Mechanical Circulatory Support in Transcatheter Aortic Valve Implantation in the United States (from the National Inpatient Sample)

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Acute circulatory collapse may rarely occur during transcatheter aortic valve implantation (TAVI). In such cases, immediate mechanical circulatory support (MCS) as a bridge to remedial interventions may be required. To define the rate of MCS utilization in TAVI patients and identify the predictors of MCS utilization in a cohort of TAVI patients. TAVI patients between January 2012 and September 2015 were identified in the National Inpatient Sample (NIS) by using the *International Classification of Diseases, 9th Revision*. Trend weights were used to generate the national estimates of MCS rate in TAVI. Multivariate regression analysis was done to identify predictors of MCS use. A total 60,985 patients underwent TAVI with 1,695 patients receiving MCS (2.8%) during index hospitalization. The most common type of MCS was intra-aortic balloon pump in 52%, followed by extra corporeal membrane oxygenator in 34%, then percutaneous ventricular assist device in 7.4%. Rate of MCS use declined over the study period from 3% in 2012 (Q1) to 1.8% in 2015 (Q3). The use of MCS during TAVI was associated with 10-fold increase in-hospital mortality (27.1% vs 2.8%, p <0.001). Predictors of MCS were congestive heart failure (OR = 2.58, p <0.001), transapical access (OR = 1.92, p <0.001), respiratory complication (OR = 5.19, p <0.001), acute myocardial infarction (OR = 4.21, p <0.001), cardiac arrest (OR = 10.65, p <0.001), and cardiogenic shock (OR = 19.09, p <0.001). In conclusion, the rate of MCS during TAVI hospitalization in the United States declined between 2012 and 2015. MCS during TAVI was associated with a 10-fold increase in in-hospital mortality. **© 2019 Elsevier Inc. All rights reserved.** **(Am J Cardiol 2019;124:1615−1620)**

Transcatheter aortic valve implantation (TAVI) is currently widely accepted as a safe alternative to surgical aortic valve replacement in high and intermediate risk patients with severe symptomatic aortic stenosis (AS).[1−4] Recent data from pivotal clinical trials[5,6] showed superior results of TAVI as compared with surgical aortic valve replacement (SAVR). Although rare, catastrophic complications (i.e., Coronary obstruction, annular rupture, cardiac tamponade, severe paravalvular regurgitation, and prosthesis embolization) can occur during TAVI leading to acute circulatory collapse.[1,2,7] In such cases, immediate mechanical circulatory support (MCS) as a bridge to remedial interventions may be required.[8,9] These hemodynamically unstable patients were excluded from the pivotal trials. Moreover, data on real-life use of MCS in the context of TAVI are scarce. As TAVI moves to be the standard of care in patient with severe aortic stenosis (AS), it would be helpful to use a large real-practice database to gain insight into characteristics of this important sub-population of TAVI patients. Herein, we aim to define the rate of MCS utilization in TAVI patients and identify the predictors of MCS utilization in a cohort of TAVI patients derived from the National Inpatient Sample (NIS) from 2012 to 2015.

Methods

The pertinent patient information for this study was derived from the NIS, Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality database from January 1, 2012 (Q1) to September 30, 2015 (Q3). The NIS is the largest publicly available all-payer administrative claims-based database with data on hospitalizations from approximately 1,000 nonfederal hospitals in 45 states.[10] The ethical principles outlined by the Declaration of Helsinki were upheld throughout the study.

The data from 2015 include the first three quarters. On October 1st, 2015, the United States transitioned from using ICD-9-CM to ICD 10-CM/PCS codes for reporting on inpatient procedures and clinical diagnoses. See supplement Table 3. Furthermore, data based on the HCUP Tools derived from ICD-10-CM/PCS codes were not included in the fourth quarter data, therefore for purposes of continuity, the data from Q4 of 2015 were left out of this study.[10] Patients with aortic stenosis (AS) were identified by International Classification of Diseases, 9th Revision (ICD-9) diagnosis codes 395.0, 395.2, 396.2, 424.1, and 746.3. TAVI patients were identified with ICD-9-CM codes 35.05

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See page 1619 for disclosure information.

