Safety and Feasibility of Subcutaneous Purse-String Suture of the Femoral Vein After Electrophysiological Procedures on Uninterrupted Oral Anticoagulation

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The aim of this study was to compare safety and feasibility of a subcutaneous purse-string suture (PSS) with manual compression (MC) to gain hemostasis in patients after multiple femoral venous punctures undergoing electrophysiological procedures on uninterrupted oral anticoagulation (OAK). A total of 784 patients who underwent catheter ablation for atrial fibrillation (n = 564) or (a)typical atrial flutter (n = 220) were assessed. Four hundred sixty-two patients received PSS (58.9%) and 322 patients (41.1%) received MC to gain hemostasis. All patients were on uninterrupted full-dose OAK. During the procedure, weight-adapted heparin was applied. Venous sheath diameter were 8Fr (n = 2)/11.5Fr (n = 1) for left atrial or 8Fr (n = 1)/6Fr (n = 2) for right atrial procedures. No protamine was administered at the end of the procedure. After PSS, patients' had 6 hours of bed rest compared with 10 hours after MC (sheath removal after 4 hours followed by a bandage for 6 hours). PSS was removed the following day. All patients underwent duplex sonography of the access site the following day. Using the PSS, hemostasis was achieved in 453 of 462 patients (98%). MC leads to hemostasis in all 322 patients. No difference was found between the 2 approaches regarding hematomas (<5 cm or >5 cm), arterio-venous fistulas, or pseudoaneurysms. No major complication such as ipsilateral leg ischemia, the need of vascular surgery, or deep vein thrombosis occurred. In conclusion, PSS is a safe and effective way to gain immediate hemostasis after multiple punctures of the femoral vein in patients undergoing catheter ablation on OAK. PSS avoids MC and leads to shorter patient immobilization. **(Am J Cardiol 2017;119:1781−1784)**

The aim of this study was to compare safety and feasibility of a subcutaneous purse-string suture (PSS) with manual compression (MC) to gain hemostasis in patients after multiple femoral venous puncture in the setting of an electrophysiological (EP) procedure.

Methods

From June 2014 to January 2016, a total of 784 patients were enrolled (61.4% men). A total of n = 564 of patients (72%) underwent treatment for paroxysmal AF. About n = 96 patients (12.2%) underwent ablation for atypical atrial tachycardia (AT) and n = 124 patients (15.8%) underwent ablation for typical atrial flutter (Figure 1). Baseline characteristics of the patients are listed in Table 1. Mean age was 64.1 years ± 12.6 in the MC group and 62.5 years ± 12.6 in the PSS group (p = 0.06). There was no significant difference in CHADSVASC score and body mass index between the groups. Regarding anticoagulation, 25.3% of the patients were on phenprocoumon, 35.5% on apixaban, 33.7% on rivaroxaban, and 5.5% on dabigatran.

All patients with paroxysmal AF or AT underwent contrast enhanced cardiac computed tomography using a special protocol to allow cardiac segmentation, esophagus localization, and to exclude intracardiac thrombus <24 h before ablation. If intracardiac thrombus could not be excluded by computed tomography, additionally, transoesophageal echocardiogram was performed. Patients with typical atrial flutter received a transoesophageal echocardiogram <24 hours before ablation to exclude intracardiac thrombus.

All patients were on uninterrupted oral anticoagulation (OAK). OAK was continued on the day of ablation with an international normalized ratio >2.0 and <3.0 or uninterrupted intake of direct oral anticoagulants (NOAK).[1]

The EP study was performed under conscious sedation with propofol, midazolam, and fentanyl. In patients with paroxysmal AF or AT, femoral access was achieved through V. femoralis puncture and insertion of 2 8Fr sheath and 1 11.7Fr (Agilis, St Jude Medical, Minneapolis, Minnesota) sheath. In patients with typical atrial flutter 2 6Fr and 1 8Fr sheath were inserted. A multipolar, steerable diagnostic catheter was placed into the coronary sinus. Patients with paroxysmal AF or AT underwent singular transseptal

Department of Electrophysiology, German Heart Center Munich, Technical University, Munich, Germany. Manuscript received December 22, 2016; revised manuscript received and accepted March 1, 2017.

See page 1783 for disclosure information.

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0002-9149/17/$ - see front matter
http://dx.doi.org/10.1016/j.amjcard.2017.03.006

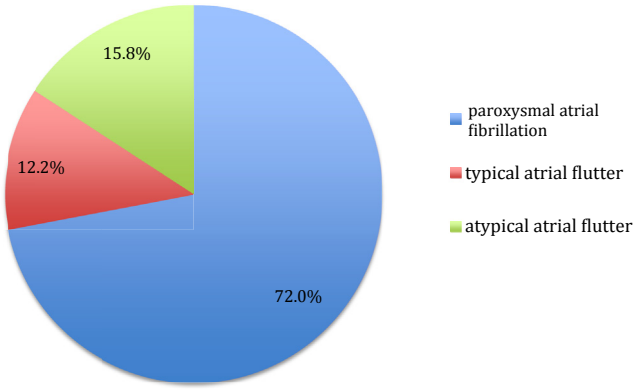

Figure 1. Atrial arrhythmias in patients undergoing ablation.

