Is there a risk in avoiding risk for younger patients with aortic valve disease?

Tom Treasure, Asif Hasan, and Magdi Yacoub argue that a culture of risk avoidance in cardiac surgery may mean patients are not getting the most appropriate treatment

Around 30,000 patients in the UK and Ireland had open heart surgery to replace the aortic valve in the five years up to March 2008, 40% of whom also had coronary bypass grafts. The annual number of replacements steadily increased, reaching 7000 in the last recorded year. Valve replacement is highly effective in averting the risk of sudden death and fatal deterioration in cardiac function, and the risk of perioperative death is now below 2.5% for all patients under 80 years old and 1% in patients under 40 years. Nevertheless, patients living with a replacement valve face a time related accrued of life threatening and disabling events. Tissue valves fail over time, and recipients of mechanical valves must take anticoagulants for life, which reduces but does not entirely prevent thrombosis and embolism and increases the risk of bleeding. We pose the question whether in ensuring that surgeons’ and institutional death rates are brought to the lowest possible levels, as they have been superbly well for older patients, insufficient consideration may have been given to younger patients.

Downsides of valve replacement

The shortcomings of heart valve substitutes have not been overcome despite years of effort. Mechanical valves, typically made of pyrolitic carbon and titanium steel, are extremely durable, but lifelong anticoagulation is mandatory. In a meta-analysis of 35 observational studies, including 23,000 patients and over 100,000 patient years the annual rate for combined thrombotic events (valve thrombosis and embolic events) for mechanical aortic valves was 1.4% at the usual intensity of anticoagulation. Higher intensity anticoagulation (international normalised ratio >3) reduces the rate to 1%, but the gain is balanced by higher bleeding rates. Over years there is a substantial cumulative risk of stroke, bleeding, and death. Thus for patients under 40, who might realistically hope for another 40 years of life, the 1% perioperative risk of death is an ever diminishing proportion of lifetime hazard. Survival of these patients, who typically have moderately severe congenital abnormalities of the aortic valve, progressively falls below that of an age matched population.

Both thromboembolic and bleeding risks can be minimised by using xenograft tissue valves and avoiding anticoagulation, but their limitation is the inevitability of valve failure. The only option to prolong survival is then reoperation. Deterioration is slower in older patients: only 10% of those who have surgery over the age of 65 and who survive to 80 are likely to need further surgery during that time. But for patients under 40 there is about 50% chance of having another aortic valve replacement within 15 years. Xenograft tissue valves have short term attractions as they permit freedom to travel, to engage in sport, and to have babies, but further valve replacements must then be included in expectations for life.

Alternative treatment

Given that younger patients face the virtual inevitability of at least one further operation or the hazards of thrombosis or bleeding, or any combination of the three, maybe it is time to reconsider the options. A candidate operation is the pulmonary autograft, first described by Donald Ross in 1967. The patient’s pulmonary valve is excised along with a cylinder of pulmonary artery and is used to replace the diseased aortic valve. The pulmonary valve and artery are then replaced with a human cadaver pulmonary artery and valve (known conventionally as a homograft).

Although the Ross pulmonary autograft operation is used by surgeons whose work includes children growing up with congenital disease of the aortic valve, it is rarely used for adults in Britain. Among 653 adults aged 18-39 years having an elective aortic valve replacement in the three years 2007-9, only 13 had this operation. The median age of the 13 was 24 years, and there were no perioperative deaths. Should the autograft operation be used more frequently? Should fully informed patients know that this surgery is one of their options, and if so what should they be told about their prospects with this operation compared with other solutions?

For information on outcomes there is a randomised trial and a systemic review and meta-analysis.

Perioperative mortality for the Ross operation in the trial was 1% (1/108). In the meta-analysis the pooled early mortality was higher at 3% (95% confidence interval 1.8% to 4.9%). In the randomised trial (in which the control patients had homograft aortic valve replacement) all operations were done by one surgeon (MY), and there was 99% actuarial freedom from re-operation at 13 years among the 108 patients randomised to the autograft. One patient had an operation, and that was at 9.5 years for dilatation of the autograft causing regurgitation. In a meta-analysis of 1749 adults who had a pulmonary autograft in 29 centres, the rate of deterioration of the valve in its new aortic position was 0.8%, varying from 0.15% to 1.9%. Deterioration is more often caused by dilatation of the thin walled pulmonary artery than by cusp failure, and technical modifications to support the valve have reduced this problem. Although failure of the allo graft valve used to substitute for the transferred native pulmonary valve was a substantial problem early on, in October 2010 the informally derived
consensus at the Ross summit in Atlanta, Georgia, was that the problem has largely been solved by routine use of oversized pulmonary homografts.

