

openheart Standards for heart valve surgery in a 'Heart Valve Centre of Excellence'

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ABSTRACT

Surgical centres of excellence should include multidisciplinary teams with specialist expertise in imaging, clinical assessment and surgery for patients with heart valve disease. There should be structured training programmes for the staff involved in the perioperative care of the patient and these should be overseen by national or international professional societies. Good results are usually associated with high individual and centre volumes, but this relationship is complex. Results of surgery should be published by centre and should include rates of residual regurgitation for mitral repairs and reoperation rates matched to the preoperative pathology and risk.

INTRODUCTION

Repair is superior to replacement for severe regurgitation caused by mitral valve prolapse.¹⁻⁴ However, repair rates are lower than desirable⁵⁻⁷ and vary widely between cardiothoracic centres. Opinion and consensus documents propose that mitral valve repair should be performed by surgeons with specialist expertise^{1 2 8-11} and adequate practice volumes^{7 9 10} in a 'Heart Valve Center of Excellence'.^{1 2} Controversy remains about what constitutes appropriate individual surgical and hospital volumes. There are also arguments for developing specialist expertise in aortic valve surgery¹² although these have not been widely rehearsed. Furthermore, the details of how surgical experience and competency for aortic or mitral valve surgery should be established and maintained have received little debate.

The purpose of this article is to discuss standards for mitral and aortic valve multidisciplinary team (MDT) practice within a 'Heart Valve Center of Excellence'.

MDT WORKING

Teams for surgical mitral valve repair and transcatheter aortic or mitral techniques are already widely regarded as necessary^{8-10 13 14}

KEY MESSAGES

What is already known?

It is increasingly accepted that multidisciplinary team working is best practice for many clinical conditions. 'Heart Valve Centres of Excellence' are referred to in recent international recommendations but without further description.

What does this article add?

This article is an international consensus on standards expected from a centre of excellence including staffing, facilities, training, processes and audit.

How might this affect practice?

The expectation is an improvement in surgical results including mortality, functional recovery, quality of life and reoperation rates.

and should work within an institution offering a minimum set of quality standards (box 1). Teams are also needed for patients during surveillance of asymptomatic severe disease to determine the optimal timing of surgery¹⁵ and for the care of patients with infective endocarditis.^{19 20} MDTs have an established pedigree in cardiovascular disease^{21 22} and demonstrate the intent to develop and maintain competencies in surgical and interventional techniques. A team approach links all aspects of care efficiently including preoperative assessment, surgery and postoperative care. Surgeons are part of the teams based on specialist focus, to a degree on surgical volume but mainly on excellent audited results.

A team approach is an essential part of transcatheter device programmes,^{13 14} but is also relevant to conventional aortic valve replacement. The assessment of aortic stenosis is particularly challenging in the elderly with, for example, the need to recognise low-flow, low-gradient aortic stenosis despite preserved LV ejection fraction²³ and the effect of low aortic compliance.²⁴ Decisions about surgery for coexistent mitral



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Box 1 Properties of surgical centers of excellence

- ▶ Specialist valve clinic¹⁵ as a hub between community, other hospitals and extracardiac departments, and between non-invasive cardiologists and surgeons and interventional cardiologists
- ▶ Expert imaging with accredited operators and departments:^{16 17}
 - Expert echocardiography including three-dimensional and stress echocardiography and perioperative transoesophageal echocardiography.¹⁸
 - Cardiac CT and magnetic resonance
- ▶ Multidisciplinary teams with specialist competencies including mitral valve repair, aortic valve repair or transcatheter aortic and mitral valve techniques
 - Named cardiac surgeons and cardiologists with special interest in valve disease, named imaging specialists, cardiac anaesthetists and interventional cardiologists specialising in transcatheter procedures
 - Regular case discussions
 - Systematic approach to reducing medical and surgical risks
- ▶ Back-up services
 - Other specialist cardiologists including heart failure and arrhythmia
 - Extracardiac specialties for example, intensive care, vascular surgery, general surgery esp gastrointestinal, neurology, renal, stroke and elderly care medicine, psychology, and dental surgery
- ▶ Data review:
 - Robust internal audit processes including repair rates, rates of residual regurgitation, complications, durability of repair and reoperation rate
 - Results available for review internally and externally
 - Involvement in national databases

regurgitation²⁵ or the advisability of replacing a less than severely stenotic aortic valve at the time of coronary bypass grafting are also frequently difficult.^{1 2}

Determining that intervention is advisable is also challenging in the presence of comorbidities which contribute to symptoms and increase the risk of cardiac

Box 2 Data for collection in repair and replacement for organic mitral or aortic valve disease

