Heart, Lung and Circulation (2019) **28,** 777–783
1443-9506/04/$36.00
https://doi.org/10.1016/j.hlc.2018.03.011

ORIGINAL ARTICLE

GroIn HaemosTAsis with a PuRse String Suture for Patients Following Catheter Ablation Procedures (GITAR Study)

Nicholas Jackson, MBBS [a,b*], Michael McGee, MBBS [a,b], Waheed Ahmed, MBBS [a,b], Allan Davies, MBBS [a,b], Jim Leitch, MBBS [a,b], Mark Mills, BMedSci [a,b], Matthew Cambourn, RN [a,b], Saad Ezad, MD [a,b], Andrew Boyle, MBBS, PhD [a,b], John Attia, MBBS, PhD [a,b], Kumaraswamy Nanthakumar, MD [c], Malcolm Barlow, MBBS [a,b]

[a]John Hunter Hospital, New Lambton, NSW, Australia
[b]The University of Newcastle, Newcastle, NSW, Australia
[c]Peter Munk Cardiac Centre, University Health Network, Toronto, Ontario, Canada

Received 22 November 2017; received in revised form 24 January 2018; accepted 8 March 2018; online published-ahead-of-print 20 March 2018

Background The most frequent complications from percutaneous electrophysiology procedures relate to vascular access. We sought to perform the first randomised controlled trial for femoral venous haemostasis utilising a simple and novel purse string suture (PSS) technique.

Methods We randomised 200 consecutive patients who were referred for electrophysiology procedures at two different hospitals to either 10 minutes of manual pressure or a PSS over the femoral vein and determined the incidence of vascular access site complications.

Results The mean age was 61.8 ± 12.1 years and 138 (69%) were male. Bleeding requiring additional pressure or a FemStop (Abbott Laboratories, Abbott Park, IL, USA) for complete haemostasis occurred in 17/99 (17%) patients in the PSS arm and 19/101 (19%) patients in the manual pressure arm ($p = 0.72$). There were no cases of haematoma prolonging hospital stay, arterio-venous fistula, pseudoaneurysm or retroperitoneal bleeding. The mean duration to achieve haemostasis was 45 seconds in the PSS arm and 10 minutes 44 seconds in the manual pressure arm ($p < 0.001$). Pain/discomfort associated with haemostasis occurred in 15/99 (15%) patients in the PSS arm and in 29/101 (29%) patients receiving manual pressure ($p = 0.03$).

Conclusions In this randomised trial we demonstrate that an easy to perform PSS is as effective at achieving haemostasis as 10 minutes of manual pressure for catheter ablation procedures. The PSS is considerably faster to perform and is more comfortable for patients than manual pressure.

Keywords Catheter ablation • Haemostasis • Vascular access

Introduction

As catheter ablations and other interventional procedures using large bore femoral venous cannulae (such as leadless pacemakers [LCPs] or left atrial appendage closure devices) become more frequent, it is critical to determine safe, efficient and cost effective methods for femoral venous haemostasis. Complications relating to vascular access are often the most

*Corresponding author at: Dr Nicholas Jackson, Cardiology Department, John Hunter Hospital, New Lambton, NSW, Australia. Tel.: +612 4921 4206., Email: Jackson@hnehealth.nsw.gov.au

frequent complications from percutaneous electrophysiology procedures [1–6], from angiographic procedures that utilise femoral arterial access and for the growing array of structural interventions that can be performed percutaneously [7–9]. Whilst numerous randomised controlled trials have been performed in the angiographic literature with vascular closure devices for reducing access site complications [7–9], none have been performed in the setting of electrophysiology ablation or femoral venous access.

Aytemir et al. [10] performed a prospective non-randomised study using a figure-of-eight (FoE) suture to achieve venous haemostasis following cryoballoon ablations (15 Fr femoral venous access). In this study the FoE suture achieved immediate haemostasis in 95% (95/100) of patients with no major vascular complications [10]. Kypta et al. [11] performed a retrospective analysis of 77 patients who had LCPs implanted (18-23 Fr sheaths) and had subcutaneous absorbable double purse string sutures for groin haemostasis. Access site complications occurred in three patients (two groin haematomas and one arterio-venous fistula) and these all resolved spontaneously within 4 weeks [11].