In the primary objective of providing a living and enduring aortic valve replacement, proponents of the pulmonary autograft believe it has stood the test of time. There is no refuting that this operation requires a patient who presented with disease of one heart valve to undergo double valve replacement, and the skill and practice required to attain consistently good results should not be underestimated. Nevertheless, when implanted by an experienced surgeon in a centre with expertise the living pulmonary valve has proved capable of functioning for long periods in the high pressure arterial circulation.

Whenever there is doubt, there is always a cry for more and better evidence. It is unlikely that a randomised trial can be used to resolve the areas of uncertainty. Although we support randomised studies and have used them to inform valve replacement strategies, this is not a choice of one valve versus another based on a short term and therefore retrievable outcome. A direct comparison of early outcomes and surrogates would favour simpler surgery because of the longer period of cardiopulmonary bypass required and the greater technical pitfalls to be negotiated with the autograft. Perioperative death and annual rates of valve failure are around 1%, and many years would be required for meaningful data to accrue. Data are already available for each adverse event (tissue valve failure, thromboembolism, bleeding), but finally we have to offer the patient a choice of risks: a haemorrhagic stroke after mechanical prosthetic implantation or a reoperation for biological prosthetic degeneration. A better research strategy might be modelling27 and individualised patient information by simulation.28

**Not every surgeon has to learn uncommon operations such as this; they need only be performed by relatively few expert hands**

Taking the long view on risk

Even if meticulous analysis of what we know already defines a type of patient for whom this operation offers the best long term strategy, there would still be obstacles to implementation. Risk avoidance among surgeons is already thought to block the route to cardiac surgery for some adult patients when an operation might be in their best interests. In the case of the Ross operation, intolerance of even a small increase in immediate risk could impede access to a better long term solution for these patients. Cardiac surgeons have achieved remarkable reductions in perioperative risk, but they are aware that in a highly monitored practice an obsession with what can easily be counted—that is, perioperative deaths—might now be stifling innovation and be an obstacle to implementing improvement. It might be time to take a longer view and a more comprehensive perspective that considers the life time risks and benefits of a patient hoping for 40 years free of stroke, anticoagulant related bleeding, and re-operation, rather than minimising short term risk, but that change will have to be carefully managed.

Hasan went to considerable lengths 10 years ago to promulgate the Ross operation by its safe introduction in a structured programme of training and support between centres.18 Despite successful operations under his mentorship, surgeons did not adopt the technique, and the profession still has a challenging wariness. This is undoubtedly a challenging operation to learn compared with the highly reproducible insertion of an off the shelf prosthetic valve. It would take many surgeons outside their comfort zone in these times when apparent poor performance is not forgiven, but the declining use of this operation is not fully justified by the available data.

The first step would be a dispassionate review of the data. At present it too often falls to individual cardiologists and surgeons to take their own view on the evidence, and that is not something they are trained to do, or can do objectively. Independent analysts might help.19 At present it falls to individual surgeons to champion innovation,20 but in a harshly critical world who will break ranks and take a risk? Implementation would have to be directed, controlled, and, most importantly, supported. Mentoring, supervision, and debriefing would be elements of such a process, not traditional in the culture of surgery. Not every surgeon has to learn uncommon operations such as this; they need only be performed by relatively few expert hands. It would be advisable to designate centres and individuals within those centres to provide this service.

In due course the Ross operation might be consigned to history for good reasons. Minimally invasive valve surgery may make a succession of tissue valve operations feasible. Home monitoring of warfarin has resulted in considerably better control and reduction of events.21 New oral drugs may simplify anticoagulation and even reduce thromboembolic risk without fear of bleeding. The dream of a mechanical valve that is thrombosis resistant may become reality. But the obstacles to innovation in a culture of caution will persist. We need the means to overcome them as part of the science of improvement,21 if not for the pulmonary autograft, perhaps for other interventions where obstacles to implementation, such as short term risk, might obstruct the way to better long term solutions.

