Transcatheter Aortic Valve Implantation in the United States: Predictors of Early Hospital Discharge

Short Title: Early Discharge after Transcatheter Aortic Valve Implantation

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Abstract

Background: There is a concerted push for adopting a minimalist strategy with emphasis on early hospital discharge for patients undergoing Transcatheter aortic valve implantation (TAVI). However, studies on discharge patterns and predictors of early discharge (≤3 days post-TAVI) are sparse, in the United States.

Methods: We analyzed using Healthcare Utilization Project, Nationwide inpatient Sample database, 2011-2012. A total of 7,321 TAVI procedures were identified. We compared in-hospital outcomes between early and late discharge cohorts, and determined the predictors of early discharge. Correlation of costs and post-TAVI length of stay was also performed.

Results: Early discharge rate post-TAVI was about 21% in the United States, in 2011-2012. Overall mean age was 81 years. In-hospital adverse outcomes post-TAVI were higher in late discharge cohort (p<0.001). Mean length of stay post-TAVI (7.7 days vs. 2.6 days) and costs ($208,752 vs. $157,663) were significantly higher in late discharge than early discharge cohort. Females, bleeding, blood transfusions, stroke, permanent pacemakers, mechanical circulatory support, acute kidney injury were associated with significantly lower adjusted odds for early discharge. Transfemoral TAVI approach, prior aortic valvuloplasty, and procedure year 2012 were associated with significantly higher odds for early discharge. We observed positive correlation between costs of hospitalization and post-TAVI length of stay (R=0.58; p<0.001).

Conclusions: Females, bleeding, blood transfusions, stroke, permanent pacemakers, mechanical circulatory support devices, renal failure were associated with lower odds for early discharge. Transfemoral approach and prior aortic valvuloplasty increased the likelihood for early discharge. Post-TAVI length of stay was associated with significantly higher hospitalization costs.

Key Words: TAVI; Early discharge

Introduction

Severe aortic stenosis (AS) is a leading cause of morbidity and mortality in the elderly adults.[1] Transcatheter aortic valve implantation (TAVI) has emerged as a promising therapeutic intervention in patients with prohibitive-, high- and intermediate-risk for surgical aortic valve replacement for severe AS.[2-4]

In the current era of cost containment, there is a concerted push for adopting a minimalist strategy in the TAVI patient population periprocedurally.[5] Constituent components of minimalist strategy generally include the following: preference for conscious sedation; transfemoral access; limiting the utility of transeophageal echocardiogram intraprocedurally; and early hospital discharge.[5]

Traditionally, a significant number of patients are kept in the hospital for prolonged monitoring ostensibly more from an abundance of caution than for valid clinical reasons, thus adding significantly to the costs of hospitalization.[6] Recent European studies have demonstrated the feasibility and safety of early hospital discharge after transfemoral TAVI.[6,7] Understanding existing nationwide discharge patterns post-TAVI is critical in order to improve early hospital discharge percentage. However, systematic studies on discharge trends post TAVI are lacking in the United States.

The primary objective of our study was to identify predictors of early hospital discharge. Secondary objectives were: 1) Compare in-hospital outcomes and healthcare resource utilization in early vs. late discharge cohorts; 2) Ascertain the relationship between costs of hospitalization and length of stay, in TAVI.

Methods

Data Source

Our analysis was performed using Healthcare Utilization Project's (HCUP) Nationwide Inpatient Sample (NIS) database, which is sponsored by the Agency for Healthcare Research and Quality (AHRQ). NIS is the largest all-payer inpatient care database available to public that represents 20% sample of all nonfederal community hospitals in the United States.[8] Weights provided by AHRQ were utilized generate national estimates representing >95% of hospital discharges.[9] It contains deidentified extensive data on demographics, clinical information, procedures performed, costs etc, for each hospitalization.

Study Population

We retrieved a total of 7,560 hospitalizations with the principal procedure of TAVI using Internal Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes (35.05 for transfemoral TAVI; 35.06 for transapical TAVI). About 239 subjects had missing values for day of length of inhospital stay and hence were excluded. Patients who suffered in-hospital death were not included this analysis considering our study objectives. Our final cohort comprised of 7,321 procedures.

