department/Admission Unit was excluded. The decision to construct the decision trees only for inpatient care results from the quality and availability of data, in particular the data reported to the National Health Fund by the health care providers. The highest quality is specific for data for which there is an economic incentive for reporting. Among other things this is the case of the procedures which underlie the settlement of a given Uniform Group of Patients. Besides, a considerable

number of patients attend specialist outpatient health care and the time gap between the first contact with the health care system (e.g. in SOC) and the first hospitalization (e.g. in the case of exacerbation of the condition) often exceeds one year. On the basis of annual treatment history analysis covering the period between the first entry into the system (i.e. in the inpatient health care system, SOC and ED/AU, this group of patients would be referred to as patients who were not provided with any treatment in the form of procedures dedicated to arrhythmia and atrioventricular block treatment) .Consequently the analysis conclusions could prove to be misleading.

Figure 6 shows the graphic visualisation of the situation under consideration. The arrows show the contacts of a hypothetic patient with the health care system. The first contact corresponds to the patient visit in SOP, the second contact may mean for example ablation procedure, while the grey field outlines the period of 365 days (or more). When analysing the patient history since the first entry into the system (first arrow) the ablation procedure would have not appear in the analysis. However, he/she would be counted among the patients for whom the inpatient health care associated with ablation treatment is meant to be the first contact with the health care system due to *arrhythmia and atrioventricular block*.
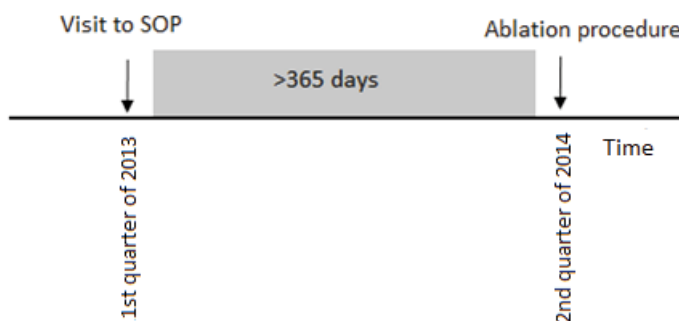
Figure 6. Conceptual explanation of the data used for construction of the empirical model of arrhythmia and atrioventricular block treatment, part 2 (source: DAiS analysis)

The study takes into consideration all procedures reported by the health service providers for inpatient care (regardless of the reported main ICD-10 of hospitalization[15]) for particular

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[15] This means that, if patient after the hospitalisation due to arrhythmia and atrioventricular block was hospitalised, e.g. due to acute coronary syndrome, and it was reported that during such hospitalisation coronarography has been carried out, this procedure will be taken into account in the this analysis.

patients with arrhythmia and atrioventricular block during the first year since the patient entry into the hospital system. Some patients whose history was analysed in this chapter have been taken into account when the incidence rate ratios for the years preceding the year 2013 were calculated. These were patients who emerged in the secondary outpatient health care, in the emergency department or admission unit in 2009–2012, while their presence in the inpatient health care system was recorded only in 2013. Finally, the study group consisted of over 57,5 thousand patients, who were recorded in the hospital system in 2013 (and were not hospitalised due to arrhythmia and atrioventricular block in the years 2009–2012[16]).

Assignment of the prevalence to each branch of the model shown on Flowchart 1 would require the individual types of arrhythmia and atrioventricular block to be specified. When constructing the empirical model for these diseases a decision was made to give up differentiating with view to this variable at the first step of the patient history analysis, and to demonstrate the total results for all analysed diagnoses in accordance with ICD-10 (i.e. I44, I45, I46, I47 and I49). Then trees were constructed for three subgroups which form a set of diagnoses '*other arrhythmia and atrioventricular block*', this is to say atrioventricular block, cardiac arrest and arrhythmia, (except of diagnosis '*atrial fibrillation and flutter*' which is dealt with here in a separate Chapter). In this context it should be emphasised that the sums of the tree values for these three subgroups will not correspond to the sums obtained for the general tree structure of the set of diagnoses '*arrhythmia and atrioventricular block*'. In a general tree structure a patient who has been hospitalized twice in 365 day period, including one hospitalisation following a diagnosis '*arrhythmia*' and one hospitalisation following a diagnosis '*cardiac arrest*', will be taken into account once only. The same patient will be also assigned to two tree structures for subgroups with diagnosis '*arrhythmia*' and '*cardiac arrest*'. Also, if a specific procedure for treatment of both symptoms is carried out (such as ablation), it will be taken into account in each of the tree structures (cf. Figure 7). It will be so because the analysis is carried out for the procedures relevant for a given disease in the annual patient treatment history under the inpatient system, regardless of the diagnosis was associated in the report submitted by the health care provider to the public payer.

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[16] The lower time limit, i.e. the year 2009, is associated with the accessibility of NHF data.
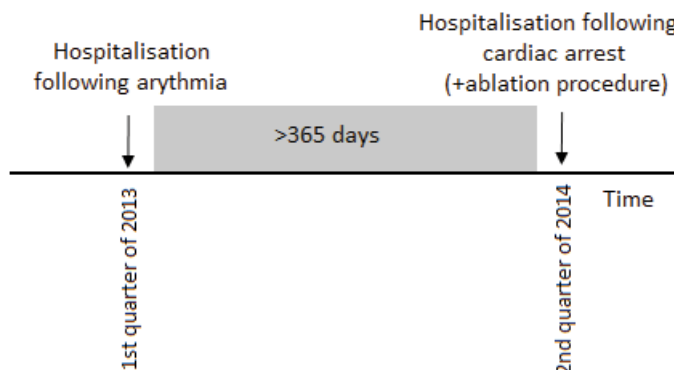
Figure 7. Conceptual explanation of the relationship between the data taken into account in the general tree structure and those in the tree structures for particular subgroups (source: DAiS analysis)

The general tree structure defines the number of patients who received particular type of therapy, i.e. for how many patients the following was reported:

– – EPS based invasive diagnostics;
– - Ablation;
– – Implantation/replacement of ICD or its component;
– – Pacemaker implantation or replacement[17].

The analyses additionally take into account the coronarography reporting, however, this information was not included in the tree structure for the sake of clarity[18]. The analysis of the services provided shows that almost 14% of patients were subject to EPS based invasive diagnosis or coronarography (6.11% of patients were subject to EPS based invasive diagnosis – cf. Table 7).

Table 7. Share of patients subjected to invasive diagnostics within one year of the first admission into the hospital (source: DAiS analysis based on NHF data)

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[17]This category is an effect of the ambiguity of ICD-9 procedures. For some of them it cannot be determined whether a new device was implanted or it was just a replacement.
[18]Furthermore, the coronography may not be reported by the health care providers if another procedure is carried out under the inpatient system, which defines a given Uniform Patient Group (such as percutaneous coronary intervention).

		EPS	
		YES	NO
Coronarography	YES	0.67%	7.74%
	NO	5.44%	86.15%

The results of conducted analysis indicate that within one year of being registered within the inpatient system patients suffering from arrhythmia and atrioventricular block most frequently have their pacemaker replaced or undergo pacemaker implantation (nearly 40%). More than 8% of patients undergo ablation, while nearly 3% of patients undergo cardioverter-defibrillator implantation (cf. Table 8). Taking into account the scope of data used for the purpose of analysing benefits for patients with arrhythmia and atrioventricular block, it is impossible to compare such data with statistics presented on Diagrams 1–4, since e.g. ICDs are not implanted exclusively into patients with arrhythmia or atrioventricular block.

Table 8. Empirical model of arrhythmia and atrioventricular block, part 1
(source: DAiS analysis based on NHF data)

Ablation	Pacemaker implantation or replacement	ICD implantation or replacement
8.41%	39.81%	2.71%

In order to formulate conclusions with regard to the full treatment pathway of patients with arrhythmia and atrioventricular block which would take into account previously defined medical procedures (i.e. EPS, ablation, pacemaker implantation or replacement and ICD implantation or replacement), it is necessary to provide information about the frequency of such procedures in relevant combinations. Visualisations in the form of trees are clear and frequently utilised means of presenting calculations of this kind. Flowchart 2 presents a tree on the treatment of arrhythmia and atrioventricular block. To ensure transparency of presented results, no further splitting of the tree branches was performed, where the sample size in each node was smaller than 100 cases. After analysing the whole graph it was concluded that in case of nearly 28 thousand patients (48% of the study population) none of the analysed procedures (including EPS) was reported during 365 days from the date of being registered in the inpatient system.

In case of 22.6 thousand patients only pacemaker implantation or replacement procedure was reported (39.4% of the study population), while ablation procedure alone was reported in case of 1.95 thousand patients (3.4% of the study population). ICD implantation or replacement procedure alone was reported in case of 1.39 thousand patients, which corresponds to 2.4% of the study population. By including also patients who were subjected to EPS based invasive diagnostics procedure in calculations, these numbers increase, respectively, to 22.7 thousand patients (39.5% of the study population) in case of pacemaker implantation or replacement alone, to 4.6 thousand patients (8.0% of the study population) in case of ablation alone and to 1.4 thousand patients (2.5% of the study population) in case of ICD implantation or replacement alone. Ablation combined with pacemaker implantation and replacement procedure was reported in 161 cases, while ablation combined with ICD implantation and replacement procedure – in 78 cases. It was reported that 3 patients underwent both the ablation procedure, as well as the pacemaker and ICD replacement/implantation procedure.

Was EPS performed?

YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths
NO	53 938	93.9%	8 845	16.4%
YES	3 508	6.1%	42	1.2%

Of which: was ablation performed?

YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths
NO	51 898	96.2%	8 831	17.0%
YES	2 040	3.8%	14	0.7%
NO	718	20.5%	4	0.6%
YES	2 790	79.5%	38	1.4%

Of which: was the replacement or implementation of the pacemaker performed?

YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths
NO	29 234	56.3%	7 122	24.4%
YES	22 664	43.7%	1 709	7.5%
NO	1 969	96.5%	12	0.6%
YES	71	3.5%	2	2.8%
NO	673	93.7%	2	0.3%
YES	45	6.3%	2	4.4%
NO	2 700	96.8%	36	1.3%
YES	90	3.2%	2	2.2%

Of which: was the implementation/replacement of ICD or its part performed?

YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths
NO	27 844	95.2%	7031	25.2%
YES	1 390	4.8%	91	6.6%
NO	22 632	99.9%	1707	7.5%
YES	32	0.1%	2	6.2%
NO	1 949	99.0%	12	0.6%
YES	20	1.0%	0	0.0%
NO	620	92.1%	2	0.3%
YES	53	7.9%	0	0.0%
NO	2 642	97.8%	32	1.2%
YES	58	2.1%	4	6.9%

Flowchart 2. Empirical model of arrhythmia and atrioventricular block treatment, part 2 (source: DAiS analysis based on NHF data)

Results of the analysis of deaths among patients diagnosed with arrhythmia and atrioventricular block (excluding atrial fibrillation and flutter), who were registered in the inpatient system indicate that the annual mortality rate amounted to 15.5%. The largest number of deaths was reported among hospitalised patients who did no undergo any cardioversion, ablation or pacemaker implantation/replacement procedure – 79% of all deaths. Patients who underwent only the cardioversion procedure accounted for 19% of deaths. The same frequency of deaths was observed among patients who underwent only the pacemaker implantation/replacement procedure. It needs to be stressed that presented conclusions do not prove the effectiveness of individual treatment regimens, but serve only as an illustration of the analysed system.

In line with the treatment regimen for arrhythmia and atrioventricular block presented on Flowchart 2, in order to describe the process of treating the diseases belonging to this group it is necessary to carry out a separate analysis with regard to arrhythmia, atrioventricular block and sudden cardiac arrest.

The tree illustrating the empirical model of arrhythmia treatment during the period of one year from being registered in the inpatient system for the first time is presented in Flowchart 3. The tree was developed on the basis of an annual hospitalisation history of 38.1 thousand patients, who were registered in the inpatient system for the first time in 2013. For each patient it was verified whether – in line with the reported data – he/she underwent the following procedures in the analysed period:

– EPS based invasive diagnostics,
– ablation,
– implantation/replacement of ICD or its part.

On the basis of this analysis it was concluded that EPS based invasive diagnostics had been reported with regard to 8.1% of patients. In the analysed period ablation procedure was reported with regard to 4.2 thousand patients (11%), while implantation/replacement of ICD or its part (electrodes or impulse generator) was reported with regard to 1.3 thousand patients (3.35%). In line with the reporting data published by the NHF 75 patients (0.2%) underwent both the ablation procedure and implantation/replacement of ICD or its part.

Among analysed patients[19] death within the first year from being registered in the inpatient system was reported in 4.23% of cases. 92% of those deaths occurred within the most numerous group, i.e. among patients whose hospitalisation history did not indicate that they had been subjected to any of the analysed procedures.

Was EPS performed?					Of which: was ablation performed?					Of which: was the implementation/replacement of ICD or the implementation/replacement of ICD's part performed?				
YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths	YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths	YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths
NO	34 998	91.9%	1570	4.49%	NO	33 273	95.1%	1556	4.68%	NO	32 121	96.5%	1481	4.61%
										YES	1 152	3.5%	75	6.51%
					YES	1725	4.9%	14	0.81%	NO	1 706	98.9%	14	0.82%
										YES	19	1.1%	0	0.00%
YES	3 076	8.1%	39	1.27%	NO	629	20.4%	2	0.32%	NO	582	92.5%	2	0.34%
										YES	47	7.5%	0	0.00%
					YES	2 447	79.6%	37	1.51%	NO	2 390	97.7%	33	1.38%
										YES	57	2.3%	4	7.02%

Flowchart 3. Empirical model of arrhythmia treatment
(source: DAiS analysis based on NHF data)

Attempt was also made to establish how often patients with arrhythmia are hospitalised due to the fact that they are diagnosed with other diseases related to arrhythmia and atrioventricular block (excluding atrial fibrillation and flutter). For this reason it was determined with regard to each analysed patient whether he/she was hospitalised due to atrioventricular block and cardiac arrest in 2009–2014. In 97% of cases no hospitalisation of this type was observed, while most frequently analysed patients were the ones hospitalised due to atrioventricular block (2.39%).

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19 I.e. those who were first registered in the inpatient system after being diagnosed with *arrhythmia* in 2013.

Table 9. Co-existence of atrioventricular block and sudden cardiac arrest among patients with arrhythmia[20] (source: DAiS analysis based on NHF data)

Only			All analysed diseases
arrhythmia	arrhythmia and atrioventricular block	arrhythmia and cardiac arrest	
97.21%	2.39%	0.39%	0.01%

With regard to atrioventricular block, the annual history of 13.2 thousand patients hospitalised due to the fact that they were diagnosed with this disease for the first time in 2013 was analysed. Flowchart 4 illustrates the results of this analysis and presents the patients' history by taking into account the frequency of EPS based invasive diagnostics or pacemaker implantation/replacement in data reported by healthcare providers to the public payer.

Conducted analysis made it possible to establish that the EPS procedure was reported with regard to 0.5 thousand patients (3.8%), while procedures related to pacemaker implantation/ replacement were reported with regard to 80% of patients. Annual mortality since the date of being registered in the inpatient system amounted to 9.1%. 82% of deaths occurred among patients who were not subjected to the EPS procedure during the one-year hospitalisation period, but who underwent pacemaker implantation/replacement procedure. The proportion of deaths within this group amounted to 9.34% (cf. Flowchart 6). It needs to be stressed that this value cannot be regarded as the measure of effectiveness of the treatment pathway EPS based diagnostics + pacemaker implantation/replacement.

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[20] Diagnosed with this disease for the first time and registered in the inpatient system with this diagnosis in 2013.

Was EPS performed?					Of which: was the implementation/replacement of the pacemaker performed?				
YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths	YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths
NO	12 657	96.2%	1 197	9.46%	NO	2 140	16.9%	215	10.05%
					YES	10 517	83.1%	982	9.34%
YES	498	3.8%	4	0.80%	NO	464	93.2%	2	0.43%
					YES	34	6.8%	2	5.88%

Flowchart 4. Empirical model of atrioventricular block treatment
(source: DAiS analysis based on NHF data)

In case of 93% of patients hospitalised for the first time in 2013 due to atrioventricular block no hospitalisation due to arrhythmia or cardiac arrest was reported in 2009–2014. In 97% of cases no hospitalisation of this kind was observed, while most frequently analysed patients were the ones hospitalised due to arrhythmia (6.70% – cf. Table 10).

Table 10. Co-existence of arrhythmia and sudden cardiac arrest among patients with atrioventricular block[21] (source: DAiS analysis based on NHF data)

Only			All analysed diseases
atrioventricular block	arrhythmia and atrioventricular block	atrioventricular block and cardiac arrest	
92.86%	6.70%	0.40%	0.04%

Sudden cardiac arrest is the last disease included in the annual analysis of the history of patients hospitalised for the first time in 2013. A procedure characteristic from the point of view of treating this disease – aside from EPS based diagnostics – is ICD implantation. In accordance with the tree presented on Flowchart 5 this procedure is carried out with regard to 4.4% of patients. The mortality rate for patients hospitalised for the first time in 2013 and

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[21] Diagnosed with this disease for the first time and registered in the inpatient system with this diagnosis in 2013.

diagnosed with the analysed disease amounted to 86.6%. It has to be stressed, however, that the analysed population does not include patients who died immediately as the result of cardiac arrest and were not hospitalised.

Was EPS performed?					Of which: was the implementation/replacement of ICD or the implementation/replacement of ICD's part performed				
YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths	YES/NO	number of patients	proportion of patients	number of deaths	proportion of deaths
0	7 118	99.8%	6 175	86.8%	0	6 813	95.7%	6 155	90.3%
					1	305	4.3%	20	6.6%
1	17	0.2%	1	5.9%	0	8	47.1%	1	12.5%
					1	9	52.9%	0	0.0%

Figure 5. Empirical model of cardiac arrest treatment
(source: DAiS analysis based on NHF data)

In case of 97.44% of patients hospitalised for the first time in 2013 due to cardiac arrest no hospitalisation due to arrhythmia or atrioventricular block was identified in 2009–2014. Such patients were most frequently hospitalised with arrhythmia (less than 2% – cf. Table 11).

Table 11. Co-existence of arrhythmia and atrioventricular block among patients with sudden cardiac arrest[22] (source: DAiS analysis based on NHF data)

Only			All analysed diseases
cardiac arrest	arrhythmia and cardiac arrest	atrioventricular block and cardiac arrest	
97.44%	1.96%	0.55%	0.06%

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[22] Diagnosed with this disease for the first time and registered in the inpatient system with this diagnosis in 2013.

