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Procedural and long-term outcome among patients undergoing expedited trans-catheter aortic valve replacement

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Abstract

Objective: Patients with rapidly deteriorating clinical status due to severe aortic stenosis are often referred for expedited transcatheter aortic valve replacement (TAVR). Data regarding the outcome of such interventions is limited. We aimed to evaluate the outcome of patients undergoing expedited TAVR.

Design and Setting: Data were derived from the Israeli Multicenter Registry.

Subjects: Subjects were divided into two groups based on procedure urgency: patients who were electively hospitalized for the procedure ($N = 3140$) and those who had an expedited TAVR ($N = 142$). Procedural and periprocedural complication rates were significantly higher among patients with an expedited indication for TAVR compared to those having an elective procedure: valve malposition 4.6% versus 0.6% ($p < 0.001$), procedural cardiopulmonary resuscitation 4.3% versus 1.0% ($p = 0.007$), postprocedure myocardial infarction 2.0% versus 0.4% ($p = 0.002$), and stage 3 acute kidney injury 3.0% versus 1.1%, ($p < 0.001$). Patients with expedited indication for TAVR had significantly higher in hospital mortality (5.6% vs. 1.4%, $p = 0.003$). Kaplan–Meier's survival analysis showed that patients undergoing expedited TAVR had higher 3-year mortality rates compared to patients undergoing an elective TAVR procedure ($p < 0.001$). Multivariate analysis found that patients with expedited indication had fourfolds increased risk of in-hospital mortality (odds ratio: 4.07, $p = 0.001$), and nearly twofolds increased risk of mortality at 3-year (hazard ratio: 1.69, $p = 0.001$) compared to those having an elective procedure.

Conclusion: Patients with expedited indications for TAVR suffer from poor short- and long-term outcomes. It is important to characterize and identify these patients before the deterioration to perform TAVR in a fast-track pathway to minimize their procedural risk.

KEYWORDS
aortic valve, transcatheter aortic valve replacement

1 | INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is a safe and effective therapy for patients with severe, symptomatic aortic valve stenosis.[1] As the patient population being referred for TAVR expands, waiting times for the procedure have extended[2] mostly due to the larger candidate population and meticulous pre-TAVR evaluation process including various imaging studies and heart team discussions.

Left untreated, patients with severe aortic stenosis (AS) will suffer frequent heart failure decompensations events often requiring hospitalization[3] and in extreme situations, patients will develop pulmonary edema and cardiogenic shock, unresponsive to medical treatment.[4] Expedited TAVR has emerged as a treatment option for these high-risk patients. However, the data regarding the procedural success and outcome of these intervention in extremely sick population is limited.

Thus, the purpose of this current study was to evaluate frequency as well as the short and long-term outcome of patients undergoing expedited TAVR among a real-life, large population with AS.

2 | METHODS

The study population included patients who underwent TAVR at four tertiary medical centers in Israel between January 2013 and December 2019. All subjects were referred to TAVR after careful evaluation by each institutional heart team. Baseline data regarding past medical history and medications were recorded by a blinded investigator into a computerized database. Study data were prospectively collected and managed using REDCap electronic data capture tools hosted at The Israeli Center for Cardiovascular Research[5] within the Israeli multicenter TAVR Registry. Data were retrospectively analyzed for the purpose of the present study. All subjects underwent detailed echocardiography before and after the procedure. Mortality data was ascertained by the Ministry of Internal Affairs Population Registry.

2.1 | Study groups and definitions

Subjects were divided into two groups based on TAVR procedure urgency: patients who were electively hospitalized for the procedure versus those who had an expedited TAVR procedure. Expedited TAVR procedure was defined as a procedure performed in hospitalized patients with refractory heart failure or cardiogenic shock, nonhospitalized patients with recurrent syncope, recurrent heart failure hospitalizations, critical AS or bail-out for complicated balloon valvuloplasty.

Patients with cardiogenic shock were referred to intervention if their clinical situation was worsening and the etiology for the cardiogenic shock was clearly associated with severe AS. Patients with other etiologies for the cardiogenic shock were treated medically. In borderline situations balloon aortic valvuloplasty was performed before TAVR as bridge to treatment as part of the diagnosis and evaluation of the patient. None of the patients with cardiogenic shock was referred to SAVR. Critical AS was defined as patients with aortic valve area ≤0.6 cm^2 a mean aortic valve gradient ≥60 mmHg and arotic valve V max ≥5 m/s.

