**Reconsidered surgical aortic valve replacement after declined transcatheter valve implantation**

**ABSTRACT**

**Background**

Outcomes for high surgical risk patients who are declined Transcatheter aortic valve implantation (TAVI) and then reconsidered for conventional aortic valve replacement (rSAVR) for severe calcific aortic stenosis are not well known.

**Methods**

This single centre, case control study (rSAVR vs Conservative group) retrospectively analysed patients for rSAVR (2009 -2019). Multivariable logistic regression was used to identify independent predictors of composite of neurological sequelae/ renal failure/ deep sternal wound infection/ re-exploration and death. Survival was compared using Kaplan-Meier curves and log rank test. A Cox proportional hazards model was used to determine predictors of survival.

**Results**

TAVI was denied in 519/1095 patients, 114(10.4%) had rSAVR (Cases) and 405(37%) were managed conservatively (Controls). Mean age for rSAVR was 80 years (IQR: 73.5-85 years). The commonest reason for declining TAVI was prohibitive high risk due to multiple co-morbidities. Among rSAVR, hospital mortality was 2.2% and stroke 4.4%. Median follow up was Conservative;14.4 months versus rSAVR;34.8 months. Five-year survival was Conservative;12.6% versus rSAVR;59.5% (overall Conservative; 38.0% versus rSAVR; 60.5%, p<0.001). rSAVR was protective (HR; 0.37, 95% CI; 0.26, 0.51, p<0.001) and high co-morbidities had high hazard (HR; 1.57, 95% CI; 1.19, 2.07, p=0.001). rSAVR had fewer hospital readmission episodes (Conservative; 13.6/ patient-year versus rSAVR; 6.9/ patient-year, p=0.002).

**Conclusions**

rSAVR may be considered in high surgical risk elderly patients who have been declined TAVI in centres with low operative mortality. rSAVR may be superior to conservative management in carefully selected patients.

**Word count – 237**

**Classifications**

Aortic valve disease; aortic valve replacement; transfemoral aortic valve implantation; cardiac surgery; percutaneous intervention; SAVR; TAVI.

**INTRODUCTION**

There have been rapid advances in transcatheter valve therapy over this decade. The short term and intermediate results of patients who undergo surgical aortic valve replacement (SAVR) and transcatheter valve implantation (TAVI) are now well known from trial data and registries (1-6). The outlook for those who are discussed but declined TAVI has not been explored in the real world scenario. The conservative management of severe calcific aortic stenosis is associated with poor outcomes. There is a paucity of outcome data for high surgical risk patients who are declined TAVI and are then reconsidered for SAVR.

The aim of this case control study was to define the outcomes of patients declined TAVI, who then subsequently received medical therapy or reconsidered SAVR (rSAVR).

Our pre-specified hypothesis was that selected rSAVR cases have a better survival and lower readmissions after surgery compared to those who were declined any intervention.

**METHODS**

*Study design*

This is a case control study. Hospital records of the regional TAVI multidisciplinary team (TAVI-mdt) meetings at Southampton General Hospital (SGH) were retrospectively analysed from May 2009 to August 2019 to identify cases that were declined for TAVI and then reconsidered for SAVR (cases). Those declined TAVI but managed conservatively served as controls.

*Ethics*

The project was registered locally, and approvals were obtained for use of data, data protection and compliance with local policies (SEV/0029, 24.10.2018). Need for individual consent was waived due to the nature of study.

*Objectives*

The objectives of the study were -

1. study perioperative outcomes of rSAVR (cases).
2. compare survival and readmissions between the Conservative group (controls) and rSAVR (cases).

A STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist of 22 items was compiled (supplement 1) for a case control study.

*Patient and public involvement*

Due to the retrospective nature of the data, patients were not involved in the design, conduct, nor recruitment of the study.

