

Is the transvenous extraction of cardioverter-defibrillator leads more hazardous than that of pacemaker leads?

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Abstract

Background: Leads used for low-voltage and high-voltage therapy delivered by implantable cardioverter-defibrillators (ICD) differ from low-voltage pacemaker (PM) leads in their diameter and complexity of structure. Although there are reports showing that the extraction of ICD leads may be hazardous, due to firm adhesions to the vascular and chamber walls of high-voltage therapy coils, clinical evidence suggests that such procedures are safe.

Aim: To compare the efficacy and safety of transvenous extraction of ICD and PM leads in patients enrolled in a single tertiary centre.

Methods: We compared the results of lead extraction procedures in 345 patients with PM and in 79 patients submitted for the lead removal including at least one ICD lead. We analysed ingrown leads i.e. over 12 month-old PM leads and over 6 month-old ICD leads, which were removed using Cook's device.

Results: Patients in the two groups differed significantly in age and gender. The ICD systems were significantly younger, less complex (fewer leads per patient) and presented higher efficacy of extraction and fewer technical difficulties. The number of major complications was similar to the encountered during extraction of PM leads. However, minor complications were significantly more frequent in the ICD group.

Conclusions: 1. Extraction of ICD and PM leads is associated with a similar risk for developing major complications, however minor complications are more often during extraction of ICD leads. 2. A larger number of double coil leads may be the cause of complications despite a shorter time period elapsing from ICD implantation. 3. A probable cause of complications during ICD lead extraction is the pronounced growth of the connective tissue around the coils. However, further studies are required to clarify this phenomenon. 4. The success rate of ICD leads extraction using our own surgical technique is similar to that reported by other investigators using laser systems.

Key words: transvenous leads extraction, ICD lead removal, complications of leads extraction

Kardiol Pol 2010; 68, 8: 884–890

INTRODUCTION

An introduction of endocardial leads in the implantable cardioverter-defibrillator (ICD) therapy at the turn of 1980's and 1990's increased significantly the number of implanted devices [1]. Growing number of ICD indications, due to the primary prophylaxis and an impact of new achievements in car-

diology extending patients' life expectancy, makes the number of patients with long period of follow-up after the ICD implantation to increase [2, 3]. The ICD lead structure, lead implantation techniques and lead removal techniques have been widely adopted from the leads used in the pacemaker (PM) therapy [1, 4, 5]. The ICD leads differ in size (diameter)

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Received: 01.03.2010 Accepted: 26.05.2010

and structural complexity (numbers of wires, thickness of isolation layer) compared to the PM leads.

The most current summary of ICD leads damage (including both 1st generation leads — coaxial, and the following generations of multi-lumen leads) proved high rate (20%) of damage during the 10-year follow-up [2]. Thus, the need for ICD leads removal, due to their mechanical and electrical malfunctioning, is growing compared to the PM leads. Hamid et al. [6] documented an increasing rate of the ICD lead removal in their own studies in all types of lead removal procedures (7.5% in 2002 and 22% in 2010). The number of successful transvenous lead extractions has increased, while the number of complications has decreased over the last 15 or so years, mainly due to new extraction tools and techniques: telescopic sheaths with rotation — cutting mechanism, locking stylets, laser and radiofrequency (RF) assisted extraction and an alternative femoral approach [7, 8].

The data comparing difficulty and safety of transvenous removal of the ICD leads and PM leads remain ambiguous. Some authors believe that the ICD lead extraction does not differ from the PM lead extraction process [6, 7, 9, 10]. Other investigators notice that different construction of ICD leads, with high-voltage therapy coils, trigger the growth of connective tissue and leads adhesions to the great vein walls and heart chambers [5, 11, 12]. The connective tissue proliferation adjacent to the lead is a well documented cause of complicating transvenous lead extraction and increasing the risk of vascular damage and right heart chambers rupture, which may trigger life threatening bleeds [11, 13]. Certain structural features of leads have been associated with higher complication rates during lead extraction such as proximal coil in the dual-coil ICD leads or various and changeable cross sectional diameter of the leads [1, 13]. Furthermore, the time from the implantation has been shown to increase unsuccessful rate of the PM lead extraction [14]. Both, patients' weight and experience of the operating team have been shown to influence the results of the extraction procedure [15].

We present the results of transvenous lead extraction of the single team working with a highly experienced operator. We would like to emphasize the uniqueness of the study population, in particular in respect to the length of time from the implantation and the frequency of dual-coil ICD leads [16]. The preliminary results have been published previously [17, 18].

