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Recommendations on the use of innovative medical technologies in cardiology and cardiac surgery and solutions leading to increased availability for Polish patients

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Abstract

There is a great need for innovative technologies that will improve the health and quality of life (QoL) of Polish patients with cardiac problems. It is important that the safety and effectiveness of the technology are confirmed by scientific evidence on which guidelines and clinical recommendations are based. Scientific evidence for medical devices is also increasingly important for decision-making in finance approval from public funds. New technologies in cardiology and cardiac surgery contribute to improved patient QoL, increased treatment effectiveness and facilitated diagnosis. Hence, it is necessary to increase accessibility to such technologies, primarily through the development of clinical recommendations, and education of medical personnel in conjunction with public funding. The aim of this publication is to present the recommendations of leading experts in the field of cardiology and cardiosurgery, supported by clinical research results, regarding the use of the cited innovative medical technologies and solutions leading to their increased availability for Polish patients. (Cardiol J 2019; 26, 2: 114–129)

Key words: coronary angioplasty, optical coherence tomography, heart failure, implantable loop recorder, mitral regurgitation, ventricular assist system, pulmonary artery pressure

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Introduction

New technologies in cardiology and cardiac surgery contribute to the improvement of quality of life (QoL) for patients by increasing the effectiveness of treatment and facilitating diagnostics. Therefore, if possible, striving to increase their accessibility primarily through the development of clinical recommendations, the education of medical personnel and public funding is paramount. Available guidelines of conduct, although very comprehensive, are constantly updated, and need to be supplemented in certain areas where innovative solutions can be applied.

Cardiovascular disease causes 45% of deaths in Poland (180,000 a year), while cancer comprises 26% of deaths. Due attention from a patient mortality perspective requires national health policy to be taken into account [1, 2]. There is, therefore, a great need for new innovative technologies that will improve the health and QoL of Polish patients with cardiac problems.

Unfortunately, the system at present significantly hinders the incorporation of innovative non-drug technologies into a basket of guaranteed services that has not adapted to medical progress. The costs of innovative medical technologies could be calculated in a new way. Nowadays, the cheapest procedures with immediate costs (direct) are chosen by the payer. However, additional costs, such as the cost of the treatment of subsequent complications, additional hospitalization and medicine, dismissal due to an inability to work, social welfare and sickness allowances and other costs are borne by a budget and patients are not taken into account. The choice of medical technology should be guided by an overall cost, and not just a greater temporary benefit through financing [3].

These recommendations are based on presentations and discussions that were held during Advisory Board meetings, which took place in cooperation with the 'Quo Vadis Cardiology?' initiative. Data collected during a questionnaire study which was conducted by the Arcana Institute are supported by clinical research results. The aim was to gather the opinions of leading experts (14 experts) in the field of conservative cardiology, interventional cardiology, electrophysiology and cardiac surgery for guidelines on the use of innovative medical technologies and solutions leading to increasing their availability for Polish patients.

The guidelines and recommendations presented apply to the following medical technologies:

- left ventricular assist systems/devices (LVAS/ /LVAD); e.g. HeartMate (HM) 3, HeartWare, BerlinHeart, TerumoHeart;
- a system for percutaneous repair of mitral regurgitation (MitraClip);
- a heart failure (HF) system for pulmonary artery pressure measurement (CardioMEMS);
- implantable loop recorders (ILR); e.g. Confirm Rx, Reveal DX and XT;
- optical coherence tomography (OCT).

Heart failure

Heart failure has become a realized epidemic of the 21 century. Almost 80% of cases result from coronary heart disease, which is accompanied by hypertension in 53% of cases. The remaining cases are the result of hypertension and other heart diseases. Heart disease has been a more frequent cause of death than cancer in Poland for many years (over 50% of deaths, amounting to approximately 60,000 deaths per year). This fact requires due attention when taking Poland's health policy into account [1, 2].

Currently, the number of patients at various stages of HF severity in Poland amounts to approximately 800,000 people [2]. Forecasts indicate that in 10 years this number will have increased by approximately 25%. A total of 60,000 people die each year due to HF and close to 150,000 are hospitalized [2]. HF hospitalization rates in Poland are among the highest in Europe (547/100,000 inhabitants) and unfortunately, despite the progress in treatment, the numbers have not changed significantly over the last 5 years (from 2008 to 2013). They are two times higher than in the Organization for Economic Co-operation and Development (OECD) countries and 5 times higher than in the United Kingdom. Total indirect costs of HF in Poland have been estimated to be approximately 4 billion PLN per year. Taking into account National Health Fund expenditure on treatment of HF at the level of approximately 900 million PLN in 2016, indirect costs of this disease in Poland are more than 4 times higher than direct medical costs [2]. This is primarily a consequence of the lack of effective medical technologies, not to mention a comprehensive model for patient care. HF is currently one of the largest unmet medical needs in Poland.

Methods of treatment

The treatment of HF aims to stop or reverse myocardial dysfunction, control symptoms and

reduce mortality. The choice of treatment depends on the type/cause of HF and clinical status of the patient [4]. If treatment options are exhausted, only heart transplantation (HTx) and mechanical circulatory support remain. HTx is currently one of the best methods of treatment of extreme HF, enabling long-term survival. Currently, the estimated annual survival for patients qualified for urgent cardiac transplant is < 50%, while after HTx, it is 50% over a 10-year period. Annually, approximately 5000 transplantations are performed worldwide, 2000 in the United States and nearly 1500 in Europe. The number of candidates for HTx is estimated to be 10 times higher. About 80–100 HTx are performed every year in Poland, while the demand is about 4 times higher [5]. The basic problem in transplantology is the limited number of organ donors. In addition, HTx is associated with a high frequency of appointments at an outpatient clinic and a long procedure. There is, therefore, an urgent need to look for other methods to support a damaged heart that would provide a longer survival time while waiting for HTx. The implantation of the ventricular assist system is a procedure that is performed in patients with severe and reversible (or irreversible) heart damage, in whom alternative treatment options have been exhausted, i.e. no other cardiac surgery is possible, and pharmacological treatment is not expected to stop further progression of the disease. Mechanical circulatory support devices are designed to support the work of the left (LVAD) or right (RVAD) ventricle. The use of ventricular assist device (VAD) was included in the 2016 European Society of Cardiology (ESC) Guidelines for the diagnosis and treatment of acute and chronic HF (Fig. 1) [6].

