New approaches to achieving hemostasis after venous access in cardiovascular patients

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ABSTRACT

Recent decades have seen a series of advances in percutaneous transvenous procedures for cardiac arrhythmias, including the implantation of leadless pacemakers. Many of these procedures require the insertion of large caliber sheaths in large veins, usually the femoral vein. Securing hemostasis efficiently and reliably at the access site is a key step to improving a procedure's safety profile. Traditionally, hemostasis was achieved by manual compression of venous access sites, but the trend toward larger sheaths and the increased use of uninterrupted anticoagulation has pushed the limits of this method. Achieving hemostasis by compression alone in these circumstances requires more attention and longer duration, leading to greater patient discomfort and prolonged immobility. In turn, manual compression may be more time-consuming for medical professionals and increase the number of occupied hospital beds. New approaches have been developed to facilitate early ambulation, decrease patient discomfort, and address the risk of access site complications. These approaches include vascular closure devices and subcutaneous suture techniques including figure-of-eight and purse-string sutures. This article reviews the new approaches applied to achieve venous access site hemostasis in patients undergoing transvenous procedures for cardiac arrhythmias.

Key words: catheter ablation, percutaneous cardiac catheterization procedures, leadless pacemaker, suture techniques, manual compression, vascular closure device

INTRODUCTION

Percutaneous transvenous procedures for cardiac arrhythmias have advanced in recent years, principally catheter ablations and leadless pacemaker implantation [1–4]. Management of atrial fibrillation (AF) has shifted from antiarrhythmic drugs and anticoagulants to ablations and left atrial appendage occlusion devices. As the range of procedures has increased, there has been an even greater increase in the absolute number of procedures performed worldwide each year. With this increase in procedure numbers to an industrial scale, the profession is under pressure to process patients quickly, mobilizing and discharging them within hours post-procedure. Other trends have magnified the importance of venous access site management in these procedures, including the development of procedures requiring larger caliber venous sheaths (Table 1), an increase in the proportion of patients who require long-term anticoagulation, and acceptance of older and more obese patients for invasive procedures.

For this review, we will consider sheaths with an outer diameter of <7 French (F) to be small-caliber, whereas sheaths of 7–10 F will be considered medium-caliber, and >10 F will be considered large-caliber. When a sheath is described, it is usually the inner diameter alone that is quoted, but the size of the puncture produced is dependent on the outer diameter. For most short sheaths, the wall is so thin that the difference between the inner and outer diameter is <1 F. For sheaths that offer adjustable deflection and enhanced stiffness, for example, for the implantation of leadless pacemakers, the wall thickness can be as great as 0.5 mm, giving a difference between internal and external sheath diameter of 3 F. For the more robust instruments used for lead extraction, the difference is even greater.

Table 1. Transvenous procedures requiring venous access, with the year in which the intervention was first reported in its approximately modern form, and the outer diameter of the largest venous sheath used in a typical case. The prevalence of each procedure is derived from registry data from the United Kingdom in 2020–2021. The procedures introduced in recent years involve fewer larger venous sheaths

Procedure	Year of introduction	Typical number of venous sheaths	Typical outer diameter of largest sheath, F	Procedures per million of population per year
Diagnostic electrophysiological study	1969	2–5	6	2
Ablation for supraventricular tachycardia	1985	3–5	7	65
Ablation of ventricular arrhythmias	1990	3	8	20
Ablation for atrial flutter	1993	3	8	50
Radiofrequency ablation for atrial fibrillation	1998	3	8.5	65
Left atrial appendage closure	2002	1	14	9
Cryoablation for atrial fibrillation	2009	2	15	47
Implantation of leadless pacemaker	2014	1	27	4

This review will not consider the implantation of permanent cardiac implantable devices that have transvenous leads: in these devices, the lead remains in the venous access site, obstructing the egress of blood and contributing to hemostasis, which makes these procedures a distinct category. We will consider all procedures that are performed through venous access but concentrate on the procedures used for the management of arrhythmias which are more numerous than those used in managing structural heart disease (Table 1).

Venous access is most often via the femoral vein, a logical choice for its large caliber and limited anatomical variation; it consistently accommodates sheaths of up to 24 F inner diameter and 27 F outer diameter [1–6]. The veins of the upper body are seldom used as jugular access is uncomfortable for the patient, subclavian or axillary venous access carries a risk of hemothorax or pneumothorax, and the veins of the arm are too small. Whereas arterial access for percutaneous coronary intervention procedures has shifted from predominantly femoral to predominantly radial in response to a decline in the size of the equipment used from 8 F to 5 F, the equipment used for transvenous intervention has evolved toward greater diameter. The upper limb veins are seldom large enough.