Outcomes

Similar to prior studies, [6,7] we defined "early discharge" as day of discharge ≤3 days post-TAVI and "late discharge" as day of discharge >3 days post-TAVI. We compared in-hospital outcomes related to TAVI, such as postoperative bleeding, blood transfusions, stroke or transient ischemic attacks (TIA), acute kidney injury (AKI), use of mechanical circulatory support, permanent pacemakers, valvuloplasty, length of hospitalization and costs between early discharge and late discharge cohorts. ICD-9-CM codes were utilized to determine these outcomes **(***Supplementary Table***).** Multivariate models were created to identify various factors and outcomes associated with early discharge. Association of hospitalization costs (estimate of charges billed by the hospital) and post-TAVI length of stay was also analyzed. Elixhauser comorbidity score was used to measure severity of comorbidity burden.[10] NIS database contains completely de-identified data, which precludes need for institutional review board approval.

Statistical Analysis

We used trend weights provided by the HCUP NIS to generate national estimates including sum, rates, mean, proportion and their standard error. To compare baseline characteristics between patients with early discharge to those with late discharge, we use chi-square test for categorical variable and t-test/Wilcoxon rank sum test for continuous variable (as appropriate). Mixed effect logistic model was utilized to assess for independent predictors of early discharge in patients after TAVI, given the nested observations in the NIS database. This model enables us to account for the potential correlation of observations within each hospital. As patient factors are nested within hospital level factors, we build a hierarchical model with unique hospital identification number as random effects in the model.

A multivariate model was created using all the significant variables based on initial univariate analysis. Gender, postoperative bleeding, blood transfusion, stroke/TIA, AKI, pacemakers, mechanical circulatory support use, year of procedure, prior aortic valvuloplasty, TAVI approach (transfemoral vs. transapical) were included in the final multivariate model after adjusting for various patient- and hospital-level factors (age, race, Elixhauser comorbidity score, hospital region, bed size, primary expected payer, median household income). Data was complete for all variables except race (6.3%) and median income (1.3%). We therefore performed multiple imputations using the chained equation procedure in STATA to account for the missing data. Correlation between hospitalization costs and the length of stay post-TAVI was evaluated via Pearson correlation coefficient. We analyzed using STATA 14 (StataCorp, College Station, TX) and SPSS Statistics 23 (IBM Corp., Armonk, NY); 2-tailed α=0.05.

Results

Baseline Characteristics (Table 1)

Early discharge and late discharge cohorts consisted of 1,557 and 5,764 procedures respectively. Mean age of overall cohort was 81 years. Study comprised of 48% females and 84.5% Whites. Elixhauser comorbidity score was lower in early discharge cohort (2.8 vs. 3.2). Approximately 85% of procedures were in 2012 and 83% were via transfemoral approach.

In-hospital Outcomes

Approximately 21% of patients were discharged in ≤3 days after TAVI. *Figure 1* depicts distribution of patients according to day of discharge post-TAVI in the entire cohort. Among early discharge cohort, approximately 85% were discharged home, but among late discharge cohort; about 40% were discharged to extended care facilities/nursing homes *(Figure 2).* Early discharge rates improved from 11% in 2011 to 22% in 2012 *(Figure 3).* Only 5% of patients who underwent transapical TAVI were discharged early as opposed to 25% among transfemoral cohort *(Figure 4).* TAVI related complications such as postoperative bleeding, stroke or TIA, need for blood transfusions, AKI, use of mechanical circulatory support (intra-aortic balloon pump, extracorporeal membrane oxygenation, Impella, Tandem Heart, cardiopulmonary bypass), new permanent pacemaker implants were significantly higher in late discharge cohort ***(****Table 2).* However, pre-TAVI aortic valvuloplasty was performed more often in early discharge cohort. Mean length of stay post-TAVI (7.7 days vs. 2.6 days) and total hospital charges ($208,752 vs. $157,663) were significantly higher in late discharge than early discharge cohort *(Table 2).*

Predictors of Early Discharge (Table 3)

Multivariate predictors that were significantly associated with lower likelihood for early discharge were: females (adjusted OR: 0.61; 95%CI: 0.44-0.83; p=0.002), postoperative bleeding (adjusted OR: 0.36; 95%CI: 0.18-0.72; p=0.004), blood transfusion (adjusted OR: 0.29; 95%CI: 0.19-0.46; p<0.001), stroke or TIA (adjusted OR: 0.13; 95%CI: 0.02-0.94; p=0.04), AKI (adjusted OR: 0.59; 95%CI: 0.38-0.96; p=0.04), permanent pacemakers (adjusted OR: 0.18; 95%CI: 0.08-0.40; p<0.001), and mechanical circulatory support use (adjusted OR: 0.31; 95%CI: 0.13-0.75; p=0.009). Year of TAVI (adjusted OR: 1.37;

95%CI: 1.12-1.67; p=0.002), transfemoral approach (adjusted OR: 4.80; 95%CI: 2.51-9.17; p<0.001) prior aortic valvuloplasty (adjusted OR: 2.40; 95%CI: 1.00-5.87; p=0.04) were associated with higher odds for early discharge.

