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In-hospital outcomes of transcatheter mitral valve repair in patients with and without end stage renal disease: A national propensity match study

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Abstract

Objectives: To study trends of utilization, outcomes, and cost of care in patients undergoing undergoing transcatheter mitral valve repair (TMVr) with end-stage renal disease (ESRD).

Background: Renal disease has been known to be a predictor of poor outcome in patients with mitral valve disease. Outcome data for patients with ESRD undergoing TMVr remains limited. Therefore, our study aims to investigate trends of utilization, outcomes, and cost of care among patients with ESRD undergoing TMVr.

Methods: We analyzed NIS data from January 2010 to December 2017 using the ICD-9-CM codes ICD-10-CM to identify patients who underwent TMVr. Baseline characteristics were compared using a Pearson χ^2 test for categorical variables and independent samples *t*-test for continuous variables. Propensity matched analysis was done for adjusted analysis to compare outcomes between TMVr with and without ESRD. Markov chain Monte Carlo was used to account for missing values.

Results: A total of 15,260 patients (weighted sample) undergoing TMVr were identified between 2010 and 2017. Of these, 638 patients had ESRD compared to 14,631 patients who did not have ESRD. Adjusted in-hospital mortality was lower in non-ESRD group (3.9 vs. <1.8%). Similarly,

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CONFLICT OF INTEREST
The authors declare no potential conflict of interest.

SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section at the end of this article.

ESRD patients were more likely to have non-home discharges (85.6 vs. 74.9%). ESRD patients also had a longer mean length of stay (7.9 vs. 13.5 days) and higher mean cost of stay ($306,300 vs. $271,503).

Conclusion: ESRD is associated with higher mortality, complications, and resource utilization compared to non-ESRD patients. It is important to include this data in shared decision-making process and patient selection.

Keywords

end-stage renal disease; percutaneous edge-to-edge mitral valve repair; percutaneous mitral valve repair with clip

1 | INTRODUCTION

Mitral regurgitation is known to be associated with progressive worsening of left ventricular ejection function (LVEF) and congestive heart failure which can lead to high rates of mortality and morbidity.[1] Contemporary guidelines recommend surgery for severe mitral regurgitation in patients with evidence of left ventricular dysfunction.[2] Percutaneous edge-to-edge mitral valve repair with MitraClip™ (Abbott Vascular, Menlo Park, CA) has shown superior safety and similar outcomes compared to conventional surgery.[3] Moreover, The Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (MR) (COAPT trial) reported improved outcomes (lower all-cause mortality and lower heart failure hospitalization at 24 months follow-up) in patients with moderate to severe mitral regurgitation who remained symptomatic despite being on maximal dose of guideline directed medical therapy.[4]

Renal disease has been known to be a predictor of poor outcome in patients undergoing mitral valve surgery.[5] In patients with end-stage renal disease (ESRD) in-hospital mortality occurs in 1 in 5 patients following mitral valve surgery.[6] However, outcome data for patients with ESRD undergoing transcatheter mitral valve repair (TMVr) remains limited. ESRD patients have decreased representation in clinical trial assessing TMVr and some of the earlier registry based data were vastly underpowered to assess clinical outcomes in this cohort of patients.[3,7,8] Therefore, our study aims to investigate trends of utilization, outcomes, and cost of care among patients with concomitant ESRD and MR undergoing TMVr from a real-world population using the National Inpatient Sample (NIS).

2 | METHODS

2.1 | Study data

NIS database from years 2010 to 2017 was used for this study. A Federal-State-Industry partnership sponsored by the Agency for Healthcare Research and Quality (AHRQ) has made several national databases possible including the NIS. The NIS is derived from State In patient Data.[9] Since NIS is compiled annually, the data can be used for analysis of disease trends over time. The methodology of NIS changed in 2012 from hospital base to national base sample; however, HCUP provided different trend weights for accurate representation over the years.[10] Institutional Review Board approval and informed consents were not required for this study given NIS is de-identified and public availability.

