Inadequacy of fluoroscopy and electrocardiogram in predicting septal position in RVOT pacing – Validation with cardiac computed tomography

Gautam Sharma a,*, Salman Salahuddin b, Prashanthan Sanders c, Himanshu Gupta b, Gurpreet Gulati d, Priya Jagia e, V.K. Bahl a

a Professor and Head, Department of Cardiology, All India Institute of Medical Sciences, New Delhi 110029, India
b Senior Resident, Department of Cardiology, All India Institute of Medical Sciences, New Delhi 110029, India
c Director, Centre for Heart Rhythm Disorders, University of Adelaide, Royal Adelaide Hospital, Adelaide 5000, Australia
d Professor, Department of Cardio Vascular and Interventional Radiology, All India Institute of Medical Sciences, New Delhi 110029, India
e Additional Professor, Department of Cardio Vascular and Interventional Radiology, All India Institute of Medical Sciences, New Delhi 110029, India

A B S T R A C T

Background: Electrocardiographic (ECG) and fluoroscopic criteria, which are the only available guides to achieve a true septal position during right ventricular outflow tract (RVOT) pacing, have been infrequently validated. We sought to validate these using cardiac computed tomographic angiography (CTA) to confirm lead position within the RVOT septum.

Methods: Forty-four patients with permanent pacemaker leads in the RVOT position underwent CTA. Lead positions in RVOT were classified as anterior, free wall, or septal location. Fluoroscopic images were obtained in 4 standard views.

Results: Only 19 (43%) patients had lead in true septal position within the RVOT in CTA while 25 patients (57%) were found to have an anterior lead location. Mean QRS axis, QRS duration, negative QRS in lead I, and notching in inferior leads were not significantly different between the two groups. The standard fluoroscopic LAO view showed a rightward-directed lead not only in all 19 patients with septal location, but also in 14/25 patients in the anterior location \( (p = 0.22) \), and thus had a sensitivity of 100% but specificity of only 16% in predicting true septal position. The posteriorly directed lead in left lateral view was more accurate in predicting true septal position with good sensitivity (73.7%) and excellent specificity (80%).

Conclusions: This study, using validation with CTA, showed that conventional ECG criteria and fluoroscopy are inaccurate in differentiating septal from anterior RVOT pacing. The fluoroscopic lateral view, as corroborated by CTA, is more reliable than the LAO view in predicting septal lead placement.

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1. **Introduction**

The right ventricular apex (RVA) has been the traditional site for ventricular pacing for more than half a century, due to the relative ease of implantation, reliability, and stability. However, RVA pacing is fraught with the long-term risk of left ventricular (LV) dysfunction, heart failure, and arrhythmias, like atrial fibrillation. This led to active interest in developing alternative sites of RV pacing, which could lead to a more physiological pattern of ventricular activation. Sites that have been studied are the low interventricular septum, mid-septum, HIS bundle, and the RV outflow tract (RVOT). Among these, RVOT pacing has gathered maximum interest due to its possible favorable hemodynamic and electrophysiological profiles, as compared to RVA pacing. RVOT pacing has been shown to result in narrower QRS complexes, lesser dyssynchrony, and better LV systolic function, as compared to RVA pacing. Within the RVOT, it is the true septal position that is most desirable. Acquiring a true septal location during pacemaker implantation is technically challenging, as fluoroscopy and occasionally electrocardiography (ECG) are usually the only guides available to achieve true septal pacing within the RVOT. These criteria, however, have not been widely validated against a true anatomic ‘gold standard’. Cardiac computed tomographic angiography (CTA) is a technique that allows complete objective assessment of the entire geometry of the RV, including the apex and the inflow and outflow tracts. We sought to validate the accuracy of ECG and fluoroscopic criteria with accurate anatomic imaging, using cardiac CTA to confirm lead position within the RVOT.

2. **Methods**

2.1. **Patient population**

Forty-four patients, who underwent permanent pacemaker implantation in the RVOT position in the Department of Cardiology at our institute, were enrolled in the study. Patients were subjected to standard 12-lead ECGs, fluoroscopy, and cardiac CT angiography for localization of lead tip position in the RVOT. All patients gave informed consent to participate in the study, which was approved by the Institutional Ethics Committee.