Summary

This paper presents the definition of diagnoses of diseases belonging to the *arrhythmia and atrioventricular block* group. *Atrial fibrillation and flutter* was excluded from this group of diseases, as it is the subject of a separate chapter of this publication. It also includes the description of characteristic features of these diseases, as well as risk factors contributing to their incidence, in particular ischemic heart disease. This paper contains also the description of the diagnostic process and guidelines for the treatment of such diseases. It also presents the results of worldwide epidemiological studies, as well as the results of analyses which make it possible to construct an empirical model of arrhythmia and atrioventricular block treatment for Poland. The conclusion is that, generally, the incidence rate of the analysed diseases is significantly higher in case of women. After taking all analysed cross-sections into account (sex, age, area of residence), significantly more pronounced differences were observed, and frequently of reverse relation (i.e. higher incidence rate among men).

Conducted analysis made it possible to establish, *inter alia*, that during the period of one year from the date of registering the patient with arrhythmia within the inpatient system such patient is in 80% of cases subjected to procedures related to pacemaker implantation/replacement. It was also established that in case of hospitalisation due to primary diagnosis of *sudden cardiac arrest*, the annual mortality (since the date of first registration in the inpatient system) amounts to 87%.

It is impossible to compare the obtained results concerning treatment pathways with data collected for other countries, as international statistics on procedures specific to treatment of arrhythmia and atrioventricular block do not indicate the type of diagnosis, on the basis of which a given procedure was carried out. For example, data concerning the number of ICD implantations include both implantations carried out in the context of heart failure treatment, as well as implantations carried out for the purpose of treating diseases referred to in this paper.

Taking into account the whole annual history of patients hospitalised for the first time in 2013 made it possible to develop a comprehensive picture of the analysis of events related to treatment of arrhythmia and atrioventricular block. Presented approach constitutes an important step in the application of quantitative methods in management of the health care

system in Poland, despite its numerous shortcomings, e.g. weaknesses of NHF reporting base (issue of *upcoding*, existence of strong incentives for reporting only procedures relating to a particular Uniform Patient Group, lack of information about patients receiving pharmacological treatment). Results of conducted analyses may serve as the basis for formulating conclusions on the future demand for particular services. Projections should take into account information about the frequency of performing particular services in relevant cross-sections (at least in the demographic cross-sections) – statistics prepared in this manner should then be collated with demographic and migratory projections.

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Treatment pathway model in atrial fibrillation and atrial flutter

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Introduction

Atrial fibrillation is the most often treated chronic arrhythmia and therefore, for the purpose of this paper, atrial fibrillation has been singled out from all other forms of cardiac arrhythmia and atrioventricular block.

Atrial fibrillation is uncoordinated, rapid (>300/min) atrial activation, which leads to the loss of effectiveness of atrial systole and to an irregular ventricular rhythm. The ventricular rate in atrial fibrillation depends on the conduction activity of the atrioventricular node, the functioning of the autonomic nervous system and the pharmaceutical treatment applied. Diagnosis is made based on the results of electrocardiography. P waves cannot be seen in a surface electrocardiogram of a patient with atrial fibrillation, and RR intervals do not make up any repetitive rhythm. Electrical activity of atria can be observed, and intervals between subsequent atrial activation waves are usually variable and lower than 200 ms (Camm et al., 2010).

Atrial flutter, on the other hand, manifests itself in rapid, but regular electrical and systolic activity of atria (at the rate of approx. 250–300/min). The risk of a brain stroke related to atrial flutter is comparable with the risk related to atrial fibrillation, and therefore the same thrombosis prevention is required in patients with atrial flutter. The rules for choosing a treatment are thus similar to those in the case of atrial fibrillation, but it should be noted that antiarrhythmic agents are less effective than ablation in the case of atrial flutter. Due to the above similarities and common co-occurrence of the two most common atrial arrhythmias, they are analysed jointly in clinical and epidemiological studies, and in the ICD 10 classification they fall within one code – I48 (atrial fibrillation and flutter), (www.icd10.pl).

Due to the length of arrhythmia and a decision on further actions (the heart rate control versus the sinus rhythm control), the following forms of atrial fibrillation can be distinguished (Camm et al., 2010):

- paroxysmal atrial fibrillation – arrhythmia of a self-limiting nature, usually lasts up to 48 hours, although an episode of atrial fibrillation may last up to 7 days;
- persistent atrial fibrillation – an episode of arrhythmia lasts more than 7 days and pharmacological or electrical cardioversion has to be used in order to stop it;
- chronic persistent atrial fibrillation – arrhythmia lasts more than one year before a decision on heart rate control strategy (cardioversion) is taken;
- permanent atrial fibrillation – it is diagnosed when atrial fibrillation is accepted by a patient and a physician and no attempt to return to sinus rhythm is made.

Each of the mentioned forms of atrial fibrillation may be detected for the first time. The progression of the disease and its transformation into a chronic/permanent form are observed in the majority of patients suffering from it. The presented classification is mostly of clinical significance, and it has little relevance in epidemiological studies (Andrade et al., 2014).

There is a very wide range of clinical symptoms of atrial fibrillation – from the so-called "silent" arrhythmia episodes, in the case of which a patient does not experience any symptoms, to palpitation, decreased exercise tolerance, fainting, even to acute decompensation of the circulatory system, which requires immediate treatment in an intensive care unit.

Atrial fibrillation leads to worse quality of life of people suffering from it, lower exercise tolerance, disorders of cognitive functions, left-ventricular systolic dysfunction, and a higher risk of hospitalization with increased mortality. Impairment of good atrial systolic function results in a significantly higher risk of thromboembolic complications, with – and above all – the risk of brain stroke being 5 times higher. Brain strokes caused by atrial fibrillation are characterized by a higher risk of death and a higher degree of disability, when compared to strokes caused by other factors (Lamassa et al., 2001). On the other hand, applying the anticoagulation therapy, as a way of preventing thromboembolic complications, increases the risk of dangerous haemorrhagic complications – gastrointestinal bleeding and central nervous system bleeding.

The aim of this article is to present the treatment structure model in atrial fibrillation and flutter in Poland. The first part of this paper presents the epidemiological aspects based on a review of international studies. Risk factors of atrial fibrillation are then discussed, as well as the diagnostic process of the disease. Next, decision-making models in atrial fibrillation and

flutter treatment are presented, together with research results related to the frequency of use given treatment procedures in selected countries. The last part of the article is dedicated to presenting the treatment structure model of the disease in Poland. Based on the NHF data, annual incidence rate of atrial fibrillation and flutter has been determined depending on age, sex and residence (urban or rural areas), which is followed by a presentation of the frequency of performing procedures of a key relevance from the point of view of the disease treatment – electrical cardioversion, ablation and implantation or replacement of a pacemaker. The frequency of performing those procedures and the relevant statistics for selected European countries have also been included.

Epidemiological analysis

Based on collective data from 184 papers, it has been estimated that in 2010 approximately 33.5 million people worldwide suffered from atrial fibrillation, and annual incidence rate amounted to almost 5 million (Chugh et al., 2014). It is observed that both prevalence and incidence rate are largely diversified in geographical terms (the highest rates have been reported in North America, the lowest in East Asia and Pacific), which may stem from differences in risk factors of the disease (arterial hypertension, diabetes, obesity), genetic differences and differences in frequency of diagnosing the disease (Chugh et al., 2014, Kodani et al., 2012). It should be noted that some episodes of atrial fibrillation are asymptomatic, which results in real frequency of arrhythmia worldwide being underestimated.

Frequency of atrial fibrillation in a population increases significantly with age, from approx. 0.5% among people aged 45–49 to over 10% among people older than 74 (Kodani et al., 2012). Epidemiological data related to atrial fibrillation may thus vary significantly depending on the cut-off point for age of the population covered by a study. Most of the studies published indicate that men are more often afflicted by the disease. An increase in frequency of atrial fibrillation occurrence in subsequent years has also been observed in epidemiological studies, e.g. in the United Kingdom in 1994–1998 the increase amounted to 14% among women and 22% among men (Majeed et al., 2001).

Table 1 presents epidemiological data related to atrial fibrillation in European countries. The largest population covered by the study was 8 million people over 18, with overall prevalence amounting to 2.13% in this group (Wilke et al., 2013).

Table 1. Atrial fibrillation – prevalence and incidence rate in European countries
(source: own study based on: Heeringa et al., 2006, Wilke et al., 2013, Stewart et al., 2001,
Majeed et al., 2001, Gomez-Doblas et al., 2014, Bonhorst et al., 2010)

Country	Cohort age	Cohort size	Period of study	Prevalence	Incidence rate
The Netherlands	≥ 55 years old	6.8 thousand	1990–1999.	Total: 5.5% 55–59 years old: 0.7% ≥ 85 years old 17.8%	9.9/1,000 patient-years 55–59 years old: 1.1/1,000 80–84 years old 20.7/1,000
Germany	No limits	8.3 million	2008	Total: 2.132% Women: 1.895% Men: 2.369% < 15 years old 0.002% 85–89 years old: 15.089%	4.112/1,000 patient-years Women: 3.868/1,000 patient-years Men: 4.358/1,000 patient-years < 15 years old 0.016/1,000 patient-years 85–89 years old: 31.064/1,000 patient-years
Scotland	45–64 years old:	15.4 thousand	1972–1979	6.5/1,000	0.54/1,000 patient-years
England and Wales	No limits	1.4 million	1994–1998	Women: 12.7/1,000 Men: 12.1/1,000 < 35 years old: fewer than 1/1,000 ≥ 85 years old: more than 100/1,000	
Spain	≥ 40 years old	8.3 thousand	no data available	4.4% (no significant differences regarding sexes) 40–49 years old: 0.3% ≥ 80 years old 17.7%	
Portugal	≥ 40 years old	10.4 thousand	no data available	2.5% (no significant differences regarding sexes) 40–49 years old: 0.2% ≥ 80 years old 10.4%	

Based on the Dutch study data presented in the table, it has been attempted to assess atrial fibrillation occurrence in the EU countries as well as to provide a prognosis for prevalence in 2060 (Krijthe et al., 2013). It has been estimated that in the EU countries in 2010 atrial fibrillation afflicted 8.8 million patients over 55 (95% confidence interval: 6.5–12.3 million), whereas, given stable prevalence in individual age groups and according to sex, this figure will increase to 17.9 million by 2060 (95%, CI: 13.6–23.7 million)[23].

Risk factors related to atrial fibrillation and diagnostic tests

One of the basic risk factors of arrhythmia is age. Over the course of time losses of atrial muscle fibres occur, which results in electrical isolation and conduction disorders within them. The risk of atrial fibrillation increases significantly over 80–85 (compare with Table 1). Yet another risk factor is male sex (the risk of arrhythmia is approx. 1.5 times higher).

Atrial fibrillation has a significant effect on the occurrence of other cardiovascular diseases, such as coronary heart disease, arterial hypertension or heart failure. These diseases related to atrial fibrillation shall be rather treated as indicators of the total cardiovascular risk and/or myocardial damage and not only as the causes of arrhythmia.

The arterial hypertension moderately (x 1.2–1.5) increases the risk of atrial fibrillation (Andrade et al., 2014), however, due to the prevalence of this disease it remains an important risk factor. It was estimated that 14% of all cases of atrial fibrillation is caused by arterial hypertension (Kannel et al., 1998). It should be noted that the presence of arterial hypertension increases also the risk of thromboembolic complications in this group of patients.

Atrial fibrillation is a frequent complication of acute coronary syndrome (Crenshaw et al., 1997). However, the relation between the occurrence of stable coronary heart disease and the impact of ischemia on the occurrence of arrhythmia has not been fully established.

Heart failure has been identified in one-third of patients suffering from atrial fibrillation (Nieuwlaat et al., 2005). Heart failure can be both the cause of atrial fibrillation (through the pressure increase and volume overload of the atrium) as well as the result of arrhythmia

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[23] Confidence intervals have been calculated, using the Wilson method of binomial distribution.

(acute decompensation of circulation or the development of the so called tachycardia induced cardiomyopathy as a result of fast ventricular activity).

Diabetes is related to atrial fibrillation risk increase of 1.5 times (Andrade et al., 2014), this results from the co-existence of other cardiovascular risk factors in patients with diabetes (coronary heart disease, heart failure, obesity, sleep apnea) as well as vasculitis and autonomic nervous system disorders in this group of patients.

Another risk factors of atrial fibrillation are excess weight and obesity. As the body mass index increases by 1, the risk of atrial fibrillation increases by 3–7% (Dublin et al., 2006).

Acquired heart defects increase the atrial fibrillation risk at least 1.8 times (in case of men) and at most 3.4 times in case of women (Kannel et al., 1998). The highest risk exists in case of combined rheumatic defect – atrial fibrillation is found in 70% of patients with combined mitral and tricuspid valve disorder (Diker et al., 1996).

Diseases of respiratory system, such as chronic obstructive pulmonary disease and obstructive sleep apnea, also very often co-exist with atrial fibrillation, what might result from an increased cardiovascular risk in this group of patients. However, the reduction of the frequency of arrhythmia paroxysms in patients treated for sleep apnea with the use of continuous positive pressure in respiratory tract indicates that this problem, which occurs almost twice as often in patients with atrial fibrillation as compared to the general population, is an independent risk factor of arrhythmia.

Patients with renal failure are more often at risk of atrial fibrillation, and this risk increases with the stage of the disease – the atrial fibrillation risk in patients with stage IV of chronic kidney disease is over 3 times higher as compared to people with maintained renal function (Alonso et al., 2011).

The atrial fibrillation remains closely related to disorder of thyroid hormones secretion – hyperthyroidism causes a 3- to 6-time increase of risk of arrhythmia (Andrade et al., 2014) which is one of the main symptoms of hyperthyroidism among older people.

The other diseases/situations often coexisting with atrial fibrillation include: cardiomyopathies (hypertrophic cardiomyopathy and some chanellopathies), congenital heart defects (which result in blood flow disorders in heart and scars after cardiac surgeries),

alcohol consumption and long-term intensive training (however, regular physical activity of moderate intensity may have an influence on reducing the risk of atrial fibrillation by reducing the cardiovascular risk). Recently, it has been also suggested that there might be a correlation between the atrial fibrillation and smoking (Heeringa et al., 2008).

An irregular pulse identified during the physical examination leads to a suspicion of atrial fibrillation, and the first stage of diagnosis involves performing the 12-lead ECG. In the case of a patient with the suspicion of atrial fibrillation an attempt to document arrhythmia in ECG performed during the occurrence of symptoms suggesting atrial fibrillation should be made. In order to diagnose arrhythmia as soon as possible the European Society of Cardiology recommends to perform screening with regard to atrial fibrillation in patients aged ≥ 65 years through a pulse check followed by an ECG (Camm et al., 2012).

If arrhythmia was not identified during the ECG, in case of patients with significant clinical symptoms and in case of people with recurrent syncopes or potential indications to anticoagulation therapy (in particular, after the stroke with an unknown cause), it is recommended to use more intensive and prolonged methods of ECG monitoring, i.e. Holter ECG monitoring (lasting from 24 hours to 7 days), registering and transferring the ECG recordings by phone, using devices activated automatically or by a patient, as well as external loop recorders. In case of selected patients it may be considered to implant ECG monitoring devices in order to establish the diagnosis.

Due to the co-existence of atrial fibrillation and other cardiovascular diseases (including heart failure, valve disorders), in case of patients with serious symptoms, diagnosed or suspected with heart disease, it is recommended to perform echocardiography. Such examination should also be considered in case of other patients with a documented or suspected atrial fibrillation.

Decision-making models in the treatment for atrial fibrillation and flutter

Guidelines for the management of atrial fibrillation in Europe are established by an international expert group within the proceedings of the European Society of Cardiology (published in 2010 and updated in 2012 – Camm et al., 2010 and Camm et al., 2012), and then adopted by Societies of Cardiology in individual countries (including by the Polish

Cardiac Society). Also US guidelines are similar to the European ones and the differences in recommendations result from the availability of particular medicines (e.g. dofetilide and ibutilide are not available in Europe, while vernakalant included in the European guidelines has not yet been approved by the US Food and Drug Administration; Trusz-Gluza 2014).

In case of patients with newly diagnosed atrial fibrillation a detailed medical history should be obtained. A clinical evaluation should include the stroke risk and the occurrence of diseases predisposing to arrhythmia. The aim of treatment of a patient suffering from atrial fibrillation is to: prevent thromboembolic incidents (anticoagulation treatment), reduce symptoms, treat coexisting cardiovascular diseases and eliminate arrhythmia.

The decision to include the anticoagulation treatment is made on the basis of the assessment of thromboembolic complications risk (in accordance with the CHA_2DS_2VASc scale which takes into account congestive heart failure or dysfunction of the left ventricular, arterial hypertension, age of 65–74 years and of ≥ 75 years, diabetes, stroke / transient ischemic attack / thromboembolic incident, vascular disease, i.e. earlier episode of myocardial infarction, arteriosclerotic vascular disease or the presence of atherosclerotic plaque in the aorta as well as the female sex). At the same time the risk of bleeding should be assessed with regard to a particular patient (in accordance with the HAS-BLED scale which takes into account the presence of: arterial hypertension, liver or kidney dysfunction, earlier episode of stroke, earlier episode of bleeding, variable INR values, age of > 65 years as well as used medicines or alcohol consumption). In the case of patients with atrial fibrillation the main source of the developing thrombus is the left atrium appendage, in the case of patients with contraindications to long-term anticoagulation treatment the percutaneous closure of the left atrium appendage may be considered, and in the case of patients undergoing open-heart surgeries it may be considered to perform surgical excision of the left atrium appendage.

The severity of clinical symptoms determines the urgent sinus rhythm restoration or a temporal slowdown of the ventricular rhythm (in case of the majority of patients). In case of patients with atrial fibrillation and myocardial ischemia, symptomatic hypotonia or heart failure as well as in case of patients with atrial fibrillation in the course of a pre-excitation syndrome with fast ventricular rhythm it is recommended to perform immediate electrical cardioversion. Electrical cardioversion relies on the depolarisation of the heart with the use

of electrical discharge that is synchronised with the occurrence of R wave in the ECG. The procedure is conducted in general anaesthesia of short duration. The planned electrical cardioversion is conducted immediately after the initiation of long-lasting strategy of sinus rhythm maintenance with the possibility of repeating the electrical cardioversion procedure in patients with worsening symptoms resistant to other methods of therapy. The sinus rhythm may also be restored through the pharmacological cardioversion (intravenous administration of the antiarrhythmic agent). The opportunities to restore the correct rhythm are smaller than in the case of electrical cardioversion, but the pharmacological cardioversion does not require anaesthesia and facilitates the selection of medicine in the long-term therapy of preventing another episodes of arrhythmia.

