Expert opinion of a Working Group on Leadless Pacing appointed by the National Consultant in Cardiology and the Board of the Heart Rhythm Section of the Polish Cardiac Society

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ABSTRACT

Permanent cardiac pacing is a recognized method of treatment of patients with sick sinus syndrome and/or atrioventricular conduction disturbances. Implantation of a traditional pacing system with transvenous leads is associated with a risk of complications, such as pneumothorax perforation of cardiac wall or cardiac device-related infection. An alternative method that may be used for permanent cardiac pacing is represented by the leadless pacemaker, implanted directly into the target cardiac chamber. Such devices have been implanted in Poland since 2016, but the number of procedures is limited due to the lack of clear reimbursement rules.

The expert panel appointed by the National Consultant in Cardiology and the Executive Board of the Heart Rhythm Section of the Polish Cardiac Society presents a statement on the use of a leadless pacemaker in Polish conditions. The statement present streatment method and results of clinical studies that confirm its safety and efficacy, indications and contraindications for its use, and precise requirements to be fulfilled by the implanting centers.

Key words: leadless pacemaker, expert opinion

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INTRODUCTION

Permanent cardiac pacing is a method of treatment commonly used in patients with bradycardia due to sinus node disease and/or atrioventricular conduction disturbances [1]. A pacemaker (PM) consists of a device can, containing the battery and the processor controlling its operation, and the lead or leads, routed transvenously into the target cardiac chambers. Implantation of a PM with endocardial leads is associated with a risk of complications during the procedure. Those complications include pneumothorax, perforation of heart chambers and dislocations [2]. The use of endocardial leads also increases the risk of lead-dependent endocarditis [3]. Last but not least, the leads are the main source of problems leading to malfunction of pacing systems, mainly due to their mechanical damage. Infections of the PM pocket, developing in the postoperative period or later, as a result of progressive skin damage or developing decubitus, constitute another crucial problem

of electrotherapy. Due to those reasons, the development of a leadless cardiac pacemaker (LCP), implanted directly into the cardiac chambers, has been carried out for many years now [5]. Currently, the PM produced by Medtronic company (Micra Transcatheter Pacing System) is the only available LCP, and therefore the majority of publications presenting the outcomes of this method are based on the analyses of the use of that particular system. One might expect though, that in the course of time other manufacturers will also introduce their own devices of that type.

CONSTRUCTION AND OPERATION OF THE LCP

The currently available LCP weighs 1.75 g, has a volume of 0.8 cm^3 and 26 mm of length. The implantation procedure involves the introduction of a vascular sheath of an outer diameter of 27 Fr through the femoral vein into the right ventricle. In the next step, having confirmed the appropriate placement of the sheath, the pacemaker's body is released from its end and fixed in the interventricular septum by means of special nitinol tines. Once stimulation threshold and appropriate sensing have been confirmed, the device is finally separated from the guiding catheter and left in the cardiac chamber. The operating parameters of the pacemaker are entirely programmable, both sensing and pacing current (energy and the pulse width), which makes the device operation identical to the PM system with transvenous leads. Adaptation of pacing rate to the physical activity is also available (rate-responsive mode). Magnetic resonance imaging is also possible in patients with that type of pacing system [6].

The leadless pacemaker is currently available in two versions the VR version — performing pacing in VVI(R) mode and the AV version — offering a possibility of ventricular pacing triggered by atrial activity (the VDD mode). This is acquired by using an accelerometer that effectively senses vibrations associated with blood flow through the tricuspid valve. Research data show that atrio-ventricular synchrony may be acquired in nearly 90% of heart beats [7–9]. The limitation of this device is, however, the relatively low upper sinus rate tracked in VDD mode, and above that rate, the device automatically switches into VVIR mode. The device life is estimated at 8–12 years, depending on the percentage of paced beats and pacing threshold.