The expedited TAVR group was further divided into two subgroups based on the urgency indication: In-hospital versus out-of-hospital indications for expedited TAVR. In-hospital expedited TAVR was defined as hospitalized patients with refractory heart failure, patients in cardiogenic shock, or cases of bail-out TAVR after complicated balloon aortic valvuloplasty. Out-of-hospital expedited TAVR was defined as patients seen in the clinic with recurrent syncope, recurrent heart failure hospitalizations, or critical AS who were referred to an expedited procedure. Patients who were referred to TAVR as a result of planned noncardiac surgery were classified as nonexpedited.

The regional ethical review board at each site approved the trial protocol, and the trial was conducted according to the principles of the Declaration of Helsinki. Institutional review board approval was obtained from all the participating centers and all patients provided signed informed consent to participate in the study.

History of ischemic heart disease, hypertension, diabetes mellitus, and history of stroke were extracted from patients' electronic medical history files based on known diagnoses or concurrent diabetic or blood-pressure lowering medications. Renal function was evaluated using the Modification of Diet in Renal Disease equation. Hospitalization course including use of inotropes, mechanical support, or need for intra-aortic balloon pump were documented. Peri-procedural outcomes and complications were recorded according to the Valve Academic Research Consortium-2.[6] Post procedural heart failure was defined as one or more of the following: evidence for pulmonary congestion or other heart failure signs requiring prolonged mechanical ventilation or an increase in the use of diuretics.

The primary outcomes of the current study were in hospital and 3-year mortality rates. Secondary outcomes included procedural and peri-procedural complication rates. Mortality rates were ascertained with the Israeli ministry of interior mortality database.

2.2 | Statistical analysis

Continuous data were compared with the Student *t* test and one-way analysis of variance. Categorical data were compared with the Chi-square test or the Fisher exact test.

Multivariate logistic binary regression modeling was used to evaluate the odds ratio (OR) for in-hospital mortality according to the prespecified groups. Additional covariates used in the model included age, gender, coronary artery disease, history of cerebrovascular attack or transient ischemic attack, hypertension, diabetes mellitus, and chronic kidney disease. OR are reported as absolute values and 95% confidence intervals (CIs).

The probability of 3-year mortality by the pre-specified TAVR groups was estimated and graphically displayed according to the method of Kaplan–Meier, with a comparison of cumulative events across strata by the log-rank test. Multivariable Cox proportional hazard regression modeling was used to evaluate hazard ratios for 3-year mortality. In the model that assessed the association between TAVR groups and the risk of mortality, additional covariates included age, gender, and cardiovascular risk factors (hypertension, diabetes mellitus, ischemic heart disease, prior stroke, chronic kidney disease). Similarly, the probability of 3-year mortality by the prespecified expedited TAV sub-groups was estimated and graphically displayed according to the method of Kaplan–Meier, with a comparison of cumulative events across strata by the log-rank test.

Statistical significance was accepted for a two-sided $p < 0.05$. The statistical analyses were performed with IBM SPSS version 25.0 and with SAS Enterprise Guide version 7.1.

3 | RESULTS

The complete database included a total of 3570 subjects who underwent TAVR. Patients with missing information were excluded from the current study ($N = 288$). The final study cohort comprised 3272 subjects, including patients electively hospitalized for the procedure ($N = 3140$; 95.7%) and those who had an expedited TAVR ($N = 142$; 4.3%). The mean age of the study population was 82 ± 7, of whom 51% were female.

Within the expedited TAVR group, the most common cause for an expedited procedure was refractory heart failure in a hospitalized patient (45 patients, 32%), followed by critical AS (39 patients, 28%), and recurrent hospitalizations due to heart failure (27 patients, 19%). Other causes were cardiogenic shock and recurrent syncope (both 8%) (Figure 1).

