Contents lists available at ScienceDirect

Indian Pacing and Electrophysiology Journal

journal homepage: www.elsevier.com/locate/IPEJ

Outcomes using a single tapered dilator for Micra leadless pacemaker implant

Moghniuddin Mohammed [a, b], Juwairiya Arshi [a], Brian M. Ramza [c, d], Alan P. Wimmer [c, d], Daniel A. Steinhaus [c, d], Michael J. Giocondo [c, d], Sanjaya K. Gupta [c, d], Omair K. Yousuf [c, d, *]

[a] Department of Medicine, Saint Luke's Hospital, Kansas City, MO, USA
[b] Department of Biomedical and Health Informatics, University of Missouri Kansas City, MO, USA
[c] Division of Cardiology, Saint Luke's MidAmerica Heart Institute, Kansas City, MO, USA
[d] University of Missouri Kansas City School of Medicine, Kansas City, MO, USA

ARTICLE INFO

ABSTRACT

Objectives: Comparison of outcomes, device deployment time (DT), and total time (TT) using a single tapered Coons dilator versus sequential serial dilation for implantation of the Micra leadless pacemaker.
Background: Micra leadless pacemaker placement requires a 23 French Micra introducer sheath (MIS) for percutaneous delivery. We sought to evaluate outcomes with use of a single tapered Coons dilator (CD) versus sequential serial dilatation (SD) method to facilitate insertion of the Micra introducer sheath.
Methods: 35 patients were included in the SD arm and 49 in the CD arm. DT and TT were recorded in minutes and cost in dollars. Analysis was performed using independent t-test between two groups and one-way ANOVA to evaluate inter-operator variability in the CD arm.
Results: Both DT and TT were significantly lower for the CD arm (15.1 ± 5.1 *vs* 23.5 ± 9.3, p < 0.0005 and 29.9 ± 14 *vs* 39.3 ± 13.5 min, p = 0.000374; respectively). The cost was also significantly lower using a CD versus SD. There was no inter-operator variability in the CD arm between 6 operators (p = 0.177 for DT and p = 0.304 for TT). No complications occurred in the SD arm. There were 3 vascular access site complications in the CD arm, all of which occurred early in the operator's experience.
Conclusion: Coons dilator is an efficient and cost-effective method for vascular dilatation to facilitate Micra leadless pacemaker insertion. Rate of complications is low and expected to improve with greater experience.

1. Introduction

Leadless pacemakers were designed to mitigate pocket and lead related complications commonly encountered with traditional transvenous pacemakers (PPM) and may reduce the risk of major adverse events by 50–63% [1–3]. The Micra transcatheter pacing system (TPS) (Medtronic, Minneapolis, MN, USA) is currently the only FDA approved leadless pacemaker. Adverse vascular access related events are the most commonly observed complications. Both, the investigational device exemption study (IDE) and post-approval registry have demonstrated a consistently low rate of access related complications (0.7–0.75%) [2,4]. The Micra TPS

requires insertion of a Micra introducer sheath (MIS), which has a 23-French inner and 27-French outer diameter. Serial dilatation (SD) involving sequential use of progressively larger diameter dilators is recommended to reduce venous resistance and facilitate insertion of the MIS [5]. Serial dilation can be cumbersome, inefficient, and may be related to increased risk. The use of Micra TPS is likely to increase in future given the ability to perform atrioventricular synchronous pacing and it is important to explore efficient and cost-effective implantation techniques [6].

The Coons single tapered dilator (CD) (Cook Medical, Bloomington, IN, USA) consists of a long distal 6-French end that progressively increases in diameter to 20-French proximally with a rigid shaft, facilitating effective dilatation (Fig. 1). The Coons dilator has been used in a variety of procedures including cannulation for VV-extracorporeal membrane oxygenation (ECMO) [7], endovascular aneurysm repair [8], vascular access for hemodialysis [9], and for drainage of intra-abdominal abscesses [10]. The performance of

* Corresponding author. 4401 Wornall Road, Kansas City, MO, 64111, USA.
E-mail address: OYousuf@saint-lukes.org (O.K. Yousuf).
Peer review under responsibility of Indian Heart Rhythm Society.

