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Experts of the Heart Rhythm Section of the Polish Cardiac Society: opinion on the use of wearable cardioverter-defibrillators in Poland

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Abstract

Sudden cardiac death (SCD) is one of the main causes of mortality in developed countries. Implantable cardioverter-defibrillators (ICDs) have become a widely used and efficient method for SCD prevention in high-risk populations. Nevertheless, there are clinical situations in which the benefit of ICD is uncertain, such as: early postinfarction left ventricular dysfunction, reversible causes of cardiomyopathy, presence of temporary or permanent ICD contraindications in high-risk populations, or when ICD is not accepted by SCD prevention candidates. Wearable cardioverter-defibrillator (WCD) can be an alternative option in these clinical circumstances. However, even though WCDs are available in the United States and many countries of Western Europe, they are still not available in Poland. The authors present clinical and organisational recommendations for WCD use in Poland, with respect to medical evidence.

Key words: indication, wearable cardioverter-defibrillator

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INTRODUCTION

Sudden cardiac death (SCD), caused by ventricular fibrillation (VF), is still one of the main causes of death in developed countries. Implantable cardioverter-defibrillators (ICDs) are a proven and common method of treatment in patients with increased risk of SCD. Indications for preventive use of ICDs are based on relevant documents of the European Society of Cardiology (ESC) [1, 2]. Currently, there are 133 centres implanting ICDs in Poland. The number of new ICD implantations in Poland reached 6366 in the year 2016. This amount is equal to almost 170 implantations per one million citizens, which is the fourth highest rate in Europe [3]. At the same time, more and more attention is paid to clinical conditions in which the risk of SCD may be significant but which do not constitute an indication for ICD implantation, as defined in the current recommendations. This refers to patients with postinfarction left ventricular (LV) damage and with reversible causes of cardiomyopathy. An increasingly frequent clinical scenario associated with increased risk of SCD and limited application of ICD involves cases in which implantation of a traditional system may cause transient or chronic complications related to transvenous ICD or in which ICD is not tolerated well by the patient.

Wearable cardioverter-defibrillators (WCDs) can be beneficial in certain groups of patients with increased risk of SCD. These devices, although available in the United States and many countries of Western Europe, are not used in Poland yet. This position paper presents the most important technical aspects and a review of literature evaluating the clinical effects of this therapy as well as the proposed organisational recommendations for referring patients for WCD.

OPERATION OF WCD

A WCD is an external device in a form of a vest that automatically detects malignant, potentially fatal ventricular tachyarrhythmias and can terminate them through defibrillation. The first report regarding WCDs appeared in 1998 and described the use of the device in persons following cardiac arrest due to ventricular arrhythmias [4].

To detect arrhythmias, WCDs use two pairs of electrodes positioned in such a way that they form two leads: front-back

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(F-B) and side-side (S-S). The electrodes are fitted on an elastic belt; they are dry and non-adhesive to the body. The belt is integrated in the vest and girds the chest at the level of the xiphoid process. The electrocardiogram (ECG) signal is analysed in the central unit positioned in the lower belt.

Three defibrillating electrodes that automatically release gel before discharge are attached to the vest: one in the apical position and two in the interscapular region. Electric wires connect the electrodes with the central unit, which contains batteries, capacitors, a processor for digital ECG analysis and tachyarrhythmia detection, and a module of defibrillation with a biphasic impulse. The central unit also contains an LCD display and a response button that allows the patient to terminate the defibrillation impulse, as well as a speaker that emits voice commands. The central unit with a battery weighs around 640 g. It can be worn on a hip belt or on a shoulder strap.

Arrhythmia analysis is performed based on one ECG lead.

Tachyarrhythmia is qualified on the basis of heart rate and morphology discriminator. The device recognises ventricular tachycardia (VT) or VF when the heart rhythm exceeds the programmed value appropriate for each of these zones. VT and VF detection can be programmed within the range of 120 to 250 bpm. The default detection values are set at 150 bpm and 200 bpm for VT and VF, respectively. The value of the defibrillating impulse in the VT zone can be programmed in the range of 75 to 150 J, and in the VF zone all discharges have the energy of 150 J.

Identification of arrhythmia triggers an alarm, firstly in the form of vibration, then sound, and finally a voice message about the coming discharge, all to warn the patient — if conscious — and any witnesses. If a conscious patient tolerates tachycardia well or detection was inaccurate, the discharge can be stopped by pressing the response button positioned on the central unit.

During one cycle of arrhythmia, the WCD can deliver up to five high-energy discharges. In the case of asystole, the device plays a voice message, aimed at potential witnesses, indicating that a rescue team needs to be called.