Patients in the expedited TAVR group were younger (80 vs. 82 years, $p = 0.002$), more likely to have had higher BMI (29.1 vs. 27.7; $p = 0.013$) and were at higher procedural risk as reflected by higher STS score (6.6% vs. 4.2%; $p < 0.001$) and EuroSCORE 2 (8.3% vs. 6.7%; $p < 0.001$). Furthermore, baseline echocardiography among expedited TAVR group showed a significantly lower baseline ejection fraction (44% vs. 56%; $p < 0.001$) and smaller aortic valve area (0.6 vs. 0.7 mm^2; $p < 0.001$), however, patients in both groups had comparable trans-aortic gradients (Table 1). Preprocedural computed tomography was done in 87.6% of elective TAVR patients and in 74% of expedited TAVR patients, $p < 0.001$.

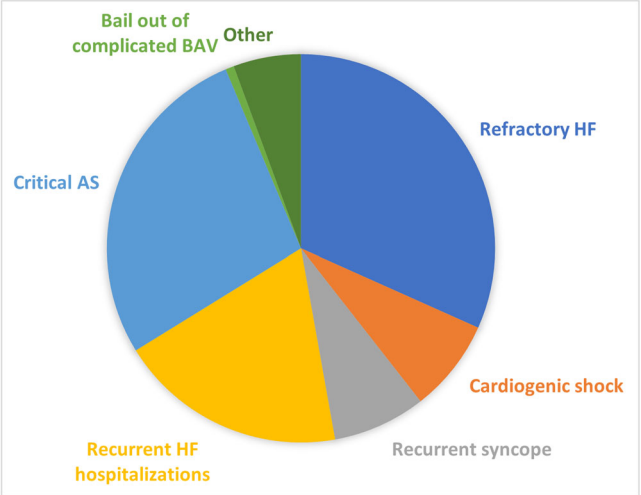

FIGURE 1 Expedited TAVR indication. The pie graph demonstrates the different indications for expedited TAVR within the study population. TAVR, transcatheter aortic valve replacement.

3.1 | Procedural and in-hospital course

Among the expedited TAVR patients, 40% (56 patients) were on inotropes before the procedure, 38% (53 patients) required mechanical ventilation support, and 33% (46 patients) required left ventricular support, which was given using an intra-aortic balloon pump in all cases.

The majority of the patients in both groups underwent TAVR procedure via a transfemoral approach (Table 1). Self-expandable valves (CoreValve, Evolut R, Evolut Pro, Boston Scientific Lotus, Boston Scientific ACURATE neo) were utilized more frequently among expedited TAVR patients (72% vs. 61%), while balloon-expandable valves (Sapien, Sapien XT, Sapien 3) were more prevalent among elective TAVR patients (38% vs. 28%, $p = 0.013$). mechanical expendable valves (Abbot Portico) were less frequently used. Operators performing expedited TAVR procedures elected to avoid balloon predilatation (balloon predilatation rates 23% vs. 35%, $p = 0.004$), however, the rates of balloon postdilatation were slightly higher among expedited TAVR patients (27% vs. 23%, $p = 0.15$) (Table 1). Device success according to VARC-2 definition tended to be lower among expedited TAVR procedures, however, this difference did not reach statistical significance. Forty-six (1.5%) of patients with nonexpedited indication to TAVR had moderate or severe paravalvular leak per angio after the procedure and 5 (3.6%) of patients with expedited TAVR indication ($p = 0.055$).

Procedural complications occurred more frequently among patients undergoing expedited TAVR including valve malposition 4.3% versus 0.7% ($p < 0.001$), valve migration 3.7% versus 0.6% ($p < 0.001$) (Table 1). Other procedural complications were numerically higher among expedited TAVR patients but did not reach statistical significance (Table 1). We also stratify patients according to valve type (eFigure S1). No major differences were found between the groups (p value nonsignificant for all).

