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Emergency interventions for cardiogenic shock due to decompensated aortic stenosis: a systematic review and meta-analysis

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ABSTRACT

Background Cardiogenic shock (CS) induced by severe aortic stenosis (AS) is a life-threatening condition with high mortality. Despite advancements in emergency interventions, the optimal treatment approach remains uncertain.

Aim This study aimed to systematically review and analyse the existing evidence on outcomes of emergency transcatheter aortic valve implantation (eTAVI) and emergency balloon aortic valvuloplasty (eBAV) in CS patients.

Methods A systematic literature review and meta-analysis was performed. The primary endpoint was mortality at 30 days. Secondary endpoints were in-hospital mortality, 1-year mortality, bleeding, major vascular complications, myocardial infarction, stroke, incidence of pacemaker implantation, acute kidney injury and aortic regurgitation.

Results Seventeen studies were included, totalling 2811 patients. The analysis revealed a 30-day mortality pooled estimated rate for eTAVI of 19% (CI 0.17 - 0.20) and for eBAV 39% (CI 0.32 - 0.46). In-hospital mortality pooled estimated rates were 11% for eTAVI (CI 0.06 - 0.18) and for eBAV 40% (CI 0.28 - 0.54). One-year mortality pooled estimated rates for eTAVI were 29% (CI 0.20 - 0.40) and for eBAV 67% (CI 0.58 - 0.74). Pooled estimated rates of any bleeding were 12% for eTAVI (CI 0.06 - 0.20) and 15% for eBAV (CI 0.10 - 0.21). The rate of major vascular complications for eTAVI was 8% (CI 0.07 - 0.10) and 3% for eBAV (CI 0.0 - 0.23).

Conclusions This meta-analysis indicates that mortality in CS due to AS remains high despite emergency interventional treatment. These findings offer critical insights for clinical decision-making optimising patient care in this critically ill population.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Current guidelines suggest balloon aortic valvuloplasty (BAV) to be considered as a bridge to surgical aortic valve replacement or to transcatheter intervention in haemodynamically unstable patients and in those with aortic stenosis (AS) who require urgent high-risk non-cardiac surgery. However, clear guidance concerning the interventional treatment of cardiogenic shock (CS) is still missing.

WHAT THIS STUDY ADDS

⇒ This meta-analysis of real-world evidence suggests that emergency transcatheter aortic valve implantation (eTAVI) is a viable option in CS (30-day mortality 19% for eTAVI vs. 39% for emergency BAV (eBAV)). However, the general mortality in AS patients admitted to the hospital in CS remains high.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Large prospective randomised trials (eBAV vs. eTAVI) are needed to determine the best therapeutic option for CS patients due to AS. Beyond selecting the appropriate therapy, a comprehensive approach addressing optimal timing of intervention, potential use of mechanical circulatory support and vascular access considerations is essential. Alternative valve sizing methods, such as transoesophageal echocardiography, may be required in emergencies.

INTRODUCTION

Severe aortic stenosis (AS) is the most common degenerative heart valve disease and poses a substantial burden in the elderly.[1 2] In the management of cardiogenic shock (CS) secondary to AS, traditional surgical aortic valve replacement (SAVR) is encumbered by a relevant risk of mortality. As a result, less invasive emergency procedures have emerged as life-saving interventions in CS, particularly emergency balloon aortic valvuloplasty (eBAV) and, more recently, emergency transcatheter aortic valve implantation (eTAVI). However, the treatment of CS due to AS still remains related to high mortality rate and its optimal management still needs to be determined.

After the first successful TAVI procedure in an inoperable case performed by Cribier *et al*,[3] the use of TAVI has been quickly

established in high-risk cases by studies involving thousands of patients. Large randomised trials have since reported considerable improvements in procedural and midterm results, with decreased complication rates owing to more experience and enhanced technology and have underscored the critical role of TAVI in treating non-operable and high-surgical-risk patients.[4–6] However, studies have been heterogeneous and only a limited number of patients in CS has been included.

CS presents a common high-risk surgical scenario, yet large prospective randomised controlled trials (RCT) for eTAVI in this context are lacking, due to the frequent exclusion of CS patients in RCTs on AS and heart failure. The current guideline considers BAV as a bridge to TAVI or SAVR in CS for patient stabilisation.[7] Although eBAV relieves the obstruction caused by AS and can improve haemodynamics rapidly, its effects are often short-lived and associated with a high rate of restenosis and early mortality.[8] TAVI is currently recommended as a class I indication for elective procedures in elderly symptomatic patients with severe, high-gradient AS. TAVI offers a more durable solution by implantation of a new prosthetic valve, thereby not only improving haemodynamics temporarily but also providing a longer-term remedy without the need for open-heart surgery. However, TAVI outcomes benefit from meticulous procedural planning including Angio/Heart-CT, which might be unfeasible in case of emergency procedures. While TAVI has been extensively studied in elective scenarios for high-risk, intermediate-risk and low-risk patients,[9] its role in the emergency setting, particularly for those in CS, is an area of growing interest and debate.

Our study aims to comprehensively review and analyse the totality of existing literature on eBAV and eTAVI in patients with AS in CS.

METHODS

Literature search strategy

A systematic literature search was conducted across multiple electronic databases, including PubMed, EMBASE and the Cochrane Library, to identify studies evaluating eBAV, eTAVI or both in the context of emergency treatment for CS. The search strategy was designed to capture all potentially relevant articles without any language or publication date restrictions. Keywords and MeSH terms related to “cardiogenic shock,” “aortic stenosis,” “balloon aortic valvuloplasty,” “transcatheter aortic valve implantation” “transcatheter aortic valve replacement” and “emergency treatment” were used for the literature search. This systematic analysis was registered on PROSPERO (CRD42024583044).

Study identification and selection

The process of study identification and selection was conducted by two independent reviewers (SGK and DB). Initially, titles and abstracts published up to May 2024 were screened to assess their relevance to the analysis. Then, data extraction was performed to collect information on study design, patient characteristics, interventional details and outcomes of interest. The whole process was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.

