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Evolution of transcatheter interventions for secondary atrioventricular valve regurgitation: How to set up an edge-to-edge structural program

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Transcatheter edge-to-edge mitral valve repair (M-TEER) has shown safety and efficacy in reducing secondary mitral regurgitation (MR) in inoperable symptomatic patients [1-2]. In selected cohorts [3-4], M-TEER can reduce hospitalization rates and improve mortality. In 2016, 13 years after the first M-TEER, first reports on transcatheter edge-to-edge tricuspid valve repair (T-TEER) demonstrated feasibility and safety [5]. T-TEER implementation was enabled by growing interventional experience, continuous technological advancement, and the recognition of the prognostic impact of tricuspid regurgitation (TR) [6]. However, establishing a successful T-TEER program is surely challenging due to the complex nature of these procedures, of the tricuspid valve and of periprocedural imaging, and thus seems unrealistic without prior M-TEER experience. We therefore sought to understand to which extent procedural M-TEER success has changed over time at our center, and possibly impacted T-TEER implementation.

The present study retrospectively analyzed intraprocedural reduction of secondary MR and TR after release of a valve specific device, in the time frame between 2018, when M-TEER was implemented in our center, through November 2020, when T-TEER procedures started, and up to the end of 2022 (Fig. 1A). Within this period, results compared results between the 55 T-TEER procedures performed up until then (age 81.8 ± 4.7, 55% females) and 3 M-TEER cohorts: the very first 55 M-TEER, the 55 M-TEER before implementation of T-TEER, and the very last 55 M-TEER (overall mean-age 78.4 ± 8.2, 49% females). In-group procedural changes were analyzed with the paired T-test, while between-groups differences underwent independent t- or ANOVA-testing. Pair-wise comparisons were corrected for post hoc. Patients were assessed by the Heart Team and only those deemed to be inoperable underwent TEER. The team consisted of one main and 2 assisting interventionalists, 3 cardiac imaging specialists, and several rotating proctors of both device manufacturers. For MR treatment either MitraClip™ 3rd and 4th generations (Abbott Medical) or PASCAL™/Ace (Edwards Lifesciences) were used, while T-TEER was performed in all but 2 cases with the specific TriClip™XT / XTW device (Abbott Medical). Echocardiographic assessment of atrioventricular valve regurgitation was in line with the latest recommendations [7]. For secondary MR, a 4-grade classification (I/IV° to IV/IV°) was used, as III/IV° was defined by an effective regurgitation orifice area (EROA) of 20-39 mm^2, coupled with regurgitation fraction ≥ 50%, while IV/IV° was present if EROA ≥ 40 mm^2. Secondary TR

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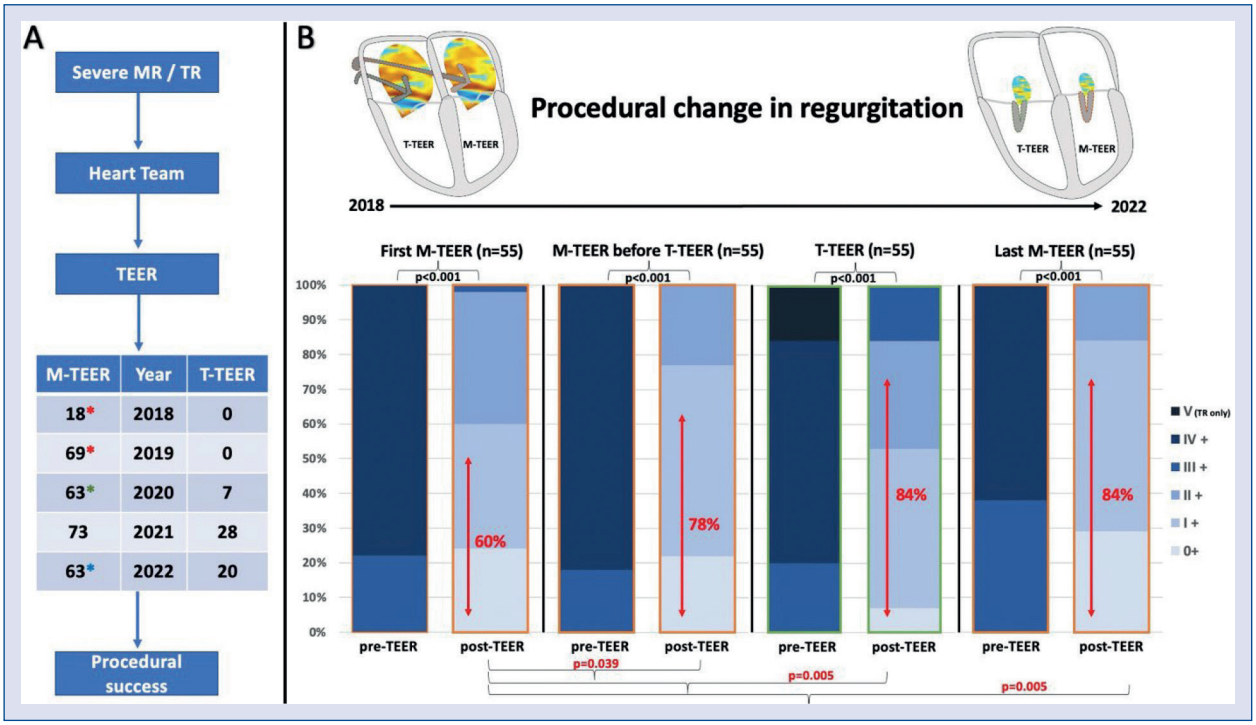

