Systematic Review

The outcomes of three decades of the David and Yacoub procedures in bicuspid aortic valve patients—a systematic review and meta-analysis

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Background: Valve-sparing aortic procedures, including the David and Yacoub procedures, have emerged as the dominant approaches in aortic aneurysm surgery, preserving the native aortic valve and thereby conferring significant prognostic benefits to the patient. Over the years, these procedures have also shown promise in patients with bicuspid valve-related aortopathy. This systematic review and meta-analysis presents the most up-to-date data on perioperative outcomes, freedom from secondary reoperation, and freedom from mortality for bicuspid valve patients undergoing valve-sparing aortic operations.

Methods: The methods for this systematic review and meta-analysis adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement. Four databases were searched, ultimately yielding 19 papers for inclusion, using appropriate search terminology. Meta-analysis using proportions or means, as appropriate, were applied. Kaplan-Meier curves were digitized and aggregated using previously validated techniques.

Results: A total of 1,159 patients were included. Males accounted for 87.4% of the cohort. The mean age of the cohort was 44.9 years. The mean aortic root diameter was estimated to be 46.3 mm, with an estimated range from 38 to 54 mm. Thirty-day mortality rate was estimated to be 1.7%. Eighty-five percent of patients in this series received the David approach, with the remainder receiving the Yacoub approach. Overall, there was low heterogeneity observed for the mean length of intensive care stay, while high heterogeneity was observed for the other remaining variables of interest. Kaplan-Meier survival estimation at 5, 10, and 15 years was 96%, 90%, and 87%, respectively. Kaplan-Meier freedom from secondary reoperation at 5, 10, and 15 years was 96%, 91%, and 88%, respectively.

Conclusions: This review demonstrates the durability and safety of the David and Yacoub valve-sparing procedures across long-term follow-up in bicuspid aortic valve patients. These procedures offer significant freedom from mortality and secondary reoperations on the aorta and valve and will likely continue to demonstrate excellent results into the future. There is a clear transition towards the David procedure, with the bulk of contemporary literature publishing on this technique.

Keywords: Valve-sparing; root replacement; root remodeling; implantation

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Introduction

Valve-sparing aortic operations have now seen over three decades of clinical experience, predominantly in the form of the David 'reimplantation' and Yacoub 'remodeling' procedures. Both approaches, in the modern era, have come to dominate aortic aneurysm surgery, with the primary technical distinctions between the two being the David procedure's preservation of the entire aortic valve and secure, straight proximal anastomosis, versus the Yacoub procedure's replacement of the three aortic sinuses via a triple-tongued graft. Excellent long-term results have been reported in previous longitudinal studies for both techniques, with exceptional freedom from mortality, freedom from significant aortic regurgitation or insufficiency, and freedom from secondary reoperations on the aortic root or the native aortic valve (1-3). The apparent benefits of both approaches include the preservation of the native aortic valve, obviating the need for life-long anticoagulation depending on valve selection, conferring more physiologic hemodynamics, and providing improved long-term durability versus modern, but still inferior, prosthetic aortic valves. With the evolution of these procedures over the years, they have also come to be recognized as suitable in the management of patients with bicuspid aortic valve (BAV)-related aortopathy, when the bicuspid valve leaflet morphology is appropriate (4-6). This systematic review and meta-analysis outlines the most contemporary aggregated data for these two approaches, with respect to their perioperative outcomes, freedom from secondary reoperation, and freedom from mortality in BAV patients.

