New surgical procedures: can we minimise the learning curve?

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The Ross procedure for aortic valve replacement was introduced at two paediatric cardiac centres (Freeman Hospital, Newcastle, and Royal Liverpool Children's Hospital) where surgeons had no previous experience of this technique. A structured programme of training and cooperation between the two centres enabled surgeons to minimise the learning curve for this procedure. We share our experience and suggest options for surgeons who wish to undertake new procedures in the current era of surgical practice and clinical governance. Issues of informed consent and risk stratification remain.

Summary points

- Surgeons have always recognised the concept of a learning curve when undertaking a new procedure
- Recent events mean that there is a lack of professional and public tolerance for suboptimal results due to a learning curve
- Learning a new technique, even for an established consultant, requires some sort of learning curve
- Introducing a new procedure in a structured way that incorporates formal training courses, cadaveric resection, and assistance from expert practitioners can reduce the learning curve

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Method

The recent General Medical Council (GMC) inquiry into the Bristol Paediatric Cardiac Surgical Unit highlighted many concerns common to all surgical specialties. At the end of the judgment, the president of the GMC listed 13 issues that the professions should address, and the senate of surgery recently published its response.[1] The concept of a learning curve, which has long been recognised by surgeons, was of particular consequence. However, the senate responded that "there should be no learning curve as far as patient safety is concerned."[1] To learn to perform a new procedure without having a learning curve is a dilemma that we, as established consultants in paediatric cardiac surgery, faced when we wanted to introduce the Ross procedure into our surgical practice.

We discussed strategies which we hoped would reduce the steepness of our learning curve, and we decided that we would:

- All undertake a course in aortic root surgery
- Refine the surgical technique with cadaveric resection
- Undertake the first operation with an expert
- Assist each other with the operation.

The first step was achieved by attending an aortic root master class run by the Royal College of Surgeons of England. Further training, especially to gain experience in the critical step of the operation, explanting the pulmonary autograft, was undertaken by cadaveric resection. The first operation was carried out by a consultant surgeon with experience of the Ross procedure (Mr W J Brawn, Birmingham Children's Hospital), assisted by one of us (AH). Thereafter all operations were undertaken as conjoint procedures, although the team leader was the consultant responsible for the patient. One of the authors (AH) was involved in all operations undertaken in this series.

The procedure

In 1967, Donald Ross described his pioneering operation for patients with aortic valve disease. The principle is to remove the patient's normal pulmonary valve and use it to replace the patient's diseased aortic valve. The coronary arteries are then implanted into this new aortic root. The resulting defect in the right ventricular outflow tract and main pulmonary artery is repaired using a homograft—a surgical tour de force. Because this operation involved two valve replacements instead of one and was associated with an appreciable mortality (it is a complex procedure demanding intense attention to detail) it did not achieve universal acceptance. Consequently, it was only Donald Ross who continued to undertake the procedure with any frequency, and his results improved noticeably over time. Interest in the procedure was rekindled in 1987 when Elkins showed that results similar to Ross's could be reproduced.[2] Experience has accumulated over the years, and the Ross procedure is now an acceptable alternative to aortic valve replacement in adults with aortic valve abnormalities, particularly in those for whom there is a medical need or personal wish to avoid the anticoagulation treatment associated with a mechanical prosthesis.

In children, the drawbacks of aortic valve replacement are more considerable. A small mechanical prosthesis has a noticeable gradient and will have to be replaced as the child grows. In addition, the child will require lifelong anticoagulation treatment. A bioprosthesis is an alternative that avoids the need for warfarin, but when these valves are used in children they calcify rapidly and are therefore inappropriate. No alternatives have been available until recently. Furthermore, some children with aortic stenosis have left ventricular outflow tract obstruction, and replacing the aortic valve does not resolve this.

The Ross procedure has been suggested as an alternative because, in theory, the pulmonary autograft in the aortic position should grow as it is a viable living structure. In addition, any subaortic stenosis can be dealt with. Experience with this operation in children has been limited, and although follow up echocardiography has shown an increase in size of the new aortic root, there was a debate as to whether this was true growth or simply dilatation, which would mean that the valve would eventually regurgitate. However, there is recent evidence to suggest that growth does occur.[3 4] In view of this, we decided to introduce the Ross procedure into our practice for children and young adults where aortic valve replacement was needed, especially if they had left ventricular outflow tract obstruction.

Table 1 Postoperative events reported to Ross procedure international registry. Reproduced with permission[5]

Complication	No of patients	% Of total complications (n=373)	% Of patients followed up (n=1983)
Stroke	18	5	0.9
Sepsis	21	6	1.1
Postoperative bleeding	35	9	1.8
Transient ischaemic attack	14	4	0.7
Endocarditis (recurrent)	7	2	0.4
Endocarditis (new)	20	5	1.0
Myocardial infarction	14	4	0.7
Cardiac dysrhythmia	52	14	2.6
Thrombus	12	3	0.6
Other*	180	48	9.1

*Chronic heart failure, renal failure, pulmonary embolism, pericardial effusion

Table 2 Follow up echocardiographic data reported to the Ross Procedure International Registry. Reproduced with permission[5]

Aortic insufficiency	No of patients	% Of total reported (n=1410)	% Of patients followed up (n=1983)
Trivial	610	43.3	30.8
Mild (1/4)	622	44.1	31.4
Moderate (2/4)	119	8.4	6.0
Moderate severe (3/4)	40	2.8	2.0
Severe (4/4)	19	1.3	1.0

Results

Between February 1996 and July 1998, 12 patients underwent the Ross procedure at the Royal Liverpool Hospital and nine at the Freeman Hospital. Fifteen patients were male. The mean age was 13 years (range 3 months to 31 years), and they had had a mean of 1.1 previous procedures. The functional diagnosis was aortic regurgitation in 14 patients and aortic stenosis in seven. One additional adult who was taken to theatre for the Ross procedure had insufficient tissue around the pulmonary valve to allow for safe explantation and underwent conventional aortic valve replacement.