Correlation of hospitalization costs and post-TAVI length of stay

Figure 5 demonstrates direct and positive correlation between costs of hospitalization and length of inpatient stay after TAVI (R=0.58; p<0.001).

Discussion

Early discharge was observed in 21% of patients after TAVI in the United States between 2011-2012. Early discharge cohort had significantly lower rates of adverse in-hospital outcomes, mechanical circulatory support use, and permanent pacemaker implantation in comparison to the late discharge cohort. Females, postoperative bleeding, blood transfusion, AKI, stroke or TIA, permanent pacemaker implantation, mechanical circulatory support use were significantly associated with lower adjusted odds of early discharge post-TAVI. However, prior aortic valvuloplasty, transfemoral TAVI approach, year of procedure were significantly associated with higher adjusted odds of early discharge. Lastly, we observed a strong positive correlation between costs of hospitalization and length of stay after TAVI.

At 30-days follow-up, bleeding complications were seen in 22.5% patients after TAVI in PARTNER trial.[11] However, postoperative bleeding rate during index hospitalization was much lower at 9.2% in our study. The stark difference in rate of bleeding complications is probably due to longer period of follow-up in former study. In addition, we noted significant association of postoperative bleeding with lower odds of early discharge consistent with prior reports.[6,7] Bleeding events requiring transfusions were 3-fold higher in the late discharge cohort and a strong predictor of lower early discharge rates in our study, congruent with prior work.[7,12] Similarly, AKI was noted more commonly in late discharge cohort and likewise strongly associated with lower likelihood of early discharge in this study. Blood transfusions are predictive of AKI and the incidence of which is estimated to be around 12% post-TAVI.[13] Bleeding events,[12] AKI,[13] and blood transfusions[12] also predict mortality post-TAVI. Avoiding vascular complications, judicious use of radiocontrast dye and avoiding prolonged intraprocedural hypotension can potentially curtail these adverse outcomes.

Stroke after TAVI is a strong predictor of mortality.[14] Similar to prior studies,[6,7,15] we noted stroke/TIA in 2.8% patients, significant proportion of which had prolonged hospitalization. Post-TAVI stroke was associated with significantly lower odds for early discharge in contrast to a prior analysis.[6] Over the years, incidence of stroke post-TAVI has declined owing to technological advancements valve deployment, experience, and case selection but opportunities for improvement remain.[5,14]

We found female gender to be significantly associated with lower likelihood for early discharge in a multivariate model, unlike a previous Italian study.[6] A recent study on all-female international TAVI registry[16] reported a low incidence of early mortality and stroke, yet mean length of stay was 12 days.

Mechanical circulatory support use in TAVI was noted in 10.6% of cases in a recent study on the same database.[17] Slightly lower utilization rate of 8.6% in current study may be ascribed to the exclusion of subjects with in-hospital mortality. Expectedly in this study, subjects who required mechanical circulatory support during TAVI were less likely to be discharged early. In addition, its use has been reported to predict higher mortality, length of stay and costs.[17]

Permanent pacemakers were implanted in approximately 10% of our cohort post-TAVI, in contrast to 5.9% and 16% in previous studies.[6,7] Varied utility of balloon-expandable valve vs. self-expandable valve in these studies explains the difference in pacemaker requirements as the latter valve is associated with significantly higher conduction blocks due to mechanical impingement.[5-7] Permanent pacemaker implantation post-TAVI was significantly associated with lower rates of early discharge in current study; in contrast, the presence of a preexisting permanent pacemakers predicted higher rates of early discharge.[6,7] Occurrence of advanced conduction blocks post-TAVI typically involves prolonged monitoring before permanent pacemaker implants are considered.

