

Percutaneous transaxillary approach for balloon aortic valvuloplasty and complex percutaneous coronary intervention with Impella support

Jerzy Sacha^{1,2} , Krzysztof Krawczyk¹, Przemysław Lipski¹,
Piotr Feusette¹, Marek Gierlotka¹

¹Department of Cardiology, University Hospital, Institute of Medical Sciences, University of Opole, Poland

²Faculty of Physical Education and Physiotherapy, Opole University of Technology, Opole, Poland

Managing complex coronary artery disease (CAD) in elderly patients with coexisting severe aortic stenosis and peripheral arterial disease can pose a significant challenge, particularly when complicated by acute coronary syndrome (ACS). Percutaneous coronary intervention (PCI) is often the preferred revascularization therapy in these situations, frequently accompanied by balloon aortic valvuloplasty (BAV) [1, 2]. However, for patients with left main stenosis (LMS), poor left ventricular function, and multiple comorbidities, PCI carries a high risk and may require mechanical circulatory support, such as the Impella pump [3]. The percutaneous transaxillary approach (PTAA) offers a promising alternative for large-bore interventions in patients without femoral access [4]. However, limited data are available on the effectiveness of PTAA in cases involving the aforementioned clinical issues.

We analyzed a series of 5 patients with complex LMS, severe aortic stenosis, and significant peripheral arterial disease, who were treated using PTAA. According to the Heart Team's recommendations, all patients were unsuitable for cardiac surgery but were eligible for PCI with Impella CP support. Given the complexity of the interventions and high risk of acute kidney injury, the Heart Team did not recommend ad-hoc transcatheter aortic valve implantation (TAVI), but instead advocated for BAV as a bridge to TAVI. Computed tomography scans revealed significant stenoses in iliac and femoral arteries, and concomitant aortic aneurysm with intraluminal thrombus in 2 cases.

Because large-bore femoral access was not feasible in all patients, BAV and Impella implantation were performed using PTAA under local anesthesia, following a previously described method [5]. All patients provided their written informed consent for the procedure. The study was conducted in compliance with the principles of the Declaration of Helsinki. Due to its retrospective nature, it was not subject to the Medical Research Involving Human Subjects Act, as per the Institutional Review Board.

Percutaneous transaxillary approach began with the insertion of a long 0.035-inch guidewire through the radial access, which served as a safety wire to enable balloon delivery or stent placement in case of complications. Subsequently, retrograde angiography was performed by injecting contrast (diluted with saline in a 1:1 ratio) through the radial artery to visualize the arterial anatomy. The axillary artery was punctured near the clavicle (i.e., the first segment of axillary artery) under ultrasound guidance, and 2 Proglide sutures were deployed for later access closure. A peel-away 14F Impella sheath was inserted, and BAV was performed. For all cases, a semi-compliant Valver balloon (Balton) 20/40 mm was used, which was inflated to 5 atm, resulting in a balloon diameter of 22 mm, and finally, an Impella CP SmartAssist was implanted. Successful PCI of the left main coronary artery was carried out in all subjects, and in some cases, multivessel PCI was performed. Upon confirming the patient's stable condition, the Impella was removed immediately after the procedure. The axil-

Address for correspondence: Jerzy Sacha, MD, PhD, Department of Cardiology, University Hospital in Opole, Al. Witosa 26, 45–401 Opole, Poland, tel: +48 77 452 06 60, fax: +48 77 452 06 99, e-mail: sachaj@op.pl

Received: 24.06.2023

Accepted: 23.12.2023

Early publication date: 22.01.2024

This article is available in open access under Creative Commons Attribution-Non-Commercial-No Derivatives 4.0 International (CC BY-NC-ND 4.0) license, allowing to download articles and share them with others as long as they credit the authors and the publisher, but without permission to change them in any way or use them commercially.

Table 1. Characteristics, procedure details, and outcomes of 5 patients undergoing balloon aortic valvuloplasty and complex percutaneous coronary intervention with Impella support *via* percutaneous transaxillary approach.

