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Risk of Bleeding in Elderly Patients Undergoing Transcatheter Aortic Valve Implantation or Surgical Aortic Valve Replacement

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Abstract: Background: Bleeding complications are strong predictors of mortality and major morbidity in elderly patients undergoing surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI). Despite the high prevalence of frailty in this population, little is known about its effects on bleeding risk. Methods: We conducted a retrospective observational study of 502 patients undergoing isolated SAVR or TAVI between January 2015 and February 2022. The occurrence of blood products transfusions and MACEs were the primary endpoints. In-hospital mortality was the secondary endpoint. Results: The Elderly group (age < 80 years old) included 475 subjects, whereas the Very Elderly group (age $\geq$ 80 years old) included 127 patients. The need for blood product transfusion was similar among the two groups, regardless of the type of procedure. MACEs occurred similarly between groups [SAVR: Elderly group: 7.9% vs. Very Elderly group: 8.6%, p = 0.864; TAVI: Elderly group: 5.5% vs. Very Elderly group: 8.7%, p = 0.378]. The was no difference in in-hospital mortality rate in patients submitted to TAVI, whereas very elderly patients had higher mortality rate compared to the elderly patients submitted to SAVR [SAVR: Elderly group: 0% vs. Very Elderly group: 2.8%, p = 0.024; TAVI: Elderly group: 4,8% vs. Very Elderly group: 8%, p = 0.389]. Conclusions: Age alone should not be considered as a predictive factor for post-operative adverse events or in-hospital mortality in elderly patients with severe symptomatic AS.

Keywords: old; elderly; aortic valve replacement; transcatheter aortic valve implantation; aortic stenosis

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1. Introduction

Aortic valve disease, especially in those cases with a stenotic pattern, is becoming more common in Europe and North America as a result of an aging population [1]. Aortic stenosis (AS) prevalence rises exponentially with age, from 0.2% in the 50–59 age group to 1.3% in the 60–69 age group to 3.9% in the 70–79 age group to 9.8% in the 80–89 age group [2]. The increase in the elderly population and advantages in surgical technique and postoperative care have correlated with a recent rise in the number of people >80 years of age who need treatment for AS.

Transcatheter aortic valve implantation (TAVI) heralded a new era in the treatment of severe and symptomatic AS in patients with high surgical risk, particularly the elderly. Age is one of the factors that the heart considers when proposing TAVI or surgical aortic valve replacement (SAVR), according to the ESC/EACTS Guidelines for the management of valvular heart disease [3]. These recommendations introduce ambiguity into routine clinical practice and offer room for interpretation. Patients are frequently referred for transcatheter treatment simply because of their advanced age.

As a result of age-related shortcomings, frailty—a geriatric condition characterized by a reduced capacity to recover from pathological or iatrogenic factors—has been identified as a significant risk factor for death and disability after TAVI and SAVR. There is a non-negligible risk of post-procedural bleeding and transfusions for patients receiving TAVI or SAVR. Major bleeding problems (defined according the Valve Academic Research Consortium guidelines) have been proven to be consistently related to both early and late mortality, with reported incidences ranging from 15% to 20% after TAVI and from 22% to 44% following SAVR [4–7]. It is unclear whether various frailty markers can help anticipate bleeding issues in elderly individuals having these treatments.

The majority of research exploring the impact of age on survival rates and early outcomes involved within-group comparisons of patients in their 80s or comparisons with patients over 90. However, comparing the in-hospital outcomes of individuals who are elderly, or over 80, with those in a younger age range might offer additional information.

Recognizing that not all patients are necessarily high-risk simply because of their old age is important. Treatment choices should continue to be available, and current recommendations should be reviewed frequently to guarantee that patients are receiving the best possible care.

The current study aimed to examine the in-hospital outcomes of senior patients treated with SAVR or TAVI, focusing on bleeding problems, and describing any variations between the octogenarians and a younger cohort. In particular, the primary outcomes included the requirement for blood transfusions and a composite of major adverse cardiovascular events (MACEs) that included bleeding reoperation, ischemic stroke, hemorrhagic stroke, and in-hospital death. Hospital death was the secondary outcome.

2. Materials and Methods

2.1. Patients and Data Collection

Between January 2015 and February 2022, 502 patients underwent isolated biological SAVR or TAVI for severe symptomatic AS. Patients were divided into two groups according to the age: Elderly group included patients under 80 years old; Very Elderly group enrolled octogenarians (patients aged ≥80 years old).

