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Outcomes of aortic valve surgery for rheumatic heart disease in Indigenous Australians: a 27-year longitudinal study

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Abstract

Background In Australia, acute rheumatic fever occurs almost exclusively in young Indigenous peoples, with young-to middle-aged Indigenous people being predominantly affected by rheumatic heart disease. This can result in a need for aortic valve surgery. Despite the increasing use of bioprosthetic valves in younger Indigenous Australians with rheumatic heart disease, there is limited long-term data comparing survival and reoperation rates between valve types or repair strategies in this high-risk population. This is a single-centre database analysis of 27 years of consecutive rheumatic heart disease aortic valve surgery and long-term results. Primary outcomes were all-cause mortality and all-cause revision surgery, as a time from index (primary) aortic valvular surgery, whether it be replacement or repair.

Results Two-hundred sixty-eight patients underwent aortic valve surgery for rheumatic heart disease. Average age at time of index surgery was 50.1 years. Sixteen (6.0%) underwent revision. Time to death (mortality recorded in 93 (34.7%)) was 6.1 ± 4.3 years. There was no difference in risk of mortality between primary replacement or repair ($HR = 1.12$; $p = 0.87$). In the replacement population, there was no survival difference between bioprosthetic or mechanical valve ($HR = 1.42$; $p = 0.11$).

Time to revision surgery was 7.9 ± 4.4 years. Aortic valve repair as primary surgery was associated with an increased risk of revision (sub-distribution hazard ratio (SHR) 8.22; $p = 0.01$). When replacement was performed, there was a significantly greater risk of revision for bioprosthetic valves, as opposed to mechanical valves ($SHR 3.26$; $p = 0.045$).

Conclusions The rheumatic heart disease population in Australia is young at time of index surgery, and there is no survival benefit to replacement or repair. Replacement should have an appropriately chosen bioprosthetic or mechanical valve replacement, with an increased risk of revision for bioprosthetic valves which is in keeping with existing literature. Primary aortic valve repair for rheumatic heart disease is associated with long-term increased risk of revision surgery.

Keywords Rheumatic heart disease, Indigenous Australians, Aortic valve surgery, Long-term outcomes

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Background

Rheumatic heart disease (RHD) is a preventable and chronic cardiovascular disease that disproportionately affects Indigenous Australians. Acute rheumatic fever (ARF) occurs almost exclusively in indigenous children, with subsequent RHD predominately affecting young- to middle-aged Aboriginal and Torres Strait Islander people [1].

The burden of RHD spans the majority of an Indigenous person's lifespan, with the risk of valvular damage increasing with severity and recurrent episodes of ARF. Over half of Indigenous Australians with ARF will progress to RHD, with greater than one-third developing severe RHD [1]. The average life expectancy of an Indigenous Australian with RHD is estimated to be 44 years [1].

In Australia, the current incidence of RHD is 49.9 per 100,000 for Indigenous peoples, which is 124 times higher when compared to the nonindigenous population. It is projected that between 2016 and 2031, 1370 Indigenous people will require valvular surgery for RHD [1]. It is estimated that approximately 1800 new RHD diagnoses are made every year in Australia, with over half being Indigenous Australians aged under 25 years of age [1].

In Australia, between 2017 and 2021, of the over 5000 Indigenous Australians living with RHD, 368 underwent heart surgery. Additionally, over this time, 382 Indigenous Australians died of RHD. In the Indigenous Australian population, the median time from diagnosis to death is 11.4 years [1, 2]. Indigenous Australians with RHD have an age at death that is 20 years younger than Indigenous Australians without RHD and greater than 30 years younger than the general Australian population [3].

The decision-making surrounding surgical intervention on RHD is complex and challenging. Traditionally, the principal points to consider regarding valve choice are that mechanical valves have long-term durability however require lifelong anticoagulation, whilst bioprosthetic valves do not require anticoagulation however have limited durability and require intervention.

However, especially in Indigenous patients, the decision between repair, bioprosthetic valve replacement or mechanical valve replacement requires that multiple factors must be taken into consideration. These factors include age, risks of anticoagulation, medication adherence, access to medical services, likelihood of future pregnancy and durability of repair or prosthesis. Additionally, the availability of and access to transcatheter valve replacement may influence decisions made with regard to the initial valve operation [1].

The current international guidelines for RHD surgery, as well as local practice in Australia, are consistent with valvular heart management of this disease at our centre regarding indication, timing and choice of intervention.

