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Current treatment of symptomatic aortic stenosis in elderly patients: Do risk scores really matter after 80 years of age?

Abbreviated title: Risk scores and aortic stenosis management

Tweet: In the choice between TAVR and SAVR in patients aged ≥ 75 , the weight of risk scores decreases markedly ≥ 80 years, 77% of patients being addressed for TAVR despite a low estimated surgical risk in clinical practice. Meanwhile, 10% of patients are still denied any intervention.

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Summary

Background. – According to the guidelines, surgical aortic valve replacement (SAVR) is recommended in patients at low surgical risk (EuroSCORE II < 4%), whereas for other patients, the decision between transcatheter aortic valve implantation (TAVI) and surgery should be made by the Heart Team, with TAVI being favoured in elderly patients.

Aim. – The RAC prospective multicentre survey assessed the respective contributions of age and surgical risk scores in therapeutic decision making in elderly patients with severe symptomatic aortic stenosis.

Methods. – In September and October 2016, 1049 consecutive patients aged ≥ 75 years were included in 32 centres with on-site TAVI and surgical facilities. The primary endpoint was the decision between medical management, TAVI or SAVR.

Results. – Mean age was 84 ± 5 years and 53% of patients were female. The surgical risk was classified as high (EuroSCORE II > 8%) in 18% of patients, intermediate (EuroSCORE II 4–8%) in 34% and low (EuroSCORE II $\leq 4\%$) in 48%. TAVI was preferred in 71% of patients, SAVR in 19% and medical treatment in 10%. The choice of TAVI over SAVR was associated with older age ($P < 0.0001$) and a higher EuroSCORE II ($P = 0.008$). However, the weight of EuroSCORE II in therapeutic decision making markedly decreased after the age of 80 years. Indeed, 77% of patients aged ≥ 80 years were referred for TAVI, despite a low estimated surgical risk.

Conclusions. – The impact of risk scores depends strongly on age, and decreases considerably after 80 years, most patients being referred for TAVI, independent of their estimated surgical risk. Despite medical advancements, 10% of patients were still denied any intervention.

Résumé

Context. – Un remplacement valvulaire aortique chirurgical est recommandé chez les patients à faible risque opératoire (EuroSCORE II < 4 %), et sinon le choix entre remplacement valvulaire aortique percutané (TAVI) et chirurgical, repose sur la Heart Team, le TAVI étant privilégié chez les patients âgés.

Objectif. – L'étude multicentrique prospective RAC évalue l'impact de l'âge et des scores de risque sur la décision thérapeutique proposée aux patients âgés porteurs d'un rétrécissement aortique serré symptomatique.

Méthodes. – En septembre-octobre 2016, 1049 patients consécutifs ≥ 75 ans ont été inclus par 32 centres disposant du plateau technique pour TAVI et chirurgie. Le critère de jugement principal était la décision entre traitement médical, TAVI ou chirurgie.

Résultats. – L'âge moyen était de 84 ± 5 ans avec 53 % de femmes. Le risque opératoire était élevé (EuroSCORE II > 8 %) chez 18 % des patients, intermédiaire (EuroSCORE II = 4–8 %) chez 34 % et faible (EuroSCORE II ≤ 4 %) chez 48 %. Le TAVI était privilégié chez 71 % des patients, la chirurgie chez 19 % et le traitement médical chez 10 %. Le choix du TAVI était associé à un âge plus élevé ($P < 0,0001$) et un EuroSCORE II plus haut ($P = 0,008$). Cependant, le poids de l'EuroSCORE II diminuait nettement ≥ 80 ans, 77 % des patients étant orientés vers un TAVI, malgré un risque chirurgical considéré comme faible.

Conclusions. – L'impact des scores de risque opératoire sur la décision thérapeutique dépend de l'âge et diminue considérablement ≥ 80 ans, la majorité des patients étant orientés vers un TAVI indépendamment de leur risque chirurgical. Malgré des progrès, encore 10 % des patients sont récusés d'une intervention.

