



Figure-of-eight suture for venous hemostasis in fully anticoagulated patients after atrial fibrillation catheter ablation

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ABSTRACT

Introduction: Limited data exists for types of venous closure and its associated complications in patients after atrial fibrillation (AF) catheter ablation. We evaluated the subcutaneous figure-of-eight closure (FO8) for achieving venous hemostasis after AF catheter ablation compared to manual pressure.

Methods: 284 consecutive patients that underwent AF catheter ablation by two operators were included. All patients received continuous therapeutic warfarin or interrupted novel oral anticoagulants (NOAC) and heparin (ACT300–400 s) without reversal. Patients were divided into two groups: 1) sheaths were left in place and pulled once ACT < 180 s, with hemostasis being achieved with manual pressure (MP); and 2) a subcutaneous FO8 suture closed the venous access site immediately after the ablation on each groin site and sheaths were removed immediately after the ablation despite full anticoagulation with heparin and warfarin or interrupted NOAC. Sutures were removed after four hours, and the patients laid flat for an additional two hours.

Results: The MP group (n = 105) was similar to the FO8 group (n = 179). Time in bed was 573 ± 80 min for MP group vs. 373 ± 49 min for FO8 group (p < 0.0001). Eleven hematomas were seen in the MP group compared to seven in the FO8 group (P = 0.041).

Conclusions: In fully anticoagulated patients undergoing AF catheter ablation, excellent hemostasis was achieved with figure-of-eight sutures, with no major vascular complications, a lower hematoma rate, and a significantly shorter flat-time-in-bed compared to manual pressure.

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1. Introduction

Atrial fibrillation (AF) catheter ablation is an effective treatment for selected patients with symptomatic, drug resistant AF [1]. To minimize procedure-related thromboembolism most operators fully anticoagulate patients with oral anticoagulants (OAC) pre-procedurally and administer high-dose heparin during the procedure, maintaining an activated clotting time (ACT) of at least 300 s [2–6]. Patients undergoing catheter ablation for AF often require multiple sheath insertions into the femoral veins, with hematoma formation being a common complication with incidence

rate of 1.01% [7]. Adequate prevention of these hematomas could potentially facilitate early mobilization, early discharge from hospital, and avoidance of long term sequelae, including femoral nerve compression neuropathy [8].

Closure of the venous access site after AF catheter ablation is usually achieved by manual compression, with the necessary staff occupied for as long as 30 min, followed by bed rest for four to 12 h once hemostasis has been achieved. An alternative approach – subcutaneous, temporary figure-of-eight suture closure technique to maintain hemostasis after removal of venous sheaths – has been described in the pediatric population and after retrograde aortic balloon valvuloplasty. Limited data exists about the use of subcutaneous, temporary figure-of-eight suture (FO8) closure technique and its associated complications in fully anticoagulated patients after AF catheter ablation. We evaluated the use of FO8 suturing for achieving vascular hemostasis after AF catheter ablation compared to that with manual pressure.

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2. Materials and methods

2.1. Patient selection

We reviewed records of consecutive patients that underwent AF catheter ablation by two operators at the Heart Rhythm Center, Beaumont Health, Royal Oak, MI from January 2012 to August 2014. Patients were divided into two groups of comparison based on the method of vascular closure for hemostasis: a historical control group from January 2012 to August 2013, whose femoral venous hemostasis was achieved by manual pressure (MP) after sheath pull once their ACT was less than 180 s; and a case study group, from September 2013 to August 2014, whose femoral venous hemostasis was achieved by a figure-of-eight (FO8) suture after sheath pull, irrespective of their ACT. Inclusion criteria included all patients 18 years or older that underwent AF catheter ablation by two cardiac electrophysiologists from January 2012 to August 2014. Exclusion criteria were the presence of left atrial thrombus, international normalized ratio (INR) > 3.5 on the day of procedure, and severe uncontrolled heart failure or any contraindications to general anesthesia. The Human Investigation Committee/Institutional Review Board of Beaumont Health approved the study.

