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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Safety and effectiveness of transvenous extraction of pacemaker and implantable cardioverter-defibrillator leads in patients under or over 80 years of age

Maciej Kempa[1], Szymon Budrejko[1], Marta Piepiorka[2], Jan Rogowski[3], Grzegorz Raczak[1], Dariusz Kozłowski[1]

[1]Department of Cardiology and Electrotherapy, Medical University of Gdansk, Poland

[2]Department of Cardiology, State Hospital, Gdynia, Poland

[3]Department of Cardiac Surgery, Medical University of Gdansk, Poland

Abstract

Background: Progressive aging of the population and the increasing number of complications of electrotherapy procedures are the main reasons of a remarkable increase in the number of transvenous extraction procedures of pacemaker (PM) and implantable cardioverter-defibrillator (ICD) leads in the elderly patients.

Aim: To assess the safety and effectiveness of such procedures in patients under or over 80 years of age. The study included all patients who underwent transvenous PM/ICD lead extraction in 2003–2011.

Methods: All patients were divided into two groups based on their age at the time of the procedure: group A included patients under 80 years of age (134 patients; 97 male, 37 female) and group B included patients over 80 years of age (26 patients; 16 male, 10 female).

Results: No differences were found between the two groups in terms of gender proportions, comorbidities, New York Heart Association (NYHA) functional class, and left ventricular ejection fraction. In total, 220 leads were removed (group A: 63 defibrillating and 122 pacing leads, group B: 2 defibrillating and 33 pacing leads). The most common indication for the lead removal procedure in both groups was infection, either in the form of PM/ICD pocket infection (46 and 13 cases, respectively) or infective endocarditis (18 and 2 cases, respectively). Procedural outcomes in both groups were not statistically different in terms of the final outcome or complication rates. The results in groups A and B were as follows: complete success 95.5% vs. 96.2%, respectively, clinical success 3% vs. 3.8%, respectively, and failure 1.5% vs. 0%, respectively, with no significant differences between the groups. No major complications of the procedure were observed in either of the groups.

Conclusions: Our findings indicate that transvenous extraction of PM/ICD leads appears to be a safe and effective procedure both in relatively younger patients and in patients over 80 years of age.

Key words: transvenous lead extraction, elderly

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INTRODUCTION

A continuous increase in availability of modern invasive methods to treat cardiac arrhythmia, widening indications for such treatment, and population aging all result in an increasing number of complications of electrotherapy occurring in the elderly. In such circumstances, many of these patients require removal of a previously implanted cardiac pacemaker (PM) or implanted cardioverter-defibrillator (ICD). Literature data on the outcomes of transvenous PM/ICD lead extraction procedures are limited. The aim of this study was to compared safety and effectiveness of such treatment in patients under or over 80 years of age.

Address for correspondence:
Maciej Kempa, MD, Department of Cardiology and Electrotherapy, Medical University of Gdańsk, ul. Dębinki 7, 80–952 Gdańsk, Poland, tel: + 48 58 349 39 10, e-mail: kempa@gumed.edu.pl

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Table 1. Indications for transvenous pacemaker (PM)/implantable cardioverter-defibrillator (ICD) lead removal according to the 2009 Heart Rhythm Society expert consensus

Infection	
Class I	Complete PM/ICD device and lead removal is recommended in case of endocarditis, sepsis, PM/ICD pocket infection, occult Gram-positive bacteriemia.
Class IIa	Complete PM/ICD device and lead removal is reasonable in case of occult Gram-negative bacteriemia.
Class III	Complete PM/ICD device and lead removal is not recommended in case of a superficial or incisional infection, with no relationship to PM/ICD, and in case of chronic bacteriemia due to a source unrelated to PM/ICD.
Thrombosis or venous stenosis	
Class I	Lead removal is recommended in case of thromboembolic events associated with thrombus on a lead, bilateral subclavian vein or superior vena cava thrombosis when implantation of an additional lead is required, superior vena cava syndrome, and venous occlusion when implantation of an additional lead is required but there is a contraindication to use venous access route on the contralateral side of the chest.
Class IIa	Lead removal is reasonable in case of venous thrombosis when implantation of an additional lead is required and there is no contraindication to use venous access route on the contralateral side of the chest.
Functional leads	
Class I	Lead removal is recommended when it induces life-threatening arrhythmias, may pose (due to its design or failure) an immediate threat to the patient if left in place, interferes with the operation of an implanted cardiac device, or interferes with the treatment of a malignancy.
Class IIb	Lead removal may be considered when it may interfere with the operation of an implanted cardiac device, may pose (due to its design or failure) a future threat to the patient if left in place, interferes with necessary imaging, or it has been abandoned and its function is performed by another lead.
Class III	Abandoned lead removal is not indicated if life expectancy is < 1 year. Lead removal is not recommended solely due to anomalous location outside the cardiovascular system (i.e., perforation).
Non functional leads	
Class I	Lead removal is recommended when it induces life-threatening arrhythmias, may pose (due to its design or failure) an immediate threat to the patient if left in place, interferes with the operation of an implanted cardiac device, or interferes with the treatment of a malignancy.
Class IIa	Lead removal is reasonable when it may pose (due to its design or failure) a future threat to the patient if left in place, interferes with necessary imaging, or it would be necessary to implant more than 4 leads on one side of the chest or more than 5 leads through the superior vena cava.
Class IIb	Lead removal may be considered during implantation of a new PM/ICD device or in order to permit implantation of an MRI conditional system.
Class III	Abandoned lead removal is not indicated if life expectancy is < 1 year. Lead removal is not recommended solely due to anomalous location outside the cardiovascular system (i.e., perforation).

