Safety and Efficacy of a Novel “Hybrid Closure” Technique in Large-Bore Arteriotomies

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Int J Angiol 2017;26:116–120.

Abstract

The “preclose” technique employing two Perclose (P) devices is well established for large-bore artery (LBA) hemostasis. Occasionally, only one Perclose deploys successfully during the initial preclose because of arterial calcification necessitating the use of the crossover balloon technique to achieve hemostasis at the LBA. We sought to determine if the combined use of one Perclose and either one Angioseal or one Mynx vascular closure device (VCD) is a safe alternative closure technique large-bore arteriotomy closure.

In total, 40 patients underwent high-risk percutaneous coronary intervention (HRPCI) with Impella support, of whom 38 had common femoral artery (CFA) arteriotomies and 2 underwent percutaneous axillary arteriotomy (AA). Prior to Impella insertion, one Perclose device was predeployed. At the end of HRPCI, Impella was removed and a 0.035” wire was inserted through the Impella sheath. This sheath was then withdrawn over the wire, and partially deployed Perclose was fully deployed. A 6-Fr sheath was advanced over a 0.035” wire into the CFA or AA, achieving hemostasis and reducing the LBA to a 6-Fr size. The 6-Fr arteriotomy was closed with a 6-Fr Mynx or Angioseal VCD. Patients were followed at day 1 and day 30.

Hybrid closure was successful in 38 of 40 cases. In one case of Mynx balloon rupture, hemostasis was achieved with heparin reversal and manual compression. In the case of Perclose failure, crossover balloon tamponade at arteriotomy site and external manual compression achieved hemostasis. Patients were free of complications at day 1 and day 30.

Hybrid closure with one Perclose and either one Mynx or one Angioseal VCD is safe and effective for LBA closure.

Keywords

- cardiac catheterization
- vascular closure device
- high-risk PCI

Use of percutaneous left ventricular (LV) assist devices such as the Impella 2.5 and Impella CP devices (Abiomed) require large-bore arteriotomies (LBAs) of up to 14 Fr (4.67 mm) for delivery. Historically, large-bore arterial access and closure has been achieved surgically with its attendant increased procedural and patient recovery time. The individual use of Mynx, Angioseal, and Perclose vascular closure devices (VCDs) has been previously described for closure of 5- to 8-

Fr common femoral artery arteriotomies.^{1–3} More recently, suture-based VCDs have also been used for percutaneous nonsurgical closure of LBA. The “Preclose” technique involving the use of two Perclose (P) (Abbott Vascular) devices for LBA closure has been described.^{4,5} However, occasionally, the second Perclose may not successfully deployed because of arterial calcification necessitating the use of the crossover balloon technique to achieve hemostasis at the LBA site.⁶

However, the combination of one Perclose and either one Angioseal or one Mynx to close LBA percutaneously has not been described. We sought to determine if the combined use of one Perclose and either one Angioseal or one Mynx VCD is a safe alternative closure technique LBA closure. We present 40 consecutive cases of Impella-supported high-risk percutaneous coronary intervention (HRPCI) performed at our institution in which this novel hybrid closure technique (one predeployed Perclose VCD coupled with one Mynx or one Angioseal VCD) was used to affect hemostasis in LBAs.

Methods

With Institutional Review Board approval, we retrospectively reviewed the procedure logs and medical records and gathered data on 40 consecutive patients who underwent HRPCI with totally percutaneous Impella support at our institution from January 2013 to July 2014 in whom the hybrid closure technique was employed to achieve hemostasis. Of these 40 HRPCI patients, 2 required left axillary arteriotomy Impella insertion due to severe bilateral lower extremity peripheral arterial disease, and the Impella device in these 2 cases was inserted and removed totally percutaneously. In the first 12 cases, hybrid closure was accomplished

Fig. 2 Prior to sheath removal at the end of the case, a 0.035" wire is inserted into the sheath and positioned in the descending aorta.

with one Perclose coupled with a Mynx VCD, and in the next 28 patients, hemostasis was obtained with one Perclose device coupled with one Angioseal VCD. Written informed consent was obtained, and standard techniques were applied for all the HRPCI procedures.