Inclusion criteria

1. Clinical studies reporting outcomes of AS patients with CS undergoing eBAV or eTAVI and reporting clinical outcomes including 30-day mortality, in-hospital mortality, 1-year mortality and periprocedural complication such as bleeding, vascular complications, myocardial infarction, stroke, new pacemaker implantation, acute kidney injury and severe aortic regurgitation.
2. CS needed to be clearly defined in the study and the procedures needed to be performed as emergency bailout.

Exclusion criteria

1. Studies that did not explicitly state that patients were in CS were excluded from our analysis. We also excluded all studies including ‘urgent’ procedures without specifying for CS patients (eg, patients presented with acute decompensated HF secondary to severe AS, but not clearly in CS).
2. Studies include non-CS and CS patients but lack reporting subgroup-specific outcomes for CS patients.
3. Studies including eTAVI procedures with transapical access.

Study outcomes

The primary outcome was 30-day mortality. Secondary outcomes were in-hospital death and 1-year mortality, any bleeding, major vascular complications, acute kidney injury, stroke, myocardial infarction, new pacemaker implantation and severe aortic regurgitation. Bleeding outcomes display any bleeding (major and minor bleeding events). All clinical outcomes were defined according to the definitions reported in each study.

Statistics

For baseline characteristics involving continuous variables, mean (SD) format was used where available. For studies reporting median and IQR, mean estimates were derived using Lou *et al*'s method,[10] while SD estimates were calculated using Wan *et al*'s method.[11] Subsequently, weighted means and pooled SD were calculated for the baseline characteristics of each procedure, accounting for SD within and between studies. To compare continuous baseline variables between the procedures, a standard two-sample t-test was employed to evaluate the statistical significance of the mean differences. The prevalence of baseline dichotomous variables was compared using a χ^2 test. For primary and secondary outcomes, the event proportions for each study were calculated and pooled event rates as well as 95% CIs were derived using a generalised linear mixed-effects model. This approach

Table 1 Overview of all eBAV studies included in the meta-analysis: study design and patient baseline characteristics

eBAV	NHLBI[14] (n=39)	Cribier *et al*[15] (n=10)	Moreno *et al*[16] (n=21)	Buchwald *et al*[8] (n=14)	Saia *et al*[17] (n=23)	Theiss *et al*[18] (n=13)	Bongiovanni *et al*[19] (n=118)	Debry *et al*[20] (n=44)	Eugène *et al*[21] (n=17)	Varela *et al*[22] (n=14)	Kilias *et al*[23] (n=22)	Nair *et al*[24] (n=46)
Study characteristics												
Year	1991	1992	1994	2001	2013	2014	2017	2018	2017	2019	2023	2024
Setting	Multicentre (24 centres)	Single centre	Single centre	Single centre	Single centre	Single centre	Multicentre (5 centres)	Multicentre (2 centres)	Single centre	Single centre	Single centre	Single centre
Country	USA, Canada	France	USA	Germany	Italy	Germany	Germany	France	France	Portugal	Germany	USA
Study inclusion criteria	eBAV in CS (blood pressure <100 mm Hg and functional class IV congestive heart failure)	eBAV as initial treatment in patients with CS due to AS CS was defined as: CS refractory to intensive medical therapy.	patients presenting in CS due to AS undergoing eBAV	eBAV in patients with critical AS and CS (sustained arterial hypotension with systolic blood pressure ≤90 mm Hg despite inotropic and pressor support; cardiac index ≤2.2 L/min/m; mean pulmonary capillary wedge pressure ≥20 mm Hg; urinary output ≤0.5 mL/kg/ hour and clinical evidence of decreased tissue perfusion)	Patients in CS with severe symptomatic AS undergoing BAV (prospectively). CS was characterised by systolic blood pressure <90 mm Hg with signs of low peripheral perfusion or the necessity to administer inotropes for circulatory support.	eBAV for treatment of CS. Each patient had presented with end stage CS requiring eBAV as final bail out solution. CS was defined as systolic blood pressure <90 mm Hg for >30 min or catecholamines required to maintain pressure >90 mm Hg during systole plus clinical signs of pulmonary congestion).	eBAV in CS with requirement of catecholamine therapy, severe acute dyspnoea (NYHA IV), cardiac resuscitation or mechanic respiratory support.	Patients with hypotensive CS (HCS) and with non-HCS due to acutely decompensated severe AS, from two centres were treated with urgent BAV.	eBAV in patients with CS. CS was defined as ≥1 sign of systemic hypoperfusion and need of catecholamines.	eBAV as bailout therapy in critical care patients presenting with CS and severe AS. CS: systolic blood pressure <90 mm Hg for >30 min or vasopressors required to achieve a blood pressure ≥90 mm Hg; pulmonary congestion or elevated left-ventricular filling pressures; signs of impaired organ perfusion with at least one of the following: altered mental status; cold, clammy skin; oliguria; increased serum-lactate	30-day mortality of rescue BAV in AS patients presenting with CS (need of catecholamines and peripheral hypoperfusion identified by the combination of several parameters including altered mental status, cold/clammy skin and extremities, oliguria or serum lactate level >2 mmol/L and absence of any clinical evidence for a non-cardiac cause of shock.	eBAV in CS in the setting of severe AS. primary outcome 30-day all-cause mortality. CS: either systolic blood pressure <90 mm Hg and signs of impaired end-organ perfusion or a right heart catheterisation with a pulmonary capillary wedge pressure ≥15 mm Hg and cardiac index ≤2.2 L/ min per metres squared in the setting of end-organ hypoperfusion
Clinical outcome reporting	Not standardised	Not standardised	Not standardised	Not standardised	VARC	Not standardised	VARC-2	VARC-2	VARC-2	Not standardised	VARC-2	Not standardised
Patient baseline characteristics												
Age (in years)	*	64±9	74±3	74±11	70±12	79±6	81±8	77±8	79±9	76±7	83.7 (8.3)	79.00 (72.25–84.75) median (IQR)
Male gender	*	8/10	10/21	7/14	13/23	8/13	66/118	33/44	*	8/14	12/22	26/46
LVEF in %	*	25±6	29±3	Not reported	40±15	Not reported	Not reported	30±14	27±11	Not reported	45 (21)	27.50 (20.00–35.75) median (IQR)
AVA in cm² before intervention	*	0.47±0.10	0.48±0.04	0.38±0.09	0.6±0.2	Not reported	Not reported	0.57±0.15	0.61±0.17	Not reported	0.7±0.2	0.65 (0.43–0.77) median (IQR)
EuroSCORE (logistic %)	*	Not reported	Not reported	Not reported	39.5±20.1	*	35.3±20.8	41.6±13.7	41±15 (EuroSCORE 2)	EuroSCORE II: emergent cases: 19±7	EuroSCORE II : 47.8 (36.8)	Not reported