Balloon aortic valvuloplasty performed prior to TAVI was associated with higher likelihood for early discharge. Aortic valvuloplasty prior to TAVI is thought to faciliate optimal sizing and smooth deployment of transcatheter valves potentially reducing paravalvular leaks.[5,18] However, a recent large meta-analysis involving 1,395 patients showed no significant difference clinical outcomes if TAVI is performed with or without prior valvuloplasty.[18] Patients who underwent TAVI more recently fared better in terms clinical outcomes as well as early discharge rates.[5,6] Similarly, TAVI in 2012 was significantly associated with early discharge as compared to 2011, likely owing to operator learning curves. Transfemoral TAVI was associated with higher rates of early discharge when compared to transapical approach. Our results are consistent with PARTNER trial,[19] in whom mean post-procedural length of stay after transfemoral approach was approximately 7 days while it was 12 days after a transapical approach. Additionally, transfemoral TAVI is associated with significant reduction in costs of hospitalization,[5,19] and the costs are even lower with a minimalist approach.[20]

Systematic studies and guidelines on ideal duration of post-TAVI monitoring are lacking.[7] Mean duration of hospitalization post-TAVI was three times longer in late discharge cohort in comparison to early discharge cohort in this study. Our results were comparable to prior work by Barbanti et al.[6] Early discharge rates improved from 5.6% to 50% from 2007 to 2014 in the same study.[6] With adoption of a minimalist approach for TAVI, early discharge rates are likely to improve significantly,[5] especially because there was no significant difference in adverse outcomes observed between early and late discharge cohorts at 30-days follow-up.[6,7] Increasing hospital volume has been tied to early discharge in an earlier study on same database.[21] Home discharge and nursing home discharge rates post-TAVI are significantly higher for early discharge and late discharge cohorts respectively.

Furthermore, financial implications of late discharge cannot be underestimated.[19,20] Total hospitalization costs were higher by one-third, in the late discharge cohort as found in our study. We also demonstrated significant positive correlation between costs of hospitalization and post-TAVI length of stay *(Figure 5).* Avoiding unnecessary procedures and routine transfer to intensive care units for post-procedural monitoring, mitigating procedural complications,[22] universal adoption of minimalist approach unless inappropriate, conscious effort to discharge early if clinically stable can potentially curtail excessive healthcare costs involved.[5-7,19,20]

We would like to point out few limitations of our study. Considering the administrative nature of the NIS database, it is subject to coding limitations as we used ICD-9-CM codes to retrieve study subjects and outcomes. However, similar methods have been used extensively in prior studies.[17,21] Overall rate of in-hospital outcomes and healthcare resource utilization should be interpreted with caution as we deliberately excluded patients who did not survive to hospital discharge. NIS database lacks information on type of transcatheter valve, surgical risk score, echocardiographic variables, degree of paravalvular leak post-TAVI, and post-discharge follow-up data, although no significant difference in clinical outcomes were noted in early discharge group at follow-up.[6,7] Both balloon expandable and self expandable types of transcatheter aortic valves were included in our study.[21] Despite these limitations, our study depicts nationally representative real-world patient data, which is largest of its kind to date, analyzing early experience of discharge patterns in the United States. While contemporary data would probably show improvements in length of stay, predictors of prolonged hospitalization post-TAVI observed in our study are likely to still be relevant. The ongoing multimodality, multidisciplinary but minimalist approach (3M) to transfemoral TAVI, a prospective study (clinical trial NCT02287662), that aims to analyze feasibility and safety of early discharge with adoption of Vancouver TAVI clinical pathway[23] could give more definitive answers.

Conclusions

Females, postoperative bleeding, blood transfusions, stroke, AKI, permanent pacemaker implantation, use of mechanical circulatory support were factors less likely to be associated with early discharge, whereas transfemoral approach, year of procedure and prior aortic valvuloplasty were more likely to be associated with early discharge after TAVI. There was a strong and positive correlation between post-TAVI length of stay and hospitalization costs.

