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Authors: Krzysztof Boczar, Andrzej Ząbek, Karolina Golińska-Grzybała, Jacek Gajek, Katarzyna Holcman, Magdalena Kostkiewicz, Jacek Lelakowski

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Krzysztof Boczar[1], Andrzej Ząbek[1, 2], Karolina Golińska-Grzybała[3], Jacek Gajek[4], Katarzyna Holcman[5], Magdalena Kostkiewicz[5], Jacek Lelakowski[1, 2]

[1]Department of Electrocardiology, The John Paul II Hospital, Kraków, Poland
[2]Institute of Cardiology, Jagiellonian University Medical College, Kraków, Poland
[3]Department of Noninvasive Cardiovascular Laboratory, John Paul II Hospital, Kraków, Poland
[4]Department of Emergency Medical Service, Wroclaw Medical University, Wrocław, Poland
[5]Department of Coronary Disease and Heart Failure, Institute of Cardiology, Jagiellonian University Medical College, John Paul II Hospital, Kraków, Poland.

Correspondence to:
Krzysztof Boczar, MD, PhD,
Department of Electrocardiology,
The John Paul II Hospital,
Prądnicka 80, 31–202 Kraków, Poland,
phone: +48 12 614 22 77,
e-mail: krzysiek.boczar@gmail.com

INTRODUCTION

The use of conduction system pacing (CSP) is expanding globally to treat patients with bradycardia, atrioventricular conduction disorders, and those requiring cardiac resynchronization therapy (CRT), through techniques like His bundle-branch pacing (HBP) and left bundle-branch area pacing (LBBAP). The increase in the use of implantable devices with HBP and LBBAP has led to the first-ever recommendations for permanent pacing using HBP pacing [1, 2]. This growing interest in CSP, along with the rapidly expanding evidence base for CSP, is expected to result in a significant increase in the number of CSP patients in the coming years.

However, the long-term performance of CSP can be impacted by the learning curve of the operators and anatomical challenges. In this population, patients with HPB are more prone to

suffer from high pacing thresholds leading to a higher likelihood of transvenous lead extraction (TLE). Furthermore, complications such as lead-dependent infective endocarditis (LDIE), local infections of the device pocket (LI), lead dysfunctions, and the presence of redundant/inactive leads can also contribute to an increased number of TLE procedures.

Currently, there is a lack of large data on TLE procedures of CSP leads, particularly HBP leads in the adult population. Our study aims to present the initial experience of performing TLE procedures in patients with HBP leads utilizing a non-*stylet* driven Medtronic 3830 lead (MDT 3830, Medtronic Inc, Minneapolis, MN, US) from the reference center's perspective.

METHODS

A prospective analysis of the records consisted of all patients with HBP leads who underwent TLE from October 2011 to February 2023. The patient inclusion criteria included the presence of a HBP lead and the need for TLE regardless of indication. The Research and Ethics Committee of Jagiellonian University approved the study protocol (KBET/259/B/2011), and written informed consent was obtained from all patients for using their anonymous data in the present study. The study protocol conformed with the Declaration of Helsinki and complied with the principles of Good Clinical Practice guidelines.

For the purpose of this study, patients whose HBP leads had been implanted for less than one year before the procedure were also included in the analysis. Data were collected from a prospectively maintained database comprising records of device implantation, follow-up at the device and general cardiology clinics, medical information obtained during the index admissions for TLE, and data on 30-day complications after the procedure. We analyzed the data regarding the presence of non-functional/abandoned leads, age of extracted leads, fluoroscopy time, extraction techniques used during TLE, the effectiveness of TLE, complete/incomplete lead removal for each lead targeted, and complications occurring during the intra-operative and 30-day post-operative period. The effectiveness of TLE procedures was defined according to the current HRS and EHRA consensus [3, 4]. The description of the TLE procedure has been presented in our previous study [5].

Statistical analysis

Continuous variables were presented as median and interquartile range (IQR) or minimum and maximum values. Categorical variables were presented as counts and percentages.

RESULTS AND DISCUSSION

The study involved nine patients who met the inclusion criteria, one of whom was female, with an median (IQR) age of 68.3 (65.9–75.7) years and a range of 61–79 years. All patients had cardiac implantable electronic devices (CIED) with HBP using a non-*stylet* driven Medtronic 3830 lead (MDT 3830, Medtronic Inc, Minneapolis, MN, US). Seven patients had a CRT with HBP (HOT-CRT), and two patients had an ICD with HBP. All CIEDs were implanted on the left side of the chest for primary prevention. TLE was performed due to LDIE (2 patients), LI (2 patients), and non-infectious indications (5 patients). Among patients with non-infectious indications, three patients required TLE due to an increase in HBP threshold, and two patients with HOT-CRT and complete ipsilateral venous occlusion required additional placement of atrial lead. In addition, 33.3% of patients had significant ipsilateral venous occlusion. The median (IQR) lead dwell time was 17.0 (9.3–20.9) months, and the majority of extracted CSP leads were over a year old.

