Experience with 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 His bundle pacing (HBP) leads in the adult population.

Aims: This study aimed to present the experience of performing TLE procedures in patients with CSP leads using a non-stylet-driven Medtronic 3830 lead in two tertiary lead extraction centers in Poland.

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

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

Conclusion: TLE from the His bundle and left bundle branch region is a 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 most cases.

Key words: transvenous lead extraction, His bundle pacing leads, cardiac pacing

BACKGROUND

Nowadays, we observe a dynamic development of conduction system pacing (CSP). CSP can be achieved by such techniques as 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]. An increase in the use of implantable devices with HBP and LBBAP has led to the issuing of 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 lack of large data on transvenous lead extraction (TLE) procedures involving CSP leads, particularly HBP leads in the adult population. Present data on TLE

WHAT'S NEW?

Our study demonstrated that transvenous lead extraction from the His bundle and left bundle branch region is a 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 of cases. Data gathered during this study provide additional guidance for clinicians in managing this unique patient population.

procedures of HBP come from research on small groups of patients and case studies [4–7].

Our study aimed to present the experience of performing TLE procedures in patients with CSP leads using 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 implantation and general cardiology clinics, medical information obtained during index admissions for TLE, and data on 30-day complications after the procedure from all patients with HBP leads who underwent TLE from October 2011 to November 2023. TLE procedures were performed at the Department of Electrocardiology, the John Paul II Hospital, Kraków, Poland, the Department of Cardiology, Multidisciplinary Public Hospital, Nowa Sól, Poland and the Department of Cardiology, Klodzko County Hospital, Kłodzko, Poland.

The patient inclusion criteria were: the presence of a HBP lead, need for TLE regardless of indication, the patient's age of over 18 years, and written consent obtained from the patient. The only exclusion criterion was the lack of patient 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 this study. The study protocol complied with the Declaration of Helsinki and the principles of Good Clinical Practice guidelines.

For 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 implantation and general cardiology clinics, medical information obtained during 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 periods. The effectiveness of TLE procedures was defined according to the current HRS and EHRA consensus [8, 9]. The description of the TLE procedure was 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 IBM SPSS Statistics Version 25.0 software (IBM Corp, Armonk, NY, US). Continuous variables were expressed as medians (interquartile range [IQR]). Categorical variables were presented as counts and percentages.

RESULTS

The study involved 38 patients who met the inclusion criteria, at a median (IQR) 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 HBP, and 2 patients had CIEDs with LBBAP. All patients had Medtronic 3830 leads. Fourteen patients had dual-chamber (DDD) or single-chamber (VVI) pacemakers, while 24 had cardiac resynchronization therapy (CRT) or implantable cardioverter-defibrillators (ICD) with HBP. All CIEDs were implanted on the left side of the chest and all defibrillators were implanted for primary prevention.

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, 6 patients had HBP lead dislocation, 30 patients required TLE due to an increase in HBP threshold, and 2 patients with CRT and complete ipsilateral venous occlusion required additional placement of atrial leads. In addition, 11 patients (28.9%) had significant ipsilateral venous occlusion.

The median (IQR) 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 of 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%).

Table 1. Baseline characteristics.

Variable	Number of complete data
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/ml	711.0 (368.0–1547.7)
Creatinine, µmol/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)

Continuous variables were expressed as medians (interquartile ranges). The categorical variables were presented as counts and percentages

Abbreviations: AF, atrial fibrillation; CRT-D, cardiac resynchronization therapy with a defibrillator; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; TIA, transient ischemic attack

Thirty leads were removed using simple traction, while 8 leads required mechanical extraction tools, including Byrd dilators (Cook Medical). In 2 patients, HBP lead was used to retrieve venous access due to complete ipsilateral venous occlusion utilizing stabilization of HBP leads *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 the TLE procedure, unintentional extraction of "healthy" (non-targeted) lead occurred only in 1 patient. This was a patient with an ICD-DR system, in whom ICD dislodged during the extraction of CSP lead. The median (IQR) 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 all 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 LBBAP. During the 30-day follow-up, there were no major or minor complications.

DISCUSSION

The increasing adoption of CSP techniques shows the rapidly evolving landscape of cardiac rhythm management. With the rapid expansion of CSP across the world, the need for lead extraction in these patients will grow in the coming years. While HBP has seen gradual adoption over the past two decades, LBBAP has gained acceptance more rapidly only in recent years, reflecting advancements in the pacing technology and evolving clinical practice.

The long-term performance of CSP by HBP or LBBAP can be impacted by the operator's learning curve and anatomical challenges inherent to this form of pacing. As per the 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 HBP procedures, and after 110 LBBAP procedures [11, 12]. Notably, as it has been shown in multiple studies, an inexperienced operator and longer procedure duration are risk factors for CIED infection [13, 14]. As a result, given the steep learning curve, CSP patients are more prone to infectious complications. Furthermore, patients with HBP frequently have high pacing thresholds and sensing issues [15, 16]. Because of these difficulties, CPS patients may have a higher likelihood of requiring TLE compared to those with conventional pacing.

