GLOBAL VOICES

A MacGyvering way to left bundle branch area pacing: Using the modified V1/V6 leads connected to the pacing system analyzer

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BACKGROUND There is a significant impediment to the availability of a fully capable electrophysiology (EP) procedure room and EP recording system due to healthcare cost restraints in resource-poor settings.

OBJECTIVE The aim of the study was to assess the feasibility and outcomes of using the conventional treadmill test machine 12-lead ECG system and modified V1 and V6 leads connected to the pacing system analyzer (PSA) to demonstrate conduction system capture during left bundle branch area pacing (LBBaP).

METHODS LBBaP was attempted by a single operator using the Medtronic 3830 lumenless leads and St. Jude/Abbott stylet-driven leads in a mixed cohort of patients at hospitals lacking an EP recording system. Conduction system capture was assessed using modified V1 and V6 leads.

RESULTS LBBaP was successful in 18 (94.7%) of 19 patients. There was excellent correlation between 12-lead ECG and modified V1 and V6 leads connected to the PSA regarding the measurement of V6 left ventricular activation time and QRS morphology change in V1 during selective to nonselective left bundle branch capture. Patient characteristics were the following: mean age of 66.7 ± 11.47 years, 52.63% male, 10.52% with ischemic cardiomyopathy, and 5.26% with nonischemic cardiomyopathy. LBBaP resulted in a QRS duration of 112.77 ±11.27 ms with a left ventricular activation time of 70.55 ± 8.02 ms. Left ventricular ejection fraction improved in the patients with cardiomyopathy from 33.4 ± 5.77% to 48.2 ± 12.37% ($P = .028$).

CONCLUSION The modified V1 and V6 leads connected to the PSA is a feasible alternative to the EP system to perform successful LLBaP.

KEYWORDS Modified leads; Additional leads; Left bundle branch area pacing; LVAT; Treadmill testing

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Introduction

Cardiac physiologic pacing should be considered in patients who require substantial ventricular pacing (>20%–40%).[1] The impediments to the universal application of left bundle branch area pacing (LBBaP) include the need for an electrophysiology (EP) recording system to measure the V6 left ventricular activation time (LVAT) and the continuous real-time visualization of the paced QRS morphology in the V1 lead to demonstrate a transition from left bundle branch block (LBBB) morphology to right bundle branch block (RBBB) morphology. However, in resource-poor settings, especially in developing countries, there is a significant limitation to the availability of fully capable EP procedure room due to healthcare cost restraints. To circumvent this, we sought to assess the performance of LBBaP in the absence of the EP system using modified V1 and V6 leads connected to the pacing system analyzer (PSA) to demonstrate conduction system capture.

Methods

Patient population and consent information

This was a prospective pilot study in which we studied 19 consecutive patients who underwent LBBaP using the Medtronic 3830 lumenless lead (MLLL) or the St. Jude/Abbott stylet-driven lead (SASDL) in hospitals lacking the standardized EP recording system. The study complied with the

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KEY FINDINGS

- The study shows that left bundle branch area pacing is feasible in patients without a standardized electrophysiology recording system with successful outcomes.
- Use of modified leads to act as surrogate for V1 with pacing system analyzer can be used for ascertaining the paced right bundle branch block morphology and right bundle branch block morphology beats.
- Measurement of the left ventricular activation time using modified V6 in the pacing system analyzer has excellent correlation with the 12-lead electrocardiogram and can be used for precise measurements during implantation.

Declaration of Helsinki, was approved by the institutional review board and all patients provided written informed consent. The indication for the pacemaker was 2:1 atrioventricular (AV) block with RBBB baseline (n = 4), complete AV block with narrow escape (n = 6), paroxysmal AV block (n = 2), and asystole with an escape rhythm (n = 7).

