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Feasibility and safety of total percutaneous closure of femoral arterial access sites after veno-arterial extracorporeal membrane oxygenation

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Abstract

To evaluate the safety and efficacy of total percutaneous closure of the femoral artery access site after veno-arterial extracorporeal membrane oxygenation (VA-ECMO) with the Perclose ProGlide device.

This retrospective observational study during an almost 2-year period included 21 patients who underwent VA-ECMO in whom the femoral artery puncture site was closed percutaneously with Perclose ProGlide devices. Technical success was defined as successful arterial closure of the common femoral artery, without the need for additional surgical or endovascular procedures. Access site complications were recorded at 24 hours and 30 days after arterial closure, such as major bleeding requiring transfusion or surgical intervention, minor bleeding, groin infection, pseudoaneurysm, and lymphocele.

Technical success was achieved in 20 patients (95.2%). One patient required surgical repair for an access site pseudoaneurysm. Eighteen femoral arteries were closed with 2 devices each, while 3 patients required the use of a third device for femoral artery access site closure to achieve adequate hemostasis. No arterial thrombosis, arterial dissection, arterial stenosis, groin infection, or arteriovenous fistula occurred during the periprocedural period (within 24 hours of arterial closure) or during 30-day follow-up.

Percutaneous closure with the Perclose ProGlide device is a feasible procedure for closing femoral arterial access sites after VA-ECMO, with a low incidence of access site complications.

Abbreviations: CFA = common femoral artery, ECMO = extracorporeal membrane oxygenation, VA-ECMO = veno-arterial extracorporeal membrane oxygenation.

Keywords: closure technique, ECMO, extracorporeal membrane oxygenation, femoral artery

Take Home Message:

Totally, percutaneous closure with the Perclose ProGlide device is a feasible procedure for closing femoral arterial access sites after VA-ECMO, with a low incidence of access site complications.

1. Introduction

The most frequent access site for veno-arterial extracorporeal membrane oxygenation (VA-ECMO) is the common femoral artery (CFA), using either an open or percutaneous technique. Currently, percutaneous closure devices for femoral arterial access sites are approved for use only when a 10-F or smaller sheath has been used.[1,2] However, the availability of the Perclose ProGlide (Abbott Laboratories, Chicago, IL) device has now made it possible to perform percutaneous vessel closure after using larger sheaths.[3,4]

The preclose technique using Perclose ProGlide, has been widely used in endovascular procedures. In a prospective randomized study, complication rates at the access site were similar in patients who underwent total percutaneous access (including percutaneous arteriotomy closure) than in those who underwent surgical cutdown and subsequent surgical closure.[5]

Editor: Muhammad Adrish.

XX and ZL contributed equally to this work.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Chinese research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This work was supported by the National Natural Science Foundation of China (81300236, 81670433, and 81970398), the Project of Zhejiang Medical Young Talents (2017), Zhejiang Medical and Health Science and Technology Project (2020RC014) and Natural Science Foundations of Zhejiang province (Q20H020059).

The authors have no conflicts of interest to disclose.

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How to cite this article: Xu X, Liu Z, Han P, He M, Xu Y, Li Yin, Xu Z, Liang Q, Huang M. Feasibility and safety of total percutaneous closure of femoral arterial access sites after veno-arterial extracorporeal membrane oxygenation. Medicine 2019;98:45(e17910).

Received: 2 June 2019 / Received in final form: 9 September 2019 / Accepted: 11 September 2019

http://dx.doi.org/10.1097/MD.0000000000017910

Total percutaneous closure of femoral arterial access sites increases patient comfort and decreases the rate of wound infections and lymphatic fistulas.[6,7] Furthermore, patients are mobilized and discharged earlier following the use of closure devices than with compression alone.[8,9]

Despite the above observations, no data have been published regarding percutaneous closure of femoral artery access sites in patients who have undergone VA-ECMO. In this study, we evaluated the safety and feasibility of a percutaneous closure technique using Perclose ProGlide to close the CFA access site after VA-ECMO.

2. Methods

2.1. Study design

This was a retrospective observational study of patients admitted to our intensive care unit (ICU) from February 2017 to October 2018. The Ethics Committee at The Second Affiliated Hospital, Zhejiang University School of Medicine approved our study protocol.

2.2. Inclusion and exclusion criteria

The study included all patients who underwent VA-ECMO and in whom Perclose ProGlide was deployed to achieve hemostasis during closure of the CFA site. Two surgeons performed the ProGlide closures in all patients. Patients were excluded if 24-hour and 30-day follow-up data regarding the access sites and other clinical outcomes were not available.