We retrospectively reviewed the medical records for patient demographics, operative details, post-operative complications, and in-hospital mortality. Individual risk was calculated by the European System for Cardiac Operative Risk Evaluation (EuroSCORE) II. Transthoracic echocardiography was the initial screening examination used to evaluate the severity of AS. Baseline characteristics, procedural data, and clinical outcomes were collected in a dedicated database after a robust check of its completeness and quality.

The study was approved by the Institutional Review Board (Approval number: ER.ALL.2018.65A). The need for individual patient consent for the study was waived by the committee.

2.2. Inclusion and Exclusion Criteria

All patients with symptomatic AS were evaluated by a multidisciplinary heart team that determined biological SAVR or TAVI indications, and were considered for the analysis. Age ≥70 years old and the implantation of a biological aortic prosthesis were two main inclusion criteria.

According to surgeon's preference, a full median sternotomy, a mini-sternotomy, or a right thoracotomy was performed and cardiopulmonary bypass (CPB) was employed in every SAVR patient. Cardioplegia was administered after application of a cross clamp. All surgical patients received a Carpentier-Edwards PERIMOUNT Magna Ease pericardial bioprosthesis (Edwards Lifesciences, Irvine, CA, USA).

TAVI patients received balloon-expandable valves (SAPIEN, SAPIEN XT, SAPIEN 3 valves; Edwards Lifesciences, Irvine, CA, USA). TAVI access and valve size were selected using computer tomography measurements.

The anticoagulant used before to surgery was low-molecular-weight heparin. Vitamin K antagonist and non-vitamin K oral anticoagulants were halted. Antiplatelet was discontinued prior to the operation. Aspirin was the only antiplatelet that was continued in cases of recent percutaneous coronary interventions.

Patients gave written informed consent before the procedure.

2.3. Definitions and Endpoints

Valve Academic Research Consortium (VARC-3) criteria were used to define periprocedural events and mortality [4]. Specifically, in-hospital mortality was intended as a death occurring $\leq$30 days after the procedure or >30 days but during the hospitalization [4]. Ischemic stroke was defined as the acute onset of focal neurological signs or symptoms conforming to a focal or multifocal vascular territory within the brain, spinal cord, or retina and fulfilling one of the following criteria: (1) signs or symptoms lasting $\geq$24 h or until death, with pathology or neuroimaging evidence of central nervous system infarction, or absence of other apparent causes; (2) symptoms lasting <24 h, with pathology or neuroimaging confirmation of central nervous system infarction in the corresponding vascular territory [4]. Hemorrhagic stroke was registered in case of an acute onset of neurological signs or symptoms due to intracranial bleeding from intracerebral or subarachnoid hemorrhage not due to trauma [5]. Also, bleeding and re-explorations for bleeding were defined according to the VARC-3 criteria [4].

The primary endpoints were the need for blood transfusions and a composite of in-hospital mortality, ischemic stroke, hemorrhagic stroke, and re-operation for bleeding as MACEs. The secondary endpoint was in-hospital mortality.

2.4. Statistical Analysis

Continuous variables are expressed as mean and standard deviation, or median and quartiles, respectively, for normally or not normally distributed variables (as tested by Shapiro–Wilk test). Continuous variables were compared using Student t test (or U test of Wilcoxon-Mann–Whitney, as appropriate). Categorical variables are presented as count and percentage and were compared using the χ^2 test or Fisher exact test, as appropriate. Covariates for the logistic regression multivariate model of in-hospital mortality were selected from univariate logistic regression analysis if p was less than 0.1 or clinically relevant. The variables presented to the model were age, type of treatment (SAVR or TAVI), gender, body mass index, New York Heart Association functional class III or IV, smoking history, previous myocardial infarction, diabetes, liver cirrhosis, dialysis, atrial fibrillation, peripheral vascular disease, left ventricular ejection fraction (LVEF), chronic obstructive pulmonary disease, previous myocardial infarction, previous cerebrovascular disease, prior definitive pace-maker implantation, and pre-operative hemoglobin value. Significance of differences was considered at p value < 0.05. All analyses were conducted using STATA version 12.0 (IBM, Armonk, New York, NY, USA) or R version 3.4.1 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

A total of 502 patients submitted to SAVR or TAVI were enrolled in the study. The Elderly group included 375 subjects, whereas the Very Elderly group included 127 patients. The preoperative characteristics are presented in Table 1.