LBBaP implantation technique using treadmill test and PSA

Using the treadmill test (TMT) machine, 12-lead ECG was connected in all the patients. The procedural steps to carry out the LBBaP consisted of localizing the lead insertion site using the ECG on the TMT machine, penetrating the interventricular septum, followed by confirmation of the left conduction system capture via the screw beats or appearance of RBBB morphology on lead V1 and testing of the electrical parameters in the form of measuring the V6 LVAT. The V6 LVAT corresponds to time taken for the depolarization wavefront to reach the epicardial lateral wall of the left ventricle.[2] The cutoff value for V6 LVAT was taken as <75 ms for patients with narrow QRS. This is in accordance with the validation studies. Similarly, for patients with compromised conduction system, a value of <101 ms was considered as diagnostically optimal and <80 ms as 100% specific. We used a criterion of <90 ms as a balance between sensitivity and specificity in a group of patients who presented with asystole/escape rhythm.[3] The modification of PSA ECG leads is described next.

PSA ECG leads and their modification

This study was conducted with MLLLs and SASDLs. Because the PSAs of both of these companies differ, they are described separately.

The Medtronic PSA ECG leads are right arm (RA), left arm (LA), right leg, and left leg (LL). This allowed us to visualize 3 channels in the PSA leads 1, 2, and 3. The LA/RA leads were placed in fourth right intercostal space, while the LL was placed in the sixth intercostal space in the midaxillary line, corresponding to lead V6. This resulted in a display of a modified lead V1 on channel 1 of the PSA and a modified lead V6 on channel 2 of the PSA, respectively (Figure 1).

The St. Jude/Abbott PSA ECG lead provides a chest lead V1 in addition to the 4 leads (RA/LA/right leg/LL), and this resulted in the derivation of 7 channels in the PSA (channels 1, 2, 3, aVR, aVL, aVF, and V1). This allowed us to connect the V1 lead of the PSA in the right fourth intercostal space to give us a modified V1. The LA electrode was placed below V6 and the aVL channel was used to record the modified V6 LVAT (Figure 2).

The calculation of QRS duration and the V6 LVAT was made at a paper speed of 100 mm/s. The 12-lead ECG was used to determine the site of initial screw in with the Medtronic system as established by standard criteria with the unipolar paced morphology at the site showing the R-wave in leads 2 and 3 demonstrating rS. The lead aVR should show the Q-wave and aVL should have a discordant R-wave. Once the lead insertion site of the implant was selected, an attempt was made to penetrate the interventricular septum and confirm the left bundle capture using the PSA leads.

With MLLLs, the lead advancement into the septum was done by rapid turns and the left bundle branch capture was confirmed by the change in the unipolar paced morphology in the modified V1 of the PSA from an LBBB morphology to RBBB morphology. It was always attempted to acquire an initial R-wave in the modified V1 during high- and low-output unipolar pacing (rSR, rsR, rR, or R-wave). Once this was achieved, the LVAT was measured in the modified lead V6 of the PSA at a sweep speed of 100 mm/s.

With SASDLs, the 58-cm Tendril lead (Abbott Cardiovascular) was taken to the basal anterior septum using the Agilis His Pro sheath support (in the initial 5 cases; Abbott Cardiovascular) or the CPS 3D locator (subsequent 5 cases; Abbott Cardiovascular). The distal cathodal crocodile clip was connected to the stylet of the Tendril lead and the anodal crocodile clip was connected to the patient's body in a unipolar fashion. As previously described, the St. Jude PSA provided the critical 5 leads (2, 3, aVR, aVL, and V1) to determine the site of initial screwing in of the lead. Unipolar pacing was done at this point, and by observing the paced QRS morphology in the PSA, the operator was able to confirm the site as the basal anterior septum. The additional advantage of the St. Jude/Abbott system was that there is real-time impedance and ECG monitoring during lead advancement in the septum, as continuous unipolar pacing from the cathodal clip could be done. This also enabled the cardinal visualization of screw beats during the implantation.