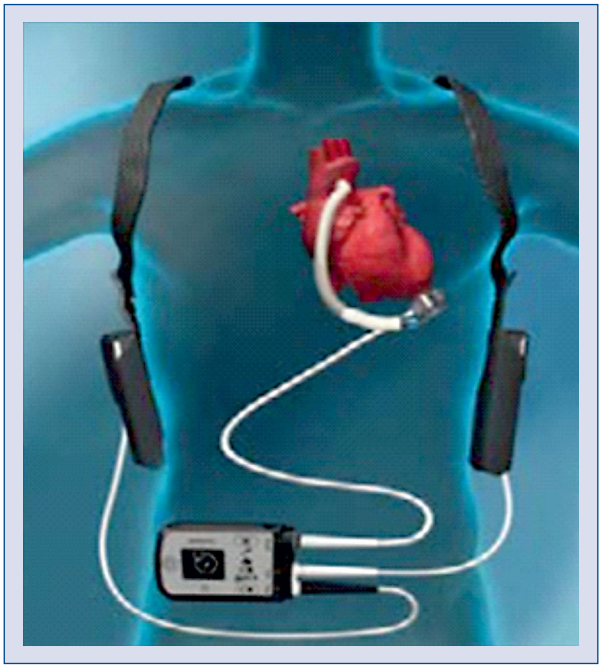

Figure 1. HeartMate — left ventricular assist system (LVAS). This is the latest third generation pump (LVAD) with continuous blood flow, which is used for long-term cardiac support of patients suffering from severe heart failure as part of bridging therapy: for transplantation, for recovery or for candidacy/decision and as a target therapy. In the HeartMate 3 pump, the rotor is suspended in an electromagnetic field, thanks to which, the spaces which are not washed away by blood are removed and the occurrence of thromboembolic complications eliminated. A characteristic feature of this system is its ability to quickly change the flow rate (every 2 s), which can produce a rise of pulsation, or imitate natural blood flow.

Clinical evidence

Details about clinical evidence — see Table 1 [7–18].

Other methods of treatment and their comparison with HM3

— Other systems for mechanical circulatory support (MCS) — without 'artificial pulse' in comparison to HM3;
— External pump supporting the left ventricle and devices for extracorporeal oxygenation of the blood (ECMO) — disadvantages: no possibility of functioning at home, need for greater medical supervision:
  • HM3 — the complexity of supplying solutions to patients with HF — the possibility of waiting quietly for improvement of the left ventricular function or surgical treatment, the possibility of long-term use (also in an outpatient mode);
— Conservative treatment — disadvantages: higher frequency of appointments at an outpatient clinic, limited availability, longer duration of the procedure:
  • HM3 — greater patient survival.

Reimbursement and economic effectiveness

The economic analysis based on 2-year results from the MOMENTUM 3 study indicated that use of the HeartMate 3 pump reduced re-hospitalizations and the number of days for re-hospitalization and therefore contributed to a significant reduction in treatment costs compared to the HeartMate 2 pump [18].

In England, the expense is covered publicly and includes all the costs of providing the ser-

Table 1. Characteristics and main outcomes of clinical trials assessing the effectiveness and safety of HeartMate (HM). The conclusions of the REMATCH study led to the construction of a less faulty and a more durable cardiac pump, namely HeartMate 2 (HM2). Based on this study, the Food and Drug Administration adopted the indication for using the HeartMate left ventricular assist device (LVAD) pump as a target therapy. The results of the ROADMAP study indicated that the HM2 pump is better than optimal medical care (OMM) in terms of patient survival, the improvement in quality of life (QoL) and of class according to New York Heart Association (NYHA) classifications. ELEVATE is a post-marketing, prospective study based on the European registry for the first commercial use of the HeartMate 3 (HM3) pump, has demonstrated high clinical efficiency and good safety of HM3. The results of the MOMENTUM 3 study show the strength of the HM3 pump and support its use in patients with severe heart failure who are forced to wait a long time for transplantation or are not eligible for transplantation. In these patients, the HM3 pump can be used as a target therapy. The 2-year overall survival in MOMENTUM 3 was 82.8% for HM3 while in the case of heart transplantation (HTx), it is approximately 84%. Patient survival for both methods is currently comparable and of great importance considering the current organ donor shortage.

