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TAVR vs balloon aortic valvotomy for severe aortic stenosis and cardiogenic shock: An insight from the national inpatient sample database

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ABSTRACT

Background: Severe Aortic stenosis (AS) complicated by cardiogenic shock (CS) represents a grave clinical condition with limited treatment options. Evidence from small observation studies favors that Transcatheter Aortic Valve Replacement (TAVR) might be a feasible option in these patients in contrast to emergent Balloon Aortic Valvuloplasty (BAV) which is associated with very high short and long-term mortality.

Methods: 11,405 hospitalizations with severe AS complicated by CS between 2016 and 2020 were identified using the National Inpatient Sample (NIS) Database, and patients were then stratified according to whether they received TAVR or BAV. Propensity-score matching was used to account for differences in the baseline characteristics. Primary and secondary outcomes were then compared between 3485 hospitalizations in direct TAVR group and with 3485 matched hospitalizations in the BAV group. The primary outcome was a composite of all-cause in-hospital death, acute cerebrovascular accident (CVA), and myocardial infarction (MI). Secondary outcomes and safety outcomes were also compared between the two groups.

Results: TAVR was associated with fewer primary outcomes events as compared to BAV {36.8 % vs 56.8 %, aOR (95%CI) = 0.38(0.30–0.47)}, due to fewer all-cause in-hospital deaths {17.8 % vs 38.9 %, aOR (95%CI) =0.34 (0.26–0.43)} and MI {12.3 % vs 32.4 %, aOR (95%CI) = 0.29 (0.22–0.39)}. TAVR was associated with higher rates of acute CVA {6.17 % vs 3.44 %, aOR (95%CI) = 1.84 (1.08–3.21)} and pacemaker implantation post procedure {11.9 % vs 6.03 %, aOR (95%CI) = 2.10 (1.41–3.18)}.

Conclusion: Direct TAVR in shock and severe Aortic stenosis is a better strategy than rescue Balloon aortic valvotomy.

1. Introduction

Transcatheter aortic valve replacement/Implantation (TAVR/TAVI) via transfemoral approach is the preferred procedure for Severe Aortic valve Stenosis (AS) for patients >65 years, who prefer bioprosthetic valve, have limited life expectancy or are high/prohibitive surgical risk for surgical aortic valve replacement [1]. This procedure is usually done in an elective setting [2]. Cardiogenic shock (CS) related to AS is a dramatic scenario, with a short-term mortality rate of up to 70 % without durable treatment [3]. Appropriate therapeutic strategy for these critically ill patients remains unclear.

While medical treatment alone is an unreliable option, and surgery is often deemed prohibitive, it is unclear whether direct TAVR or BAV followed by elective TAVR after medical stabilization should be performed [1,4]. Inotropic agents may be used, but with an increased risk of arrhythmias with dobutamine, and an increase in afterload with vasopressive agents [5,6]. Balloon aortic valvuloplasty (BAV) could be a life-saving strategy in patients in CS, especially when surgical risk seems prohibitive [7,8]. Currently, BAV may be considered in

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hemodynamically unstable patients, as a bridge to surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR), or as a palliative measure (class IIb recommendation) [1]. Only small observational studies have been published to date-most, that too before the widespread use of TAVR [3,7,9]. Short-term mortality by BAV in this patient population is reported to be in the range of 30 %–40 % [10, 11]. BAV does not improve the natural history of the disease and may even worsen it by inducing myocardial dysfunction or acute AR [12].

Improvements in TAVR procedures have allowed the utilization of direct TAVR in critically ill patients usually as rescue therapy. However, data on this approach is limited due to the small sample size and observational nature of all studies on this topic [13,14].In one study 23 patients who underwent emergent TAVR had better immediate procedural mortality compared to 118 patients who underwent emergent BAV (8.7 % vs 20.3 %) [13]. In another observation study, 27 patients with cardiogenic shock and severe aortic stenosis underwent emergent TAVR and had a 30-day mortality rate of 33.3 % [14]. These findings suggest that direct TAVR might be a viable option in such patients. Hence, we sought to compare the strategy of direct TAVR for cardiogenic shock complicating severe AS to urgent BAV utilizing a nationwide database of the National Inpatient Sample (NIS).