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Figure Legends:

Figure 1: Bar diagram of day of discharge after TAVI in entire cohort

Figure 2: Bar diagram of discharge destination stratified according to discharge timing

Figure 3: Bar diagram of discharge timing stratified according to year of procedure

Figure 4: Bar diagram of discharge timing stratified according to TAVI approach

Figure 5: Scatter plot diagram of costs of hospitalization vs. length of stay (day of discharge) after TAVI

Table 1: Baseline Characteristics

Variables	Early Discharge Cohort	Late Discharge Cohort	Overall	P Value
Total number of procedures	1,557	5,764	7,321	
Age, mean	80.9±0.24	81.2±0.11	81.1±0.10	0.298
Female, %	38.8	50.6	48.1	<0.001
Race, %				<0.001
White	83.2	84.8	84.5	
Black	6.1	3.3	3.9	
Hispanics	3.4	2.9	3.0	
Median household income national quartile for patient's ZIP code, Percentile				<0.001
0-25th	20.4	22.0	21.6	
26th-50th	23.7	21.7	22.1	
51st-75th	30.3	25.1	26.2	
76th-100th	25.7	31.2	30.0	
Primary expected payer, %				<0.001
Medicare	87.2	90.9	90.1	

Medicaid	0.6	1.2	1.1	
Private insurance	10.3	6.4	7.3	
No insurance	0.6	0.4	0.5	
Elixhauser comorbidity score (mean,±SE)	2.8±0.03	3.2±0.02	3.1±0.18	<0.001
Year of procedure				<0.001
2011	9.1	16.5	14.9	
2012	90.9	83.5	85.1	
TAVI approach				<0.001
Transfemoral	95.3	80.0	83.3	
Transapical	4.7	20.0	16.7	
Hospital Characteristics				
Hospital bed size, %				<0.001
Small	5.5	1.0	1.9	
Medium	15.8	12.1	12.9	
Large	78.7	86.9	85.2	
Hospital region, %				<0.001
Northeast	20.7	30.9	28.7	
Midwest	25.6	23.5	23.9	
South	39.8	37.0	37.6	
West	13.9	8.7	9.8	

Table 2: In-hospital Outcomes and Healthcare Resources Utilization

Outcomes	Early Discharge Cohort	Late Discharge Cohort	Overall	P Value
Postoperative bleeding, %	4.8	10.4	9.2	<0.001
Blood transfusion, %	11.2	33.4	28.7	<0.001
Stroke/TIA, %	0.3	3.5	2.8	<0.001
AKI, %	6.5	18.2	15.7	<0.001
Any mechanical circulatory support, %	2.9	10.2	8.6	<0.001
Intra-aortic balloon pump, %	0.3	1.4	1.2	<0.001
ECMO, %	0.0	0.2	0.1	0.100
Impella/Tandem Heart, %	0.3	0.2	0.3	0.591
Cardiopulmonary bypass, %	2.3	8.7	7.3	<0.001
Permanent pacemakers post-TAVI, %	2.6	11.5	9.6	<0.001
Prior aortic valvuloplasty, %	4.2	2.2	2.6	<0.001
Length of stay post-TAVI (mean±SE, days)	2.6± 0.01	7.7±0.07	6.6±0.06	<0.001
Hospital charges (mean±SE, $)	157,663± 2,062	208,752± 1,581	197,895± 1,343	<0.001
Disposition, %				<0.001
Home	84.7	59.3	64.7	
Extended care facility	14.4	39.5	34.1	

TIA: Transient ischemic attack; AKI: Acute kidney injury; ECMO: Extracorporeal membrane oxygenation; TAVI: Transcatheter aortic valve implantation

Table 3: Multivariate Predictors of Early Discharge after TAVI

	Adjusted Odds Ratio#	95% Confidence Interval	P value
Female	0.61	0.44-0.83	0.002
Postoperative bleeding	0.36	0.18-0.72	0.004
Blood transfusion	0.29	0.19-0.46	<0.001
Stroke/TIA	0.13	0.02-0.94	0.04
AKI	0.59	0.38-0.96	0.04
Permanent pacemaker implantation	0.18	0.08-0.40	<0.001
Mechanical circulatory support	0.31	0.13-0.75	0.009
Year*	1.37	1.12-1.67	0.002
Transfemoral TAVI approach@	4.80	2.51-9.17	<0.001
Prior aortic valvuloplasty	2.40	1.00-5.87	0.04

#Model adjusted for baseline demographic variables: age, race; hospital level characteristics; Elixhauser comorbidity score; primary expected payer; median household income
*Year 2012 vs. 2011; @Transfemoral TAVI approach vs. Transapical TAVI approach

