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Torque device suture technique to achieve hemostasis in large-bore venous access

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Abstract

Objectives: To describe and compare a novel technique using a torque device to manage figure-of-eight suture tension for venous access hemostasis in patients who have undergone atrial septal defect (ASD) or patent foramen ovale (PFO) closure.

Background: Large bore venous access has become increasingly important in transcatheter procedures, but management of hemostasis can be time-consuming and/or resource intensive. As such, various techniques have sought to provide cost effective and safe alternatives to manual compression. We describe a modification of the figure-of-eight suture technique wherein we apply a torque device to manage variable suture tension instead of tying a knot and compare it to the standard figure-of-eight suture technique.

Methods: We performed a retrospective study of 40 consecutive patients who underwent ASD or PFO closure, 20 of whom underwent standard figure-of-eight technique and 20 of whom underwent figure-of-eight with torque device modification. Bleeding Academic Research Consortium definitions were used to categorize bleeding events.

Results: The groups were similar in age, gender, weight, aspirin use, platelet count, procedure time, hemoglobin, and international normalized ratio. Standard figure-of-eight suture had seven patients with bleeding, with six classified as BARC II and one as BARC I. Figure-of-eight plus torque device had three patients with bleeding, with two classified BARC II and one as BARC I. There were no incidences of hematoma in either group.

Conclusion: The torque device suture technique is a unique modification of the figure-of-eight suture technique to achieve venous hemostasis. In addition, the modification allows secure and variable suture tension as well as easy removal by nursing staff.

KEYWORDS

closure, figure-of-eight, venous hemostasis

1 | INTRODUCTION

The proliferation of endovascular procedures from structural heart interventions to electrophysiology ablations, pulmonary thrombectomy, and atrial septal defect (ASD) and patent foramen ovale (PFO) closures has led to increasing use of large-bore venous access that can increase the risk of bleeding, access site complications, and increased length of hospitalization. Typically, manual compression has been used after sheath removal to achieve post-procedure venous hemostasis; however, full anticoagulation may prohibit immediate sheath removal or require reversal of anticoagulation. Recently, the figure-of-eight suture technique has become a more widely used alternative as it has been shown to be as safe and effective as manual compression.[1,2] An innovative twist on this technique is the use of a stopcock device to apply tension on venous access site suture in lieu of the figure-of-eight suture knot for hemostasis after radiofrequency catheter ablation of atrial fibrillation.[3] Here, we describe the use of a 0.035" in torque device (Boston Scientific, Marlborough, MA and Terumo Interventional Systems, Somerset, NJ) as an alternative to the stopcock device or suture knot to apply tension on figure-of-eight sutures. This technique provides operators with the ability to increase or decrease tension on the suture, as needed, to achieve and maintain secure hemostasis. In this preliminary evaluation, figure-of-eight plus torque device closure technique appears to be similar or better in efficacy when compared to standard figure-of-eight suture technique.

2 | MATERIALS AND METHODS

After informed consent was obtained, charts of 20 consecutive patients who underwent ASD or PFO percutaneous closure with figure-of-eight and torque device closure technique at our tertiary academic center were retrospectively reviewed and compared to 20 patients who underwent ASD or PFO percutaneous closure with standard figure-of-eight suture without the use of torque device. The data collected included patient demographics, type of hemostasis (figure-of-eight with torque device or standard figure-of-eight suture), length of stay (time from procedure to discharge), length of procedure, anticoagulation type, post-procedure bleeding from groin site, hematoma or pseudoaneurysm formation, preprocedure international normalized ratio (INR), hemoglobin and platelet count, and use of antiplatelet therapy. Bleeding events were noted as any mention of bleeding in the electronic medical record and Bleeding Academic Research Consortium (BARC) definitions were used to categorize bleeding events.[4] Patients who had been on therapeutic anticoagulation (whether warfarin or Xa inhibitors) had their anticoagulation held prior to procedure. Those on aspirin, clopidogrel, or both were continued on their therapy prior to intervention.

2.1 | Venous hemostasis technique

Venous access was obtained using ultrasound guidance with micropuncture system and an 8 Fr sheath was placed in the femoral vein. Procedural anticoagulation was achieved with intravenous heparin with a target ACT of 250–300 s. After percutaneous ASD or PFO closure was completed, closure with either standard figure-of-eight suture technique or figure-of-eight and torque device technique was performed. All patients were then loaded with 325 mg aspirin and 300 mg of clopidogrel.

In the standard figure-of-eight technique group, 0 silk or 0 Ethibond (Ethicon, Bridgewater, NJ) sutures were placed in the skin and the needle was passed once on the caudal side of the sheath insertion site and once on the cranial side of the insertion site, with diligence to avoid the femoral vasculature. After removing the needle, the sheath was pulled out while the suture was simultaneously tightened to achieve hemostasis and knotted. A sterile dressing was then placed on the site.