2. Methods

This is a retrospective cohort study analyzing the National Inpatient Sample (NIS) database for the years 2016 to 2020. The NIS database is the largest inpatient database in the United States, part of the Healthcare Cost and Utilization Project (HCUP), sponsored by the Agency for Healthcare Research and Quality. The NIS is derived from billing data submitted by hospitals to statewide data organizations. It contains information on demographic and clinical characteristics as well as resource use obtained from discharge abstracts. Unweighted data from the NIS contain >7 million hospital stays each year, representing an approximate 20 % sample of annual hospital discharges in the United States. Using validated sample weights, weighted data from the NIS contain >35 million annual discharges, which represents a national estimate of total annual hospital discharges in the United States [15,16]. The NIS includes all patients, including those covered by Medicare, Medicaid, private insurance, and the uninsured. For Medicare, the NIS includes Medicare Advantage patients, a population that is often missing from Medicare claims data but constitutes as many as 30 % of Medicare beneficiaries [17]. The NIS reports data uses the International Classification of Diseases; the International Classification of Diseases-10th Edition (ICD-10) from October 2015, before which the International Classification of Diseases-9th Edition was used [15,16]. Data from the NIS have been used to describe healthcare utilization, access, charges, quality, and outcomes [15,16]. This study was deemed exempt by the Institutional Review Board, as data are deidentified and publicly available.

2.1. Study population

The NIS database from 2016 to 2020 was queried to identify patients who were hospitalized with shock and had either balloon aortic valvuloplasty or Transcatheter Aortic Valve Replacement during the index hospitalization (see Fig. 1). ICD-10 diagnosis and procedure codes were used for the identification of the relevant patient population (Supplemental Table 1). Patients who received both BAV and TAVR were excluded. Patients <18 years of age were also excluded.

Co-morbidities were identified using Elixhauser Comorbidity Software Refined for ICD-10-CM [18]. Co-morbidities that were relevant to our study and not included in Elixhauser Comorbidity Software Refined for ICD-10-CM were identified by querying the dataset for their respective ICD-10 diagnostic codes. Relevant outcome variables were also identified by ICD-10 diagnostic and procedure codes. These included the following variables: Acute Cerebrovascular accident (which included both ischemic or hemorrhagic stroke) and myocardial infarction (STEMI or NSTEMI), Acute Kidney Injury (AKI), Renal replacement therapy, blood transfusion, vascular complications, Postoperative bleeding, heart block, permanent pacemaker implantation (Supplemental