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and 35.06. The following ICD-9-CM codes were used to identify the subgroup of patients who required MCS: 37.61 for intra-aortic balloon bump (IABP), 37.62 and 37.68 for percutaneous ventricular assist device (PVAD) including Impella and TandemHeart, 39.65, and 39.66 for extracorpeal membrane oxygenation (ECMO). We identified 2 groups of patients who underwent TAVI; one that required MCS during index hospitalization (MCS group), and one that did not require MCS (Non-MCS group). Additionally, patients who underwent concomitant non-aortic valve surgery or coronary bypass surgeries were excluded from the study.

Statistical analyses were done using RStudio (Boston, MA) version (R 3.2.4). Categorical variables were described using frequencies and percentages. The unpaired student *t* test, Chi-square test, or Fisher exact test were performed as appropriate when comparing the groups. Discharged weights provided by NIS to generate national

Table 1
Baseline characteristics of study population from NIS

Variable	Mechanical circulatory support			p Value
	Overall (n = 60985)	No (n = 59290)	Yes (n = 1,695)	
Age (mean ± sd))	80.96 ± 8.73	81 ± 8.66	79.41 ± 10.76	0.001
Women	28995 (47.5%)	28275 (47.7%)	720 (42.5%)	0.066
Asian/Native American/Other	2580 (4.2%)	2485 (4.2%)	95 (5.6%)	
Black	2265 (3.7%)	2175 (3.7%)	90 (5.3%)	
Hispanic	2265 (3.7%)	2155 (3.6%)	110 (6.5%)	
White	53875 (88.3%)	52475 (88.5%)	1400 (82.6%)	
Hypertension	49000 (80.3%)	47780 (80.6%)	1220 (72.0%)	<0.001
Congestive heart failure	5220 (8.6%)	4900 (8.3%)	320 (18.9%)	<0.001
Diabetes mellitus	17840 (29.3%)	17395 (29.3%)	445 (26.3%)	0.242
With complications	3720 (6.1%)	3615 (6.1%)	105 (6.2%)	1.000
Chronic lung disease	20050 (32.9%)	19570 (33.1%)	480 (28.3%)	0.080
Peripheral vascular disease	17900 (29.4%)	17320 (29.2%)	580 (34.2%)	0.053
Transapical approach TAVR	9605 (15.7%)	9165 (15.5%)	440 (26.0%)	<0.001
Anemia	15810 (25.9%)	15425 (26.0%)	385 (22.7%)	0.192
Electrolyte disturbance	15295 (25.1%)	14560 (24.6%)	735 (43.4%)	<0.001
Renal failure	21705 (35.6%)	20995 (35.4%)	710 (41.9%)	0.016
Liver dysfunction	1570 (2.6%)	1510 (2.5%)	60 (3.5%)	0.335
Hypothyroidism	12450 (20.4%)	12120 (20.4%)	330 (19.5%)	0.711
Alcoholism	665 (1.1%)	645 (1.1%)	20 (1.2%)	1.000
Malignancy	2195 (3.6%)	2155 (3.6%)	40 (2.4%)	0.274
Neurological disease	4655 (7.6%)	4520 (7.6%)	135 (8.0%)	0.897
Obesity	9035 (14.8%)	8850 (14.9%)	185 (10.9%)	0.049
Weight loss	2825 (4.6%)	2625 (4.4%)	200 (11.8%)	<0.001
Income (Percentile)				0.354
0-25th	13615 (22.3%)	13175 (22.2%)	440 (26.0%)	
26th to 50th	14950 (24.5%)	14580 (24.6%)	370 (21.8%)	
51st to 75th	15605 (25.6%)	15190 (25.6%)	415 (24.5%)	
76th to 100th	16815 (27.6%)	16345 (27.6%)	470 (27.7%)	
Payor (Percentile)				0.004
1. Medicare or Medicaid	55580 (91.1%)	54120 (91.3%)	1460 (86.1%)	
2. Private insurance	4290 (7.0%)	4105 (6.9%)	185 (10.9%)	
3.Other/self-pay/no charge	1115 (1.8%)	1065 (1.8%)	50 (2.9%)	
Weekend admission	3685 (6.0%)	3540 (6.0%)	145 (8.6%)	0.064
Elective admission	46940 (77.0%)	45840 (77.3%)	1100 (64.9%)	<0.001
Location				0.473
1. Rural	455 (0.7%)	445 (0.8%)	10 (0.6%)	
2. Urban nonteaching	5875 (9.6%)	5680 (9.6%)	195 (11.5%)	
3. Urban teaching	54655 (89.6%)	53165 (89.7%)	1490 (87.9%)	
Bed				0.817
1. Small	2965 (4.9%)	2895 (4.9%)	70 (4.1%)	
2. Medium	10920 (17.9%)	10615 (17.9%)	305 (18.0%)	
3. Large	47100 (77.2%)	45780 (89.7%)	1320 (77.9%)	
Year				0.002
2012	7640 (12.5%)	7400 (12.5%)	240 (14.2%)	
2013	13440 (22.0%)	12935 (21.8%)	505 (29.8%)	
2014	19815 (32.5%)	19325 (32.6%)	490 (28.9%)	
2015	20090 (32.9%)	19630 (33.1%)	460 (27.1%)	

