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Survival and cause of death after isolated primary aortic valve replacement at Oslo University Hospital (2012–2021): a retrospective registry-based study

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ABSTRACT

Background The treatment of aortic valve disease has changed following the introduction of transcatheter aortic valve replacement (TAVR). Hence, the selection of patients for surgical aortic valve replacement (AVR) is changing. Thus, we aimed to study survival and causes of death following surgical AVR at a large Scandinavian Centre in the period 2012–21.

Methods Information about the surgical procedure, survival and cause of death was obtained from the National Norwegian Health Registries. The latest clinical information about the deceased patients was made available from the local hospitals and examined to evaluate the causes of death from The Norwegian Cause of Death Registry.

Results From 2012 to 2021, the number of surgical implantations of aortic valve bioprostheses (AVR(b)) and patient age at the time of surgery decreased. Outcomes were excellent, with 30-day survival of 98.6% following AVR(b) and 99.8% following AVR(m). 1-year survival after AVR(b) improved from 96.4% in the first half to 98.4% in the second half of the study period, probably due to a reduction of operative risk during the study period. Non-cardiovascular mortality was the most frequent cause of death, followed by cancer, cardiovascular and valve-related death. Deaths due to cerebral bleeding or stroke were the least frequent with 10-year estimators of 1.3% and 1.6% following AVR(m) and AVR(b), respectively. The inter-rater reliability between The Norwegian Cause of Death Registry and the journal information provided was moderate, with an unweighted Cohen's kappa of 0.56 (0.47–0.64).

Conclusions Valve-related death and death from cerebral bleeding or stroke was rare after surgical AVR. Survival was high and improved during the study period. Surgical AVR may be performed safely in low-risk patients.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Surgical aortic valve replacement (AVR) has been the gold standard for treating aortic valve disease. After the introduction of transcatheter AVR, patient selection to AVR has changed. When designing studies comparing these modalities, calculation of sample size, survival and complication rates may rely on older studies of surgical AVR.

WHAT THIS STUDY ADDS

⇒ This study presents survival and complication rates, as well as cause of death following surgical AVR in a recent cohort at a large Scandinavian Centre.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study may be helpful in estimating sample size in prospective studies of survival following aortic valve treatment, as well as providing results from everyday contemporary practice that may be a support in clinical decision-making.

INTRODUCTION

The treatment for aortic valve disease is evolving, as more patients are being treated with catheter-based techniques (TAVR).[1] Surgical aortic valve replacement (AVR) is currently performed in patients with severe aortic stenosis and low surgical risk or in patients who are poor candidates for TAVR, as well as in patients with severe aortic regurgitation. Open-heart surgery comes with inherent convalescence and more discomfort than a catheter-based procedure. Robust data on the risk of complications, as well as operative mortality and long-term survival, are useful when discussing treatment options. Hence, we wanted to study survival and causes of death in a 10-year cohort treated with isolated primary surgical AVR at Oslo University Hospital (2012–2021).

METHODS

Standard surgical AVR was defined as primary isolated implantation of a biological

Table 1 Demonstrates preoperative risk factors as proportions (%) or median (25-75 percentile) and missing values (%).

	AVR(b)	25–75 p	Missing (%)	AVR(m)	25–75 p	Missing (%)
Number	1300			596		
Age (years)	72	(67–77)	0.0	56	(49-61)	0.0
Female sex (%)	39		0.0	28		0.0
Urgency (%)	0.3		0.0	0.5		0.0
Extracardiac arteriopathy (%)	8.2		61.5	4.4		50.5
Previous cardiac surgery (%)	0		0.2	0		0.0
Chronic lung disease (%)	12.2		61.4	8.5		50.5
Critical preoperative state (%)	0.2		60.4	1.0		49.5
CCS class four angina (%)	1.4		72.9	0.5		69.1
Recent MI (%)	3.6		61.1	1.0		49.8
Surgery on thoracic aorta (%)	5.7		66.0	9.4		55.5
Left main stem stenosis (%)	0.5		9.3	0.0		11.9
Hypertonia (%)	56.8		1.1	41.2		1.8
Previous PCI (%)	9.2		12.5	6.1		11.4
MDT-meeting decision (%)	96.9		70.2	98.4		59.1
Poor mobility (%)	5.3		0.7	2.4		0.5
Active endocarditis (%)	0		0.2	0		0.7
Weight (kg)	80	(71–92)	1.4	85	(75–97)	1.2
Height (cm)	174	(166–180)	6.9	176	(70–181)	4.7
Preop creatinine (mmol/L)	82	(70–94)	66.2	77	(67–89)	55.0
NYHA class	3	(2–3)	16.9	2	(2–3)	13.9
CCS class	1	(0–2)	74.9	1	(0–2)	66.6
Euroscore	4	(4-10)	78.5	3	(2-3)	57.9
Euroscore II	1.3	(0.94–2)	68.4	0.8	(0.66–1.11)	59.2
Renal impairment (%)	19.0		5.5	11.2		5.7
Diabetes (%)	16.4		0.5	12.2		0.7
Reduced LV function (%)	20.4		62.3	15.8		52.2
Pulmonary hypertension (%)	18.2		68.7	9.3		58.6
Other than isolated CABG (%)	100		65.9	100		54.4
Arrhythmia (%)	15.5		66.3	9.5		56.0