Continued

Table 1 Continued

eBAV	NHLBI[14] (n=39)	Cribier *et al*[15] (n=10)	Moreno *et al*[16] (n=21)	Buchwald *et al*[8] (n=14)	Saia *et al*[17] (n=23)	Theiss *et al*[18] (n=13)	Bongiovanni *et al*[19] (n=118)	Debry *et al*[20] (n=44)	Eugène *et al*[21] (n=17)	Varela *et al*[22] (n=14)	Kilias *et al*[23] (n=22)	Nair *et al*[24] (n=46)
Comorbidities												
Coronary artery disease	*	Not reported	8/21	5/14	12/23	*	74/115	Not reported	9/17	Not reported	18/22	37/46
Chronic pulmo-nary disease	*	1/10	3/21	Not reported	6/23	*	9/55	9/44	3/17	2/14	6/22	16/46
Active malignancy	*	Not reported	3/21	Not reported	5/23	*	20/79	Not reported	4/17	Not reported	Not reported	Not reported
Pacemaker before intervention	*	Not reported	Not reported	Not reported	2/23	*	16/105	Not reported	Not reported	Not reported	Not reported	9/46
Atrial fibrillation	*	Not reported	Not reported	Not reported	7/23	*	54/88	24/44	10/17	4/14	15/22	29/46
CKD	*	Not reported	9/21	Not reported	21/23	*	Not reported	23/44	5/17	2/14	14/22	20/46
Hypertension	*	Not reported	Not reported	Not reported	13/23	*	Not reported	Not reported	10/17	11/14	Not reported	34/56
Previous MI	*	2/10	Not reported	0/14	12/23	*	49/115	14/44	Not reported	1/14	Not reported	10/46
BAV as bridging procedure/follow-up												
Bridge to SAVR/ TAVR?	0	6 AVR after 5 months in average after BAV (range, 6 days to 18 months)	1 AVR after 24 hours, 3 after 60±14 days after eBAV	2 SAVR after 8 and 16 days one after 16 hours (massive insufficiency)	1 SAVR in hospital	4 TAVI at unknown time after BAV	32 TAVI after average of 91 days (median 35 days)	10 TAVI, 2 SAVR (median 79 days)	7 SAVR, 9 TAVR (median 15 days, range 1–47 days)	5 TAVR, 1 SAVR	*	Not reported
Follow-up	30-day	In hospital, up to 27 months	In hospital, 30 days, 1 year	In hospital, 30 days, 1 year up to 24 months (median follow-up 595 days, IQR 455–896)	30 days, 1 year, 2 years	In hospital	30 days	1 year	2 years	30 days	30 days	30 days, 90 days, 1 year

*No subgroup analysis for CS patients.
AS, aortic stenosis; AVA, aortic valve area; CKD, chronic kidney disease; CS, cardiogenic shock; eBAV, emergency balloon aortic valvuloplasty; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.

was chosen due to its generally superior performance compared with conventional two-step methods for meta-analyses of proportions.[12] Of note, CIs were calculated using the Wilson interval, in order to limit the possible biases related to the inclusion of studies with small sample sizes.[13] The heterogeneity among the studies was assessed using the I^2 statistic and LRT test of heterogeneity. To test the consistency in the pooled estimates of the primary endpoint, a leave-one-out analysis was performed, sequentially excluding each study from the meta-analysis to assess its impact on the pooled estimates.

All statistical analyses were performed by using R version 4.3.3.

RESULTS

Study selection

We included a total of 17 studies[8 14–29] reporting outcomes for eBAV and eTAVI for a total of 2811 patients: 7 studies reporting outcome data for eTAVI[19 24–29] and 12 for eBAV.[8 14–24] With the exception of two studies,[19 24] all the investigations were single-arm studies. Studies design, endpoints and further information of included studies are provided in table 1 for eBAV and table 2 for eTAVI.

Baseline characteristics

A detailed analysis of comorbidities and baseline features of eBAV and eTAVI patients is displayed in online supplemental table. The mean age in the eBAV population was 78.1±8.7, while in eTAVI, the mean age was 81.84±7.93 (p<0.001). Male patients were 59.36% of the patients undergoing eBAV and 56.46% of those undergoing eTAVI (p=0.34). BAV patients exhibited a lower aortic valve area compared with TAVI patients (0.58±0.16 cm^2 vs 0.70±0.24 cm^2, p<0.001) and also a significantly lower mean left ventricular ejection fraction (LVEF) than TAVI patients (31.82 ±14.6% vs 47.56 ±20.9%, p<0.001). BAV patients had a higher mean aortic transvalvular gradient than TAVI patients (42.76±15.43 mm Hg vs 36.61±16.65 mm Hg, (p<0.001). The Logistic EUROscore was similar in the two groups.

Primary outcome and mortality rate

The pooled estimated rate for mortality at 30 days was 39% (CI 0.32 - 0.46, I^2=40%) for eBAV and 19% (CI 0.17 - 0.20, I^2=45%) for eTAVI (figure 1). In-hospital mortality was 40% (CI 0.28 - 0.54, I^2=75%) for eBAV and 11% (CI 0.06 - 0.18, I^2=90%) for eTAVI . The pooled estimated rate for 1-year mortality was 67% (CI 0.58 - 0.74, I^2=75.5%) and 29% (CI 0.20 - 0.40, I^2=50%) for eBAV and eTAVI, respectively (figure 2). Leave-one-out sensitivity analysis did not detect any differences from the main analysis (online supplemental figure 1).