Figure 1: Bar diagram of day of discharge after TAVI in entire cohort

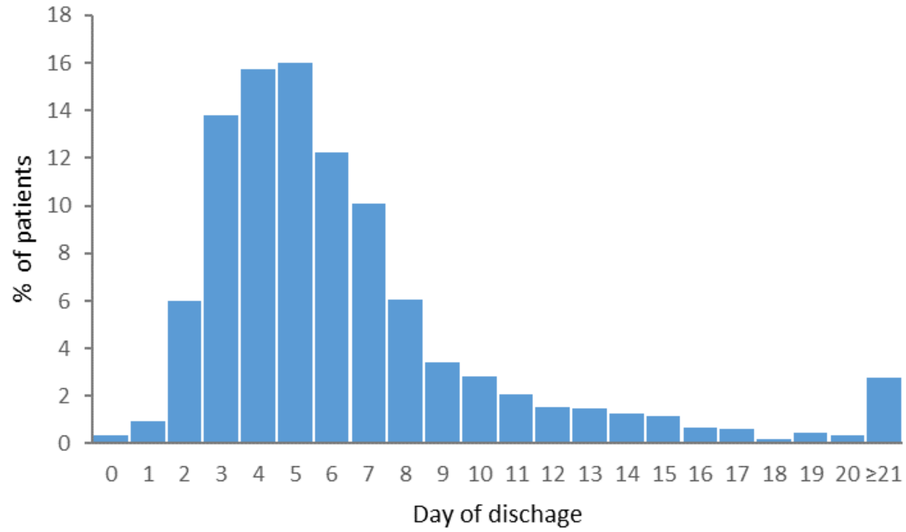

Figure 1 **Figure 2: Bar diagram of discharge destination stratified according to discharge timing**

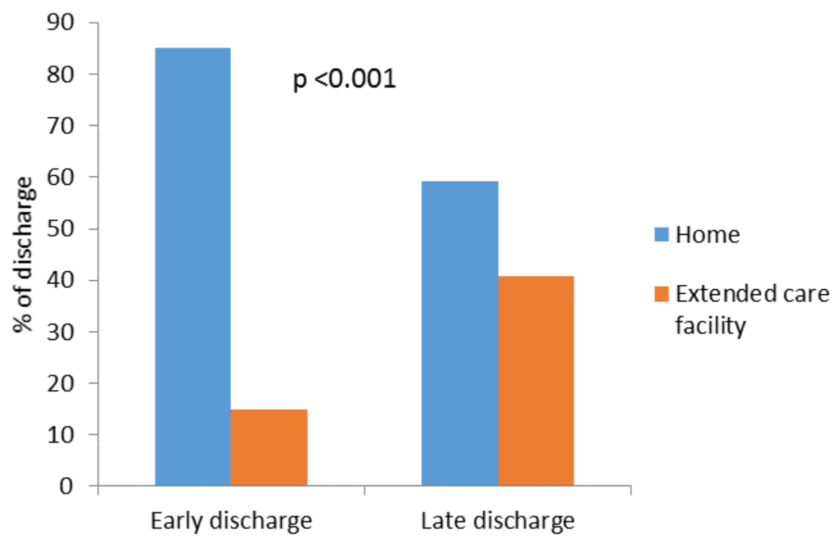

Figure 2 **Figure 3: Bar diagram of discharge timing stratified according to year of procedure**

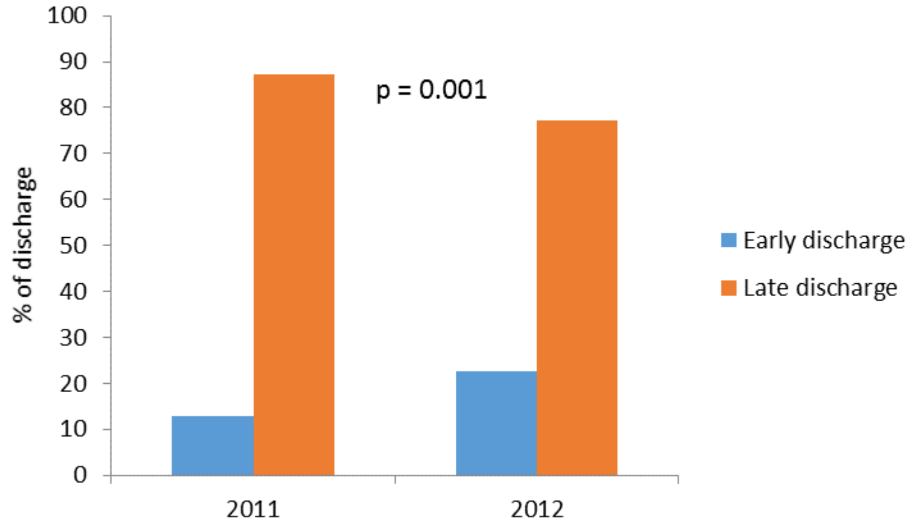

Figure 3 **Figure 4: Bar diagram of discharge timing stratified according to TAVI approach**

