

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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