TABLE 1 Study population and procedural data

Variable	Elective TAVR (*N* = 3140)	Urgent TAVR (*N* = 142)	*p* value
Clinical characteristics			
Age	82 ± 7	80 ± 12	0.002
Female gender	1,602 (51)	79 (56)	0.26
BMI	27.7 ± 5	29.1 ± 7	0.013
Coronary artery disease	1476 (48)	63 (45)	0.45
Prior CVA/TIA	437 (14)	20 (14)	0.98
Diabetes mellitus	1188 (39)	51 (37)	0.64
Hypertension	2608 (86)	117 (84)	0.64
Atrial fibrillation	916 (30)	40 (29)	0.70
Chronic kidney disease	1227 (39)	41 (29)	0.013
STS score	4.2 ± 3.3	6.6 ± 4.9	<0.001
Euroscore2	6.7 ± 5.7	8.3 ± 30.8	<0.001
Echocardiographic findings			
Ejection fraction	56 ± 10	44 ± 15	<0.001
Aortic peak gradient (mmHg)	73 ± 27	70 ± 31	0.27
Aortic mean gradient (mmHg)	45 ± 15	43 ± 21	0.62
Aortic valve area (cm)	0.7 ± 0.19	0.6 ± 0.19	<0.001
Systolic pulmonary artery pressure (mmHg)	39 ± 16	42 ± 20	0.09
General anesthesia	939 (25%)	35 (26%)	NS
Vascular access (Femoral artery)	3458 (93%)	128 (90%)	NS
Valve type			
Self-expandable	1776 (61%)	99 (72%)	0.013
Balloon-expandable	1102 (38%)	38 (28%)	
Mechanically-expandable	37 (1.3%)	0 (0%)	
Valve size			
23 mm	475 (15%)	20 (14%)	NS
26 mm	1145 (36%)	65 (46%)	
29 mm	1150 (37%)	41 (29%)	
34 mm	87 (2.8%)	7 (5%)	
Balloon predilatation	1090 (35%)	35 (23%)	0.004
Balloon postdilatation	714 (23%)	39 (27%)	0.15
Device success	2956 (96%)	136 (94.4%)	0.79
Procedural complications			
Need of second valve	62 (2.0)	6 (4.3%)	0.06
Conversion to open surgery	13 (0.6%)	1 (1.4%)	0.33
Unplanned use of cardiopulmonary bypass	5 (0.2%)	0 (0%)	0.70
Coronary obstruction	9 (0.4%)	1 (1.4%)	0.17
Cardiac tamponade	33 (1.1%)	3 (2.1%)	0.29
Annular rupture	8 (0.3%)	0 (0%)	0.63
Valve malposition	12 (0.6%)	3 (4.3%)	<0.001
Valve migration	19 (0.7%)	5 (3.6%)	<0.001
Procedural CPR	19 (1.0%)	3 (4.3%)	0.007
Procedural VF/VT	16 (0.7%)	0 (0%)	0.49

Abbreviations: BMI, body mass index; TAVR, transcatheter aortic valve replacement.

Postprocedure in-hospital complications were significantly more frequent among patients undergoing expedited TAVR as compared to those having an elective procedure (Figure 2). Periprocedural myocardial infarction occurred more frequently among expedited TAVR patients 3.1% versus 0.4% ($p < 0.001$), as well as stage 3 acute kidney injury 2.3% versus 0.9%, ($p = 0.002$), in-hospital heart failure (9.6% vs. 3.2%, $p = 0.001$) (Figure 2). In addition, length of stay was significantly higher among the Expedited TAVR group (8 vs. 2.5 days, $p = 0.002$). Interestingly, no significant differences in the rates of vascular complications or bleeding events were found.

Accordingly, patients with an expedited indication for TAVR had significantly higher in-hospital mortality rates compared to elective TAVR patients (6.0% vs. 1.5%, $p = 0.002$). Univariate analysis found expedited TAVR to be associated with a significant 4-folds increased risk of in-hospital mortality (OR: 4.3, 95% CI: 1.61–11.69, $p = 0.004$). Binary logistic multivariate analysis adjusted for age, gender, and cardiovascular risk factors found that patients with expedited indication had fourfolds increased risk of in-hospital mortality (OR: 4.07, 95% CI: 1.81–9.14, $p = 0.001$) (Figure 3).

3.2 | Long term outcome

Patients who underwent expedited TAVR had significantly higher 3-year mortality compared to elective TAVR patients (32.4% vs. 17.4%, $p < 0.001$). Kaplan–Meier's survival analysis showed that the cumulative probability of 3-year mortality was significantly higher among subjects undergoing expedited TAVR compared to patients undergoing an elective TAVR procedure (*p* value log-rank <0.001, Figure 4A). Cox regression multivariate analysis indicated that expedited TAVR procedure was the strongest independent predictor for 3-year mortality with nearly twofolds increased risk of mortality at 3-year (hazard ratio: 1.69, 95% CI: 1.23–2.32, $p < 0.001$) compared to those having an elective procedure (Figure 5).