2.2 | Study population and design

We analyzed NIS data from January 2010 to December 2017 using the International Classification of Diseases, ninth Revision, Clinical Modification (ICD-9-CM) codes and International Classification of Diseases, 10th Revision, Clinical Modification ICD-10-CM codes. We used ICD-9-CM code of 35.97 and ICD-10-CM code of 02UG3JZ to identify patients who underwent TMVr. Our selected population of ESRD was identified using ICD 9 code of 585.6 for ESRD and V451 for Hemodialysis status. While ICD-10 codes for N18.6 for ESRD and Z992 for hemodialysis status was used. All diagnosis field were queried to select the patient population. Under 18-years-old were excluded from the study.

2.3 | Study endpoints

Primary study endpoint was in patient mortality. Secondary endpoints were; (a) In-hospital complications; (b) Hospital cost and length of stay (LOS); (c) Discharge disposition (home vs. non-home discharges). Flow sheet of our selection of patients is shown in Figure 1. Associated procedures and complications were identified using ICD-9-CM and ICD-10-CM codes (See supplementary S1).

2.4 | Statistical analysis

Baseline characteristics of patients undergoing TMVr with and without ESRD are given in Table 1. To account for potential confounding factors and selection bias, a propensity score-matching model was developed using logistic regression to derive two matched groups for comparative outcomes analysis. Markov chain Monte Carlo (MCMC) method was used for missing data imputation to avoid data loss before propensity matching. A nearest neighbor 1:1 variable ratio, parallel, balanced propensity-matching model was made using a caliper width of 0.2 was used. Out comes before and after propensity match are given in Table 2. Descriptive statistics were presented as frequencies with percentages for categorical variables and as means with SDs for continuous variables. Baseline characteristics were compared using a Pearson X^2 test and Fisher's exact test for categorical variables and independent samples *t*-test for continuous variables. All statistical analyses were performed using Statistical Package for Social Science (SPSS) version 26 (IBM Corp) and R 3.5 for propensity matched analysis.

3 | RESULTS

3.1 | Baseline characters and unadjusted results

A total of 15,260 cases (nationally weighted sample) of patients who underwent TMVr were identified between 2010 and 2017. Of these, 638 patients had ESRD compared to 14,631 patients who did not have ESRD. ESRD patients were younger (mean age of 68.6 years vs. 77.3, $p < .01$) and included lower proportion of females (37.4 vs. 47.5%, $p < .01$), and whites (46 vs. 79.1%, $p < .01$). Baseline comorbidities like congestive heart failure (79.0 vs. 79.1%, $p = .95$), chronic pulmonary disease (26.6 vs. 26.8% $p = .92$) was similar between two groups. ESRD group had higher proportion of coronary artery disease (67.9 vs. 59.6%, *p* < .01), diabetes mellitus (34.4 vs. 9.4%, *p* < .01), hypertension (57.1 vs. 49%, *p* < .01), and peripheral vascular disease (19.6 vs. 12.5%, *p* < .01) (Table 1).

On unadjusted analysis, the percentage of in-hospital mortality (3.9 vs. 2.3%, *p* = .01), cardiogenic shock (7.7 vs. 4.3%, *p* < .01), blood transfusion (14.1 vs. 6.6%, *p* < .01), cardiac arrest (4.7 vs. 1%, *p* < .01), mechanical ventilation (12.5 vs. 5.8%, *p* < .01), pneumonia (6.2 vs. 2.8%, *p* < .01), and PCI (2.3 vs. 1.2%, *p* < .01) were significantly higher for patients with ESRD when compared to patients without ESRD undergoing TMVr (Table 2).

The mean LOS (13.5 vs. 5.1 days, *p* < .01), cost of hospitalization ($307,473 vs. $208,011, *p* < .01) and non-home discharge (25.1 vs. 12.6%, *p* < .01) were significantly higher for patients in the ESRD patients when compared to the control group (Table 2).

3.2 | Propensity-match results

A total of 639 ESRD patients were matched with 603 patients without ESRD. Both groups were evenly matched within 0.2 *SD*. There was no significant difference between the baseline characters of the two cohorts (Table 1). In-hospital mortality worsen further in ESRD group as compared to without ESRD group (3.9 vs. <1.8%, *p* = .02). In contrast to the pooled analysis, most of the complications were not powered enough for statistical significance (Table 2). The mean LOS (13.5 vs. 7.9 days, *p* = < .01), mean total charges per hospitalization ($306,300 vs. $271,503, *p* < .01) and non-home discharges (25.1 vs. 14.3%, *p* < .01) were significantly higher in the ESRD group when compared to without ESRD. Table 2.