2.2. Anticoagulation

All patients were anticoagulated before the procedure. Warfarin was continued without interruption through the time of ablation, with frequent INR checks leading up to the procedure, and a goal INR of 2.0–3.0 at the time of ablation. Patients who were taking the newer oral anticoagulants (NOACs) were asked to take their last scheduled NOAC dose on the evening prior to the procedure. A transesophageal echocardiogram was performed before the procedure in patients with paroxysmal AF and CHA₂DS₂-VASc score of ≥2 and in all patients with persistent AF, if they presented with atrial fibrillation on the day of the procedure. Oral antiplatelet therapy was not stopped if chronically prescribed. During the procedure, unfractionated heparin was given prior to or immediately after successful transeptal puncture for left atrial access. A 100 U/kg bolus was given intravenously, and an infusion of 12–15 U/kg body weight was started as infusion. ACT was measured at 15 min intervals, with additional doses of heparin given until the ACT consistently reached 300–350 s, after which time ACT was measured every 30 min.

2.3. Ablation techniques

All procedures were performed by two experienced cardiac electrophysiologists with similar techniques in ablation and in achieving venous hemostasis. All procedures were performed under general anesthesia. Bilateral femoral venous accesses were obtained by the Seldinger technique using an 18 Gauge needle. One six French (Fr) short sheath and one 8.5 Fr long sheath were placed in the right femoral vein, and one 8.5 Fr long sheath was placed in the left femoral vein. In case of accidental puncture of the femoral artery, a manual compression of the puncture site was performed for at least five minutes with visual confirmation of no further arterial bleeding before a new puncture of the femoral vein was attempted. In all patients, vascular access was guided by manual palpation without ultrasound guidance. Patients underwent standard pulmonary vein isolation with or without additional substrate modification as per operator discretion.

2.4. Venous hemostasis

After the completion of ablation, for patients in the MP group,

the physician exchanged the long 8.5 Fr sheaths for short 8 Fr sheaths. The short venous sheaths remained in place on both groins and were sutured to the skin at the end of the procedure. The site was observed for a few minutes. If there was bleeding around the sheath sites, manual pressure was held. This was recorded as 'holding time on the table.' Afterwards the patients were transferred to the post-anesthesia recovery room and eventually to the telemetry floor. Their ACT was checked as per institutional protocol. Once ACT was <180 s, venous sheaths were removed by the nursing staff with immediate manual pressure for 30 min to achieve hemostasis. Bed rest was implemented for six hours afterwards. If there was further bleeding, manual pressure was applied for an additional 10–30 min to achieve hemostasis, and bed rest was extended as needed.

Patients in FO8 group had a specific FO8 pattern suturing at their sheath sites: a 1 silk suture attached with a curved needle passed from the medial to the lateral aspect of the body, on a plane just inferior to the sheath(s) entry site, with the needle delving deep into the subcutaneous tissue by roughly 1–1.5 cm but not so as to enter any vasculature. After the needle exited the skin, the needle was then brought from the medial to the lateral aspect of the body, on a plane just superior to the sheath(s) entry site, again delving into the tissue 1–1.5 cm deep but not so as to enter any vasculature or the sheaths (Fig. 1A–C). This created an FO8 pattern. Traction was applied on the suture with a locking knot gathering the folds of skin and subcutaneous tissue to tamponade the venipuncture sites as the sheaths were pulled out. Additional knots were added to reinforce the closure as needed (Figure 2A–D). The site was observed for few minutes, and if there was any bleeding at the site, manual pressure was applied to achieve hemostasis. This manual pressure was recorded as "holding time on the table" for this group. The patients were then transferred to the post anesthesia recovery room and then to the telemetry floor. Bed rest was ordered for 4 h, after which time sutures on both groins were removed as per the hospital protocol (Appendix 1). An additional two hours of bed rest was ordered after removal of sutures. If patients had oozing/bleeding from the site, manual pressure was applied for 10–30 min to achieve hemostasis, and bed rest was extended for an additional two hours.

