5-14-2022

Preclosure of large bore venous access sites in patients undergoing transcatheter mitral replacement and repair

Mustafa Mohammed

Paul Nona

Elian D. Abou Asala

Michael Chiang

Alejandro Lemor

See next page for additional authors

Authors

Mustafa Mohammed, Paul Nona, Elian D. Abou Asala, Michael Chiang, Alejandro Lemor, Brian P. O'Neill, Tiberio Frisoli, James Lee, Dee Dee Wang, William W. O'Neill, Marvin H. Eng, and Pedro A. Villablanca

Received: 9 January 2022 | Revised: 18 April 2022 | Accepted: 3 May 2022

DOI: 10.1002/ccd.30229

ORIGINAL ARTICLE - CLINICAL SCIENCE

WILEY

Preclosure of large bore venous access sites in patients undergoing transcatheter mitral replacement and repair

Mustafa Mohammed DO[1] | Paul Nona MD[2] | Elian Abou Asala MD[1] | Michael Chiang MD[2] | Alejandro Lemor MD, MSc[2] | Brian O'Neill MD[2] | Tiberio Frisoli MD[2] | James Lee MD[2] | Dee D. Wang MD[2] | William W. O'Neill MD[2] | Marvin Eng MD[2] | Pedro A. Villablanca MD, MSc[2]

[1]Department of Medicine, Henry Ford Hospital, Detroit, Michigan, USA

[2]Center for Structural Heart Disease, Henry Ford Hospital, Detroit, Michigan, USA

Correspondence
Pedro A. Villablanca, MD, MSc, Center for Structural Heart Disease, Henry Ford Hospital, 2799 West Grand Blvd, Detroit, MI 48202, USA.
Email: Pvillab1@hfhs.org

Abstract

Objective: We aim to report on the efficacy and safety of large bore venous access (LBVA) preclosure with Perclose™ (Abbott Vascular Devices) suture-mediated device use following transcatheter edge-to-edge (TEER) and replacement (TMVR).

Background: Patients requiring TEER and TMVR require LBVA. Clinical outcome data on the use of suture-mediated devices for LBVA site closure are limited.

Methods: Between 2012 and 2019, 354 consecutive high-risk patients with mitral valvular heart disease underwent TEER ($n = 287$) with MitraClip and TMVR ($n = 67$) with Edwards Sapien Valves. Patients had LBVA with 24 or 16 French sheaths. All patients underwent preclosure of LBVA except for one that underwent manual hemostasis.

Results: There were no closure device failures. None of the cases required surgical repair of the access site following venous preclosure. Two cases had large hematomas (>6 cm) following Perclose in each group. Six cases had small hematomas (<6 cm and >2 cm) with three in each group. There was one major bleeding using Mitral Valve Academic Research Consortium 2 definition (retroperitoneal bleed from arterial puncture) unrelated to the venous closure. Transfusion related to vascular access complication was required in five cases. There were two immediate acute deep venous thromboses postprocedure; one of which occurred after preclosure. There were no arteriovenous malformations, pseudoaneurysms, or access site infections reported following Perclose.

Conclusion: In this large sample size analysis, Proglide preclosure technique is a feasible and safe alternative approach to achieving hemostasis after removal of LBVA sheaths in patients undergoing TEER and TMVR. Randomized trials are needed to compare the different modalities of hemostasis.

KEYWORDS

mitral clip, Perclose, TEER, TMVR, venous access

1 | INTRODUCTION

Severe mitral regurgitation (MR) is associated with substantial morbidity and mortality.[1] With recent advances in technology, percutaneous transvenous interventions have evolved as promising nonsurgical treatment options of such valvular pathology. Transcatheter replacement (TMVR) and transcatheter edge-to-edge repair (TEER) requires large bore accesses ranging from 14Fr to 24Fr. These comprised of commonly used 24Fr MitraClip system (Abbott Vascular Devices), 14/16Fr Sapien 3 system (Edwards Lifesciences), and the newer devices including the 22Fr Pascal system (Edwards Lifesciences) or the 24Fr M3 system (Edwards Lifesciences), and so on.

