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Early Versus Standard Discharge After Transcatheter Aortic Valve Replacement

A Systematic Review and Meta-Analysis

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ABSTRACT

OBJECTIVES This study sought to assess the clinical outcomes of patients undergoing transcatheter aortic valve replacement (TAVR) with early discharge (ED) versus standard discharge (SD) pathways.

BACKGROUND Minimalist approaches for TAVR have been developed targeting different aspects of the procedure such as local anesthesia or sedation, intraprocedural imaging, vascular access, post-operative monitoring and care, and discharge planning. Their incorporation into routine clinical practice aims to reduce length of hospital stay and health care cost utilization without adversely affecting outcomes when compared with standard approaches.

METHODS The authors conducted a search of MEDLINE and EMBASE to identify studies that investigated ED (≤3 days) versus SD in TAVR patients. Random-effects meta-analyses were used to estimate the effect of ED compared with SD with regard to 30-day mortality after discharge, 30-day readmission rate, and need for permanent pacemaker implantation (PPI) following discharge.

RESULTS Eight studies including 1,775 participants (ED, n = 642) fulfilled the inclusion criteria. The mean age was 82.4 years and STS score was 6.7. Meta-analyses evaluating discharge to 30-day mortality (odds ratio [OR]: 0.65; 95% confidence interval [CI]: 0.23 to 1.82; $I^2 = 0\%$) and discharge to 30-day new PPI (OR: 1.61; 95% CI: 0.19 to 13.71; $I^2 = 40\%$) showed no significant difference in an ED compared with a SD strategy. Notably, ED patients were less likely to be readmitted after ED when compared with SD patients (OR: 0.63; 95% CI: 0.41 to 0.98; p = 0.04, $I^2 = 0\%$).

CONCLUSIONS ED following uncomplicated TAVR is safe in terms of discharge to 30-day mortality or need for PPI following discharge. Moreover, ED patients experienced a lower rate of readmissions. These data support the safety of programs aiming an ED pathway in selected TAVR patients. Institutional protocols with the input from different members of the multidisciplinary heart team should be devised to optimize discharge processes to improve health care resource utilization. (J Am Coll Cardiol Intv 2018;11:1759–71) © 2018 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CI = confidence interval

ED = early discharge

ICU = intensive care unit

LoS = length of stay

OR = odds ratio

PPI = permanent pacemaker implantation

SD = standard discharge

TAVR = transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) has become the alternative treatment for patients with severe symptomatic aortic stenosis deemed at high or intermediate risk for surgical aortic valve replacement (1,2). Improved and lower profile devices and ever-increasing operator and heart team experience has resulted in much improved clinical outcomes and has allowed a new focus on periprocedural care for a rapid recovery and discharge pathways (3,4). "Minimalist" approaches have been developed targeting different aspects of the procedure, such as local anesthesia or sedation, intraprocedural imaging, vascular access, post-operative monitoring and care, and discharge planning (3-7). Single-center studies have shown that adoption of strict, TAVR-specific clinical care pathways helped to identify candidates for safe early discharge (ED) after TAVR (4,8). The incorporation of these strategies into routine clinical practice has reduced length of hospital stay (LoS) and health care cost utilization without adversely affecting index procedural outcomes when compared with standard approaches (9,10). LoS and 30-day readmission rates are important quality of care indicators and predictors of outcome in the elderly (11); however, considerable differences in LoS (1 to 11 days) are reported in contemporary TAVR registries (12,13). In addition, it is unclear whether an ED following TAVR procedures is associated with an increased risk of early unplanned 30-day readmissions. Therefore, the aim of our study was to perform a systematic review and meta-analysis to assess mortality, readmission rates, and need for permanent pacemaker implantation (PPI) at 30 days following an ED versus standard discharge (SD) pathways.

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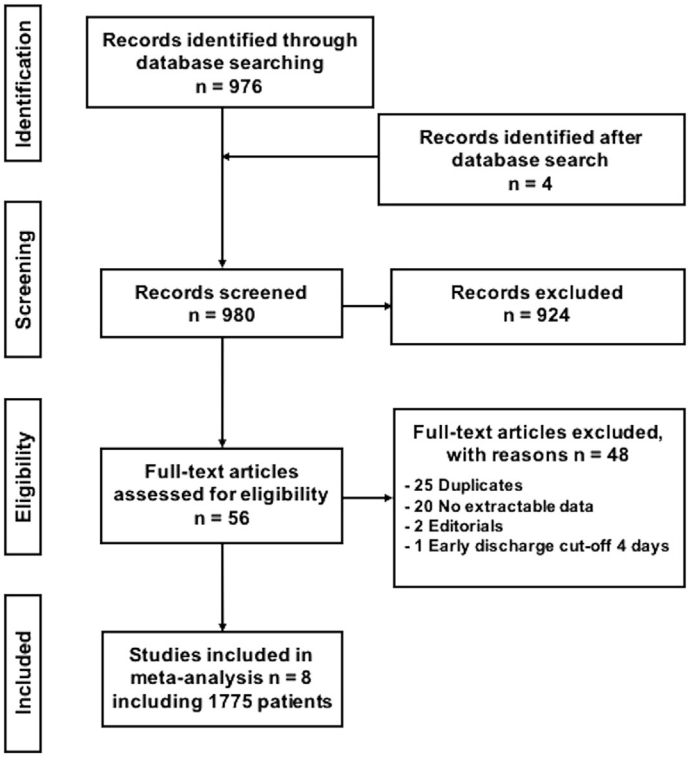
FIGURE 1 PRISMA Flow Diagram



Flow diagram based on PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses).

METHODS

SEARCH STRATEGY. We conducted a search of MEDLINE, EMBASE, and conference abstracts, from conception to December 2017 using OvidSP (Ovid Technologies, Norwood, Massachusetts). The terms used were: *transcatheter aortic valve implantation* OR *TAVI* OR *transcatheter aortic valve replacement* OR *TAVR* AND *discharge*. Two studies were published while the manuscript was being prepared and were also included in the quantitative synthesis. Institutional review board approval and patient consent were not required because of the systematic review and meta-analysis nature of this study.

STUDY SELECTION. The titles and abstracts yielded by the search were independently screened and extracted by 2 investigators (R.A.K. and M.T.) against the inclusion criteria. Additional studies were retrieved by checking the bibliography of included studies and relevant reviews. The full reports of potentially relevant studies were retrieved, and data were independently extracted on study design, participant characteristics, discharge groups, outcome events, follow-up, and results. Any discrepancies between reviewers were resolved by consensus after consulting a third investigator (R.B.).

