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EDITORIAL

Hostile Territory: Navigating Complex Iliofemoral Access for a Transfemoral First Strategy in Patients Undergoing Transcatheter Aortic Valve Replacement

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With an estimated 400,000 procedures performed worldwide and indicators pointing to a growth rate of 40% annually, transcatheter aortic valve replacement (TAVR) has outpaced surgical aortic valve replacement (SAVR) as the primary modality to treat symptomatic severe aortic stenosis in high-, moderate- and, currently under investigation, low-risk patients.[1–3]

The primary and/or preferred route for TAVR delivery has always remained the transfemoral (TF) approach. Some benefits of a TF approach include lower in-hospital, 30-day and 1-year mortality, shorter length of stay, lower median hospitalization cost, option to complete the procedure without general anesthesia and endotracheal intubation, and ergonomic familiarity for implanting physicians.[4] However, the TF approach carries the inherent risk of vascular access complication and, in some series, a higher risk of procedural stroke due to disruption of atherosclerotic debris from the aortic wall or the aortic valve itself during TAVR delivery and/or deployment.[5,6] Nonetheless, with the evolution of TAVR systems to smaller profile delivery catheters, refinement of vascular access and closure techniques, and use of cerebral embolic protection, all signals point to sustained low rates of vascular complications and procedural stroke.[6,7] Accordingly, in the most recent publications from the Society of Thoracic Surgeons (STS)/Transcatheter Valve Therapy (TVT) registry, in 2015 86.6% of TAVR procedures were performed using the TF approach.[7]

In select patients with perceived "high risk" vascular anatomy (e.g. small femoral arteries, extensive obstructive atherosclerotic disease, moderate–severe calcification, and/or severe tortuosity), alternative access sites for TAVR have included trans-apical, trans-subclavian, direct aortic, trans-carotid, and trans-caval.[8–10] The vast majority of these alternative access procedures are usually conducted under general anesthesia and carry higher rates of morbidity and mortality; though a selection bias in this patient population certainly exists.[8]

Overall, in cases where some or even all "high risk" features are present, there is little in the literature or guidelines to help implanting physicians objectively select one particular access route over the other. In one small series, a combination of iliac diameter plus calcification was an excellent predictor of major vascular complication and mortality after TF-TAVR though the findings remain to be validated in a larger cohort.[11] The 2017 American College of Cardiology (ACC)/American Heart Association (AHA) TAVR expert consensus statement lists "small luminal diameter, dense and circumferential and/or horseshoe calcifications, and severe tortuosity" as being common in patients referred for TAVR.[12] To summarize the writing committee recommendations: presence of these features increased the risk for access site complications and consideration should be made into utilizing alternative access.[12] However, in patients with these "high risk" vascular features, a *de facto* non-TF route is not supported by any clinical data and whether attempting a TF strategy is even feasible is unknown.

In this issue of *Structural Heart*, Staniloae et al.[13] attempt to answer this particular clinical question; is a "TF first" strategy feasible in patients with "high risk" (i.e. hostile access) undergoing TAVR? The authors report on a contemporary but limited number of patients that were retrospectively analyzed at a single center. They sought to identify patients with evidence of hostile (or "high risk") iliofemoral vasculature (Table 1). Out of 377 patients undergoing TAVR over a 12-month period from 2016 to 2017, 28 patients (or 7.4% of their yearly cohort) met the pre-specified definition of hostile access. Entry into this group appears to have been driven primarily by severely calcified (100% of them) and small diameter arteries (average 4.7 mm, range 3.8–5.4 mm). Only two patients had prohibitive anatomy due to obstructive common femoral artery disease for which non-stent-based durable solutions do not exist. The principal finding of this investigation is that 92.8% (n = 26 out of 28) of the patients in the hostile access group were successfully treated with TF TAVR with a little under half (46%) requiring pretreatment with balloon angioplasty and in one case, the use of orbital atherectomy. None of these successfully treated patients required covered or non-covered stenting immediately post-TAVR, though longer-term follow-up data was not presented.