In case of patients with symptomatic recurrence of atrial fibrillation undergoing pharmacological antiarrhythmic therapy as well as in case of patients who prefer further control of the heart rhythm, a radiofrequency ablation is recommended. Also it should be considered to apply the radiofrequency ablation of atrial fibrillation as the first line treatment in selected patients with symptomatic paroxysmal atrial fibrillation as an alternative to pharmacological antiarrhythmic therapy. Ablation relies on intended and selected destruction (mostly through thermal method) of the part of a heart tissue which has an arrhythmogenic effect. The aim of ablation of atrial fibrillation is the isolation of pulmonary veins. This procedure requires a precise and very often long handling of intracardiac electrode, long time of exposition to X-rays, and should be conducted in an experienced facility by an adequately trained electrophysiologist.

In case of other patients (with sustained atrial fibrillation) a strategy of controlling the ventricular rate is adopted, i.e. pharmacological treatment slowing down the rhythm (without an attempt to restore the sinus rhythm). In exceptional cases of arrhythmia not responding to the pharmacological treatment, it is necessary to conduct ablation of the atrioventricular junction with the implantation of an artificial pacemaker.

So far none of the treatment methods for patients with atrial fibrillation (maintaining the sinus rhythm versus leaving the arrhythmia with a control of the ventricular rate) has been identified as having the precedence over others and the clinical decision in each case is taken

by the physician in charge and accepted by the patient. The discussed model of treatment of atrial fibrillation in Poland is illustrated in flowchart 1.
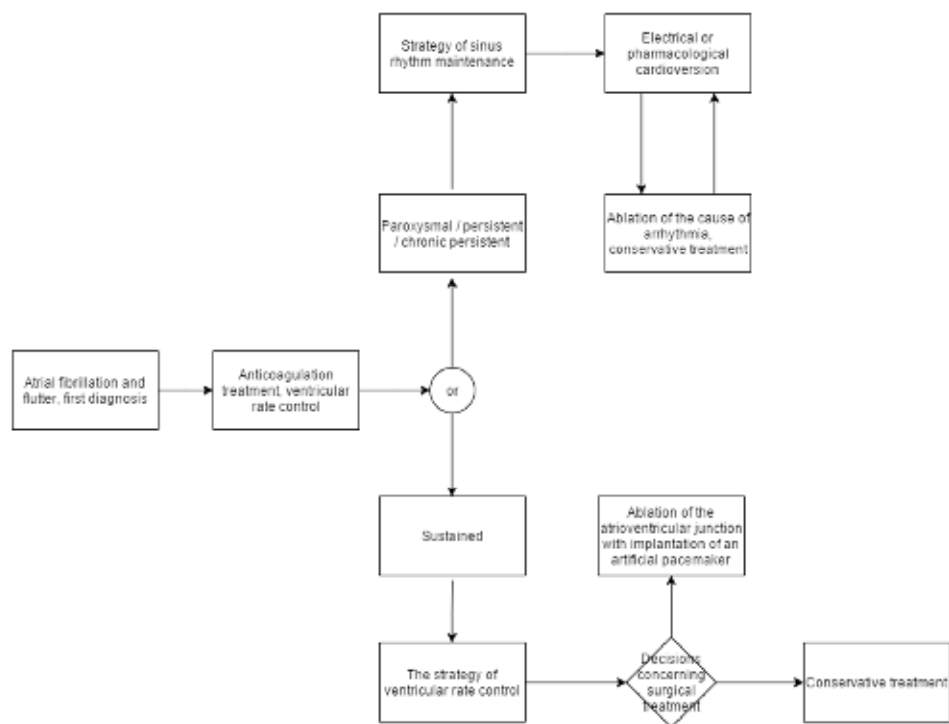
Flowchart 1. A theoretical model of treatment of atrial fibrillation in Poland
(own study based on guidelines of the European Society of Cardiology)

Table 2 presents study results concerning the treatment of patients with atrial fibrillation in European countries, covering in total 13 thousand patients. Polish facilities took part in two of them (no data available on the number of patients covered in Poland with the EORP-AF study). Only in the case of the PREFER Study the results are presented for particular countries. In each of the studies, procedures performed in patients with atrial fibrillation during one year of observation were reported. The differences in the use of resources (significantly higher frequency of radiofrequency ablation in PREFER and EORP-AF studies as compared to EHS Study on AF) may be explained by the development of electrophysiology in the last two years and a higher class of recommendations for this procedure set out in the current guidelines of the European Society of Cardiology.

Table 2. Treatment in patients with atrial fibrillation under a one-year observation – results of studies conducted in European countries (source: own study based on: Nieuwlaat et al., 2005, Nieuwlaat et al., 2008, Kirchhof et al., 2014, Lip et al., 2014, Lip et al., 2014)

		EHS on AF	PREFER							EORP – AF
			Total	France	Germany/Austria/Switzerland	Italy	Spain	Great Britain		Belgium, Denmark, Greece, Norway, Poland, Italy, Portugal, Romania, Netherlands
Area		35 countries of the Western and Central Europe and Mediterranean area¹								Belgium, Denmark, Greece, Norway, Poland, Italy, Portugal, Romania, Netherlands
Period		2003–2004	January 2012 – January 2013							February 2012 – March 2013
Number of patients with atrial fibrillation		3.9 thousand	7.2 thousand	1.5 thousand	1.8 thousand	1.9 thousand	0.9 thousand	1.2 thousand		2.4 thousand
Procedures performed in patients within one year (% of patents)	Pharmacological cardioversion	13	19.5	26.1	12.8	27.3	17.7	10.2		5.1
	Electrical cardioversion	12.7	18.1	14.4	19.1	21	14.5	19.7		9.7
	Radiofrequency ablation	2.8	5	4.7	5.8	4.4	3.7	5.9		4.4
	Implantation of an artificial pacemaker	4	no data available	no data available	no data available	no data available	no data available	no data available		no data available

Empirical model of treatment for atrial fibrillation and atrial flutter in Poland

Determination of the crude incidence and incidence rate of atrial fibrillation and flutter in Poland

The first component necessary to develop a treatment model is the number of new cases with diagnosed atrial fibrillation and flutter. The first step undertaken in Chapter Cardiovascular diseases in Poland – the results of the predictive model for 2015–2025, was the estimation of incidence of this disease at 82.2 thousand cases in 2013 (213.5 cases per 100 thousand inhabitants) in order to make the forecast for 2015–2020. One has to underline that this value was calculated taking into account hospitalized patients as well as those who were treated at secondary outpatient care facilities (SOC) and at Emergency Department/ Hospital Admission Unit (ED/AU). Defining incidence only based on hospitalized patients could result in major underestimations, as not every manifestation of atrial fibrillation or atrial flutter ends in hospital admission; e.g. paroxysmal atrial fibrillation and atrial flutter may be eliminated by pharmacological cardioversion or it is possible that the heart beat will return to the sinus rhythm during the stay at ED/AU, as a consequence of which there is no need for hospitalization. The group of newly diagnosed patients was dominated by women (52%, incidence rate ratio 216.1 per 100 thousand women; men - 48%, incidence rate ratio 210.7 per 100 thousand men).
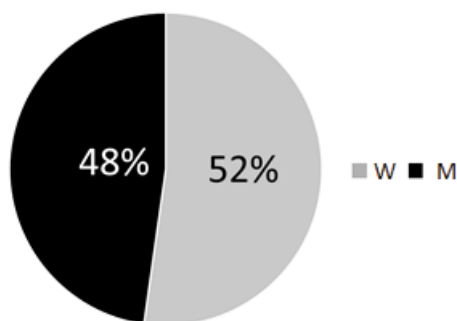

Figure 1. The structure of new patients with diagnosed atrial fibrillation and atrial flutter in relation to sex in 2013 (source: DAiS analysis based on NHF data)

Age is another analysis profile when examining incidence. Age was divided into the following groups: (0; 18), <18; 45), <45; 55), <55; 65), <65;75) <75;85) and 85+. The number

of cases per particular group together with the incidence rate ratios per 100 thousand population in each group are presented in Table 3. The greatest number of atrial fibrillation and atrial flutter cases were observed in the penultimate age group (25.34 thousand cases), the smallest number - in the first group (less than 60). In relative terms, i.e. after the size of a given age group is taken into account, the incidence rate ratio grows with age and reaches the highest value for the group of 75–85 year olds (cf. Table 3).

Table 3. Incidence and incidence rate of atrial fibrillation and atrial flutter in relation to age groups in 2013 (source: DAiS analysis based on NHF data)

Age group	Number of cases (in thousands)	Ratio per 100 thousand of population
(0; 18)	0.06	0.8
<18; 45)	3.51	22.9
<45; 55)	5.04	102.1
<55; 65)	17.34	312.1
<65; 75)	23.80	782.3
<75; 85)	25.34	1,262.7
85+	7.12	1,141.0

Using reporting data from NHF enabled to construct the incidence rate ratios by the patient's place of residence. 68% of new patients diagnosed with atrial fibrillation and atrial flutter came from urban areas. Also, taking account of the number of population of those areas points to a higher incidence rate among the urban patients (urban area: 241.5 cases per 100 thousand of population, rural area: 170.8 cases per 100 thousand of population – cf. Table 4).

Table 4. Incidence and incidence rate of atrial fibrillation and atrial flutter in relation to place of residence (urban/rural area) in 2013 (source: DAiS analysis based on NHF data)

	Number of cases (in thousand)	Ratio per 100 thousand of population
urban area	56.2	241.53
rural area	26.0	170.7

In order to obtain the most accurate results, the incidence projection was made with the use of incidence rate ratios for sex + age group + residence area profile. The incidence rate ratios for each of these groups have been presented in Tables 3 and 4.

Table 5. Incidence (in thousand) of atrial fibrillation and atrial flutter in relation to all analysed profiles in 2013 (source: DAiS analysis based on NHF data)

Sex	urban/rural area	Age group						
		(0; 18)	<18; 45)	<45; 55)	<55; 65)	<65; 75)	<75; 85)	85+
W	urban area	0.01	0.78	1.07	4.81	8.63	10.71	3.42
	rural area	0.01	0.41	0.59	2.24	3.94	4.88	1.46
M	urban area	0.02	1.42	2.09	6.98	7.81	6.82	1.62
	rural area	0.01	0.90	1.30	3.32	3.42	2.94	0.62

Table 6. Incidence rate (in thousand) of atrial fibrillation and atrial flutter in relation to all analysed profiles in 2013 (source: DAiS analysis based on NHF data)

Sex	urban/ rural area	Age group						
		(0; 18)	<18; 45)	<45; 55)	<55; 65)	<65; 75)	<75; 85)	85+
W	urban area	0.67	17.06	69.89	242.22	740.73	1,320.22	1,243.20
	rural area	0.54	13.80	61.22	236.63	687.26	1,008.01	795.37
M	urban area	1.16	30.84	148.98	423.48	924.72	1,531.14	1,611.94
	rural area	0.71	28.20	123.63	338.96	744.83	1,101,45	951.43

It was mentioned earlier that the incidence rate expressed as the number of cases per 100 thousand of population was not considerably different for women and men (men – 210.7 per 100 thousand of population, women – 216.1 per 100 thousand population). However, taking into account the subsequent profiles, larger differences are observed - e.g. for the last age group the incidence rate among men from urban areas is by 30% higher that among women in the same group.

Empirical model of treatment

The construction of an empirical model of treatment is based on the data covering hospital treatment. Such a limitation of the set results from a decision to build decision-making trees only for hospital treatment. This is justified by quality and availability of data, including the type of data which is reported by service providers to the public payer. The highest quality data is the one for which there is a strong economic incentive for reporting - i.a. those procedures

which condition clearance of a given Uniform Patient Group. Besides, a considerable number of patients are covered by the outpatient health care, including private health care services, and the time lapse between the first visit in a secondary outpatient care (AOC) facility and the first hospitalization (e.g. in the case of exacerbation of the condition) often exceeds one year. In the analysis concerned, that group of patients would have been categorized as patients who were not provided with treatment in the form of the procedures under consideration, which would have led to wrong conclusions. Flowchart 2 shows a graphic visualisation of the situation under consideration. The bars show points in time which correspond to a hypothetical patient's contacts with the health care system. The first bar corresponds to the patient visit in SOC facility, the second bar corresponds to ablation procedure, while the grey field outlines the period of 365 days. When analysing the patient's history from his/her first registration in the health care system, ablation procedure would not be considered - as opposed to patients for whom hospitalization including ablation is the first contact with the health care system due to *atrial fibrillation and atrial flutter*.
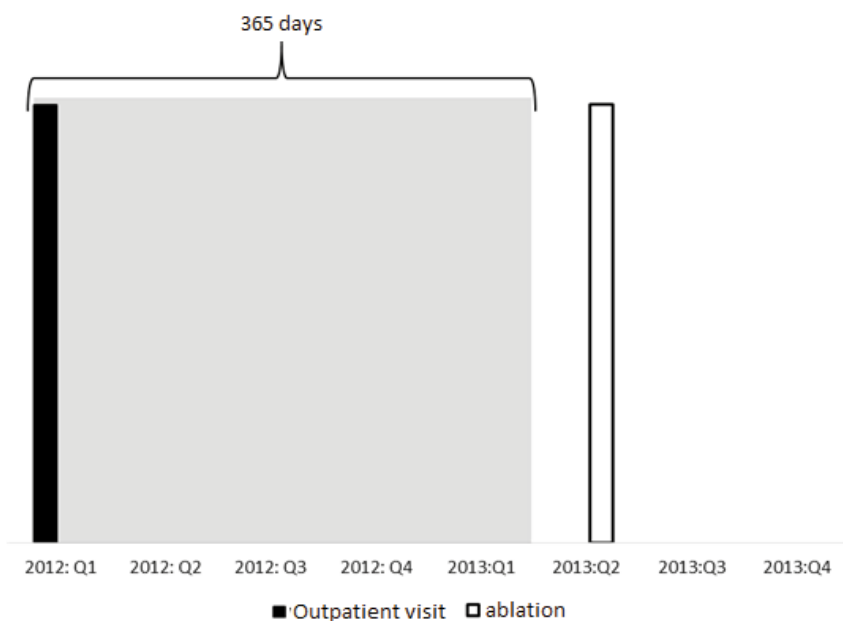
Flowchart 2. Conceptual explanation of the data used for construction of the empirical model of atrial fibrillation and atrial flutter (source: DAiS analysis based on NHF data)

The study takes account of all hospitalization procedures reported (regardless of the main ICD-10 disease reported for hospitalization[24]) or particular patients, who were provided within 365 days of the first registration of the patient in the inpatient system with the diagnosed atrial fibrillation and atrial flutter. Some patients analysed in this chapter have been included in counting incidence rate in previous years – this concerns patients, who appeared in secondary outpatient care system, in emergency department at hospital admission unit between 2009 and 2012 and were recorded in the inpatient system only in 2013. Finally, the study group consisted of over 43 thousand patients, who were registered in the inpatient system in 2013 (and were not hospitalised due to atrial fibrillation and atrial flutter in the years 2009–2012[25]).

A full parametrization of the model presented in Flowchart 1 is impossible due to limitations of reporting - there was no requirement to differentiate among the specific types of atrial fibrillation and atrial flutter (i.e. paroxysmal, persistent, persistent long-term and chronic). The type of the disease may be inferred by the investigator only based on the procedures reported, however, due to a low added value of such an analysis, the differentiation into types of the disease under consideration was not conducted. The investigators focused on defining how many patients received a particular type of therapy, i.e. how many patients were reported to have undergone:

– EPS or coronarography based invasive diagnostics,
– ablation,
– electrical cardioversion,
– pacemaker implantation or replacement[26].

The analysis of services provided showed that every tenth patient was reported with being subjected to EPS or coronarography (in case of 0.4% of the total number of patients both types of procedures were reported, in case of 2.9% - only EPS and in case of 7.2% - only coronarography - cf. Table 7).

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[24] This means that, if a patient after the hospitalisation due to atrial fibrillation and atrial flutter was hospitalised, e.g. due to acute coronary syndrome and it was reported that during such hospitalisation coronarography was performed, this procedure will be taken into account in the this analysis.
[25] The lower time limit, i.e. the year 2009, is associated with the accessibility of NHF data.
[26] This category is an effect of the ambiguity of ICD-9 procedures. For some of them it cannot be determined whether a new device was implanted or it was just a replacement.

Table 7. Share of patients subjected to invasive diagnostics within one year of the first admission into the hospital (source: DAiS analysis based on NHF data)

		Coronarography	
		YES	NO
EPS	YES	0.4%	2.9%
	NO	7.2%	89.6%

Moreover it was demonstrated that patients suffering from atrial fibrillation and atrial flutter are most often subjected to cardioversion within one year of first appearance within the inpatient system (more than one fifth). Nearly 12% of patients have pacemaker implanted or replaced, and every twentieth patient is subjected to ablation (cf. Table 8). Compared to information from Table 2 which presents data for other European countries, it has been established that the percentage of patients subjected to electrical cardioversion in Poland during 365 days of starting treatment is higher than in all the studied cohorts and it is by 7 percentage points higher than in the UK, for which the highest percentage of such patients is recorded[27]. Statistics concerning the implantation of an artificial pacemaker are very similar. It must be underlined, however, that this analysis also takes account of pacemaker replacement, hence comparison of the results may be biased. In case of ablation, results obtained for Poland are similar to those obtained in the studies presented above.

Table 8. Empirical model of treatment for atrial fibrillation and atrial flutter part 1 - share of patients, who were provided with particular procedures
(source: DAiS analysis based on NHF data)

Electrical cardioversion	Ablation	Pacemaker implantation or replacement
26.6%	5.2%	11.6%

In order to draw comprehensive conclusions about the course of treatment of patients with atrial fibrillation and atrial flutter it is necessary to analyse the frequency of performed procedures in appropriate combinations. Decision trees are a convenient and frequently applied form used to present this type of analyses. Flowchart 2 presents such a decision tree

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[27] This may be the case because the presented studies included patients who were treated for more than a year, and the frequency of electrical cardioversion decreases with the period of living with the disease.

for treating atrial fibrillation and atrial flutter. To ensure transparency of presented results, no further splitting of the tree branches was performed, where the sample size in each node was smaller than 100 cases. After analysing the whole graph it was concluded that in case of nearly 26 thousand patients (60% of the study cohort) none of the analysed procedures was reported during 365 days from the date of being registered in the inpatient system. 10.5 thousand patients were subjected only to cardioversion (24%) It was reported that 109 patients from the cohort under consideration (0.25%) underwent both the ablation procedure, as well as the pacemaker and ICD replacement/implantation procedure. Patients who underwent the three procedures under consideration accounted for mere 0.05% (23 patients).