3.3 | Temporal trends in mortality, length of stay, and cost of care

Mortality has decreased in both groups over the time, but overall trended in higher in ESRD group (Figure 2) Overall, we noticed increased in procedures in both groups, however, overall, the proportion remained unchanged over the years (Figure 3). Similarly, cost of care decreased in ESRD group but increased slightly in without ESRD group (Figure 4(a)). LOS decreased in both groups but more in ESRD group (Figure 4(b)).

4 | DISCUSSION

We report the following main findings in our contemporary real-world population study of TMVr outcomes in patients with and without ESRD. (a) In-hospital mortality is significantly higher in patients with ESRD undergoing TMVr intervention. (b) Mortality associated with ESRD in TMVr has progressively decreased over the years. (c) Patients with ESRD have worse periprocedural morbidity after TMVr and consequently, longer LOS and higher cost of stay as compared to non-ESRD patients.

TMVr has emerged as an alternative to surgical mitral valve repair in patients with severe symptomatic primary mitral regurgitation and are at high or prohibitive surgical risk.[11] At least half of the patients with severe MR are not deemed candidates for surgery. The most common reason for denial of surgery is age, decrease LVEF, grade III MR, and increase Charleston co-morbidity index.[12] Data from the Society of Thoracic Surgeons Adult Cardiac Surgery Database (2002–2010) showed significantly higher mortality with surgical mitral valve repair in the dialysis patients compared to non-dialysis patients (9.3 vs. 2.3%).[13] The significantly higher mortality in contemporary cohort studies with surgical repair makes transcatheter therapy a possible alternative in an appropriately selected patient. Data from the NCDR TVT registry suggest that chronic kidney disease (CKD) is very prevalent in this patient population—77% of patients undergoing TMVr in the United States had kidney disease and 23% of the patients had stage 4 or 5 renal disease.[13,14] However, it is important to note that advanced renal disease is often not represented in landmark trials evaluating cardiovascular interventions.[3,15,16] Real world registry data shows approximately 20–40% of the patients have renal disease.

Multiple studies reported that CKD is an independent predictor of mortality in patients undergoing TMVr.[14,17] A previous NIS database analysis of 2012–2014 data looking at 535 CKD and 130 ESRD hospitalization for TMVr reported higher mortality of 5% and 7.7% in patients with CKD and ESRD respectively.[18] Similarly the National Cardiovascular Data Registry Transcatheter Valve Therapy registry reported in-hospital mortality of 6.5%, 30 day mortality of 13.5% 1 year mortality of 33% in patients with ESRD on dialysis.[14] The in-hospital mortality of 3.9% is lower than that reported in prior studies. It is notable that those studies were performed prior to 2016. This is likely due to a couple of factors. First, a selection bias likely occurred in the recent years where ESRD patients may have been denied TMVr due to poor outcomes and futility reasons. Second, accumulating experience with technique may have also resulted in decreased mortality.[19] The number of procedures have increased multi-fold in the latter part of the study compared to earlier years and is a marker of cumulative experience. Furthermore, the low rate of procedure related complications observed in our study and demonstrated in other contemporary cohorts suggest TMVr procedure per se is safe in ESRD patients.[20] The poor outcomes in patients with renal disease are not solely due to lack of treatment efficacy because similar mortality rates are observed across other cardiovascular therapies as well like TAVR and PCI.[21,22] For instance, ESRD patients undergoing TAVR have a 21% increased risk of mortality despite adjustment of other comorbidities.[23] It has been postulated that in patients with ESRD, systemic inflammation leads to valvular calcification and is associated with increased cardiovascular mortality. Furthermore, renal disease is associated significant mitral annular calcification which leads to significantly increased risk of poor procedural outcomes because of leaflet extension of annulus calcification and infiltration of calcium into the adjacent conduction system.[14,24,25] Yet another reason for the high mortality associated with ESRD is the worse peri-procedure complications. One study reported that there was an independent association between impaired renal function and bleeding events across all stages of renal disease.[14] Our study reports that patient with ESRD undergoing TMVr have a higher rate of requiring blood transfusions. Previous studies on TAVR in patients with renal disease have reported similar results reporting increased risk of bleeding requiring blood transfusions.[26,27] The reason for increased bleeding complication in patients with ESRD could be multifactorial secondary to uremia, platelet dysfunction, anemia, use of antiplatelet drugs, antithrombotic drugs and coagulopathy.[28] Furthermore, operator experience has been shown to be associated with improvement in periprocedural complications.[29]

