

Transcatheter Mitral Valve Replacement (TMVR) – Why so few?

Monika Halas, MD¹, Jane Kruse BSN¹, Adin-Cristian Andrei PhD², Christian Elenbaas, MS², S. Christopher Malaisrie, MD¹, James L. Cox, MD¹, Patrick M. McCarthy MD¹

¹Division of Cardiac Surgery, Northwestern University Feinberg School of Medicine and Northwestern Memorial Hospital, Chicago, IL, ²Division of Biostatistics, Department of Preventive Medicine, Northwestern University, Chicago, IL

Background

Mitral Regurgitation (MR), the most prevalent form of valvular heart disease, remains a formidable public health care problem. Non-surgical interventional treatment is based on important arguments, such as the poor prognosis if left untreated and the reluctance for open surgery in elderly patients with severe comorbidities. Fortunately, there are several new options available. Transcatheter mitral valve replacement (TMVR) has emerged as a compelling possibility after successful implementation of transcatheter aortic valve replacement interventions.

Research Objectives

Despite the advancement in technology, progress of TMVR therapy remains slow and feasible only for selected patients. We sought to determine the relative frequency of interventional MR treatment options, with a focus on the use of TMVR.

Methods

From 9/18/2015 (when TMVR first became available in our institution) until 12/31/2019, 732 patients underwent a mitral intervention or evaluation for TMVR. Inclusion criteria used for analysis was TMVR, MitraClip, and surgical MV repair or replacement procedures. Data was collected from our prospective STS database and TVT Registry. Patients with prior mitral replacement surgery, bacterial endocarditis, concomitant aortic valve replacement, aneurysm > 5.0 were excluded. Patients that failed to enroll in TMVR intervention were carefully reviewed in terms of their MR etiology and reason for screen fail and followed on their alternative management choice.