Venous access site hemostasis has traditionally been achieved by manual compression which remains effective for small caliber venous sheaths and is the standard against which other methods of achieving venous hemostasis are judged. Even with smaller sheaths, hemostasis with compression can take up to 30 minutes to achieve, which is uncomfortable for the patient and burdensome to medical staff [6–11]. The mandatory period of immobilization of 4–8 hours after manual compression further increases the cost and nuisance [6, 7 11–13]. It produces a real risk of deep vein thrombosis in addition to bleeding risks associated with incomplete control or from access site vascular injury leading to a hematoma, arteriovenous fistulae, and pseudoaneurysm [6–8, 11–13].

Venous access site bleeding events, such as hematoma, pseudoaneurysm, and arteriovenous fistula, are the most common complications after venous catheterization, with a reported incidence ranging from 0% to 13% [1, 6, 14–19]. Of these complications, the most serious are pseudoaneurysms and arteriovenous malformations, which occur only if an artery is punctured inadvertently. These may require corrective intervention such as thrombin injection, stent implantation, or surgery. The issue of access site closure is, therefore, linked to the expertise with which access is secured: perfect closure of a venous puncture becomes unimportant if an adjacent, inadvertent arterial puncture is left unsealed. Until recently, avoidance of inadvertent arterial puncture depended on the experience and technical expertise of the operator; more recently, the use of ultrasound has facilitated avoiding these complications even for less experienced operators [20, 21].

Factors associated with the occurrence of venous access site complications include the use of multiple venous access sites, larger caliber sheaths, and anticoagulation, as well as advanced age and the presence of multiple comorbidities [1, 5, 8, 17, 18]. Raised venous pressure and poor tissue strength due to comorbidities and advanced age can also increase the bleeding risk, as can patient obesity. Venous access site complications cause pain and reduce mobility, increase cost and extend hospital stays; they can even cause death or permanent disability [1, 5, 14, 16, 18].

The transvenous procedures used in treating arrhythmias require multiple venous access points and often involve mid-large caliber sheaths (8–24 F) [1, 5, 6, 8, 18, 22]. The trend towards large-caliber sheaths and the use of uninterrupted anticoagulation often prolong the manual compression process and undermine its effectiveness even further [6–11]. Alternative approaches to achieving an immediate and safe venous access site hemostasis are becoming increasingly important and include subcutaneous suture techniques and vascular closure devices [5–8, 22–26].

INTERRUPTION AND REVERSAL OF ANTICOAGULATION

Long-term anticoagulation has become the norm in patients with atrial arrhythmias, and this patient group has come to account for a majority of procedures carried out for arrhythmia management. As well as the long-term anticoagulant, these patients require additional anticoagulation with heparin during the procedure, creating a potential overlap of effects. Traditionally, percutaneous procedures carried out on patients requiring long-term anticoagulation were performed with interruption of the long-term agent, and the use of bridging heparin. This approach was associated with a high rate of adverse events, both thromboembolic and hemorrhagic. Randomized clinical trials, therefore, investigated uninterrupted anticoagulation with either vitamin K antagonists (VKA) or non-vitamin K antagonist oral anticoagulants (NOACs) vs. the traditional approach.

In the COMPARE trial, Di Biase et al. [27] showed that uninterrupted use of VKA was associated with significantly fewer thromboembolic and bleeding events when compared with interrupted anticoagulation with bridging heparin. In this randomized clinical trial with 1584 patients, the incidence of thromboembolic events was more than 15-fold higher in the interrupted group which also experienced more bleeding events [27]. The guidelines adopted the concept of uninterrupted VKA for AF ablation and were more recently extended to include NOACs on the basis of three randomized clinical trials comparing uninterrupted NOACs and VKA for AF ablations (VENTURE-AF, RE-CIRCUIT, AXAFA AFNET) [28–30]. These trials show that uninterrupted NOACs are safe, with rates of bleeding and thromboembolic events even lower than those for uninterrupted warfarin [28–30].

Reversal of heparin at the end of a procedure is desirable to hasten hemostasis at the access site. Unfortunately, the only agent available for this purpose is protamine, a biological agent that is prone to adverse effects [31]. The balance of its risks and benefits has not been addressed in a randomized trial, but the agent is widely used.

