REVIEW ARTICLE

Impact of Concomitant Mitral Regurgitation on Outcomes after Transcatheter Aortic Valve Implantation for Aortic Stenosis: A Systematic Review and Meta-Analysis

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Abstract

Introduction: Moderate-to-significant mitral regurgitation (MR) is frequently observed in patients with severe symptomatic aortic stenosis who undergo transcatheter aortic valve replacement (TAVR). However, its prognostic significance remains uncertain, as earlier trials often excluded MR, and contemporary guidelines are conflicting. This meta-analysis quantified the impact of preprocedural MR on mortality, stroke, bleeding, and rehospitalization after TAVR and explored whether age, sex, or left ventricular ejection fraction (LVEF) modified the mortality risk. **Materials and Methods:** PubMed and Cochrane Library were searched until October 15, 2023, according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. English-language studies comparing TAVR outcomes in patients with and without MR were included in this review. The risk of bias was assessed using the Newcastle-Ottawa and RoB 2.0 tools. Pooled effects were estimated using Mantel-Haenszel random-effects models, with subgrouping, sensitivity analyses, and meta-regression for age, male gender, and LVEF. **Results:** Twenty-four studies (n = 23,796; mean age = 81.8; 45.6% male) met the criteria, with no evident publication bias and high methodological quality. Baseline MR was associated with higher all-cause mortality at 30 days (relative risk [RR]: 1.68, 95% confidence interval [CI]: 1.31–2.15), 6 months (RR: 1.94, 95% CI: 1.30–2.90), 1 year (RR: 1.75, 95% CI: 1.38–2.22), and 2 years (RR: 95% CI: 1.30, 1.08–1.56); the excess risk was consistent in observational studies, while RCT subgroup estimates were neutral at longer follow-up. MR was not associated with stroke (RR: 0.83, 95% CI: 0.67–1.04) or bleeding (RR: 0.95, 0.88–1.04) but was linked to increased rehospitalization (RR: 1.79, 1.06–3.04). Meta-regression analysis showed no correlation between mortality and age, sex, or LVEF. **Conclusion:** Concomitant MR identifies a high-risk TAVR population warranting enhanced assessment and follow-up. Future work should stratify by MR severity and etiology and evaluate post-TAVR MR evolution to refine patient selection and mitral intervention strategies.

Key words: Aortic stenosis, clinical outcomes, mitral regurgitation, mortality, transcatheter aortic valve replacement

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INTRODUCTION

Aortic stenosis (AS) and mitral regurgitation (MR) are the most prevalent structural heart diseases, where moderate-to-significant MR tends to be a common finding in patients with severe, symptomatic AS undergoing transcatheter aortic valve replacement (TAVR). Previous trials on TAVR excluded patients with MR; however, with its recent widespread use, concerns have been into the prognostic value of concomitant MR. Data suggests this association to be present in almost a third of the patients with severe AS.[1-3] Several studies have identified significant MR to be a risk factor for mortality in patients post-TAVR.[3] This presents a challenge when the predictors of MR improvement remain ill-defined.

The impact of TAVR on post-procedural MR remains ambiguous, with some studies suggesting an improvement while others suggesting no change or worsening.[4-8] The recommended guidelines also show conflict. While the American Heart Association/American College of Cardiology guidelines recommend the treatment of MR in patients with surgical aortic valve replacement, the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery recommend against any additional interventions.[9,10]

The aim of this study is to evaluate the impact of concomitant pre-procedural MR on mortality at different time intervals and other clinical outcomes, such as stroke, bleeding, and rehospitalization in patients with severe AS undergoing TAVR. Additional meta-regression analysis was undertaken to identify if age, gender, and left ventricular ejection fraction (LVEF) had any impact on mortality outcome.

MATERIALS AND METHODS

This systematic review and meta-analysis adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[11,12]

An electronic search of PubMed and the Cochrane Library covered the period until October 15, 2023, using predefined medical subject headings and Boolean operators. Articles not written in English were excluded. The search strategy combined the keywords "aortic stenosis," "transcatheter aortic valve replacement," "transcatheter aortic valve implantation," "mitral regurgitation," and "mitral prolapse."