Abbreviations and acronyms

TPS	Transcatheter Pacing System
MIS	Micra Introducer Sheath
SD	Serial Dilatation
CD	Single Tapered (Coons) Dilator
VV-ECMO	Veno-Venous Extracorporeal Membrane Oxygenation
DT	Deployment Time
TT	Total Time of Procedure
DAPT	Dual Anti-Platelet Therapy

Fig. 1. Single tapered Coons dilator — Fig. 1 shows Coons dilator consisting of long distal taper of 6-French to 20-French and a rigid dilator shaft.

the Micra transcatheter pacemaker system in the IDE study using the manufacturer recommended SD technique demonstrates a high level of implant success and relatively low adverse event rates [2]. The objective of this study is to evaluate and compare outcomes between the previously recommended serial dilation technique and the simplified single tapered Coons dilator to facilitate femoral venous insertion of the introducer sheath. This is the first study to assess the safety and efficacy of the Coons dilator in the delivery of the Micra TPS for leadless pacemaker implant. In addition, a cost analysis comparing the two approaches was also performed.

2. Methods

This is a retrospective study of all adult patients who underwent Micra TPS implant at Saint Luke's Mid-America Heart Institute,

Kansas City, Missouri between April 2014 and September 2018. Data was collected via retrospective review of patient charts in the electronic health records. The primary objective is to compare deployment time (DT), defined as time from femoral venous access to first deployment of the device and total time (TT), defined as time from femoral venous access to sheath removal. The secondary objective includes comparison of complications, pacemaker parameters, and cost between the two delivery methods. We also sought to analyze the reliability of the new technique by assessing inter-operator variability in the CD arm comparing DT and TT for 6 different electrophysiologists implanting the device. The Internal Review Board at Saint Luke's Hospital approved this study.

Analysis was performed using R version 3.5.3 on Windows 64-bit platform [11]. Continuous variables are presented as mean $\pm$ SD and categorical variables are presented as frequencies and percentages. Appropriate transformation was applied if the data did not meet criteria for normality. Independent *t*-test was used to compare the continuous variables and Chi square/Fisher-exact test was used to compare categorical variables between the CD and SD groups as deemed appropriate. Homogeneity of variances criteria as assessed by Levene's test was met. One-way ANOVA was used to compare DT and TT between the 6 operators in the CD arm. We also performed a sensitivity analysis by removing the cases of Operator 1 who has exclusively used the CD technique. Multiple regression was performed to analyze predictors of total procedural time duration. Two-sided p-value<0.05 was accepted as level of significance to reject the null hypothesis.

3. Results

3.1. Study population and baseline characteristics (Fig. 2, Table 1)

A total of 88 patients underwent Micra leadless pacemaker implantation at our institution during the study period. 4 patients were excluded due to insufficient documentation in the procedure log. Of the 84 patients included, 35 were in the SD arm and 49 in the CD arm (Fig. 2).