COMPRESSION

Any puncture in any vessel can be closed by compressing the vessel with enough force to arrest flow through it for long enough for a clot to form in the puncture that is solid enough to resist the pressure in the vessel. In contrast to arterial punctures, the force promoting bleeding from a vein is low, permitting closure with just light pressure applied for a relatively short duration. Until the 21st century, electrophysiological interventions were generally performed through sheaths of 8 F or less, and anticoagulation was usually interrupted for the performance of procedures. In these circumstances, closure of the puncture site is achieved by local pressure alone.

Manual pressure is usually applied by the operator, sometimes by an assistant. For compression of short duration, this can be done in the procedure room, but this is inefficient as it delays the subsequent procedure and ties up multiple healthcare professionals. As the pressure is gentle, it can be maintained during patient transfer and continued by professionals not involved in the procedure. In this situation, labor-saving options include the application of pressure using a weight, such as a sandbag or a bag of liquid, or the application of a clamp, such as the FemoStop™ (Abbott Vascular, Santa Clara, CA, US). Although clamps and weights are used sporadically, they have not been compared to simple manual pressure in any substantial randomized trial for venous closure. These forms of pressure do not depend on the human hand; however, for this review, these methods will be grouped under the heading "manual compression".

SUTURE TECHNIQUES

Subcutaneous suture techniques include the figure-of-eight (FO8) suture and purse-string suture, both of which have been applied widely for venous site closure. Multiple studies have established the efficacy and safety of the suture techniques, particularly FO8, even after procedures involving multiple femoral venous accesses with up to 24 F caliber sheaths. Suture techniques offer immediate hemostasis with comparable venous access complication rate to manual compression [5, 8, 16, 22, 23, 25, 32, 33].

Figure-of-eight suture

In the temporary subcutaneous FO8, a large-diameter non-absorbable braided suture on a large needle is passed caudally to the venous sheath insertion site and advanced through the subcutaneous tissue avoiding the femoral vein. The needle is then crossed over the sheath and reinserted in the subcutaneous tissue cranial to the venous sheath insertion site and advanced through the subcutaneous tissue again. Both ends of the suture are caught, and the knots are set to compress above the puncture site (Figure 1A). The FO8 suture achieves hemostasis by gathering the subcutaneous soft tissue to create a mechanical tamponade effect on the venous puncture site. Ultrasound studies confirm the compressive effect of subcutaneous soft tissue and demonstrate that venous structure is preserved after suture removal without stenosis or thrombosis [34].

The FO8 suture, also named the z-stitch or fellow-stitch was described by Bagai and Zhao et al. in 2008 [35] as a means of achieving hemostasis after removal of larger caliber venous sheaths in fully anticoagulant patients. Subsequent randomized and non-randomized studies compared FO8 suture to manual compression after large caliber (8–24 F) femoral venous sheath removal. They showed that the FO8 achieved hemostasis in less than a minute and resulted in significantly faster ambulation and shorter overall hospital stay and significantly fewer access site complications. The difference is driven mainly by bleeding and hematoma even though more patients in the manual compression group underwent heparin reversal with protamine [5, 6, 8, 24, 25, 32].

A number of studies for electrophysiological procedures favored the FO8 suture compared to manual compression due to more-immediate hemostasis and early ambulation with or without administration of protamine [5, 24, 25, 32, 36]. More recently, an observational registry involved 434 ablations for AF using 8–15 F venous sheaths

