HSPC The Open Access Publisher

JCCM ISSN 2575-0143 JOURNAL OF CARDIOLOGY AND CARDIOVASCULAR MEDICINE

Research Article

Femoral venous closure: A single-centre retrospective analysis in real world all comers with MynxGrip® vascular closure device

Alexander Harvard[1], Shamin Thirunavukarasu[2], Afzal Hayat[2], Abid Ullah[2], Reza Aghamohammadzadeh[2], Cathy Mary Holt[1] and Nadim Malik[1,2]*

[1]The University of Manchester, Division of Cardiovascular Sciences, Core Technology Facility, 46 Grafton Street, Manchester M13 9NT, UK

[2]Manchester Heart Centre, Purple Zone 1st Floor, Manchester Foundation Trust, Oxford Road, Manchester M13 9WL, UK

Abstract

Background: Vascular closure devices (VCD) are routinely used to achieve haemostasis following percutaneous arterial procedures. The extravascular polyethylene-glycol based MynxGrip® device (Cardinal Health) received FDA approval for use in the closure of femoral veins, but so far limited data is available on its use, especially with concomitant use of anticoagulants.

Method: This is a retrospective analysis of data from a single-centre on the effectiveness and complication rates following the use of the MynxGrip® device for femoral venous closure in patients undergoing diagnostic/interventional (temporary pacing during balloon aortic valvuloplasty, or electrophysiology) procedures utilising 5-7F sheaths.

Results: 85 patients (mean age 74 years) underwent femoral venous closure with the MynxGrip® device. 51.8% were male. The rate of concomitant anticoagulant or antiplatelet use was 52.9%. Device deployment was 100% successful with full haemostasis in all cases. There were no major vascular complications (bleeding, thrombosis, or infections). There was one case of a minor small venous hematoma which did not require treatment. The mean length of stay was less than 1 day (67.1% patients discharged the same day) and overnight stay only indicated by interventional procedure.

Conclusion: This data supports safety and efficacy of the MynxGrip® device for femoral venous closure with same-day discharge, even with concomitant aggressive antiplatelet and anticoagulant use. It has the potential for use in other large bore venous access sites.

More Information

***Address for Correspondence:** Nadim Malik, Professor, MBBS, MA, MD, FRCP, FESC, Interventional Consultant Cardiologist, Division of Cardiovascular Sciences, The University of Manchester, Room 3.31b, Core Technology Facility, 46 Grafton Street, Manchester M13 9NT, United Kingdom, Tel: 00 44 161 2768907; Email: Nadim.malik@manchester.ac.uk

Submitted: 23 April 2020
Approved: 17 June 2020
Published: 18 June 2020

How to cite this article: Harvard A, Thirunavukarasu S, Hayat A, Ullah A, Aghamohammadzadeh R, et al. Femoral venous closure: A single-centre retrospective analysis in real world all comers with MynxGrip® vascular closure device. J Cardiol Cardiovasc Med. 2020; 5: 136-140.

DOI: 10.29328/journal.jccm.1001100

ORCiD: orcid.org/0000-0002-5288-9302

Keywords: Vascular closure device (VCD); Femoral venous closure; MynxGrip®; Anticoagulants; Antiplatelets

Introduction

Vascular closure devices (VCDs) are routinely used to achieve haemostasis following percutaneous arterial procedures as they have a number of distinct advantages over the standard method of manual pressure [1]. VCDs are known to reduce time to haemostasis, allow earlier ambulation, are less time consuming for clinicians, and improve comfort for patients [2]. A number of VCDs are currently available, and are broadly categorised by their mechanism as either 'active' or 'passive' approximators (1). A recent systematic review of randomised controlled trials (RCTs), and a Cochrane review including data from over 19,000 patients across 52 RCTs, have demonstrated similar efficacy, safety and complication rates in closure of arteriotomy with VCDs, compared to manual pressure [3,4]. The use of VCDs has been encouraged further by the increasing number of patients who require complex endovascular procedures on the back ground of concomitant significant comorbidities whilst also requiring aggressive antiplatelets and anticoagulants.

However, the use of VCDs in closure following large bore

venous cannulation is less defined. Femoral venous access is required during various cardiac procedures, such as right heart catheterisation, insertion of temporary pacing wire with or without other procedures (e.g. complex PCI, Balloon Aortic Valvuloplasty-BAV, Transcatheter Aortic Valve Implantation-TAVI), electrophysiology (EP) studies including atrial/ventricular ablations, leadless pacemaker (Micra) implantation, percutaneous closure of septal defects or patent foramen ovale [5]. Thereafter, venous haemostasis following sheath removal is achieved by the application of manual pressure, for between 10-15 minutes, sometime more, but usually followed by a period of prolonged immobilisation. The use of VCDs for venous closure would therefore be advantageous if it fills the need for comfortable and reliable haemostasis reducing risks of access-site complications (bleeding, haematoma, pseudoaneurysm and infections) whilst allowing safe and early mobilisation as well as discharge [1].