After proximal left bundle or fascicular capture, the 12-lead ECG was recorded at high/low output and unipolar and bipolar pacing to confirm the ECG recorded from the PSA. The final QRS duration and V6 LVAT from the 12-lead ECG and the PSA were noted in all cases and analyzed. If the LVAT measured was < 75 ms for patients with narrow baseline QRS or <90 ms for patients with baseline LBBB at high- and low-voltage unipolar/bipolar pacing and if V1 showed a transition from selective to nonselective capture or left ventricular septal to nonselective left bundle branch

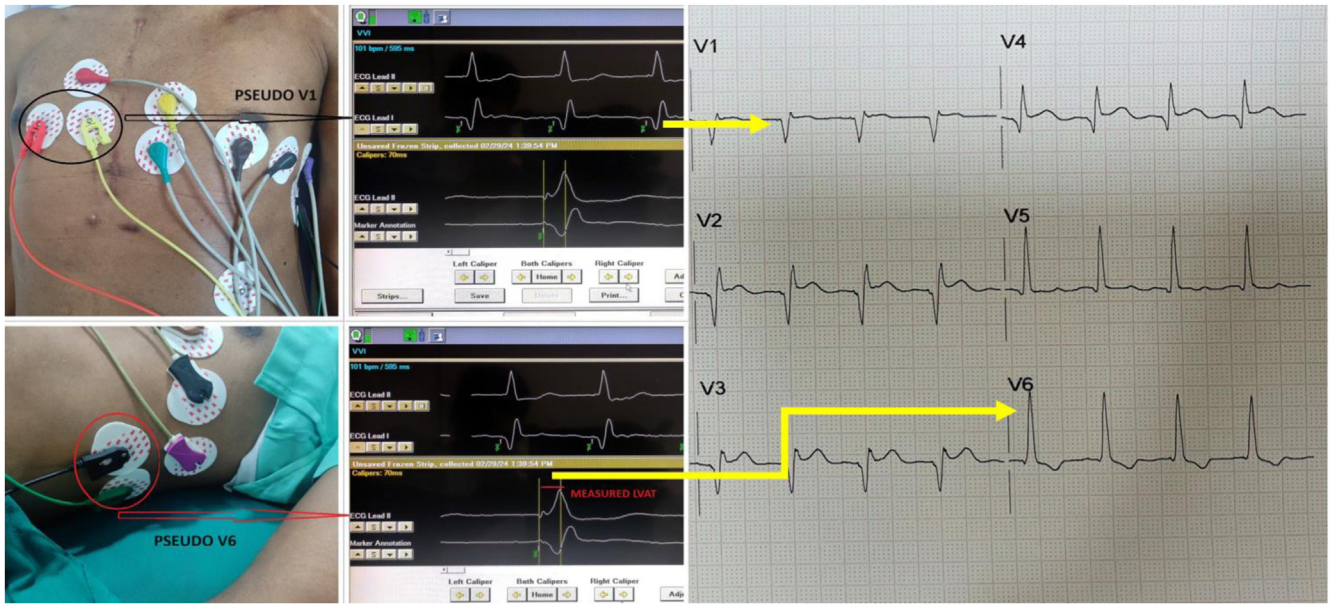

Figure 1 Novel limb lead repositioning (left) on the chest wall allowing the generation of pseudo-V1 and pseudo-V6 electrocardiograms (ECG) on the programmer (middle) correlating with the 12-lead ECG (right). The left panels show the generation of pseudo-V1 (top) with the Medtronic system, while the lower left panel shows visualization of pseudo-V6 and calculation of the left ventricular activation time. The middle panel shows the measured left ventricular activation time from the pacing system analyser (PSA). The treadmill test machine was used for visualization of screw beats during pacing. The arrows connect the novel lead positioning on the chest wall (black/ red circles) to the PSA to V1/V6 on the 12-lead ECG (yellow arrows). Simultaneous ECG is shown in the right panel, showing the correlation of pseudo-V1 and pseudo-V6 on the PSA with V1 and V6 on the 12-lead standardized ECG.

capture, the lead position was accepted. If a qR or QR morphology was noted in modified V1, and V6 LVAT was not fixed at high- and low-output pacing, additional lead rotations were made to acquire an initial R-wave in the paced QRS in V1 along with shortening of the LVAT.

Statistical analysis

The agreement between measurements of QRS duration and LVAT on the PSA and the 12-lead ECG was assessed using Bland-Altman plots, and the reliability of the measurements was done using interclass correlation coefficient.