In this study, we randomised patients undergoing electrophysiology ablations (minimum sheath size 8.5 Fr) to a purse string suture (PSS) over the femoral venous access site or manual pressure. We sought to compare the safety, effectiveness and comfort of these two techniques for venous haemostasis and determine any other predictors of vascular access site complications.

Method

Patients

We randomised consecutive patients who were referred for electrophysiology procedures at two different hospitals in Newcastle from 2013 to 2015 either manual pressure or a PSS. All patients gave prior written consent to take part in the study and the study was approved by the local ethics committee.

Patients included in the study were referred for electrophysiology procedures that involved femoral venous access with a minimum sheath size of 8.5 Fr. Patients that required femoral arterial access for ablation were excluded from the study, as were patients that had ablation procedures where only 6, 7 or 8 Fr sheaths were required (as vascular access complications are substantially less common in this group) [12]. Randomisation was performed electronically in groups of eight with the application Randomizer for Clinical Trial (Medsharing 2016).

Vascular Access and Ablation Procedures

Vascular access was achieved with the Seldinger technique using a 7Fr Cook® needle to puncture the femoral vein at or below the level of the groin crease. Ultrasound (US) was used on an 'as-needed' basis, generally for obese and overweight patients and for patients where access proved difficult without imaging. In cases where US was not used, the needle was advanced without a syringe attached to allow for greater tactile feel to identify if the needle was passed through the anterior wall of the femoral vein or if it was approaching the femoral artery (arterial pulsations are felt through the needle). The size and number of sheaths used were recorded for every procedure, as was the occurrence of an inadvertent arterial puncture.

The majority of procedures performed were for atrial fibrillation and the majority of these ablations utilised the cryoballoon and 15 Fr FlexCath® sheath. These procedures were performed as previously described by Jackson et al. [13]

Haemostasis Techniques

Manual pressure consisted of 10 minutes of firm downward pressure over the vascular access site performed by nursing or medical staff trained in this technique. If haemostasis was not achieved at this time, then additional pressure was allowed and this was recorded as an additional intervention. If this was still insufficient then a FemStop® (Abbott Laboratories, Abbott Park, IL, USA) could be applied to achieve ongoing haemostasis. After haemostasis was achieved, patients were instructed to lie supine or semi erect (up to 30 degrees of elevation at the waist) for 4 hours, at which time they could mobilise if there was no further bleeding or bruising.

In the suture arm, haemostasis was achieved with a 1.0 monofilament suture tied so as to pull the skin and subcutaneous tissue together firmly. The 1.0 monofilament is ideal as it has a very high tensile strength and it will easily allow the knot to slide along itself. An instructional video is linked to the online manuscript. In Figure 1A the suture was positioned a centimetre below and two to three centimetres above the access point of the sheaths through the skin as shown. The suture needle was passed relatively deeply in the subcutaneous tissue so that it travelled just above (but not through) the femoral vein (the suture should be tied by the person who gained access so they know how deeply the femoral vessels run). In panels B and C, a Fisherman's knot was then tied in the suture so that the knot would only slide in one direction. In panel D, the knot was then slid down against the skin firmly to achieve haemostasis as all sheaths were removed and two additional half hitches could then be tied to further anchor the knot. This knot was left in place for 4 hours with the patient supine (up to 30 degrees of elevation at the waist), at which time the knot was cut, the suture was removed and the patient could mobilise. Any additional interventions required to achieve haemostasis were recorded.

Anticoagulation

For patients on warfarin this was continued for ablation procedures and the INR was kept at 2–3. For patients on non-vitamin K oral anticoagulants (NOACs) the dose in the morning of the procedure was generally withheld and then the NOAC would be restarted at the next scheduled dose if there were no bleeding issues. Heparin was given following transseptal punctures to aim for an ACT of $\geq$300 seconds.

