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Aortic valve replacement: is porcine or bovine valve better?

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Abstract

A best evidence topic in cardiac surgery was written according to a structured protocol. The question addressed was: 'Is porcine or bovine valve better for aortic valve replacement?' Altogether, 562 papers were found using the reported search, of which 15 represented the best evidence to answer the question. All papers represent either level 1 or 2 evidence. The authors, journal, date, country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. This best evidence paper includes 9880 patients from 1974–2006 to compare both valve types. All studies compared either all or some of the following outcomes: complication, durability, mortality, functional status and haemodynamic function. Ten of 15 papers assessed the complication profile due to aortic valve replacement in both valve types. Four papers concluded that bovine valves are superior, whereas only one favoured porcine valves. Five papers showed a similar complication profile between both valves. Six of 15 papers commented on valve durability. Both porcine and bovine valve groups have two papers each to support their superiority in valve durability. Two papers demonstrated similar durability in both valves. There are 11 papers comparing the postoperative mortality. We suggest that there is no difference in mortality profile as eight papers showed that both valves had similar mortality profiles. Two papers supported bovine valve and one paper supported porcine valve in this aspect. There were four papers assessing the postoperative functional status, with three papers suggesting that both valve types had similar clinical improvement postoperatively. Eleven papers compared the haemodynamic function. Nine papers were in favour of bovine valves. Two papers demonstrated similar haemodynamic profiles in both valves. In conclusion, the bovine valve is superior in its complication and haemodynamic profiles. Both bovine and porcine valves have comparable results with regard to the mortality, post-operative functional status and valve durability. Significant variability between the valve manufacturers, study designs, study period and patient population in the above studies impose limitations to the comparison of both valves.

Keywords: Aortic valve replacement • Porcine • Bovine • Outcome • Survival • Complication • Durability • Mortality • Clinical improvement • Haemodynamic

INTRODUCTION

A best evidence topic (BET) was constructed according to a structured protocol. This is fully described in the ICVTS [1].

THREE-PART QUESTION

In [patients undergoing bioprosthetic aortic valve replacement (AVR)] does [porcine or bovine valve] result in better [survival, clinical outcomes and complication rates?].

CLINICAL SCENARIO

In a cardiac surgery clinic, you are consulted by a 70-year old gentleman with aortic stenosis who is referred for AVR. The patient has searched the web and wonders whether a porcine or bovine valve is better. As a consultant cardiac surgeon you decide to review the literature to resolve this question. You specifically want to know the survival, clinical outcomes and complication rates of these valves in AVR.

SEARCH STRATEGY

We perfomed a Medline search from 1946 to April 2012 using OVID interface [aortic valve replacement.mp. or aorta valve/or heart surgery.mp. or heart valve prosthesis/or heart valve surgery.mp. or aortal valve prosthesis.mp. or heart valve bioprosthesis.mp.] AND [porcine valve.mp. or porcine bioprosthesis.mp. or bovine valve.mp. or bovine bioprosthesis.mp. or xenograft.mp.] AND [survival/or survival rate/or overall survival.mp. or adverse outcome.mp. or treatment outcome/or postoperative complications/or complication.mp. or durability.mp. or preoperative complication.mp.]

SEARCH OUTCOME

Five hundred and sixty-two papers were found using the reported search. From these, six level-1 and nine level-2 evidence papers were identified. These provided the best evidence to answer the question (Table 1). Inclusion criteria were level 1 or 2 evidence, and human studies that compared porcine and

