

Session 6:

Life Quality and Expectancy after Heart Valve Replacement

The 'Threshold Age' in Choosing Biological Versus Mechanical Prostheses in Western Countries

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The Journal of Heart Valve Disease 2004;13 (Supplement 1): S91-S94

There is little difficulty in deciding the type of valve for the young patient, unless contraindications to anti-coagulant use exist. The mechanical valve, with its assured durability, is the usual choice for those below middle age. Similarly, with the patient of advanced age, the prospect of being able to avoid anticoagulants makes a bioprosthesis a common choice. The difficult decision is in deciding the 'threshold age' at which it is likely that the bioprosthesis will outlive the patient. Advocacy of too early a 'threshold age' may result in otherwise healthy patients of advanced age facing the risk of structural valve deterioration and the prospect of a prohibitive reoperation hazard.

What evidence exists to inform the decision on 'threshold age'?

Evidence from guidelines

The American College of Cardiology/American Heart Association Task Force has produced authoritative guidelines, with a good evidence base, for the management of patients with valvular heart disease, published in 1998 (1). These guidelines recommend a bioprosthesis for patients aged ≥ 65 years needing aor-

tic valve replacement (AVR), and who do not have risk factors for thromboembolism (atrial fibrillation, severe left ventricular dysfunction, previous thromboembolism, and hypercoagulable conditions). A bioprosthesis is recommended for those aged over 70 years who need mitral valve replacement (MVR) and who do not have risk factors for thromboembolism.

Evidence from randomized trials

The Edinburgh Trial compared outcome with a Björk-Shiley mechanical valve or a bioprosthesis for isolated AVR or MVR in 472 patients recruited between 1975 and 1979 and followed for an average of 20 years (2). The now well-recognized structural valve deterioration of bioprostheses, commencing at about six to eight years after surgery, was demonstrated, as were bleeding problems associated with the anticoagulation necessary with mechanical valve use. Thromboembolic risks were identical for each valve type. The need for reoperation and its associated risk (overall 30-day mortality of 14%) influenced the recommendation of the group that bioprostheses be restricted to single AVR where life expectancy was not thought to exceed 10 years. It is notable that in this trial, at five years 15% of the aortic, and 36% of mitral bioprosthesis patients, were receiving anticoagulants. By 15 years, the figures had risen to 33% and 57%, respectively. A bioprosthesis therefore is no guarantee of freedom from anticoagulation.

The Veteran Affairs Randomized Trial compared outcome for single AVR or MVR in 575 men, with a Björk-Shiley mechanical valve or a bioprosthesis; patients

Presented at *The ideal human heart valve substitute: 50 years between perceptions and realities* meeting, September 2003, Naples, Italy

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were recruited between 1977 and 1982, and followed beyond 15 years (3). Structural valve deterioration of the bioprostheses occurred most commonly in men under 65 years of age. The investigators suggested that a bioprosthesis would be advantageous in those aged over 65 years.

Evidence from non-randomized comparative studies

A comparative study from the Duke University Medical Center reviewed 841 patients undergoing first-time isolated AVR between 1976 and 1996 in an attempt to optimize selection criteria for biological or mechanical valves in AVR (4). Survival free from valve-related morbidity at 10 years was better for the mechanical group in those aged 65 years or less, but better for the bioprosthetic group in those aged over 65. The authors recommended a bioprosthesis for the aortic position in those aged over 65, as well as for younger patients with co-morbidity suggesting a life expectancy of less than 10 years.

A comparative study from the UCLA group of Khan and colleagues (5) compared the experience of 2,533 patients having St. Jude mechanical valves or bioprostheses over a 20-year period, and analyzed outcomes for those aged below 65 and those aged ≥ 65 years. These authors showed similar survival for mechanical and biological valve patients over 20 years in both age groups. The trade-off between increased hemorrhage risk with mechanical valves and late reoperation for bioprosthetic valve failure was well documented.

Evidence from series of single valve types

The Minneapolis group of Emery and colleagues (6) reported on 2,390 AVRs with the St. Jude mechanical valve, with a 20-year follow up. The target INR was 1.8 to 2.5, and low-dose aspirin was included. The bleeding rate was 1.07% per patient-year (pt-yr), the thromboembolic rate 0.59% per pt-yr, and no structural failure occurred.

The Vancouver group of Jamieson et al. (7) reported on 2,237 AVRs and 1,582 MVRs performed between 1975 and 1995 using the Carpentier-Edwards porcine bioprosthesis. These authors analyzed complications by actuarial and cumulative incidence ('actual') methods, and showed that the recommendation of a bioprosthesis for the aortic position could be justified in patients aged over 60 years, and for the mitral position in patients over 70.