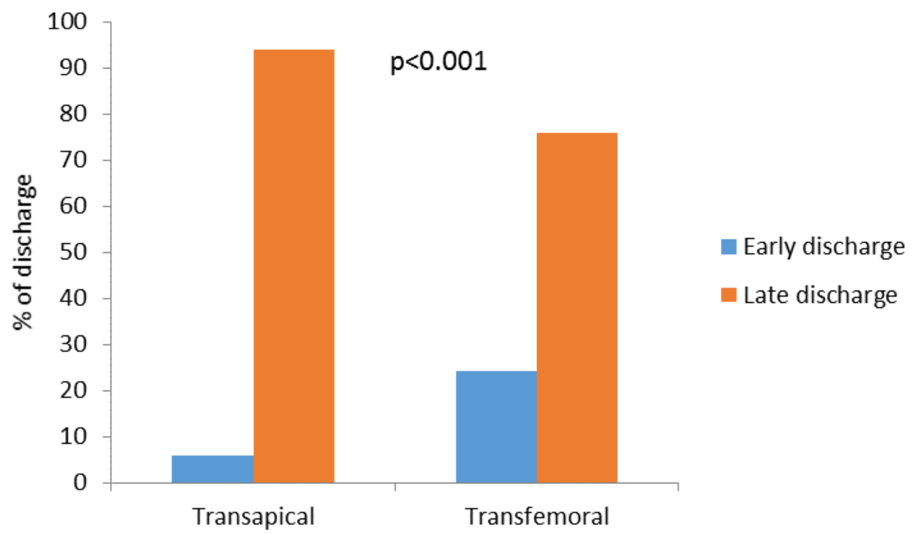

Figure 4 **Figure 5: Scatter plot diagram of costs of hospitalization vs. length of stay (day of discharge) after TAVI**

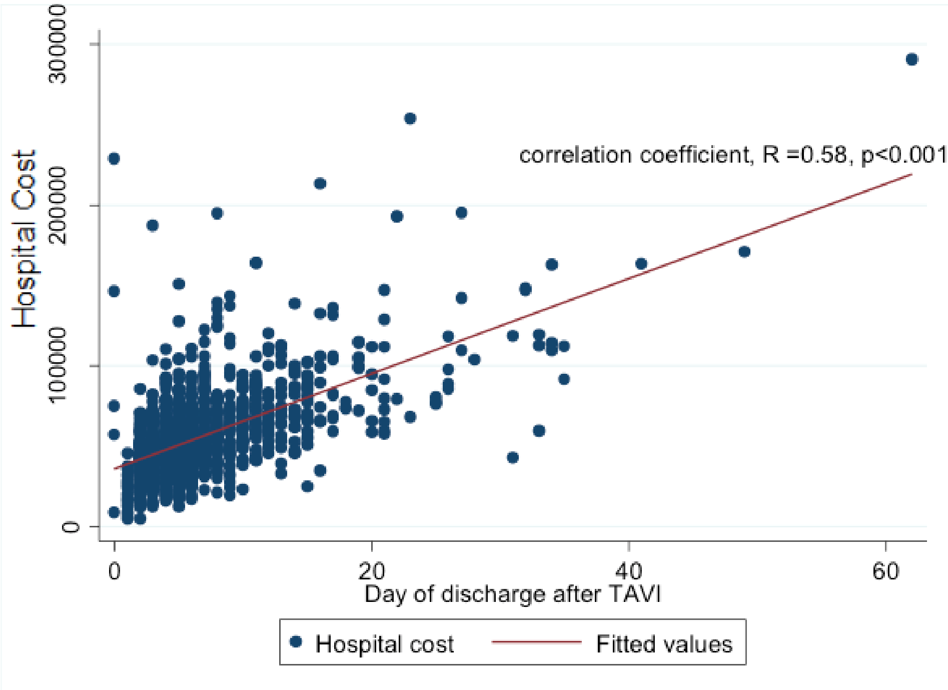
Hospital Cost
300000
200000
100000
0
correlation coefficient, R =0.58, p<0.001
0
20
40
60
Day of discharge after TAVI
Hospital cost
Fitted values

FIGURE 5