CHARACTERISTICS					
Study name	**Type of study**	**Population**	**Intervention**	**Comparator**	**Outcomes**
REMATCH [7, 8]	RCT	> 65 years old NYHA IV not eligible for HTx	HeartMate XVE	OMM	OS, QoL, median NYHA, adverse events
ROADMAP [9, 10, 11]	Observational	NYHA class IIIB/IV heart failure, with indications for LVAD but not dependent on intravenous inotropic drugs	HeartMate 2	OMM	Survival together with improvement in the length of a 6MWD ≥ 75 m after 12 months
ELEVATE [12]	Post-marketing, prospective study based on the European registry	Mean age: 56 years 48% ischemic etiology 70% inotropic 65% bridge to transplant 33% INTERMACS 1–2 38% INTERMACS 3 29% INTERMACS 4–6 8% ECMO	HeartMate 3	–	6MWD
MOMENTUM 3 [13, 14, 15, 16, 17, 18]	RCT	NYHA IIIB or IV Resistant to OMM	HeartMate 3	HeartMate 2	Stroke or reoperation to replace or remove the pump, free survival

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	RESULTS						
Study name	**Overall survival**	**Event free survival**	**6MWD**	**QoL**	**Median NYHA**	**Change in NYHA**	**Adverse events**
REMATCH	**1-year:** 52% vs. 25% (p = 0.002) **2-year:** 23% vs. 8% (p = 0.09)	–	–	Better physical (p = 0.01) and emotional (p = 0.03) results, and depression was less frequent (p = 0.04)	**1-year:** II vs. IV	**HM2 group:** 25% change to class I; 52% change to class I **OMM group:** 0% change to class I; 29% change to class II	Incidence 2.35 times higher in HM group (most common: power cord infections leading to sepsis, bleeding and device failures)
ROADMAP	**1-year:** 80% vs. 63% (p = 0.022) **1-year with improvement in 6MWD:** 39% vs. 21% (p = 0.012) **2-year:** 70% vs. 41% (p < 0.001) **2-year with the improvement in 6MWD:** 30% vs 12% (p = 0.012)	–	–	PHQ-9: 5 vs. 1 (p < 0.001)			Incidence after 1-year: 1.89 times higher in HM2 group than OMM Most common: HM2 — bleeding; OMM — worsening of heart failure
ELEVATE	**1-year:** 74%	**–**	**1-year:** from 106 to 380 m	Significant increase of the patients QoL		82% NYHA I or II	Device thrombosis: 0.3% Serious bleeding: 29% Serious infection: 44% Stroke-type event: 8%
MOMENTUM 3	**2-year:** 82.8% vs. 76.2% (p = 0.16)	**6-months:** 86.2% vs. 76.8% (p < 0.001 for non-inferiority; p = 0.004 for superiority) (events: stroke or reoperation to replace or remove the pump) **2-years:** 77.9% vs. 56.4% (p < 0.001 for superiority)					Reoperation due to pump failure: 0.7% vs. 7.7% (p = 0.002) Pump thrombosis: 0% vs. 10.1%

6MWD — 6-minute walk distance; RCT — randomized clinical trial; ECMO — extracorporeal membrane oxygenation; OS — overall survival; INTERMACS — Interagency Registry for Mechanically Assisted Circulatory Support; PHQ-9 — Patient Health Questionnaire 9

vice, costs of hospitalization, diagnostic tests, medical devices and medicines. In Australia, services are provided as part of hospitalization are settled within the framework of the Diagnosis Related Groups (DRG) group funding system. A similar situation is present in New Zealand and Estonia. In Greece, funding is based on KEN-DRG groups (a combination of cost estimates from selected public hospitals and the 'imported' cost weight). In Germany, hospitalizations for the implementation of a cardiac support procedure are financed on the basis of the G-DRG system. In Croatia, under the public system, patients are required to pay 25% of the value of services provided as part of hospitalization and 40% of the value of services in an outpatient mode. The highest cost of implanting artificial chambers is observed in New Zealand, and the lowest, in Germany.

The cost of implanting artificial heart chambers, according to National Health Fund, ranges from 126,601 PLN to 375,207 PLN [19]. According to an analysis of impact on the organization of the healthcare system carried out by Agency for Health Technology Assessment and Tariff System (AOTMiT), financing the implantation of VAD pumps will result in a reduction of costs in this area. Potential savings will result from the fact that the patient treatment processes are conducted in outpatient mode at home, in contrast to patients treated with external pumps who are permanently hospitalized. Savings resulting from a reduction in medical costs could be allocated to other benefits. In addition, a comprehensive care model for patients with VAD can provide them with optimal supervision and treatment, which will certainly translate into an improvement of treatment results, the reduction of serious complications and mortality [4].

Expert recommendations

Experts indicated that using HM3 will contribute to an improvement in patient survival, QoL, treatment efficiency, the reduction of treatment costs and reduction in occurrence of adverse cardiovascular events.

Experts also pointed out that using HM3 will primarily affect not only a reduction in the number of patient hospitalizations, a reduction in additional procedures and diagnostic tests, but also a reduction in the need for medications. In Poland, approximately 100 heart pump insertions should be performed per year, which would satisfy the needs of patients. About 46 pumps are implanted every year in Poland (these are mainly HM3 pumps). The highest benefit from HM3 is received by patients in the INTERMACS 3 and 4 class. These are outpatients who stay at home and are not treated in hospital. These are also patients with normal right ventricle and no pulmonary hypertension, i.e. patients with a low risk of complications.

From the patient perspective using heart assist pumps as a target therapy is beneficial because it significantly improves QoL. The use of these pumps is important to the payer because it reduces the number of patient hospitalizations, procedures diagnostic tests, and additionally decreases the need for medicine. Periodical infections which occur due to using a power cord, may lead to a need for removal of the heart pump. In this case, the patient is referred for heart transplant. Therefore, an appropriate selection for a cardiac surgery center where cardiac transplants are performed requires recommendations for such an indication. Work is underway to construct a pump that will not require the use of an external power cord. In this case, implantation of this pump could be used as a target therapy.

Heart assist pumps should only be implanted in transplant centers. In this type of center, a full treatment profile should be available: all treatment options are in one place and comprehensive patient care is provided.

In Poland, the same services are performed during the implantation of a cardiac support pump as during HTx (a patient's qualification for the pump or transplant is the same). There is no procedure that would cover the cost of hospitalization after implantation of a heart pump. There is also a need to create a system for the comprehensive care for a patient with an LVAD.