Resource utilization has become increasingly important in recent time with Medicare spending for ESRD continuing to show an uptrend. The total Medicare spending on both

CKD and ESRD patients was approximately $114 billion in 2016.[30] Our study reports increase resource utilization in terms of increase LOS and cost of hospitalization in patients with ESRD undergoing TMVr. The results have been replicated in studies looking at renal disease cost in patients with coronary artery and valvular disease.[31,32]

Despite the expected overall increase in mortality and periprocedural morbidity in ESRD patients, TMVr may perform better than medical management in select patients not deemed candidates for surgical intervention.[1,7,8] Heart team discussion in ESRD patients should be individualized taking into account overall life expectancy, etiology of mitral regurgitation and comorbidity burden. Further research is needed to guide patient selection and assess long-term outcomes of TMVr in ESRD patients.

NIS is an administrative claim-based database that uses ICD-9-CM codes for diagnosis, although we have used procedure codes that are less prone to error, it may be subject to error. NIS collects data on in-patient discharges and each admission is registered as an independent event. NIS samples are not designed to follow patients longitudinally so long-term outcomes could not be assessed from the present dataset. Like any retrospective database study association does not mean causation and conclusion should be drawn cautiously. The measures of frailty that could help predict outcomes could not be evaluated given the inherent limitations of NIS. Moreover, data on functional class improvement, procedural success, residual mitral regurgitation, valve anatomy and valvular calcification could not be obtained.

5 | CONCLUSION

We report real word data on in-hospital outcomes of TMVr in ESRD hospitalizations, a subset that has been excluded from RCTs. ESRD is associated with higher mortality, peri-procedural morbidity, and resource utilization compared to non-ESRD patients. Further studies are needed to guide patient selection and assess the long-term benefits of TMVr in ESRD patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations:

AHRQ	Agency for Healthcare Research and Quality
COPD	chronic obstructive pulmonary disease
HCUP	Healthcare Cost and Utilization Project

ICD-10-CM	International Classification of Diseases, 10th revision, clinical modification
ICD-9-CM	International Classification of Diseases, 9th revision, clinical modification
TMVr	transcatheter mitral valve repair with clip

