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Tricuspid Valve Transcatheter Edge-to-Edge Repair (TriClip): Initial Outcomes and Experience in Türkiye

Triküspit Kapak Transkateter Uçtan Uca Onarım (TriClip): Türkiye'deki İlk Sonuçlar ve Deneyimler

ABSTRACT

Objective: This study aims to assess the efficacy and safety of tricuspid valve (TV) transcatheter edge-to-edge repair (TEER) procedures using the MitraClip or TriClip device in high-risk patients with severe secondary tricuspid regurgitation (TR) and provide Turkish-specific data on procedural outcomes and clinical follow-up.

Methods: This study enrolled 42 high-risk patients with severe secondary TR who underwent transcatheter edge-to-edge repair using either the MitraClip or TriClip device. Patient selection criteria included severe TR, high surgical risk (EuroScore ≥ 8 and Tricuspid Regurgitation Impact Severity Score (TRI-SCORE) ≥ 6), symptomatic despite medical therapy, and anatomical suitability for TriClip. Patients underwent rigorous evaluation by a specialized cardiac team before the procedure, including 2D/3D transesophageal echocardiography to assess eligibility.

Results: The study achieved a 100% procedural success rate, defined as successful implantation and at least one-degree reduction in TR severity. Post-procedure assessments revealed that 88.1% of patients had mild to moderate TR, indicating significant improvement, while only 11.9% retained severe TR. During the median follow-up of 11.5 months, rehospitalization occurred in 23.8% of patients, and mortality was observed in 7.1% of patients, demonstrating a favorable safety profile. Comparative analysis between TriClip and MitraClip devices showed similar efficacy and safety outcomes, with no significant differences in procedural durations or complication rates.

Conclusion: The study demonstrates the effectiveness and safety of TV TEER using TriClip or MitraClip devices in managing severe secondary TR in high-risk patients. Procedure success, improved TR severity, and favorable clinical outcomes were observed, supporting the role of transcatheter techniques in TR management.

Keywords: National data, procedure outcomes, transcatheter edge-to-edge repair, tricuspid regurgitation

ÖZET

Amaç: Bu çalışmanın amacı, ciddi sekonder triküspit yetersizliği (TY) olan yüksek riskli hastalarda MitraClip veya TriClip cihazı kullanılarak triküspit uçtan uca onarım (TEER) işlemlerinin etkinliğini ve güvenliğini değerlendirmek ve işlem sonuçları ve prosedürler hakkında Türkiye'ye özgü veriler sağlamaktır.

Yöntem: Bu çalışmaya, MitraClip veya TriClip cihazı kullanılarak uçtan uca transkateter onarım uygulanan ciddi sekonder TR'li 42 yüksek riskli hasta dahil edildi. Hasta seçim kriterleri arasında şiddetli TY, yüksek cerrahi risk (EuroScore ≥ 8 ve TRI-SCORE ≥ 6), tıbbi tedaviye rağmen semptomatik olma ve TriClip'e anatomik uygunluk yer alıyordu. Hastalar işlemden önce uzman bir kalp ekibi tarafından uygunluğun değerlendirilmesi için 2D/3D transözofageal ekokardiyografi de dahil olmak üzere titiz bir değerlendirmeye tabi tutuldu.

Bulgular: Çalışmada, başarılı implantasyon ve TY şiddetinde en az bir derecelik azalma olarak tanımlanan %100'lük bir prosedür başarı oranı elde edildi. İşlem sonrası değerlendirmeler, hastaların %88,1'inde hafif ila orta dereceli TY'nin olduğunu ortaya çıkardı; bu da anlamlı iyileşmeye işaret ediyordu. Hastaların yalnızca %11,9'unda ileri TY'nin korunduğu görüldü. Ortalama 11,5 aylık takip sırasında hastaların %23,8'inde yeniden hastaneye yatış meydana geldi ve hastaların %7,1'inde mortalite gözlendi; bu da olumlu bir güvenlik profili ortaya koyuyor. TriClip ve MitraClip cihazları arasındaki karşılaştırmalı analiz, benzer etkinlik ve güvenlik sonuçları gösterdi; işlem süreleri veya komplikasyon oranlarında anlamlı bir fark yoktu.

Sonuç: Çalışma, yüksek riskli hastalarda ciddi ikincil TY'nin tedavisinde TriClip veya MitraClip cihazları kullanılarak yapılan TEER'in etkinliğini ve güvenliğini göstermektedir. TY tedavisinde transkateter tekniklerin rolünü destekleyen prosedür başarısı, TY şiddetinde iyileşme ve olumlu klinik sonuçlar gözlendi.

Anahtar Kelimeler: Ulusal veriler, işlem sonuçları, transkateter uçtan uca onarım, triküspit yetersizliği

ORIGINAL ARTICLE
KLİNİK ÇALIŞMA

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Tricuspid regurgitation (TR) is a valve disease characterized by the backflow of blood from the tricuspid valve (TV) into the right atrium. Prevalence of moderate-severe TR is relatively low, affecting approximately 0.55% of the general population, and rises to 4% among individuals aged 75 years and older. The incidence of TR is notably correlated with advancing age.[1] In about 90% of cases, TR is classified as secondary or functional in nature, meaning it is primarily a consequence of factors such as tricuspid annular enlargement or leaflet tethering rather than a structural abnormality of the valve itself.[2] Functional TR commonly manifests in patients with underlying left heart valve diseases, pulmonary arterial hypertension, or conditions like atrial fibrillation (AF) where tricuspid annular dilation occurs independently.[3]

The clinical significance of TR extends beyond its immediate hemodynamic impact, as it has been identified as an independent risk factor for increased cardiovascular morbidity and mortality during long-term follow-ups.[4] Numerous studies have demonstrated a direct correlation between the severity of TR and adverse patient outcomes, underscoring the importance of timely diagnosis and appropriate management strategies.