*Referral and assessment for TAVI*

The TAVI referral follows a structured, documented protocol at our institution as per British Cardiovascular Society, British Cardiovascular Intervention Society, and Society for Cardiothoracic Surgery service specifications, TAVI care pathway guidelines and recommendations (7-9). Surgical referrals from 14 regional and local referral centres for surgical aortic valve replacements (SAVR) for severe calcific aortic stenosis were initially screened by a cardiac surgeon. All patients had an echocardiogram for assessment of cardiac valves and function and either a conventional angiogram or CT angiogram for coronary assessment. The patients are then reviewed either as in-patient or in the clinic by the cardiac surgeon. These were formally discussed at the TAVI-mdt if deemed unsuitable or too high risk for SAVR. As per UK National Institute of Health and Care Excellence (NICE, Interventional Procedures Guidance, IPG586 (revised); July 2017, original IPG421; March 2012) only high to intermediate risk patients were considered for referral for TAVI. All referred patients had a TAVI protocol CT scan to assess for suitability of vascular approach (transfemoral or transapical), assess the geometry and calcification of the aortic root and ascending aorta. The valve area was measured for sizing of the transcatheter aortic valve. All further tests for risk profiling and other co-morbidities including neurological assessment and dementia screening were completed. All patients were discussed and investigations reviewed at the TAVI-mdt that comprised of at least one each of the following - cardiac surgeon, TAVI interventional cardiologist, cardiac CT radiologist, non-interventional cardiologist (echocardiography), TAVI co-ordinator and/or an interventional radiologist and a vascular surgeon. TAVI-mdt decisions were formally documented and patients were then reviewed by a cardiologist and/or cardiac surgeon to discuss the outcomes of the TAVI-mdt. Among patients who were denied TAVI, a consensual decision (patient and family, cardiac surgeon, cardiologist) was made for further intervention and rSAVR or conservative management. As part of the consultations, a second re-affirmation opinion from another consultant cardiac surgeon outside the purview of the TAVI-mdt was sought, if needed, for very high surgical risk and technically difficult cases.

rSAVR was done as conventional aortic valve replacements with full sternotomy, cardiopulmonary bypass and cold cardioplegic arrest with mild hypothermia using conventional sutured aortic prostheses. Specifically, partial/ hemi-sternotomies/ other minimally invasive approaches and suture-less valves were not used in this study.

Reasons for denial for TAVI were analysed and grouped as technical/procedural (vascular access, dilated roots, large annulus, low coronary ostia, calcified mitral shelf and severe hypertrophy) and clinical/patient related (considered very high risk, significant co-morbidities, refusal or minimal symptoms). Data for patients accepted for rSAVR were collated and analysed for demographics and surgical risk profile, operative characteristics, and post-operative outcomes from the hospital database (Patient Administration System, e-CAMIS, Yeadon, Leeds, UK). Survival was collected from Patient Administration System (e-CAMIS) and the National Healthcare Service Spine Portal Summary Care Records (SCR) which is an electronic database of GP medical records linked to the hospital database.

*Statistical analysis*

Baseline demographics used for calculation of logistic EuroSCORE for risk assessment are presented in Table 1. Continuous and categorical variables were compared using a Mann-Whitney (or student’s t-test for normal distributions) and χ2 test, respectively. Multivariable logistic regression was used to identify independent predictors of a composite of neurological sequelae/ renal failure/ deep sternal wound infection/ re-exploration and death for rSAVR. The primary outcome of interest was mortality. The secondary outcomes was the composite of neurological sequelae (transient ischemic attack or stroke), renal failure, deep sternal wound infection, re-exploration or death and survival. Survival was estimated using Kaplan-Meier curves for the groups and subgroups and compared using a log-rank (Mantle Cox) test. A Cox proportional hazards model was used to determine predictors of survival. All statistical analyses were done using Stata 14.0 (College Station, TX). A P<0.05 was considered statistically significant.

**RESULTS**

Total 1095 patients were referred to the TAVI-mdt for the period (Figure 1). 519 (47.4%) were denied TAVI. Twenty two (2.2%) patients were excluded from analysis as they had rSAVR elsewhere and their perioperative data was not available. Of the remaining, 114(10.4%) had rSAVR (Cases) and other 405 patients (37%) were managed conservatively (Controls) (Figure 1, Table 1). The median follow up was 1.2 (IQR: 0.5-2.1) and 2.9 (IQR: 1.6-4.3) years for the Conservative and rSAVR arms, respectively. The mean age for rSAVR was 80 years (IQR: 73.5-85 years). The commonest reason for declining TAVI was prohibitive high risk due to multiple co-morbidities (48.1%;Conservative versus 20.2%; rSAVR, Table 2). Overall, 72.2% in Conservative versus 57.0% in rSAVR were refused TAVI based on clinical/patient reasons as opposed to technical/procedural considerations (Conservative: 22% vs rSAVR: 38.6%).