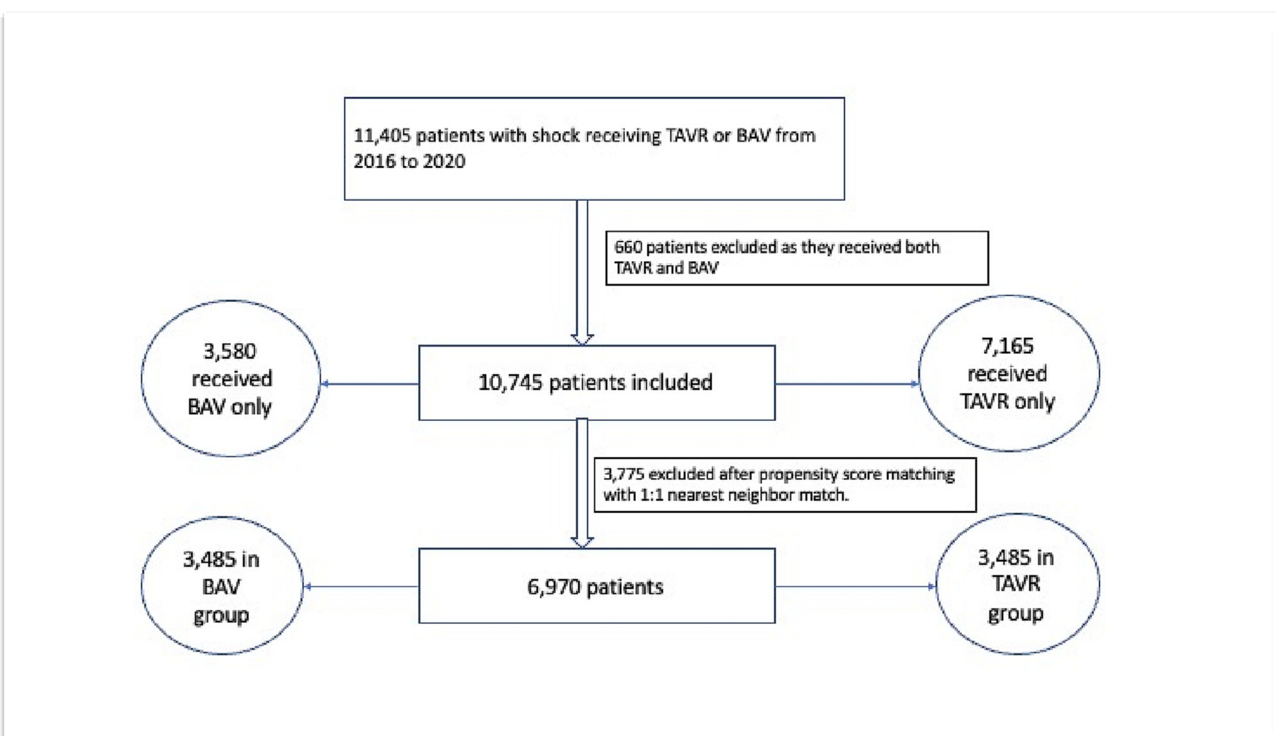

Fig. 1. Figure showing flowchart of patients included in study groups.

Table 1). The study population was divided into two groups, the TAVR group, and the BAV group. Baseline characteristics were compared between the study groups before and after propensity score matching. These included age, gender, racial distribution, and 15 different comorbidities (Table 1, Fig. 2, Supplementary Fig. 1, and Supplemental Table 2).

2.2. Outcomes

Primary efficacy outcome was a composite of All-cause In-hospital death, Acute Cerebrovascular accident (which included both ischemic or hemorrhagic stroke), and myocardial infarction (STEMI or NSTEMI). Secondary outcomes include individual components of the primary outcome, Acute Kidney Injury (AKI) needing renal replacement therapy, and Length of stay. Primary safety outcome was a composite of bleeding needing blood transfusion, vascular complications, and heart block needing permanent pacemaker implantation. Secondary safety outcomes included individual components of primary safety outcome. Primary and secondary efficacy outcomes along with primary and secondary safety outcomes were compared in the matched groups after propensity score matching.

2.3. Statistical analysis

Stata 17 (Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC) was used for statistical analysis. Statistical significance was defined as a *P* value <0.05. Discharge weights provided by the HCUP were applied to generate the national estimates as recommended [19]. Baseline characteristics were compared between the two groups by calculating the absolute percentage and the odds ratio of all relevant variables using multivariate logistic regression to evaluate the potential association. We also calculated the Standardized Mean Difference (SMD) of all baseline characteristics variables to assess the balance between the groups. For a given variable SMD < 0.1(10 %) was deemed to be the threshold for the existence of balance for that variable between two study groups [20,21].

Pearson's Chi-Square test was used for categorical variables, while the students *t*-test was used for continuous variables. Descriptive statistics were reported in frequencies with percentages for categorical variables, while continuous variables were reported in mean, standard deviation, and median values. The 95 % confidence interval was calculated for these continuous variables. The median was reported for skewed continuous variables. We utilized the median test to assess the statistical significance of medians.

To limit selection bias, we employed propensity score methodology to match the two groups to all baseline characteristics at a 1:1 ratio. The nearest neighbor technique was adopted to match each case to the control, which is closest to the calculated propensity score, with a caliper width of 0.01. The propensity score was calculated from the following baseline matching variables: Age, gender, race, and following comorbidities Congestive Heart Failure, Cardiac Arrhythmias, Valvular Heart Disease, Pulmonary Vascular Disease (which includes pulmonary hypertension, pulmonary embolism or Cor pulmonale, etc.), Peripheral Vascular Disease, chronic lung disease, Diabetes Mellitus, Hypertension, Renal Failure, Chronic Liver Disease, Obesity, Metastatic Cancer, Anemia, paralysis (quadriplegia). After propensity score matching, all baseline variables were assessed for balance by calculating SMD. Balancing was confirmed to all baseline characteristics as SMD for all variables was <0.1(10 %) (Table 1 and Fig. 2).