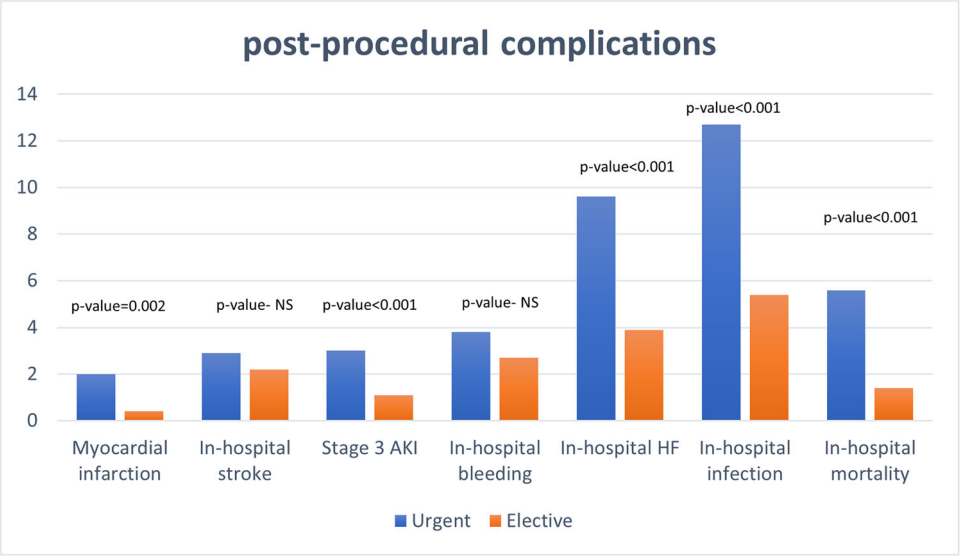

FIGURE 2 Procedural and periprocedural complication rates. Procedural and periprocedural complication rates according to the prespecified study groups

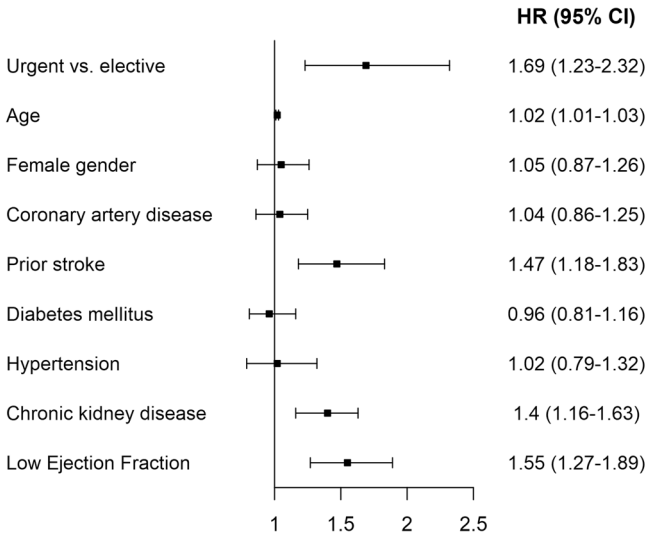

FIGURE 3 Binary logistic multivariate regression analysis for in-hospital mortality. CI, confidence interval; HR, hazard ratio.

3.3 | Sub-group analysis

Patients with expedited indication for TAVR were further divided based on indication for procedure urgency. A total of 56 patients (39%) had an in-hospital indication for expedited TAVR (hospitalized patients with refractory heart failure, cardiogenic shock, or bail-out TAVR after complicated balloon aortic valvuloplasty), while the remaining 86 patients (61%) had an out-of-hospital expedited indication for TAVR (patients seen in the clinic with recurrent syncope, recurrent heart failure hospitalizations or critical AS). Kaplan–Meier's survival analysis