*Operative outcomes*

Operative data is presented in supplementary table 1. Among patients with rSAVR, the hospital mortality was 2.2%. Significant morbidities of rSAVR included re-explorations for bleeding (3.3%) and stroke (7.8%)(Table 3). Multivariable regression did not identify any of the preoperative variates as predictors of worse composite of neurological sequelae/ renal failure/ deep sternal wound infection/ re-exploration and death.

The mean length of hospital stay for rSAVR was 10.5 days and 60% of the patients were discharged home. 31.1% required further rehabilitation due to age, frailty, social circumstances and living alone, or consequence, morbidity or complications of surgery.

*Survival*

Five-year survival was 12.6% for the Conservative versus 59.5% for rSAVR versus group respectively. Survival was Conservative; 38.0% versus rSAVR; 60.5%, p<0.001(Figure 2). Stratified survival was significantly better at all time points for rSAVR (78.5% versus 91.2%, p=0.007 at 6 months, 64.1% versus 84.1%, p<0.001 at 1 yr and 12.6% versus 59.5%, p<0.001 at 5 yrs for Conservative and rSAVR groups respectively, Appendix Table 2). Among patients undergoing rSAVR, an adverse neurological history was the only independent predictor of survival (HR; 3.10, 95% CI; 1.14, 8.41, P=0.027). Overall, rSAVR was protective (HR; 0.37, 95% CI; 0.26, 0.51, p<0.001) and high co-morbidities at the time of multidisciplinary evaluation were associated with a significant hazard (HR; 1.57, 95% CI; 1.19, 2.07, p=0.001) for survival.

Survival was superior for rSAVR on sub-analyses based on age (Non-octogenarians: Conservative 36.4% versus rSAVR; 62.2%, p<0.001, Octogenarians: Conservative 42.4% versus rSAVR 61.9%, p<0.001), considerations for refusal of TAVI (Clinical/ patient related: Conservative: 42.9% versus rSAVR 64.9%, p<0.001 Technical/procedural: Conservative 34.1% versus rSAVR 51.7%, p<0.001), operative risk and co-morbidities (Conservative 38.5% versus 58.1%, p<0.001) (Figures 3-5).

The number of hospital readmissions rate (overall number of patients readmitted in each group) was similar (Conservative; 20.5% versus rSAVR; 21.1%, p = 0.687). The number of hospital readmission episodes rate (total number of readmission episodes/patient-year) was better for rSAVR (Conservative; 13.6/ patient-year versus rSAVR; 6.9/ patient-year, p=0.002).

**DISCUSSION**

Conservative management of severe calcific AS is associated with universal poor prognosis, rapid symptomatic deterioration and death. In a study of natural history of severe AS in patients aged 75 ± 13 years, survival at 1 year, 5 years, and 10 years was 62%, 32%, and 18%, respectively (10). Independent predictors of poor survival were advanced age, low LV ejection fraction, heart failure, elevated serum creatinine level, and systemic hypertension. Pharmacotherapy usually has no impact on survival.

Pellikka et al found that the probability of remaining symptom free without SAVR was 82%, 67%, and 33% at 1, 2, and 5 years, respectively (11). Aortic valve area and left ventricular hypertrophy predicted symptom development. The 1-, 2-, and 5-year probabilities of remaining free of surgery or cardiac death were 80%, 63%, and 25%, respectively. Multivariate predictors of all-cause mortality were age (hazard ratio [HR], 1.05; P<0.0001), chronic renal failure (HR, 2.41; P=0.004), inactivity (HR, 2.00; P=0.001), and aortic valve velocity (HR, 1.46; P=0.03). Sudden death without preceding symptoms occurred in 4.1% of the un-operated patients. Patients with peak velocity > or =4.5 m/s had a higher likelihood of developing symptoms (relative risk, 1.34) or having surgery or cardiac death (relative risk, 1.48).

