INTRODUCTION

Implantation of cardiac implantable electronic devices (CIEDs) has been growing steadily as a result of expanding indications, with most implantations involving the placement of a transvenous right ventricular (RV) pacemaker or implantable cardioverter-defibrillator (ICD) lead. Avoiding the free wall when implanting RV leads is critical to reduce the risk of perforation and pacing-mediated cardiomyopathy resulting from ventricular dyssynchrony. While various fluoroscopic criteria have been suggested to confirm the septal placement of RV leads, these remain imperfect on account of cardiac rotational variations and the crescent shape of the right ventricle. While various fluoroscopic criteria have been suggested to confirm the septal placement of RV leads, these remain imperfect on account of cardiac rotational variations and the crescent shape of the right ventricle. 

This pilot study evaluated the feasibility and impact of real-time transthoracic echocardiogram (TTE) during RV lead placement.

Method: Consecutive patients undergoing transvenous RV lead placement and had a point of care ultrasound team available for TTE guidance were included in the study. TTE was performed to confirm or refute the septal position of RV lead initially positioned using fluoroscopy; leads were repositioned until a septal position was confirmed on TTE. The primary outcome measured was whether the use of TTE resulted in lead repositioning.

Result: Among the 26 patients included in the study, real-time TTE during RV lead placement resulted in reposition of the lead to a septal position in 38.5% of patients.

Conclusion: Use of real-time TTE guidance during fluoroscopic RV lead placement is feasible and can aid in confirming a septal position.
METHODS

Consecutive subjects who underwent transvenous pacemaker or ICD placement and had a point of care ultrasound (POCUS) team available for real-time validation were included in this pilot study from November 2018 to December 2020. The POCUS team at Loma Linda University is led by three cardiac anesthesiologists with rotating residents. This pilot study was approved by the Loma Linda University IRB (IRB number 5170194), with informed consent obtained from all patients involved, and the study followed the ethics and integrity policies. Exclusion criteria were emergent procedures, leadless or His bundle pacemakers (where septal guiding sheaths are used), and procedures that utilized transesophageal echocardiogram (TEE) (such as re-implantation after lead extraction). The majority of the procedures were performed under monitored anesthesia care with local anesthesia. The protocol for utilization of TTE is displayed in Figure 1A. The prepping and draping process was modified with a sterile drape (Ioban) covering the chest allowing access to obtain TTE images on different windows (Figure 1B). A POCUS team member would scrub in the procedure with a sterile sleeve on the echo probe (Butterfly Network, Inc, CT, USA) during the placement of the RV lead. The Butterfly echo probe was used in this study because of the portability of a handheld unit and the functionality of being able to connect to a mobile device for viewing, understanding that the images may be less clear compared to a traditional 2-D TTE machine. After positioning of the RV lead, TTE was performed with patients remaining in supine position. Initial location of the RV lead was evaluated in the parasternal long and short axis, and apical and subcostal views. Color Doppler across the tricuspid valve was also performed to rule out significant TR. After a joint review with the implanting electrophysiologist, a decision would be made regarding lead adjustment. The final lead position would be documented according to the TTE image. The primary outcome measured was whether the use of TTE resulted in lead repositioning. Additionally, the following data points were documented: time to perform TTE; image quality of TTE; and procedure time and fluoroscopy time. Immediate and 30-day complications (including pericardial effusion, pneumothorax, lead dislodgement, lead malfunction, infection, and pocket hematoma) were also recorded.

RESULTS

Among 26 patients included in the final analysis, six underwent ICD placement and 20 underwent pacemaker placement. Patient demographics are demonstrated in Table 1. TTE resulted in reposition of the RV lead in 10 patients (38.5%) with final lead position identified as septal on all patients. Seven of the 10 patients had a final lead position in the mid-papillary septal wall, two patients in the apical septal wall, and one patient in the basal septal wall (Figure 2). The mean time to perform the TTE exam was 1.4 minutes, with the shortest ultrasound time at 45 seconds and the longest at 2.8 minutes. The subcostal and apical windows achieved the greatest number of high-quality images. A 5-point Likert scale was used to rate image quality (1 = poor, 2 = adequate, 3 = adequate, 4 = good, 5 = excellent).
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3 = clinically useful, 4 = good, 5 = excellent), 69% reached above a 4 on subcostal view, 35% reached above a 4 on apical view, and parasternal views were only obtained on 15% of patients secondary to adequate images obtained on the other views. There were no complications identified immediately or within 30 days in this cohort of patients (Table 2).

4 | DISCUSSION

To our knowledge, this is the first study to utilize real-time TTE to facilitate CIED RV lead placement. We demonstrated that the use of TTE to guide standard RV lead placement was feasible and led to repositioning of the lead in 38.5% of the patients; a final septal position was confirmed in all patients.

