

Prevalence and Impact of Diabetes Mellitus in Patients Undergoing Transcatheter Tricuspid Valve Repair Using the Edge-to-Edge Technique

INTRODUCTION

Diabetes mellitus (DM) is prevalent among patients with cardiovascular disease and is associated with a worse outcome after interventional valve procedures.¹ Transcatheter-based therapies for tricuspid regurgitation, including edge-to-edge repair (TEER), have emerged as an alternative to surgery in high-risk patients with severe tricuspid regurgitation.^{2,3} Previous studies investigating the prognostic impact of DM after mitral TEER have produced conflicting results.^{4,5} Although 15-22% of patients enrolled in contemporary tricuspid TEER trials had DM,^{6,7} no study has directly evaluated the influence of DM on outcomes after tricuspid TEER. This study aims to assess the prevalence and impact of DM in a real-world cohort of patients undergoing tricuspid TEER.

METHODS

All consecutive patients who underwent tricuspid-TEER between November 2020 and March 2023 were retrospectively included. All patients presented with symptomatic severe tricuspid regurgitation (TR) and were evaluated by an interdisciplinary heart team, which deemed them unsuitable for surgery. Procedures were performed following established techniques.⁸ Procedural success was defined as implantation of at least 1 clip with ≥ 1 -grade reduction in TR.

In-hospital outcomes included procedural success and all-cause mortality. One-year outcomes included all-cause mortality, hospitalization for acute heart failure (HF), and the composite of both. Echocardiographic follow-up was conducted in survivors at 1 year. Follow-up information was obtained from hospital records, treating cardiologists, patients, or family members. For deceased patients, dates of death were confirmed through primary care physicians.

The study was a retrospective observational analysis of routinely collected clinical data. According to local regulations, ethics committee approval was not required and was waived. The study was conducted in accordance with the Declaration of Helsinki.

Continuous variables are expressed as mean \pm standard deviation and compared using the independent *t*-test. Categorical variables are expressed as counts (percentages) and compared using Pearson's χ^2 test. Statistical significance was defined as $P < .05$.

RESULTS

A total of 105 patients were included. Among them, 29 patients (27.6%) had DM including 13 patients with insulin therapy. Baseline characteristics and echocardiographic parameters were comparable between both groups (Table 1).

Intra-Hospital Outcome

Procedural success was achieved in 92.4% of patients and did not differ significantly between those with and without DM (96.6% vs. 90.8%; $P = .320$). The number and position of implanted clips, mean transvalvular gradients, and postprocedural

SCIENTIFIC LETTER

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Table 1. Clinical Characteristics and Outcome of the Study Population

	All (n=105)	DM (n=29)	Non-DM (n=76)	P
Age, years	80 ± 6.4	78.8 ± 7.2	80.5 ± 6.1	.205
Males, n (%)	42 (40)	9 (31)	33 (43.4)	.247
HTN, n (%)	87 (82.9)	27 (93.1)	60 (78.9)	.085
Atrial fibrillation, n (%)	93 (88.6)	26 (89.7)	67 (88.2)	.829
Chronic renal failure, n (%)	82 (78.1)	25 (86.2)	57 (75)	.214
PAD	9 (8.6)	2 (6.9)	7 (9.2)	.705
COPD	17 (16.2)	6 (20.7)	11 (14.5)	.439
CAD, n (%)	60 (57.1)	18 (62.1)	42 (55.3)	.529
Previous cardiac surgery	10 (9.5)	3 (10.3)	7 (9.2)	.859
Previous M-TEER, n (%)	25 (23.8)	6 (20.7)	19 (25)	.643
Previous TAVI	3 (2.9)	1 (3.4)	2 (2.6)	.822
CIED	25 (23.8)	10 (34.5)	15 (19.7)	.458
LV-EF, %	53.8 ± 10.6	54.8 ± 12	53.8 ± 10.6	.673
TAPSE, mm	20.7 ± 5.1	20.9 ± 5.6	20.6 ± 5.0	.764
RVEDD, mm	45.8 ± 5.5	45.0 ± 4.1	46.2 ± 5.9	.379
TR severity, n (%)				.450
I	-	-	-	
II	-	-	-	
III	60 (57.2)	17 (58.6)	43 (56.6)	
IV	41 (39)		29 (38.2)	
V	4 (3.8)	0	4 (5.3)	
Intrahospital outcome				
Success of the procedure	97 (92.4)	28 (96.6)	69 (90.8)	0.320
Intrahospital mortality, n (%)	9 (8.6)	2 (6.9)	7 (9.2)	0.705
TR severity				0.231
I	51 (48.6)	19 (65.5)	32 (42.1)	
II	43 (41)	9 (31)	34 (44.7)	
III	6 (5.7)	1 (3.4)	5 (6.6)	
IV	4 (3.8)	0 (0)	4 (5.3)	
V	1 (1)	0 (0)	1 (1.3)	

DM, diabetes mellitus; TEER, transcatheter edge-to-edge repair, HTN, arterial hypertension, PAD, peripheral artery disease, CAD, coronary artery disease, CIED, cardiac implantable electronic devices, COPD, chronic obstructive pulmonary disease, LV-EF, left ventricular ejection fraction, TAPSE, tricuspid annular plane systolic excursion, RVEDD, right ventricular end diastolic diameter, TR, tricuspid regurgitation.