Due to a revision in the registry mid-way through the study period, the variables with many missing values were only available for the last half of the study period. The proportion of missing values relates to the total number of cases.
AVR, aortic valve replacement; CABG, coronary artery bypass grafting; CCS, The Canadian Cardiovascular Society; LV, left ventricular; MDT, multidisciplinary team; MI, myocardial infarction; NYHA, The New York Heart Association; PCI, percutaneous coronary intervention.

or mechanical aortic valve prosthesis. Hence, patients undergoing REDO sternotomy and concomitant procedures such as supracoronary graft (SCG) or coronary artery bypass grafting (CABG) were not included. Patients with active endocarditis (according to Euroscore 2 definition[2]) or undergoing emergency or salvage procedures were also excluded.

Data on patients from Oslo University Hospital were extracted from The Norwegian Cardiac Surgery Registry. The registry contains information about heart operations performed from 2012 and operations through 2021 were included. Dates of death registered in The Norwegian National Population Register until 29 May 2023 were provided. The information from The Norwegian Cardiac Surgery Registry was matched with data from The Norwegian Cause of Death Registry using the unique National 11-digit personal identifier. As the data in The Norwegian Cause of Death Registry are processed before delivery is available, the last death date from The Norwegian Cause of Death Registry was 31 December 2021. Hence, for the last 17 months of observation for survival, the cause of death was not available for the project.

Two medical students and a surgeon in training obtained medical records from the local hospitals that had been in care for the deceased patients included in this study. Medical records were investigated to identify the

likely cause of death, when possible. The cause of death audit was cross-checked with data from The Norwegian Cause of Death Registry to analyse inter-rater reliability. Death causes were categorised as follows: valve-related, cerebral bleeding or stroke, other cardiovascular, cancer and non-cardiovascular.

Death within 30 days, endocarditis, aortic valve disease and complications to cardiovascular implants (International Classification of Diseases, Tenth Revision (ICD-10) codes I33, I38, I39, B37.6, I35 and T82) were considered as 'valve-related deaths'. Stroke deaths were classified using the ICD-10 codes I6x, which include cerebral bleeding and ischaemic stroke. The remaining Ixx codes were considered as other 'cardiovascular deaths'. Cancer was explained by ICD-10 Cxx and the remaining codes were registered as 'non-cardiovascular deaths'.

The results are presented as median (25th–75th percentile) and proportions (%). Time-to-event analyses were performed using the Kaplan-Meier survival estimator. Relative survival analysis with age, sex and calendar year-based death risk from Statistics Norway was used to account for different group composition.[3] The proportions of the different causes of death after AVR(b) or AVR(m) were analysed using the Fisher's exact test. For the subdistributions of causes of death after AVR(b) or AVR(m), the cumulative incidence functions were calculated using the R-package 'cmprsk'.[4] Cox proportional hazards analysis was also performed. Variables with more than 30% missing values were not included in the multivariate analysis.

Statistical analyses were performed using RStudio (Posit team (2023). RStudio: Integrated Development Environment for R. Posit Software, PBC, Boston, MA. URL: http://www.posit.co/. R Core Team (2023). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.) The invaluable R packages are referenced in the online supplemental file 1.