Table 1: Best evidence papers

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Reichenspurner *et al.* (1995), Thorac Cardiovasc Surg, Germany [2] Cohort studies (level 2)	Period: 1978–1990 476 porcine valves were implanted in 423 patients (313 aortic, 147 mitral, 16 tricuspid). Models [Carpentier-Edwards (CE) bioprostheses, CE supra-annular bioprostheses, Hancock bioprostheses 1st generation, Hancock bioprostheses 2nd generation] 647 bovine valves were implanted in 577 patients (438 aortic, 201 mitral, 8 tricuspid). Models (Hancock extracorporeal, Ionescu-Shiley, CE, Mitroflow)	Incidence of thromboembolic (TE) complications	Incidence of TE Porcine 1.8% vs bovine 0.9% per patient-year Long-term TE freedom rate. Bovine valve had significant lower long-term TE free rate at 5, 6, 7 years postop ($P < 0.05$)	Although the incidence of TE and IE is lower within bovine valve, long-term durability rates are significantly inferior when compared to porcine valve In addition, porcine valve shows satisfying long-term results regarding TE and IE rates In conclusion, older patients and patients with contraindication for anti-coagulative therapy would benefit from porcine valve
		Incidence of infectious valve endocarditis (IE)	Incidence of IE Porcine 0.5% vs bovine 0.25% per patient-year (no statistic significance) IE free rate (at 9 years) follow-up Porcine 90.7% vs bovine 93.6%	
		Incidence of primary tissue failure (PTF) based on degeneration tissue alterations	Porcine global incidence rate 6 years: 6 ± 3.5% 8 years: 18 ± 7.1% 10 years: 60 ± 13.1% Bovine 6 years 36 ± 6.5% 8 years 68 ± 10% 10 years: 86 ± 19.5% PTF results were significant better in porcine at 7, 8, 9 years postop ($P < 0.001$)	
		Long-term survival rates	At 10 years Porcine (67.8%) vs bovine (61.0%) From 3 to 8 years postop Porcine long-term survival rate was higher ($P < 0.05$) Long-term survival rate dependant on preop NYHA class	
Gao *et al.* (2004), J Am Coll Cardiol, USA [3] Cohort studies (level 2)	Period: 1974–1996 518 AVR porcine CE vs 1021 AVR CE bovine valve	Bioprosthetic valve dysfunction	At 10 years Kaplan–Meier freedom from explantation for structural valve deterioration (SVD): Porcine 92 ± 2% vs bovine 98.5 ± 1% Actual freedom Porcine 96 ± 1% vs bovine 98.9 ± 1% At 15 years Kaplan-Meier and actual freedom Porcine 87 ± 1%, 95 ± 1%, respectively	10-year freedom from thromboembolism was similar in porcine and bovine valves 10-year freedom from IE was similar in porcine and bovine valves Compared with CE porcine valve, CE bovine valve has superior durability. Its freedom from SVD and reoperation makes it the bioprosthesis of choice in this centre
		Thromboembolic events	Prosthetic valve thrombosis Porcine valve (0.03%/per patient-year) vs 0% bovine valve Thromboembolic events 10-year freedom from thromboembolism	

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
			Porcine 80 ± 2% vs bovine 87 ± 2% (*P* = 0.24)	
		Bioprosthetic valve endocarditis (IE)	10-year freedom from IE Porcine 98 ± 1% vs bovine 99 ± 1% (*P* = 0.3)	
		Operative and long-term mortality	At 10 years Kaplan-Meier freedom from explant Porcine 90 2 vs bovine97 ± 1% (*P* = 0.04) Operative Porcine 7.7% vs bovine 4.2% Long-term mortality Porcine 34 ± 2% vs bovine 38 ± 6%, similar mortality (*P* = 0.29)	
Chambers *et al.* (2008), J Thorac Cardiovasc Surg, UK [4] Randomized control trial (level 1)	100 patients were randomized to have single bioprosthetic aortic valve [Medtronic Mosaic porcine or Carpentier-Edwards Perimount bovine (CE-*P*)]. One patient received a mechanical valve due to aberrant coronary origin. Total subjects were 99 patients (51 with porcine and 48 with bovine valve)	Haemodynamic function	At 1 year Peak transvalve pressure difference Porcine 28 ± 13 vs bovine19 ± 9 mmHg (*P* < 0.0001) Mean pressure Porcine 17 ± 7 vs bovine11 ± 5 mmHg (*P* < 0.0001) At 1 year: Effective orifice Porcine 1.28 ± 0.46 vs bovine 1.47 ± 0.45 cm^2 (*P* =0.05) At 1 year (no differences in pre- and postop LV dimensions (LVDD), LV mass index (LVMI), fractional shortening (FS) and LV outflow velocity (LVOT VTI) LVDD Pre: porcine 5.1 ± 0.86 vs bovine 4.9 ± 1.1 cm (*P* = NS) Post: porcine 4.5 ± 0.8 vs bovine 4.6 ± 0.9 cm LVMI Pre: porcine 233 ± 123 vs bovine 211 ± 77 g/m^2 (*P* = NS) Post: porcine 152 ± 50 vs bovine 160 ± 62 (*P* = NS) FS Pre: porcine 35 ± 9 vs bovine 32 ± 11% (*P* = NS) Post: porcine 36 ± 8 vs bovine 34 ± 10 (*P* = NS) LVOT VTI Pre: porcine 21 ± 5 vs bovine 20 ± 5 (*P* = NS) Post: porcine 22 ± 5 vs bovine 20 ± 5 (*P* = NS)	Better haemodynamic function in a bovine compared with a porcine stented valve Non statistic significant trend to a larger effective orifice in bovine valve No difference in exercise ability between two valve types Both groups showed large improvement in anxiety, depression, mental and physical health. No difference in two valve types Conclusion: minor differences in haemodynamic function in favour of the bovine valve. Both valves had similar and significant improvements in life quality, exercise ability and regression of LV mass

