Bringing big data to vascular complications during atrial fibrillation ablation

Gareth Wynn[1]

[1]University of Melbourne

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Dr Gareth Wynn MBChB MD(Res)

gareth.wynn@unimelb.edu.au

Affiliations:

University of Melbourne, Melbourne Australia

The Royal Melbourne Hospital, Melbourne Australia

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Atrial fibrillation (AF) ablation has consistently been shown to be superior to medical therapy for the control of AF and relief of symptoms/ quality of life[1,2]. However, many patients are never considered for AF ablation and, in some cases, concerns about procedural safety may be a factor that limits access. Numerous technological advances have occurred within AF ablation over the last two decades and complication rates have steadily improved[3]. Although complications relating to vascular access have reduced due to the introduction of ultrasound guided cannulation as the standard of care, they remain the major contributor to the overall complication rate of AF ablation[3-5]. Whilst they may not always be life threatening, vascular complications can have an important effect on quality-of-life and may make same day discharge difficult, thereby reducing the efficiency and cost effectiveness of the procedure[4].

The use of vascular closure devices (VCDs) has become commonplace to achieve haemostasis after femoral arterial access. For AF ablation, although access is venous rather than arterial, haemostasis may still be difficult to achieve by manual compression due to the use of multiple sheaths and therapeutic heparinisation, which may be combined with uninterrupted, or very briefly interrupted, oral anticoagulation. This, along with a move, in many countries, towards same day discharge, makes the use of VCDs a potentially attractive option. However, the use of multiple VCDs in a single vein may increase the risk of venous stenosis or occlusion and thrombosis[6].

As overall complication rates of AF ablation have improved, with time and experience, the rates of serious complications in contemporary practice have fallen to between 2-3%[3]. Whilst undoubtedly a positive change, this relatively low rate can make it difficult to perform an adequately sized study with the power to detect a significant difference when trialling an intervention or approach to reduce complications. This may be one reason why recent advances such as contact force sensing catheters and pulsed field ablation have, thus far, failed to show safety benefits[7].

In this issue of the Journal, Mills and colleagues from Liverpool, in the UK, take a novel approach to this problem by utilising a commercial database from the United States to support the idea that vascular close your devices reduce AF ablation related complications [REF TO BE ADDED BY JOURNAL]. The TriNetX database has been used by this group, and others, to assess the association between AF ablation and outcomes such as dementia but has not been used previously to assess the impact of an intervention on ablation safety[8]. The study is, by its nature, observational and non-randomised and therefore is limited by the inherent uncontrollable biases of non-randomised data. In addition, the database provides anonymized patient records based on clinical coding. Databases such as this can only ever be as good as the data that has been included and neither we nor the authors are able to assess the accuracy of that process. However, the approach does allow for a very large data set with over 14000 patients in each propensity-matched group, vastly out numbering the sample size in any prospective AF ablation study. Whilst it's possible that the absolute numbers produced by this sort of data may not be completely accurate the very large sample size does reduce the risk that occasional errors in coding had a significant effect on the overall direction of results and the differences between the two studied arms. Using this approach, and correcting for known potential confounders, the authors were able to show a significantly lower rate of vascular complications in those who those patients who had undergone AF ablation with vascular closure devices coded for during the same admission. The authors also undertook falsification endpoint analysis which, without eliminating the risk of undetected bias, add confidence that the association found was not due to chance. The results are in keeping with a number of small randomised and observational studies that have suggested vascular closure devices to be safe and effective in reducing complications and enabling early or same day discharge [9,10].

It is unfortunate that the authors were not able to perform cost effectiveness analysis of the use of VCDs compared to other haemostasis strategies. AF ablation may be performed with anywhere between 1 to 5 catheters and larger access sheaths may require use more than one VCD. The associated coast of VCD use may therefore be considerable and the cost-benefit will depend on healthcare funding model and modesl of care, such as whether same day discharge is otherwise achievable and desired. This question is especially pertinent as cheaper alternatives, such as a "figure-of-eight" or 'purse string" suture with or without a three-way stopcock, have also been shown to be superior to manual pressure alone[11].

That notwithstanding, the authors of this study should be commended for their innovative and novel approach, both to addressing both the important issue of complications as a primary research focus, as well as to tackling the difficulties in doing so when the overall complication rate is relatively low and therefore large cohorts are required to produce adequate statistical power. It should be noted that the study is not funded by industry and the authors were unable to provide data on closure on which closure devices were used. Whilst, to a degree, this lack of granular information could be considered a weakness of the methodology and data set, the independence of the investigators should give us some confidence in their findings and conclusion. Indeed, the authors have been appropriately reserved in their conclusions in light of the observational nature of the study, describing the observed observations without over-interpretation.

Undoubtedly, the era of big data has arrived for atrial fibrillation studies, but, until now, had not reached the arena of atrial fibrillation ablation[12]. In their paper, Mills and colleagues give us much to think about both in terms of using large datasets to study AF ablation and, of course, of the potential to reduce bleeding complications through the use of VCDs.

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