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# **Hybrid method of large bore arterial access closure: Single-center initial experience based on percutaneous coronary artery interventions assisted with left ventricle support device**

Artur K. Pawlik et al., Novel method of large bore arterial closure: Initial experience

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## **Introduction**

Despite advancement in surgical techniques, cardiologic patients are often not good candidates for surgery due to a large burden of comorbidities or frailty syndrome.

Transcatheter aortic valve replacement, endovascular aortic repair and percutaneous coronary interventions (PCI) assisted with percutaneous left ventricle assist devices (pLVAD) are gaining in popularity, gradually replacing alternative surgical methods [1].

The aim of the present study is to delineate initial experience of vascular closure device application based on a series of patients undergoing high-risk PCI with pLVAD.

Twenty-one consecutive patients treated with high-risk PCI with pLVAD were included in accordance with the Heart Team opinion. Data were collected retrospectively. The procedures were performed by highly experienced operators and were elective, except for 1

case. The efficacy endpoint was successful vascular closure. The safety endpoint were in-hospital complications with special regard for hemorrhagic events which remained in line with the criteria proposed by the Bleeding Academic Research Consortium (BARC) [2]. Additional vascular access site imaging examinations were performed in the case of suspecting arterial dissection, false aneurysm or retroperitoneal hemorrhage. Perclose Proglide (PP; Abbott Vascular, California, USA) and Angio-Seal VIP (AS; Terumo Corporation, Tokyo, Japan) were used for vascular closure in the presented series of cases. Vascular closure failure was defined as an inability to fully deploy the closure devices or the necessity to implement adjunctive procedures at an access site other than additional vascular puncture site compression. The large bore arteries (LBA) was defined as vascular access exceeding 8-French. Nonetheless, in the present study, in all assessed puncture sites 14-French sheaths were inserted, except for 1, where a 19-French sheath was used. The closure method was chosen at the discretion of the operator by his experience. All LBA were obtained under the control of fluoroscopy and managed applying 1 of the following methods.

### **Double Angio-Seal VIP**

After the insertion of the pLVAD, 2 0.035” guidewires are introduced into the femoral lumen and a 14-French sheath is explanted. Subsequently, shafts of 2 AS systems are put into the femoral artery. After the deployment of the first AS, manual compression is applied for a couple of minutes. Then, the second system is deployed with subsequent manual compression.

### **Double Perclose Proglide**

Both Perclose Proglide systems should be partially deployed before insertion of a large sheath, in concordance to the instructions available on the producer’s website [3]. The main difference compared to a single PP deployment is an imperative of 30-degree PP rotation in opposing directions before opening a “foot” inside the femoral artery. There is also the technically demanding maneuver of large sheath protrusion and simultaneous advancement of the PP’s knots in order to be deployed. In the case of lack of hemostasis, there is a possibility to use an additional VCD (if the wire is still in the vessel), a compression device or manual compression could also be introduced.

### **Angio-Seal VIP + Perclose Proglide**

Perclose Proglide is deployed in a “perclose” manner before insertion of a large sheath. After the PCI and explantation of the pLVAD, the large sheath is protruded under the

control of the artery manual compression proximally to the arterial puncture. The compression aims to limit blood loss during sheath protrusion and, at the same time, it must not hinder advancement of the knot. Afterwards, a 6-French sheath is inserted, and if a hemostasis is achieved, the 6-French or 8-French AS is deployed in a standard manner. The process is finalized with the PP knot tightening (white stitch).

Baseline patient characteristics are shown in Table 1. The most frequently chosen technique was LBA closure with AS + PP (57.1%), then PP + PP (33.3%) and AS + AS (9.5%). Closure failure occurred in 2 double PP cases due the stitch rupture. The most common complication was a hematoma not demanding surgical management. In 1 case in the AS + PP group, the procedure was complicated by a retroperitoneal hematoma that was treated pharmacologically and by transfusion of 2 units of packed red blood cells. In this case, the LBA was not a source of the bleeding, but the contralateral femoral 7-French access closed by a single AS. One procedure with the double PP technique was complicated by a pseudoaneurysm which was treated with thrombin injection. In 2 cases of hybrid closure, despite successful deployment of devices, the Femostop (Medline Industries, Illinois, Northfield, USA) was applied due to local oozing. There were no cases of arterial puncture infection or the need for surgical intervention.