Outcomes were compared between the two matched groups by estimating the percentage of the particular outcome and calculating the adjusted Odds ratio of the outcomes in the TAVR group compared to the BAV group (Fig. 3, Supplementary Figs. 2, 3 and Supplemental Tables 3 to 6).

3. Results

11, 405 patients were identified who were hospitalized for shock and had TAVR or BAV. 660 patients were excluded as they had received both BAV and TAVR during the same hospitalization. Out of the remaining 10,745 patients, 7165 patients were noted to have to TAVR alone and 3580 patients were noted to have BAV alone (see Fig. 1).

The mean age of the study population was 76.19 years (Standard deviation (SD) = 10.45 years). Males constituted 41.2 % of the study population and females 58.8 %. Whites constituted 84.6 %, Blacks 6.03 %, Hispanics 4.78 %, Asian and Pacific Islanders 1.59 %, Native Americans 0.43 %, and other races 2.61 %. The TAVR group constituted 66.7 % (7165/10,745) and the BAV group 33.3 % (3580/10,745) of the study population. The median length of stay was 11 days {interquartile range (IQR) = 6–18 days}. Death during index hospitalization occurred in 24.9 % of patients and 75.1 % of patients survived till hospital discharge (Supplemental Table 7).

There was no difference in the age of the two groups with the mean age being 76.20 years (SD = 10.55 years) in the TAVR group and 76.17 years (SD = 10.25 years) in the BAV group. On comparison of baseline characteristics peripheral vascular disease and coagulopathy were more common in the TAVR group with OR of 1.5 {95 % Confidence interval (95 % CI) =1.2–1.9, *p*-value <0.001} and 1.4 (95 % CI = 1.1–1.7, p-value <0.001) respectively. Congestive heart failure, pulmonary vascular disease, Diabetes Miletus, and Liver disease were less common in the TAVR group (Table 1, Supplementary Fig. 1). Baseline characteristics were assessed for adequate balance by calculation of Standardized Mean Difference (SMD) for each variable. A value of less than (0.10) or 10 % was considered the threshold for adequate balance.

After the Propensity score matching 3485 patients in the TAVR group were matched to 3485 patients in the BAV group. SMD of all baseline characteristics was calculated after propensity score matching. Adequate balance was achieved for all baseline characteristics after propensity score matching. Outcomes were assessed in the matched groups.

The primary efficacy outcome (composite of All-cause In-Hospital death, Acute CVA, and MI,) occurred in 36.8 % of the TAVR group and 56.8 % of the BAV group, {adjusted Odds ratio of Hazard, aOR =0.38 (95%CI = 0.30–0.47, *p*-value <0.001). This lower rate of primary

Table 1
Baseline characteristics of the BAV group and TAVR group after matching.

Variable	BAV group N = 3485	TAVR group. N = 3485	*P* value
Age	76.14	75.67	0.40
(SD)	(10.20)	(10.64)	
Males	61.5 %	62.4 %	
Females	38.5 %	37.6 %	0.75
White	81.8 %	82.1 %	0.89
Blacks	6.5 %	6.5 %	1.00
Hispanics	3.9 %	3.6 %	0.78
Asian or Pacific Islanders	1.7 %	2.2 %	0.56
Native Americans	0.4 %	0.4 %	1.00
Other Races.	2.4 %	2.2 %	0.71
Congestive heart failure	94 %	95.1 %	0.35
Cardiac arrhythmias	70.7 %	70.3 %	0.86
Valvular heart disease	90.8 %	89.2 %	0.29
Pulmonary vascular disease	33 %	34.6 %	0.54
Peripheral vascular disease	20.1 %	19.8 %	0.89
Chronic pulmonary disease	29.6 %	30.6 %	0.69
Diabetes Miletus	43.3 %	47.6 %	0.12
Hypertension	85.4 %	84.6 %	0.72
Renal failure	51.9 %	54.1 %	0.44
Liver disease	21.1 %	22.5 %	0.53
Obesity	15.4 %	15.4 %	1.00
Metastatic Cancer	1 %	1 %	1.00
Coagulopathy	27.4 %	27.3 %	0.95
Anemia	8.3 %	8.5 %	0.92
Past Paralysis.	2 %	2.4 %	0.58

