Received: 11 January 2019 | Accepted: 11 March 2019

DOI: 10.1002/joa3.12179

ORIGINAL ARTICLE

WILEY Journal of Arrhythmia Open Access

Comparing the catheter delivery system and the stylet delivery system for ventricular lead placement in pacemaker implantation—The CATS delivery system randomized controlled trial

Kenichiro Yamagata MD, PhD | Kohei Ishibashi MD, PhD | Kenzaburo Nakajima MD | Naoya Kataoka MD, PhD | Tsukasa Kamakura MD, PhD | Mitsuru Wada MD | Yuko Inoue MD, PhD | Koji Miyamoto MD, PhD | Satoshi Nagase MD, PhD | Takashi Noda MD, PhD | Takeshi Aiba MD, PhD | Satoshi Yasuda MD, PhD | Kengo Kusano MD, PhD

Department of Cardiovascular Medicine, National Cerebral and Cardiovascular Center, Osaka, Japan

Correspondence
Dr. Kenichiro Yamagata, Department of Cardiovascular Medicine, National Cerebral and Cardiovascular Center, Osaka, Japan.
Email: look.cardiology@gmail.com

Abstract

Background: Right ventricular lead placement is one of the fundamental procedures during pacemaker implantation through the subclavian vein. Currently, there are two techniques to deliver the lead to the right ventricle: the catheter and stylet delivery systems. Surgeons, especially trainees in the early stage of training, are known to face difficulty while delivering the lead to the right ventricle. The objective of this study is to investigate and compare the two techniques of lead delivery by trainees in patients who are scheduled to undergo pacemaker implantation.

Methods: This is a prospective, single-center, randomized controlled clinical trial. One-hundred patients who were scheduled to undergo pacemaker implantation with a right ventricular lead will be randomized such that the pacemaker can be implanted via either the catheter delivery system or the stylet delivery system at a 1:1 ratio. The primary endpoint is the total number of attempts needed to place the lead in the ideal position. Secondary endpoints are the efficacy and safety of the implantation procedure. All implantation procedures will be performed by trainees under the supervision of expert cardiologists.

Results: The results of this study are currently under investigation.

Conclusion: This will be the first clinical trial to compare the efficacy and safety of the catheter delivery system and the stylet delivery system during the implantation of the ventricular lead in pacemaker implantation. Our findings are expected to improve the lead implantation procedure by providing information about which delivery system to choose in which situation.

KEYWORDS
catheter delivery system, pacemaker implantation, randomized trial, stylet delivery system, trainee

1 | INTRODUCTION

Pacemaker implantation is a common procedure performed as a first line therapy for patients with symptomatic bradycardia.[1,2] Most pacemakers are implanted below the collarbone and the leads are inserted through the subclavian vein.[3] The main complications associated with lead implantation are cardiac perforation, lead dislodgement, and lead malfunction.[4,5] Currently, there are two main methods to deliver the pacing lead from the subclavian vein to the right ventricle. One is the stylet delivery system (SDS) and the other is the catheter delivery system (CDS). SDS requires experience in shaping the stylet and manipulating the lead through the tricuspid annulus to deliver the lead to the right ventricle.[6] CDS is a relatively new technique introduced in 2012. The delivery method is completely different from SDS as the lead is delivered to the right ventricle through a catheter that is available with multiple preshaped features according to the location in which the lead should be positioned. The physician does not have to shape the stylet, and the catheter can be introduced into the right ventricle over the wire. Moreover, some of these catheters always point to the interventricular septum, which may help avoid cardiac perforation. With regard to these characteristics, CDS may improve the implantation procedure, especially for trainees, without increasing the risk of procedure-related complications. However, no randomized controlled trial has previously addressed the question regarding the optimal lead implantation technique, especially when the implantation is being performed by trainees in the early stage of training. Therefore, this study aims to investigate and compare the two techniques of lead delivery by trainees in patients who are scheduled to undergo pacemaker implantation.

2 | METHODS

2.1 | Ethics and registration

This is a multicenter, randomized controlled prospective study (UMIN Clinical Trials Registry UMIN000031849). All equipment was set up with no sponsor support. The study protocol was approved by the institutional review board (Ethics Committee) at National Cerebral and Cardiovascular Center, Japan. The study has been conducted in compliance with the Declaration of Helsinki.[7] Informed consent will be obtained from the patients and/or their legal guardians.

2.2 | Physician characteristics and patient inclusion and exclusion criteria

The physicians performing the procedure were all trainees at the National Cerebral and Cardiovascular Center, Japan. They had previously performed less than five pacemaker implant operations as first operator but were appropriately trained to qualify for this study by assisting in implantations. The flow diagram is shown in Figure 1.