METHODS

We analysed electrophysiological laboratory data regarding implantation, replacement, and removal of PM/ICD leads in 2003–2011. For further analysis, we selected only those patients who underwent transvenous lead removal procedures. Due to a recent increase in the number of such procedures performed urgently due to early implantation complications such as cardiac perforation or early PM infection, we also analysed patients who were treated less than one year after the implantation.

Indications for lead removal were categorised using the classification published in the 2009 Heart Rhythm Society (HRS) expert consensus (Table 1) [1]. Procedural outcome was defined as a complete success when it was possible to remove the entire lead, including all its components, from the vascular bed. A clinical success was defined as an outcome when it was possible to remove most of the lead, leaving only its small fragment that did not adversely affect overall procedure objective and did not increase the risk of perforation, embolism, or infection. All procedures that did not result in a complete or clinical success as defined above were considered failure. Complications were categorised as major (death, cardiovascular injury requiring invasive treatment, pulmonary embolism requiring invasive treatment, stroke, complications of general anaesthesia leading to prolonged hospitalisation) or minor (pericardial effusion or pleural haematoma not requir-

Table 2. Clinical characteristics of patients in group A (patients under 80 years of age) and group B (patients over 80 years of age)

	Group A	Group B	P
Number of patients	134	26	–
Age [years]	19–79 (mean 60.4 ± 14.3)	80–90 (mean 83.7 ± 3.2)	< 0.001
Women/men	37 (27.6%)/97 (72.4%)	10 (38.5%)/16 (61.5%)	NS
Concomitant disease:			
Coronary artery disease	60 (44.7%)	12 (47.2%)	NS
Hypertension	61 (45.5%)	16 (61.5%)	NS
Renal failure	21 (15.7%)	4 (15.4%)	NS
Diabetes	37 (27.6%)	11 (42.3%)	NS
NYHA class (mean)	1.5	1.5	NS
Left ventricular ejection fraction [%]	15–65 (mean 40 ± 14.5)	25–60 (mean 43.6 ± 9.6)	NS

ing drainage, pocket haematoma requiring decompression, venous thrombosis, pulmonary embolism, pneumothorax, blood loss requiring transfusion) [1].

Lead removal procedure

Lead removal procedure was performed in the operating room of the electrophysiology laboratory. Patient preparation included obtaining a consent, basic laboratory blood tests, blood and wound cultures (if indicated), chest X-ray to evaluate lead location, and echocardiography (if necessary, including transoesophageal echocardiography) to exclude lead thrombosis that would preclude transvenous lead removal. At least 2 units of cross-matched blood were provided as a backup for each procedure to be used in the management of possible complications. Our cardiac surgical team was informed about the planned procedure schedule. High-risk procedures were performed directly in the cardiac surgical operating room under general anaesthesia, with backup surgical team ready to perform emergency thoracotomy and a rescue surgical procedure, including under cardiopulmonary bypass if needed.

Routine procedures were performed under local anaesthesia, or in sedated patients with an option to use general anaesthesia if needed. Our basic approach was direct traction through the subclavian vein, in some cases with the use of a locking stylet (Liberator, Cook) and telescopic teflon or polyurethane sheaths that allow freeing the lead from adhesions in the cardiovascular system. If necessary, femoral vein access route was used with the use of a femoral work station. Since 2011, we were also able to use a cutting sheath system (Evolution, Cook).