2.2. **Technique of lead implantation in RVOT**

Standard 58- or 60-cm bipolar active fixation leads with steroid-eluting electrodes were used for all implants. The single, senior operator self-shaped ventricular lead stylet to facilitate successful lead deployment onto the RVOT septum and carried out the entire procedure of pacemaker implantation. For the purpose of lead placement, RVOT was divided as defined by Mond et al. into three regions: the septum, which lays posteriorly, the free wall in front, and between them, the narrow anterior wall of the RVOT. Successful lead positioning was confirmed by the three fluoroscopic views: posteroseptal (PA), 40 right-anterior-oblique (RAO), and 40 left-anterior-oblique (LAO). During RVOT lead implantation, the PA view was used to position the lead in the midsection or outflow tract. The 40° RAO is then used to confirm that the lead is not in the coronary sinus or great cardiac vein. The 40° LAO was used to distinguish the three areas within these locations. In this view, free wall positioning places the lead tip anteriorly (or leftward), septal positioning places the lead posteriorly (or rightward), and anterior wall positioning places the lead pointing superiorly. The multiple fluoroscopic views were used to ensure correct lead placement. Target site was mid-septum or high septum in PA view and rightward facing lead in LAO view, but in patients where this target could not be achieved, because of difficulty to obtain stable position or failure to obtain good thresholds and sensitivity parameters, a less than optimal position was accepted.

2.3. **Electrocardiography**

Twelve-lead ECGs were obtained in all patients, acquired both at baseline, and during forced paced (at 100 beats per minute) QRS complexes. ECGs were analyzed for several parameters including QRS axis, QRS duration, amplitudes of all limb leads, limb lead polarity, and presence or absence of notching in limb leads.

2.4. **Fluoroscopy**

Fluoroscopic images were acquired in four standard views postprocedure i.e. PA, LAO-40°, RAO-40°, and left lateral (LL) views.

Fluoroscopic images were analyzed for confirmation of lead position in RVOT using PA and RAO views. The LAO and LL views were analyzed for position within the RVOT. The lead tip was designated as having either a leftward, rightward, or superior orientation in the LAO view, and an anterior, posterior or superior orientation in the LL view. Two senior radiologists and a cardiologist independently analyzed the fluoroscopic images and together they decided the final fluoroscopic lead position by consensus.

2.5. **CT angiography**

Cardiac CTA (64-slice Dual Source Siemens Definition) was performed in all 44 patients to delineate the position of the pacemaker lead tip in the RVOT. CT scans were analyzed in axial sections perpendicular to the long axis of the RVOT, and multiple orthogonal views to confirm lead tip position in the RVOT. Lead tip locations were designated as anterior, free wall, or septal in location (Fig. 1). Two radiologists who were blinded to the fluoroscopic findings of the patients analyzed the CTA for final lead position. All patients underwent routine interrogation of the pacemaker after the CTA.

2.6. **Statistical analysis**

Statistical analyses were performed using SPSS software (SPSS, Inc., Chicago, IL, USA).

Continuous data were analyzed using paired Student’s t-test. Fisher’s exact test was used for evaluating dichotomous variables. Continuous values are expressed as mean ± SD. A p-value of <0.05 was considered statistically significant.
Fig. 1 – Axial section of cardiac computed tomographic image showing the septum, anterior, and the lateral wall in right ventricular outflow tract (RVOT).

3. Results

Forty-four patients were enrolled in the study, with a mean age of 58 ± 13 years. There were 33 males (74%). Thirty-one patients (70%) had a dual-chamber pacemaker, while the rest had single-chamber pacemakers. Complete heart block was the most common indication for receiving a pacemaker in the study (84%), while 4 patients (9%) had sick sinus syndrome (Table 1). Out of 44 patients undergoing permanent pacemaker implantation, CT angiography delineated 19 (43%) patients to have lead tip in the septal portion of RVOT and twenty-five (57%) patients in the anterior RVOT. No patient had a lead lodged in the RVOT free wall. Mean distance of the lead tip from the pulmonary valve was 2.07 ± 0.83 cm in the anterior group, and 2.15 ± 0.57 cm in the septal RVOT group (p = 0.77).