In order to broaden patient access to HM3, experts first of all point to a need for adequate public funding, equipping clinical centers (apart from the technology itself) and increasing the level of awareness of the technology in the medical environment. The need for increased awareness about the availability of HM3 is also connected with a low level of awareness of this technology among physicians, especially primary care physicians. They mainly recommend drugs to young patients with HF, although they are eligible candidates for LVAD implantations.

Mitral regurgitation

Mitral regurgitation (MR) is currently the second most common valve defect in Europe [20]. The frequency of this defect increases with age and it is estimated that there are currently 2–2.5

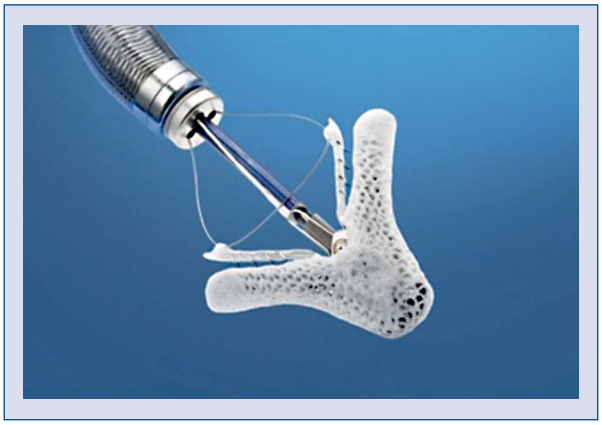

Figure 2. MitraClip — a system for percutaneous repair of mitral regurgitation. The MitraClip system is used for percutaneous repair of mitral valve mitigation of the beating heart as an alternative to conventional cardiac surgery. The procedure is performed in a suitably adapted hemodynamic laboratory using transesophageal echocardiography and fluoroscopy [21]. The MitraClip system consists of an implant, an introductory catheter and an implant placement system that enables it to be placed on the mitral valve leaflet, causing it to be permanently approached, and a double-mitral valve is formed, thereby preventing blood from regressing. MitraClip is introduced into the mitral valve outlet via the venous system (femoral vein, inferior vena cava and then, after puncturing the atrial septum, to the left atrium) without opening the chest.

million people suffering from MR in the United States, and this number will double by 2030 due to an increase in size of the aging population [21]. The treatment of isolated mitral leaflet repair using the 'edge-to-edge' method was introduced in 1991 by Alfieri to repair prolapse of the anterior mitral leaflet [22]. The operation consists of sewing both mitral leaflets in the central part in order to increase contact of the anterior and posterior leaflets, which leads to a reduction of regurgitation. This technique is also useful in the loss of the posterior or both leaflets. A double orifice mitral valve, which is obtained through this procedure, does not usually cause narrowing of the mitral outlet, even in combination with annuloplasty, and, as a result, its surface area is reduced. This is the basis for the method of percutaneous treatment of MR (MitraClip) (Fig. 2) [21].

MitraClip is usually used to treat people with severe, post-infarction heart disease. In Europe, it is estimated that almost 1% of the population struggles with functional MR that results from a left ventricle defect after heart attacks or primary cardiomyopathy. In Poland, the figure amounts to approximately 400,000 people. Unfortunately, there are still far too few MitraClip procedures, due to a limited reimbursement by the National Health Fund. The MitraClip device reaches a price of approximately 80,000 PLN. However, the cost of long-term, repeated patient hospitalizations are comparable [23].

The MitraClip system has been used around the world since 2008. In Poland, only 9 centers perform procedures using MitraClip, which limits the frequency of this treatment in our country. A procedure using the MitraClip system, as a method of repairing heart valve leaflets, should be performed only at highly specialized centers.

Clinical evidence

Clinical trials have demonstrated the efficacy and safety of using MitraClip for percutaneous repair of MR. This was also confirmed on the basis of data from registers (Table 2) [24–28].

MITRA-FR, the first randomized, controlled trial of the percutaneous clip coaptation in degeneration of the mitral valve, showed no benefit of the MitraClip in addition to optimal medical care [29]. Over a 12-month period, 152 patients randomized to treatment with MitraClip experienced improvements of the MR grade and New York Heart Association (NYHA) class, but similar improvements were also seen in the 137 patients treated with optimal medical therapy. Over 12 months, the primary composite endpoint of all-cause death and unplanned re-hospitalization for HF had no significant difference between groups: 54.6% in the intervention group and 51.3% in the control group (odds ratio [OR] 1.16; 95% confidence interval [CI] 0.73–1.84). The limitation of the MITRA-FR study was that patients in the optimal medical care arm were not optimized before the trial, hence adjustments were performed after the trial had started.

The results of another randomized clinical trial, COAPT, in which 78 centers from the United States and Canada participated, showed a clear clinical efficacy of MR treatment with the use of MitraClip [30]. The COAPT trial is a United States Investigational Device Exemption, which was designed for Food and Drug Administration (FDA) approval of MitraClip for secondary MR. Patients with HF, in whom MR develops secondary to left ventricular dysfunction, have a poor prognosis, with reduced QoL, frequent hospitalizations due to HF and decreased survival. There are no proven therapies for secondary MR in HF. Guideline-directed medical therapy and cardiac resynchro-

Table 2. Summary of main results of studies and registries assessing efficacy and safety of the MitraClip system for percutaneous repair of mitral regurgitation [24]. In clinical trials and in medical practice (registry data), in patients with high operational risk (mean age 74–82), the MitraClip system for percutaneous repair of mitral regurgitation was associated with very high clinical efficacy (86–100%), which translated into an absence of death, cardiac surgeries or reoperations. The annual mortality after MitraClip implantation was low and ranged from 15% to 26%. In addition, the MitraClip system made it possible to achieve a low rate of hospitalizations due to heart failure within 1 year after surgery (7–23%) [24–28].