Table 1. Pre-operative characteristics of the overall population, the younger and the older cohorts.

Variable	Overall	Elderly (Age < 80) 375 Pts	Very Elderly (Age ≥ 80) 127 Pts	*p* Value
Age	77.0 ± 3.5	75.5 ± 0.1	81.3 ± 0.1	<0.001
Male	259 (51.59%)	195 (52.0%)	64 (50.4%)	0.754
BMI (kg/m^2)	27.8 ± 5.4	28.0 ± 5.9	27.2 ± 5.3	0.105
EF (%)	53.2 ± 20.1	52.9 ± 23.1	53.7 ± 10.4	0.369
Hemoglobin (g/dL)	12.6 ± 5.9	12.5 ± 1.8	12.3 ± 1.7	0.767
DM type 2	149 (30.2%)	112 (30.4%)	37 (29.6%)	0.861
Dyslipidemia	256 (59.5%)	196 (61.2%)	60 (54.5%)	0.216
Hypertension	379 (87.1%)	279 (86.6%)	100 (88.5%)	0.613
COPD	132 (26.3%)	92 (25%)	40 (32%)	0.127
NYHA class III or IV	300 (70.1%)	227 (70.7%)	73 (68.2%)	0.626
Smoking	124 (29.4%)	99 (31.7%)	25 (22.9%)	0.083
Liver cirrhosis	8 (1.59%)	7 (1.87%)	1 (0.79%)	0.401
Dialysis	18 (4.79%)	12 (4.2%)	6 (6.4%)	0.386
AF	228 (46.6%)	177 (48.2%)	51 (41.8%)	0.218
Peripheral vascular disease	49 (9.86%)	38 (10.2%)	11 (8.7%)	0.623
Prior MI	80 (15.9%)	64 (17.0%)	16 (12.7%)	0.247
Permanent pace-maker	49 (9.86%)	30 (8.0%)	19 (15.3%)	0.018
Cerebrovascular disease	35 (8.29%)	23 (7.3%)	12 (11.0%)	0.233
EuroSCORE II	7.7 (8.7)	7.70 (0.5)	7.51 (0.9)	0.572

Abbreviations: BMI, body mass index; EF, ejection fraction; DM, diabetes mellitus; COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association; AF, atrial fibrillation; MI, myocardial infarction.

Cardiovascular risk factors including dyslipidemia and hypertension were common. About 70% of the overall population were in New York Heart Association (NYHA) class III or IV. Table 2 describes the pre-operative characteristics according to the chosen procedure.

Table 2. Characteristics of the two population groups according to the received procedure.

Variable	Group SAVR 247 Pts		*p* Value	Group TAVI 255 Pts		*p* Value
	Age < 80 173 Pts	Age ≥ 80 74 Pts		Age < 80 202 Pts	Age ≥ 80 53 Pts	
Age	74.9 (2.8)	82.2 (1.7)	<0.001	76.0 (2.3)	80.4 (1.2)	<0.001
Male	90 (50.8%)	33 (47.1%)	0.600	105 (53%)	31 (54%)	0.857
BMI (kg/m^2)	27.1 (5.2)	26.3 (4.5)	0.144	28.6 (5.5)	28.2 (5.9)	0.299
EF (%)	53.5 ± 9.7	52.8 ± 6.8	0.595	52.5 ± 30.7	54.9 ± 13.9	0.586
Hemoglobin (g/dL)	12.9 ± 1.5	12.3 ± 1.8	0.012	12.0 ± 1.9	12.3 ± 1.5	0.329
DM type 2	31 (17.5%)	16 (22.8%)	0.335	81 (42%)	21 (38%)	0.575
Dyslipidemia	83 (46.9%)	30 (42.8%)	0.566	113 (79%)	30 (75%)	0.586
Hypertension	142 (80.2%)	59 (84.3%)	0.460	137 (94%)	41 (95%)	0.824
COPD	42 (24.3%)	20 (29.4%)	0.412	50 (25.6%)	20 (35%)	0.161
NYHA class III or IV	56 (42%)	24 (45%)	0.693	171 (90%)	49 (90%)	0.961
Smoking	40 (22.7%)	11 (15.7%)	0.221	59 (43%)	14 (36%)	0.403
Liver cirrhosis	0 (0%)	1 (1.43%)	0.111	7 (3.54%)	0 (0%)	0.150
Dialysis	3 (3.4%)	4 (11.1%)	0.09	9 (4.6%)	2 (3.5%)	0.719
AF	93 (52.8%)	33 (48.5%)	0.546	84 (44%)	18 (33%)	0.161
Peripheral vascular disease	12 (6.8%)	4 (5.8%)	0.779	26 (13.4%)	7 (12%)	0.826
Prior MI	39 (22%)	10 (14.5%)	0.183	25 (12.6%)	6 (10%)	0.669
Permanent pace-maker	12 (6.8%)	12 (17.6%)	0.011	18 (9.1%)	7 (12%)	0.457
Cerebrovascular disease	5 (2.8%)	4 (5.7%)	0.275	18 (13.2%)	8 (20%)	0.260
EuroScore II	2.3 ± 2.0	3.8 ± 3.1	<0.001	10.1 ± 9.4	10.2 ± 9.8	0.861