ELIGIBILITY CRITERIA. We only included English written studies evaluating ED versus SD in patients undergoing TAVR. Our primary outcomes of interest were mortality from discharge to 30 days and 30-day readmission. The secondary outcome was the need for PPI after discharge to 30 days. The outcomes of interest and follow-up were also extracted on a pre-formatted table. As mentioned in the preceding text, disagreements were resolved by consensus.

TABLE 1 Baseline Characteristics

First Author, Year (Ref. #)	Strategy	Mean Age, (yrs)	Male, %	Logistic EuroSCORE	STS Score	Previous Pacemaker	Multivessel Disease, %	LVEF, %	CKD, %	COPD, %	PVD, %
Aldalati, 2018 (19)	Total ED SD	82.6 ± 6.7 81.8 ± 7.7 82.8 ± 6.5	50.2 48 50.5	20.8 ± 10 16.7 ± 9 21.7 ± 11	NA	NA	17.7 14 17	LVEF <30% 12/319 (3.8) 4/56 (7) 8/263 (3)	NA	90/319 (28) 14/56 (5.3) 76/263 (29)	78/319 (25) 8/56 (14) 70/263 (27)
Alkhalil, 2018 (20)	Total ED SD	82.5 82.7 ± 7.5 82.2 ± 8.1	44.4 44.4 44.4	NA	8.3 8.2 ± 3.9 8.5 ± 4.6	19/108 (17.6) 8/54 (14.8) 11/54 (20.4)	NA	51.3 53.3 ± 12 51.8 ± 13	NA	NA	15/108 (14) 7/54 (13) 8/54 (15)
Rathore, 2017 (22)	Total ED SD	80.6 ± 8.5 81.5 ± 7.6 80.3 ± 8.8	49 59 46	NA	6.9 ± 3.3 6.3 ± 2.7 6.8 ± 3.4	15/100 (15) 6/22 (27) 9/78 (12)	NA	52.5 51.6 ± 13.5 53.7 ± 12.5	38/100 (38) 10/22 (45) 28/78 (36)	NA	NA
Lauck, 2016 (4)	Total ED SD	81.5 ± 7.9 81.6 ± 7.9 81.3 ± 7.8	60.6 59.3 61.3	NA	6.4 ± 3.8 6.5 ± 3.4 6.4 ± 4.1	NA	NA	LVEF <30% 35/393 (9.0) 7/150 (4.7) 28/243 (12)	NA	46/393 (12) 12/150 (8) 34/243 (14)	NA
Serletis-Bizios, 2016 (23)	Total ED SD	84.7 ± 5.4 84.4 ± 5.8 85.4 ± 4.8	52 47 59	15.3 ± 8.5 15.7 ± 8.8 14.7 ± 8.0	NA	19/130 (15) 12/76 (16) 7/54 (13)	NA	63.0 ± 13.1 62.7 ± 13.9 63.4 ± 14.1	NA	NA	8/130 (6) 7/76 (9) 1/54 (2)
Barbanti, 2015 (8)	Total ED SD	80.0 81.1 ± 4.9 80.7 ± 5.7	41.9 43.8 40.8	NA	6.3 6.0 ± 4.2 6.5 ± 4.5	21/267 (7.9) 9/89 (10) 12/178 (6.7)	NA	51.8 51.9 ± 11.5 51.8 ± 12.9	79/267 (30) 26/89 (29) 53/178 (30)	76/267 (29) 20/89 (23) 56/178 (32)	15/267 (5.6) 5/89 (5.6) 10/178 (5.6)
Durand, 2015 (3)	Total ED SD	84.0 ± 6.8 83.7 ± 6.9 84.2 ± 6.2	43.0 47.9 40.3	16.9 ± 9.6 15.6 ± 9.6 17.6 ± 9.5	NA	38/337 (11.3) 20/121 (16.5) 18/216 (8.3)	NA	59.0 ± 16.3 59.7 ± 16.3 58.7 ± 16.3	NA	59/337 (17.5) 20/121 (16.5) 39/216 (18.1)	35/337 (10) 15/121 (17) 20/216 (9.3)
Parry-Williams, 2014 (21)	Total	83	58	22	NA	NA	NA	<35%: 18/121 (15)	Cr >200: 7/121 (5.8)	42/121 (34)	28/121 (23)

Values are mean ± SD, mean, or n/N (%).

CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; Cr = creatinine (μmol/l); ED = early discharge; LVEF = left ventricular ejection fraction; NA = not applicable or available; PVD = peripheral vascular disease; SD = standard discharge; STS = Society of Thoracic Surgeons.

Endpoints were reported, when available, in accordance with the Valve Academic Research Consortium-2 (VARC) definitions (14). The reporting of outcomes had to include either crude events in each group or any risk/odds estimate (risk ratio, odds ratio [OR]) with 95% confidence intervals (CIs). There was no restriction based on the design of the study or duration of follow-up. We excluded isolated case reports/case series (≤3 patients), reviews, and editorial comments on the subject. When duplicate reports of the same study were identified, only the report with the most complete dataset and detailed methodology description was included. A flow diagram is provided following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (**Figure 1**) (15).

QUALITY AND RISK OF BIAS ASSESSMENT. A Cochrane Risk Of Bias Assessment Tool: for Non-Randomized Studies of Interventions (ACROBAT-NRSI) (16) was employed to assess the risk of bias of the included studies, and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) (17) was used to assess the strength of evidence.

DATA ANALYSIS. RevMan (Review Manager version 5.3; Nordic Cochrane Centre, Copenhagen, Denmark) was used to perform random- and fixed-effects meta-analyses using the Mantel-Haenszel method to determine pooled OR for dichotomous data with regard to post-TAVR outcomes in patients discharged early (≤3 days) versus patients discharged in standard fashion (>3 days). The Cochrane Q-statistic (I^2) was used to assess the consistency among studies with $I^2 < 25\%$ indicating low, $I^2 = 25\%$ to 50% moderate, and $I^2 > 75\%$ high statistical heterogeneity (18). Where there was insufficient data or studies for meta-analysis, we pooled the studies using weighted average or performed narrative synthesis of studies that were too heterogeneous to pool.