This lends our study a high degree of external generalisability. However, there are social, cultural and geographical complexities that impact decision-making. Additionally, the surgical repair of rheumatic valvular disease is significantly more technically challenging than most non-rheumatic pathologies. Where possible, especially in children and young adults, valve repair is the intervention recommended, providing it can likely be achieved and provide a durable long-term outcome. There are significant challenges regarding valve replacement in younger patients, including rapid prosthesis degeneration, management of anticoagulation, particularly in women of childbearing age, and patient-prosthesis mismatch with patient growth [1].

Since the 1990s, globally, the use of bioprosthetic valves has increased due to concerns with bleeding, thromboembolic events and valve thrombosis associated with a mechanical valve. Long-term propensity-matched studies comparing bioprosthetic versus mechanical valves in the general population have shown relatively equivalent survival or superiority of mechanical valves [4] [5] [6] [7]. In the Australian Indigenous population, registry data suggests a trend to increasing use of bioprosthetic valves; however, there is limited data available regarding the long-term outcomes of rheumatic valve surgery stratified by valve choice [1].

A major concern regarding the use of bioprosthetic valves in young Indigenous patients is the risk of structural valve deterioration (SVD). There have been reports of early SVD within 2 to 3 years following implantation, particularly in the younger population. Particular concern exists within the young Indigenous female population with reports of accelerated SVD during pregnancy [1].

This study aims to evaluate the long-term outcomes of aortic valve surgery in Indigenous Australians with rheumatic heart disease, with specific focus on survival and need for reoperation following aortic valve repair versus replacement and between mechanical and bioprosthetic prostheses. By leveraging 27 years of single-centre longitudinal data, we seek to provide evidence that informs lifetime valve strategy decision-making in this uniquely vulnerable and underrepresented patient cohort.

Methods

This is a retrospective analysis of prospectively collected data at a single large tertiary centre. Consecutive patients presenting to our institution between January 1992 and September 2023 for aortic valve surgery secondary to a diagnosis of rheumatic heart disease were included. All cases were reviewed in a multidisciplinary heart team meeting comprising cardiologists, cardiothoracic surgeons and Indigenous health practitioners. The final decision

regarding the surgical technique and prosthesis type was individualised based on patient-specific clinical and social factors. We excluded all patients who did not have a diagnosis of RHD or who underwent surgery not including the aortic valve. All patients were followed up until death or, in the case of survival, until the 30th of September 2023. Baseline demographic data, comorbidities and the details surrounding the index surgery were recorded for all patients (ANZSCTS National Cardiac Surgery Database; Data Definitions Manual, Version 4, January 2018 — Appendix 1). Institutional Review Board approval waiver was obtained prior to commencement of this study.

Outcomes measured

The main outcomes of interest were all-cause mortality and all-cause revision (reoperation) following index valvular surgery for rheumatic heart disease. We also determined risk factors for mortality or revision using preoperative characteristics as independent variables within our studied population. Our secondary outcomes of interest were to compare all-cause revision and mortality based on the type of procedure performed (replacement versus repair), as well as based on the type of replacement (mechanical versus bioprosthetic).

Statistical analysis

Continuous variables were recorded as median \pm interquartile range, whereas discrete variables were displayed as count (percentage). Risk factor analysis for all-cause mortality was performed using a univariate Cox-regression model, with assumption of proportionality confirmed. Survival functions for all-cause mortality were analysed using Kaplan-Meier survival curves, and where applicable, those with different categories were compared using hazard ratios (HR). Risk factor analysis for all-cause revision was performed using a competing risk model, with death used as a competing risk. Although Kaplan-Meier survival curves were used to illustrate overall revision, we utilised cumulative incidence competing risk functions to analyse revision outcomes with different categories. These were compared using sub-distribution hazard ratios (SHR). All statistical analyses were performed using Stata version 18.0 (StataCorp, TX, USA). The threshold for statistical significance was set at p -value of 0.05.

Results

Two-hundred and sixty-eight patients met our inclusion and exclusion criteria. They were followed up for a mean of 8.2 ± 5.8 years. Out of these 268 patients, 16 had revision surgery. The average age of patients at the time of their index surgery was 50.1 years. There were more non-smokers (33.2%) than smokers, but the proportion

of males to females were roughly equal. At the time of surgery, most patients had NYHA class 2 heart failure (36%). Otherwise, most patients did not have a history of hypertension, diabetes, renal disease, peripheral vascular disease or cerebrovascular disease. A total of 13.1% of patients had a previous open-heart surgery. Noteworthy, pulmonary hypertension and abnormal ejection fraction were usually absent within our patient population. Our patient demographics and relevant comorbidities are shown in Table 1