Appropriate management of the large bore venous access (LBVA) is essential to prevent vascular complications and facilitate early patient mobilization and discharge. Traditionally, hemostasis for venous access was achieved by manual compression or surgical suturing technique like mattress suture or figure-of-eight suture. While they are effective methods for hemostasis, they are often time consuming, lead to patient discomfort, or increase the patient's risk of deep vein thrombosis (DVT).[2] Suture-mediated closure devices, such as the Perclose ProGlide™ system (Abbott Vascular) is a safe alternative to manual compression for patients who required arterial access.[3–5] A robust amount of data exists on closure devices for arterial access, and use of such devices has been shown to decrease bleeding and length of stay when compared to manual compression.[3–5] There is scant literature evaluating closure device use in large-venous access. Perclose Proglide was introduced in 2004 and approved by the Federal Drug Administration (FDA) in 2013.[4] These devices were initially approved solely as an arteriotomy closure device. In 2018, the FDA approved Perclose ProGlide device for use in venous access site. Perclose ProGlide is indicated for use in large access up to 26 French sheaths arterial and 29 French sheaths venous. Through this study, we seek to report on the efficacy and safety of LBVA preclosure with proglide suture-mediated device use following TEER and TMVR.

2 | METHODS

In this retrospective, single center cohort, 354 patients were identified from 2012 to 2019 who had severe mitral disease and underwent TEER ($n = 287$) with MitraClip and TMVR ($n = 67$) with Edwards Sapien Valves. Proglide has been used since the inception of TEER and TMVR programs at our institution in all patients.

2.1 | Preclosure technique

Femoral venous access was obtained by usual techniques under fluoroscopy and ultrasound guidance in all patients; see Figure 1. After wire insertion, an 8Fr dilator was introduced for dilatation of the soft tissue tract. Subsequently, a Perclose Proglide device was