RESULTS

STUDY POPULATION. A total of 8 (3,4,8,19-23) observational studies met the inclusion criteria for the meta-analysis (**Figure 1**), including 1,775 participants, 642 of which followed an ED pathway. The mean age was 82.4 ± 1.5 years, and 50.0% (887 of 1,775) were female. Among studies reporting logistic

TABLE 2 Procedural Characteristics and Outcomes

First Author, Year (Ref. #), Country	Procedural Characteristics	Type of Valve, Approach	Time-Frame of Assessment	Outcomes	Early Discharge	Standard Discharge
Aldalati, 2018 (19) England	ED Conscious sedation: 2/56 (3.5), general anesthesia: 54/56 (96), procedure time: 101 ± 121 min, contrast volume: 116 ± 52 ml SD Conscious sedation: 0/263 (0), general anesthesia: 263/263 (100), procedure time: 108 ± 42 min, contrast volume: 116 ± 54 ml	ED Transfemoral percutaneous: 40/56 (71), transfermoral-surgical cutdown: 12/56 (22), transapical: 4/56 (7), SAPIEN XT: 31/56 (55), SAPIEN 3: 20/56 (36), other: 5/56 (9) SD Transfemoral percutaneous: 71/263 (27%), transfemoral surgical cutdown: 78/263 (30), transapical: 111/263, other: 3/263 (1), SAPIEN-XT: 217/263 (82), SAPIEN-3: 40/263 (16), other: 6/263 (2)	30 days	Discharge to 30-day mortality 30-day stroke 30-day readmission 30-day acute kidney injury 30-day life-threatening bleed 30-day major vascular complication	0/56 (0) 0/56 (0) 2/56 (3.6) 0/56 (0) 0/56 (0) 0/56 (0)	3/263 (1.1) 10/263 (3.8) 25/263 (9.5) 24/263 (9) 21/263 (8) 15/263 (5.7)
Alkhalil, 2018 (20) United States	ED Local anesthesia/conscious sedation: 100%, fluoroscopy: 19 ± 8 min, contrast volume: 79 ± 42 ml, TTE: 54/54 (100%) SD Local anesthesia/conscious sedation: 100%, fluoroscopy: 20 ± 11 min, contrast volume: 88 ± 51 ml, TTE: 54/54 (100)	ED Transfemoral: 100%, percutaneous access mainly and some occasions surgical cutdown, CoreValve: 32/54 (59.3) SAPIEN and SAPIEN-XT: 22/54 (40.7) SD Transfemoral: 100%, percutaneous access mainly and some occasions surgical cutdown), CoreValve: 27/54 (50), SAPIEN & SAPIEN-XT: 27/54 (50)	In-hospital and 30 days	Major vascular complications* Minor vascular complications* New dialysis* New permanent pacemaker implantation Discharge to 30-day mortality* 30-day stroke* 30-day readmissions*	1/54 (1.9) 1/54 (1.9) 0/54 (0) 14/163 (8.6) 0/54 (0) 0/54 (0) 2/54 (3.7)	1/54 (1.9) 5/54 (9.3) 0/54 (0) 27/108 (26) 3/54 (5.6) 2/54 (3.7) 7/54 (13)
Rathore, 2017 (22) United States	ED Monitored anesthesia care: 20/22 (90) SD Monitored anesthesia care: 29/78 (37)	ED Transfermoral: 100% SD Transfermoral: 100%	In-hospital and 30 days	Discharge to 30-day mortality Stroke Blood transfusion Vascular complications New permanent pacemaker implantation 30-day readmission	0/22 (0) 0/22 (0) 0/22 (0) 0/22 (0) 0/22 (0) 3/22 (14)	0/78 (0) 2/78 (2.6) 5/78 (6.4) 8/78 (10) 11/78 (14) 8/78 (10)
Lauck, 2016 (4) Canada	ED Local anesthesia/conscious sedation: 91/150 (61), general anesthesia: 59/150 (39), cardiac catheterization laboratory: 58/150 (38.7), hybrid operation room: 92/150 (61), urinary catheter 1/150 (0.6) SD Local anesthesia/conscious sedation: 38/243 (16), general anesthesia: 205/243 (84), cardiac catheterization laboratory: 1/243 (0.4), hybrid operation room: 242/243 (99.6), urinary catheter 19/243 (7.8)	ED Transfemoral 100%, SAPIEN-XT: 123/150 (82), SAPIEN 3: 23/150 (15), CoreValve: 2/150 (1.3), other: 2/150 (1.3) SD Transfemoral 100%, SAPIEN-XT: 185/243 (76.1), SAPIEN-3: 33/243 (13.6), CoreValve: 16/243 (6.6%), Other: 9/243 (3.7)	In-hospital and 30 days	Discharge to 30-day mortality Periprocedural myocardial infarction 30-day readmission Stroke Life-threatening bleeding Major bleeding Minor bleeding Major vascular complications New dialysis New permanent pacemaker	1/150 (0.7) 0/150 (0) 12/150 (8) 0/150 (0) 0/150 (0) 1/150 (0.7) 1/150 (0.7) 0/150 (0) 0/150 (0) 4/150 (2.7)	4/243 (1.6) 0/243 (0) 30/243 (12) 3/243 (1.2) 3/243 (1.2) 10/243 (4.1) 6/243 (2.5) 5/243 (2.1) 1/243 (0.4) 23/243 (9.5)

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EuroSCORE, the mean score was 15.9 ± 0.6 in ED cohorts compared with 19.3 ± 3.5 in SD patients (3,19,21,23), whereas in those reporting Society of Thoracic Surgeons (STS) Predicted Risk of Mortality score, the mean scores were 6.63 ± 1.0% and 6.69 ± 1.0%, respectively (4,8,20,22). Among all TAVR patients, 11.9% (112 of 942) had a previously implanted permanent pacemaker; 15.2% (55 of 362) in the ED group and 9.8% (57 of 580) in the SD group (3,8,20,22,23). Further details on participants baseline characteristics are presented in Table 1.

