**Early vs Standard Discharge After Transcatheter Aortic Valve Implantation: A Systematic Review and Meta-analysis**

Rafail A. Kotronias,1,2 MBChB, MSc; Michael Teitelbaum,3 MD; John G. Webb, MD4; Darren Mylotte,5 MBBCh, MD; Barbanti Marco,6 MD, PhD; David A. Wood,4 MD; Brennan Ballantyne,3 MD; Alyson Osborne,3 MD; Karla Solo,7 MSc; Chun Shing Kwok,1,8 MBBS, MSc; Mamas A. Mamas,1,8 BMBCh, DPhil; Rodrigo Bagur,1,3,7 MD, PhD

1Keele Cardiovascular Research Group, Institute for Applied Clinical Science and Centre for Prognosis Research, Institute of Primary Care and Health Sciences, University of Keele, Stoke-on-Trent, UK.

2Oxford University Clinical Academic Graduate School, Oxford University, Oxford, UK.

3London Health Sciences Centre, Western University, London, Ontario, Canada.

4Centre for Heart Valve Innovation, St. Paul’s Hospital, University of British Columbia, Vancouver, BC, Canada.

5Galway University Hospitals, National University of Ireland, Galway, Ireland.

6Division of Cardiology, Cardio-Thoracic-Vascular Department, University of Catania, Catania, Italy.

7Department of Epidemiology and Biostatistics, Schulich School of Medicine & Dentistry, Western University, London, Ontario, Canada.

8The Heart Centre, Royal Stoke Hospital, University Hospital of North Midlands Trust,

Stoke-on-Trent, UK.

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**Corresponding author**

Rodrigo Bagur, MD, PhD, FAHA

University Hospital, London Health Sciences Centre, Western University

339 Windermere Road, N6A 5A5, London, Ontario, Canada

Phone: +1-519-663-3997 - FAX: +1-519-434-3278.

E-mail: rodrigobagur@yahoo.com

**Abstract**

**Objectives:** We sought to assess the clinical outcomes of patients undergoing transcatheter aortic valve implantation (TAVI) with early discharge (ED) versus standard discharge (SD) pathways.

**Background:** Minimalist approaches for TAVI have been developed targeting different aspects of the procedure such as local anesthesia or sedation, intra-procedural imaging, vascular access, post-operative monitoring and care, and discharge planning. Their incorporation into routine clinical practice aim to reduce length of hospital stay (LoS) and healthcare cost utilisation without adversely affecting outcomes when compared to standard approaches.

**Methods:** We conducted a literature search of MEDLINE and EMBASE to identify studies that investigated ED (≤3 days) versus SD in TAVI patients. Random-effects meta-analyses were used to estimate the effect of ED compared with SD with regards to 30-day mortality after discharge, 30-day re-admission 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 Society of Thoracic Surgeons score was 6.7. Meta-analyses evaluating discharge to 30-day mortality (OR: 0.65, 95%CI 0.23-1.82, I2=0%) and discharge to 30-day new PPI (OR: 1.61, 95%CI 0.19-13.71, I2=40%) showed no significant difference of an ED compared to a SD strategy. Notably, ED patients were less likely to be re-admitted after ED when compared to SD patients (OR: 0.63, 95%CI 0.41-0.98, P=0.04, I2=0%).

**Conclusion:** ED following uncomplicated TAVI is safe in terms of discharge to 30-day mortality or need for PPI following discharge. Moreover, ED patients experienced a lower rate of re-admissions. These data support the safety of programs aiming an ED pathway in selected TAVI patients. Institutional protocols with the input from different members of the multi-disciplinary heart team should be devised to optimize discharge processes to improve healthcare resource utilisation.

**Condensed abstract**

Length of stay following transcatheter aortic valve implantation (TAVI) may be reduced owing to device improvements, increased operator experience and procedural minimalistic approaches. We conducted a systematic review and meta-analysis assessing clinical outcomes of TAVI patients following early versus standard discharge pathways. Eight studies including 1,775 participants were analyzed. An early discharge strategy showed similar outcomes in terms of discharge to 30-day mortality (OR: 0.65, 95%CI 0.23-1.82) and new permanent pacemaker implantation after discharge (OR: 1.61, 95%CI 0.19-13.71), while associated with reduced 30-day re-admission rates (OR: 0.63, 95%CI 0.41-0.98, P=0.04). Hence, early discharge pathways appear safe in selected TAVI patients.