KEYWORDS

Aortic stenosis;

Risk assessment;

Surgical aortic valve replacement;

Transcatheter aortic valve implantation

MOTS CLÉS

Rétrécissement aortique ;

Risque opératoire ;

Remplacement valvulaire aortique chirurgical ;

Remplacement valvulaire aortique percutané

Abbreviations: AS, aortic stenosis; ESC, European Society of Cardiology; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Background

Randomized trials first validated transcatheter aortic valve implantation (TAVI) in patients contraindicated to or at high risk from surgery, and then confirmed its efficacy in patients at lower surgical risk [1]. Surgical risk scores initially played an important role in patient selection, but the clinical judgement of the Heart Team was rapidly emphasised in guidelines [2, 3]. The use of a surgical risk score – particularly EuroSCORE II – remains useful for identifying patients at low risk from surgery [4]. Surgical aortic valve replacement (SAVR) is indeed recommended in patients at low estimated risk (EuroSCORE II \leq 4%), whereas for patients with an increased surgical risk, or with other risk factors (e.g. chest radiation), the decision between SAVR and TAVI should be made by the Heart Team, with TAVI being favoured in elderly patients (Class I recommendation) [4, 5]. Large registries have shown a decrease in estimated surgical risk over the past few years, whereas the mean patient age has remained unchanged [6]. Given the importance of age and surgical risk scores in decision making, we aimed to analyse the respective significance of these variables in the therapeutic choice in elderly patients.

The RAC survey was specifically designed: (1) to assess prospectively the indications for TAVI, SAVR and medical therapy in elderly patients referred for severe symptomatic aortic stenosis (AS); and (2) to analyse the respective contribution of surgical risk scores and age in decision making between the three therapeutic options.

Methods

Population

The RAC study was a national multicentre prospective survey that included consecutive patients aged \geq 75 years who were hospitalized for severe symptomatic AS in 32 French centres with on-site TAVI and SAVR facilities [6]. Patients were included between 01 September and 31 October 2016 if they had severe AS according to current guidelines [2, 4], associated with New York Heart Association class II–IV dyspnoea, angina or syncope.

The choice of the type of prosthesis for TAVI and SAVR was left at the discretion of investigators, as was the approach route for TAVI. The complete list of investigators can be found in the [Appendix](#).

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki, as reflected in approval by the ethics committee of the French Society of Cardiology and by the National

Commission for Data Protection and Liberties. All patients provided written informed consent. The trial is registered at <https://www.clinicaltrials.gov> (identifier: NCT03343314).

Primary endpoint

The primary endpoint was the Heart Team's therapeutic decision between TAVI, SAVR and medical management (including balloon aortic valvuloplasty).

Patient characteristics and risk scores

Baseline patient characteristics were collected for the 1049 patients with a therapeutic decision. We detailed comorbidities not included in the usual surgical risk scores: history of radiotherapy, cirrhosis, active neoplasia and the presence of coronary artery disease.

Multivariable surgical risk scores were analysed as recommended in the guidelines [2-5]. EuroSCORE II was preferred because its calibration is better than that of the logistic EuroSCORE [4, 7]. Patients with missing data that precluded calculation of the EuroSCORE were excluded. Risk scores were thus calculated for 956 patients.

Emergency intervention was defined as required within 24 hours, and patients were dichotomized between emergency or non-emergency procedures, as published previously [8]. The population was divided into low, intermediate and high risk using validated cut-offs (EuroSCORE II \leq 4%, 4–8% and $>$ 8%, respectively) [2, 3].

Data management

Data were recorded on a standardized electronic case report form and sent to a central secure database hosted by the French Society of Cardiology.

Statistical analysis

Continuous variables are expressed as mean and standard deviation, and categorical variables as number and percentage. Statistical differences between the three treatment groups were assessed by the Kruskal-Wallis test for continuous variables, and the χ^2 test for categorical variables. Graphical renditions of cumulative risk were used to represent the cumulative probability of each type of

treatment depending on the patients' risk scores, overall and for different age groups (75–79, 80–84 and ≥ 85 years).

Multivariable multinomial logistic models were used to assess the association between the therapeutic decision and patient characteristics, taking into account all characteristics described previously and the treating centre.

An interaction variable between age and EuroSCORE II was introduced in a second set of models. In these models, for interpretation purposes, age was divided into three groups: ≤ 79 , 80–84 and ≥ 85 years. The 956 patients with no missing data for the explanatory variables were included in the modelling.

All analyses were performed using SAS® software, version 9.4 (SAS Institute, Cary, NC, USA).

Results

Population characteristics

In the RAC survey, 1101 consecutive patients with severe symptomatic AS were screened in 32 centres; 1049 had a non-pending therapeutic decision and form the basis of the study (Fig. 1). The characteristics of these patients are detailed in Table 1, for the whole population and the three therapeutic option groups (SAVR, TAVI and medical treatment). Patients were on average 84 years of age, and 47% were men. Patients in the SAVR group were younger than in the other therapeutic option groups. Left ventricular ejection fraction was preserved in 86% of patients treated by SAVR, but in only 77% and 60% in the TAVI and medical treatment groups, respectively ($P < 0.0001$). Consistently, systolic pulmonary artery pressure was lower in the SAVR group compared with the other groups.

Risk scores

The EuroSCORE was calculated for each of the 956 patients with no missing data, and the results are presented in Table 2. The Logistic EuroSCORE and EuroSCORE II were on average 18% and 6%, respectively, reflecting the advanced age of the population and the inherent burden of comorbidities. The scores increased significantly from the SAVR group to the medical treatment group, with the TAVI group in between.

According to EuroSCORE II, 18% of the total population was considered to be at high risk (estimated in-hospital mortality > 8%), whereas 48% was at low risk (estimated mortality ≤ 4%). Regarding the three treatment groups, low-risk patients represented 80% of patients in the SAVR group, 43% in the TAVI group and 27% in the medical treatment group ($P < 0.0001$) (Fig. 2A and Table 2).

Therapeutic decision

The therapeutic decision was TAVI in 748 patients (71%), SAVR in 199 (19%) and medical treatment in 102 (10%), including balloon aortic valvuloplasty in 23 (Table 1). Of the 102 patients who were denied TAVI and SAVR, the reasons cited by the responsible practitioner were functional impairment in 31 (30%), age in 29 (28%), cognitive impairment in 22 (22%), comorbidities in 19 (19%), patient refusal in 16 (16%), contraindication to TAVI (anatomical issues and life expectancy < 1 year) in 14 (14%) and other reasons in 22 (22%). In the medical treatment group, 15% of patients were aged > 80 years and 24% were at low estimated surgical risk, but only four patients combined these conditions. Moreover, seven patients had a history of chest radiation, one had cirrhosis and six had a history of cardiac surgery. Hence, TAVI could have been offered preferentially to these patients; however, seven patients refused intervention and four had a contraindication to the TAVI procedure. The 23 patients who underwent balloon aortic valvuloplasty differed significantly from those who received medical treatment only: they were more often male, and had a more severely impaired left ventricular ejection fraction and a higher EuroSCORE II (Table A.1).

The distribution of therapeutic decision across the patient age groups is illustrated in Fig. 2B for the whole cohort and in Fig. 2C for patients at low estimated surgical risk.

Patient characteristics associated with the therapeutic decision

There were significant differences in age and risk scores between the three treatment groups: patients treated with SAVR were younger and had lower risk scores. Indeed, compared with the SAVR group, the logistic EuroSCORE and EuroSCORE II both doubled in the TAVI group and then increased again by 30–50% in patients receiving medical treatment (Table 2).

The probability of being treated with SAVR varied greatly with age (Fig. 3A). Indeed, a patient aged < 80 years was likely to be treated with SAVR (> 50%), particularly if they were in the low-risk or

intermediate-risk category. On the other hand, a patient aged ≥ 85 years had a probability of $< 5\%$ of having SAVR, regardless of risk scores. As for TAVI treatment, with increasing age, patients were more likely to be treated with TAVI, and this probability increased progressively with risk score (Fig. 3B). Regarding the medical treatment group, both elevated age and risk score accounted for the increased probability of being contraindicated for invasive therapeutic options (Fig. 3C). The increase in the probability of medical treatment with risk score was particularly marked in patients aged ≥ 85 years.

The multinomial regression models were performed using EuroSCORE II, as recommended in the European Society of Cardiology (ESC) guidelines (3,4).

TAVI versus surgery

Of the 691 patients treated with TAVI, 296 (43%) were at low surgical risk according to risk scores. Among those patients, six had cirrhosis, 20 had a history of radiation and 22 had cancer; these comorbidities are not considered in the EuroSCORE. However, 242 patients (82%) did not have any of these comorbidities to explain the choice of TAVI. We found that age, EuroSCORE II risk category, history of radiotherapy and history of cirrhosis were significantly associated with the decision to treat a patient with TAVI rather than SAVR (Table 3). In particular, patients at intermediate and high surgical risk were, respectively, 3 and 11 times more likely to be treated with TAVI.

In the model with an interaction between age and EuroSCORE II, we found that the probability of being treated with TAVI rather than SAVR increased particularly with surgical risk in patients aged < 80 years (Table A.2). The impact of surgical risk score on decision making decreased markedly over the age of 80 years and was no longer significant in patients aged ≥ 85 years, with as many as 90% of patients being treated by TAVI despite a low estimated surgical risk.

Medical treatment versus TAVI

Practitioners reported advanced age as an argument for medical treatment in 28% of patients, but age was no longer significant in the multivariable analysis. Only high surgical risk was significantly associated with the likelihood of medical treatment over TAVI, with a 4-fold increase (Table 3). The importance of high surgical risk over age was further confirmed in the model with interaction (Table A.2).

Multivariable models considered an overall centre effect of the models ($P = 0.006$ in the model with interaction, and $P = 0.02$ in the model without interaction).

Discussion

In this survey, elderly patients with severe symptomatic AS were considered for TAVI or SAVR in 90% of cases, whereas 10% received medical treatment. About two-thirds of patients in the medical treatment group were considered at low or intermediate risk, and the main reasons to deny an interventional treatment were reduced autonomy, comorbidities and advanced age. The choice of TAVI over SAVR was associated with older age and higher EuroSCORE II, but the weight of risk assessment decreased markedly after the age of 80 years. Indeed, as many as 77% of patients aged ≥ 80 years were offered TAVI while at low estimated surgical risk.

Evolution of indications for TAVI over time

TAVI was first developed to treat patients at high risk from surgery, and surgical risk scores then played an important role in patient selection. Growing evidence showed the limitations of the predictive performance of these scores, in particular calibration drift [9-11]. Nevertheless, risk scores are still taken into account in recent guidelines, which provide thresholds contributing to the choice between SAVR and TAVI [4, 5]. SAVR is indicated in low-risk patients, whereas a multifactorial approach by the Heart Team is preferred in patients with increased estimated surgical risk or comorbidities not considered in the EuroSCORE (chest radiation therapy, cancer, etc.) [4, 5]. In this survey, the most frequent therapeutic decision was TAVI in 71% of patients, although high-risk patients represented only 18% of the population. Current practices thus anticipated the extension of indications for TAVI to intermediate-risk patients, which was then confirmed in the 2017 guidelines [4, 5]. Indeed, intermediate-risk patients represented 38% of the present population treated by TAVI. Moreover, as many as 43% of patients in whom there was a decision to perform TAVI were at low estimated surgical risk. Among those patients, only 16% had a comorbidity that might explain the choice of TAVI, whereas the others should, in theory, have been orientated to surgery.

The choice of TAVI over SAVR in low-risk patients

In the RAC survey, TAVI was the therapeutic choice in 64% of low-risk patients, although only one randomized trial supported this strategy at that time [12]. Moreover, patients aged ≥ 80 years were most often considered for TAVI, regardless of their surgical risk. In the very elderly, guidelines are therefore poorly followed regarding referral for surgery, and age outweighs the estimated surgical risk when decision making in clinical practice.

This current trend towards an extension of indications for TAVI to low-risk patients, in particular in patients aged ≥ 80 years, is consistent with recent reports, despite no corresponding recommendation in guidelines [13-15]; it highlights the need for country-specific and updated cost analyses to assess the impact on healthcare expenses. This is of particular importance because of the expected increase in the number of elderly patients with AS in the coming decades. Several factors may account for this choice. Non-inferiority of TAVI versus SAVR regarding morbimortality may be an incentive to favour TAVI in elderly patients. Indeed, cardiac surgery is usually associated with a prolonged length of stay compared with TAVI [16-18]. This is paramount in elderly patients, who are less likely to be discharged home, and are more likely to require rehabilitation and/or institutionalization after a long hospital stay. TAVI, compared with SAVR, also reduces the risk of atrial fibrillation, acute kidney injury and bleeding, with high-certainty evidence [19]. A recent review on patients' preferences regarding TAVI or SAVR further confirmed these data, with most participants choosing minimally invasive procedures, with a shorter hospital stay and recovery period [20]. In addition, the potential concerns about TAVI, such as the consequences of pacemaker implantation and uncertainties regarding long-term valve durability, have a lower impact in patients with shorter life expectancy, although no negative signal appeared with TAVI prostheses [21]. Choosing TAVI over SAVR in patients aged ≥ 80 years, regardless of their risk scores, could therefore be discussed.

Severe symptomatic AS and medical treatment

In the RAC survey, an intervention was denied in 10% of patients. Single-centre series in early experience with TAVI reported higher rates of 16–26% [22, 23]. The development of TAVI has led to a decrease in the percentage of patients who are denied intervention, compared with when SAVR was the only treatment [24, 25]. In the present study, patients treated medically exhibited significantly higher risk scores than others, which contrasts with older series, in which patients allocated to TAVI or medical treatment exhibited similar baseline characteristics [26]. The main reason for conservative

treatment during that period was the refusal to undergo intervention by almost half of the patients, whereas only 16% of patients refused any intervention in our study [26]. These results suggest better selection of patients referred for severe symptomatic AS over time.

However, in 28% of cases, the reason cited by practitioners for not considering any intervention was the advanced age of the patient. Considering remaining life expectancy, one may wonder whether this is an effective strategy, regarding medical and economic facts (rehospitalization because of untreated AS) [27]. The benefit/risk ratio must be weighed carefully in elderly patients, given their burden of comorbidities, with frequent multifactorial dyspnoea and increased risks of procedural complications. Personalized evaluation of this particular population is of utmost importance, to better select patients who could really benefit from TAVI, and to avoid futile interventions. On the other hand, patients treated conservatively exhibit a poor outcome, and TAVI is known to lower mortality, improve quality of life and limit iterative hospitalizations, including in elderly patients [28].

Study limitations

Frailty was not assessed in the present analysis, although it contributes to the therapeutic choice, particularly in elderly patients. Frailty is indeed common in older adults and was associated with both major bleeding after aortic valve replacement and higher mid-term mortality in a recent series, thus confirming its prognostic impact [29]. However, the prevalence of frailty substantially differs according to the scale used, and its contribution is therefore difficult to evaluate in the absence of a standardized assessment [30]. Only patients from centres with both on-site TAVI and SAVR were included, which may constitute a referral bias, but avoided a potential treatment allocation bias. The analyses were performed with EuroSCORE II, using the thresholds for low and high risk provided in the ESC guidelines [4]. Although EuroSCORE II was not specifically designed for very elderly patients, its predictive performance remains correct in octogenarians [10]. We chose not to use the STS PROM score in this prospective survey, as its many variables make it rather tedious in clinical practice, and they are not collected as standard of care in our country.

Conclusions

In patients aged ≥ 75 years presenting with severe symptomatic AS, the therapeutic decision was TAVI in $> 70\%$ of cases. Age played a major role in the choice between TAVI and SAVR, and

superseded the surgical risk assessment after the age of 80 years. Given the many advantages of TAVI in elderly patients, we endorse the current practice of choosing TAVI over SAVR after the age of 80 years, regardless of risk scores. Medical treatment was still decided upon in 10% of patients, with more than one out of four practitioners citing advanced age for this decision, which may be debatable.

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Declaration of interest

B. I. Modest fees from the companies **Edwards Lifesciences, Boehringer Ingelheim** and **Novartis**.

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The other authors declare that they have no conflict of interest concerning this article.

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Figure legends

Figure 1. Flowchart of the RAC survey.

Figure 2. A. Histogram of the distribution of risk categories according to the allocated treatment. B. Histogram of the distribution of allocated treatment according to age categories in the whole cohort. C. Histogram of the distribution of allocated treatment according to age categories in the subgroup of patients at low surgical risk. SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

Figure 3. Probability of treatment decision based on age and EuroSCORE II. A. The probability of being treated with surgical aortic valve replacement (SAVR) varied greatly with age and to a lesser extent with risk score. B. The probability of being treated with transcatheter aortic valve implantation (TAVI) increased with age and risk score, the importance of risk score varying with age category. C. The probability of being treated medically increased with both age and risk score.

Table 1 Baseline characteristics of the 1049 patients.

| | Total | SAVR | TAVI | Medical treatment | <i>P</i> |
|---|--------------------|-------------------|-------------------|----------------------|----------|
| | (<i>n</i> = 1049) | (<i>n</i> = 199) | (<i>n</i> = 748) | (<i>n</i> = 102) | |
| Age (years) | 83.6 ± 4.9 | 79.2 ± 3.1 | 84.5 ± 4.5 | 85.8 ± 5.5 | < 0.0001 |
| Male sex | 489 (46.6) | 107 (53.8) | 343 (45.9) | 39 (38.2) | 0.03 |
| Body mass index (kg/m ²) ^a | 26.6 ± 5.1 | 27.3 ± 4.5 | 26.6 ± 5.2 | 25.8 ± 5.8 | 0.004 |
| COPD | 115 (11.0) | 14 (7.0) | 86 (11.5) | 15 (14.7) | 0.09 |
| Lower limb arteritis | 199 (19.0) | 19 (9.6) | 162 (21.7) | 18 (17.7) | 0.0005 |
| Poor mobility | 35 (3.3) | 3 (1.5) | 26 (3.5) | 6 (5.9) | 0.12 |
| Previous cardiac surgery | 129 (12.3) | 13 (6.5) | 110 (14.7) | 6 (5.9) | 0.0009 |
| Creatinine clearance ^b (mL/min/1.73 m ²) | 50.5 ± 21.7 | 62.9 ± 18.5 | 48.5 ± 21.7 | 42.1 ± 18.3 | < 0.0001 |
| Dialysis | 16 (1.5) | 0 | 13 (1.7) | 3 (2.9) | 0.27 |
| Diabetes mellitus | 290 (27.7) | 54 (27.1) | 208 (27.8) | 28 (27.4) | 0.42 |
| Insulin-requiring diabetes | 100 (9.5) | 10 (5.0) | 80 (10.7) | 10 (9.8) | 0.05 |
| LVEF ^c (%) | | | | | < 0.0001 |
| ≤ 30 | 46 (4.5) | 3 (1.5) | 30 (4.1) | 13 (13.4) | |
| 31–50 | 188 (18.2) | 24 (12.3) | 138 (18.7) | 26 (26.8) | |
| > 50 | 797 (77.3) | 168 (86.2) | 571 (77.3) | 58 (59.8) | |
| sPAP (mmHg) | | | | | < 0.0001 |
| ≤ 30 | 459 (43.8) | 114 (57.3) | 313 (41.8) | 32 (3.1) | |
| 31–55 | 450 (42.9) | 77 (38.7) | 324 (43.3) | 49 (48.0) | |
| > 55 | 140 (13.3) | 8 (4.0) | 111 (14.8) | 21 (20.6) | |
| Aortic valve area ^d (cm ²) | 0.71 ± 0.19 | 0.74 ± 0.21 | 0.71 ± 0.18 | 0.67 ± 0.19 | 0.03 |
| Mean aortic gradient ^e (mmHg) | 48.4 ± 14.7 | 50.6 ± 13.4 | 48.3 ± 14.6 | 44.7 ± 16.9 | 0.005 |
| CCS angina class 4 | 53 (5.1) | 11 (5.7) | 37 (5.0) | 5 (5.0) | 0.93 |
| Critical state | 28 (2.7) | 2 (1.0) | 15 (2.0) | 11 (10.1) | < 0.0001 |
| Emergency procedure | 13 (1.2) | 3 (1.5) | 6 (0.8) | 4 (3.9) ^f | 0.03 |
| History of radiotherapy | 49 (4.7) | 6 (3.0) | 36 (4.8) | 7 (6.9) | 0.31 |

| | | | | | |
|-----------------------|------------|----------|------------|-----------|-------|
| Cirrhosis | 15 (1.4) | 1 (0.5) | 13 (1.7) | 1 (1.0) | NA |
| Neoplasia | | | | | 0.002 |
| Previous | 136 (13) | 19 (9.5) | 103 (13.8) | 14 (13.7) | |
| Active | 27 (2.6) | 5 (2.5) | 18 (2.4) | 4 (3.9) | |
| History of CAD | | | | | 0.002 |
| Myocardial infarction | 119 (11.3) | 12 (6.0) | 86 (11.5) | 21 (20.6) | |
| Stable angina | 132 (12.6) | 17 (8.5) | 107 (14.3) | 8 (7.8) | |

Data are expressed as mean \pm standard deviation or number (%). CAD: coronary artery disease; CCS:

Canadian Cardiovascular Society; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; NA: not available; SAVR: surgical aortic valve replacement; sPAP: systolic pulmonary artery pressure; TAVI: transcatheter aortic valve implantation.

^a Patients for whom data were available: total ($n = 1001$); SAVR ($n = 184$); TAVI ($n = 721$); medical treatment ($n = 96$).

^b Patients for whom data were available: total ($n = 975$); SAVR ($n = 180$); TAVI ($n = 700$); medical treatment ($n = 95$).

^c Patients for whom data were available: total ($n = 1031$); SAVR ($n = 195$); TAVI ($n = 739$); medical treatment ($n = 97$).

^d Patients for whom data were available: total ($n = 941$); SAVR ($n = 169$); TAVI ($n = 681$); medical treatment ($n = 91$).

^e Patients for whom data were available: total ($n = 1001$); SAVR ($n = 188$); TAVI ($n = 717$); medical treatment ($n = 96$).

^f Four emergency balloon aortic valvuloplasties.

Table 2 Risk scores of the 956 patients.

| | Total | SAVR | TAVI | Medical treatment | <i>P</i> |
|------------------------|-------------------|-------------------|-------------------|----------------------|----------|
| | (<i>n</i> = 956) | (<i>n</i> = 176) | (<i>n</i> = 691) | (<i>n</i> = 89) | |
| Logistic EuroSCORE (%) | 18.0 ± 13.0 | 9.3 ± 5.3 | 19.3 ± 12.5 | 25.0 ± 18.4 | < 0.0001 |
| EuroSCORE II (%) | 5.9 ± 6.1 | 3.0 ± 2.3 | 6.2 ± 5.9 | 9.2 ± 9.5 | < 0.0001 |
| EuroSCORE II | | | | | < 0.0001 |
| High risk | 175 (18.3) | 9 (5.1) | 135 (19.5) | 31 (34.8) | |
| Intermediate risk | 321 (33.6) | 27 (15.3) | 260 (37.6) | 34 (38.2) | |
| Low risk | 460 (48.1) | 140 (79.6) | 296 (42.8) | 24 (27.0) | |

Data are expressed as mean ± standard deviation or number (%). SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

Table 3 Multivariable multinomial logistic regression model of patient characteristics associated with the therapeutic decision.

| | Odds ratio (95% CI) | |
|--|---------------------|---------------------------------|
| | TAVI (versus SAVR) | Medical treatment (versus TAVI) |
| Age (per 1-year increase) | 1.45 (1.36–1.55) | 1.05 (0.99–1.11) |
| Sex (ref: men) | 0.92 (0.57–1.47) | 1.15 (0.68–1.93) |
| Body mass index (per 1 kg/m ² increase) | 1.04 (0.99–1.09) | 0.98 (0.93–1.03) |
| EuroSCORE II | | |
| Low risk | Ref | Ref |
| Intermediate risk | 3.03 (1.71–5.37) | 1.80 (0.96–3.39) |
| High risk | 11.14 (4.43–28.00) | 3.72 (1.91–7.26) |
| History of radiotherapy (ref: no) | 5.62 (1.87–16.94) | 1.01 (0.34–3.02) |
| Cirrhosis (ref: no) | 11.01 (1.18–102.52) | 0.85 (0.10–7.37) |
| Active neoplasia (ref: no) | 0.88 (0.21–3.66) | 2.12 (0.59–7.64) |

CI: confidence interval; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

1,101 patients
screened

52 patients excluded (4.7%)
for pending therapeutic decision

1,049 patients
included in the study

93 patients (8.9%) with missing
data for risk score calculation

956 patients
for risk score analysis