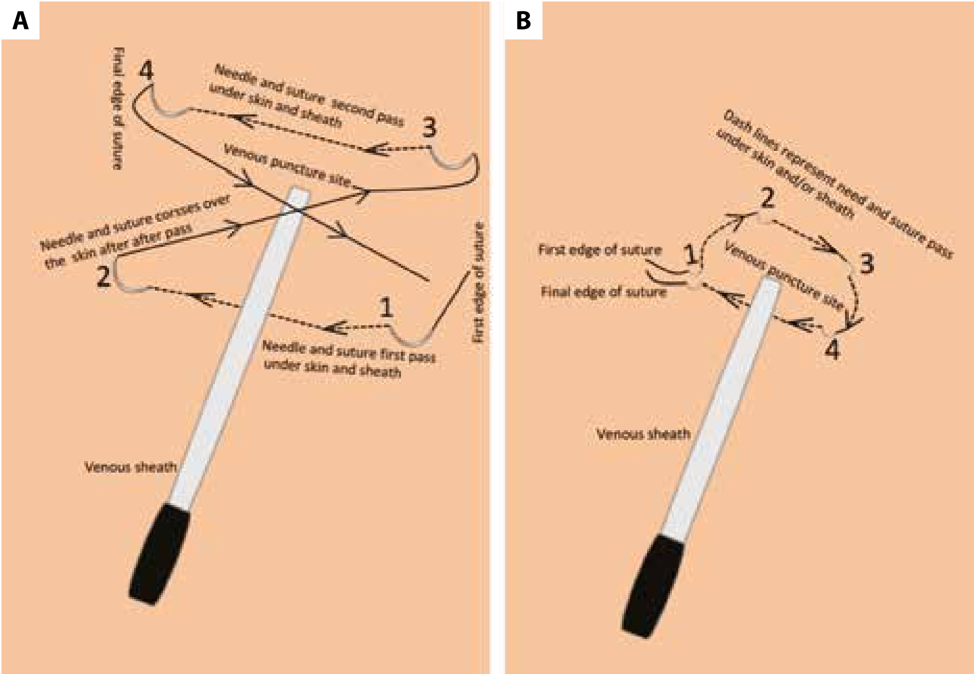

Figure 1. Percutaneous skin closure with a figure-of-eight suture (**A**) and a purse-string suture (**B**)

on interrupted anticoagulation showed that FO8 is safe and is associated with a significantly shorter time to hemostasis (9 [7–12.1] minutes vs. 20 [15–20] minutes; *P* <0.001) and time to ambulation (2.2 [1.3–3.5] hours vs. 6.5 [5.1–7.8] hours; *P* <0.001). It was associated with a better rate of same-day discharges (12.3% vs. 3.2%; *P* <0.001), and a non-significantly lower rate of complications (1.5% vs. 2.6%; *P* = 0.401) [5]. Other procedures for cardiac arrhythmias including the closure of the left atrial appendage demonstrated the usefulness of the FO8 suture with a shorter time to hemostasis (0 vs. 14 minutes; *P* <0.001), shorter turnaround time (defined as the time from sheaths' removal to first venous puncture for the next patient) (58.6 ± 14 minutes vs. 77 ± 33.9 minutes; *P* = 0.004), with no evidence of minor or major vascular access complications either immediately or at 3-month follow-up [24, 25, 32, 36].

The feasibility of FO8 suture has been confirmed for venous sheaths up to an internal diameter of 24 F and an external diameter of 29 F [6, 8, 16]. A randomized controlled trial by Pracon et al. [6] evaluated the FO8 suture among 86 patients who underwent percutaneous procedures for structural heart disease using venous caliber sheaths ranging from 10–22 F in the presence of an anticoagulant and observed that FO8 suture achieved quicker hemostasis (<1 minute vs. 12 minutes; *P* <0.001), earlier patient ambulation (7 vs. 16, hours; *P* <0.001), and fewer venous access site complications (13.3% vs. 36.7%; *P* <0.05). Another cohort study involving 949 patients who underwent procedures for atrial septal defect, patent ductus arteriosus, ruptured sinus of Valsalva aneurysm, or mitral stenosis involving venous sheaths >12 F in the presence of unfractionated heparin noted that median time to hemostasis (1.1 vs. 14.3 minutes; *P* <0.001), time in the recovery room (2.2 vs. 21.6 minutes; *P* = 0.003), time to ambulation (3.3 vs. 18.9 hours; *P* <0.001), and hospital stay (24.6 vs. 36.8 hours; *P* <0.001) were significantly shorter in the FO8 suture group compared to the manual compression group [8]. Minor vascular access site complications such as hematoma (6 [1.6%] vs. 1 [0.2%]; *P* <0.001), and femoral vein thrombosis (4 [1.1%] vs. 0 [0%]; *P* <0.001) were significantly less common in the FO8 suture group, but the rate of rebleeding and arteriovenous fistula showed no difference between the groups (*P* >0.05) [8]. Studies in pediatric patients treated for structural heart disease with procedures requiring venous sheaths up to 22 F also revealed a significantly shorter time to hemostasis and a non-significant lower rate of vascular complications with FO8 suture than manual compression [37, 38].

A few studies have modified FO8 suture by adding a torque device such as a three-way stopcock to manage suture tension. Yorgun et al. [18] compared modified FO8 with a three-way stopcock versus standard FO8 suture in patients undergoing cryoballoon ablation for AF using a 15 F outer diameter venous sheath. They found that immediate hemostasis was achieved in 100 % vs. 90.7% (*P* <0.001) with the modified FO8 compared to the standard form. Time to hemostasis (0.78 ± 0.24 minutes vs. 1.66 ± 0.32 minutes) and time to leaving the procedure table (4.71 ± 1.46 minutes vs. 6.10 ± 2.13 minutes) were shorter with the modified FO8 suture (*P* <0.001), but time to ambulation (4 [4–6] hours vs. 4 [4–10] hours; *P* = 1) and time to discharge (1.2 ± 0.4 days vs. 1.3 ± 0.6 days; *P* = 0.232) were similar in both groups. Access site complications including any groin complication (0% vs. 12%, *P* = 0.002),