PROCEDURAL DATA. Three studies used exclusively local anesthesia or conscious sedation in ED and SD patients (3,20,23). In studies employing both general and local anesthesia or conscious sedation, ED patients were more likely to receive local anesthesia or conscious sedation 61.4% (181 of 295) than SD patients 31.4% (215 of 684) (4,8,19). Femoral (99%) and fully percutaneous (97%) access was used in ED patients (3,4,8,19,20,22,23). Similarly, 82% of SD patients had fully percutaneous femoral access, albeit 7% received surgical cutdown and 10% underwent transapical TAVR (3,4,8,19,20,22,23). The

TABLE 2 Continued

First Author, Year (Ref. #), Country	Procedural Characteristics	Type of Valve, Approach	Time-Frame of Assessment	Outcomes	Early Discharge	Standard Discharge
Serletis-Bizios, 2016 (23) France	ED Local anesthesia (100%), contrast: 164 ± 53 ml, fluoroscopy Time: 18 ± 7 min SD Local anesthesia (100%), contrast: 163 ± 63 ml, fluoroscopy time: 20 ± 11 min	ED Transfemoral: 100%, SAPIEN-3: 28/76 (37), SAPIEN-XT: 47/76 (62) SD Transfemoral: 100%, SAPIEN-3: 20/54 (38), SAPIEN-XT: 34/54 (63), Direct Flow 1/54 (2)	In-hospital and 30 days	Periprocedural myocardial infarction	0/76 (0)	1/54 (1.9)
				Stroke	0/76 (0)	1/54 (1.9)
				Life threatening bleeding	0/76 (0)	3/54 (5.6)
				Major bleeding	1/76 (1.3)	9/54 (17)
				Minor bleeding	6/76 (7.9)	5/54 (9.3)
				Major vascular complications	1/76 (1.3)	11/54 (20)
				Minor vascular complications	15/76 (20)	10/54 (19)
				Acute kidney injury	2/76 (2.6)	2/54 (3.7)
				Permanent pacemaker implantation	5/76 (6.6)	11/54 (20)
				Discharge to 30-day mortality	1/76 (1.3)	0/54 (0)
				30-day rehospitalization	3/76 (4)	7/54 (13)
				30-day combined endpoint (death and hospitalization)	4/76 (5.3)	7/54 (13)
Barbanti, 2015 (8) Italy	ED General anesthesia: 1/89 (1.1), local anesthesia 88/89 (99), TEE guidance: 0/89 (0) SD General anesthesia: 1/178 (0.9), local anesthesia 177/178 (99), TEE guidance: 1/178 (0.6)	ED Transfemoral (100%), SAPIEN: 26/89 (29), CoreValve: 60/89 (67), Lotus: 1/89 (1.1), Portico: 2/89 (2.2) SD Transfemoral (100%), SAPIEN: 52/178 (29.1), CoreValve: 126/178 (71), Lotus: 0/178 (0), Portico: 0/178 (0)	In-hospital and 30 days	Stroke	0/89 (0.0)	2/178 (1.1)
				Life-threatening bleeding	1/89 (1.1)	10/178 (5.6)
				Major bleeding	3/89 (3.4)	11/178 (6.2)
				Minor bleeding	3/89 (3.4)	13/178 (7.3)
				Major vascular complications	2/89 (2.3)	16/178 (9.1)
				Minor vascular complications	9/89 (10)	17/178 (9.7)
				Acute kidney injury	13/89 (15)	42/178 (24)
				Pacemaker	7/89 (7.9)	33/178 (19)
				Discharge to 30-day mortality*	2/89 (2.2)	3/178 (1.7)
				30-day any bleeding*	1/89 (1.1)	0/178 (0)
				30-day new pacemaker*	0/89 (0)	2/178 (1.1)
				30-day rehospitalization*	1/89 (1.1)	2/178 (1.1)
				30-day combined safety endpoint*	3/89 (3.4)	5/178 (2.8)
				30-day acute kidney injury*	5/89 (5.6)	N/A
Durand, 2015 (3) France	ED Local anesthesia (100%), contrast: 184 ± 64 ml, fluoroscopy time: 19 ± 12 min, procedural time: 84 ± 44 min SD Local anesthesia (100%), contrast: 201 ± 80 ml, fluoroscopy time: 20 ± 6.9 min, procedural time: 111 ± 46 min	ED Transfemoral: 100%, SAPIEN-XT: 100% SD Transfemoral: 100%, SAPIEN-XT: 100%	In-hospital and 30 days	Periprocedural myocardial infarction	0/121 (0)	2/216 (0.9)
				Stroke	0/121 (0)	6/216 (2.8)
				Life-threatening bleeding	0/121 (0)	22/216 (10)
				Major bleeding	6/121 (4.9)	30/216 (14)
				Minor bleeding	7/121 (5.8)	18/216 (8.3)
				Major vascular complications	7/121 (5.8)	45/216 (21)
				Minor vascular complications	8/121 (6.6)	17/216 (7.8)
				Acute kidney injury	8/121 (6.6)	42/216 (19)
				Permanent pacemaker implantation	4/121 (3.3)	15/216 (6.9)
				Discharge to 30-day mortality	0/121 (0)	2/216 (0.9)
				30-day rehospitalization	4/121 (3.3)	9/216 (4.2)
				30-day combined primary endpoint	4/121 (3.3)	11/216 (5.1)
Parry-Williams, 2014 (21) England	NA	ED Transfemoral 89/121, transapical 23/121, transaortic 9/121, SAPIEN and SAPIEN-XT SD Transfemoral, transapical, transaortic, SAPIEN and SAPIEN XT	30 days	Discharge to 30-day mortality	0/74 (0)	0/47 (0)
				30-day readmission	7/74 (9.5)	3/47 (6.4)

Values are n/N (%) unless otherwise indicated. *After 1:1 propensity matching.

AKI = acute kidney injury; IV = intravenous; OR = odds ratio; TEE = transesophageal echocardiography; TTE = transthoracic echocardiogram; other abbreviations as in Table 1.

balloon-expandable Edwards SAPIEN valve systems (Edwards Lifesciences, Irvine, California) were implanted in 83% of patients and the self-expanding CoreValve (Medtronic, Minneapolis, Minnesota) in 16%; with no difference between the ED and SD groups, 83% and 15% versus 83% and 16%, respectively (3,4,8,19–21,23). Further procedural characteristics are described in **Table 2**.

DISCHARGE PATHWAYS. Five studies (3,8,19,22,23) reported median intensive care unit (ICU) LoS, ED patients stayed ≤1 day, whereas median ICU LoS among SD patients varied from 1 to 4 days. Six studies (3,8,19-21,23) used local discharge processes and pathways, yet only 1 developed a dedicated and standardized TAVR discharge pathway (4). Seven studies (3,4,8,19-21,23) defined ED as a LoS ≤3 days, with 1 study (22) setting the cutoff at 1 day. Discharge destinations were reported by 2 studies (4,20), with home being the destination in 88.9% of ED and 66.6% of SD patients, the remaining being discharged to supporting facilities. Further details on discharge strategies are outlined in **Table 3**.