Methods

Literature search strategy

The methods for this systematic review adhered to the guidelines outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (7). Four electronic databases were used to perform the literature searches, encompassing EMBASE, Ovid MEDLINE, PubMed, and SCOPUS. These databases were searched from the date of database inception through to December 2023. For the examination of the perioperative and long-term outcomes of valve-sparing procedures and approaches, a search strategy using the combination of keywords and Medical Subject Headings (MeSH) including (David AND Yacoub) OR (remodeling OR reimplantation OR valve-sparing OR valve sparing OR VSRR) was utilized and is visually presented by the PRISMA flow diagram (see Figure S1). The David and Yacoub procedures were selected as the primary operations of interest, as opposed to valve repair procedures (e.g., ring annuloplasty, etc.). Predefined selection criteria were applied to assess for inclusion (see *Inclusion and exclusion criteria*). Each study was screened independently by three co-authors (ARWS, CJWS, JSS), with any conflicts resolved prior to progression through mutual agreement. Where the title and/or abstract provided insufficient detail in the determination of relevance for additional screening, a full-text review of the record was carried out in the first instance.

Inclusion and exclusion criteria

Studies were included in the review if they examined the perioperative and postoperative (short- and long-term) outcomes of interest in patients undergoing valve-sparing root remodeling or reimplantation procedures as isolated approaches (see *Primary and secondary endpoints*). Studies were excluded for: (I) non-English reporting; (II) narrative reports; (III) studies without clear recruiting details; (IV) no mention of perioperative and postoperative patient outcomes; (V) aggregate data not split between subgroups, preventing analysis; (VI) full texts not readily available via institutional access. Reference lists of the included studies were reviewed at completion of the database search to identify any extra, relevant studies not already included.

Primary and secondary endpoints

The primary endpoints of analysis were freedom from mortality, freedom from secondary reoperation, and thirty-day mortality in bicuspid valve patients undergoing aortic root remodeling or reimplantation procedures.

The secondary endpoints of analysis included technical success, as defined by surgical completion of the operation without conversion to root-replacing procedures, blood loss, tube duration, length of stay (LOS; hospital and ICU stay), number of cases for learning curve (if reported), and other perioperative and postoperative details.

Data extraction, critical appraisal, and quality assessment

Two independent reviewers extracted data directly from publication texts, tables, and figures (JSS, CJWS). A

Table 1 Demographic characteristics

Characteristics	Data; studies reported of total	Statistical values
Cohort total number (male proportion)	1,159 (87.4); 19/19	95% CI: 83.6–91.3% (tau^2=0.0061)
Age, years, mean (SE)	44.9 (1.1); 19/19	95% CI: 42.7–47.1 (I^2=93.2%)
Aortic root diameter, mm, mean (SE)	46.3 (3.9); 11/19	95% CI: 38.7–54.0 (I^2=99.9%)
Cross clamp time, minute, mean (SE)	147.9 (12.2); 14/19	95% CI: 124.0–172.0 (I^2=99.8%)
Length of hospital stay, days, mean (SE)	8.0 (1.3); 7/19	95% CI: 5.4–10.6 (I^2=99.7%)
Length of intensive care, hours, mean (SE)	46.3 (1.2); 5/19	95% CI: 43.9–48.7 (I^2=0%)
Thirty-day mortality (per study), %, mean (SE)	1.7 (0.29); 16/19	95% CI: 0.9–2.3% (I^2=0%)

CI, confidence interval; SE, standard error.

third reviewer independently reviewed and confirmed all extracted data (ARWS). Differing opinions between the two main reviewers were resolved through discussion led by the primary investigator. Attempts were made to clarify insufficient/indistinct data from authors of included studies, as required. Data were extracted in a way that each study was effectively treated as a case series, irrespective of underlying design. The Canadian Institute of Health Economics Quality Appraisal score was used as the quality assessment tool (8). Studies were defined as low quality with scores <10/19, moderate quality ≥10/19, and high quality >15/19.