Treatment factors and patient outcomes

Elective surgery accounted for a significant majority of our included patients. Aortic valve replacement was substantially more common than repair. A total of 47.4% of patients also had a concurrent mitral valve procedure. Postoperatively, patients spent a median of 46.1 h in intensive care. Postoperative pneumonia was seen in 17.0% of patients, representing the most common immediate postoperative complication we encountered. The

Table 1 Patient demographic and comorbidities ($n = 268$)

Age, years	50.50 (33.00–66.00)
Gender	
Male	135/268 (50.37)
Female	133/268 (49.63)
Weight, kg	70.00 (58.00–81.00)
EuroSCORE	3.33 (2.08–7.32)
Current smoker	89/268 (33.21)
Hypertension	126/265 (47.55)
NYHA class	
1	78/253 (30.83)
2	91/253 (35.97)
3	72/253 (28.46)
4	12/253 (4.74)
Diabetes	
Type 1 diabetes	2/267 (0.75)
Type 2 diabetes	48/267 (17.98)
No	217/267 (81.27)
Renal disease	12/267 (4.49)
Peripheral vascular disease	13/267 (4.87)
Cerebrovascular disease	18/267 (6.74)
Pulmonary hypertension	
Severe (>55 mmHg)	37/267 (13.86)
Moderate (31–55 mmHg)	14/267 (5.24)
None	216/267 (80.90)
Ejected fraction estimate	
Severe (<30%)	6/258 (2.33)
Moderate (30–45%)	38/258 (14.73)
Mild (45–60%)	71/258 (27.52)
Normal (>60%)	143/258 (55.43)
Previous open-heart surgery	35/268 (13.06)

median length of hospital stay was 8.0 days. A detailed analysis of treatment factors and patient outcomes were shown in Table 2.

All-cause mortality

Of the included population, a total of 93 patients died in the follow-up period. The average time to death, if occurred, was 6.1 ± 4.3 years. The survival function for all-cause mortality is shown in Fig. 1. Cox regression analysis showed that increasing age at time of index surgery, a history of renal disease or cerebrovascular disease and severe pulmonary hypertension were associated with an increased risk of mortality. The results of our regression analysis are shown in Table 3. There was no difference in the risk of mortality between patients who had a replacement versus a repair ($HR=1.70$; $p=0.465$). If replacement was performed, there was also no statistically significant difference between mechanical and bioprosthetic valve replacement in terms of mortality ($HR=1.23$; $p=0.359$). The Kaplan–Meier plots are shown in Figs. 2 and 3.

All-cause revision

As previously mentioned, 16 patients were revised, with a mean of 7.9 ± 4.4 years between the primary and

revision surgery. The survival function for all-cause revision is shown in Fig. 4. Competing risk analysis showed that younger age at index surgery was associated with an increased risk of revision ($SHR=0.92$; $p<0.001$). The results of our survival analysis are shown in Table 4. When comparing the survivorship between replacement and repair, aortic valve repair was shown to have a similar risk of revision ($SHR 2.91$; $p=0.174$). Similarly, when replacement was performed, there was a significantly greater risk of revision for bioprosthetic valves, as opposed to mechanical valves ($SHR 3.27$; $p=0.043$). When adjusted for age, this result was even more significant statistically ($SHR 4.58$; $p=0.015$). The cumulative incidence competing risk function is shown in Figs. 5 and 6.

Discussion

In Australia, acute rheumatic fever (ARF) occurs almost exclusively in young (5–14 years) Indigenous peoples, with young- to middle-aged Indigenous people being predominantly affected by RHD. The peak incidence of RHD occurs in Indigenous people between 35 and 44 years of age. Of the young Indigenous people diagnosed with ARF, over half (52%) will progress to RHD within 10 years, with over one-third of those progressing to severe RHD within 10 years [1].

Our demographic data (Table 1) was similar to previously reported surgical cohorts undergoing valve surgery for rheumatic heart disease [8] [9]. This highlights the significant burden RHD has on younger Indigenous Australians, with our median age for surgical valve intervention being 50.5 years of age. Additionally, it highlights the significant comorbidities experienced by younger Indigenous Australians including hypertension, type II diabetes mellitus and renal disease. Furthermore, the significant rates of cigarette smoking suggest poorer social determinants of health and how public health campaigns are ineffectively reaching the most vulnerable Indigenous communities.