RESULTS

From 2012 to 2021, 1897 patients underwent standard surgical AVR. One of the patients was not registered in The Norwegian National Population Register and was excluded from the study. During the study period, 433 patients died, of whom 340 died before the end of 2021. The Norwegian Cause of Death Registry provided causes of death throughout 2021. In addition, we retrieved medical records from the local hospitals for 232 patients, and the cause of death was evaluated from the information that was available from the medical records. The inter-rater reliability was moderate, with an unweighted Cohen's kappa of 0.56 (0.47–0.64). Therefore, as the

Table 2 Demonstrates postoperative complications as proportions (%) or median (25-75 percentile) and missing values (%)

	AVR(b)	25–75 p	Missing (%)	AVR(m)	25–75 p	Missing (%)
Number	1300			596		
Postoperative length of stay (days)	4.4	(1.3–7.5)	27.9	4.0	(1.5–6.5)	23.7
Mechanical ventilation >24 hours (%)	0.5		16.0	0.4		16.3
Postoperative mechanical circulatory support (%)	0.2		3.2	0.2		4.7
Postoperative max creatinine (mmol/L)	81	(66–96)	66.6	76	(64–88)	55.0
Postoperative renal dysfunction (%)	2.7		15.5	2.2		14.9
Postoperative dialysis (%)	0		86.7	0		78.5
Postoperative MI (%)	0.1		9.6	0.4		9.2
Postoperative stroke (%)	0.7		6.2	0.4		5.0
Postoperative revision for bleeding (%)	6.4		0.8	3.2		0.7
Postoperative mediastinitis (%)	0.8		1.1	0.2		0.8
Postoperative sepsis (%)	0.2		6.5	0		5.0
Postoperative other infection (%)	1.9		62.6	0.7		52.5
Postoperative vascular and access-related complications (%)	0		65.9	0		55.4
Postoperative valve regurgitation (%)	0.5		69.9	0.4		59.1
Postoperative anticoagulants (%)	58		68.6	100		55.7
Postoperative death in department (%)	0.3		15.6	0		12.1
New cardiac surgery during department stay (%)	0.4		15.6	0.2		12.1
30-day mortality (%)	1.38		0.0	0.17		0.0

Due to a revision in the registry mid-way through the study period, most of the variables with many missing values were only available for the last half of the study period. The proportion of missing values relates to the total number of cases.
MI, myocardial infarction.