The use of some VCDs for femoral venous closure has been reported, mainly from small retrospective studies (summarised in table 1) [6-15]. Coto, et al, (2002) studied the use of AngioSeal (St Jude) to close the common femoral vein in 110 patients undergoing cardiac catheterisation or intervention requiring venous access, demonstrating 100% successful deployment and haemostasis without complication [6]. In another retrospective analysis of 26 patients undergoing EP procedures, with a total of 73 femoral vein access sites closed using AngioSeal, Maraj, et al. (2015) reported device success of 98.7%, with one case of minor bruising and no major bleeding or venous complications [7]. Likewise, Shaw, et al. (2004) retrospectively examined use of Perclose devices (Abbott Vascular) for femoral vein closure in 42 patients following cardiac catheterisation [8]. The device success was reported as 88.9%, with 3 cases of small hematoma, 1 access-site infection and 1 deep vein thrombosis [8]. Subsequent other studies have evaluated an alternative 'pre-closure' technique in which the 6F Perclose device is deployed at the start of the procedure followed by insertion of larger venous sheaths of up to 24 Fr, with tightening of the sutures delayed until the sheath is removed from the vessel, demonstrating similarly higher success rates and only minimal minor bleeding complications [9-13]. Two separate retrospective studies involving use of VASCADE device (Cardiva Medical) in 21 and 102 patients respectively reported 93.8% and 99% haemostasis with a few minor hematomas, one case of deep vein thrombosis and one device failure despite a significant proportion of patients receiving some periprocedural antiplatelet or anticoagulation therapy [14,15].

MynxGrip® (Cardinal Health) is a passive approximator that uses a polyethylene glycol (PEG) sealant which actively adheres to the vessel surrounding the arteriotomy/venotomy site to achieve haemostasis. The sealant readily absorbs blood and subcutaneous fluid to rapidly expand and fill the access tract to physically close the site. The lack of an intravascular component theoretically reduces the risk of intravascular embolization. In 2014, the MynxGrip® device (Cardinal Health) received U.S. Food and Drug Administration (FDA) approval for use in a venous occlusion. However, only limited published data on the safety and efficacy of the MynxGrip® (Cardinal Health) in femoral venous closure is available. A preclinical study, in a porcine model, demonstrated the effectiveness of using the MynxGrip® following 7F sheath use with 30-day follow-up evaluation using venography plus doppler ultrasound demonstrating normal flow and no evidence of intravascular sealant, thrombosis or distal embolism [16].

Ben-Dor, et al. (2018) in a prospective randomised clinical trial in 208 patients undergoing diagnostic/interventional procedures evaluated use of MynxGrip® device for venotomy closure, compared with manual pressure and reported 100% success in achieving effective haemostasis, with no significant vascular or bleeding complications (in either group) whilst reducing mean time to haemostasis to 0.12 minutes, compared to an average of 7.6 minutes with manual pressure [17]. However, this study did not fully evaluate for concomitant use of necessary antiplatelets/anticoagulants nor their consequences on venous closure with use of MynxGrip®.

Aims

The present study aimed to retrospectively evaluate the safety, efficacy and outcomes following femoral venous closure using 5-6F MynxGrip® in real-world patients attending the Catheter Laboratory whilst on concomitant antiplatelets and anticoagulants, with results compared to those without such therapies.

Table 1: Summary of studies evaluating VCDs for femoral venous closure.

Ref	N	Device	Sheath	Success	Bleeding	Thrombosis	Infection
Coto (6)	110	AngioSeal	8 Fr	100%	0	0	0
Maraj (7)	26	AngioSeal	6-8 Fr	98.7%	0	0	0
Shaw (8)	42	Perclose	5-14 Fr	(40/45) 88.9%	3 (7.1%)	1 (2.4%)	1 (2.4%)
Mahadevan (9)	146	Perclose	7-14 Fr	(202/205) 98.5%	2 (1.4%)	0	0
Mylonas (10)	45	Perclose	14 Fr	(43/45) 95.6%	0	0	0
Rüter (11)	72	Perclose	14 Fr	N/A	1 (1.4%)	0	0
Hamid (12)	243	Perclose	8-24 Fr	304/310 (98.1%)	0	0	0
Geis (13)	80	Perclose	24 Fr	37/40 (92.5%)	3 (7.5%)	0	0
Dou (14)	21	VASCADE	5-10 Fr	30/32 (93.8%)	2 (9.52%)	1 (4.76%)	0
Hmoud (15)	102	VASCADE	7 Fr	101/102 (99.0%)	0	0	0