**Clinical Perspectives**

**What’s known?**

Contemporary TAVI 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’s new?**

Early discharge (≤3 days) strategy in uncomplicated TAVI is as safe as standard discharge in terms of discharge to 30-day mortality, re-admission rates and new pacemaker implantation.

**What’s 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 TAVI devices needs to be further studied.

**Abbreviation List**

CI: confidence interval

ED: early discharge

ICU: intensive care unit

LoS: length of stay

OR: odds ratio

PPI: permanent pacemaker implantation

SD: standard discharge

TAVI: transcatheter aortic valve implantation

**introduction**

Transcatheter aortic valve implantation (TAVI) 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 peri-procedural care and rapid recovery and discharge pathways(3,4). “Minimalist” approaches have been developed targeting different aspects of the procedure, such as local anesthesia or sedation, intra-procedural imaging, vascular access, post-operative monitoring and care, and discharge planning(3-7). Single-centre studies have shown that adoption of strict, TAVI-specific clinical care pathways, helped to identify candidates for safe early discharge (ED) after TAVI(4,8). The incorporation of these strategies into routine clinical practice has reduced length of hospital stay (LoS) and healthcare cost utilization without adversely affecting index procedural outcomes when compared to standard approaches(9,10). LoS and 30-day re-admission rates are important quality of care indicators and predictors of outcome in the elderly(11), however, considerable differences in LoS (1-11 days) are reported in contemporary TAVI registries(12,13). In addition, it is unclear whether an ED following TAVI 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, re-admission rates and need for permanent pacemaker implantation (PPI) at 30 days following an ED versus standard discharge (SD) pathways.

**Methods**

**Search Strategy**

We conducted a search of MEDLINE, EMBASE and conference abstracts, from conception to December 2017 using OvidSP (Ovid Technologies). 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 two investigators (RAK and MT) 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 (RB).

**Eligibility Criteria**

We only included English written studies evaluating ED versus SD in patients undergoing TAVI. Our primary outcomes of interest were mortality from discharge to 30 days and 30-day re-admission. The secondary outcome was the need for permanent pacemaker implantation (PPI) after discharge to 30 days. 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 (CI). 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. The outcomes of interest and follow-up were also extracted on a pre-formatted table. As above mentioned, disagreements were resolved by consensus.

**Data Analysis**

RevMan (Review Manager version 5.3, Nordic Cochrane Centre, København, Denmark) was used to perform random- and fixed-effects meta-analyses using the Mantel-Haenszel method to determine pooled OR for dichotomous data with regards to post-TAVI outcomes in patients discharged early (≤3 days) versus patients discharged in standard fashion (>3 days). The Cochrane Q-statistic (I2) was used to assess the consistency among studies with I2<25% indicating low, I2 25-50% moderate, and I2>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 of which, 642 followed and ED pathway. The mean age was 82.4±1.5 years and 50.0% (887/1775) were female. Among studies reporting logistic EuroSCORE, the mean score was 15.9±0.6 in ED cohorts compared to 19.3±3.5 in SD patients(3,19,21,23), whilst 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 TAVI patients, 11.9% (112/942) had a previously implanted permanent pacemaker; 15.2% (55/362) in the ED group and 9.8% (57/580) 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 early and standard discharge 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% (181/295) than patients SD patients 31.4% (215/684)(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 cut-down and 10% underwent transapical TAVI(3,4,8,19,20,22,23). The balloon-expandable Edwards SAPIEN valve systems (Edwards Lifesciences Inc., Irvine, California) were implanted in 83% of patients and the self-expanding CoreValve (Medtronic, Minneapolis, Minnesota) in 16%; with no significant difference between the ED and SD groups, 83% and 15% vs 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, whilst 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 one developed a dedicated and standardised TAVI discharge pathway(4). Seven studies(3,4,8,19-21,23) defined ED as a LoS ≤3 days with one study(22) setting the cut-off at 1 day. Discharge destinations were reported by two studies(4,20), with home being the destination in 88.9% of ED and 66.6% of SD patients, the remaining being discharges 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 four studies(19,22-24), with no information available in the other four(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 six studies were at serious risk of bias and two were identified as having low risk of bias for both, discharge to 30-day mortality and re-admission 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, re-admission and new PPI rates at 30 days**

A total of six studies(3,4,8,19,20,23) reported on discharge to 30-day mortality and eight (3,4,8,19,20,22-24) on 30-day re-admissions. Crude outcomes in ED versus SD patients are presented in **Table 2**. Mortality between discharge and 30 days occurred in 1.1% (19/1775) of patients, and 7.0% (125/1775) of discharged patients were re-admitted within 30 days. Two studies(8,23) reported causes of death in ED patients and one(19) reported causes of 30-day re-admissions in both groups. Of the 4 deaths that occurred in the ED group, the cause of death was reported in 3. One patient suffered a fatal myocardial infarction at day 9, and two 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% (6/923).