Anemia = Hemoglobin <13.5 g/dL in men and <12.0 g/dL in women. Obesity = body mass index ≥30.0.

estimates were used for statistical analysis. All statistical tests were two sided and p value <0.05 was considered significant. Trend weights were appropriately used to generate the national estimates of quarterly operative volume. Mann-Kendall trend test was used to test the trend's significance. Univariate and multivariate logistic regression analysis were performed to calculate the association between independent factors and MCS in TAVI population.

Results

A total estimate of 60,985 patients were identified with severe aortic stenosis who underwent TAVI during the study period. Patients who required MCS were younger (79.4 years vs 81.0 years, p <0.001), more likely to have underlying congestive heart failure (18.9% vs 8.3%, p <0.001), and have undergone transapical access (26% vs 15.5%, p <0.001). Compared with patients in Non-MCS group, patients in MCS group were less likely to be Caucasian (82.6% vs 88.5%, p = 0.006) and have hypertension (72% vs 80.6%, p <0.001). Hospital status was similar between 2 groups: teaching hospitals (87.9% vs 89.7%, p = 0.47), large hospitals (77.9% vs 77.2%, p = 0.8) (See Table 1).

The rate of MCS utilization was 2.8% of TAVI procedures during the study period. There was a significant variability in the rate of MCS utilization; 3% (2012 Q1) to a peak of 4.3% (2013 Q4) to a nadir of 1.8% (2015 Q3), Mann-Kendall trend test p value 0.03 (See supplement Table 1 and Figure 1).

The need for any MCS device with TAVI was associated with about 10-fold increase in in-hospital mortality (27.1% vs 2.8%, p <0.001). IABP use was associated with the highest mortality, followed by pVAD and ECMO (30.3% vs 24% vs 17.5%, respectively) (See supplement Table 2). In-hospital complication rate was also significantly higher in MCS group as compared with non-MCS group (79.4% vs 50.8%, p <0.001). Cardiac complications were significantly greater in the MCS group citing incidence of cardiogenic shock, arrest, acute myocardial infarction, and tamponade. Total cost and length-of-stay were also significantly increased in the MCS group as compared with non-MCS group ($92,613 vs $55,701, p <0.001 and 12.2 days vs 7.4 days, p <0.001, respectively).