Figure 1. TMVR Exclusion Criteria

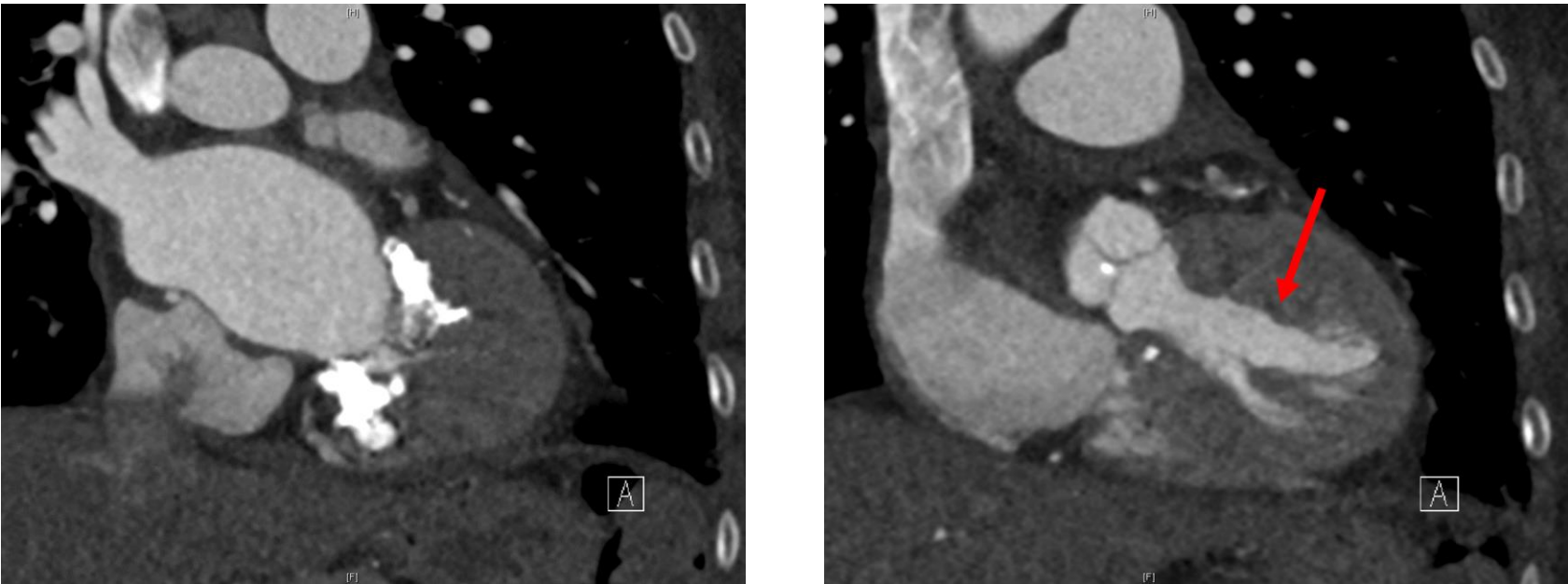


Figure 1. Mitral Annular Calcification (MAC) and small LV cavity. High surgical risk patient needing mitral valve replacement, but also not a candidate for TMVR due to extreme calcification and small LV cavity that would have caused LVOT obstruction.

Figure 2. MR Etiology

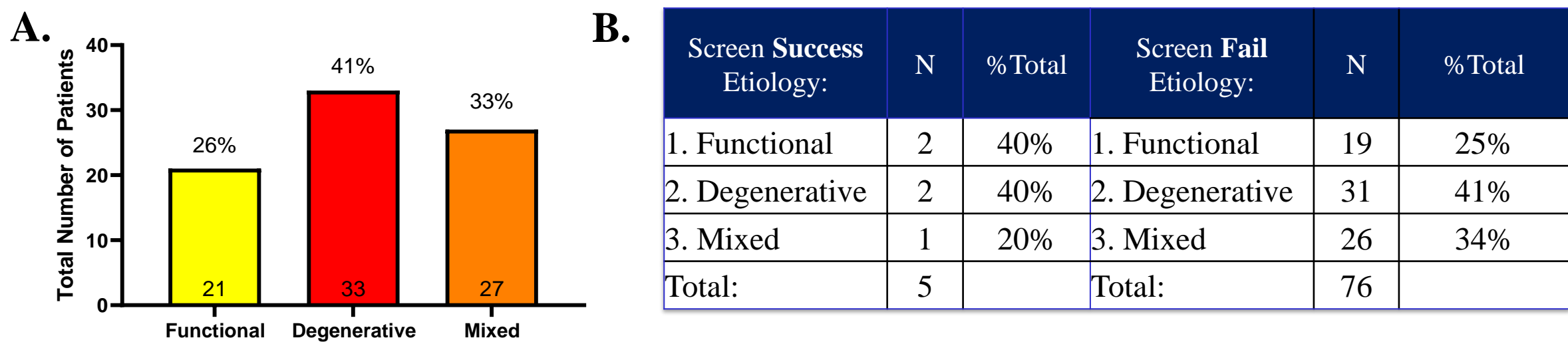


Figure 2. Analysis of MR Etiology in patients screened for TMVR enrollment. A. Graphical presentation of MR etiology in all screened patients. No statistically significant differences. B. Table depicting analysis of MR etiology in patients that were successfully enrolled in TMVR study in comparison to patients that failed to enroll.