METHODS

We analysed retrospectively a 4 year-old database of 424 patients who underwent percutaneous endovascular endocardial lead extraction, during which 764 leads were extracted. The database includes baseline characteristics, indications to transvenous lead extraction, number of extracted leads, leads age and model, location of the lead implantation in the heart, as well as the extraction procedure information: time, technique and complications.

We compared technical difficulties and complications between the patients with transvenous ICD lead extraction and the PM lead extraction group. Group I comprised patients in whom at least one ICD lead was extracted. The remaining patients who underwent extraction of PM leads only were included in Group II.

The main inclusion criterion was the need for the use of mechanical equipment during transvenous lead extraction. The additional criterion was the length of PM and ICD lead stay in the cardiovascular system: > 12 months and > 6 months, respectively.

The following features were compared between the study groups: 1) age and gender; 2) indications for transvenous lead extraction because of infection (localised pocket infection and lead dependent infective endocarditis) and non-infectious indications (mechanical and electrical lead malfunction, the need of lumen restoration during PM/ICD system upgrade, redundant lead removal during the change of pacing systems); 3) number of leads present per patient; 4) mean age of removed leads; 5) success rate — complete removal of all leads as planned prior to the procedure; 6) technical difficulties: duration of the procedure and necessity of the technique change during the procedure; 7) complications of the extraction procedure defined by the Heart Rhythm Society (HRS) recommendations [19].

Description of the lead extraction techniques

The leads with available proximal ends at the PM/ICD pocket were removed using the Cook's device (Fig. 1). In order to make the leads stiffer, we advanced metal leaders into the leads lumen. Very sporadically the locking-stylets were used only in situations where there was a possibility of grabbing very distal end of the lead. In order to provide equal and simultaneous tension to the leads during counter traction, the strong ligatures were attached to the proximal end of the lead. All the lead layers and the metal guiding wire were firmly tied with the use of those ligatures.

We used the Byrd polypropylene telescopic dilators of all sizes (blue, yellow, green, white and orange) in two available lengths. On rare occasions, we used metal sheaths allowing passing through tight and strong fibrotic tissue beneath the clavicle. In case of significant resistance of the tissue while dis-attaching the leads from the vascular wall and heart chamber walls, we exchanged the pair of catheters with another pair of bigger diameter. The laser and RF enhancement were not used in our study. The detailed description of the used technique was presented in one of our previous studies, calling these procedures typical ones [20].

Leads with displaced proximal ends into the cardiovascular system were extracted usually via femoral approach. Sporadically, the cervical internal vein access or subclavian vein on the opposite site to the PM/ICD pocket were used. Additionally, if the access technique was changed during the procedure, we would call the procedure as modified. In this