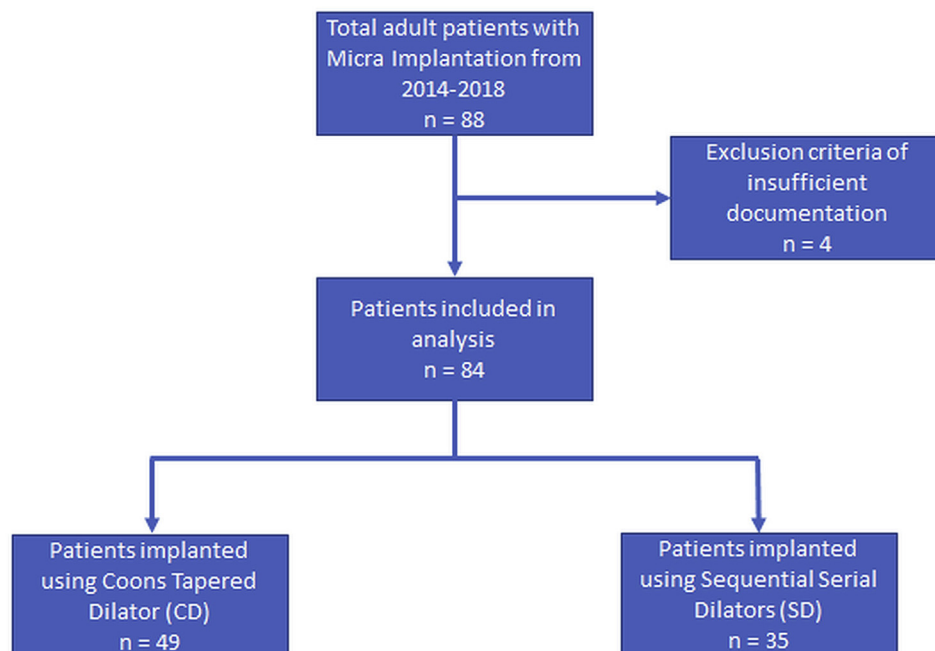Table 1 shows the baseline characteristics of the patients, which

Fig. 2. Patient flow diagram — Fig. 2 shows study population, inclusion and exclusion criteria.

Table 1
Baseline characteristics and co-morbidities of study cohort.

Characteristic	Serial Dilatation (n = 35)	Coons Dilator (n = 49)	p-value
Age in years			
Mean ± SD	74.3 ± 12.3	81.4 ± 8	0.004
Minimum-maximum	38—90	59—96	
Male	21 (60)	31 (63.3)	0.761
Race			0.455
Caucasian	34 (97.1)	45 (91.8)	
African-American	1 (2.9)	2 (4.1)	
BMI (mean ± SD)	28.7 ± 7.4	29.2 ± 6.7	0.739
PVD	2 (5.7)	9 (18.4)	0.111
Hypertension	29 (82.9)	42 (85.7)	0.721
Diabetes Mellitus	10 (28.6)	18 (36.7)	0.434
Atrial Fibrillation	28 (80)	45 (91.8)	0.188
CAD	19 (54.3)	30 (61.2)	0.525
CHF	16 (45.7)	27 (55.1)	0.396
CVA	11 (31.4)	9 (18.4)	0.166
Anticoagulant use			0.23
Warfarin	16 (45.7)	13 (26.5)	
Apixaban	8 (22.9)	20 (40.8)	
Rivaroxaban	2 (5.7)	5 (10.2)	
Antiplatelet use			0.963
Aspirin	16 (45.7)	24 (49)	
Clopidogrel	2 (5.7)	2 (4.1)	
DAPT	1 (2.9)	2 (4.1)	

Values are n (%) unless otherwise indicated. BMI — Body mass index, CAD — Coronary Artery Disease, CHF — Congestive heart failure, CVA — Cerebrovascular Accident, DAPT — Dual Anti-platelet Therapy, PVD — Peripheral Vascular Disease.

were similar between the two groups. Patients in the CD arm were significantly older compared to patients in the SD arm (81.4 ± 8 years *vs* 74.3 ± 12.3 years, p = 0.004). 1 patient was on dabigatran in the CD arm. There were no other significant differences between the two groups.

3.2. Deployment time (DT) and total time (TT) between CD and SD arm (Table 2, Fig. 3)

The mean deployment time (DT) for the CD group was significantly shorter than the mean deployment time for the SD group (15.1 ± 5.1 *vs* 23.5 ± 9.3 min, respectively; p < 0.0005). The mean TT for the CD group was significantly lower than the mean TT for the SD group (29.9 ± 13.9 *vs* 39.3 ± 13.5 min, respectively; p = 0.003). Table 2 shows the procedural volume stratified by operator and dilatation technique.