Figure 3. Screen Fail Analysis

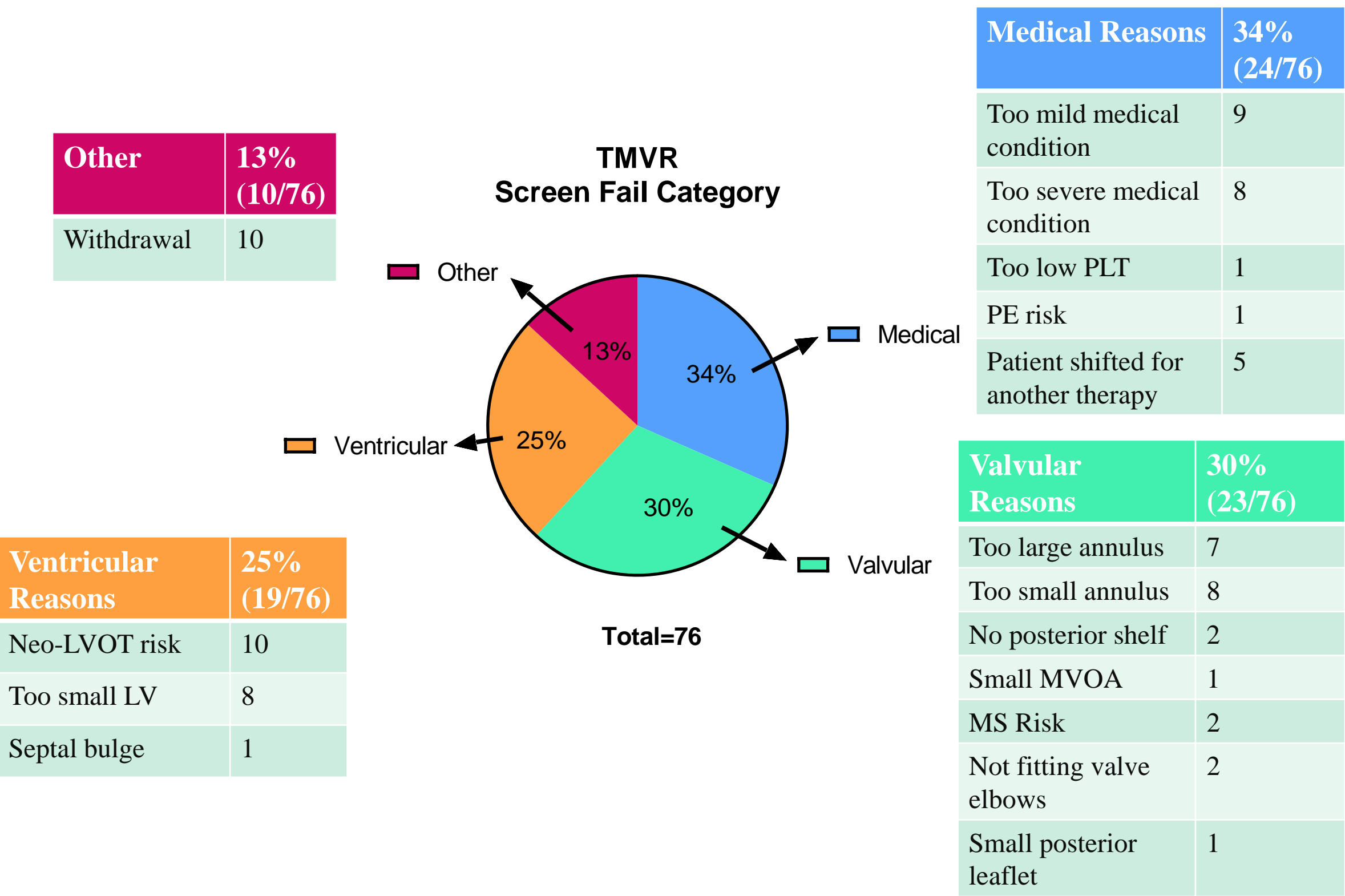


Figure 3. Analysis of the screen failure in the TMVR enrollment process. Patients that failed to enroll in TMVR clinical trial were analyzed, and reasons were divided into 4 categories. Most patients failed to enroll due to medical reasons (34%, N=24/76), then due to Valvular Reasons (30%, N=23/76), followed by Ventricular Reasons (25%, N=19/76). Ten patients (13%) withdrew from the enrollment process.

Results

Of these 732 mitral interventions, 412 patients underwent mitral valve repair (56%); 88 had surgical MVR (12%); 180 had MitraClip (25%); 47 MViV (6.4%); 5 TMVR (1%). TMVR screening identified 81 patients. Only 5 (6%) qualified for TMVR, whereas 76 (94%) failed the screening process due to: inadequate medical condition (32%; n=24/76); valvular technical implant difficulties such as size of the annulus (30%, n=23/76); anticipated ventricular problems such as neo-LVOT risk (25%; n=19/76); and withdrawal from TMVR therapy 13% (n=10/76). For alternative treatment choice medical management was the most prevalent (50%, n=38/76), followed by surgical MV replacement (16%, n=12/76); MitraClip (13%, n=10/76); and in 11% unknown (n=8/76). In medically managed patients 30-day and 1-year mortality were 2% (n=2/38) and 13% (n=5/38), respectively.