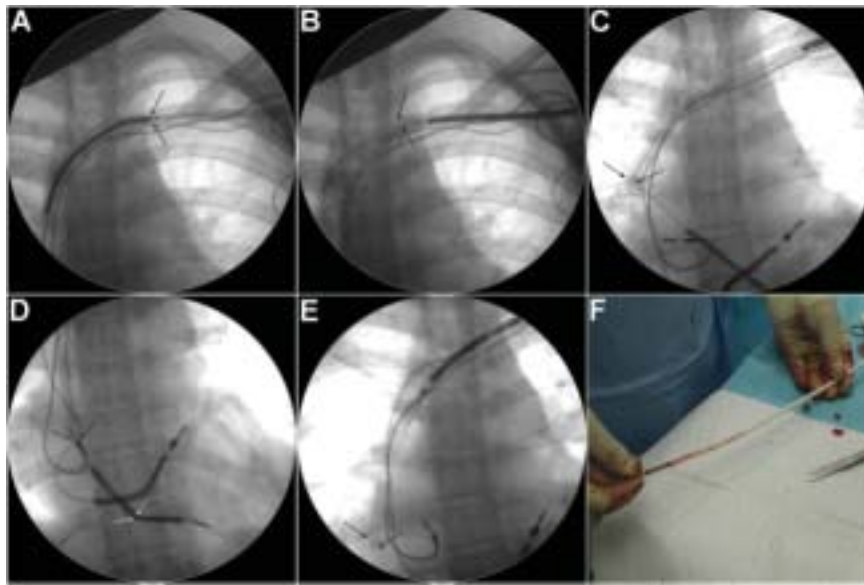


Figure 1. Fluoroscopic image **A–E** and intraoperative **F** of the redundant ICD lead extraction previously implanted in the right ventricular apex. The arrows point out the distal portion of Byrd dilator; **A.** Start of the procedure: the end of the dilator is located at the beginning of the proximal coil of the double coil ICD lead in the left subclavian vein; **B.** Proximal coil is located, after cutting it off, inside the dilator; the end of the dilator is located at the beginning of the brachiocephalic vein; **C.** The end of the dilator is located at the junction of superior vena cava and the right atrium; the proximal coil is located inside the dilator, and the distal coil projects on the vertebral column; there are two active leads visible: in the atrium and the new ICD lead implanted to the outflow of the right ventricle; **D.** The white arrows point out the distal end of the inner sheath; the black arrows point out the outer telescopic pair of the Byrd sheaths; **E.** The removed leads after the separation from the vessels and heart chamber wall inside the Byrd dilator; **F.** The removed ICD leads with the inner white sheath of the Byrd dilator

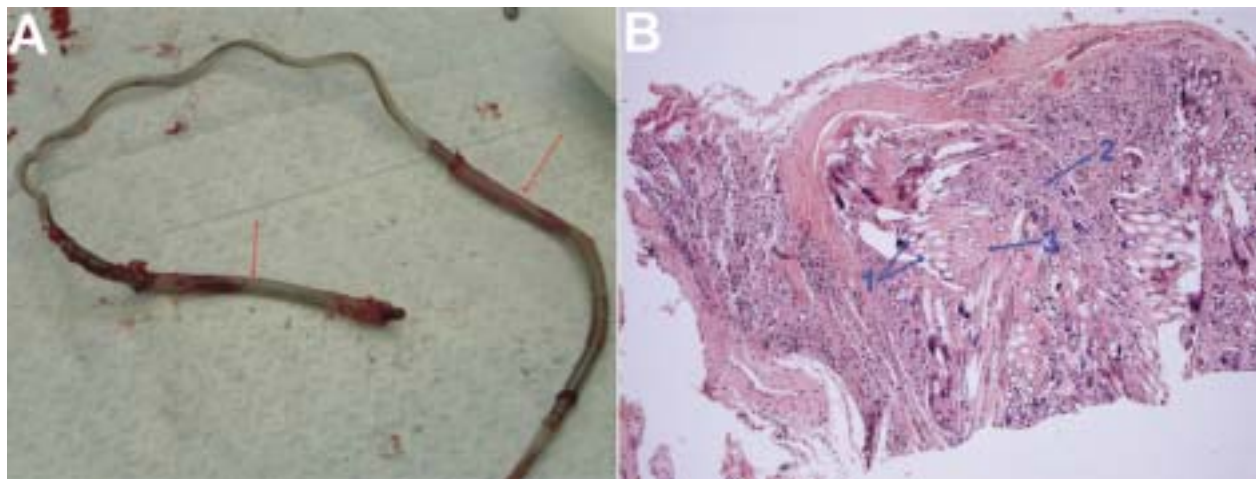


Figure 2. A. Intraoperative picture of the removed ICD lead with macroscopic tissue growth at the coil of the lead (arrows); **B.** Microscopic picture of the removed tissue and the ICD lead: connective tissue (arrow #3), inflamed tissue (arrow #2), empty spots after the ICD coil extraction (arrow #1)

particular group of patients, we utilised the individually modified techniques most frequently. The description of used techniques has been published previously and the techniques were referred as atypical techniques [20]. The removed leads were assessed macroscopically and tissue growth on the external layer of the ICD lead was present in particular in

the defibrillating coil region (Fig. 2A). The presence of collagen and inflammatory cells embedded into the grooves of the ICD lead was confirmed microscopically (Fig. 2B).

If the extraction was performed because of the inflammatory indication, the aim was to remove all leads currently present in the heart. In case of non-inflammatory indications,

Table 1. Age and gender, indications to transvenous lead extraction, number of leads present per patient in the entire study population and the two study groups

	PM patients	ICD patients	P
Number of patients	345 (89%)	79 (11%)	
Age [years]	65.7 ± 17.3	57.6 ± 16.1	< 0.0001
Gender (males)	206 (59.7%)	52 (65.8%)	0.043
Indications			
Non-infectious	185 (46.1%)	56 (70.9%)	0.0076
Infectious	160 (53.6%)	23 (29.1%)	0.0076
No. of extracted leads per patient	2.15 ± 0.85	1.80 ± 0.81	0.0009

we extracted the damaged, abandoned, displaced or unnecessary leads only.

All lead extraction procedures were performed under general anaesthesia (propofol) with monitoring all vital signs, in the operating room with cardiac surgery and anaesthesia backups.

