

HEART

Editorial

The United Kingdom Heart Valve Registry: the first 10 years

On 1 January 1986 the United Kingdom Heart Valve Registry (UKHVR) began collecting data on patients receiving artificial heart valve implants in NHS hospitals. Using a simple dataset and restricting outcome indicators to death and reoperation, the voluntary cooperation of all UK cardiac surgical units has been established and maintained. By the end of 1995, data on more than 45 000 patients had been entered on the database. Annual reports have been distributed to all participating units, and the Department of Health (Medical Devices Agency) has continued to fund the registry which is based in the cardiac surgery unit at the Hammersmith Hospital in London.

Trends in heart valve implantation

In the early years of the registry (1986-89) around 5000 artificial valves were implanted each year in just over 4500 patients.¹ Since 1989 there has been a steady increase in numbers and, in 1994, 6000 valves were implanted in 5500 patients as first time operations (fig 1). Closer inspection of the data shows that this 20% increase in activity has occurred principally in the elderly population (over 70 years of age at the time of their first valve replacement operation). The overall percentages of single valve versus double valve replacements has remained at 90% and 10%, respectively, each year since 1986. Aortic valve replacements have increased since 1986 from 54% to 64% compared with a fall in mitral replacements from 45% to 35% (fig 1), probably reflecting two distinct phenomena—the increase in mitral valve repair procedures and the reduction in chronic rheumatic valve disease in the UK population.

The issue of patient age is a major influence on both heart valve replacement operations and on the short and long term results of surgery. In 1986, the mean age of

patients having their first time valve replacement was 58.5 years (median 60). By 1994 this had risen to 63.4 years (median 65). In 1986, only 12% of patients were older than 70 at the time of their first valve replacement, in 1994 this figure had risen to 29%. The issue of increasing age also has relevance for the issues of valve design and manufacture.

Trends in artificial valves implanted

What determines surgical preference when choosing the particular valve to implant? Who takes the decision: the surgeon? the cardiologist? the patient? Each is involved to a greater or lesser extent with the consequences of the decision. We would like to believe that decisions are based upon sound scientific evidence rather than on some rather vague "feel good" factor which rests on an individual's subjective preference for a particular artificial valve. Certainly, data from the UKHVR show clear trends and changes in the valves of choice over the past 10 years (fig 2).

The principal changes include the following:

- increased preference for mechanical versus bioprosthetic valves
- shift from single leaflet to bileaflet mechanical valves
- reduced use of pericardial bioprosthetic valves
- use of stentless bioprostheses since 1992.

In 1986 mechanical valves accounted for just over half the total (54% *v* 46% bioprosthetic). By 1994 mechanical valves were used in 74% of cases. This trend is particularly interesting given the relative increase in operations in elderly patients (usually aortic valve replacements with the majority in sinus rhythm). It suggests that perceived concerns over earlier valve failure with bioprosthetic valves outweigh possible benefits of avoiding anticoagulation even in more elderly patients. It is true that valve preference in

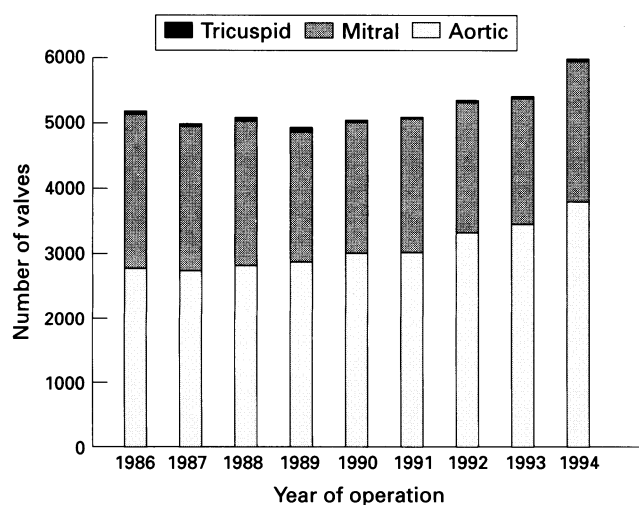


Figure 1 Number and site of valve implants.

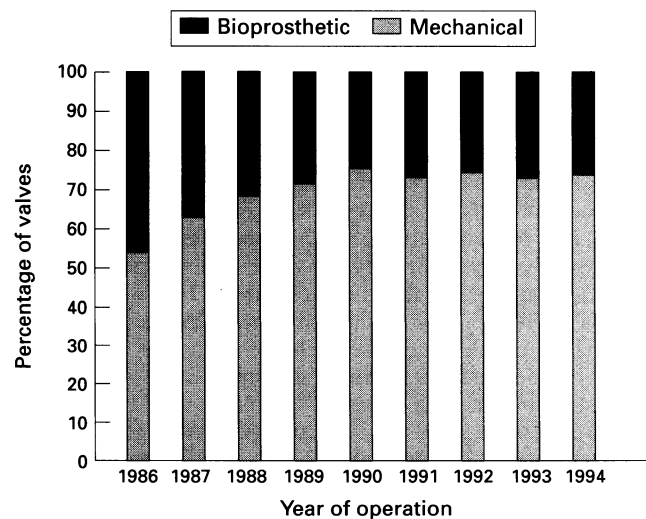


Figure 2 Percentage distribution of bioprosthetic and mechanical valves.