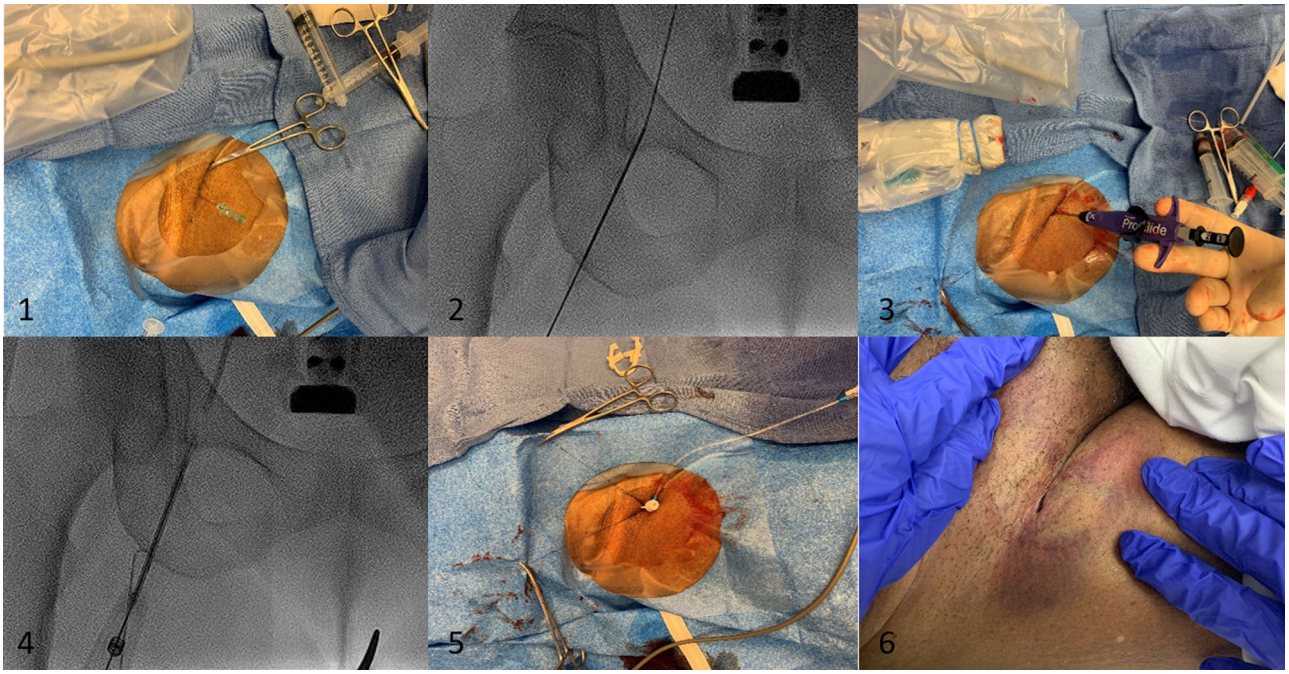

FIGURE 1 Steps for perclose deployment in big bore venous sheath. (1) Vascular access is obtained under ultrasound and fluoroscopic guidance using a micropuncture needle. (2) Needle placement is confirmed under fluoroscopy and guidewire is advanced. (3) After obtaining vascular access, the Perclose device is inserted and positioned over the wire using standard technique. (4) Fluoroscopy is used to verify correlation of Perclose foot plate with access site. (5) Perclose sutures are secured with clamps before large bore venous sheath insertion. (6) Femoral vein access at the completion of the case after Perclose sutures are tied and cut and hemostasis is obtained. [Color figure can be viewed at wileyonlinelibrary.com]

inserted and the wire removed. Intraluminal positioning of the Proglide device was confirmed by slow blood flow out of the side port and then, the footplate of the device was deployed and the device pulled back and sutures set as usual correlating with needle access on fluoroscopy. The footplates were released, and the device partially retrieved until the port for the guidewire was visible. The guidewire was reintroduced into the vein and the device removed, proceeding with second Perclose deployment as we described. Two Perclose for LBVA has been established since the beginning of the TEER and TMVR program as our default strategy mimicking what was done in larger bore arterial access. The additional step of correlating needle entry with Perclose footplate anchoring has been used from the beginning of our program to confirm that suture deployment correlates with needle entry into the vessel hence, avoiding and decreasing possible complications like vessel dissection (more likely in artery than vein) or vessel closure as a consequence of anchoring both, the anterior and posterior vessel wall.[6] After positioning the suture, the vein was further predilated for guide and sheath insertion. All patients received heparin for activated clotting time >300 s and antibiotics pre and postprocedure. Following access-site closure, the sutures were tightened at the end of the procedure upon removal of the LVBA from the vein and a light compression bandage was used for 2 h. Heparin was not reversed. Patient mobilization was started after 4 h. Anticoagulation and antiplatelet regimen were based upon operator preference or clinical indication. If no evidence of active bleeding or vascular complication, full antithrombotic and antiplatelet regimen was started same night of the procedure.

Patient demographics, clinical and procedural data, and 30-day mortality outcomes were collected and analyzed. Vascular access complications up to 1-year Postprocedure was analyzed. Vascular access complications are defined as DVT, hematoma (large or small; large defined as greater than 6 mm), retroperitoneal hemorrhage, access site infection, pseudoaneuysm, transfusion related to access site, surgical repair of access site or development of arteriovenous malformations. We used the Mitral Valve Academic Research Consortium 2 (MVARC 2) criteria definition for outcomes of interest.[7] Vascular imaging was not routinely obtained unless clinically indicated.

The puncture site of all patients was examined clinically and if there was concern for any vascular complication, color duplex

TABLE 1 Patient demographics.