- Preoperative aetiology and grading of the valve lesion
 Preoperative MDT classification for repair as repair 'almost certain', 'likely', 'unlikely' or 'not feasible'
 Mortality and morbidity at 30 days
 Early postoperative haemodynamic function:
- ▶ Transvalve velocity and mean gradient (all positions) and effective orifice area (aortic position) of replacement or transcatheter valves
 - ▶ Presence and grade of paraprosthetic regurgitation
 - ▶ Residual regurgitation and new obstruction after repair or systolic anterior motion of the anterior mitral leaflet
- Follow-up:
- ▶ Durability of repair based on echocardiography
 - ▶ Requirement for redo procedure
- MDT, multidisciplinary team

Table 1 Example targets for surgical outcomes in repair of mitral valve prolapse

	Rate
Mortality	<1% ^{4 9}
Major complication rate	<2% ⁴
Repair rate for P2 prolapse	≥90%
Significant residual mitral regurgitation	≤5% at 5 years ^{9 29}
Reoperation rate	
Posterior repair	≤1–4% p.a. ²⁹
Anterior repair	≤2–5% p.a. ^{29 30}

p.a., per annum.

surgery.¹ These difficulties require collaboration between many disciplines including respiratory, renal and elderly care medicine. There is also increasing focus on surgical issues such as prosthesis selection²⁶ including the potential for patient-prosthesis mismatch.²⁷

Cardiac centres providing valve surgery should have robust audit processes^{8 28} to monitor all clinical outcomes which should be available for regular internal and external review. There should also be a willingness to enter data in collaborative research and audit studies to allow benchmarking of risk stratified mortality. Examples of surgical data for collection are suggested in [box 2](#) and example targets for mitral valve repair in [table 1](#).

MITRAL VALVE SURGERY**Developing expertise**

Surgeons performing mitral repair surgery should undergo focused training in mitral repair, in atrial fibrillation ablation,⁹ and in tricuspid annuloplasty⁸ as part of their basic local board certified surgical training. Surgeons should also be mentored through new repair techniques and ideally in the implantation of new types of replacement heart valve to minimise the effects of the 'learning curve' on adverse results.^{9 31 32}

There is a tendency for new products to require increasingly technique-sensitive implantation procedures, and regulatory bodies have insisted that manufacturers implement training and accreditation programmes where this is necessary to reduce procedural risk.³³ The International Standard for transcatheter valves³³ requires manufacturers to "establish a structured training program for the physician and staff who will be involved in the periprocedural care of the patient". This principle should be seen as the rule rather than the exception although there is a strong argument for the processes to be supervised by organisations independent of the manufacturers for example national and international cardiovascular professional societies. Effective training measures could be accomplished by collaborative working within units, visits to other units or by visiting external experts.

Surgeon and hospital volumes

The relationship between case volume and outcomes for surgery and percutaneous interventions is complex, but volume recommendations already exist or are being discussed for PCI,³⁴ vascular surgery³⁵ and percutaneous valve techniques.^{13 14} What constitutes sufficiently high individual surgeon or hospital volumes to maintain good results for repair of mitral valve prolapse is controversial. A large retrospective review³³ showed that mitral repair rates were higher and mortality rates lower in large volume hospitals. A high hospital volume partly reflects high individual surgeon volumes^{7 31} but may also be a surrogate for excellent facilities and processes (box 1).

Annual thresholds of 20–40 mitral valve repair procedures for individual surgeons^{7 9 10 36} have been suggested based on expert consensus or the observation from retrospective analyses that repair rates are on average higher among higher volume surgeons. Similarly hospital volumes of >50/year have been suggested,⁹ although studies in the USA³⁶ have not confirmed that centre volume alone reliably predicts outcome.

For mitral valve replacement, no individual surgeon thresholds have been identified. Lower mortality rates are shown in higher volume centres,³⁷ including one study with centre volumes >80/year for repairs and replacements.³⁸

Minimal access mitral surgery has great appeal for patients and cardiologists. The cosmetic advantage is obvious, and when successful allows patients a quicker recovery. Data from one center³² suggests that the learning set for minimal access mitral repair is 75–125 operations and that a minimum of one operation each week is necessary to maintain good results.³² The authors noted a marked variation in the contours of learning curves among individual surgeons. The technique is challenging for the surgeon and the entire theatre team, and may not be reliably achieved by all centres.

These few studies are all retrospective making it difficult to control for the characteristics of individual patients or surgeons and repair rates were not matched with the preoperative likelihood of repair. Within the populations there were low-volume surgeons with high repair rates and high volume surgeons with low repair rates.^{7 36} Furthermore, these publications did not record non-fatal complications including stroke and bleeding, rates of residual mitral regurgitation or need for redo surgery. In view of these limitations, we propose that the ability to demonstrate good results (table 1) is a more important standard than the attainment of volume targets.

Assignment for mitral valve repair

In patients with mitral regurgitation, surgical assignment differs according to the likelihood of repair. Repairable primary disease should be operated by surgeons with special expertise in valve repair^{8 9} and acceptable results (table 1). Some types of P2 repair in degenerative disease may be relatively straightforward, but it is not

always possible to guarantee this during preoperative assessment.^{8 9} A surgeon without specialist expertise might then find him or herself forced to implant a replacement valve while a more specialised surgeon might have successfully repaired it.