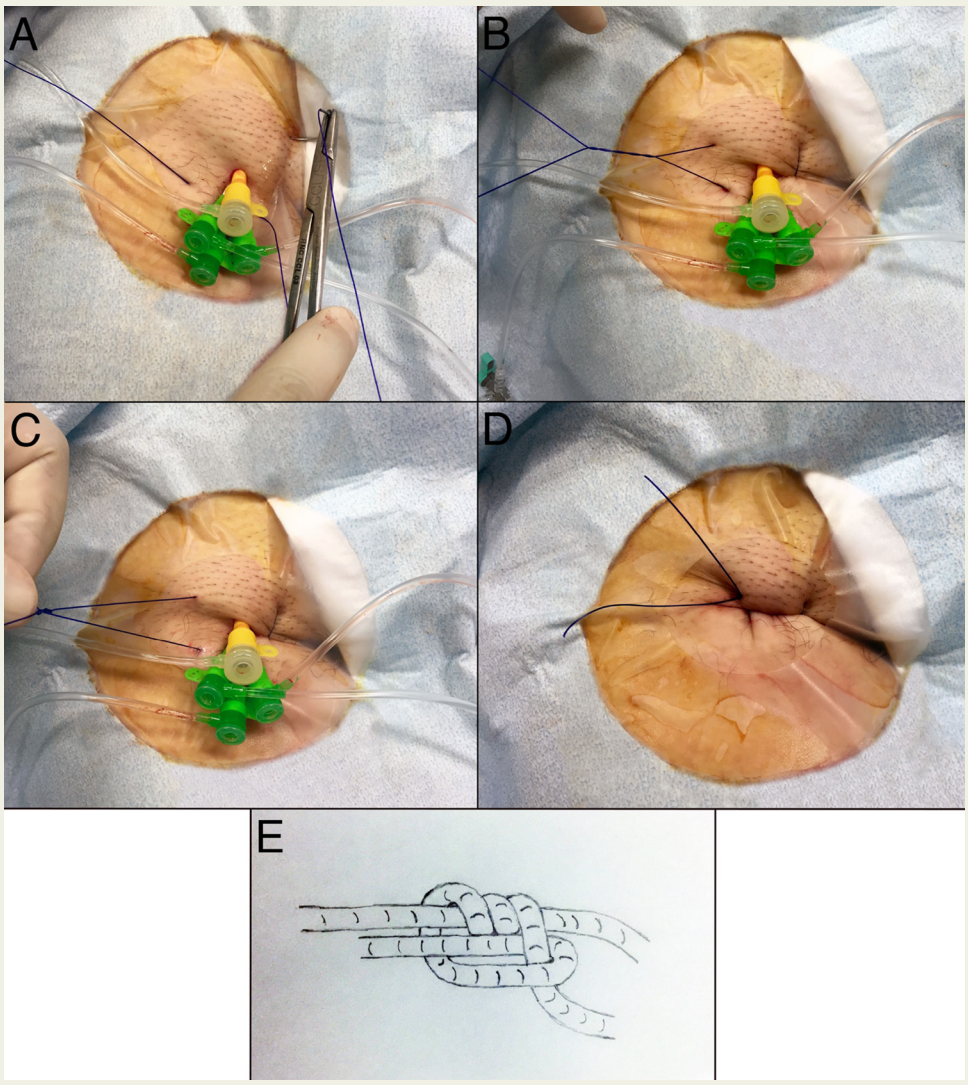

Figure 1 The purse string suture is tied using a 1.0 monofilament suture. The needle is passed from lateral to medial 1 cm below the entry point of the sheaths to the skin and then from medial to lateral 2–3 cm above the sheaths entry point (Panel A). The person who places the sheaths should tie the purse string suture so they are aware of the depth of the vessels and can pass the needle just above the femoral vessels to achieve the best haemostasis. The needle is then cut free and a Fisherman's knot is tied in the suture (Panels B and C). This knot is then slid down firmly to pull together the skin and subcutaneous tissues as shown (Panel D). Panel E shows a cartoon of the suture once it is tied and before it is pulled tight. In addition, the attached video from the methods section shows a step-by-step tutorial of how to tie the purse string suture.