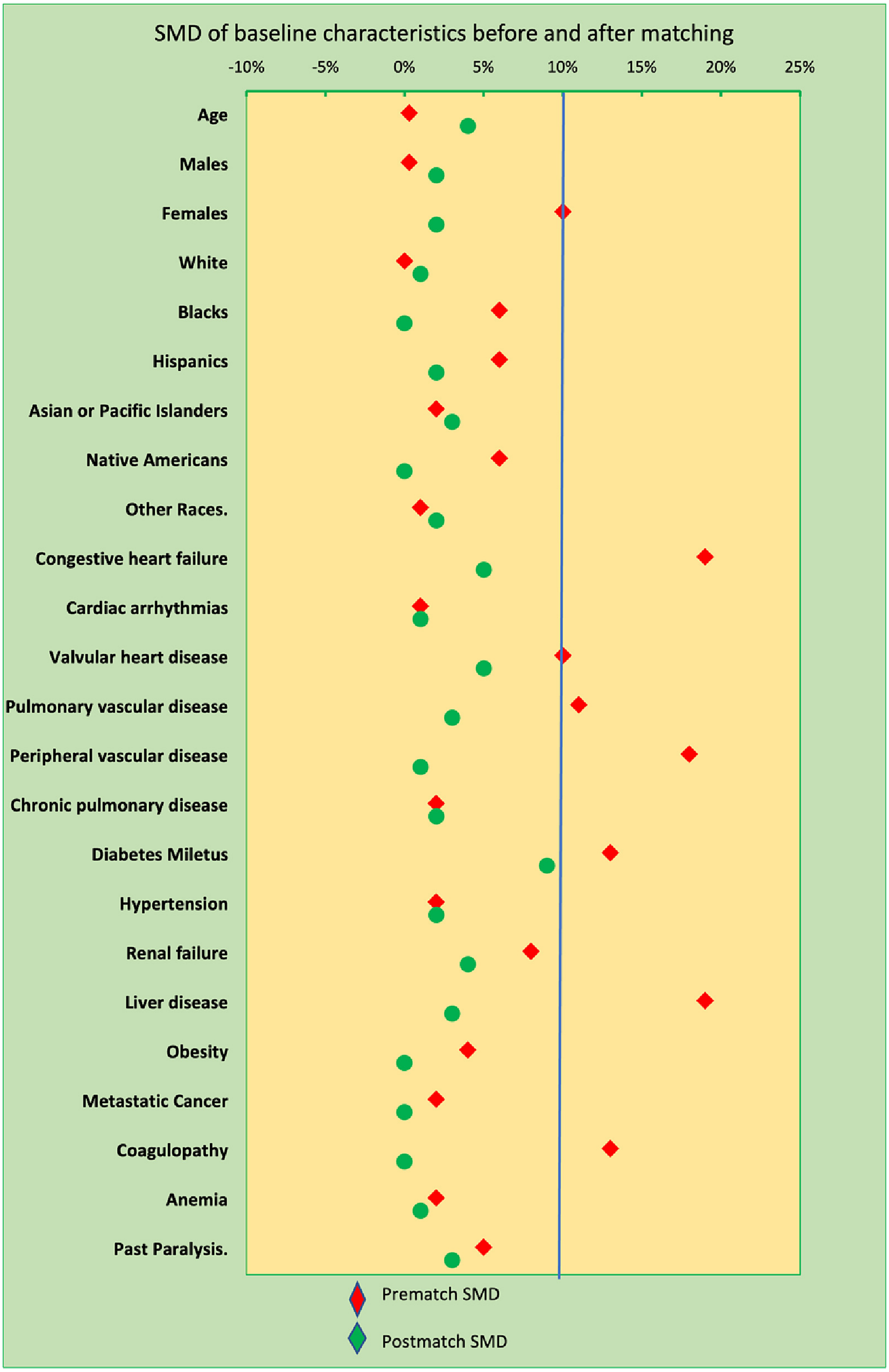

Fig. 2. Standardized Mean Difference (SMD) of baseline characteristics before and after matching.