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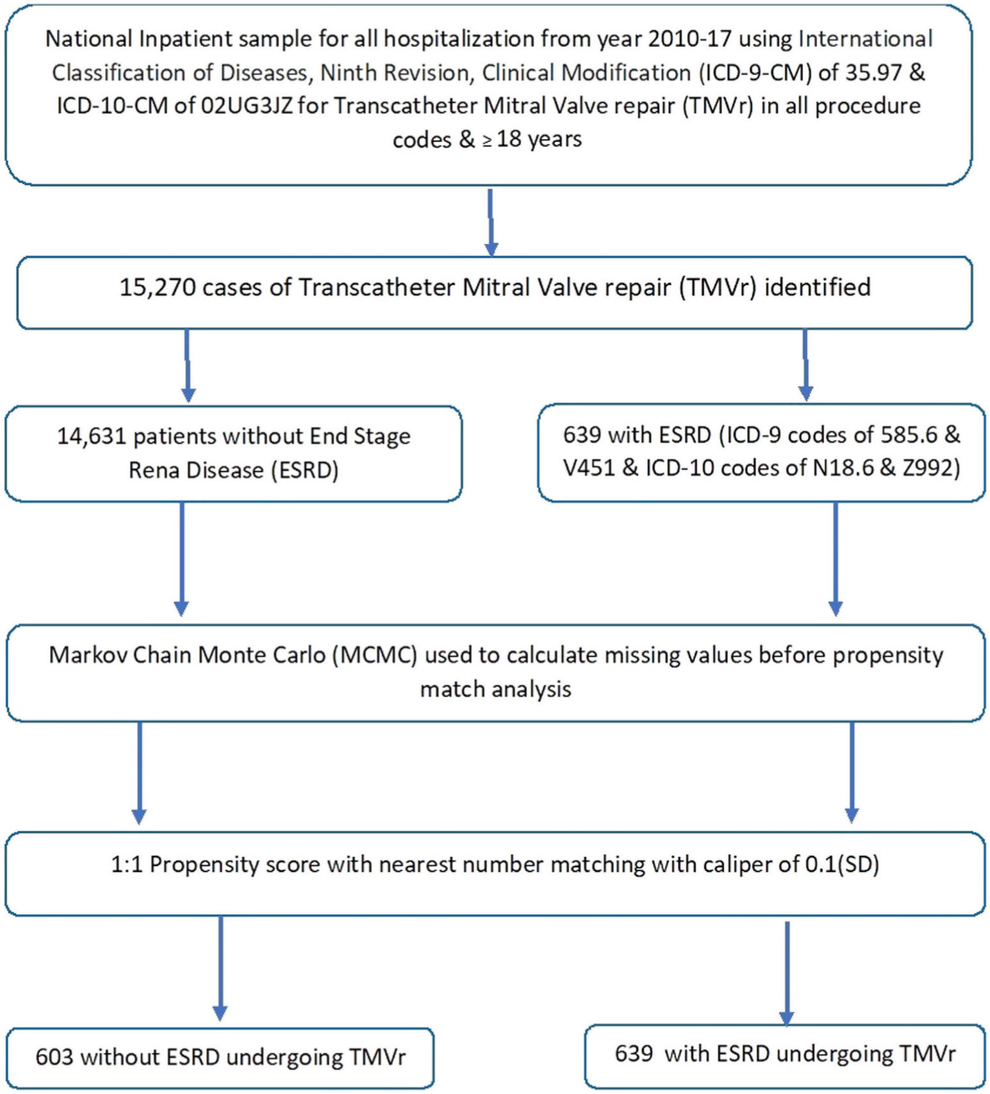

FIGURE 1.
Flow sheet of our article

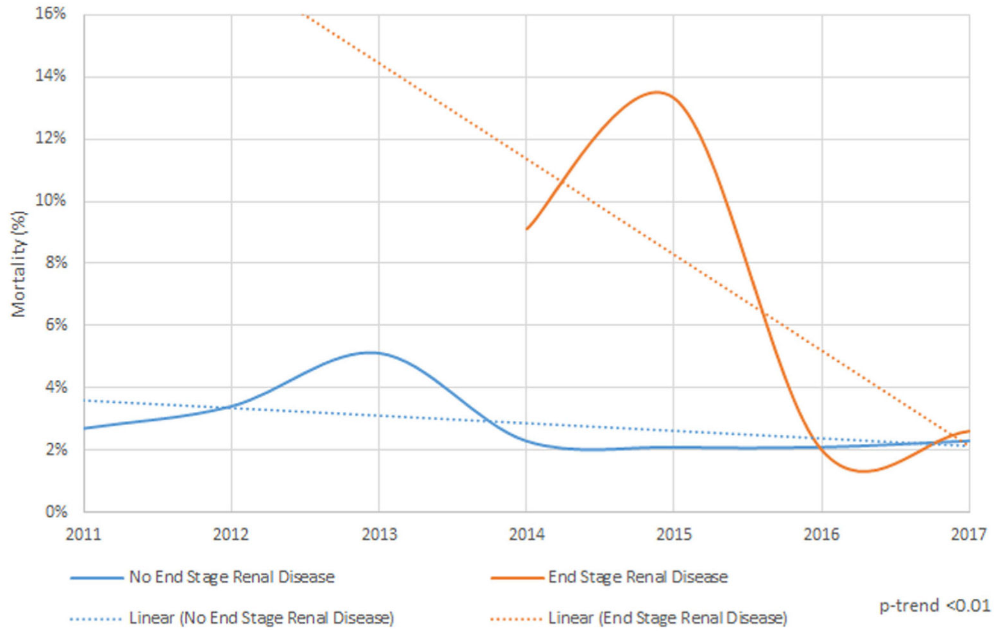

FIGURE 2.