Additionally, a >2-fold increase was seen in acute kidney injury (38.9% vs 16.9%, p <0.001) and respiratory complications (39.8% vs 11.3%, p <0.001) (See Table 2). The following predictors were associated with MCS use: Congestive heart failure (OR = 2.58, p <0.001), transapical access (OR = 1.92, p <0.001), respiratory complication (OR = 5.19, p <0.001), acute myocardial infarction (OR = 4.21, p <0.001), cardiac arrest (OR = 10.65, p <0.001), and cardiogenic shock (OR = 19.09, p <0.001) (See Table 3).

The use of a second MCS device (n = 125) was associated with even a greater mortality compared with one MCS device (52% vs 25%, p <0.001). In the subgroup of patients who required a second MCS device during the index hospitalization (n = 125 patients): IABP plus ECMO (n = 85 patients, 68%) was associated with a mortality of 41.2%, IABP plus pVAD (Impella and TandemHeart) (n = 25 patients, 20%) was associated with a mortality of 100%, and ECMO plus pVAD (n = 15 patients, 12%) was associated with a mortality of 33.3%.

Discussion

Our study aimed to describe the rate and predictors of MCS utilization in a large cohort of NIS patients who underwent TAVI between 2012 and 2015. A number of important findings can be discerned from this study: First, the rate of MCS use in TAVI represents a small proportion (2.8%) and has declined over the yearly quarters to 1.8% in 2015 (Q3). Second, predictors of MCS use include

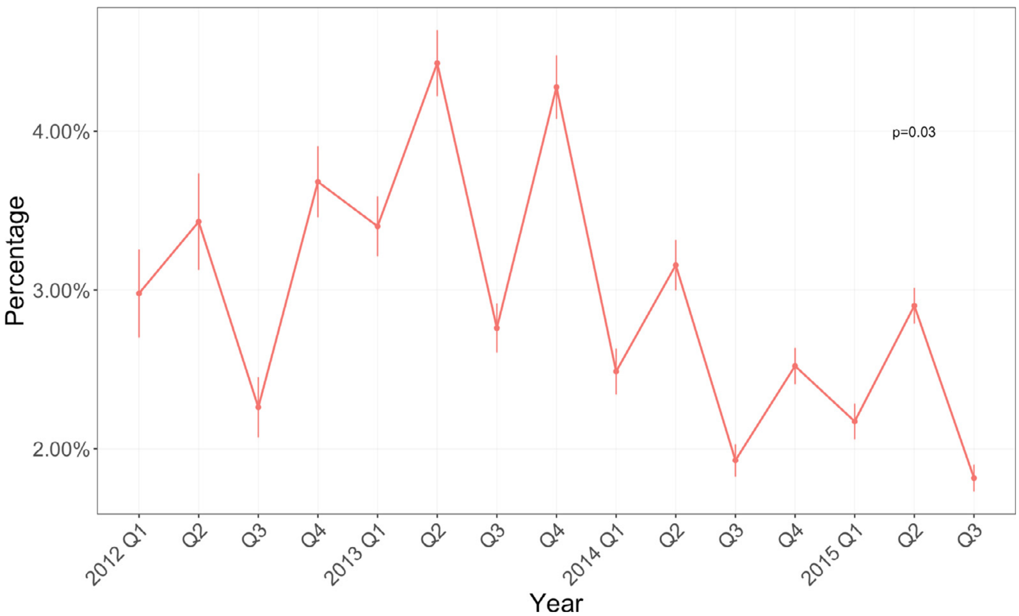

Figure 1. Trend of MCS utilization with TAVI from 2012 to 2015. MCS =mechanical circulatory support; TAVI = transcatheter aortic valve implantation.