CURRENT KNOWLEDGE ABOUT THE SAFETY OF USE AND EFFICACY OF LCP

The research data collected so far confirm the safety of use and efficacy of LCP. A procedural success rate of 99.2% was reported for the very first study of 725 patients who underwent PM implantation. During the follow-up of 6 months, serious complications were observed in 25 patients, resulting mainly from mechanical damage to the heart wall or femoral vein, that occurred during the implantation procedure [10]. During follow-up prolonged up to 12 months, 96% of patients were free from serious complications of the therapy, and thus the rates of serious complications were reduced by 48% in comparison with patients having transvenous systems, as reported in earlier studies [11]. It has been thereby confirmed that the incidence of complications during implantation of LCP is lower compared to a traditional PM, the reoperation rate is lower, and final pacing and sensing parameters are stable. In another study, including 795 patients, LCP was successfully implanted in 99.6% of cases and serious complications occurred in 1.5% of patients during 1-month follow-up [12]. In the follow-up period extended to 12 months, altogether including 1817 patients, serious complications were reported in 2.7% of patients, which equals to 63% reduction in comparison with the patients undergoing PM implantation with transvenous leads [13].

Although the leadless pacemaker offers a valuable alternative for the commonly used transvenous systems, is not free from certain limitations. Implantation technique, small size, and healing into the heart wall may result in significantly more difficult removal of the device if such a necessity occurs [14–16]. LCP cannot be used in patients with a filter in the inferior vena cava, with mechanical tricuspid valve, or in the case of femoral vein anatomy precluding the introduction of a sheath size required for LCP implantation. The procedure is also contraindicated if there is any risk of potential interference with other previously implanted devices or intolerance of materials that the device is made of. Nonetheless, LCP is a cardiac pacing modality for patients without vascular access needed for traditional PM implantation, or patients with skin lesions that increase risk of infection of a transvenous system. Moreover, LCP may be a safe therapeutic option for patients with infective complications of previously implanted transvenous systems, or at high risk of such events [17]. Of note, in an obvious manner, the use of LCP eliminates the risk of endocardial lead-related complications, as well as local complications affecting the PM pocket, which have always been the weak point of traditional permanent cardiac pacing.

Leadless cardiac pacemaker implantations have been performed in Poland since January 2016, however, its use is limited by the lack of clear rules for reimbursement, and it follows individual applications to the National Health Fund or is performed as part of clinical trials.

A working group appointed by the National Consultant in Cardiology and the Board of the Heart Rhythm Section of the Polish Cardiac Society, having analyzed the available data and related it to participants' personal experience, issues an opinion on the use of leadless pacing systems in Polish conditions.

RECOMMENDATIONS FOR IMPLANTATION OF A LCP

A. Implantation of a leadless cardiac pacemaker should be considered (class IIA of recommendations) in the following clinical settings in patients qualified for permanent cardiac pacing:

1. Lack of vascular access or other reasons precluding or significantly limiting the possibility of performing a standard transvenous implantation

This recommendation applies to the damage of the vascular system, both the subclavian vein and superior vena cava, resulting from an illness, iatrogenic causes, the use of vascular ports and other similar situations, as well as congenital abnormalities and anomalies in the cardiovascular system, and the history of their treatment (e.g. the history of tricuspid valve repair or implantation of a tricuspid bioprosthesis).

2. Recurrent or permanent focal or systemic inflammation, that may lead to (or led in the past) infective endocarditis

This recommendation, for example, includes patients with infected orthopedic or other implants, in whom infection of the implant is difficult to control and radical treatment is not planned. It also applies to patients with chronic inflammatory disorders of the skin or other organs, that increase the risk of infective endocarditis.

3. Comorbidities (or necessary medical interventions) that led to infective endocarditis, and therefore to the extraction of the traditional cardiac pacing system

This recommendation applies to patients undergoing dialysis or other analogous therapeutic interventions requiring permanent vascular access, as well as patients on long-term immunosuppressive treatment, or with other comorbidities that significantly and permanently impair the immunity.