Statistics

Meta-analyses of proportions or means were performed for categorical and continuous variables, as appropriate, by an independent reviewer. A random effects model was used to account for differing regions, surgeon experience, surgical technique and equipment, and management protocols across the included studies. Means and standard deviations were calculated from the median, where reported, using the methods described by Wan and colleagues (9). Pooled data, standard deviations (SD), and standard error (SE) are presented as N (%) ± SD or SE (X) with 95% confidence intervals (CI). For outcome data, heterogeneity amongst studies was assessed using the I^2 or tau^2 statistics as appropriate for the variable of interest. Thresholds for these values were considered as low, moderate, and high heterogeneity as 0–49%, 50–74% and ≥75%, respectively. Meta-analysis of proportions or means were performed using Stata (version 17.0, StataCorp, College Station, TX, USA). Risk of bias was assessed using the Risk of Bias in Non-randomized Studies – of Interventions (ROBINS-I) tool and has been visually presented (see Figure S2) (10).

Funnel plots were generated using R [R Core Team (2021). R Foundation for Statistical Computing, Vienna, Austria] in the R Studio environment (RStudio: Integrated Development Environment, PBC, Boston, MA, USA), with Egger's and Begg's tests applied for assessment of small-study effects and publication bias. Survival data were calculated from the aggregation of Kaplan-Meier (KM) curves from the included studies, where reported, by utilizing the methods of Guyot and colleagues (11). Digitization of KM curves was performed using DigitizeIt (version 2.5.9, Braunschweig, Germany) and survival meta-analysis was performed using Stata (version 17.0, StataCorp). KM curves were not included for aggregation in the instance where the number at risk at each time interval was not reported, or where graph quality was low (to the extent where clear digitizing of the original curve could not take place). Time intervals of 5, 10, and 15 years were chosen for ease of readability across long-term follow-up.

Results

One thousand fourteen hundred and seventy-eight studies were identified from the initial literature search. Following removal of duplicate and irrelevant studies, 76 studies were assessed for full-text eligibility. Nineteen retrospective cohort studies were included in the final meta-analysis (12-30). Baseline patient demographic data and included perioperative data are presented in *Table 1* and *Table 2*. A total of 1,159 patients were identified in the included studies, of which 87.4% were male. The mean estimate of the age of the patients was 44.9 years. The estimated mean aortic root diameter prior to operation

Table 2 Individual study details

Author	Study type	Year	Cohort number (male)	Aortic root (mm)	CCT (min)	Hospital LOS	FFR	30-day mortality	LTS
Patel	Retrospective	2021	67	44 [40–48]	204 [185–226]	5 [5–7]	96	2	94 (10 yr)
Beckerman	Retrospective	2018	48	NR	NR	6 (±2)	96 (freedom from AVR)	NR	NR
Ouzounian	Retrospective	2019	39	52 (±8)	116 (±28)	NR	NR	0	100 (10 yr)
Liu	Retrospective	2022	22	48.6 (±7.9) Asc Ao	69.0 (±21.8)	10.6 (±5.0)	96.6 (±3.4) (10 yr)	0	95.2 (±4.6) (10 yr)
Deas	Retrospective	2021	38	51.4 (±4.9) Asc Ao	105.4 (±27.8)	11.2 (±4)	94.5 (±3.1) (10 yr)	0	85.6 (±4.7) (10 yr)
Beckerman	Retrospective	2020	44	50 (±9) Asc Ao	227.4 (±43.5)	NR	NR	0	97
Martín	Retrospective	2017	40	NR	117 (±25)	13 (±5)	98 (1 yr), 88 (5 yr), 79 (10 yr), 74 (20 yr)	0	98 (1 yr), 94 (5 yr), 90 (10 yr), 88 (20 yr)
Aicher	Retrospective	2004	57	NR	104 (±19.3)	NR	98±2 (1 yr), 97±2 (3 yr), 97±2 (5 yr)	0	96±3 (5 yr)
Karciauskas	Retrospective	2019	50	NR	NR	NR	98	0	NR
Urbanski	Retrospective	2022	27	47.4 (±10) Asc Ao	97 [86.5–114.0]	NR	92.3±5.2 (5 yr), 83.9±7.4 (10 yr)	1	96.8 (±2.2) (10 yr)
Kari	Retrospective	2014	95	53 (±6)	NR	NR	89.1±3.8 (10 yr combined freedom from AI + AVR)	0	99 (5 yr), 94 (10 yr), 88.9 (12 yr)
Badiu	Retrospective	2010	68	NR	NR	NR	90 (77–97 confidence interval) (8 yr)	NR	98 (87–100) (8 yr) (n=1 death)
Miyahara	Retrospective	2016	11	NR	127 (±42)	NR	100% estimated	0	100% 5 yr estimated
Beckmann	Retrospective	2020	40	NR	167.5 (±24.7)	NR	88.7±5.4 (5 yr)	0	100 (5 yr)
Huuskonen	Retrospective	2021	76	54 (±8) max aorta diameter	112 (±21)	NR	100 (1 yr), 92 (5 yr), 86 (10 yr)	1	99 (1 yr), 99 (5 yr), 85 (10 yr)
Vallabhajosyula	Retrospective	2016	110	52 (±6)	127 (±22)	NR	99 (1 yr), 93 (5 yr), 87 (10 yr)	2	98 (1 yr), 96 (5 yr), 93 (10 yr)
Nguyen	Retrospective	2021	50	50 (±6) Asc Ao	–	–	98±2 (5 yr)	0	100 (5 yr)
Kayatta	Retrospective	2019	40	47 (±9) Asc Ao	238 (±50)	7 (±4)	100 (5 yr)	0	100 (5 yr)
Tanaka	Retrospective	2021	44	NR	162 (±27)	NR	93±4 (5 yr)	0	95.7 (n=2 deaths) (5 yr)

