Transcarotid TAVI with the Myval Octacor valve: A single-center initial experience

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INTRODUCTION

Amid an aging, multimorbid population, transcatheter aortic valve implantation (TAVI) has emerged as the leading therapy for severe aortic stenosis, contingent on transfemoral feasibility. [1]. Over the past decade, procedure volumes have steadily increased worldwide, as reflected in large national registries [2]. At present, the vast majority (~95%) of TAVI procedures are performed *via* the femoral route; nevertheless, despite progressive downsizing of delivery systems, ~3%–4% of candidates remain unsuitable for transfemoral (TF) access owing to diffuse atherosclerosis, ilio-femoral tortuosity, abdominal aortic aneurysm, or other hostile anatomies, necessitating alternative access strategies [3]. Among non-femoral options, transthoracic routes (transapical or transaortic) have largely fallen out of favor because of their invasiveness and disruption of thoracic structures, whereas transcarotid (TC) and subclavian/axillary access have emerged as the principal contemporary alternatives in appropriately selected patients [4].

Against this backdrop, the Myval Octacor (Meril Life Sciences, Vapi, Gujarat, India) has been introduced as a next-generation balloon-expandable (BE) transcatheter heart valve engineered to enhance deliverability and deployment control. Key attributes include direct on-balloon crimping (simplifying loading and minimizing arch manipulations), a broad size matrix with intermediate diameters, and compatibility with a 14-Fr expandable sheath (Python) and Navigator balloon delivery system; a dedicated OctaAlign technique has been described for commissural alignment. Early multicenter experiences have reported high technical/device success, low rates of moderate-severe paravalvular leak (PVL), and acceptable 30-day safety [5, 6]. Given these features (which are particularly attractive over the short carotid-to-annulus trajectory), we evaluated surgically exposed TC BE-TAVI using Myval Octacor in patients without a viable transfemoral route.

METHODS

Study design and setting

We conducted a single-center, retrospective case series encompassing all five consecutive adult patients who underwent TC-TAVI with Myval Octacor between 2024 and 2025 at a tertiary cardiac surgery center equipped with a hybrid operating room.

Eligibility and pre-procedural assessment

Patients had symptomatic severe aortic stenosis and were deemed unsuitable for transfemoral access based on computed tomography angiography of the aorto-ilio-femoral axis (diffuse peripheral artery disease, marked tortuosity, abdominal aortic aneurysm, and/or failed prior transfemoral attempt). Suitability of the common carotid artery was confirmed by computed tomography angiography and duplex ultrasound; significant carotid stenosis or unstable plaque was excluded. Baseline echocardiography established valve severity and annular sizing. The vascular access route (TC vs. subclavian/axillary) was selected after comprehensive review of clinical and imaging

data by the multidisciplinary TAVI team, and in the patients described, advanced peripheral artery disease and/or unfavorable anatomy of the subclavian/axillary arteries favored the TC approach.

Peri-procedural management

Procedures were performed under general anesthesia with fluoroscopic, transesophageal echocardiographic, ultrasound, and near-infrared cerebral oximetry monitoring. Intravenous unfractionated heparin (100 U/kg) targeted an activated clotting time >250 s; protamine was administered at the operator's discretion.

Access and implantation technique

Transcarotid access was obtained by surgical exposure of the common carotid artery (side selection individualized; left favored when both sides were equivalent). Two 5-0 monofilament purse-string sutures were placed on the adventitia with a proximal silicone loop for hemostatic support. Following needle puncture and a 6-Fr introducer, a stiff ventricular guidewire was positioned across the aortic valve. A 14-Fr expandable sheath was advanced; predilatation and deployment of a BE prosthesis (Myval Octacor, Meril Life Sciences) were performed under rapid pacing (guidewire-based or transvenous right ventricular lead). After sheath removal, the arteriotomy was closed using pre-placed sutures; brief distal clamping and flushing were applied, and post-repair angiography confirmed carotid patency. All carotid exposures and surgical access to the common carotid artery were performed by an experienced cardiac surgeon. Insertion of the expandable sheath probably transiently reduced ipsilateral carotid flow for approximately 5 minutes; however, continuous monitoring of regional cerebral oxygenation with near-infrared spectroscopy did not show clinically relevant decreases in regional cerebral saturation during this phase of the procedure.

Outcomes and definitions

The primary endpoint was device success; early safety through discharge included stroke/transient ischemic attack (TIA), major vascular and bleeding complications, PVL, and new permanent pacemaker implantation. Endpoint terminology followed Valve Academic Research Consortium version 3 (VARC-3) [7] where applicable. Procedural metrics (fluoroscopy time, contrast volume), valve size, access side, and length of stay were recorded.

Statistical analysis

Data are presented as n (%) for categorical variables and median (interquartile range) for continuous variables; ranges are provided for transparency; no comparative hypothesis testing was planned for this descriptive series.