Traditionally, treatment options for TR have included both surgical and non-surgical interventions. Despite advancements in surgical techniques, outcomes following isolated TV surgery, whether repair or replacement, have not shown substantial improvements in mortality rates over time.[5] Among surgical interventions, tricuspid annuloplasty is commonly favored, with TV replacement reserved for cases where annuloplasty is deemed unsuitable.[6] Notably, TV replacement carries a higher perioperative mortality risk, ranging from 10% to 20% across different cohorts, and is associated with poorer long-term survival outcomes compared to other valve replacement surgeries.[7] Consequently, there is a growing interest in exploring catheter-based treatment modalities for patients with severe isolated TR, aiming to mitigate risks associated with invasive surgical procedures.

ABBREVIATIONS

AF	Atrial fibrillation
ALT	Alanine transaminase
ASE	American Society of Echocardiography
AST	Aspartate transaminase
CABG	Coronary artery bypass grafting
EACVI	European Association of Cardiovascular Imaging
EF	Ejection fraction
EROA	Effective Regurgitant Orifice Area
NYHA	New York Heart Association
pro-BNP	Pro-brain natriuretic peptide
RV	Right ventricular
RVol	Regurgitation volume
STS	Society of Thoracic Surgeons
TEER	Transcatheter edge-to-edge repair
TR	Tricuspid regurgitation
TRI-SCORE	Tricuspid Regurgitation Impact Severity Score
TRILUMINATE	Trial to Evaluate Treatment With Abbott Transcatheter Clip Repair System in Patients With Moderate or Greater Tricuspid Regurgitation
TTE	Transthoracic echocardiography
TV	Tricuspid valve
VC	Vena contracta
XT	Extended reach
XTW	Extended reach wide

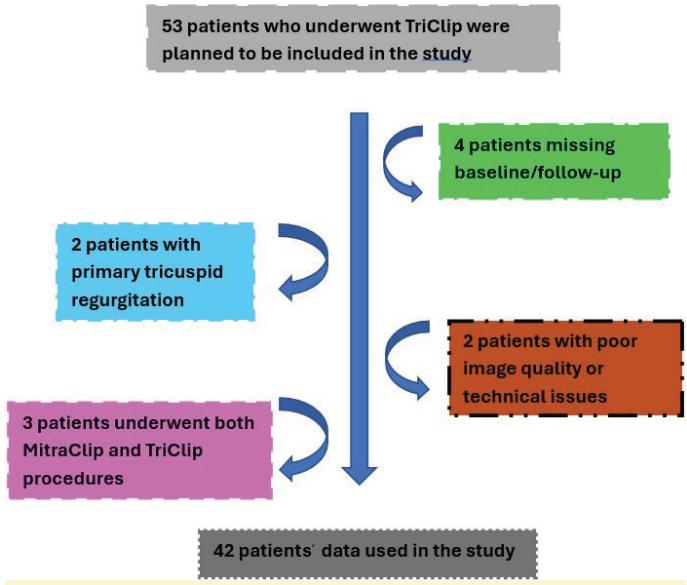

Figure 1. Flowchart of study subjects.

One such innovative approach is the utilization of transcatheter devices like the Triclip (Abbott, Chicago, IL, USA) system, designed specifically for the management of severe TR.[8] The TriClip device functions through an edge-to-edge repair mechanism analogous to the well-established MitraClip device used in mitral valve repair. Presently, edge-to-edge repair techniques stand out as the preferred transcatheter method for TR treatment, supported by evidence demonstrating substantial reductions in TR severity and symptomatic improvement post-procedure.[9-14] The TRILUMINATE (Trial to Evaluate Treatment With Abbott Transcatheter Clip Repair System in Patients With Moderate or Greater Tricuspid Regurgitation) study, a multicenter prospective investigation utilizing the TriClip system, reported significant reductions in TR severity levels, decreased hospitalization rates, and a notable downtrend in mortality rates following intervention.[10]

The primary objective of this study is to present Turkish-specific data regarding the outcomes of the tricuspid transcatheter edge-to-edge repair (TEER) procedure in patients diagnosed with massive and torrential secondary TR. These patients were selected based on having anatomical and clinical characteristics suitable for tricuspid TEER, absence of contraindications, and ongoing symptoms despite medical intervention.

Materials and Methods

Data were gathered from 53 patients in total who had TV TEER using the MitraClip or TriClip device in various centers in Türkiye between March 2021 and December 2023. The evaluation of the results of 11 patients was not possible for a variety of factors, as illustrated in Figure 1. The data of the remaining 42 symptomatic severe secondary TR patients (31 women, 11 men) were evaluated observationally.

The MitraClip and TriClip systems are both transcatheter devices designed for edge-to-edge repair of heart valves but are tailored for different anatomical and functional requirements. The MitraClip system, which was first designed for mitral valve repair

has been adapted for use in tricuspid valve repair in some cases. It consists of a cobalt-chromium clip covered with a polyester fabric, designed to grasp and approximate the leaflets to reduce regurgitation.

The TriClip system, on the other hand, is specifically engineered for tricuspid valve repair. It features a similar clip design to MitraClip but is optimized for the tricuspid valve's unique anatomical characteristics, such as the larger annulus and more complex leaflet structure. TriClip devices also allow for enhanced maneuverability and positioning within the tricuspid valve due to their tailored delivery system and clip sizes that better accommodate the tricuspid anatomy.

Patients in our study received either the MitraClip or TriClip device based on individual anatomical considerations and device availability. Comparative analysis of the outcomes based on the type of device used was conducted to understand any potential differences in procedural success and patient outcomes.