Results

Baseline characteristics

Patient characteristics were the following: mean age 66.7 ± 11.47 years, 52.63% male, 10.52% ischemic cardiomyopathy, and 5.26% nonischemic cardiomyopathy.

Lead implantation success

LBBaP was attempted in 19 patients using the modified V1 and V6 leads and was successful in 18 (94.7%) patients. The success rate was 90% (n = 9 of 10) with the MLLL and 100% (n = 8 of 8) with the SASDL. The 1 patient in which we failed to achieve conduction system capture with

Figure 2 (Left) The lead positioning with the St Jude Abbott PSA. (Middle) The pacing system analyzer (PSA) screen during lead screw in demonstrating dynamic impedance monitoring, changes in paced electrocardiographic (ECG) morphology, and screw beats. (Right) The corresponding treadmill test ECG during the implantation. The red arrows connect the novel lead positioning on the chest wall to the PSA. The yellow rectangle insert shows transition from the left bundle branch block morphology to right bundle branch block during continuous pacing during screwing of the lead. The blue oval insert shows screw beats prior to left posterior fascicle capture during screwing. LA = left arm.

Table 1 Baseline and procedural characteristics

Patients	19
Successful LBBaP	18 (94)
Age, y	66.7 ± 11.47
Male, %	52.63
Indication for pacing	
2:1 AV block with RBBB baseline	4
Complete AV block with narrow escape	6
Paroxysmal AV block	2
Asystole/escape rhythm	7
Ischemic cardiomyopathy, %	10.52
Nonischemic cardiomyopathy, %	5.26
Procedural characteristics	
Fluoroscopic duration, min	11.57 ± 2.58
Procedural time, min	108.78 ± 29.20
QRS duration, ms	112.77 ± 11.27
LVAT, ms	70.55 ± 8.02

Values are n, n (%), %, or mean ± SD.

AV = atrioventricular; LBBaP = left bundle branch area pacing; LVAT = left ventricular activation time; RBBB = right bundle branch block.

the MLLL had extremely hypertrophied septum due to underlying moderate aortic stenosis.

Procedural outcomes and statistical analysis

LBBaP threshold was 0.59 ± 0.168 V and the R-wave amplitude was 12 ± 3.5 mV, which remained stable during the mean follow-up of 15.9 ± 13.67 months. The mean fluoroscopic duration was 11.57 ± 2.58 minutes and the procedural time was 108.78 ± 29.20 minutes. LBBaP resulted in QRS duration of 112.77 ± 11.27 ms with an LVAT of 70.55 ± 8.02 ms. LVEF improved in the patients with cardiomyopathy from 33.4 ± 5.77% to 48.2 ± 12.37% (P = .028) (Table 1). There was excellent agreement between the 12-lead ECG and the modified V1 and V6 leads connected to the PSA regarding the measurement of V6 LVAT and QRS morphology change in V1 during selective to nonselective left bundle branch capture, with the values lying within 95% limits in the Bland-Altman plot (Figure 3) and the interclass coefficient showing excellent reliability for both QRS duration (0.93) and LVAT (0.91) (Figure 3).

Complications and long-term follow-up

There were 2 acute lead septal perforations during the implantation procedure, one with the MLLL and the SASDL each. However, this was identified intraprocedurally, and the leads were successfully repositioned at a slightly distal site for left bundle branch area capture. There were no instances of pocket infection or pocket hematoma requiring re-exploration. The LBBaP threshold was stable during the mean follow-up of 15.9 ± 13.67 months, and there were no patients with late lead dislodgements or rise in lead thresholds requiring revision.

Discussion

In this novel feasibility study, we report on the modification of the PSA ECG leads to guide LBBaP in the absence of an EP recording system.

