Comparison of clinical outcomes between transthoracic echocardiography and X-Ray guided left bundle branch pacing for bradycardia: a randomised control trial - An Editorial

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Abstract

Conduction system pacing has brought about a shift in the delivery of device therapy. Although gaining growing adoption, challenges remain; one of which is higher fluoroscopy times. Yang et al describe reducing and even aiming to eliminate fluoroscopy in left bundle area pacing implantation and replacing lead visualisation with transthoracic echocardiography. This editorial reviews these methods in context with recent developments in conduction system pacing and current literature.

Comparison of clinical outcomes between transthoracic echocardiography and X-Ray guided left bundle branch pacing for bradycardia: a randomised control trial - An Editorial

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Abstract
Conduction system pacing has brought about a shift in the delivery of device therapy. Although gaining growing adoption, challenges remain; one of which is higher fluoroscopy times. Yang et al describe reducing and even aiming to eliminate fluoroscopy in left bundle area pacing implantation and replacing lead visualisation with transthoracic echocardiography. This editorial reviews these methods in context with recent developments in conduction system pacing and current literature.

Introduction:
Left bundle area pacing (LBBAP) is a paradigm shift in the delivery of implantable cardiac device therapy. It marries the benefits of a largely physiological ventricular activation whilst overcoming the technical challenges faced during His-bundle pacing such as high thresholds and procedural barriers. (1)

Left bundle area pacing has shown improvement in New York Heart Association Class, left ventricular ejection fraction, heart failure related hospitalisation and shorter QRS duration in observational literature. It is a promising technique with growing adoption worldwide. (2)

Despite these advancements in delivering physiological pacing, challenges do remain; evolving capture diagnostics, multiple pacing sites without established drawbacks and benefits and longer procedural and fluoroscopy times compared to right ventricular pacing. (1,3) As such, the authors investigate an unexplored approach to overcoming some of these barriers with transthoracic echocardiography (TTE) at the time of implant in place of fluoroscopy to direct lead position.

A fluoroless implant with echocardiography in conventional pacing has been demonstrated in literature (4), however direct visualisation of the lead in LBBAP with echocardiography and the associated benefits has not undergone extensive review. The authors hypothesise reduction in procedural and fluoroscopic times in patients who undergo lead implant guided by direct visualisation with TTE compared to conventional fluoroscopic guided implants.

Discussion
60 prospective patients were recruited from a single centre: Fuwai Hospital, China with 1:1 randomisation to either fluoroscopic or TTE-guided left bundle area lead placement. There were no significant differences in the demographics between the two groups. Patients with cardiac resynchronisation therapy (CRT) indications were excluded, and the mean ejection fraction was >55% in both groups. As such caution should be exercised when considering the results of this study in patients who are undergoing LBBAP as a form of CRT with impaired left ventricular function, as there may be additional challenges in this cohort of patients that have not been explored in this study.

Of the 30 randomised to TTE guided implant, 5 patients did not have adequate echocardiographic windows and so underwent fluoroscopic guidance. While the authors take note of these 5 patients, they do not highlight that they are crossovers. Moreover, it is unclear if intention to treat or per protocol statistical analysis has been undertaken. It would be recommended to describe these methods in view of the crossovers.

The study details the acquisition of the TTE images allowing for reproducibility. Robust criteria including QRS transition, abrupt reduction in left ventricular activation time (LVAT) between low and high outputs and absolute LVATs was used to establish left bundle branch capture and under which circumstances left ventricular septal capture (LVSP) was accepted (LVSP n= 6, LBBAP n =54). This gives the reader confidence that the procedural and fluoroscopic times were not confounded by a difference in procedural complexity.
The authors report that there was no difference in overall procedure time (TTE = 9 minutes vs fluoroscopy=12 minutes, p=0.063), but a significant reduction in fluoroscopy time (TTE= 2.5 minutes vs fluoroscopy= 5 minutes, p= 0.002). Table 1 describes fluoroscopy times of cardiac devices demonstrating higher fluoroscopy time in CRT and LBBAP implants. Cumulative radiation exposure is a well-documented operator risk that has been minimised through various approaches that include personal lead protection, lead shields, image intensifier position, reduced frame rate and short acquisitions (5-6). With the reduction in fluoroscopy time in this study, cumulative radiation exposure to implanters is further reduced through a novel method.