Method

A retrospective analysis of electronic clinical records was conducted to identify patients in whom the MynxGrip® device was used for femoral venous closure following cardiac procedures at our institution. Anonymised data collated included baseline patient demographics (age, sex, current smoking, body mass index - BMI), comorbidities (hypertension, hypercholesterolemia/statin use, diabetes mellitus, previous myocardial infarction, previous coronary artery bypass graft surgery, previous stroke/transient ischaemic attack, peripheral vascular disease, estimated glomerular filtration rate-eGFR) and current use of antiplatelets and/or anticoagulants.

For clarity, the following clinical definitions were used: Current smoking was defined as smoking within the last 3 months. Hypertension was defined as either current use of antihypertensive drug treatment, or a previously recorded blood pressure ≥ 160 mmHg systolic or ≥ 95 mmHg diastolic. Diabetes mellitus was defined as the need for oral anti-diabetic agents, a previous fasting glucose ≥ 11.1 mmol/L or a diagnostic oral glucose tolerance test. Hypercholesterolaemia was defined as a total serum cholesterol ≥ 5 mmol/L or current statin use.

Procedural data collected included the indication for the procedure and venous sheath size (5/6F) used. MynxGrip® device *efficacy* was defined as the ability of device to achieve 'full haemostasis' within a minute following deployment as per manufacturer's instructions. MynxGrip® device *failure* was defined as 'any requirement for conversion to manual pressure to achieve haemostasis'. MynxGrip® device safety was assessed by including any bleeding from the venotomy site, haematoma formation, haemoglobin drop requiring transfusion, local or systemic infections, deep vein thrombosis or re-admission with any access-site related complications within 30 days of discharge. The discharge date and length of hospital stay was also recorded.

Statistical analysis

GraphPad Prism was used for data analysis and appropriate t-tests were applied according to categorical or continuous data. For all analyses, the criterion for statistical significance was set at $p < .05$.

Results

A total of 85 patients were identified as having undergone femoral venous closure with the MynxGrip® device. In 64 patients (75.3%) femoral venous access was required for temporary pacing wire insertion during balloon aortic valvuloplasty (BAV), and a further 21 patients (24.7%) underwent EP study with or without ablation. Baseline characteristics of the cohort are as shown in Table 2. Mean age was 74 years, and 44 (51.8%) male and 41 (48.2%) female. 55 patients (64.7%) were on antiplatelets and/or anticoagulants; 25 (29.4%) on Aspirin alone, 12 (14.1%) on dual antiplatelet therapy (DAPT-Aspirin with Clopidogrel/Ticagrelor), and 18 (21.2%) on an oral anticoagulants alone (Warfarin, Apixaban or Rivaroxaban). 2/18 patients (2.4%) were also on anticoagulant with Aspirin, 3/18 (3.5%) on Clopidogrel and 5/18 (5.9%) on DAPT (Aspirin plus Clopidogrel).

Table 2: Baseline patient characteristics.

	N	%
Current smoking	9	10.6
Hypertension	32	37.6
Hyperlipidaemia or Statin use	30	35.3
Diabetes	14	16.5
Previous MI	14	16.5
Previous CABG	7	8.2
Previous stroke/TIA	10	11.8
Peripheral vascular disease	3	3.5
eGFR < 45	18	21.2

MI: Myocardial Infarction; CABG: Coronary Artery Bypass Graft; TIA: Transient Ischaemic Attack; eGFR: estimated Glomerular Filtration Rate.

Success of device deployment was 100%. Full haemostasis with haemostasis time < 1 minute after deployment was 100%. No cases required reversion to manual pressure to achieve haemostasis. There were no serious complications; bleeding/requirement for transfusion, pseudoaneurysm, access-site infections, or deep-vein thrombosis (DVT). There was a single case of a small venous hematoma which did not require any treatment and did not affect the length of stay. 67.1% patients discharged the same day. 77/85 patients (90.5%) were discharged the same or next day with 8 patients (9.4%) had a length of stay greater than 1 day, which was cardiac procedure related rather than any femoral venous access complications/issues. There were no readmissions within 30 days. Lastly, comparison between patients on any antiplatelets/anticoagulants (55 patients) with those without any such medication (30 patients) did not show any differences in success of device, complications, length of stay or 30-day follow up.

