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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: 209 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 = 104). Time in bed was 573 ± 80 min for MP group vs. 366 ± 35 min for FO8 group ($p < 0.0001$). Eleven hematomas were seen in the MP group compared to four in the FO8 group ($P = 0.04$).
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.

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 CHA_2DS_2-VASc score of $\geq$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

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