Meta-analyses evaluating outcomes showed that there were no statistical significant differences in effect estimates for ED as compared to SD patients in terms of discharge to 30-day mortality (OR: 0.65, 95%CI: 0.23-1.82, I2=0%), **Figure 2**. Notably, ED patients were less likely to be re-admitted for any cause within 30 days of discharge (OR: 0.63, 95%CI: 0.41-0.98, P=0.04, I2=0%), **Figure 2**. Patients that followed a SD pathway were more likely to have a pre-existing PPI (OR: 1.57, 95%CI: 1.00-2.46, P=0.05, I2=17%);however, no significant difference in effect estimates was found for the need of new PPI after discharge (OR: 1.61, 95%CI: 0.19-13.71, I2=40%), **Figure 3**. Sensitivity analysis comparing random- versus fixed-effects suggests no difference in effect estimates between the two 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 TAVI is safe in selected patients, and showing similar rates of discharge to 30-day mortality with a lower 30-day re-admission 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 observe 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 if 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, peri-procedural complications can occur which 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.

**Peri-procedural Complications**

Typically, serious complications with TAVI occur within the first 24-48 hours of the procedure(25-30). Therefore, TAVI recipients have been traditionally monitored in high dependency units for signs of hemodynamic instability, vascular, cerebrovascular and rhythm complications for at least 24 hours. Thereafter, the focus of their care changes to early ambulation and resumption of their normal self-care activities, whilst being less intensively monitored for peri-procedural complications, such as arrhythmias or conduction disturbances(3,4,23,31). The latter is considered to be amongst the key obstacles to ED due to its unpredictability, especially after TAVI 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, while 50% of new conduction disturbances occur intra-procedurally, 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, thus, likely related to the fact that 83% of the studied population received a balloon-expandable TAVI device. Hence, one could argue that our results are only generalizable to TAVI with the balloon-expandable valve since a small proportion (16%) of the included studies used the Medtronic CoreValve system. Nonetheless, Barbanti and colleagues(8) reported that TAVI with Medtronic CoreValve was not associated with prolonged stay, though a pre-existing PPI was the strongest independent predictor for ED after TAVI.

**Early Discharge 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 amongst ED patients. All deaths were of cardiovascular origin, but occurring >7 days post-TAVI, 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 prohibitively high. Nevertheless, two studies(8,20) use a propensity matching methodology to control for confounders and show that ED is not associated with higher mortality, new PPI or re-admissions.

Interestingly, we found that ED patients were less likely to be re-admitted at 30 days, and this is in line with a recently published analysis of the US National re-admissions database suggesting that prolonged stay after TAVI was independently associated with 30-day re-admissions(39). This effect may be partially explained by a higher comorbidity burden, but also the increasing incidence of healthcare associated infections (HAI) per day of stay. Since infections account for 13% of re-admissions(39) and for 18% to 30% of 30-day mortality in TAVI patients(40,41), a reduction in LoS and resulting HAIs may drive further improvement in TAVI outcomes and thus, reduction in resource utilisation. In this regard, studies have shown that patients receiving general anesthesia were more likely to incur respiratory complications such as pneumonia(42-44) after TAVI, again, partially explaining a longer LoS. Moreover, surgical femoral access and general anesthesia provide no advantages in terms of procedural complication rates compared to percutaneous femoral access and local anesthesia/conscious sedation. However, the later was associated with a reduction in LoS by 1-1.5 days(45,46).

**Early Discharge Window**

 To date, the ED approach has been adopted worldwide, however, no consensus has been reached on optimal LoS for minimalistically treated TAVI patients without peri-procedural complications. Indeed, while one study established a cut-off for an ED strategy at 4 days(47), isolated reports of same-day discharge following TAVI have also emerged(48). Our meta-analysis suggests that ED (≤3 days) is as safe in terms of discharge to 30-day mortality, re-admissions and new PPI after discharge as compared to SD. Furthermore, Kamioka and colleagues(49) recently showed that next-day discharge is safe after transfemoral TAVI using balloon-expandable valve and reported no significant differences in terms of mortality and cardiovascular readmission as compared to SD, but next-day discharge patients had lower likelihood of readmission for non-cardiovascular causes than SD patients(49). Therefore, the results of the FAST-TAVI(50) and the Multidisciplinary, Multimodality, But Minimalist Approach to Transfemoral Transcatheter Aortic Valve Replacement (3MTAVR, ClinicalTrials.gov: NCT02287662) registries dedicated to studying discharge practices after TAVI are much awaited to further inform current practices. In the meantime, we propose a framework to guide discharge practices after TAVI (**Figure 4**).