Bioprosthetic versus mechanical valve replacement

Current guidelines recommend that a mechanical prosthesis should be considered in the aortic position in patients aged less than 60 years of age [10]. Despite this, there is a growing trend globally in the placement of bioprosthetic valves over mechanical valves in both the aortic and mitral position, particularly in younger patients [4]. This trend has been attributed to the fact that mechanical valves require lifelong anticoagulation with warfarin and are associated with an increased risk of thromboembolism and haemorrhage with patients seeking to avoid these risks [4]. Conversely, we are also aware that bioprosthetic valves are associated with increased

Table 2 Treatment factors and outcomes

Case urgency	
Urgent	25/267 (9.36)
Elective	242/267 (90.64)
Aortic valve procedure	
Replacement	244/268 (91.04)
Mechanical	122
Tissue	122
Repair	6/268 (3.27)
Root reconstruction	8/268 (2.99)
TAVI	10/268 (3.73)
Concurrent mitral valve procedure	
Replacement	118/268 (44.03)
Repair	9/268 (3.36)
None	141/268 (52.61)
Concurrent tricuspid valve procedure	
Replacement	4/268 (1.49)
Repair	15/268 (5.60)
Others	15/268 (5.60)
None	234/268 (88.24)
Time spent intubated, hours	19.15 (11.97–30.81)
Time spent in ICU, hours	46.10 (25.00–99.50)
Postoperative renal failure	35/261 (13.41)
Postoperative pneumonia	44/259 (16.99)
Postoperative stroke	1/267 (0.37)
Length of stay, days	8.00 (6.00–13.00)

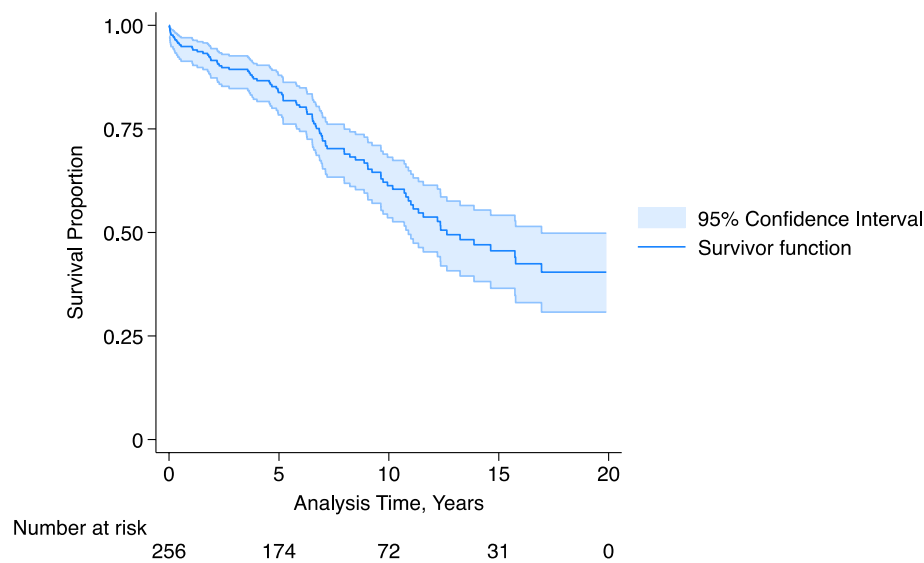


Fig. 1 Survival curve for all-cause mortality for aortic valve surgeries

Table 3 Univariate analysis for predictors of mortality using demographic and comorbidity data as independent variables

	Hazard ratio	Standard error	p-value
Age	1.02	0.01	<0.001
Female gender	1.45	0.30	0.079
Weight	1.00	0.01	0.460
Current smoker	0.75	0.18	0.219
Hypertension	1.25	0.26	0.298
NYHA class			
2	1.79	0.54	0.052
3	2.26	0.658	0.007
4	1.95	1.08	0.226
Diabetes			
Type 1	1.66	1.68	0.616
Type 2	1.22	0.32	0.433
Renal disease	3.90	1.55	0.001
Peripheral vascular disease	2.24	0.79	0.022
Cerebrovascular disease	2.62	0.85	0.003
Pulmonary hypertension			
Moderate (31–55 mmHg)	1.17	0.69	0.794
Severe (> 55 mmHg)	2.13	0.55	0.003
Ejection fraction			
Mild (45–60%)	1.23	0.31	0.414
Moderate (30–45%)	1.12	0.35	0.702
Severe (< 30%)	0.66	0.67	0.686
Previous open-heart surgery	1.29	0.41	0.430

rates of structural valve deterioration requiring reoperation [4].

