



Centre for CLINICAL EFFECTIVENESS

How effective are 21mm bioprosthetic and mechanical aortic replacement valves in aiding regression of left ventricular hypertrophy with reduction in left ventricular mass and improvement in patient quality of life and NYHA classification?

Dr Paul A. Fennessy, Dr Paul Antonis, Associate Professor Jeremy Anderson

Centre for Clinical Effectiveness, Monash Medical Centre, Southern Health Care Network,
246 Clayton Rd, Clayton VIC 3168, Australia.

Telephone: +61 3 9550 2726
Fax: +61 3 9550 2727
Email: Paul.Fennessy@med.monash.edu.au

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CENTRE FOR CLINICAL EFFECTIVENESS

The Centre for Clinical Effectiveness exists to enhance patient outcomes through the clinical application of evidence-based research. The Public Health Division, Department of Human Services, Victoria, and the Southern Health Care Network fund the Centre. The Centre is also affiliated with the Faculty of Medicine, Monash University. Amongst other programs, the Centre operates an Evidence Centre that accepts requests to identify and critically appraise the available evidence on particular clinical topics. It offers this service to staff of the Southern Health Care Network, especially Program Directors, who will use the information provided to influence medical planning and decision-making.

Rationale

The Centre for Clinical Effectiveness Evidence Centre searches for best available evidence by a strategy that incorporates two factors:

1. A hierarchy that reflects methodological quality, that is the likelihood of systematic bias affecting the research results reported.
2. A desire to limit the amount material provided if adequate, sound, research summaries already exist.

The Evidence Centre goes first to databases that enable us to identify systematic reviews, then evidence-based clinical practice guidelines or health technology assessments, then individual randomised controlled trials. If adequate, sound, summaries of the best evidence available are found in this way then individual research trials are not included in the report. If adequate summaries are not found our search strategy becomes considerably broader and may incorporate individual studies that may be more prone to bias, less generalisable, or have other difficulties identified through our critical appraisal of their methodology. For this reason, when citing research, we describe the quality of evidence (i.e. "Level of Evidence") appropriate for each study as defined by the Australian National Health & Medical Research Council (1995; see Appendix).

REQUEST MADE BY:

Ms Althea Barr, research coordinator at Monash Medical Centre's Heart & Chest Clinical Program, approached the Centre in December 1998 requesting a literature search and critical appraisal of 21mm bioprosthetic and mechanical replacement valves in aiding regression of left ventricular hypertrophy with reduction in left ventricular mass and improvement in patient quality of life. This report covers much of the available material.

CLINICAL REQUEST

Brief Summary

- We identified 28 articles that matched our search requirements. However, only **five** articles met specific requirements. Twenty three articles were excluded for reasons outlined below.
- Of the five articles assessed, one reached level III evidence (DePaulis *et al.* 1998) and the remainder level IV evidence (Bertolini *et al.* 1998, Kadir *et al.* 1998, McDonald *et al.* 1997, Gehlot *et al.* 1996).
- While most authors demonstrated an improvement of NYHA class, LVM was only assessed in one article (DePaulis *et al.*), 21mm bioprosthetic valves were not always differentiated from other valve sizes or valve types within the same study (Bertolini *et al.*, DePaulis *et al.*, Gehlot *et al.*) and an improvement in quality of life described by Bertolini *et al.* was not substantiated.
- Many of the excluded articles (see Reference section) described the benefit of AVR in patients aged 70 years or more but no data on valve size was reported.

Details Of Evidence Request

Patients	Elderly patients (70 years+) with aortic valve disease (stenosis or regurgitation) undergoing aortic valve replacement
Interventions	21mm bioprosthetic valve
Comparisons	21mm valve (mechanical or otherwise)
Outcomes	Regression of left ventricular hypertrophy with reduction in left ventricular mass, improvement in patient quality of life

Search terms

Cardiac terms:	valve replacement, (ventricular) hypertrophy, LVH, (ventricular) mass, LVM, h(a)emodynamic, NYHA, ventricular function
Valve terms:	prosthesis, bioprosthesis, valve, mechanical, transgenic, Medtronic, mosaic, porcine
Patient terms:	quality of life, lifestyle, satisfaction, questionnaire, age 65+

Refinements, Searching & Reporting Constraints

We have included all language articles published since 1993 that report improvement in cardiac anatomy and function and quality of life following aortic valve replacement surgery. Our electronic searching was finalised on 18 January 1999. This excluded a number of articles we believed offered little or no additional relevant information (e.g. letters to editors, editorials, short - <2 page length - reviews). Subjects underwent aortic valve replacement surgery with either a bioprosthetic valve or a mechanical valve. The prime outcomes of interest are regression of left ventricular hypertrophy with reduction in left ventricular mass and improvement in patient quality of life.