Table 2
Patient characteristics (n = 157)

Time from ED to transition appointmentAverage (St. dev)2.3 (2.3)	
Age (years)	
Mean (range) ± standard deviation	65 (25-100) ± 15
Men	87 (55%)
White	118 (75%)
Black	27 (17%)
Hispanic	3 (2%)
Other	9 (6%)
Body mass index (kg/m^2)	
<18.5	3 (2%)
18.5-24.9	35 (22%)
25.0-29.9	53 (34%)
>30.0	66 (42%)
Previous atrial fibrillation diagnosis	60 (38%)
Hypertension	105(67%)
Type 2 diabetes mellitus	29 (18%)
Hyperlipidemia	47 (30%)
Obstructive sleep apnea	29 (18%)
Alcohol use	85 (54%)
Heavy alcohol use*	21 (13%)
Current tobacco abuse	10 (6%)
Chronic obstructive pulmonary disease	4 (3%)
Hyperthyroidism	4 (3%)
Hypothyroidism	4 (3%)
Heart failure reduced ejection fraction	20 (13%)
Heart failure preserved ejection fraction	6 (4%)
Coronary artery disease	18 (11%)
Mechanical valve	0 (0%)
Previous atrial fibrillation or atrial flutter ablation (%)	4 (3%)
CHA_2DS_2-VASc	2.4
Ejection fraction	
>55%	103 (65%)
35-50%	17 (11%)
<35%	3 (2%)
No Echo/Not documented in Echo	34 (22%)
Left atrial size	
Normal	51 (32%)
Mild	27 (17%)
Moderate	17 (11%)
Severe	12 (8%)
No Echo/Not documented in Echo	50 (32%)
Right atrial size	
Normal	92 (58%)
Mild	22 (14%)
Moderate	4 (3%)
Severe	1 (1%)
No Echo/Not documented in Echo	38 (24%)
Emergency department intervention	
None	73 (46%)
Diltiazem	49 (31%)
Metoprolol	30 (19%)
Diltiazem and Metoprolol	5 (3%)
Adenosine	2 (1%)
Severity of atrial fibrillation (SAF) scale (n = 155)	
Average (range)	1.6 (0-3)
St Dev	1.1

transapical access, congestive heart failure, cardiac arrest, cardiogenic shock, acute myocardial infarction, and presence of respiratory complications. Third, MCS utilization was associated with a 10-fold increase of in-hospital mortality, and significant increase of total hospital cost and length of stay.

Initially, the rate of MCS increased from (3%) in 2012 (Q1) to 4.3% in 2013 (Q4). Remarkably, the rate of MCS use dropped significantly in subsequent yearly quarters to 1.8% in 2015 (Q3). This observation could be explained by smaller device profiles and improved performance, increased operator experience, and preference for transfemoral over transapical access during the same period.[4] Interestingly, the initial increase in the rate of MCS use coincides with the reported increase in transapical access in 2013 (Q3).[11] The transapical access had been previously shown to be associated with a higher rate of life-threatening complications and cardiovascular collapse.[11,12]

Our study found that in the cohort of patients who required MCS device, there was a high incidence of congestive heart failure, cardiac arrest, cardiogenic shock, acute myocardial infarction, and presence of respiratory complications. It is unclear whether the presence of these outcomes was secondary to the underlying severe AS or the TAVI procedure itself. Regardless, the presence of these findings portends a worse prognosis. One in 4 patients in the MCS group died within the index hospitalization. Similar findings were reported in PARTNER trial substudy which found that use of MCS was associated with a higher 1 year mortality when compared with patients without MCS use (49.1% vs 21.6%, p <0.001).[13] The high mortality rate with MCS device is likely explained by the underlying pathology that prompted its use in the first place. Indeed, we found that rates of in-hospital complications were higher in the MCS group. Although chronological order cannot be discerned from NIS, it is plausible that in majority of cases, TAVI-related complications and hemodynamic instability from severe aortic stenosis were the reasons of MCS utilization in these patients.

Remarkably, the need for a second MCS device was associated with even greater mortality (52%). A previous study and meta-analysis had shown similar observations with a greater in-hospital mortality with the combination of IABP and ECMO (55.9% to 58.4%).[14,15] It is imperative to emphasize that this finding is a mere observation and should be interpreted as an interesting association that requires further investigation to ascertain the utility of combined MCS devices in TAVI procedures complicated by hemodynamic instability.