RESULTS AND DISCUSSION

Among 5 consecutive patients ineligible for transfemoral delivery, device implantation succeeded in all cases (5/5; 100%). No peri-procedural stroke or TIA occurred, and the early postoperative course was uncomplicated in all patients with primary wound healing. No new focal neurological deficits, delirium, or other central nervous system symptoms were observed during the index hospitalization. One patient required a transient dobutamine infusion on the day of the procedure because of peri-procedural hypotension, whereas all remaining patients remained hemodynamically stable without the need for inotropic support. Per VARC-3, technical success was achieved in 5/5 cases, and device success at discharge was 5/5. Early safety through discharge showed no events. There were no deaths, strokes/TIAs, life-threatening/major bleeding, major vascular complications, acute kidney injury stage 2–3, PVL ≥ moderate, or new permanent pacemaker implantation. One patient underwent immediate surgical revision of the carotid arteriotomy for suspected residual narrowing with restoration of normal flow; this access-site event was adjudicated as not meeting VARC-3 major vascular criteria. Supporting data from the series are summarized in Table 1.

Transcatheter aortic valve implantation has secured a durable role in the management of severe aortic stenosis and exemplifies rapid iterative innovation. Contemporary guidelines endorse transfemoral access as the default route whenever anatomically feasible [1]. Progressive downsizing and refinement of delivery systems have expanded TF eligibility; in national registries TF use increased to ~95% by 2019, leaving only a small minority of candidates requiring non-femoral access [8]. In current practice, extrathoracic alternatives — principally TC and subclavian/axillary — have largely displaced the earlier transthoracic (transapical/transaortic) routes due to lower invasiveness and improved outcomes in appropriately selected patients [9]. These observations are consistent with Polish single-center data comparing TC and transfemoral access, which demonstrated similar short-term safety and efficacy [10], as well as reports describing carotid-specific complications that can be effectively managed within experienced TAVI Teams [11].

Across observational cohorts and meta-analyses, TC-TAVI demonstrates outcomes broadly comparable to TF-TAVI after adjustment, with no consistent excess in early mortality or stroke; estimates vary by era and case mix [12]. When TC is compared with transaxial, several analyses suggest similar mortality with a trend of fewer neurologic events for TC, although heterogeneity persists and dedicated data from randomized studies are lacking [13]. These data support TC access as a principal contemporary alternative when TF delivery is precluded [9].

In this context, we selected a BE platform (Myval Octacor) for surgically exposed TC delivery in patients without a viable TF route. Two device attributes were pragmatically attractive for the short carotid-to-annulus trajectory: 1) direct on-balloon crimping, which minimizes manipulations in the arch and expedites the "occlusion window" of the carotid, and 2) a broad size matrix with intermediate

Table 1. Baseline characteristics, procedural details, and outcomes (n = 5)

Patient ID	Age, years	Sex	NYHA class	Euro-SCORE II, %	Access side (L/R)	Reason non-femoral	Valve size, mm	Rapid pacing method	Contrast volume, ml	PVL at discharge	New PPI	Neurologic event (stroke/TIA)	Hospital stay, days
1	90	M	III	10.0	R	PAD, TAAA	29.0	E (Pacel)	80	No	No	No	9
2	69	F	IV	50.7	L	PAD	23.0	W	100	No	No	No	4
3	67	F	III	4.1	L	Obesity, PAD	24.5	W	100	No	No	No	5
4	71	M	IV	3.4	L	Obesity, PAD, failed transfemoral attempt	24.5	W	100	No	No	No	4
5	83		III	30.8	L	PAD, TAAA	30.5	E (5F Pacel)	150	No	No	No	11
Summary, median (IQR)	71 (69–83)			10.0 (4.1–30.8)					100 (100–100)				
	VARC-3 outcomes (through discharge) — Technical success: 5/5 (100%) — Device success (discharge): 5/5 (100%) — Early safety: no events — All-cause death: 0/5; stroke/TIA: 0/5; major vascular complication: 0/5; life-threatening/major bleeding: 0/5; AKI stage 2–3: 0/5; PVL ≥moderate: 0/5; new PPI: 0/5 — Minor access-site event (non-major): 1/5[a]												

[a]Immediate surgical revision of the carotid arteriotomy for suspected residual narrowing on completion angiography, with restoration of normal flow; adjudicated as non-major per VARC-3

Abbreviations: AKI, acute kidney injury; Euro SCORE II, European System for Cardiac Operative Risk Evaluation II; IQR, interquartile range; NYHA, New York Heart Association; PAD, peripheral artery disease; PPI, permanent pacemaker implantation; PVL, paravalvular leak; TAAA, thoracoabdominal aortic aneurysm; TIA, transient ischemic attack; VARC-3, Valve Academic Research Consortium v. 3

diameters, facilitating annular matching. Published device reviews and early Octacor series likewise highlight precise deployment and low paravalvular regurgitation, although large comparative datasets are still evolving [14]. In our hands, implantation behavior was predictable, translating into a strong sense of positional control over the short delivery path. Our experience also complements the contemporary Polish expert opinion on transcatheter aortic valve implantation for failed surgical and transcatheter prostheses, which highlights the expanding role of newer-generation BE platforms in complex structural heart interventions [15].

A practical nuance relates to the expandable sheath: after valve passage, we noted occasional loss of circularity with potential perisheath oozing. We mitigated this by applying a proximal silicone loop and meticulous purse-strings; in one case, immediate surgical revision of the arteriotomy restored normal carotid flow. These workflow refinements may be useful for surgical TC programs and align with the broader move toward standardized extrathoracic access practices [9].

This 5-patient, single-center experience demonstrates the feasibility and safety of surgically exposed TC-TAVI with the Myval Octacor, supporting TC access as a preferred non-femoral pathway and motivating multicenter comparative evaluation of BE valves.

Article information

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