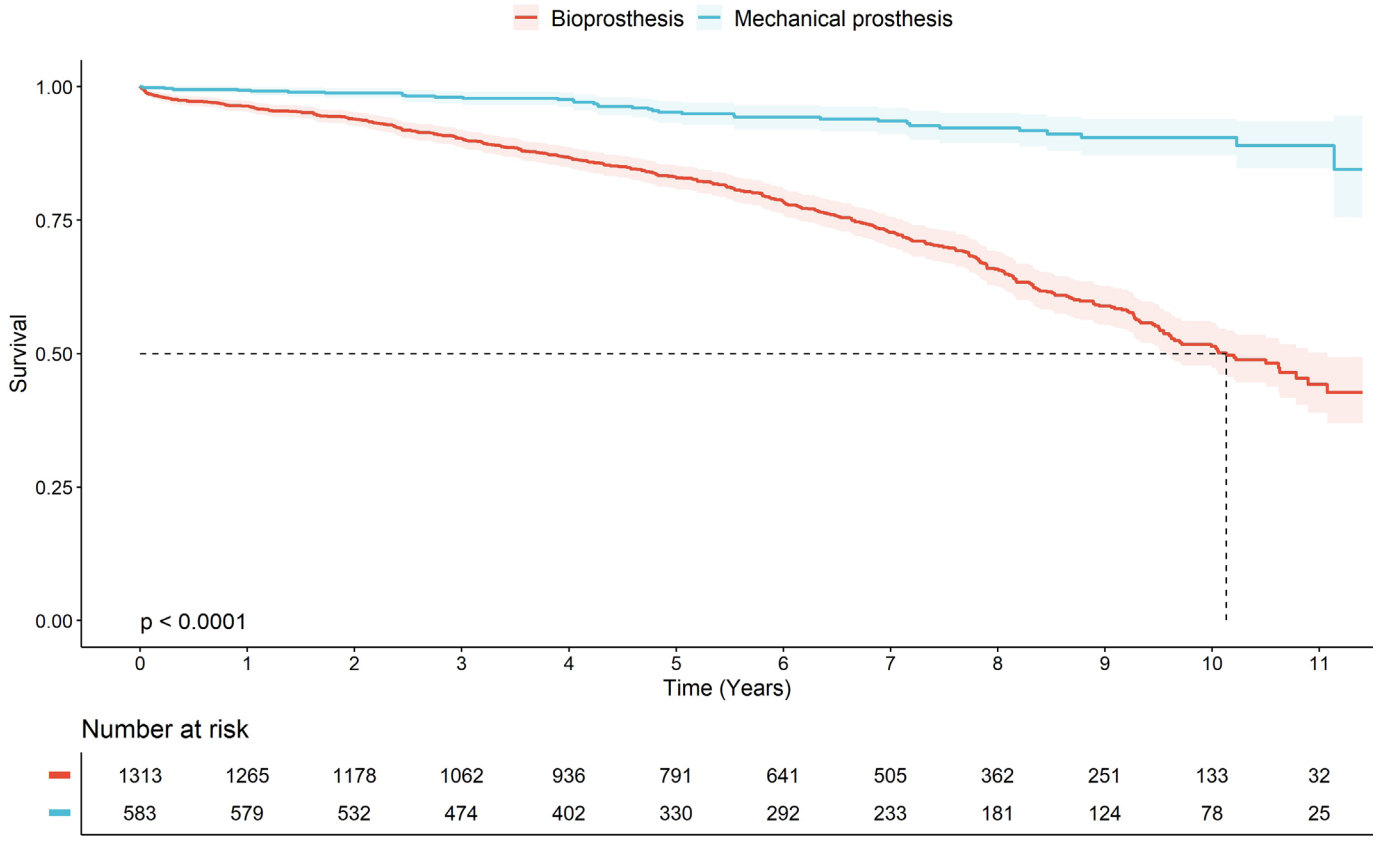

Figure 1 Crude survival for patients operated with biological or mechanical aortic valve prosthesis (log-rank test).

Norwegian Cause of Death Registry provided a cause of death in a greater number of cases, this was used for the analyses.

A biological aortic valve prosthesis AVR(b) was implanted in 1300 patients and a mechanical prosthesis AVR(m) was implanted in 596 patients. The patients receiving an AVR(m) were younger than the patients receiving an AVR(b) (table 1). There was a decline in the annual number of AVR(b) implanted from a maximum of 197 in 2013 to 86 in 2021. For AVR(m), the numbers were stable between 46 and 72 annually, without a trend. The median age for the AVR(b) patients declined from 77 (71–82) years in 2012 to 67 (64–72) years in 2021, while the median age for AVR(m) was stable between 53 (42–59) and 59 (53–64) years annually without a trend. The preoperative risk factors for AVR(b) and AVR(m) are summarised in table 1.

Operative 30-day survival was 98.6% for AVR(b) and 99.8% for AVR(m). In 2012, operative survival for AVR(b) was 98.1% and, in 2021, it was 100%. There was a strong trend towards better operative 30-day survival for AVR(b) in the late half of the period (99.4% (98.9%–99.9%) vs 98.7% (98.0%–99.4%)) and a significant 1-year survival improvement (98.4% (97.6%–99.3%) vs 96.4% (95.3%–97.5%)). For AVR(m), there was no trend over time, as 30-day survival was 100% both at the beginning and the end of the study period. The lowest operative survival for AVR(m) was 97.8% in 2017 (there was one early postoperative death in the AVR(m) group during the whole study period). For AVR(b), the lowest operative survival was 96.6% (93.9%–99.3%) in 2014 (6 deaths). The postoperative complications are summarised in table 2.

Median survival after AVR(b) was 10.2 (9.5–11.1) years (figure 1). In total, there were 392 deaths among AVR(b) and 41 among AVR(m) in the study period (30.2% and 6.9%, respectively). The survival estimators at 10 years were 51.3% (47.0%–55.5%) for AVR(b) and 88.3% (83.5%–91.8%) for AVR(m). Following AVR(m), mortality was not significantly different from the background population (figure 2). For AVR(b), there was a trend towards increased mortality compared with the background population from 8 years postoperatively.

As expected, there was increased mortality from unknown causes towards the end of the study period, as the causes of deaths were not available for the last 17 months. However, non-cardiovascular mortality was the most frequent cause of death (n=124, 28.6% of total deaths). Stroke was the least usual cause (n=21, 4.8% of total deaths). Although the cumulative incidence functions for most causes of death were significantly different between AVR(b) or AVR(m) (non-cardiovascular mortality ($p<0.001$), cancer ($p<0.001$), cardiovascular ($p=0.003$), unknown ($p<0.001$) and valve-related death ($p=0.001$)), the proportions of the different causes of death were not different between AVR(m) than AVR(b) ($p=0.21$). The 10-year estimator for cerebral haemorrhage/stroke was similar after AVR(m) and AVR(b) (1.3% (0.07%–2.6%) and 1.5% (0.8%–2.3%), respectively, $p=0.56$). Thus, as