4. Comorbidities (or medical interventions) that led to local damage within the pocket of the implanted pacemaker, resulting in its removal, or conditions in which the implanted device restricts or precludes the use of specific oncologic therapeutic interventions (e.g. radiotherapy)

This recommendation applies to patients undergoing radiotherapy in the course of oncologic treatment if it overlaps the pocket of the traditionally implanted pacemaker.

B. Implantation of a leadless cardiac pacemaker may be considered (class IIB of recommendations) in the following clinical settings in patients qualified for permanent cardiac pacing:

1. Comorbidities (or medical interventions) leading to an increased risk of infective endocarditis

This recommendation applies to patients undergoing dialysis or other analogous therapeutic interventions requiring permanent vascular access, as well as patients on long-term immunosuppressive treatment, or with other comorbidities that significantly and permanently impair the immunity.

2. Comorbidities or clinical situations (or medical interventions) possibly leading to local damage of the pacemaker pocket or the leads

This recommendation applies to patients undergoing radiotherapy or in whom radiotherapy is considered in the course of oncologic treatment if it overlaps the traditional pacemaker pocket, and implantation of a traditional pacemaker is planned. This recommendation also applies to patients potentially or chronically pacemaker dependent, in whom the risk of mechanical damage to the transvenous lead(s) is increased due to the nature of their work or limited supervision because of other socio-medical factors.

3. Comorbidities (or medical interventions) requiring permanent or periodical vascular access

This recommendation applies to patients, in whom there is an increased probability that vascular access may be needed for reasons other than implantation of a cardiac pacemaker.

4. Anticipated small percentage of pacing in young patients with a long life expectancy

This recommendation applies to young patients, requiring only ventricular pacing or with only occasional atrioventricular conduction disturbances. In such cases, the possible risks and benefits of the procedure should be evaluated with special care.

C. Leadless cardiac pacemaker should be avoided (class III of recommendations) in the following clinical situations in patients qualified for permanent cardiac pacing:

1. Sick sinus syndrome, especially with maintained retrograde ventriculoatrial conduction, in case of chronic bradycardia, when a high percentage of ventricular pacing is anticipated

This contraindication applies to patients with chronic (non-paroxysmal) sinus bradycardia, in whom, due to the

high percentage of pacing and maintained retrograde conduction, atrial contraction occurs nearly simultaneously with ventricular contraction (when atrioventricular valves are closed), causing the symptoms of pacemaker syndrome.

In all of the abovementioned recommendations, in case of maintained sinus rhythm, implantation of a leadless pacemaker capable of ventricular pacing triggered by atrial rhythm should be preferred.

REQUIREMENTS FOR CENTERS IMPLANTING LCP

Apart from the centers that have already performed implantation of LCP systems, cardiology centers that have the most considerable experience in performing cardiac electrophysiology and electrotherapy procedures, as well as in the treatment of early and late complications of such procedures, including transvenous lead extractions should be preferred. The availability of cardiac surgery in the center is essential. The possibility of performing outpatient follow-up visits of patients after electrotherapy and electrophysiology procedures is indispensable.

It is recommended to introduce the national registry of leadless pacemaker implantations and regular supervision from appropriate regulatory boards over the centers performing such procedures.

SUMMARY

Leadless pacemaker implantation is an important therapeutic option for patients requiring permanent cardiac pacing, in whom the use of a transvenous system is impossible or is associated with a high risk of complications. The possibility of maintaining vascular access intact for the purpose of future treatment and interventions is an important merit. It should be noted that the number of Polish centers utilizing this method is small, and their experience limited, which is mainly due to the current reimbursement regulations. The authors of that statement believe that introduction of clear reimbursement rules and fees covering entirely the costs of the procedure will result in increased availability of that method to fully satisfy the demand in Poland, which is estimated at approximately 300 procedures annually.

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