Results of the analysis of deaths among patients diagnosed with atrial fibrillation and atrial flutter who were registered in the inpatient system indicate that the annual mortality rate amounted to 6.82%. The largest number of deaths was reported among hospitalised patients who did not undergo any cardioversion, ablation or pacemaker implantation/replacement procedure – 73% of all deaths. Patients who underwent only the cardioversion procedure accounted for 12% of deaths; patients who underwent only the pacemaker replacement/implantation procedure accounted for 13.2% of all deaths. It needs to be stressed that the presented conclusions do not prove the effectiveness of individual treatment regimens, but serve only as an illustration of the analysed system.

Cardioversion?					Including: ablation?					Including: pacemaker implantation or replacement?				
YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths	YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths	YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths
NO	31 874	73.4%	2 588	8.12%	NO	30 137	94.6%	2551	8.46%	NO	25 868	85.8%	2 161	8.35%
										YES	4 269	14.2%	390	9.14%
					YES	1 737	5.4%	37	2.13%	NO	1 651	95.0%	35	2.12%
										YES	86	5.0%	2	2.33%
YES	11 578	26.6%	374	3.23%	NO	11 043	95.4%	362	3.28%	NO	10 572	95.7%	348	3.29%
										YES	471	4.3%	14	2.97%
					YES	535	4.6%	12	2.24%	NO	512	95.7%	11	2.15%
										YES	23	4.3%	1	4.35%

Flowchart 2. Empirical model of treatment for atrial fibrillation and atrial flutter part 2 (source: DAiS analysis based on NHF data)

Summary

The above article presents a definition of atrial fibrillation and atrial flutter, including a description of characteristic features of particular types of the disease, as well as risk factors for the arrhythmia occurrence, diagnostic tests and guidelines on treatment regimen, including guidelines on how to prevent complications related with atrial fibrillation and atrial flutter. Study results concerning the frequency of applying particular procedures in particular European countries and groups of countries are presented. They are followed by a construction of an empirical model of treatment of atrial fibrillation and atrial flutter for Poland, based on reporting data from the National Health Fund, concerning hospitalization. The article states that, generally, the incidence rate of the analysed diseases is higher in women. However, taking into account all analysed sections (i.e. age group, sex and patient's place of origin), this factor is higher for men. Moreover, this value increases with age. A comparative analysis of the results obtained for Poland and results presented in the international research shows that in fact the electrical cardioversion and the implantation of artificial pacemaker is used more frequently (with the proviso that model for Poland also includes the procedure of replacement of this type of devices). The frequency of the application of ablation procedures is similar to the frequencies presented for other countries.

Presented approach is characterised by the overall analysis of the events related to the atrial fibrillation and flutter treatment by taking into account the annual patients' history who were registered in the inpatient system for the first time. Despite many restrictions (including shortcomings of the reporting base of the National Health Fund related to the phenomenon of upcoding, reporting mainly procedures with the highest value / determining Uniform Patient Group and the lack of information on patients who receive anticoagulation treatment), performed analysis constitutes an important step in the application of quantitative methods in management of the health care system in Poland. The results may constitute the basis for forecasting demand for the particular services. At this stage it is necessary to consider the frequency of implementation of the particular services in appropriate demographic profile and to confront statistics constructed in such manner with demographic forecast. In addition, the research on the frequency of hospitalisation caused by brain stroke and other complications following atrial fibrillation and flutter (after hospitalisation caused by this disease), i.e. attempt of the assessment of treatment results (including to the level of

the individual healthcare providers, after the relevant data standardisation eliminating the influence of the demographic features and the medical history of individual patients), would be a valuable extension of the presented analysis.

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Treatment pathway model in heart failure

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Introduction

The heart failure is a pathophysiological state in which, due to irregularities of the heart anatomy and functions, heart is not able to deliver oxygen to tissues in the amount sufficient to cover their metabolic needs. The most frequent symptoms of this disease include: dyspnoea and fatigue during physical effort or at rest and peripheral oedemas (around the ankles and shank).

According to the definition given by the European Society of Cardiology, heart failure may be diagnosed on the basis of the subjective and objective symptoms and objective features of systolic (left ventricular ejection fraction < 40–45%) and diastolic heart dysfunctions identified in imaging examination (usually in echocardiography). In dubious cases, the improvement of the clinical condition after application of the pharmacological treatment typical for this disease supports the diagnosis of the heart failure. The heart failure can be divided into: 1) systolic (with reduced or increased cardiac output) and 2) diastolic (with preserved left ventricular systolic function). Depending on the dominant symptoms from the part of pulmonary circulation or main circulation, we can distinguish left-, right- and double-ventricular failure.

In order to assess the stage of the disease, the four-level classification according to New York Heart Association (NYHA) is used most frequently. According to NYHA, in the class I physical effort does not cause greater fatigue, dyspnoea or palpitation; in class II a slight physical activity limitation can be observed (there are no symptoms at rest but normal activity causes fatigue, palpitation or dyspnoea); class III patients are characterised by the significant limitation of the physical activity (without symptoms at rest but any activity, that is lower than the normal activity, causes appearance of the symptoms); while in class IV any physical activity causes symptoms and the symptoms appear even at rest (McMurray et al., 2012).

Heart failure occurs usually as a result of other cardiovascular diseases leading to heart dysfunction (ischemic heart disease, arterial hypertension, different forms of cardiomyopathy, advanced valve failures), more rarely occurs in the course of other systems' diseases or is the

consequence of the treatment application (e.g. oncological treatment). The incidence rate and prevalence of heart failure is influenced by the prevalence of the cardiovascular diseases, as well as the quality of the health care of patients with, for example, acute coronary syndrome, and ageing of population. It is estimated that in Europe there are approximately 15 million of patients with heart failure (Dickstein et al., 2008). Over the last decades, mortality rate caused by heart failure has significantly decreased, mainly due to introduction of drugs having proven influence on the survival, however, prognosis is still poor – only half of patients survive 5 years from the moment of the disease diagnosis (Jhund et al., 2009). The heart failure is also related to the huge burden for the hospital treatment and is the reason for 1–2% of all hospitalisations, including the main reason for admissions to hospital among people aged over 65. (Alla et al., 2007).

Epidemiological analysis

Heart failure is usually the end form of the common cardiovascular diseases. Symptoms of the heart failure (e.g. fatigability, dyspnoea, peripheral oedemas) are not specific and thus the difficulties of making a proper diagnosis are not rare. In addition, discreet symptoms at the early stage may not be taken seriously by both the patients and by physicians, therefore it is difficult to make diagnosis. The epidemiological studies often use different diagnosis criteria for heart failure, such as clinical criteria based on Framingham Heart Study (occurrence of two major criteria, such as increased central venous pressure, rales, S3 gallop, or presence of one major and two minor criteria, such as bilateral ankle oedema, dyspnoea on ordinary exertion, hepatomegaly) as well as the criteria of the European Society of Cardiology (which also take into account the results of imaging examinations). Some studies are based on the diagnosis codes entered in the hospital discharge information sheet. Adopting different diagnosis criteria for diagnosing heart failure may be the reason why the results concerning incidence rate and prevalence are divergent. The differences in obtained values may also result from the age limits of the studied populations.

Heart failure prevalence assessed in a Dutch study (Bleumink et al., 2004; Rotterdam Study) amounted to 5.5% (from 0.7% for the age group 55–59 to 17.8% for the age group

>85 year old) whereas in the USA – 2.2% (Retfield et al., 2003) (a study carried out in Olmsted county among 45 year old and older persons).

The data on incidence rate and mortality/survival rate of the heart failure patients are reported in a larger number of epidemiological studies (Table 1). Incidence rate is higher among men and is increasing with age. However, the data on incidence rate developments during the observation are not internally consistent (in the USA the incidence has not changed significantly in Olmsted study, while in Framingham study the incidence has dropped, whereas the most recent European study carried out in Spain reported an increased incidence).

In general, an improved survival rate is observed among the heart failure patients that is associated to a large extent with the use of angiotensin converting enzyme inhibitors introduced in pharmacological treatment thirty years ago, and next with the use of the drugs which belong to beta-blockers group. In the case of Framingham study the survival rate in the case of heart failure diagnosis was increasing by 12% in the following decades (statistically significant improvement both among the men and women). However, in the case of Olmsted study the survival rate improvement was observed mainly among the men and young people. However, it must be emphasised that heart failure is still a disease with poor outcome - five-year survival rate amounts to about 50%.

Table 1. Incidence rate and survival/mortality rate of heart failure in the European countries and in the USA. Source: based on Bleumink et al., 2004, Cowie et al. 1999, Cowie et al., 2000, Gomez-Soto et al., 2011, Retfield et al., 2003, Levy et al., 2002)

Country	Population age	Population size	Heart failure diagnosis criteria	Period of study	Incidence rate	Survival/mortality rate
The Netherlands	≥55 years old	7 983	according to European Society of Cardiology	1989–2000	14.4/1000 man-years in total (17.6/1000 man-years for men and 12.5 man-years for women), the incidence rate was increasing with age from 1.4/1000 man-years for 55-59 year old group up to 47.4/1000 man-years for over 90 year old patients.	Survival rate: 86% after 30 days; 63% after 1 year; 51% after 2 years and 35% after 5 year observation.
Great Britain	≥25 years old	151 000	according to European Society of Cardiology	20 months	1.3 cases/1000 persons/year in total (from 0.02/1000 persons/year for 25-34 year old group up to 11.6/1000 for over 85 year old patients; higher in the case of men – age adjusted incidence ratio - 1.75)	Survival rate: 81% after 1 month; 75% after 6 months; 62% after 12 months and 57% after 18 months.
Spain	≥14 years old	267 231	Framingham Study criteria	2000–2007	296/100 thousand persons/year in the year 2000; an increase up to 390/100 thousand persons/year in the year 2007	in the year 2007 risk of death was, respectively, 12.1%, 28.8% and 61.4% for 30 day, 1 year and 4 year observation
USA (Olmsted)	no data available	4 537	ICD-9 classification and Framingham Study criteria	1979–2000	Higher among men (378/100 thousand) than among women (289/100 thousand), has not changed significantly over time.	Survival rate lower among men then among women (relative risk 1.33), generally has improved (in 1979–1984, 5-year survival rate was 43% versus 52% in 1996–2000
USA (Framingham)	no data available	Framingham Study population	Framingham Study criteria	1950–1999	among men: 627/100 thousand persons/year in 1950–1969 and 564/100 thousand persons/year in 1990–1999; among women: 420/100 thousand persons/year in 1950–1969 and 327/100 thousand persons/year in 1990–1999.	30-day, annual and 5 year mortality among men dropped down from 12%, 30% and 70% in 1950–1969 to 11%, 28% and 59% respectively, in 1990–1999. 30-day, annual and 5 year mortality among women was 18%, 28% and 57% in 1950–1969 to 10%, 24% and 45% respectively, in 1990–1999.

In Framingham Study the risk of heart failure during further life for over-forties was 21% for men and 20.3% for women, and it has not changed significantly with age (20.2% and 19.3%, respectively for 80 year old men and women). The risk was distinctly lower for persons who had not had a myocardial infarction recorded in the interview (11.4% for men and 15.4 for women at the age of 40), however, it doubled for persons with arterial hypertension >/=160/100 mm Hg (compared to persons with correct pressure), (Lloyd-Jones et al., 2002). The study carried out in Europe (Rotterdam Study) showed that the risk of heart failure was 33% for men and 29% for women at the age of 55 (Bleumink et al., 2004).

Epidemiological studies provide scanty data on prevalence, incidence rate and change-in-time trends for heart failure in relation to the left ventricular ejection fraction. The data published suggest that the frequency of heart failure occurrence with retained ventricular ejection fraction has increased in time (Owan et al., 2006).

Risk factors related to heart failure and diagnostic tests

Apart from age and male sex the ischemic heart disease is cited in the first place among the heart failure risk factors. During 7–8 years following the myocardial infarction the heart failure occurs in over one third of patients, in particular in patients with left ventricular dysfunction that had already been found during the ischemic incident (Hellerman et al., 2003). A close link between ischemic heart disease and heart failure can be explained by the fact that the atherosclerosis risk factors (dyslipidemia, smoking) are also the heart failure risk factors. It is worth emphasising the interdependence between the progress in myocardial infarction intervention treatment and the heart failure incidence and prevalence trends. On the one hand, the improved survival rate of patients with myocardial infarction may lead to an increase in the number of heart failure patients, but on the other hand, early reperfusion therapy may lead to an increase in the number of patients with myocardial damage. The first thesis has been confirmed by Framingham Heart Study which observed an increase in the post-infarction heart failure incidence rate from 10% in 1970–1979 up to 23.1% in 1990–1999 with simultaneous drop in 30-day mortality caused by myocardial infarction from 12.1% to 4.1% (Velagaleti et al., 2008). However, the second thesis was confirmed by Olmsted Study

which showed 2% annual drop in post-infarction heart failure incidence rate over the period 1979–1994 (Chen et al., 1999).

Arterial hypertension is another heart failure risk factor. Though the heart failure risk due to the arterial hypertension is lower than in the case of myocardial infarction (Mosterd et al., 2007), high frequency of arterial hypertension occurrence makes it a major risk factor for development of the disease, particularly among women (according to Framingham Study the heart failure risk among men with arterial hypertension is over two times higher while among women - three times higher).

Diabetes also contributes to a higher risk of heart failure, particularly in women (over 3.5 times higher). Diabetes also affects the prognosis in patients with the diagnosed disease - the frequency of diabetes occurrence in patients hospitalised because of heart failure exacerbation is almost two times higher than in patients with chronic stable form of disease (De Cais et al., 2015), and the Olmsted Study observed that 5-year survival rate of patients with heart failure and diabetes is only 37% compared to 46% of the heart failure patients who are not diabetics (From et al., 2006).

Obesity is also increasing the risk of heart failure (body mass index >30 increases the risk twice; Kenchaiah et al., 2003). As opposed to diabetes, however, a moderate obesity of 1st degree (compared to the correct body mass) in patients with diagnosed heart failure is linked to higher survival rate (so called obesity paradox).

Among other heart failure risk factors attention should be given to cardiotoxic regimens of oncological treatment. An aggressive chemotherapy increases the chances of long survival of the patients but also increases the risk of heart failure development, even several years following the treatment. The Scandinavian Study found over 5 times higher risk of heart failure occurrence in a group exceeding 32 thousand persons treated for cancer in their childhood (Gudmundsdottir et al., 2015).

Diagnosis of the heart failure may be difficult, particularly at the early stage of the disease, because the most frequent symptoms (such as dyspnoea after an effort or during a rest, fatigue, oedemas at the ankles) are not specific and must be distinguished from other diseases. Correct diagnosis is particularly difficult in obese aged patients with chronic lung diseases and in patients treated with diuretics. Attention should be given to other cardiovascular

system diseases which may be potential reason for the myocardium damage. On physical examination, apart from oedema in lower parts of the body, rales and crepitations over the lung fields, hypertension in jugular veins, hepatojugular reflux and S3 gallop are usually found.

The basic imaging diagnostic method for a patient with suspected heart failure consists in transthoracic echocardiogram which allows to evaluate the heart structure, ventricular systolic function and measurement of ventricular ejection fraction, as well as evaluation of diastolic function. It is also recommended to perform a 12-lead resting electrocardiogram in order to evaluate types and rates of heart beat as well as the shape and width of QRS complexes. As for the laboratory tests it is recommended to carry out biochemical blood tests (including electrolytes, kidney function, liver enzymes and bilirubin, iron metabolism) as well as thyroid function tests and full blood morphology examination. These tests will allow to diagnose potentially reversible causes of heart failure, to determine the possibility of symptomatic treatment of the patient and to obtain prognostic values. In order to exclude other reasons of dyspnoea in patients with suspected heart failure a determination of natriuretic peptide levels (low levels below threshold indicate low probability of heart failure) should be taken into consideration; besides, this test has a prognostic value as well.

A general radiography of the chest is useful, in particular for diagnosis of acute heart failure (an image of stagnated lung circulation/pulmonary oedeme).

The diagnostis of heart failure in selected patients should possibly include heart magnetic resonance (especially when the result of echocardiography does not allow full diagnosis to be made). In patients who qualify for revascularization a coronarography (evaluation of the coronary vessels in patients with angina pectoris) or perfusion/myocardium ischemia imaging (i.e. stress echocardiography, magnetic resonance, perfusion scintigraphy of myocardium or positron emission tomography in patients with suspected heart ischemia in order to check for reversal of ischemia and myocardium vitality) should be considered.

Endomyocardial biopsy is rarely carried out when the heart failure cause is still unclear and a disease that needs specific treatment is suspected (such as myocarditis, infiltration or storage disorder). The examination is also indicated in the case of acute heart graft rejection.

In the case of patients with heart failure diagnosed during examinations preceding heart graft or mechanical circulatory support a catheterization of the right and left heart is carried out to determine pulmonary ventricular resistance.

What is more, in the case of patients with heart failure, performing an exercise test should be considered (for the determination of the existence of a reversible myocardial ischemia ,as part of the evaluation performed prior to heart transplantation or implantation of a mechanical circulatory support device, and for setting out the recommendations concerning physical effort and for predictive purposes).

Decision-making models in heart failure treatment

Guidelines for the diagnosis and treatment of acute and chronic heart failure in Europe are established by an international expert group within the proceedings of the European Society of Cardiology, and then adopted by Societies of Cardiology in individual countries, including by the Polish Cardiac Society. The latest version of these recommendations is from 2012 (McMurray et al., 2012), and its co-author from the Polish cardiology community is Professor Janina Stępińska (Institute of Cardiology in Warsaw). Therefore, the recommendations on the diagnosis and treatment of heart failure are uniform, with differences relating only to the level of implementation of these guidelines in different European regions. The assessment of the application of these recommendations in clinical practice involves *inter alia* the determination of the percentage of patients receiving medications of proven effect increasing the survival rate and patients treated with implantable devices (implantable cardioverter-defibrillators, resynchronisation therapy).

In the period 2009–2011, the European Society of Cardiology conducted a pilot study (ESC-HF Pilot), aimed at assessing the characteristics of patients with acute and chronic heart failure, the use of treatment resources and results in individual European regions (Maggioni et al., 2013). The study involved the participation of 136 cardiology centres in 12 countries of: Northern Europe (Denmark, Norway and Sweden), Eastern Europe (Poland and Romania), Western Europe (Austria, France, Germany, and Netherlands) and Southern Europe (Greece, Italy and Spain). It should be noted that the majority of centres located in Eastern Europe (26 out of 36) were Polish facilities. The demographic and clinical characteristics, and also

the treatment of patients with acute heart failure varied significantly from one region to another. Patients from Eastern Europe were younger, in which case the cause of heart failure was more frequently coronary heart disease, they had higher values of systolic arterial blood pressure and more frequently received beta-blockers and inhibitors of the renin–angiotensin–aldosterone system. Patients from Northern Europe demonstrated a significantly lower left ventricular ejection fraction. In Eastern European countries a significantly lower cardioverter-defibrillator implantation rate was observed in this group of patients. Similarly, the observations concerned in patients with chronic heart failure, however in this group, the use of beta-blockers and angiotensin-converting enzyme inhibitors was similar across Europe and indicated appropriate application of current recommendations. Generally, implantable devices recommended in the case of heart failure were significantly less frequently implanted in patients from Eastern Europe (Poland and Romania), however this ratio was considerably higher in Western and Southern European countries.