There was a significant difference between the two groups even after removing cases of Operator 1 (N = 15) who has exclusively used CD for vascular access dilatation. The mean DT in this analysis was 15.3 ± 5.2 and 23.5 ± 9.3 min for CD and SD group respectively (p < 0.005). Similarly, the mean TT was also significantly lower in the CD group at 32.1 ± 15.5 min compared to SD group at 39.3 ± 13.5 min (p = 0.0452).

Repositioning of the device after initial deployment was

performed in 23 (27.4%) patients of which 8 (9.5%) were in SD arm and 15 (17.9%) were in CD arm. This difference in total time persisted even though the rate of repositioning of the device was slightly higher in the CD arm.

We also compared fluoroscopy time (FT) when data was available (data was missing for 1 patient in the SD and 3 patients in the CD group). There was no significant difference between the two groups. The FT was 7.4 ± 4.5 min for the SD group and 7.2 ± 4.8 min for the CD group (p = 0.884).

3.3. Deployment time (DT) and total time (TT) in the CD arm stratified by operators (Fig. 4)

The average DT (minutes) for each operator was as follows: operator 1 was 14.7 ± 4.9, operator 2 was 15.3 ± 6; operator 3 was 17.9 ± 5.5; operator 4 was 14.9 ± 2; operator 5 was 11 ± 4; and, operator 6 was 18.4 ± 3.3 min. Device deployment time was not statistically different amongst the different operators (p = 0.177). Effect size was calculated as $\omega2 = 0.059$, suggesting that only 5.9% of the variance in device deployment time is accounted for by differences amongst the operators.

The average TT (minutes) duration for each operator was as follows: operator 1 was 25 ± 7.9; operator 2 was 29.6 ± 15.3; operator 3 was 33.29 ± 18.17; operator 4 was 36.4 ± 13.4; operator 5

Table 2
Procedural volume stratified by operator and vascular dilatation method.

| Operator	Procedure	Volume	Total Time (minutes)	Deployment Time (minutes)
Operator 1	Coons Dilator	15	25.0 ± 7.9	14.7 ± 4.9
Operator 2	Serial Dilator	13	34.7 ± 7.7	22.2 ± 5.9
Operator 2	Coons Dilator	13	29.6 ± 15.3	15.3 ± 6
Operator 3	Serial Dilator	8	49.9 ± 11.6	34.9 ± 9.8
Operator 3	Coons Dilator	5	33.3 ± 18.2	17.9 ± 5.5
Operator 4	Serial Dilator	4	47.9 ± 16.2	21.2 ± 2.6
Operator 4	Coons Dilator	5	36.4 ± 13.4	14.9 ± 2.1
Operator 5	Serial Dilator	9	30.0 ± 11.4	16.0 ± 5.1
Operator 5	Coons Dilator	6	26.7 ± 13.8	11.0 ± 4.1
Operator 6	Serial Dilator	1	61.8	24.8
Operator 6	Coons Dilator	5	39.8 ± 18.8	18.4 ± 3.3
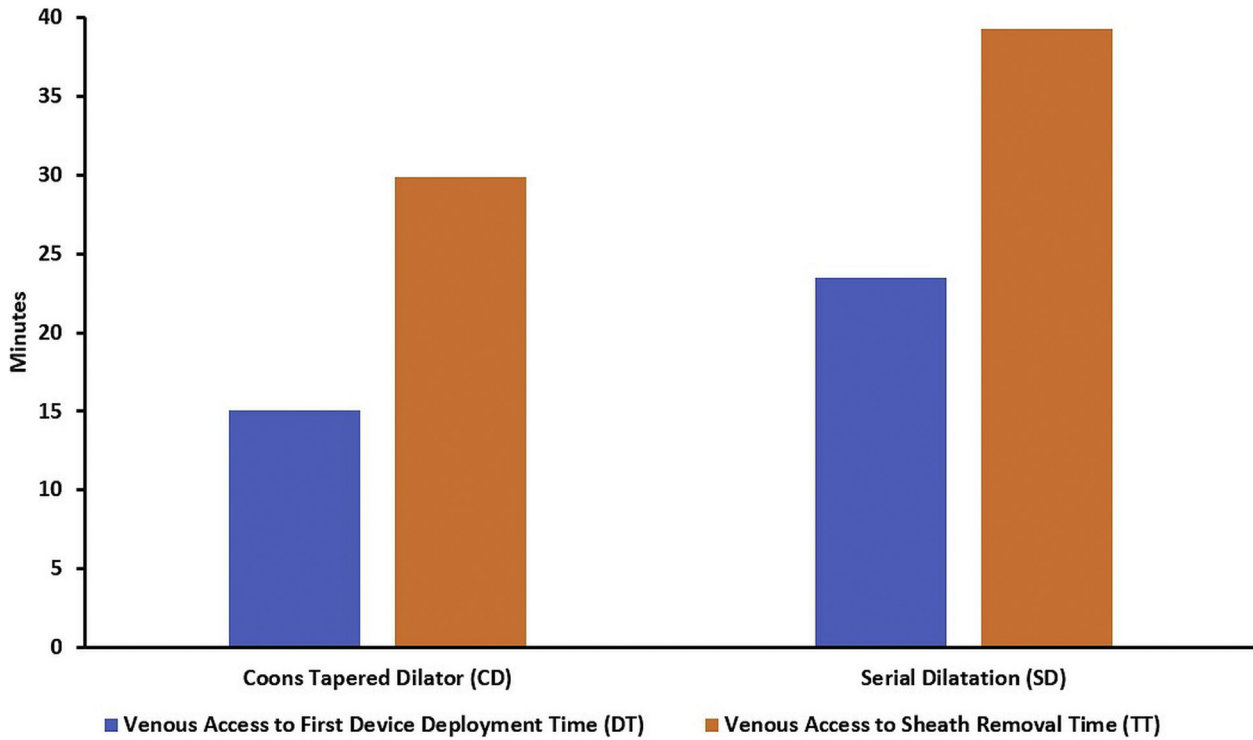
Fig. 3. Deployment and Total procedural time between the two vascular access strategies – Fig. 3 shows mean deployment and total time for single tapered (CD) and serial dilatation (SD) group.