Abbreviations: BMI, body mass index; EF, ejection fraction; DM, diabetes mellitus; COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association; AF, atrial fibrillation; MI, myocardial infarction.

In the Elderly patients group, the chosen access for SAVR was often a full sternotomy (155/173, 89.5%), whereas for TAVI patients, it was the femoral artery (158/202, 78.2%). In the Very Elderly group, the preferred access for SAVR was full sternotomy (67/74, 90.5%), whereas the mini-sternotomy (2/74, 2.7%) or the right thoracotomy (5/74, 6.7%) were rarely performed. In the same group, TAVI was mostly performed through a femoral access (45/53, 84.9%), whereas the trans-apical approach was chosen in 15% (8/53) of the patients.

The need for red blood cells (RBCs) transfusion was similar between the elderly and the very elderly patients even if they received SAVR (X^2: 4.02, p = 0.674) or TAVI (X^2: 9.73, p = 0.204) Figure 1.

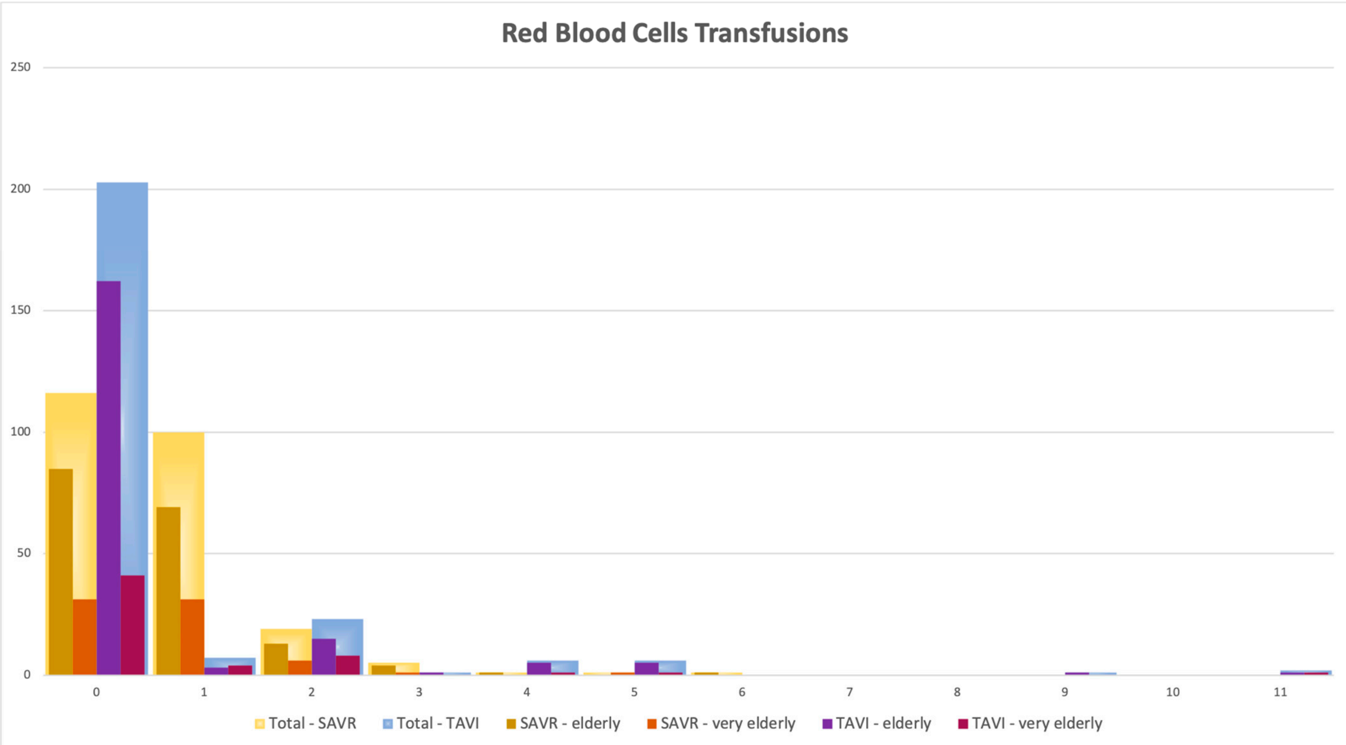

Figure 1. Red blood cell transfusions in the Elderly and Very Elderly group patients, also considering the performed procedure.

The need for fresh frozen plasma (FFP) was very low for both groups, and similar for both procedures in each group (SAVR: X^2: 6.33, p = 0.176; TAVI: X^2: 3.66, p = 0.170), Figure 2.

Platelet transfusions were rarely needed both in the SAVR and in TAVI patients, and there was no difference between the elderly and very elderly subjects (SAVR: X^2: 3.70, p = 0.054; TAVI: X^2: 3.62, p = 0.164).

Bleeding events were similar between elderly and very elderly patients either after SAVR (p = 0.268) or TAVI (p = 0.147), Table 3. Re-explorations for bleeding were needed in the SAVR patients but similarly between the patients below and over 80 years old, Table 3.

MACEs occurred similarly between groups either after SAVR (p = 0.864) or TAVI (p = 0.378).

Elderly patients submitted to SAVR had a significantly lower in-hospital mortality than the very elderly patients (0% vs. 2.8%, p = 0.024), Table 3. The was no difference in in-hospital mortality rate among patients submitted to TAVI, Table 3.

