Heart, Lung and Circulation (2019) **28,** e7–e9
1443-9506/04/$36.00
https://doi.org/10.1016/j.hlc.2018.05.202

LETTER TO THE EDITOR

Characteristics and Gender Difference With Transcatheter Pulmonary Valve Replacement: An Analysis of 960 Hospitalisations from the National Inpatient Sample

Keywords Epidemiology • Gender • Transcatheter pulmonary valve replacement

To the Editor,

Transcatheter pulmonary valve replacement (TPVR) with the Melody valve (Medtronic, Inc., Minneapolis, MN, USA) is safe and effective in reducing right ventricular outflow tract obstruction (RVOTO) and eliminating pulmonary regurgitation (PR) in children with complex heart disorders affecting the pulmonary valve [1,2]. Although the surgical alternative demonstrated similar safety and efficacy outcomes, it is also associated with limited lifespan and may require reoperation. The United States (US) Food and Drug Administration approved the Melody valve after the Investigative Device Exemption trial for the treatment of RVOTO. In addition to its encouraging short- and mid-term outcomes, the TPVR procedure continues to yield positive haemodynamic and clinical outcomes up to 7 years following the procedure [1,2]. The objective of this article is to assess the demographic and baseline data, cost of care, length of stay (LOS), and other in-hospital outcomes associated with TPVR hospitalisations. Additionally, this is the first study to investigate gender differences in these TPVR hospitalisations.

The National Inpatient Sample (NIS) database from 2012 to 2014 was used for this study. The NIS is sponsored by the

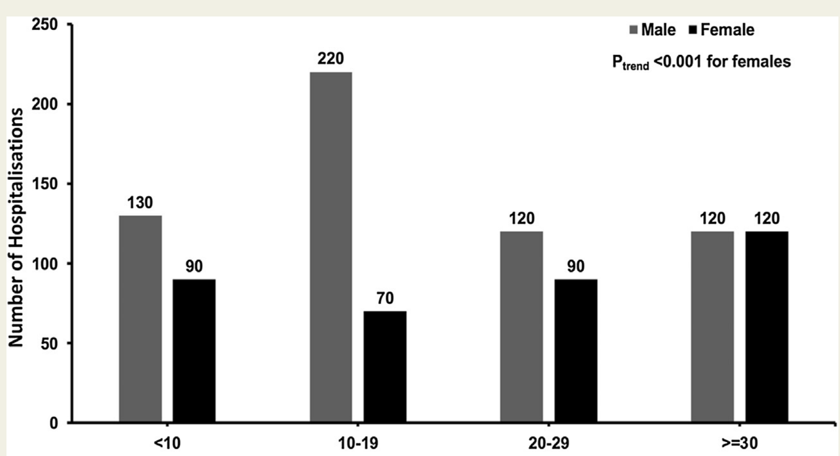

Figure 1 Gender distribution stratified by age-group who underwent transcatheter pulmonary valve replacement.

Table 1 **Baseline Characteristics in hospitalisations undergoing TPVR (transcatheter pulmonaray valve replacement): In Overall Hospitalisations and Stratified by Gender.**

Variable Name	Overall Population (n = 960)	Male (n = 590)	Female (n = 370)	p Value
Age, Years	21.8 [0–86]	20.5 [0–66]	23.8 [0–86]	0.16
Race				
Caucasian	480 (50.0%)	300 (50.8%)	180 (48.6%)	0.003
African-American	75 (7.8%)	35 (5.9%)	40 (10.8%)	
Hispanic	165 (17.2%)	105 (17.8%)	60 (16.2%)	
Other/Missing[1]	240 (25.0%)	150 (25.5%)	90 (24.3%)	
Admission Type				
Elective Admission	775 (81.6%)	490 (83.0%)	285 (79.2%)	0.13
Urgent/Emergent Admission[2]	175 (18.4%)	100 (17.0%)	75 (20.8%)	
Primary Payment Method				
Medicare	85 (8.8%)	45 (7.6%)	40 (10.8%)	0.007
Medicaid	275 (28.7%)	185 (31.4%)	90 (24.3%)	
Private Insurance	490 (51.0%)	305 (51.7%)	185 (50.0%)	
Other	110 (11.5%)	55 (9.3%)	55 (14.9%)	
Hospital Bed Size				
Small	95 (9.9%)	70 (11.9%)	25 (6.8%)	0.018
Medium	270 (28.1%)	170 (28.8%)	100 (27.0%)	
Large	595 (62.0%)	350 (59.3%)	245 (66.2%)	
Hospital Location				
Rural	5 (0.5%)	0 (0%)	5 (1.4%)	0.005
Urban	955 (99.5%)	590 (100%)	365 (98.6%)	
Elixhauser Comorbidities				
Chronic Pulmonary Disease	50 (5.2%)	35 (5.9%)	15 (4.1%)	0.20
Coagulation Disorder	35 (3.7%)	30 (5.1%)	5 (1.4%)	0.003
Diabetes	45 (4.7%)	30 (5.1%)	15 (4.1%)	0.46
Obese	60 (6.3%)	35 (5.9%)	25 (6.8%)	0.61
In-Hospital Outcomes				
In-Hospital Mortality	5 (0.5%)	0 (0%)	5 (1.4%)	0.005
Adjusted In-Hospital Mortality[3]	N/A	1.01 (0.99-1.03)		0.91
Length of Stay	1 (1-2)	1 (1-2)	1 (1-2)	0.96
Cost	$46,268 ($32,029-$57,390)	$48,699 ($34,183-$60,486)	$42,385 ($28,506-$55,135)	<0.001
Discharge to home	925 (96.4%)	570 (96.6%)	355 (96.0%)	0.018
Discharge to other short-term facility/ acute care facility/Home health care	30 (3.0%)	20 (3.4%)	10 (1.7%)	