Characteristic	TEER (*n* = 287)	TMVR (*n* = 67)	Overall group (*n* = 354)
Average age (SD)	79 (9.73)	75 (12.01)	78 (10.28)
Female	150 (52%)	43 (64%)	193 (55%)
Male	137 (48%)	24 (36%)	161 (45%)
Average weight (SD)	77 kg (20.67)	73 kg (18.44)	77 kg (20.31)
Average height (SD)	167 cm (11.17)	167 cm (10.73)	167 cm (11.08)
Average BMI (SD)	27.7 (6.70)	26.7 (6.51)	27.5 (6.67)
Diabetes mellitus	90 (31%)	26 (39%)	116 (33%)
Hypertension	267 (93%)	63 (94%)	330 (93%)
Coronary artery disease	137 (48%)	32 (48%)	169 (48%)
History of MI	87 (30%)	19 (28%)	106 (30%)
History of CABG	75 (26%)	25 (37%)	100 (28%)
Average EF (SD)	52 (12.69)	55 (13.63)	53 (12.90)
Average PAP (SD)	46 (15.23)	59 (20.90)	49 (17.27)
Average creatinine (SD)	1.44 (0.869)	1.43 (0.908)	1.44 (0.876)
Stroke	34 (12%)	9 (13%)	43 (12%)
Atrial fibrillation	195 (68%)	49 (73%)	244 (69%)
Peripheral arterial disease	47 (16%)	10 (15%)	57 (16%)
Aspirin use	198 (69%)	45 (67%)	243 (69%)
PGY12 use	64 (22%)	15 (22%)	79 (22%)
Warfarin use	74 (26%)	50 (75%)	124 (35%)
NOAC use	73 (25%)	7 (10%)	80 (23%)

Note: Percentages are rounded to the nearest whole number.
Abbreviations: BMI, body mass index (kg/m^2); CABG, coronary artery bypass grafting; EF, ejection fraction; MI, myocardial infarction; NOAC, novel oral anticoagulant; PAP, pulmonary artery pressure; SD, standard deviation; TEER, transcatheter edge-to-edge repair; TMVR, transcatheter replacement.

sonography was ordered to exclude or confirm complications during the admission or at follow-up in clinic. Clinical follow-up included assessment of femoral pulse, presence of hematoma, bruits, and signs of venous incompetence.

As this is a descriptive study in a single cohort of patients, statistical analysis was limited to descriptive analysis with medians and interquartile ranges reported for continuous variables and percentages shown for categorical variables. All analyses were performed with SPSS version 24 (SPSS, Inc).

3 | RESULTS

Out of the cohort of 354 patients that underwent percutaneous mitral valve therapy, 287 underwent TEER with mitral clip and 67 TMVR with Edward Sapien valves. Patient demographics are represented in Table 1. The average length of stay for the group was 6 days with a median of 3 days. The overall group had an average age of 78 (SD 10.28), there were 161 males and 193 females.

Overall, the two groups had similar patient populations with similar comorbidities, with a high prevalence of hypertension and atrial fibrillation. More than half of the patients were on antiplatelet therapy. Left ventricular ejection fraction average was comparable between the two groups.

Postprocedure venous vascular access complications are represented in Table 2. Regardless of mitral intervention, vascular access complications were rare. All cases of the development of DVT (four patients) occurred in patients who underwent TEER. Only two were acute with one that occurred following Perclosure device use with manual compression and the other was following manual compression. The other two that occurred were unrelated as they occurred 2 years later on the contralateral side. The incidence of small or large hematoma development was higher in the TMVR group compared to TEER; 4.5% versus 1.05% for small hematoma and 1.5% versus 0.35% for large hematoma.

There were two major bleeds by MVARC 2 definition both retroperitoneal bleeds. One occurred in the TEER group and occurred spontaneously likely in setting of thrombocytopenia. The second major bleed occurred in one of the TMVR cases following an arterial bleed and required stenting. Among the 354 cases, five required transfusions related to vascular access, three in the mitral clip group and two in the TMVR group. Seventeen of the 354 patients required transfusion not related to vascular access, 10 in mitral clip group and seven in the TMVR group. There were no arteriovenous malformations reported, pseudoaneurysms or infections at access site. Finally, unilateral edema of the affected leg was never observed in all cases.