In a meta-analysis of 4 retrospective studies, patients with severe asymptomatic AS had 3.5-fold higher rate of all-cause death with a watchful-waiting strategy compared with SAVR (12). There was substantial heterogeneity between the pooled studies and older, sicker patients with significant co-morbidities were more likely to be in the conservative group.

All of above studies were however confined to the general population groups. Data from PARTNER1 cohort B (standard treatment versus TAVI for severe AS) in a high surgical risk population (mean age 83.2 years, Society of Thoracic Surgeons Predicted Risk of Mortality 11.7%, corresponding mean logistic EuroSCORE of 28.4) similar to this study showed a dismal survival of 49.3% at 1 yr, 32.4% at 2 yrs, 19.1% at 3 yrs and 6.4% at 5 yrs in the standard treatment arm of the trial (13). Mean survival was 31 months in the TAVI group versus 11.7 months with conservative treatment.

Comparison with these studies may not be strictly appropriate for our analysis. These studies included patients where SAVR was the initial interventional modality against conservative management. Our study however considers the question of conservative management versus rSAVR in patients who have previously been turned down for SAVR and then again for TAVI based on technical factors or their high risk profile. In an analysis similar to this study, Subramanianian et al looked at a cohort of 75 patients to evaluate the triage process by examining the outcomes for elderly patients screened for TAVI but who subsequently underwent AVR (14). Their mean age was 80.4±3.6 years with a mean left ventricular ejection fraction of 55±16%, and mean logistic EuroSCORE of 13±7%. Hospital mortality was 1.3% with cumulative survival of 88.5%, 87.1% and 72.7% at 6, 12, and 36 months respectively. Postoperative morbidity included permanent stroke in 2.5%, respiratory failure in 11% and pacemaker implantation in 2.5%.

SAVR may be considered too high risk and refused at the initial surgical referral based on factors like cognitive impairment, muscle wasting, frailty, malnutrition, excess alcohol intake, liver cirrhosis and reduced life expectancy due to age and other co-morbidities. None of these factors are captured by the risk scoring systems in SAVR or TAVI. TAVI itself has a number of limitations that would warrant rSAVR after careful consideration. Technical reasons for refusal of TAVI related to bicuspid valves, annulus asymmetry, degree of aortic valve calcification, small root (not requiring root enlargement), low lying coronary ostia or associated aorto-mitral calcific shelves per-se should not in themselves increase the technical risk of rSAVR. However other factors like multiple procedures, peripheral vascular disease and vascular inaccessibility, severe calcifications of root, ascending aorta or arch, central and peripheral vascular aneurysms of the aorta and its main branches and patient factors related to old age, frailty, cognitive impairment and dementia can significantly increase the complexity, risk and postoperative management of rSAVR. Hernandez-Vaquero showed that in patients > 75yrs who underwent SAVR and survived the operation, life expectancy and survival rates were similar to that of the general population (HR 1.07, 95% CI 0.94-1.22) (15).

For truly asymptomatic patients with preserved ventricular function, there is a 1-1.5% risk of sudden cardiac death/year that justifies surgery in institutions with operative mortality of less than 1% (16-18). However these patients develop symptoms more often than they suddenly die. In a cohort of asymptomatic patients with severe AS and trans-valvular peak velocities >5.0 m/s and preserved LV function, 6-year cardiac and all-cause mortality rates were 0% and 2±1% in the SAVR group and 24±5% and 32±6% in the conventional treatment group, respectively (P<0.001) (19). After propensity matching, the risk of all-cause mortality was significantly lower in the operated group than in the conventional treatment group (hazard ratio, 0.135; 95% confidence interval, 0.030 to 0.597; P=0.008). Predictors of poor outcome are age, peak velocity> 5.0 m/s, progression of gradients, response to exercise testing and B-type natriuretic peptide levels.

For high risk cases where TAVI is not suitable, conservative management may avoid the morbidity of surgery. Stress testing if feasible, may be helpful to segregate asymptomatic patients with contractile reserve from the false negative ones. Delay in intervention after discussion at a TAVI-mdt for both TAVI and rSAVR for false negative symptoms is itself associated with a worse outcome.