Table 2. Vascular closure devices that are Food and Drug Administration-approved for use on venous access sites

Device name	Manufacturer	Mechanism	Puncture size	Indicated use
VASCADE	Cardiva Medical, Santa Clara, CA, US	Collapsible disc and collagen-mediated closure system	5–7 F	Venous or arterial closure
Mynx	Cardis, Cardinal Health, Dublin, OH, US	Polyglycolic acid plug-mediated closure system	5–7 F	Venous or arterial closure
Perclose ProGlide	Abbott Vascular, Santa Clara, CA, US	Suture-mediated closure system — suture through vessel access site	5–24 F for venous 5–21 F for arterial	Venous or arterial closure

rebleeding (0% vs. 6.7%; $P = 0.007$), and minor hematoma (0% vs. 5.3%; $P = 0.43$) were less common in the modified FO8 than the standard FO8 group [18]. Another case series also described the use of the Flowstasis device (Inari Medical, Irvine, CA, US) in addition to FO8 sutures to achieve effective venous hemostasis in a variety of cardiovascular patients treated by procedures requiring venous caliber up to 24 F sheaths [39].

Purse-string suture

The purse-string is an alternative suture method in which a large-gauge non-absorbable braided suture on a needle is passed in and out on four points around the venous sheath forming a square. The running stitch circles the sheath in such a way that when the ends are pulled, subcutaneous tissue is compressed to pressure on the puncture site (Figure 1B).

The purse-string has been applied in a few studies using sheaths up to 24 F. It shows significant advantages compared to manual compression with a magnitude of difference similar to that of the FO8 [22, 23, 33, 40]. The randomized GITAR study involving ablations for AF using 8.5–15 F venous sheaths in presence of anticoagulant reported that the average time required to achieve hemostasis was significantly reduced (0.45 ± 2.0 minutes vs. 10.44 ± 2.2 minutes; $P < 0.001$) in the purse-string group than manual compression group, respectively. Significant pain or discomfort was less common in the purse-string group (15/99 [15%] vs. 29/101 [29%]; $P = 0.03$) [40]. An observational cohort study by Kottmaier et al. including 784 AF patients who underwent ablation on uninterrupted oral anticoagulation reported that purse-string suture was safe and effective, achieving hemostasis after multiple venous access without protamine administration and with shorter immobilization time than manual compression. No difference was found regarding hematomas <5 cm (13.6% vs. 11.5%, $P = 0.39$) or >5 cm (8.7% vs. 7.8%; $P = 0.69$), arterio-venous fistulas (3.9% vs. 2.2%; $P = 0.22$), or pseudoaneurysm (0.87% vs. 7.8%; $P = 0.69$) [33]. Another study by Akkaya et al. [23] reported that venous access site closure with a purse-string suture without the use of protamine or compression appears to be safe and feasible in patients undergoing mitral valve repair with MitraClip (Abbott Vascular, Santa Clara, CA, US) implantation using a 24 F caliber venous sheath. Similarly, Kypta et al. [22] favored the safety of subcutaneous double purse-string sutures in patients on anticoagulation undergoing leadless pacemaker implantation using sheaths with 18–23 F internal diameter, and 27 F outer diameter.

VASCULAR CLOSURE DEVICES

Vascular closure devices were first introduced in the early 1990s mainly for arterial access closure. These devices fall into two categories depending on their mechanism of action: passive approximation devices that tamponade the vascular access site on the adventitial side to achieve hemostasis and active approximation devices that mechanically seal the opening in the vessel. A variety of devices are available for closure of arterial access and have become the universal standard of care for mid-to-large bore punctures of femoral arteries. They improve time to hemostasis and ambulation and avoid groin complications, even in patients treated with anticoagulant and/or antiplatelet drugs [17, 41, 42].

In contrast to their success in arterial closure, closure devices have been slow to penetrate the field of venous closure. The US Food and Drug Administration (FDA) approved the VASCADE collagen-mediated closure system (VASCADE, Cardiva Medical, Santa Clara, CA, US), Perclose ProGlide suture-mediated closure system (Abbott Vascular, Santa Clara, CA, US), and Mynx polyglycolic acid plug-mediated closure system (Cardinal Health, Dublin, OH, US) for venous access closure as detailed in Table 2. Recent studies demonstrated these devices to have significantly improved safety, hemostasis, and ambulation times in different procedures involving multiple femoral venous accesses with mid-large caliber sheaths up to 24 F [5, 7, 16, 26, 43, 44].