Left bundle pacing has emerged as a reliable means to achieve physiological pacing to the left ventricle. LBBaP is defined as capture of the left bundle, which may be recorded as capture of the LBB potential, as paced morphology of the right bundle branch pattern, or through V6 LVAT.[4] During measurements of the LVAT, precise measurements are mandatory, as differences of 5 to 10 ms are vitally important. Because this is best achieved using digital calipers and a fast sweep speed, the modified lead V6 and the PSA was used for measurements.[3]

There have been no studies previously using TMT and PSA programmers only, intraoperatively, to guide placement of the LBBaP. The PSA programmer was used for analysis of left bundle capture during follow-up, postoperatively, in a study by Tan and colleagues,[5] by generating pseudo-V1 and pseudo-V6 ECGs on the programmer resembling the 12-lead ECG signals. In this study, there was an excellent agreement for V6 LVAT (correlation coefficient 0.91). The study was carried out with the use of Medtronic devices only and the authors emphasized the need for validation of the results in other systems. We extended this to the St Jude/Abbott system. Because this system already provides with 7 channels including V1, the pseudo-V1 was derived from placing the V1 in the fourth intercostal space on the right side. For the pseudo-V6, the LA electrode

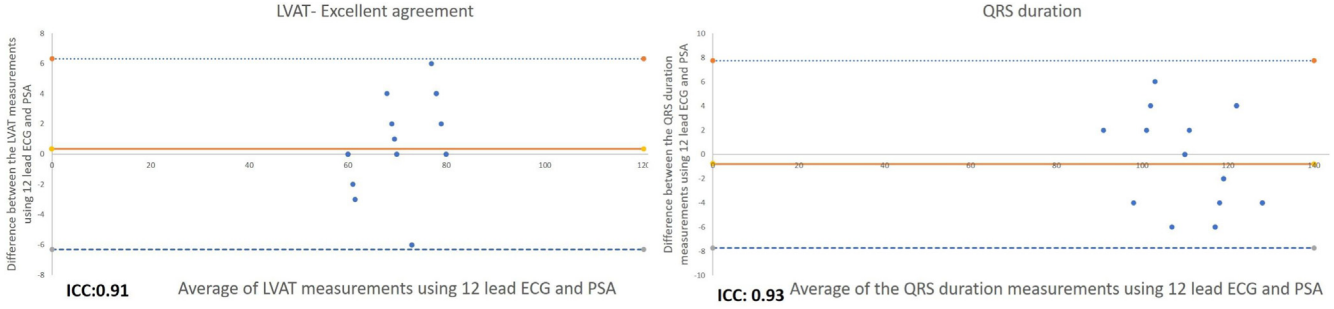

Figure 3 Bland-Altman plot to show agreement between the measurement of left ventricular activation time (LVAT) on the pacing system analyzer (PSA) and the 12-lead electrocardiogram (ECG) (left) and between the measurements of QRS duration on 12-lead ECG and PSA (right). All the data points lie within ±1.96 SD of the mean difference, indicating excellent agreement between 2 measurement techniques for both LVAT and QRS duration. ICC = intraclass correlation coefficient.

was placed in the left fifth intercostal space along the mid-axillary line and the aVL channel was to record the V6 LVAT.[5]

In the initial prospective studies on LBBaP, the success varied from 80% to 94%.[6] This improved to 94% in a study by Vijayaraman and colleagues.[7] This is similar to what we could successfully achieve in our series and thus provides a way for achieving left bundle area pacing without the standardized EP recording system. We believe that the simple addition of the modified V1 and V6 leads to the PSA could enable physicians to demonstrate accurate conduction system capture during LBBaP.

Limitations

This is a single operator, pilot study. However, the study provides an important means to LBBaP using a PSA and TMT machine. Although this has limited applicability in hospitals that have a standard EP recording system, the study highlights the use of modified leads in resource-limited settings.

Conclusion

In this pilot feasibility study, we have identified that the modified V1 and V6 leads connected to the PSA are an alternative to the EP recording system to perform successful LBBaP with excellent agreement and reliability of the values using the PSA with the 12-lead ECG. This approach may be useful to other EP operators practicing in hospitals with health resource constraints and unavailability of EP recording systems.

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Patient Consent: All patients provided written informed consent.

Ethics Statement: The study was approved by the institutional review board. The study complies with the Declaration of Helsinki.

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