In a retrospective database study published by Song et al. in 2024, they identified in younger patients

(50–70 years) that long-term mortality was significantly increased in patients who underwent mechanical aortic valve replacement [4]. With respect to complications, they showed that bioprosthetic valves were associated

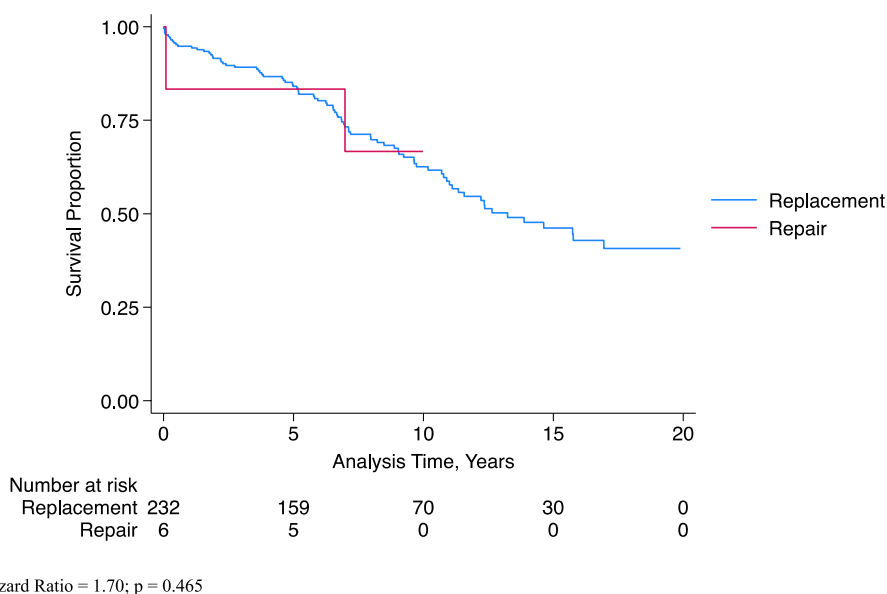


Fig. 2 Survival curve for all-cause mortality by procedure type. Hazard ratio = 1.70; p = 0.465

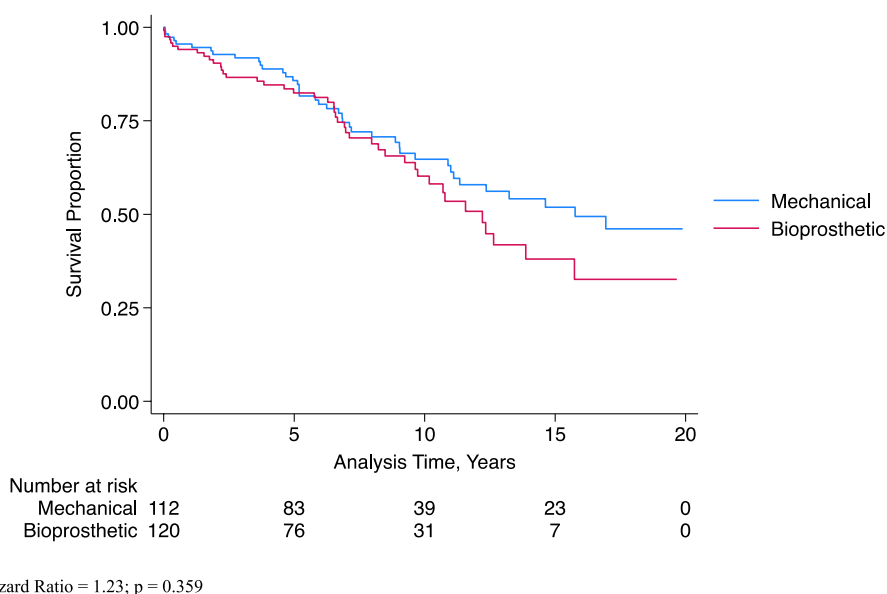


Fig. 3 Survival curve for all-cause mortality by type of aortic valve replacement. Hazard ratio = 1.23; p = 0.359

with lower incidence of stroke and bleeding whilst having an increased risk of requiring a reoperation [4].

Our results showed that bioprosthetic aortic valves are associated with a higher rate of reoperation. Indigenous Australian with rheumatic heart disease did not appear to have a long-term survival advantage with mechanical prosthesis in this analysis. This is an important result; as clinicians, we often invest significant discussion and thought in the choice between mechanical

or bioprosthetic. This is a worthwhile investment as our study would indicate that an appropriately chosen mechanical or bioprosthetic valve wherein factors such as social determinants of health, especially health literacy and access to medical care, are taken into account results in a nonsignificant difference in mortality and an appropriate increase in revision rate for bioprosthetic replacements.