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Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
		Clinical event rates	Early death (30 days) Porcine 1 vs bovine 1 patient Late death (1–12 months) Porcine 3 vs bovine 5 Perioperative strokes Porcine 3 vs bovine 2 patients Early TE Porcine 2 patients vs bovine 1 patient Late TE Porcine 2 vs bovine 1 patient	
		Exercise capacity	6-min walk distance (m) Porcine: preop: 255, postop: 366 ($P < 0.0001$) Bovine: preop: 223, postop: 334, ($P = 0.002$)	
		Overall health 1 year after operation	Anxiety score (1 year) Porcine: preop 7.2 ± 3.7, postop 5.0 ± 3.0 ($P = 0.001$) Bovine: preop 7.6 ± 4.4, postop 4.2 ± 3.7 ($P < 0.0001$) Depression score (1 year) Porcine: preop 5.9 ± 3.5, postop 4.4 ± 2.8 ($P = 0.003$) Bovine: preop 6.1 ± 4.1 postop 4.4 ± 3.7 ($P = 0.32$) Physical composite score (1 year) Porcine: preop 28.1 ± 11.8, postop 38.3 ± 11.7 ($P < 0.0001$) Bovine preop 26.0 ± 9.9 postop 38.3 ± 12.03 ($P < 0.0001$) Men Mental composite score (1 year) Porcine: preop 47.6 ± 10.8 post 51.1 ± 8.6 ($P = 0.005$) Bovine: preop 45.2 ± 11.8 post 49.9 ± 12.6 ($P = 0.009$)	
Jamieson *et al.* (2006), Asian Cardiovasc Thorac Ann, Canada [5] Cohort studies (level 2)	Period: 1981–1999 Aortic valve replacement: Carpentier-Edwards supra-annular porcine valve was implanted in 1825 patients in Vancouver, Canada vs Period: 1984–2001 CE-*P* was implanted in 1430 patients 1984–2001 in Tours, France	Mortality	Early mortality Porcine 5.0% vs bovine 2.8% per patient-year ($P < 0.001$) Late mortality Porcine 6.48% vs bovine 4.76% per patient-year Survival at 15 years (all age group) Porcine 29.3 ± 1.5 vs bovine 35.2 ± 3.1% ($P = 0.0009$) Survival (patients <65 years old) Porcine 51.0 ± 2.9% vs bovine 61.2 ± 4.7% ($P = 0.0165$)	Early and late mortality and overall survival differentiate the populations in this study and favour bovine over porcine valve. This is related to the preponderance of concomitant CABG in the porcine valve population Actual freedom from SVD did not differentiate the populations, but in the age groups ≤60 years, the bovine was superior to the porcine

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Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
			Survival (patients ≥65 years old) Porcine 19.6 ± 1.6% vs bovine 17.6 ± 4.2% ($P = 0.0104$)	Concomitant CABG likely decreased the incidence of SVD in porcine valve because of the reduced survival
		Valve-related mortality	Linearized rate Porcine 1.14% vs bovine 1.28% per patient-year ($P = 0.3572$) Overall actuarial freedomat 15 years Porcine 82.0 ± 1.6% vs bovine 79.3 ± 2.8% (not significant difference) Actual freedom at 15 years Porcine 88.5 ± 0.9% vs bovine 84.9 ± 1.7%	Conclusion: both valves have excellent and comparable durability at 15 years. Both bioprostheses provide excellent clinical performance for AVR, especially in patients >60 years old
		Valve-related reoperation	Linearized occurrence rate Porcine 1.09% per patient-year vs bovine 0.63% ($P = 0.0005$) Actuarial freedom at 15 years Porcine 73.7 ± 2.3% vs bovine 81.9 ± 3.8% (not significantly different) Actual freedom at 15 years Porcine 87.8 ± 1.0% vs bovine 90.2 ± 1.7%	
		SVD	Actual freedom (>70 years) at 15 years Porcine 98.2 ± 0.6% vs bovine 99.6 ± 0.4% Actual freedom (61–70 years) at 15 years Porcine 93.0 ± 1.5% vs bovine 92.7 ± 2.5% Actual freedom (51–60 years) at 15 years Porcine 75.4 ± 3.6% vs bovine 84.8 ± 5.6% Actual freedom (41–50 years) at 15 years Porcine 63.1 ± 6.4% vs bovine 85.8 ± 6.6% Actual freedom (≤40 years) at 15 years Porcine 48.4 ± 7.5% vs bovine 72.6 ± 14.6%	
Chaudhry *et al.* (2000), J Heart Valve Dis, UK [6]	Period: Feb 1987–Mar 1990 170 patients undergoing aortic valve replacement (AVR) or mitral valve replacement (MVR) or both	Mortality rate Operative mortality (≤30 days or before discharge)	Operative mortality Porcine (5 patients) vs bovine (2 patients) AVR operative mortality Porcine (2 patients) vs bovine (1 patient)	Operative mortality was not related to the prosthesis implanted No difference in freedom from reoperation at 11 years