The lead tip pointing leftward on the left anterior oblique (LAO) view with fluoroscopy is the most commonly used sign of septal lead placement confirmation. However, this sign does not rule out the possibility of lead position in the recess between the RV free wall and septum, where deployment can lead to catastrophic complications. While other complex fluoroscopic criteria have been suggested, the ease of use, wide availability, and low cost associated with TTE to guide RV septal lead position offer a feasible option to supplement current fluoroscopic techniques. In addition, TTE can also diagnose lead-related tricuspid valve dysfunction which can be difficult to determine by fluoroscopy alone. Significant tricuspid regurgitation (TR) defined as ≥2+ and incidence of TR worsening by 1 or more grades has been reported in 10%-39% of patients receiving transvenous CIEDs with RV leads and can pose a challenge for subsequent management (Figure 3). However, significant pacemaker-induced TR immediately postimplantation is uncommon (11%-17%) and is often trace to mild. In our study, we did not identify any case with worsening TR using 2D TTE color Doppler post-RV lead placement. The utilization of real-time 2D TTE to guide lead repositioning for prevention of TR will need more evaluation, given that 2D TTE has low sensitivity on spatial identification between lead and valve/subvalvular apparatus when comparing to 3D TTE.

Our study has several limitations to consider. First, our sample size is relatively small without a control group to compare differences. Secondly, TTE guidance can prolong the procedure time; however, we believe that the few extra minutes spent is worth...
| Subject | Manufacturer      | Fluoroscopic time (min) | Procedure time (min) | TTE reposition | Time of implant | 15- to 30-day follow-up |
|---------|-------------------|-------------------------|----------------------|----------------|----------------|------------------------|
|         |                   |                         |                      |                | Threshold (V)  | R-wave (mV)           | Impedance (Ohms)       |
| 1       | St Jude Medical   | 2.3                     | 52                   | No             | 0.3 @ 0.5 ms  | 5.7                   | 750                    |
|         |                   |                         |                      |                | 0.25 @ 0.5 ms | 8                     | 440                    |
| 2       | St Jude Medical   | 5.3                     | 83                   | No             | 0.75 @ 0.5 ms | 3.9                   | 580                    |
|         |                   |                         |                      |                | 0.5 @ 0.5 ms  | 7.3                   | 530                    |
| 3       | St Jude Medical   | 8.3                     | 97                   | Yes            | 0.5 @ 0.5 ms  | 9.6                   | 465                    |
|         |                   |                         |                      |                | 0.75 @ 0.5 ms | 7.6                   | 481                    |
| 4       | Medtronic         | 4                       | 56                   | Yes            | 0.7 @ 0.5 ms  | 9                     | 852                    |
|         |                   |                         |                      |                | 1 @ 0.5 ms    | 12.4                  | 513                    |
| 5       | Medtronic         | 17                      | 116                  | No             | 0.7 @ 0.5 ms  | 15.6                  | 684                    |
|         |                   |                         |                      |                | 0.5 @ 0.4 ms  | 12.4                  | 570                    |
| 6       | St Jude Medical   | 3.1                     | 62                   | Yes            | 0.75 @ 0.4 ms | 6.8                   | 660                    |
|         |                   |                         |                      |                | 0.75 @ 0.5 ms | 12.9                  | 418                    |
| 7       | Medtronic         | 5.4                     | 58                   | No             | 0.75 @ 0.5 ms | 9.6                   | 524                    |
|         |                   |                         |                      |                | 0.625 @ 0.5 ms| 11.9                  | 494                    |
| 8       | St Jude Medical   | 35.2                    | 182                  | No             | 0.7 @ 0.5 ms  | 9.5                   | 493                    |
|         |                   |                         |                      |                | 0.75 @ 0.5 ms | 8.9                   | 440                    |
| 9       | Medtronic         | 5.35                    | 34                   | No             | 0.5 @ 0.4 ms  | 15.6                  | 684                    |
|         |                   |                         |                      |                | 0.5 @ 0.4 ms  | 12.4                  | 570                    |
| 10      | Medtronic         | 3.9                     | 66                   | Yes            | 0.7 @ 1 ms    | 13                    | 690                    |
|         |                   |                         |                      |                | 0.75 @ 0.4 ms | 12.9                  | 418                    |
| 11      | Medtronic         | 5.6                     | 57                   | Yes            | 0.8 @ 1 ms    | 6.1                   | 558                    |
|         |                   |                         |                      |                | 1.375 @ 0.4 ms| 6.9                   | 494                    |
| 12      | Medtronic         | 16.7                    | 135                  | Yes            | 0.7 @ 0.5 ms  | 6.6                   | 651                    |
|         |                   |                         |                      |                | 0.625 @ 0.4 ms| 5                     | 437                    |
| 13      | Medtronic         | 5.8                     | 52                   | No             | 0.5 @ 0.5 ms  | 16.1                  | 912                    |
|         |                   |                         |                      |                | 0.875 @ 0.5 ms| 10.8                  | 494                    |