The patients in our study had a high prevalence of comorbidities, including dyslipidemia (100%), atrial fibrillation (88.9%), ischemic heart disease (77.8%), hypertension (77.8%), diabetes (55.5%), history of myocardial infarction (55.5%), previous cardiac surgery (44.4%), and chronic kidney disease (44.4%).

The TLE of the Medtronic 3830 lead was technically challenging due to its lumenless design, narrow caliber, cable-fixed exposed helix and inability to use stylets. Furthermore, a high tensile strength of the Medtronic 3830 lead due to its presence of an inner cable and a non-retractable helix may pose a risk of myocardial avulsion [6, 7]. Nonetheless, the extraction efficacy of all targeted HBP leads was high and achieved 100%. Five leads were removed using simple traction, while four leads required more mechanical extraction tools, including Byrd dilators (Cook Medical). In two patients, HBP lead was used to retrieve venous access due to complete ipsilateral venous occlusion utilizing stabilization of HBP lead via a femoral approach with a Needle Eye Snare. Median (IQR) fluoroscopy time was 0.1 (0.07–1.53) minutes. The longest fluoroscopy times were recorded when HBP electrodes were used to regain venous access. There were no intra-procedural major or minor procedural complications (Table 1).

While TLE procedures of CSP leads are well documented in the pediatric population, there is limited data in the adult population [8]. The study by Vijayaraman et al. is the only one to report a retrospective analysis of 30 adult patients who underwent TLE of HBP leads, with a mean dwell time of 25 (18) months, which were successfully extracted with manual traction alone in most cases [9]. Additional data is derived from case descriptions such as our previous

case study, where we reported a successful complex mechanical extraction of HBP lead to retrieve venous access in an upgrade procedure [10].

TLE procedures, although safe, carry the risk of both major and minor complications. As proved by Tajstra et al., who presented complications rate of TLE of approximately 5.6% in more than 800 patients.When determining the factors associated with TLE procedure complications, authors showed that presence of comorbidities like prior dialysis, chronic kidney disease, and ventricular tachycardia were independent factors of a higher risk of TLE-related in-hospital complications. Futhermore, heart failure, and older age can independently affected 12-month mortality [11]. In the analyzed small population of patients with HBP, a high percentage of effectiveness and safety of TLE procedures was achieved despite the high prevalence of comorbidities which, according to the authors, can be explained by the short lead dwell time and the experience of the operators. However, it is reasonable to assume that with the increase lead dwell time, the profile of safety and complications of TLE procedures will be similar to a large-scale studies.

An additional area of interest is the issue of performing TLE procedures of HBP leads in patients with complex clinical situations. On this basis, as previously described by the authors the implementation of HBP proved to an effective and safe pacing method in a heart transplant recipient [12]. Altough, authors did not obserwed additional complications of performing TLE procedures in heart transplant recipients, manging of malfunctional or infected HBP leads is impaired by the lack of large-scale data on TLE procedures in this group of patients.

In conclusion, based on the analyzed study population, the TLE procedure appears to be safe and effective. However, to obtain a more reliable assessment of its long-term effectiveness and safety in an expanding population of patients with CSP, it is necessary to conduct a large multicenter prospective study.

Article information

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Table 1

Patient	Sex	Age, year	Pacing system	LVEF, %	Indication for TLE	Dwell time HIS pacing lead, months	Tools	Results of the TLE procedure	Fluoroscopy time, minutes
No 1	M	76.3	CRT-D HIS	24	Lead dysfunction	17.3	T	Full success	0.18
No 2	F	66.1	CRT-D HIS	35	Lead dysfunction	22.0	T	Full success	0.083
No 3	M	65.8	CRT-D HIS	50	Up-grade	10.9	CSF	Full success	6.42

No 4	M	79.7	CRT-P HIS	17	LDIE	6.9	T	Full success	0.1
No 5	M	73.1	CRT-D HIS	26	LDIE	7.8	T	Full success	0.05
No 6	M	66.5	CRT-D HIS	38	Local infection	15.1	T	Full success	0.1
No 7	M	61.2	CRT-D HIS	25	Local infection	17.0	T	Full success	0.05
No 8	M	68.3	CRT-D HIS	20	Up-grade	19.8	T	Full success	0.1
No 9	M	75.1	CRT-D HIS	35	Up-grade	43.3	C	Full success	2.88

Abbreviations: C, lead removal with polypropylene sheets; CRT-D HIS, cardiac resynchronization therapy with His bundle pacing; CSF, lead removal with polypropylene sheets combined with stabilizing the lead via femoral; T, simple traction; LDIE, lead dependent infective endocarditis; LVEF, left ventricular ejection fraction; TLE, transvenous lead extraction