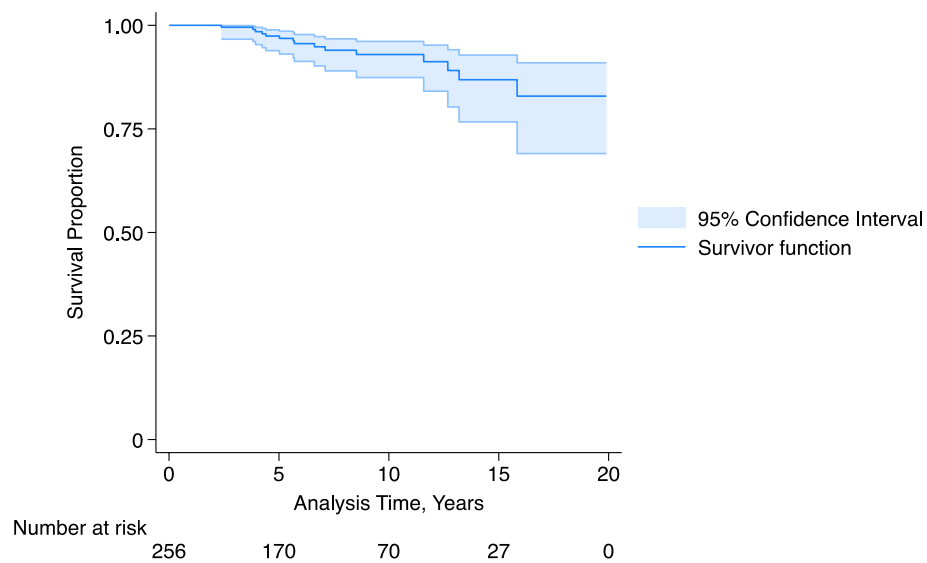
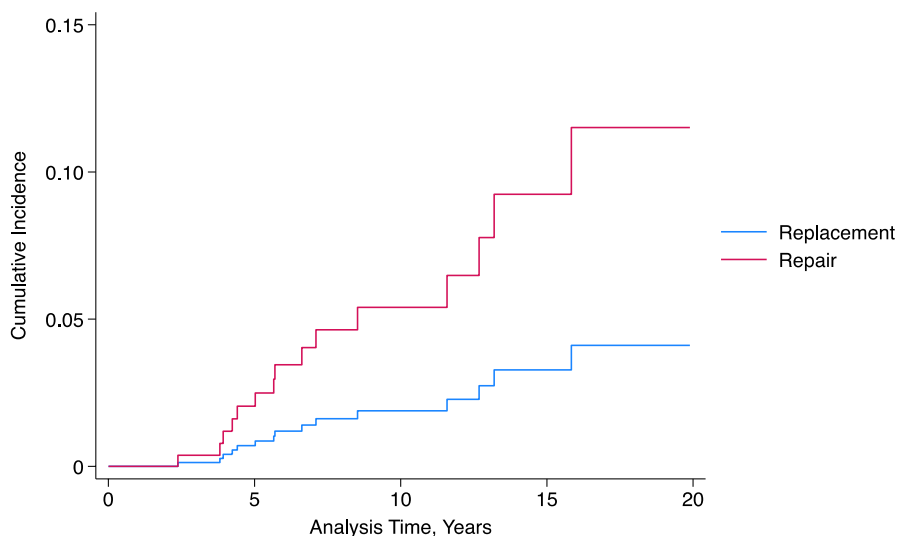


Fig. 4 Survival curve for all-cause revision for aortic valve surgeries

Table 4 Univariate predictors of revision using demographic and comorbidity data as independent variables with death as a competing risk