efficacy outcome was driven by lower rates of All-cause In-Hospital death and Myocardial infarction in the TAVR population. All-cause In-hospital death was 17.8 % in the TAVR group vs 38.9 % in the BAV group, (aOR =0.34, 95%CI 0.26–0.43, $p < 0.001$). Myocardial infarction was again less common in the TAVR group as compared to the BAV group {12.3 % vs 32.4 %, aOR = 0.29, 95%CI = 0.22–0.39, p value<0.001}. Although acute CVA was more common in the TAVR group {6.17 % vs 3.44 %, aOR = 1.84, 95 % CI = 1.08–3.21, p value 0.02}, it did not shift the composite primary efficacy outcome in favor of BAV group. There was no statistically significant difference in AKI needing renal replacement therapy and length of stay between the two groups (Fig. 3, Supplementary Fig. 2, and Supplemental Tables 3 and 4).

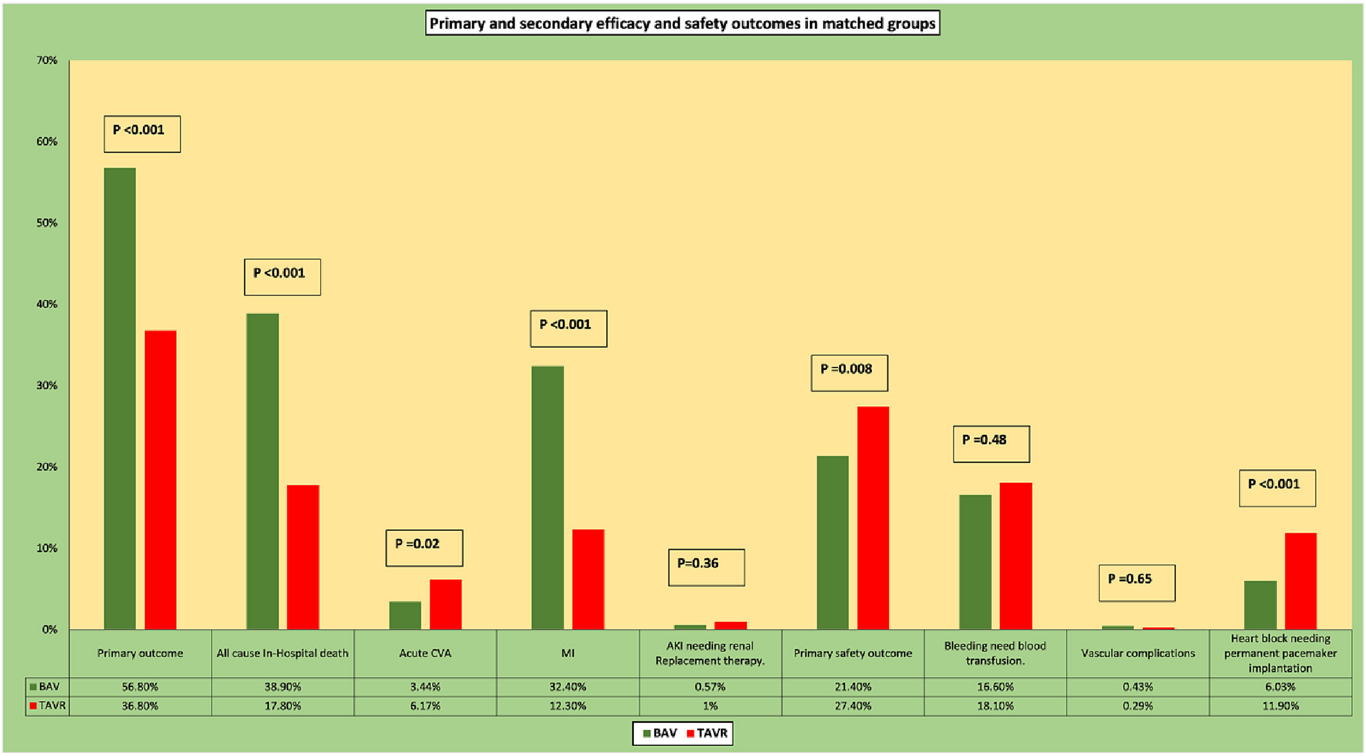

Fig. 3. Comparison of primary and secondary efficacy and safety outcomes between the TAVR group and BAV group.

