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Letters

RESEARCH CORRESPONDENCE

A Prospective Registry of Intravascular Lithotripsy-Enabled Vascular Access for Transfemoral Transcatheter Aortic Valve Replacement

Randomized controlled trials of transcatheter aortic valve replacement (TAVR) included both transfemoral and alternative access approaches for valve delivery (1), but the best outcome, superiority to surgical aortic valve replacement, was only achieved in transfemoral patients (2,3). Unfortunately, a significant number of patients remain ineligible for routine transfemoral access due to peripheral arterial disease, which precludes delivery of large-diameter transcatheter valve delivery systems.

Intravascular lithotripsy (IVL) to facilitate transfemoral access was recently published as a case report (4). To further understand the potential role of IVL in patients deemed to have prohibitive iliofemoral vascular disease, a multicenter registry was created to prospectively study patients receiving IVL before attempting transfemoral TAVR.

Between January and July 2018, 4 centers in Italy and 4 centers in the United States established a prospective case series of all patients undergoing iliac or femoral arterial IVL (Shockwave Medical, Santa Clara, California) to facilitate transfemoral passage of delivery systems for TAVR. All patients were required to have severe symptomatic aortic valvular stenosis, at least intermediate risk of mortality for surgical valve replacement, aortic valvular anatomy compatible with safe implantation of existing transcatheter valve sizes, and lower extremity vasculature deemed ineligible for standard transfemoral access due to severe calcific peripheral arterial occlusive disease. Inclusion was guided by the pre-operative lower limb computed tomography angiography.

Vascular access, anticoagulation, introduction of guidewires and catheters, and lower extremity angiography were conducted according to standard best care practices of each participating institution. The use of pre-dilatation, balloon sizing, delivery of IVL pulses, and provisional stenting were left to the discretion of the operator. The primary study endpoint was the success rate of transfemoral delivery of a TAVR system after IVL.

Forty-two consecutive patients were studied, and results are summarized in **Table 1**. All patients achieved successful sheath passage and TAVR intervention. Femoral access was achieved percutaneously in >90% of patients. Reference vessel diameter was 8.1 mm, lesion minimum diameter 4.3 mm, with average stenosis of 58.6%. Average maximum calcium arc was 265.5°. The majority of IVL was performed with a 7-mm catheter (84.6%). No iliofemoral arterial perforation or dissection requiring stent implantation was observed. Vascular hemostasis was achieved with percutaneous sutures >90% of the time. Access site complications were low (4.6%) with 1 patient developing pseudoaneurysm and 1 requiring endarterectomy.

IVL, by disrupting intimal and medial calcification, alters vessel compliance to allow for the safe passage of large-bore delivery sheaths. This expands the patient cohort that could be eligible for transfemoral access for TAVR procedures. IVL-enabled transfemoral access offers several advantages. First, it preserves the established benefits of TAVR: decreased morbidity and mortality, fewer hospital days, and reduced cost. Second, although alternative access options exist, they are more invasive and have a significant learning curve (1,5). IVL leverages the familiarity of a balloon-based intervention, minimizing the learning curve regardless of a center's volume.

In conclusion, IVL may represent a straightforward technique to preserve the benefits of reduced morbidity and mortality of transfemoral TAVR in patients with calcified peripheral arterial disease.

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TABLE 1 Baseline Demographic and Lesion Characteristics and Procedural Outcomes

Baseline Characteristics	(N = 42)	Procedural Details	(N =42) (47 Lesions)	TAVR Outcomes	(N = 42)
Sex					
Male	44.0 (18)	Site access	90.5 (38)	Transfemoral valve delivery success	100 (42)
Female	56.0 (24)	Percutaneous	9.5 (4)		
		Cutdown			
Age, yrs	80.5 ± 7.3 (range 59–93)	Moderate sedation utilized	66.7 (28)	TAVR performed at same time as IVL	100 (42)
		General anesthesia utilized	33.3 (14)		
Baseline valve area, cm^2	0.8 ± 0.2	Pre-dilatation	6.3 (3)	Type of valve	
				Sapien 3 (Edwards)	57.1 (24)
				Evolut R (Medtronic)	33.3 (14)
				Evolut Pro (Medtronic)	9.5 (4)
Baseline ejection fraction	52.6 ± 12.4	IVL catheter size	2.5 (1)	Size of valve	
		5.0 × 60 mm	10.2 (4)	20 mm	2.4 (1)
		6.0 × 60 mm	10.2 (4)	23 mm	24.3 (10)
		6.5 × 60 mm	84.6 (33)	26 mm	46.3 (19)
		7.0 × 60 mm		29 mm	19.5 (8)
				34 mm	4.8 (2)
STS %	8.8 ± 5.5	Number of pulses per lesion	166 ± 68.0	Post-TAVR mean gradient	7.6 ± 3.9
				Aortic regurgitation*	
				None or trace	73.1 (30)
				Mild	24.3 (10)
				Moderate	2.4 (1)
				Severe	0 (0)

Lesion Characteristics	(N = 47)	Access Site Outcomes	(N = 42) (47 Lesions)
Target lesion location	78.7 (37)	Complications	
Common iliac	10.6 (5)	Perforation	0 (0)
External iliac	8.5 (4)	Flow-limiting dissection	0 (0)
Common femoral	2.1 (1)	Provisional stent	0 (0)
Abdominal aorta		Pseudoaneurysm	2.3 (1)
		Endarterectomy	2.3 (1)
Reference vessel diameter, mm†	8.1 ± 1.6	Access site closure method	
		Transcatheter sutures/device	92.8 (39)
		Surgical/stent	4.7 (2)
		Manual	2.3 (1)
Target lesion diameter, mm*	4.3 ± 1.1		
Diameter stenosis, %	58.6 ± 17.5		
Target lesion length, mm†	37.4 ± 23.3		
Calcification, max arc†	265.5 ± 88.3		
Calcification, min CSA†	15.7 ± 10.4		

Values are % (n) or mean ± SD. *Missing single data entry. †missing 2 to 4 data entries.
CSA = cross-sectional area; IVL = intravascular lithotripsy; TAVR = transcatheter aortic valve replacement.

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