Statistical analysis

Patient data were collected in a MS Excel 2003 database. All statistical analyses were performed using a Statistica 10 PL package (StatSoft) licensed to the Medical University of Gdansk. Descriptive statistics included, as needed, numbers and percentages, mean values and standard deviations, and medians and interquartile ranges. Normal distribution of continuous variables in the study groups was verified using the Shapiro-Wilk W test. As continuous variables evaluated in this study proved to have a non-normal distribution, the groups were compared using the Mann-Whitney U test. Percentage data were compared using a significance test for proportions. For all calculations, the null hypothesis rejection threshold was $\alpha = 0.05$. Calculated p values less than 0.05 were given as $p \leq 0.05$, $p \leq 0.01$, or $p \leq 0.001$.

RESULTS

Overall, we analysed data collected in 4362 patients treated in our electrophysiology laboratory in the study period. Among these, 160 patients underwent transvenous lead removal. The patients were divided into two groups: group A included patients under 80 years of age (134 patients; 97 men, 37 women) and group B included patients over 80 years of age (26 patients; 16 men, 10 women). We compared clinical characteristics of the patients, including concomitant disease, indications for lead removal, lead age, and procedural outcomes including possible complications. These data are shown in Tables 2 and 3. The two groups did not differ significantly in regard to gender proportions, concomitant disease, New York Heart Association (NYHA) functional class, and left ventricular ejection fraction. Overall, 220 leads were removed, including 155 pacing leads and 65 defibrillating leads. One lead was removed in 106 patients, two leads in 49 patients, three leads in 4 patients, and one patient had 4 leads removed. The mean time from lead implantation to its removal was 39.9 months (median 25, range 0.1–336) in group A and 55.2 months (median 48, range 1–156) in group B ($p < 0.05$). Among 155 pacing leads, 111 were older than one year, and 57 of 65 defibrillating leads were older than 6 months. Of 65 defibrillating leads, 63 were removed in patients in group A. The most common indication for lead removal in both groups was infection, either in the form of PM/ICD pocket infection or infective endocarditis. In group

Table 3. Indications for transvenous lead removal in group A (patients under 80 years of age) and group B (patients over 80 years of age), categorised based on the 2009 Heart Rhythm Society expert consensus, and data on the type and location of removed leads

	Group A	Group B	P
Indications			
Endocarditis (class I)	18 (13.4%)	2 (7.7%)	NS
Pocket infection (class I)	46 (34.3%)	13 (50%)	< 0.05
Venous thrombosis (class IIa)	2 (1.5%)	0 (0%)	NS
Lead failure (class IIb)	56 (41.8%)	6 (23.1%)	NS; 0.054
Removal of redundant leads (class IIb)	8 (6%)	5 (19.2%)	< 0.05
Right ventricle perforation (class III)	4 (3%)	0 (0%)	NS
Lead type			
Defibrillating	63 (47%)	2 (7.7%)	< 0.001
Pacing atrial	65 (48.5%)	12 (46.2%)	NS
Pacing ventricular	53 (39.6%)	21 (80.8%)	< 0.001
Pacing coronary sinus	4 (3%)	0 (0%)	NS
Lead age [months]	0.1–336 (mean 39.9 ± 44)	1–156 (mean 55.2 ± 43.6)	< 0.05

A, leads were more frequently removed due to their damage (41.8% vs. 23.1%, p = 0.054), while in group B they were more frequently redundant (6% vs. 19.2%, p < 0.05). Removal failure occurred in 2 patients in group A. In the first case, an excess length of the lead in the right subclavian vein resulted in formation of a loop, with lead translocation and adhesion within the internal jugular vein, which precluded insertion of a locking stylet and the use of telescopic sheaths. This patient was thus treated surgically without success and he died due to sepsis. In the other case, incomplete lead removal resulted in its small fragment (a 1-cm tip detached at the level of the pacing ring) left in the subclavian vein. The indication for lead removal in this case was PM pocket infection. Two years after the procedure, the patient has a dual-chamber ICD implanted on the same side of the chest. During 1-year follow up, no infection recurrence was observed. Clinical success was noted in 4 cases in group A. In group B, all procedures were successful, with complete success in 25 cases and clinical success in 1 female patient referred for atrial lead removal due to its complete detachment and translocation to cardiac chambers. We were unable to recover the lead completely, and its small, about 1 cm long fragment remained in the atrial wall. Six months later, the patient successfully underwent implantation of a dual-chamber ICD.

