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Surgical aortic valve replacement in the era of transcatheter aortic valve implantation: a review of the UK national database

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ABSTRACT

Objectives To date the reported outcomes of surgical aortic valve replacement (SAVR) are mainly in the settings of trials comparing it with evolving transcatheter aortic valve implantation. We set out to examine characteristics and outcomes in people who underwent SAVR reflecting a national cohort and therefore 'real-world' practice.

Design Retrospective analysis of prospectively collected data of consecutive people who underwent SAVR with or without coronary artery bypass graft (CABG) surgery between April 2013 and March 2018 in the UK. This included elective, urgent and emergency operations. Participants' demographics, preoperative risk factors, operative data, in-hospital mortality, postoperative complications and effect of the addition of CABG to SAVR were analysed.

Setting 27 (90%) tertiary cardiac surgical centres in the UK submitted their data for analysis.

Participants 31 277 people with AVR were identified. 19 670 (62.9%) had only SAVR and 11 607 (37.1%) had AVR +CABG.

Results In-hospital mortality for isolated SAVR was 1.9% (95% CI 1.6% to 2.1%) and was 2.4% for AVR+CABG. Mortality by age category for SAVR only were: <60 years=2.0%, 60–75 years=1.5%, >75 years=2.2%. For SAVR+CABG these were; 2.2%, 1.8% and 3.1%. For different categories of EuroSCORE, mortality for SAVR in low risk people was 1.3%, in intermediate risk 1% and for high risk 3.9%. 74.3% of the operations were elective, 24% urgent and 1.7% emergency/salvage. The incidences of resternotomy for bleeding and stroke were 3.9% and 1.1%, respectively. Multivariable analyses provided no evidence that concomitant CABG influenced outcome. However, urgency of the operation, poor ventricular function, higher EuroSCORE and longer cross clamp and cardiopulmonary bypass times adversely affected outcomes.

Strengths and limitations of this study

► This is a large study of consecutive participants who have undergone surgical aortic valve replacement ±coronary artery bypass graft surgery in the UK, reporting contemporary outcomes.

► This study includes people of all age groups and risks factors, and elective as well as urgent and emergency operations.

► The results are of in-hospital mortality and complications and longer-term follow-up data are not available.

Conclusions Surgical SAVR±CABG has low mortality risk and a low level of complications in the UK in people of all ages and risk factors. These results should inform consideration of treatment options in people with aortic valve disease.

BACKGROUND

Aortic valve disease, especially aortic stenosis affects 5% of the population and 3.9% of those between the ages of 70 and 79 and nearly 10% of those above the age of 80.[1] Severe aortic stenosis when untreated has a risk of death of 50% at 2 years.[2] Conventionally the gold standard of treatment has been surgical aortic valve replacement (SAVR). However, the role of transcatheter aortic valve implantation (TAVI) has evolved in recent years. TAVI was first introduced in 2002, initially being performed in high risk inoperable patients.[3] The original Placement of Aortic Transcatheter Valves (PARTNER)

trial demonstrated a significant reduction in mortality, repeat hospitalisation and cardiac symptoms compared with inoperable patients who had only medical therapy.[4] The original PIVOTAL study also demonstrated significantly higher survival at 1 year in high-risk patients who underwent SAVR.[5]

The role of TAVI is being extended to lower risk and younger patients based on recent trials comparing SAVR with TAVI.[6 7] Several studies suggest there has been a change in demographics and types of surgical valves used since the advent of TAVI.[8–10] There has been a trend of increased use of tissue valves and a decrease in the use of mechanical valves in recent years.[11] This may be due to the evolution of TAVI practice whereby younger patients can have a tissue valve with the view that they have a TAVI valve in the future when the tissue valve has deteriorated, so called valve-in-valve.[12 13]

The series in the literature reporting outcomes of SAVR are generally unit based.[9 14] Also, people with aortic valve disease are given information about the outcomes of SAVR which may be out of date and incorrectly extrapolated from smaller studies. There is a lack of contemporary national data to assess the outcomes of SAVR (mortality and complications), and to demonstrate the trend in use of prosthetic valves which would inform people with aortic valve disease better. There are some perceived complications of surgery that may be understood by referring general practitioners and cardiologists to be prohibitive risks for surgery.