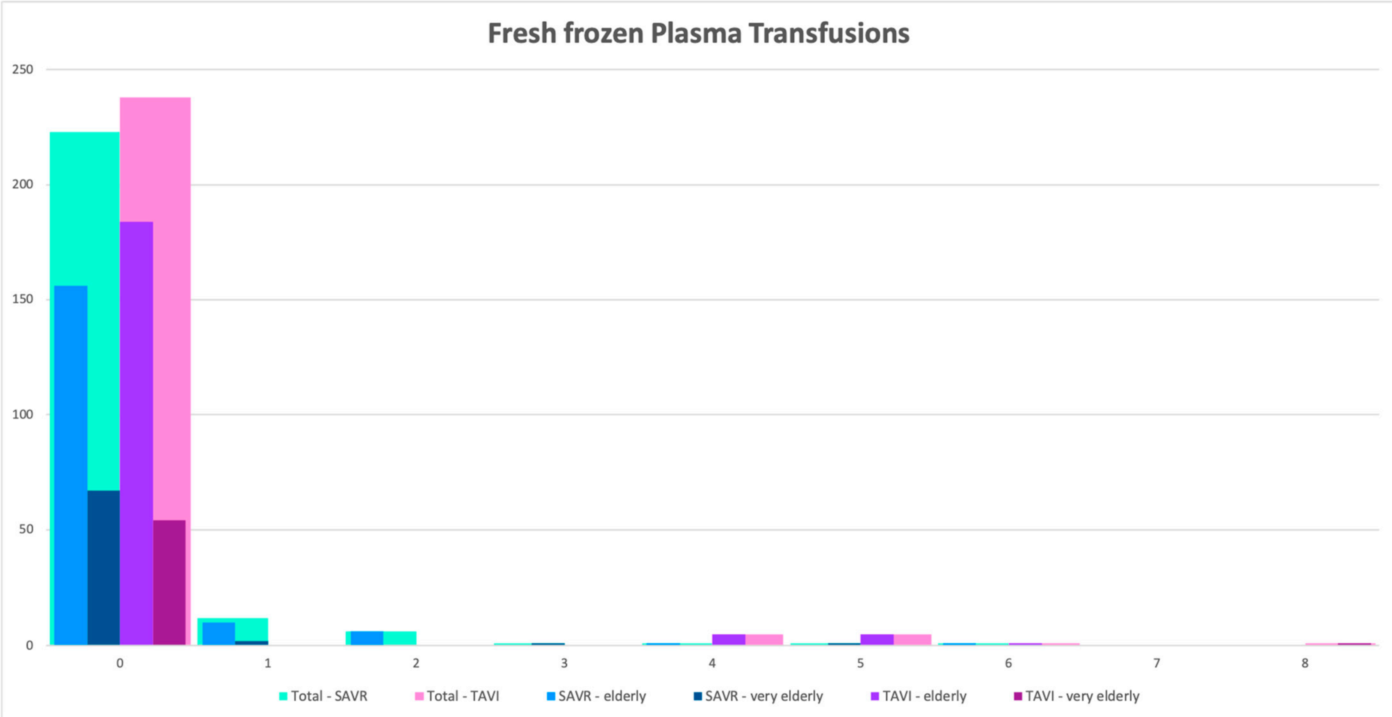

Figure 2. Fresh frozen plasma transfusions in the Elderly and Very Elderly group patients, also considering the performed procedure.

Table 3. In-hospital outcomes of the two groups population according to the received procedure.

Variable	Group SAVR 247 Pts		*p* Value	Group TAVI 255 Pts		*p* Value
	Age < 80	Age ≥ 80		Age < 80	Age ≥ 80	
Stroke	0 (0%)	1 (1.4%)	0.144	5 (2.9%)	1 (1.9%)	0.706
Bleeding	18 (10.2%)	4 (5.7%)	0.268	20 (10.8%)	10 (18.2%)	0.147
Re-operation for bleeding	13 (7.3%)	2 (2.8%)	0.183	0 (0%)	0 (0%)	-
Intracranial bleeding	1 (0.6%)	1 (1.4%)	0.495	0 (0.0%)	1 (1.8%)	0.006
Atrial fibrillation	75 (42.4%)	32 (45.7%)	0.633	9 (4.9%)	3 (5.5%)	0.860
Vascular complications	2 (1.1%)	0 (0.0%)	0.372	21 (11.4%)	8 (14.6%)	0.523
ICU stay	2.5 (2.3)	3.4 (3.2)	0.006	2.42 (3.77)	3.32 (7.60)	0.116
Hospital LOS	12.46 (13.27)	13.10 (6.49)	0.220	11.96 (9.74)	11.84 (11.26)	0.468
Re-operation for prosthesis dysfunction	0 (0%)	0 (0%)	-	0 (0%)	1 (1.8%)	0.066
Post-op endocarditis	0 (0%)	2 (2.8%)	0.024	0 (0%)	0 (0%)	-
In-hospital mortality	0 (0%)	2 (2.8%)	0.024	8 (4.8%)	4 (8%)	0.389
MACE	14 (7.9%)	6 (8.6%)	0.864	11 (5.5%)	5 (8.7%)	0.378

4. Discussion

The findings of the current study show that age "per se" had no effect on blood product transfusions, MACEs, and the in-hospital mortality rate in elderly and very elderly patients undergoing SAVR or TAVI. SAVR continues to be the preferred treatment for symptomatic severe aortic stenosis. However, because of their advanced age, concomitant conditions, and elevated surgical risk, one-third of elderly patients are not even eligible for surgery [8]. Since Cribier performed the first ground-breaking procedure in 2002, TAVI has evolved into the accepted standard of care for patients with symptomatic severe AS who are ineligible for surgery. The Placement of AoRTic TraNscathetER Valve (PARTNER) 1 study proved that TAVI is better than the medical treatment. TAVI has so been viewed as a potential alternative for high-risk individuals who are inoperable [9].

Age has historically been the main justification for denying people open heart surgery [10]. In the German Aortic Valve Registry (GARY), the most important factor influencing patients' decisions to choose TAVI or SAVR was their age (mean age: 78.9 vs. 67.5 years, respectively) [11]. An aging society and an overall increase in men's and women's life expectancy over the past ten years have led to an increase in the proportion of older patients. Age has long been considered to be the primary risk factor for many serious, life-threatening illnesses, such as cardiovascular disease, cancer, and neurodegenerative diseases. Our capacity to endure injury and stress decreases as we age, and the likelihood of illness, disability, and death rises. All of these biological events and processes are governed by time. Calendar age is a common estimate of the pace of biological aging in daily life since it is universal and easily accessible. In fact, there are multiple age-related changes at every organizational level, from the molecular to the organismal to the populational. Another crucial clinical finding is how significantly the phenotype of aged people has altered over time. These days, elderly patients not only add years to life, but also life to years. As people age, age-related changes take place at varied rates. For instance, older people of a particular chronological age have different physical and cognitive abilities. As a result, biological aging is uneven and frequently disproportional to the passage of time. However, while we cannot cheat aging, we cannot say that aging is synonymous with frailty.