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BEST EVIDENCE TOPIC

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Prospective randomized trial (level 1)	Assigned randomly to receive either Bioflo bovine valve (85 patients) or Carpentier-Edwards (CE) supra-annular porcine valve (85 patients)	Valve-related mortality	MVR operative mortality Porcine (2 patients) vs bovine (1 patient)	At 11 years, no significant difference was in the probability freedom from endocarditis
		Valve-related mortality and morbidity	Freedom from valve-related mortality at 11 years Porcine 91.0 ± 3.5% vs bovine 89.5 ± 3.9% ($P = 0.4$)	The quality of a bioprosthetic is directly related to its ability to resist SVD. However, no difference in freedom from SVD at 11 years in between two valves
			Freedom from all valve-related morbidity and mortality at 11 years Porcine 64.9 ± 6.3% vs bovine 58.3 ± 6.7% ($P = 0.4$)	No differences in SVD between different age groups No difference was evident between two valves regarding thromboembolism risks
		Survival rate	At 11 years Porcine 55.3 ± 6.8% vs bovine 41.4 ± 6.8% ($P = 0.15$)	14% difference in overall survival rate at 11 years (higher in porcine group) but did not reach statistical significance
		Reoperation	Porcine 8 patients vs bovine 5 patients Freedom from reoperation at 11 years Porcine 86.88 ± 4.2% vs bovine 84.8 ± 5.9% ($P = 0.8$)	Conclusion: both porcine and bovine offered excellent long-term clinical results
		Complications	SVD Porcine 11 patients vs bovine 10 patients Freedom from SVD at 11 years Porcine 87.5 ± 4.2% vs bovine 83.9 ± 5.4% ($P = 0.9$) Non-structural valve dysfunction Only 1 porcine patient in MVR Thromboembolism Porcine 12 patients vs bovine 12 patients Freedom from thrombo-embolism at 11 years Porcine 83.5 ± 5.3% vs bovine 82.6 ± 5.7% ($P = 0.9$) Freedom from Anticoagulant-related haemorrhage at 11 years Porcine 85.5 ± 5.0% vs bovine 85.9 ± 4.5% ($P = 0.9$) Freedom from endocarditis at 11 years Porcine 96.3 ± 2.1 vs bovine91.2 ± 3.2% ($P = 0.4$)	This RCT showed no difference in clinical performance between a well-tested porcine valve and a representative of the 2nd generation of bovine valves, whether in aortic or mitral positions
		Functional status	All valves Preop: 52% in NYHA class I or II Postop: 91% in class I or II (Porcine 87% vs porcine 97%) Mean peak aortic gradient Porcine 30.6 ± 19.7 mmHg vs bovine 30.3 ± 15.9 mmHg, $P = 0.9$	

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Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Casabona *et al.* (1992), Ann Thorac Surg, Italy and Brazil [7] Cohort studies (level 2)	Study group: 27 patients undergoing isolated AVR received stentless porcine aortic valve vs 30 patients who received stentless bovine aortic valve Control groups: two groups of 30 patients who had either tilting-disc mechanical valve (Omnicarbon) or stented porcine bioprosthesis (Biocor) Follow-up Stentless porcine 9 ± 4 months Stentless bovine 14 ± 5 months Stented porcine 17 ± 7 months Mechanical 29 ± 12 months	Aortic valve area	Valve size 23 Stentless porcine 1.59 ± 0.3 vs stentless bovine 1.50 ± 0.06 cm^2 Valve size 25 Stentless porcine 1.76 ± 0.3 vs stentless bovine 1.63 ± 0.1 cm^2 Valve 27 Stentless porcine 1.76 ± 0.04 vs stentless bovine 1.77 ± 0.1 cm^2 Valve size 29 Stentless porcine 2.20 ± 0.04 vs stentless bovine 1.99 ± 0.4 cm^2	No significant differences were found within the two groups of stentless valves Trivial central aortic regurgitation was more common in stentless bovine valve than stentless porcine valve. It could depend on a more difficult sizing and positioning of the pericardial valve and could therefore be related to the surgeon's experience There are no clear differences, and therefore, no substantial advantages that may justify the use of one type of stentless valve over the other. Both are superior to stented bioprosthesis and become the first choice when a tissue valve is indicated and the patient has a small aortic annulus
		Trivial central aortic regurgitation	Stentless porcine (18.5%) vs stentless bovine (43.3%), ($P = 0.04$)	
		Mortality	3 patients with stentless porcine died within 30 days of operation 1 patient with stentless bovine valve had a sudden death 6 months after operation	
		Maximum velocity across the valve (V_{max})	Valve size 23 Stentless porcine 2.22 ± 0.6 vs stentless bovine 1.93 ± 0.03 m/s Valve size 25 Stentless porcine 2.72 ± 0.1 vs stentless bovine 1.91 ± 0.3 m/s Valve 27 Stentless porcine 1.98 ± 0.4 vs stentless bovine 1.86 ± 0.5 m/s Valve size 29 Stentless porcine 1.80 ± 0.1 vs stentless bovine 1.55 ± 0.5 m/s	
Pelletier *et al.* (1989), Ann Thorac Surg, Canada [8] Prospective cohort studies (level 2)	Period: 1976–1988 A total of 1593 patients underwent valve replacement (AVR, MVR, multiple valve replacement ± CABG) with Carpentier-Edwards porcine (878) or bovine bioprosthesis (715) (316 Ionescu-Shiley, 295 Carpentier-Edwards, and 178 Mitroflow valves) Follow-up Porcine (average 74 months) vs bovine (average 34 months)	Survival	30-day mortality Porcine (9.0%) vs bovine (5.2%) ($P < 0.01$) Early mortality rate of AVR Porcine (6.6%) vs bovine (3.8%) ($P > 0.05$) Early mortality rate of multiple valve replacement Porcine (15.6%) vs bovine (10.5%) ($P > 0.05$) Late mortality rate (linearized) Porcine 2.9% per patient-year bovine 3.5% per patient-year	Overall patient late survival was similar in two groups Among late survivors, excellent clinical improvement was obtained after valve replacement with either type The higher rate of reoperation because of endocarditis among bovine valve was probably due to aggressive attitude toward early surgical treatment at that time Although there is a tendency for survival of porcine valves to be

