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with marked symptomatic improvement at 30-day follow-up.

Despite the impressive long-term results of MV repair, repair failure can occur. The morbidity and mortality associated with reoperative mitral surgery can be substantial. Transcatheter modality may well be the solution for some of these patients. However, the result of TMVIR is less encouraging, with frequent valve migration, embolization, paravalvular leak, and LVOTO. Experience with large, incomplete, flexible annuloplasty rings has been disappointing. A mitral-specific TMVR system might facilitate positioning, fixation, and sealing, while incorporating features designed to reduce the potential for LVOTO.

Our experience demonstrates the feasibility and excellent early clinical and hemodynamic outcomes that can be achieved in patients with failed repair with large, flexible and incomplete rings using the Neovasc Tiara TAMI system.

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RESEARCH CORRESPONDENCE

Transcatheter Treatment of Severe Tricuspid Regurgitation Using the Edge-to-Edge Repair Technique in the Presence and Absence of Pacemaker Leads

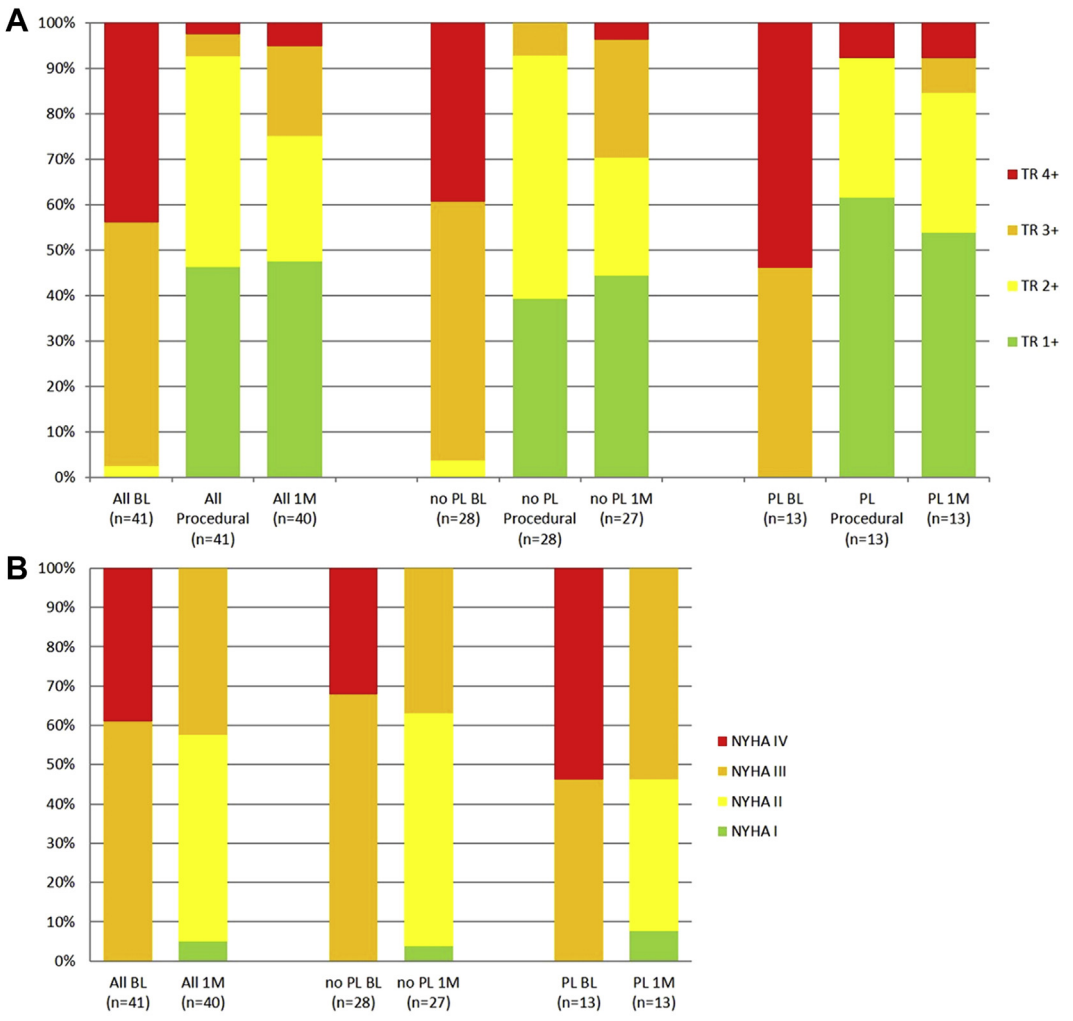
Tricuspid regurgitation (TR) is associated with significant morbidity and mortality (1). Recently, transcatheter edge-to-edge repair has been shown to be an alternative treatment option in selected patients with severe TR (2). Heart failure patients are frequently treated with cardiac pacemakers including resynchronization and implantable cardioverter-defibrillator devices. Therefore, the aim of this study was to assess the feasibility and safety of the edge-to-edge repair technique in inoperable patients with severe TR in the presence and absence of pacemaker leads (PL).