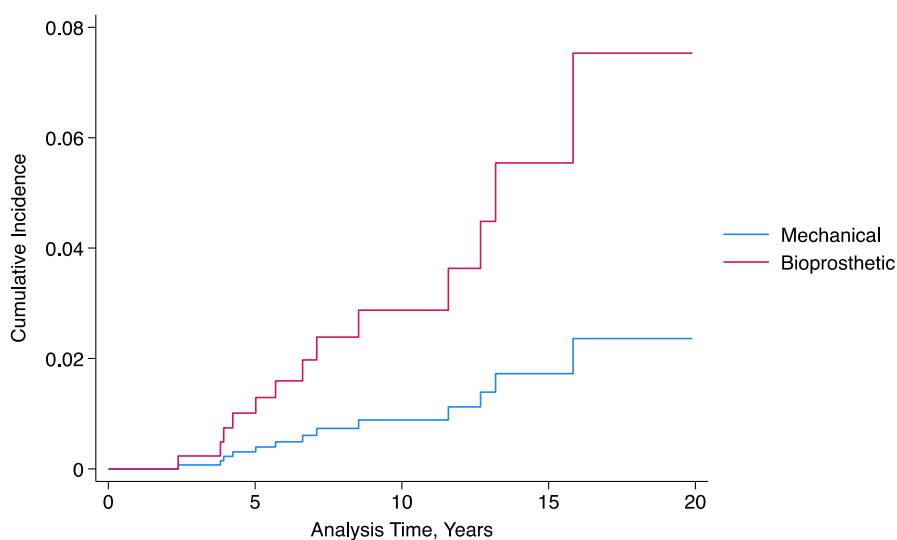
	Sub-distribution hazard ratio	Standard error	p-value
Age	0.92	0.02	<0.001
Female gender	0.98	0.49	0.961
Weight	1.00	0.02	0.981
Current smoker	1.81	0.90	0.236
Hypertension	0.25	0.16	0.028
NYHA class			
2	1.02	0.58	0.978
3	0.56	0.41	0.450
4	1.38	1.42	0.755
Diabetes			
Type 1	Not estimable*		
Type 2	0.29	0.30	0.277
Renal disease	1.70	1.65	0.586
Peripheral vascular disease	Not estimable*		
Cerebrovascular disease	Not estimable*		
Pulmonary hypertension			
Moderate (31–55 mmHg)	1.95	2.03	0.521
Severe (> 55 mmHg)	1.40	0.89	0.602
Ejection fraction			
Mild (45–60%)	1.00	0.60	0.994
Moderate (30–45%)	0.88	0.68	0.869
Severe (< 30%)	4.71	5.39	0.176
Previous open-heart surgery	3.24	1.91	0.045

* None of the patients receiving revision surgery had these risk factors



SHR = 2.91; p = 0.174

Fig. 5 Cumulative incidence competing risk function for all-cause revision by procedure type. *SHR* = 2.91; *p* = 0.174



SHR = 3.27, p = 0.043

Fig. 6 Cumulative incidence competing risk function for all-cause revision by type of aortic valve replacement. *SHR* = 3.27, *p* = 0.043

Replacement versus repair in primary surgery

In this study, when the revision rate between primary replacement and repair was examined, it indicated aortic valve repair was associated with a similar rate of revision (*SHR* 1.70; *p* = 0.465). We would like to soften any conclusion that may be drawn here, as our results are based on a limited number of primary repairs (16 of 268, representing 6.0%). We would counsel caution in applying this to clinical practice.

A 2022 meta-analysis highlights the challenges of aortic valve repair in rheumatic heart disease. Zhao et al’s systematic review only identified 418 patients who underwent rheumatic aortic valvuloplasty. Early pooled results suggested a low in-hospital mortality (3.2%) and excellent 5-year survival (94.5%). However, the 5-year reoperation rate was nearly 10%, raising concerns regarding long-term durability. They showed that deterioration in insufficiency occurred early on follow-up, suggesting limited

lasting benefit in valve competence. (A) Their data support our concerns that aortic valve repair in the rheumatic population—although technically feasible—may be associated with a higher risk of early reoperation [12].

VIV options for bioprosthesis

With increasing frequency of placement of aortic bioprosthetic valves in Indigenous Australians with RHD, we need to consider the lifetime management of this patient cohort. Transcatheter aortic valve in valve implantation is being increasingly investigated as an alternative to redo surgical aortic valve replacement. In a meta-analysis by Ahmed and Levy in 2021, they showed that at 30 days, valve-in-valve transcatheter aortic valve implantation was associated with a lower mortality; however, redo surgical aortic valve replacement had a lower rate of paravalvular regurgitation, patient-prosthesis mismatch and postoperative gradients [11]. It must be recognised, however, that this data is not obtained from randomised control trials and lacks long-term follow-up, which is essential for lifetime management of rheumatic valve disease.

Future and lifetime management

The lifetime management of Indigenous Australians with rheumatic heart disease is challenging both in respect to surgical aspects of care and decision-making; as well as social determinants of health and impacts of surgery on patients' lives. We have seen a trend towards increasing use of bioprosthetic valves. A bioprosthesis does not impact long-term survival ($HR=1.23$; $p=0.359$) but does result in an increased risk of revision ($SHR 3.27$; $p=0.043$) when compared to mechanical valves. Our study is consistent with existing literature [13, 14] that has shown that over the longer term, bioprosthetic valves undergo structural valve deterioration requiring more frequent reoperation than mechanical options.

We have illustrated that rheumatic valve repair, although theoretically providing long-term benefits, has been associated with higher rates of reoperation. Further increasing the complex decision-making in the Indigenous Australian cohort with RHD is the evolution of the transcatheter valve in valve option in both the aortic and mitral position. Currently, in the literature, there is insufficient data on the long-term outcomes of transcatheter valve in valve procedures, especially in younger Indigenous Australians.