Secondary outcomes

Bleeding and major vascular complications

Only three studies reported bleeding after eBAV while six studies reported these outcomes after eTAVI. In seven studies, bleeding has been reported according to the VARC 2 and one study according to the VARC 3 criteria. The pooled estimated rate for any bleeding was 12% (CI 0.06 - 0.20, I^2=60%) for eTAVI and 15% (CI 0.10 - 0.21, I^2= 15%) for eBAV (figure 3). Seven studies reported major vascular complications for eBAV while six for eTAVI; of these, nine studies reported vascular complications according to VARC criteria. Major vascular complications had pooled estimated rates of 8% (CI 0.07 - 0.10, I^2=40%) for eTAVI and 3% (CI 0.0 - 0.23, I^2= 71%) for eBAV (figure 4).

Other outcomes

Postprocedural pacemaker implantation rates were only 1% for eBAV (CI 0.0 - 0.38, I^2= 85%), while 9% for eTAVI (CI 0.08 - 0.11, I^2= 75%) (online supplemental figure 2). The rate of stroke was reported in 11 studies. The pooled estimated stroke rate in eBAV patients was 1% (CI 0.00 - 0.04, I^2=79%) and 4% in eTAVI patients (CI 0.03 - 0.05, I^2=75%). For eBAV, the pooled estimated rate of myocardial infarction was 3% (CI 0.01 - 0.07, I^2=85%) and 1% (CI 0.01 - 0.02, I^2=79%) for eTAVI. Postprocedural valvular regurgitation was reported in three studies for eBAV and in five studies for eTAVI. For eBAV, the estimated rate for severe aortic regurgitation was 6% (CI 0.02 - 0.16, I^2=54%) and 4% for eTAVI (CI 0.04 - 0.05, I^2=79%). Postprocedural acute kidney injury rates were reported in seven studies for eBAV and five studies for eTAVI. The estimated pooled rate in eBAV patients was 13% (CI 0.04 - 0.35, I^2= 79%) and 15% in eTAVI patients (CI 0.07 - 0.30, I^2=96%).

DISCUSSION

We here provide a structured review and meta-analysis on eBAV and eTAVI in CS including the totality of existing evidence available. The main findings of our study are that both eBAV and eTAVI in this setting are associated with high rates of mortality.

Clinical challenges

Treatment of CS due to AS remains a challenging scenario and its optimal clinical management still needs to be determined and, up to date, no randomised trial investigated the optimal interventional therapy of this cohort. Current guidelines suggest BAV to be considered as a bridge to SAVR or to transcatheter intervention[30] in haemodynamically unstable patients and in those with AS who require urgent high-risk non-cardiac surgery (recommendation level IIb, evidence C).[7] However, clear guidance concerning the interventional treatment of CS is still missing and its optimal timing still needs to be determined. This comprehensive review provides the largest analysis performed so far and valuable insights to guide clinical decision-making in CS patients.

Additionally to the need for clear and evidence-based guidelines, the number of patients presenting with CS due to severe AS has been rising over the last years.[27 29]

Table 2 Overview of all eTAVI studies included in the meta-analysis: study design and patient baseline characteristics

eTAVI	Frerker *et al*[25] (n=27)	Bongiovanni *et al*[19] (n=23)	Fraccaro *et al*[26] (n=51)	Masha *et al*[27] (n=2220)	Steffen *et al*[28] (n=47)	Piriou[29] (n=38)	Nair[24] (n=24)
Study characteristics							
Year	2016	2017	2020	2020	2022	2022	2024
Setting	Single centre	Multicentre	Multicentre	Multicentre	Single centre	Multicentre	Single centre
Country	Germany	Germany	11 European centres	USA	Germany	France	USA
Study inclusion criteria	Outcomes of TAVR as a rescue therapy in patients with CS due to acutely decompensated AS; CS: SBP <90 mm Hg or need of catecholamines	eTAVI in CS with requirement of catecholamine therapy, severe acute dyspnoea (NYHA IV) requiring respiratory support, cardiac resuscitation	eTAVI in CS due to AS CS: (a) SBP <90 mm Hg for >30 min or vasopressors required to achieve a blood pressure ≥90 mm Hg; (b) pulmonary congestion or elevated left-ventricular filling pressures; (c) signs of impaired organ perfusion with at least one of the following criteria: altered mental status; cold, clammy skin; oliguria+increased serum-lactate	Patients who presented with CS before TAVR. The primary outcome of interest was 30-day mortality. Secondary outcomes included 30-day procedural complications. CS was defined as inotrope use within 24 hours before TAVR, preprocedural cardiac arrest, preprocedural use of mechanical circulatory support or cardiopulmonary bypass.	eTAVI in patients with CS due to severe AS CS: SBP <90 mm Hg Lactate ≥2 mmol/L Catecholamine Tx	eTAVI in patients with severe aortic disease and CS: SBP<90 mm Hg or need of catecholamines	eTAVI in CS in the setting of severe AS. primary outcome 30-day all-cause mortality CS: either SBP <90 mm Hg and signs of impaired end-organ perfusion or a right heart catheterisation with a pulmonary capillary wedge pressure ≥15 mm Hg and cardiac index ≤2.2 L/min per metres squared in the setting of end-organ hypoperfusion
Clinical outcome reporting	VARC-2	VARC-2	VARC-2	VARC-2	VARC-3	VARC-2	Not standardised
Patient baseline characteristics							
Age (in years)	78±9	76±11	76±13	83 (median)	81.2 (median)	73±11.2	79.00 (75.50–84.25) median (IQR)
Male gender	12/27	19/23	25/51	1232/2220	36/47	31/38	17/24
LVEF in %	39.5±15.4	Not reported	LVEF≤35%–29.4% (15/51)	53 (median)	38 (median)	24±12.8	33.50 (22.00–41.25) median (IQR)
AVA in cm^2 before intervention	0.8±0.2	Not reported	0.7±0.2		0.6 (0.5–0.8) median (IQR)	0.76±0.32	0.61 (0.42–0.77) median (IQR)
Euro-score (logistic)	60.4±21.1	37.7±18.1	EuroSCORE II 27.89±22.85 (49)	Not reported	Not reported	35±25.2	Not reported
Comorbidities							
Soronary artery disease	19/27	15/23	17/51	Not reported	38/47	Not reported	20/24
Chronic pulmonary disease	6/27	5/23	9/51	356/2203	16/47	4/38	8/24
Active malignancy	Not reported	2/23	0/47	Not reported	11/47 (active or history)	Not reported	Not reported