3.1 Electrocardiography

Mean QRS duration of the patients with CT-proven septal RVOT lead position was narrower in septal group as compared to anterior group; however, it did not reach statistical significance (143 ± 18 ms vs 148 ± 21 ms, p = 0.38). QRS axis did not differ significantly between both groups (71 ± 5° vs. 74 ± 4°; anterior vs. septal; p = 0.20). QRS in lead I was negative in 14 patients (74%) in the septal group, and also in 15 patients (60%) amongst the anterior RVOT group (p = 0.52). Thus QRS negativity in lead I could not differentiate a septal versus anterior lead position. There was no significant difference with respect to notching in any of the limb leads, including inferior leads, comparing the two groups (Table 2).

3.2 Fluoroscopy

All patients showed appropriately placed RVOT position of the pacemaker lead in the PA and RAO fluoroscopic projections. In LAO view, the lead was oriented rightwards in 40/44 (91%) patients. Anatomic imaging by CT, however, revealed that only 19 out of these 40 patients indeed had a ‘true’ septal lead placement, while the lead was directed anteriorly in rest 21 patients, and thus LAO had very low specificity in predicting septal position (specificity = 16%, Table 3). However, all patients with a CT-proven septal lead position had a rightward facing lead in the LAO view making it 100% sensitive in predicting septal lead position. Among the 19 patients with a septal lead position, 14 patients had a posteriorly directed lead and 5 were directed superiorly in the LL view (p = 0.001). Among the 25 patients with an anterior lead position as judged by CT angiography, 11 had an anteriorly facing lead on fluoroscopy in the LL view, while 9 had a superiorly oriented lead, and only 5 were directed posteriorly (Table 3). Thus, a posteriorly direction of lead in LL view had good sensitivity (73.7%) and excellent specificity (80%) and positive predictive value (73.7%) in predicting septal lead position (Table 3).

4. Discussion

In this study, we systematically evaluated the role of fluoroscopic imaging and paced QRS morphology in determining segmental location of pacing lead in the RVOT, as validated by CTA. Differentiation between septal and anterior/free wall location has traditionally been based on fluoroscopic landmarks and paced QRS morphology. Proper validation of final lead position using these guides, compared to an adequate ‘gold standard’, has never been conclusively performed. A recent study by Pang et al.15 has also validated the fluoroscopic lead positioning with CT. They have also found a very low percentage (21%) of true septal position with traditional fluoroguidance and have gone on to suggest a protocol based

| Table 1 – Baseline characteristics of the study population. |
|-------------------|-------------------|
| All patients (n = 44) |
| Age (years) | 58 ± 13 |
| Male/female (n) | 33/11 |
| Dual/Single chamber (n) | 31/13 |
| Indication for pacemaker (n, %) |
| Complete heart block | 36 (82%) |
| Sick sinus syndrome | 4 (9%) |
| Others | 4 (9%) |

| Table 2 – ECG characteristics. |
|-------------------|-------------------|
| CT-proven anterior RVOT lead (n = 25) | CT-proven septal RVOT lead (n = 19) |
| QRS axis (°) | 71 ± 5 | 74 ± 4 |
| QRS duration (ms) | 148 ± 21 | 143 ± 18 |
| Negative QRS in lead I (°) | 15 (60%) | 14 (74%) |
| Limb lead notching (°) | 19 (76%) | 11 (58%) |
| • Lead I | 13 (52%) | 11 (58%) |
| • Lead II | 13 (52%) | 10 (53%) |
| • Lead III | 16 (64%) | 8 (42%) |
| • Lead aVL | 12 (48%) | 12 (63%) |

CT, cardiac tomography; RVOT, right ventricular outflow tract.
mainly on the RAO view to guide true septal positioning. Few studies have used transthoracic echocardiography and electro-anatomical mapping as modalities for validating lead position. CTA provides accurate delineation of RV geometry and RVOT, and hence would be a gold standard in localization of lead position in RVOT.