2.5. Follow-up

All patients resumed oral anticoagulation on the same evening after the procedure. Patients were observed overnight, and both groins were examined the next morning by the Cardiac Electrophysiology team. Primary outcome was time-to-ambulation post procedure. Secondary outcomes included all types of vascular complications including groin bleeding, hematoma (size > 3 cm), retroperitoneal bleeding, pseudoaneurysm, or arteriovenous fistula. Major vascular complication was defined by the need for blood transfusion, vascular intervention, or vascular surgical intervention as a result of access site complication. All patients were followed up with phone call by a registered nurse three days after hospital discharge, and then in-person in one and three months by the operating electrophysiologist to evaluate any vascular access-related complication. Clinical follow-up included assessment of femoral pulse, presence of hematoma or bruits, or signs of venous occlusion. Patients were evaluated by arterial and venous ultrasound duplex if clinically indicated, as directed by the physician. Patients were also instructed to contact the office for any concerning changes in access sites.

2.6. Data analysis

The distribution of continuous variables was examined to

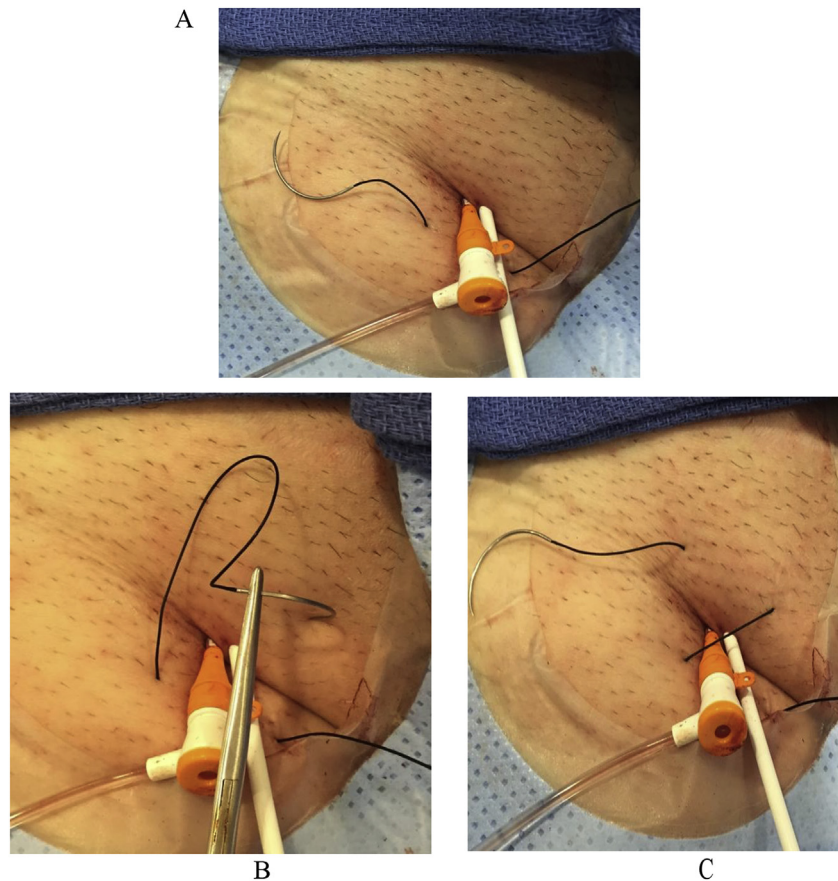


Fig. 1. (A) A silk suture attached to a curved needle is passed medially to laterally on the body, on a plane just inferior to the sheath and deep into the subcutaneous tissue. (B–C) The needle is brought medially to laterally on the body, on a plane just superior to the sheath and deep into the subcutaneous tissue.

choose between parametric and non-parametric summaries and methods of inference. If the variables were normally distributed, mean (standard deviation) was used as a descriptive summary, and student t-tests were used to compare groups. If the variables were not normally distributed, median (lower quartile, upper quartile) was used to report the summaries, and the Mann-Whitney *U* test (Wilcoxon Rank Sum test) was used to compare groups. The results for categorical variables were summarized with counts (percentages). Groups were compared on categorical variables using either Pearson's Chi-square test or Fisher's Exact test. Odds ratios with associated 95% confidence intervals were obtained to compare two groups on a binary outcome variable, enabling one to assess the clinical importance of possible effects and indicate its relationship with the observed data. To control for the effects of other categorical variables (i.e. potential confounding variables), the Mantel-Haenszel test was used along with an estimate of the common odds ratio controlling for the effect of a third variable. Two-sided *P* values less than 0.05 were considered statistically significant. The statistical analysis was performed with SAS System for Windows version 9.3 (SAS Institute, Inc., Cary, North Carolina).