In order to inform practitioners, people with aortic valve disease and the cardiac surgical community, we set out to examine the results of contemporaneous SAVR in a multicentre study of UK cardiac surgical units, in the era of TAVI. In addition, we summarise and interpret some of the more recent trials on the management of aortic valve disease.

METHODS

Data

This is an analysis of prospectively collected data of people who underwent SAVR±coronary artery bypass graft (CABG) surgery between April 2013 and March 2018 in the UK and Republic of Ireland. Anonymised data were submitted to the Society for Cardiothoracic Surgery of Great Britain & Ireland for 27 of the 30 units and then stored in a secure database. This period was chosen to reflect fairly contemporary practice and also the data is submitted in March every year. The data are collected by each unit, validated and then submitted to the National Institute of Cardiovascular Outcome Research (NICOR). It took approximately 9 months to collect, validate and clean all the data. The outcome measures recorded are based on strict definitions provided by NICOR to provide uniformity.

Only participants who had had first time surgery, SAVR±CABG were included. All participants immaterial of their risk for surgery, people of all age groups and

risk factors were included. Those who required other concomitant procedures like replacement of parts of the aorta, aortic root enlargement, other valve procedures and redo surgery were excluded.

Pre-operative risk factors and operative features

Baseline demographic data; significant medical history such as diabetes, renal dysfunction, hypertension or stroke; predominant aortic valve pathology (stenosis or regurgitation or mixed valve disease) and preoperative left ventricular ejection fraction (LVEF) were collected. EuroSCORE is the risk stratification model used in the UK. Logistic EuroSCORE was collected as well as EuroSCORE II where available. The latter was only used since 2017 and therefore not available for all participants. Logistic EuroSCORE was divided into three categories: <3%, 3%–6%, >6%.

LVEF was divided into three categories: good (EF >50%), moderate (EF 30%–50%) and poor (EF <30%). Transient ischaemic attack was defined as any neurological symptoms lasting <24 hours. Stroke was defined as new neurological dysfunction persisting >24 hours. Operative data including operative urgency: elective, urgent and emergency/salvage were recorded. Elective was defined as when the person was admitted from home, urgent meaning that the person was admitted with an urgent condition and required surgery during the same hospital admission, emergency and salvage meaning that surgery was required within 24 hours of admission and/or the person was in extremis. Other parameters including cardiopulmonary bypass (CPB) time, cross clamp time (CCT), type of valve implanted as well as concomitant CABG surgery performed were also collected.

Postoperative outcomes

Postoperative complication data were collected with the main focus being in-hospital mortality, new stroke, return to theatre for bleeding, deep sternal wound infection and duration of postoperative hospital stay.

Statistical analysis

Once the records for all participants were collated and the data cleaned, each factor was summarised using descriptive methods. Categorical variables are presented as N (%) and continuous variables are presented as median (IQR). New strokes were recoded to be either no stroke or any cerebrovascular accident (transient or permanent). The natural log of postoperative length of stay (days) was used due to positive skewed distribution of this variable. Univariate models were used, logistic regression for binary outcomes and linear regression for continuous outcomes, to assess the impact of the key explanatory variables. In these models, a two-tailed p <0.05 was considered significant. The population analysed included all the participants with data collected, with results checked in the subset who had SAVR only (without CABG). Building on this, a multivariable model with all key variables in the model to assess which had the most impact on each of

Table 1 Multivariable modelling of postoperative outcomes using preoperative and operative factors