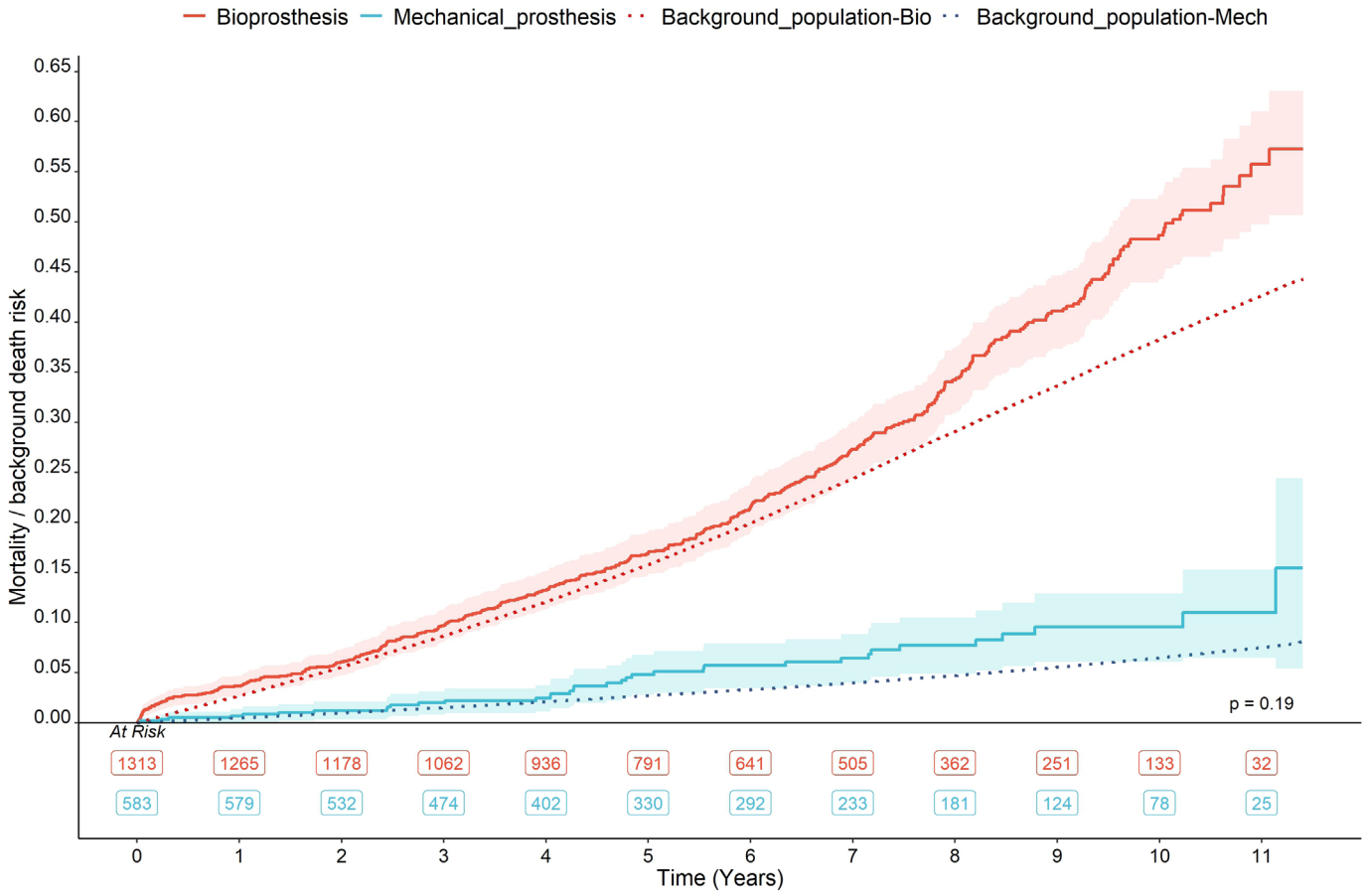

Figure 2 After operation with biologic or mechanical aortic valve prosthesis, mortality was not different when related to the age-matched and sex-matched background population death risk (log-rank-type test[3]).

total mortality was higher among the AVR(b) patients, cerebral haemorrhage/stroke was a more common cause of death among AVR(m) than AVR(b) (12% (n=5) and 4% (n=16) of deaths, respectively) (figure 3).

59 patients died from valve-related mortality (13.6% of the total deaths). This proportion was similar for biological and mechanical prostheses. The 10-year estimators for valve-related deaths were 4.8% (3.4%–6.1%) and 1.4% (0.3%–2.5%), respectively. Among the valve-related deaths, a mix of aortic valve diseases (ICD-codes I350, I352, I358, I359) accounted for 48%, while endocarditis was 20% and 30-day postoperative deaths were 32% of the valve-related deaths (figure 4). Endocarditis accounted for the same proportion of valve-related deaths among AVR(b) and AVR(m) (21%) (n=11) and 17% (n=1) of deaths), respectively). In addition, two of the early postoperative deaths were reported as endocarditis. Both occurred after AVR(b), at 13 and 20 days postoperatively. Death from endocarditis occurred in a median of 2.7 (0.3–4.9) years after AVR, the latest after 8.7 years.