Patients aged 20-90 years with an indication for a bradycardia pacemaker requiring a right ventricle lead will be considered eligible for the study. Patients with a known vascular access problem or a previously implanted medical device at the implantation site will be excluded.

2.3 | Surgical procedure

The pacemaker system available for CDS is manufactured by Medtronic (Select Secure system; Minneapolis, MN) and those for SDS are manufactured by Abbott (St. Paul, MN), Boston Scientific (Marlborough, MA), Biotronik (Berlin, Germany), and Sorin (Clamart, France). The pacemaker pocket formation and vascular access operations will be performed based on the preference of the operator, who is assigned to the patients randomly. After successful lead implantation, the pocket closure will also be performed by the trainee operator. The entire procedure will be supervised by an expert cardiologist, with experience of more than 100 pacemaker implantations.

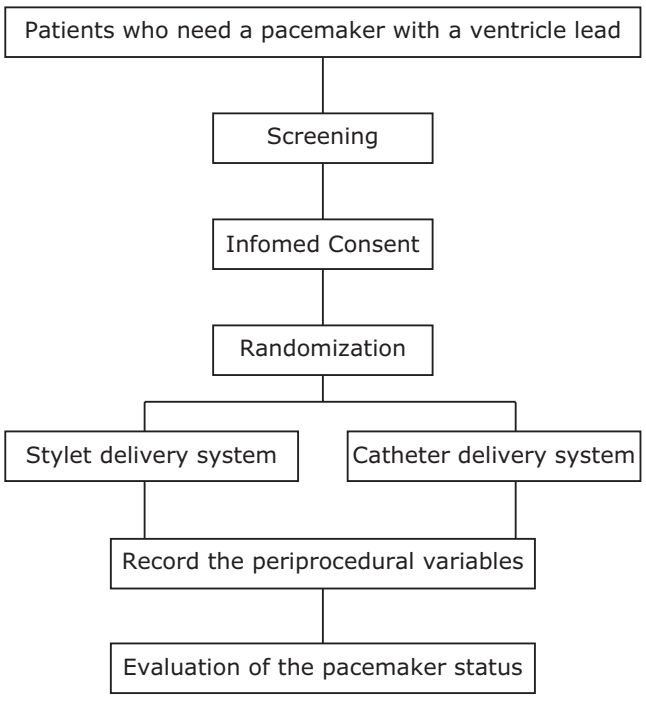

FIGURE 1 Flow diagram of the study

2.4 | Randomization

The patients will be randomized at a 1:1 ratio to either the CDS group or the SDS group. Randomization is performed using an in-house validated mail-based system, based on a minimization scheme with stratification by the operator. The patients' group allocations will be revealed to the surgeon at least 1 day before the operation.

The study was designed to enroll 100 patients, which produces a two-sided 95% confidence interval for the between-group difference in the number of attempts needed to place the lead, with a distance from the difference in means to the limits that is equal to 0.198, 0.397, and 0.794 when the estimated standard deviations are 0.5, 1.0, and 2.0, respectively.

2.5 | Data collection

The patient characteristics at enrollment, periprocedural variables, and outcome variables at follow-up that will be analyzed are presented in Table 1. To record the intraprocedural parameters, recording will start when the lead is inserted into the sheath and end when a sensing threshold >5.0 mV and pacing threshold <1.0 V at 0.5 ms is achieved, or when the supervising cardiologist determines that the trainee cannot accomplish the procedure safely. The primary endpoint is the total number of attempts needed to place the lead in the ideal position. For safety considerations, the incidence of lead perforation, lead dislodgement after implantation, and other complications requiring intervention will be recorded.

TABLE 1 Patient baseline characteristics and parameters measured in the study

Patient characteristics
Age, years
Male sex, n (%)
Body height, cm
Body weight, kg
12-lead electrocardiograms
Heart rate
QRS duration
Chest x-ray
Lead position
Other abnormal findings, n (%)
Indication for pacemaker implantation
Sick sinus syndrome
Atrial fibrillation with bradycardia
Complete atrioventricular block
Advanced atrioventricular block
Lead parameters
Pacing threshold
Sensing threshold
Intraprocedural parameters
Fluoroscopy time (min)
Fluoroscopy (dosage)
Lead delivery time (min)
Need for changing physician (yes/no)
Number of attempts to achieve ideal lead parameters (n)
Complication requiring medical intervention

Patients will be evaluated at the pacemaker outpatient clinic within 14 days of the procedure and again at 1 month.