Predictor	Missing	Category	Hospital mortality		Return to theatre for bleeding		New stroke		Post-operative length of stay (days)	
			OR	P value	OR	P value	OR	P value	OR	P value
Age (years)	7.9%	Per unit increase	1.03 (1.02–1.04)	<0.001	1.01 (1.00–1.01)	0.006	1.02 (1.01–1.03)	0.001	1.00 (1.00–1.00)	<0.001
Gender	10.3%	Female	–		–		–		–	
		Male	0.63 (0.51–0.77)	<0.001	1.18 (1.02–1.36)	0.026	1.02 (0.80–1.29)	0.89	0.94 (0.93–0.96)	<0.001
LVEF	3.1%	Good (>50%)	–		–		–		–	
		Moderate (30%–50%)	1.48 (1.18–1.85)	0.001	1.08 (0.91–1.27)	0.38	1.13 (0.86–1.48)	0.38	1.08 (1.06–1.10)	<0.001
		Poor (<30%)	1.90 (1.36–2.69)	<0.001	1.10 (0.82–1.48)	0.53	0.78 (0.44–1.38)	0.40	1.07 (1.03–1.11)	0.001
EuroSCORE logistic	12.1%	Per unit increase	1.02 (1.02–1.03)	<0.001	1.01 (1.00–1.01)	0.16	1.00 (0.99–1.02)	0.30	1.01 (1.01–1.01)	<0.001
Operative urgency	0.02%	1.Elective	–		–		–		–	
		2.Urgent	1.63 (1.30–2.00)	<0.001	1.26 (1.08–2.00)	0.002	1.08 (0.83–1.41)	0.55	1.18 (1.16–1.20)	<0.001
		3.Emergency	6.87 (4.70–10.16)	<0.001	2.22 (1.51–3.26)	<0.001	7.65 (5.00–11.70)	<0.001	1.78 (1.67–1.90)	<0.001
		4.Salvage	11.79 (5.73–24.27)	<0.001	1.51 (0.56–4.02)	0.41	4.38 (1.47–13.1)	0.008	1.25 (1.07–1.46)	0.006
Cumulative bypass time (mins)	2.4%	Per unit increase	1.02 (1.01–1.02)	<0.001	1.00 (1.00–1.01)	<0.001	1.00 (1.00–1.01)	<0.001	1.00 (1.00–1.00)	<0.001
Cumulative cross clamp time (mins)	2.5%	Per unit increase	0.99 (0.99–0.99)	<0.001	1.00 (1.00–1.00)	0.23	1.00 (0.99–1.00)	0.58	1.00 (1.00–1.00)	0.78
CABG	0%	No	–		–		–		–	
		Yes	1.15 (0.93–1.42)	0.20	1.07 (0.93–1.24)	0.33	1.12 (0.88–1.42)	0.37	1.03 (1.00–1.05)	<0.001

CABG, coronary artery bypass graft surgery; LVEF, left ventricular ejection fraction.

the outcomes was created. Stata/MP V.15.1 (StataCorp) was used for all analyses. Multiple imputation of missing data was not performed. The missingness was mostly negligible. There was no missing mortality and the data is shown in table 1.

Patient and public involvement

Patients and public were involved in the original design of the database.

RESULTS
Descriptive analysis

In total 31277 patients were included. Of these, 19670 (62.9%) had only SAVR and 11607 (37.1%) had SAVR +CABG. There were 14.4% below the age of 60, 46.9% between 60 to 75% and 36.7% older than 75 years with 7.9% missing age data. There were 1.9 times more males than females (10.3% missing).

Regarding preoperative risk factors, 75.2% had good LVEF, 17.3% had moderate and 4.3% had poor LVEF. 74.3% of the operations were elective, 24% were urgent and 1.7% were emergency or salvage operations.

Logistic EuroSCORE had a median of 1.83 with an IQR of 0.06–6.0. In total, 50% of patients were classified as low risk (<3%), 16% as medium risk (3—6%) and 22% high risk (>6%). 3792 patients (12.1%) were missing data. The median EuroSCORE II was 1.95 (IQR 0.67–4.8) although with 56.5% with missing data, as this was introduced into the database in 2017. The median CPB time was 104 min (IQR 82–135) and CCT was 79 min (IQR 61–101).

For valve implant replacement type, 70% had a tissue valve, 12.2% a mechanical valve and 0.2% had homograft or autograft valves. For 17.3% the entry for valve type was unclear. The ratio of mechanical implant to bioprosthetic implant use has remained stable over time.

Overall mortality was 2.4% (95% CI 2.2% to 2.6%) and mortality for isolated SAVR for all participants was 1.9% (95% CI 1.6% to 2.1%). The mortality figures analysed for different age ranges and for categories of EuroSCORE are shown in table 2.