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COMMENTARY

Unintended consequences of governance

Treasure and colleagues present data on the Ross operation and argue that it has a place for treating younger patients with aortic valve disease and may be a better option than surgery with conventional valves. Despite good reported short and longer term outcomes after the Ross procedure, they suggest that low volumes in the UK are due to intense scrutiny of mortality, which is driving surgeons to offer a treatment with the lowest procedural risk (which is measured) rather than the best overall lifetime risk to the patient (which is not). The arguments presented are around the Ross procedure, but the themes are generic and highlight concerns about the importance of using the “right” measures and possible unintended negative consequences from governance processes.1

All cardiac surgery in NHS hospitals in the UK, and many operations in private institutions, is included in the Society for Cardiothoracic Surgery of Great Britain and Ireland national database.2 Data are analysed and returned to hospitals and surgeons to drive improvements and are screened to identify mortality that is higher than expected.3 The data have been published at hospital level for a decade and at individual surgeon level since 2005 through the Care Quality Commission website. Obvious questions about the programme are, has it improved quality of care for patients, have high risk patients been denied surgery as a result, and have there been other unintended consequences?

Risk adjusted in-hospital mortality in the UK has definitely fallen—by more than 50%—since the database programme was introduced, and more elderly and high risk patients are coming to surgery each year.4 It is becoming increasingly accepted that collecting and feeding back data to clinical teams, and publishing them openly, is an effective way of driving quality improvement.4 Data are mixed on whether this results in risk averse behaviour—there is anecdotal evidence that it does, but the magnitude of any effect has not been measurable in the UK.5

The programme to measure and publish outcomes in cardiac surgery in the UK was held to account after the public inquiry into deaths of children operated on at Bristol Royal Infirmary,6 but despite generic themes and recommendations in that report, there have been ongoing important failures of clinical governance outside cardiac surgery—most notably at Mid Staffordshire NHS Foundation Trust.7 Effective measurement and scrutiny of outcomes would identify any such failures early and should change the culture of the profession and organisations to prevent the scandals from occurring.

Better regulation of both organisations and individuals through clinical outcomes is clearly necessary, but proper engagement of clinical specialists in the methods of analyses and subsequent investigations is essential to ensure that all the benefits of scrutiny to improve quality are achieved, and the tendency towards any possible negative consequences, such as those suggested by Treasure and colleagues are minimised. In addition, to truly achieve this aim will probably also require large scale reconfiguration of service delivery (with centralisation of some services to maximise volumes) and careful management of controlled innovation, which will together raise some serious challenges to the medical profession and the organisations in which it works.

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COMMENTARY

Talking to patients about surgical innovations

Surgeons talk to patients before operating on them, but what is communicated during consultations is generally unknown and understudied. Consultations in which new procedures are discussed are also unchartered territory because surgical innovation often takes place outside the context of standard regulatory approval. Treasure and colleagues raise these issues with respect to aortic valve surgery in young people.1 Standard surgery offers a low immediate risk of death (1%) but necessitates life time anticoagulation and repeat surgery that carries a higher risk. An alternative procedure, the Ross pulmonary autograft, is associated with a 3% in-hospital mortality and better lifestyle outcomes, but it is technically more difficult than routine valve replacement and not within the armamentarium of all cardiac surgeons. The challenge, therefore, is whether surgeons should inform patients about outcomes of both procedures and whether to routinely offer the innovative operation even if that means transferring the patient to another centre and surgical team.

The difficulties of communicating these complex issues to patients are rarely examined or reported for new procedures. Yet consulting is generally unknown and on them, but what is communicated during consultations is essential to ensure that all the benefits of scrutiny to improve quality are achieved, and the tendency towards any possible negative consequences, such as those suggested by Treasure and colleagues are minimised. In addition, to truly achieve this aim will probably also require large scale reconfiguration of service delivery (with centralisation of some services to maximise volumes) and careful management of controlled innovation, which will together raise some serious challenges to the medical profession and the organisations in which it works.

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will influence treatment choice. When given full impartial information about aortic valve surgery some may choose the Ross procedure and others choose standard surgery. But it is unknown whether current surgical practice allows patients to make individual choices. Patients do sign up for novel operations, and case series (often reported without ethical approval) do not specify whether innovative treatments were declined. Indeed only within randomised controlled trials are these data reported, and well designed and conducted randomised trials in surgery are scarce.