In Cox proportional hazard multivariate analysis, age (HR 1.07 (95% CI 1.04 to 1.1), severe renal dysfunction (HR 2.15 (95% CI 1.45 to 3.2), diabetes (HR 1.45 (95% CI 1.03 to 2.0) and year of surgery 2014 (HR 1.59 (95% CI 1.06 to 2.4) were significantly associated with increased risk of death for AVR(b). For AVR(m) age (HR 1.08 (95% CI 1.05 to 1.12) and severe renal dysfunction (HR 7.0 (95% CI 2.1 to 23.6) were significant. We did not find any risk factor significantly associated with valve-related death.

DISCUSSION

In this retrospective registry-based study, we found survival to be comparable to age-matched and sex-matched background population up to 7 years postoperatively after isolated primary AVR. Non-cardiovascular causes of death and cancer were the most frequent causes of death, while valve-related causes of death and stroke were the least frequent.

In median, the age of patients receiving AVR(m) was 16 years younger than for AVR(b). Hence, a much better 10-year survival of 88.3% (83.5%–91.8%) for AVR(m) than 51.3% (47.0%–55.5%) for AVR(b) was to be expected.

The number of patients receiving AVR(b) decreased during the study period, as did their age at surgery. The activity of the catheter-based programme (TAVR) at our institution has increased during the period, and this availability and altered patient selection is the most likely explanation for this change. Hence, the higher comorbidity among patients operated in the beginning of the