Table 2 Mortality (%) for different categories of age and EuroSCORE

Euroscore	N (%)	SAVR+CABG (mortality %)	SAVR (mortality %)
<3%	15619 (50.0)	2.0	1.3
3%–6%	5020 (16.1)	0.9	1.0
>6%	6846 (21.9)	4.4	3.9
Age (years)		**SAVR+CABG**	**SAVR**
<60		2.2	2.0
60–75		1.8	1.5
>75		3.1	2.2

CABG, coronary artery bypass graft; SAVR, surgical aortic valve replacement.

Overall, 3.9% (3.6% in SAVR only) of participants had resternotomy for postoperative bleeding or tamponade, 0.04% (0.06% in SAVR only) had reoperation for valvular problems (significant paravalvular leak and early endocarditis), 0.7% (0.6% SAVR only) had reoperation for other cardiac problems, 0.2% (0.15% for SAVR only) had rewiring of sternum for sterile wounds and 0.14% (0.06% for SAVR only) had rewiring of sternum for infection. Transient ischaemic attack occurred in only 0.6% and 1.1% had a stroke (no missing data).

Median postoperative length of stay was 7 days (IQR: 6–11) in those with SAVR only and 8 days (IQR: 6–12) in all patients.

The number of bypass grafts was not analysed due to concerns about inconsistent reporting of data describing the number of grafts.

When comparing the two subsets of patients, the characteristics of those with SAVR alone were broadly similar to those with SAVR+CABG. In SAVR alone there were more people aged <60 years (19.3% vs 6.2%), but less people were older than 75 (30.1% vs 43%). A higher proportion of those with SAVR+CABG were male (68% vs 54%). Bypass time was an average of 37 min shorter and CCT 27 min in the SAVR alone group. Among those with only SAVR the mechanical valve usage was greater, at 16% vs 7%.

Regression analysis
Univariable

Taken in isolation, all preoperative risk factors were associated with an increased odds of death, as was addition of CABG. The same pattern was observed when analysing the need for reoperation or surgery, with all explanatory variables indicative of a worse outcome without taking into account any others. For new stroke only age, EuroSCORE, operative urgency, EF and cumulative bypass and CCT affected a negative outcome (but not gender), as did CABG. All factors predicted a longer postoperative length of stay, including CABG.

As a sensitivity analysis, age categories were also assessed. When included as a continuous variable, age was significant both on its own and in all the multivariable models. All participants were categorised into <60, 60–75 and >75 years of age. Those 60–75 were at a lower odds of death in comparison to those <60 (OR 0.71, 95% CI 0.53 to 0.95, p=0.021) with no difference in those >75 (OR 1.09, 95% CI 0.82 to 1.45) in the AVR alone group. These findings were different in the SAVR+CABG group, with no significant difference in those 60–75 (OR 0.81, 95% CI 0.64 to 1.03) but an increased risk in those >75 (OR 1.09, 95% CI 1.12 to 1.76, p=0.004).

Multivariable analyses

Analysis of postoperative outcomes using multivariable models including all preoperative and operative factors are shown in table 1. This demonstrated that age (OR 1.03 (95% CI 1.02 to 1.04), p<0.001), moderate EF (OR 1.48 (95% CI 1.18 to 1.85), p<0.001), poor EF (OR 1.90

(95% CI 1.36 to 2.69), p<0.001), logistic EuroSCORE (OR 1.02 (95% CI 1.02 to 1.03), p<0.001), urgent operation (OR 1.63 (95% CI 1.30 to 2.00, p<0.001), emergency surgery (OR 6.87 (95% CI 4.70 to 10.16), p<0.001) and longer CPB times affected mortality (OR 1.02 (95% CI 1.01 to 1.02), p<0.001).

When all other variables were taken into account CABG was not significantly associated with an increase in the risk of death (OR 1.15 (95% CI 0.93 to 1.42), p=0.20).