There has been one death. This patient had undergone two previous operations and died suddenly two weeks after surgery. Postoperative endocarditis was suspected, but echocardiograms failed to show any evidence of this. The necropsy excluded coronary embolism, myocardial infarction, or tamponade, and the patient's death remains unexplained.

To place postoperative morbidity in context, complications reported to the Ross procedure international registry are shown in the tables.[5] All our patients had postoperative echocardiograms. Twenty patients had minimal or mild aortic regurgitation and only one patient had moderate aortic regurgitation. This patient, a 10 year old boy, had subaortic obstruction and had outgrown his original prosthetic aortic valve. There was no other morbidity.

Discussion

The Academy of Medical Royal Colleges has addressed the question of the introduction of new procedures into practice by establishing a register—the safety and efficacy register for new interventional procedures. Procedures are graded in categories from A to D: A, established procedures; B, requiring ongoing audit; C1, requiring continuing observational study; C2, should be part of a randomised control trial; D, should not be undertaken. It may well be valuable to include in this categorisation the degree of training needed to introduce a new procedure—we would place the Ross operation in category C1.

The learning curve

The Ross procedure is a technically demanding operation with the potential for appreciable morbidity and mortality. In particular, explantation of the patient's pulmonary valve risks injury to the left anterior descending coronary artery and, more specifically, to its first septal branch. There is a learning curve associated with this operation. In Donald Ross's own series, 23% of patients died during the first year of the operation and 18% in the second year.[6] In the subsequent 10 years, the surgical mortality in 188 patients was 9%. Even in patients operated on more recently, mortality is higher in early experience: Stelzer had three deaths in the first 15 patients but only four deaths in the subsequent 130 patients.[7] We feel that our strategy has paid dividends, not only in limiting the mortality but also in minimising the morbidity that would have been associated with an operation such as the Ross procedure.

No surgeon would wish to attempt a procedure that is beyond his or her competence. Yet, how does he or she introduce a new procedure that will ultimately benefit patients? Patients, and in the case of children, their parents, increasingly want to know about an individual surgeon's results, and without some basis for confidence they are unlikely to want to be "guinea pig" on the first occasion that a surgeon performs a procedure. Yet every surgeon has to perform a procedure for the first time.

Higher surgical trainees will, of course, learn complex procedures under the direct tuition and

supervision of an established consultant experienced in the particular technique … or will they? For technically complex operations, especially if the consultant performs them infrequently, there will be a natural reluctance to allow even an experienced trainee to undertake these procedures. This may be particularly so in the new era where surgeons' results will be available to the public and consultants are responsible for the results of their trainees. Trainees may thus not have the opportunity to perform a particular procedure until they have been appointed to a consultant post. How, therefore, do they start? Furthermore, how does an established consultant learn a new technique without having a learning curve?

Alternatives or ameliorations

There are few options. Strict regulations in the United Kingdom prevent surgeons practising a new operation on animals. The surgeon may visit an established consultant to watch an operation, but, as a visitor, will not be allowed to perform it. A better option, therefore, is for a surgeon to invite a more experienced surgeon to the unit to act as assistant—but not all surgeons will be in this privileged position. Perhaps the royal colleges should appoint peripatetic experts who would travel around the country. A further alternative is to attend a specifically designed course as we did, and therefore the onus must be on the surgical colleges to provide these facilities. As a minimum, we would suggest that consultants undertaking a new procedure should have another consultant surgeon capable of performing the operation as their assistant. By these methods we believe confidence can be given to patients (and in the case of children, their parents) and new procedures introduced into surgical practice with limitation on the amount of morbidity and a low mortality.

Informed consent

The other major issue is of informed consent. The GMC insists that surgeons must quote their own mortality figures. How many cases does a surgeon need to perform before he or she can begin to quote an accurate statistical risk? We have had one death, but it would obviously be ridiculous to quote a low mortality. As health professionals, we understand the concept of small sample size and confidence intervals, but how do we explain these to a patient or parent? Can we stratify patients by risk and quote different risks for patients undergoing what is apparently the same procedure? The recent GMC inquiry into events in Bristol seemed to suggest not.

Competing interest: None declared.

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Lurigancho prison: Lima's "high school" for criminality

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"It is the largest prison in Lima." Juan, the coordinator of my visit to Lurigancho, says. "There is room for 1600 prisoners, but much more people are being kept inside."

"How many?" I ask.

"Well, the authorities do not even know. Let us assume that there are 6000 people, which at least is the number given by the prisoners themselves—who are accurately keeping count of the number. You shall see that the prison is overcrowded and the prisoners themselves are the boss."

My visit to Lurigancho prison in Lima is on behalf of Médecins Sans Frontières to see if it can help the prisoners. It sounds strange: prisoners running a prison their way. Once inside the gates I see a prisoner leave his cell, lock the door, and nonchalantly pocket the key. He is going out for lunch within the prison. In Lurigancho the prisoner is indeed the boss.

Summary points

- Around 6000 prisoners are interned in Lurigancho, which should only accommodate 1600 prisoners
- Inside, the prisoners are "in charge"
- HIV is a time bomb for the prison and local community
- The prisoners are a core transmission group for HIV
- Prostitution, tattooing, and drug misuse are rife in Lurigancho

A western style fortress

Lurigancho is located on the outskirts of Lima and comprises around 20 pavilions surrounded by a carefully guarded wall. With its watchtowers the prison looks like a fortress in a western. The prison operates on a simple informal agreement between the prison