Other studies have deployed devices for venous access closure that are FDA-approved only for arterial access [45, 46]. Coto et al. [45] noted successful closure of ≤8 F femoral venous access and no major complications using 8 F ANGIO-SEAL collagen-mediated device (St. Jude Medical, Little Canada, MN, US) in 110 patients even in the presence of anticoagulation and/or antiplatelet drugs. Similarly, Maraj et al. [46] showed the ANGIO-SEAL to be safe and effective for closing multiple venous access sites in electrophysiological procedures using 7–10 F caliber venous sheaths.

VASCADE device

The VASCADE collagen-mediated device is a passive approximator device that includes a bioresorbable thrombogenic collagen plug and a nitinol disc. The device is inserted

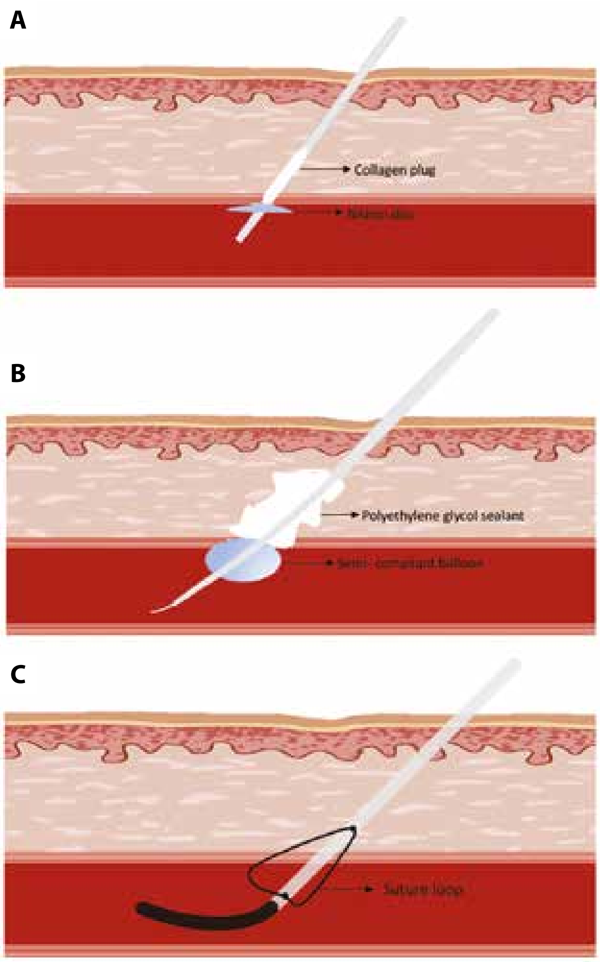

Figure 2. The VASCADE collagen-mediated vascular closure system (**A**) is a passive approximator device. A low-profile collapsible disc is deployed intraluminally against the wall, and the collagen plug is deployed extraluminally over the vessel access site, resulting in hemostasis. The Mynx vascular closure system (**B**) is also a passive approximator. A semi-compliant balloon that is inflated inside the vessel to serve as an anchor, as the polyethylene glycol sealant is deployed extraluminally over the vessel access site, resulting in hemostasis. The Perclose ProGlide sutured mediated vascular closer system (**C**) is an active approximator. A suture loop is formed to close the vessel access site

through the venous sheath, the disc is brought against the wall, and the resorbable extravascular collagen plug is deployed into the tissue tract left by the sheath resulting in hemostasis. The disc is then collapsed and removed (Figure 2A). The FDA approved the VASCADE device for 5–7 F caliber sheath use for both venous and arterial closures.

AMBULATE, a recent multicenter randomized trial addressed the use of the VASCADE device in patients undergoing catheter ablation for AF using either radiofrequency energy or cryoballoon on uninterrupted anticoagulants. The patients had multiple venous access sites with 7–15 F sheaths. The device demonstrated non-inferiority with regard to access site complications but significantly improved time to ambulation (2.8 ± 1.3 hours vs. 6.1 ± 1.6 hours; P <0.001), time to hemostasis (6.1 ± 3.7 hours vs. 13.7 ± 6.5 hours; P <0.001), and time to eligibility for discharge (3.1 ± 1.3 hours vs. 6.5 ± 1.9 hours; P <0.001). Patient satisfaction was high, and the use of pain medications was low in the VASCADE group (P <0.05) [7].