Figure 4. Screen Fail Follow-up Analysis

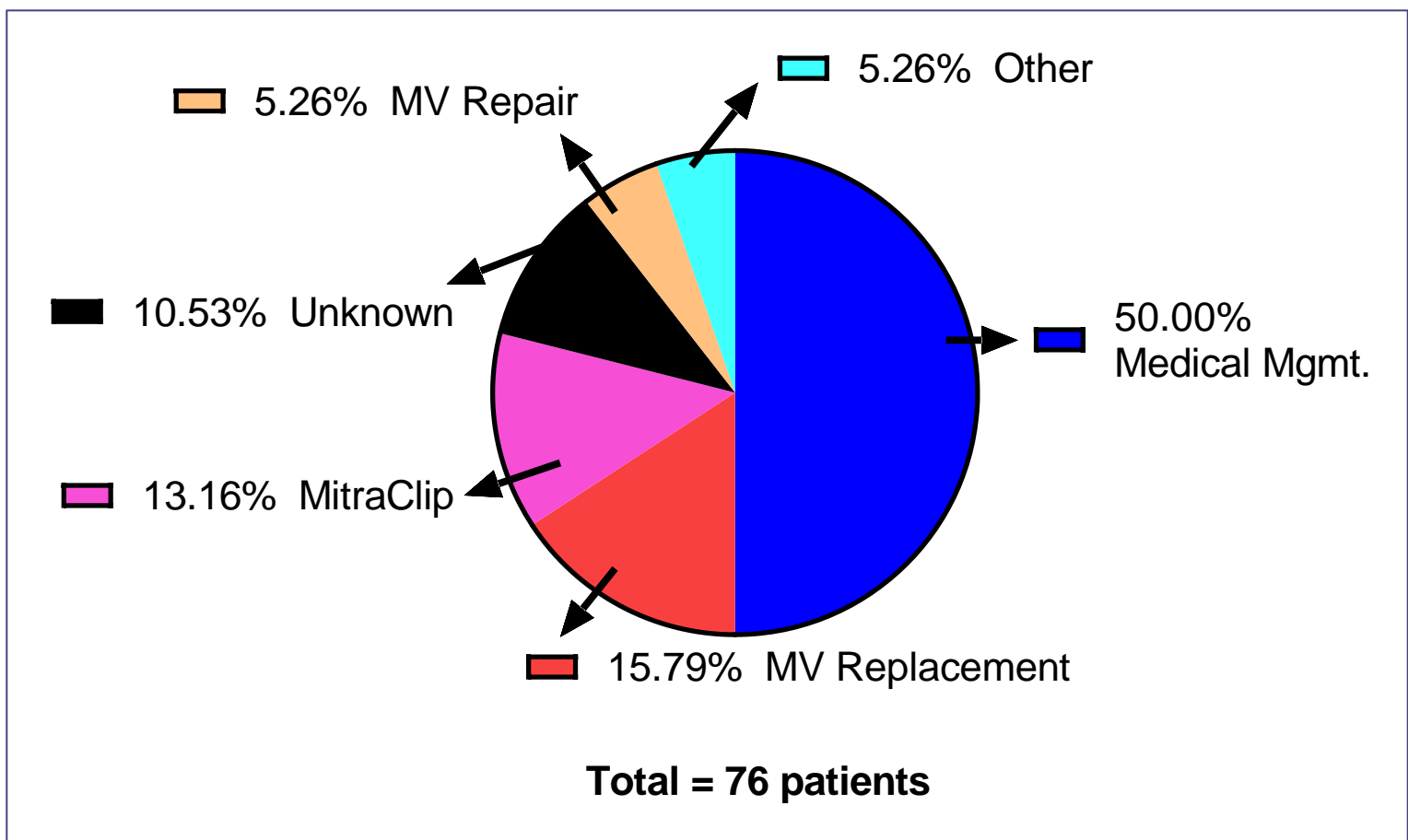


Figure 4. Follow-up on the patients that failed to enroll in TMVR clinical trial. Most of the patients was managed medically (50%), 16% received surgical MVR, 13% had MitraClip, 5% underwent mitral valve repair.

Conclusions

TMVR theoretically is a valuable option for patients requiring mitral intervention. However, its application is limited by current technology, primarily due to anatomical limitations in patients. Survival for medically managed screen failures remains lower than desirable. Hence, there is still an unmet need for technical improvements in TMVR devices.