QUALITY ASSESSMENT. Ascertainment of outcomes was via retrospective review of medical records (3,23). Reported loss to follow-up was <5% in 4 studies (19,22-24), with no information available in the other 4 (4,8,20,21). Two studies (8,20) used propensity-matched analyses to address confounding. Risk of bias assessment according to ACROBAT-NRSI indicated that 6 studies were at serious risk of bias, and 2 were identified as having low risk of bias for both discharge to 30-day mortality and readmission rates, respectively (**Table 4**). The strength of the evidence as appraised by the GRADE tool is detailed in **Table 5**.

DISCHARGE TO 30-DAY MORTALITY, READMISSION, AND NEW PPI RATES AT 30 DAYS. A total of 6 studies (3,4,8,19,20,23) reported on discharge to 30-day mortality and 8 (3,4,8,19,20,22-24) on 30-day readmissions. Crude outcomes in ED versus SD patients are presented in **Table 2**. Mortality between discharge and 30 days occurred in 1.1% (19 of 1,775) of patients, and 7.0% (125 of 1,775) of discharged patients were readmitted within 30 days. Two studies (8,23) reported causes of death in ED patients, and 1 (19) reported causes of 30-day readmissions in both groups. Of the 4 deaths that occurred in the ED group, the cause of death was reported in 3. One patient had a fatal myocardial infarction at day 9, and 2 had fatal cerebrovascular accidents (1 embolic ischemic stroke on day 30 associated with poor compliance of anticoagulation for atrial fibrillation, and 1 hemorrhagic stroke on day 11). Three studies (3,8,19) reported on new post-discharge PPI with an incidence of 0.65% (6 of 923).

Meta-analyses evaluating outcomes showed that there were no statistically significant differences in effect estimates for ED as compared with SD patients in terms of discharge to 30-day mortality (OR: 0.65; 95% CI: 0.23 to 1.82; $I^2 = 0\%$) (**Figure 2**). Notably, ED patients were less likely to be readmitted for any cause within 30 days of discharge (OR: 0.63, 95% CI: 0.41 to 0.98; $p = 0.04$; $I^2 = 0\%$) (**Figure 2**). Patients that followed a SD pathway were more likely to have a pre-existing PPI (OR: 1.57; 95% CI: 1.00 to 2.46; $p = 0.05$; $I^2 = 17\%$); however, no significant difference in effect estimates was found for the need of new PPI after discharge (OR: 1.61; 95% CI: 0.19 to 13.71; $I^2 = 40\%$) (**Figure 3**). Sensitivity analysis comparing random- versus fixed-effects suggests no difference in effect estimates between the 2 models **Table 6**. Our confidence in estimates was very low, owing to indirectness, imprecision, risk of bias due to the observational nature of the studies, and potential selective reporting of outcomes (**Table 5**).

DISCUSSION

The main finding of this meta-analysis of 8 observational studies is that ED by day 3 after TAVR is safe in selected patients, and showing similar rates of discharge to 30-day mortality with a lower 30-day readmission rate after ED. We also found similar rates of need for PPI after discharge. However, this evidence basis consists of low-quality studies confounded by selection bias. Finally, we observed marked variability in institutional discharge programs/protocols, suggesting a limited evidence basis around best practice. Therefore, it is unlikely that this will be defined by future randomized controlled trials, and thus, the current study represents an important synthesis of available evidence.

PATIENT ELIGIBILITY. The safety of ED strategies is based on a multidisciplinary team approach, from pre-screening through post-procedural, physiological, functional, and social assessments of patient suitability (3,4,23). The first step is the establishment of a patient's baseline functional and physiological baseline status to determine whether an ED pathway is appropriate. Next, candidates are assessed for suitability for a minimalistic procedure, and employing percutaneous transfemoral access under local anesthesia and sedation. Although patients may be eligible for ED, periprocedural complications can occur and can then render the patient unsuitable for ED. The main aspects of care, although homogeneous thus far, are the introduction of a minimalist approach, early stepdown, early ambulation, and resumption of self-caring activities.

TABLE 3 Discharge Characteristics

First Author, Year (Ref. #)	Strategy	Discharge From ICU (Days ± Days)	Discharge From Hospital (Days ± Days)	Early Discharge Cutoff	Discharge Home, %	Discharge to Supported Facility, %	Discharge Program Characteristics
Aldalati, 2018 (19)	ED SD	0.9 ± 1.6 1.4 ± 1.8	3 ± 0.0 8.3 ± 6.0	≤3 days	NA	NA	Patients had general anesthesia (other than 2 who had conscious sedation), and were eligible for early discharge if they had no evidence of conduction disturbance (or already paced), no change in renal function, and no bleeding or requirement for blood transfusion
Alkhalil, 2018 (20)	ED SD	NA	2.3 ± 0.8 5.5 ± 2.3	≤3 days	44/54 (81)* 10/54 (19)*	42/54 (78)* 12/54 (22)*	Patients had minimally invasive strategy using percutaneous transfemoral access, with TTE under local anesthesia and minimal conscious sedation, 24-h temporary pacemaker in ICU
Rathore, 2017 (22)	ED SD	22.1 ± 2.2 h 48.5 ± 27.5 h	1 3.4 ± 2.3	<1 day	NA	NA	No general anesthetic, Foley catheter, or central lines used. Safe discharge was based upon lack of complications, early ambulation and family support
Lauck, 2016 (4)	ED SD	<24 h	1.3 ± 0.8 3.3 ± 0.8	≤2 days	150/150 (100) 234/243 (96)	0 9/243 (3.7)	Vancouver TAVR discharge pathway
Serletis-Bizios, 2016 (23)	ED SD	24 h 24 h	2.2 ± 0.5 6.5 ± 2.6	≤3 days	NA	NA	All patients underwent transfemoral with local anesthesia and were monitored for 24 h in ICU. Before discharge TTE was obtained
Barbanti, 2015 (8)	ED SD	1.2 ± 0.4 3.6 ± 1.9	2.1 ± 0.8 6.5 ± 3.5	≤3 days	NA	NA	Program based on early de-escalation of pacing wires, ICU monitoring, and physician-led assessments of safety for discharge
Durand, 2015 (3)	ED SD	1 ± 0.8 2 ± 1.5	3 ± 0.8 6 ± 3.0	≤3 days	NA	NA	All patients underwent transfemoral with local anesthesia and were monitored for 24 h in ICU. Before discharge, TTE was obtained
Parry-Williams, 2014 (21)	ED SD	NA	NA	<4 days	NA	NA	No information available

Values are mean ± SD or n/N (%) unless otherwise indicated. *After 1:1 propensity matching.
ICU = intensive care unit; IQR = interquartile range; other abbreviations as in Tables 1 and 2.