Older age, (OR 1.01 (95% CI 1.00 to 1.01), p<0.006), longer CPB time (OR 1.00 (95% CI 1.00 to 1.01), p<0.001), urgent (OR 1.26 (95% CI 1.08 to 2.00), p<0.002) and emergency surgery (OR 2.22 (95% CI 1.51 to 3.26), p<0.001) were significant factors in identifying people requiring return to theatre for bleeding. Again, CABG did not affect the odds of returning to theatre (OR 1.07 (95% CI 0.93 to 1.24), p=0.33).

Factors affecting stroke were age, (OR 1.02 (95% CI 1.01 to 1.03), p<0.001), emergency (OR 7.65 (95% CI 5.00 to 11.70, p<0.001) or salvage surgery (OR 4.38 (95% CI 1.47 to 13.1) p=0.008) and CPB times (OR 1.00 (95% CI 1.00 to 1.01), p<0.001). As in the other outcomes, addition of CABG did not affect the outcome (OR 1.12 (95% CI 0.88 to 1.42), p=0.37).

Age, male gender, moderate and poor EF, operative urgency, higher logistic EuroSCORE and cumulative bypass time significantly all affected postoperative length of stay.

DISCUSSION

This study reports contemporary results of SAVR and SAVR + CABG in the UK, reflecting real world practice, reporting an overall mortality of 1.9% and 2.4%, respectively. We have shown a low mortality and complication rate for all comers following surgery in people requiring SAVR or SAVR + CABG. The complications were low with 3.9% resternotomy for bleeding, 0.04% reoperation for valvular problems and 1.1% stroke. Surprisingly, having accounted for other risk factors, addition of CABG did not adversely affect the outcomes.

The strengths of the study include its large number of participants, no exclusion of urgent and emergency/salvage cases, and inclusion of all risk participants. The limitations are that three centres were unable to take part, possible coding errors in using large databases, lack of detailed echocardiographic data on valve annular size and presence or absence of preoperative infective endocarditis which can adversely affect outcomes. In addition, the results are in-hospital mortality and complications and the database lacks longer follow-up information.

Data from the current study are consistent with other large international studies. Data from the US Society of Thoracic Surgeons (STS) database demonstrated in-hospital mortality for isolated SAVR of 2.5% and incidence of stroke of 1.5%.[15] A recent analysis of the Japanese Cardiovascular Surgery database which assessed the outcomes of patients undergoing SAVR over a 8-year period has demonstrated a similar in-hospital mortality of 2%.[16] They also demonstrated a reduction in mortality over time, despite increasing surgical risk. The age of the patients in our study is lower than some of the trials of SAVR and TAVI. This is probably due to the selection criteria in these trials where older patients were selected.

We had set out to analyse the results of SAVR in the UK to inform practitioners treating people with aortic valve disease and inform people with this condition in an era where other therapies for management of aortic valve disease are evolving with expanding indications. Although the current study did not examine people who received TAVI, we discuss the various trials of SAVR and TAVI reported in the context of the literature and compare them with the results of the current study.

In tables 3–5, the demographics, procedural details and outcomes of the current study are compared with the respective sub-groups of the published trials. Table 5 shows low mortality and complication rate in the participants of this study following surgery in people who required SAVR or SAVR+ CABG. The trials comparing AVR and TAVI have enrolled and classified patients according to the risk of surgery, in particular the more recent trials.[6 7] The most commonly used surgical risk stratification score is the STS risk score, although this scoring system has been validated in the US population. We have used Euro-SCORE and shown that mortality is low in all categories of risk.

There are several recent trials comparing SAVR with TAVI. A meta-analysis of six of these trials performed by Barili et al reported that mortality was affected by the treatment modality with a time-varying effect: TAVI was related to better survival in the first months after implantation whereas, after 40 months, it was a risk factor for all-cause mortality.[17] The NOTION trial, which compared outcomes of patients estimated to have low surgical risk who underwent either TAVI or SAVR demonstrated similar early mortality results, with mortality of 2.1% in TAVI group vs 3.7% in the SAVR group, p=0.380.[18] The PIVOTAL trial of low-risk patients also reported similar results between those who underwent TAVI compared with SAVR, with early mortality of 0.5% in TAVI group and 1.3% in SAVR.[7] In addition, the 5-year results of the PARTNER 2 study, comparing TAVI versus SAVR in intermediate surgical risk demonstrated no significant difference in the incidence of death or stroke at 5 years following SAVR or TAVI.[19] The mortality in the intermediate EuroSCORE risk category of the current study was 1.0% for SAVR only and 0.9% for SAVR + CABG. PARTNER 3, however, demonstrated significantly lower mortality in the TAVI group compared with SAVR (1% vs 2.5%, p=0.01) at 1 year.[6] An observational study of 7618 patients comparing SAVR with TAVI at 5 years showed, however, that in a real-world population with low and intermediate risk, SAVR was associated with lower mortality and major adverse cardiac events, although this was with first generation TAVI devices.[20]