**Limitations**

The present study has several limitations. The main limitation lies with the small number of studies, patients and events informing each outcome, and the non-randomized 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, on the other hand, there are many issues that go into the decision-making process that are not accounted for preoperative risk scores and/or other measurable variables. Therefore, procedural strategies were heterogeneous amongst included studies reflecting inter-institutional variability and preferences. Also, the decision to follow an ED strategy was at the discretion of the Heart Team and without a consistent cut-off 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 TAVI device, for further comparisons across the cohorts. Hence, given that more than 80% of this analysis included patients who underwent TAVI with the balloon-expandable valve, our results must be interpreted accordingly. Although randomised-controlled trials may help determine the ideal pathway to follow, these might be difficult to undertake. Certainly, more data must be accrued to better characterise the determinants and predictors of ED.

**CONCLUSION**

Early discharge following uncomplicated TAVI is safe in selected patients without negatively impacting on discharge to 30-day mortality, re-admission rates and need for PPI following discharge. These data support the safety of current programs aiming an ED pathway in selected patients undergoing TAVI. Institutional protocols with the input from different members of the multi-disciplinary Heart Team should be devised to optimize discharge pathways and hence, help improve healthcare resource utilisation.

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**Table 1: Baseline Characteristics**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study ID**Records identified through database searching MEDLINE and EMBASE.(n = 555)ScreeningIncludedEligibilityIdentificationRecords screened(n = 555)Records excluded(n = 477)Full-text articles assessed for eligibility(n = 78)Full-text articles excluded, with reasons (n = 60)* No data (n = 24)
* Reviews (n = 6)
* Duplicate (n = 19)
* Protocol (n = 2)
* Editorials and case series

(n = 4) adasd | **Strategy** | **Mean Age (years)**  | **Male (%)** | **Logistic EuroSCORE** | **STS score** | **Previous Pacemaker (%)** | **Multivessel disease (%)** | **LVEF (%)** | **CKD** **(%)** | **COPD (%)** | **PVD (%)** |
| Aldalati,2017(19) | TotalEDSD | 82.6±6.781.8±7.782.8±6.5 | 50.24850.5 | 20.8±1016.7±921.7±11 | NA | NA | 17.71417 | 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,2017(20) | TotalEDSD | 82.582.7±7.5182.2±8.12 | 44.444.444.4 | NA | 8.38.17±3.908.53±4.58 | 19/108 (17.6)8/54 (14.8)11/54 (20.4) | NA | 51.2653.29±1251.78±13.0 | NA | NA | 15/108 (14)7/54 (13)8/54 (15) |
| Rathore,2017(22) | TotalEDSD | 80.6±8.581.5±7.680.3±8.8 | 495946 | NA | 6.9±3.296.3±2.676.8 ±3.45 | 15/100 (15)6/22 (27)9/78 (12) | NA | 52.551.6±13.553.7±12.5 | 38/100 (38)10/22 (45)28/78 (36) | NA | NA |
| Lauck,2016(4) | TotalEDSD | 81.5±7.981.6±7.981.3±7.8 | 60.659.361.3 | NA | 6.4±3.86.5±3.46.4 ± 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) | TotalEDSD | 84.7±5.484.4±5.885.4±4.8  | 524759 | 15.3±8.515.7±8.814.7±8.0 | NA | 19/130 (15)12/76 (16)7/54 (13) | NA | 63.0±13.162.7±13.963.4±14.1 | NA | NA | 8/130 (6)7/76 (9)1/54 (2) |
| Barbanti, 2015(8) | TotalEDSD | 80.081.1±4.980.7±5.7 | 41.943.840.8 | NA | 6.36.0±4.26.5±4.5 | 21/267 (7.9)9/89 (10)12/178 (6.7) | NA | 51.851.9±11.551.8±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) | TotalEDSD | 84.0±6.883.7 ± 6.984.2 ± 6.2 | 43.047.940.3 | 16.9±9.615.6 ± 9.617.6 ± 9.5 | NA | 38/337 (11.3)20/121 (16.5)18/216 (8.3) | NA | 59.0±16.359.7 ± 16.358.7 ± 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) |

ED: early discharge, CKD: chronic kidney disease, COPD: chronic obstructive pulmonary disease, LVEF: left ventricular ejection, NA: not applicable, PVD: peripheral vascular disease, SD: standard discharge, STS: Society of Thoracic Surgeons.