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Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
			Global actuarial survival at 5 years Porcine 80 ± 1% vs bovine 79 ± 2%	better than that of bovine valves in all positions, it reaches significance only with mitral position
		Complications	Thromboembolism Porcine 1.08% vs bovine 2.01% per patient-year Freedom from thromboembolism AVR (*P* = NS) Porcine at 10 years 96 ± 1 vs bovine at 6 years 94 ± 2% Multiple valve replacement (*P* = NS) Porcine at 10 years 86 ± 5 vs bovine at 6 years 88 ± 4% Endocarditis Porcine 0.47% vs bovine 1.39% per patient-year AVR (*P* = NS) Porcine at 10 years 95 ± 2 vs bovine at 6 years 942 ± 4% Multiple valve replacement (*P* = 0.05) Porcine at 10 years 96 ± 3 vs bovine at 6 years 88 ± 5% Haemorrhage Porcine 0.35% vs bovine 0.41% per patient-year Haemolysis No significant haemolysis detected in both valves PTF Porcine 2.0% vs bovine 20.98% per patient-year (*P* < 0.01) Actuarial freedom AVR at 6 years Porcine 98 ± 1 vs bovine at 94 ± 4% (*P* >0.05) Freedom from all valve-related complications at 6 years AVR Porcine 90 ± 2 vs bovine at 79 ± 5% (*P* = 0.05) Valve survival at 6 years AVR Porcine 89 ± 2 vs bovine at 82 ± 4% (*P* = NS)	However, if freedom from all valve-related complications is considered, results are significant better with porcine valve in all positions In conclusion, the Carpentier-Edwards porcine bioprosthesis appears to perform better than pericardial valves after three or four years
		Reoperation	Porcine 2.14% vs bovine 2.07% per patient-year Freedom from reoperation at 6 years Porcine 96 ± 1 vs bovine 91 ± 4% (*P* >0.05)	

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Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
			Indication for reoperation PTF Porcine 88% vs bovine 48% ($P < 0.0001$)	
			Prosthesis valve endocarditis Porcine 3.8% vs bovine 30% ($P < 0.0001$)	
		Clinical improvement	Among patients who survived without reoperation Porcine (94%) vs bovine 98% remained NYHA class I or II after average of 79 months and 36 months follow-up respectively	
Eichinger *et al.* (2005), J Thorac Cardiovasc Surg, Germany [9] Prospective randomized study (level 1)	Period: August 2000–September 2002 Aortic valve replacement: 66 patients with Medtronic Mosaic porcine vs 70 patients CE-*P* Follow-up 10 months postoperation by echocardiography at rest and at stress	Mean pressure gradient	At rest Valve size 21 and 23 Bovine better than porcine, ($P = 0.001$) Valve size 25 No difference in porcine and bovine ($P = 0.139$) During exercise Valve size 21 and 23 Bovine has lower pressure than porcine ($P < 0.05$) Valve size 19 and 25 No difference in porcine and bovine ($P > 0.05$)	Both porcine and bovine show satisfactory haemodynamic results at rest and at stress Bovine valve was superior in terms of mean pressure gradient in small size valve (21 and 23) Patient–prosthesis mismatch is common in AVR with small valve size. No difference between both valves
		Mean stroke volume	Valve size 21 and 23 No difference in porcine and bovine	
		Patient–prosthesis mismatch Effective orifice area index (EOAI) EOAI >0.85 cm^2/m^2 = mismatch not present EOAI ≤0.85 cm^2/m^2 = moderate mismatch EOAI ≤0.65 cm^2/m^2 = severe mismatch	Severe mismatch Size 19 Procine 100% vs bovine 100% Size 21 Porcine 46.2% vs bovine 40% Size 23 Porcine 22.7% vs 13% Size 25 Porcine 10% vs 20%	
		Left ventricular mass regression	All patients showed regression in LV mass and mass index Absolute amount of LV mass regression No difference between porcine and bovine valves	