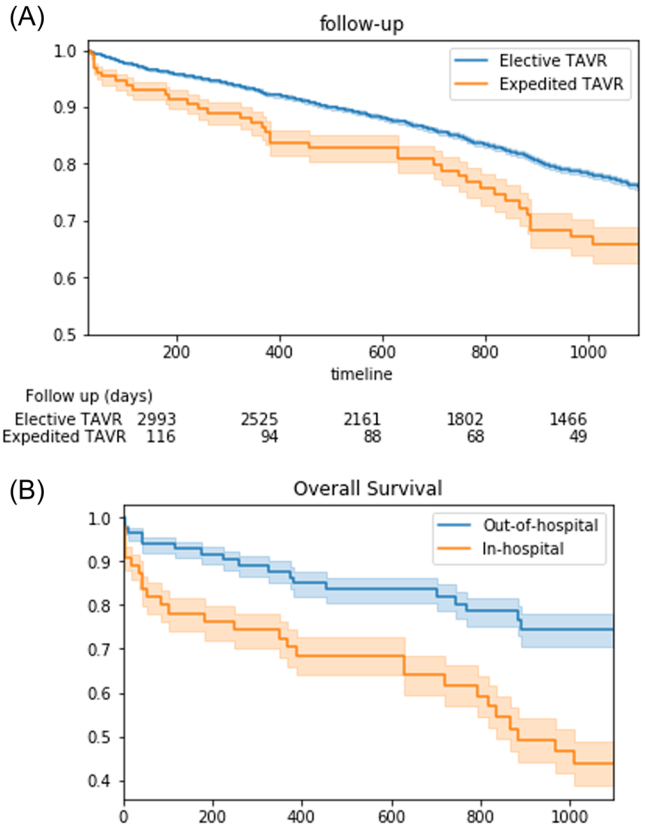

FIGURE 4 Kaplan–Meier's survival analysis for 3-year mortality. (A) Kaplan–Meier's survival analysis evaluating 3-year mortality rates according to expedited versus elective TAVR (B) Kaplan–Meier's survival analysis evaluating 3-year mortality rates according to sub-group expedited TAVR groups *p* value log-rank <0.001. TAVR, transcatheter aortic valve replacement.

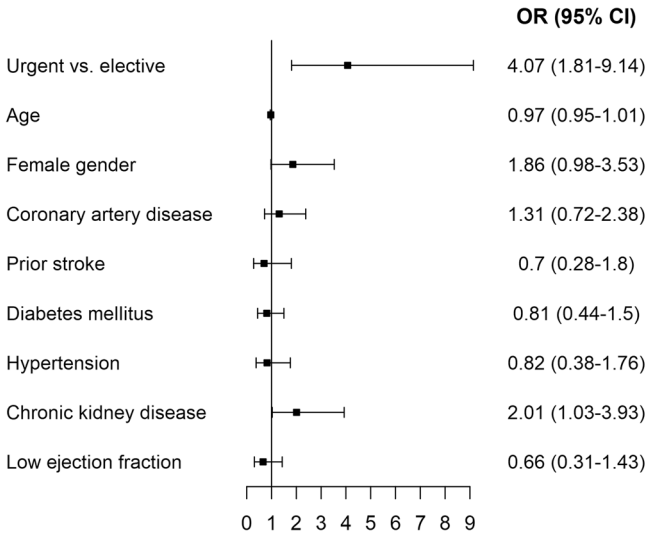

FIGURE 5 Multivariate cox regression analysis for 3-year mortality. CI, confidence interval.

showed that the cumulative probability of mortality was significantly higher among subjects with an in-hospital indication for expedited TAVR compared to patients with out-of-hospital indication to undergo TAVR (log-rank $p = 0.001$) (Figure 4B).

4 | DISCUSSION

The findings of the present study indicate that the performance of TAVR in expedited settings is associated with a significantly higher risk for procedural and in-hospital complications, as well as in-hospital mortality as compared to elective procedures. Furthermore, the early hazard observed among patients undergoing expedited TAVR remains also at long-term follow-up with higher long-term mortality rates. In these patients, expedited procedure emerges as the single most powerful predictor for short- and long-term mortality.

Furthermore, to the best of our knowledge, the present study shows for the first time, that the type of indication for the urgency of TAVR has a significant impact on outcome. Patients who undergo expedited TAVR for "in-hospital" indication such as refractory heart failure, cardiogenic shock or bail-out TAVR after complicated balloon aortic valvuloplasty have worse outcome as compared to other nonhospitalized patients who undergo TAVR.

These findings underscore the importance of timely intervention in appropriately selected patients at risk for clinical deterioration. Given the wide adoption of this successful procedure as an alternative to surgery and the increase in the number of candidates, there is a need for parallel expansion of the infrastructure on the national level, for evaluating patients toward TAVR and performing the procedure on time.

The findings in the current study should emphasize the fact that TAVR is not an entirely elective procedure, and that delaying the procedure in unstable or rapidly deteriorating patients is associated with higher early and late hazards.