It is widely acknowledged that the TLE of the Medtronic 3830 lead may be technically challenging due to its lumenless design, narrow caliber, cable-fixed exposed helix, and the operator's 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 an inner cable and a non-retractable helix may pose a risk of myocardial avulsion [4, 5]. Finally, there is a question of the feasibility of reimplantation of CPS in order to guarantee the continuity of this therapy in appropriate patients.

The findings of our two-center study expand upon currently scarce literature concerning TLE of CSP leads. Previously, we published a case series concerning HBP lead extraction [5]. Our present study, conducted on a 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 (100%) of complete lead removal/extraction. It highlights that TLE procedures in patients with CSP leads are feasible and, most importantly, safe and effective. Our findings suggest that mechanical or powered extraction tools can be utilized effectively without the need for locking stylets, which addresses 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 dwelling time 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, without any lasting damage to the His–Purkinje system or other complications. 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 the observational retrospective character of the study and the 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

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REFERENCES

1. Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2019; 140(8): e382–e482, doi: 10.1161/CIR.0000000000000628, indexed in Pubmed: 30586772.
2. Glikson M, Nielsen JC, Kronborg MB, et al. ESC Scientific Document Group. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. Eur Heart J. 2021; 42(35): 3427–3520, doi: 10.1093/eurheartj/ehab364, indexed in Pubmed: 34455430.
3. Chung MK, Patton KK, Lau CP, et al. 2023 HRS/APHRS/LAHRS guideline on cardiac physiologic pacing for the avoidance and mitigation of heart failure. Heart Rhythm. 2023; 20(9): e17–e91, doi: 10.1016/j.hrthm.2023.03.1538, indexed in Pubmed: 37283271.
4. Vijayaraman P, Subzposh FA, Naperkowski A. Extraction of the permanent His bundle pacing lead: Safety outcomes and feasibility of reimplantation. Heart Rhythm. 2019; 16(8): 1196–1203, doi: 10.1016/j.hrthm.2019.06.005, indexed in Pubmed: 31200093.
5. Boczar K, Ząbek A, Golińska-Grzybała K, et al. Initial experience with transvenous lead extraction of His bundle pacing leads. Kardiol Pol. 2023; 81(7-8): 775–777, doi: 10.33963/KP.a2023.0125, indexed in Pubmed: 37270831.
6. Boczar K, Ząbek A, Dębski M, et al. Transvenous extraction of His bundle pacing lead: New challenge in the field of lead extraction. Cardiol J. 2019; 26(6): 805, doi: 10.5603/CJ.2019.0120, indexed in Pubmed: 31970741.
7. Migliore F, Pittorru R, De Lazzari M, et al. Transvenous lead extraction of lumenless 3830 pacing lead in conduction system pacing: a single-center experience. J Interv Card Electrophysiol. 2024; 67(1): 175–182, doi: 10.1007/s10840-023-01590-0, indexed in Pubmed: 37365481.
8. Kusumoto FM, Schoenfeld MH, Wilkoff BL, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm. 2017; 14(12): e503–e551, doi: 10.1016/j.hrthm.2017.09.001, indexed in Pubmed: 28919379.
9. Bongiorni MG, Burri H, Deharo JC, et al. ESC Scientific Document Group. 2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS. Europace. 2018; 20(7): 1217, doi: 10.1093/europace/euy050, indexed in Pubmed: 29566158.
10. Ząbek A, Boczar K, Ulman M, et al. Mechanical extraction of implantable cardioverter-defibrillator leads with a dwell time of more than 10 years: insights from a single high-volume centre. Europace. 2023; 25(3): 1100–1109, doi: 10.1093/europace/euac272, indexed in Pubmed: 36660771.
11. Jastrzębski M, Kiełbasa G, Cano O, et al. Left bundle branch area pacing outcomes: the multicentre European MELOS study. Eur Heart J. 2022; 43(40): 4161–4173, doi: 10.1093/eurheartj/ehac445, indexed in Pubmed: 35979843.
12. De Leon J, Seow SC, Boey E, et al. Adopting permanent His bundle pacing: learning curves and medium-term outcomes. Europace. 2022; 24(4): 606–613, doi: 10.1093/europace/euab278, indexed in Pubmed: 34849722.
13. Polyzos KA, Konstantelias AA, Falagas ME. Risk factors for cardiac implantable electronic device infection: a systematic review and meta-analysis. Europace. 2015; 17(5): 767–777, doi: 10.1093/europace/euv053, indexed in Pubmed: 25926473.
14. Mounsey JP, Griffith MJ, Tynan M, et al. Antibiotic prophylaxis in permanent pacemaker implantation: a prospective randomised trial. Br Heart J. 1994; 72(4): 339–343, doi: 10.1136/hrt.72.4.339, indexed in Pubmed: 7833191.
15. Vijayaraman P, Naperkowski A, Subzposh FA, et al. Permanent His-bundle pacing: Long-term lead performance and clinical outcomes. Heart Rhythm. 2018; 15(5): 696–702, doi: 10.1016/j.hrthm.2017.12.022, indexed in Pubmed: 29274474.
16. Frausing MH, Bæk AL, Kristensen J, et al. Long-term follow-up of selective and non-selective His bundle pacing leads in patients with atrioventricular block. J Interv Card Electrophysiol. 2023; 66(8): 1849–1857, doi: 10.1007/s10840-023-01488-x, indexed in Pubmed: 36753028.