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BEST EVIDENCE TOPIC

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Walther *et al.* (2004), Circulation, Germany [10] Prospective randomized study (level 1)	Period: March 2000–April 2003 AVR: 100 patients were randomized to receive Medtronic Mosaic porcine or Perimount bovine valves	Circulatory function	Comparable between groups	Bovine valve has haemodynamic advantage compared to porcine valve
		Maximum trans-valvular blood flow velocity (m/s)	Baseline function (size 25) Porcine 2.54 ± 0.5 vs bovine 2.05 ± 0.4 ($P < 0.05$) Follow-up Porcine 2.45 ± 0.6 vs bovine 2.18 ± 0.3 ($P < 0.05$)	More pronounced left ventricular mass regression in bovine valve
		Transvalvular mean pressure gradient (mmHg)	Baseline function (size 25) Porcine 14.9 ± 7.1 vs bovine 11.3 ± 3.7 ($P < 0.05$) Follow-up Porcine 14.3 ± 6.7 vs bovine 11.2 ± 3.9 ($P > 0.06$)	In summary, both valves provide acceptable haemodynamic function with significant left ventricular mass regression in all patients. However, haemodynamic profile was better in bovine valve
		Left ventricular regression	Left ventricular mass index (baseline, size 23) Porcine 204 ± 89 vs bovine 156 ± 52	
Czer *et al.* (1987), Chest, USA [11] Cohort study (level 2)	Period: January 1976–March 1984 656 patients underwent isolated aortic, isolated mitral or double aortic MVR Porcine (Hancock standard, Carpentier-Edwards) vs bovine (St Jude Medical bileaflet)	Mortality, late survival and valve-related death	Early mortality Porcine 7.5% vs bovine 10.2% (P = NS) Survival Porcine 72 ± 3% vs bovine 71 ± 3% (P = NS) Freedom from valve-related death Porcine 93 ± 2% vs bovine 94 ± 2% (P = NS)	No early mortality difference between two valves Porcine valve has higher structural failure rate No significant difference in freedom from complication rates between two valves Porcine valve has higher reoperation rate
		Valve-related complication	Structural failure 1–4 years Porcine <1% per patient-year vs bovine 0% After 4 years Porcine 3–4.5% vs bovine 0% $P < 0.05$ Embolism rate (5 years) Porcine 92% vs bovine 92% (P = NS) Freedom from haemorrhage at 5 years Porcine 93 ± 3% vs bovine 91 ± 2%. No difference Bacterial endocarditis Porcine 1.0 per patient-year vs bovine 0.5% per patient-year	Conclusion: both valves achieved a comparable operative and late survival, total complication rates, freedom from valve-related morbidity and mortality after 5 years Limited durability, susceptibility to infection and inferior haemodynamic function remains major drawback in porcine valve
		Reoperation	Porcine 1.4% per patient-year vs 0.46% per patient-year ($P < 0.05$)	
		Functional status of survivors	Larger proportion of bovine valve in NYHA class 1 and smaller proportion in class 3 and 4 ($P < 0.001$)	