Fluoroless conduction system implants have been achieved using invasive electroanatomical mapping, and although reports of this by Patel et al have demonstrated feasibility, patients are introduced to the additional risk of an invasive approach (7). With reduction in fluoroscopy times and an alternative method for lead visualisation during deployment, Yang et al further demonstrate the possibility of achieving a left bundle lead implant with almost no fluoroscopy. The authors note the difficulties in completely eliminating fluoroscopy due to the inability of TTE to identify distal lead engagement, which was also described by Patel et al.

Table 1: Fluoroscopy times for cardiac devices

<table>
<thead>
<tr>
<th>Year</th>
<th>Device</th>
<th>Study design</th>
<th>Fluoroscopy time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022</td>
<td>LBBAP</td>
<td>Observational N=2533 All patients with LBBAP lead</td>
<td>9 (5.5–14.6)</td>
</tr>
<tr>
<td>2023</td>
<td>LBBAP</td>
<td>Observational N=1778 CRT indication</td>
<td>17 (2-31)</td>
</tr>
<tr>
<td>2023</td>
<td>CRT</td>
<td>Observational N=1778 CRT indication</td>
<td>16 (4-28)</td>
</tr>
<tr>
<td>2019</td>
<td>Dual Chamber PPM</td>
<td>Observational N=697 Indication for cardiac device</td>
<td>1.95 (1.15-3.48)</td>
</tr>
</tbody>
</table>

Table 1: Fluoroscopy times for cardiac devices
The similarity in overall procedure time between TTE and fluoroscopy guided implants could be attributed to the ingenuity of adding TTE to the procedure. Firstly, limited sonographer experience of acquiring echocardiograms during the implant could result in limited views to visualise the lead, compromised quality of images and inefficient acquisitions. Secondly, limited experience in interpreting lead position and progression by TTE by the implanting operator could add to overall procedure time both alone and in combination with TTE operator inexperience. In contrast, device operators are well versed in interpreting fluoroscopic images through widespread use in conventional pacing, resulting in more efficient overall procedure times.

The study reports that TTE proved to be a reliable alternative to fluoroscopy with no different in left bundle area capture success rates and electrical parameters such as threshold, impedance and sensed R-wave. There were no complications in the recruited patients, which is significantly lower than that reported in literature. (10) Additionally the electrical parameters remained stable both at implant or during the follow up period, consolidating that TTE is a safe and feasible alternative.

Limitations and Future Work

Pacemakers are often implanted in centres without advanced electrophysiology equipment, and although the benefit of adding echocardiography is noted, the service is often inundated from high demand limiting availability for use in the catheter laboratory. The addition of TTE in device implantation adds an additional layer of complexity to a relatively novel procedure and already pressured services. Additional costs of the TTE machine and the TTE operator should also be considered.

A well described challenge is failure of lead progression due to entanglement where the lead is unable to penetrate the septum as it becomes entangled in the endocardium. Further rotations result in difficulties in untangling the lead and damage to the helix. Although not explored in this study, it would be interesting to understand TTE capabilities of identifying myocardial entanglement as described by Jastrzebski et al. (11)

To develop the use of echocardiography further, the authors could consider the role of intra-cardiac echocardiography (ICE) to aid in fluoroless device implantation, overcoming challenging windows and poor image quality (12). Although the reduction in radiation would need to be weighed against the risks associated with additional venous access. Another approach would be to identify fluoroscopic features of successful site of deployment and lead progression through the basal inter-ventricular septum, to both reduce procedure and fluoroscopic time, whilst minimising the learning curve of adopting new method.

Conclusions

The authors described an alternative approach to reducing fluoroscopy time using TTE guided left bundle lead implantation. Although overall procedural time was unchanged, this study demonstrates TTE successfully reduces fluoroscopic time, is feasible, safe and low risk.

References