Trends in mortality in no end stage renal disease (ESRD) and ESRD patients in transcatheter mitral valve repair

FIGURE 3.
Trends in procedures in no end stage renal disease (ESRD) and ESRD patients in transcatheter mitral valve repair

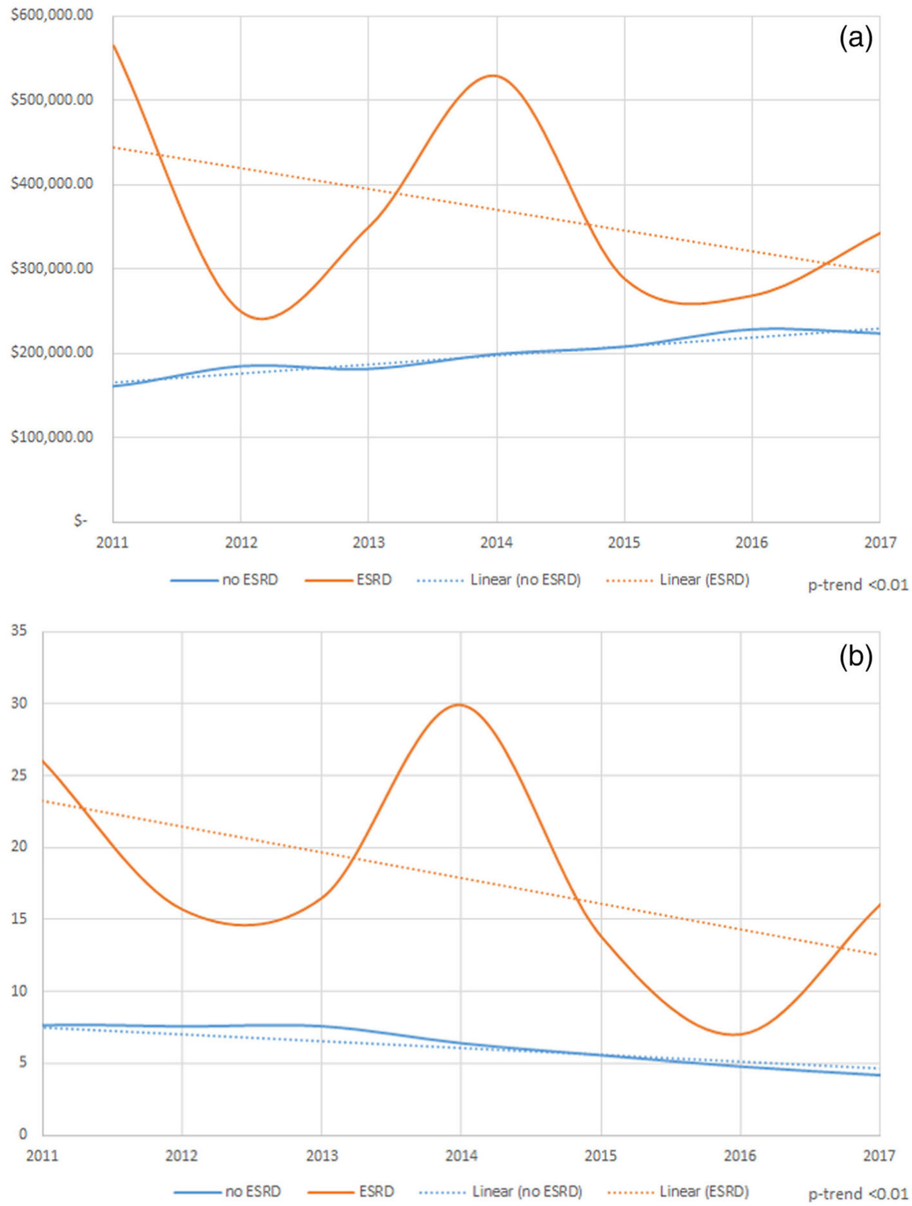

FIGURE 4.

