In-Hospital Outcome In Patients With Acyanotic Congenital Heart Disease Undergoing Transcatheter Aortic Valve Replacement.

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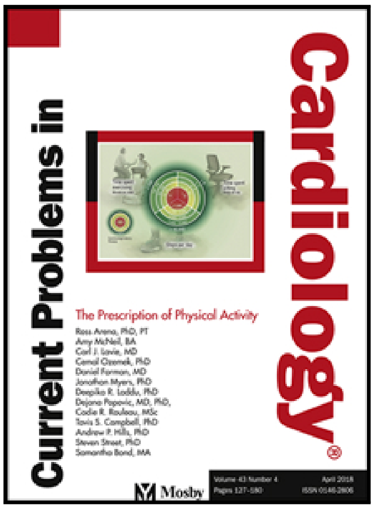

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Introduction:

The annual incidence of congenital heart disease (CHD) in the United States is 40,000 in newborns and approximately 1.4 million in adults. (1) Many adults living with CHD have acyanotic congenital heart disease (ACHD). The ventricular septal defect (VSD) is the most common CHD (41.8%), followed by the atrial septal defect (ASD) (13.1%). Other common acyanotic CHD include coarctation of the aorta, patent ductus arteriosus, corrected transposition of great arteries, pulmonary valve, and subaortic stenosis. (1) With the advancement in identification and nomenclature of the spectrum of ACHD, combined with the advent of minimally invasive techniques for correction of the defect, cardiovascular imaging to delineate anatomy, and other therapeutic options, the life expectancy of individuals with ACHD has dramatically improved. (2) As these patients enter the eighth decade of their lives, the risk of calcification and aortic stenosis increases akin to the population without ACHD. (3) Current evidence supports transcatheter aortic valve replacement (TAVR) over surgical aortic valve replacement in individuals with moderate to high surgical risk. (4,5) Additionally, younger adults with ACHD are at higher risk for surgical complications due to the high likelihood of a history of previous sternotomies, laying the foundation for consideration of TAVR. (6) However, current guidelines from professional societies do not include the role of TAVR in this specific patient population. (2,7) Extensive literature search also revealed limited data on the subject. The authors hope to bridge the gap by investigating the incidence of in-hospital all-cause mortality, resource utilization, and complications in patients with ACHD undergoing TAVR.

Methodology:

National inpatient samples from 2016-to 2018 were utilized to conduct the study. Analyses were performed using STATA, version 16.0 (StataCorp., College Station, Texas, USA). (8) We identified adult patients undergoing TAVR (02RF38H, 02RF38Z, 02RF48Z) using appropriate ICD-10-PCS codes and further stratified according to the presence and absence of acyanotic congenital heart disease (ACHD) (Q210, Q211, Q251, Q250, Q205, Q244, Q221). (9,10) We used the 1:1 propensity matching method using the greedy algorithm and multivariate regression analysis to adjust for potential confounders. A non-parsimonious multivariate logistic regression model was developed for estimation of the propensity score using demographic characteristics. 1:1 matching was done using a caliper of 0.1 using the psmatch2 command. The multivariable regression analysis model was built by including all confounders that were significantly associated with the outcome of the univariable analysis. In addition, variables deemed essential determinants of the outcomes based on literature were forced into the model. Logistic regression was used for binary outcomes, and linear regression was used for continuous outcomes (LOS, total hospitalization charges, and costs). Demographic variables were compared using the student t-test. All P values were two-sided, with 0.05 as the threshold for statistical significance. The study's primary outcome is to identify the impact of ACHD on all-cause in-hospital mortality and complications. Secondary outcomes of interest were resource utilization.

Results:

N=134,170 patients were identified who had TAVR done between 2016-and 2018 using appropriate ICD-10-PCS codes. Patients aged ≤ 18 years were excluded (N=25). Baseline characteristics of the population (4,5) are shown in table 1. Out of 134,170 patients that underwent TAVR, 1,170 (0.87%) were noted to have ACHD, as shown in figure 1. Atrial septal defect (ASD) comprises the most common ACHD (78%). One thousand one hundred fifteen matched pairs were generated after propensity matching. Both the groups had similar age and gender distribution (mean age 79 years, 46% females in the non-ACHD group and mean age 78 years, 50% females in the ACHD group). The ACHD group had a higher burden of co-morbidities including atrial fibrillation (46.2% vs. 38.8%, p=0.016), pulmonary hypertension (27.4% vs. 17.5%, p<0.001), metabolic syndrome (1.3% vs. 0.3%, p=0.005), peripheral vascular disease (29.5% vs. 24.1%, p=0.049), alcohol use disorder (3.0% vs. 1.3%, p=0.018), coagulation disorder (22.7% vs. 12.8%, p<0.001), drug abuse (1.3% vs. 0.4%, p=0.043), liver disease (7.3% vs. 3.1%, p<0.001) and electrolyte disturbances (20.5% vs. 14.9%, p=0.017). The incidence of discharge to skilled nursing facilities (18% vs. 13.2%, p <0.001) and home health care (28.6% vs. 20.9%, p <0.001) were higher in the ACHD group. ACHD patients had higher odds of in-hospital mortality following TAVR (4.7%% vs. 1.5%, p=0.024, OR 2.07, CI, 1.10-3.91). However, there is no increased mortality risk in the propensity-matched cohort in ACHD patients (OR 1.43, p=0.59). The results are summarized in Tables 2 and 3.