Study	Age [years]	DMR [%]	Acute success [%]	1-year mortality [%]	One-year HF hospitalization [%]
STS/ACC TVT	82	85.9	92.8	25.9	20.2
SENTINEL	74	28	95.4	15.3	22.8
ACCESS-EU	74	20.6	91.7	19.2	19.8
EVEREST II HRS*	76	29.9	86	22.8	–
EVEREST PR**	82	100	95.3	23.6	18
GRASP	72	23.9	100	16.2	7.1
TRAMI	76	93.8	97	20.3	14.1
MITRA Swiss	77	38	85	15.4	–

DMR — degeneration of the mitral valve, HF — heart failure; *HRS — high surgical risk cohort, **PR — percutaneous repair cohort

nization therapy may provide only symptomatic relief in some patients.

In this parallel-controlled, open-label, multicenter trial, 614 patients with HF and moderate-to-severe or severe secondary MR, who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy, were enrolled. Patients were randomly assigned to transcatheter mitral-valve repair (MitraClip) plus medical therapy (device group) or medical therapy alone (control group). The annualized rate of all hospitalizations due to HF within 24 months was 35.8% per patient-year in the device group, compared with 67.9% per patient-year in the control group (hazard ratio [HR] 0.53; 95% CI 0.40–0.70; $p < 0.001$). The rate of cases that were free from device-related complications at 12 months was 96.6% (lower 95% confidence limit, 94.8%; $p < 0.001$ for comparison with the performance goal). Death from any cause within 24 months occurred in 29.1% of patients in the device group compared with 46.1% in the control group (HR 0.62; 95% CI 0.46–0.82; $p < 0.001$). All-cause mortality within 24 months was significantly lower with device-based treatment than with medical therapy alone (29.1% vs. 46.1%; HR 0.62; 95% CI 0.46–0.82; $p < 0.001$). The number of patients needed to be treated to save one life within 24 months was 5.9 (95% CI 3.9–11.7) in the device group.

One possible reason for different outcomes between the MITRA-FR and COAPT studies was that in MITRA-FR, among the patients that were receiving HF medicines at baseline, variable adjustments in each group during a follow-up in comparison to 'real-world' practice was allowed. In the COAPT study, the Clinical Events Committee confirmed patients for whom maximally-tolerated guideline-directed medical therapy was not effective at baseline and there were few major changes during a follow-up. What is more, the procedural complications rate in MITRA-FR was almost 2 times higher than in the COAPT study (14.6% vs. 8.8%).

In this patient group, the use of MitraClip resulted in a lower rate of hospitalizations due to HF and lower all-cause mortality within 24 months of follow-up in comparison to medical therapy alone, while maintaining a very high rate of cases that were free from device-related complications [30]. As such, MitraClip was the first therapy that was shown to improve the prognosis of patients with HF by reducing secondary MR due to left ventricular dysfunction. Therefore, if MitraClip is the first-line therapy, it improves the prognosis of patients with HF by reducing secondary MR due to left ventricular dysfunction.

Reimbursement and economic effectiveness

As part of an economic analysis performed by AOTMiT, the use of MitraClip technology was compared with symptomatic pharmacological treatment as the only available therapeutic option in the target group of patients [31]. The results of the analysis indicated that the use of MitraClip tech-

nology provides better clinical effects compared to pharmacotherapy. Both the expected survival time and the quality-adjusted life years were prolonged. The ratio of additional costs to additional effects indicated that the use of MitraClip technology was cost-effective, i.e. it provided additional clinical effects at an acceptable additional cost. In a 10-year time horizon, the average cost of an additional year of life (when using MitraClip, compared to pharmacotherapy) is 36,502 PLN, and the average cost of an additional quality-adjusted year is 47,853 PLN, thus clearly below the profitability threshold (105,801 PLN).

Expert recommendations

In 2017, 140 treatment procedures were performed using the MitraClip system. However, this figure is still too low in relation to demand, while at the same time there is a continuous increase in the number of valvular interventions in Poland.

According to experts, there should be 10–20 centers that perform treatment with the use of MitraClip, this treatment includes refunds for patient transport to the center (declarations based on epidemiological data). Qualification and treatment should be carried out only at highly specialized centers.

Hemodynamic monitoring

Pulmonary artery (PA) pressure monitoring provides earlier detection of HF progression than other markers (i.e. patient weight, symptoms, blood pressure) [32]. PA pressure measurement, along with biochemical markers, have become the standard tools for managing all forms of HF. In combination with clinical symptoms, PA pressure measurement provides a rational basis for the choice of drug dosage.

The CardioMEMS system consists of an implantable wireless sensor with an introductory catheter, an electronic patient system, and a patient database for clinical review. The sensor is implanted using known catheter deployment methods and remains implanted for the rest of the patient's life. It does not have wires, generators or batteries which require replacement. The CardioMEMS system for pulmonary hemodynamic monitoring was approved by the FDA in 2014 and received a Conformité Européenne (CE) mark in 2011. It provides measurement of PA pressure non-invasively anytime and anywhere, enabling quick adjustments of therapy. A 15 × 3.5 mm CardioMEMS sensor is implanted into the lumen of the PA. Measurements are sent wirelessly via a transmitter, and the system is able to monitor PA pressure. The important thing to note is that the increase of intracardiac pressure and PA pressure precedes HF decompensation by several days. The PA CardioMEMS sensor provides non-invasive pressure data (PA waveform, systolic, diastolic, and moderate arterial pressure and heart rate). CardioMEMS provides direct PA pressure measurement and avoids the disadvantages associated with PA catheters and impedance measurements. Patients send information about daily pressure or as recommended, and this information is transmitted to a secure website. If the PA pressure exceeds set threshold values, clinicians are automatically informed.

