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Experience with transvenous lead extraction of His bundle pacing leads

Short title: Transvenous lead extraction of His bundle pacing leads

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ABSTRACT

Background: Nowadays, we observe a growing interest in conduction system pacing (CSP). Therefore, we expect the number of patients with CSP to increase significantly in the coming years. However, there is a lack of large data on transvenous lead extraction (TLE) procedures of CSP leads, particularly HBP leads in the adult population.

Aims: Study aims to present experience of performing TLE procedures in patients with CSP leads utilizing a non-*stylet* driven Medtronic 3830 lead in two tertiary lead extraction centers in Poland.

Methods: A prospective analysis of the records consisted of all patients with HBP leads who underwent TLE from October 2011 to November 2023.

Results: The study involved 38 patients, with a median (Q1–Q3) age of 69.7 (65.6–76.0) years, 8 of whom were female (21.1%). The median (Q1–Q3) lead dwell time was 15.5 (8.7–19.8) months, Thirty leads were removed using simple traction, while eight leads required mechanical extraction tools. All leads with lead dwell time over 42 months required mechanical extraction tools. The median (Q1–Q3) fluoroscopy time was 1.03 (0.07–11.5) min. There were no intra-procedural major or minor procedural complications. The radiological and clinical success was achieved in 100% of targeted CSP leads.

Conclusion: TLE from the His bundle and left bundle branch region is safe and effective procedure, with no lasting damage to the His-Purkinje system. Successful re-implantation of the lead in the His-Purkinje conduction system is possible in the majority cases.

Keywords: transvenous lead extraction, His bundle pacing leads, cardiac pacing

WHAT'S NEW?

Our study proved that transvenous lead extraction from the His bundle and left bundle branch region is safe and effective procedure, with no lasting damage to the His-Purkinje system or other complications.

Successful re-implantation of the lead in the His-Purkinje conduction system is possible in the majority cases.

The data gathered during this study provide additional guidance for clinicians in managing this unique patient population.

BACKGROUND

Nowadays, we observe a dynamic development of conduction system pacing (CSP). CSP can be achieved by techniques like His bundle-branch pacing (HBP) and left bundle-branch area pacing (LBBAP). The main objective of CSP is to restore or preserve synchrony of ventricular contraction in patients with bradycardia, atrioventricular conduction disorders, and those requiring cardiac resynchronization therapy (CRT) [1–3]. The increase in the use of implantable devices with HBP and LBBAP has led to the first-ever recommendations for permanent pacing using HBP and LBBAP [3].

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. Currently, there is a lack of large data on TLE procedures of CSP leads, particularly HBP leads in the adult population. Present data on TLE procedures of HBP result from research on small groups of patients and case studies [4–7].

Our study aims to present experience of performing TLE procedures in patients with CSP leads utilizing a non-*stylet* driven Medtronic 3830 lead (MDT 3830, Medtronic Inc, Minneapolis, MN) in two tertiary lead extraction centers in Poland.

METHODS

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 of all patients with HBP leads who underwent TLE from October 2011 to November 2023. TLE procedures were performed at Department of Electrophysiology, The John Paul II Hospital, Kraków, Poland, Department of Cardiology, Multidisciplinary Public Hospital, Nowa Sól, Poland and Department of Cardiology, Klodzko County Hospital, Klodzko, Poland.

The patient inclusion criteria were: the presence of a HBP lead, the need for TLE regardless of indication, patient's age over 18 years and written consent obtained from the patient. The patient's exclusion criterion was the lack of patient's consent to participate in the study.

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/CSP 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 [8, 9]. The description of the TLE procedure has been presented in our previous study [10]. In the group of patients undergoing reimplantation, His-Purkinje bundle, and left bundle branch area pacing were the first choice to recapture conduction system pacing. If it was not possible to obtain effective conduction system pacing, depending on the clinical situation, right ventricular pacing was implemented.

Statistical analysis

Statistical analyses were performed using by IBM SPSS Statistics Version 25.0 software (IBM Corp, Armonk, New York, United States). Continuous variables are expressed as median

(interquartile range (Q1–Q3). The categorical variables were presented as counts and percentages.

RESULTS

The study involved 38 patients who met the inclusion criteria, with a median (Q1–Q3) age of 69.7 (65.6–76.0) years, 8 of whom were female (21.1%). Thirty-six patients had cardiac implantable electronic devices (CIED) with His bundle pacing (HBP), and 2 patients had CIED with left bundle branch area pacing (LBBAP). All patients had a Medtronic 3830 lead. Fourteen patients had a dual-chamber (DDD) or single-chamber (VVI) pacemaker, while 24 had a cardiac resynchronization therapy (CRT) or implantable cardioverter-defibrillator (ICD) with HBP. All CIEDs were implanted on the left side of the chest and all defibrillators were implanted for primary prevention.

Transvenous lead extraction (TLE) was performed for various reasons, including lead-dependent infective endocarditis (LDIE) (n = 3), local infection (LI) (n = 4), and non-infectious causes (n = 31). Among patients with non-infectious indications, six patients had HBP lead dislocation, thirty patients required TLE due to an increase in HBP threshold, and two patients with CRT and complete ipsilateral venous occlusion required additional placement of atrial lead. In addition, 11 patients (28.9%) had significant ipsilateral venous occlusion.

The median (Q1–Q3) lead dwell time was 15.5 (8.7–19.8) months, and the majority of extracted CSP leads were over a year old. Some patients with complete venous occlusion required additional lead placement. Additionally, 11 patients (28.9%) had significant ipsilateral venous occlusion.

The patients in our study had a high prevalence of comorbidities, including chronic heart failure with median LVEF 39.0 (30.7–55.0), hypertension (92%), atrial fibrillation (63%), ischemic heart disease (50%), diabetes (50%), history of myocardial infarction (37%), and chronic kidney disease (44%).