Continued

Table 2 Continued

eTAVI	Frerker *et al*[25] (n=27)	Bongiovanni *et al*[19] (n=23)	Fraccaro *et al*[26] (n=51)	Masha *et al*[27] (n=2220)	Steffen *et al*[28] (n=47)	Piriou[29] (n=38)	Nair[24] (n=24)
Pacemaker before intervention	Not reported	1/23	4/51	424/2220	12/47	Not reported	8/24
Atrial fibrillation	14/27	7/23	10/51	1138/2220	13/47	14/38	16/24
CKD	17/27	Not reported	33/51	1090/2220	41/47	16/38	12/24
Hypertension	22/27	Not reported	38/51	Not reported	41/47	28/38	16/24
Previous MI	Not reported	4/23	6/51	679/2214	11/47	Not reported	5/24
Follow-up							
	1 year	1 month	1 year	1 year	2 year	1 year	1 year

AS, aortic stenosis; CKD, chronic kidney disease; CS, cardiogenic shock; eTAVI, emergency TAVI; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; SBP, systolic blood pressure; TAVI, transcatheter aortic valve replacement.

Mortality and complications in eBAV and eTAVI

In general, mortality rates in patients presenting in CS due to decompensated AS are high. A study comparing elective and urgent TAVI outcomes showed that patients undergoing urgent TAVI experienced a 4-fold increase in 30-day mortality rates (17.5% for urgent TAVI compared with 4% for elective TAVI, p=0.001), along with an increased incidence of cardiovascular mortality within 30 days (25.3% in non-elective vs 15.1% in elective, p=0.043), life-threatening bleeding (11.5% in non-elective vs 4.1% in elective, p=0.018) and vascular complications (11.5% in non-elective vs 4.6% in elective, p=0.031).[31] Given the high-risk setting in decompensated AS patients, our meta-analysis points towards a favourable pooled estimated 30-day and 1-year mortality rate in the eTAVI group. A recent meta-analysis investigating 36 886 patients undergoing eTAVR found that while urgent TAVR was associated with higher mortality and readmission rates compared with elective TAVR, it demonstrated a reduced mortality risk and comparable safety profile relative to urgent SAVR or BAV, supporting the feasibility of eTAVI in CS settings.[32] This result is in line with the only previous smaller meta-analysis in this field.[33] Wernly *et al* reported a 30-day mortality rate for eBAV (total sample size 238) of 46.2% (CI 30.3% to 62.5%; I^2=74%) and for eTAVR (total sample size 73) of 22.6% (95% CI 12.0% - 35.2%; I^2 =26%)[33] also pointing towards eTAVI for the preferred emergency procedure. While this prior analysis only incorporated 8 studies including 311 patients, our meta-analysis is now reporting outcomes for eBAV and eTAVI for a total of 2811 patients from 17 studies.

Furthermore, a recent US study evaluated readmission rates in patients who received TAVI or BAV as an urgent procedure. In the urgent TAVI group, the rate of all-cause readmissions within 30 days was notably reduced (15.4% vs 22.5%, with an adjusted HR (aHR) of 0.92 (0.90 - 0.95), p<0.001) when contrasted with the urgent BAV group. This trend persisted for readmissions at 90 days, where the aHR was 0.75 (p=0.005). Readmissions at 30 days due to cardiovascular reasons and congestive heart failure were also decreased in the urgent TAVI group (aHR of 0.93, p<0.001 and aHR of 0.98, p=0.040, respectively) compared with those in the BAV group. Moreover, the urgent TAVI group experienced a significant reduction in 90-day readmissions for cardiovascular reasons.[34] While this study has not been included in our analysis as the urgent procedure did not meet the criteria for CS, these findings are in line with our results regarding the favouring trend towards eTAVI and our pooled estimated rates for adverse events are only slightly higher. The 30-day mortality rates observed in this study reflect the outcomes of a critically ill population with inherently high mortality. While these rates provide valuable real-world insights into the outcomes of eTAVI and eBAV, they should not be interpreted as evidence of causality, as the lack of a non-interventional arm precludes definitive conclusions about the direct impact of these procedures on survival.