No major complications were noted in either group. Minor complications in group A included pocket haematoma in 5 patients, small pericardial effusion (with no need for drainage) in 2 patients, and pneumothorax in 1 patient. Among patients over 80, a pathological amount of pericardial effusion that required no intervention was found in 1 patient. Outcomes and complications in the two groups are shown in Table 4.

Table 4. Outcomes and complications in group A (patients under 80 years of age) and group B (patients over 80 years of age)

	Group A	Group B	P
Complete success	128 (95.5%)	25 (96.2%)	NS
Clinical success	4 (3%)	1 (3.8%)	NS
Failure	2 (1.5%)	0 (0%)	NS
Minor complications:			
Haematoma	5 (3.7%)	0 (0%)	NS
Pericardial effusion	2 (1.5%)	1 (3.8%)	NS
Pneumothorax	1 (0.8%)	0 (0%)	NS
Major complications	0 (0%)	0 (0%)	NS
Need to use femoral access	3 (2.2%)	1 (3.8%)	NS

DISCUSSION

While the relationship between patient age and the risk of PM/ICD implantation complications has been studied, literature data regarding the risk of lead removal procedures in the elderly are very limited. Few authors who analysed this issue suggested that safety and effectiveness of these procedures were comparable to that in younger patients, but the mean age of their patients was much lower than in our sample [2, 3]. These authors indicated that important risk factors included not the patient age but rather lead age, lead type, and operator experience. Only Rodriguez et al. [4] studied very elderly patients who were over 80 years of age. Those 118 patients were treated with the use of a laser lead removal system and despite their advanced age (mean 85 ± 3.8 years) they did not experience complications more frequently than younger patients. Effectiveness of these procedures in both age groups

was also comparable. Similar results were obtained in our study. The procedure resulted in a complete success in nearly all octogenarians with no major complications. Clinical success was noted in only 1 patient in this group, and a small amount of pericardial effusion that required no intervention was seen also in only 1 patient. This was the only complication noted in the group of patients above 80 years of age. Interestingly, complication rate was not increased despite the fact that the mean lead age in this patient group was 4 years (median 48 months compared to 24 months in group A, $p < 0.05$). It should also be noted, however, that only 2 patients in this group has a defibrillating lead removed. This might have contributed to the low complication rate observed, as experts believe that pacing lead removal is easier and safer compared to defibrillating lead removal [5]. In our study, we found some differences in indications for lead removal between the two patient groups. Among younger patients, a trend ($p = 0,054$) towards more frequent lead failure requiring subsequent lead removal was seen, particularly regarding defibrillating leads. This is probably related to the fact that subjects undergoing ICD implantation are on average younger than those undergoing PM implantation [6]. In contrast, lead removal procedure in older patients was more frequently undertaken due to the presence of redundant leads when the pacing mode was changed or a previously implanted PM was upgraded to an ICD. In these patients, PM/ICD pocket infection was also a more common indication for lead removal.

Another issue that deserves a comment is lead age. According to the HRS expert consensus, lead extraction refers to removal of a lead that has been implanted for more a year, or lead removal using specialised equipment such as a locking stylet or telescopic sheaths. Younger leads removed by simple traction are referred to as explanted. We analysed all subsequent patients who underwent lead removal regardless of lead age. This has resulted in a shorter mean time from lead implantation to removal compared to other reports [5]. It is also possible that the difference in the age of removed leads reflects different characteristics of patients referred to the most experienced centres in Poland (such as centres in Lublin and Cracow). Thus, the most difficult patients may be expected to be referred to such centres, so our analysis likely included selected difficult cases, including those patients in whom previous attempts to remove a lead in another centre failed. Our analysis to include all consecutive patients resulted from the fact that the number of very early complications of electrotherapy procedures had increased in the recent years, including both acute and subacute cardiac perforations and early infections. In these settings, lead removal procedures, although often technically relative simple, are associated with a high risk of a need for cardiac surgical intervention, and according to guidelines some of these situations (cardiac perforation) constitute a priori indications for cardiac surgical treatment. In our sample, four such procedures were successfully performed using the transvenous approach and thus avoiding thoracotomy. It should be stressed that all procedures, and not only the high-risk ones, were preceded by appropriate logistic measures that included careful patient preparation, correction of any water and electrolyte imbalances, instituting antibiotic therapy (prophylactic in non-infective cases, and culture-guided in infections), and preprocedural echocardiographic examination to reduce the risk of embolic complications by excluding the presence of large bacterial vegetations or thrombi on a lead. The interventional team was always informed about the type and age of leads. The procedure was also preceded by radiological imaging. One of the most important aspects of preprocedural preparation was providing cardiac surgical backup. If the procedure was undertaken in the electrophysiological laboratory, this included beginning the procedure at such time of the day that allowed immediate patient transfer to the cardiac surgical operating room if needed, and assigning a person to coordinate actions of the cardiac surgical team. High-risk procedures were performed directly in the cardiac surgical operating room, in general anaesthesia and under full preparation to perform immediate thoracotomy if needed. During the procedure, also the cardiac surgical team remained fully prepared for any necessary surgical intervention. Such logistic measures undertaken as a preparation for lead removal procedures are recommended both in the 2009 HRS expert consensus ready and by Polish experts [7, 8].