We excluded a number of articles from critical appraisal for the following reasons:

- Mean age of patients was < 65 years
- Age range of patients indicated that majority were < 65 years
- Valve size was not reported in the article or mean size of valve was > 21mm
- Article described an experimental (i.e. non-clinical) study
- Pericardial valve

RESULTS

From our sources we identified and appraised 5 separate articles which we categorised as follows:

Evidence-based clinical practice guidelines	0
Non-evidence-based clinical development and use guidelines	0
Systematic reviews or meta-analyses	0
Randomised controlled trials	0
Well-designed controlled trials, cohort or case-control analytic studies	1
Descriptive case series	4
Consensus reports, narrative reviews	0
Economic studies	0

We are reasonably confident these figures represent the most important findings published to date based on our refinements, searching and reporting constraints.

EVIDENCE SUMMARIES

Format

Evidence Summaries are in the form of spreadsheets (found at the back of the report). Each spreadsheet contains the article citation, the study design with level of evidence available according to NHMRC guidelines (1995), patient description, scientific validity of the article, results and pertinent remarks from the authors and Centre for Clinical Effectiveness reviewer.

REFERENCES

ARTICLES APPRAISED

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APPENDIX

Disclaimer

The information in this report is a summary of that available and is primarily designed to give readers a starting point to consider currently available research evidence. Whilst appreciable care has been taken in the preparation of the materials included in this publication, the authors and Southern Health Care Network do not warrant the accuracy of this document and deny any representation, implied or expressed, concerning the efficacy, appropriateness or suitability of any treatment or product. In view of the possibility of human error or advances of medical knowledge the authors and Southern Health Care Network cannot and do not warrant that the information contained in these pages is in every aspect accurate or complete. Accordingly, they are not and will not be held responsible or liable for any errors of omissions that may be found in this publication. You are therefore encouraged to consult other sources in order to confirm the information contained in this publication and, in the event that medical treatment is required, to take professional expert advice from a legally qualified and appropriately experienced medical practitioner.

Australian National Health & Medical Research Council's Levels of Evidence

The quality of the evidence presented in this report was systematically assessed and classified according to the NHMRC's *Guidelines for the Development and Implementation of Clinical Practice Guidelines* (1995):

- | | |
|-----------|---|
| Level I | Evidence obtained from a systematic review of all relevant randomised controlled trials |
| Level II | Evidence obtained from at least one properly designed randomised controlled trial |
| Level III | Evidence from well-designed controlled trials without randomisation; well-designed cohort or case-control analytic studies preferably from more than one centre or research group; multiple time series with or without the intervention. |
| Level IV | Opinions of respected authorities, based on clinical experience, descriptive studies, reports of expert committees |

APPENDIX

Databases

We searched the following databases and websites in this order:

Cochrane Library CD-ROM
Best Evidence CD-ROM
OVID Medline
CINAHL
Bandolier
Agency for Health Care Policy and Research (AHCPR)
NHS Centre for Reviews and Dissemination (NHS CRD)
Aggressive Research Intelligence Facility (ARIF)
Cliniweb
Effectiveness Matters
Internet Database of Evidence-Based Abstracts and Articles (IDEA)
National Institutes of Health (NIH)
Evidence-based surgery
Health Star
Federal Drugs Authority (FDA)
Medical Matrix
Medscape
MedMark
Canadian Medical Association
American Heart Association
National Heart Lung and Blood Institutes (NHLBI)
CardioSource
Intervent.org
Heart Surgery Forum
European Society of Cardiology
Society of Thoracic Surgeons
Cardiothoracic Surgery Network
American Medical Association
Megacrawler
HotBot
American College of Surgeons
American College of Chest Physicians