Our study results should be interpreted in the context of its limitations. First, there is an inherent limitation of the NIS database as data are derived from hospital claims without access to individual procedural and radiographic data. Second, NIS database lacks data on 30-day and long-term follow-up. Third, inconsistencies in diagnosis coding may bias the measured outcomes; this bias is unlikely to be systemic should affect both groups to similar degree. Fourth, co-morbid conditions and complications were reported from ICD-9 coding during index hospitalization and were not able to be reported according to the Valve Academic Research Consortium (VARC − 2) definitions, as NIS lacks individual clinical and laboratory data.[16] Additionally, due to the nature of the NIS database, it is impossible to infer causality or isolate mortality that directly resulted from MCS. Finally, chronological order of events cannot be discerned from NIS. However, caution should be taken when

Table 3
Univariate and multivariate logistic regression analysis to select predictors of requiring MCS during TAVI

Variables	Univariate			Multivariate		
	OR	95% CI	p Value	OR	95% CI	p Value
Age (year)	0.98	[0.97,0.99]	<0.001	0.99	[0.98,1.01]	0.24
Men	1.23	[0.99,1.54]	0.06	1.36	[1.07,1.73]	0.01
Hypertension	0.62	[0.49,0.79]	<0.001	1	[0.77,1.33]	0.97
Congestive heart failure	2.58	[1.94,3.39]	<0.001	1.78	[1.28,2.44]	<0.001
Access (Transapical)	1.92	[1.49,2.45]	<0.001	1.64	[1.24,2.15]	<0.001
Electrolyte abnormalities	2.35	[1.89,2.93]	<0.001	1.21	[0.93,1.57]	0.15
Chronic kidney disease	1.31	[1.05,1.64]	0.01	1.14	[0.89,1.45]	0.3
Underweight	2.89	[2.02,4.01]	<0.001	1.11	[0.73,1.65]	0.6
Elective admission	0.54	[0.43,0.68]	<0.001	0.87	[0.67,1.14]	0.3
Vascular complication	2.19	[1.42,3.23]	<0.001	1.55	[0.92,2.5]	0.09
Hemorrhagic complication	1.68	[1.16,2.36]	<0.001	1.12	[0.73,1.67]	0.58
Blood transfusion	1.38	[1.07,1.77]	0.01	0.95	[0.71,1.26]	0.75
Cardiac tamponade	4.69	[2.42,8.31]	<0.001	1.72	[0.79,3.46]	0.15
Respiratory complication	5.19	[4.14,6.5]	<0.001	1.86	[1.4,2.47]	<0.001
Neurologic complication	1.49	[0.84,2.43]	0.14	1.15	[0.61,2]	0.63
Sepsis	3.11	[0.74,8.69]	0.06	1.47	[0.29,5.27]	0.59
Acute kidney injury	3.14	[2.5,3.92]	<0.001	1.13	[0.85,1.5]	0.4
Acute myocardial infarction	4.21	[2.94,5.89]	<0.001	2.61	[1.72,3.87]	<0.001
Use of vasopressor	2.44	[1.34,4.08]	<0.001	1.02	[0.52,1.86]	0.95
Cardiac arrest	10.65	[8.05,13.95]	<0.001	4.38	[3.13,6.06]	<0.001
Cardiogenic shock	19.09	[14.7,24.68]	<0.001	8.02	[5.85,10.95]	<0.001

Underweight defined as BMI ≤18.5 kg/m^2.

interpreting outcomes of such devices, and the observed association with worse outcomes should be considered hypothesis generating.

In conclusion, the rate of MCS during TAVI hospitalization in the United States declined between 2012 and 2015. MCS during TAVI was associated with about 10-fold increase in in-hospital mortality, and significant increase of total hospital cost and length of stay. These findings are hypothesis generating, and further prospective studies are needed to further investigate these observations.

Disclosures

Dr. Ruiz is a consultant for St Jude Medical, Abbott Vascular, CardiacImplants, MitrAssist, Mitral Bridge and Tendyne. The remaining authors have nothing to disclose.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.08.013.

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