

# Occurrence and extraction of implantable cardioverter-defibrillator leads with conductor externalization

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## Abstract

**Background:** *The increasing number of patients with implantable cardioverter-defibrillators (ICD) contributes to the rising number of patients qualifying for a transvenous lead extraction (TLE) due to infection, vascular or lead failure related indications. The purpose of this study was to perform a retrospective analysis of the occurrence of conductor externalization in TLE patients and to assess the success rate in the extraction of these leads.*

**Methods:** *TLE procedure was performed between 2012 and 2014 of 428 electrodes in 259 patients. Out of these, 143 (33.4%) leads in 138 (52.9%) patients were ICD leads. The indications for the TLE in ICD patients were: infection in 37 patients, lead failure in 84 patients, and others in 17 patients. Conductor externalization was observed in 8 ICD leads (5.6%) in 8 (5.8%) patients. The mean dwelling time for externalized leads was 87.9 (55 to 132) months compared to 60.1 (3 to 246) months of the remaining 135 ICD leads ( $p = 0.0329$ ). All externalized leads were successfully and completely extracted using device traction, mechanical telescopic sheaths and/or autorotational cutting sheaths. No complications of lead extraction procedures were observed in 8 patients with externalization.*

**Results:** *Patients with lead externalization were often in a better New York Heart Association functional class (I or II) compared to those in the rest of the study group ( $p = 0.0212$ ).*

**Conclusions:** *Conductor externalization is a rare finding in patients undergoing TLE. This occurs with different manufacturers and lead types. In this complication transvenous lead extraction with the mechanical extraction tools can be safely performed. (Cardiol J 2018; 25, 2: 221–228)*

**Key words:** lead extraction, defibrillation leads, conductor externalization

## Introduction

Currently, patients are more often and more eagerly qualified for transvenous lead extraction (TLE) procedures because of their high effective-

ness and low complication rate [1, 2]. Moreover, there is a growing number of patients with implantable cardioverter-defibrillator (ICD) leads that need to be extracted mostly due to non-infectious reasons [3]. Each particular lead element (conduc-

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**Table 1.** Clinical characteristics of patients with and without conductor externalization in implantable cardioverter-defibrillators leads (number of patients: 138).

	Conductors' non-externalized (n = 130)	Conductors' externalized (n = 8)	P
Patient age [years]	57.7 ± 14.6	53.8 ± 20.0	NS
Sex (male)	98 (75.4%)	6 (75%)	NS
NYHA class during surgery:			0.0212
I and II	74 (57%)	8 (100%)	
III and IV	56 (43%)	0 (0%)	
Main diagnosis:			NS
Coronary artery disease	62 (47.7%)	4 (50%)	
Dilated cardiomyopathy	36 (27.6%)	0 (0%)	
Hypertrophic cardiomyopathy	14 (10.9%)	3 (37.5%)	
Other diagnosis	18 (13.8%)	1(12.5%)	
Indication for extraction:			
Infection	37 (28.5%)	0 (0%)	NS
Lead failure	76 (58.4%)	8 (100%)	0.0210
Other indications	17 (13.1%)	0 (0%)	NS

NYHA — New York Heart Association; Other diagnosis: idiopathic ventricular fibrillation, long QT syndrome, arrhythmogenic right ventricular cardiomyopathy, catecholaminergic polymorphic ventricular tachycardia, idiopathic ventricular tachycardia, Danon disease, congenital and acquired heart defect

tors, insulation as well as the device connectors) is prone to failure [4]. The specific type of ICD lead damage is the externalization of internal conductor. An externalization of inner conductors seems possible in each lead with multi-tunnel construction, however, its occurrence is more likely in certain types of leads. It depends not only on the material type of outerhigh-voltage cables, construction and localization of the inner tunnels in the lead but also on the tension occurring on the lead [5].

The purpose of the study was to perform a retrospective analysis of the occurrence of conductor externalization among patients undergoing transvenous lead extraction procedure. Extraction success rate of these leads was also analyzed.

The project was approved by the Bioethics Committee of Institute of Cardiology and complies with the Declaration of Helsinki.