2.6 | Monitoring

At each visit after the operation, the principal investigator or other investigators will interview the patient. When an adverse event occurs, the principal investigator or investigator will follow the patient until the adverse event is resolved and will enter the data into the website.

The data monitoring committee, which is independent of the investigators, will perform the central monitoring of the data stored on the website.

2.7 | Data quality control and management

The primary investigator or other investigators must follow the instructions of this study protocol. They cannot modify the protocol without permission from the ethics committee and must record any deviation from it.

When any new data are identified that requires revision of the protocol, and the data monitoring committee recommends revision, the representative investigator of the trial will revise the protocol. The revision of the protocol must be approved by the ethics committee.

2.8 | Statistical analysis

The intention-to-treat analyses will be performed in both the total population of all participating cardiologists, and in the separate subgroups of expert operators, and trainees.

Continuous variables will be presented as mean ± standard deviation, median with interquartile range (25th-75th percentiles), or range (minimum and maximum) and compared using either a two-sided *t* test or the Mann-Whitney U test for independent samples, as appropriate. Fisher's exact test will be used for analyzing categorical variables. A $P < 0.05$ is considered significant. All analyses will be performed using the SPSS 17.0 statistical package (SPSS, Inc., Chicago, IL).

3 | RESULTS

The results of this study are currently under investigation.

4 | DISCUSSION

Implantation of a permanent pacemaker is a common procedure performed by both trainees and cardiology specialists. Patients

requiring pacemaker implantation are geriatric with comorbid conditions.[8] Thus, a safe and efficient technique is required. SDS has been the only method for lead delivery for more than 20 years and is currently the standard technique for lead implantation. Currently, CDS is reported to be an important delivery system when performing His-pacing and implanting leads in patients with congenital heart disease.[9,10] In this study, we will compare SDS and CDS to test our hypothesis that the catheter-based delivery system is a safer and significantly more efficient technique than SDS, as the specific catheter always points to the interventricular septum. Thus, CDS does not need special training as is needed for shaping the stylet and manipulating the lead to cross the tricuspid annulus in SDS. The number of pacemaker implantations required is growing worldwide and this study may help determine the optimal technique for lead delivery and result in improved pacemaker surgery.

5 | CONCLUSIONS

The CATS delivery system trial will be the first prospective investigation assessing and comparing the clinical benefit and safety of the CDS and SDS techniques in pacemaker implantation. These findings may provide guidance, especially to trainees, in deciding on the optimal surgical technique to use for patients undergoing pacemaker implantations.

CONFLICT OF INTEREST

The authors declare no conflict of interests for this article.

ORCID

Kenichiro Yamagata https://orcid.org/0000-0002-9571-7017
Kengo Kusano https://orcid.org/0000-0002-5760-9285

REFERENCES

1. Brignole M, Auricchio A, Baron-Esquivias G, Bordachar P, Boriani G, Breithardt OA, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: the Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). Eur Heart J. 2013;34:2281–329.
2. Kusumoto FM, Schoenfeld MH, Barrett C, Edgerton JR, Ellenbogen KA, Gold MR, 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. J Am Coll Cardiol. 2018; 10.1016/j.jacc.2018.10.044
3. Rajappan K. Permanent pacemaker implantation technique: part I: arrhythmias. Heart. 2009;95:259–64.
4. Kirkfeldt RE, Johansen JB, Nohr EA, et al. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. Eur Heart J. 2014;35:1186–94.
5. Gupta N, Kiley ML, Anthony F, et al. Multi-center, community-based cardiac implantable electronic devices registry: population, device utilization, and outcomes. J Am Heart Assoc. 2016;5:e002798.
6. Rajappan K. Permanent pacemaker implantation technique: part II. Heart. 2009;95:334–42.
7. World Medical A. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310:2191–4.
8. Greenspon AJ, Patel JD, Lau E, et al. Trends in permanent pacemaker implantation in the United States from 1993 to 2009: increasing complexity of patients and procedures. J Am Coll Cardiol. 2012;60:1540–5.
9. Dandamudi G, Vijayaraman P. How to perform permanent His bundle pacing in routine clinical practice. Heart Rhythm. 2016;13:1362–6.
10. Garnreiter J, Whitaker P, Pilcher T, et al. Lumenless pacing leads: performance and extraction in pediatrics and congenital heart disease. Pacing Clin Electrophysiol. 2015;38:42–7.

How to cite this article: Yamagata K, Ishibashi K, Nakajima K, et al. Comparing the catheter delivery system and the stylet delivery system for ventricular lead placement in pacemaker implantation—The CATS delivery system randomized controlled trial. *J Arrhythmia*. 2019;35:524–527. https://doi.org/10.1002/joa3.12179