



# National Trends in Major Bleeding Requiring Transfusion and Permanent Pacemaker Implantation Rates Post-transcatheter Aortic Valve Replacement

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## Editorial

TAVR has become the favoured Aortic Valve Replacement (AVR) strategy in elderly patients with Aortic Stenosis (AS) and is approaching equipoise with surgical AVR in younger patients [1]. Multiple contemporary studies have shown a significant proportion of patients undergoing TAVR requiring PPMI which led to significantly longer length of stay and incurred higher charges [2,3]. With improvements in valve delivery systems, improved operator experience and heart teams, and growing inclusion of younger and lower risk patients, we hypothesized that major complication rates (i.e major bleeding requiring a transfusion or need for Permanent Pacemaker Implantation [PPMI]) would have decreased.

The National Inpatient Sample (NIS) database is the largest publicly available all-payer inpatient healthcare database in the United States, estimating more than 30 million hospitalizations nationally when weighted. Hospitals are stratified according to geographic region, bed size, teaching status and urban/rural location, with patient and hospital level data recorded at the time of discharge and weighted to ensure that they are nationally representative. Using ICD-10 PCS codes we identified patients who underwent TAVR from 2016 to 2019 (N=217,710) and those who required blood transfusion or PPMI during the same admission. A major complication was defined as suffering a bleeding event requiring a transfusion or needing a PPMI. Charlson Comorbidity Index (CCI) score was used as a measure of comorbidity burden [4]. We assessed temporal trends in



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individual and composite major complications. Independent predictors of major complication rates and individual complications were identified using a multivariate logistic regression model based upon univariate predictors ( $p < 0.2$ ) identified from baseline variables.

We noted that 12.6% (N=27,390) of TAVR patients suffered a major complication of which 12,000 required a transfusion and 16,740 underwent a PPMI. Complication rates decreased significantly from 15% in 2016 to 11% in 2019 (Figure 1a). Independent predictors of a major complication were female gender (aOR 1.1,  $p=0.002$ ), history of COPD, history of pulmonary hypertension (aOR 1.14,  $p=0.001$ ), history of liver disease (aOR 1.42,  $p < 0.001$ ) and Hispanic ethnicity (aOR 1.25,  $p=0.001$ ) (Figure 1b and Table 1). Increasing Charlson Comorbidity Index (CCI) score was predictive of major complication, with every point increase leading to a near doubling of the odds of having a complication (Figure 1b and Table 1). With regards to PPMI, females had 12% lower odds of requiring a device while those with obesity and Diabetes (DM) had a 24% and 11% higher risk respectively (Figure 1b and Table 1). Females had a significantly higher odds of major bleeding needing a transfusion (aOR 1.57,  $p < 0.001$ ) as were African Americans (aOR 1.57,  $p < 0.001$ ) and Hispanics (aOR 1.54,  $p < 0.001$ ). Increasing CCI score and presence of history of liver disease also predicted a higher need for transfusion (Figure 1b and Table 1).

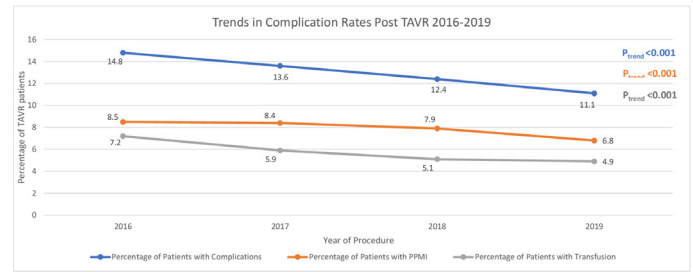


Figure 1A: Trends in Complications rates post-Tavr (2016-2019).

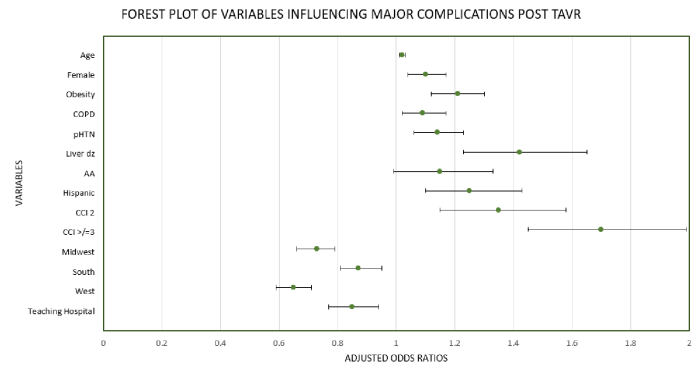


Figure 1B: Forest plot of variables influencing major complications post TAVR.

Table 1: Adjusted multivariate predictors of Complications after correcting for year across 2016-2019.