Patients with severe secondary or mixed type TR (massive or torrential) who are at high surgical risk (EuroScore ≥ 8% and Tricuspid Regurgitation Impact Severity Score (TRI-SCORE) ≥ 6), who are symptomatic despite optimal medical treatment, and who meet the anatomical and clinical eligibility for TriClip were included in the study. The patients were evaluated by a cardiac team consisting of a cardiologist specializing in valvular disease, a cardiovascular surgeon specializing in valve surgery, and an anesthesiologist. Those with comorbid diseases that would prevent the expected benefit from TR reduction after the TriClip procedure were excluded from the study. Patients with active endocarditis, rheumatic valve disease, a mean TV gradient above 5 mmHg, and intracardiac/inferior vena cava/femoral vein thrombus were also excluded.

Before the procedure, patients' suitability for tricuspid TEER was evaluated by 2D/3D transesophageal echocardiography. Patients were excluded from the study if they had rheumatic valve involvement, coaptation defect ≥ 10 mm, significant right ventricular dilatation and dysfunction, systolic pulmonary artery pressure > 65 mmHg, pulmonary vascular resistance > 4 Woods unit (WU), and if the cause of TR was primarily implantable cardioverter-defibrillator/pacemaker lead related.

Before the procedure, patients who presented with resistant hypervolemic status were treated to achieve euvolemic status with medical treatment, especially intravenous diuretic therapy. This approach positively changed the anatomy of the right heart chambers and the annulus size, reduced the large coaptation distance, and facilitated interventional treatment. Patients who were symptomatic and burdened despite diuretic treatment, with mild or moderate left ventricular dysfunction, preserved right ventricular function, no evidence of precapillary pulmonary hypertension, and only mild/moderate renal dysfunction, were considered to benefit from TEER and were included in the study.

Echocardiographic assessments adhered to current guidelines and were conducted using a Philips CX50 Ultrasound Machine equipped with S5-1 and X7-2t xMatrix probes for transthoracic echocardiography (TTE) and transesophageal echocardiography (TOE), respectively. Given the challenges associated with visualizing the TV apparatus, including thinner leaflets, variable anatomy, and wide coaptation distances compared to mitral procedures, all patients underwent both transesophageal and transgastric echocardiography.

The morphological characteristics of the TV were assessed using 2D and 3D TEE imaging from the transgastric short-axis view. Functional anatomy evaluations were performed using 3D TTE and 3D TOE. The severity grading of TR relied on color and spectral Doppler parameters. Patients were classified based on the Carpentier classification as Type I (annular dilatation) or Type IIIb (right ventricular/right atrial dilatation).

Specific indicators of massive and torrential TR included extensive systolic leaflet separation, reversed hepatic vein systolic flow via pulsed wave Doppler, and triangular (early peaking) continuous wave Doppler TR signals. Right ventricular (RV) and right atrial (RA) dilatation were considered supportive signs. As per American Society of Echocardiography (ASE) and European Association of Cardiovascular Imaging (EACVI) guidelines, severe TR was defined as an Effective Regurgitant Orifice Area (EROA) ≥ 0.40 cm^2 and Regurgitation Volume (RVol) ≥ 45 mL. However, recognizing that patients undergoing transcatheter TV intervention often present with anatomical failures exceeding the typical EROA threshold, an expanded classification now includes "massive" and "severe" TR categories.

Quantitative assessments of TR severity involved estimating the anatomical regurgitant orifice area and quantifying regurgitation volume (RVol) via vena contracta measurements. Massive TR was characterized by a vena contracta (VC) width ≥ 9 mm in two orthogonal 2-dimensional views. Given the non-circular coaptation zone of TR, 3D color evaluation complemented traditional 2D measurements to ensure accuracy in assessing TR severity.

Offline image analysis was conducted to determine the maximum VC, categorizing TR into three severity groups: severe (VC ≥ 7 mm), massive (VC 14–20 mm), and torrential (VC ≥ 21 mm). Additional indicators of severe TR included a coaptation gap > 8.5 mm and mild tethering at the central jet location. Evaluation encompassed various echocardiographic views, including the 4-chamber view, mid-esophageal (0-30°) and deep esophageal (0-30°) axes, and the posterior, septal, and anterior TV leaflets for TEER, tricuspid coaptation gaps, regurgitant orifice location, and chordal anatomy, particularly in the 2-chamber and transgastric (30-60°) short-axis views.

Patients were monitored in the coronary intensive care unit for the first 24 hours after the procedure and then transferred to the cardiology service if deemed necessary. Post-procedure follow-ups were conducted before discharge and at the first month. Subsequent follow-ups were left to the physician's discretion, with no specific protocol followed.

In addition to assessing baseline clinical and echocardiographic parameters, the study also includes a one-month follow-up evaluation and comparative analysis based on the type of device utilized during the TEER procedure. The results reported include in-hospital data, 30-day data, and median follow-up data of 11 months. Early and late outcomes were analyzed to determine any differences in the results over time. As stated in the results,

differences between early and late outcomes were clarified, showing that while some improvements were immediate, others became evident only at later follow-ups. This distinction helps in understanding the progression and sustained impact of the TEER procedure on patient health.

The research followed the ethical guidelines specified in the Declaration of Helsinki. There was no utilization of AI-powered tools such as Large Language Models (LLMs), chatbots, or image generators in developing this article. The study received approval from Istanbul Yeni Yüzyıl University Science, Social and Non-invasive Health Sciences Research Ethics Committee on March 4, 2023, with reference number 2024/03-1233, under the supervision of the Scientific Research Applications Review Commission. Written informed consent was obtained from all participants involved in the study.