The vest itself, without the attached components, weighs about 400 g and should be worn directly on the skin and under the clothes. It should be well fitted to ensure the electrodes adhere to the skin properly. The vest should be periodically replaced and washed. It should also be removed for activities related to the patient's personal hygiene. The manufacturer recommends limiting the duration of such activities to 1 h a day.

CURRENT KNOWLEDGE AND THE MOST IMPORTANT CLINICAL SITUATIONS IN WHICH A WCD CAN BE USED

Patients following recent myocardial infarction (< 40 days)

During the first six months following a myocardial infarction (MI), 7% of patients die suddenly [5]. This proportion is the greatest among patients with LV ejection fraction (LVEF) ≤ 30%. The risk of sudden death decreases with time from infarction, which is said to be due to improving LV function, among other factors. It has been indicated that LV function returns to normal values within two months in 22% of patients. In patients with LVEF ≤ 35% in the acute phase of MI, a decrease in LVEF values to < 30% after three months was observed in 84% of patients not treated with coronary angioplasty and in 77% of patients following revascularisation [5]. Despite the high risk of sudden death, the results of two randomised studies showed no evidence that ICD implantation reduces total mortality in these groups of patients [6, 7]. The lack of advantages of ICD implantation is said to be due to causes of sudden death other than VT/VF, such as repeated MI, cardiac rupture, or pulmonary embolism. It is estimated that only about a half of SCDs in this period are caused by ventricular tachyarrhythmias [5]. According to the WEARIT II register, the risk of VT/VF is 2% in three months [8]. A similar frequency of permanent arrhythmia was observed in the study by Chung et al. [9]. An important conclusion from the WEARIT II register is that arrhythmia often regresses after it is detected. In 90 of 120 episodes of arrhythmia, patients cancelled the therapeutic action by pressing the response button. In the remaining cases, arrhythmia was interrupted by the first high-energy intervention of the WCD [8].

After three months, ICDs were implanted in 42% of patients included in the register. Planned implantation was most often cancelled due to lack of indications resulting from improvement in the LV function [8].

In a large register by Epstein et al. [10] analysing patients following MI in whom WCD therapy was applied within three months from the event (n = 8453), 309 adequate interventions due to ventricular tachyarrhythmia were noted in 1.6% of patients. Therapy delivered by the device was effective in 91% of cases. Overall, 75% of WCD interventions occurred in the first month of observation and most often (in 93% of cases) they were necessary in patients with LVEF < 35% [10].

The recently completed VEST trial (Vest Prevention of Early Sudden Death Trial and VEST Registry), the first randomised study on WCD in a post-MI population with low LVEF, which enrolled 2302 patients within seven days of hospital discharge after an acute MI with a mean LVEF of 28.2%, demonstrated that WCD did not reduce the rate of sudden or arrhythmic death in the first 90 days when added to guideline-directed medical therapy (1.6% vs. 2.4%; p = 0.18); however, total mortality was reduced in the WCD subgroup (3.1% vs. 4.9%; p = 0.04). It is worth noting that of the total 48 participants in the WCD arm who died, 36 were not eventually equipped with the device at the time of death. There were 1.3% of appropriate and 0.6% of inappropriate shocks in the device group. These results suggest that more studies are needed to understand WCD outcome in this population, and potential benefit could be enhanced by identifying subgroups of higher risk [11].

Patients following revascularisation

In patients with LVEF ≤ 35%, the risk of sudden death in the first month following coronary artery bypass grafting (CABG) is increased. In a study comparing the use of WCD in patients with LVEF ≤ 35% following CABG and percutaneous coronary intervention (PCI) with a suitably chosen group of patients, a reduction of mortality by 57% post CABG and by 80% post PCI was observed in patients without WCD [12].

As is the case of patients after MI, LVEF should be measured after three months and indications for implanting an ICD need to be considered.

Wearable cardioverter-defibrillators cannot be used in patients after CABG, who use elastic belts to stabilise the sternum in the early postoperative period.

Myocarditis

Due to the reversibility of the process and a high probability of significant improvement of LV function, the risk of sudden death is temporary; therefore, protecting patients in this period with WCDs seems to be an attractive concept. Single reports based on small patient groups indicate that WCDs are efficient in this patient group, with an intervention rate of 5.7% (two of 35 patients) [5, 13].