Current practice and recommendations

Our current practice involves collaborative discussion between the patient, their family, our dedicated Aboriginal healthcare practitioners and the cardiothoracic surgeon. Through our collaborative discussion, if the patient has sufficient health literacy, access to medical care,

lifestyle that supports the use of warfarin and in women and no further desire for children, then a mechanical valve is considered. However, given the majority of our Indigenous Australians requiring valve surgery for RHD are from remote locations with poor social determinants of health, bioprosthetic valve replacement is usually considered. In patients electing for a bioprosthetic valve, they are counselled regarding the risks of structural valve deterioration with future need to undergo either reoperation for redo valve replacement or transcatheter valve-in-valve procedure.

Limitations

This is a longitudinal database analysis spanning 27 years. Whilst this has offered us a unique chance to examine long-term results of a relatively uncommon disease, a lot has evolved over this time in terms of surgical technique as well as social factors limiting homogeneity.

This analysis examined all-cause mortality; cause of death was not investigated for differentiation into cardiogenic or non-cardiogenic.

Future research

Given the increasing use of bioprosthetic valves being used in younger Indigenous Australians for RHD, further research is essential to review the long-term outcomes of varying lifetime valve strategies. The RHD Indigenous Australian cohort is likely to require multiple valve interventions in their lifetime, including the following: primary valve operation, reoperation for second primary valve operation, valve-in-valve procedure following structural valve deterioration and reoperation for structural valve deterioration of valve-in-valve prosthesis or surgical bioprosthesis. Assessing the outcomes of these varying lifetime strategies will help us guide future generations of Indigenous Australians with RHD to select the appropriate strategy to minimise their lifetime morbidity and mortality and optimise their quality of life.

Conclusions

In this 27-year longitudinal study of aortic valve surgery for rheumatic heart disease in Indigenous Australians, we found no difference in long-term all-cause mortality between valve replacement and repair or between mechanical and bioprosthetic prostheses. However, aortic valve repair and bioprosthetic valve replacement were both associated with significantly higher rates of reoperation. These findings underscore the importance of carefully considering durability and reoperation risk when selecting valve strategies in this population. Our results provide long-term outcome data to inform surgical decision-making in Indigenous Australians with rheumatic aortic valve disease.

Abbreviations

RHD	Rheumatic heart disease
ARF	Acute rheumatic fever
SVD	Structural valve deterioration
SHR	Sub-distribution hazard ratio

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s43057-025-00167-z>.

Supplementary Material 1: Appendix 1: ANZSCTS Data Definitions Manual Version 4.1.1 2018.

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Authors' contributions

Name: RS, BMBS. Contribution: This author conceived, designed, submitted to ethics and governance, registered as QA and realised the study protocol. This author also formulated and completed the methodology of this project, prepared the drafts, analysed and prepared the data and approved and submitted the final manuscript. Name: TSC, BMBS. Contribution: This author conceived, assisted with designing, conducted the statistical analyses, analysed and prepared the data, critically revise the drafts and approved the final manuscript. Name: D-YL, MBBS. Contribution: This author conceived; assisted with designing, writing and submitting the protocol to ethics and governance; realised the study; and approved the final manuscript. Name: CM, BMBS. Contribution: This author conceived; assisted with designing, writing and submitting the protocol to ethics and governance; realised the study; and approved the final manuscript. Name: GC, MBBS. Contribution: This author conceived; assisted with designing, writing and submitting the protocol to ethics and governance; realised the study; lended departmental support; revised the drafts; and approved the final manuscript. Name: SRA, BMBS. Contribution: This author conceived; assisted with designing, writing and submitting the protocol to ethics and governance; realised the study; and approved the final manuscript. Name: GR, BMBS. Contribution: This author conceived; assisted with designing, writing and submitting the protocol to ethics and governance; realised the study; lended departmental support; revised the drafts; and approved the final manuscript. Name: JB, BMBS PhD. Contribution: This author conceived; assisted with designing, writing and submitting the protocol to ethics and governance; realised the study and statistical analysis; revised the drafts; approved the final manuscript; and is the supervisor and takes final responsibility for the content of this study.

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Data availability

Full database is available upon reasonable written request.

Declarations**Ethics approval and consent to participate**

Institutional Review Board approval waiver was obtained prior to commencement of this study, and this analysis was added to the Quality Assurance Registry of our local ethics office as per the Southern Adelaide Local Health Network Office for Research Quality Assurance versus Research Project Exemption Guidelines (SALHN/QA.4751).

Consent for publication

Consent has been obtained for publication.

Competing interests

J. B. has a research grant from Edwards Lifesciences. J. B. is a proctor for Edwards and Medtronic. The other authors declare that they have no competing interests.

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