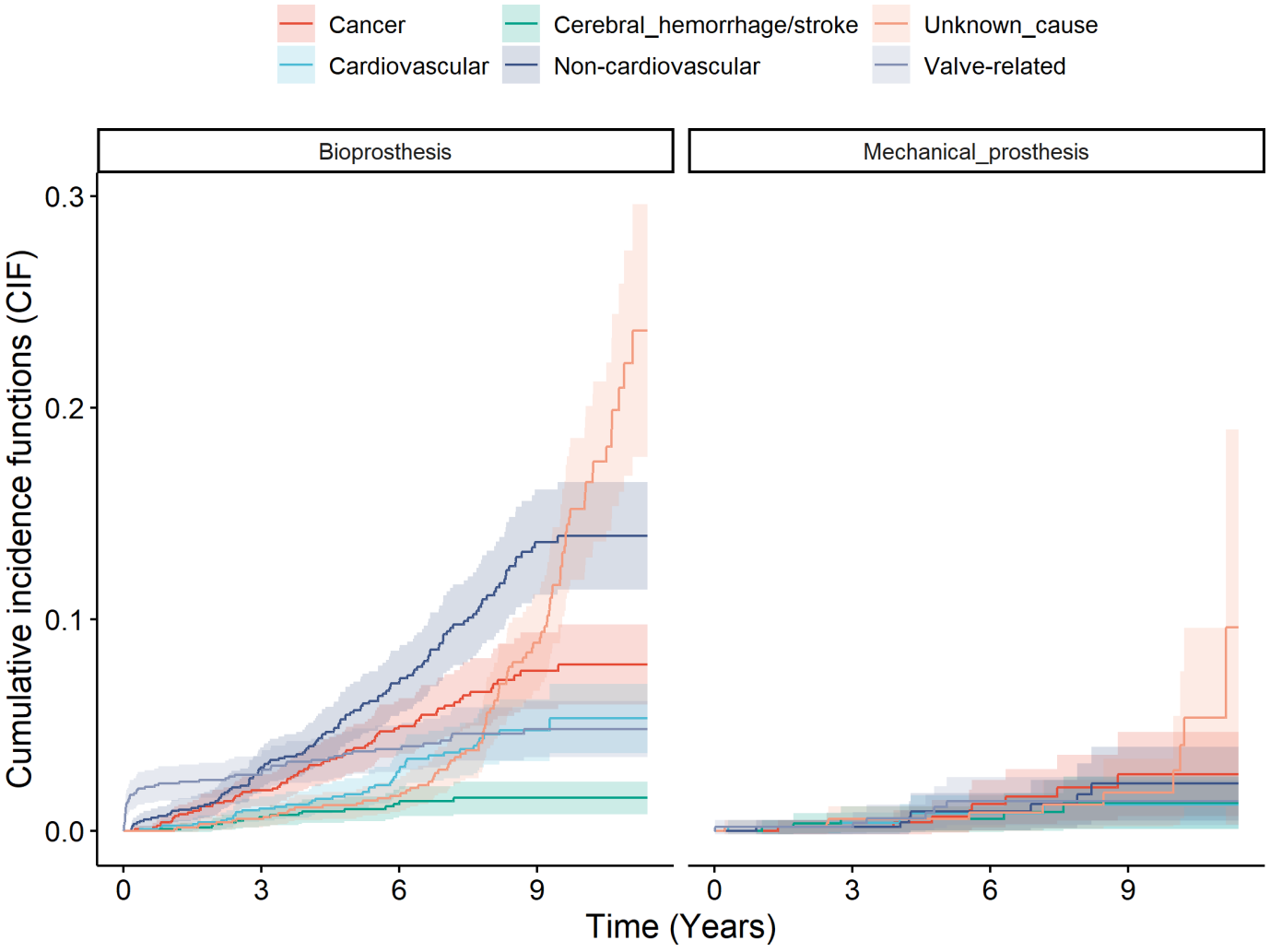

Figure 3 Causes of death in patients operated with biological or mechanical aortic valve prosthesis, presented as cumulative incidence functions.

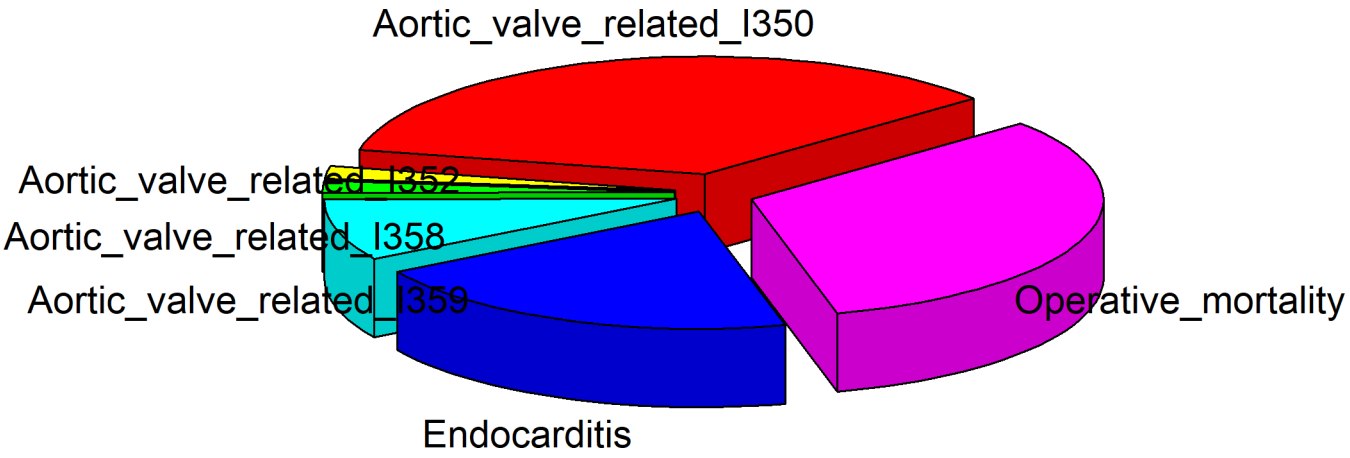

Figure 4 Distribution of causes of death in 59 patients who were categorised as dead from valve-related mortality (13.6% of the total deaths). Six were operated with mechanical prosthesis and 53 with biologic prosthesis. Among the valve-related deaths, a mix of aortic valve diseases (International Classification of Diseases, Tenth Revision (ICD-10) codes I350, I352, I358, I359) accounted for 48%, while endocarditis was 20% and 30-day postoperative deaths were 32% of the valve-related deaths.

period may contribute to the apparent excess death risk after 7 years, compared with the background population.

Patients undergoing surgery for active endocarditis or REDO sternotomy are at increased surgical risk.[2] Traditionally, these patients represent a relatively small proportion of isolated AVR surgeries. In addition, these subgroups are rather heterogeneous; therefore, we decided to exclude these patients from this study. Concomitant procedures such as SCG or CABG would also contribute to a heterogeneous study population and were therefore not included in this study. However, among the included patients, 50 operations had 'planned surgery on thoracic aorta' as a risk factor (Euroscore 2). All operations were registered as isolated valve surgery, but due to limitations in the NCSP codes available, we cannot rule out that aortic procedures, such as ascending aortic surgery or aortic root enlargement, were performed in some cases. Only 1 of these 50 patients died in the study period.