(a) Trends in cost of care in no end stage renal disease (ESRD) and ESRD patients in transcatheter mitral valve repair. (b) Trends in length of stay in no ESRD and ESRD patients in transcatheter mitral valve repair

TABLE 1

Baseline characteristics of the study population

	Unmatched			Propensity matched		
Variable n (%)	**No end stage renal disease (14631)**	**End stage renal disease (639)**	***p*-value**	**No end stage renal disease (603)**	**End stage renal disease (639)**	***p*-value**
Age median (SD)	77.3 (11.0)	68.6 (11.2)	<.01	69.5 (14.7)	68.6 (11.2)	.20
Female	6,950 (47.5)	239 (37.4)	<.01	200 (33.2)	239 (37.4)	.12
Race						
White	11,568 (79.1)	294 (46.0)	<.01	319 (52.9)	294 (46.0)	.05
African American	888 (6.1)	180 (28.1)		144 (23.9)	180 (28.2)	
Hispanic	925 (6.3)	75 (11.7)		75 (12.4)	75 (11.7)	
Other	1,249 (8.5)	90 (14.1)		65 (10.8)	90 (14.1)	
Elective admission	11,032 (75.7)	399 (62.4)	<.01	418 (69.4)	399 (62.5)	<.01
Comorbidities and previous medical history						
Anemia	3,125 (21.4)	370 (57.9)	<.01	150 (24.9)	370 (57.9)	<.01
Atrial fibrillation	2,853 (19.5)	109 (17.1)	.12	94 (15.6)	109 (17.1)	.48
Congestive heart failure	11,578 (79.1)	505 (79.0)	.95	464 (77.0)	505 (79.0)	.37
Coagulopathy	1714 (11.7)	115 (18.0)	<.01	104 (17.3)	115 (18.0)	.74
Collagen vascular disease	588 (4.0)	15 (2.3)	.03	<11 (1.6)[a]	15 (2.3)	—
Chronic pulmonary disease	3,919 (26.8)	170 (26.6)	.92	165 (27.3)	170 (26.6)	.76
Coronary artery disease	8,724 (59.6)	434 (67.9)	<.01	418 (69.4)	434 (67.9)	.56
Cerebrovascular disease	749 (5.1)	20 (3.1)	.02	25 (4.1)	20 (3.1)	.33
Diabetes (with complications)	1,374 (9.4)	220 (34.4)	<.01	195 (32.4)	220 (34.4)	.43
Hypertension	7,166 (49.0)	365 (57.1)	<.01	338 (56.0)	365 (57.1)	.7
Hypothyroidism	2,775 (19.0)	90 (14.1)	<.01	75 (12.4)	90 (14.1)	.40
Peripheral vascular disease	1828(12.5)	125 (19.6)	<.01	105 (17.4)	125 (19.6)	.34
Obesity	1,414 (9.7)	95 (14.9)	<.01	90 (14.9)	95 (14.9)	.97
Smoking	613 (4.2)	50 (7.8)	<.01	55 (9.1)	50 (7.8)	.4
Liver disease	329 (2.2)	25 (3.9)	<.01	24 (4.0)	25 (3.9)	.9
Weight loss	693 (4.7)	59 (9.3)	<.01	75 (12.4)	59 (9.3)	.07