We analyzed 41 consecutive patients treated for primarily secondary symptomatic severe TR from March 2016 to April 2017 at the Munich University Hospital. Results of the first 18 patients have been reported previously (2). In 13 out of these 41 patients a transtricuspid valve PL, including implantable cardioverter-defibrillator leads, was present. Patients with PL were included if the latter was not the predominant reason for TR.

Clips were implanted using a modified steering technique as previously described (2). A "triple orifice technique," where clips are placed between the septal and anterior as well as the septal and posterior tricuspid leaflet, was used in most patients. Alternatively, a "bicuspidalization technique" was used, where clips are placed between the septal and anterior tricuspid leaflet.

Mean patient age was 79 ± 7 years with a Society of Thoracic Surgeons score of 7 ± 6. Most patients experienced pulmonary hypertension as expressed by a transtricuspid gradient of 38 ± 14 mm Hg. Two-thirds of patients were treated simultaneously for severe TR and severe mitral regurgitation (MR). Baseline characteristics did not differ between both groups except for a lower left ventricular ejection fraction in the PL group (51 ± 14 in the no-PL group vs. 39 ± 13 in the PL group; $p = 0.008$). The triple orifice technique was applied in 46% and 77% of patients in the no-PL and the PL group, respectively.

FIGURE 1 **TR Grade and NYHA Functional Class Status During 30-Day Follow-Up**



TR grade **(A)** and NYHA status **(B)** during 30-day follow-up. BL = baseline; NYHA = New York Heart Association; PL = pacemaker leads; TR = tricuspid regurgitation.

Procedure times for TR intervention were 101 ± 33 min in the no-PL group and 96 ± 31 min in the PL group ($p = 0.56$).

TR grade could be improved by at least 1 grade in all but 1 patient in the PL group. Post-procedural TR ≤2+ was present in 93% and 92% of patients without and with PL, respectively ($p > 0.99$) (Figure 1A).

At 30-day follow-up, a persistent reduction of at least 1 TR grade was achieved in 93% and 92% of patients without and with PL, respectively ($p > 0.99$). The rate of patients with TR ≥3+ could be reduced from 96% to 29% ($p = 0.02$) in the no-PL group and from 100% to 15% in the PL group ($p < 0.001$) (Figure 1A).

Improvement of at least 1 New York Heart Association functional class was achieved in 89% and 69% of patients without and with PL, respectively ($p = 0.18$). The rate of patients with New York Heart Association greater than or equal to functional class III could be reduced from 100% to 36% in the no-PL group ($p < 0.001$) and from 100% to 54% in the PL group ($p = 0.01$) (Figure 1B). A significant clinical benefit concerning reduction in the rate of patients in New York Heart Association greater than or equal to functional class III was observed for patients treated

for isolated TR ($p = 0.04$) and patients treated for combined TR and MR ($p < 0.001$).

Considering adverse events, 1 patient in the PL group treated for TR and MR developed a cardioembolic stroke 2 weeks following the procedure. Another patient in the no-PL group experienced single-leaflet clip detachment after an initially successful procedure. In 1 patient in the PL group, puncture-related arteriovenous fistula was operated following the clip procedure. Of note, we did not observe any device dysfunctions.

Considering all 41 patients, we observed a mean increase in the 6-min-walking distance of 59 m (95% confidence interval: 29.8 to 88.6 m; $p = 0.001$), a mean decrease in the level of N-terminal pro-B-type natriuretic peptide of 1,989 pg/ml (95% confidence interval: −687 to 5,286 pg/ml; $p = 0.25$), and an improvement in quality of life as expressed by a mean reduction of the Minnesota Living with Heart Failure Questionnaire (MLHFQ) score of 13.8 (95% confidence interval: 8.6 to 20; $p = 0.001$). Results were comparable in both groups. Right ventricular function and estimated pulmonary artery pressure did not significantly change during follow-up.

This study demonstrates that edge-to-edge repair is feasible in selected patients with severe TR independent of the presence of PL. Most patients with PL were treated using a triple orifice technique, which imitates the surgical "clover technique." In this context, the presence of PL might lead to more complex TR jet origins necessitating the placement of clips in different commissures. Reduction of TR was associated with a clinical benefit at 30 days in patients without and with PL.

The small number of patients, the lack of a randomized controlled trial design, and the concomitant treatment of severe MR in two-thirds of patients are major limitations of this study. However, based on the promising results presented here, edge-to-edge repair might be considered as an alternative treatment option in selected patients with severe TR independent of the presence of PL.

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