Annuloplasty rings are a part of the regular work of all cardiac surgeons, but good results are not guaranteed. Choosing the size of the ring and when to use adjuvant treatments (eg, cutting chords or left ventricular reshaping) may be difficult. Repair procedures for functional mitral regurgitation should therefore be performed under the auspices of a surgeon with specialised training and interest in valve repair.

If an MDT decides that repair is not possible, there is an argument for cardiac surgeons without competencies in repair to be free to replace the mitral valve. This would allow surgeons to remain competent to perform emergency mitral valve surgery on-call for example, for acute endocarditis or papillary muscle rupture. No consensus exists and arrangements should be made locally acknowledging the difficulty of balancing on-call rosters and the need for specialisation.

AORTIC VALVE SURGERY

Developing expertise

Models for collaborative working in aortic valve intervention already exist. Conventional aortic valve replacement is part of basic surgical training. However, as for the mitral position, new designs of replacement valve having implantation techniques different from established valves should initially be used under guidance to minimise adverse effects from the learning curve. The Ross operation is complex and must be learned at a specialist centre.

Repair techniques are feasible in bicuspid or prolapsing aortic valves but remain underutilised. Approximately 60% of regurgitant aortic valves may be repaired at a specialist center^{40 49} while repair is uncommon in the UK database.⁵ Aortic root remodelling may be necessary as part of these repair procedures.³⁹ Specialist experience and expertise is needed for the whole team since careful preoperative assessment and intraoperative imaging are essential.^{40 41} Repair can avoid the complications of a replacement valve although a proportion require revision in the immediate postoperative period.⁴² Thereafter the reoperation rate is approximately 2–3% p.a.^{42 49} although results beyond 10 years are not established.

Minimal access aortic valve surgery is increasingly accepted.⁴³ There are ongoing trials to define if there is an advantage to mini-sternotomy (down to the 3rd or 4th space) and manubrium only (2nd space).⁴⁴ These techniques which may present special challenges and require careful training and proctorship for the surgeon and theatre team. These minimal access techniques may be further progressed by the availability of sutureless valves which are also in the process of evaluation.⁴⁵

Volumes

The effect of procedural volume has been observed for aortic valve replacement⁵⁰ with a mortality rate of 9.1% for surgeons with annual volumes of less than 22 cases compared with a rate of 6.5% for those with annual volumes exceeding 42 cases. No volume data are available for aortic valve repair. As for the mitral position, individual surgeon and hospital volumes are unlikely to be perfect surrogates for outcome data and the ability to demonstrate good results is more important than working to volume targets.

NATIONAL ORGANISATION

Ideally universal entry onto national databases should be required. In the UK, outcome data adjusted for case-mix and compared against a contemporary peer-group standard are published for hospitals and individual surgeons.⁴⁶ There is a quality assurance 'Governance Toolkit' which allows surgeons to monitor their own performance, an approach which has been shown to reduce procedural deaths for coronary intervention in programmes run in some US states.⁴⁷ A guidance report 'UK heart surgery today: accessible information for patients'⁴⁶ might allow patients to make better-informed decisions about their surgery.

Universal recording of all surgical valve procedures in national databases should be required, as is the case for transcatheter devices in the USA.^{13 14} These would generate early warning of generic problems, but also facilitate the evaluation of new techniques and help determine the feasibility of wider dissemination. In the past, however, design problems with heart valves have first been identified, not through registries, but through the vigilance of clinicians who reported their concerns to their national regulatory authorities.⁴⁸ Clinicians should therefore make use of established reporting systems for adverse incidents related to all medical devices.

National cardiovascular professional societies should set up databases recording valve implantations. They could also establish, coordinate and monitor specialist training for all members of heart valve MDTs including surgeons, interventional cardiologists and cardiologists, anaesthesiologists and scientists specialising in imaging. It would also be ideal to have a pathology laboratory, independent of valve manufacturers, examining explanted valves to determine mechanisms of failure.

Referral patterns to a national centre of excellence will be subject to individual national organisation. Potentially no cardiac surgery other than that required in trauma centres should occur outside cardiac centres of excellence. An interim stage must involve demonstrating unequivocally through the accumulation of prospective data that specialist centres of excellence attain better results matched by case mix and the preoperative characteristics of the valve.

CONCLUSION

Broad consensus favours organisation into MDTs with specialisations appropriate to the case-mix and type of

intervention being offered. There should be structured training programmes for the physicians and staff involved in the periprocedural care of the patient and these should be overseen by national professional societies. While it is recognised that good results are usually associated with relatively high individual and centre volumes, this relationship is complex. Results of surgery need to include detailed information about acute and longer-term haemodynamic results and adverse events including the need for redo surgery matched to the pre-operative pathology and risk. These results should be readily available to patients, referrers and government agencies.

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