Table 1
Baseline characteristics

Variables	Manual compression n= 322	Purse-string suture n= 462	p-value
Age Mean (years)	64.1 +/-12.6	62.5 +/-12.6	0.06
Male	64.1%	59.5%	0.17
BMI (kg/m^2)	27.1 +/-6.0	27,2 +/-4.5	0.88
CHADSVASC Score	2.2 +/-1.6	2.1 +/-1.65	0.33
Apixaban	37.7%	35%	0.12
Rivaroxaban	29.6%	35.4%	0.24
Dabigratan	4.2%	6.7%	0.06
Phenprocoumon	28.5%	22.9%	0.1
Activated clotting time (sec.)	279.8 +/-38.7	283.5 +/-37.2	0.24

BMI = body mass index.

puncture with double access to the left atrium with a steerable 11.5Fr sheath. After transseptal puncture a weight-adapted heparin bolus was given followed by continues heparin administration. Activated clotting time was targeted between 280 seconds for patients under direct oral anticoagulants and 300 seconds for patients under phenprocoumon. Patients with typical atrial flutter received a bolus of 5000 IE heparin before ablation. All patients with paroxysmal AF underwent antral circumferential pulmonary vein isolation through radiofrequency (RF) application with an 8Fr irrigated tip catheter. In patients with AT, linear lesions were created to ablate macro or localized reentries through RF application with an 8Fr irrigated tip catheter. In patients with typical atrial flutter ablation of the cavotricuspidal isthmus was performed through RF application with an 8Fr irrigated tip catheter or 8Fr temperature ablation catheter.[2,3]

The PSS was performed by a 0-silk subcutaneous suture that was passes in and out on 4 places around the sheaths forming a square. The running stich circled the sheath in a way that when the ends of the sutures are pulled subcutaneous tissue is tightened to create a mass that performs pressure on the puncture site (Figure 2). After the PSS was applied, patients had 6 hours of bed rest. The suture was removed after 12 hours. In the MC group, hemostasis was achieved by removing the sheath 4 hours after procedure without assessing activated clotting time. After hemostasis was achieved a groin compression bandage was indicated for 6 hours.

Patients were routinely examined by medical stuff before catheterization. All patients received a duplex sonography of the access site the day after the procedure. In the duplex scan, possible vascular complications such as hematoma <5 cm, hematoma>5 cm, pseudoanaurysm, and arteriovenous fistula were assessed.[4] Before discharge from the hospital, all patients were examined regarding groin infection.

Continuous variables are presented as mean ± SD or median. Categorical data are expressed as frequencies and percentages. Univariate comparisons were performed using the *t* test (continuous variables) and chi-square test. A p value of <0.05 was considered statistically significant. All analyses were performed using SPSS for Mac, version 20.0 (SPSS Inc., Chicago, Illinois).

Results

A total of 784 received a subcutaneous PSS (n = 462; 58.9%) or MC (n = 322 patients; 41.1%) to gain hemostasis at the end of the procedure. In 453 of 462 patients (98%) with PSS, hemostasis was achieved. Due to suture rupture during knotting or insufficient PSS, n = 9 patients failed to gain hemostasis using PSS. MC was used for those patients. MC was performed effectively in all 322 patients.

Clinical outcomes according to treatment to gain hemostasis are listed in Table 2. No difference was found in the duplex scan between the 2 approaches regarding hematomas smaller or larger than 5 cm, arterio-venous (AV) fistulas or pseudoaneurysms. No major complication such as ipsilateral leg ischemia, retroperitoneal hematoma, the need of vascular surgery, or deep vein thrombosis occurred. All hematomas were treated conservatively. No patient received blood transfusion. Independently from the technique used to gain hemostasis, patients under NOAKs showed a significantly lower rate for hematomas >5 cm compared with patients under phenprocoumon with n = 31 (phenprocoumon) and n = 34 (NOAKs; p <0.01). Clinical examination on the day of discharge revealed no late complications.

Discussion

The main finding of this study is that a subcutaneous PSS technique is as safe and efficacious as MC after femoral venous access to gain hemostasis in patients on OAK undergoing EP procedures. It additionally shortens the time consumption for medical staff and increases patient comfort due to shorter immobilization time.

MC to gain hemostasis after EP procedures is the standard approach in most centers. Different approaches to gain immediate hemostasis such as “figure of eight suture” or vascular closing devices are also available.[5–8] To our knowledge, this is the first large study that compares a PSS with MC showing no difference regarding bleeding complications after sheath removal.

A main reason to use the PSS is to reduce time to hemostasis, support earlier mobilization after sheath removal, and to enhance patient comfort. To gain hemostasis, PSS acquires only 2 to 5 minutes, whereas MC might occupy medical stuff for as long as 30 minutes, therefore resulting in a decreased need for qualified medical stuff leading to cost and time reduction. Due to its simplicity,