### Methods

In years 2012–2014, the procedure of TLE was performed in 259 patients at the Institute of Cardiology in Warsaw. A total of 428 leads were extracted, out of which 143 (33.4%) in 138 (52.9%) patients were defibrillator leads. The indications for extraction in ICD patients were: a device-related infection in 37 patients and lead failure in 84 patients. Other indications including late perforation (4 patients), occlusion of the venous system with the aim of regaining venous access (7 patients) or lead dislocation (6 patients) were also observed. The lead failure was defined as an electric failure with noise leading to inappropriate shocks, as well as changes in the lead threshold, impedance, and/or sensing parameters. Clinical and device information especially concerning defibrillator leads externalization were obtained from our database of TLE procedures. Additional data were retrieved from clinical records. General demographic data was also collected. Clinical characteristics of the study group is shown in Table 1.

Pacing malfunctions were observed in 7 (5.1%) patients with ICD lead failure and high-voltage circuit malfunctions were noted in 6 (4.3%) patients. 71 (51.4%) patients, including all with externalizations, were diagnosed with both pacing and sensing malfunctions including an inappropriate detection of ventricular arrhythmias but without notable high-voltage circuit malfunction.

The routine management before the TLE procedure contained 2-dimensional radiological evaluation or fluoroscopic evaluation aiming to identify all implanted leads, their fixation mode, localization and integrity. Cine fluoroscopy was performed in right anterior oblique, posteroanterior and left anterior oblique projections. Lead conductor externalization was defined as the ap-

pearance of conductors outside the lead body on fluoroscopy or X-ray picture in any of the views. Such radiologic evaluation allowed proper detection of externalizations in defibrillator leads in 8 patients (Fig. 1).

Each lead extraction procedure performed was due to non-infectious indications and was combined with concurrent implantation of a new system, except for 1 patient who had thoracotomy. In the case of infectious indications, the implantation of a new system was postponed until infection was eliminated.

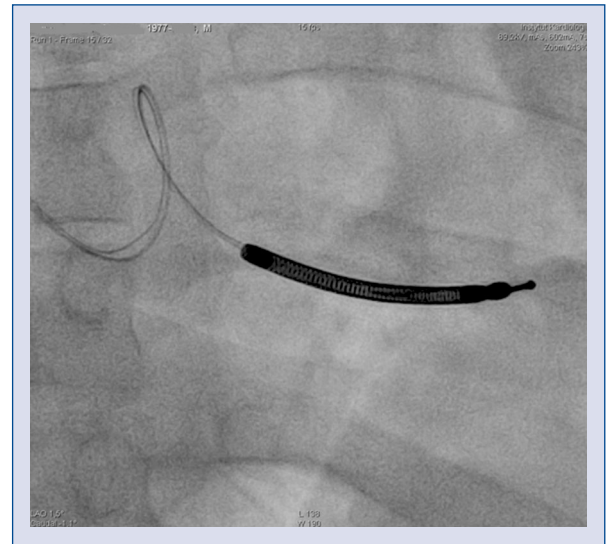
Due to the complexity and possible complications the procedures were carried out in hybrid operating room conditions in order to provide complete cardiothoracic backup as well as general anesthesia safety. The extractions were performed under fluoroscopy.

Lead extraction techniques were introduced gradually, starting from the less invasive to the more advanced, that is from a simple traction through device traction and, finally with the use of mechanical systems. Radiological and clinical success of the procedure was defined as in the literature [1].

Device traction was used most frequently. It was performed with the use of steel or polypropylene mechanical telescopic sheaths (Cook Vascular, Leechburg, PA, USA) rotated manually along the lead to dissect adhesions to the vascular system. Sheath diameter depended on the lead diameter and was changed for a bigger one if there were any difficulties in covering all lead elements as well as adhesions around it with the sheath. The biggest available diameter (13 F) was applied a priori for the leads with visible externalization, what enabled covering the lead body with externalized cables and potential cable adhesions. If required, the use of a standard stylet or locking stylet Liberator Beacon Tip (Cook Vascular, Leechburg, PA, USA) helped to ensure the stiffness of the leads with preserved internal lumen. The stiff connection of all parts of an extracted lead is, in general, a key issue for the success and safety of a procedure, however, it is of the utmost importance in the case of leads with externalization. This was obtained with the use of a tight self-locking knot.

Moreover, in 1 patient, the 'Bulldog' Lead Extender (Cook Vascular, Leechburg, PA, USA) was used beside the locking stylet in order to preserve traction on externalized conductors.