EVIDENCE SUMMARY <div style="border: 1px solid black; padding: 5px; text-align: center;"> 21mm BIOPROSTHETIC AORTIC VALVES </div>	STUDY DESIGN & NHMRC LEVEL OF EVIDENCE	DESCRIPTION: Patients, Interventions, Comparisons, Outcomes, Inclusion & Exclusion Criteria	VALIDITY: Methodology, rigour, selection, opportunity for bias.	RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate.	AUTHORS' COMMENTS: Risk/benefit, limitations.	REVIEWER'S COMMENTS: Risk/benefit, methodology, conclusions.
Depaulis,R.; Sommariva,L.; Colagrande,L.; Dematteis,G.M.; Fratini,S.; Tomai; Bassano,C.; Depeppo,A.P.; Chiariello,L. Regression of left ventricular hypertrophy after aortic valve replacement for aortic stenosis with different valve substitutes. Journal of Thoracic & Cardiovascular Surgery 1998;116:590-598.	Non-randomised controlled trial. Level III evidence.	<p>Patients: n=30 selected from 158 pts over 2 years, M&F, mean age 65+ (range U/K), all with stenosis & 2 in each of 3 groups with regurg; inclusion criteria - in-house preop echo, no other valvular disease, no Hx of hypertension (but mild HT with Rx OK), normal LVF, no or trivial aortic regurg at F/U, diameter between 21-23 mm for stented valves. Pts <70 received mechanical valve; pts >70 received biologic valve.</p> <p>Intervention: Group I: stentless bioprosthetic valves (n=10; Toronto SPV, St Jude Medical & Sorin Biomedical) with mean size 24.1mm; Group II: stented valves (n=10; Hancock) with mean size 21.4mm; Group III: mechanical valves (n=10; CarboMedics bileaflet) and mean size 21.4mm. Choice based on surgeon's preference. Control group nil Hx of cardiac disease.</p> <p>Outcomes: NYHA class, LVM, gradient, wall thickness.</p> <p>Exclusions: nil reported.</p>	<p>Randomisation: no.</p> <p>Follow up: 13 months Group I; 15 months Group II; 12 months Group III.</p> <p>Blinding: yes.</p> <p>Similar groups: some dissimilarities.</p> <p>Potential for bias: no randomisation, valve sizes were meaned and no individual details offered, control pts slightly younger than Rx groups, small pt numbers, U/K how many pts received 21 mm valves.</p>	NYHA class - n=27/30 pts improved to class I, other 7 to class II. LVM - reduced in all groups with nil difference between groups gradient - reduced in all groups with group I offering best reduction. wall thickness - all bioprosthetic valves reduced both IV septum and posterior wall thickness significantly.	"Because pt numbers are small we could not use LVM regression after 1 year to distinguish among pts undergoing AVR for aortic stenosis by means of valve prostheses with different hemodynamic performances."	Reader should be aware that results were not reported for individual valve sizes and that the 'meaning' of valve sizes makes it impossible to differentiate benefits.

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Bertolini,P.; Luciani,G.B.; Vecchi,B.; Pugliese,P.; Mazzucco,A. Aortic valve replacement with the Biocor PSB stentless xenograft. Annals of Thoracic Surgery 1998;66:425-430.	Descriptive study. Level IV evidence.	Patients: n=106 (50M 56F), mean age 70 years, all >65 years, contraindicated for warfarin, stenosis and/or regurg in 103. Intervention: aortic valve replacement with either Biocor PSB, Toronto SPV or O'Brien-Angell stented or stentless bioprosthetic valves. Surgeon's choice for valve type. Outcomes: NYHA class, valve problems, LV function. Exclusions: not reported.	Randomisation: no. Follow up: mean F/U = 39 +/- 14 months (range 6-66 months).NB: hemodynamic data for 6 months only. Blinding: U/K. Similar groups: U/K. Potential for bias: valve size meaned so no individual valve size results, no randomisation of patients, U/K how many pts received 21mm valves, LV mass not recorded, different valve size data not reported, despite the positive authors' quote QOL was not analysed, U/K if all AVR were Biocor PSB valves-abstract and Methods differ.	NYHA class - improvement from mean of class 2.9 to class 1.4. Echo results show valve regurg no greater than mild (except in pt with endocarditis). Peak pressure gradient at 6 months dependent on valve size: 24+/-15 with 21mm valve (type U/K).	"AVR using the Biocor PSB stentless xenograft offers excellent mid-term (outcomes). Hemodynamic performance is favorable and QOL satisfactory."	Difficult to determine much from this paper since the Abstract and Methods differ with respect to valve types used in patients.
Kadir,I.; Izzat,M.B.; Birdi,I.; Wilde,P.; Reeves,B.; Walsh,C.; Bryan,A.; Angelini,G. Hemodynamic performance of the 21-mm St. Jude bioimplant prosthesis using dobutamine Doppler echocardiography. American Journal of Cardiology 1998;81:599-603.	Descriptive study. Level IV evidence.	Patients: n=11 (8M 3F), mean age 75 years (range 67-82), nil cardiac Rx, inclusion criteria not reported. Intervention: AVR with the St Jude Medical BioImplant 21mm prosthetic valve. Outcomes: LV function, pressure gradients. Exclusions: not reported.	Randomisation: no. Follow up: mean F/U at 10.8 +/- 5.1 months after surgery. Blinding: U/K. Similar groups: N/A. Potential for bias: no randomisation or blinding, no inclusion or exclusion criteria reported, F/U range not reported, no data on QOL.	All pts had good LV function, with dobutamine stress test tolerated well by n=7/11 pts with nil impairment in contractility detected. n=9/11 in NYHA class I postop. Mean gradient rose from 30mmHg at rest to 49mmHg under stress test. Nil association with BSA.	"...the size 21mm St Jude Bioimplant prosthesis exhibits suboptimal hemodynamic performance with transvalvular gradients consistent with mild to moderate aortic stenosis, both at rest and under stress conditions."	