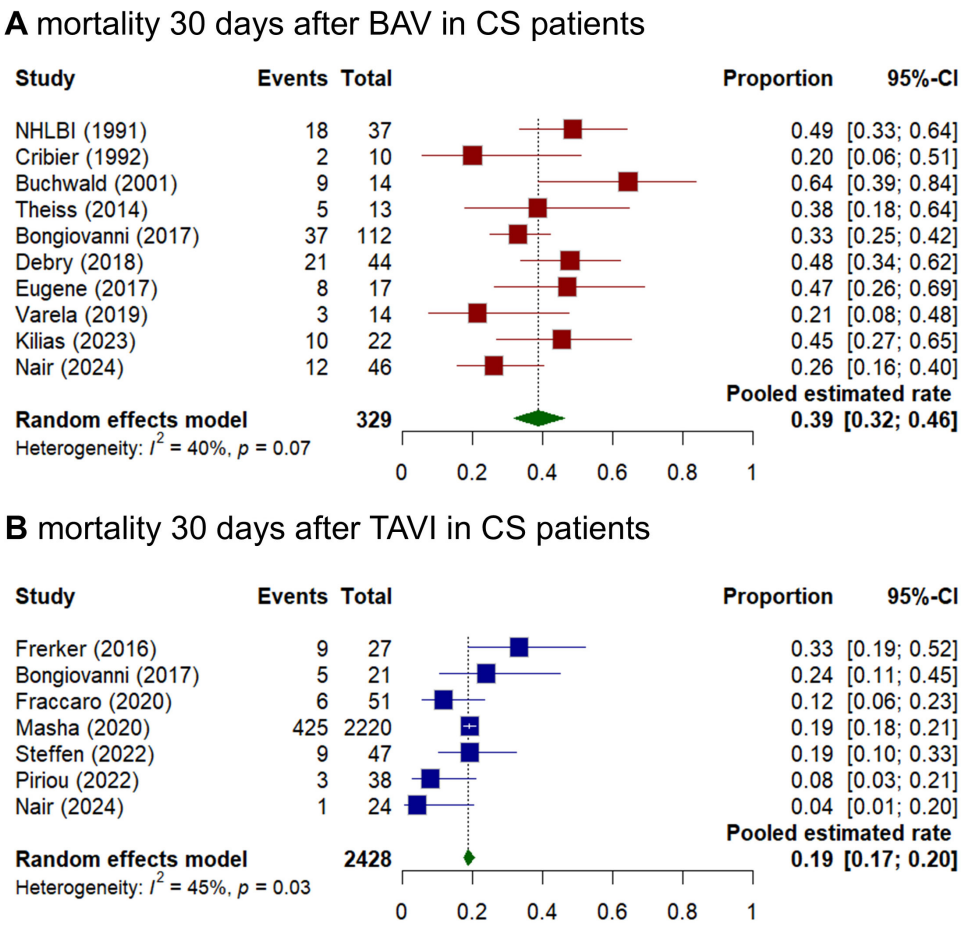

Figure 1 30-day mortality. Pooled estimated rates for 30-day mortality after eBAV (A) and after eTAVI (B) in CS patients. CS, cardiogenic shock; eBAV, emergency balloon aortic valvuloplasty; eTAVI, emergency transcatheter aortic valve implantation.

Investigating outcomes in a non-interventional cohort would be both ethically and practically challenging, as withholding potentially life-saving interventions in this setting is not feasible.

Even when evaluating long-term outcomes at 5 and at 7 years after TAVI, as reported by Ichibori *et al*, patients identified with high or prohibitive surgical risk exhibited encouraging long-term survival outcomes post-TAVI procedure, with rates of 58.8% at 5 years and 45.3% at 7 years.[35] Also interestingly, mortality rates in early BAV studies from 1991[14] remain consistent decades after,[20] indicating that mortality is rather phenotype-associated and procedure-associated than related to gained expertise or improved technique of the method over the years. Nevertheless, none of the studies included in the analysis and cited so far were randomised. Therefore, a selection bias definitely needs to be acknowledged, particularly in those countries and healthcare systems with limited quotas of TAVI available.

In addition, eBAV can cause severe acute regurgitation, which can worsen the already compromised haemodynamics of CS. Nevertheless, our results show a rather low pooled estimated rate of severe aortic regurgitation for eBAV (6%) but a relatively high rate for eTAVI (4%).

Of note, in the largest prospective non-randomised trial on eTAVI in CS patients,[27] authors emphasised that despite the expected higher mortality rate in CS patients compared with non-CS patients, mortality rate was associated with the degree of CS.[27] It seems that mortality in the CS group was not predominantly influenced by complications arising from the procedure but is instead determined by the severity of CS.[27] Given the critical nature of CS, the timing of intervention is particularly important, as any delay could lead to irreversible organ damage. Further research should focus on defining the optimal time point for intervention, as well as exploring patient selection criteria and long-term outcomes. While there are no longitudinal studies investigating the optimal time point for interventional treatment in CS, one study showed that within an acute heart failure cohort, a trend for reduced all-cause mortality at 2 years was noted for patients undergoing TAVI within 60 hours of admission in comparison to those treated later.[36] However, the 30-day all-cause mortality rates were similar between both groups.[36] Further studies should focus on the right time point of intervention in CS patients with structural investigation of CS severity with right heart catheterisation.[37]

Patient selection for eTAVI and eBAV might additionally impact patient outcomes. eTAVI is generally performed on patients who are less critically ill, with better preserved left ventricular function and lower rates of coronary artery disease. In contrast, eBAV is often chosen for patients

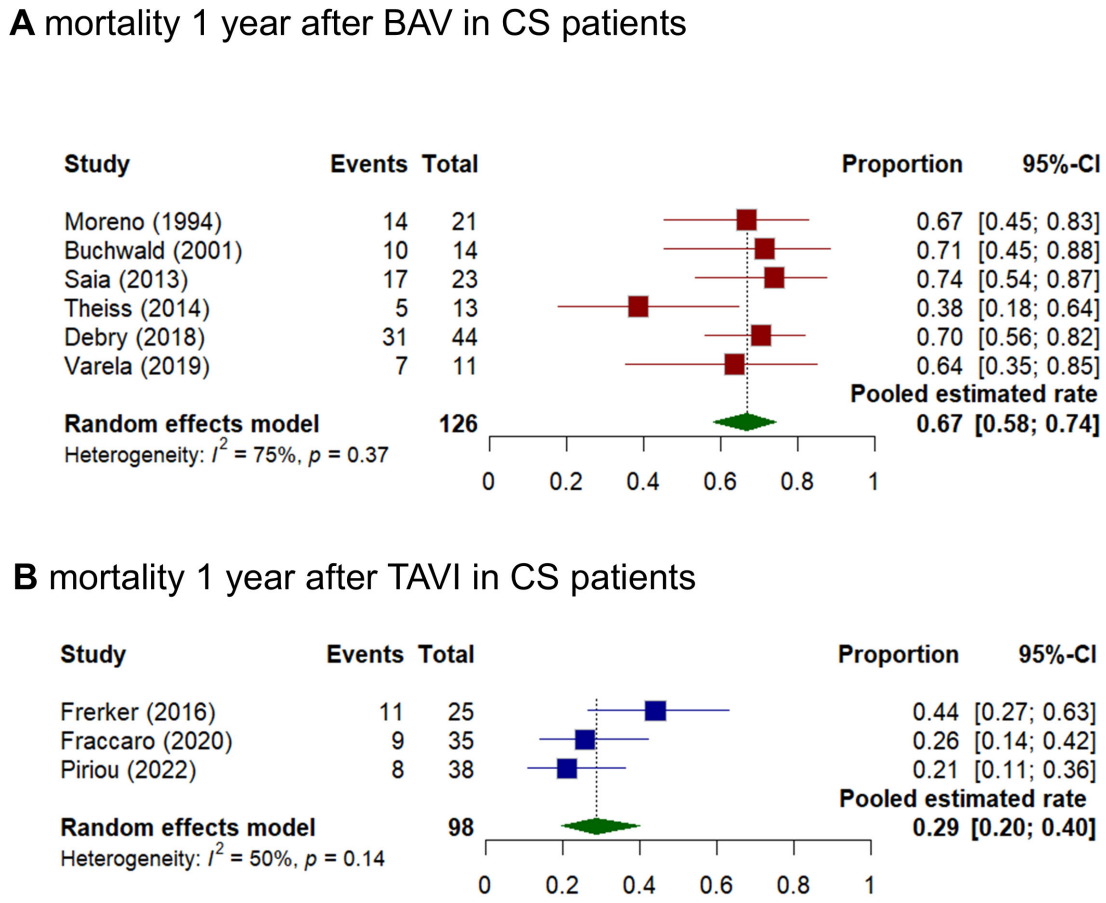

Figure 2 One-year mortality. Pooled estimated rates for 1-year mortality after eBAV (A) and after eTAV (B) in CS patients. CS, cardiogenic shock; eBAV, emergency balloon aortic valvuloplasty; eTAVI, emergency transcatheter aortic valve implantation.