In the torque device group, instead of tying a knot, the free ends of the figure-of-eight suture were threaded into the 0.035" in torque device. The torque device was then advanced over the suture, achieving firm tension at the skin and soft tissue and the sheath was removed (Figure 1 and Video S1). The torque device was then locked into position to maintain tension needed to achieve hemostasis. The suture was then trimmed and a sterile dressing placed on the site.

Continuous variables are presented as means with *SD*. Categorical variables were summarized as percentages. Statistical analyses including unpaired *t* test were done on all continuous variables, chi-square test was used to compare bleeding rates, and calculations were performed using Microsoft Excel (Microsoft Corporation, Redmond, WA).

3 | RESULTS

A total of 40 consecutive patients from May 2017 to March 2019 were included in the analysis during which time there were no differences in interventional techniques or sheaths used in the two groups, and the procedures were performed by the same operator. Twenty consecutive patients underwent standard figure-of-eight suture for venous hemostasis followed consecutively by 20 patients who underwent figure-of-eight plus torque device technique for hemostasis. Immediate hemostasis was achieved in all cases. Anticoagulation was not reversed in any of the patients. Unpaired *t* test demonstrated no statistically significant difference in patients from both groups in age, weight, INR, hemoglobin, creatinine, length of stay, procedure time, and platelet count (Table 1).

There was one major complication whereby a patient in the standard figure-of-eight group had left atrial perforation during PFO device deployment requiring emergent pericardiocentesis. Afterward, he was managed conservatively and had no need for reintervention. A total of seven patients in the standard figure-of-eight suture group had bleeding from the groin site, with six defined as BARC II and one as BARC I. In the figure-of-eight plus torque device group, three patients had bleeding with two classified as BARC II and one as BARC I. Chi-square analysis of bleeding rates between the two groups were not statistically significant (p value = .144), likely due to the small size and pilot nature of the study. The average procedure time was

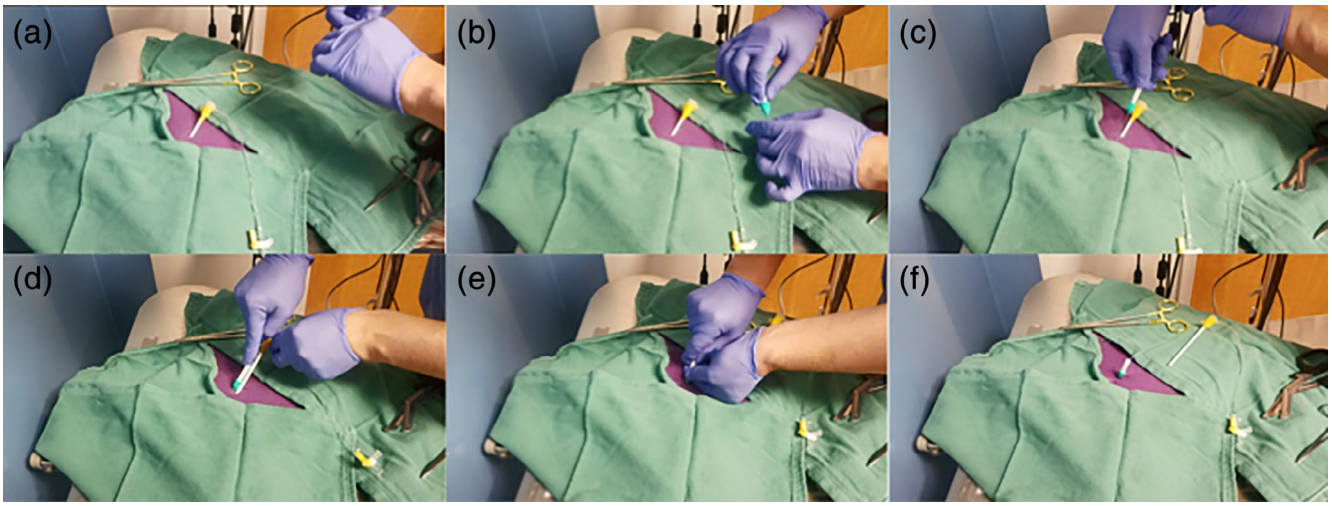

FIGURE 1 Torque device venous access closure technique. (a) Figure-of-eight suture; (b) suture ends being threaded through torque device; (c) with applied tension, the torque device is advanced; (d) tension maintained during sheath removal; (e) torque device locked into position to maintain tension for hemostasis; (f) hemostasis with torque device in position