| 14      | St Jude Medical   | 6.5                     | 69                   | No             | 0.5 @ 0.5 ms  | 10.6                  | 650                    |
|         |                   |                         |                      |                | 0.75 @ 0.5 ms | 7.3                   | 530                    |
| 15      | Medtronic         | 25.2                    | 15                   | No             | 0.5 @ 0.5 ms  | 3.4                   | 570                    |
|         |                   |                         |                      |                | 0.5 @ 0.5 ms  | 6.3                   | 494                    |
| 16      | Medtronic         | 12.8                    | 111                  | Yes            | 0.3 @ 1 ms    | 2.3                   | 624                    |
|         |                   |                         |                      |                | 0.875 @ 0.4 ms| 3.8                   | 456                    |
| 17      | St Jude Medical   | 3.6                     | 34                   | No             | 0.4 @ 0.4 ms  | 7.6                   | 890                    |
|         |                   |                         |                      |                | 0.625 @ 0.4 ms| 9                     | 590                    |
| 18      | Medtronic         | 9.1                     | 79                   | No             | 1.25 @ 0.4 ms | 4.3                   | 1178                   |
|         |                   |                         |                      |                | 0.5 @ 0.4 ms  | 4.9                   | 779                    |
| 19      | Medtronic         | 12.0                    | 76                   | No             | 0.5 @ 0.5 ms  | 8                     | 1337                   |
|         |                   |                         |                      |                | 0.75 @ 0.4 ms | 4.9                   | 532                    |
| 20      | St Jude Medical   | 3.1                     | 59                   | No             | 0.6 @ 0.4 ms  | 12                    | 1150                   |
|         |                   |                         |                      |                | 0.75 @ 0.4 ms | 12                    | 710                    |
| 21      | Medtronic         | 3.3                     | 53                   | Yes            | 1.1 @ 0.5 ms  | 6                     | 1370                   |
|         |                   |                         |                      |                | 0.875 @ 0.5 ms| 10.1                  | 513                    |
| 22      | Medtronic         | 4.4                     | 58                   | No             | 0.375 @ 0.5 ms| 12.5                  | 855                    |
|         |                   |                         |                      |                | 0.75 @ 0.5 ms | 17.4                  | 665                    |
| 23      | St Jude Medical   | 4.4                     | 51                   | Yes            | 0.7 @ 0.4 ms  | 7.9                   | 670                    |
|         |                   |                         |                      |                | 0.5 @ 0.4 ms  | 6.8                   | 480                    |
| 24      | Medtronic         | 6.5                     | 50                   | No             | 0.5 @ 0.4 ms  | 5.2                   | 665                    |
|         |                   |                         |                      |                | 0.375 @ 0.4 ms| 8.9                   | 513                    |
| 25      | Boston Scientific | 3.5                     | 69                   | Yes            | 0.5 @ 0.4 ms  | 19.8                  | 739                    |
|         |                   |                         |                      |                | 0.4 @ 0.4 ms  | 19                    | 729                    |
| 26      | Medtronic         | 3.2                     | 62                   | No             | 0.38 @ 0.5 ms  | 13.8                  | 710                    |
|         |                   |                         |                      |                | 0.5 @ 0.5 ms  | 15.6                  | 580                    |
the risk of complications that occur from lead placement in the RV free wall. Third, obtaining TTE images in this study required an additional operator. However, most implanting electrophysiologists are already proficient with basic TTE skills that can be improved with experience to obtain satisfactory images, negating the need for an additional TTE operator. Fourth, in our experience, the recess between the RV septum and free wall was the most prone to give a false appearance of the lead tip being "septal" on fluoroscopy, requiring reposition with TTE. While we do not have data for individual patients regarding the most frequent sites where leads had to be repositioned from, this would be useful to obtain in follow-up studies. Fifth, given the pilot nature of our study, the number of attempts to deploy screws was not recorded in our initial data set. Sixth, given that most of our implants are performed with limb leads only, and 12-lead electrocardiograms postprocedure would not show paced QRS morphology in patients who had implants for preserved atrioventricular conduction with intrinsic QRS complexes, we do not have complete data on all patients regarding QRS duration and morphology. Lastly, we agree that 3-D TTE, TEE, or CT scan would provide a much clearer image given the complex structure of the right ventricle. Currently, 3-D TTE is not available at our institution. TEE would increase the risk of complications related to esophageal intubation and would also require general anesthesia for most patients, and hence, this was not performed. While CT scan can provide useful images, it is not possible to use in real-time for placement of leads. Hence, a 2-D TTE device was chosen as the imaging modality in our study.

5 | CONCLUSION

This pilot study demonstrated the utility of real-time TTE during CIED RV lead placement. Our results showed that TTE can be performed in a short amount of time with good quality and led to repositioning of RV lead in 38.5% of patients. These results encourage larger studies to evaluate the utility of real-time TTE for CIED RV lead placement.

CONFLICTS OF INTEREST

None.

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