Patients' characteristics		Procedure and outcomes	
Age [years]	78 (73–84)	PCI of LM	5 (100)
Male/female	3 (60)/2 (40)	PCI of LAD/Cx/RCA	5 (100)/1 (20)/2 (40)
Body mass [kg]	76 (48–105)	IVUS/rotablation/IVL	5 (100)/3 (60)/1 (20)
BMI [kg/m ²]	26 (22–34)	Swan-Ganz	3 (60)
Hypertension	5 (100)	Final LVEF [%]	42 (30–60)
Prior stroke	1 (20)	Final mean AGr [mmHg]	35 (24–40)
Heart failure	5 (100)	Final SYNTAX I	12 (8–35)
NYHA class	3 (1–4)	Diameter of AxA [mm]	6 (5–7.5)
PAD	5 (100)	Left/right axillary access	4 (80)/1 (20)
Diabetes	3 (60)	AxA–subclavian angle [deg]	85 (79–108)
COPD	0 (0)	Radial access for PCI	3 (60)
Renal failure	4 (80)	Heparin [IU]	12500 (9500–15000)
Risk of AKI (Mehran) [%]	57.3 (57.3–57.3)	Contrast volume [mL]	290 (260–463)
GI disease/prior bleeding	4 (80) / 2 (40)	Intra-procedural fluid [mL]	1000 (1000–2500)
Malignancy	2 (40)	Procedure time [min]	190 (150–254)
Prior MI	3 (60)	Radiation dose [mGy]	1490 (624–4912)
Prior PCI	3 (60)	Number of proglides	2 (2–3)
Prior CABG	1 (20)	Angioseal usage	3 (60)
Atrial fibrillation	2 (40)	Protamine usage	3 (60)
Pacemaker	1 (20)	Access site closure failure	0 (0)
Left main stenosis	5 (100)	Vascular surgery	0 (0)
Three-vessel disease	5 (100)	Hematoma	2 (40)
ACS	3 (60)	Hemoglobin drop [g%]	1.5 (1–5.3)
NSTEMI	2 (40)	Blood transfusion	2 (40)
UNA	1 (20)	Creatinine change [mg%]	0.06 (–0.17–0.19)
SYNTAX I	50 (33–64.5)	AKI	0 (0)
EuroSCORE II	18.51 (6.12–74.5)	Pacemaker implantation	0 (0)
STS Score	7.729 (4.152–15.69)	Peri-procedural MI	0 (0)
LVEF [%]	40 (15–56)	Peri-procedural stroke/TIA	0 (0)/0 (0)
Mean AGr [mmHg]	40 (15–56)	Brachial plexus injury	0 (0)
AVA [cm ²]	0.46 (0.3–0.5)	Hospital stay [days]	15 (6–26)
hsTNT [ng/L]	53.5 (31.6–1111)	Final NYHA class	1 (2–3)
ProBNP [ng/L]	5317 (1130–20823)	Hospital death	0 (0)

Values are number of cases (percentage) or median (lower–upper limit). ACS — acute coronary syndrome; AGr — aortic gradient; AKI — acute kidney injury; AVA — aortic valve area; AxA — axillary artery; BMI — body mass index; CABG — coronary artery bypass grafting; COPD — chronic obstructive pulmonary disease; Cx — circumflex artery; GI — gastrointestinal; hsTNT — high-sensitivity troponin T; IVL — intravascular lithotripsy; IVUS — intravascular ultrasound; LAD — left anterior descending artery; LM — left main; LVEF — left ventricular ejection fraction; MI — myocardial infarction; NSTEMI — non-ST-segment elevation myocardial infarction; NYHA — New York Heart Association; PAD — peripheral arterial disease; PCI — percutaneous coronary intervention; ProBNP — pro-B-type natriuretic peptide; RCA — right coronary artery; STS — Society of Thoracic Surgeons; TIA — transient ischemic attack; UNA — unstable angina

lary access was closed with Proglides, although AngioSeal was used in 3 cases to stop oozing. In 1 case, a peripheral 7.0 mm balloon was used to tamponade the axillary artery, and compression was applied using a Proglide's pusher and hemostatic sponge to address residual bleeding, following the method described elsewhere [6].

None of the patients required vascular surgery, stent grafts, or any other intervention. In each case, the integrity of the closure site was documented angiographically via retrograde contrast injection through the radial artery. Table 1 presents the patients' characteristics, procedural details, and outcomes.

All patients were elderly and had multiple comorbidities and complex coronary lesions, with the majority presenting with ACS. Consequently, the opinion of cardiac surgeons, the EuroSCORE, and the Society of Thoracic Surgeons score indicated that cardiac surgery would pose an unacceptable risk. Their primary issue was highly symptomatic CAD involving LMS, necessitating revascularization. As such, the Heart Team recommended PCI with BAV as the initial procedure, followed by staged TAVI. Two of our patients presented with chronic coronary syndrome and were in preparation for oncological treatment. In light of the ACTIVATION study, the benefit of PCI in stable CAD before TAVI remains a subject of debate [7]. However, given the patients' conditions, the Heart Team advocated for complete revascularization and BAV for both. Following PCI and BAV, all patients experienced significant improvement with release of angina and decrease in New York Heart Association class, along with an increase in the left ventricular ejection fraction, and they were all discharged home. One patient underwent successful staged TAVI via the same transaxillary access, while three others are under close monitoring in preparation for TAVI. Unfortunately, one patient died due to heart failure deterioration one month after the procedure.

The percutaneous transaxillary approach has proven to be a safe procedure for structural and complex coronary cardiac interventions. Both axillary arteries are suitable for this approach, but the left one is preferred due to the smoother arterial trace. It is noteworthy that even a quite sharp angle between the axillary and subclavian arteries (Table 1) does not preclude Impella insertion. Although challenging for elderly patients, none of them required general anesthesia, and they all cooperated well. However, the procedures were lengthy, lasting up to 4 hours, and were associated with high radiation doses and contrast volumes. Despite the very high risk of post-PCI acute kidney injury (57.3% in all subjects according to the Mehran risk score), no such event occurred, which may be attributed to the renal protective effects of the Impella pump and adequate hydration — the majority of patients were monitored with a Swan-Ganz catheter [8]. Two patients required red blood cell transfusion due to significant hematoma formation. Overall, two major and one minor vascular complications according to VARC-3 criteria, and one type 1 and two type 3b bleeding events as per BARC definition had to be recognized [9, 10]. There were no other adverse events such as myo-

cardial infarction, stroke, or brachial plexus injury. Percutaneous access site closure was successfully achieved in each case, and no surgical intervention was needed. Based on this data, we conclude that PTAA is a viable alternative for large-bore complex cardiac interventions in elderly patients with high risk and lack of femoral access.