We also noted a possible trend towards higher complication odds (cardiac complications such as pericardial complications, need for pericardial drain or cardiac implantable electronic device (CIED), and cardiac arrest) in patients with ACHD undergoing TAVR. However, the odds did not reach statistical significance based on multivariate analysis. The overall rate of complications was very low and of unclear clinical significance. On propensity matching, no difference was found in the incidence of overall cardiac complications between patients with ACHD and patients without ACHD, except STEMI (OR 4.16, 95% CI, 1.08-16.00, p=0.038). There appears to be no increased risk of AKI and ischemic stroke in the ACHD population.

Notably, the length of hospital stay was significantly higher in patients with ACHD (mean 5.84 days) when compared to patients without ACHD (mean 4.31 days). The mean total cost was also higher in the ACHD group undergoing TAVR (mean $58,041 vs. mean $50,046 in the non-ACHD group). Hospital resource utilization is higher in the ACHD group in the form of increased LOS (5.84 days vs. 4.31days, p< 0.001) and higher mean total cost ($58,041 vs. $50,046).

Discussion

Our study of patients undergoing TAVR using the most recent NIS database showed that less than 1% of patients had concomitant congenital heart disease. ASD comprises the most common ACHD (78%). The results of our study indicated comparable all-cause in-hospital mortality between the ACHD group and the non-ACHD group undergoing TAVR after propensity matching. Furthermore, the results did not reveal significant differences between the in-hospital complications, except for STEMI, in patients with ACHD. The group with ACHD undergoing TAVR was noted to have higher resource utilization, such as more extended hospital stay, the overall cost of hospitalization, and discharge to a skilled nursing facility or home health care services.

The 2020 guidelines by the American College of Cardiology (ACC)/American Heart Association (AHA) for the management of valvular heart disease do not include the patient population with ACHD that develop aortic stenosis. (11) While the 2018 AHA/ACC guidelines for the management of ACHD encourage balloon valvuloplasty for non-calcified or minimally calcified aortic stenosis, often seen in younger patients, the society recommends TAVR for older patients that meet the criteria of 'high risk,' approached in a multidisciplinary manner. (2) The 2020 European Society of Cardiology guidelines for ACHD management also emphasize valve replacement as the treatment of choice in patients with calcified valves and symptomatic severe aortic stenosis. The procedure of choice remains TAVR in high-risk patients, if technically feasible. Furthermore, the guidelines mention that the indication of TAVR in ACHD is "rapidly evolving" in patients with LVOT obstruction and aortic coarctation. (7)

The lack of clear guidelines reflects the gap in understanding outcomes with TAVR in ACHD. The extensive literature search revealed isolated case reports and a case series including 13 ACHD patients that underwent TAVR in the UK. (12–15) The case series included patients aged 27.8 to 84.2 years old with various ACHD spectrums. All 13 patients tolerated the procedure well, and only three patients had complications in the form of a permanent epicardial pacemaker, paravalvular aortic regurgitation, and displacement of the implanted valve. There was no 30-day mortality or secondary complications (cardiac or non-cardiac) in any patients. (12) Our study indicates no higher mortality rate in patients with ACHD after propensity matching. Also, no differences were noted in secondary outcomes, both cardiac and non-cardiac, between the ACHD and non-ACHD groups. The comparable mortality risk in ACHD patients with their counterparts is encouraging as a preliminary finding utilizing a large database. It is largely related to comparable in-hospital complications following the procedure and a large proportion of ASD patients in the ACHD group who remain largely asymptomatic in their lifetime. The higher risk of STEMI observed in the ACHD cohort is likely related to their higher cardiac and non-cardiac comorbidity burden. Whether ACHD patients undergoing TAVR will benefit from routine preop angiogram will be an area of active research in the future. Interestingly, the cost and length of hospitalization in the ACHD group were higher than in the non-ACHD group, likely due to the requirement of multidisciplinary teams, advanced cardiac imaging, and periprocedural monitoring.