In patients with massive adhesions or calcifications which could not be separated by means of manually rotated sheaths, the mechanical autoro-



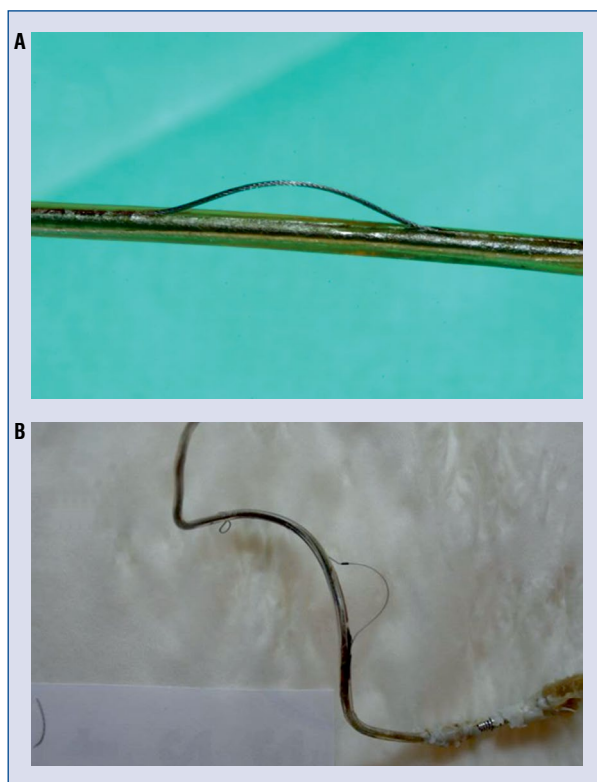
**Figure 1.** Fluoroscopic evaluation of Kainox RV lead, dwelling time 126 months.

tating 'Evolution' system (Cook Vascular, Leechburg, PA, USA) was used. For the electrodes with visible externalization, as in the case of telescopic sheaths, the Evolution system with the maximum available dimension (that is 13 F) was used.

The extracted electrodes were evaluated by macroscopic examination in order to prove externalizations and detect hematin deposits in the leads. Contrary to acute damage when only fresh blood occurs in the lead body, the hematin deposits indicate various levels of the insulation damage before the TLE procedure (Fig. 2). The leads extracted during the last 6 months were assessed using microscopic examination to confirm externalization and to determine the extent of the damage. Endocardial leads were analyzed with an optical microscope with  $0.5\text{--}4.0\times$  magnification and all abnormalities of the outermost insulation coating were photographed (Fig. 3).

### Statistical analysis

Statistical analysis was performed with the SAS 8.2 statistical package (SAS, Institute Inc, Cary, NC, USA). The results are presented in the form of arithmetic means and standard deviations of quantity attributes or as the frequency and percentage of the distinguished units of nominal features. The study of nominal variables involved using contingency tables, and the distribution of features were analysed first by the Pearson  $\chi^2$  test. In cases where the expected value of the observation in the cell was less than 5, the Fisher exact test



**Figure 2.** Macroscopic evaluation after extraction; **A.** Riata ST lead dwelling time 71 months; **B.** Linox lead dwelling time 57 months.

was additionally used. The Shapiro-Wilk test verified the compliance of distribution of continuous variables with a normal distribution. To compare the significance of differences occurring between mean values, depending on the homogeneity or heterogeneity of variance, the t-test or Cochran-Cox test were used respectively. Verifications of null hypotheses were carried out assuming the level of statistical significance  $\alpha \leq 0.05$ .

## Results

Among the 143 extracted defibrillator leads externalization was identified before the TLE procedure in 8 (5.6%) defibrillator leads in 8 (5.8%) patients, namely (time from implantation to the extraction is given in brackets and expressed in months): one Kainox RV (Biotronik Berlin Germany) (126 months), one Linox (Biotronik Berlin Germany) (57 months), one SPL (Ventritex — St. Jude Medical Inc. Sylmar, CA, USA) (132 months), one Riata ST (St. Jude Medical Inc. Sylmar, CA, USA) (71 months) and four Riata (St. Jude Medi-

cal Inc. Sylmar, CA, USA) (96, 93, 73, 55 months, respectively) leads (Table 2).