Discussion

The main finding of this retrospective study is that femoral venous closure with the MynxGrip® device is effective and safe in real-world cohort of patients undergoing diagnostic or interventional catheterisation procedures, even with concomitant use of aggressive antiplatelets and anticoagulants. The only documented complication was a small venous hematoma of no clinical consequence.

Our findings are consistent with that of a number of other retrospective published abstracts [19,20], and a prospective randomised clinical study funded by the manufacturer of MynxGrip®, Cardinal Health, comparing the use of this device with manual pressure that similarly reported 100% success rate for device deployment and haemostasis without complications [17]. Previous published data however did not assess for concomitant use of antiplatelet and/or

anticoagulants. Accordingly, our independent all-comers real world data with 5/6F sheaths that includes patients on various combinations of antiplatelets/anticoagulants dictated by clinical needs establishes the efficacy and safety of the use of MynxGrip® for femoral venous closure in such high-risk patients also.

Admittedly, although the MynxGrip® device has widely been proved to be safe, there have been isolated case reports of serious vascular complications, including one case of popliteal artery embolization [22]. It is therefore plausible that a larger study would be needed to establish if such distal embolization might also occur following venous closure as well define any clinical consequences arising thereof (i.e. any Deep Vein Thrombosis/Pulmonary Embolism).

Generally, bleeding and local vascular complications remain amongst the most common complications of any cardiac catheterisation procedure. In previous literature complications after femoral venous access closure by manual compression, following catheter ablation procedures, are reported at a low rate of 1.4% [24]. In addition, studies of VCDs in arterial closure have generally failed to demonstrate any reduction in complications, compared with manual pressure [3]. Therefore, given that complication rates associated with venous access are generally low, it is likely that any reduction in venous access related morbidity would require a study with very large number of patients to discern any statistically significant differences, compared to manual compression alone or the use of an alternate device. In addition, the use of MynxGrip® outside of femoral venous closure is yet to be documented. The widespread use of large bore venous access in seriously ill patients (such as in Intensive Care Units), nearly always closed by manual compression, might allow alternate applications for the use of MynxGrip® and may allow such a study in future.

Conclusion

This retrospective analysis supports the existing published data that the MynxGrip® device is effective and safe for use in femoral venous closure, and we now report similar benefits in patients using aggressive antiplatelets/anticoagulants. Along with previous reports that the MynxGrip® device is more comfortable for patients, its greater use in venous closure leading to improved patient comfort, shorter time to haemostasis and reduced length of stay in all cases would offer another major advantage. Future applications of the MynxGrip® device may even evolve to closure of other large bore venous access sites.

Limitations of study

As complications following venous access are relatively low, particularly when compared to that of arterial access complications, the small number of patients studied in this report may therefore not necessarily identify true complication rates which ideally would require a study with a larger number of patients to identify. The retrospective nature of this analysis meant that some data on patient outcomes including comfort and time to ambulation was not fully extracted, and therefore fully identified. Furthermore, the use of the MynxGrip® for venous closure was based on the clinical decision made by the practitioner, which may theoretically introduce an element of selection bias, with higher-risk patients more likely to experience complications having haemostasis managed with just manual pressure (i.e. excluded). Lastly, the lack of randomisation or a control group consisting of patients in whom femoral venous closure was achieved with manual pressure alone or the use of another device means that no definitive conclusions can be drawn from this data on the superiority of venous closure using the MynxGrip®.

Ethics declaration

None required. However, in conformity with our institutional guidelines only anonymised data regarding the use of MynxGrip® was retrospectively extracted from computerised records and used for work in this manuscript.

References

1. Noori VJ, Eldrup-Jørgensen J. A systematic review of vascular closure devices for femoral artery puncture sites. J Vasc Surg. 2018; 68: 887-899. **PubMed:** https://pubmed.ncbi.nlm.nih.gov/30146036

2. Fargen KM, Hoh BL, Mocco J. A prospective randomized single-blind trial of patient comfort following vessel closure: extravascular synthetic sealant closure provides less pain than a self-tightening suture vascular compression device. J Neurointerv Surg. 2011; 3: 219-223. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/21990828

3. Robertson L, Andras A, Colgan F, Jackson R. Vascular closure devices for femoral arterial puncture site haemostasis. Cochrane Database Syst Rev. 2016; 3: CD009541. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/26948236

4. Cox T, Blair L, Huntington C, Lincourt A, Sing R, et al. Systematic Review of Randomized Controlled Trials Comparing Manual Compression to Vascular Closure Devices for Diagnostic and Therapeutic Arterial Procedures. Surg Technol Int. 2015; 27: 32-44. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/26680377