These results might not reflect the practice in other centres and therefore need to be taken in context and interpreted cautiously. The all-comers mortality for first time SAVR has been consistently below 0.5%/ year for over a decade now at our centre and 2.2% for octogenarians over last 2 decades (20). The STS database reports a 30 day all-cause mortality of 1.9% (all risk categories inclusive, 2018) for isolated aortic valve replacements which is almost 4 times our reported mortality (21). This would be much higher for centres in the upper centiles of the mortality range. Even after re-evaluation of co-morbidities, careful considerations and re-appraisal of surgical risk, consultations with patients, their families and other clinicians, rSAVR could be offered to only a fifth of these patients found unsuitable for TAVI. There may have been a selection bias in the evaluation of this cohort of very high risk patients. With expanding indications for TAVI which involve even low to intermediate risk patients now, there is also the possibility of overzealous TAVI referrals. This is however unlikely in TAVI programs in the UK with limitations of funding and capacity. Just over half of the referred patients were accepted for TAVI in our program. Although the reasons for denial of TAVI were classed as technical/procedural and clinical/patient related, the high surgical risk was still the common denominator between the 2 groups. An important patient insight from this study is also that only 3.2% of the patients voluntarily refused further surgical intervention and opted for conservative management after being declined for TAVI despite consultations and communication of perceived high surgical/clinical risk by the surgical team.

There is the potential option of minimally invasive aortic valve replacement and use of sutureless valves in this cohort of patients to reduce the operative morbidity of surgery and help with faster postoperative recuperation and return to normal activity. Our study did not employ any of these techniques.

rSAVR can offer hope for amelioration of symptoms of breathlessness, feeling of wellbeing and confidence, reduced hospital admission episodes, better quality of life, independence and improved survival towards the end of their lives in a cohort of carefully selected, very high risk, elderly patients that are unsuitable for TAVI. .

**Limitations**

This is a retrospective analysis and therefore does not adequately balance the study groups for comparison or correct for inherent selection biases for rSAVR patients. TAVI case volumes were limited by capacity and funding in the program for many years so there may be a selection bias for the TAVI declined cases. The number of patients for subgroup survival analysis was small so may not be entirely representative. Although deaths were fully captured from the NHS digital tracking and linkages to GP medical records, hospital readmission episodes would not have been adequately captured by virtue of our wide multisource referral base. The risk scoring system underscores the perceived clinical/surgical risk related to frailty and age in these very high risk study groups. These are single centre results from a high volume, academic centre of excellence with a very low historical institutional mortality for isolated SAVR. These results and conclusions therefore may not be representative of wider cardiac surgical practice in other centres.

**CONCLUSION**

rSAVR should be considered in elderly high surgical risk patients who are unsuitable for TAVI, in centers with low operative mortality. rSAVR may be superior to conservative management in carefully selected patients.

*Ethical approval - SEV/0029, 24.10.2018*

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*Disclosures and conflicts of interest*

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**Tables**

Table 1. Demographics for patients that underwent reconsidered Surgical Aortic Valve Replacement (rSAVR)

Table 2. Reasons for denial of transcatheter aortic valve implantation (TAVI) after multidisciplinary team discussion

Table 3. Outcomes of reconsidered Surgical Aortic Valve Replacement (rSAVR)

Table 4. Cox proportional hazards model for long term survival (rSAVR and conservative management)

Supplementary Table 1 – Operative characteristics of reconsidered Surgical Aortic Valve Replacement (rSAVR) group

**FIGURE LEGENDS**

Figure 1. STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) data flow chart for the study for cases and controls discussed at the Transcatheter Aortic Valve Implantation multidisciplinary meeting. *TAVI – transcatheter aortic valve replacement, rSAVR - reconsidered Surgical Aortic Valve Replacement.*

Figure 2. Overall survival

Figure 3. Survival by non-octogenarians (A) and octogenarians (B)

Figure 4. Survival by clinical (A) and technical (B) causes of denial for transcatheter aortic valve replacement

Figure 5. Survival by low (A) and high-risk\ multiple co-morbidities (B) candidate as a cause of denial of transcatheter aortic valve replacement