4 | DISCUSSION

This retrospective study sought to investigate the safety and utility of Perclose device following mitral repair procedures. There is scarce data on this topic and to the best of our knowledge, this is the largest study investigating venous vascular complications following the use of Perclose closure device. This study has two major findings: (1) Using the pre-closure technique is safe and efficacious for closure of the LBVA site and can be performed with a suture-mediated device in TEER and TMVR procedures despite frequent use of potent antiplatelet and anticoagulant agents. (2) Two devices can be used at the same access sites in the same vein. Overall, there was an extremely low rate of vascular access complications for the use of such devices.

It is known based on prior studies that vascular complications are less common with venous access compared with arterial access. Nevertheless, using large-bore access affects complication rates and rates of early mobilization. There are few studies to date reporting on venous applications of arteriotomy closure devices and in most of the published work, perclose device has been investigated.[8] Among those studies, only one study reports on the use of sheath sizes >14Fr.[9] The information on LBVA management in MitraClip trials is sparse. The EVEREST II trial, transfusion of blood ≥2 units was high,

TABLE 2 Complications following perclosure.

Complication type	TEER (*n* = 287)	TMVR (*n* = 67)	Overall (*n* = 354)
Deep vein thrombosis	2 (0.7%)	0	2 (0.56%)
Large hematoma >6 cm	1 (0.35%)	1 (1.5%)	2 (0.56%)
Small hematoma <6 and >2 cm	3 (1.05%)	3 (4.5%)	6 (1.7%)
Retroperitoneal hemorrhage	1 (0.35%)	0	1 (0.28%)
Infection	0	0	0
Transfusion related to vascular access	3 (1.05%)	2 (3.0%)	5 (1.4%)
Transfusion not related to vascular access	10 (3.5%)	7 (10.4%)	17 (4.8%)
Surgical repair of access site	0	0	0
Pseudoaneurysms	0	0	0
Arteriovenous malformations	0	0	0

Abbreviations: TEER, transcatheter edge-to-edge repair; TMVR, transcatheter replacement.

in up to 13% of patients, without further details on the technique of groin management.[10] Other large registries also do not specify groin management despite a significant bleeding complication >3%.[11,12]

In 2004, Shaw et al. initially advocated for the use of suture-mediate closure device for venous access site. In his study, they investigated the use of 6Fr Perclose device on mostly 7Fr sheaths with low complication rates and device failures.[13] The use of a single device was initially described by Feldman et al. for ~14Fr sheath size in mitral valvotomy procedures.[3]

A smaller cohort of 72 patients analyzed the use of Perclose on venous access for patients undergoing TEER with MitraClip. In this study, routine ultrasound was used postprocedure to assess for both the amount and severity of vascular complications. No complications of DVTs or fistula were reported, the study did report one major bleeding complication requiring transfusion which was related to access site and five others not related to the access site.[14] Similar results were observed in an another TEER study where all patients were followed with ultrasound postprocedure to look for venous vascular access complications following use of Perclose for 24Fr venous access. Among this cohort of 42 patients, 35 had follow-up ultrasound 3–364 days postprocedure. They also observed no proximal DVT, femoral vein stenosis >50% and no significant difference in right versus left femoral vein diameter.[15] The largest study on closure devices to date which included 243 patients was reported by Hamid et al. In this study perclose device was used on large femoral access sites with mean size of 11Fr sheath and they reported no immediate complications or any complications at 12 months follow up. They did note failure of device deployment in eight cases with no complications observed. Hamid et al. also reported most patients had early mobilization (within 2–4 h) and early discharge (37% on the same day) postprocedure. It is important to note that Hamid et al, reported on the use of only single closure device.[9]

In Geis et al, Perclose device was compared with conventional manual compression with figure-of-eight. Each of the two groups had 40 patients and 24Fr sheath was used which is larger compared to other studies. They reported no significant difference in complications but did note three deployment failures with no access site complications and one AV fistula in perclose group requiring surgical repair. On the other hand, they also noted that perclose device allowed for quicker mobilization and faster transfer out of the intensive care unit.[8] Another study compared perclose device versus Z-suture by Steppich et al. They also reported no significant difference in vascular complications and noted in the Perclose device group less radiation time, contrast volume and amount of heparin use as well as faster hemostasis.[16]