Study selection followed predefined criteria; randomized controlled trials (RCTs) or observational studies examining post-surgical outcomes in patients undergoing TAVR for AS were eligible. Studies involving TAVR patients with valvular disorders other than MR were excluded. The primary outcomes were mortality at 30 days, 6 months, 1 year, and 2 years. Secondary outcomes included post-operative bleeding (major or minor), rehospitalization, and post-procedural stroke. These outcomes were compared between patients who underwent TAVR with and without MR.

Two independent reviewers extracted the study and population characteristics (age, sex, comorbidities, follow-up duration, and mean change in outcomes) using Microsoft Excel. Categorical variables were recorded as the total population and events, and continuous data were noted as the mean with standard deviation.

The risk of bias and quality were assessed using the Newcastle-Ottawa Scale for observational studies and the Cochrane RoB 2.0 tool for clinical trials.[13,14] Studies scoring 8 or 9 on the Newcastle-Ottawa Scale were considered low risk, while those scoring 6 or 7 were considered medium risk. Higher scores indicate better methodological quality.

Outcomes were pooled using the Mantel-Haenszel Random-effects model with Review Manager (version 5.3. The Cochrane Collaboration). Continuous data are presented as mean differences and 95% confidence intervals (CIs), and dichotomous data as odds ratios with 95% CI. Statistical significance was set at $P < 0.05$. Heterogeneity was examined using the Cochrane Q statistic and the inconsistency factor (I^2). Significant heterogeneity was defined as an I^2 value >75%, with I^2 values of 25–50%, 50–75% as moderate, and >75% as low, moderate, and high heterogeneity, respectively. Leave-one-out sensitivity analyses were used to assess whether any study was driving the results or high heterogeneity. Subgrouping was performed by design; that is, studies were grouped into RCTs and observational studies for analysis. Coefficients with 95% CI and standard errors were calculated in the meta-regression of mortality based on age, sex, and LVEF using OpenMeta Analyst and Comprehensive Meta-Analysis 3.0 software.

RESULTS

The literature search identified 2,780 studies. After excluding duplicates ($n = 1,730$) and irrelevant studies, 24 remained for final analysis.[1,3,8,15-35] See the PRISMA flowchart [Figure 1]. The final analysis included 23,796 patients with AS and concomitant MR. Nearly half were male ($n = 10,859$, 45.6%), and the mean age was 81.8 years; balloon-expandable valves were the most frequently used. Most were prospective cohort studies, and only three were RCTs. The baseline characteristics are presented in Table 1.

Inverted funnel plots showed no significant publication bias, as the data points were evenly distributed [Figure 2]. All studies were of high quality, scoring ≥7 stars on the Newcastle-Ottawa Scale, and the RCT quality assessment indicated no high risk of bias.