4.1. ECG criteria

Several ECG criteria have been proposed as indicative of septal pacing. Mond et al. described that a negative or isoelectric-paced QRS complex in lead I is diagnostic of a septal position, whereas free wall position would show a positive QRS in lead I. Also, anterior RVOT pacing results in a broader QRS duration and would show notching in the inferior leads, particularly lead III. These criteria, however, have been disputed. Burri et al. recently studied ECG characteristics of pacing from mid-septum and anterior free wall using electroanatomical mapping with a NavX system. The authors found that a negative QRS in lead I was more frequent with anterior than with mid-septal pacing. Interestingly, notching of QRS in inferior leads and lead I was more common in mid-septal pacing compared to anterior wall pacing sites. Similarly, few studies using electroanatomical mapping found that a negative QRS in lead I was common in both anterior septal and free wall sites.

In our study, using accurate anatomical localization, we demonstrated that 74% of patients with leads in the septal position, as delineated by CT, had a negative QRS in lead I. However, 60% of patients in the anterior RVOT group too showed negativity in lead I (p = 0.52), demonstrating the inadequacy of QRS negativity in lead I for septal localization (Fig. 2). Moreover, we found no difference in the presence of QRS notching in any of the limb leads, including inferior leads.

Table 3 – Fluoroscopic characteristics of patients with sensitivity, specificity, PPV, and NPV for rightward orientation of lead in LAO and posterior orientation of lead in LL view.

<table>
<thead>
<tr>
<th></th>
<th>CT-proven septal RVOT lead (n = 19)</th>
<th>CT-proven anterior RVOT lead (n = 25)</th>
<th>p value</th>
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<tbody>
<tr>
<td>LAO view (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rightward orientation</td>
<td>19</td>
<td>21</td>
<td>0.12</td>
</tr>
<tr>
<td>Not rightward orientation</td>
<td>0</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Left lateral view (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior orientation</td>
<td>14</td>
<td>5</td>
<td>0.001</td>
</tr>
<tr>
<td>Superior orientation</td>
<td>5</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Anterior orientation</td>
<td>0</td>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>

Sensitivity = 19/19 = 100%
Specificity = 4/25 = 16%
PPV = 19/40 = 47.5%
NPV = 4/4 = 100%

Sensitivity = 14/19 = 73.7%
Specificity = 20/25 = 80%
PPV = 16/19 = 73.7%
NPV = 25 = 80%

![Fig. 2](image-url)
These findings, in keeping with the results of other studies,\textsuperscript{15} show that marked heterogeneity exists in the ECG characteristics of pacing from a septal site, and that the conventional ECG criteria, including lead I negativity and inferior leads notching, are inaccurate in reliably predicting septal location of an RVOT lead.

4.2. Fluoroscopic criteria

Fluoroscopy remains the conventional guide for accurate lead placement during pacemaker implantation. The standard PA and 40°-RAO views help in positioning within the RVOT. For further differentiation between the septal and free wall aspects of the RVOT, the 40°-LAO view has been proposed to be useful, where septal positioning is characterized by a rightward orientation of the lead tip, whereas free wall positioning is seen with the lead tip facing leftward or anteriorly.\textsuperscript{10,11}

In addition to standard PA, LAO, and RAO views, LL was done during postprocedure fluoroscopy to confirm the lead position. In the LL view, a posteriorly directed lead indicates a septal location, whereas a free wall/anterior lead would be directed anteriorly or superiorly.