CardioMEMS is indicated for patients with HF class III according to NYHA, who were hospitalized due to HF in the previous year. It is not recommended for patients who cannot take dual antiplatelet or anticoagulant medications for a month subsequent to PA sensor implantation.

The recommendation of the CardioMEMS system is included in the 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic HF in symptomatic patients with HF, who had been previously hospitalized due to HF, thereby reducing the risk of rehospitalization (class IIb) [6].

Clinical evidence

Detail about clinical evidence — see Table 3 [33, 34].

Reimbursement and economic effectiveness

Currently, the CardioMEMS device is not financed from public funds in Poland. In clinical trials and on the basis of registry data in the United States, the use of the CardioMEMS system contributes to a significant reduction in the frequency of hospitalization and mortality, this directly translates into a reduction of costs associated with the treatment of HF [34].

Monitoring of heart rhythm disorders

Most cardiac arrhythmias can be diagnosed using standard ECG or Holter monitoring, but in some cases, arrhythmia is elusive and presently it was only suspected as a mechanism of the unconsciousness. Sometimes rhythm disorders occur so rarely that they cannot be predicted or triggered. In such cases, an ILR is required. The primary indication for ILR implantation is the diagnosis of syncope. It can also be used to differentiate heart palpitations of a symptomatic character that are rare: the records received enable a differentiation of sinus, ventricular and supraventricular tachycar-

Table 3. Characteristics and main outcomes of clinical trials assessing the effectiveness and safety of CardioMEMS. CardioMEMS is the first and only Food and Drug Administration-approved heart failure (HF) monitoring system that significantly reduces the number of HF hospitalizations and improves quality of life and physical performance. In clinical trials, the use of the CardioMEMS system for pulmonary artery (PA) measurement reduced hospitalizations by 33% over an average period of 18 months. CardioMEMS is an economical way to control the condition of patients with New York Heart Association HF class III. In Poland, work is currently underway to prepare for the first implantation of the device.

CHARACTERISTICS					
Study	**Study type**	**Population**	**Intervention**	**Comparator**	**Outcomes**
CHAMPION [33]	Randomized clinical trial	HF	CardioMEMS	No PA monitoring	Frequency of hospitalizations associated with HF
MEDICARE registry [34]	Real-world data	HF	CardioMEMS	–	Hospitalisation due to HF and mortality
Desai et al. [34]	Real-world data	HF	CardioMEMS	–	–

RESULTS			
Study	**Frequency of hospitalizations associated with HF**	**Mortality**	**Costs**
CHAMPION	**6-months:** 30% reduction compared to control **Observation period:** 39% reduction compared to control ($p < 0.0001$)	–	–
MEDICARE registry	24% reduction	1-year: 30% reduction	–
Desai et al.	5 months: 45% reduction		Significant reduction in costs associated with HF treatment

dias. ILR can also be used to monitor heart rhythm in patients before and after ablation treatment due to atrial fibrillation. The use of ILR is indicated in the ESC Guidelines:

— 2009 and 2018 — regarding the diagnosis and management of syncope [35, 36];
— 2015 — concerning the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death [37];
— 2016 — for the treatment of atrial fibrillation [38].

In the latest ESC Guidelines from 2018, indications for the use of ILR have been extended to patients [36]:

— with suspected anecdotal epilepsy;
— who experience unexplained falls;
— with primary cardiomyopathy or inherited arrhythmogenic disorder, who are at low risk of sudden cardiac death, as an alternative to implantable cardioverter-defibrillator (ICD).

The new guidelines emphasize the role of long-term diagnosis in the absence of a documented cause of syncope, and ILR value has gained a new class of indications, namely IA.

Confirm Rx is an under-the-skin implantable long-lasting heart rate recorder, which is currently the only one in the world with Bluetooth technology. Thanks to this, it connects directly to the patient's smartphone, which eliminates the need for a handy event recorder and a stationary transmitter. Through this technology, the recording of an abnormal heart rhythm can be immediately sent to the central control system, where data are stored and then analyzed by a doctor, who takes appropriate action depending on the cause of the symptoms. The advantage of Confirm Rx is the small size of the device (the pursuit of miniaturization) and only a few dozen seconds of procedure, which makes it possible to implant the device in a treatment room. The procedure is carried out in the subcutaneous area and enables long-term diagnostics. Confirm Rx is the simplest and easiest to implant device among the devices of this type available on the market.

The first ILR implantation in Poland was carried out in 2015 (it was not Confirm Rx but another device, without Bluetooth technology) [39]. The first implantation of the Confirm Rx recorder in a child recently has been done. Such devices are

currently not reimbursed in Poland. Confirm Rx is currently under reimbursement procedure in France. In Germany, mHealth (mobile health — services related to telemedicine) have independent funding. Many countries, including the United States, are implementing a procedure to increase the availability of this technology for their patients.