Overall efficacy of the vascular closure in the presented series was 90.4%, which was comparable to the data reported by other authors. In the literature, the success rate varies from 91.4% to 100% [4–8]. Nonetheless, Toggwailer et al. [9] described the necessity of additional surgery in almost 28% of early patients due to vascular complications, with an impressive reduction to 2% at the end of the study. A decrease in arterial complications in the access site over time was also observed in other studies regarding procedures with LBA [10]. Thus, lower success rate in the present study could be mainly attributed to the initial nature of the series and the learning curve. Contrary to the PP system, the AS is not meant to be mixed with other VCDs by the instruction of use. Nonetheless, available literature provided reliable and favorable outcomes of this method [6, 7]. Based on our experience, comparing the hybrid method with others, it seems to have a higher efficacy and lower rate of bleeding complications in class > 2 according the BARC classification.

The main finding of this study is that initial experience of the hybrid LBA closure technique gives promising results and is more effective compared to other methods analyzed in the presented work. While the patient sample size is too small to draw definitive conclusions, the present outcomes are consistent with those reached in other studies, showing high effectiveness and safety of the hybrid closure method [6, 7]. Nonetheless, further

investigation in randomized controlled trials is needed to compare different methods of LBA closure.

**Conflict of interest:** None declared

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<b>Table 1.</b> Patient baseline characteristics and procedural outcomes.			
	<b>AS + PP (n = 12)</b>	<b>PP + PP, AS + AS (n = 9)</b>	
<b>Patient characteristics</b>			
Age [years]	63.9 ± 7.7	69.8 ± 10.2	
Gender, males	10 (83.3%)	9 (100%)	
Body mass index [kg/m <sup>2</sup> ]	25.7 ± 4.0	28.4 ± 3.9	
LVEF [%]	18.4 ± 3.9	23.2±9.1	
Arterial hypertension	9 (75%)	7 (77.8%)	
Diabetes mellitus	5 (41.7%)	2 (22.2%)	
Peripheral artery disease	0 (0%)	2 (22.2%)	
eGFR < 60 mL/min/1.73 m <sup>2</sup>	3 (25%)	4 (44.4%)	
<b>Peri- and postprocedural outcomes</b>			
LBA closure failure	0 (0%)	2 (22.2%)	
HNF during PCI, 1000 U	10 ± 1.5	11.1 ± 2.2	
Contrast administration [mL]	388.2 ± 119.1	316.7 ± 148	
Inotropes or vasopressors during PCI	3 (25%)	1 (1.1%)	
Hemoglobin drop during hospitalization [g/dL]	2 ± 2	3.5 ± 2.5	
BARC	1	4 (33%)	3 (3.35)
	2	1 (8.3%)	0 (05)
	3	2 (16.6%)	4 (44.45)

Cases of RCP transfusions	1 (8.3%)	0 (0%)
Pseudo-aneurysm treated with thrombin injection	0 (0%)	1 (1.1%)
VCD deployment failure	0 (0%)	2 (22.2%)
Surgical management of hemorrhagic complication	0 (0%)	0 (0%)
Arterial puncture site infection	0 (0%)	0 (%)

Data presented as mean  $\pm$  standard deviation for continuous variables and counts (percentages) for nominal variables; AS — AngioSeal VIP; BARC — bleeding classification system definitions; LVEF — left ventricle ejection fraction; PCI — percutaneous coronary intervention; RCP — red cell package; LBA — large bore access; HNF — non-fractionated heparin; PP — Perclose Proglide; VCD — vascular closure device.