Missing[1]-125, [2]-10.
[3]Adjusted for race, age, all hospital-related variables, and comorbidities.

Healthcare Cost and Utilization Project and is described previously [3,4]. The NIS represents more than 4000 US hospitals which represent more than 95% of the US population. All hospitalisations that underwent TPVR (n = 960) were identified using the appropriate *International Classification of Diseases, Ninth Revision, Clinical Modification* procedure code, 35.07. Categorical variables were reported as a frequency in percentages and compared using Chi-square tests; whereas, age was reported as the mean (minimum-maximum) and compared using the Student's T-test. Length of stay (LOS) and cost were analysed using Mood's test and represented as a median with interquartile range because of its non-normal distribution. We performed multivariate logistic regression analysis to analyse adjusted mortality. The adjustment was performed for age, sex, race, hospital-level characteristics, and all comorbidities. We did not require Institutional Review Board approval as the database has deidentified hospitalisations.

A total of 960 hospitalisations that underwent TPVR were identified. The study cohort had a mean age of 21.8 years and consisted primarily of males (61.5%). Female hospitalisations for TPVR increased as age increased while male hospitalisations remained stable (Figure 1). Additionally, half of the hospitalisations in both groups were Caucasian (50%).

Nearly 80% of procedures were carried out during elective admissions in both groups. Furthermore, private insurance was the primary form of payment for over half the hospitalisations (51%), which was followed by Medicaid (28.7%), and Medicare (8.8%) (p-value = 0.007). Elixhauser comorbidities were compared among the groups, and coagulation disorders were significantly higher in males (5.1% vs 1.4%, p-value = 0.003). Other comorbidities such as chronic pulmonary disease, diabetes, and obesity were comparable between the sexes. In-hospital mortality was 1.4% for females; whereas, mortality was absent in males (adjusted p-value = 0.91). All the hospitalisations were discharged within 24 hours of admission, and more than 95% of the hospitalisations were discharged to home in both groups. Finally, the median cost of hospital stay was significantly higher for males compared to females ($48,699 vs $42,385, $p < 0.001$) (Table 1).

This study represents the largest till date, a nationally representable sample of hospitalisations undergoing TPVR. As indications for the use of TPVR increased, the trend in the utilisation of TPVR during the study period increased. Many patients undergo surgical RVOT conduit or pulmonary valve placement first during their lifetime and may require revision later in life; thus, the age ranges were from 1 year to 86 years in this study [5]. Although minor baseline differences existed between males and females, comparable outcomes were noted after adjustment. However, females had the significantly lower cost of hospitalisation care. The in-hospital mortality was very low in this study (0.5%) compared to a previously recorded pooled meta-analysis results (1.5%) [5] and other major clinical trials [2]. While this study lacked information on success rates, a pooled analysis of 19 observational studies demonstrated the TPVR procedural success rate to be 96.2%. Moreover, studies have indicated that serious adverse events are not frequently encountered during TPVR. Additionally, as noticed in this study, TPVR can safely be performed in both genders without yielding differences in outcomes. Length of stay was one day in both groups, which is shorter than surgical replacement and suggests that TPVR does not require as much postoperative care. Cost of hospitalisations was higher in males; however, future studies are warranted to further assess the association of male gender to higher cost. Further advancement in this field may improve outcomes. For example, the recently developed SAPIEN XT (Edward Lifesciences, Irvine, CA, USA) made treatment possible in patients with large conduit diameters.

This study has several limitations as presented with any retrospective, observational analysis from NIS [3]. There was no data on echocardiographic or magnetic resonance imaging volumetric parameters, which limits the analysis of haemodynamics and functional improvement pre- and post-procedure. Lack of follow-up limits the analysis of longitudinal outcomes in these cohorts. However, the use of NIS enabled the analysis of large numbers of hospitalisations undergoing TPVR, a relatively rare procedure. In conclusion, TPVR remains a less invasive, safe, and effective treatment option for both genders.

Conflict of Interest

The authors report no relationships that could be construed as a conflict of interest.

Funding Source

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Acknowledgement

None.

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Received 16 April 2018

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