Statistical analysis

The results are presented as means ± standard deviations (SD). We used χ^2 test to compare variables. We adopted a p value of < 0.05 as statistically significant.

RESULTS

There have been 764 intracardiac, ingrown leads removed in 424 patients between March of 2006 and March of 2010 (ranging from 1 to 6 leads per patient). The group of patients with PM lead extraction was significantly larger. The patients with PM and ICD differed significantly in respect to age and gender. The ICD patients were significantly younger and more often males. Compared to the PM group, the ICD patients had significantly less leads extracted (2.15 vs 1.8) and more often underwent the procedure due to the non-infectious indications (Table 1).

In the ICD group, there were 142 leads removed, of which 83 were ICD leads and 59 PM leads. Thus, 4 out of 79 patients had 2 ICD leads removed. The extracted ICD leads accounted for 11% of all 764 removed leads. The double coil ICD leads and these with an active fixation accounted for 74.7% and 51.8%, respectively. The three-fold higher prevalence of double-coil leads in our study accounts for our experience in performing procedures with leads of such structure.

The time from the implantation to the extraction was significantly shorter in the ICD group patients, in particular in isolated ICD leads ($p < 0.0001$) (Fig. 3). The majority of the ICD leads (80; 96.4%) were removed using a subclavian vein access (ICD pocket). In the remaining 3 (3.6%) patients in whom the procedure was complicated, there was a need to change the technique to femoral access in two patients, and to the subclavian access on the opposite site to the ICD pocket in one patient.

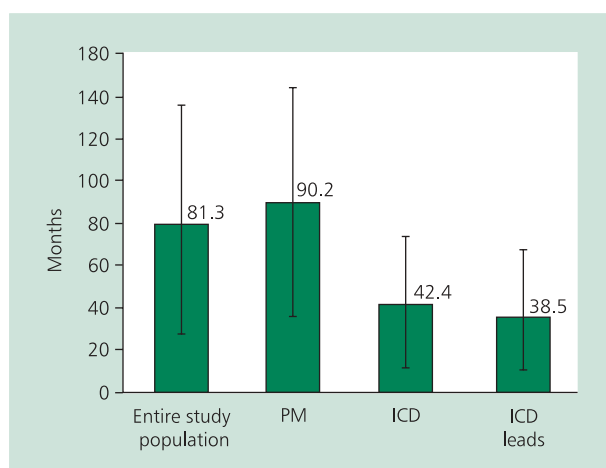


Figure 3. The mean time elapsing from the original implantation in the entire study population, the two study groups, and in the group of 83 ICD leads

The successful rate of the extraction procedure was high and significantly higher in the ICD patients. The difficulties differed among the study groups, and were more frequent in the PM patients (Table 2). The percentage of major complications in both groups did not differ, while minor complications were significantly more frequent in patients with removed ICD leads (Table 2).

The major complications were encountered in 6 patients (Table 2) of whom 5 experienced cardiac tamponade. Of the 5 patients with tamponade, 3 were treated with pericardiocentesis and the remaining 2 required surgical intervention. The 6th patient was diagnosed with hemothorax, however, the complication did not require surgery and the patient received blood transfusion only. During one of the open-heart surgery procedures, the coronary sinus rupture due to PM lead (not the ICD lead) extraction was identified as the cause of cardiac tamponade.

The minor complications in the ICD group occurred in 6 patients: hemothorax (2×), cardiac tamponade (1×), pulmonary embolism (1×), increased tricuspid valve regurgita-

Table 2. Comparison of technical difficulties, major and minor complications, success rate of lead extraction in the two study groups

	PM patients	ICD patients	P
Technical difficulties	59 (17.1%)	3 (3.8%)	0.0045
Major complications	4 (1.2%)	2 (2.5%)	0.6764
Minor complications	8 (2.3%)	6 (7.6%)	0.0436
Complete lead extraction	316 (91.6%)	78 (98.7%)	0.0467

tion (1 ×) and subclavian vein thrombosis (1 ×). All minor complications were treated pharmacologically with no need to proceed to surgical intervention or blood transfusion. There were no deaths during lead extraction procedures.