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Variable n (%)	Unmatched			Propensity matched		
	No end stage renal disease (14631)	End stage renal disease (639)	*p*-value	No end stage renal disease (603)	End stage renal disease (639)	*p*-value
Region						
Northeast	2,511 (17.2)	95 (14.9)	.03	99 (16.5)	95 (14.9)	.05
Midwest	3,375 (23.1)	124 (19.5)		84 (13.9)	124 (19.5)	
South	4,920 (33.6)	235 (36.7)		220 (36.4)	235 (36.7)	
West	3,826 (26.1)	185 (28.9)		200 (33.2)	185 (28.9)	
Urban/rural						
Rural	55 (0.4)	0	.06	0	0	.41
Urban, non-teaching	1,329 (9.1)	45 (7.0)		50 (8.3)	45 (7.0)	
Urban, teaching	13,246 (90.5)	594 (93.0)		553 (91.7)	594 (93.0)	
Hospital size						
Small	820 (5.6)	30 (4.7)	.5	20 (3.3)	30 (4.7)	.04
Medium	2,523 (17.2)	105 (16.4)		130 (21.6)	105 (16.4)	
Large	11,287 (77.1)	504 (78.9)		453 (75.1)	504 (78.9)	
Primary payer						
Medicare Medicaid	12,716 (86.9)	585 (91.5)	<.01	523 (86.7)	540 (84.5)	.5
Private insurance	1,600 (10.9)	44 (6.9)		35 (5.8)	45 (7.0)	
Other	314 (2.1)	<11 (<2)[a]		45 (7.5)	54 (8.5)	
Median household income for patient ZIP code						
0-25th percentile	3,289 (22.5)	180 (28.2)	<.01	183 (30.4)	180 (28.2)	<.01
26th-50th percentile	3,393 (23.2)	145 (22.7)		110 (18.3)	145 (22.7)	
51st-75th percentile	4,061 (27.8)	174 (27.3)		134 (22.3)	174 (27.3)	
76th-100th percentile	3,888 (26.6)	140 (21.9)		175 (29.0)	140 (21.9)	

Note: Basic characteristics of the patients who underwent transcatheter mitral repair with and without ESRD before and after propensity matched analysis.

[a]Numbers less than 11 are not reportable per HCUP guidelines. 1:1 matched analysis within 0.2 *SD*.

TABLE 2

Hospital encounter outcomes and resource utilization of the study cohort

Variable	Unadjusted			Adjusted		
	No end stage renal disease (14631)	End stage renal disease (639)	*p*-value	No end stage renal disease (603)	End stage renal disease (639)	*p*-value
In-hospital mortality	339 (2.3)	25 (3.9)	.01	<11 (<1.8)[a]	25 (3.9)	—
Cardiogenic shock	624 (4.3)	49 (7.7)	<.01	60 (10.0)	49 (7.7)	.16
Post Op stroke	61 (0.4)	<11 (<1.8)[a]	—	<11 (<1.8)[a]	<11 (<1.8)[a]	—
Vascular complications	90 (0.6)	<11 (<1.8)[a]	—	<11 (<1.8)[a]	<11 (<1.8)[a]	—
Blood transfusion	816 (6.6)	90 (14.1)	<.01	40 (6.6)	90 (14.1)	<.01
Cardiac arrest with CPR	140 (1.0)	30 (4.7)	<.01	20 (3.3)	30 (4.7)	.20
Mechanical ventilation	846 (5.8)	80 (12.5)	<.01	60 (10.0)	80 (12.5)	.15
Pneumonia	414 (2.8)	39 (6.2)	<.01	25 (4.1)	39 (6.2)	.20
Urinary tract infection	819 (5.6)	45 (7.0)	.12	70 (11.6)	45 (7.0)	<.01
Pericardiocentesis	125 (0.9)	<11 (<1.8)[a]	—	<11 (<1.8)[a]	<11 (<1.8)[a]	—
Pericardial effusion	330 (2.3)	15 (2.3)	.02	20 (3.3)	15 (2.3)	.30
PCI	169 (1.2)	15 (2.3)	<.01	<11 (<1.8)	15 (2.3)	.38
Discharged home	12,485 (87.4)	460 (74.9)	<.01	508 (85.7)	460 (74.9)	<.01
Non-home	1,792 (12.6)	154 (25.1)		85 (14.3)	154 (25.1)	
Length of stay, mean (*SD*), days	7.1 (5.1)	13.5 (36.7)	<.01	7.9 (10.3)	13.5 (36.7)	<.01
Cost of hospitalization, mean (*SD*) $	208,011 (163,157)	307,473 (344,387)	<.01	271,503 (259,870)	306,300 (343,290)	.04

Note: Clinical outcomes and hospital utilization in transcatheter mitral repair with and without end stage renal disease (ESRD) before and after propensity matched analysis.

[a] <11 numbers are not reportable per HCUP guidelines. 1:1 matched analysis within 0.2 *SD*.