was 26.7 ± 13.8; and, operator 6 was 39.8 ± 18.8 min. The total procedural duration was not statistically different amongst the different operators (p = 0.304). Effect size was calculated as $\omega 2 = 0.025$, suggesting that operator differences may acount for a 2.5% variance in total time duration.

3.4. Predictors of total time (Fig. 5)

Multivariate regression was used to identify predictors of total time duration in the study population. Simultaneous entry method

was used for variables of age, BMI, ultrasound use, dilatation technique and operator volume, which we hypothesized would influence the procedural times. SD and Operator 1 was used as reference for procedure and operators, respectively. Only 2 operators performed ultrasound guided vascular access, which was used for 20 procedures in the CD and 9 procedures in the SD arm. Using the CD technique improved the procedure efficiency by 8.7 min compared to the SD group, even after accounting for other variables in the model (p = 0.0097). None of the other predictors were significant.
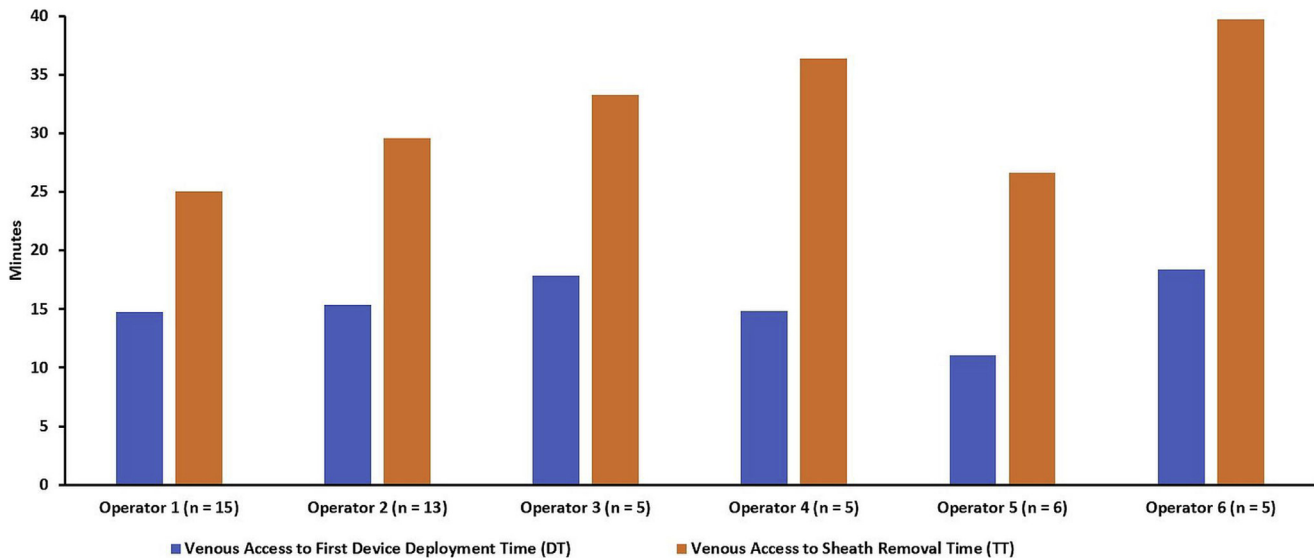