De novo diagnosis of cardiac failure

In this patient group, the probability of LV function improvement after an adequately long treatment is high. Therefore, the use of WCD in this period is theoretically substantiated in patients with significantly impaired LV function. It should be noted that arrhythmias requiring WCD intervention are more frequent in this patient group (ca. 1% during three months of observation) [8]. This clinical situation is not included in the ESC recommendations.

Potentially reversible causes of cardiomyopathy

This group of diseases includes peripartum cardiomyopathy, Takotsubo cardiomyopathy, and cardiac failure in patients undergoing cancer treatment. These are potentially reversible forms of cardiomyopathy, in which the risk of sudden death is less known or transient, but still significant. In peripartum cardiomyopathy, WCD interventions for VT/VF were needed in three out of seven patients using the device, during an observation period lasting from 25 to 345 days (mean, 81 days) [14]. There are no studies regarding the use of WCD in other cardiomyopathies.

Patients awaiting heart transplantation or LV assist device implantation

In this group, ICD implantation is reasonable in ambulatory patients awaiting heart transplantation or LV assist device implantation. However, taking into account the theoretically limited duration of therapy, potential complications, and economical aspects, the use of WCD can be considered in this patient group. Data from an American register listing 121 patients awaiting heart transplantation showed that WCD is highly efficient in this population. WCD interventions occurred in seven (6%) persons [15]. The use of WCD in this patient group is recommended by the International Society for Heart and Lung Transplantation (class I, level of recommendation C) [16]. According to German data, these patients constitute 20% of patients protected with WCDs [5].

Patients following ICD removal or with temporary contraindications for ICD implantation

Infections related to cardiac electrotherapy devices, including ICD, are an increasingly common clinical issue. They occur in 0.5% to 1.5% of patients after first implantation [17]. The rate increases to as much as 4% to 5% after device replacement or expansion. Repeated implantation should often be postponed due to anti-infection treatment or wound healing. Through the use of a WCD, surgery can be postponed and patient hospitalisation time can be reduced. This is particularly significant in patients with indications for ICD implantation due to secondary prevention of sudden death (history of VT/VF). In this group, the device was usually used for three to six weeks. WCD interventions occurred in 5% of patients [18]. The use of WCDs in these situations is listed in the recommendations of the Heart Rhythm Society regarding electrode removal.

Other clinical situations

Wearable cardioverter-defibrillators can be useful in patients with congenital arrhythmogenic diseases, particularly in severe forms of Brugada syndrome and prolonged QT syndromes, during diagnostics or treatment with drugs that prolong QT intervals.

Some authors advocate the call for WCD use in patients undergoing dialysis, who are at high risk of complications, especially infections and vascular complications [19]. A long-term alternative to be considered in such patients is a subcutaneous ICD [20].

THE STATUS OF WCD IN THE ESC RECOMMENDATIONS REGARDING VENTRICULAR ARRHYTHMIAS AND PREVENTION OF SCD

Based on the 2015 ESC recommendations on the prevention of SCD [1, 2], the use of WCD can be considered:

1. In adult patients with impaired LV systolic function, when improvement of LV systolic function is probable. Potential clinical scenarios include: (i) the time to ICD insertion or full recovery in patients after inflammatory heart diseases with LV systolic dysfunction and/or electrical instability (**class II a of recommendation**); (ii) the waiting period for a heart transplantation or ICD implantation, peripartum cardiomyopathy, active period of myocarditis, or arrhythmias in the early phase of MI (**class II b of recommendation**).
2. In high-risk patients (no revascularisation, previous impairment of LV function, or arrhythmias within < 48 h from the onset of acute coronary syndrome [ACS], polymorphic VT, or VF) within 40 days from MI **(class II b of recommendation**).

Table 1. Potential indications for the use of wearable cardioverter-defibrillators (WCDs)

Clinical situations	Special clinical situations
Patients at high risk following an infarction (< 40 days)	LVEF ≤ 35% Previous impairment of left ventricular function Transient exacerbation of heart failure VT/VF < 48 h from the onset of ACS Permanent monomorphic asymptomatic VT No revascularisation
Cardiomyopathies with potentially reversible course	Acute myocarditis Peripartum cardiomyopathy Cardiac failure in the course of cancer treatment Takotsubo cardiomyopathy
Patients awaiting heart implantation or left ventricular assist device implantation	–
Patients following revascularisation (< 3 months)	LVEF ≤ 35% Previous impairment of left ventricular function Transient exacerbation of heart failure (LVEF ≤ 35%) VT/VF < 48 h from the revascularisation Permanent monomorphic asymptomatic VT
Patients following ICD removal awaiting a postponed reimplantation of the device	Mostly patients with indications resulting from secondary prophylaxis or with history of justified ICD interventions
Newly recognised cardiac failure with ≤ 35% in the period of optimal pharmacotherapy implementation	–
Significant contraindications to transvenous ICD implantation	–

ACS — acute coronary syndrome; ICD — implantable cardioverter-defibrillator; LVEF — left ventricular ejection fraction; VF — ventricular fibrillation; VT — ventricular tachycardia

Because there have been no randomised studies, the use of WCD is based on expert opinions as well as on the results of registers and observational studies (**level C of recommendation**). There are no data on the use of WCDs in children.