Statistical Analysis

The distribution of parameters was evaluated using the Shapiro-Wilk test. Continuous variables were presented as either mean and standard deviation or median and interquartile range, depending on the distribution. Categorical variables were represented as frequency and percentage. Group comparisons were conducted using either the χ^2 test or Fisher's exact test for categorical variables, and the Student's t-test or Mann-Whitney U test for continuous variables. Paired comparisons between measurements at two different time points were assessed using the paired Student's t-test or Wilcoxon signed-rank test, as appropriate. Statistical significance was determined using p-values, with a threshold set at 0.05. All statistical analyses were performed using SPSS software version 25.0 (SPSS, Inc, Chicago, IL, USA).

Results

The study included 42 patients with an average age of 70.7 (± 14.0) years, with 31 (73.8%) being female. All patients were categorized as high risk according to EuroScore II and TRI-SCORE assessments. Based on the New York Heart Association (NYHA) functional classification, all patients were classified as class 3 or 4, with the majority falling into NYHA class III, comprising 26 patients (61.9%). Loop diuretics were used by all patients, and the most prevalent comorbidities were chronic renal failure (88.1%) and AF (85.7%). Hepatic failure (Child-Pugh B and C) was observed in 6 patients, while only 2 patients (4.8%) had an implantable cardiac device.

The median follow-up time for the total population was 11.5 (8.5-16.25) months. The median total procedure time was 90 (72.5-120) minutes, and the median device implantation time was 35 (24.8-48) minutes. Among the patients, 29 (69%) were treated using the TriClip device, while 13 (31%) received treatment with the MitraClip device. Regarding clip position, isolated anteroseptal placement was utilized in 28 (67%) patients, isolated posterior placement in 3 (8%) patients, and a combination of anteroseptal and posterior septal placement in 11 (25%) patients. Clips of 55% Extended Reach (XT) and 45% Extended Reach Wide (XTW) types were employed, resulting in technical and functional success achieved in all patients. A comprehensive overview of demographic and clinical characteristics is provided in Table 1.

Table 1. Baseline Clinical Characteristics of the Study Population

Patient Characteristics	Value
Age (years)	70.7 ± 14.0
Sex (female%)	31 (73.8)
BMI (kg/m^2)	25.9 ± 2.7
EuroScore II	20.6 (8.4-42.1)
TRI-SCORE	8.7 (6.4-11.6)
Systolic Blood Pressure (mmHg)	118.9 ± 14.4
Diastolic Blood Pressure (mmHg)	75.7 ± 9.7
Heart Rate (bpm)	82.5 ± 11.4
Furosemide Dose (mg)	90 ± 21.8
Creatinine (mg/dL)	1.4 ± 0.5
GFR (ml/min/1.73 m^2)	46.3 ± 16.7
ALT (IU/L)	45 (34-59.8)
AST (IU/L)	42 (33.8-64)
Pro-BNP (pg/mL)	893.5 (602.8-1302)
Hemoglobin (g/dL)	11.1 ± 1.7
Hematocrit (%)	33.4 ± 4.8
NYHA Functional Classification (%)	
Class 3	26 (61.9)
Class 4	16 (38.1)
Pretibial Edema	
None-Mild	14 (33.3)
Moderate-Severe	28 (66.7)
Ascites	8 (19.0)
Beta-Blocker	32 (76.2)
ACEi/ARB	22 (52.4)
Sacubitril-Valsartan	1 (2.4)
SGLT2 Inhibitor	0 (0)
MRA	29 (69.0)
Loop Diuretics	42 (100)
Anticoagulation	
Warfarin	19 (45.2)
NOAC	14 (33.3)
Acetylsalicylic Acid	12 (28.6)
ICD/CRT	2 (4.8)
HT	23 (54.8)
DM	10 (23.8)
CAD	12 (28.6)
Heart Failure	29 (69.0)
CRF	37 (88.1)
Hepatic Failure (Child-Pugh B and C)	6 (14.3)
AF	36 (85.7)
Anemia	25 (59.7)
Device Implantation Duration (min)	35 (24.8-48)
Total Procedure Duration (min)	90 (72.5-120)
Number of Clips	
1	22 (52.4)
2	18 (42.9)
3	2 (4.8)
Device Type	
TriClip	29 (69.0)
MitraClip	13 (31.0)
Technical Success	42 (100)
Functional success	42 (100)
Follow-up Time	11.5 (8.5-16.25)

ACE, Angiotensin-Converting Enzyme; AF, Atrial Fibrillation; ARB, Angiotensin II Receptor Blocker; BMI, Body Mass Index; BNP, Brain Natriuretic Peptide; CAD, Coronary Artery Disease; CRF, Chronic Renal Failure; CRT, Cardiac Resynchronization Therapy; DM, Diabetes Mellitus; GFR, Glomerular Filtration Rate; HT, Hypertension; ICD, Implantable Cardioverter Defibrillator; IQR, Interquartile Range; MRA, Mineralocorticoid Receptor Antagonist; NYHA, New York Heart Association; SGLT2, Sodium-Glucose Cotransporter-2; STS, Society of Thoracic Surgeons.
*Values are mean ± SD, median (IQR), or n [n/N if missing data] (%).
*Interquartile range [25% percentile-75% percentile].