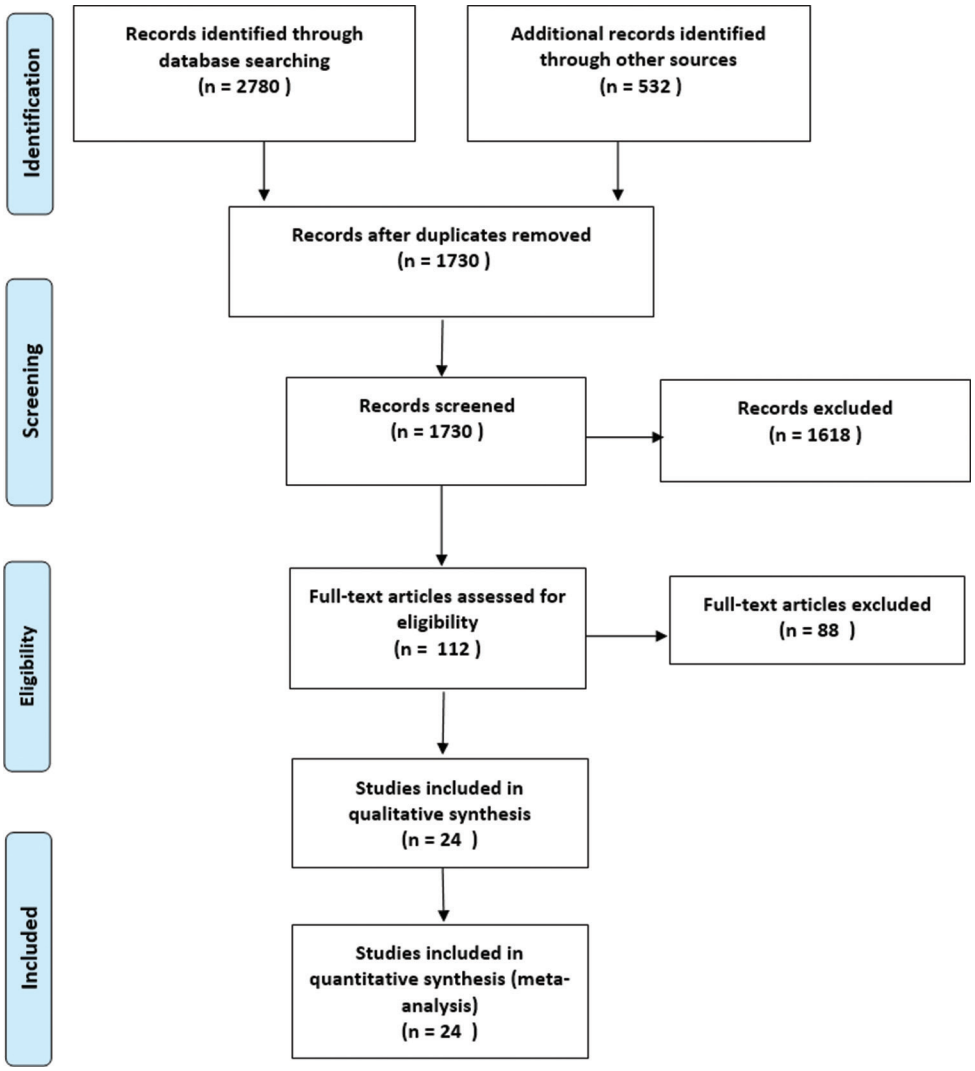

Figure 1: Preferred Reporting Items for Systematic Reviews and Meta-Analysis flowchart of study selection

Pooled analysis revealed that patients with baseline MR had significantly higher 30-day all-cause mortality than those without (relative risk [RR]: 1.68 [95% CI: 1.31, 2.15], $P < 0.0001$, $I^2 = 52\%$). Subgroup analysis comparing RCTs and observational studies showed no significant differences (P-interaction = 0.34), although observational studies largely contributed to heterogeneity [Figure 3].

Seven studies reported that patients with baseline MR had significantly higher 6-month all-cause mortality (RR: 1.94 [95% CI: 1.30–2.90], $P = 0.001$, $I^2 = 82\%$) [Figure 4]. Significant heterogeneity was noted ($I^2 = 82\%$, $P < 0.00001$). Sensitivity analysis indicated that removing Cortis *et al*. reduced heterogeneity ($I^2 = 49\%$, $P = 0.08$).

Nineteen studies reported a significantly increased 1-year mortality in patients with baseline MR (RR: 1.75 [95% CI: 1.38-2.22], $P < 0.0001$, $I^2 = 87\%$). Subgroup analysis showed that RCTs found no difference in outcomes (RR: 1.11 [95% CI: 0.66–1.87], $P = 0.68$, $I^2 = 73\%$), while observational studies indicated significantly higher mortality in patients with MR (RR: 1.97 [95% CI: 1.48-2.62], $P < 0.0001$, $I^2 = 89\%$) [Figure 5].

Eight studies provided the data. The combined analysis demonstrated an increase in mortality among patients with MR at baseline (RR: 1.30 [95% CI: 1.08–1.56], $P = 0.006$, $I^2 = 65\%$). Significant heterogeneity ($I^2 = 65\%$, $P = 0.006$) was mitigated by excluding Feldt *et al*. ($I^2 = 44\%$, $P = 0.10$).[28] Subgroup analysis by study type showed that RCTs found no difference between those with and without MR at baseline (RR: 1.14 [95% CI: 0.80–1.64], $P = 0.47$, $I^2 = NA$), whereas observational studies indicated higher mortality with MR at baseline (RR: 1.32 [95% CI: 1.04–1.66], $P = 0.02$, $I^2 = 72\%$) [Figure 6].