Variable	Adjusted OR (PPMI or Transfusion)	Adjusted OR (PPMI)	Adjusted OR (Transfusion)	p-value (PPMI or Transfusion)	p-value (PPMI)	p-value (Transfusion)	95% CI (PPMI or Transfusion)	95% CI (PPMI)	95% CI (Transfusion)
Year (Compared to 2016)	0.89	0.92	0.87	<0.001	<0.001	<0.001	0.87-0.92	0.89-0.95	0.83-0.90
Age	1.02	1.02	1.02	<0.001	<0.01	<0.01	1.01-1.03	1.01-1.02	1.01-1.03
Female	1.10	0.88	1.57	0.002	<0.01	<0.01	1.04-1.17	0.82-0.95	1.44-1.72
DM	0.92	1.11	0.72	0.072	0.04	<0.01	0.85-1.00	1.01-1.23	0.63-0.83
HTN	1.02	1.08	0.95	0.548	0.06	0.26	0.96-1.09	0.99-1.17	0.87-1.04
CKD	0.98	0.99	0.95	0.648	0.84	0.4	0.90-1.07	0.89-1.10	0.85-1.07
CVA	1.23	1.08	1.47	0.001	0.36	<0.001	1.08-1.40	0.92-1.28	1.24-1.74
Obesity	1.21	1.25	1.10	<0.001	<0.01	0.09	1.12-1.30	1.14-1.36	0.99-1.22
CHF	0.84	0.95	0.72	<0.001	0.23	<0.01	0.79-0.90	0.87-1.03	0.65-0.79
COPD	1.09	1.03	1.18	0.014	0.56	0.001	1.02-1.17	0.94-1.12	1.07-1.30
Pulmonary HTN	1.14	1.10	1.22	0.001	0.06	<0.01	1.06-1.23	0.99-1.21	1.1-1.36
Smoking	0.92	0.91	0.92	0.011	0.01	0.1	0.86-0.98	0.84-0.98	0.84-1.01
Liver disease	1.42	1.04	1.94	<0.001	0.77	<0.01	1.23-1.65	0.84-1.27	1.61-2.34
Weekend	1.48	1.22	1.85	<0.001	0.03	<0.01	1.29-1.70	1.02-1.47	1.55-2.21
Race (Compared to White)									
AA	1.15	0.83	1.57	0.057	0.08	<0.01	0.99-1.33	0.68-1.02	1.3-1.88
Hispanic	1.25	1.06	1.54	0.001	0.48	<0.01	1.10-1.43	0.90-1.26	1.29-1.84
Asian or Pacific Islander	1.05	0.95	1.18	0.731	0.95	0.4	0.80-1.37	0.68-1.33	0.8-1.75
Native American	0.92	0.85	1.17	0.797	0.69	0.7	0.50-1.69	0.39-1.85	0.5-2.74
Others	0.79	0.76	0.83	0.03	<0.05	0.22	0.65-0.98	0.58-0.99	0.62-1.11
Primary Insurance (Compared to Medicare)									
Medicaid	1.07	0.64	1.55	0.146	0.04	0.01	0.98-1.17	0.41-0.98	1.11-2.16

Private	1.00	0.95	1.10	0.992	0.55	0.26	0.88-1.31	0.81-1.11	0.97-1.25
Self-pay/others	1.40	0.85	1.17	0.092	0.85	0.02	0.95-2.06	0.46-1.57	1.03-1.34
Charlson Comorbidity Score (Compared to 0)									
1	1.17	0.97	1.7	0.054	0.77	<0.01	0.99-1.36	0.81-1.17	1.3-2.26
2	1.35	1.06	2.18	<0.001	0.52	<0.01	1.15-1.58	0.88-1.28	1.66-2.88
>/=3	1.70	1.18	3.41	<0.001	0.08	<0.01	1.45-1.99	0.98-1.42	2.6-4.5
Hospital Region (Compared to NE)									
Midwest	0.73	1.08	0.39	<0.001	0.16	<0.01	0.66-0.79	0.97-1.21	0.34-0.44
South	0.87	1.01	0.72	0.001	0.84	<0.01	0.81-0.95	0.91-1.12	0.65-0.81
West	0.65	0.92	0.40	<0.001	0.13	<0.01	0.59-0.71	0.82-1.03	0.34-0.46
Annual Income by Zip (Compared to <43,999)									
44,000-55,999	1.07	1.15	0.94	0.146	0.01	0.35	0.98-1.17	1.03-1.29	0.82-1.07
56,000-73,999	1.10	1.10	1.10	0.037	0.11	0.15	1.01-1.20	0.98-1.23	0.97-1.25
>74,000	1.20	1.24	1.17	<0.001	<0.01	0.02	1.09-1.32	1.10-1.38	1.03-1.34
Teaching Hospital (Compared to Non-teaching)	0.85	0.99	0.66	0.001	0.99	<0.01	0.77-0.94	0.88-1.13	0.57-0.75
Hospital Bedsizes (Compared to small)									
Medium	1.04	1.06	1.09	0.600	0.494	0.43	0.90-1.19	0.89-1.26	0.89-1.33
Large	1.11	1.19	1.10	0.086	0.03	0.32	0.98-1.26	1.01-1.39	0.91-1.32

This analysis highlights an important national trend towards lesser major complication rate with 1 in 7 patients suffering a complication in 2016 compared to 1 in 9 in 2019. However, with increasing adoption of TAVR in younger patients, we need to redouble efforts to decrease complication rates below the most recent 2019 threshold, especially for those patients at continued elevated risk of complications highlighted in this analysis.

**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: Harold L. Dauerman reports a relationship with Medtronic Inc that includes: consulting or advisory and funding grants. Harold L. Dauerman reports a relationship with Boston Scientific Corp that includes: Consulting or advisory and funding grants. Editorial Board- Dr HLD.

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