Heparin was reversed at the end of the procedure at the discretion of the operator (this decision was made prior to randomisation). Antiplatelet agents such as aspirin and clopidogrel were continued for procedures.

Study Endpoints

The groin was examined for bruising, bleeding or any complications immediately following the PSS/manual pressure, at 4 hours, at 24 hours and then at follow-up (3 months following the procedure). Bleeding events were grouped into four categories in this study: 1) No evidence of bleeding; 2) minor bruising visible but not requiring any intervention; 3) bleeding requiring additional pressure or a FemStop® to achieve complete haemostasis; and, 4) bleeding requiring diagnostic studies, prolonging hospitalisation or requiring surgical or procedural intervention.

The primary endpoints of the study were the occurrence of any bruising or bleeding requiring intervention or not and the occurrence of bruising or bleeding requiring intervention (category 3 or 4). Vascular complications such as pseudoaneurysms, retroperitoneal bleeding or arterio-venous fistulae were only looked for with imaging if there was a clinical indication on review. At the time of the PSS/manual pressure patients were asked if they experienced any discomfort. A simplified numerical rating score for pain [14,15] was used where patients could rate their pain as nil (0), mild (1), moderate (2) or severe (3). A mean pain score was then calculated for each group (PSS and manual pressure).

Statistical Analysis

Continuous variables are presented as mean ± standard deviation and categorical values are presented as absolute number and percentage. Continuous variables were compared using Students t-test (unpaired) and categorical variables were compared using Fisher's exact text. Pain scores were compared using a two-tailed Mann-Whitney U test. Univariate and multivariate regression models were performed to identify any significant predictors of bleeding and a variance inflation factor (VIF) was calculated to look for multicollinearity. A p-value of <0.05 was considered statistically significant.

Results

A total of 200 consecutive patients (138 (69%) male, mean age 61.8 ± 12.1 years) were enrolled and randomised for the trial. Baseline characteristics are shown in Table 1. On one occasion the PSS had to be repeated as the knot locked and could not be slid down sufficiently to provide haemostasis (this required only brief additional manual pressure before the suture was repeated).

Event rates for bruising/bleeding are shown in Table 2. There were no significant differences in the rates of bleeding or vascular complications between the PSS and the manual pressure groups. Nor were there any significant differences in the rates of complications requiring intervention. There were no pseudo-aneurysms, retroperitoneal bleeds or arterio-venous fistulae in either group in this study. An inadvertent arterial puncture occurred in 2/99 (2%) patients in the PSS arm and in 0/101 (0%) patients in the manual pressure arm ($p = 0.5$).

The mean period of manual pressure required to achieve haemostasis was 0:45+/−2 minutes in the PSS arm and 10:44 +/−2.2 minutes in the manual pressure arm ($p < 0.001$). Pain associated with haemostasis occurred in 15/99 (15%) patients in the purse string suture arm and 29/101 (29%) patients receiving manual pressure ($p = 0.03$). All patients described their pain as mild, except for one patient in the PSS arm and four patients in the manual pressure arm who experienced moderate pain. The mean pain score was 0.15+/−0.39 in the

Table 1 Characteristics of the Patients at Baseline.

	Purse String Suture	Pressure	P value
Number	99	101	
Age (years)	61.7 ± 12.2	61.9 ± 12.5	0.36
Sex (% male)	69%	69%	1
Procedure (%)			
Cryoballoon PVI	72	68	0.44
RF PVI	11	11	1
Typical flutter	12	15	0.68
Other	5	5	1
BMI (Kg/m2)	29.0 ± 4.2	29.7 ± 5.2	0.31
Duration (min)	108 ± 72.5	99 ± 20	0.14
Number of sheaths	3.0 ± 0.2	3.0 ± 0.2	0.46
Maximum sheath size	13.6 ± 2.3	13.5 ± 2.4	0.85
INR all patients (mean ± SD)	1.9 ± 0.8	1.8 ± 0.7	0.38
INR on warfarin (mean ± SD)	2.5 ± 0.4	2.4 ± 0.4	0.04
NOAC (%)	33 (33.3)	27 (26.7)	0.47
Aspirin (%)	3 (3.0)	7 (6.9)	0.34
Clopidogrel (%)	2 (2.0)	0 (0)	0.5
ACT (mean ± SD)	296 ± 88	321 ± 68	0.11
Protamine administered (%)	12 (12.1)	16 (15.8)	0.21
Thrombocytopaenia (%)	2 (2.0)	1 (1.0)	0.5
GFR < 30 (%)	0	1 (1.0)	1
Type 2 Diabetes (%)	8 (8.1)	4 (4.0)	0.37
Heart failure (%)	3 (3.0)	3 (3.0)	1