EVIDENCE SUMMARY <div style="border: 1px solid black; padding: 5px; text-align: center;"> 21mm BIOPROSTHETIC AORTIC VALVES </div>	STUDY DESIGN & NHMRC LEVEL OF EVIDENCE	DESCRIPTION: Patients, Interventions, Comparisons, Outcomes, Inclusion & Exclusion Criteria	VALIDITY: Methodology, rigour, selection, opportunity for bias.	RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate.	AUTHORS' COMMENTS: Risk/benefit, limitations.	REVIEWER'S COMMENTS: Risk/benefit, methodology, conclusions.
McDonald, M.L.; Daly, R.C.; Schaff, H.V.; Mullany, C.J.; Miller, F.A.; Morris, J.J.; Orzulak, T.A. Hemodynamic performance of small aortic valve bioprostheses: is there a difference? <i>Annals of Thoracic Surgery</i> 1997;63:362-366.	Descriptive study. Level IV evidence.	<p>Patients: n=151 (63M 88F), mean age 77 years (range 21-98), 97% NHYA class III or IV, stenosis in 82%, regurg in 2% and mixed in 16%, some concomitant procedures.</p> <p>Intervention: AVR with 3 different prostheses: Carpentier-Edwards pericardial (n=25, 8M 17F, mean age 75, n=23 class III/IV), Medtronic Intact (porcine; n=18, 2M 16F, mean age 77, n=17 class III/IV), Carpentier-Edwards Porcine (n=25, 3M 22F, mean age 78, n=25 class III/IV). NB: values are for 21mm valves ONLY. Surgeon's choice for valve type during surgery.</p> <p>Outcomes: pressure gradient, orifice area.</p> <p>Exclusions: mitral valve replacements.</p>	<p>Randomisation: no.</p> <p>Follow up: < 2 weeks (prior to discharge).</p> <p>Blinding: no.</p> <p>Similar groups: yes.</p> <p>Potential for bias: no randomisation or blinding, short F/U, few functional tests performed, data was analysed retrospectively, study group was <10% of overall population described, some pts <65 years but cannot identify, inclusion and exclusion criteria.</p>	21mm valve pressure gradients (mmHg): CEs pericardial - 23+/-10 Medtronic - 19+/-8 CE Porcine - 19+/-7 Orifice area (cm ²): CE pericardial - 1.5+/-0.4 Medtronic - 1.6+/-0.5 CE Porcine - 1.6+/-0.3	"The in vivo hemodynamic performance of these 3 prostheses is similar."	Reader should be aware that F/U is quite short (<2 weeks) and functional results were not compared with baseline data.
Gehlot, A.; Mullany, C.J.; Ilstrup, D.; Schaff, H.V.; Orzulak, T.A.; Morris, J.J.; Daly, R.C. Aortic valve replacement in patients aged eighty years and older: early and long-term results. <i>Journal of Thoracic & Cardiovascular Surgery</i> 1996;111:1026-1036.	Descriptive study. Level IV evidence.	<p>Patients: n=322 (171M 151F), mean age 83 years (range 80-92), 86% class III/IV, 79% had stenosis & 9% mixed stenosis and regurg, 43% had concomitant procedures (e.g. CABG, MVR).</p> <p>Intervention: n=287 porcine or pericardial bioprosthesis, n=3 homograft, n=32 mechanical. NB: Preop hemodynamic functions not recorded if clinical symptoms indicated aortic valve disease. Valve sizes: <20mm=39, 21-22mm=104, >22mm=176.</p> <p>Outcomes: graft patency, angina rate, death, MI, hand function, complications.</p> <p>Exclusions: poor ulnar collateral flow, +ve Allen test.</p>	<p>Randomisation: no.</p> <p>Follow up: mean 46 months (up to 15 years).</p> <p>Blinding: U/K.</p> <p>Similar groups: U/K.</p> <p>Potential for bias: no randomisation, U/K if blinded measurements or if groups similar, U/K how many 21mm valves implanted, no functional studies.</p>	At 1 year: 272/278 in class I/II. At 47 months: 214/261 in class I/II; 92% said they were in better condition than before.	"Risk factors for AVR in octogenarians include female gender, unstable symptoms, poor EF, renal impairment, CABG". "...the outlook for operative survivors is excellent..."	Reader should be aware that porcine and pericardial valve types are not differentiated and functional results are minimal.