with more severe left ventricular dysfunction and a higher prevalence of coronary artery disease, conditions that are associated with increased mortality.[38] Although eTAVI has shown favourable outcomes, these differences in patient selection suggest that eBAV may still be the preferred intervention for patients with higher risk profiles or those in environments where TAVR is not available.[38]

Moreover, previous studies often employed older-generation devices that had larger delivery profiles and a higher risk of paravalvular leak. The use of newer-generation devices, which have smaller delivery systems and improved sealing mechanisms, may reduce these risks and improve outcomes in this patient population.

Ethical and practical considerations for treatment decision-making

Notably, studies in the meta-analysis that reported a cause-specific mortality stated that mortality was mostly not due to complications such as bleeding, stroke or myocardial infarction but due to multiorgan failure or septic conditions,[25] resulting in pooled estimated rates for procedural complications being considerably lower than pooled estimated mortality rates in-hospital and after 30 days. The findings suggest that concurrent conditions, including chronic renal failure, severe three-vessel disease and frailty, could significantly influence the rate of early mortality following procedures such as eTAVI or eBAV. In order to take these considerations into account as well as patient will and ethical aspects, a brief emergency heart team meeting might be beneficial to improve outcomes and avoid futility.[39] Such a team discussion should also include consideration of precipitating factors or triggers (eg, acute coronary syndrome, atrial fibrillation, infections) that should be addressed before proceeding with eTAVI.[39]

Limitations

Despite two studies,[19 24] all other studies included in the meta-analysis were single-arm studies, making a direct group comparison unfeasible. This reliance on single-arm studies limits our ability to draw definitive conclusions, as it restricts the analysis to a pooled estimated rate for each endpoint. Thus, our findings should be considered hypothesis-generating only. Furthermore, secondary endpoint data were not available in all studies and, most importantly, were not assessed at the same time and using the same standards in all studies. Some studies assessed secondary endpoint data at 30 days while others reported those data in hospital. In addition, we noted a relevant heterogeneity of the reported secondary endpoints, which did not always comply with the VARC-2/3 criteria (predominantly in the older studies, table 2).[40] This heterogeneity, combined with the lack of standardisation, particularly for the secondary endpoints, introduces

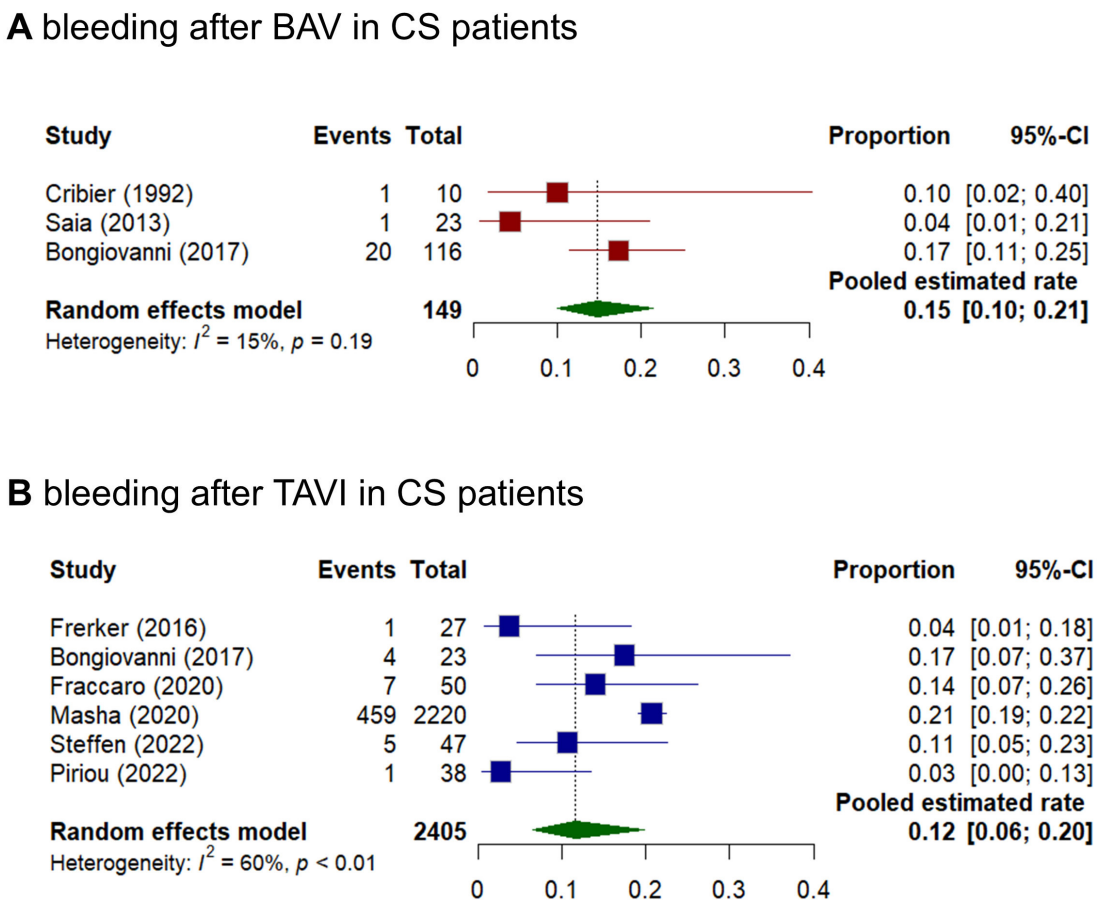

Figure 3 Bleeding complications. Pooled estimated rates for bleeding after eBAV (A) and after eTAVI (B) in CS patients. CS, cardiogenic shock; eBAV, emergency balloon aortic valvuloplasty; eTAVI, emergency transcatheter aortic valve implantation.

variability that can obscure the true effects and reduce the reliability of our findings. Therefore, these data should be interpreted with caution, and the generalisability of the results may be limited. In addition, in 23% of the eBAV patients, the procedure was used as a bridging procedure for a valve replacement with either TAVI or SAVR, adding a further bias in our analysis (table 1). However, a clear indication of the time point of the second intervention is not available, as only median and ranges are provided.