This is especially true in the context of AS, where the multidisciplinary heart team will take the patient's risk profile, anatomical and functional concerns, and other aspects into account when recommending SAVR or TAVI as a therapeutic option. Several risk factors could interfere with the choice of procedure. For instance, following SAVR, chronic obstructive pulmonary disease (COPD) is linked to greater morbidity and death in patients with severe aortic stenosis. As a result, many older patients with severe aortic stenosis and concurrent COPD are scheduled TAVI, which is a lower risk procedure, rather than surgery. Dziewierz and colleagues recently reported that patients with severe aortic stenosis who receive TAVI may experience long-term results that are significantly impacted by COPD [12]. According to our findings, the TAVI group included more COPD patients than the surgical group did. Despite these results, there was no significant difference in the rate of MACEs or in-hospital mortality between SAVR and TAVI patients. We could speculate that additional variables influence these results. Moreover, other studies are in line with our results, reporting that COPD did not affect overall survival or survival from cardiac death [13,14].

Moreover, also according to the PARTNER trials, 14% of SAVR cases and 10% of TAVI cases result in severe bleeding, a potentially fatal side effect of aortic valve replacement [15]. Our analysis showed no difference between elderly and very elderly patients submitted either to SAVR or TAVI. However, the rate of bleeding events of the very elderly patients submitted to TAVI was higher compared to the elderly group, but without statistically significance. Moreover, bleeding events in TAVI patients were higher than those in the SAVR group. Our findings align with those presented by Kolar and associates in a retrospective cohort analysis that examined TAVI and SAVR in octogenarians [16]. They found that whereas 6.7% of patients submitted to SAVR and 11.0% of TAVI patients experienced serious bleeding, the difference was not statistically significant [16]. The TAVI group may have a higher incidence of bleeding issues because of the size of the delivery devices that were employed.

Similarly, we found no significative difference between the elderly and the very elderly group in both SAVR and TAVI patients. Conversely, Taghizadeh-Waghefi and colleagues found that SAVR patients $\geq$75 years old required more blood transfusions than the younger group [17]. The increased prevalence of anemia in older age groups may be one explanation for this [18]. However, the propensity-matched analysis did not support this outcome, which is consistent with our findings. On the other hand, research by Ismayl and colleagues revealed that older TAVI patients—octogenarians and nonagenarians—received more blood transfusions than younger ones [19]. Additionally, there were more bleeding episodes in the elderly groups. These results contradicted ours. The majority of TAVI patients are elderly and fragile, and they run the risk of developing ischemia and bleeding problems [20,21].

According to the literature, there is a strong correlation between significant bleeding events and blood diseases. Frequently, the existence of baseline hematological issues results in increased bleeding complications related to coagulation factors and thrombocytopenia [22]. A prior study found that after TAVR and SAVR, there is a three-fold increase in one-year mortality after major bleeding [23]. Age—or better, frailty—is one of the patient risk factors that is crucial in determining procedural major bleeding.

Current surgical risk scores, like the Society of Thoracic Surgeons (STS) score and the European System for Cardiac Operative Risk Evaluation (EuroSCORE) score, have significant limitations when it comes to supporting treatment decisions, clinical care, and outcome evaluation in older adults because they do not include risk factors like frailty [3]. These risk scores, indeed, assume age as frailty [24]. Frailty is characterized conceptually as a reduced ability to recover from iatrogenic or pathological stressors as a result of deficits associated with ageing, such as gait speed, grip strength, weight loss, cognitive impairment, exhaustion, and inactivity [24]. Moreover, quality of life (QoL) and both mental and functional state are crucial metrics for evaluating the results of therapeutic interventions tailored to each individual patient, particularly in the group of people with shorter life expectancies [25]. Objective data from both functional and cognitive assessments can help target specific diagnostic needs and direct treatment decisions [25].

Despite the encouraging outcomes of SAVR for octogenarians that have been documented in the literature, there is still a reason for worry over the fact that a significant number of old patients who would benefit from conventional surgery are turned away due to their advanced age and assumed frailty [24]. Regardless of age, up to 50% of patients with AS who are awaiting definitive intervention are frail [26,27]. Frailty—rather than age—is a significant risk factor for death and disability after TAVI and SAVR, according to the FRIALTY-AVR trial [24]. In older patients receiving TAVI and SAVR, Bendayan and colleagues demonstrated that frailty is associated with post-procedural significant bleeding, which is then associated with a higher risk for mid-term mortality [28].