While randomized controlled trials are required to further evaluate mortality outcomes in patients with ACHD requiring aortic valve replacement, the broad spectrum of the disease entity will make it challenging to design. Even in the presence of guidelines, the approach for management will include multidisciplinary teams with the clinical cardiologist, ACHD cardiologist, cardiothoracic surgeon, structural heart disease interventionalist, and cardiovascular imaging specialist at the very least.

The limitations of our study include coding inaccuracies in the population-based database and the lack of long-term follow-up, including readmission of the population included. Additionally, the authors lacked details on other interventions performed with TAVR, if any, during the hospitalization (for example, repair of the congenital defect) and details of the TAVR (including valve specifics and access).

Conclusion:

Despite the limitations, the study points toward the possible safety of pursuing TAVR in this population provided the availability of adequate technical support and operator competency. The study also helps to throw light on this unique population at high risk of mortality and complications with conventional surgical aortic valve techniques.

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Figure 1. Inclusion criteria for study population. VSD- ventricular septal defect, ASD-atrial septal defect, COA-Coarctation of aorta, PDA-patent ductus arteriosus, TGA-transposition of great arteries.

Table 1: Baseline characteristics of patient undergoing transcatheter aortic valve replacement (TAVR)

	Non-propensity unmatched			Propensity matched		
	With CHD N (%)	Without CHD N (%)	P value	With CHD N (%)	Without CHD N (%)	P value
Total population	1,170	133,000		1,115	1,115	
Female	590 (50.4)	61,193 (46.0)	0.17	565 (50.7)	565 (50.7)	1.00
Age in years (mean ± SD)	78.05 ± 10.56	79.66 ± 8.41	0.026	77.22 ± 11.02	78.15 ± 10.48	0.37
Race (%)			0.23			0.91
White	1,073 (91.7)	115,549 (86.9)		1,020 (91.5)	1,010 (90.6)	
Black	15 (1.3)	5,706 (4.3)		15 (1.4)	20 (1.8)	
Hispanic	56 (4.8)	6,544 (4.9)		55 (4.9)	50 (4.5)	
Asian	0 (0.0)	1,796 (1.4)		0 (0.0)	0 (0.0)	
Native American	0 (0.0)	333 (0.3)		0 (0.0)	0 (0.0)	
Others	26 (2.2)	3,072 (2.3)		25 (2.2)	35 (3.1)	
Hospital Bedsize (%)			0.87			0.68
Small	80 (6.8)	8,845 (6.7)		70 (6.3)	65 (5.8)	
Medium	210 (18.0)	25,736 (19.4)		205 (18.4)	180 (16.1)	
Large	880 (75.2)	98,419 (74.0)		840 (75.3)	870 (78.0)	
Charlson score (%)			0.15			0.94
0	65 (5.6)	7,900 (5.9)		60 (5.4)	75 (6.7)	
1	185 (15.8)	23,528 (17.7)		180 (16.1)	175 (15.7)	
2	180 (15.4)	26,959 (20.3)		175 (15.7)	180 (16.1)	
3	740 (63.3)	74,613 (56.1)		700 (62.8)	685 (61.4)	
Chronic comorbidities (%)						

Atrial Fibrillation	540 (46.2)	51,591 (38.8)	0.016	510 (45.7)	520 (46.6)	0.84
Prior Stroke	165 (14.1)	16,146 (12.1)	0.37	155 (13.9)	140 (12.6)	0.68
Prior MI	110 (9.4)	17,503 (13.2)	0.09	110 (9.9)	125 (11.2)	0.64
Prior PCI	180 (15.4)	29,712 (22.3)	0.011	180 (16.1)	160 (14.4)	0.59
Prior CABG	180 (15.4)	23,475 (17.7)	0.36	180 (16.1)	165 (14.8)	0.70
Pulmonary HTN	320 (27.4)	23,288 (17.5)	<0.001	305 (27.4)	265 (23.8)	0.40
Hypertension	1,030 (88.0)	119,261 (89.7)	0.43	985 (88.3)	985 (88.3)	1.00
Obesity	220 (18.8)	25,204 (19.0)	0.96	220 (19.7)	205 (18.4)	0.72
Dyslipidemia	725 (62.0)	94,842 (71.3)	0.001	700 (62.8)	725 (65.0)	0.62
Metabolic Syndrome	15 (1.3)	372 (0.3)	0.005	15 (1.4)	15 (1.4)	1.00
PVD	345 (29.5)	32,013 (24.1)	0.049	330 (29.6)	320 (28.7)	0.83
CHF	905 (77.4)	99,351 (74.7)	0.35	865 (77.6)	830 (74.4)	0.42
Chronic lung disease	365 (31.2)	38,384 (28.9)	0.43	350 (31.4)	355 (31.8)	0.91
DM	450 (38.5)	49,742 (37.4)	0.08	430 (38.6)	395 (35.4)	0.51
CKD	405 (34.6)	42,600 (32.0)	0.40	380 (34.1)	375 (33.6)	0.92
Anemia	45 (3.9)	5,107 (3.8)	1.00	40 (3.6)	50 (4.5)	0.64
CAD	800 (68.4)	92,714 (69.7)	0.66	775 (69.5)	695 (62.3)	0.12
Smoking	360 (30.8)	46,670 (35.1)	0.17	355 (31.8)	310 (27.8)	0.35
Alcohol use	35 (3.0)	1,689 (1.3)	0.02	35 (3.1)	45 (4.0)	0.61
Coagulation Disease	265 (22.7)	16,958 (12.8)	<0.001	245 (22.0)	175 (15.7)	0.09
Depression	115 (9.8)	10,534 (7.9)	0.26	115 (10.3)	65 (5.8)	0.06