PERIPROCEDURAL COMPLICATIONS. Typically, serious complications with TAVR occur within the first 24 to 48 h of the procedure (25-30). Therefore, TAVR recipients have been traditionally monitored in high dependency units for signs of hemodynamic instability, vascular, cerebrovascular, and rhythm complications for at least 24 h. Thereafter, the focus of their care changes to early ambulation and resumption of their normal self-care activities, while being less intensively monitored for periprocedural complications, such as arrhythmias or conduction disturbances (3,4,23,31). The latter is considered to be among the key obstacles to ED due to its unpredictability, especially after TAVR with self-expanding or mechanically expandable bioprostheses (32). Notably, 15% of the ED patients in our analysis had previous PPI as opposed to 10% of the SD group (**Figure 3**). Hence, discharge is not usually delayed in this subset of patients. However, the need for new PPI certainly delays discharge (31,33). Indeed, although 50% of new conduction disturbances occur intraprocedurally, 44% occur within 3 days after intervention (31,34). Early discharge in these patients is assuredly feasible with protocols for arrhythmia monitoring (35-37), or early PPI indications such us same-day implantation (38). It should be pointed out that our study did not find a higher likelihood for new PPI requirement from discharge to 30 days among those following an ED pathway, likely related to the fact that 83% of the studied population received a balloon-expandable TAVR device. Hence, one could argue that our results are only generalizable to TAVR with the balloon-expandable valve because a small proportion (16%) of the included studies used the Medtronic CoreValve system. Nonetheless, Barbanti et al. (8) reported that TAVR with Medtronic CoreValve was not associated with prolonged stay, though a pre-existing PPI was the strongest independent predictor for ED after TAVR.

ED AND CLINICAL OUTCOMES. Our meta-analysis shows that ED strategy is safe in terms of discharge to 30-day mortality. Only 2 studies report on causes of death among ED patients. All deaths were of cardiovascular origin, but occurring >7 days post-TAVR, therefore, events that would have not been obviated by a prolonged stay. In terms of 30-day VARC complications, inferences cannot be drawn from current studies because their temporal relation to discharge is unknown, and the degree of confounding is

TABLE 4 Risk of Bias Assessment of Discharge to 30-Day Mortality and 30-Day Readmission According to the ACROBAT-NRSI Tool

First Author, Year (Ref. #)	Bias Due to Confounding	Bias in Selection of Participants	Bias in Measurement of Interventions	Bias due to Departures From Intended Interventions	Bias Due to Missing Data	Bias in Measurement of Outcomes	Bias in Selection of Reported Results	Overall Risk of Bias Judgment
Discharge to 30-day mortality								
Aldalati, 2018 (19)	Serious	Low	Low	Low	Moderate	Low	Low	Serious
Alkhalil, 2018 (20)	Low	Low	Low	Low	Moderate	Low	Low	Low
Lauck, 2016 (4)	Serious	Low	Low	Low	Low	Low	Low	Serious
Serletis-Bizios, 2016 (23)	Serious	Low	Low	Low	Low	Low	Low	Serious
Barbanti, 2015 (8)	Low	Low	Low	Low	Low	Low	Low	Low
Durand, 2015 (3)	Serious	Low	Low	Low	Low	Low	Low	Serious
30-day readmission								
Aldalati, 2018 (19)	Serious	Low	Low	Low	Moderate	Low	Low	Serious
Alkhalil, 2018 (20)	Low	Low	Low	Low	Moderate	Low	Low	Low
Rathore, 2017 (22)	Serious	Low	Low	Low	Low	Low	Low	Serious
Lauck, 2016 (4)	Serious	Low	Low	Low	Low	Low	Low	Serious
Serletis-Bizios, 2016 (23)	Serious	Low	Low	Low	Low	Low	Low	Serious
Barbanti, 2015 (8)	Low	Low	Low	Low	Low	Low	Low	Low
Durand, 2015 (3)	Serious	Low	Low	Low	Low	Low	Low	Serious
Parry-Williams, 2014 (21)	Serious	Low	Low	Low	Low	Low	Low	Serious

ACROBAT-NRSI = A Cochrane Risk Of Bias Assessment Tool for Non-Randomized Studies of Interventions.

prohibitively high. Nevertheless, 2 studies (8,20) used a propensity matching methodology to control for confounders and showed that ED is not associated with higher mortality, new PPI, or readmissions.

Interestingly, we found that ED patients were less likely to be readmitted at 30 days, and this is in line with a recently published analysis of the U.S. National Readmissions Database suggesting that prolonged stay after TAVR was independently associated with 30-day readmissions (39). This effect may be partially explained by a higher comorbidity burden, but also by the increasing incidence of health care-associated infections per day of stay. Because infections account for 13% of readmissions (39) and for 18% to 30% of 30-day mortality in TAVR patients (40,41), a reduction in LoS and resulting

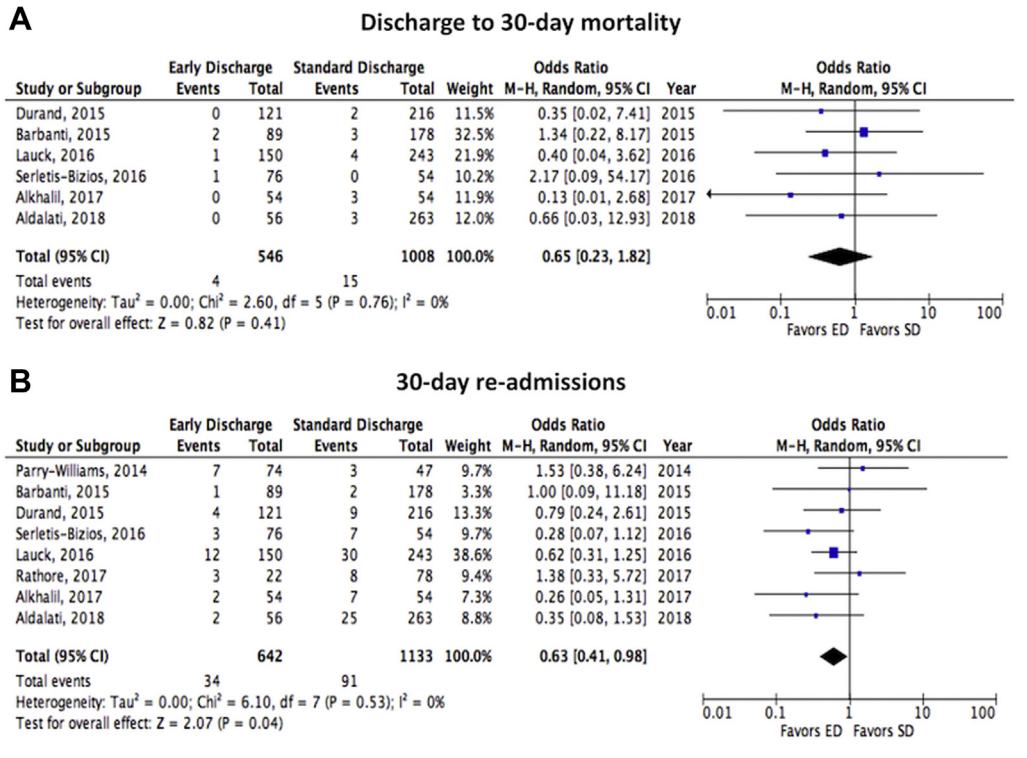
TABLE 5 GRADE Assessment of Overall Strength of Evidence