Table 2. Baseline Echocardiographic Characteristics of the Study Population

Echocardiographic Characteristics	Value
LVEF%	49.5 ± 11.5
LVEDD (mm)	51.9 ± 3.9
LVESD (mm)	38.4 ± 5.4
LVEDV (ml)	164.6 ± 44.2
LAD (mm)	48.6 ± 2.7
LAVI (mL/m^2)	44.4 ± 11.5
RVEF%	40.1 ± 4.7
RAD (mm)	48.8 ± 2.5
RVD (mm)	45.3 ± 2.2
PASP (mmHg)	48.8 ± 4.8
TR Severity	
Massive	24 (57.1)
Torrential	18 (42.9)
TR Characteristics	
Central	32 (76.2)
Eccentric	10 (23.8)
TR Vena Contracta (mm)	19.7 ± 4.6
TR Etiology	
Functional	41 (97.6)
Mix (Functional + Degenerative)	1 (2.4)
Prosthetic Valve	
Mitral valve replacement	13 (31.0)
Aortic valve replacement	4 (9.5)

EF, Ejection Fraction; EROA, Effective Regurgitant Orifice Area; LAD, Left Atrial Dimension; LAVI, Left Atrial Volume Index; LVEDD, Left Ventricular End-Diastolic Dimension; LVEDV, Left Ventricular End-Diastolic Volume; LVESD, Left Ventricular End-Systolic Dimension; MR, Mitral Regurgitation; PASP, Pulmonary Artery Systolic Pressure; RAD, Right Atrial Diameter; RVA, Right Ventricular Diameter; RF, Regurgitation Fraction; TR, Tricuspid Regurgitation.
*Values are mean ± SD, median (IQR), or n [n/N if missing data] (%). Interquartile range [25% percentile-75% percentile].

The mean left ventricular ejection fraction (EF%) of the patients before the procedure was 49.5%, while the right ventricular EF% was 40.1%. The mean pulmonary artery systolic pressure (PASP) was measured at 48.8 (± 4.8) mmHg among the patients. TR was categorized as either massive (24 patients) or torrential (18 patients) in all individuals, with central TR noted in 32 patients (76.2%). Functional TR was predominant, observed in 41 patients, whereas only 1 patient had a mixed etiology. Detailed echocardiographic characteristics can be found in Table 2.

Following tricuspid valve transcatheter edge-to-edge repair, a significant reduction in functional TR was observed in all 42 secondary TR patients with massive or torrential TR. Post-procedure assessments revealed mild to moderate TR in 34 patients (88.1%), while severe TR persisted in 5 patients (11.9%), as illustrated in Figure 2.

Following the procedure with the TriClip device, mild to moderate TR was observed in 25 patients, while severe TR was observed in 4 patients. In comparison, after the procedure with the MitraClip device, mild to moderate TR was observed in 12 patients, with severe TR observed in 1 patient (Figure 3).

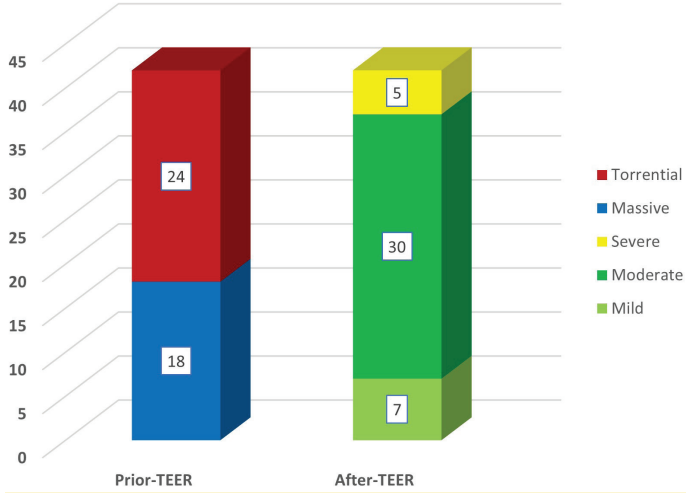

Figure 2. Bar graph showing the distribution of tricuspid regurgitation severity before and after transcatheter edge-to-edge repair.

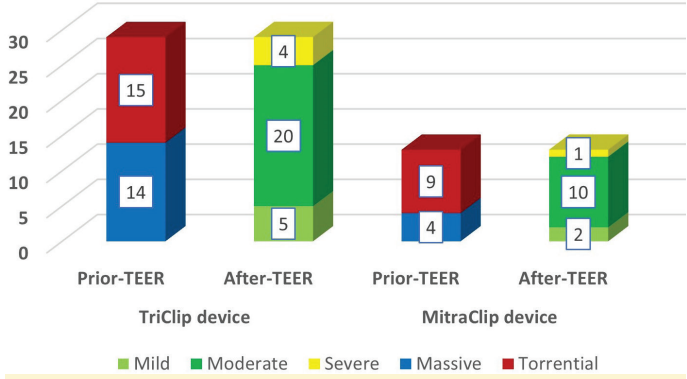

Figure 3. Bar graph showing the distribution of tricuspid regurgitation severity before and after transcatheter edge-to-edge repair by device type.

In the first month after the procedure, there was a notable improvement in functional capacity, with only 4 patients remaining in NYHA class 3, 28 patients improving to NYHA class 2, and 8 patients achieving NYHA class 1. This improvement reflects a significant enhancement in patients' functional status following transcatheter tricuspid edge-to-edge repair.

During the median follow-up period of 11.5 (8.5-16.25) months, rehospitalization occurred in 10 patients (23.8%), while mortality was observed in 3 patients (7.1%). Among the 3 deaths, 2 patients died due to heart failure, and 1 patient died because of acute renal failure. Rehospitalization was primarily due to worsening heart failure in 6 patients, while 2 patients were rehospitalized due to supraventricular arrhythmias, and 2 patients were rehospitalized for non-cardiac causes. Further details regarding rehospitalization and mortality timelines are depicted in Figure 4.