2.3. Preclose technique with perclose ProGlide

All procedures were performed according to the ProGlide manufacturer's instructions. The patients were administered local anesthesia at the access site, and all procedures were conducted in a separate room in the ICU. Ultrasound was used to select the CFA access site. The artery was then punctured under ultrasound guidance, followed by insertion of an 8-F sheath. A VA-ECMO sheath was then inserted under ultrasound guidance into the abdominal aorta, and the patients subsequently received an intravenous bolus of unfractionated heparin to achieve an activated partial thromboplastin time of 60 to 80 seconds.

On the day of ECMO withdrawal, the VA-ECMO sheath was removed, leaving a 0.035-in guidewire in the artery. A Perclose ProGlide device was inserted over the guidewire and the first set of sutures was deployed. Another set of sutures was then placed in the same manner with a Perclose ProGlide device positioned at a different angle. While 1 surgeon manually compressed the puncture site, the other surgeon tightened the knot with the knot pusher. A third Perclose ProGlide device was used when necessary to achieve hemostasis. The guidewire was removed after hemostasis was achieved, and additional manual compression was applied if necessary to control any residual oozing of blood.

2.4. Outcome assessments and definitions

The closure time for procedure was recorded. Haemoglobin, hepatic function tests, and renal function tests were measured 1 day before and daily after the closure procedure. The length of ICU and hospital stay was also recorded. Stenosis of the CFA access site and the presence of other complications were routinely evaluated by ultrasonography at 1 month after closure.

Perclose technical success was defined as successful arterial closure of the CFA access site without the need for adjunctive surgical or endovascular procedures. Access-related complications were defined as events that occurred at the arterial access site, including periprocedural bleeding requiring transfusion, acute lower limb ischemia, groin infection, device failure, arterial thrombosis, arterial dissection, pseudoaneurysm, femoral arterial stenosis, arteriovenous fistula, hematoma, and lymphocele in the periprocedural period (up to 24 hours after closure) and during 30 days of follow-up. Primary device failure was defined as obvious closure site bleeding after 2 Perclose ProGlides deployed, and complete device failure was defined as closure site bleeding which need surgical intervention.

2.5. Statistical analysis

Quantitative variables are reported as mean ± standard deviation. Discrete variables are presented as number and percentage. Significance was defined as $P < .05$. Graphpad 7.0 software was used for all data analyses.

3. Results

3.1. Baseline and procedural characteristics

Baseline characteristics are presented in Table 1. Twenty patients had heart failure, 7 of whom also had respiratory failure. ECMO was successfully initiated by a percutaneous technique at all CFA access sites, without the need for conversion to open surgery. The mean closure time was 23 minutes. Three patients required blood transfusion because their hemoglobins were lower than 60 g/L.

Table 1

Patient and procedural characteristics.

Age, yr	42.0 ± 19.5
Male/female	10/21 (47.6)
Body mass index, kg/m^2	24.3 ± 3.8
Hypertension, ratio	19.0
Diabetes mellitus, ratio	9.5
CAD, ratio	4.8
Hyperlipidemia, ratio	9.5
Heart failure, ratio	95.2
Respiratory failure, ratio	38.1
Veno-arterial ECMO, ratio	100
Procedure time, min	23 ± 15
ICU stay, d	6.0 ± 9.2
Hospital stay, d	14.5 ± 11.2
Blood transfusion*, ratio	14.3
Periprocedure antiplatelet medications†, ratio	19.0
Periprocedure anticoagulant medications†, ratio	90.5
CFA access site	
Diameter, mm	6.5 ± 0.6
Calcification, ratio	4.8
Sheath size, ratio	
<18F	26.3
≥18F	76.2
Technical success rate, ratio	96.2
Number of Perclose ProGlide devices, ratio	
3	14.3
2	84.7

CAD = coronary artery disease, CFA = common femoral artery, ICU = intensive care unit, SD = standard deviation, VA-ECMO = veno-arterial extracorporeal membrane oxygenation.

* Administration of at least 1 blood transfusion in the 30-day follow-up.

† Periprocedure refers to the time of 24 h after closure.

This was due to bleeding at the vascular access site in only 1 patient; the other 2 patients required transfusion for severe anemia rather than overt bleeding. A third Perclose ProGlide closure device was required in 3 patients because of severe oozing at the access site. The ICU and hospital lengths of stay were 6 days and 14.5 days, respectively.