Expedited TAVR is a more complex procedure especially in patients with low blood pressure, concurrent use of inotropes, and mechanical support. In addition, as part of the general critical status of the patients, renal function is compromised. Additional contrast exposure during the procedure significantly increases the risk of acute kidney injury as reflected in the numbers of the current study. Interestingly, there was a clear differentiation in terms of outcome, with regard to patients who required an expedited TAVR procedure during their hospitalization (e.g., cardiogenic shock or refractory heart failure) and those who were hospitalized for the purpose of performing an expedited procedure (e.g. recurrent hospitalizations or syncope episodes). This, in part, may be attributed to the risk associated with prolonged hospitalization before the procedure. Accordingly, early identification of this subset of patients, may promote earlier procedures and lower their early and long-term risk.

In agreement with the findings in the present study delayed access to TAVR was found to be associated with poor outcomes.[7] Even a modest increase in wait time, according to analysis performed on the PARTNER database, has a substantial effect on the effectiveness of TAVR in inoperable patients and high-risk surgical candidates. One-year mortality increases by 30% if TAVR is postponed. When TAVR wait times exceeded 60 days, mortality with TAVR exceeds surgery. On the same note, an increase in waiting time is associated with adverse outcomes while on the wait list.[2] Our study supports these findings.

The findings in the present study stand in contrast to those reported by Landes et al.[8] In a study evaluating 410 patients who underwent TAVR, 27 (6.6%) had expedited TAVR due to refractory heart failure. The researchers found that expedited TAVR was not associated with increased 30-day mortality rates. However, none of the patients' in their study required inotrope or mechanical support which might reflect a less severe population. In addition, these findings might be related to the relatively small study group.

Conversely, the main findings of the present study are in line with two, recently published datasets.[9,10] The first, an analysis from the U.S. Nationwide Inpatient Sample database[9] evaluated more than 42 K patients hospitalized for TAVR procedure between 2011 and 2014 of whom 10 K (24%) had expedited TAVR. In this analysis, expedited TAVR was associated with a higher incidence of cardiogenic shock, use of mechanical circulatory support, and acute kidney injury. However, the main limitation of this analysis is the definition of urgency which was based on the hospitalization type. This approach may include non-expedited TAVR cases as expedited and vice-versa. Indeed, a quarter of patients in this retrospective database were regarded as "expedited TAVR". Since this is an extremely high number compared to other studies, it probably reflects the "nonelective" patients rather than the "truly expedited" patients. The present study was prospectively designed to assess accurately true expedited cases and provide, real-life,

data on the outcome of patients undergoing TAVR in an expedited setting.

Another large registry is the STS/ACC TVT Registry that was utilized for assessment of the outcome of patients undergoing expedited procedure.[10] In this analysis, 10% of patients underwent expedited/emergency TAVR. The findings of this analysis are compared with the results of the present study. Patients who had expedited TAVR had significantly lower rates of procedural success, higher rates of acute kidney injury and mortality. However, the precise clinical etiology for defining the urgency of a procedure was unavailable. In view of this limitation, one of the main findings of the present study, that add to prior knowledge, indicate that not all "expedited patients" are the same in terms of procedural safety and outcome: In-hospital indication for expedited TAVR (hospitalized patients with refractory HF, cardiogenic shock or bail-out TAVR after complicated balloon aortic valvuloplasty) have a worse outcome as compared to nonhospitalized patients with severe AS.

5 | LIMITATIONS

The present study has several limitations. First, this is a retrospectively analyzed prospective registry which is a nonrandomized, nonblinded observational study, and therefore it is subjected to limitations inherent in this design. Second, despite multivariate analysis and adjustment for multiple factors, expedited TAVR patients probably represent a sicker group of patients, which might have contributed to the worse outcomes of this group. Third, we do not have information regarding the time frame that non-expedited patients waited before TAVR procedure.

6 | CONCLUSIONS AND CLINICAL IMPLICATIONS

Patients with expedited indications for TAVR are at risk for higher in-hospital complication rates and mortality as compared to elective patients. These early hazards are also translated to the poor long-term outcome for expedited TAVR patients. Hence, it is important to characterize and identify these patients before deterioration to perform TAVR in a fast-track pathway to minimize their procedural risk.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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