In our study, we found that the rightward orientation of lead in standard LAO had 100% sensitivity and negative predictive value in predicting septal lead position but a very low specificity of 16% (Table 3). This clearly highlights the inadequacy of the LAO view alone, which is conventionally the operator’s view, to reliably and correctly predict septal location within the RVOT. On the other hand, although the LL had lower sensitivity, it had excellent specificity and positive predictive value. This is in keeping with conventional fluoroscopic criteria for septal localization from earlier studies.\textsuperscript{10,11} Thus using LL view at least once during the procedure will greatly increase the success of true septal lead placement. Sometimes during device implantation, it is challenging to get the LL position, and in that case, a steep LAO might be useful. A recent study by Pang et al. has also highlighted these facts about the inadequacy of standard fluoroscopic views like LAO and RAO alone, in guiding to a true septal lead position.\textsuperscript{15} They have suggested a new protocol in which they propose that the lead is more likely to be in true septum if it lies in the middle of the cardiac silhouette in the RAO long-axis projection and has an angle of 40–60° in LAO view with the angle being between a line drawn parallel to the lead tip and a horizontal line drawn in LAO view.\textsuperscript{16}

Few studies, using 2D and 3D echocardiographic validation, have shown a similar disagreement between the fluoroscopic criteria and actual lead position on echocardiography.\textsuperscript{2,3,7,12} The reason as to why this discrepancy occurs in the predictive accuracy of fluoroscopic views is because the anterior RVOT actually shares a leftward alignment along with the septal wall, whereby a rightward facing lead on the LAO could have an equal chance of either being on the anterior or on the septal wall (Figs. 3 and 4). Furthermore, there is variation in the individual patients’ RVOT size, anatomy relative orientation of the anterior and septal RVOT walls, and rotation of heart. The RVOT curves posteriorly as we ascend toward pulmonary valve, making it difficult for exact septal lead placement in RVOT, and one may have to settle for an alternate location. Interestingly the septal leads were more toward the anterior aspect of the true septum, which could be due to more stability at this position (Fig. 3B). Also, none of the cases had their leads on the free wall of the RVOT on CT imaging. This could be because of the fact that the current fluoroscopy criteria are good enough to differentiate free wall from anterior/septal location but not good enough to differentiate septal from anterior location in RVOT. Also, the use of either manually preshaped or commercially available stylets with a distal posterior angulation in all the cases has improved the technique of RVOT lead placement.

Acquiring a true septal location is a technically challenging task. We feel that the use of stiffer stylets, generous distal posterior angulation of the stylet, and use of the lateral view (or as-steep-as possible LAO) will help in guiding the operator toward accurate septal placement.

4.3. Implications of the study

Most important finding of this study is that the use of the lateral view (or as-steep-as possible LAO) in addition to LAO may increase the accuracy and success of septal lead implantation. Findings of this study would also help explain why studies comparing RVOT vs RV apical pacing have generally failed to show significant difference.\textsuperscript{13,14} Nearly all

Fig. 3 – Figure showing agreement between LAO (3A), LL (3C), and CTA image (3B) in RVOT septal pacing site. (A) LAO view showing rightward oriented lead in RVOT; (B) CTA showing lead (arrow tip) in RVOT septum; (C) LL view showing lead directed posteriorly.
studies that have reported the effects of septal pacing with or without comparison to RVA pacing have used fluoroscopic landmarks for validation of septal position. In fact, even ongoing randomized trials that are studying the effects of RV septal pacing compared to RVA pacing have used, in their study design, only the LAO view as the landmark for septal placement. This would imply that the many patients with lead not in true RVOT septum will be included and that the database of patients with so-called RV septal pacing, in fact, does not necessarily consist wholly of only ‘true’ septal pacing.

5. Limitations

It is a single-center small study. Although, on the basis of the results of this study, LL view was found to be a better predictor of RVOT septal lead placement; we used it only after the lead implantation because it is practically challenging to obtain this view while maintaining strict asepsis.

6. Conclusions

Accurate localization of lead position using CT angiography revealed that the conventional ECG criteria and standard LAO view in fluoroscopy are inaccurate in differentiating septal from anterior RVOT pacing. The lateral view, as corroborated by CTA, is more reliable than the LAO view in confirming septal placement.

Author contribution

Gautam Sharma – Concept/design; Salman Salahuddin – Concept/design, Data collection; Himanshu Gupta – Data analysis/interpretation, Drafting article; Prashanthan Sanders – Critical revision of article; Gurpreet Gulati and Priya Jagia Data – analysis/interpretation;

Conflicts of interest

The authors have none to declare.

REFERENCES