3.2. Complications

With respect to complications within 24 hours of closure, 3 patients required a third Perclose ProGlide device to close the access site because of device failure (Table 2). Three patients required additional manual compression to stop oozing at the access site (classified as minor bleeding). One patient required blood transfusion and surgical intervention for major bleeding at the access site; closure in this patient was considered a technical failure, leading to an overall technical success rate of 95.2% (20 of 21 patients). This was the same patient who required a transfusion within 24 hours of closure, experienced later complications, because he developed a femoral arterial pseudoaneurysm and hematoma at the vascular access site 3 days after percutaneous closure, which required surgical repair. This patient had severe femoral artery calcification. No arterial thrombosis, arterial dissection, arterial stenosis, arteriovenous fistula, groin infection, or lymphocele was observed at the access site in the 20 patients who underwent follow-up ultrasound examination.

4. Discussion

The use of percutaneous closure devices to seal femoral arterial access sites has been increasing during the past decade.[10–13] Because it is widely accepted that percutaneous arterial closure offers a wide range of advantages, we perform VA-ECMO using a totally percutaneous approach when possible. Among the various percutaneous arterial closure devices, suture-mediated systems such as Perclose ProGlide, offer the advantages of surgical type of vessel closure. In this study, we found that total percutaneous closure of the femoral arterial access site with Perclose ProGlide after VA-ECMO had a technical success rate of 95.2%, a short closure time, and an acceptable rate of device-related complications. There was no mortality related to the technique in our series. Only 1 patient developed a femoral artery pseudoaneurysm requiring prompt vascular intervention. This patient had a small (6.5 mm) CFA, with more than 50% calcification.

Previously published studies have reported success rates varying from 71% to 100% for percutaneous closure after endovascular aneurysm repair.[2,3,5,14–19] Our 95% technical success rate was at the high end of this range. Previous studies noted various factors associated with percutaneous closure failure, including a small-diameter access vessel, certain types of closure devices, femoral artery calcification, access vessel tortuosity, and groin scars.[17,20,21] Technique failure has been observed most commonly in obese patients, patients with calcifications of the CFA, and patients who received larger introducer sheaths. Traul et al identified an increasing failure rate of the preclose technique with larger sheaths (≥22 F); 5 (38.5%) of 13 patients treated with a large-bore sheath required conversion to open surgery to close the artery.[22] However, Eisenack et al found that sheath size played a minor role in the failure of hemostasis, and that complication rates did not differ according to sheath size in logistic regression analysis.[6] In the present study, 4 patients had closure site bleeding, 3 of whom were managed by manual compression. The only patient who required transfusion and postprocedural surgical intervention had severe femoral artery calcification.

Traul et al demonstrated a significant association between morbid obesity and the incidence of conversion to open surgery and complications after percutaneous endovascular aneurysm repair.[22] Teh et al reported a high incidence of bleeding related to morbid obesity, which was a main risk factor for complications of percutaneous closure.[21] Of note, our study included no patients with morbid obesity. In our clinical experience, cannulation of the profunda femoris or superficial femoral artery may cause vessel rupture or occlusion if the arterial puncture site is too low. These complications can be avoided by identifying the CFA using ultrasound guidance.

Table 2

Periprocedural and 30-day vascular access site complications after veno-arterial extracorporeal membrane oxygenation.

	n/N (%)	Treatment
24-h complications		
Minor complications		
Minor bleeding	3/21 (14.3)	Compression
Major complications		
Major bleeding (vascular intervention or transfusion acquired)	1/21 (4.8)	Blood transfusion
Acute lower limb ischemia (acute arterial dissection/occlusion)	0/21	–
Groin infection	0/21	
Device failure		
Primary device failure	3/21 (14.3)	3rd device and manual compression
Complete device failure	0/21 (0)	
30-day complications		
Arterial thrombosis	0/21	–
Arterial dissection	0/21	–
Pseudoaneurysm	1/21 (4.8)	Surgical intervention
Arterial stenosis (>50%)	0/21	–
Arteriovenous fistula	0/21	–
Hematoma	1/21 (4.8)	Compression
Groin infection	0/21	
Lymphocele	0/21	

VA-ECMO = veno-arterial extracorporeal membrane oxygenation.

4.1. Limitations

This study has limitations that should be noted. For example, it was a retrospective, nonrandomized, observational study with a relatively small number of patients and was conducted at a single centre. Because of the lack of randomization, the surgeons' preferences and experiences likely played a role in the choice of treatment. In addition, our database does not provide information on long-term follow-up and thereby prevented us from comparing the incidence of iliofemoral stenosis. Our findings should be prospectively verified in a larger patient population.

5. Conclusions

This study demonstrates that total percutaneous closure of CFA access sites using 2 Perclose ProGlide devices after VA-ECMO is safe and effective when performed with a very meticulous technique by well-trained surgeons in carefully selected patients. The mortality and morbidity rates appear to be acceptable, but further larger studies involving longer follow-up are necessary to determine long-term complication rates.

Author contributions

Conceptualization: Xin Xu, Zhenjie Liu, Man Huang.
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