Worth mentioning that not many studies looked at use of other devices. Although there are some studies which include Coto et al. who described use of angio-seal for femoral vein closure in 110 patients. In this study, they reported no bleeding complications and reported that ambulation time occurred 2–6 h following device deployment.[17]

Our study did not have a comparison group, but previous studies have compared manual compression to figure-of-eight closure and analyzed rates of complication. Based on prior studies, it was noted that FoE had lower rates of complications and faster time to hemostasis compared to manual compression.[18] Those differences in complications were most pronounced for hematoma, bleeding and for sheath size >10 as they noted reduced complications in FoE compared to manual compression.[19]

5 | LIMITATIONS

This study has several limitations. First, the retrospective nature and lack of a control arm. Second, routine vascular follow-up imaging was not performed, and thus subclinical vascular complications may be underreported. Third, suture-mediate vascular closure devices have a good success rate however, they are limited by a steep learning curve, availability, and cost. Last, comparison of 1 versus 2 Perclose or either manual compression or FoE is lacking in our study as the 2 Perclose strategy has been the standard of care for LBVA (define as 14Fr or bigger size) at our institution. Randomized trials are needed to compare suture-mediated versus other modalities of hemostasis.

6 | CONCLUSION

Proglide preclosure technique is a feasible and safe alternative approach to achieve hemostasis after removal of LBVA sheaths in patients undergoing TEER and TMVR. The use of such devices reduces patient discomfort and allows for early mobility. Randomized trials are needed to compare suture-mediated versus other modalities of hemostasis

CONFLICTS OF INTEREST

Dr. Marvin Eng is a clinical proctor for Edwards Lifesciences, Medtronic, and Boston Scientific. Dr. Tiberio Frisoli is a clinical proctor for Edwards Lifesciences, Abbott, Boston Scientific, and Medtronic. Dr. Brian O'Neill has served as a consultant and received research support from Edwards Lifesciences. Dr. James Lee is a consultant for HeartFlow. Dr. William W. O'Neill has served as a consultant for Abiomed, Edwards Lifesciences, Medtronic, Boston Scientific, Abbott Vascular, and St. Jude Medical; and serves on the Board of Directors of Neovasc Inc. Dr. Dee Dee Wang is a consultant to Edwards Lifesciences, Boston Scientific, receives research grant support from Boston Scientific assigned to employer Henry Ford Health System, is a member of the Edwards CLASP IITR Steering Committee, and Abbott PARADIGM Steering Committee. Dr. Marvin Villablanca is a clinical proctor for Edwards Lifesciences and consultant for Angiodynamics and Teleflex. All other authors report no relevant financial disclosures.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this study as no new data were created or analyzed in this study.

ORCID

Mustafa Mohammed http://orcid.org/0000-0003-3207-5843
Paul Nona http://orcid.org/0000-0002-4758-7211
Brian O'Neill http://orcid.org/0000-0001-5206-1639
Dee D. Wang https://orcid.org/0000-0002-5784-9924
Marvin Eng http://orcid.org/0000-0002-0334-6504