Table 2. Percentage of patients with heart failure and implanted implantable devices in individual European regions (Source: based on results from the ESC-HF Pilot Survey; Maggioni et al., 2013).

Europe	Northern	Eastern	Western	Southern
Patients hospitalised due to acute heart failure				
ICD, %	7.9	3.9	11.5	7
CRT-P, %	0.7	0.3	0.9	0.4
CRT-D, %	4.3	1.8	4.1	4.1
Outpatients with chronic heart failure				
ICD, %	6.6	4.7	18.4	15.6
CRT-P, %	2.4	0.3	0.6	0.9
CRT-D, %	5.2	1.7	11.9	10.5

A different study (Veldhuisen et al., 2009) analysed the total number cardiac resynchronisation system implantations (CRT, including with defibrillator function – CRT-D) in 15 countries of Western Europe (data were sourced from the EUCOMED register for collecting information on the number of devices sold by companies in individual countries). Generally, within 5 years this number has increased by 115% (from 46/million of inhabitants in 2004 to 99/million in 2008). This change was due to an increase in the percentage of patients

with implanted CRT with defibrillator function (from 55% in 2004 to 75% in 2008). Among the analysed European countries, the majority of resynchronisation devices in 2008 were implanted in Italy, Netherlands and Germany (Figure 1).
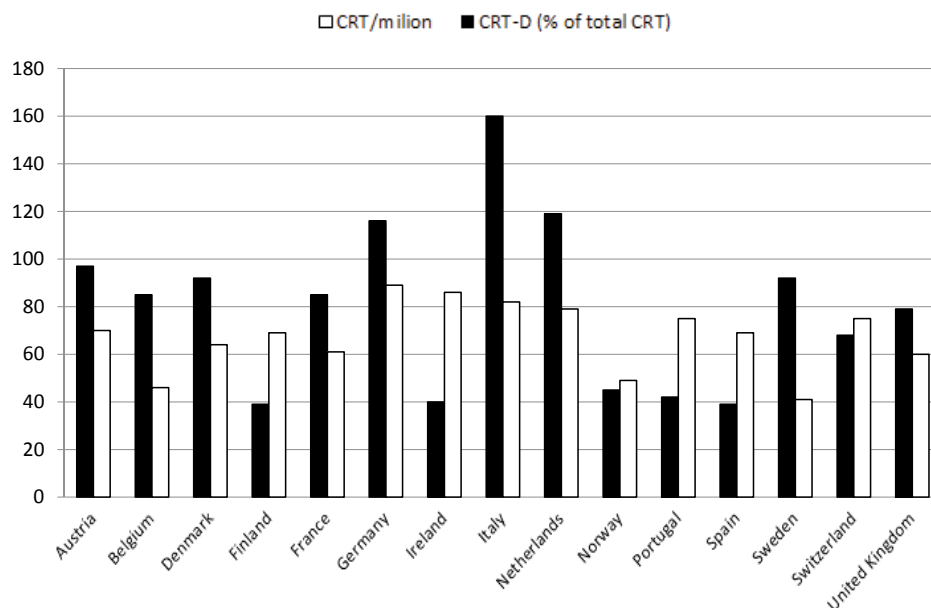
Figure 1. Cardiac resynchronisation system implantations (per one million of inhabitants) and the percentage of implanted resynchronisation systems with defibrillator function in particular Western European countries in 2008 (Source: own study based on Veldhuisen et al., 2009)

In the following years the EUCOMED data included also Poland[28]. In 2013, the number of resynchronisation systems sold in Poland (including systems with pacemaker function – CRT-P and with defibrillator function – CRT-D) was evidently lower than the average for all analysed European countries.

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[28] http://www.eucomed.org/uploads/_medical_technology/facts_figures/CRM_Graphs_2015.pdf, access date: 27.10.2015.
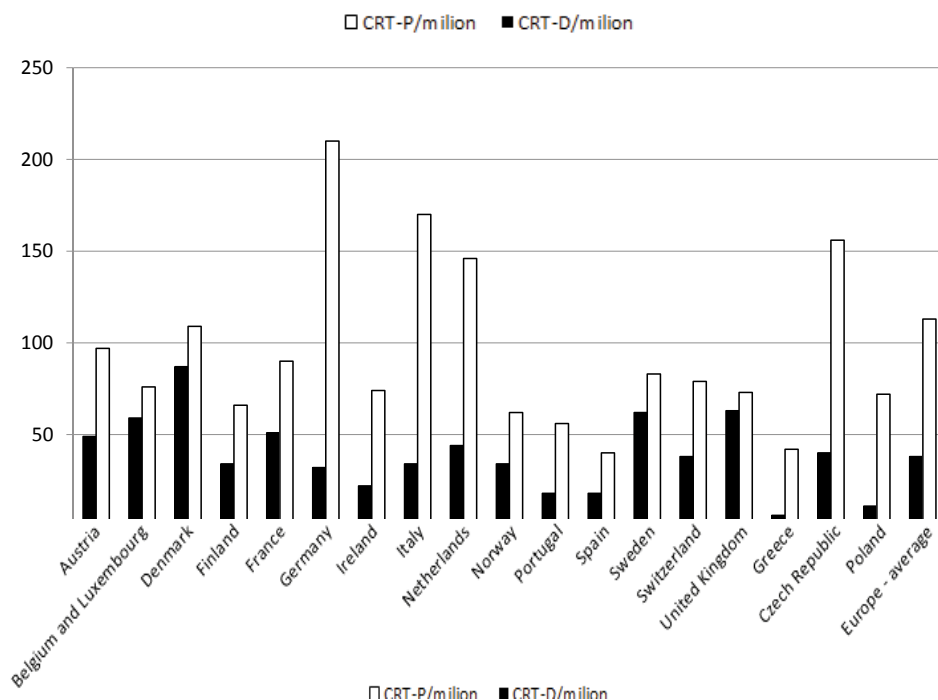
Figure 2. Implantations of cardiac resynchronisation systems with pacemaker function (CRT-P) and defibrillator function (CRT-D) (per one million of inhabitants) in European countries in 2013 (Source: own study based on EUCOMED data[29])

The aim of treating patients with heart failure is to reduce the symptoms and improve the quality of life, prevent hospitalisation and increase the survival rate, including preventing sudden deaths.

The treatment of heart failure should strive to eliminate/treat the causes of myocardium dysfunctions. Symptomatic treatment is implemented based on the level of advancement of heart failure according to NYHA and is mostly based on pharmacotherapy (McMurray et al., 2012). Specific attention should also be paid to the recommendations relating to changing the lifestyle (body mass control, smoking cessation, preventive vaccinations).

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[29] http://www.eucomed.org/uploads/_medical_technology/facts_figures/CRM_Graphs_2015.pdf

In the symptomatic treatment of each patient with heart failure with lower left ventricle systolic function, one must consider the application of neurohumoral pathway antagonists with proven effect of reducing the risk of hospitalisation due to heart failure and the risk of death – i.a. angiotensin-converting enzyme inhibitors, beta-blockers, and mineralocorticoid receptor antagonists.

Other medications with less benefits for patients with symptomatic (class II–IV acc. to NYHA) heart failure include: angiotensin receptor antagonists, ivabradine, digoxin. Diuretics are also used for reducing dyspnoea and edema.

Although in the case of patients with an advanced form of the disease, death is caused by the failure of heart as a pump, in the case of patients with milder symptoms, the majority of deaths occur unexpectedly and are caused by ventricular arrhythmia. Thus, an important role in preventing death in the case of patients with heart failure is played by implantable cardioverter-defibrillators (ICD), which purpose is to interrupt the life threatening instances of arrhythmia. An indication for ICD implantation as part of secondary prevention of sudden cardiac death is the history of cardiac arrest and sustained ventricular tachycardia. The implantation of a device is recommended in this group of patients, regardless of the level of damage to the myocardium (left ventricular ejection fraction), however, a good general condition of the patient with a high life expectancy is essential. As part of primary prevention of a sudden cardiac death, ICD implantation is recommended in the case of patients with symptomatic heart failure of class II–III according to NYHA and with left ventricular ejection fraction ≤35% (despite at least 3 month-long optimal pharmacotherapy). The condition, as in the case of secondary prevention, is the life expectancy in a good functional condition of more than one year. Implantation is not recommended in patients with severe heart failure (of class IV acc. to NYHA), who are not eligible for the implantation of a ventricular assist device or for heart transplantation.

Patients with heart failure and asynchrony of left ventricular contraction, with the view to limiting the risk of hospitalisation and premature death, undergo cardiac resynchronization therapy (CRT). CRT implantation is recommended in patients with heart failure in the functional class II, III and at an ambulatory facility in class IV according to NYHA, and with permanently lowered left ventricular ejection fraction (despite optimal pharmacotherapy), whose life

expectancy in good functional condition exceeds a year. In patients with such indications for ICD implantation, resynchronization therapy with defibrillator function (CRT-D) is applied.

The ultimate method for treating patients with end-stage heart failure is heart transplantation. However, due to the large number of candidates for the procedure and the limited number of organ donors, centres of the highest reference level increasingly often apply long-term mechanical circulatory support (devices for supporting the functions of the left ventricle or both ventricles). Such devices, initially used as part of a bridging treatment until transplantation, currently may be considered for patients eligible for transplants. These devices are also applied in the case of patients who are not eligible for transplantation with the view to improving the functions of target organs to such a degree that the patient qualifies for transplantation. Mechanical circulatory support devices may also be implanted temporarily until the function of the heart improves to such a degree that disconnecting the device will be possible (for instance in patients with myocarditis or peripartum cardiomyopathy).

The presented procedure concerns patients with chronic heart failure with decreased left ventricle systolic function. In the case of acute heart failure, diagnostic and treatment processes are carried out simultaneously. The therapy involves the application of oxygen, diuretics and vessel dilating agents, opioids and inotropic drugs, and in some cases also methods of short-term, temporary mechanical circulatory support (i.a. intra-aortic balloon pumps, other percutaneous methods of supporting heart function and extracorporeal blood oxygenation).

In the case of patients with heart failure with preserved left ventricle systolic function, no recommendations for pharmacological standards decreasing prevalence and mortality have been presented to date. Similarly as in the case of patients with lower left ventricle systolic function, diuretics are applied to alleviate subjective and objective symptoms of the disease. Of key importance is also the issue of treating underlying conditions – arterial hypertension, coronary heart disease and atrial fibrillation (heart rate control). The model of treatment of heart failure in Poland is illustrated in Flowchart 1.
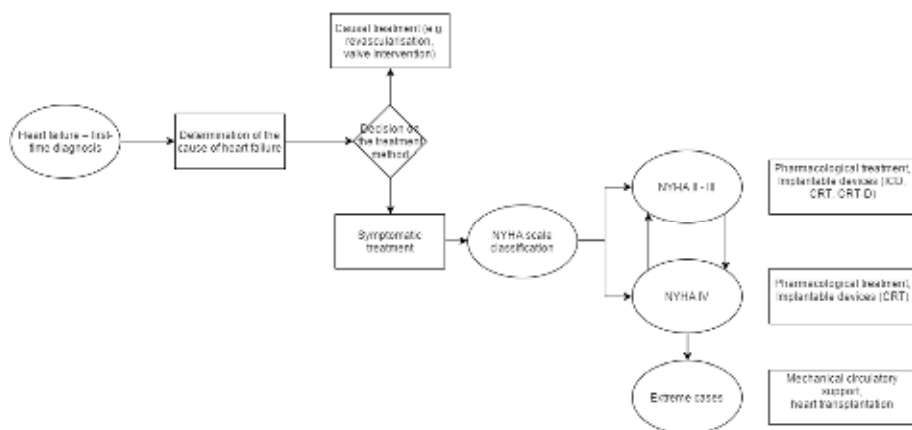
Flowchart 1. The model of treatment of heart failure in Poland (Source: own study based on the guidelines of the European Society of Cardiology)

Empirical model of treatment of heart failure in Poland

Determination of the crude incidence and incidence rate of heart failure in Poland

The first step in the analysis of the model of treatment of heart failure is the determination of the number of patients affected by this disease. This will allow for defining the proportion of patients undergoing a given method of treatment in the total number of patients. In line with the methodology set out in Chapter X, the incidence of this disease was estimated at 119.5 thousand of cases in a single year (310.4 cases per 100 thousand inhabitants). This value covers, with the exception of patients undergoing hospitalisation, those patients diagnosed with this disease who came into contact with healthcare services within the Specialist Outpatient Care (SOC) or at an Emergency Department/Hospital Admission Unit (ED/HAU).

Analysing new cases in relation to sex, among the new patients the majority were women (63.5 thousand cases – 319.8 female patients per 100 thousand of population; men – 56 thousand cases – 300 male patients per 100 thousand population). When taking into account the age structure, higher incidence rates concern men (see Table 3).

Table 3. Incidence rate of heart failure by gender and age groups
(own study based on CSO and NHF data)

Age group	Incidence ratio per 100 thousand population	
	women	men
(0; 18)	1.9	2.0
<18;45)	8.1	16.5
<45;55)	52.4	130.0
<55;65)	189.1	424.8
<65;75)	702.9	1085.7
<75;85)	2063.4	2596.8
85+	3728.4	4600.4

As already indicated in Table 1, age has a significant impact on the incidence rate of heart failure. As shown in Table 4, the incidence rate ratio of this disease increases with age. However, in absolute terms, the age group <75;85) was characterised by the highest number of new cases of heart failure – this age group is more than three times greater than the age group 85+, which translates into the final number of new cases.

Table 4. Incidence and incidence rate of heart failure by age groups
(own study based on CSO and NHF data)

Age group	Number of cases (in thousands)	Ratio per 100 thousand population
(0; 18)	0.14	2.0
<18;45)	1.89	12.3
<45;55)	4.49	90.9
<55;65)	16.70	300.6
<65;75)	26.37	867.0
<75;85)	45.20	2252.6
85+	24.70	3959.8

Based on the reporting data from NHF, it was only possible to determine the incidence rate ratios broken down by the patient's place of residence (urban/rural area). About 61.3% of new patients in 2013 were residents of urban areas. Also, in case of the incidence rate ratio values

per 100 thousand inhabitants, dominant are urban areas – 315 new cases per 100 thousand population; rural areas: 303.4 new cases per 100 thousand population (cf. Table 5).

Table 5. Heart failure incidence and incidence rate in relation to place of residence (urban/ rural area) in 2013 (source: own study based on NHF and Central Statistical Office data)

Place of residence	Number of cases (in thousand)	Ratio per 100 thousand of population
urban area	73.26	315.0
rural area	46.24	303.4

Incidence rate analyses have been made for each group defined by age (age group), sex and place of residence. Details have been shown in Table 6.

Table 6. Heart failure incidence and incidence rate in relation to all analysed profiles in 2013 (source: DAiS analysis based on NHF data)

	Sex	Place of residence	Age group						
			(0; 18)	<1.2)	<1.2)	<1.2)	<1.2)	<1.2)	85+
Number of cases (in thousand)	W	urban area	0.04	0.39	0.83	3.61	7.67	15.89	10.36
		rural area	0.02	0.22	0.47	1.93	4.55	10.82	6.73
	M	urban area	0.06	0.80	1.88	7.08	8.92	11.10	4.63
		rural area	0.02	0.48	1.31	4.08	5.24	7.39	2.98
Ratio per 100 thousand of population	W	urban area	2.3	8.5	54.2	182.2	658.6	1959.5	3762.4
		rural area	1.4	7.3	49.4	203.7	792.8	2237.6	3677.3
	M	urban area	2.8	17.3	134.0	429.8	1056.4	2492.6	4602.3
		rural area	1.1	15.2	124.7	416.6	1139.6	2770.5	4597.4

A detailed group analysis allows for further examination of earlier observed phenomena. Incidence rate ratios in particular groups for population 55+ are higher in rural areas than their counterparts in urban areas. However, due to a different age structure of rural and urban areas, information in Table 5 provides that incidence rate ratio in urban areas is slightly higher (in men - urban area: 312.4; rural area 283.0; in women - urban area: 317.3; rural area 323.7 newly diagnosed patients per 100 thousand population

Empirical model of treatment

Empirical model of treatment for first-time patients has been developed. For the purposes of the development, the set of newly diagnosed patients has been limited to hospitalized patients only, as taking account of patients treated in outpatient facilities would lower the

statistics in terms of treatment applied. The study takes into account all hospitalization procedures reported to NHF, which were provided to patients under analysis within 365 days of the first registration of the patient in the inpatient system with the diagnosed heart failure. Analyses of those procedures did not include verification of diagnosis based on which the procedures were applied[30]. Finally, the analysis took account of 101 patients who were hospitalized in 2013 due to heart failure, but who were not hospitalized due to this diagnosis between 2009 and 2012 (the lower time limit results from NHF data availability).

The investigators focused on defining how many patients received a particular therapy, namely:

- – PCI or CABG (causal treatment)
- – heart valve surgery (causal treatment)
- – CRT implantation/replacement31
- – ICD implantation/replacement as a method of preventing sudden cardiac death.

Heart transplants have not been taken account of in the analysis due to a different model of funding for that type of procedure, and such information is not found in the NHF (this procedure is funded from another separate budget).

According to the analysis of invasive diagnostics, every 10th patient received coronarography. Approx. 4.38% of patients underwent causal treatment (cf. Table 7).

Table 7. Share of patients subjected to causal treatment due to heart failure, 2013.
(source: DAiS analysis based on NHF data)

Treatment	Share of hospitalized patients
Valve interventions	0.7%
Including percutaneous valve intervention	0.04%
Including surgical procedures	0.66%
PCI	3.36%
CABG	0.6%
Total[5]	4.38%

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[30]Thus, a patient who was subjected to coronarography otherwise than due to heart failure is treated as a patient who was provided with coronarography (within 365 days of hospitaliztion due to heart failure).
[31]Equivocality of the category results from equivocality of procedure codes, e.g. 00.54 Implantation or replacement of a pacemaker system, impulse generator for defibrillation (only) [CRT-D]

Additionally, it was observed that almost 4.5% were treated by CRT or ICD implantation/ replacement (Table 8). The implantation of ICD was twice more common than the implantation of CRT (including the one with defibrillator function).