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Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Dalmau *et al.* (2007), Interact CardioVasc Thorac Surg, Spain [12] Prospective randomized study (level 1)	AVR: 43 patients with Medtronic Mosaic porcine bioprosthesis vs 43 patients with Edward Perimount Magna bovine valve Follow-up: 1 year	Mean pressure gradient	Porcine gradient is higher than bovine in size 19, 21, 23, 25, 26 mm Size 21 mm ($P < 0.001$) Size >23 mm ($P = 0.01$) Size 25 mm ($P = 0.016$)	Conclusion: haemodynamic outcomes of bovine valves were better than porcine
		Indexed mean effective orifice area (EOA)	Porcine 0.97 ± 0.22 cm^2/m^2 vs bovine 1.12 ± 0.21 cm^2/m^2 ($P < 0.001$)	
		Patient–prosthesis mismatch (IEOA ≤ 0.85 cm^2/m^2)	Prevalence Porcine 26.8% vs bovine 6.9% ($P < 0.01$)	
		LV mass regression	Absolute amount of LV mass regression Porcine −72.5 ± 54.4 vs bovine −70.7 ± 50.5 (no significant difference)	
Borger *et al.* (2007), Ann Thorac Surg, Canada [13] Cohort study (level 2)	Period: 2004–2005 AVR ± concomitant procedures: 57 patients with Medtronic Hancock II porcine valve vs 57 patients with Carpentier-Edwards Perimount Magna bovine valve	Mortality	Early postoperative morality Porcine 4% vs bovine 2% ($P = 0.5$)	Bovine valves showed significant lower mean and peak gradient Patient–prosthesis mismatch was significantly higher in porcine Bovine valves had better haemodynamic results
		Transvalvular gradient	Peak transvalvular gradient (mmHg) Porcine 32.3 ± 7.4 vs bovine 22.1 ± 7.4 ($P < 0.001$) Mean gradient Porcine 18.5 ± 15.5 vs bovine 10.4 ± 4.0 ($P < 0.001$)	
		Patient–prosthesis mismatch	Porcine 52% vs bovine 30% ($P = 0.02$)	
		EOA	EOA (cm^2) Porcine 1.29 ± 0.34 vs bovine 1.40 ± 0.24 ($P = 0.07$)	
Wagner *et al.* (2007), J Thorac Cardiovasc Surg, Germany [14] Cohort study (level 2)	Period: 2000–2004 AVR: 50 patients received CE Perimount bovine valve, 70 patients received Perimount Magna bovine valve, 44 patients received Mosaic porcine valve, and 28 patients received Soprano bovine valve Follow-up: 6 months	Mean systolic pressure gradients	Porcine valve has higher gradient compared to bovine valves ($P < 0.05$)	Satisfactory haemodynamic results in patients with a small aortic annulus The pericardial, completely supra-annular Magna bioprosthesis with a reduced sewing ring indicated the lowest pressure gradients seems to deal best with the challenge of achieving good haemodynamic in patients with a small aortic annulus
		Effective orifice fraction (EOF)	Porcine valve has lower EOF compared to the bovine valves (35.2%) vs Perimount (41.9%), Magna (45.1%), Soprano (45.8%)	
		Patient–prosthesis mismatch	Porcine has more patient-prosthesis mismatch (69%) vs bovine valves, lowest in Soprano valve (32%)	
		EOAI (cm^2/m^2)	Porcine (0.75 ± 0.24) vs Perimount (0.90 ± 0.25), Magna (0.93 ± 0.22), Soprano (0.92 ± 0.15) ($P < 0.05$)	
Suri *et al.* (2009), Ann Thorac Surg, USA [15] Prospective randomized study (level 1)	Period 2004–2006 AVR: Edwards Perimount bovine ($n = 76$) vs Medtronic Mosaic porcine valve ($n = 76$)	Mean aortic valve gradient (mmHg)	Porcine 20.4 vs 13.4 ($P < 0.001$)	Both valves had similar regression in LV mass, despite small differences in prosthetic haemodynamics 1 year after surgery
		Mean indexed aortic valve area (cm^2/m^2)	At dismissal Porcine 0.9 vs bovine 1.1 ($P < 0.01$)	

Continued

BEST EVIDENCE TOPIC

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
	Follow-up: 1 year		At 1 year Porcine 0.9 vs bovine 1.1 ($P < 0.001$)	
		Regression in LVMI (g/m^2)	Porcine −32.4 vs bovine −27.0 ($P = 0.40$)	
		Early deaths	None in both types of valve	
Dalmau *et al.* (2011), Eur J Cardiothoracic Surg, Spain [16] Prospective randomized study (level 1)	Period: 2004–2006 AVR: Edwards Perimount Magna bovine (54) vs Medtronic Mosaic porcine valve (54) Follow-up: 1 and 5 years	Mean transvalvular gradients (mmHg)	At 1 year Porcine 16.3 ± 7.6 vs bovine 10.3 ± 3.4 ($P < 0.0001$) At 5 year Porcine 16.8 ± 8.7 vs bovine 9.6 ± 3.5 ($P < 0.0001$)	The study clearly demonstrates a favourable haemodynamic function of the bovine valve up to 5 years after implantation. With long-term follow-up, Magna valves were found to haemodynamically outperform the porcine valve and such improvements positively affected LV hypertrophy regression
		IEOAs $cm^2\ m^{-2}$	At 1 year Porcine 0.96 ± 0.22 vs bovine 1.10 ± 0.22 At 5 year Porcine 0.76 ± 0.19 vs Bovine 1.02 ± 0.25	
		Absolute left ventricular mass index	At 1 year Porcine −26.3 ± 43.8 vs bovine −30 ± 36.2 (no significant difference) At 5 year Porcine −4.3 ± 36.1 vs bovine −47.4 ± 35.1 ($P < 0.0001$)	
		Overall survival at 5 years	Porcine 79.6 ± 4.1% vs bovine 94.4 ± 2.2% ($P = 0.039$)	

NS: not significant.

bovine valves in AVR ± concomitant procedures. Studies that compared stented and stentless valves were excluded.

RESULTS

Reichenspurner *et al.* [2] compared Carpentier-Edwards (CE), CE Supra-annular, Hancock first and second generation porcine valves in 423 patients and Hancock-Extracorporeal, Ionescu-Shiley, CE, Mitroflow bovine valves in 577 patients in AVR, mitral valve (MVR) or multiple valve (MR) positions from 1978 to 1990. The freedom rate from thromboembolic complications was significantly lower in bovine valves. The long-term results of primary tissue failure and long-term survival rates were significantly better in porcine valves.