The current study also shows that the in-hospital mortality rate and MACEs were comparable across octogenarians and ultra-octogenarians after TAVI. SAVR seems to be related to a higher mortality rate in the ultra-octogenarian patients. In comparison to TAVI, SAVR might have a greater physical impact and entail a lengthier recovery. In a recent propensity score matching analysis, Kolar and colleagues showed a shorter hospital stay, lower in-hospital mortality, and lower 30-day mortality in octogenarian TAVI patients vs. SAVR patients [16]. Age may not be as important in determining procedural outcome after TAVI given the unquestionable less intrusive nature of TAVI. However, our findings support the growing consensus that SAVR should not be refused based solely on an individual's age. A considerable number of old patients who would benefit from conventional surgery are turned away for treatment because of their age and perceived weakness, despite the positive outcomes of SAVR for octogenarians having been recorded in the literature [29]. In their small retrospective observational trial, Gavalaki and colleagues reported a 30-day mortality rate of 0% and a 1-year mortality of 3.6%, confirming that SAVR can be safely performed, especially in experienced high-volume centers, even in the elderly [30]. Moss and associates' brief retrospective observational study revealed positive results for the elderly population (age $\geq$ 80 years) [31]. The mortality rate (5.9%) was acceptable and consistent with data previously published in this age group undergoing SAVR or TAVI. Similarly, in a retrospective study comparing octogenarians versus younger patients receiving TAVI, the 30-day mortality rate was 9% in both groups [32]. Furthermore, according to Van den Brink and colleagues, age should not be a factor in determining eligibility for TAVI [33]. In patients under the age of 85 and patients beyond the age of 85, the 30-day and 1-year all-cause death rates following TAVI were similar (4.4% vs. 5.6% and 6.6% vs. 5.6%; p = 0.521). There were discrepant findings in other registries that assessed TAVI in the extremely elderly. Vendrik and co-workers demonstrated comparable mortality in individuals up to five years old, regardless of age [34]. On the other hand, patients who were >90 years old and >80 years old, respectively, saw an increase in in-hospital mortality, according to other papers [35,36]. In their multicenter prospective Spanish TAVI registry, Cepas-Guillén and colleagues reported their results comparing nonagenarian patients with severe aortic stenosis with patients aged 75 to 89 years old who had the same treatment [33]. The authors observed a higher in-hospital mortality rate in nonagenarian patients without significant differences at the 1-year follow-up [37]. However, the presence of comorbidities such atrial fibrillation or declining renal function—rather than age—was substantially associated with a higher all-cause mortality risk in the multivariate analysis.

These findings support the idea that, when deciding which patients to submit to SAVR or TAVI, frailty—rather than age—should be taken into account as a potential risk factor for mortality and unfavorable outcomes. The multidisciplinary heart team must consider characteristics including frailty, multimorbidity, and disability in addition to clinical and surgical risk factor classification in order to determine the expected benefit of TAVI or SAVR in the aged population.

Study Limitations

There are numerous limitations that need to be recognized. First, a large academic medical facility with a primarily Caucasian population served as the setting for our investigation. Therefore, additional analysis of the generalizability of our findings to medical facilities with different patient demographics or lower procedural volumes is warranted. Second, a small sample size hinders our ability to find a difference in discrimination for procedure-specific cohorts that might be clinically significant. Thirdly, because the study was conducted using an observational, retrospective approach, it is subject to related inherent bias. Additionally, SAVR might have been provided to patients more frequently if they were in better health, which is a potential source of selection bias. Additionally, including solely in-hospital mortality may have overestimated the safety advantage of TAVI over SAVR, since we know from numerous other research studies and clinical experience that mortality resulting from recent cardiac surgery can occur weeks to months later.

5. Conclusions

Our research demonstrates that treatment with SAVR or TAVI results in equal outcomes for elderly and very elderly patients with severe aortic stenosis. With the introduction of TAVI as a minimally invasive alternative for patients who may be at high risk, the results for this specific cohort are becoming a topic of interest. Major cardiovascular adverse events and in-hospital mortality in older patients are not significantly influenced by age. Our findings add to the growing corpus of research supporting the safety and effectiveness of either SAVR or TAVI in patient groups who may be at high risk. The “frailty” factor should take center stage rather than the “age” component. A future large multicenter study prospective study should evaluate the frail patient undergoing SAVR or TAVI.

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