Table 8. A share of patients with implanted/replaced ICD/CRT, 2013
(source: DAiS analysis based on NHF data)

		CRT implantation/replacement	
		YES	NO
ICD implantation/replacement	YES	0.03%	3.01%
	NO	1.42%	95.54%

A comparison of the data with Figure 2 shows differences resulting from methodology (83 CRT devices per one million inhabitants according to Figure 2, almost half of that value results from NHF data analysis - treatment provided within 365 days of the patient's being recorded in inpatient system). One can draw a conclusion that half of the patients require such treatment within one year of the diagnosis.

A full analysis of services provided to patients requires a presentation of frequency of procedures used in all the combinations. To this end the data can be presented in the form of a decision tree, where each branch refers to application or non-application of a given procedure. Flowchart 2 presents a detailed decision tree of procedures applied in the treatment of heart failure. Data on the reported procedures does not enable an analysis of a respective pharmacological treatment.

When analysing the following flowchart, one can conclude that within 365 days of being registered in the inpatient system, almost 92% of patients did not undergo the analysed procedures and more than 90% patients were provided with symptomatic treatment only. 3933 patients (approx. 4%) were treated by means of PCI or CABG. Percutaneous coronary intervention is the most frequently applied procedure - 3400 patients, i.e. approx. 3.4% of all patients hospitalized due to heart failure. Inferences concerning a relation between therapies or between a therapy applied and probability of death are made difficult due to the fact that many patients receive only pharmacological treatment, and inferences based on a scarce number of observed patients subjected to treatment is biased to a respective extent. It needs to be stressed that the presented conclusions do not prove the effectiveness of individual treatment regimens.

Flowchart 2. Empirical model of heart failure treatment (source: DAiS analysis based on NHF data)

Was PCI performed?

YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths
NO	97662	96.6%	3982	4.08%
YES	3400	3.4%	159	4.68%

Including: CABG?

YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths
NO	97129	99.4%	3970	4.09%
YES	533	0.6%	12	2.25%
NO	3326	97.8%	159	4.78%
YES	74	2.2%	0	0.00%

Including: heart valve surgery

YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths
NO	96663	99.5%	3964	4.10%
YES	466	0.5%	6	1.29%
NO	365	68.5%	9	2.47%
YES	168	31.5%	3	1.79%
NO	3300	99.2%	159	4.82%
YES	26	0.8%	0	0.00%
NO	59	79.7%	0	0.00%
YES	15	20.3%	0	0.00%

Including: percutaneous valve intervention

YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths
NO	96638	100.0%	3964	4.10%
YES	25	0.0%	0	0.00%
NO	461	98.9%	6	1.30%
YES	5	1.1%	0	0.00%
NO	365	100.0%	9	2.47%
NO	168	100.0%	3	1.79%
NO	3294	99.8%	159	4.83%
YES	6	0.2%	0	0.00%
NO	24	92.3%	0	0.00%
YES	2	7.7%	0	0.00%
NO	59	100.0%	0	0.00%
NO	15	100.0%	0	0.00%

Including: CRT implantation or replacement

YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths
NO	95309	98.6%	3916	4.11%
YES	1329	1.4%	48	3.61%
NO	25	100.0%	0	0.00%
NO	452	98.0%	6	1.33%
YES	9	2.0%	0	0.00%
NO	359	98.4%	9	2.51%
YES	6	1.6%	0	0.00%
NO	165	98.2%	3	1.82%
YES	3	1.8%	0	0.00%
NO	3177	96.4%	154	4.85%
YES	117	3.5%	5	4.27%
NO	24	100.0%	0	0.00%
NO	59	100.0%	0	0.00%
NO	15	100.0%	0	0.00%

Including: ICD implantation or replacement

YES/NO	Number of patients	Proportion of patients	Number of deaths	Proportion of deaths
NO	92596	97.2%	3820	4.1%
YES	2713	2.8%	96	3.5%
NO	1305	98.2%	45	3.4%
YES	24	1.8%	3	12.5%
NO	25	100.0%	0	0.0%
NO	439	97.1%	5	1.1%
YES	13	2.9%	1	7.7%
NO	347	96.7%	9	2.6%
YES	12	3.3%	0	0.0%
NO	157	95.2%	3	1.9%
YES	8	4.8%	0	0.0%
NO	2885	90.8%	143	5.0%
YES	292	9.2%	11	3.8%
NO	114	97.4%	5	4.4%
YES	3	2.6%	0	0.0%
NO	23	95.8%	0	0.0%
YES	1	4.2%	0	0.0%
NO	56	94.9%	0	0.0%
YES	3	5.1%	0	0.0%
NO	14	93.3%	0	0.0%
YES	1	6.7%	0	0.0%

Summary

The authors of this article have presented basic information concerning heart failure - definition, symptoms and signs, classifications used when describing patient's condition. In addition, information was presented on epidemiology: known risk factors, differences in incidence by sex. This was followed by a description of diagnostic tests and guidelines for clinical pathway. Attention was also paid to European studies concerning the application of various therapeutic methods, and in particular the application of CRT and ICD devices.

Further on the authors presented results of the analysis of NHF data. Based on that an empirical model of treatment of heart failure in Poland was constructed. The authors presented statistics on incidence and incidence rate. According to the analysis, incidence is higher in women than in men, and it is higher in urban rather than in rural areas. A detailed analysis by sex, age groups and place of residence reveals more complex relationships. Of course age significantly influences incidence rate. Among the same age group it is men who are at a bigger risk of developing the disease. However, in terms of sex and age, the risk is higher in case of urban inhabitants.

The analysis of treatment procedures in Poland shows that if a patient has been registered in the inpatient system (most frequently in a symptomatic group E54 CIRCULATORY INSUFFICIENCY < 70 years of age WITHOUT PW) pharmacological treatment is provided. Percutaneous coronary intervention is the most frequently used procedure. Death rate within 365 days of the first visit in hospital related to heart failure amounts to 4%. However, more detailed analyses that relate death risk with therapeutic decisions are highly biased.

The approach presented is an attempt at a comprehensive description of heart failure care pathways in Poland. This first step is not free from various errors resulting i.a. from NHF reporting specificity - reporting procedures which impact service price, upcoding (e.g. heart failure diagnosis enables the hospitalization of older patients who suffer from circulatory problems which are not precisely defined - group E54). It is another big challenge to include pharmacological treatment - so important in heart failure treatment - in the care pathway. However, despite the above mentioned limitations of this study its results may constitute the basis for forecasting demand for the particular services in Poland.

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Cardiovascular diseases in Poland – the results of the predictive model for 2015–2025

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Introduction

The diseases of the circulatory system are the main cause of death in Poland and worldwide. According to the WHO estimates they cause as many as 31% of deaths (World Health Organization, 2015). Therefore it is beyond any doubt that they are and will be one of the main causes of morbidity and mortality and a burden on health care systems. Hence, a need arises to address the issue of predicting the number of new cases.

Incidence modelling constitutes an important measure that helps evaluate the functioning of the health care system. It allows to determine the current epidemiological situation, to examine the relationships and phenomena as well as to identify the factors which affect the health of the whole population. Quantitative research is used to define disease prevalence processes. The estimation of the future prevalence constitutes an important element of the health policy, particularly when the health strategies are developed at the regional level[32].

This chapter presents the methodology of projecting incidence rate of cardiovascular diseases in Poland and the results of that projection for the years 2015–2025. The first part of the study brings closer the methodology of calculating the cardiac disease incidence, describes the empirical data source used (the data have provided an input for prediction models) and points out at a significant problem associated with reliable preparation of input data to ensure that the results are burdened with the lowest possible error. The further part of the analysis shows the results of the forecast of incidence of cardiovascular diseases in Poland for the years 2015–2025 under the baseline option, i.e. assuming fixed incidence rate ratios for the adopted demographic structure. The article ends with a summary of the prediction results and compilation of major conclusions.

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[32]The use of real data for projection of future values of factors such as incidence or incidence rate, in order to decide on treatment regimen, is referred to as evidence-based management as opposed to the decisions based on expertise (Evidence-Based Medicine Working Group, 1992).

Historical data as input information for predictive purposes

In order to estimate the future values of a phenomenon the input information, or historical data, which provides a prediction basis needs to be precisely defined. In Poland there is no database which would contain all patients with cardiac diseases. In the case of oncological diseases the role of database is fulfilled by National Cancer Registry. As for the cardiac diseases there are 3 medical registers in Poland: National Register of Acute Coronary Syndromes PL-ACS[33], National Register of Interventional Cardiology Procedures (ORPKI[34]) and National Register of Cardiac Surgeries (KROK[35]). The first of these registers was established in 2003 in Silesia region, is now operational throughout Poland and is run by Professor Lech Poloński, Śląskie Centrum Chorób Serca [*Silesian Centre for Cardiac Diseases*] Zabrze. The Register of Cardiac Surgeries KROK was established in 2005 by Professor Zbigniew Religa who was Minister of Health at that time, in order to continue the Report "Polish Cardiac Surgery" annually issued by Professor Marian Śliwiński. The last register, ORPKI, has been run by Uniwersytet Jagielloński Collegium Medicum since 2014.

However, none of these Registers are sufficient to gather information on the cardiovascular event incidence rate and its forecast values. The register of patients with acute coronary syndrome differs from the patient numbers reported by the National Health Fund. The preliminary comparative analysis shows that the patients are not reported by all facilities. Besides, reporting to PL_ACS is rather quick whereas the reports to NHF re prepared only after the patient is released when the physicians have more complete clinical history of the patient. Furthermore, acute coronary syndromes constitute only one of the several cardiac disease streams, hence the necessary predictive information could not be obtained even with a complete register. On the other hand, KROK is a register of cardiac surgeries and includes only one method of cardiac patient treatment. The third register, ORPKI, does not contain patient IDs which would allow to link information with NHF reported data. Besides, ORPKI also covers only a part of cardiac diseases and, therefore, cannot be used for designing a standardised method of analyses.

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[33]http://pl-acs.pl/
[34]http://www.orpki.pl/
[35]http://www.krok.org.pl/

Hence, it must be assumed that the only comprehensive source of cardiac patients' data is the National Health Fund (NHF) database which contains the reported information on the services provided. However, it must be borne in mind that these are billing data which provide a basis for the settlement of accounts between the payer and healthcare provider, and not epidemiological data on the patient condition. Therefore, in order to determine the date of patient diagnosis it is necessary to apply the decision rules that are described further.

Identification of first-time patients

In order to determine the number of new cardiac cases, it is necessary to first identify the patients who started treatment for a given disease in a given year (first-time patients). To this end the NHF reported data have been reviewed for patients who benefited from the inpatient treatment, secondary outpatient care in the ambulatory setting and in Emergency Department/Admission Unit (Table 1).

Table 1. Definitions

Inpatient care, HOSPITAL	Information on the patient stay, settled on the basis of catalogue product 1a or 1b - NHF settlement products concerning the inpatient services (JGP catalogue and the catalogue of other reasons for hospitalisation)
ED stay/ Admission Unit, ED	arrival of patient to ED/AU followed by immediate hospitalisation
SOC stay, SOC	Contract implemented under Secondary Outpatient Care (contract for TYPE OF SERVICES = 2), including Ambulatory Cost-intensive Diagnostic Services (ACDS)

The analysis included the services with diagnoses based on the International Classification of Diseases (ICD), revision 10 (ICD–10). The corresponding ICD–10 codes were assigned to the cardiac disease streams (cf. Table 2), while taking care to avoid excessively detailed streams. Due to the 5th character reporting problems (local coding customs are of importance) the first three characters of ICD–10 code were taken into account. Table 2 shows proper streaming. First eight streams account for about 90% of cardiac diseases cases in Poland.

Table 2. Cardiac diseases streams classified according to ICD10 codes (source: DAiS analysis based on ICD10 classification)

Description	ICD 10
Ischemic heart disease	I20, I21, I24, I25
Heart failure	I50
Atrial fibrillation and flutter	I48
Other types of arrhythmia and atrioventricular block	I44-I47, I49
Cardiomyopathies	I42, I43
Congenital heart defects	Q20-Q26
Acquired heart defects	I05-I09, I34-I37
Pulmonary embolus	I26
Endocarditis	I33, I38, I39
Pericardial diseases	I30-I32
Other diseases of pulmonary vessels	I27, I28
Aortic aneurysm	I71
Myocarditis	I40,I41
Rheumatic heart disease	I00-I02
Other diseases (not precise, not classified)	I51, I52

In the case of cardiac diseases the first-time patient will be defined for the years 2011-2013 based on the 2009–2014 NHF data (patient history may be reviewed at least two years back and one year forward). The patient who is entered into the NHF reporting system during this period will be considered a new one (first-time patient), if he/she was recorded in the context of a given diagnosis for the first time.

Thus, for each patient:

a) for 2011 it will be possible to review at least previous 2 years his/her history,

2009	2010	2011
Patient has not been recorded in the system		New patient

b) for 2012 it will be possible to review at least previous 3 years his/her history,

2009	2010	2011	2012
Patient has not been recorded in the system			New patient

c) for 2013 it will be possible to review at least previous 4 years his/her history,

2009	2010	2011	2012	2013
Patient has not been recorded in the system				New patient

Three pathways of recording the patient entry in the system have been considered: hospital, SOC and ED/AU Depending on the further patient history those in respect of whom an in-depth analysis of reported health services was necessary were defined (cf. Table 3). These were patients whose observed visit could be, with a sufficient degree of probability, a *follow-up* visit, i.e. the patient should not be qualified a first-time patient.

Table 3. Classification of the first-time patients based on the records in the system

First record:	Recorded again within 365 days			
	HOSPITAL	ED	SOC STAY, SOC	N.A.
HOSPITAL	Record date: HOSPITAL	Record date: HOSPITAL	Record date: HOSPITAL	Record date: HOSPITAL
SOC	Record date: SOC	Record date: SOC	Record date: SOC	Product analysis in SOC
ED	Record date: ED	Record date: ED	Record date: ED	Record date: ED

Patients who were recorded in the hospital or at ED/AU were automatically taken into account as first-time patients in the calculation of incidence rate. If a patient visited for the first time in SOC and has not been recorded again in the system during the following 365 days[36], the visit reported were thoroughly reviewed. On that basis the probability that this was a first-time patient was assigned. For example, in case of a report such as post-hospitalisation visit where the patient was not recorded in the hospital, he/she has been classified as "New patient, given that the reason for hospitalisation could be different than cardiac disease (predominant), however the analysed disease has been diagnosed in the patient". However, in the case of W11 advice (out-patient advice without any indication of the tests specified in the list qualifying for higher payment - the simplest out-patient advice) a 100% probability was assigned to a *follow-up* patient.

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[36]Therefore, 2014 data could not be used – 2015 patient history which would allow for additional classification of the patients under review not available.

Also, patients who were registered for the first time in SOC and were diagnosed as suffering from myocardial infarction and pulmonary embolus were excluded. Due to their severity patient with these diseases cannot be treated in the ambulatory setting (patients are treated in the hospital due to the life-threatening condition). It was assumed that a SOC visit with such diagnosis represents a continuation of the hospital treatment.

Determination of incidence rate ratios

Incidence rate is affected both by a number of external factors and population characteristics. Many diseases are strongly correlated with age, sex and place of residence. In order for the analysis to take account of those factors at least partially, patients were categorized into groups. Each of the profiles by which categorization was made enables the forecast to take account of changes in that factor (population aging, migration to/from urban/ rural areas).

In order to take into account the impact of demographic changes on cardiovascular incidence rate ratios the following cross-sections were made:

a) urban/rural area - classification based on the last digit of patient TERYT identifier (based on NHF Database of Insured Individuals), pursuant to the ORDINANCE OF THE COUNCIL OF MINISTERS[37] of 15 December 1998

	urban/rural area
1 - urban gmina	urban area
2 - rural gmina	rural area
3 - rural-urban gmina	rural area
4 - a town in a rural-urban gmina	urban area
5 - a rural area within a rural-urban gmina	rural area
8 - districts of Warszawa-Centrum gmina	urban area
9 - delegations and districts of other urban gminas	urban area

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[37]Ordinance of the Council of Ministers of 15 December 1998 concerning detailed principles for keeping, applying and making available the National Official Register of the Territorial Division of Poland and the related obligations of central and local government administration units. (Journal of Laws 1998 No 157 item 1031).

b) age in division into the following age groups:

<0:18), <18:45), <45:55), <55:65), <65:75), <75:85), 85+

c) sex

Due to the above-mentioned division, 28 groups of patients were made up. Relevant incidence rates ratios were developed for each of these groups separately.

For the purposes of further work a method of calculating incidence rate ratios based on empirical data must be defined. Depending on features of an issue under consideration various approaches can be applied:

–   ratios calculated for patients registered in a given year - the analysis includes only patients who were diagnosed during the year under analysis, the ratios are fixed values which are defined based on a single "point" in time;

–   average value - a solution which enables increasing the group size (increasing the sample size). The values of the ratios are average values from a few observations (years) - this eliminates various irregular fluctuations. The ratios are fixed values defined based on several observations (several "points" in time)

–   extrapolation based on data collected and expert know-how on epidemiology - the ratios are values which vary according to the principles defined by experts or according to the character of changes among particular observations (e.g. linear growth, exponential growth, ratio unchangable in time, etc.)

Due to the fact that the available data allows for defining only three values of ratio in time (incidence rate ratio in 2011, 2012, 2013) extrapolation and estimations of incidence rate ratio would be highly biased. Thus, the baseline forecast is a projection which assumes incidence rate ratios which are stable in time in particular groups. Scenarios which assume methodology projection as an additional assumption may be an element of model sensitivity analysis.

The analysis of the obtained ratios showed their instability in time. The values were dropping, which is related to the so-called data enhancement. As it was said earlier, by analysing the 2013 data follow-up patients can be taken account of more precisely than for the year 2011.

Due to the above, ratios calculated based on the 2013 cohort were assumed as incident rate ratios. This allows for the most accurate isolation of new cases. Those ratios were calculated in division into 28 groups defined by patient age, sex and place of residence.

Incidence forecast

Incidence forecast for the years 2015-2025 has been calculated based on 2013 incidence rate ratios. Incidence rate ratios have been calculated separately for each group of diseases by dividing the number of patients by the cohort size. Patients were categorized by sex, place of residence (urban/rural area) and 7 age groups (0–17, 18–44, 45–54, 55–64, 65–74, 75–84, 85 and more). A separate incidence rate ratio was calculated for each of the 28 sub-cohorts.

