

1 **To the editor:**

2 **Fluoroscopy Guided Axillary Vein Access versus Cephalic Vein Access in Pacemaker**  
3 **and Defibrillator Implantation: Randomized Clinical Trial of Efficacy and Safety**

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29 **To the Editor**

30 We read with interest the article by Dr Jiménez-Díaz and colleagues. This prospective trial  
31 randomised 240 patients undergoing permanent pacemaker or implantable-cardioverter  
32 defibrillator implant (ICD) to either cephalic or fluoroscopy-guided axillary access. The  
33 axillary approach, compared with the cephalic, provided a higher success rate, shorter time to  
34 access and implantation duration. There were no significant differences in terms of  
35 complications.

36 We want to address some points that we feel negatively impact the validity and clinical  
37 implications of this interesting study. We believe that no conclusions at all could be drawn on  
38 this topic by a single-centre trial, including two operators only. Operator experience, personal  
39 confidence and skills have a huge impact on the rate and time to successfully use the cephalic  
40 access. For example, the success rate on the cephalic group in this study was numerically higher  
41 for operator 2 vs. operator 1 (71.2% vs. 82%,  $p=0.18$ ); although this was not statistically  
42 significant, the small sample size might account for that. The same principles apply to axillary  
43 vein access. Both operators routinely used an 18-G cannula, with either a standard 0.035 inch  
44 J-shaped or hydrophilic guidewire. We reserve the use of cannula only for very small cephalic  
45 veins, and we feel that inserting either the guidewire or the lead directly after the venotomy  
46 represents an easier and quicker approach. Of note, 49.2% of the cases in the cephalic group  
47 were single-chamber devices; in our experience, these are the cases where advancing the lead  
48 in the cephalic vein with no use of guidewire represents the fastest technique.

49 Finally, we should not forget the small but definite risk of pneumothorax associated with both  
50 the subclavian and axillary approach. Rate of pneumothorax requiring drainage was 0.9% in  
51 the Danish Pacemaker and ICD Registry [1]; the present study was clearly underpowered to  
52 detect differences between the cephalic and axillary access on this relevant complication, as a  
53 sample size of more than 1700 patients would be required with alfa 0.05 and power 80%.

54 In conclusion, we believe that cephalic access should represent the first choice for pacemaker  
55 and ICD implants. Routine use of this approach allows operators to increase their confidence  
56 and skills, with subsequent reduction of the rate of failure and procedural time. The location of  
57 the incision (which should be medial enough) represents a crucial step for optimising the  
58 chance and the quickness to identify the cephalic vein.

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61 [1] Kirkfeldt RE, Johansen JB, Nohr EA, Jørgensen OD, Nielsen JC. Complications after  
62 cardiac implantable electronic device implantations: an analysis of a complete, nationwide  
63 cohort in Denmark. *Eur Heart J*. 2014;35(18):1186-1194. doi:10.1093/eurheartj/eh511.

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