This raises the question of whether surgeons should be trained to discuss innovative procedures with patients and agree to consultations being studied. Some may welcome qualitative evaluation of consultations, just as many routinely invite colleagues into theatre to watch them operate. But at present, there is no clear way forward with this. In the mean time, when surgical innovations are being offered to patients, the numbers of patients being offered, accepting, and declining a new procedure should be reported. This could supplement the IDEAL (idea, development, evaluation, assessment, and long term study) framework for evaluating surgical innovation, which recommends reporting of outcomes of both new and standard procedures during the early stages of surgical innovation. This approach will give some indication of whether surgeon-patient consultations are based on information of importance to patients as well as surgeons.

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BLOGS ON BMJ.COM

Annabel Ferriman: What a way to decide the future of the NHS

Health secretary Andrew Lansley’s proposals to “reform” the NHS recently found some backers. For more than nine months doctors, nurses, think tanks, and academics have been begging Lansley to rethink his ideas. By the start of the “pause” in April, it looked as though the government would take some of these criticisms on board and make concessions.

Now large scale changes look less likely. Recently we saw the return of tribalism in politics. Lansley got a rapturous response when he addressed the 1922 Tory backbench committee in mid-May. All the MPs banged their desks to show their support, cheered him to the rafters, and lauded his reforms as the saving of the NHS. Why? Had they been scrutinising new research about the effect of GP commissioning on health outcomes or the financial implications of all trusts getting foundation status? No, of course not. They loved him because he was one of them and not one of the “yellow bastards” (the Liberal Democrats), whom they are saddled with in coalition government.

Ever since the Lib Dem leader Nick Clegg said that the Health Bill had to be modified, support for Lansley has been growing. The Tories are no more convinced now that the reforms will work than they were before the AV referendum and the local council elections on 5 May, but they don’t want those Lib Dems to steal any credit for “saving the NHS.” This is Tory politics blue in tooth and claw. They hate Clegg for trying to exercise more power at a time when he and his followers should be accepting less, since the local elections showed the Lib Dems at a new low.

For a brief few weeks in April and May it looked as though the government might be swayed by research on healthcare to make some sensible changes. But now it is goodbye evidence based policies. Farewell rational decision making. Welcome tribal politics, wheeling and dealing on amendments to the Health and Social Care Bill, and fancy footwork on the part of Cameron.

Many concessions are likely to go by the board, because if the Tories are seen to concede anything on the bill it will look like a feather in Clegg’s cap and a dent in Cameron’s virility. What a way to determine the future of the NHS.

Annabel Ferriman is news editor, BMJ.

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Ann McPherson: I wanted to choose to die

Ann McPherson, winner of BMJ Group’s health communicator award, died on 28 May of pancreatic cancer. Too ill to attend last month’s awards ceremony in London, she nominated husband Klim and the actor Hugh Grant, a supporter of her Healthtalkonline venture, to collect it on her behalf. Ann’s Diary of a Teenage Health Freak book was the subject of a BMJ medical classic article in 2009 (http://bit.ly/7E6k).

A month earlier, she had argued in the BMJ that dying patients should be allowed to choose the time and place of their death (http://bit.ly/1dWcBh). Find out more about Ann’s life as a GP and campaigner in Charles Warlow’s obituary on page 1263. The online version of Charles’ obituary also includes a video interview with Ann. It was filmed last month at her home in Oxford.

In this blog she gives her final message: “I’m feeling pretty bloody awful. The nurse and doctor came today to incise the abscess around my chest drain and made the unhelpful suggestion that I might need some antibiotics even though antibiotics make me sick. ’The GP certainly understands where I am coming from, but when I said that I can’t understand why I have to carry on living like this and why I can’t just die, the nurse said, ‘Well you might change your mind.’ ”

“I think it very unlikely I will change my mind, and even if I did I don’t care. It is nice to see people but if I had the choice there is no question that I would prefer to be dead than to see people.

‘Because I feel so ill. I know everyone is different. It’s nothing specific. I just feel ill, and there seems to be nothing that can make that better. I am already on large doses of morphine and midazolam and haloperidol so that I mostly don’t have pain or sickness, but I still feel ill.

“I feel really furious at this. I think it is cruel. In my practice I saw people who felt like this, and I felt I had let them down.”

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See OBITUARY, p 1263

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ANALYSIS

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