Then, the above ratios were multiplied by a forecast population in each of the above mentioned subpopulations, as a result of which the forecast incidence of particular cardiovascular diseases was obtained. One has to underline that the calculated forecast assumes that the incidence rate ratios will remain stable in time, and it is only demographic structure of particular regions of Poland that is going to change. Due to that, the formula for a projection of a number of a given cardiovascular event is as follows:

$$new\ cases_{r,k} = \sum_{w \in W} \sum_{p \in P} \sum_{z \in Z} population\ size_{w,p,z,r} * wsp_{w,p,z,k}$$

Where:

$new\ cases_{r,}$ - forecast number of cases of a given disease in year

$k \in K$ - set of analysed cardiovascular diseases

W - set of analysed age groups

P - set of analysed sexes

Z - set of analysed places of residence

$population\ size_{w,p,z,r}$ - CSO forecast number of inhabitants in year, in age group, sex and place of residence z

$wsp_{w,p,z,r}$ - cardiovascular disease incidence rate ratio , calculated for the age group , sex and place of residence z

In order to calculate the total number of new cases we use incidence rate ratio (it is not a sum of particular disease incidence rate ratio, and it takes account of polypathology).

$$new\ cases_r = \sum_{w\,\in\,W} \sum_{p\,\in P} \sum_{z\,\in Z} population\ size_{w,p,z,r} * wsp_{w,p,z}$$

Incidence of cardiovascular diseases in Poland in 2011-2013

Based on the methodology applied, the total number of newly diagnosed cardiovascular patients in the years 2011-2013 has been determined. The NHF database of reported services served as the data source. Incidence was defined in three stages. During the first one, for each patient the date of first service provided due to a cardiovascular disease was defined (first appearance within the system).   Then a number of patients was defined, who appeared for the first time within the system in a given year. Another stage involved an analysis of services reported as provided to patients, who were registered for the first time in the system with a given diagnosis by visiting a doctor within the secondary outpatient care system (SOC) and did not appear again in the system within the following 365 days. Based on the product analysis, probability was assigned that this is the first appearance of the patient within the system.   Moreover, patients who were diagnosed with myocardial infarction (I21) or pulmonary embolism (I26) and received SOC treatment as their first treatment of the disease were excluded from the analysis. It was decided that, due to their acute course, treatment should not be started in outpatient facilities, so those visits were treated as a continuation of inpatient treatment or incorrect coding of services reported in respect of SOC. Due to this approach, almost 180 thousand patients with various cardiovascular diagnoses[38] who received treatment in SOC facilities in 2011-2013 could be categorized as new cases. They accounted for nearly 25% of cardiac patients who were reported with receiving treatment solely within outpatient setting funded from the state budget (cf. Figure 1).

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[38]These are new cases and not unique patients. A case means admitting a patient with one diagnosis. If, during a year, a patient suffered from 2 different diseases, they will be counted as two new cases.
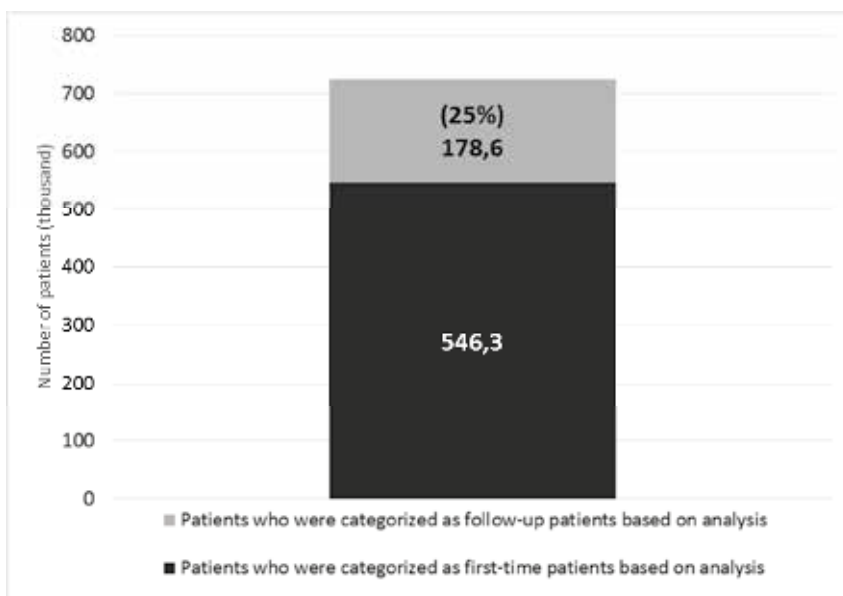
Figure 1. The total number of unique cardiovascular patients treated in secondary outpatient care facilities, who were not hospitalized or threated at ED/AU within one year of being registered in the system. Data aggregated for years 2011-2013 (source: DAiS analysis based on NHF data)

By applying the above mentioned rules, total incidence of cardiovascular diseases in Poland has been determined. According to the applied methodology, in 2011-2013 incidence amounted to 817.1 thousand, 774.3 thousand and 747.8 thousand, respectively. (Table 4). It has to be underlined that those figures show the total number of cases, not the total number of patients. One patient with several different new cardiovascular diagnoses was counted several times. If each patient had been taken account of only once, then in 2013 their number would have equalled 365 thousand (this means that on average each patient was diagnosed with two (new) different cardiovascular diseases. The results for the subsequent years have been presented in Table 4. 178.6 thousand patients who appeared in the system with an outpatient visit and who were not admitted anywhere for 365 days with the same diagnosis, and were counted as new cases, accounted for approx. 8% of all cases in 2011-2013.

Table 4. New patients and new cardiovascular cases between 2011–2013
(source: DAiS analysis based on NHF data)

	2011	2012	2013
New cardiovascular cases	815,057	772,308	745,830
Patients	432,673	382,890	367,065

A visible drop in the number of new cases and number of patients is most probably related with " cleaning " the database of the records of those patients who developed a given disease in earlier years (so called follow-up patients, who continue treatment), and according to the applied methodology, they are treated as new patients.   This is directly related with the scope of data which was analysed - patients are checked if they appeared in the system earlier, which, considering the current scope of data, means in 2009 or later. In this way patients who appeared in the system in 2011 after 3 years of being diagnosed for the first time are still treated as new (there is no data concerning their first appearance in the system - they appeared in 2008, when NHF reporting provided data to those types of analyses). In case of patients who appeared in the system in 2013, their (at least) 4-year history is verified.

Due to the above, the years 2011 and 2012 have been treated as a buffer which enables sufficient enhancement of the data for the year 2013, for which the analysis of incidence and incidence rate of cardiovascular diseases in Poland was made. Another possible factor which has impact on the number of new cases includes increased share of services funded entirely with private funds - in such case data on the service provided is not reported to NHF.

Cardiovascular diseases were defined as 15 separate groups of diseases, of which in the year 2013, 8 biggest groups in terms of the number of cases accounted for 93% of all the cases (Figure 2). The most frequently diagnosed diseases included: ischemic heart disease, heart failure, atrial fibrillation and flutter and other types of arrhythmia and atrioventricular block.
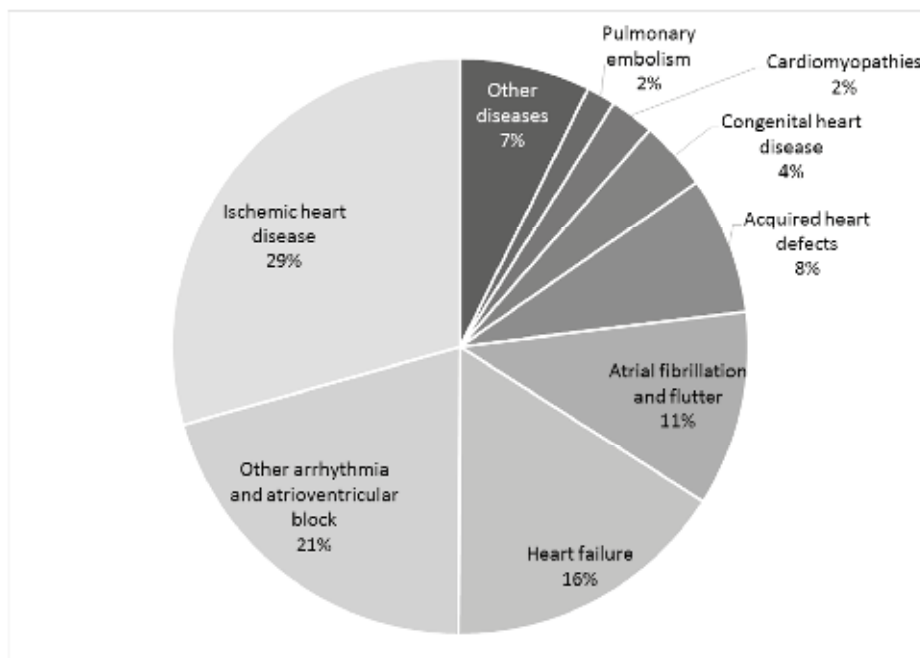
Figure 2. The structure of incidence of cardiovascular diseases in 2013
(source: DAiS analysis based on NHF data)

Among cardiovascular diseases, the highest incidence risk is related to ischemic heart disease, which in 2013 was diagnosed in over 219 thousand patients (almost 30% of all diagnoses). It was followed by other types of arrhythmia and atrioventricular block (153.1 thousand) and heart failure (119.5 thousand). The least frequent cardiovascular diseases include rheumatic heart disease (more than 350 cases) or endocarditis (less than 1,570 cases) (Figure 3).
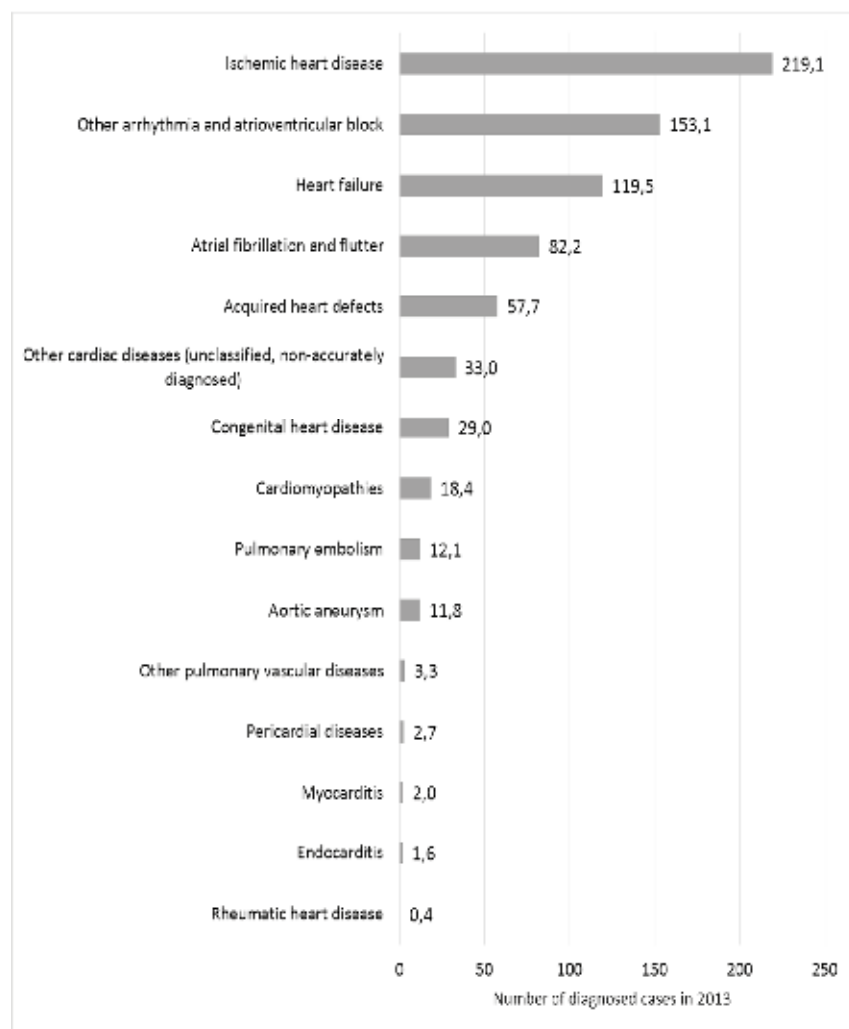
Figure 3. Incidence of cardiovascular diseases in Poland in 2013 (source: DAiS analysis based on NHF data)

Exact data concerning incidence of cardiovascular diseases is shown in Table 5, which presents values for the period 2011 - 2013 for selected disease streams based on ICD-10 codes. One has to notice that the summary number of cases differs from the number of patients, as one patient could develop several diseases during one year. As it has already been mentioned, those values indicate that each patient suffered on average from two cardiovascular diseases.

The biggest drop in absolute values was noticed in case of ischemic heart disease (approx. 56 thousand), which can be related with the above mentioned database enhancement. However, there are disease streams in which case incidence increased during the period analysed. In percentage terms, the greatest number of new patients developed pulmonary embolism (16% more in 2013 than in 2011) or had congenital heart defect (9% more). This can be related with improving diagnostic technology and changes in the treatment of those diseases (increased access to diagnostic methods which enable to diagnose pulmonary embolism, increasing survival rate of people suffering from congenital heart defect) as well as in the characteristics of those diseases (database enhancement related mainly to chronic diseases).

Table 5. Incidence of cardiovascular diseases in 2011-2013
(source: DAiS analysis based on NHF data)

Diagnosis	ICD-10	Absolute values			Change 2011-2013
		2011	2012	2013	2011-2013
Ischemic heart disease	I20, I21, I24, I25	275,678	240,504	219,131	-21%
Other types of arrhythmia and atrioventricular block	I44-I47, I49	145,954	147,979	153,092	5%
Heart failure	I50	136,001	128,331	119,494	-12%
Atrial fibrillation and flutter	I48	85,368	83,604	82,196	-4%
Acquired heart defects	I05-I09, I34-I37	58,225	58,479	57,676	-1%
Other heart diseases (not precise, not classified)	I51,I52	35,000	33,332	32,988	-6%
Congenital heart defects	Q20-Q26	26,553	28,612	29,029	9%
Cardiomyopathies	I42, I43	20,257	19,158	18,437	-9%
Pulmonary embolus	I26	10,430	11,290	12,142	16%
Aortic aneurysm	I71	11,287	11,039	11,793	4%
Other diseases of pulmonary vessels	I27, I28	3,791	3,377	3,300	-13%
Pericardial diseases	I30-I32	2,545	2,697	2,660	5%
Myocarditis	I40, I41	1,868	1,973	1,974	6%
Endocarditis	I33, I38, I39	1,606	1,506	1,568	-2%
Rheumatic heart disease r	I00-I02	497	427	351	-29%
Number of cases		**815,057**	**772,308**	**745,830**	**-8%**
Number of patients		**432,673**	**382,890**	**367,065**	**-15%**

In 2013 the largest number of patients with cardiovascular diseases lived in the following voivodeships: Mazowieckie, Śląskie, Wielkopolskie and Małopolskie (cf. Map 1) The lowest number of cases was recorded in Lubuskie, Opolskie, Podlaskie and Świętokrzyskie Voivodeships. These values, however, are mainly due to the population size of each voivodeship, which implies that in voivodeships with a large number of inhabitants, greater number of cases may be expected, whereas in sparsely populated regions this rate is correspondingly lower. Therefore, incidence provides information indicating the extent of an analysed phenomenon. However, absolute values recorded between areas of varying numbers of inhabitants cannot be directly compared. That is why, apart from incidence, incidence rate was also calculated. This rate, in contrast to incidence, indicates the relative value of new cases per 100 thousand inhabitants of an analysed area. It was calculated both for each disease separately, and as a total incidence rate to determine the number of new cardiac patients (taking into account multiple pathologies). The greatest incidence rate was recorded in Śląskie, Łódzkie, Dolnośląskie and Mazowieckie Voivodships, where about 1 out of 100 inhabitants has in 2013 started treatment in relation with a cardiovascular disease. The lowest incidence rate was recorded in the following voivodeships: Podkarpackie, Wielkopolskie, Warmińsko-Mazurskie and Małopolskie (cf. Figure 4). The difference between extreme values of this rate (the highest in Łódzkie and the lowest in Podkarpackie voivodeships) reached almost 17%. However, these values are subject to the impact of the sex structure and age groups, which are also of great importance in the case of cardiovascular diseases.

Figure 4. Total incidence (left-side map) and incidence rate (right-side map) of cardiovascular diseases in 2013 (source: DAiS analysis based on NHF data)

In order to illustrate the differentiation within the analysed cardiovascular disease stream, incidence rate ratios were also counted for individual diseases. Figure 5 presents general values for Poland. For instance, the highest incidence rate concerned IHD and was 569 per 100 thousand inhabitants of Poland (1 per 180 people).
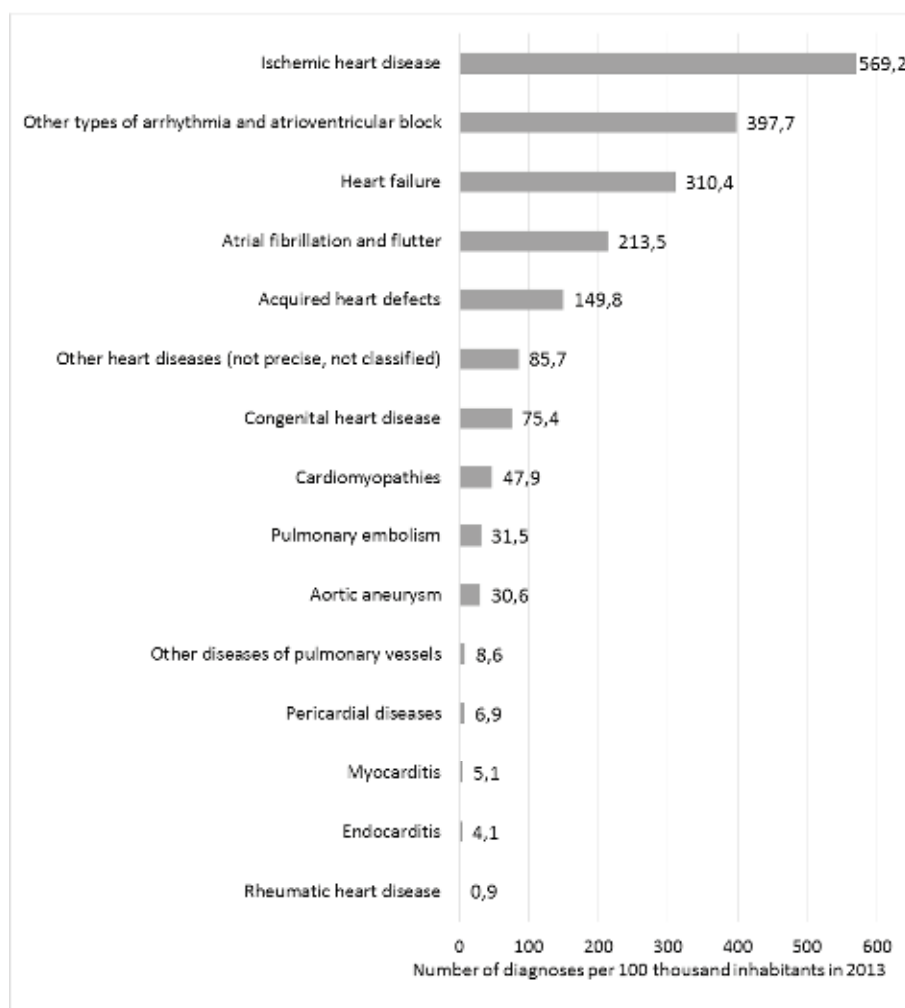

Figure 5. Incidence rate of cardiovascular diseases in Poland in 2013
(source: DAiS analysis based on NHF data)

Incidence projection for 2015–2025

Taking into account the risks related to heart diseases, and also the fact that the Polish population is ageing, it is necessary to project the incidence values for future years. Developing forecasts requires historical input data that will allow for referencing the current situation to expected values. The forecasts of epidemiological statistics allow for estimating the demand for medical services related to cardiovascular diseases and medical equipment, which translates into the estimation of the cost of treatment. This implies that forecasts play a vital role in developing health care policies. They allow for adjusting to the future health care needs of the population.

