Transcatheter Mitral Valve Implantation: Who are we Treating and What may we Expect?

The field of transcatheter mitral valve implantation (TMVI) is rapidly expanding and numerous devices are becoming available that offer new treatment options for mitral regurgitation (MR) in high risk, frail, or inoperable patients.[1] MR represents a substantial healthcare burden and, when severe, contributes significantly to the detrimental prognosis observed in medically-treated patients.[2] Device design, preclinical, and early clinical experiences with TMVI have been individually published or presented at several international cardiology meetings. However, these reports often represent isolated, heterogeneous, and fragmented clinical experiences, limiting a comprehensive overview of advancement in this clinical setting. As more than 250 patients have been treated so far, the aim of this report is to pool together data regarding different devices, thus better characterizing the TMVI population in terms of both clinical profile and early outcomes. We systematically reviewed published literature and relevant websites reporting on TMVI and selected only cohorts >10 patients with clearly specified or deducible Mitral Valve Academic Research Consortium outcomes[3] to be included in this analysis. Rates are expressed as percentage of number of subjects with valid data. The crude proportion and the pooled rate with estimated 95% confidence interval intervals were calculated using a DerSimonian-Laird binary random-effects model. Statistical analyses were conducted with Comprehensive Meta-Analysis v.2 (Biostat Inc., Englewood, New Jersey).

A total of 272 patients were treated with 7 different devices, mean age of 73.7 ± 8.7 years (67% males) (Table). Most patients had functional MR (76%) and symptomatic advanced heart failure (HF) with New York Heart Association (NYHA) class ≥3 in 80% and a mean left ventricular ejection fraction of 42.6 ± 11.0%, with a high prevalence of atrial fibrillation (59%). In these early clinical experiences, technical success rate was as high as 92%, with 2% procedural deaths. Surgical conversion was needed in 4% of cases. After TMVI all patients with available data, except 1, showed reduction of MR to absent/trace or mild grade (100%).

Despite favorable procedural outcomes, 30-day mortality was 13% (most cases being of cardiovascular cause) and device success was 79%. Thirty-day rate of mitral valve reintervention was 4%, with 3% device thrombosis. The proportion of patients with severe HF symptoms was reduced after TMVI, as NYHA class ≥3 was recorded in only 24%. In included studies, a mean follow-up of 9.4 months was available. By this time, 23% patients died (mostly due to cardiovascular causes). Benefits of MR regurgitation were maintained (NYHA class ≥3 in 16%), while 13% were rehospitalized for HF. At follow-up, 100% had MR grade <2. All patients with available echocardiographic follow-up data had none/trivial or mild MR (100%). A device thrombosis rate of 5% was observed.

Table
Categorical values are expressed as proportions (n/N) and quantitative measurements as mean ± SD, as appropriate. Values are approximated at the first decimal.

Results	Observed n/N (%)	Pooled estimate rate % (95% C.I.)
Baseline characteristics		
Age (years)	73.7 ± 8.7	
Males	183/272 (67%)	68.8 (60.2-77.3)
New York Heart Association class ≥3	244/272 (80%)	83.8 (71.0-96.6)
Left ventricular ejection fraction	42.6 ± 11.0	
Society of Thoracic Surgeons' score	7.8 ± 5.8%	
Atrial fibrillation	124/210 (59%)	59.2 (52.6-65.8)
Functional mitral regurgitation	206/272 (76%)	73.9 (61.8-86.0)
Degenerative mitral regurgitation	36/272 (13%)	11.9 (7.2-16.7)
Procedural outcomes		
Technical success	227/246 (92%)	93.6 (89.2-97.9)
Procedural death	4/234 (2%)	0.9 (0-2.0)
Conversion to surgery	11/255 (4%)	2.8 (0-5.9)
Left ventricle outflow tract obstruction	9/243 (4%)	2.2 (0.7-5.0)
Mitral regurgitation none/mild	191/192 (100%)	98.7 (97.2-100)
Mitral regurgitation moderate/severe	1/192 (1%)	1.3 (0-2.8)
30-day outcomes		
Death	32/239 (13%)	17.0 (7.3-27.8)
Cardiovascular death	18/153 (12%)	10.1 (2.6-17.6)
Device success	98/124 (79%)	81.1 (74.0-88.2)
New York Heart Association class ≥3	23/95 (24%)	22.5 (6.0-38.9)
Stroke	2/118 (2%)	2.8 (0-5.8)
Heart failure hospitalization	9/103 (9%)	7.8 (2.7-13.0)
Mitral valve reintervention	7/198 (4%)	1.8 (0-3.7)
Device thrombosis	3/104 (3%)	1.7 (0-4.2)
Device embolization/malpositioning	3/134 (2%)	1.8 (0-4.0)
Mitral regurgitation none/mild	159/159 (100%)	99.1 (97.7-100)
Mitral regurgitation moderate/severe	0/167 (0%)	0.9 (0-2.4)
Follow-up outcomes		
Mean follow-up (months)	9.4	
Death	48/206 (23%)	22.8 (17.1-28.5)
Cardiovascular death	36/169 (21%)	20.9 (14.8-27.0)
New York Heart Association class ≥3	18/116 (16%)	14.3 (8.0-20.6)
Stroke	8/181 (4%)	4.5 (1.6-7.5)
Heart failure hospitalization	17/130 (13%)	11.6 (0.1-23.0)
Mitral valve reintervention	4/161 (3%)	2.0 (0-4.2)
Device thrombosis	7/147 (5%)	3.8 (1.0-8.7)
Device embolization/malpositioning	2/184 (1%)	0.9 (0-4.2)
Mitral regurgitation none/mild	108/108 (100%)	98.8 (96.8-100)
Mitral regurgitation moderate/severe	0/108 (0%)	1.2 (0-3.2)

These preliminary data raise several interesting considerations. The vast majority of patients presents with functional MR, underlining the association of this condition with baseline clinical high-risk profile and feasibility with current TMVI technology (larger ventricles with lower risk of left ventricular outflow obstruction). The low procedural mortality and high device success rate reinforce the safety and feasibility of TMVI. However, 30-day mortality seems higher than that reported in major studies on other mitral transcatheter repair therapies (eg, MitraClip).[4,5] As some devices require a hybrid percutaneous/surgical approach

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with transapical access, there is concern for potential myocardial injury that may, to some extent, account for this discrepancy. On the other hand, there is a striking reproducible and sustained reduction of MR both at 30day and at longer-term follow-up. This translated into a sizeable clinical benefit in terms of HF symptoms reduction.

While these findings must be interpreted with caution and need doubtlessly to be validated in future large-scale studies and prospective randomized trials, they nevertheless seem encouraging in a field that continuously attempts treatment of very high or prohibitive clinical risk patients to effectively address a relevant health burden.

Disclosures

Dr Latib is a consultant for Medtronic, Abbott and Cardiovalve. None of the other authors has relevant conflicts of interest to disclose.

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