3. Results

A total of 284 patients underwent AF ablation by these two operators during this study period (65% male, mean age 62 ± 10.7 years). Hemostasis was achieved by manual compression in 105 patients (mean age 63 ± 12 years, 60% male, mean BMI 30.0 ± 3.5 kg/m²). The mean pre-procedural INR was 2.51 ± 0.27 , prevalence of NOAC use was 22%, and the post-ablation ACT was

309 ± 60 s. Hemostasis was achieved by FO8 suture in 179 patients (mean age 61 ± 10 years, 69% male, mean BMI 29.5 ± 3.1 kg/m²). The mean pre-procedural INR was 2.50 ± 0.39 , prevalence of NOAC use was 48%, and the post-ablation ACT was 315 ± 58 s. Baseline characteristics of these two groups are described in Table 1. Patients in MP group had higher CHA₂DS₂-VASc score (2.2 ± 1.4 vs 1.9 ± 1.3 , $p = 0.02$), and NOACs were used more commonly in FO8 group ($p < 0.0001$).

The hold-time on the table immediately after the completion of the ablation did not differ between the MP and the FO8 groups (Table 1). The total time of bed rest for MP group was significantly longer than FO8 group (573 ± 80 min vs 373 ± 49 min, $p < 0.0001$). After sheath pull, eleven patients in MP group had bed rest time longer than six hours due to groin hematoma compared to seven patients in FO8 group ($p = 0.5$). In a subset of 145 patients who had aPTT levels drawn prior to suture removal at four hours, the level was 45 ± 12 s.

A total of 20 patients had prolonged bed rest time (>360 min) after vascular hemostasis. In MP group, 11 patients had groin vascular access complication and one had pericardial drainage leading to longer bed rest time, whereas the FO8 group had seven patients with groin vascular access complication and one with pericardial drainage ($p = \text{NS}$). There were a total of 18 hematomas in the study group: 11 in MP group (10.5%) and seven in FO8 group (3.9%, $p = 0.041$). Ten were left groin, and eight were right groin. Ten patients were receiving warfarin, and eight patients were on a NOAC. Among the 13 patients in the MP group with hematoma, two of them developed arteriovenous fistula, whereas two other patients developed pseudoaneurysm. One patient required surgical

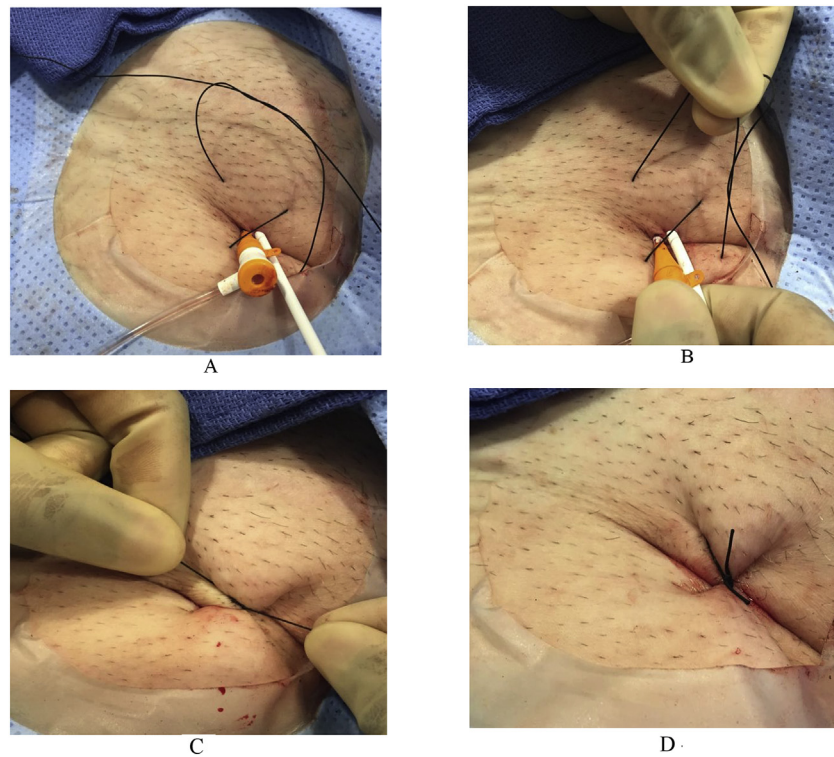


Fig. 2. (A–B) Figure-of-8 configuration prior to locking suture. (C) Both the sheaths are pulled out while maintaining traction on the suture. (D) Completed right groin figure-of-8 suture.