Data were presented as mean (± standard deviation) or median [range], unless otherwise specified. CCT, cross clamp time; LOS, length of stay; FFR, freedom from reintervention; LTS, long-term survival; yr, year; NR, not reported; AVR, aortic valve regurgitation; Asc Ao, ascending aorta; AI, aortic valve insufficiency.

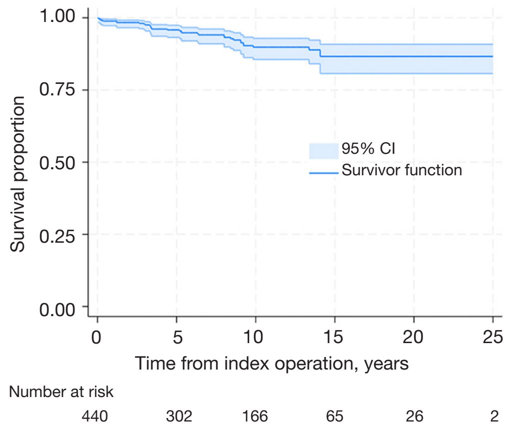

Figure 1 Kaplan-Meier survival estimate: freedom from mortality. CI, confidence interval.

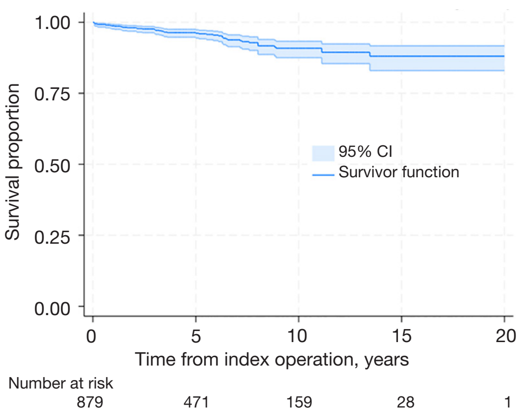

Figure 2 Kaplan-Meier estimate: freedom from secondary reoperation. CI, confidence interval.