DISCUSSION

The transvenous leads extraction of 83 leads in 79 ICD patients, out of 764 leads removed in 424 patients, indicates higher success rate with less technical difficulties and comparable rates of major complications and higher rate of minor complications, compared to the PM patients. The successful radiological extraction was achieved using the HRS recommendations, and was associated with the entire lead removal [19]. The unsuccessful lead removal process was defined as partial radiological success when either the tip of the lead or its fragment was left inside, regardless clinical success. Because the ICD leads are composed of many single wires, they are stronger and more difficult to break, in particular in their end portion. In case of PM lead extraction, we sometimes observe on the chest x-ray that the end tip of the lead is left in the chamber wall.

The ICD extraction was associated less frequently with technical difficulties, such as: lead breakage or its dissection, lead's fragment thickening, missing part of the lead and pulmonary vessel embolisation, thickening of the connective tissue binding the two leads, dislocation of the active lead or breakage of the Byrd dilator. The technical difficulties prolonged the procedure, required other instruments usage or access site to be changed. The ICD leads were less susceptible to the damage during the traction, regardless of their age.

The leads extraction procedure using the polypropylene telescopic Byrd dilators allows to assess the degree and strength of the connective tissue wrapped around the lead and the vessel or the chamber wall. It is important to emphasize, that the most time-consuming stage of the ICD lead extraction procedure was the phase of dis-attaching the proximal coil of the lead from the surrounding tissues which were the thickest at this location. Preparation of the distal part of the lead was significantly less time consuming.

Similarly to our study, Saad et al. [10] focused on the leads extraction, but in contrast to our work, they used laser enhancement technique. The authors removed 161 ICD leads between 1991 and 1999 and 368 PM leads between 1996

and 1998, and achieved comparable success rate between the study groups. The mean time elapsing from the ICD implantation was approximately 6 months shorter when compared to our study and, significantly, 38 ICD leads were extracted via simple traction — underscoring less extensive connective tissue growth between the leads and cardiovascular system walls. However, there was no information on how many double coil leads were removed. Another difference between our study and the discussed article were the indications for lead extraction — significantly higher rate of infectious indications in both groups, ICD and PM, in the study by Saad et al. [10], when compared to ours. Based on the records of patients enrolled into our database between 2006–2010, the ICD leads were extracted mainly due to non-infectious indications. The above fact proves the lower reliability of recently used in Poland certain models of ICD leads. There are also some similarities between the article by Saad et al. [10] and our study. The time elapsing from the ICD implantation was significantly shorter than the time from the PM implantation. Moreover, the ICD systems were less complex compared to PM (the ICD systems had fewer leads per patient).

The other studies described the results of ICD endocardial leads extraction based on various number of patients, starting from teens [5, 9, 12], through less than a hundred [4, 6, 8], to a couple hundred patients [7, 15]. There was no analysis in respect to the degree of difficulty of removing the ICD leads compared to the PM leads. Furthermore, the available studies did not analyse the structural features of leads (coils) or the mean time elapsing from ICD implantation [6–9, 12, 15]. Kantharia et al. [4] reported on 11 out of 47 removed ICD leads with the mean time elapsing from ICD implantation shorter than 6 months (of which 3 were less than 1 month-old).

Most likely the longer mean time elapsing from PM implantation played an important role in our observation. The time the lead stayed in the cardio-vascular system was proven by Byrd et al. [14] as a risk factor associated with two fold increase of worse outcomes of leads extraction every 3 years from the implantation. It has been documented by the histopathology examination of the hearts with ICD leads, that there is a significant tissue growth in the chamber wall of the heart close to the implanted coils [11]. We had similar observations during our study. The

ICD leads extracted in our center had, in majority, the unfavorable double-coil structure, which was highlighted in the literature [1, 13]. This may explain comparable to the PM leads major complications rate, and increased rate of minor complications in the ICD patients, regardless of the shorter mean time elapsing from ICD implantation.

CONCLUSIONS

1. Extraction of ICD and PM leads is associated with a similar risk for developing major complications, however minor complications rate is higher during extraction of ICD leads. It is, however, characterised by a lower degree of technical difficulties and a greater number of successfully removed leads.
2. A larger number of double-coil leads may be the cause of increased complications rate despite a shorter time period elapsing from ICD implantation.
3. A probable cause of complications during ICD lead extraction is the pronounced growth of the connective tissue around the coils. However, further studies are required to clarify this phenomenon.
4. The success rate of ICD leads extraction using our own surgical technique is similar to that reported by other investigators using laser enhanced systems.

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Czy przezrylne usuwanie wrośniętych elektrod kardiowertująco-defibrylujących jest bardziej ryzykowne niż elektrod rozrusznikowych?