Thirty day mortality of patients undergoing heart valve reoperation or further operation

Year	Number of deaths	Number of patients studied	30 day mortality (%)
1986	8	43	18.60
1987	19	64	29.69
1988	21	86	24.42
1989	25	93	26.88
1990	16	101	15.84
1991	20	94	21.28
1992	13	115	11.30
1993	19	139	13.67
1994	25	187	13.37
Total	166	922	18.00

patients older than 70 still favours bioprosthetic over mechanical (64% *v* 36% in 1994), but this represents a 15% shift from bioprosthetic to mechanical since 1986 in the elderly population.

Within the mechanical valve groups, the increased preference for bileaflet valves has been dramatic and has been at the expense predominantly of single leaflet valves. In 1986, 55% of all mechanical valves implanted were single leaflet type, only 22% were bileaflet. The corresponding figures for 1994 were 16% and 76%. Ball valve (Starr-Edwards valve) use has fallen steadily from 23% in 1986 to 7% in 1994.

This dramatic shift towards bileaflet valves may be attributable to several factors. Improved haemodynamics with the bileaflet design are a widely perceived benefit, but perhaps the much publicised strut fracture complication of the Bjork-Shiley convexo-concave valve has been an even more powerful stimulus to change.²

Interestingly, it was the potential for improved haemodynamics which led to the introduction of pericardial bioprosthetic valves. The pericardial design avoided the restrictive effect of the septal muscle band integral to the original porcine valves. In 1986, 26% of all bioprosthetic valve implants were pericardial but by 1991 this figure had fallen precipitously to 4%. It is generally believed that reports of high early failure rates with the Ionescu-Shiley pericardial valve³ were the reason for this shift in preference, although more encouraging longer term reports with other pericardial valve designs may be reflected in a slight recovery in use during 1992–94.

Trends in early and late mortality after heart valve replacement

A most significant feature of the UKHVR is the link to the Office of Population Censuses and Surveys (OPCS), recently renamed the Office for National Statistics (ONS). Identification details for each patient registered with the UKHVR are sent to the ONS for tracking. If any registry patient dies, the ONS sends to the UKHVR office a copy of the death certificate which includes accurate recording of date, place, and certified cause(s) of death. The UKHVR is therefore able to provide uniquely comprehensive and accurate data for early mortality (true 30 day rather than in-hospital), and for longitudinal survival analyses.

Early (30 day) mortality for all first time valve replacement operations has fallen steadily from 7.37% in 1986 to 4.33% in 1994. This fall in early mortality is particularly gratifying considering the relative increase in elderly patients operated on during that time. Early mortality is consistently higher for mitral (7%) versus aortic sites (5%), for double valve replacements (9%) versus single (5%), for females (6.5%) versus males (5%), and for patients aged over 70 (8%) versus younger patients (5%).

Early mortality after reoperation is substantially higher than for first time procedures. From 1986–90 it remained at around 20–25%; however, during 1992–94 it fell to

around 12% (table). The reoperation cohort in the database includes more than 1000 patients that will provide increasingly important information for assessing risks of reoperation procedures, particularly where the issue of elective reimplantation of at risk artificial heart valves needs to be considered.

In addition to early mortality data, the registry provides actuarial survival data which, in the next annual report, will include 10-year follow up intervals. We have been deliberately conservative in our publication of long term outcomes, particularly in relation to the performance of individual valves. To date, we have restricted published longitudinal data for both reoperation and death to broad categories (such as valve site, single/double implants, sex, and age groups) in order to avoid drawing premature and possibly misleading conclusions by considering valve specific data too early.

Actuarial survival for all patients is around 60% at 10 years post-implantation. There are no differences between males and females, but site of valve implantation is significant: aortic (65%), mitral (57%), and tricuspid (31%). The major factor influencing survival after valve replacement surgery is patient age; 65% at 10 years for patients younger than 70 years at the time of valve implant compared with 42% for older patients.

Onwards and upwards

Despite the considerable volume of data already generated from the UKHVR and published in the annual reports, the real value of the registry is only beginning to be realised. It is in the second 10 year period that we will see greatly increased returns on the considerable investment already put into this project. Donaldson⁴ was quite right in describing a [disease] register as "... a long term investment ... that will be just as valuable for those concerned with the needs assessment, clinical and epidemiological research, disease prevention and service evaluation as for those concerned with patient care and support".

The UKHVR dataset of more than 45 000 patients (growing at over 5000 patients annually) all tracked through ONS for mortality data has already proved to be a unique data resource. Specific research projects currently in progress include:

- influence of age on early and late mortality
- prediction of mortality in valve reoperations
- accuracy and completeness of certified cause(s) of death
- results of valve replacement surgery in patients older than 80.

The registry also fulfils an important regulatory role as the dataset includes individual implanted valve serial number. Concerns over performance of individual heart valves did not start and stop with the Bjork-Shiley strut fracture issue, as indicated by the paper by Hurlé *et al* in this issue⁵ that raises concerns over the Wessex porcine valve's long term performance. Such questions will certainly continue to be raised as long as artificial heart valves are implanted in patients—for there is currently no such thing as the perfect artificial valve.

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