Patients with the lead externalization were often in better New York Heart Association (NYHA) functional class (I or II) compared with the rest of the study group ( $p = 0.0212$ ). An electrical lead failure occurred more frequently in this group ( $p = 0.0210$ ). However, there were no differences in the mean age, sex or underlying heart disease (Table 1).

The clinical success of the TLE was obtained in all patients from the analyzed group. All externalized electrodes were completely removed. Out of 135 leads without externalization, 132 (97.7%) leads were extracted entirely and in 3 patients electrode fragments shorter than 4 cm were left.

The mechanical autorotating system was used in 1 (12.5%) patient with externalization and 17 (13.1%) out of 130 remaining patients ( $p = \text{NS}$ ).

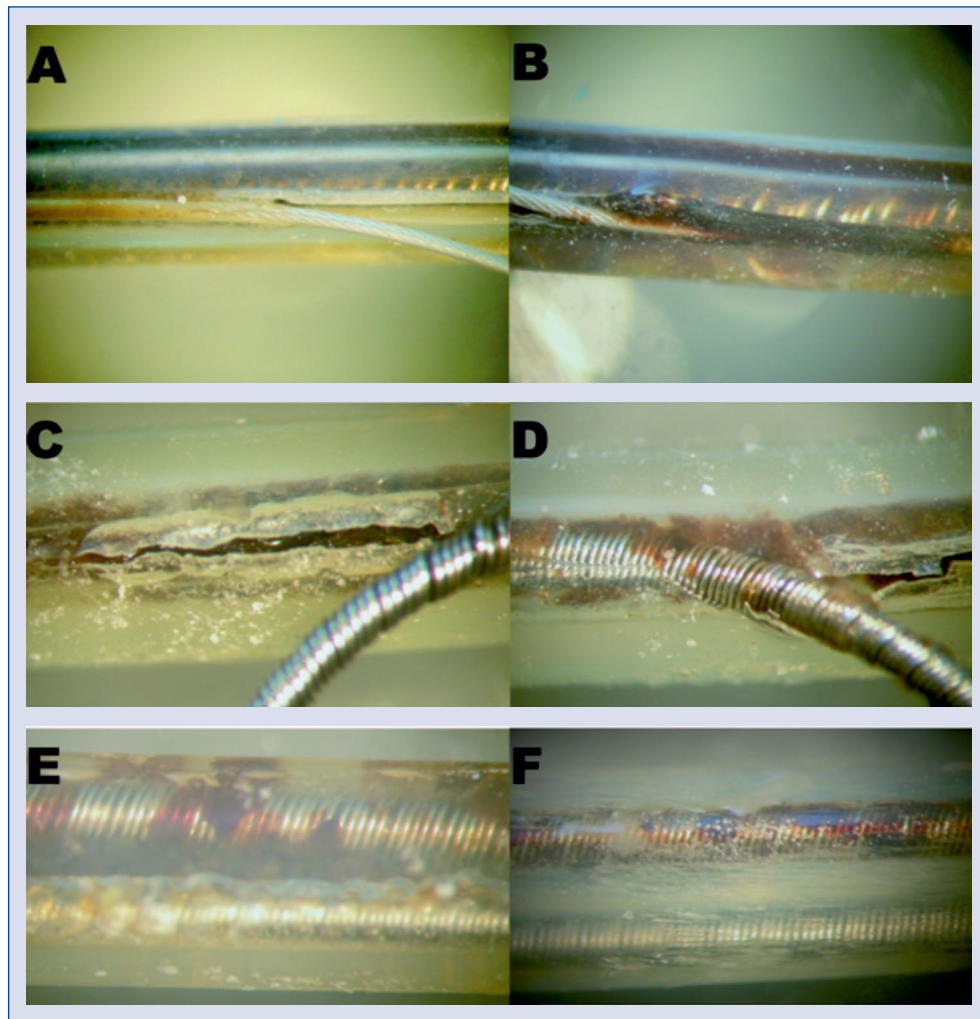
The mean dwelling time for externalized leads (8 cases) equaled 87.9 months (55–132) and was longer in comparison to the rest of the ICD leads (135 leads) — 60.1 months (3–246) ( $p = 0.0329$ ). Passive fixation leads were more common in the group with externalization (75% vs. 17%;  $p < 0.001$ ). The number of either all or high-voltage only leads implanted in a particular patient, single or dual coil lead construction and type of implanted device had no influence on increased incidence of externalization (Table 3).