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Streszczenie

Wstęp: Wprowadzenie na przełomie lat 80. i 90. ubiegłego stulecia elektrod endokawitarnych do terapii kardiowertującej-defibrylującej (ICD) zwiększyło lawinowo liczbę tych układów. Konstrukcje elektrod ICD, techniki implantacji, a następnie usuwania są adaptowane z doświadczeń z elektrodami do przewlekłej stymulacji serca (PM). Elektrody ICD różnią się jednak od PM zarówno rozmiarem (średnica), jak i konstrukcją. Wykazano także wysoki odsetek uszkodzeń tych elektrod, z czego wynika zwiększone zapotrzebowanie na zabiegi usuwania elektrod ICD w porównaniu z elektrodami PM. Dotychczasowe doniesienia na temat trudności i bezpieczeństwa przezrylnego usuwania elektrod ICD w porównaniu z elektrodami PM dostarczają różnych informacji.

Cel: Celem pracy było porównanie skuteczności i ryzyka zabiegów usuwania elektrod ICD oraz elektrod PM w materiale własnym.

Metody: Retrospektywnej analizie poddano dane z istniejącej od 4 lat bazy informacji o zabiegach przezrylnych usuwania elektrod endokawitarnych, obejmującej 424 pacjentów, u których usunięto 764 elektrod. Porównano trudności techniczne i powikłania występujące podczas przezrylnego usuwania elektrod PM oraz elektrod ICD. W tym celu wydzielono dwie podgrupy: I — pacjentów, u których wśród usuwanych elektrod była co najmniej 1 elektroda ICD, II — pozostałych pacjentów, u których usuwano jedynie elektrody PM. Zasadniczym kryterium naboru do badania była konieczność użycia podczas procedury przezrylnego usuwania elektrod urządzeń mechanicznych. Elektrody z dostępnym końcem w loży stymulatora/kardiowertera usuwano, posługując się urządzeniami mechanicznymi — dylatorami firmy Cook. Elektrody z końcem przemieszczonym do układu sercowo-naczyniowego usuwano z dostępu z żyły udowej.

Wyniki: Od marca 2006 do marca 2010 roku usunięto 764 wrośnięte elektrody wewnątrzsercowe u 424 pacjentów (1–6 elektrod na 1 chorego). Podgrupa pacjentów, u których usunięto tylko elektrody PM, była znacznie liczniejsza. Osoby z układami PM i ICD różniły się istotnie wiekiem i płcią. Pacjenci z grupy ICD byli znacznie młodsi, z dominacją płci męskiej. U chorych z układami ICD usunięto istotnie mniej elektrod w porównaniu z pacjentami z układami PM (1,8 v. 2,15) oraz częściej kierowano ich na zabiegi usuwania z powodów nieinfekcyjnych. Czas, który upłynął od momentu implantacji do zabiegu usuwania elektrod, był istotnie krótszy w przypadku wszystkich elektrod w grupie chorych z układami ICD, ze szczególną istotnością dla wyizolowanej grupy elektrod ICD. Skuteczność wykonanych zabiegów była wysoka, zwłaszcza w grupie chorych z układami ICD. Trudności techniczne odróżniły podgrupy; wystąpiły istotnie częściej u pacjentów z układami PM. Odsetek dużych powikłań nie różnił się w obu podgrupach, natomiast małe powikłania były istotnie częstsze u chorych z usuwanymi elektrodami ICD. Nie odnotowano zgonów w związku z procedurą usuwania elektrod.

Wnioski: 1. Usuwanie elektrod ICD jest porównywalne pod względem ryzyka dużych powikłań z usuwaniem elektrod PM przy zwiększonym ryzyku małych powikłań. Cechuje się natomiast mniejszym stopniem trudności technicznych i większą liczbą skutecznie usuniętych elektrod. 2. W badanej populacji przewaga elektrod dwuzwojowych może być przyczyną powikłań tych zabiegów, mimo krótszego czasu przebywania elektrod ICD w układzie sercowo-naczyniowym. 3. Prawdopodobną przyczyną powikłań przy usuwaniu elektrod ICD jest nasilony rozrost tkanki łącznej wokół ich zwojów. 4. Skuteczność zabiegów usuwania elektrod ICD z zastosowaniem własnych technik operacyjnych jest porównywalna z danymi z ośrodka stosującego laser.

Słowa kluczowe: przezrylne usuwanie elektrod, skuteczność usuwania elektrod, powikłania usuwania elektrod

Kardiologia 2010; 68, 8: 884–890

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Praca wpłynęła: 01.03.2010 r. Zaakceptowana do druku: 26.05.2010 r.