Table 3 Baseline characteristics in the current study (UK SAVR) and those in other national registries and recent trials comparing SAVR with TAVI

Characteristic	UK SAVR SAVR N=31 277	Thourani et al[15] SAVR N=141 905	Tokuda et al[16] SAVR N=20 514	Partner 2A[22] SAVR N=1021	TAVI N=1011	Partner 3[6] SAVR N=454	TAVI N=496	Evolut[7] SAVR N=678	TAVI N=725	Pivotal[5] SAVR N=357	TAVI N=390	NOTION[18] SAVR N=135	TAVI N=145
Age (mean±SD)	70.1±11.5	67.6±13.4	NR	81.7±6.7	81.5±6.7	73.6±6.1	73.3±5.8	73.6±5.9	74.1±5.8	83.2±6.4	83.1±7.1	79±4.7	79.2±4.9
% Male	59	58	51.1	54.8	54.2	71.1	67.5	66.2	64	52.4	53.1	53.8	52.8
BMI (kg/m²)	28.9±5.5	29.3±6.6	NR	28.3±6.2	28.6±6.2	30.3±5.1	30.7±5.5	NR	NR	NR	NR	NR	NR
NYHA class III/IV (%)	44.4	38.4	15.9	76.3	77.3	23.8	31.2	28.4	25.1	86.9	85.7	45.5	48.6
Logistic EuroSCORE (%)	4.3±7.3	NR	NR	NR	NR	1.5±0.9*	1.5±1.2*	NR	NR	18.6±13.0	17.7±13.1	8.9±5.5	8.4±4.0
Diabetes mellitus (%)	22.2	25.5	NR	34.2	37.7	30.2	31.2	30.5	31.4	45.4	34.9	20.7	17.9
Chronic kidney disease (%)	3.1	NR	NR	5.2	5.0	0.2	0.2	0.1	0.4	12.8	12.2	0.7	1.4
Hypertension (%)	64.9	NR	NR	NR	NR	NR	NR	82.6	84.8	96.1	95.1	76.3	71.0
Peripheral vascular disease (%)	8.7	9.2	NR	32.9	27.9	7.3	6.9	7.5	8.3	41.7	41.1	6.7	4.1
Previous stroke (%)	8.2	12.6	0.13	31	32.1	5.1	3.4	10.2	11.8	14.0	12.6	16.3	16.6
COPD (%)	13.4	NR	13.6	30.0	31.8	6.2	5.1	15.0	18.0	9.0	13.3	11.9	11.7
LV ejection fraction (%)	53.2	54.9±12.9	NR	55.3±11.9	56.2±10.8	66.2±8.6	65.7±9.0	61.9±7.7	61.7±7.9	NR	NR	NR	NR
Coronary artery disease (%)	37.1	NR	NR	66.5	69.2	28.0	27.7	NR	NR	75.9	75.4	NR	NR
Atrial fibrillation	10.3	NR	5.6	35.2	31.0	18.8	15.7	14.5	15.4	45.9	40.9	25.6	27.8
Permanent pacemaker	1.9			12.0	11.7	2.9	2.4	3.8	3.2	21.3	23.3	4.4	3.4

*EuroSCORE II reported only.
BMI, body mass index; COPD, chronic obstructive pulmonary disease; LV, left ventricular; NR, not reported; NYHA, New York Heart Association classification; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Table 4 Operative characteristics in the current study (UK AVR) and those in other national registries and recent trials comparing SAVR with TAVI