Potential indications for the use of WCDs are presented in Table 1.

IDENTIFICATION OF WCD CANDIDATES AND ORGANISATION OF CARE

1. The decision to use a WCD must be made by a cardiac specialist.
2. Referral for WCD therapy should be performed and implemented in a centre accredited by the Working Group on Heart Rhythm at the Polish Cardiac Society and with solid experience in the identification and treatment of patients using ICDs.
3. Staff in the centre directly implementing the WCD method in a patient must be thoroughly trained with regard to the technical aspects of the device and able to provide comprehensive instructions on the rules of WCD use to the patient and his/her family.
4. Follow-up visits should take place in the specialist centre, as described above, at least once a month or after each incident triggering the WCD system.
5. A patient treated with a WCD must remain in telephone contact with the supervising centre.
6. The manufacturer emphasises that WCDs efficiently prevent SCD provided they are used at least 23 h a day. Due to the nature of the WCD method, patients (and, preferably, their families/carers) should declare understanding of, compliance with, and discipline regarding the proposed method.
7. WCDs are not recommended for patients with impaired perception of vibrations or deafness.

THE POTENTIAL STATUS OF WCDS IN POLAND: THE MOST URGENT NEEDS AND RECOMMENDATIONS

1. Experts consider WCDs a much-needed therapeutic tool in clinical situations such as reversible causes of LVEF impairment, transient contraindications for ICD implantation, and other clinical situations which are hard to define clearly: (i) increased risk of SCD; and (ii) indications for ICD protection in congenital arrhythmogenic conditions. These situations have been described in detail in the present document; they are uncommon but clinically significant in the authors' opinion. The exact number of

such situations in Poland is not known, but it does not exceed 250 persons a year.

2. The population of Polish patients at risk of SCD following an ACS does not differ from the European population in terms of the size and clinical condition. In 2014, the number of adults with a history of ST-segment elevation MI was 830 per one million, and about 91% of such patients were treated with PCI. Assuming that LVEF ≤ 35% at discharge from hospital is found in 15% to 20% of patients, those with the highest risk during three-month observation should be identified in this group.
3. Recommended time of WCD use is three months. In the case of marked improvement in SCD risk factors but without full recovery of the patient and the continuous risk of SCD, the therapy can be prolonged.

The team suggests that significant risk factors should include the following: (i) a history of sustained VT or VF during the first 48 h of ACS; (ii) a history of an episode of acute heart failure (documented shock or pulmonary oedema), which was stable in New York Heart Association functional class I to III; (iii) a history of asymptomatic permanent VT.

Patients with the above risk factors constitute a population of about 500 persons at greatest risk in whom temporary protection (up to three months) with a WCD can be considered; after that period, the decision to use ICD therapy should be made and implemented in accordance with current standards.

It is important to note, however, that the use of WCDs in patients directly after MI and with reduced LVEF still raises the question about SCD reduction, so practitioners should be very cautious when referring this group of patients for WCD therapy, and such referral should be based on thorough individual evaluation of a patient's risk profile. One should be aware of other clinical circumstances listed in the section "Current knowledge and the most important clinical situations in which a WCD can be used".

SUMMARY

The wearable cardioverter-defibrillator can be a valuable therapeutic method in the population of patients at risk of SCD in whom there are no indications for ICD implantation or ICD therapy is contraindicated due to significant reduction of LVEF that is reversible or can be managed in another way, as well as in patients with indications for ICD implantation in whom it is temporarily or chronically not recommended. The largest target population in which WCD therapy should be considered are patients with LVEF ≤ 35% within three months of MI, among whom mortality due to SCD does not exceed 1% to 2%. The team of experts suggest that indications in this group should be limited to selected clinical situations in which the risk of SCD is increased to ca. 7%. The nature of the method is such that WCD treatment should be performed by experienced teams in close cooperation with the patient and their family. At the stage of referral, other generally recognised factors affecting SCD risk should be taken into account.

The authors estimate that the population of patients that might require the use of WCDs should currently be less than 750 persons a year.

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