In 2016, The Norwegian Cardiac Surgery Registry did a major change, including a new registry platform/software as well as several changes and adjustments of risk factors, including the change from Euroscore 1 to Euroscore 2. Thus, several risk factors are not available for the first half of the period. For the last half of the period, in addition to Euroscore 2 risk factors, other new risk factors were registered due to the changes in the Registry in 2016 (eg, registration of insulin vs non-insulin dependent diabetes mellitus). ICD codes and NCSP codes were not imported during the 2016 upgrade. Hence, information about the diagnosis leading to AVR is only available from the latter half of the period, when 84% were registered as aortic stenosis.

Active endocarditis, according to the Euroscore definition, is defined as 'patients still on antibiotic treatment for endocarditis at the time of surgery'.[2] In the audit, we found one patient with high endocarditis risk who had been treated with antibiotics for infective endocarditis but was not using antibiotics at the time of surgery. That patient died from early prosthetic valve endocarditis. One might discuss if this patient should have been excluded from the study. However, we decided to stay loyal to the defined criteria. That patient, as one of seven patients, had implanted a new valve model. It seemed evident, with the excessive endocarditis risk in this patient's course, that the death most likely was unrelated to the valve model. Apart from this particular case, none of the valve prosthesis models used were associated with increased risk of death or valve-related death. Hickey *et al* reported larger hazard rates than expected for Sorin Mitroflow and for Sorin Biological series. These models were not implanted in our cohort.[5]

Prosthetic valve endocarditis is a serious condition and a concern when deciding to perform a heart valve replacement. Even though endocarditis was an infrequent cause of death, being observed in 0.7% of the patients, it remains a relevant and important cause of valve-related death and is of similar frequency to operative mortality. Hence, endocarditis prophylaxis seems important for patients with prosthetic heart valves.[6]

According to the data from The Norwegian Cause of Death Registry,[7] eight of the patients (0.4%) had emigrated and three patients (0.16%) had missing data by the end of 2021. In addition, for 8 of the 340 registered as dead before 2022, a cause of death was not registered. Hence, for 99% of the patients, survival data were available and among these, a cause of death was registered in 97.6%. When comparing the causes of death from our audit with the Norwegian Cause of Death Registry, the inter-rater reliability was moderate. In Norway, the cause of death is usually stated by the physician examining the deceased patient at the time of death and not necessarily the clinician with the most knowledge of the patient. Unfortunately, the autopsy rates in Norway have declined.[8] Thus, the cause of death registered may not be correct. However, as the Registry provided a cause of death in a significantly greater number of cases, this was used for the analyses.

A large study including 54 866 AVRs between 1998 and 2013 in Sweden was published in 2021.[9] The rates of death from cancer and other non-cardiovascular causes in that study were comparable to our findings. However, in our study, the rate of cardiovascular mortality was lower. The Swedish study represents an earlier time period and also included concomitant coronary artery bypass surgery or supracoronary aortic graft implantation. Hence, both differences in patient morbidity and risk, as well as changes in surgical indication guidelines, advocating earlier surgery for aortic valve disease, may contribute to this apparent difference.[1]

We believe that the improved survival after AVR(b) observed during the study period in our study probably is a result of less preoperative risk factors in the latter period, due to patients with high surgical risk being selected to undergo TAVR.

The criteria for the selection of patients to AVR or TAVR have been evolving during the study period, and the discussion is still ongoing, especially for younger patients with low surgical risk. This is also addressed in recent studies, especially for patients with tricuspid aortic valve stenosis.[10–13] Our study presents a 10-year cohort operated with isolated primary AVR at a large Scandinavian Centre. The high survival and low complication rate reported, as well as a low rate of valve-related deaths, demonstrates that surgical AVR may be performed safely in low-risk patients.

Contributors JLB: project idea, data acquisition, analysis and writing. He is the corresponding author and the one responsible for the overall content (guarantor). SSW: data acquisition, writing/editing assistance. TKT: data acquisition, writing/editing assistance. AMO: data acquisition, writing/editing assistance.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval The study complies with the Declaration of Helsinki. The project applied for approval from the Regional Committees for Medical and Health Research Ethics (REK) that found the project to be beyond the scope of the Health Research Act and thus not requiring such approval (Ref. 327336). The Norwegian Directorate of Health authorised exemption from confidentiality allowing the local hospitals to provide medical information about the deceased patients (Ref. 21/33834-2). The study was recommended by the Data protection officer at Oslo University Hospital (Ref. 21/24241) and approved by Oslo University Hospital in accordance with institutional protocol and national regulations. The clinical information was stored deidentified on a secure server approved for such data storage and according to the project approval.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Anonymised data may be shared on reasonable request.

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