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Femoral venous hemostasis after atrial fibrillation ablation: Is figure-of-eight suture the way to go?

Catheter ablation of atrial fibrillation has been widely accepted as an effective therapy for drug refractory symptomatic atrial fibrillation (AF) or as first line therapy in select patients with symptomatic paroxysmal AF [1,2]. Several factors impact procedural outcomes and associated complications including patient characteristics, procedure volume and operator technique [3,4]. The risk of complications from catheter ablation of AF have been reported to be between 5 and 7%, with vascular complications being most common (2–4%) [2–4]. Venous sheaths ranging from 6 to 15 F are routinely used to access the femoral veins. Given the overall thromboembolic risk (0.5–5%) and periprocedural cerebral emboli (up to 10%) during AF ablation, most operators have shifted their approach to one of uninterrupted anticoagulation with more aggressive anticoagulation during the procedure to maintain an activated clotting time (ACT) > 300 seconds [3,5,6]. The evidence thus far suggests no difference in the complication rates between uninterrupted Vitamin K antagonists (VKA) and novel oral anticoagulants (NOAC) [7–9].

While the incidence of thromboembolic events is on the decline, the rate in femoral vascular complications continues to be a source of considerable distress for the patient and the physician [3,7]. Although most are not life-threatening, these events prolong hospital stay, increase patient discomfort and at times may require vascular surgery intervention. Operators worldwide, therefore, have been paying special attention towards ensuring safe venous access and uncomplicated hemostasis post procedure. The published rate of groin hematoma associated with ablation procedures is as high as 13% with the incidence of femoral pseudoaneurysm and arteriovenous fistulae being 0.93 and 0.54% respectively [10,11]. Existing data points to the ultrasound guided vascular access as being fast, safe and effective in anticoagulated patients with the potential to reduce the rate of complications [12,13]. An important and sometimes challenging aspect of post procedure care is achieving adequate hemostasis particularly when uninterrupted anticoagulation is a goal. Manual compression, while being the standard method of achieving hemostasis, may require prolonged hold time, partial reversal of anticoagulation as well as post-procedure bed rest of 4–12 hours [14].

The figure of eight (FO8) suture was first described with structural heart disease interventions in children but more recent reports point to this technique being a cost-effective hemostatic method after catheter ablation of AF [14–16]. The technique involves caudal (deep) to cranial (superficial) suture around the sheath(s) insertion site(s) including the subcutaneous tissue but avoiding the femoral vessels to plug the venotomy [14]. *Issa and Amr* reported a 98.4% success in achieving immediate hemostasis without heparin reversal in a randomized study of 123 patients. Venous hemostasis using the FO8 suture was associated with less frequent utilization of FemoStop™ compression device as well as fewer vascular and thromboembolic events [15]. Standard venous access sheaths of 6F–11.5 F were used in all patients. Except for higher body mass index in the FO8 group, the patients did not differ in terms of their demographic characteristics [15]. In another non-randomized study of 124 patients undergoing cryotherapy using the 15F FlexCath Advance steerable sheath, the incidence of hematoma with FO8 suture was reported as 2.4% with a success rate of 92%. The authors, however, used additional compression dressing post suture application [13].

In this issue of the Journal, Lakshmanadoss et al. report the results of a retrospective, single center study comparing the FO8 suture to manual pressure (MP) to achieve hemostasis in 209 patients undergoing AF ablation [17]. As with previously published studies, heparin was not reversed but the ACT was allowed to drift below 180 seconds before sheath pull and manual hold. Femoral vein access was anatomically guided without ultrasound support in all patients. The hematoma rate in this study for the FO8 group was 3.9% versus 10.1% in the MP group, a statistically significant difference. Hemostasis with FO8 suture shortened the time to ambulation after procedure. It could be argued however, in light of available data, that use of ultrasound guided access may have lowered the incidence of major vascular complications in this study [12,13]. In reality, vascular complications are not dependent entirely on the adequacy of post procedure hemostasis but on a combination of factors including the site and technique of puncture, patient characteristics, as well as peri- and post-procedural anticoagulation [4].

Uninterrupted anticoagulation for AF ablation remains a topic of considerable controversy with concerns about balancing the bleeding and thromboembolic events as well as healthcare costs related to prolonged hospital stay. The evidence to date suggests that uninterrupted NOAC therapy with intra-procedural heparin is at least as safe if not superior to warfarin in this regard [8,9,19]. The F08 group in the study by Lakshmanadoss [17] had more than twice as many patients on NOACs (48% vs 21.9%) when compared to the MP group. Therefore, it is possible that NOAC use may have contributed to a lower hematoma rate in the F08 group, with the advantage of early mobilization. The sample size of the study, however, did not allow multivariate modeling to determine the impact of oral anticoagulation on hemostatic technique.

While vascular closure devices remain an option, the FO8 suture maybe a safer and perhaps more cost-effective alternative especially where multiple venous sheaths are used [18]. A different suture technique using the purse string suture showed no difference

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in rate of vascular complications when compared with manual compression [20]. The beauty of the F08 technique is that it simple and easy to learn and the results of the study by Lakshmanadoss et al. clearly support the safety and utility of the F08 technique and corroborates those of previous investigators [11,15–17]. The shorter time on bed rest has definite clinical implications in terms of patient comfort, hospital stay and implied healthcare cost. While the authors in this study allowed for an additional wait time to achieve an ACT <180 seconds before MP, previous investigators have used protamine to allow immediate sheath removal [15]. It may be of interest to also study the effect of heparin reversal on reducing bleeding complications and time to ambulation with various venous hemostatic techniques. Smaller studies of patients undergoing catheter ablation with heparin reversal prior to sheath removal suggest relative safety with low bleeding/thrombotic complications and shorter hold time [21,22]. The post procedure bed rest time however, still ranged up to ~10 hours despite protamine administration in those studies [21]. In the absence of randomized studies, definitive conclusions about heparin reversal and durable hemostasis with FO8 suture cannot be made.

The current study from Lakshmanadoss et al., while providing encouraging data on the utility of FO8, is not without limitations. This is a single center, retrospective study and the results should therefore be interpreted with caution, especially since small sample size precluded multivariate regression analyses. Randomized studies with control of confounding factors such as ultrasound guided venous access, with and without partial reversal of anticoagulation after procedure, time to ambulation as well as resumption of oral anticoagulation are needed to firmly establish short and long-term efficacy of the simple and elegant F08 technique.

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