Certainty Assessment							Patients, n/N (%)		Effect			
Studies, N	Study Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Considerations	Early Discharge	Standard Discharge	Relative, OR (95% CI)	Absolute, (95% CI)	Certainty	Importance
Discharge to 30-day mortality												
6	Observational studies	Very serious*	Not serious†	Serious‡	Serious§	All plausible residual confounding would reduce the demonstrated effect	4/546 (0.7)	15/1,008 (1.5)	0.65 (0.23–1.82)	5 fewer per 1,000 (from 11 fewer to 12 more)	⨁◯◯◯ Very low	Critical
30-day readmission												
8	Observational studies	Very serious*	Not serious†	Serious‡	Serious§	All plausible residual confounding would reduce the demonstrated effect	34/642 (5.3)	91/1,133 (8.0)	0.63 (0.41–0.98)	27 fewer per 1,000 (from 2 fewer to 44 fewer)	⨁◯◯◯ Very low	Critical

*Very serious risk of bias due to confounding. †Unimportant, small variation in point estimates with large overlap in CIs and low I^2. ‡Most participants received balloon-expandable Edwards SAPIEN valve systems. §Confidence intervals overlap no effect with small total number of events.

CI = confidence interval; OR = odds ratio.

FIGURE 2 Discharge to 30-Day Mortality and 30-Day Readmission According to Discharge Strategy

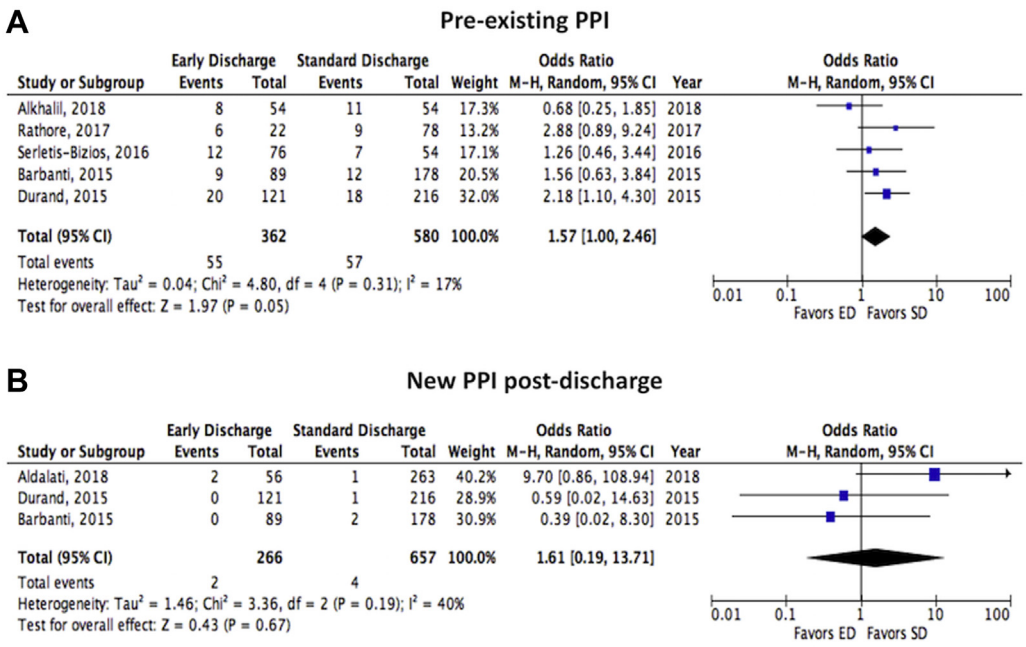


Forest plots of pooled treatment effect estimates of **(A)** discharge to 30-day mortality, **(B)** readmission rates at 30 days, in patients undergoing transcatheter aortic valve replacement following an early versus standard discharge pathways. ED = early discharge; CI = confidence interval; M-H = Mantel-Haenszel; SD = standard discharge.

health care-associated infections may drive further improvement in TAVR outcomes and, thus, reduction in resource utilization. In this regard, studies have shown that patients receiving general anesthesia were more likely to incur respiratory complications such as pneumonia (42-44) after TAVR, again, partially explaining a longer LoS. Moreover, surgical femoral access and general anesthesia provide no advantages in terms of procedural complication rates compared with percutaneous femoral access and local anesthesia/conscious sedation. However, the latter was associated with a reduction in LoS by 1 to 1.5 days (45,46).

ED WINDOW. To date, the ED approach has been adopted worldwide; however, no consensus has been reached on optimal LoS for TAVR patients without periprocedural complications. Indeed, although 1 study established a cutoff for an ED strategy at 4 days (47), isolated reports of same-day discharge following TAVR have also emerged (48). Our meta-analysis suggests that ED (≤3 days) is as safe in terms of discharge to 30-day mortality, readmissions, and new PPI after discharge as compared with SD. Furthermore, Kamioka et al. (49) recently showed that next-day discharge is safe after transfemoral TAVR using balloon-expandable valves and reported no significant differences in terms of mortality and cardiovascular readmission as compared with SD, but next-day discharge patients had lower likelihood of readmission for noncardiovascular causes than SD patients (49). Therefore, the results of the FAST-TAVI (Feasibility And Safety of Early Discharge After Transfemoral Transcatheter Aortic Valve Implantation) (50) and the 3MTAVR (Multidisciplinary, Multimodality, But Minimalist Approach to Transfemoral Transcatheter Aortic Valve Replacement; NCT02287662) registries, dedicated to studying discharge practices after TAVR, are much awaited to further inform current practices. In the meantime,

FIGURE 3 Pre-Existing Pacemakers and Need for Pacemaker Implantation After Discharge According to Discharge Strategy



(A) Forest plot of pooled treatment effect estimates of proportion of patients with pre-existing permanent pacemaker implantation (PPI), **(B)** proportion of patients requiring PPI after discharge to 30 days. Abbreviations as in Figure 2.

we propose a framework to guide discharge practices after TAVR (Figure 4).