Success of the hybrid closure of the LBA was defined as complete hemostasis achieved totally percutaneously after deployment of both closure devices. Failure was defined as ongoing bleeding after deployment of both closure devices or deployment failure of either device. Complications were defined as retroperitoneal hematoma, access site hematoma of at least 5 cm in diameter, vascular perforation, access site bleeding causing ≥ 2 g in hemoglobin or requiring transfusion, pseudoaneurysm (we elected only to perform vascular testing for pseudoaneurysm only if clinically indicated), and limb ischemia.

Our cohort of patients underwent HRPCI with the Impella device support, which was deployed and removed totally percutaneously in all cases. Initial arteriotomy was achieved using micropuncture needle followed by insertion of 6-Fr sheath. A sheath angiogram was then performed to document adequate vessel size to accommodate up to a

Fig. 1 Prior to insertion of either a 13- or 14-Fr sheath, the arteriotomy is "preclosed" with only one Perclose vascular closure device. (A) A 13.5-Fr Impella sheath with only one partially deployed Perclose in place. (B) A 14-Fr Cook sheath with only one partially deployed Perclose in place.

Fig. 3 With the 0.035 wire in place, the Perclose is simultaneously deployed as the Impella sheath is being withdrawn.

Fig. 4 A 6-Fr sheath is then quickly advanced over the 0.035" wire to achieve partial hemostasis effectively reducing the large-bore artery to a 6-Fr size.

14-Fr sheath. Then, prior to insertion of the Impella sheath, one Perclose device was partially deployed. Once the Impella sheath was in place, the Impella device was deployed through the Impella sheath and delivered in the retrograde fashion into the LV cavity for support during HRPPI (►Fig. 1A, B). The Impella device was deployed through the Impella sheath and delivered in a retrograde fashion into the LV cavity for support during the HRPPI. The HRPPI was then conducted in the usual fashion, and at the end of the procedure after removal of

Fig. 5 (A) Mynx vascular closure device (VCD) is finally deployed in a usual fashion achieving complete hemostasis in almost all cases. (B) Angioseal VCD is finally deployed in a usual fashion achieving complete hemostasis in almost all cases.

Fig. 6 A posthigh-risk percutaneous coronary intervention. Left common femoral artery angiogram performed from the contralateral side demonstrating excellent vessel integrity after large arteriotomy closure using hybrid closure technique.

Impella device, a 0.035" guidewire was passed through the Impella sheath (►Fig. 2) and the sheath was slowly withdrawn. The previously placed Perclose device was then quickly deployed as the Impella sheath was being withdrawn (►Fig. 3). Once the Impella sheath was withdrawn and the previously partially deployed Perclose was now fully deployed, a 6-Fr sheath was quickly advanced over the 0.035" wire, achieving immediate hemostasis and thereby effectively reducing the LBA to a 6-Fr size (►Fig. 4). In the Mynx group, one sheath had to be upsized to a 7-Fr sheath due to bleeding around the 6-Fr sheath after Perclose deployment, and complete hemostasis was achieved after deployment of the Mynx. A similar scenario occurred in two cases in the Angioseal arm for which the sheath was upsized to 8-Fr with subsequent complete hemostasis being achieved with an 8-Fr Angioseal VCD (►Fig. 5A, B). A final angiogram of the vessel that harbored the LBA was obtained by injecting contrast through a catheter advanced from the contralateral PCI sheath, and vessel integrity was confirmed angiographically (►Fig. 6).