Fig. 4. Differences in Deployment and Total Time amongst various operators in the Coons Dilator arm – Fig. 4 shows mean deployment and total time for six operators in the single tapered dilator group.
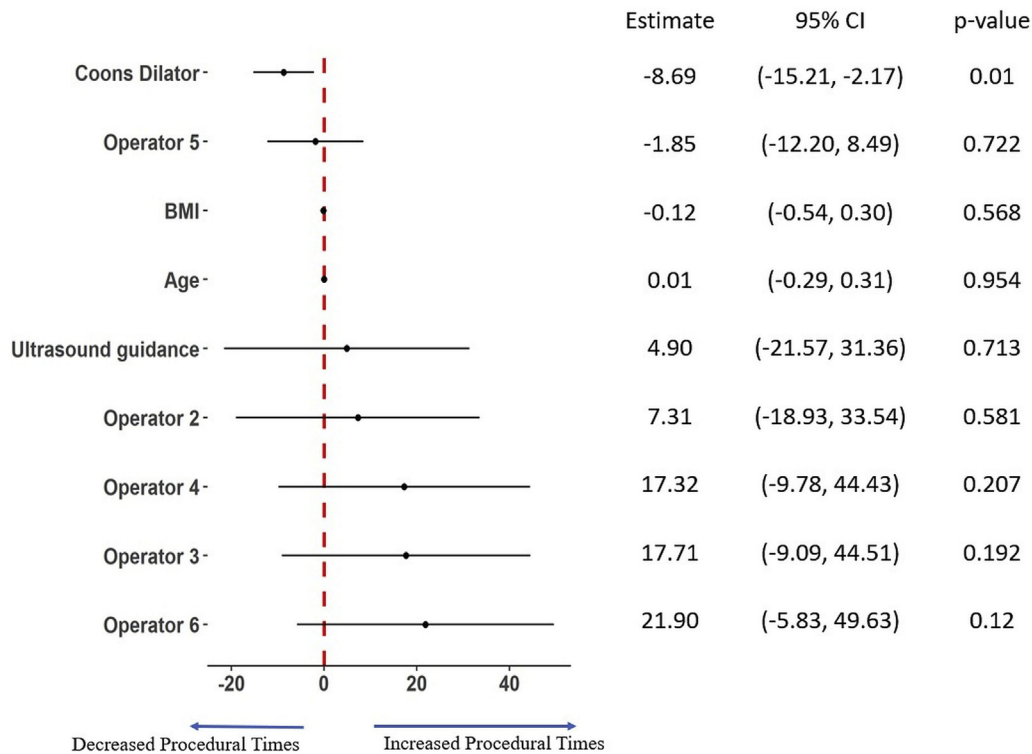
	Estimate	95% CI	p-value
Coons Dilator	-8.69	(-15.21, -2.17)	0.01
Operator 5	-1.85	(-12.20, 8.49)	0.722
BMI	-0.12	(-0.54, 0.30)	0.568
Age	0.01	(-0.29, 0.31)	0.954
Ultrasound guidance	4.90	(-21.57, 31.36)	0.713
Operator 2	7.31	(-18.93, 33.54)	0.581
Operator 4	17.32	(-9.78, 44.43)	0.207
Operator 3	17.71	(-9.09, 44.51)	0.192
Operator 6	21.90	(-5.83, 49.63)	0.12