Clinical evidence

The location of ILR devices in the ESC Guidelines and the widening of the indications for their use has support in the results of many randomized clinical trials showing a significant advantage of ILR over standard diagnostics. In a meta-analysis of 5 randomized clinical trials, which are presented in the ESC 2018 Guidelines on diagnosis and management of syncope, 660 patients with unexplained syncope were randomized to standard management (external loop recorders, incline test, electrophysiological study) or extended monitoring with ILR [36]. The result showed that the use of ILR increased by almost 4 times the chance of diagnosing unexplained cases of syncope compared to the standard procedure (relative risk [RR]) 3.7; 95% CI 2.7–5.0; p = 0.001). Statistical analysis carried out by the authors of the study showed the statistical significance of the results obtained. In patients with a bundle branch block in whom the atrioventricular block is likely to occur despite a negative complete electrophysiology study, arrhythmia was observed in 41% of these patients (70% atrioventricular blocking) due to ILR monitoring, based on a pooled analysis from 3 clinical trials [36]. In patients who were suspected of epilepsy, but treatment turned out to be ineffective, results of a pooled analysis of clinical trials showed that the attack was documented by ILR in 62% of patients, with 26% of the patients in whom it was caused by arrhythmias [36]. Among patients with unexplained falls, the results from a pooled analysis of clinical trials showed that the attack was documented by ILR in 70% of patients, with 14% of patients in whom it was caused by arrhythmia.

Other diagnostic methods used to monitor heart disorder and their comparison with Confirm Rx™

- Other subcutaneous implantable recorders (Reveal, BioMonitor 2):
  - CRx — additional features, e.g. Bluetooth communication;
- Telemonitoring/smartphone applications connected with an external device:
  - CRx — possible diagnosis of the type of arrhythmias (similar to a pacemaker);
- Electrocardiography:
  - CRx — usually makes it possible to give a final diagnosis;
- External recorders (including loop):
  - CRx — independent from patient, long-term, constant monitoring; diagnostic efficiency;
- Holter;
- Implantable pacemakers and defibrillator (ICD).

Reimbursement and economic effectiveness

These devices, which are used to detect asymptomatic arrhythmias and conduction disorders, are not currently reimbursed in Poland. Confirm Rx is currently under reimbursement procedure in France. In Germany, mHealth (mobile health — services related to telemedicine) have independent funding. Most countries, including the United States, are implementing a procedure to increase the availability of this technology for their patients.

In a randomized clinical trial of syncope assessment ('Cost Implications of Testing Strategy in Patients with Syncope'), it was concluded that a strategy of prolonged monitoring with implantable recorders is a more cost–effective and efficient diagnostic approach than conventional testing in patients with recurrent, unexplained syncope and preserved left ventricular function. The strategy of primary monitoring significantly reduced the cost by $2016 (p = 0.002) [40].

In a randomized study in the early use of an ILR syncope evaluation (FRESH study), it was concluded that in patients with unexplained syncope, the early use of an ILR had a superior diagnostic yield in comparison to the conventional strategy, with lower healthcare-related costs [41].

In a randomized Diamantopoulos 2016 study, it was concluded that insertable cardiac monitors are a cost–effective diagnostic tool for the prevention of recurrent stroke in patients with a cryptogenic stroke [42].

In a randomized Giada 2007 study, despite the higher initial cost, the cost per diagnosis in the ILR group was lower than in the conventional strategy group (€3056 ± €363 vs. €6768 ± €6672, p = 0.012) for diagnosis of recurrent unexplained palpitations [43].

In a Davis 2012 study, ILR monitoring was found to be a likely cost–effective strategy for patients in the United Kingdom National Health

Service, who had experienced infrequent episodes of transient loss of consciousness, which had either remained unexplained or were suspected to be of arrhythmia-origin after an initial assessment and specialist cardiovascular assessment [44].

Expert recommendations

The indication of experts on groups of patients who would benefit from the use of Confirm Rx, are in line with the ESC Guidelines. The majority of experts also indicated that the use of Confirm Rx would contribute to improved diagnoses of the disease, patient safety, treatment efficiency, reduction in the frequency of appointments/hospitalizations, treatment costs and occurrence of adverse cardiovascular events (including stroke and sudden cardiac death). In order to broaden patient access to Confirm Rx, experts primarily pointed to financing of the technology from public funds and development of recommendations for use of this technology.

Methods of intravascular imaging

Optical coherence tomography is an intravascular visualization method based on the reflection of an infrared light beam, which has been used in interventional cardiology since the beginning of this century. This method is characterized by high resolution, up to 10 times higher than intravascular ultrasound (IVUS). It provides faster and longer image acquisition (compared to IVUS) and co-acquisition with angiography. Thanks to OCT, the accurate assessment of bifurcation and atherosclerotic plaque, thrombus diagnosis, early analysis of angioplasty effects, analysis of restenosis and optimization of percutaneous coronary intervention (PCI) surgery are possible. It also provides three-dimensional reconstruction of blood vessels.

The recommendation on the use of OCT is included in the ESC Guidelines:

— 2013 — regarding the management of stable coronary heart disease [45];
— 2014 — concerning myocardial revascularization [46];
— 2018 — concerning myocardial revascularization [47].

In current European clinical practice guidelines from 2018, OCT is recommended for stent optimization and was moved from class IIb to class IIa; e.g., OCT should be considered in the detection of stent-related mechanical problems, which lead to restenosis (class IIa) [47].

In the latest ILUMIEN OPTIS apparatus, which is used for intravascular imaging, the OCT method was integrated with the fractional flow reserve method. The integration of both methods in one platform enables the combination of two techniques to optimize coronary angioplasty procedures in 1 patient. Due to the increase of frequency, it became possible to significantly accelerate the operation of the pull-back device in the system and significantly reduce the amount of contrast administered to the coronary artery. Owing to the small diameter of the Dragonfly catheter, it is possible to visualize tight changes in the coronary arteries. The axial resolution is only 15 μm with 10 mm penetration of the light beam. The fractional flow reserve measurement module in the system operates in a wireless mode, thanks to which it can be used in many cardiac laboratories without the need for complicated installations [48].

Clinical evidence

The predominance of intravascular imaging with OCT over IVUS and angiography during PCI has been confirmed in clinical trials (Table 4) [49–50].