Evidence from literature reviews and meta-analyses

Birkmeyer and colleagues (8) used mathematical modeling based on randomized clinical trials and large follow up studies for AVR to come to the conclusion that "...mechanical valves are preferred for AVR patients less than 60 years old (but that) most patients

currently undergoing AVR are elderly and would benefit more from tissue valves."

Puvimanasinghe et al. (9) used meta-analysis and mathematical modeling to gain further insight into AVR with mechanical or bioprosthetic valves, and suggested that the currently recommended age of 65 for using a bioprosthesis could be lowered further.

Complications of mechanical and biological valves relevant to 'threshold age'

Rahimtoola (10) has shown that structural valve deterioration begins at about year 5 after MVR, and at year 8 after AVR. Stented and unstented porcine bioprostheses appear equally vulnerable. The pericardial bioprosthesis has a lower rate of structural valve deterioration than porcine, and homografts have a similar rate to porcine bioprostheses.

Arom's group (11) reviewed 796 patients receiving St. Jude mechanical valves, who were aged ≥ 70 years and showed a hemorrhage rate of only 0.48% per pt-yr and a thromboembolic rate of 0.8% per pt-yr. The target INR was 1.8 to 2.5 for aortic valves, and 2.5 to 3.2 for mitral valves.

Further evidence was provided by Masters et al. (12) that, with a target INR of 2.5 to 3.5, patients aged over 65 are not at increased risk of bleeding or thromboembolism compared to those aged 65 or under.

The risk of reoperation for failed aortic or mitral bioprostheses has been highlighted by Akins et al. (13). Although these authors achieved a low mortality of 4.8% for elective first time reoperation, almost 40% of their patients required reoperation on an urgent or emergency basis, with higher mortality. Age over 65 years was also predictive of higher mortality. The literature review provided by these authors showed a reported reoperative mortality of 10% or greater.

Current practice in Britain

Perhaps mirroring recommendations and the consensus of the literature, in 2001 44.5% of almost 5,600 aortic valve replacements reported to the UK valve registry (14) were made with biological valves. Moreover, among those patients aged over 70 years, 93% received a bioprosthesis.

What could alter current perceptions and practice?

Two developments that should be borne in mind when considering a 'threshold age' are the increasing life expectancy in Western countries, and the likelihood that timely intervention (particularly for the commonly occurring calcific aortic stenosis in the eld-

erly) may give survival which is little different from that of the age- and sex-matched population.

In the USA, in 1980 (which is representative of the time that many of the patients forming the basis of recent reports were having valve surgery) a 65-year-old white male had an expectancy of a further 14.2 years; in 2000, this had risen to 16.3 years. For a white female, the respective figures were 18.4 and 19.2 years (15).

In the UK, in 1980 a 65-year-old male could expect on average 12.96 more years, (16) and in 1999-2001 this had risen to 15.66 years (17); corresponding figures for females were 16.91 (16) and 18.03 years (17).

Most Western European countries have seen similar increases in life expectancy, with a substantial proportion of the population being above 65 years of age - the commonly suggested 'threshold age' for a bioprosthesis to be used.

Evidence that AVR can give a similar survival relative to the general population comes from Kvidal and colleagues in Sweden (18), who reported that patients over 70 years of age, following successful AVR, had a survival at least as good as their age- and sex-matched general population, for 15 years.

In summary, therefore, much of the current perception and practice suggesting a 'threshold age' in the mid-60s for bioprosthesis use reflects outcomes based on clinical experience that dates back one or two decades. It should be noted that the ACC/AHA guidelines (1) do indeed recommend that mechanical prostheses be used in patients with 'expected long life spans', though no guidance is given as to how this is assessed. Clinicians must bring to bear their own intuitive assessment of the individual patient, knowledge of co-morbidity and of coronary anatomy (which is usually available from angiography as part of the investigation). The fit, otherwise healthy patient even in their mid-70s with a family history of longevity may well be better served by a mechanical valve. Structural valve deterioration seems inevitable if the patient lives long enough (10), and reoperation - even in the best of hands - is not without significant risk (13). The demonstration of low bleeding and thromboembolic risk in the elderly with a low-intensity, carefully supervised anticoagulation regimen, should make the outlook for the elderly patient with a mechanical valve very satisfactory (11,12). Thus, in the light of current evidence, the 'threshold age' must be interpreted flexibly.

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