Thirty leads were removed using simple traction, while eight leads required 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. All leads with lead dwell time over 42 months required mechanical extraction tools. In the group of patients with CSP and multiple pacing leads requiring reimplantation after TLE procedure, unintentional extraction of “healthy” (non-targeted) lead occurred only in 1 patient. This was a patient with ICD-DR

system in whom ICD dislodged during extraction of CSP lead. The median (Q1–Q3) fluoroscopy time was 1.03 (0.07–11.5) min. 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**). The radiological and clinical success was achieved in 100% of targeted CSP leads. In the group of patients undergoing reimplantation, conduction system pacing was the target location in 26 patients. Successful re-implantation of the lead in the His-bundle was achieved in 2 patients. The remaining patients received left bundle branch area pacing. During 30-day follow up period there were no major or minor complications.

DISCUSSION

The increasing adoption of CSP techniques shows rapidly evolving landscape of cardiac rhythm management. With the rapid expansion of CSP across the world, the potential need for lead extraction in these patients is anticipated to grow in the coming years. While HBP has seen gradual adoption over the past two decades, LBBAP has gained acceptance more rapidly in recent years, reflecting advancements in pacing technology and evolving clinical practice. Long-term performance of CSP by His bundle pacing (HBP) or left bundle branch area pacing (LBBAP) can be impacted by the learning curve of the operators and anatomical challenges inherent to this form of pacing. As per European Heart Rhythm Association (EHRA) consensus statement on conduction system pacing, the learning curve for experienced device implanters is considerable when they begin implanting conduction system leads, and observed flattening of the fluoroscopy duration was reported after 30–50 cases for HBP, and after 110 cases for LBBAP [11, 12]. Noteworthy, as it has been shown in multiple studies, the inexperienced operator and the longer procedure duration are risk factors for CIED infection [13, 14]. As a result, given the steep learning curve, patients with CSP are more prone to infectious complications. Furthermore, patients with HBP frequently have high pacing thresholds and sensing issues [15, 16]. Because of these aforementioned difficulties, patients with CPS may have a higher likelihood of transvenous lead extraction (TLE) compared to those with conventional pacing.

It is a widely acknowledged that the TLE of the Medtronic 3830 lead may be technically challenging due to its lumenless design, narrow calibre, cable-fixed exposed helix and inability to use stylets and locking stylets. Furthermore, a deep intraventricular septal location of LBBAP and 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 [4, 5]. Finally, there

is a question relating to the feasibility of reimplantation of CPS to guarantee continuity of this therapy in patients who require reimplantation.

The findings of our bicentric study expand upon currently scarce literature concerning the transvenous lead extraction (TLE) of conduction system pacing (CSP) leads. Previously, we published a case series concerning His bundle pacing lead extraction [5]. Our present study on much larger sample highlights several key observations regarding the efficacy and safety of TLE procedures in patients with CSP leads, offering valuable insights into the management of this evolving therapeutic modality.

The main finding of our study is the high overall success rate of complete lead removal/extraction of 100%. It highlights that TLE procedures in patients with CSP leads are feasible and most importantly are safe and effective. Our findings suggest that mechanical or powered extraction tools can be utilized effectively without the need for a locking stylet, addressing concerns regarding lead extraction in this patient population. We observed that extraction tools were necessary only in a small percentage of cases, primarily in patients with longer lead dwell times, indicating the potential impact of lead duration on the complexity of extraction. In addition, our study demonstrated the safety of lead removal from the interventricular septum in the His bundle or left bundle branch region, with no lasting damage to the His-Purkinje system or other complications encountered. Finally, successful re-implantation of the lead in the His-Purkinje conduction system was achieved in the majority of attempted cases.

Study limitations

The main limitation is observational retrospective character of the study and relatively small study population. Additionally, the relatively shorter dwell time of LBBAP leads precludes definitive conclusions regarding the feasibility of lead extraction after longer dwell times. Prospective assessment and further studies are warranted to evaluate the feasibility of extraction after extended dwell times.

CONCLUSION

In conclusion, our study provides valuable insights into the safety and efficacy of TLE procedures in patients with CSP leads, offering guidance for clinicians in managing this unique patient population. Moving forward, continued research and prospective studies are essential to refine techniques and optimize outcomes in patients undergoing CSP.

Article information

Conflict of interest: None declared.

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Table 1. Baseline characteristics.

Table 1	
Variable	Number of complete data n (%)
Age (years)	68.1 (65.6–76.0)
Female, n (%)	8 (21.1%)
LVEF (%) before procedure	39.0 (30.7–55.0)
NYHA class III or IV, n (%)	13 (34.2%)
NT-pro BNP (pg/dL)	711.0 (368.0–1547.7)
Creatinine (umol/L)	100.0 (86.7–126.7)
Diabetes mellitus, n (%)	19 (50.0%)
Coronary artery disease, n (%)	19 (50.0%)
MI, n (%)	14 (36.8%)
Hypertension, n (%)	35 (92.1%)
AF, n (%)	24 (63.2%)
Stroke or TIA, n (%)	5 (13.2%)
ICD or CRT-D, n (%)	18 (47.4%)
Lead dwell time (months)	15.5 (8.7–19.8)
Lead extraction time (min)	1.03 (0.07–11.5)
<p>AF — atrial fibrillation, CRT-D — Cardiac resynchronization therapy with a defibrillator, ICD — implantable cardioverter-defibrillator, LVEF — left ventricular ejection fraction, MI — myocardial infarction, NYHA class — New York Heart Association Functional Classification, TIA — Transient ischemic attack.</p> <p>Continuous variables are expressed as median (interquartile range (Q1–Q3)). The categorical variables were presented as counts and percentages.</p>	