With rates of TF utilization continuing to increase, this study further lends support to developing a comprehensive TF-TAVR program with one that includes endovascular pretreatment of iliofemoral atherosclerotic disease that would otherwise prohibit TAVR delivery.[7,14,15] Traditionally, non-TF TAVR patients self-select as being higher risk patents and consequently short- and longer-term outcomes have proven to be inferior.[4] The current study has demonstrated that with careful screening, pretreatment, and cross-over protection, >

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Table 1. Specific definition for hostile (i.e. "high risk") vascular access.

(1) Arterial diameter < 5.0 mm
(2) Arterial diameter < 5.5 mm with severe calcification or severe tortuosity
Severe calcification = 270–360°circumferential calcium
Severe tortuosity = any iliofemoral angle of < 90°
(3) Severe tortuosity with severe calcification irrespective of arterial diameter

Note. Adapted from Staniloae et al.[13]

99% of all comers can indeed be treated with a TF approach thereby reducing the potential for increased morbidity and mortality with non-TF approaches. The "pre-treatment" of these patients deserves particular emphasis. Most contemporary series specifically evaluating TF-TAVR vascular injury description, rates, and treatment do so after TAVR has been attempted and without consideration for pre-treatment.[11,16,17] Hence there is continued excitement in increasing TF candidacy with pre-treatment of hostile lesions in efforts to minimize post TAVR vascular complication rates. Whether this strategy will be dominant remains to be seen with larger validating data sets.

Most impressive with this data set is that all patients with hostile access received a simple screen such as advancing a 14 Fr sheath through the diseased segments of the iliofemoral tree. If resistance was encountered, the segment was pre-treated with balloon angioplasty. While small linear dissections were noted, none of the pre-treated segments required stenting and only one lesion with severe 360 circumferential calcium at the common iliac required atherectomy followed by angioplasty alone without stenting. This strategy results in a success rate of 92% on the hostile access group (or 98.9% of all-comers at this single center) with the two failures a result of iliac perforation after the delivery sheath was placed and the valve traversed the diseased segments containing 360° of calcification. As the authors had cross over protection in all cases, the iliac perforations were rapidly and safely treated with covered stents. Whether cross over technique is indeed necessary in all-comers or just in hostile access patients was not specifically evaluated though some data would suggest that this approach does not lead to increased harm.[18]

Additionally, the use of only a self-expanding valve (Medtronic Evolut-R) by Staniloae et al.[13] deserves attention. This is an important discussion point as the latest publication from the TVT registry[7] indicates that in 2015, approximately 25,000 TAVRs were performed in the US of which 66% used balloon expandable valves. The generalizability of a TF-first strategy to patients receiving balloon expandable (with their larger delivery sheaths) is unknown. Furthermore, the use of the Evolut- R allows the implanters to place the 14 Fr InLine sheath thereby minimizing the size of the delivery system. This strategy, however, does not make use of the most current Medtronic valve—the Evolut Pro. This was conceived due to the higher incidence, albeit small, of moderate or greater perivalvular leak (PVL) seen when placing the Evolut-R device compared to its balloon expandable counterparts.[19] The Evolut Pro system requires a minimal luminal diameter of 5.5 mm in the access vessel and a 16 Fr InLine sheath to be used for valves 29 mm and smaller. One has to wonder whether the tradeoff of a TF-first approach with increased PVL is worth it in the long run to the patient who might have benefited from a valve with better sealing and lower permanent pacemaker rates.[20] An argument could be made that the percutaneous or cut down axillary approach under conscious sedation in order to place the Evolut Pro might be worth it in this 7.4% of the patients.

While the message of this paper is clear, most TAVR operators should heed caution. The data presented, while encouraging, is that from a small series at a single center with well experienced implanters utilizing a single valve manufacturer. The hypothesis generating findings in this study clearly warrant additional prospective and targeted validating studies before widespread adoption is considered. Implanters considering a TF first approach best be adept at endovascular intervention and rescue with strong consideration of cross over protection in patients meeting criteria for hostile access.

Disclosure statement

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