Figure 1. A. Timeline of transcatheter edge-to-edge repair (TEER) procedures in our hospital, including 3 different M-TEER groups (the very first 55*, the 55 before T-TEER implementation*, and the very last 55*); **B.** Regurgitation reduction (↑) to optimal (MR 0+/TR I+) or acceptable levels (MR I+/TR II+). MR — mitral regurgitation; TR — tricuspid regurgitation

was evaluated using the latest 5-grade (I/V° to V/V°) classification [8]. Optimal results were defined as residual MR 0+ (none or trace) or TR I+ (mild or mild-to-moderate), while acceptable results were considered MR I+ (mild or mild-to-moderate) and TR II+ (moderate or moderate-to-severe).

All patients were highly symptomatic, with an average of 2.1 ± 0.6 (MR) vs. 2.7 ± 0.7 (TR) ($p < 0.001$) admissions for acute heart failure during the 12 months prior to TEER. Also, 81.2% MR patients were in NYHA class III–IV vs. 87.3% TR ($p = 0.818$). Overall, technical success was 100%, with on average 1.1 ± 0.3 clips/procedure implanted in M-TEER patients and 1.6 ± 0.6 in T-TEER. Continuous improvement in procedural and device times from the first to the last M-TEER group stood out: 85.4 ± 34.6 vs. 62.6 ± 19.4 ($p < 0.001$) and 44.4 ± 24.3 vs. 27.9 ± 13.9 ($p < 0.001$) minutes, as well as from the first 25% T-TEER procedures (n=11) to the remaining 75% ($n = 44$): 171.8 ± 88.7 vs. 99.3 ± 26.5 ($p < 0.001$) and 81.9 ± 37.5 vs. 60 ± 28.4 minutes ($p = 0.037$). In all groups, regurgitation was successfully and significantly reduced (Fig. 1B), with the exception of 2 T-TEER cases with coaptation gaps of 15 mm. MR reduction to optimal or acceptable levels increased over time from 60% at the start of the M-TEER program to 78% after 12-18 months ($p = 0.039$), and 84% ($p = 0.005$) after approximately 3 years. Two years after the first M-TEER, T-TEER was implemented and achieved 84% optimal or acceptable residual TR (Fig. 1B), better than initial M-TEER ($p = 0.005$) and similar to the middle ($p = 0.466$) and last M-TEER cohorts ($p = 1.000$), despite higher mean-EROA (78.5 ± 32.2 mm^2 vs. 44.8 ± 16.1 mm^2 in all MR patients, $p < 0.001$), more complex anatomy, more challenging imaging, and sicker patients. TEER safety aspects proved to be excellent, counting only 4 complications during M-TEER, of which 2 hematomas, one requiring blood transfusion, one relevant atrial septal defect after transseptal puncture, treated by interventional closure the following day, as well as one case of single leaflet attachment (SLA) (0.6%). Equally, T-TEER led to only one SLA (1.8%), with otherwise 2 postprocedural blood transfusions for known gastrointestinal angiodysplasia. All patients were discharged, on average after 5.3 ± 4.3 (M-TEER) vs. 6.1 ± 5.3 days (T-TEER), $p = 0.277$.

We therefore describe a single-center experience with implementation of TEER procedures for treatment of MR and TR, in an established interventional department trying to take the next "structural step". Our team was faced with an elderly, highly symptomatic cohort of 220 patients, that were turned down for cardiac surgery due to extensive comorbidities. First, M-TEER was introduced, which proved to be very safe and effective in reducing MR, and led to continuous result improvement over a period of 36 months, which matches outcomes and progress from international registries [9]. Shortly after CE-marking of the first specific tricuspid device in 2020 [10], we also introduced T-TEER, which significantly reduced TR in 96% of the patients, while proving to be extremely safe. Procedural success was in part due to improved technological features of both echocardiography machines and valve devices. However, the main driving factor behind the successful implantation of T-TEER was, in our opinion, increasing familiarity with M-TEER. Moreover, T-TEER patients showed better procedural results than the initial M-TEER cohort. This is not self-evident, considering the fact that TEER devices are similar, while morphological aspects of atrioventricular valves and procedural guiding are not alike. Some limitations of this study need to be considered. First, this is a single-center experience, with no change in team composition over the 5-year span. Results may not apply to other centers. Also, a comparison to T-TEER procedural outcomes without prior M-TEER experience is not available.

In conclusion, gains in knowledge and experience, coupled with technological advances, have significantly impacted procedural M-TEER success over time and allowed similar successful implementation of a T-TEER program. Previous M-TEER experience is recommended before starting T-TEER.

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