TABLE 1 Patient characteristics

	Figure-of-eight (*n* = 20)	Figure-of-eight plus torque device (*n* = 20)	*p* value
Age (years)	48.3 ± 15.6	47.2 ± 13.3	.84
Number of males	6 (32%)	5 (26%)	
Weight (kg)	87.5 ± 18.3	90.6 ± 22.8	.64
Hypertension	10 (50%)	9 (45%)	
Aspirin	16 (80%)	14 (70%)	
Clopidogrel	10 (50%)	4 (20%)	
DAPT	8 (40%)	4 (20%)	
Creatinine	0.93 ± 0.26	0.86 ± 0.15	.30
Platelet count	252.9 ± 62.5	246.1 ± 49.2	.70
INR	1.06 ± 0.08	1.09 ± 0.23	.59
Anticoagulation use	4 (20%)	7 (35%)	
Warfarin	0	2 (10%)	
Factor Xa inhibitor	4 (20%)	5 (25%)	
Hemoglobin	12.6 ± 1.81	13.0 ± 1.56	.46
Length of stay (days)	1.26 ± 0.56	1.05 ± 0.22	.13
Procedure length (minutes)	90.6 ± 43.1	81.3 ± 25.1	.41

Abbreviations: DAPT, dual antiplatelet therapy; INR, international normalized ratio.

90.6 ± 43.1 min in the standard figure-of-eight group and 81.3 ± 25.1 min in the figure-of-eight plus torque device group and the average length of stay was 1.26 ± 0.56 days in the standard figure-of-eight suture group as compared to 1.05 ± 0.22 days in the figure-of-eight plus torque device group. No patients in either group developed an access site hematoma or pseudoaneurysm that is most likely due to noted bleeding not being vascular and more likely oozing related to venous access site.

4 | DISCUSSION

We have reported a unique, new modification to figure-of-eight suture technique using a torque device to achieve hemostasis that had a lower incidence of minor bleeding compared to standard figure-of-eight suture technique at our tertiary hospital after percutaneous ASD/PFO closures.

Standard figure-of-eight suture is a well-tolerated, safe, and resource efficient alternative to manual compression for hemostasis of femoral venous access sites with the added benefit of reduced procedure time, decreased time to hemostasis, reduced bleeding rate, and allowed for earlier patient ambulation.[1,2] However, standard figure-of-eight suture technique has some limitations: First, insufficient tension with the suture knot can result in failure of hemostasis. Second, suture tension can only be released by cutting the suture, such that if rebleeding occurs, manual hemostasis is required. In contrast, Payne et al. provided an innovative improvement with the application of a stopcock device that allowed for variable suture tension without the need to cut or tie a knot and allowed for easy suture removal.[3] Our technique replaces the stopcock with a torque device that improves the level of tension achieved. In addition, the screw of the torque device ensures more secure tension and reduces the likelihood of inadvertent suture tension release.

Similar to the stopcock device, suture removal with figure-of-eight plus torque device may be easier than standard figure-of-eight and requires no additional equipment. In addition, the torque device can be tentatively loosened to partially release tension and allow for inspection of the access site, but also allows reapplication/tightening in the event of rebleeding. The suture can then be removed without a suture removal kit.

To the best of our knowledge, this is the first description of using a figure-of-eight plus torque device to achieve venous hemostasis after percutaneous ASD or PFO closure. It appears to be a safe and effective method of providing hemostasis after closure and had lower

rates of postprocedural minor bleeding than standard figure-of-eight suture. It also has the added benefit of easy removal or reapplication by the nursing staff. We have since applied this technique to other access sites with even larger bore sheaths including a 31F percutaneous right ventricular assist cannula (ProTek Duo, Livanova, London, England) from the internal jugular vein and 16F Sapien E-sheath (Edwards Lifesciences, Irvine, CA) from the femoral vein after closure device failure with excellent success.

Our study does have limitations. It is a pilot retrospective study, which could potentially lead to selection bias and is a single center study with a small number of patients that can reduce our power to detect bleeding outcomes between the two groups.

5 | CONCLUSION

In this proof of concept pilot study, our novel figure-of-eight plus torque device closure technique was effective at managing venous access hemostasis after percutaneous ASD or PFO closure. The pilot nature of this initial evaluation precluded a power calculation, and as such we are unable to conclude a significant reduction in bleeding or noninferiority when compared to conventional techniques. However, limited analyses demonstrated no significant difference between patient populations.

CONFLICT OF INTEREST

Ponraj Chinnadurai is a full-time senior staff scientist at Siemens Healthcare, USA. C. Huie Lin is a data monitoring committee member of ACI clinical, speaker for Abiomed, course director for Gore Medical, and proctor for Abbott Structural Heart.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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