Limitations of the study

This was a retrospective study that included a relatively small patient sample which is related the fact that we summarised a single-centre experience only. However, this might have also had some advantages as well, as nearly all patients were treated by the same operating team, and we analysed consecutive patients without any preselection of the collected data.

CONCLUSIONS

Our findings indicate that transvenous extraction of PM/ICD leads appears to be a safe and effective procedure both in relatively younger patients and in patients over 80 years of age. Outcomes in these two groups did not differ significantly. Such procedures should be performed in reference centres by experienced electrophysiology teams with full cardiac surgical backup, as potential complications, although rare, may require emergency rescue surgery, also including the use of cardiopulmonary bypass.

Conflict of interest: *none declared*

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Bezpieczeństwo i skuteczność zabiegów przezżylnego usuwania elektrod stymulujących i defibrylujących wśród pacjentów przed i po 80. rż.

Maciej Kempa[1], Szymon Budrejko[1], Marta Piepiorka[2], Jan Rogowski[3], Grzegorz Raczak[1], Dariusz Kozłowski[1]

[1]Klinika Kardiologii i Elektroterapii Serca. Gdański Uniwersytet Medyczny, Gdańsk
[2]Oddział Kardiologii, Szpital Miejski, Gdynia
[3]Klinika Kardiochirurgii, Gdański Uniwersytet Medyczny, Gdańsk

Streszczenie

Wstęp: Rosnąca liczba powikłań elektroterapii oraz starzenie się populacji powodują, że konieczność wykonywania zabiegów przezżylnego usunięcia elektrod stymulatorów (PM) i kardiowerterów-defibrylatorów serca (ICD) wśród chorych w podeszłym wieku jest coraz większa.

Cel: Celem analizy była ocena bezpieczeństwa i skuteczności wykonywania obu tych procedur w dwóch grupach wiekowych: u osób przed i po 80. rż.

Metody: Badaniem objęto kolejnych pacjentów poddanych zabiegowi przezżylnego usuwania elektrod PM/ICD w latach 2003–2011, podzielonych na dwie grupy w zależności od wieku w chwili zabiegu: grupa A — przed ukończeniem 80. rż. (134 chorych; 97 mężczyzn, 37 kobiet) i grupa B — po 80. rż. (26 chorych; 16 mężczyzn, 10 kobiet).

Wyniki: Grupy nie różniły się istotnie pod względem płci, chorób współistniejących, klasy wydolności ocenionej w skali NYHA i wartości frakcji wyrzutowej lewej komory. Łącznie usunięto 220 elektrod (grupa A: 63 defibrylujące i 122 stymulujące; grupa B: 2 defibrylujące i 33 stymulujące). Głównym wskazaniem do zabiegu w obu grupach były infekcje przebiegające jako zakażenie loży PM/ICD (odpowiednio 46 i 13 przypadków) lub dające obraz infekcyjnego zapalenia wsierdzia (odpowiednio 18 i 2 przypadki). Wyniki zabiegów przeprowadzonych w grupach A i B to, odpowiednio: sukces całkowity 95,5% *vs*. 96,2%, sukces kliniczny 3% *vs*. 3,8%, niepowodzenie 1,5% *vs*. 0% i nie różniły się statystycznie znamiennie. W obu grupach nie rejestrowano dużych powikłań przeprowadzonego zabiegu.

Wnioski: Wyniki analizy wskazują, że zabieg przezżylnego usuwania elektrod PM i ICD jest procedurą bezpieczną i może być skutecznie wykonywany zarówno u osób młodych, jak i wśród pacjentów po 80. rż.

Słowa kluczowe: przezżylne usuwanie elektrod, wiek podeszły

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Adres do korespondencji:
dr n. med. Maciej Kempa, Klinika Kardiologii i Elektroterapii Serca, Gdański Uniwersytet Medyczny, ul. Dębinki 7, 80–952 Gdańsk, tel: +48 58 349 39 10, e-mail: kempa@gumed.edu.pl
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