A multicenter observational study of the device included 803 patients who underwent ablations or left atrial appendage closure on uninterrupted anticoagulation using 7–11 F venous sheaths. The VASCADE reduced venous access site complications (0% vs. 2.4%; P = 0.004), time to hemostasis (6.2 ± 2.1 minutes vs. 13.7 ± 3.6 minutes; P <0.001), and urinary complications (0% vs. 3.8%; P <0.001) [26]. A large part of the difference demonstrated in this study derived from complications of peri-procedural urinary catheterization for AF ablation, apparently a common routine in North America, but very rarely used in Europe. Urinary catheterization has a high rate of complications, usually urinary infection but sometimes trauma requiring urethral surgical repair. The single-arm AMBULATE-CAP study enrolled 168 patients. In addition to focusing on vascular-related complications, the requirement for urinary catheterization, no protamine administration, and same-day discharge were also reviewed [47]. This follow-on study seems to confirm the safety of the device, with no major adverse events. However, its performance against other approaches has not been studied in a randomized clinical trial.

A study of venous thrombectomy requiring venous sheath ≥5 F noted a 93.8% immediate hemostasis success rate for VASCADE but an 18.8% rate of venous access site complications [48, 49]. The authors of these studies commented that the VASCADE was easy to use and more suitable for venous use than devices that include a component that remains intravascular [7, 26, 48, 49].

Mynx device

The Mynx device (AccessClosure, Mountain View, CA, US) is a passive approximator that contains an extravascular polyethylene glycol sealant to plug the vascular puncture site. A semi-compliant balloon is inflated in the vessel to act as an anchor; after sealant deployment, the balloon is deflated and removed (Figure 2B). Hemostasis is achieved by the expansion of the sealant in the tissue track by rapid absorption of subcutaneous fluids. The FDA approved the Mynx for 5–7 F caliber sheath in both venous and arterial sites. A multicenter randomized trial assessed the safety and efficacy of the Mynx compared to manual compression in 208 patients who underwent procedures via femoral venous access. They noted a similar rate of venous access site complications but significantly reduced time to hemostasis with the Mynx (0.2 ± 0.9 minutes vs. 7.6 ± 5.7 minutes; P <0.001) [44]. The device has given similar results in arterial access sites [50, 31].

Perclose ProGlide

The Perclose ProGlide suture-mediated device is an active approximator, FDA-approved to use for closure of venous 5–24 F and arterial 5–21 F sheath-site closure. The Perclose ProGlide is inserted over the guidewire until the free flow of blood to the side port of the device confirms the intravascular position. Then the lever is pulled to employ its footplate inside the vessel lumen, which is held against the wall, following which the needle is employed, forming a suture loop, and hemostasis is then achieved by tightening the sutures (Figure 2C).

Several studies illustrated safe and immediate hemostasis of venous access sites up to 24 F in the presence of an anticoagulant and/or antiplatelet drugs using Perclose or ProGlide devices in patients who underwent procedures for cardiac arrhythmias or structural heart repairs. Its use reduced time to mobilization leading to early discharge and no venous access site complications at immediate and up to 1-year follow-up [5, 16, 43, 52–56]. Recent insights have been provided by the prospective vascular closure for cardiac ablation registry which included 434 patients treated for AF or atrial flutter using 8–15 F venous sheaths on interrupted anticoagulation. Outcomes of three approaches including Perclose ProGlide, FO8 suture, and manual compression were compared. The authors observed significant differences in time to hemostasis (ProGlide device: 7 minutes vs. FO8: 9 minutes vs. manual compression 20 minutes; $P < 0.001$), time to ambulation (ProGlide device: 2.2 hours vs. FO8: 2.2 hours vs. manual compression: 6.5 hours; $P < 0.001$), and the rate of same-day discharge (ProGlide device: 18.7% vs. FO8: 12.3% vs. manual compression: 3.2%; $P < 0.001$). However, there was a similar rate of access site complications among the three groups [5]. The use of postoperative analgesics was slightly lower in ProGlide (46.7%) and FO8 (47.8%) groups compared to the manual compression group (50%), but no significant difference was observed among the three groups ($P = 0.869$) [5].

A retrospective registry-based cohort study using 24 F venous caliber sheath for MitraClip (Abbott Vascular Devices, Santa Clara, CA, US) implantation compared ProGlide devices and FO8 sutures. It showed that both techniques are feasible and safe, but there was no benefit of one strategy over the other in relation to complications including major bleeding (3.1% vs 2.7%; $P = 0.81$), arteriovenous fistula (4.7% vs. 4.7%; $P = 0.98$), hematoma (24% vs. 22%; $P = 0.70$), pseudo-aneurysm (4.7% vs. 3.9%; $P = 0.77$%), and blood transfusion (5.3% vs. 6.3%; $P = 0.73$) [16]. Similarly, Yeo et al. [52] evaluated short and long-term safety and efficacy of double ProGlide Perclose in 42 mitral valve repair by MitraClip implantation using 24 F caliber venous access and observed through duplex ultrasound successful immediate hemostasis and no venous access site complications at 1 month to 1 year. Geis et al. [43] also concluded that using the Perclose ProGlide device is feasible and safe, allows earlier patient mobilization, and may reduce the post-interventional duration of stay in an intensive care unit compared to manual compression in patients having MitraClip implantation.