Decreased Procedural Times   Increased Procedural Times

Fig. 5. Multiple regression model for Total Time. Use of Coons dilator significantly shortened the total procedural time after accounting for patient and operator characteristics.

3.5. Safety outcomes

Major peri-procedural complications including in-hospital mortality, need for additional intervention, including surgery, prolonged hospitalization, or readmission were evaluated. There were no device related complications of dislodgement or pericardial effusion in either group.

There were no procedure related complications in the SD arm. The CD arm had 3 complications, each ocuring in 3 distinct patients; these included retroperitoneal bleedrequiring blood transfusion, pseudoaneurysm with AV fistula requiring surgical repair, and pseudoaneurysm of common femoral vein, managed conservatively. Vascular access related complications were slightly higher in the CD arm as compared to the SD arm ($p = 0.1425$). There was no procedure related mortality in either group.

3.6. Cost

A single tapered Coons dilator costs $19.42 (USD) at our institution. Sequential serial dilatation method requires at least 4 progressively increasing dilators from 8-French to 20-French. However, up to 7 dilators may be used in some institutions. The total cost can range from $21.80 to as high as $38.15. A CD may result in up to 51% in cost savings than the SD method, and at best, is similarly priced.

4. Discussion

The Micra leadless pacemaker implant has a low rate of complications and the performance efficacy is high. Similar to previous studies, our study demonstrates a high-level of successful implants of 100%. Our study shows that the deployment time and total procedural time duration can be reduced by approximately 8 and 10 minutes, respectively for Micra TPS implant using a single tapered Coons dilator compared to the traditional serial dilatation method that is commonly used. This may also result in potentially reduced costs.

Deployment time was felt to be an important surrogate of efficiency of the CD given that it is exclusively used for vascular access. Data on TT duration was also collected to compare the results with other published studies; however, it is important to note that factors beyond vascular access may influence total procedural times.

The average total time of 39.3 ± 13.5 min in our study cohort using the SD method was similar to the duration reported in previous studies [2,12,13]. In the early study of Micra TPS [12], the total procedural time was 37 ± 21 min (11—154 min). This was consistent with the IDE study, which reported the mean total time (defined as introducer in/out time) of 34.8 ± 24.1 min and median of 28 min [2]. A detailed analysis of the effect of operator experience on procedural times for Micra TPS showed that the procedure duration decreased with increasing experience [14].

The mean total time duration using the CD in our study was significantly lower at 29.9 ± 13.9 min even when compared to other larger cohorts. Fluoroscopy time was not significantly different between the two cohorts and was similar or slightly better compared to previous studies [2,15].

Operator volume and its impact on procedural outcomes are well estaboshed [16—19]. The LEADLESS II trial [20] demonstrated a 6.8% rate of device-related complications for the initial 10 cases versus 3.6% for subsequent implants. Influence of operator experience was also observed in the Micra TPS study with a reduction of 2% in procedural duration seen for every subsequent implant [14]. Operator experience did not influence adverse event rates.