Results

A total of 40 patients underwent LBA closure using this new "hybrid closure technique." Patient characteristics for the Perclose + Angioseal and Perclose + Mynx cohorts are shown in ►Table 1. All HRPPI patients received intravenous (IV) heparin to achieve an activated clotting time (ACT) of >200 seconds. Though all patients received a loading dose of glycoprotein IIb/IIIa (GPIIb/IIIa) inhibitors, no patient left the catheterization laboratory with IV heparin or GPIIb/IIIa inhibitors on board. Also, ACT at the end of the procedure was <300 seconds in all patients. All HRPPI patients were on dual antiplatelet therapy at the time of LBA closure. Complete hemostasis was achieved in 38 of the 40 patients. There were two cases of hybrid closure technique failure. Mynx balloon rupture after successful Perclose deployment occurred in one case, leaving a 6-Fr hole in the common femoral artery (CFA),

Table 1 Patient characteristics and results

Patient characteristics	Perclose + Angioseal		Perclose + Mynx	
	N		N	
No. of patients	28		12	
Mean age (y)	71	± 9.3	72	± 11.5
Mean ejection fraction (%)	44	± 16.5	43%	± 0.17
Mean body mass index (kg/m ²)	29	± 6.3	29.1	± 6.3
Systolic heart failure	16	37%	5	42%
Diabetes mellitus	16	37%	7	58%
Hyperlipidemia	20	46%	6	50%
Hypertension	29	67%	11	92%
End-stage renal disease	3	7%	1	8%
Coronary artery disease	27	62%	12	100%
Peripheral arterial disease	8	19%	3	25%
Mean blood urea nitrogen (mg/dL)	28.6	± 16	22.7	± 9.7
Mean creatinine (mg/dL)	2.1	± 2.8	1.2	± 0.24
Mean activated clotting time (s)	240	± 34	230	± 31
Mean international normalized ratio	1.1	± 0.16	1.2	± 0.3
Smoker former	4	13%	1	8%
Smoker current	7	23%	1	8%
Results				
Clinical end point	Preprocedure		Postprocedure	
Mean hemoglobin	11.84 ± 1.83		10.84 ± 1.98	
Retroperitoneal hematoma	N/A		0	
Access site hematoma	N/A		0	
Vascular perforation	N/A		0	
Pseudoaneurysm	N/A		0	
Acute limb ischemia	N/A		0	

Abbreviation: N/A, not applicable.

and Perclose (preclosure) failure occurred in the other, leaving a 14-Fr hole in the CFA. Heparin was reversed, and manual compression to achieve complete hemostasis was used in the case of the Mynx balloon rupture. In the case of the Perclose failure, heparin reversal and the crossover balloon technique for LBA site tamponade from within⁴ along with prolonged external manual compression were successfully employed. All patients were free of predefined clinical end points at day 1 and day 30.

Discussion

VCDs are routinely used in diagnostic and interventional catheter-based procedures performed through 5- to 8-Fr sheaths. They are as effective as manual compressions in achieving hemostasis and reducing vascular complications.⁷ Currently, VCDs are also being employed in catheter-based interventions requiring LBA.⁸ There is a report of use of two Angioseal VCDs to close LBA.⁹ Though the “preclosure” technique using two Perclose devices for percutaneous LBA

closure has been in vogue for some time, our technique employing one Perclose coupled with one Mynx or one Angioseal VCD for a totally percutaneous LBA closure has not been previously reported. In our experience, use of one Perclose in conjunction with one Mynx or one Angioseal VCD is a safe and effective alternative to the double-Perclose technique for a totally percutaneous LBA closure. Our study is limited by a sample size of 40 patients and relatively short follow-up period. A larger patient cohort and longer term follow-up is needed to corroborate our findings.

Conclusions

Our study demonstrates that in the setting of HRPCL, hybrid closure using one Perclose coupled with one Mynx or one Angioseal VCD is a simple, safe, and effective alternative to the double-Perclose technique for a total percutaneous LBA closure, particularly in the setting of failure of the second Perclose device. This technique may also have potential future application for LBA closure in the setting of transcatheter aortic valve replacement.

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