Drug Use	15 (1.3)	545 (0.4)	0.043	10 (0.9)	10 (0.9)	1.00
Hypothyroidism	210 (18.0)	27,105 (20.4)	0.37	205 (18.4)	275 (24.7)	0.10
Liver disease	85 (7.3)	4,123 (3.1)	<0.001	80 (7.2)	95 (8.5)	0.60
Electrolytes Disturbances	240 (20.5)	19,844 (14.9)	0.017	230 (20.6)	275 (24.7)	0.28

Table 2: Disposition at discharge from acute care hospital of patients post transcatheter aortic valve replacement (TAVR)

	With CHD	Without CHD	P value
Disposition (%)			<0.001
Routine	550 (47.0)	85,027 (63.9)	
Transfer to Short-term Hospital	15 (1.3)	532 (0.4)	
Skilled Nursing facility	210 (18.0)	17,596 (13.2)	
Home Health Care	335 (28.6)	27,797 (20.9)	
Against Medical Advice	5 (0.4)	93 (0.1)	
Died	55 (4.7)	1,955 (1.5)	
Unknown	0 (0.0)	0 (0.0)	

Table 3: Multivariate non-propensity and propensity matched analysis showing difference of mortality in acyanotic heart disease patients (ACHD) undergoing transcatheter aortic valve replacement (TAVR) compared to adults without ACHD undergoing TAVR

Univariate Analysis		Multivariate Regression Analysis			
		Non-Propensity Matched		Propensity Matched	
OR (95% CI)	P-Value	OR (95% CI)	P-Value	OR (95% CI)	P-Value
3.30 (1.80-6.05)	<0.001	2.07 (1.10-3.91)	0.024	1.43 (0.38-5.30)	0.594

Table 4: Secondary outcome percentage with odds ratio (OR) of patients with acyanotic heart disease (ACHD) undergoing transcatheter aortic valve replacement (TAVR) compared to patients without ACHD undergoing TAVR. AMI: acute myocardial infarction, NSTEMI: non-ST elevated myocardial infarction, STEMI: ST-elevated myocardial infarction, CIED: cardiac implantable electronic device, AKI: acute kidney injury, IABP: intra-aortic balloon pump, LVAD: left ventricular assist device, ECMO: extra-corporeal membrane oxygenation.