Data concerning the types of implanted leads were available for 101 patients from the study group (Table 3). For the patient implanted outside of the center herein, not all of the data about leads were possible to obtain. Out of all available lead types only the lead from the Riata family had a greater incidence of externalization.

During the last 6 months of the study optical microscope analysis of leads confirms inside-out insulation abrasion in 2 out of 25 leads (Fig. 3).

No complications of the lead extraction procedure were observed in 8 patients with externalization. In the remaining 130 patients, complications occurred in 4 patients ( $p = \text{NS}$ ). There were two major complications (1.6%), one tamponade, treated surgically and one breakage of a polypropylene telescopic sheath used for TLE, which also required thoracotomy for its removal. Minor complications were observed in 2 (1.6%) patients: a case of femoral artery embolism treated with an embolectomy and 1 case of a massive hematoma which required non-invasive treatment and prolonged hospitalization. Additionally, in 2 patients





**Figure 3.** Optical microscope analyze of transvenously removed implantable cardioverter-defibrillator leads with conductor exposure; **A, B.** Linx lead; **C, D.** SPL lead; **A-F.** Hematine deposits; **A-D.** Cable externalization.

**Table 2.** Type of extracted implantable cardioverter-defibrillators leads (101 available)

Type of lead	Producer	Conductors' non-externalized (n = 93)	Conductors' externalized (n = 8)
Riata ST	St. Jude Medical Inc. Sylmar, CA, USA	4 (80%)	1 (20%)
Riata	St. Jude Medical Inc. Sylmar, CA, USA	4 (50%)	4 (50%)
Durata	St. Jude Medical Inc. Sylmar, CA, USA	15 (100%)	0 (0%)
Linx family	Biotronik Berlin Germany	30 (96.8%)	1 (3.2%)
Kainox	Biotronik Berlin Germany	4 (80%)	1 (20%)
SPS	Biotronik Berlin Germany	3 (100%)	0 (0%)
Sprint Quarto	Medtronic Minneapolis, USA	17 (100%)	0 (0%)
Sprint	Medtronic Minneapolis, USA	2 (100%)	0 (0%)
Fidelis	Medtronic Minneapolis, USA	6 (100%)	0 (0%)
TVL	Ventritex — St. Jude Medical Inc. Sylmar, CA, USA	5 (100%)	0 (0%)
SPL	Ventritex — St. Jude Medical Inc. Sylmar, CA, USA	3 (75%)	1 (25%)

**Table 3.** Clinical characteristics of the leads with conductor externalization (number of leads: 143).

	Conductors' non-externalized (n = 135)	Conductors' externalized (n = 8)	P
Lead age [months]	60.1 ± 43.8	87.9 ± 29.4	0.0329
Passive fixation	23 (17%)	6 (75%)	< 0.001
Single-coil lead	80 (59.3%)	3 (37.5%)	NS
Number of implanted leads (during extraction):			NS
1	66 (48.9%)	7 (87.5%)	
> 1	69 (51.1%)	1 (12.5%)	
Number of implanted ICD leads (during extraction):			NS
1	126 (96.9%)	7 (87.5%)	
2	4 (3.1%)	1 (12.5%)	
Device type:			NS
CRT-D	31 (27.4%)	0 (0%)	
ICD-DR	53 (39.3%)	2 (25%)	
ICD-VR	45 (33.3%)	6 (75%)	
Lead type (101 — 70.6% available)			< 0.005
Riata lead	8 (61.5%)	5 (38.5%)	
Other	85 (95.6%)	3 (4.4%)	

ICD — implantable cardioverter-defibrillator; ICD-VR — single chamber ICD; ICD-DR — dual chamber ICD; CRT-D — ICD with resynchronization therapy

there were complications of new implantations including implantable cardioverter-defibrillators with resynchronization therapy (CRT-D) implantation on the opposite side of the chest related to an inability to regain access from the side of extracted leads and the atrial lead repositioning in another patient before discharge from the hospital.

### Discussion

In the presented database information was found concerning SPL (Ventritex — St. Jude Medical Inc. Sylmar, CA, USA) and Kainox (Biotronik, Berlin, Germany) lead externalization was not widely known in literature previously. Until recently, the occurrence of externalization was mainly described in the context of Riata (St. Jude Medical Inc. Sylmar, CA, USA) leads. The latest reports indicate, however, the possibility of externalization occurrence in Linox (Biotronik, Berlin, Germany) and Kentrox (Biotronik, Berlin, Germany) leads [6–8]. In observance of this, the fluoroscopic evaluation seems to be necessary in wider populations and not only with leads under advisory [9].