Hamid et al. [53] performed procedures in 243 patients for congenital or structural heart repairs requiring 8–24 F venous sheaths in the presence of anticoagulants. They reported that the Perclose ProGlide achieved efficient hemostasis with no evidence of hematoma or fistula formation or other venous access site complications either immediately or at late follow-up. Mahadevan et al. [54] evaluated the efficacy of the 6 F Perclose device in 146 adult patients undergoing the closure of congenital cardiac defects using ≥10 F caliber venous on anticoagulant and/or antiplatelet drugs and similarly noted immediate hemostasis in 99% of patients and no evidence of hematoma, fistula, or infection. A randomized trial by Ozawa et al. [55] assessed the safety and efficacy of Perclose compared to manual compression after procedures in pediatric patients using 8–14 F venous sheaths. They demonstrated that the Perclose group had reduced time to hemostasis (6.2 ± 0.9 minutes vs. 14.9 ± 1.1 minutes; $P < 0.05$) but no difference in the occurrence of vascular complications determined by ultrasound. Despite this favorable literature, there is a small risk of device failure and complications: thrombus formation, pseudoaneurysm, and infection have been reported [10, 16].

Rarer still, but widely known are reports of Perclose device breakage and embolization despite senior operator experience; in one case this required snaring to retrieve the broken device from the arterial system [57]. Another case required emergency surgery to retrieve the device from the femoral vein [58]. It is important to know about any potential risks for any device that may be used in the interventional lab so that swift action may be undertaken in the rare event that this problem occurs.

FINANCIAL IMPLICATIONS

The use of vascular closure devices or suture techniques could reduce some expenses through a lower rate of vascular complications and shorter time to hemostasis, ambulation, and discharge, and prevention of urinary catheterization, but it also costs. Mohanty et al. [26] reported that the use of the VASCADE device reduced the overall procedure-related cost by minimizing the utilization of urinary catheters and associated complications, as well as by lowering the usage of pain medications after catheter-based electrophysiology procedures including left atrial appendage closure. They found the use of the VASCADE device resulted in an estimated potential cost savings of more than $27 000 related to urinary catheter complication management and ≥$1627 for pain management as compared to manual compression [26]. However, these calculations are valid only for a system in which analgesia is expensive and in which there is a widespread use of urinary catheterization in the manual closure group, an option that may be avoided. Vascular closure devices are more expensive than sutures and may not be adopted by poorer healthcare systems. Additional trial evidence could permit a more sophisticated analysis of the cost-effectiveness of closure devices and suture techniques in different patient populations.

FUTURE PROSPECTS

The first generation of vascular closure devices was designed principally for arterial closure. Devices are now available that are proven to work on venous access sites. The trend of using larger-bore venous sheaths to permit more complex interventions for cardiac arrhythmias is likely to continue. Improved closure of the resulting access sites will be increasingly important, and benefits may be more pronounced if we continue the trend toward acceptance of patients of advanced age, with multiple comorbidities including abnormal liver and renal functions. We now have a range of devices commercially available for venous hemostasis and a range of established suture techniques. Randomized trials have shown that several of these are superior to manual hemostasis in specific patient groups. Larger-scale trials are needed to compare these techniques and devices with one another and to quantify costs and benefits of these devices compared to manual compression in a broader patient group.

CONCLUSIONS

Effective venous hemostasis is essential for the safe performance of procedures for cardiac arrhythmias. Manual compression has been the gold standard for achieving hemostasis, but new approaches including subcutaneous sutures and closure devices have shown clear advantages, particularly when larger sheaths are used in patients committed to uninterrupted anticoagulation. These methods achieve immediate hemostasis, facilitate early ambulation, and earlier discharges with fewer venous access site complications compared with manual compression [5–7, 23, 33]. The uptake of these methods has to date been limited, perhaps because of the lack of large-scale randomized trials on the subject and cost-effectiveness analysis. When combined with an improved quality of vascular puncture due to the use of ultrasound guidance, these closure methods have the potential to achieve improved procedure efficiency, comfort, and safety.

Article information

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