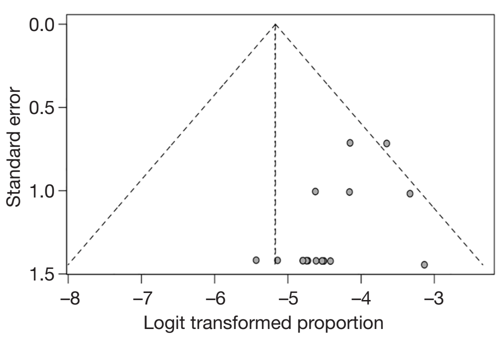

Figure 3 Funnel plot assessment for 30-day mortality.

was 46.3 mm. The estimated mean cross clamp time was 147.9 minutes. The estimated mean length of hospital stay was 8 days. The estimated mean length of intensive care stay was 46.3 hours. The estimated mean thirty-day mortality was 1.7%. Eighty-five percent of patients underwent the David procedure, versus the Yacoub. Of the included papers, nine studies reported freedom from mortality curves (14,15,17,18,20,25,27,28), and 15 studies reported freedom from secondary reoperation curves (14-21,24-30) amenable to aggregated KM analysis. Six studies were deemed to be of moderate risk of bias, with those remaining as low risk (15-17,24,26,30) (see Figure S2). All studies were determined to be of high quality on quality assessment, with the exception of 5 (15,18,19,28,30) which were deemed of moderate quality. Baseline patient demographic data for medical comorbidities were poorly reported across all included studies, with insufficient data reported for meta-analysis for type 2 diabetes mellitus, hypertension, coronary artery disease, peripheral vascular/arterial disease, chronic obstructive pulmonary disease/emphysema, and smoking history. Perioperative data, including operation time, blood loss, and learning curve, were also not reported sufficiently for meta-analysis. KM survival estimation at 5, 10, and 15 years was 96%, 90%, and 87%, respectively (see *Figure 1*). KM freedom from secondary reoperation at 5, 10, and 15 years was 96%, 91%, and 88%, respectively (see *Figure 2*).

Assessment of publication bias with Begg's and Egger's tests for thirty-day mortality demonstrated z=1.63 (P=0.10) and t=−3.10 (P=0.01); given the statistical significance of Egger's but not Begg's test, discordance between small and large studies should be suspected. Funnel plot assessment of thirty-day mortality also demonstrated asymmetry, favoring small-study effects and/or publication bias given right-skewing of the data points (see *Figure 3*). There is a clear transition towards the David procedure, with the bulk of contemporary literature publishing on this technique.

Discussion

Valve-sparing aortic operations, particularly the David and Yacoub procedures, have revolutionized the field of aortic aneurysm surgery. Over the last three decades of clinical practice, these techniques have become the dominant approaches in aortic aneurysm surgeries due to their ability to preserve the native aortic valve, and thereby offer a number of benefits to the patient. These procedures were initially only indicated in those with a morphologically intact tricuspid aortic valve with aortic root or ascending aortic aneurysms, though as a consequence of favorable early results, this was expanded to include those with valve prolapse, stress fenestrations, and bicuspid morphology (23). This systematic review and meta-analysis evaluated the outcomes of these valve-sparing aortic operations, specifically focusing on bicuspid valve patients, with respect to long-term freedom from mortality and freedom from secondary reoperation.

The pooled outcomes from the present review have demonstrated excellent results consistent with the findings of previous longitudinal studies, reporting long-term freedom from mortality, minimal postoperative aortic regurgitation or insufficiency, and minimal secondary reoperations on the aortic root or native aortic valve in BAV cohorts (2,31-34). The preservation of the native aortic valve, even in bicuspid patient cohorts, clearly offers several advantages over a prosthetic valve replacement. Principally, these advantages would be more physiological hemodynamics, the mitigation of the need for anticoagulation in those receiving mechanical prostheses, and improved native valve durability over that of even modern prosthetic replacements (35). Given the population presenting symptomatic due to BAV pathology tend to be far younger, with a considerably higher postoperative life expectancy, the appeal of these procedures in offering low likelihood of a secondary procedure and minimized medical treatment is apparent (19). Careful preoperative evaluation and assessment of valve morphology is critical, however; the congenitally fused cusp in bicuspid patients is obviously smaller than in tricuspid patients, taking up only approximately 55% of the root circumference, versus 67% in normal anatomy (19). Additionally, its insertion is higher than that of the larger non-coronary cusp, such that the depth of the sinuses differs significantly, making appropriate realignment a complex task. This surgical complexity demands that only operators experienced in the management of bicuspid aortopathy in high-volume centers undertake these patients, such that reoperation likelihood is as minimal as possible. A reimplantation approach appears to be superior in this respect, as the entire aortic valve apparatus is supported within the prosthetic graft (13,29,35), a sentiment that is reflected by the overwhelming majority of the patients in this series having had received the David approach, and prior 20-year follow-up results (36,37). Valve-sparing procedures also appear to be superior to alternative procedures like the Bio-Bentall with respect to postoperative neurological outcomes, based on direct comparative studies (i.e., stroke and transient ischemic attacks) (27).