Characteristic	UK SAVR SAVR N=31277	Thourani et al[15] SAVR N=141905	Tokuda et al[16] SAVR N=20514	Partner 2A[22] SAVR N=1021	Partner 2A[22] TAVI N=1011	Partner 3[6] SAVR N=454	Partner 3[6] TAVI N=496	Evolut[7] SAVR N=678	Evolut[7] TAVI N=725	PIVOTAL[5] SAVR N=357	PIVOTAL[5] TAVI N=390	NOTION[18] SAVR N=135	NOTION[18] TAVI N=145
Operative urgency													
Elective (%)	74.3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Urgent (%)	24	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Emergency/salvage (%)	1.7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Concomitant CABG (%)	37.1	NR	NR	NR	–	12.8	–	13.6	–	4.8	–	1	–
Staged PCI	–	NR	NR	–	NR	–	6.5	–	6.9	–	0.3%	NR	0
Cross clamp time (minutes)	79.0	77.0±28.5	NR	NR	–	74.3±27.78	–	68.7±29.0	–	74.0±31.4	–	NR	NR
Cardiopulmonary bypass time (minutes)	104	104.9±39.1	NR	NR	–	97.7±33.75	–	93.4±40.2	–	104.0±45.8	–	NR	NR
Procedure time (minutes)	NR	NR	NR	NR	NR	208.3±62.1	58.6±36.5	276.6±79.5	148.2±55.1	221±84.8	60.4±35.3	177.2±39.8	90.3±38.6

AVR, aortic valve replacement; CABG, coronary artery bypass graft surgery; NR, not reported; PCI, percutaneous coronary interverntion; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Table 5 Outcomes following SAVR in the current study (UK AVR) and those in other national registries and recent trials comparing SAVR with TAVI

Outcome	UK SAVR SAVR N=31277	Thourani et al[15] SAVR N=141905	Tokuda et al[16] SAVR N=20514	Partner 2A[22] SAVR N=1021	Partner 2A[22] TAVI N=1011	Partner 3[6] SAVR N=454	Partner 3[6] TAVI N=496	Evolut[7] SAVR N=678	Evolut[7] TAVI N=725	PIVOTAL[5] SAVR N=357	PIVOTAL[5] TAVI N=390	NOTION[18] SAVR N=135	NOTION[18] TAVI N=145
In-hospital death/30-day mortality (%)	1.9	2.5	NR	8.0	6.1	1.1	0.4	1.3	0.5	4.5	3.3	3.7	2.1
Stroke (%)	1.1	NR	1.6	6.1	5.5	2.4	0.6	3.4	3.4	6.2	4.9	3.0	1.4
Reoperation for bleeding* (%)	3.6	3.9	3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Post procedure bleeding* (%)	–	NR	NR	43.4	10.4	11.9	1.2	7.5	2.4	69.5	41.7	11.3	20.9
Deep sternal wound infection (%)	0.14	0.3	1.1	NR	–	NR	–	NR	–	NR	–	NR	–
Length of hospital stay (days)	7	7.9±7.2	NR	NR	–	7.0	3.0	NR	NR	NR	NR	8.9±6.2	12.9±11.6
New pacemaker implantation (%)	1.6	NR	NR	6.9	8.	4.0	6.5	6.1	17.4	7.1	19.8	1.6	34.1

*Reoperation for bleeding and postoperative bleeding were major and required intervention.
AVR, aortic valve replacement; NR, not reported; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Role of coexistent coronary artery disease and its management

Sixty per cent of patients with aortic valve disease undergoing SAVR and 65% of those undergoing TAVI have coexisting coronary artery disease.[21] In our series, 37% had coexistent coronary artery disease and underwent concomitant CABG. The addition of CABG did not adversely affect outcomes. The USA[15] and Japanese[16] series did not look into concomitant CABG. The percentage of concomitant CABG in our series is higher than the trials of SAVR/TAVI. This probably reflects the selection criteria in the latter. In PARTNER 2, although both groups had a similar number with coexistent coronary artery disease, 14.5% of the SAVR group had concomitant CABG compared with 3.9% of the TAVI group who had percutaneous intervention (table 4).[22] SAVR may, therefore, be the preferred treatment modality in those with aortic stenosis and multivessel coronary artery disease requiring revascularisation.