**Table 2: Procedural characteristics and outcomes**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author,** **year, country** | **Procedural characteristics** | **Type of valve, Approach** | **Time-frame of assessment** | **Outcomes** | **Early Discharge** | **Standard Discharge** |
| Aldalati, 2017(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 cut down: 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%), Transfermoral surgical cut down: 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 | 0/56 (0%) | 3/263 (1.1%) |
| 30-day stroke | 0/56 (0%) | 10/263 (3.8%) |
| 30-day re-admission | 2/56 (3.6%) | 25/263 (9.5%) |
| 30-day acute kidney injury | 0/56 (0%) | 24/263 (9%) |
| 30-day life-threatening bleed | 0/56 (0%) | 21/263 (8%) |
| 30-day major vascular complication | 0/56 (0%) | 15/263 (5.7%) |
| Alkhalil, 2017(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 cut-down, CoreValve: 32/54 (59.3%) SAPIEN and SAPIEN-XT: 22/54 (40.7%)**SD**Transfemoral: 100%, Percutaneous access mainly and some occasions surgical cut-down), CoreValve: 27/54 (50%), SAPIEN & SAPIEN-XT: 27/54 (50%)  | In-hospital and 30 days | Major vascular complications± | 1/54 (1.9%) | 1/54 (1.9%) |
| Minor vascular complications± | 1/54 (1.9%) | 5/54 (9.3%) |
| New Dialysis± | 0/54 (0%) | 0/54 (0%) |
| New permanent pacemaker implantation | 14/163 (8.6%) | 27/108 (26%) |
| Discharge to 30-day mortality± | 0/54 (0%) | 3/54 (5.6%) |
| 30-day stroke± | 0/54 (0%) | 2/54 (3.7%) |
| 30-day readmissions± | 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 | 0/22 (0%) | 0/78 (0%) |
| Stroke | 0/22 (0%) | 2/78 (2.6%) |
| Blood transfusion | 0/22 (0%) | 5/78 (6.4%) |
| Vascular complications | 0/22 (0%) | 8/78 (10%) |
| New permanent pacemaker implantation | 0/22 (0%) | 11/78 (14%) |
| 30-day readmission | 3/22 (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 | 1/150 (0.7%) | 4/243 (1.6%) |
| Periprocedural myocardial infarction | 0/150 (0%) | 0/243 (0%) |
| 30-day re-admission | 12/150 (8%) | 30/243 (12%) |
| Stroke | 0/150 (0%) | 3/243 (1.2%) |
| Life threatening bleeding | 0/150 (0%) | 3/243 (1.2%) |
| Major bleeding | 1/150 (0.7%) | 10/243 (4.1%) |
| Minor bleeding | 1/150 (0.7%) | 6/243 (2.5%) |
| Major vascular complications | 0/150 (0%) | 5/243 (2.1%) |
| New dialysis | 0/150 (0%) | 1/243 (0.4%) |
| New permanent pacemaker | 4/150 (2.7%) | 23/243 (9.5%) |
| 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 | Peri-procedural 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 re-hospitalisation | 3/76 (4%) | 7/54 (13%) |
| 30-day combined endpoint (death and hospitalisation) | 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-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 re-hospitalisation± | 1/89 (1.1%) | 2/178 (1.1%) |
| 30-day combined safety end point± | 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 | Peri-procedural 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 rehospitalisation | 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 re-admission | 7/74 (9.5%) | 3/47 (6.4%) |

±: After 1:1 propensity matching. AKI: acute kidney injury, ED: early discharge, IV: Intravenous, OR: Odds ratio, SD: standard discharge, TTE: transthoracic echocardiogram.