Baseline characteristics are shown for the purse string suture and manual pressure groups. The mean ACT is in each group is calculated only from patients who received heparin (as other patients did not receive an ACT). Mean INR recordings are for all patients on warfarin or not (as all patients had their INR tested on the day of the procedure).

Abbreviations: PVI, pulmonary vein isolation; RF PVI, radiofrequency pulmonary vein isolation; BMI, body mass index; INR, international normalised ratio of prothrombin time; NOAC, non-vitamin K antagonist oral anticoagulant; ACT, activated clotting time; GFR, glomerular filtration rate.

Table 2 Outcomes by Category and Time Period.

Endpoint	Suture (Mean)	Pressure (Mean)	Odds Ratio	P value
Any bruising/bleeding (%)	25 (25)	29 (29)	0.84 (0.45–1.57)	0.58
Bleeding requiring additional Pressure or FemStop (%)	17 (17)	19 (19)	0.89 (0.43–1.84)	0.78
Required additional Pressure (%)	11 (11)	6 (6)	1.97 (0.70-5.56)	0.20
Required FemStop (%)	6 (6)	13 (13)	0.44 (0.16–1.20)	0.11
Bleeding requiring intervention or prolonging hospital stay (%)	0 (0)	0 (0)	NA	NA
Immediate (%)	9 (9)	17 (17)	0.49 (0.21–1.17)	0.11
1–4 hours (%)	12 (12)	9 (9)	1.41 (0.57–3.51)	0.46
4–24 hours (%)	4 (4)	3 (3)	1.37 (0.30–6.31)	0.68

Breakdown of the rates of bruising/bleeding with the PSS versus manual pressure (results are shown as absolute number and percentage for each group). Any bruising or bleeding (categories 2 and 3), bleeding requiring additional Pressure or FemStop® (category 3) and bleeding requiring intervention or prolonging hospital stay (category 4). Any bruising or bleeding is then broken down into the time points at which it occurred.

PSS arm versus 0.32+/−0.55 in the manual pressure arm (p = 0.07).

Table 3 shows univariate and multivariate regression analyses for predictors of vascular access site complications. The use of heparin, NOACs, and cryoballoon ablation were univariate predictors of bleeding following vascular access. On multivariate analysis, heparin was removed from the analysis due to its close relationship to the measurement of activated clotting time (ACT). There were no statistically significant relationships with vascular access site bleeding identified on multivariate analysis and the VIF was 1.06 suggesting there was no multicollinearity.

Complications unrelated to vascular access in this study included one patient in the purse string suture arm with a phrenic nerve palsy that resolved after 1 month and one patient in the purse string suture arm had pericardial tamponade at transseptal puncture that was drained without further complication (both patients were undergoing cryoballoon ablation).

Table 3 Results for the univariate and multivariate analyses for predictors of vascular access site bleeding.