The previous part of this paper presents the number of new cases of cardiovascular diseases in Poland in 2011–2013. Based on this data, the incidence rate of cardiovascular diseases was determined. Incidence rate ratios were calculated separately for each specified disease type, broken down into 7 age groups (0–17, 18–44, 45–54, 55–64, 65–74, 75–84, 85 and over), sex and place of residence (urban or rural area). The incidence forecast for the years 2015–2025 has been calculated based on 2013 ratios. Constant over time incidence rate ratio values concerning cardiovascular diseases were assumed, so the estimations are mainly based on a demographic forecast[39]. An additional assumption adopted for developing the forecast was that there was no effect of the medical progress on the incidence of cardiovascular diseases. A hypothesis was also made that there would be no changes in the population behaviour which would affect the exposure to risk factors of cardiovascular diseases.

The estimations suggest an increase in the number of new patients with cardiovascular diseases within the next few years. In 2015 there will be 377 thousand patients suffering from at least one cardiovascular disease, and this number will increase to 426 thousand in 2025. This implies an increase of almost 13% within 10 years (Figure 6). The total number of new cases of cardiovascular diseases[40] will increase from 746 thousand in 2015 to 857 thousand in 2025. The ratio of diseases per one patient will change slightly, from 1.98 in 2015 to 2.02 in 2025. This indicates a slightly increasing phenomenon of multiple pathologies.

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[39] The paper used the demographic forecast developed by the Central Statistical Office, http://demografia.stat. gov.pl/bazademografia/Prognoza.aspx.
[40] In this analysis, a patient diagnosed with two cardiovascular diseases is treated twice (two new cases).
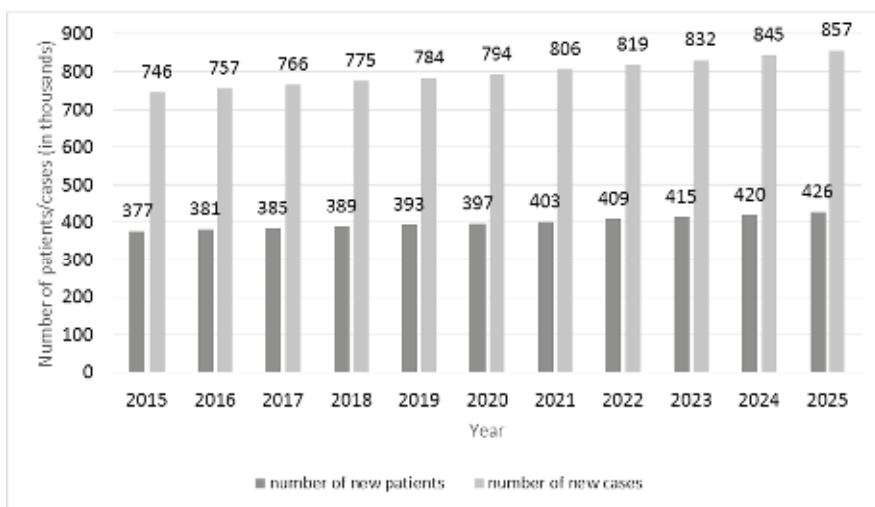
Figure 6. Total incidence of cardiovascular diseases projection for 2015–2025
(source: DAiS analysis based on NHF data)

When analysing the incidence in the regional context, the largest number of cardiac patients in 2015 should be expected in the following voivodeships: Mazowieckie, Śląskie, Wielkopolskie and Małopolskie. The lowest values will be recorded in the following voivodeships: Świętokrzyskie, Podlaskie, Opolskie and Lubuskie (cf. Figure 7). The situation will be similar in 2025, except for the fact that the lowest incidence value is projected in the Opolskie Voivodeship.
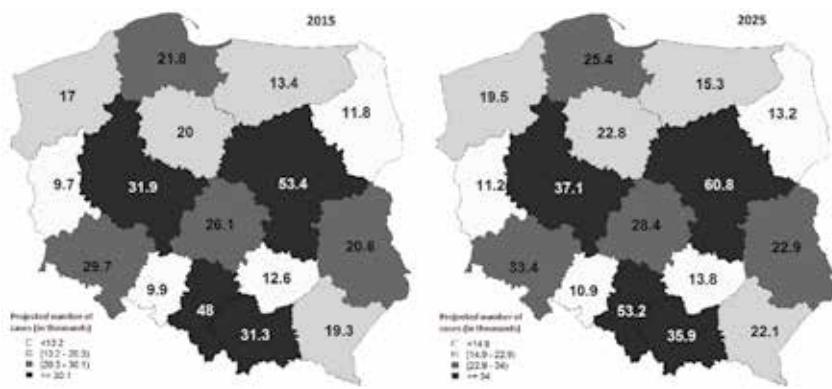
Figure 7. Incidence of cardiovascular diseases projection for 2015 and 2025, by voivodeship (source: DAiS analysis based on NHF data)

In the next decade, an increase in the incidence values should be expected in all voivodeships. The largest increases will be observed in Northern, North-West and South-West parts of Poland (cf. Figure 8). The largest increase of 16% is projected in Wielkopolskie and Pomorskie Voivodeships. A slightly lower increase in the number of new patients with cardiovascular diseases is estimated for the following voivodeships: Zachodniopomorskie, Lubuskie, Warmińsko-Mazurskie, Małopolskie and Podkarpacie (15%). The lowest increase will be observed in the following voivodeships: Łódzkie, Opolskie and Świętokrzyskie, where it will not exceed 10%. Differences in incidence values are mainly due to the differentiated demographic structure of individual voivodeships.
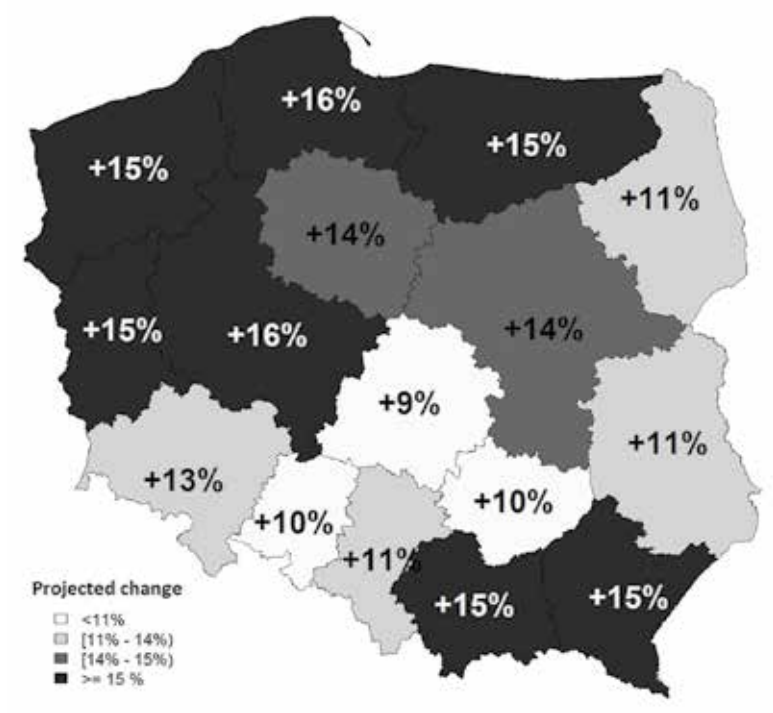
Figure 8. Percentage increase in the incidence of cardiovascular diseases in Poland in 2015–2025 (source: DAiS analysis based on NHF data)

As mentioned before, separate incidence rate ratios were specified for each cardiovascular disease stream. Figure 9 presents the projected number of cases of individual diseases in 2015 and 2025. Ischemic heart disease will continue to be the dominant problem faced by Poles. According to the forecast, 226 thousand people will suffer from this disease in 2015 and 258.1 thousand in 2025. The largest changes in absolute terms relate to the most common diseases, i.a. ischemic heart disease or heart failure.
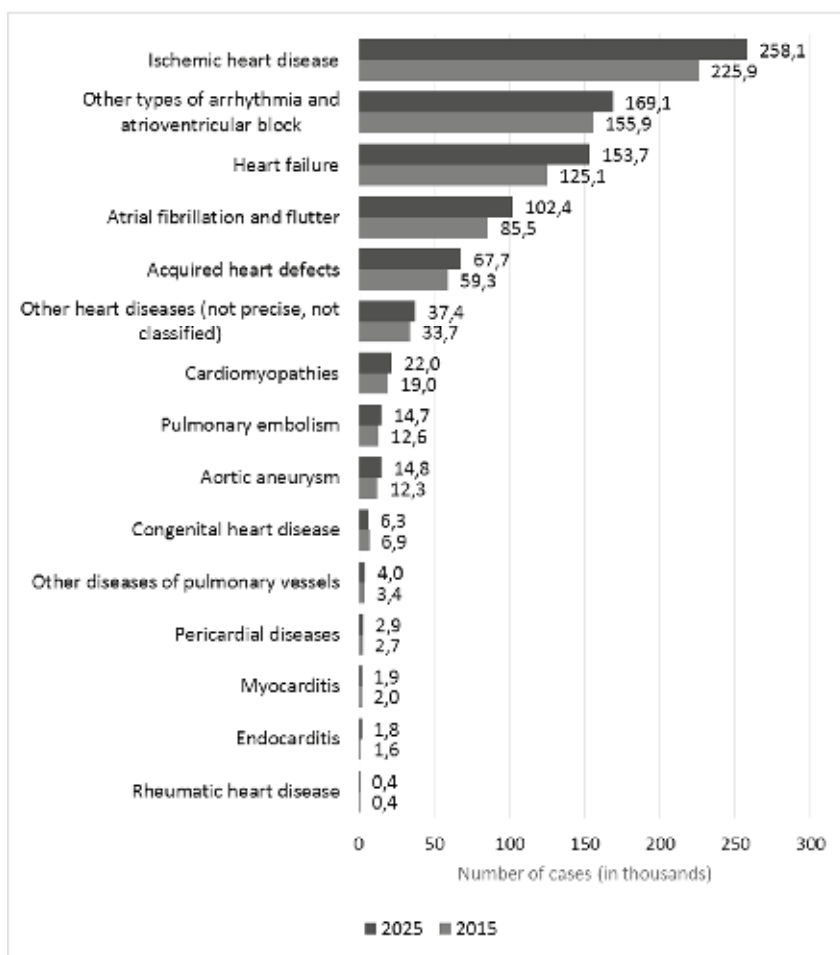
Figure 9. Incidence of cardiovascular diseases projection, by diseases
(source: DAiS analysis based on NHF data)

Figure 10 shows the relative increase in the number of cases of a particular disease in 2015–2025. The number of cases of heart failure and aortic aneurysm is projected to increase at over 25%. Although in absolute terms the increase in the incidence rate of ischemic heart disease was the largest, in relative terms it is in the eighth position (14%). It is worth noticing that the forecast suggests that there will be a drop in the number of cases of myocarditis and in the number of patients with congenital heart defects. This is due to the fact that

these diseases are characteristic for young age, which, with the worsening population ageing process, translates into a lower number of forecast cases.
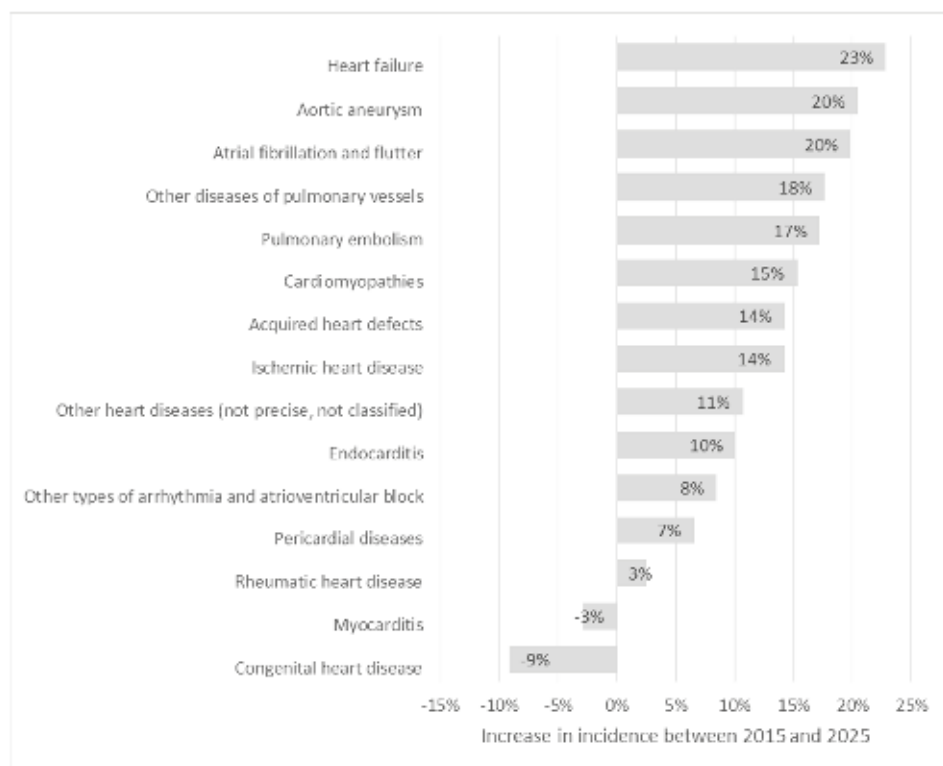

Figure 10. Changes in the incidence of cardiovascular diseases between 2015 and 2025 (source: DAiS analysis based on NHF data)

As the estimations are mainly based on the projections of the demographic structure, changes in the incidence will be due to the changes in the population, age structure, sex proportions or place of residence proportions. As may be seen in Figure 11, the number of patients in younger age groups will decrease in the years 2015–2025. In the age group 55-64, a 21% drop in the number of new patients with cardiovascular diseases will be observed. People who were in this age group in 2015 will ten years later move to the next age group (65-74), in which heart diseases are more frequent, and thus the number of cases will increase significantly in this age group.
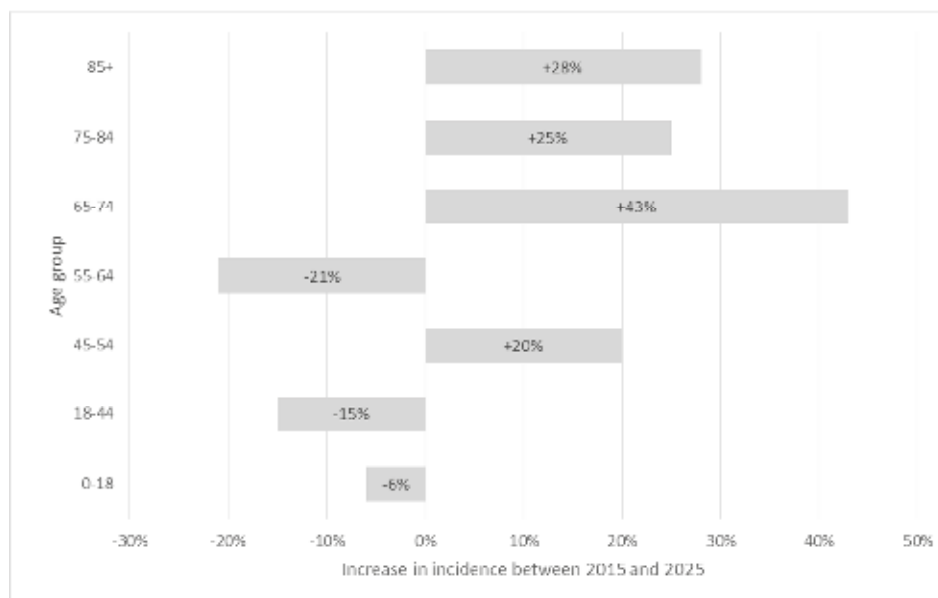
Figure 11. Changes in the patient age structure between 2015 and 2025 (source: DAiS analysis based on NHF data)

Summary

One of the key elements used in epidemiological analyses is incidence, defined as the number of newly diagnosed patients in the given year (Rothman, Greenland, 2005). The determination of the value of this indicator allows for defining the risk of developing a given cardiovascular disease, as, by converting the value to the population, it is possible to assess how serious threat is associated with a particular disease. Cardiovascular diseases have for years been the most frequent causes of death in Poland, killing more people in Poland than on average in the EU (Wojtyniak et al., 2012). This provides the basis for carrying out an analysis of the epidemiological situation and for projecting future incidence. Such projection provides basis for estimating future health care needs of the population and for developing a proper response to these needs. Cardiovascular diseases are most common in older people, therefore, with the on-going ageing of the population, an increase in the number of new cases of these types of diseases and in the demand for related health care costs should be expected.

When faced with the problem of no epidemiological data concerning cardiovascular diseases, in order to estimate these indicators, the decision was made to use the reporting database of the National Health Fund. The authors are aware of the limitations of the settlement database (the so-called upcoding). This is why the analyses performed took into account the indicator values for each disease stream separately, and also the total value, which is not the sum of individual indicators, but the value comprising cardiovascular polypathology. When using this method, the impact of the differentiation in the coding of particular disease types (ICD-10) between healthcare providers is eliminated from the estimations.

Based on the analyses performed it may be concluded that, within the next decade, the number of cases of heart failure, aortic aneurysm and atrial fibrillation and flutter will increase at the fastest rate. However, as regards the increase in absolute terms, the largest increase will be observed in the case of most common diseases, i.e. heart failure and ischemic heart disease. The projected increase in the number of new cases within the next years varies between voivodeships, and this differentiation is most likely due to the projected demographic characteristics of the population of given areas, i.a. the distribution with regard to age and sex, but also with regard to the place of residence. Other factors that may affect the regional differentiation is the life style of people and the availability of health care services.

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