**Table 3. Discharge characteristics**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study (Author, Year)** | **Strategy** | **Discharge from ICU (days ± days)** | **Discharge from hospital (days ± days)** | **Early discharge cut-off** | **Discharge home (%)** | **Discharge to supported facility (%)** | **Discharge program characteristics** |
| Aldalati, 2017(19) | EDSD | 0.93±1.61.43±1.8 | 3±0.08.3±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, 2017(20) | EDSD | NA | 2.3±0.765.5±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-hour temporary pacemaker in ICU |
| Rathore, 2017(22) | EDSD | 22.1±2.2 hours48.5±27.5 hours | 13.4±2.3 | <1 day | NA | NA | No general anaesthetic, Foley catheter or central lines used. Safe discharge was based upon lack of complications, early ambulation and family support |
| Lauck, 2016(4) | EDSD | <24 hours | 1.3±0.75 3.3±0.75 |  ≤2 days | 150/150 (100)234/243 (96) | 0%9/243 (3.7) | Vancouver TAVI discharge pathway |
| Serletis-Bizios, 2016(23) | EDSD | 24 hours24 hours | 2.2±0.56.5±2.6 | ≤3 days | NA | NA | All patients underwent transfemoral with local anaesthesia and were monitored for 24 hours in ICU. Prior to discharge TTE was obtained |
| Barbanti, 2015(8) | EDSD | 1.2±0.43.6±1.9 | 2.1±0.86.5±3.5 | ≤3 days | NA | NA | Programme based on early de-escalation of pacing wires, ICU monitoring and physician led assessments of safety for discharge |
| Durand, 2015(3) | EDSD | 1±0.82±1.5 | 3±0.86±3.0 | ≤3 days | NA | NA | All patients underwent transfemoral with local anaesthesia and were monitored for 24 hours in ICU. Prior to discharge TTE was obtained |
| Parry-Williams, 2014(21) | EDSD | NA | NA | <4 days | NA | NA | No information available |

±: After 1:1 propensity matching; ED: Early discharge; ICU: Intensive Care Unit; IQR: Interquartile Range; SD: standard discharge; TTE: transthoracic echocardiogram

**Table 4: Risk of bias assessment of discharge to 30-day mortality and 30-day readmission according to the ACROBAT-NRSI tool**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **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 Judgement** |
| **Discharge to 30-day Mortality** |
| Aldalati, 2017(19) | Serious | Low | Low | Low | Moderate | Low | Low | Serious |
| Alkhalil, 2017(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 Re-admission** |
| Aldalati, 2017(19) | Serious | Low | Low | Low | Moderate | Low | Low | Serious |
| Alkhalil, 2017(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.

**Table 5: GRADE Assessment of Overall Strength of Evidence**

| **Certainty Assessment** | **№ of patients** | **Effect** | **Certainty** | **Importance** |
| --- | --- | --- | --- | --- |
| **№ of studies** | **Study design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **Early discharge** | **Standard discharge** | **Relative(95% CI)** | **Absolute(95% CI)** |
| **Discharge to 30-day Mortality** |
| 6 | observational studies | very serious1 | not serious2 | serious3 | serious4 | all plausible residual confounding would reduce the demonstrated effect | 4/546 (076%) | 15/1008 (1.5%) | **OR 0.65**(0.23-1.82) | **5 fewer per 1,000**(from 11 fewer to 12 more) | ⨁◯◯◯VERY LOW | CRITICAL |
| **30-day Re-admission** |
| 8 | observational studies | very serious1 | not serious2 | serious3 | serious4 | all plausible residual confounding would reduce the demonstrated effect | 34/642 (5.3%) | 91/1133 (8.0%) | **OR 0.63**(0.41-0.98) | **27 fewer per 1,000**(from 2 fewer to 44 fewer) | ⨁◯◯◯VERY LOW | CRITICAL |

CI: confidence interval; OR: odds ratio

1. Very serious risk of bias due to confounding
2. Unimportant, small variation in point estimates with large overlap in CIs and low I2.
3. Most participants received balloon-expandable Edwards SAPIEN valve systems.
4. Confidence intervals overlap no effect with small total number of events.

**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 re-admissions | 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 two models.

**Figure legends**

**Figure 1. PRISMA Flow Diagram.** Flow diagram based on PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses).

**Figure 2.** **Discharge to 30-day mortality and 30-day re-admission according to discharge strategy.** Forest plots of pooled treatment effect estimates of **(A)** discharge to 30-day mortality, **(B)** re-admission rates at 30 days, in patients undergoing transcatheter aortic valve implantation following an early versus standard discharge pathways. ED: Early Discharge. SD: Standard Discharge. M-H: Mantel-Haenszel. CI: confidence interval.

**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. ED: Early Discharge. SD: Standard Discharge. M-H: Mantel-Haenszel. CI: confidence interval.

**Figure 4. Early Discharge Pathway.** Flowchart showing considerations to guide early discharge pathways following transcatheter aortic valve implantation.