Table 1
Baseline characteristics.

Baseline Characters	Manual compression (n = 105) (Mean ± S.D.)	Figure-of-8 suture (n = 179) (Mean ± S.D.)	p value
Age, in years	63.4 (11.6)	61.1 (10.2)	0.07
Male gender	63 (60%)	123 (68.7%)	0.14
Body mass index	30.0 ± 3.5	29.5 ± 3.1	0.57
Left ventricle ejection fraction, in %	57 ± 2	58 ± 7	0.78
Coronary artery disease	21 (20%)	32 (17.9%)	0.66
Hypertension	40 (38.1%)	76 (42.5%)	0.47
Diabetes mellitus	32 (30.5%)	42 (23.5%)	0.19
Peripheral vascular disease	20 (19.0%)	26 (14.5%)	0.32
Paroxysmal atrial fibrillation	62 (59.0%)	118 (65.9%)	0.25
CHA ₂ DS ₂ -VASc score	2.2 ± 1.4	1.9 ± 1.3	0.02
Average INR	2.51 ± 0.27 (n = 82)	2.50 ± 0.39 (n = 93)	0.75
Newer oral anticoagulant	23 (21.9%)	86 (48.0%)	<0.0001
Antiplatelet drugs	31 (30%)	55 (30.7%)	0.91
Right ventricle systolic pressure	21.9 ± 4.1	22.9 ± 6.2	0.79
Duration of Procedure, in minutes	210 ± 45	222 ± 59	0.24
Post-ablation ACT at the end, in seconds	309 ± 60	315 ± 58	0.76
Clinical Outcome	Manual compression	Figure-of-8 suture	p value
Holding time on table, in minutes	15.7 ± 4.2	15.4 ± 4.7	0.47
Time on bed rest, in minutes	573 ± 80	373 ± 49	<0.0001
Major Hematoma	11 (10.5%)	7 (3.9%)	0.041

correction for pseudoaneurysm. Seven patients in FO8 group developed groin hematoma after the removal of FO8 suture, all of which resolved within 15–30 min of manual pressure. Of these seven patients, two patients developed arteriovenous fistula, neither of which required surgical intervention.

Two patients had pericardial tamponade requiring pericardiocentesis (one in each group). One patient in MP group developed TIA in the postoperative period despite having therapeutic INR. There were no transfusions, clinical evidence of venous thrombosis or occlusion, cases of late bleeding, retroperitoneal

bleeding, subsequent site infections, nor mortality experienced in any of the patients in the two groups.

4. Discussion

In a cohort of patients undergoing catheter ablation for AF, excellent hemostasis was achieved with the use of subcutaneous, temporary FO8 suture closure technique after removal of venous sheaths in fully anticoagulated patients immediately after procedure. Lower vascular complication rates and shorter bed rest time

were observed with FO8 compared to the conventional manual pressure method. In this patient population, venous hemostasis was achieved in all patients with similar holding time on the table for both groups. When compared to the MP group, total time of bed rest for MP group was significantly shorter for the FO8 group in spite of having similar post procedure ACT levels. Patients who had venous hemostasis by MP method had a higher incidence of major groin hematoma when compared to FO8 group. There were no significant differences in the frequency of complications with regard to the baseline characteristics including antiplatelet drugs, level of INR on the day of the procedure, and ACT post procedure. NOACs were used more often in FO8 group when compared to MP group which reflects the change in our practice pattern over a period of time. This could have impacted the hematoma formation.