TR severity were also comparable. In-hospital mortality rates were similar (6.9% vs. 9.2%; $P = .705$) (Table 1).

One-Year Outcome

At 1 year, all-cause mortality did not differ significantly between patients with and without DM (29.6% vs. 23.4%; $P = .535$). Heart failure (HF) hospitalization occurred in 48.1%

of patients with DM and 35.9% of those without ($P = .277$). The composite endpoint of death or HF hospitalization was likewise comparable. Among 1-year survivors, TR severity remained similar between groups (Figure 1).

DISCUSSION

In this real-world cohort undergoing tricuspid TEER, nearly 1-third of patients had DM—slightly higher than proportions observed in TRILUMINATE and other multicenter cohorts.^{6,7} Our data demonstrate that DM does not influence procedural success, early outcomes, or 1-year prognosis after tricuspid TEER.

Prior studies evaluating mitral TEER have yielded inconsistent findings: while the COAPT trial post-hoc analysis suggested worse outcomes in patients with DM,⁴ other registries found no significant differences.⁵ Importantly, no previous study has specifically addressed the impact of DM after tricuspid TEER. Our findings indicate that DM should not be

HIGHLIGHTS

- Diabetes was present in 27.6% of patients undergoing tricuspid transcatheter edge-to-edge repair (TEER).
- Procedural success was similar in diabetics and non-diabetics.
- One-year mortality did not differ by diabetes status.
- Heart failure hospitalization at 1 year was comparable.
- Tricuspid TEER appears safe and effective in diabetic patients.

One Year-Outcome

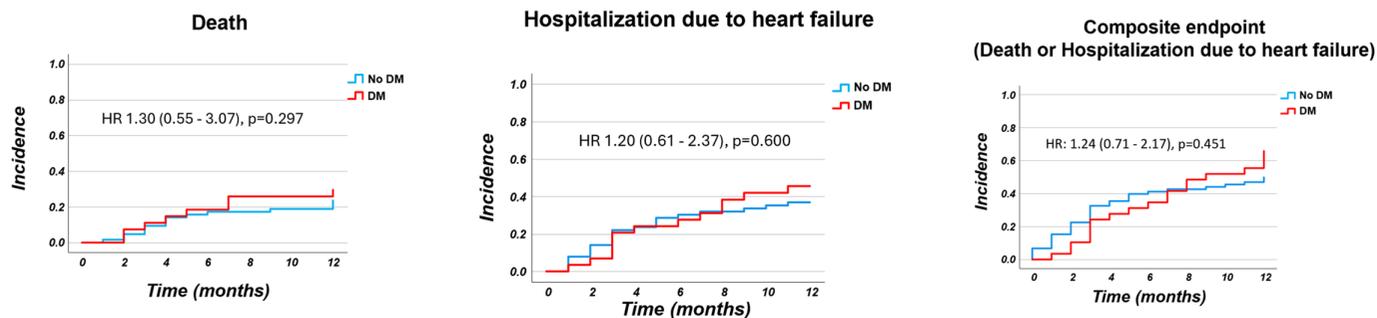


Figure 1. Kaplan–Meier curves comparing 1-year outcomes between patients with and without diabetes mellitus (DM).

considered a negative prognostic factor when selecting candidates for tricuspid TEER.

The relatively high 1-year mortality observed in our cohort reflects the advanced age and extensive comorbidity burden typical of patients referred for tricuspid intervention. These findings align with previously published registries and meta-analyses evaluating transcatheter tricuspid interventions.^{3,9,10}

Limitations

Despite being the first study to assess the impact of DM in patients undergoing tricuspid TEER in a real-world cohort, we acknowledge that it has limitations. The main limitation of the study is its retrospective observational nature. In addition, and as in any registry study, selection bias cannot be excluded. Last, the study suffers from the usual shortcomings of a single-centre study.

CONCLUSION

Diabetes mellitus is common among patients undergoing tricuspid TEER but does not adversely affect procedural success, in-hospital outcomes, or one-year mortality or HF hospitalization.

Ethics Committee Approval: Ethics committee approval was waived due to the retrospective observational nature of the study. The study was conducted in accordance with the Declaration of Helsinki.

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

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