In consideration of the intrinsic differences between the David and Yacoub approaches, there appears to be a clear preference in the literature towards that of the David as aforementioned, with almost all patients in this series having undergone a reimplantation procedure. The proposed mechanism from a number of authors is that the superior results over the remodeling approach are likely due to the annular stabilization provided by the secure, straight proximal anastomosis—despite meticulous technique, a remodeling approach naturally leaves unsupported residual aortic root tissues, as well as the inter-leaflet and subcommisural tringles (38,39). The reimplantation approach functionally excludes all tissues at risk of future dilatation through their inclusion within the prosthetic graft (37). Limited new data on the long-term outcomes of the remodeling technique prevented direct comparison between the two approaches in the present study. Future research using propensity score-matching could be of benefit in this regard.

The findings of the present systematic review and meta-analysis are notably in-keeping with other contemporary reviews, though the focus of these studies tends to be on patients with connective tissue disorders (e.g., Marfans, Loeys-Dietz) or acute aortic catastrophes (40-42). Another systematic review and meta-analysis published recently by our fellow colleagues, with a sole focus on the David procedure utilized in cohorts after 2010, is the most supportive of the presented results, with freedom from mortality and secondary reoperation almost directly comparable to our cohort (43). The combined, independently derived results, highlight the significant freedom from secondary operation through to long-term follow-up. A critical point of consideration here, however, is to note that freedom from secondary reoperation does not necessarily mean freedom from failure of the index operation, as the majority of included studies analyzed do not make note of echocardiographic findings longitudinally. Additional study on long-term, progressive BAV stenosis and insufficiency in the setting of valve-sparing aortic procedures are needed in this respect.

Limitations

The limitations of the present study include the inherent limitations of conducting a large-scale meta-analysis, such as the potential for aforementioned publication bias, the variability in the study methodology and predominant retrospective analyses, and the different surgical procedures of reimplantation and remodeling. Given the small number-at-risk out to follow-up past 15 years, interpretation here must be done with caution. Additionally, the limited availability of comorbidity and perioperative data limited the analysis only to a certain number of outcomes. Future studies with larger sample sizes and standardized reporting of outcomes are critical in providing the field with accurate long-term outcomes and potential predictors of success for valve-sparing aortic operations in BAV patients. Whilst the present meta-analysis has demonstrated favorable outcomes, it is important to acknowledge the presence of heterogeneity among the included studies. There was low heterogeneity observed for the mean length of intensive care, while high heterogeneity was observed for the other remaining variables (I^2 values ranging from 93.2% to 99.9%), likely due to variations in baseline patient valve function, small study effects, and the potential for publication bias.

Conclusions

The present systematic review and meta-analysis demonstrates the durability and safety of the David and Yacoub valve-sparing procedures across long-term follow-up in BAV patients. Significant freedom from mortality and secondary reoperation on the root and valve are the principal benefits to a younger patient population, alongside obviating the need for life-long anticoagulation and the risks entailed. Longer term follow-up will continue to play a critical role in outlining the course of patients having received these approaches, as will monitoring how they evolve to manage ever-increasingly complex surgical pathologies and comorbidities.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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