Conflict of interest: None declared

References

1. Diaz Quintero L, Gajo E, Guerrero M, et al. Balloon aortic valvuloplasty followed by Impella®-assisted left main coronary artery percutaneous coronary intervention in patients with severe aortic stenosis as a bridge to transcatheter aortic valve replacement. *Cardiovasc Revasc Med.* 2021; 22: 16–21, doi: [10.1016/j.carrev.2020.06.003](https://doi.org/10.1016/j.carrev.2020.06.003), indexed in Pubmed: [32532627](https://pubmed.ncbi.nlm.nih.gov/32532627/).
2. Singh V, Yadav PK, Eng MH, et al. Outcomes of hemodynamic support with Impella in very high-risk patients undergoing balloon aortic valvuloplasty: Results from the Global cVAD Registry. *Int J Cardiol.* 2017; 240: 120–125, doi: [10.1016/j.ijcard.2017.03.071](https://doi.org/10.1016/j.ijcard.2017.03.071), indexed in Pubmed: [28377189](https://pubmed.ncbi.nlm.nih.gov/28377189/).
3. Leick J, Werner N, Mangner N, et al. Optimized patient selection in high-risk protected percutaneous coronary intervention. *Eur Heart J Suppl.* 2022; 24(Suppl J): J4–JJ10, doi: [10.1093/eurheartj-suppl/suac060](https://doi.org/10.1093/eurheartj-suppl/suac060), indexed in Pubmed: [36518889](https://pubmed.ncbi.nlm.nih.gov/36518889/).
4. Giordano A, Schaefer A, Bhadra OD, et al. Percutaneous vs. surgical axillary access for transcatheter aortic valve implantation: the TAXI registry. *Panminerva Med.* 2022; 64(4): 427–437, doi: [10.23736/S0031-0808.22.04750-4](https://doi.org/10.23736/S0031-0808.22.04750-4), indexed in Pubmed: [35638242](https://pubmed.ncbi.nlm.nih.gov/35638242/).
5. Sacha J, Krawczyk K, Gwóźdź W, et al. Fully percutaneous transaxillary aortic valve replacement with effective bailout plan for vascular complications. *JACC Cardiovasc Interv.* 2020; 13(23): 2811–2812, doi: [10.1016/j.jcin.2020.09.061](https://doi.org/10.1016/j.jcin.2020.09.061), indexed in Pubmed: [33189644](https://pubmed.ncbi.nlm.nih.gov/33189644/).
6. Sacha J, Krawczyk K, Brzeziński Z, et al. Simple method how to avoid stenting in complicated percutaneous transaxillary access. *JACC Cardiovasc Interv.* 2022; 15(18): e201–e202, doi: [10.1016/j.jcin.2022.07.029](https://doi.org/10.1016/j.jcin.2022.07.029), indexed in Pubmed: [36137702](https://pubmed.ncbi.nlm.nih.gov/36137702/).
7. Patterson T, Clayton T, Dodd M, et al. ACTIVATION (Percutaneous Coronary Intervention prior to transcatheter aortic Valve implantation): A Randomized Clinical Trial. *JACC Cardiovasc Interv.* 2021; 14(18): 1965–1974, doi: [10.1016/j.jcin.2021.06.041](https://doi.org/10.1016/j.jcin.2021.06.041), indexed in Pubmed: [34556269](https://pubmed.ncbi.nlm.nih.gov/34556269/).
8. Flaherty MP, Moses JW, Westenfeld R, et al. Impella support and acute kidney injury during high-risk percutaneous coronary intervention: The Global cVAD Renal Protection Study. *Catheter Cardiovasc Interv.* 2020; 95(6): 1111–1121, doi: [10.1002/ccd.28400](https://doi.org/10.1002/ccd.28400), indexed in Pubmed: [31355987](https://pubmed.ncbi.nlm.nih.gov/31355987/).
9. Généreux P, Piazza N, Alu MC, et al. VARC-3 WRITING COMMITTEE. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. *Eur Heart J.* 2021; 42(19): 1825–1857, doi: [10.1093/eurheartj/ehaa799](https://doi.org/10.1093/eurheartj/ehaa799), indexed in Pubmed: [33871579](https://pubmed.ncbi.nlm.nih.gov/33871579/).
10. Mehran R, Rao SV, Bhatt DL, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. *Circulation.* 2011; 123(23): 2736–2747, doi: [10.1161/CIRCULATIONAHA.110.009449](https://doi.org/10.1161/CIRCULATIONAHA.110.009449), indexed in Pubmed: [21670242](https://pubmed.ncbi.nlm.nih.gov/21670242/).