Primary safety outcome events occurred in 27.4 % of patients in the TAVR group and 21.4 % of patients in the BAV group (aOR of Hazard = 1.39, 95%CI = 1.08–1.79, p value = 0.009). This was mainly driven by higher rates of heart block needing permanent pacemaker in the TAVR group, {11.9 % vs 6.03 %, aOR of Hazard =2.10, 95 % CI =1.41–3.18, *P* value<0.001). There was no statistically significant difference in bleeding needing blood transfusion and vascular complication between the two groups (Fig. 3, Supplementary Fig. 3, supplemental Table 5 and 6).

4. Discussion

This study is the first of its kind study which compares outcomes in patients between urgent BAV vs urgent TAVR in patients with severe AS utilizing a large database of the national inpatient sample. The main findings of our study are (a) Patients who undergo urgent TAVR had fewer co-morbidities as compared to patients who underwent urgent BAV, (b) The all-cause in-hospital mortality rate was lower in patients undergoing TAVR as compared to BAV, (c) TAVR was associated with a lower rate of myocardial infarction, (d) Incidence of Acute stroke was more common in TAVR as compared to BAV, (e) The rate of implantation of permanent pacemaker was more in the TAVR as compared to BAV.

This study showed that patients who undergo urgent TAVR had fewer co-morbidities as compared to patients who underwent urgent BAV. This is quite intuitive as BAV might have been regarded as more appropriate for much sicker patients even though both groups were having cardiogenic shock. The effect of these differences in co-morbidity burden on the outcomes of the study was countered by propensity score matching. The all-cause in-hospital mortality rate was lower in TAVR as compared to BAV. This finding is consistent with the earlier observational studies. In one study 23 patients underwent emergent TAVR. This group had better immediate procedural mortality compared to 118 patients who underwent emergent BAV (8.7 % vs 20.3 %) [13]. 30 days mortality rates were lower in the emergent TAVR group compared to the emergent BAV group (23.8 % vs 33 %) [13]. Due to the small sample size, these differences were not statistically significant. In another observation study, 27 patients with cardiogenic shock and severe aortic stenosis underwent emergent TAVR and had a 30-day mortality rate of 33.3 % [14]. In-Hospital mortality in our study cohort was 17.8 % which is the lower 30-day mortality rate reported by the above two observation studies. However, this reduced rate is consistent with 30-day mortality rate (19.1 %) reported by Masha et al. in their observation study involving 2220 patients with severe AS and cardiogenic shock using the STS/ACC TVT (Society of Thoracic Surgeons and the American College of Cardiology Transcatheter Valve Therapy) registry [22]. Masha et al. compared TAVR in patients with severe AS and cardiogenic shock to those without cardiogenic shock in patients >65 years of age using the STS/ACC TVT registry [22]. This study reported 30-day mortality in cardiogenic shock cohort comparable to our study which is significantly higher compared to the non-cardiogenic shock group [22]. However, the study did not compare TAVR vs BAV in the shock cohort. In our study, the in-hospital mortality rate was very high in the BAV cohort at 38.9 %. This is again consistent with two relatively recent observational studies on emergent BAV in patients with severe AS with acute heart failure or cardiogenic shock showed a significantly elevated 1 monthly mortality after BAV with one study reporting an early mortality of 30 % [10] and the other one reporting a 1-month mortality of 47 % [11].