The pooled analysis found no significant difference in stroke between patients with and without MR at baseline (RR: 0.83 [95% CI: 0.67–1.04], $P = 0.11$, $I^2 = 0\%$). The heterogeneity was not significant. No significant subgroup differences were found (RCTs and observational) (P-interaction = 0.85). Five studies showed no significant difference in bleeding

Table 1: Characteristics of included studies

Study	Study design	Country	Follow-up	*n* total; Male (%)	Mean age (years)	Valve used
Rodés-Cabau *et al.*[15]	Prospective	Canada	8 months	339; 152 (44.8)	81±8	BEV
Leon *et al.*[16]	Analysis of a RCT	USA	1.6 years	171; 82 (45.8)	83.1±8.6	BEV
Gilard *et al.*[17]	Prospective	France	144 days	3,195; 1,630 (51)	82.7±7.2	BEV/ SEV
Toggweiler *et al.*[8]	Prospective	Canada	2 years	451; 212 (47)	81.5	BEV
Barbanti *et al.*[3]	Analysis of a RCT	United States	2 years	331; 192 (58)	83.64	BEV
Bedogni *et al.*[1]	Prospective	Italy	1 year	1,007; 452 (44.9)	81.2±5.6	BEV
D'Onofrio *et al.*[18]	Prospective	Italy	1 year	774; 328 (42.4)	81±6.7	BEV
Sabaté *et al.*[19]	Prospective	Spain	244 days	883; 421 (47.7)	81.4±6	BEV/SEV
Zahn *et al.*[20]	Prospective	Germany	12.9 months	1,318; 547 (39.3)	81.7±6.1	BEV/SEV
Khawaja *et al.*[21]	Retrospective	UK	2 year	316; 181 (57.3)	82.06	BEV
Lindman *et al.*[22]	Analysis of a RCT	USA	1 year	542; 254 (50.1)	84.6±8.5	BEV
O'Sullivan *et al.*[23]	Prospective	Switzerland	1 year	113; 67 (59.3)	82.09	BEV/SEV
Cortés *et al.*[24]	Prospective	Spain	6 months	1,110; 465 (41.9)	80.84±6.93	BEV/SEV
Amat-Santos *et al.*[25]	Retrospective	Spain	6 months	813; 191 (23.5)	81	BEV/SEV
Abdelghani *et al.*[26]	Prospective	Germany	Unspecified in hospital outcomes	967; 454 (46.8)	80.6±6.2	BEV
Abdullah *et al.*[27]	Retrospective	USA	unspecified (30 days for readmission)	3,022; 1,490 (49.3)	81.7	Unspecified
Feldt *et al.*[28]	Prospective	Sweden	30 days	1,712; 856 (50)	81.45	BEV/SEV
Miura *et al.*[29]	Retrospective	Japan	2 years	1587; 473 (29.8)	85.5	Unspecified
Murdoch *et al.*[30]	Prospective	Multicenter	2 years	339; 214 (63.2)	79	Unspecified
Mauri *et al.*[31]	Retrospective	Germany	2 years	777; 370 (47.6)	81.6	BEV/SEV
Ben-Assa *et al.*[32]	Prospective	Israel	4.3 years	486; 209 (43)	82.8±6	BEV/SEV
Freitas-Ferraz *et al.*[33]	Prospective	Multi center	1 year	308; 225 (73)	80.5±7.2	BEV
Giannini *et al.*[34]	Prospective	Italy	1 year	2964; 1268 (42.8)	82.4	SEV
Ferruzzi *et al.*[35]	Prospective	Italy	1 year	268; 126 (47)	81±5.96	BEV/SEV

Study	NYHA III/IV (%)	STS PROM	EuroSCORE	Mod- severe MR (%)	LVEF %
Rodés-Cabau *et al.*[15]	308 (90.9)	9.8±6.4	27.7±16.3	27 (8.0)	55±14
Leon *et al.*[16]	165 (92.2)	11.2±5.8	26.4±17.2	38 (22.6)	53.9±13.1
Gilard *et al.*[17]	-	14.4±11.9	21.9±14.3	661 (20.7)	53.2±14.1
Toggweiler *et al.*[8]	402 (89.13)	7.83	-	132 (29.3)	58.45
Barbanti *et al.*[3]	176 (53.17)	11.86	-	65 (19.6)	-
Bedogni *et al.*[1]	701 (63.3)	8.0±2.4	23.1±14.1	337 (33.5)	51.5±11.9
D'Onofrio *et al.*[18]	621 (80.2)	10.8±8.5	25.6±16.3	199 (25.7)	52.9±12.8
Sabaté *et al.*[19]	644 (72.9)	-	17.4±11.3	55 (6.2)	56.4±13.3
Zahn *et al.*[20]	1,156/1,309 (88.3)	-	20.3±13.2	42 (3.2)	53.5±14.5
Khawaja *et al.*[21]	218 (69.0)	6.08	21.9	60 (19)	49.2
Lindman *et al.*[22]	-	10.52±5.5	-	135/507 (26.6)	52.0±12.6
O'Sullivan *et al.*[23]	88 (77.9)	7.95	34.3	61 (54)	34.26

(Contd...)