Externalization was observed more often in older and passive fixation leads in individuals with lower NYHA. These observations are in line with other evidence [10–12]. A factor which may

explain this is heart contraction strength which may additionally have an influence on intracardiac movement of the electrode. Also the fact that some of the externalized leads had been implanted approximately 10 years ago and was most probably the reason why passive fixation leads were more frequent in this group. At present, the tendency is to use active fixation leads.

Some electrical parameters in the externalized electrodes, such as R wave value, may be susceptible to interference, whereas other parameters usually stay unaltered. The rate of completely faulty leads remains low [13, 14]. In the present group high voltage circuit failure stayed low, however the response of such leads during high-voltage intervention and measurements conducted with low-voltage current do not provide any clear-cut answers [15]. The hitherto conducted analyses suggest that further damage of externalized leads might occur during high-voltage intervention and therefore result in a short-circuit which would mean unsuccessful intervention. However, such leads might not demonstrate any failure signs beforehand [16, 17]. In this group with conductor externalization lead failure, pacing and sensing malfunction were the first sign and indication for lead extraction.

Microscopic evaluation showing insulation damage with hematin deposit may influence the

decision to qualify to TLE more urgently. Faulty leads can promote thrombus formation and embolism as well as bacterial colonization leading to infective endocarditis [18–20]. In this population no externalization was found in microscopic evaluation and negative in fluoroscopic assessment but the number of leads evaluated is relatively low.

The presented lead extraction efficacy concerning electrodes with conductor externalization and other leads as well as ICD leads under advisory seems to be similar to that presented in the literature [1, 21–23]. The use of additional tools in order to provide supplementary traction on the externalized cables when necessary guarantees more efficient and safer performance of the procedure [21–24]. For this purpose, in one patient from the group a ‘Bulldog’ Lead Extender was used apart from the typical locking stylet. A self-tightening knot was used that secured lead integrity and possibility of traction on each of its elements. However, specific systems dedicated to that function are commercially available at present. In the case of leads with an externalization, telescopic sheaths and ‘Evolution’ system with the maximum available diameter were used in the presented center, enabling covering not only the lead body but also externalized cables and potential cable adhesions. These tools are sufficient to provide successful and safe TLE in leads with externalization.

### Limitations of the study

The retrospective character of the present study contributed mainly to the study limitations. The small number of patients limited the possibility of revealing either externalization risk factors or occurrence of rare TLE complications. The lack of the data concerning the diameter of applied telescopic sheaths, the remaining lead types, fluoroscopy and the course of the procedures made it impossible to conduct more precise analyses. Finally, the exclusive use of mechanical extraction tools may be another limitation concerning the extraction techniques used in the studied population.

### Conclusions

Conductor externalization is a rare finding in patients undergoing TLE. This occurs with different manufacturers and lead types. In this complication TLE with the mechanical extraction tools can be safely performed.

**Conflict of interest:** A. Maciąg — lecturer’s fee and travelling grants from St. Jude Medical,

Medtronic, Biotronik and Cook Medical; P. Syska — lecturer’s fee and travelling grants from St. Jude Medical, Medtronic, Biotronik and Cook Medical; M. Sterliński — investigator, consulting and educational fees from Biotronik, Medtronic, St. Jude Medical, Zoll and Cook Medical; A. Kołodzińska — no conflict; A. Oręziak — investigator in clinical trials sponsored by Biotronik, travelling grants from Biotronik, St. Jude Medical, Cook Medical and lecture fees from Biotronik and St. Jude Medical; K. Kuśmierski — no conflict; M. Marciniak-Emmons — no conflict; A. Przybylski — proctor to Cook Medical, consultant to Biotronik, Medtronic, lecturer fees from St. Jude Medical; Ł. Szumowski — investigator in clinical trials sponsored by Biotronik, travelling grants from Biotronik, Biosense-Webster, St. Jude Medical, lecture fees from Biotronik, Medtronic, St. Jude Medical and Biosense-Webster; G. Opolski — no conflict; H. Szwed — no conflict.

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