Univariate Analysis		
Variable	**Odds Ratio**	**P value**
Age Group (over 65)	0.68 (0.327 – 1.411)	0.301
Male sex	0.65 (0.307 – 1.376)	0.261
Cryoballoon ablation	3.48 (1.285 – 9.441)	0.014
Prior procedure	0.72 (0.295 – 1.777)	0.481
Procedure duration	0.76 (0.368 – 1.573)	0.462
High INR (>3.0)	1.77 (0.446 – 7.039)	0.416
BMI (<25 control)		
25-30	1.81 (0.564 – 5.779)	0.320
>30	1.18 (0.349 – 3.999)	0.788
Heparin	3.45 (1.362 – 8.754)	0.009
Protamine	0.78 (0.089 – 6.868)	0.82
NOAC	2.51 (1.199 – 5.282)	0.015
ACT (<298 control)		
298–360	0.6 (0.197 – 1.820)	0.367
>360	2.33 (0.923 – 5.877)	0.073
Multivariate Analysis		
Variable	**Odds Ratio**	**p Value**
Cryoballoon ablation	0.51 (0.15 – 1.72)	0.277
NOAC	2.17 (0.905 – 5.179)	0.083
ACT (<298 control)		
298–360	0.51 (0.163 – 1.596)	0.247
>360	2.11 (0.803 – 5.545)	0.129

Abbreviations: INR, international normalised ratio of prothrombin time; BMI, body mass index; NOAC, non-vitamin K antagonist oral anticoagulant; ACT, activated clotting time.

Discussion

This is the first prospective, randomised study to show that a quick and inexpensive intervention such as the PSS, is as effective as 10 minutes of manual pressure at preventing access site bleeding following electrophysiology procedures. This suture is quick and easy to perform, it significantly reduced nursing staff time for achieving haemostasis and lead to less discomfort for patients than manual pressure as well.

It is well established that the most common adverse events associated with an electrophysiology intervention are vascular access complications [1,2,4,6]. The frequency of these complications increases with increased sheath size, multiple vascular punctures and full dose anti-coagulation [1,4,6,16] (all of these risk factors are highly relevant to procedures

such as atrial fibrillation ablation). Given that at least three different vascular punctures are performed for electrophysiology procedures, the use of vascular closure devices such as Angio-Seal™ (Terumo Corporation, Tokyo, Japan), Perclose ProGlide™ (Abbott Laboratories, Abbott Park, IL, USA) or ExoSeal® (Cordis Corporation, Milpitas, CA, USA) to close each puncture individually becomes time consuming, expensive and may be difficult to perform if the punctures sit closely together. These devices all need to be performed a number of times for the operator to become competent as well. In this study, a single 1.0 monofilament suture was inexpensive (~AU$3.50), took less than a minute to perform and provided haemostasis for all punctures at the same time by pulling firmly together the skin and subcutaneous tissues over all venous punctures. In addition, given that the suture is completely removed after 4 hours there is no foreign material left in situ to create an increased risk of infection.

In the study of a FoE suture by Aytemir et al. [10], this was effective in achieving immediate haemostasis in 95% of patients following cryoballoon ablation with no major vascular complications. This study used sequential allocation of FoE suture versus manual pressure, however, so operators were aware of patient allocation prior to obtaining venous access and performing the procedure, which may have introduced a bias to the study. They also used a silk suture, which, on one occasion, snapped as it was tied and manual pressure was required for haemostasis. Prior to this study, we used a 0.0 silk suture, however, we changed to the 1.0 monofilament due to occasional snapping of the silk suture (we found the monofilament was both stronger and allowed the Fisherman's knot to slide more freely). On one occasion in this study, the knot failed to slide down and achieve adequate tension, however, this occurred very early on in an operator's experience and a second knot was able to be retied in its place.

In a retrospective analysis by Kypta et al. [11], 77 patients who had LCPs implanted (18–23 Fr sheaths), a subcutaneous absorbable double purse string suture was effective for groin haemostasis with only two groin haematomas and one arterio-venous fisula in their study. In this retrospective study with no comparison arm, this technique appeared effective, however, even moreso than the FoE suture in the study by Aytemir et al. [10], we feel this technique is more time consuming and complex than is necessary given the results of this randomised study with a simple PSS.

There was no instance of symptomatic arteriovenous fistula, pseudo-aneurysm or retroperitoneal bleeding in this study. This may, in part, reflect the use of a syringe-less technique for venous access and the use of ultrasound at the operator's preference (primarily for patients with a high BMI) to minimise and identify inadvertent arterial punctures (only two (1%) occurred in this study). There was no incidence of symptomatic venous thrombosis in this study; this is consistent with the study by Cilingiroglu et al. [17] which showed that with a FoE suture there is a compressive effect on the subcutaneous soft tissue over the femoral vein but no incidence of thrombus or venous stenosis after suture removal.