Treatment of coronary artery disease in TAVI patients may require more than one hospital admission and can often result in incomplete revascularisation and its consequent increased morbidity and mortality. A meta-analysis by Sankaramangalam et al demonstrated that while there was no increase in mortality in patients with coronary artery disease who underwent TAVI at 30 days, there was a significant increase in mortality at 1 year following TAVI in these patients.[23] The economic costs of readmission after TAVI have been demonstrated to be higher than in those who are readmitted after surgery and so untreated coronary disease which later requires readmission will have cost implications.[24 25] Surgery has the advantage of addressing all the pathology with one operation.

Durability and choice of prosthetic valves

In choosing the technique of treatment for aortic valve disease, life expectancy of the person and durability of the valve need to be considered. Ideally, the prosthetic valve should be durable for the person's lifetime. Both of these are related to person's age. In the UK, a 50-year-old woman has a life expectancy of 34 years and a 70-year-old man a life expectancy of 14 years.[26]

The durability of bioprosthetic valves is well documented in the surgical literature and is inversely proportional to person's age. Structural valve deterioration has been demonstrated to increase exponentially beyond 10 years following surgery.[27 28] Considering the UK life expectancy,[26] a 70-year-old man has a 5% risk of reoperation and a 50-year-old woman has a 30% chance of needing a second operation.

Surgery has the advantage of offering the patient a mechanical or a bioprosthetic valve. The option of a mechanical valve which is only available in surgical SAVR should not be overlooked especially in younger people. In the current study, we have shown a fairly consistent ratio of tissue to mechanical valve use. However, the reported literature shows that the number of mechanical valve implantations has reduced in comparison to bioprosthetic valves.[10] Mechanical valves are durable, with one group reporting 6.9% reintervention rate at 15 years vs 12.1% in those who underwent surgery with a bioprosthesis.[29] For this reason, it has been the most commonly considered prosthesis in those under the age of 60, as in our study where 60.2% of participants <60 years had a mechanical valve. Mechanical valves have the disadvantage of requiring anticoagulation, although, newer generations require a lower level of anticoagulation.[30] Whilst mechanical valves are more durable, this has to be balanced against the greater risk of bleeding.[29] At 15 years follow-up, Chiang et al also demonstrated no significant difference in survival and stroke between patients who underwent SAVR with mechanical vs bioprosthetic valve.[29] Another group demonstrated in the 50–70 years old cohort that survival at 5 years was higher in patients who had undergone SAVR with mechanical valve versus bioprosthesis and also demonstrated similar freedom from major bleeding events.[31]

Bicuspid aortic valve and aneurysm of the aorta

A significant number of patients requiring SAVR have bicuspid aortic valve, which has an incidence of 1%–2% in the general population and may present with aortic valve stenosis, regurgitation and ascending aortic aneurysm. The type of native aortic valve is not recorded in the database of our study. BAV may be present in up to 30% of patients undergoing SAVR.[32] Bicuspid aortic valve anatomy, larger annular size, bulky and asymmetric leaflet calcification and dilated ascending aorta all pose technical challenges to TAVI which are not prohibitive risk factors for surgery. In fact, associated pathology of aneurysms of the aortic root and ascending aorta can be treated at the time of SAVR with little additional risk.[33]

European guidelines recommend discussing people with aortic valve disease in a multidisciplinary setting referred to as Heart Team, comprising of a surgeon, a non-interventional and an interventional cardiologist.[34] This will allow the best treatment option to be put forward to the person.

CONCLUSIONS

SAVR with and without CABG has low mortality risk and a low level of complications in the UK in people of all ages and risk factors. Our study provides real-world experience of surgical results to improve understanding of the risks of surgery and decision making in a multidisciplinary team setting with heart team. The results of this study can be used by people with aortic valve disease, referring general practitioners, physicians, surgeons and policy-makers. Future studies need to address long-term follow-up including factors like quality of life which are currently not collected by the specialist centres.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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