5. Tsui JY, Collins AB, White DW, Lai J, Tabas JA. Videos in clinical medicine. Placement of a femoral venous catheter. N Engl J Med. 2008; 358: e30. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/18579807

6. Coto HA. Closure of the femoral vein puncture site after transcatheter procedures using Angio-Seal. Catheter Cardiovasc Interv. 2002; 55: 16-19. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/11793489

7. Maraj I, Budzikowski AS, Ali W, Mitre CA, Kassotis J. Use of vascular closure device is safe and effective in electrophysiological procedures. J Interv Card Electrophysiol. 2015; 43: 193-195.

8. 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: 439-443. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/15558775

9. Mahadevan VS, Jimeno S, Benson LN, McLaughlin PR, Horlick EM. Pre-closure of femoral venous access sites used for large-sized sheath insertion with the Perclose device in adults undergoing cardiac intervention. Heart. 2008; 94: 571-572. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/17085529

10. Mylonas I, Sakata Y, Salinger M, Sanborn TA, Feldman T. The use of percutaneous suture-mediated closure for the management of 14 French femoral venous access. J Invasive Cardiol. 2006; 18: 299-302. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/16816433

11. Rüter K, Puls M, von der Ehe K, Tichelbäcker T, Sobisiak B, et al. Preclosure of femoral vein access site with the suture-mediated Proglide device during MitraClip implantation. J Invasive Cardiol. 2013; 25: 508-510. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/24088424

12. 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: 586-590. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/22431302

13. Geis NA, Pleger ST, Chorianopoulos E, Müller OJ, Katus HA, et al. 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: 1346-1353. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/24694560

14. Dou E, Winokur RS, Sista AK. Venous Access Site Closures Using the VASCADE Vascular Closure System. J Vasc Interv Radiol. 2016; 27: 1885-1888. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/27886954

15. Hmoud H, Sturla M, Delucia L, DeGregorio L, DeGregorio J. Closure of mid-bore venotomies with VASCADE VCD after right and left heart catheterization. Catheter Cardiovasc Interv. 2019; 93: 626-630. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/30280486

16. Srivatsa SS, Srivatsa A, Spangler TA. Mynx vascular closure device achieves reliable closure and hemostasis of percutaneous transfemoral venous access in a porcine vascular model. J Invasive Cardiol. 2015; 27: 121-127. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/25661765

17. Ben-Dor I, Craig P, Torguson R, Rogers T, Buchanan KD, et al. MynxGrip® vascular closure device versus manual compression for hemostasis of percutaneous transfemoral venous access closure: Results from a prospective multicenter randomized study. Cardiovasc Revasc Med. 2018; 19: 418-422. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/29656937

18. Hutchings D, Hayat A, Karunakaran A, Malik N. Success, Safety, and Efficacy of the Mynx Femoral Closure Device in a Real-World Cohort: Single-Center Experience. J Invasive Cardiol. 2016; 28: 104-108. **PubMed:** https://pubmed.ncbi.nlm.nih.gov/26945253

19. Verma D, Lee N, Tandar A, Badger T, Dranow E, et al. A Propensity Score Analysis of Venous Access Closure Using Extravascular Closure Device In High Risk Patients. J Am College Cardiol. 2014; 64: B248-B.

20. Waksman R, Ben-Dor I, Rogers T, Torguson R, Buchanan K, et al. Mynxgrip vascular closure device is safe and effective for hemostasis of percutaneous transfemoral venous access closure. J Am College Cardiol. 2018; 71: 1432.

21. Fields JD, Liu KC, Lee DS, Gonda SJ, Dogan A, et al. Femoral artery complications associated with the Mynx closure device. AJNR Am J Neuroradiol. 2010; 31: 1737-1740.

22. Islam MA, George AK, Norris M. Popliteal artery embolization with the Mynx closure device. Catheter Cardiovasc Interv. 2010; 75: 35-37. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/19708082

23. Noor S, Meyers S, Curl R. Successful reduction of surgeries secondary to arterial access site complications: a retrospective review at a single center with an extravascular closure device. Vasc Endovascular Surg. 2010; 44: 345-349. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/20484072

24. Gupta A, Perera T, Ganesan A, Sullivan T, Lau DH, et al. Complications of catheter ablation of atrial fibrillation: a systematic review. Circ Arrhythm Electrophysiol. 2013; 6: 1082-1088. PubMed: https://www.ncbi.nlm.nih.gov/pubmed/24243785