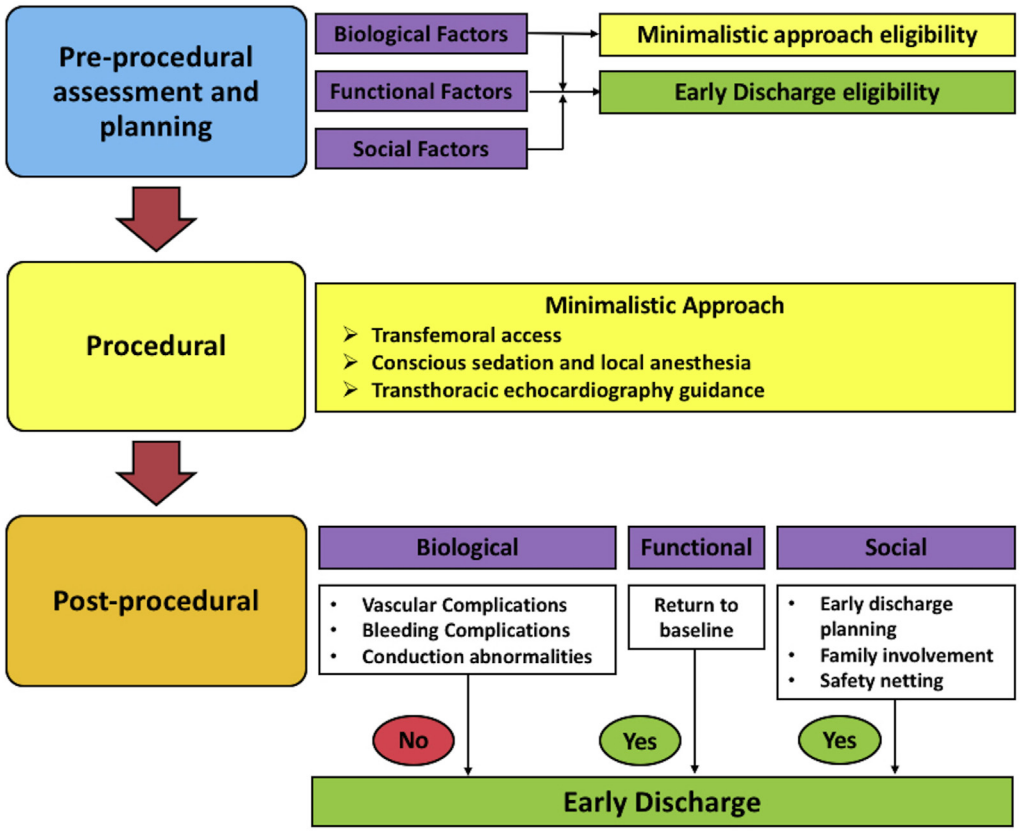
STUDY LIMITATIONS. The main limitation lies with the small number of studies, patients, and events informing each outcome, and the nonrandomized nature of the included studies that introduce selection bias. Included studies sought to identify predictors of ED and develop pathways protocols. Patients selected for ED are certainly highly selected and likely to be lower risk, although the mean reported STS score was 6% in our pooled studies. On the other hand, there are many issues that go into the decision-making process that are not accounted by pre-operative risk scores and/or other measurable variables. Therefore, procedural strategies were heterogeneous amongst included studies reflecting interinstitutional variability and preferences. Also, the decision to follow an ED strategy was at the discretion of the heart team and without a consistent cutoff in terms of days. Importantly, programs discharging patients early tend to be more experienced, and this results in better outcomes, regardless of the discharge pathway. Individual-patient data were not available, precluding, therefore, adjustments for any differences in baseline clinical data or type of TAVR device, for further comparisons across the cohorts. Hence, given that more than 80% of this analysis included patients who underwent TAVR with the balloon-expandable valve, our results must be interpreted accordingly. Although randomized controlled trials may help determine the ideal pathway to follow, these might be difficult to undertake. Certainly, more data must be accrued to better characterize the determinants and predictors of ED.

TABLE 6 Sensitivity Analysis Comparing Random- Versus Fixed-Effects Models

Outcome	Random-Effects Model	Fixed-Effects Model
Discharge to 30-day mortality	0.65 (95% CI: 0.23–1.82)	0.58 (95% CI: 0.22–1.51)
30-day readmissions	0.63 (95% CI: 0.41–0.98)	0.61 (95% CI: 0.40–0.93)
New pacemaker permanent implantation	1.61 (95% CI: 0.19–13.7)	1.49 (95% CI: 0.37–5.91)

Sensitivity analysis comparing random- versus fixed-effects shows no changes in effect estimates between the 2 models.
CI = confidence interval.

FIGURE 4 ED Pathway



Flowchart showing considerations to guide early discharge pathways following transcatheter aortic valve replacement. ED = early discharge.

CONCLUSIONS

Early discharge following uncomplicated TAVR is safe in selected patients without having a negative impact on discharge to 30-day mortality, readmission rates, and need for PPI following discharge. These data support the safety of current programs aiming an ED pathway in selected patients undergoing TAVR. Institutional protocols with the input from different members of the multidisciplinary heart team should be devised to optimize discharge pathways and, hence, help improve health care resource utilization.

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PERSPECTIVES

WHAT IS KNOWN? Contemporary TAVR series show a wide variation in terms of length of stay after the procedure, and this is despite increasing operator experience, improved and lower profile devices, and adoption of minimalistic approaches.

WHAT IS NEW? Early discharge (≤3 days) strategy in uncomplicated TAVR is as safe as standard discharge in terms of discharge to 30-day mortality, readmission rates, and new pacemaker implantation after discharge.

WHAT IS NEXT? Studies examining the cost-effectiveness of early discharge strategies of the established balloon-expandable and self-expanding devises are required. The safety of early discharge strategies for newer TAVR devices needs to be further studied.

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