A comparison was conducted based on the device subtypes utilized in the study. The median device implantation duration with the TriClip device was 40 minutes (25-55), while with

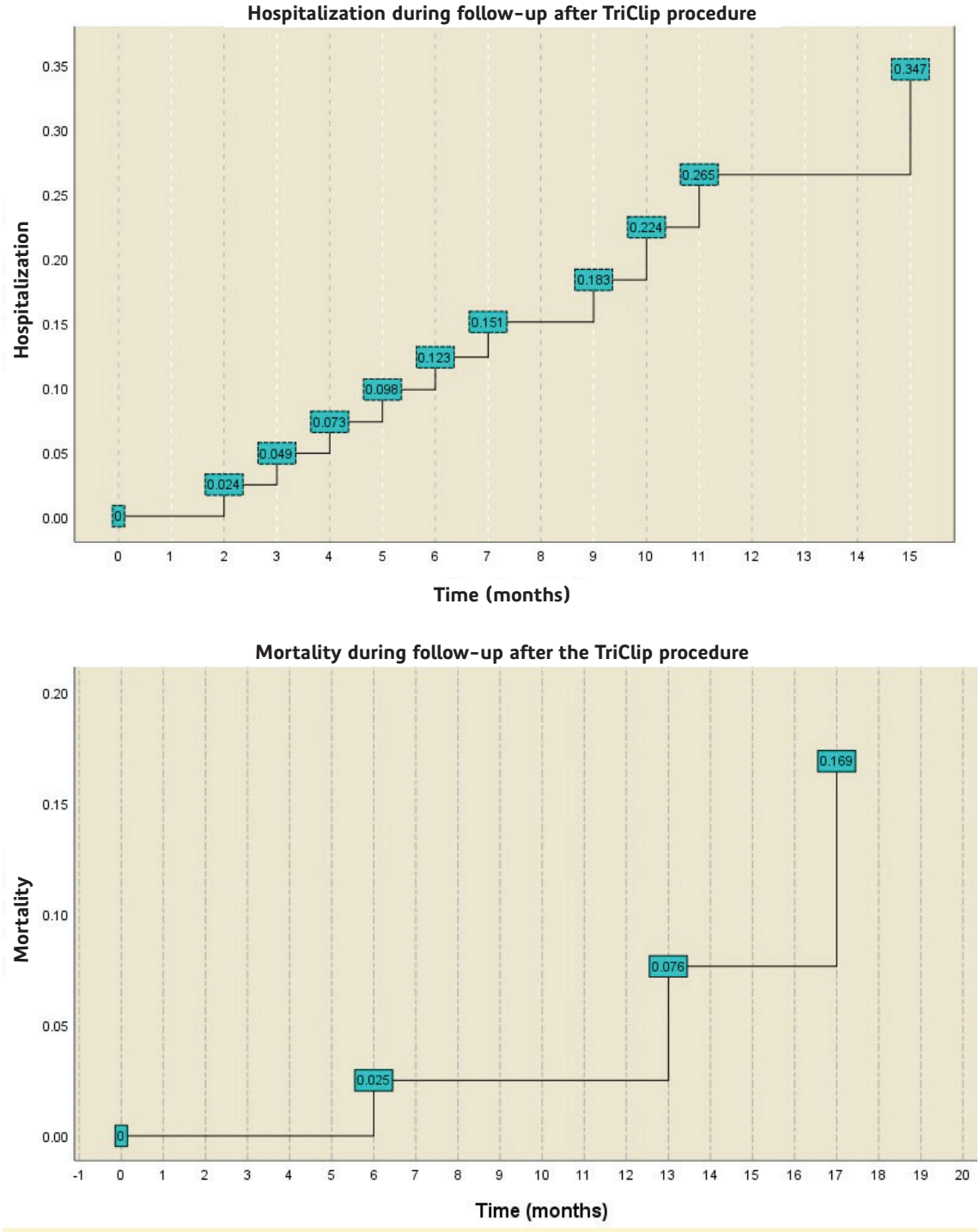

Figure 4. Timeline and data on rehospitalization and mortality during follow-up after transcatheter edge-to-edge repair.

the MitraClip device, it was 35 minutes (20-45) (P = 0.10). Additionally, the median total procedure duration with the TriClip device was 95 minutes (65-120), whereas with the MitraClip device, it was 85 minutes (60-115) (P = 0.47). Notably, more than one clip was used in 14 patients (48.3%) with the TriClip device and in 6 patients (46.2%) with the MitraClip device.

There were no cases of mortality during hospitalization following either device implantation. However, acute renal failure was observed during hospitalization in 2 patients using the MitraClip device, while no cases were reported in patients using the TriClip device (P = 0.03).

Regarding post-procedure outcomes, rehospitalization rates were noted in 6 patients (20.7%) with the TriClip device and in 4 patients (30.8%) with the MitraClip device. The hazard ratio (HR) for rehospitalization was calculated as 0.72 (95% confidence interval [CI]: 0.084-6.35, P = 0.61). Mortality during

Table 3. Comparison of Echocardiographic and Clinical Characteristics Before and After One Month Following the Procedure According to Device Type

Patient Characteristics	TriClip Device (n = 29)		*P*	MitraClip Device (n = 13)		*P*
	Pre-Procedure	Post-Procedure		Pre-Procedure	Post-Procedure	
LVEF%	53.3 ± 8.7	53.5 ± 8.5	0.540	41.1 ± 12.9	42.2 ± 13.2	0.420
RVEF%	39.8 ± 4.8	40.1 ± 4.2	0.125	40.7 ± 4.8	41.3 ± 4.5	0.165
TV Gradient (mmHg)	2.2 ± 0.4	2.2 ± 0.8	0.765	2.0 ± 0.6	1.8 ± 0.4	0.560
PASP (mmHg)	47.2 ± 4.1	36.2 ± 3.7	<0.001	52.4 ± 4.6	42.2 ± 5.9	<0.001
Creatinine (mg/dL)	1.3 ± 0.2	1.1 ± 0.2	<0.001	1.6 ± 0.8	1.0 ± 0.2	<0.001
GFR (ml/min/1.73 m^2)	46.8 ± 13.8	57.2 ± 11.5	<0.001	45.2 ± 22.4	64.7 ± 19.8	0.004
Hemoglobin (g/dL)	10.9 ± 1.9	10.6 ± 1.8	0.890	11.4 ± 2.0	11.2 ± 2.2	0.855
ALT (IU/L)	46 (32-80)	32 (29-52.5)	<0.001	43 (36.5-48)	40 (37-48)	<0.001
AST (IU/L)	42 (32.5-78)	30 (28-53)	<0.001	45 (39-63)	39 (33-51)	<0.001
Pro-BNP (pg/mL)	784 (563-986)	451 (343.5-632)	<0.001	1123 (869-4125)	613 (393-1161)	<0.001
Furosemide Dose (mg)	90.3 ± 19.0	33.8 ± 9.4	0.014	89.2 ± 27.8	36.9 ± 13.8	0.029
NYHA Functional Class	3.3 ± 0.4	1.7 ± 0.2	<0.001	3.4 ± 0.3	1.8 ± 0.2	<0.001