In this study a univariate regression model suggested that the use of heparin, NOACs and cryoballoon ablation were predictive of access site bleeding. All patients undergoing cryoballoon ablation received heparin following transseptal puncture and were more likely to be on NOACs, so there is a degree of correlation between all of these risk factors (including ACT as well). This may explain why, on multivariate analysis, there were no significant predictors of vascular access site bleeding in this study (despite no multicollinearity on VIF testing). Two prospective non-randomised studies suggested that a shorter duration of post procedural anticoagulation with enoxaparin [4] and a three-pronged strategy using a small access needle (21G), no bridging anticoagulation and no femoral arterial access for monitoring may reduce vascular access complications [6]. Other studies looking at AF ablation have suggested use of clopidogrel [1], female gender [1,18], ablation early in the clinical year (July/August) [1], increased age [4,18,19], use of bridging with unfractionated heparin [6,16] and lack of ultrasound guidance [19] increased the risk of vascular access complications. These studies all differed from the present study in that they included only patients undergoing AF ablation (19% of patients in this study had non AF procedures) and they lacked a randomised design. Overall, multiple factors related to AF ablation including the use of multiple, large bore sheaths and the need for anticoagulation appear to increase the risk of vascular access complications and other modifiers such as age, female gender and bridging anticoagulation are likely to increase this risk further.

In this study the PSS saved 10 minutes of a trained staff's time per case and was better tolerated than manual pressure. In cases where patients were confused post anaesthetic and flexed their right leg or coughed due to laryngeal irritation we found that the PSS continued to provide excellent haemostasis (which is another potential advantage). Whether patients may be able to mobilise sooner than 4 hours after a case with the PSS is possible and is a worthwhile subject for further study.

Limitations

Although this is the first prospective randomised study to compare the safety and efficacy of a purse string suture to manual pressure it was only conducted at two sites and a larger scale multicentre study would be important for further validation. Although we discuss the pros and cons of different suture techniques for venous haemostasis from different trials, a randomised trial with head-to-head comparison of different suture techniques is the only way to definitively determine which technique is superior.

Use of ultrasound to guide access was not routine in this study as this reflects usual practice at the institutions were the study was performed. Furthermore, inadvertent arterial access occurred in only two (1%) cases and both of these were in the PSS arm. Assessment for arterio-venous fistulae and pseudoaneurysm with US was only performed if there was a clinical indication so small

pseudoaneurysms or arteriovenous fistulae without symptoms may have gone undetected.

Conclusion

In this randomised trial we demonstrate that an easy to perform purse string suture is as effective at achieving haemostasis as 10 minutes of manual pressure for electrophysiology procedures. This technique is considerably faster to perform than manual pressure and is more comfortable for patients making it increasingly relevant with the growing number of interventions requiring femoral venous access.

Conflict of Interest

No conflicts of interest to disclose for any of the authors.

Funding

No funding was received for this publication.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.hlc.2018.03.011.

References

[1] Baman TS, Jongnarangsin K, Chugh A, Suwanagool A, Guiot A, Madenci A, et al. Prevalence and predictors of complications of radiofrequency catheter ablation for atrial fibrillation. J Cardiovasc Electrophysiol 2011;22(6):626–31.

[2] Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman J, et al. Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. Circ Arrhythm Electrophysiol 2010;3(1):32–8.

[3] Kwak JJ, Pak HN, Jang JK, Kim SK, Park JH, Choi JI, et al. Safety and convenience of continuous warfarin strategy during the periprocedural period in patients who underwent catheter ablation of atrial fibrillation. J Cardiovasc Electrophysiol 2010;21(6):620–5.

[4] Prudente LA, Moorman JR, Lake D, Xiao Y, Greebaum H, Mangrum JM, et al. Femoral vascular complications following catheter ablation of atrial fibrillation. J Interv Card Electrophysiol 2009;26(1):59–64.