TAVR was associated with a lower rate of myocardial infarction as compared to BAV. These findings might be since TAVR involves coronary evaluation pre-procedure and might lead to revascularization of otherwise undiscovered coronary artery disease in this patient population that is prone to CAD. Also, TAVR leads to better unloading of LV due to better relief of obstruction and thus should decrease myocardial oxygen demand making it less prone to ischemia. The benefit in In-Hospital death and Myocardial infarction comes at the cost of a slightly higher rate of strokes and an increased rate of implantation of permanent pacemaker. Although the risk of stroke was higher in the TAVR group this was only slightly higher than the BAV group and comparable to stroke in general for TAVR which is estimated at 2.7 %–5.5 % [23]. There are several patient-specific and procedure-related factors that increase the risk of early stroke (within 10 days of procedure) in TAVR [24]. Patient-

related factors include female gender, CKD, previous history of stroke, low body mass index (BMI), history of falls, new onset atrial fibrillation and absence of coronary artery bypass surgery (CABG) [24]. In addition to these factors several procedure related factors increase risk of early stroke in TAVR which include small AV annulus size, increased total time in Cath lab, increased time of delivery catheter in the body, rapid pacing, Balloon pre-dilatation, valve repositioning and pure AS without regurgitation [24]. Also, TAVR likely involves forceful manipulation of calcified aorta, stenotic aortic valve resulting in a higher frequency of cerebral events through debris embolization [24].

Again, the increased rate of pacemaker implantation (11.9 %) in the TAVR group is lower than the rate in general for TAVR which is estimated to be 14.9 %–16 % [25,26]. All these findings suggest that direct TAVR is not only a viable option but a superior treatment strategy for cardiogenic shock complicating severe AS.

The following are the main limitations of this study. First, our study being an observational study, we could not exclude all the possible confounding factors that would possibly affect our study results. An attempt to reduce this was done by propensity score matching accounting for all the several baseline characteristics and comorbidities. The balance concerning known relevant confounding factors was achieved after propensity score matching. However, this does not limit the effect of unknown confounders. Second, the NIS is liable for documentation and coding errors as this is an administrative claims database. Nevertheless, NIS has been extensively validated internally as well as externally [17]. Annual data quality assessments are performed to maintain the internal validity of the database [17,27]. Estimates, clinical characteristics, and procedural data from NIS have been externally validated against data from the American Hospital Association annual survey database, national hospital discharge service, and the med PAR inpatient database from centers from Medicare and Medicaid services [17,28]. Third, NIS only provides in-hospital data [15,16]. It does not provide long-term outcomes beyond the discharge day which limits the follow-up period for event evaluation beyond the hospitalization period. Fourth, we could not exclude patients that were included in the TAVR group and might have got BAV in last past as this database provides data regarding index hospitalization only. However, all patients had shock during the index hospitalization, and even if BAV had been done before index hospitalization it probably had no positive hemodynamic effect during the index hospitalization. Fifth, this observational study is based on coding data and the evidence provided by this study is circumstantial. There is no insight into the differential procedure specific and hemodynamic characteristics of the two patient groups which must be considered while interpreting the findings of our study. Lastly, our study reported a high rate of MI (combination of STEMI and NSTEMI). This was mainly due to overall higher rate of NSTEMI (18.9 %) compared to STEMI (3.87 %). Although, our study group represented sick cohort with cardiogenic shock, there is possible that higher proportion of MI was due to NSTEMI being coded for type 2 MI.

5. Conclusion

Direct TAVR in shock and severe Aortic stenosis is a better strategy than rescue Balloon aortic valvotomy as it is associated with better All-cause death and incidence of myocardial infarction during index hospitalization but is associated with increased risk of stroke and risk of heart block needing a permanent pacemaker. Length of stay is not statistically different between the two approaches. Randomized controlled trials to test this strategy are the need of the hour.

CRediT authorship contribution statement

Sibghat Tul Llah: Conceptualization, Methodology, Software, Formal analysis, Supervision, Data curation. **Sumaiya Sharif:** Conceptualization, Resources, Writing – original draft. **Sami Ullah:** Visualization, Writing – original draft. **Shoaib Altaf Sheikh:** Visualization, Writing – review & editing. **Mohamed Adil Shah:** Visualization, Writing – review & editing. **Obeid M. Shafi:** Supervision, Visualization, Writing – review & editing, Methodology. **Tawseef Dar:** Software, Validation, Formal analysis.

Declaration of competing interest

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.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2023.05.006.

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