ALT, Alanine transaminase; AST, Aspartate transaminase; GFR, Glomerular filtration rate; LVEF Left ventricular ejection fraction; PASP, Pulmonary artery systolic pressure; pro-BNP, Pro-brain natriuretic peptide; RVEF, Right ventricular ejection fraction; TV Tricuspid Valve.

the follow-up period was observed in 2 patients (6.9%) with the TriClip device and in 1 patient (7.7%) with the MitraClip device, resulting in an HR of 1.07 (95% CI: 0.095-11.95, *P* = 0.96).

A comparison was made between patients using the TriClip and MitraClip devices before and after the procedure regarding echocardiographic and clinical characteristics. Both groups exhibited a significant decrease in PASP, creatinine, alanine transaminase (ALT), aspartate transaminase (AST), pro-brain natriuretic peptide (pro-BNP) levels, furosemide dose, and NYHA functional class at the one-month follow-up, as detailed in Table 3.

Discussion

Tricuspid regurgitation is a common condition with a poor prognosis, and historically, treatment options have been limited to diuretics and surgery.[15] Notably, redo surgery for symptomatic TR patients who have undergone prior coronary artery bypass grafting (CABG) or mitral valve surgery carries significant risks.[7] In a study by Dreyfus et al.,[16] the early and mid-term outcomes of patients undergoing isolated tricuspid surgery were examined, focusing on the impact of patient clinical and valve structures on survival. The study found that isolated TV surgery was associated with high mortality rates; however, mortality and morbidity were more closely correlated with patient clinic factors (NYHA 3/4 RV failure symptoms), echocardiographic findings (moderate/severe RV dysfunction and dilatation), and laboratory markers (low-risk factors) rather than TR etiology and mechanism.

The existing risk assessment tools, such as the Society of Thoracic Surgeons (STS) and logistic EuroSCORE/EuroSCORE-II, are not specifically tailored for TV surgeries, highlighting the need for an updated mortality risk scoring system.[16] Dreyfus et al.[17] introduced the TRI-SCORE risk score model to predict mortality following isolated TV surgery, comprising 8 variables with a total score ranging from 1 to 12. Scores of 6 and above indicate a high surgical risk. Accurate risk assessment using TRI-SCORE is essential for optimizing outcomes in patients undergoing TV surgical interventions.

Therefore, the TriClip procedure has emerged as a promising treatment option for this group of patients whose chances of effective treatment are limited. However, transcatheter methods in the treatment of TR have some difficulties. The TV consists of three leaflets, and excessive dilatation of the tricuspid annulus and the resulting leaflet coaptation defect are some of these difficulties. Echo images are often suboptimal. Additionally, previous mitral and aortic valve surgeries pose a further challenge for imaging in these patients.[18] However, these difficulties are overcome with increasing experience and the use of different echocardiographic devices (such as intracardiac echocardiography) and modalities.

The effectiveness and safety of the TriClip procedure have been demonstrated in many studies. Nickenig et al.[19] investigated 64 patients who underwent TV repair using the MitraClip device and published their 30-day follow-up results in 2017. As a result of this study, it has been shown that edge-to-edge repair of TR with the MitraClip device is feasible and safe. The most important study in this field is the TRILUMINATE (Trial to Evaluate Treatment With Abbott Transcatheter Clip Repair System in Patients With Moderate or Greater Tricuspid Regurgitation) study.[10] The study was planned as a prospective, single-arm study with a total of 85 patients from 21 centers in the USA and Europe. The included patients had moderate to severe TR and did not need surgery for the left heart. Exclusion criteria were severe pulmonary hypertension and left ventricular EF value < 20%. Seventy-five percent of the patients have NYHA III-IV heart failure symptoms, and 33% have previous heart surgery. "Implant success" evaluated immediately after the procedure was measured as 100%. In other words, clips could be placed between the leaflets in all planned patients. At 30 days, the primary efficacy endpoint was achieved with at least a one-degree reduction in TR in 86.6% of patients. The echocardiographic evaluation showed that the tricuspid regurgitant volume decreased, the annular diameter decreased, the mean gradient improved, and thus cardiac output improved.