[5] Wazni OM, Beheiry S, Fahmy T, Barrett C, Hao S, Patel D, et al. Atrial fibrillation ablation in patients with therapeutic international normalized ratio: comparison of strategies of anticoagulation management in the periprocedural period. Circulation 2007;116(22):2531–4.

[6] Abhishek F, Heist EK, Barrett C, Danik S, Blendea D, Correnti C, et al. Effectiveness of a strategy to reduce major vascular complications from catheter ablation of atrial fibrillation. J Interv Card Electrophysiol 2011;30(3):211–5.

[7] Chou TM. Vascular complications and arteriotomy closure devices during percutaneous coronary procedures. J Am Coll Cardiol 2005;45(12):2095–6. author reply 6.

[8] Dangas G, Mehran R, Kokolis S, Feldman D, Satler LF, Pichard AD, et al. Vascular complications after percutaneous coronary interventions following hemostasis with manual compression versus arteriotomy closure devices. J Am Coll Cardiol 2001;38(3):638–41.

[9] Gregory D, Midodzi W, Pearce N. Complications with Angio-Seal vascular closure devices compared with manual compression after diagnostic cardiac catheterization and percutaneous coronary intervention. J Interv Cardiol 2013;26(6):630–8.

[10] Aytemir K, Canpolat U, Yorgun H, Evranos B, Kaya EB, Sahiner ML, et al. Usefulness of 'figure-of-eight' suture to achieve haemostasis after removal of 15-French calibre femoral venous sheath in patients undergoing cryoablation. Europace 2016;18(10):1545–50.

[11] Kypta A, Blessberger H, Lichtenauer M, Kammler J, Lambert T, Kellermair J, et al. Subcutaneous double 'purse string suture' – a safe method for femoral vein access site closure after leadless pacemaker implantation. Pacing Clin Electrophysiol 2016;39(7):675–9.

[12] Scheinman MM, Huang S. The 1998 NASPE prospective catheter ablation registry. Pacing Clin Electrophysiol 2000;23(6):1020–8.

[13] Jackson N, Barlow M, Leitch J, Attia J. Treating atrial fibrillation: pulmonary vein isolation with the cryoballoon technique. Heart Lung Circ 2012;21(8):427–32.

[14] Chapman CR, Casey KL, Dubner R, Foley KM, Gracely RH, Reading AE. Pain measurement: an overview. Pain 1985;22(1):1–31.

[15] Bode K, Breithardt OA, Kreuzhuber M, Mende M, Sommer P, Richter S, et al. Patient discomfort following catheter ablation and rhythm device surgery. Europace 2015;17(7):1129–35.

[16] Calkins H, Kuck KH, Cappato R, Brugada J, Camm AJ, Chen SA, et al. 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design: a report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. Developed in partnership with the European Heart Rhythm Association (EHRA), a registered branch of the European Society of Cardiology (ESC) and the European Cardiac Arrhythmia Society (ECAS); and in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS), and the Society of Thoracic Surgeons (STS). Endorsed by the governing bodies of the American College of Cardiology Foundation, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, the Asia Pacific Heart Rhythm Society, and the Heart Rhythm Society. Heart Rhythm 2012;9(4):632–96. e21.

[17] Cilingiroglu M, Salinger M, Zhao D, Feldman T. Technique of temporary subcutaneous "Figure-of-Eight" sutures to achieve hemostasis after removal of large-caliber femoral venous sheaths. Catheter Cardiovasc Interv 2011;78(1):155–60.

[18] Spragg DD, Dalal D, Cheema A, Scherr D, Chilukuri K, Cheng A, et al. Complications of catheter ablation for atrial fibrillation: incidence and predictors. J Cardiovasc Electrophysiol 2008;19(6):627–31.

[19] Wynn GJ, Haq I, Hung J, Bonnett LJ, Lewis G, Webber M, et al. Improving safety in catheter ablation for atrial fibrillation: a prospective study of the use of ultrasound to guide vascular access. J Cardiovasc Electrophysiol 2014;25(7):680–5.