REFERENCES

1. Bangalore S, Arora N, Resnic FS. Vascular closure device failure: frequency and implications: a propensity-matched analysis. *Circ Cardiovasc Interv*. 2009;2(6):549-556.
2. Bagai J, Brilakis ES. Preclosing large venous sheaths with perclose can facilitate advanced structural heart interventions. *Catheter Cardiovasc Interv*. 2013;81(4):591.
3. Solomon LW, Fusman B, Jolly N, Kim A, Feldman T. Percutaneous suture closure for management of large French size arterial puncture in aortic valvuloplasty. *J Invasive Cardiol*. 2001;13(8):592-596.
4. Vinayakumar D, Kayakkal S, Rajasekharan S, Thottian JJ, Sankaran P, Bastian C. 24h and 30 day outcome of Perclose Proglide suture mediated vascular closure device: an Indian experience. *Indian Heart J*. 2017;69(1):37-42.
5. Baim DS, Knopf WD, Hinohara T, et al. Suture-mediated closure of the femoral access site after cardiac catheterization: results of the suture to ambulate aNd discharge (STAND I and STAND II) trials. *Am J Cardiol*. 2000;85(7):864-869.
6. Le TB, Kim JH, Park KM, Jeon YS, Hong KC, Cho SG. Iatrogenic iliofemoral vein dissection: a rare complication of femoral artery puncture. *Vasc Endovascular Surg*. 2018;52(6):482-485.
7. Stone GW, Adams DH, Abraham WT, et al. Clinical trial design principles and endpoint definitions for transcatheter mitral valve repair and replacement: part 2: endpoint definitions: a consensus document from the Mitral Valve Academic Research Consortium. *Eur Heart J*. 2015;36(29):1878-1891.
8. Geis NA, Pleger ST, Chorianopoulos E, Muller OJ, Katus HA, Bekeredjian R. Feasibility and clinical benefit of a suture-mediated closure device for femoral vein access after percutaneous edge-to-edge mitral valve repair. *EuroIntervention*. 2015;10(11):1346-1353.
9. Hamid T, Rajagopal R, Pius C, Clarke B, Mahadevan VS. Preclosure of large-sized venous access sites in adults undergoing transcatheter structural interventions. *Catheter Cardiovasc Interv*. 2013;81(4):586-590.
10. Feldman T, Foster E, Glower DD, et al. Percutaneous repair or surgery for mitral regurgitation. *N Engl J Med*. 2011;364(15):1395-1406.
11. Baldus S, Schillinger W, Franzen O, et al. MitraClip therapy in daily clinical practice: initial results from the German transcatheter mitral valve interventions (TRAMI) registry. *Eur J Heart Fail*. 2012;14(9):1050-1055.
12. Maisano F, Franzen O, Baldus S, et al. Percutaneous mitral valve interventions in the real world: early and 1-year results from the ACCESS-EU, a prospective, multicenter, nonrandomized post-approval study of the MitraClip therapy in Europe. *J Am Coll Cardiol*. 2013;62(12):1052-1061.
13. Shaw JA, Dewire E, Nugent A, Eisenhauer AC. Use of suture-mediated vascular closure devices for the management of femoral vein access after transcatheter procedures. *Catheter Cardiovasc Interv*. 2004;63(4):439-443.
14. Rüter K, Puls M, von der Ehe K, et al. Preclosure of femoral vein access site with the suture-mediated Proglide device during MitraClip implantation. *J Invasive Cardiol*. 2013;25(10):508-510.
15. Yeo KK, Yap J, Tan JW, Lim ST, Koh TH. Venous access closure using the double-proglide preclose technique after mitraclip implantation: long-term clinical and duplex ultrasound outcomes. *J Invasive Cardiol*. 2016;28(2):40-43.
16. Steppich B, Stegmuller F, Rumpf PM, et al. Vascular complications after percutaneous mitral valve repair and venous access closure using suture or closure device. *J Interv Cardiol*. 2018;31(2):223-229.
17. Coto HA. Closure of the femoral vein puncture site after transcatheter procedures using Angio-Seal. *Catheter Cardiovasc Interv*. 2002;55(1):16-19.
18. Atti V, Turagam MK, Garg J, et al. Efficacy and safety of figure-of-eight suture versus manual pressure for venous access closure: a systematic review and meta-analysis. *J Interv Card Electrophysiol*. 2020;57(3):379-385.
19. Mujer MT, Al-Abcha A, Flores J, Saleh Y, Robinson P. A comparison of figure-of-8-suture versus manual compression for venous access closure after cardiac procedures: an updated meta-analysis. *Pacing Clin Electrophysiol*. 2020;43(8):856-865.

How to cite this article: Mohammed M, Nona P, Abou Asala E, et al. Preclosure of large bore venous access sites in patients undergoing transcatheter mitral replacement and repair. *Catheter Cardiovasc Interv*. 2022;1-6. doi:10.1002/ccd.30229