Eighty percent of patients were evaluated at NYHA I-II symptom level 30 days after TriClip. Considering the safety endpoints, no patient experienced death, myocardial infarction (MI), or stroke, and no patient required open surgery. New-onset renal failure developed in only one patient, and a > 5 mmHg gradient was measured in the TV in four patients. Although it was a small study with 85 patients and randomized controlled studies are needed, it was very promising that the study reached its primary endpoint at a high rate and had a low complication rate. Finally, 2-year follow-up results were announced. At the 2-year follow-up, TR decreased by at least one grade in 85.4% of patients, with a significant reduction in hospitalizations (49%). Additionally, improvements in KCCQ-OS (The Kansas City Cardiomyopathy Questionnaire Score) continued for 2 years.[10]

In our study, procedures were performed using both the MitraClip device and the TriClip device. All patients were secondary severe TR patients with a high surgical risk profile. Prior to the procedure, all patients exhibited poor NYHA III or IV functional capacity. Consistent with expectations, renal failure and AF were among the most common comorbid conditions observed in these patients. Procedure success, defined as implant success and at least a one-degree reduction in TR, was 100%, aligning with findings from previous studies. Notably, no mortality occurred during the procedure, and emergency surgery was not required. Rehospitalization rates were better than anticipated during the approximately one-year follow-up period. This study underscores the effectiveness and safety of the TEER method for severe secondary TR. Furthermore, our findings demonstrate the successful execution of these procedures in our country.

Although our study did not show a significant difference between the MitraClip and TriClip devices, it is essential to consider findings from other significant studies. The TRILUMINATE study, evaluating the TriClip device, demonstrated promising outcomes in patients with severe TR. At 30 days, 86.6% of patients achieved at least a one-grade reduction in TR, similar to our findings of high procedural success. The study reported no mortality, MI, or stroke within 30 days post-procedure, aligning with our zero mortality rate during the intervention. Long-term outcomes from TRILUMINATE indicated that 85.4% of patients maintained at least a one-grade reduction in TR at two years, with a 49% reduction in hospitalizations, underscoring the potential durability of the TriClip repair.[10]

The BRIGHT Registry (Broad MitraClip Registry for Analyzing Real-world Outcomes with the MitraClip System), a real-world observational study, provides valuable insights into the MitraClip device for tricuspid valve repair. It included a broader patient population with varying comorbidities and TR severity, reflecting real-life clinical scenarios. The registry highlighted substantial reductions in TR severity and improvements in symptoms and quality of life, consistent with controlled studies. The real-world data also emphasized the low incidence of procedural complications, reinforcing the safety profile of TEER in diverse clinical settings.[14]

Our study, alongside the TRILUMINATE study and BRIGHT Registry, contributes to the growing evidence supporting TEER methods for tricuspid valve repair. While we observed no significant differences between the MitraClip and TriClip devices, the complementary findings from these larger studies underscore the importance of patient selection and procedural expertise. To further validate our results and explore potential differences, larger-scale randomized controlled trials with extended follow-up durations are necessary. These studies should refine patient selection criteria and optimize procedural techniques to enhance outcomes for patients with severe TR.

While the study provides valuable insights into the effectiveness and safety of tricuspid valve TEER procedures, several limitations should be acknowledged. Firstly, the sample size of the study, comprising 42 patients, may limit the generalizability of the findings to broader populations. Additionally, the observational nature of the study design and the lack of a control group hinder the establishment of causal relationships between the TriClip or MitraClip devices and the observed outcomes. Moreover, the relatively short median follow-up period of 11.5 months may not capture long-term complications or the durability of the procedures. The exclusion of patients with certain comorbidities and anatomical characteristics may introduce selection bias, impacting the external validity of the results. Lastly, the reliance on echocardiographic assessments, while standard practice, may have inherent limitations in accurately capturing all aspects of TR severity and functional outcomes. These limitations warrant cautious interpretation of the study findings and emphasize the need for larger-scale randomized controlled trials with longer follow-up durations to validate the efficacy and safety of transcatheter TEER methods comprehensively.

Conclusion

In conclusion, the study highlights the emerging role of transcatheter techniques, particularly the TriClip procedure, in managing severe TR in high surgical risk patients. The initial data from Türkiye corroborates findings from international studies, demonstrating the efficacy and safety of TriClip alongside the MitraClip device in achieving significant reductions in TR severity and improving patient outcomes. Notably, the procedure success rate was 100%, with no mortality observed during the intervention, indicating a favorable risk-benefit profile. The study underscores the importance of accurate patient selection based on clinical and echocardiographic criteria, as well as the need for ongoing evaluation and follow-up to assess long-term outcomes. These findings contribute to the growing body of evidence supporting TEER methods as viable alternatives to traditional surgical interventions, particularly in patients with limited treatment options and high surgical risks associated with redo surgeries. Further research and randomized controlled trials are warranted to validate these outcomes and refine patient selection criteria for optimal clinical outcomes.

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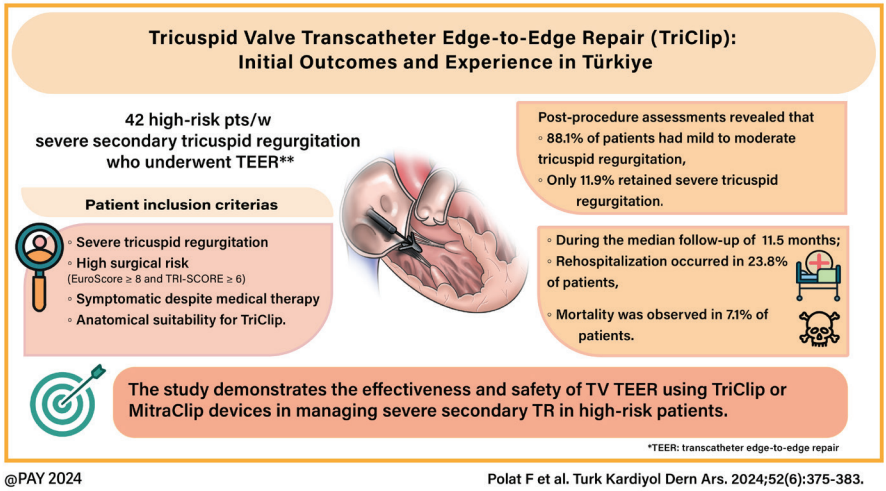

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