Gao *et al.* [3] conducted a cohort study comparing 518 CE porcine and 1021 CE bovine valves in the AVR position from 1974–1996. Both valve types had a similar long-term mortality rate and freedom from thromboembolism and IE at 10-year follow-up.

Chambers *et al.* [4] performed a randomised control trial (RCT) comparing 51 Medtronic Mosaic (MM) porcine and 48 CE Perimount bovine valves in AVR. They examined the transvalvular pressure, effective orifice area (EOA), left ventricular (LV) dimension, LV mass index, fractional shortening and LV outflow velocity. It showed minor differences in haemodynamic function in favour of bovine valves.

Jamieson *et al.* [5] conducted a cohort study comparing 1825 CE supra-annular porcine valves from 1981–1989 in Vancouver and 1430 CE Perimount bovine valves in AVR from 1984 to 2001 in Tours. It showed bovine valves had better mortality and survival rates.

Chaudhry *et al.* [6] conducted an RCT in an UK centre from 1987–1990 comparing 85 CE supra-annular porcine and 85 Bioflo bovine valves in AVR and/or MVR. The results showed no difference in the overall mortality, functional status and freedom from reoperation, endocarditis, SVD or thromboembolic events.

Casabona *et al.* [7] completed a cohort study comparing 27 stentless porcine/bovine valves with 30 Omnicarbon mechanical valves/stented porcine Biocor bioprosthesis. They also made

comparisons between two stentless valves, which showed no difference in postoperative aortic valve area, maximum velocity across the valve and mortality.

Pelletier *et al.* [8] performed a cohort study comparing 878 CE porcine and 715 Ionescu-Shiley, CE and Mitroflow bovine valves in AVR, MVR or MR from 1976–88. It showed similar late survival rates and clinical improvement. However, the freedom from all valve-related complications was significantly better in porcine valves.

Eichinger *et al.* [9] conducted an RCT comparing 68 MM porcine valve and 70 CE Perimount bovine valves in AVR in the years 2000 to 2002. There was no difference in patient–prosthesis mismatch. The bovine valve had lower mean pressure gradient at rest and during exercise 10 months after operation.

Walther *et al.* [10] carried out an RCT on 100 patients from 2000–2003 comparing MM porcine and Perimount bovine valves. Transvalvular blood flow velocity and mean pressure were assessed. Both valves showed acceptable haemodynamic function with significant LV mass regression with overall better haemodynamic profile in bovine valves.

Czer *et al.* [11] conducted a cohort study on 656 patients comparing Hancock standard and CE porcine valves with St Jude Medical bileaflet bovine valves in AVR, MVR or MR positions from 1976–1984. Both porcine and bovine valves had a similar mortality rate. Porcine valves had higher structural failure rates with higher reoperation rates. Bovine valves showed better functional status postoperatively.

Dalmau *et al.* [12] performed an RCT in Spain comparing 43 MM porcine valves with 43 Edward Perimount Magna bovine valves in AVR position. Mean pressure gradient, EOA and LV mass regression were examined. Bovine valves showed better haemodynamic function with lower patient–prosthesis mismatch prevalence at 1-year follow-up.

Borger *et al.* [13] performed a cohort study comparing 57 Medtronic Hancock II porcine valves with 57 CE Perimount Magna bovine valves in AVR and/or concomitant procedures in 2004 to 2005. Bovine valves showed better peak and mean transvalvular gradients with lower patient–prosthesis mismatch.

Wagner *et al.* [14] compared 50 CE Perimount bovine valves, 70 Perimount Magna bovine valves, 44 MM porcine valves and 28 Soprano bovine valves through a cohort study in Germany. They demonstrated that generally bovine valves had better haemodynamic performance compared with porcine valves.

Suri *et al.* [15] conducted an RCT from 2004 to 2006 examining 76 Edwards Perimount bovine and 76 MM Porcine valves. Despite small differences in haemodynamic performance, both valves had similar LV regression after 1 year follow-up.

An RCT performed by Dalmau *et al.* [16] from 2004 to 2006 comparing 54 Edwards Perimount Magna bovine and 54 MM showed superior haemodynamic function in bovine valves leading to LV regression. Patients with bovine valves also had better overall survival rate at 5 years.

CLINICAL BOTTOM LINE

In conclusion, the bovine valve is superior in its complication and haemodynamic profile. Both bovine and porcine valves have comparable results with regard to the mortality, postoperative functional status and valve durability. Significant variability between the valve manufacturers, study designs, study period and patient population in the above studies imposes limitations to the comparison of both valves.

Conflict of interest: none declared.

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eComment. The current bioprosthesis of choice for aortic valve replacements

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I read with great interest the paper by Yap *et al.* regarding the best valve substitute for aortic valve replacement [1]. In their results, they included six randomized