Other methods of intravascular imaging

Other methods of intravascular imaging including:

— magnetic resonance;
— coronary angiography;
— scintigraphy;
— thermography (experimental).

Patient groups and indications in which the use of OCT will provide the greatest benefit:

— young patients with unstable angina and border atherosclerotic lesions;
— patients with left main trunk disease and/or the disease of major coronary vessels;
— the assessment of the causes of thrombosis/restenosis;
— the optimization of stent implantation (e.g. left coronary artery stump, bifurcations) — the ambiguous results of angiography, e.g. suspected thrombus, calcifications;
— the evaluation of atherosclerotic plaque;
— the evaluation of the effectiveness of PCI and stent apex.

Patient groups and indications in which the use of OCT will provide a potential benefit (in addition):

— the diagnosis of acute coronary syndrome (including acute coronary syndrome without critical lesions, myocardial infarction (STEMI/NSTEMI, MINOCA) — the assessment of morphology of atherosclerotic lesions (dif-

Table 4. Characteristics and main outcomes of clinical trials assessing the effectiveness and safety of optical coherence tomography (OCT).

CHARACTERISTICS							
Study		**Study type**	**Population**	**Intervention**	**Comparator**		**Outcomes**
CLI-OPCI [49]		Retrospective	Patients undergoing PCI	Imaging using angioplasty supported by OCT	Imaging using angioplasty		The incidence of cardiac death or MI after 1 year following surgery
ILUMIEN III [50]		RCT	Patients undergoing PCI	Imaging using OCT	Imaging using angiography or IVUS		Minimum stent area
RESULTS							
Study	**Diagnosis of PCI-related abnormalities**	**Risk of cardiac death**	**Risk of heart death or MI**	**MI or re-revascular-ization**	**Minimum stent area**	**Dissemination of the vessel**	**Incorrect stent placement**
CLI-OPCI	34.7% by OCT	1.2% vs. 4.5% ($p = 0.010$)	6.6% vs. 13% ($p = 0.006$)	9.6% vs. 14.8% ($p = 0.044$)	–	–	–
ILUMIEN III	–	–	–	–	5.79 mm^2 vs. 5.89 mm^2 (IVUS) vs. 5.49 mm^2 (angiography) ($p = 0.0014$ for non-inferiority vs. IVUS)	13.6% vs. 26.1% (IVUS) ($p = 0.091$)	More frequent using IVUS ($p = 0.022$) and angiography ($p < 0.001$)

IVUS — intravascular ultrasound imaging; MI — myocardial infarction; PCI — percutaneous coronary intervention; RCT — randomized clinical trial

ferentiation between atherosclerotic plaque rupture and atherosclerotic plaque erosion, the diagnosis of unstable/atherosclerotic plaques);
— coronary heart disease (the evaluation of coronary lesions);
— the unclear results of coronarography;
— bifurcation.

Expert recommendations

Experts have indicated that the use of OCT will primarily affect the reduction of the number of diagnostic tests and additional procedures. It will also contribute to improvements in the diagnosis of the disease, patient safety, treatment efficiency, the reduction of treatment costs, the occurrence of adverse cardiovascular events and the improvement of the quality of interventions on coronary vessels.

Experts stated that patients have better results after OCT-assisted vs. non-assisted intervention (similar conclusions for IVUS). At present in Poland, OCT is only reimbursed in ophthalmology, however, experts have indicated that in cardiology OCT should be reimbursed and be equally as available as IVUS. This technology is reimbursed in most European Union countries. Both methods should therefore be the technologies to be used by choice, based on the operator's decision. In order to broaden patient access to OCT, experts mainly pointed out recommendations for using this technology, obtaining financing from public funds and increasing the number of centers that use this technology.

Conclusions

The aim of this publication is to present the recommendations of leading experts in the field of cardiology and cardio-surgery, which are supported by clinical research results, regarding the use of cited innovative medical technologies and solutions that lead to an increase of their availability for Polish patients.

When considering the country's health policy in Poland, diseases of the cardiovascular system requires due attention given that they are an even more frequent cause of death than cancer. There is a great need to introduce new innovative technologies to improve health and QoL of Polish patients with cardiac problems. These are not only medical technologies that can be further used directly in the treatment of patients (LVAD, e.g.: HeartMate 3; the system for percutaneous repair of MR: MitraClip), but also diagnostic technologies that enable faster and more effective detection of the disease (ILR, e.g. Confirm Rx, PA pressure measurement systems: CardioMEMS) or increase the effectiveness of treatment (OCT). The safety and effectiveness of the described technologies have been confirmed in numerous scientific studies, not only in randomized clinical trials, but also in observational studies subsequent to the introduction of the technology into medical practice. Both guidelines and clinical recommendations can be based on this evidence. Scientific evidence for medical devices is also increasingly important for making decisions about their financing from public funds. The use of the above-mentioned technologies also affects a reduction in the number of additional medical services, namely the number of hospitalizations, the reduction in the quantity of diagnostic tests or the demand and use of medicines, which can directly translate into a reduction of costs. Currently, the largest obstacle to the introduction of innovative health technologies is a lack of public funding, an incorrect calculation of costs associated with individual technologies and a system that hinders the incorporation of innovative non-drug technologies into a guaranteed benefit package.

New diagnostic and therapeutic technologies in cardiology and cardiac surgery contribute improvement in patient QoL and an increase treatment effectiveness. The use of these technologies also reduces direct costs, such as drug use, additional diagnostic tests and indirect costs such as additional hospitalizations, absence from work or permanent inability to work. It is therefore necessary to increase their availability, primarily through the development of clinical recommendations, education of medical personnel and public funding.

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