Our study demonstrated zero device-related adverse events, including in-hospital dislodgement or need for system revision, pericardial effusion, or cardiac surgery. There was no in-hospital mortality. The post-approval registry [4] showed a very low rate of major complications (1.5%) and the IDE study [2] demonstrated a slightly higher rate of adverse events (2.89%). Vascular access site

complications are unique to this population as the Micra TPS requires a 23 French introducer sheath. The rate of access site complications has remained consistent at 0.6—0.75% amongst several studies [2—4]. In our study, we observed a 3.5% rate of major access site complications (n = 3). All three cases were in the Coons dilator cohort. Although there were no vascular access related adverse events in the SD arm, the findings were not statistically significant. No operator had more than one complication using the CD. Given the small number of events, further analysis was performed to better understand the observed complications.

- Patient 1 was an 86-year-old woman who developed a pseudoaneurysm and AV fistula. She was on uninterrupted dual antiplatelet therapy. This was the operator's 5th case using the CD. Vascular access was not obtained under ultrasound guidance.
- Patient 2 was an 80-year-old woman on apixaban who developed a retroperitoneal hematoma. This was the operator's 3rd case using the CD. Vascular access was obtained under ultrasound guidance.
- Patient 3 was an 86-year-old man on warfarin who developed an AV fistula that was managed conservatively. This was the operator's 6th case using the CD. Vascular access was not obtained under ultrasound guidance.

There are several factors that may have contributed to these 3 complications, including advanced age, use of dual antiplatelet or anticoagulant therapy, lack of ultrasound guidance, and potentially operator experience. Advanced age is a well-known risk factor for vascular access related complications [3]. Patients in the CD arm were significantly older than the patients in the SD group (81.4 ± 8 vs 74.3 ± 12.3 years, p = 0.004). The patients in the CD arm were also older compared to patients in the IDE study (75.9 ± 10.9 years) and post-approval registry (75.2 ± 14.2 years) [2,4]. Additionally, our study had greater number of patients with atrial fibrillation (AF) and coronary artery disease (CAD) compared to the IDE study (72.6% AF and 28.2% CAD) and the post-approval registry (66.9% AF and 16.6% CAD). Though the pre- and peri-operative anticoagulation use was at the discretion of the operator in the IDE study, the number of patients on anticoagulation and/or antiplatelet therapies is not known.

The SD technique was used early on during the Micra TPS implant experience at our institute and it is possible that there may have been a selection bias. The patients in the CD arm were much older and we adapted that technique as our experience evolved.

Lastly, ultrasound guidance for vascular access is known to reduce access site complication [5,12]. Ultrasound was not used in 2 of the 3 patients who had a vascular access site complication. Ultrasound use has not been assessed in previous studies of Micra TPS implants [12]. The use of ultrasound should be encouraged to minimize vascular access site complications. In our study ultrasound was used in only 29 patients; 20 in the CD arm and in the SD arm.

4.1. Limitations

The study is limited due to its small sample size and being a retrospective single center analysis. Though we had zero device related complications and 3 vascular access related complications in the Coons dilator arm, the exact etiology is difficult to conclude. Further study in a larger cohort will provide greater insight into specific predictors of adverse events. We have not analyzed the cost of complications which might offset the cost benefit of the CD technique. Furthermore, the cost-benefit may be of limited significance in countries where the reuse of sheaths and catehters is a

common practice. The study is limited to in-hospital outcomes. Long-term outcomes and electrical performance over time was not assessed.

4.2. Conclusions and clinical implications

Initial use of a single tapered Coons dilator to facilitate vascular access for the Micra delivery system has demonstrated a high-level of implant success, efficiency, and is potentially cost effective. There were 3 access related complications in the CD arm that all occured in patients with advanced age (≥80 years). Precaution must be taken during insertion of large bore sheaths, particularly in the elderly population. Further studies should be performed to better evaluate the safety and efficacy of this venous dilation technique.

Competency in medical knowledge

The present study demonstrates the safety, efficiency and potential cost-effectiveness of the single tapered dilator for venous dilatation to facilitate Micra leadless pacemaker implantation. Further studies will be needed to better evaluate the safety of this technique, particularly in the elderly poopulation.specifically in patients aged 80 years and older.

Declaration of competing interest

None.

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