Table 1: *(Continued)*

Study	NYHA III/IV (%)	STS PROM	EuroSCORE	Mod- severe MR (%)	LVEF %
Cortés *et al*.[24]	579 (66.9)	5.5	13.5	177 (15.9)	60
Amat-Santos *et al*.[25]	431 (71.6)	6.9	-	303 (37.3)	62.51
Abdelghani *et al*.[26]	-	5.2±4.6	-	273/958 (28.5)	54.31
Abdullah *et al*.[27]	-	-	-	1,511 (all MR)	-
Feldt *et al*.[28]	1586 (92.6)	-	-	308 (18.05)	1009 (58.9%) >50%LVEF
Miura *et al*.[29]	792/1587 (49.9)	6.8	13.2	144 (9.0)	63.9
Murdoch *et al*.[30]	305 (90)	8.9	-	111 (32.7)	50.9
Mauri *et al*.[31]	-	-	4.8	285 (36.6)	51
Ben-Assa *et al*.[32]	-	4.1±2.6	23±14	86 (17.7)	56.1
Freitas-Ferraz *et al*.[33]	253 (82.1)	8.3±4.9	-	115 (37.3)	30.7±9.4
Giannini *et al*.[34]	-	7.97	19.8	1234 (41.6)	52.1
Ferruzzi *et al*.[35]	111 (41.4)	-	4.2±3.95	57 (21.3)	47.7±12.7

Data presented as mean±standard deviation and n (%), *n*: Number of patients, %: Percentage of patients. BEV: Balloon-expandable valve; SEV: Self-expandable valve; NYHA: New York heart association, STS PROM: Society of thoracic surgeons predicted risk of mortality, LVEF: Left ventricular ejection fraction, RCT: Randomized control trial, MR: Mitral regurgitation

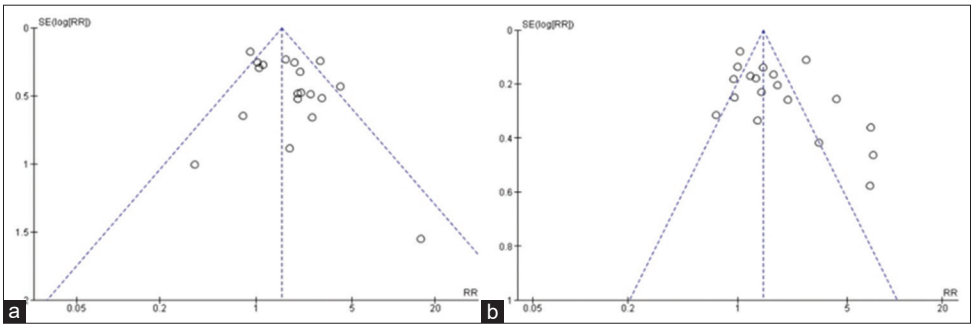

Figure 2: Funnel plots representing publication bias for (a) All-cause mortality at 30 days, (b) All-cause mortality at 1 year

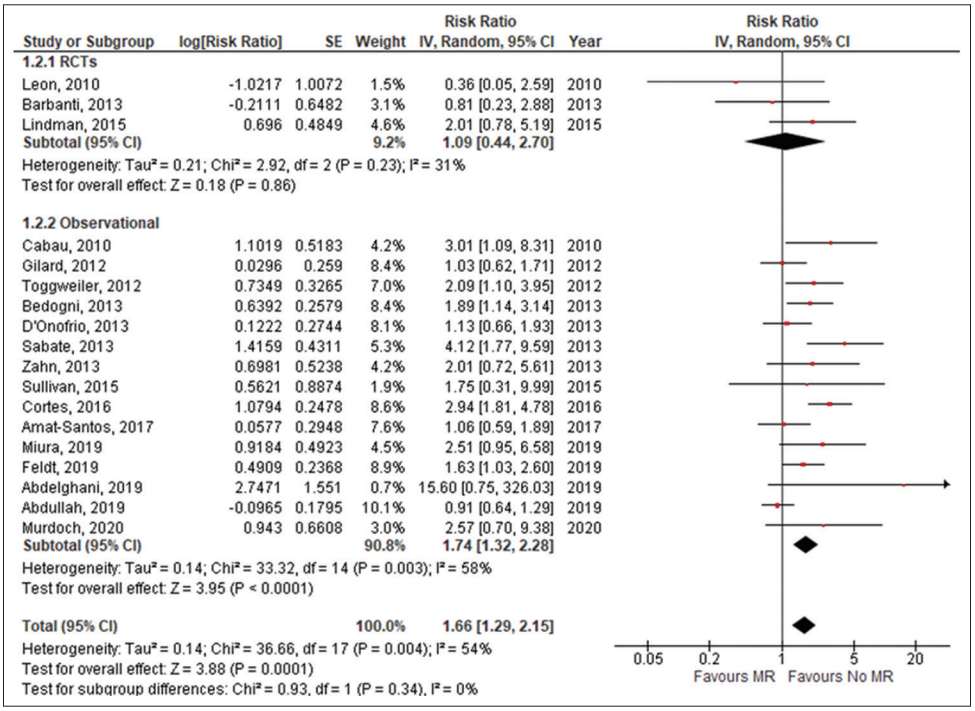

Figure 3: All-cause mortality at 30 days stratified by type of study

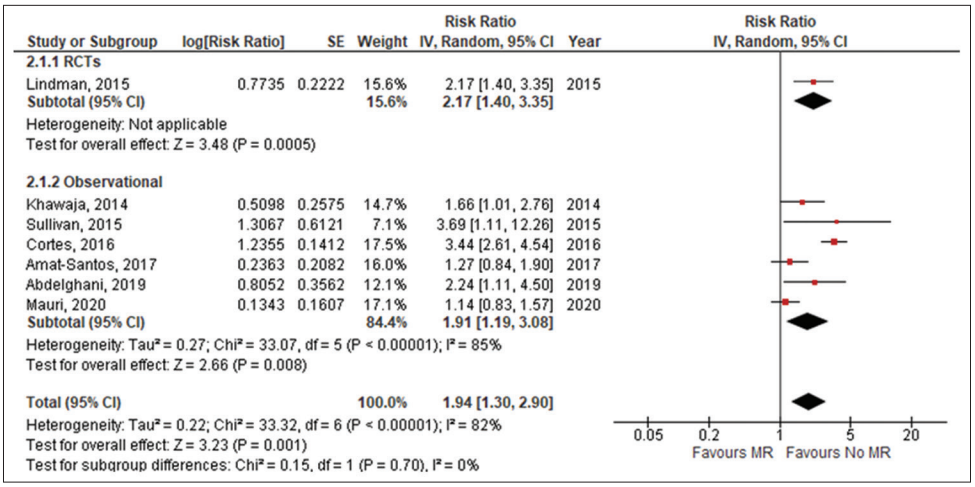

Figure 4: All-cause mortality at 6 months

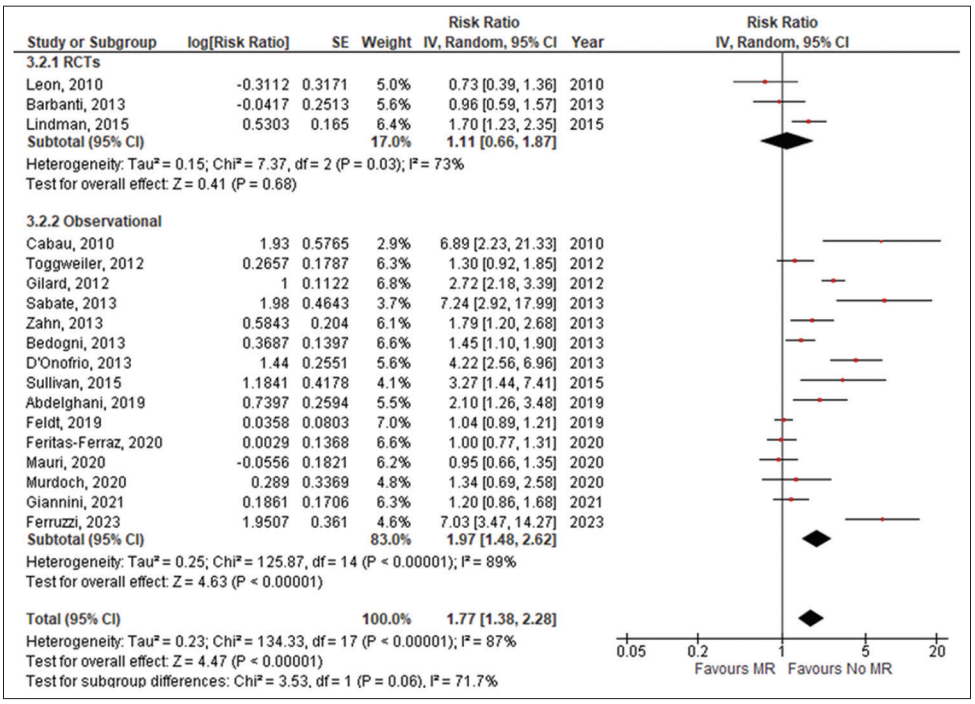

Figure 5: All-cause mortality at 1-year stratified by type of study

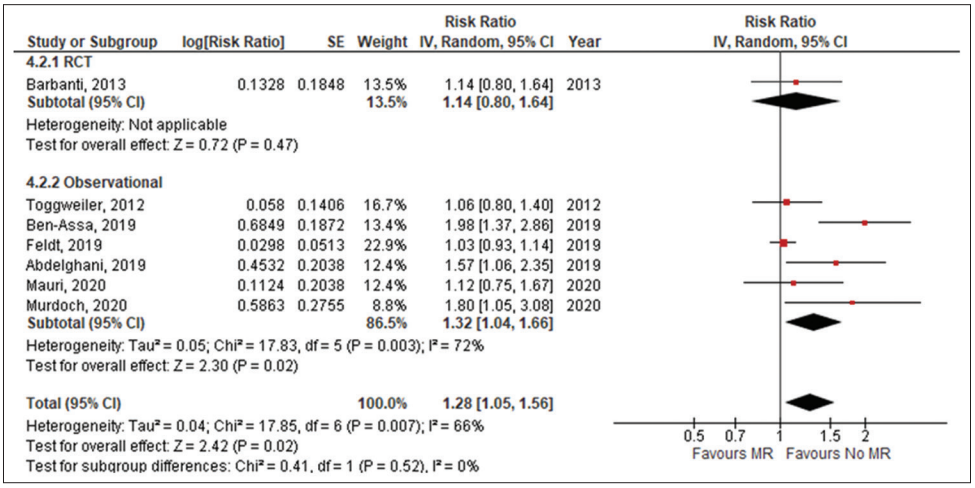

Figure 6: All-cause mortality at 2 years stratified by type of study

between patients with or without MR at baseline (RR: 0.95 [95% CI: 0.88–1.04], $P = 0.27$, $I^2 = 0\%$). No significant subgroup differences (RCTs and observational) were noted (P-interaction = 0.10). The pooled analysis showed a significantly higher rehospitalization risk in patients with MR at baseline than in those without (RR: 1.79 [95% CI: 1.06-3.04], $P = 0.03$, $I^2 = 86\%$). Sensitivity analysis did not reveal any significant heterogeneity.

Meta-regression of mortality outcomes by age, male gender, and LVEF

Meta-regression of all-cause mortality at 30 days, 6 months, 1 year, and 2 years showed no correlation with age, male gender, and LVEF. All coefficients, their respective lower and upper limits, and *P*-values are detailed in Table 2.

DISCUSSION

TAVR is a minimally invasive procedure that replaces stenosed aortic valves that compromise the blood supply. Patients with severe AS often have underlying mitral valve regurgitation.[36] Studies suggest that approximately 20% of patients with AS undergoing TAVR have mild-to-moderate MR.[37] The prognostic effects of MR on TAVR outcomes remain uncertain. TAVR was associated with 2.2–29% mortality via the transfemoral approach.[38] With underlying MR, TAVR mortality rates increase.[24] This meta-analysis pooled 24 studies to evaluate the effects of underlying MR on post-operative adverse events after TAVR.

Our analysis revealed a positive relationship between underlying MR and mortality at all follow-ups, with 6-month death rates being the highest among patients with MR (RR: 1.94; $P < 0.001$). MR increases TAVR mortality, similar to the effects observed in patients with surgical aortic valve replacement.[24] Consistent with increased mortality, MR severity may worsen post-procedure, leading to left ventricular failure; this suggests careful consideration for patients with moderate-to-severe MR.[24] A similar meta-analysis by Chakravarty *et al*. reported high mortality in patients with moderate-to-severe baseline MR undergoing TAVR compared to those without MR (RR: 1.48, 95% CI: 1.31–1.68, $P < 0.00001$).[39] Conversely, some studies have suggested MR grade improvement after TAVR.[1,4,8] Factors such as MR severity and type could affect outcomes, warranting further research. Another meta-analysis of 17 studies supports our findings, observing a direct relationship between death rates and baseline MR; however, it disclosed that MR severity improved by at least one grade post-TAVR (RR: 0.56, 95% CI: 0.45–0.66).[40]

We found no significant relationship between post-operative bleeding or stroke in patients with or without MR (RR: 0.83 (95% CI: 0.67, 1.04), $P = 0.11$, $I^2 = 0\%$; RR: 0.95 (95% CI: 0.88, 1.04), $P = 0.27$, $I^2 = 0\%$). However, significantly

Table 2. Meta-regression of mortality outcomes on different time intervals based on age, male gender, and LVEF.

Outcome	Co–variates											
	Age (years)				Male gender				LVEF (%)			
	Co-efficient	S.E	95% CI (LL, UL)	p-value	Co-efficient	S.E	95% CI (LL, UL)	p-value	Co-efficient	S.E	95% CI (LL, UL)	p-value
30-day all-cause mortality	−0.044	0.097	−0.233, 0.266	0.651	0.002	0.014	−0.025, 0.028	0.906	0.010	0.026	0.041, 0.062	0.690
6-months all-cause mortality	0.003	0.129	−0.249, 0.256	0.980	0.011	0.015	−0.019, 0.041	0.487	−0.012	0.029	−0.069, 0.045	0.684
1-year all-cause mortality	−0.100	0.115	−0.325, 0.125	0.386	−0.021	0.016	−0.053, 0.011	0.200	0.011	0.022	−0.033, 0.054	0.629
2-year all-cause mortality	−0.029	0.077	−0.180, 0.122	0.709	0.00	0.015	−0.029, 0.029	0.984	−0.005	0.023	−0.050, 0.040	0.841

S.E: Standard error; 95% CI: 95% confidence interval; LL: Lower limit; UL: Upper limit; LVEF: Left ventricular ejection fraction.

higher rehospitalization rates occurred in patients with baseline MR, suggesting worsening MR grade or post-operative complications (RR: 1.79 (95% CI: 1.06, 3.04), $P = 0.03$, $I^2 = 86\%$). Subgrouping by study type revealed no differences between the groups.

This review updates previous studies with its sample size, inclusion of updated RCTs, and perspectives. However, this meta-analysis had several limitations. First, the patients with MR were not filtered by severity or type, which could have led to bias, as patients with severe MR can have a worse prognosis than those with low-grade MR that might improve after the procedure. Second, regression analysis was not performed, which can downgrade risk factors such as age, sex, and comorbidities associated with MR and TAVR outcomes.

CONCLUSION

This systematic review and meta-analysis showed that concomitant MR is a significant prognostic indicator in patients undergoing TAVR for severe AS. Patients with pre-existing MR had higher all-cause mortality at 30 days, 6 months, 1 year, and 2 years post-TAVR and were more likely to be re-hospitalized. However, baseline MR was not associated with an increased risk of stroke or bleeding complications.

These findings suggest that MR identifies a high-risk group requiring preprocedural assessment and monitoring. Although MR appears to worsen survival, the mechanisms and predictors of post-TAVR MR improvement remain unclear. Studies should examine MR severity, cause, and post-procedural changes affecting long-term outcomes, enhance patient selection, and guide mitral valve interventions.

INSTITUTIONAL REVIEW BOARD STATEMENT

Not applicable.

INFORMED CONSENT STATEMENT

Not applicable.

DATA AVAILABILITY STATEMENT

Not applicable.

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