After removal of a vascular access sheath, hemostasis is most typically achieved by manual compression, followed by a period of four to six hours bed rest, and eventually with slow ambulation a few hours later. Manual compression and prolonged bed occupancy increases patient discomfort and has cost implications [9,10]. At times, vasovagal reactions may ensue due to the painful manual compression. Although there is no data to accurately assess the degree of patient discomfort during and after manual compression and prolonged bed rest, clinical observations undeniably attest to such plight.

To avoid manual compression and reduce patient discomfort, few authors have used arterial closure devices to achieve femoral venous hemostasis. Three main closure types for successfully achieving femoral artery hemostasis include a suture (Perclose; Abbott Vascular, Illinois, USA), an intravascular plug (Angioseal; St Jude Medical, Minnesota, USA), or a metal clip external to the lumen (Starclose; Abbott Vascular). A suture-mediated Perclose device has been successfully used to achieve rapid hemostasis in the presence of anticoagulation in adults undergoing congenital cardiac intervention [11]. Femoral venous hemostasis has been achieved with a collagen vascular closure device (Angioseal) in patients that required peri-procedural anticoagulation and multiple vascular access sites [12]. However, these devices are resource-intensive, are associated with steep learning curves, and may be associated with patient discomfort during deployment. Compared to these vascular closure devices, the FO8 suture technique is easy to perform. More importantly, a single FO8 suture could be placed for attaining hemostasis after multiple ipsilateral femoral venous accesses. The FO8 technique has been labeled a “fellows’ stitch,” claiming the ease-to-master and the miniscule amount of time to deploy (<30 s) factors as ultimate advantages [13]. In addition, FO8 suture is a significantly more cost effective approach compared with a commercially available closure device. Our results corroborate the findings of a recent study which evaluated the efficacy of this technique [14]. Similarly, two other groups reported the use of FO8 suturing to achieve hemostasis even with larger sheath removals [15,16].

4.1. Mechanism of FO8 suture closure

Previous studies showed the safety and mechanism of FO8 suture techniques for femoral venous hemostasis in adult and in pediatric population after diagnostic/interventional cardiac catheterization [13,14]. To describe the mechanism by which hemostasis is achieved by FO8 suture, the needle takes a subcutaneous bite on both the medial and lateral aspects and on the cranial and caudal aspects of the venous access, gathering the encompassed skin and underlying tissue to involute onto the venous puncture site, creating a tamponade effect. Venography performed immediately after figure-of-eight closure showed no extravasations but some vasoconstriction at the previous sheath entry point,

caused by the external compression of the surrounding soft tissue afforded by the suture. In that study, vascular ultrasound was performed the following day after FO8 was removed, and the veins manifested normal compressibility without evidence of thrombus [17].

4.2. Limitations

This was a nonrandomized retrospective case control cohort, thereby being potentially vulnerable to inherent bias. We did not use ultrasound guidance for vascular accesses which may have increased the incidence of vascular complications, including arteriovenous fistula and pseudoaneurysm. However, the access approach was the same for both groups. There were a limited number of patients with hematoma. The sample size did not justify fitting multivariate logistic modeling. The two methods of vascular closure were used over non-overlapping time periods. As a result, temporal changes in practice, such as the increased use of NOACs, may confound the method of vascular closure. The analysis did not take into account possible operator differences or the learning curve associated with use of the two closure techniques.

4.3. Conclusion

In fully anticoagulated patients undergoing atrial fibrillation catheter ablation, excellent venous hemostasis can be achieved safely and effectively with figure-of-eight suturing, with no major vascular complications and a lower hematoma rate. This technique does not require any reversal of anticoagulation and is associated with a shorter time on bed rest compared to manual pressure. It involves a very short learning curve and is a cost effective technique.

Financial disclosure

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Conflicts of interest

None.

Author contributions

Dr. Umashankar Lakshmanadoss – Concept, Data collection, analysis and interpretation, drafting article.

Dr. Wai Shun Wong - Concept, Critical revision of article, Approval of article.

Dr. Ilana Kutinsky - Critical revision of article.

Dr. M. Rizwan Khalid - Statistics, Critical revision of article.

Dr. Brian Williamson - Critical revision of article.

Dr. David E Haines - Concept, Critical revision of article, Approval of article.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ipej.2017.02.003>.

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