Moreover, the studies included in our meta-analysis were conducted over a wide time range, contributing to heterogeneity and potentially impacting the reliability of pooled estimates.

The studies incorporated into our analysis cover an extensive historical period, reflecting the comprehensive nature of our research. However, our three oldest studies from the 1990s had a limited weight in our pooled rates, mainly due to their small sample sizes. Despite this, the evolution in clinical practice and patient management over time introduces another layer of variability, which may impact the study's conclusions. Of note, our leave-one-out sensitivity analyses did not detect any differences (online supplemental figure 1).

In addition, CS is a condition with a wide range of severity, which is not easy to harmonise and compare. The studies included in our meta-analysis are characterised by relevant heterogeneity and did not report outcomes according to the SCAI classification. A further relevant limitation is the lack of information concerning the strategy used to achieve valve sizing in eTAVI. In elective cases, CT scan is the gold standard to evaluate access site and annulus size. However, anecdotal cases of urgent TAVI with sizing using transoesophageal echocardiography or BAV have been reported.[41] The absence of high-resolution anatomical data from CT scans could have influenced acute outcomes and prognosis, further complicating the interpretation of our results.

CONCLUSION

This meta-analysis is the first study analysing the totality of existing literature on emergency interventions in CS patients due to decompensated AS. Despite its limitations, our meta-analysis of real-world evidence suggests that eTAVI is a viable option in this complex clinical scenario. However, the overall mortality in AS patients presenting with CS remains high. Further larger comparative studies with a prospective randomised design with standardised outcome reporting are needed to substantiate evidence and guide clinical decision-making.

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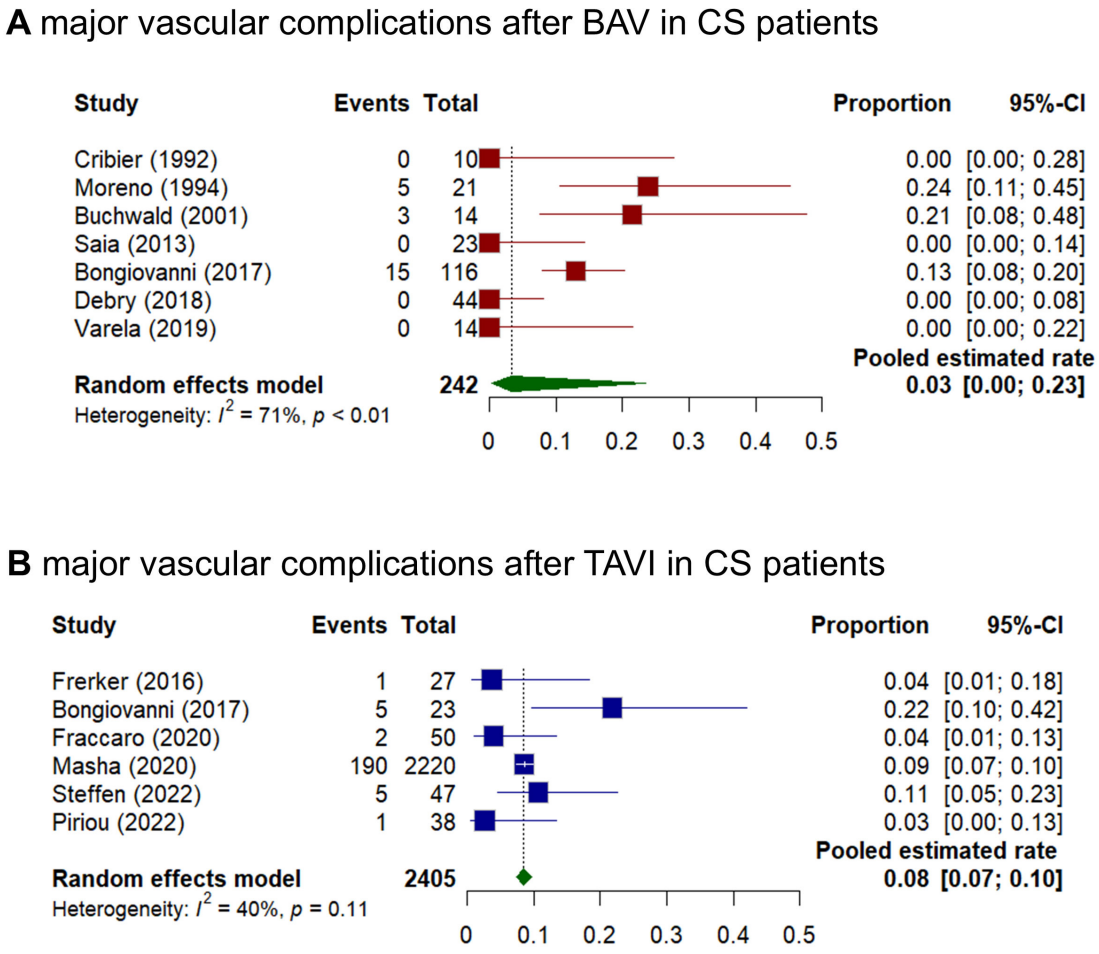

Figure 4 Vascular complications. Pooled estimated rates for major vascular complications after eBAV (A) and after eTAVI (B) in CS patients. CS, cardiogenic shock; eBAV, emergency balloon aortic valvuloplasty; eTAVI, emergency transcatheter aortic valve implantation.

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