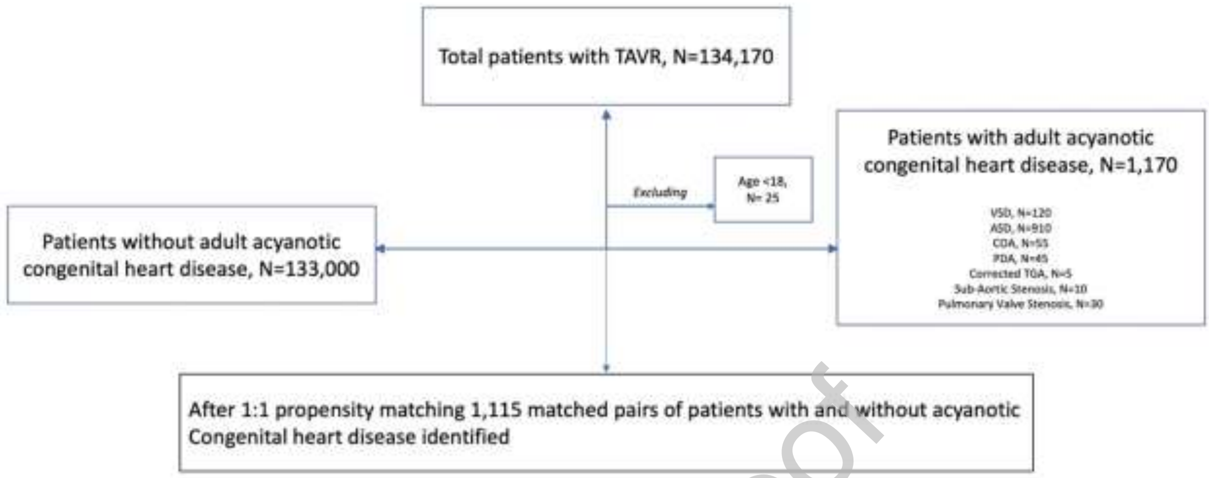
Variable	With CHD N (%)	Without CHD N (%)	Multivariate Regression Analysis, OR (95%-CI), P-value	
			Non-Propensity Matched	Propensity Matched
Ischemic stroke	25 (2.1)	2,487 (1.9)	1.00 (0.41-2.45), 1.00	1.90 (0.41-8.86), 0.42
Hemorrhagic stroke	5 (0.4)	80 (0.1)	6.14 (0.54-69.25), 0.14	-
Pericardial drain	20 (1.7)	1,370 (1.0)	1.38 (0.50-3.79), 0.54	0.08 (0.01-1.59), 0.10
Mechanical ventilation	45 (3.9)	3,830 (2.9)	0.83 (0.39-1.79), 0.64	0.94 (0.39-2.29), 0.89
AMI	30 (2.6)	2,660 (2.0)	1.16 (0.47-2.86), 0.75	0.97 (0.33-2.81), 0.95
NSTEMI	10 (0.9)	1,835 (1.4)	0.56 (0.15-2.13), 0.39	0.52 (0.13-2.08), 0.35

STEMI	10 (0.9)	239 (0.2)	4.16 (1.08-16.00), 0.04	-
CIED use	140 (12.0)	14,630 (11.0)	1.02 (0.68-1.52), 0.92	1.03 (0.57-1.85), 0.93
Cardiac arrest	40 (3.4)	2,421 (1.8)	1.47 (0.71-3.05), 0.30	0.96 (0.36-2.52), 0.93
Cardiogenic shock	60 (5.1)	3,086 (2.3)	1.32 (0.65-2.70), 0.44	1.28 (0.44-3.67), 0.65
Hemorrhage	30 (2.6)	2,301 (1.7)	1.25 (0.56-2.81), 0.59	-
AKI	165 (14.1)	14,244 (10.7)	0.63 (0.61-1.39), 0.71	0.63 (0.32-1.24), 0.18
AKI requiring dialysis	0 (0.0)	931 (0.7)	-	-
Respiratory failure	135 (11.5)	8,924 (6.7)	1.32 (0.85-2.03), 0.22	0.96 (0.49-1.89), 0.91
IABP	15 (1.3)	599 (0.5)	1.50 (0.44-5.08), 0.51	-
Impella	5 (0.4)	386 (0.3)	0.79 (0.15-4.34), 0.79	-
LVAD	5 (0.4)	27 (0.0)	3.91 (0.50-30.64), 0.19	-
ECMO	10 (0.9)	306 (0.2)	1.74 (0.42-7.20), 0.45	-
Complete heart block	120 (10.3)	13,114 (9.9)	0.97 (0.63-1.50), 0.91	0.90 (0.47-1.69), 0.74
Pericardial complications	20 (1.7)	1,104 (0.8)	1.74(0.62-4.86), 0.29	-
Valvular complications	5 (0.4)	1,051 (0.8)	0.51 (0.07-3.72), 0.50	-
Para-valvular leak	5 (0.4)	811 (0.6)	0.73 (0.10-5.35) 0.76	-

Table 5: Resource utilization in patients undergoing transcatheter aortic valve replacement (TAVR) in patients with and without acyanotic congenital heart disease (ACHD).

Variable	Without CHD	With CHD	P value
Mean LOS (Days)	4.31 ± 5.46	5.84 ± 6.31	<0.001
Mean Total Cost ($)	50,046 ± 25,885	58,041 ± 43,674	0.008

Figure 1: Inclusion criteria for study population



Legend: VSD- ventricular septal defect, ASD-atrial septal defect, COA-Coarctation of aorta, PDA-patent ductus arteriosus, TGA-transposition of great arteries.

Declaration of interests

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: