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PII: S2589-790X(22)00204-9

DOI: https://doi.org/10.1016/j.cjco.2022.10.003

Reference: CJCO 587

To appear in: *CJC Open*

Received Date: 24 June 2022

Revised Date: 20 September 2022

Accepted Date: 7 October 2022

Outcomes in Patients Undergoing Surgical Aortic Valve Replacement With and Without a Pre-Operative Heart Team Assessment

Short Title: Role of Heart Team Assessment in SAVR Patients

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Disclosure Statement:

We have no conflicts of interest to disclose.

Funding Statement:

We have no funding sources to disclose.

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Word count: 4815

Key Words: Heart Team, Aortic stenosis, surgical aortic valve replacement

Glossary of Abbreviations

HT: heart team

TAVR: transcatheter aortic valve replacement

SAVR: surgical aortic valve replacement

CABG: coronary artery bypass graft

AVA: aortic valve area

CAD: coronary artery disease

LVEF: Left ventricular ejection fraction

NYHA: New York Heart Association

PPM: Permanent pacemaker

SAVR: surgical aortic valve replacement

STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality

MDT: Multi-disciplinary team

Summary

In patients undergoing surgical AVR, referral to the Heart Team is primarily driven by chronological age rather than overall surgical risk profile. Patients considered for TAVR, and therefore receive a Heart Team assessment, but ultimately undergo SAVR, have a low complication rate. A more integrated approach to aortic stenosis should be considered.

Central Message:

Referral to the Heart Team is primarily driven by age, despite these patients having comparable overall surgical risk profile to those directly referred to surgery.

Perspective statement:

Patients undergoing surgical AVR are often comorbid. Our study demonstrates that patients referred directly to cardiac surgery have similar outcomes compared to those assessed by the Heart Team prior to undergoing surgical aortic valve replacement. However, current referral patterns are based on limited information, therefore resulting in an incomplete risk assessment, and potentially restricting the number of patients being seen by the Heart Team. Having a single designated referral centre for valvular disease would therefore allow all AS patients to undergo a more thorough work-up and screening, such that they can then be referred directly to surgical or transcatheter valve replacement, based on the results.

Abbreviated Legend for Central Picture:

Kaplan-Meier curves comparing the 1-year incidence of mortality across patient groups.

Abstract

Background: This study sought to compare characteristics and outcomes of patients that underwent SAVR after being referred to a Heart Team (HT), to those referred directly for SAVR.

Methods: An analysis of patients that underwent SAVR from 2015 to 2020 was conducted. Patients were categorized into 3 groups (i) H-HT: patients referred to the HT from 2015 to 2017 (historical cohort), (ii) C-HT: patients referred to the HT from 2018 to 2020 (contemporary cohort), and (iii) No-HT: patients referred directly to cardiac surgery from 2018 to 2020. Two sub-analyses were performed: H-HT versus C-HT patients, and C-HT versus No-HT patients. The primary outcome was a composite of in-hospital mortality, prolonged intubation, re-operation, sternal wound infection, and stroke.

Results: This study consisted of 288 patients, distributed as follows: H-HT (n=45), C-HT (n=51), and No-HT (n= 192). The mean age of H-HT, C-HT, and No-HT patients was 76.3±6.9, 73.3±7.6, and 69.6±9.7 years, respectively (p=0.0001). H-HT, C-HT and No-HT patients had an average STS score of 4.8±2.2, 3.2±1.6, and 4.2±2 (p= 0.002), respectively. The composite outcome rate was more than 5 times higher in the H-HT group compared to the C-HT group (20.0 vs 3.9%, p= 0.02), and numerically higher in group No-HT compared to C-HT (13.0 vs 3.9%, p=0.07).

Conclusions: Referral to the HT appears to be primarily driven by higher chronological age rather than overall risk profile. Patients assessed by the Heart Team prior to undergoing SAVR

have a low incidence of complications, comparable to patients referred directly to cardiac surgery.

Word Count: 250

Introduction

The emergence of transcatheter aortic valve replacement (TAVR) has broadened patient eligibility for valve replacement. Over the past decade, the implementation of TAVR into clinical practice has resulted in an overall decrease in mortality for patients undergoing either TAVR or surgical AVR (SAVR) [1,2].

The considerations used to assess whether TAVR or SAVR should be pursued include procedure feasibility from an anatomical perspective (bicuspid aortic valve, size of the aortic root, diameter of the aortic annulus, mediastinal anatomy, etc.), as well as patient-specific variables, such as frailty, comorbidities and age [3,4]. Specifically, for patients between 65 and 80 years, both procedures should be considered. Current American guidelines emphasize patient symptoms (or lack thereof), echocardiographic parameters, and the degree of aortic valve calcification in addition to the aforementioned variables, for defining and the severity of aortic stenosis (AS), and therefore, determining the most optimal and patient-specific course of treatment [5].

These recommendations will undoubtably lead to a significant increase in Heart Team (HT) referrals. But not all patients will be deemed eligible for TAVR, and a sizeable proportion will undergo SAVR. The clinical characteristics of these latter patients are currently unknown. Their outcomes, as compared to patients referred directly for SAVR, also have not been studied.

We sought to compare characteristics and outcomes of patients undergoing SAVR after being referred directly, without HT assessment, to those undergoing SAVR after being assessed by a HT. The temporal trends of patient characteristics were also considered.

Methods

Study Design

An analysis of adults undergoing surgical aortic valve replacement (SAVR) for severe aortic stenosis at the McGill University Health Centre (MUHC) from January 1, 2015, to January 1, 2020, was performed. The typical referral process for AVR begins with the general practitioner referring a patient for a transthoracic echocardiogram if symptoms are present or if a murmur is heard. Once presence of aortic stenosis confirmed, the patient is referred to a general cardiologist or internist for follow-up. Once the aortic stenosis is believed to be severe, the patient is then referred to the Heart Team or the cardiac surgeon. At our institution, there is no single designated referral centre for valvular disease- the referring physician is free to send the patient to the specialist they deem the most appropriate.

Patients were categorized into the following three groups: (i) H-HT: patients that underwent SAVR from 2015-2017, after a Heart Team assessment (historical Heart Team cohort); (ii) C-HT: patients that underwent SAVR from 2018-2020, after a Heart Team assessment (contemporary Heart Team cohort); (iii) No-HT: patients that underwent SAVR from 2018 to 2020, after direct referral to cardiac surgery. After the publication of major randomized controlled trials pertaining to intermediate-risk patients in 2016 [6] and 2017[7], along with updated guideline recommendations in 2017[8], we observed a change in the referral patterns to our Heart Team for TAVR or SAVR consideration in the beginning of 2018. In addition, the CCS proposed updated guidelines for the management of aortic stenosis in 2019, whereby the decision to undergo TAVR became guided by several patient-specific factors, which include but extend beyond age [3,4]. As such, we chose to divide patients in our study into groups (i) and (ii) for the purpose of observing temporal differences in physician referral patterns for TAVR. Groups (ii) and (iii) allowed us to exclusively evaluate the role of the Heart Team in a contemporary cohort.. For patients seen by the Heart Team, including the contemporary cohort and historical cohort, reasons for not proceeding with TAVR were recorded and are displayed in Figure 1 and Figure 2, respectively. For all patients, data regarding comorbidities, echocardiographic data, procedure details, and post-operative outcomes were collected from medical records. The predicted risk of mortality (PROM) was calculated using the Society of Thoracic Surgeons (STS) risk model for every patient. Two analyses were performed; the first was a temporal trend comparison of groups H-HT versus C-HT. The second analysis evaluated the role of the Heart Team by comparing groups C-HT versus No-HT. The results of this study have been organized to reflect these two sub-analyses. It should be noted that all cases of CABG +AVR in the no-HT group were assessed, in order to determine if these patients could have alternatively undergone TAVR + PCI. Cases where TAVR + PCI were not feasible were excluded from the study. This study was registered and approved by the Research Ethics Board of the McGill University Health Centre.

Study Population

Medical charts of patients undergoing surgical aortic valve replacement from 2015 to 2020 were screened to determine if patients met the following inclusion criteria: (1) adults with severe aortic stenosis, with or without regurgitation, (2) assessed for either transcatheter or surgical aortic valve replacement and underwent surgical aortic valve placement, (3) patients that underwent concomitant cardiac surgeries were also included if these procedures were equally feasible percutaneously. It should also be noted that the severity of aortic stenosis in this study was based on echocardiographic parameters, as opposed to symptom burden. As such, while the majority of patients presented with notable symptoms, asymptomatic patients (Class I) were included if they also presented with a reduced ejection fraction (<50%), or underwent concomitant cardiac procedures, as this would qualify them to undergo TAVR or SAVR, according to recent guidelines[9]. Subgroup analyses excluding concomitant surgeries were performed. Patients were excluded if they underwent valve replacement for reasons other than aortic stenosis and therefore would not be a suitable candidate for TAVR, such as pure aortic regurgitation or infective endocarditis.

Pre-operative Assessments

For patients seen by the Heart Team, a multi-disciplinary assessment was performed. This assessment consisted of a consultation with a nurse practitioner, an interventional cardiologist, and a frailty evaluation. The role of the nurse practitioner was to take the patient history, perform a clinical exam, and review any imaging, biochemical, or electrocardiogram reports from the referring centre, and present all relevant findings to the interventional cardiologist. Nurse practitioners also provided assistance for patient follow-up along the care continuum, both before and after the procedure. In addition, patients also underwent a transthoracic echocardiogram, a coronary angiogram, and a cardiac CT after having been seen by the multidisciplinary team (MDT) at our centre. The results of these tests, as well as the impression of the MDT were presented at Heart Team rounds and discussed among interventional cardiologists and cardiac surgeons to determine whether the patient would benefit most from TAVR, SAVR, or medical management. Anatomical considerations included: aortic annulus diameter, aortic valve morphology (calcification, bicuspid, valve-in-valve), location of the coronary ostia, and size of the aortic sinuses. Reasons for which patients seen by the Heart Team did not proceed with TAVR were recorded. In patients referred directly to cardiac surgery, only transthoracic echocardiogram and coronary angiogram were performed.

Frailty

In addition to analyzing clinical parameters and procedural outcomes, frailty was assessed by the healthcare team where possible. Among this small subset, frailty was measured using the Essential Frailty Toolset (EFT), which uses the following four parameters to assess the risk of 1-year morality in patients undergoing SAVR or TAVR: hemoglobin (g/dL), serum albumin (g/dL), chair rise time (time to complete 5 sit-to-stand chair rises without using arms), and cognitive impairment (determined using the Mini-Mental State Examination) [10].

Outcomes

The primary outcome was a composite of post-operative complications prior to discharge, including in-hospital mortality, re-operation, sternal wound infection, stroke, and readmission [4]. The secondary outcome was 1-year all-cause mortality following SAVR. Vital status at 1 year was determined through data available in medical records.

Statistical approach

Continuous data are reported as mean ± standard deviation or median (interquartile range), and categorical variables are reported as number of patients and percentages. Categorical data were compared using the chi-square test, and continuous data using the one-way ANOVA or the Kruskal-Wallis test, as appropriate. Student t-test and Fisher's exact test were used for pairwise comparisons. Events are reported as counts of first occurrence per type of event. One-year survival data was estimated using the Kaplan-Meier method and compared with the log-rank test. In order to identify the independent predictors of the composite outcome and of Heart Team referral, variables with a p-value < 0.10 on univariate analysis were included in stepwise multivariate logistic regression models. A p-value <0.05 was considered significant. Statistical analyses were performed with SPSS version 23 (IBM Corp, Armonk, NY).

Results

Overall Baseline Characteristics

This study consisted of 288 patients with aortic stenosis, who were treated surgically at the MUHC from 2015 to 2020. Of these patients, 45 were seen by the Heart Team from 2015-2017 (H-HT), 51 were seen by the Heart Team from 2018-2020 (C-HT), and 192 were referred directly to cardiac surgery from 2018 to 2020 (No-HT). In the 2015-2017 period, an additional 182 patients underwent TAVR after being assessed by the Heart Team, and in the 2018-2020 period, there were 194. Therefore, the proportion of patients undergoing SAVR after being considered for TAVR remained stable at about 20% over the study period.

Temporal Trend Analysis: *H-HT versus C-HT*

Baseline Characteristics

The mean age among patients in groups H-HT and C-HT were 76.3 and 73.3 years, respectively (p =0.045), with the proportion of males being similar across both groups: H-HT (55.6%), C-HT (51.0%) (p= 0.67) (Table 1). Furthermore, a significantly greater proportion of H-HT patients had known coronary artery disease (CAD), compared to C-HT (60.0% versus 31.4%, p= 0.007). A similar trend was observed regarding the prevalence of chronic obstructive pulmonary disease, with 26.7% of H-HT patients having COPD, as compared to 9.8% in C-HT patients (p=0.04). These differences were reflected in the respective STS-PROM scores of each group, with H-HT patients having a mean score of 4.8±2.2, which was significantly higher compared to 3.2±1.6, as seen in C-HT patients (p <0.0001). Lastly, frailty was measured in a subset of H-HT and C-HT using the Essential Toolset (EFT). Using this scale, patients were found to be equally frail, with H-HT patients having a mean score of 1.21±1.10, as compared to 1.20±1.01in C-HT patients (p = 0.96). Other baseline characteristics were similar between both groups.

Reasons for Not Undergoing TAVR

The primary reason for undergoing SAVR over TAVR among H-HT patients was "acceptable surgical candidacy - low or intermediate risk" in 27 out of 45 patients. In 9 patients, TAVR was technically not feasible due to large anatomy (n= 7) or an increased risk of coronary obstruction (n= 2). For 2 patients, SAVR was preferred due to the presence of complex CAD which would best be treated through surgical revascularization techniques. SAVR was preferred in the 7 remaining patients for other non-specified reasons. The primary reason for undergoing SAVR over TAVR among C-HT patients was "low surgical risk" in 20 out of 51 patients. TAVR was technically not feasible in 18 patients, due to an increased risk of coronary obstruction (n= 13) or large anatomy (n= 5). In addition, 8 patients within this group had a bicuspid aortic valve. For 6 patients, SAVR was the preferred approach due to the presence of complex CAD. In 3 patients, SAVR was also preferred due to an increased risk of paravalvular leak. Finally, SAVR was preferred in the 7 remaining patients for other non-specified reasons.

Procedural Characteristics

Patients in groups H-HT and C-HT underwent similar procedures, with 40% of H-HT patients undergoing an isolated SAVR, as compared to 58.8% of C-HT patients (p = 0.10) (Table 2). In addition, no significant difference was observed in terms of the proportion patients between H-HT and C-HT groups that underwent concomitant procedures (p = 0.67), or the number of bypassed vessels when patients underwent concomitant coronary artery bypass graft procedures (p= 0.81). Also, the device sizes used between both groups were similar, with 31% of H-HT patients requiring a device less than 21mm, as compared to 44% in the C-HT group (p=0.38). The cross-clamp times were similar between patients in H-HT (78.7 minutes) and C-HT (89.8 minutes) (p=0.19). No significant difference was observed for time spent on cardio-pulmonary bypass in H-HT (99.6 minutes) and C-HT patients(110.1 minutes) (p= 0.08).

Outcomes

The results of the primary composite outcome demonstrated that H-HT patients were more likely to experience at least one of the endpoints of the composite as compared to patients in the C-HT group: the incidence was 20.0% among H-HT patients and 3.9% in C-HT patients (p= 0.02; Table 3). No significant differences were observed between groups H-HT and C-HT for individual in-hospital outcomes such as major bleeding, tamponade, new onset arrythmias, new pacemaker implantation, acute kidney injury. Length of stay in the intensive care unit (ICU) and total hospital length of stay were similar between groups H-HT and C-HT.

At 1 year, no statistically significant difference in outcomes was observed between H-HT and C-HT patients, with 5 deaths occurring in the H-HT group, and 3 deaths occurring in the C-HT group (p=0.69). No endocarditis was observed in either group, and the rates of readmission were similar, with 17 patients (37.8%) being readmitted in group H-HT, and 12 patients (23.5%) in group C-HT (p=0.18). Post-operative echocardiographic findings were similar across both groups and are displayed in Table 3.

Heart Team analysis: *C-HT versus No-HT*

Baseline Characteristics

Patients seen by the Heart Team were significantly older than those referred directly to cardiac surgery, as the mean age among patients in group C-HT and No-HT were 73.3 and 69.6 years, respectively (p =0.01; Table 1). The proportion of males was similar across both groups: group C-HT (51.0%), group No-HT (63.0%), (p= 0.67). A significantly greater proportion of group No-HT patients were obese, as compared to group C-HT (34.0% versus 17.6%, p= 0.03). Similarly, a greater proportion of patients in group No-HT had known CAD (50.3% versus 31.4%, p= 0.007). Patients in group No-HT also had a higher overall surgical risk than the those in group C-HT, as determined by their respective STS-PROM scores (4.2±2.5 versus 3.2±1,6, p=0.007). Significant differences were also observed in terms of echocardiographic parameters between the two groups, with the mean aortic valve area for patients in group C-HT of 0.77 cm^2, as compared to 0.96 cm^2 in group No-HT (p=0.04). Finally, both groups of patients were found to be equally frail using the EFT, with C-HT patients having a mean score of 1.20±1.01, as compared to 1.13±1.06 in group No-HT (p= 0.96).

Procedural Characteristics

A greater proportion of patients seen by the Heart Team (58.8%) underwent isolated SAVR, as compared to those referred directly to cardiac surgery (42.2%) (p= 0.04; Table 2). More specifically, 31.4% of patients in group C-HT underwent a CABG procedure, compared to 43.2% in group No-HT (p= 0.47) with no difference when comparing the number of bypassed vessels between each group (p= 0.74). Smaller devices (<21mm) were used more often in group C-HT than No-HT (44% vs 25%, respectively; p=0.02). Cross-clamp times were similar between patients in group C-HT (89.9 minutes) and group No-HT (91.4 minutes) (p=0.76). No significant difference was observed for time spent on cardio-pulmonary bypass in group C-HT (110.1 minutes) and group No-HT (112.8 minutes) (p= 0.08).

Outcomes

The incidence of experiencing the composite endpoint was more than tripled in patients referred directly to cardiac surgery versus those seen by the Heart Team during the same period, however this difference did not reach statistical significance (group No-HT: n=25, 13.0% vs group C-HT: n=2, 3.9%; p=0.07; Table 3). Similarly, in-hospital death was numerically higher in patients referred directly to cardiac surgery (n=12, 6.3%), compared to those seen by the Heart Team (n=2, 3.9%) (p= 0.74). In addition, post-operative tamponade (group C-HT: n=0; group No-HT: n=7 (3.6%), p= 0.36), sternal wound infection (group C-HT: n=0; group No-HT: n=5 (2.6%), p= 0.59), and the implantation of a permanent pacemaker (group C-HT: n=0; group No-HT: n=6 (3.6%), p= 0.35), exclusively occurred in patients referred directly to cardiac surgery. All patients had a median ICU stay of 2 days (p=0.47) and mean overall hospital length of stay of 9 days (p=0.96).

Overall Outcomes Across Groups H-HT, C-HT and No-HT

Similar survival patterns were observed across all three groups, although the highest incidence of mortality was seen in Group No-HT(Figure 3). In the total cohort, two independent predictors of the composite outcome were identified: surgery involving the aortic root (OR 3.4 (1.5 - 7.8); p=0.004) and STS score: (OR 1.2 (1.1 -1.4) per 1 point increase; p=0.001). Aside from these two predictors, no other clinical variable reached the univariate statistical significance to be included in the mulvariate model. For patients undergoing concomitant aortic root procedure in groups H-HT and C-HT, TAVR was considered unsuitable because of risk of coronary obstruction in 4 of 18 cases.

Outcomes Based on Procedure Type

A supplemental analysis was performed where patients undergoing concomitant valve, left atrial appendage closure, septal myomectomy procedures were excluded. Patients in group C-HT had a significantly lower incidence of the composite outcome as compared to group H-HT(group H-HT: n= 7, (17.1%) vs group C-HT: n= 1, (2.2%), p=0.02) and group No-HT (group No-HT: n=24 (12.9%) vs group C-HT: n= 1, (2.2%), p=0.03) (Supplemental Table S1) . Similar results were observed when aortic root procedures were excluded from the analysis (group H-HT: n= 4, (12.9%) vs group C-HT: n= 0, (0%), p=0.03) and No-HT (group No-HT: n=17 (10.7%) vs group C-HT: n= 0, (0%), p=0.03) (Supplemental Table S2). Excluding procedures with more than two bypasses demonstrated similar results, with no patients in group C-HT experiencing the composite outcome (group H-HT: n= 3, (10.3%) vs group C-HT: n= 0, (0%), p=0.08) and No-HT (group No-HT: n=13 (9.6%) vs group C-HT: n= 0, (0%), p=0.07) (Supplemental Table S3). Lastly, no significant differences were observed in either the composite or death, when isolated SAVR procedures were compared across all three groups (Supplemental Table S4).

Predictors of Heart Team referral

Univariate and multivariate analysis of predictors of HT referral are displayed in Table 4. Independent predictors include: Age, STS-PROM, obesity, hypertension and mean aortic gradient. Of note, while hypertension, mean gradient and age are positive predictors (i.e. older age increases the likelihood of HT referral), obesity and STS-PROM inversely predict HT referral (higher STS-PROM decreases likelihood of referral).

Discussion

This study analyzed temporal trends among patients with severe AS who were preoperatively assessed by the HT and ultimately underwent SAVR from 2015-2017 (H-HT) and from 2018-2020 (C-HT). The outcomes of patients considered but refused for TAVR were also compared to patients not assessed for TAVR (No-HT).

The key findings of this study can be summarized as follows: (1) more patients with aortic stenosis are now being seen by the Heart Team prior to undergoing SAVR, although the majority continue to be directly referred to surgery; (2) current referral patterns suggest that age is the primary factor for determining direct referral to cardiac surgery, while other relevant patient-specific factors are less often considered, and (3) the heart team assessment is associated with favourable outcomes in patients undergoing SAVR. These findings are reassuring for patients assessed by the Heart Team but refused for TAVR.

Temporal Trends: H-HT versus C-HT

Temporal trends demonstrate that more patients with AS undergoing SAVR are being assessed by the Heart Team at our institution, as compared to previous years. In addition, these same patients are of lower surgical risk as compared to the past. This was demonstrated by comparing STS-PROM scores of group H-HT versus group C-HT. Factors which may have contributed to a lower STS score include: (i) an increased proportion of C-HT patients undergoing isolated SAVR as opposed to concomitant procedures, (ii) a lower mean age among C-HT patients as compared to H-HT patients, and (iii) a smaller proportion of C-HT patients having an LVEF less than or equal to 30% versus those in group H-HT. TAVR was reserved for high-risk patients in the 2015-2017 period in our institution, therefore those of intermediate risk would undergo SAVR, also explaining a higher risk profile in the historical cohort. Since then, TAVR has been expanded to intermediate (and even some low-risk patients), meaning proportionally less intermediate risk patients are undergoing SAVR.

Overall, contemporary patients experienced more favourable outcomes compared to the historical cohort. The composite endpoint was five times higher in group H-HT versus group C-HT, and this may be attributed to H-HT patients being significantly older than C-HT patients, having the highest mean STS score, having a higher prevalence of coronary artery disease, as well as being the group that underwent more concomitant surgeries, including root procedures.

Only when considering isolated SAVR did the differences between the groups disappear. Remarkably, the multivariable logistic regression analysis demonstrated that the need for root procedures was found to be an independent predictor for the composite endpoint. Aortic root replacement is inherently linked with high mortality and morbidity rates [11,12]. Despite improved protection to the brain and myocardium as a result of technical advancements in thoracic surgery, mortality and morbidity rates remain elevated [13,14].

Sotiris et al demonstrated an elevated incidence of operative mortality in patients with aortic stenosis undergoing aortic root surgery (6.5%) as compared to those without aortic stenosis (3.5%). Additionally, increased rates of acute renal failure and prolonged length of stay were observed [15]. This could be explained by the technical challenges encountered in such combined procedures, the need for procedural expertise, as well as the effects on patient outcomes when CBP time is increased. Whether these patients can be considered for TAVR as an alternative option remains unclear. In at least one fifth of cases, TAVR was contra-indicated specifically for aortic root reasons.

The incidence of in-hospital all-cause mortality in group C-HT was 3.9% and was comparable to previously published trials of patients following SAVR with preoperative Heart Team assessment (SURTAVI and PARTNER 2), which showed a mortality rate ranging between 1.7% and 4.1% , respectively [16 17]. Other in-hospital outcomes including but not limited to myocardial infarction, major bleeding, acute kidney injury and new onset atrial fibrillation, showed no significant difference among our three groups, similarly to results seen in the PARTNER 2 trial of intermediate-risk patients that underwent SAVR [17].

No difference was observed when comparing all-cause mortality at 1 year across all three groups, which ranged from 7.9% to 11.4%. This is lower than other studies consisting of intermediate risk STS-score patients, showing 1-year mortality rates between 13.6% to 16.9% [17-21]. Studies demonstrating higher 1-year mortality rates may be explained by an older patient population with mean STS scores on the upper limit of the intermediate STS score range.

The Effects of the Heart Team: C-HT versus No-HT

While more patients with aortic stenosis undergoing SAVR are being assessed by the Heart Team as compared to previous years, the majority continue to be directly referred to cardiac surgery. Referral to the heart team was observed to be primarily driven by chronological age in a multivariable model, despite patients having a lower mean STS score, comparable frailty scores, and undergoing fewer concomitant procedures. In fact, once adjusted for age, higher STS scores actually predicted direct referral to surgery rather than to the HT. These findings could be attributed to incomplete assessment of patients by the referring physician prior to referral. In addition, variations and complexities in coronary anatomy may have influenced the need for a concomitant CABG procedure, as opposed to percutaneous revascularization, therefore increasing the STS-PROM score. This information along with the STS-PROM score itself would not have been known by physicians at the time of referral in most cases. In addition, variables in the statistical model could be fraught with multicollinearity.

Of note, no significant difference across in-hospital outcomes were observed among patients seen by the Heart Team compared to those directly referred to surgery. These results are aligned with those of other studies [17]. Similarly, all-cause mortality at 1 year was similar for group C-HT and group No-HT patients, which is comparable to other studies consisting of intermediate risk STS-score patients, showing 1-year mortality rates between 13.6% to 16.9% [17-21]. However, the incidence of readmission after 1 year was higher among patients referred directly to surgery ((23.5%) versus those seen by the HT (12%) (p=0.045), indicating that a more thorough patient baseline assessment potentially serves to improve long-term outcomes, more so than in-hospital outcomes.

Moving forward, we argue in favor of having a single designated referral centre for valvular disease, such that referring physicians do not need to decide which intervention may be best for each patient, with the limited information known at the time of referral. For example, it would not be possible for the referring physician to compute the STS score accurately, as many elements would be unavailable to them, most importantly the extent of CAD. Having a single referral centre also offers the opportunity to thoroughly assess frailty for all patients, which would also contribute to an enhanced screening process. Therefore, having a single referral centre would allow for more patients to have the opportunity to be seen by the HT, regardless of age.

Role of the Heart Team: Now and in the Future

There are benefits and challenges associated with the Heart Team assessment. Multidisciplinary approaches and discussions, optimal treatment options, risk score adjustments, increased patient satisfaction, and a sense of “shared” responsibility, are among some of the strengths of the Heart Team. The Heart Team also offers the opportunity to integrate new modalities and innovative approaches for complex cases, all while enhancing patient risk-stratification. For example, the Heart Team could provide input in situations where concomitant CABG could be avoided in high-risk patients at a progressed stage of the disease (for example, by suggesting PCI + TAVR when feasible). This thorough assessment process may very well explain why patients assessed by the HT in our cohort experienced improved post-operative outcomes, despite presenting at an older age. Essentially, the presence of a HT ultimately serves to create a more robust selection process for both surgical and non-surgical candidates.

Despite the numerous advantages and opportunities such an approach offers, some challenges are present. The role of the Heart Team inherently involves increased discussion among surgeons and interventionalists. For the benefits of the Heart Team to be realized, these discussions and ensuing decisions must be done in a timely fashion so as to avoid delays in treatment, especially for patients at an already advanced stage of the disease. In addition, large discussion groups can make it easier for the voice of the patient to be lost. Essentially, while the expertise of surgeons and interventionalists is imperative, final decision-making should always include and accommodate (when possible) patient preferences. Lastly, cost effectiveness and clinical efficiency must be considered when deciding if a preoperative Health Team assessment would benefit an individual patient [22].

In the future, as TAVR continues to be expanded to younger and lower risk patients, the involvement of the Heart Team will become increasingly important as discussions will be centered around valve durability, future coronary access and pacemaker rates, among others. Current guidelines only clearly outline treatment protocols for extreme ends of the age and risk spectrums. A large proportion of patients fall somewhere in the middle, meaning their optimal course of care is not as obvious and requires a more in-depth discussion [1].

Fundamentally, while the Heart Team is challenging to organize, its implementation offers tremendous opportunities for experts to collectively discuss and decide how to provide the best care on a patient-specific level. The results of these discussions currently provide better patient outcomes in SAVR patients and will become increasingly critical as TAVR expands to younger cohorts.

Limitations

The main limitation to our study is its retrospective nature, with the inherent biases this entails. However, a randomized trial of Heart Team assessment in patients undergoing SAVR is not practical. In addition, given the low number of patients per group, adjustment for baseline characteristics was not possible. The generalizability and representativity of the findings are limited due to the study being conducted at a single center. In addition, this study relied on medical records data which may include missing entries. Finally, while the participants of this study almost entirely consisted of older adults, frailty data was only available for a select number of participants. Only 1 frailty evaluator is currently available at our institution, making it difficult to assess the frailty status of all patients seen in a given clinic. As a result, few conclusions can be drawn from this information alone. The lack of frailty data among patients undergoing cardiac surgery at our institution may reflect our own inherent bias towards patient age. In the future, the incorporation of frailty assessments should be extended to all severe AS patients, such that we can offer a more thorough patient work-up to ultimately improve both short and long-term patient outcomes.

Conclusion

Patients assessed by the Heart Team prior to undergoing SAVR have a low incidence of complications, comparable to patients referred directly to cardiac surgery. While patients referred directly to cardiac surgery are relatively younger in age, their surgical risks are not significantly lower, and their frailty status is equivalent to those patients that are seen and assessed by the Heart Team. An integrated approach to patients with severe aortic stenosis should be considered when deciding upon the most optimal course of care.

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Table 1. B

Variable	H-HT: 2015-2017 (n=45)	C-HT: 2018-2020 (n=51)	No-HT: 2018-2020 (n=192)	p-value (H-HT vs C-HT)	p-value (C-HT vs No-HT)
Age	76.3±6.9	73.3±7.6	69.6±9.7	0.045	0.01
Male sex	25 (55.6)	26 (51.0)	121 (63.0)	0.67	0.15
STS-PROM, %	4.8±2.2	3.2±1.6	4.2±2.5	<0.0001	0.007
Obesity	5 (11.1)	9 (17.6)	65 (34.0)	0.40	0.03
Diabetes	16 (35.6)	18 (35.3)	65 (33.9)	1	0.87
Hypertension	34 (75.6)	41 (80.4)	121 (63.0)	0.63	0.02

Dyslipidemia	26 (57.8)	29 (56.9)	100 (52.1)	1	0.64
Active smoker	4 (8.9)	2 (3.9)	19 (10.6)	0.27	0.30
NYHA Class 3 or 4	15 (40.5)	21 (53.8)	64 (58.2)	0.26	0.71
Known CAD	27 (60.0)	16 (31.4)	96 (50.3)	0.007	0.02
Atrial arrhythmia (flutter or fibrillation)	10 (22.2)	11 (21.6)	30 (15.6)	1	0.30
Previous PPM	2 (4.4)	2 (3.9)	11 (5.8)	1	1
Previous SAVR	1 (2.2)	1 (2.0)	9 (4.7)	1	0.69
Previous stroke or TIA	4 (8.9)	5 (9.8)	15 (7.8)	1	0.58
Peripheral vascular disease	2 (4.4)	3 (5.9)	8 (4.2)	1	0.70
Chronic obstructive pulmonary disease	12 (26.7)	5 (9.8)	27 (14.1)	0.04	0.49

LVEF, %	57.7±15.7	57.8±12.2	57.2±12.1	0.97	0.75
LVEF ≤ 30%	4 (9.3)	3 (5.9)	10 (5.6)	0.67	1
Mean aortic gradient, mmHg	58.2±16.0	55.2±20.3	46.1±20.0	0.43	0.06
AVA, cm^2	0.75±0.24	0.77±0.20	0.96±0.64	0.65	0.04
Aortic insufficiency greater than mild	5 (11.1)	7 (13.7)	31 (16.1)	0.76	0.83
Creatinine (umol/L)	87.5±27.5	94.9±47.4	94.7±50.6	0.36	0.98
Dialysis	1 (2.2)	0 (0.0)	2 (1.0)	0.47	1
Essential Frailty Toolset score*	1.21±1.10	1.20±1.01	1.13±1.06	0.96	0.87

Values are mean ± SD or n (%). AVA = aortic valve area; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PPM = permanent pacemaker; SAVR = surgical aortic valve replacement; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; TIA = transient ischemic attack. *Frailty was assessed in the following number of patients in each group: n=28, 20, and 23 in groups A, B and C, respectively).

Table 2. Procedural characteristics.

Variable	H-HT: 2015-2017 (n=45)	C-HT: 2018-2020 (n=51)	No-HT: 2018-2020 (n=192)	p-value (H-HT vs C-HT)	p-value (C-HT vs No-HT)
Isolated SAVR	18 (40.0)	30 (58.8)	81 (42.2)	0.10	0.04
Concomitant procedure				0.67	0.47
CABG (1 or more)	16 (35.6)	16 (31.4)	83 (43.2)		
Root	10 (22.2)	8 (15.7)	29 (15.1)		
Mitral valve	3 (6.7)	2 (3.9)	4 (2.1)		
Other	3 (6.7)	2 (3.9)	3 (1.6)		
Concomitant CABG no.				0.81	0.74
1	10 (22.2)	8 (15.7)	35 (18.2)		
2	29 (8.9)	4 (7.8)	25 (13.0)		
3	2 (4.4)	3 (5.9)	16 (8.3)		
4	0 (0.0)	1 (2.0)	6 (3.1)		
5	0 (0.0)	0 (0.0)	1 (0.5)		
Device size				0.38	0.02
Small (21 mm or less)					
Medium (23 to 25 mm)	14 (31.1)	22 (44.0)	48 (25.1)		
Large (27 mm or more)	25 (55.6)	21 (42.0)	119 (62.3)		

	6 (13.3)	7 (14.0)	24 (12.6)		
Cross clamp time (min)	78.7±28.9	89.8±32.2	91.4±33.8	0.19	0.76
CPB time (min)	99.6±34.6	110.1±41.7	112.8±43.8	0.08	0.70

Values are mean ± SD or n (%). CABG = coronary artery bypass graft; CPB = cardio-pulmonary bypass; SAVR = surgical aortic valve replacement.

Table 3. In-hospital and 1-year outcomes.

In-hospital outcome	H-HT: 2015-2017 (n=45)	C-HT: 2018-2020 (n=51)	No-HT: 2018-2020 (n=192)	p-value (H-HT vs C-HT)	p-value (C-HT vs No-HT)
Composite endpoint	9 (20.0)	2 (3.9)	25 (13.0)	0.02	0.07
Death	4 (8.9)	2 (3.9)	12 (6.3)	0.41	0.74
Stroke	1 (2.2)	1 (2.0)	5 (2.6)	1	1
Myocardial infarction	0 (0.0)	0 (0.0)	2 (1.0)	1	1
Major bleeding	10 (22.2)	5 (9.8)	30 (15.6)	0.16	0.37
Tamponade	1 (2.2)	0 (0.0)	7 (3.6)	0.47	0.35
Sternal wound infection	1 (2.2)	0 (0.0)	5 (2.6)	0.47	0.59
New onset atrial arrhythmia	11 (24.4)	15 (29.4)	41 (21.4)	0.65	0.26
New pacemaker implantation	3 (6.7)	0 (0.0)	6 (3.1)	0.10	0.35
Acute kidney injury	3 (6.7)	1 (2.0)	5 (2.6)	0.34	1
ICU stay (median days, IQR)	2 (2 - 4)	2 (2 - 3)	2 (1 - 3)	0.20	0.47
Hospital stay (median days, IQR)	10 (7 - 14.5)	9 (7 - 14)	9 (6.25 - 13)	0.34	0.96

1-year outcome					
1-year death*	5 (11.4)	3 (7.9)	16 (10.0)	0.69	0.74
Readmission	17 (37.8)	12 (23.5)	23 (12.0)	0.18	0.045
Valve endocarditis	0 (0.0)	0 (0.0)	1 (0.5)	1	1
LVEF, %	58.0 ± 9.0	54.7 ± 13.7	54.0 ± 12.2	0.35	0.80
AVA, cm^2	1.61 ± 0.50	1.84 ± 0.59	1.86 ± 0.73	0.30	0.94
Mean gradient > 20 mmHg	0 (0.0)	2 (11.1)	6 (6.8)	0.23	0.62
Mean gradient, mmHg	11.7 ± 3.7	13.6 ± 10.2	11.1 ± 5.2	0.45	0.12
Paravalvular regurgitation > mild	0 (0.0)	0 (0.0)	0 (0.0)	1	1

Values are mean ± SD or n (%), unless otherwise specified. *Kaplan-Meier estimate; log-rank p-values. ICU = intensive care unit, IQR = inter-quartile range. Acute kidney injury was defined as a greater than 2-fold increase in serum creatinine within 48 hours of surgery.

Table 4. Univariate and multivariate predictors of HT referral.

Parameter	Univariate analysis		Multivariate analysis		
	OR	p-value (crude)	OR	95% CI	p-value (adjusted)
Age* (per 5-year increment)	1.43	<0.001	**1.43**	**1.15-1.78**	**0.001**
Female sex*	1.50	0.11	1.57	0.83-2.96	0.16
STS-PROM* (per 1% increment)	0.96	0.45	**0.70**	**0.58-0.83**	**<0.001**
Obesity	0.33	0.001	**0.37**	**0.18-0.78**	**0.009**
Hypertension	2.10	0.01	**2.34**	**1.17-4.68**	**0.02**
Known CAD	0.80	0.38	-	-	-
Chronic obstructive pulmonary disease	1.32	0.42	-	-	-
LVEF* (per 5% increment)	1.02	0.73	0.89	0.29-1.00	0.06
Mean aortic gradient (per 5 mmHg increment)	1.15	<0.001	**1.17**	**1.08-1.28**	**<0.001**
AVA (per 0.1 cm^2 increment)	0.86	0.003	-	-	-
Creatinine (per 5 umol/L increment)	0.99	0.58	-	-	-

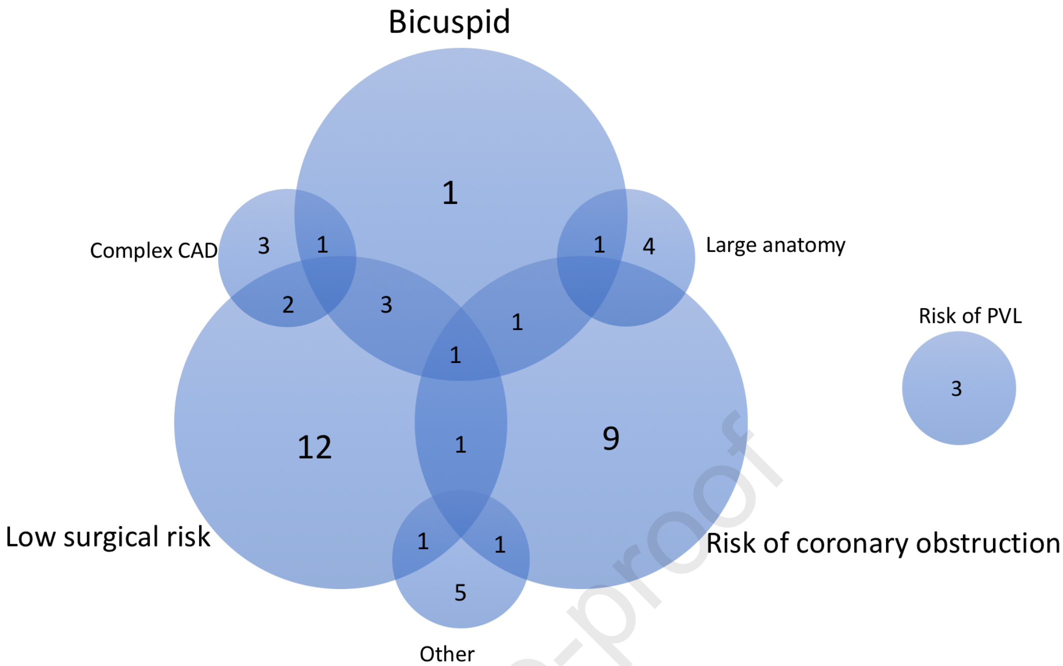
* Age, sex, STS-PROM and LVEF were forced into the model. Abbreviations as per Table 1.

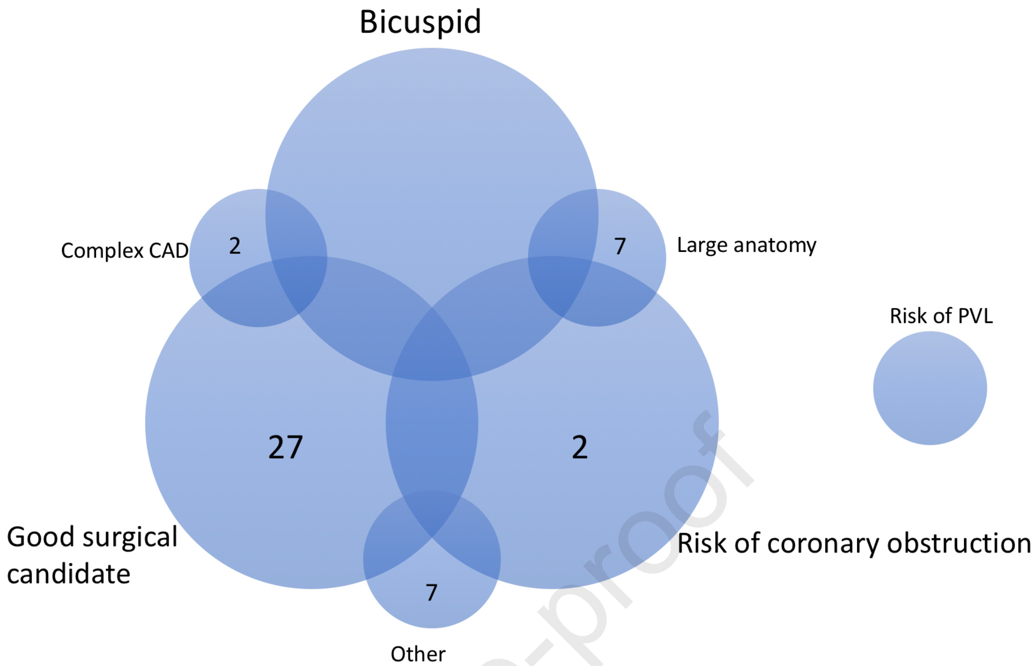
Figure Legends

Figure 1: Reasons for SAVR preference over TAVR in patients considered for both approaches in the 2018-2020 group (C-HT). The three main reasons for selection of SAVR were the presence of a bicuspid aortic valve, small anatomy with increased risk of coronary obstruction, and low surgical risk. Less common reasons included complex coronary artery disease (in addition to severe aortic stenosis) that would be better revascularized surgically, anatomy too large for available TAVR devices, prohibitive calcium burden with increased risk of paravalvular leak, and other reasons described in the text.

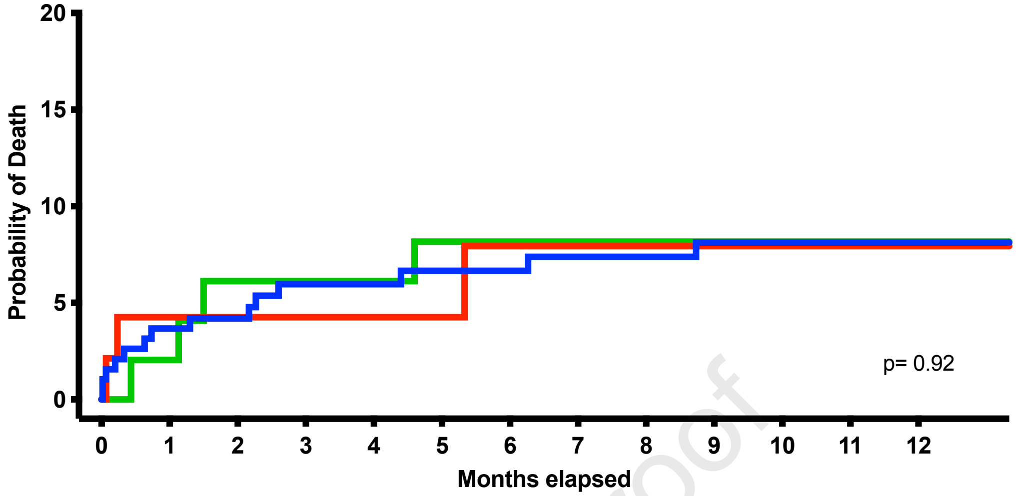
Figure 2: Reasons for SAVR preference over TAVR in patients considered for both approaches in the 2015-2017 group (H-HT). The main reason for selection of SAVR was good surgical candidacy in the majority of patients. Less common reasons included large anatomy that could be treated surgically, increased risk of coronary obstruction, and other non-specified reasons.

Central Figure/ Figure 3: Kaplan-Meier curves comparing the 1-year incidence of mortality across patients seen by the Heart Team from 2015-2017 (H-HT) and 2018-2020 (C-HT), and those referred directly to cardiac surgery (No-HT).


Bicuspid
1
Complex CAD
3
1
Large anatomy
1
4
2
3
1
1
Risk of PVL
3
12
1
9
Low surgical risk
1
1
Risk of coronary obstruction
5
Other


Bicuspid
Complex CAD
2
7
Large anatomy
Risk of PVL
27
2
Good surgical candidate
Risk of coronary obstruction
7
Other

Mortality after SAVR stratified by date and Heart Team assessment



No. at risk				
No Heart Team 2018-20	192	182	131	118
Heart Team 2018-20	51	49	28	15
Heart Team 2015-17	45	44	41	41

No Heart Team
Heart Team 2018-2020
Heart Team 2015-2017