Minimally Invasive Mitral Surgery: Dangerous to Dabble

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Abstract: The introduction of any new surgical technique is fraught with dangers and difficulties, and in cardiac surgery, these potential negative outcomes are magnified by inherent small margins for error. Buxton’s law states that it is always too early for rigorous evaluation (of a new technique) until, unfortunately, it is suddenly too late (1). This insightful statement was used to describe the phenomenon often seen in the introduction of new technologies or procedures in medicine. There is a natural reluctance to subject new techniques to standardized assessment too early in the introductory phase in an attempt to avoid negatively biased results while operator learning is still occurring (2). Over the last two or three decades, this phenomenon has been described as the learning curve and has most often been applied to minimally invasive surgery of all specialties, including general surgery, gynecology, and cardiothoracic surgery. Buxton’s concern was justified, because by the time the procedure has become well practiced, there is a reluctance to subject it to rigorous trials on the argument that this will deny the latest, and perhaps greatest, treatment to patients. Whereas each argument, pre-emptive assessment, or delaying access is valid in isolation, the combination is a dangerous system to follow because it prevents rigorous evaluation and denies best practice. Keywords: minimally invasive, mitral valve, perfusion, learning curve.

As the complexity of cardiac surgery increases as a result of increasing comorbidities of patients and the introduction of advanced technologies, the achievement and maintenance of surgical excellence have become more challenging (3). The decision to introduce a new surgical technique is often made by an individual surgeon but has implications for the entire surgical team. In cardiac surgery, the success or failure of the procedure will rest significantly with these team members and a good surgeon quickly recognizes this. Well before knife is ever put to skin, the surgeon must engage anesthetists, operating room nurses, perfusionists, and cardiologists in planning and resourcing the new procedure. The surgeon must then ensure all members are adequately trained and ideally have performed under supervision at an experienced center. The team as a whole must then monitor surgical performance and patient outcomes to ensure both are acceptable. It quickly becomes evident that undertaking a new and complex surgical procedure requires a significant commitment of time, resources, and specially trained team members. A recent study that identified characteristics of cardiac surgical teams that were able to successfully adopt minimally invasive cardiac surgery (MICS) identified a number of factors that predicted success (3,4). Of primary importance was the surgeon’s outlook toward the new technology. Those surgeons who actively recruited team members created an environment of psychological safety and viewed the technology as a fundamental change in the way surgery is performed and had much greater success compared with those who viewed the technology as simply a “plug-in” change, ultimately making no effort to challenge the surgical team. The Royal Adelaide Hospital introduced the minimally invasive program over 5 years ago, adhering to these guiding principles of successful program introduction.

MINIMALLY INVASIVE MITRAL SURGERY

Carpentier, Chitwood, Mohr, and others first introduced minimally invasive mitral surgery (MIMVS) in the mid-1990s in Europe and the United States. The drive behind the development was less surgical trauma, blood loss, transfusion, and pain, which translates into a reduced hospital stay, faster return to normal activities, less use of rehabilitation resources, and overall healthcare savings. Early skepticism focused on the “cost” of these improvements, largely
longevity of repair, adequate exposure, and stroke rates. A recent meta-analysis concluded that MIMVS is a safe and durable alternative to conventional sternotomy and is associated with reduced morbidity (5). On the back of these results, minimally invasive mitral repair or replacement has become the standard of care at specialized cardiac centers across the globe.

Concurrent to the development of minimally invasive surgery, the surgical indications for the treatment of mitral disease have also changed. Improvements in the understanding of mitral pathology have led to preference for repair over replacement in degenerative disease owing to equal durability and reduced mortality (6,7). This evolution has continued toward surgery being offered to patients with minimal or no symptoms (8). The caveat with offering an early operation is it must be in a specialized center that can offer a greater than 90% chance of repair with mortality less than 1%.

What exactly defines a specialized mitral valve center is not well documented. In overall terms, an institution that has a focus on mitral surgery with documented acceptable outcomes could consider themselves a specialist center; however, this would be a shallow definition open to criticism. Considering all mitral surgery, a true specialized center must be able to offer the full gamut of treatment options including medical therapy, percutaneous intervention, and surgical repair or replacement. This requires at a basic level a cooperative approach between the cardiologist and surgeon with understanding of the pathology and indications for intervention. On the surgical side, a team including anesthetists, echocardiographers, perfusionists, and scrub nurses must work in unison with clear understanding of roles and common goals. Fortunately, many of these individuals’ roles are very similar regardless of whether the procedure is mitral surgery, aortic surgery, or coronary grafting and thus easily transferable. This is not the case when considering minimally invasive surgery.

Minimally invasive mitral surgery defines teamwork in the cardiothoracic environment. Each team member’s role is significantly altered when compared with a sternotomy approach. The anesthetists contend with single lung ventilation and an open heart procedure as well as needing advanced transesophageal echo (TEE) skills to assess both pathology and repair. Perfusionists must become competent at femoral bypass with vacuum-assisted drainage and be acutely aware of signs of complications of femoral arterial cannulation. Scrub nurses are crucial in assisting adequate set-up, handling of long cumbersome instruments, and the creation of a repair including neochordae. Even the surgical assistant must be able to learn to provide delicate suture tension from a contralateral minithoracotomy. The skills a surgeon must acquire include distant proprioception, two-dimensional visuospatial recognition from thoracoscopy, femoral cannulation, and remote suture handling. If any one of these team members is not adequately trained or experienced, then outcomes will suffer. This training and experience is the learning curve of MIMVS.

**THE ROYAL ADELAIDE HOSPITAL EXPERIENCE**

The Royal Adelaide Hospital minimally invasive program started in 2006 with a robotic mitral program. A team including a surgeon, anesthetists, perfusionists, and nurses traveled to the United States for training and proctoring before the program started. The hospital had purchased a DaVinci system primarily for the urology team and this was modified for cardiac surgery. Despite adequate training and support, the robotic program was abandoned after 15 cases because the team felt the learning curve was too steep and patient outcomes were being jeopardized. Factors identified that contributed to poor outcome included the need to be in a general rather than cardiac operating room, prolonged bypass times, and inadequacy of repairs.

In 2007, after an internal review, it was decided to pursue a minimally invasive program using the “Leipzig” technique. The team traveled to the Leipzig Heart Center and again underwent proctoring, this time under Professor Mohr. The lessons learned from the robotic program were invaluable and allowed the new program to flourish. This technique uses a right anterolateral minithoracotomy with a camera and crossclamp ports. Perfusion is through femorofemoral cannulation with vacuum-assisted drainage using a centrifugal pump. To date, a total of 225 minimally invasive mitral operations has been performed. This includes 184 repairs and 41 replacements. Mean patient age is 63.2 years (+/-14.0) and 133 (59.1%) were male. Patient comorbidities included hypertension, 59.8%; atrial fibrillation, 53.3%; chronic obstructive pulmonary disease, 27.7%; and renal impairment, 19.0%. Mean preoperative New York Heart Association class was 2.2 with 31.0% being Class III or IV. The predominant indication for surgery was severe mitral regurgitation (96.4%) secondary to myxomatous disease (78.6%). Mean preoperative ejection fraction was 61.7% ± 10.3% and left ventricular diastolic diameter was 57.0 mm.

The repair rate for all-comers with degenerative disease was 89.7%. When isolated to single leaflet disease, it was 98.6%, both results equivalent to leading institutions. For the repairs, the majority (98.4%) received annuloplasty rings and 77.7% had neochordae. Mean cardiopulmonary bypass (CPB) time was 123.3 minutes and crossclamp time was 72.4 minutes. Intensive care unit median length of stay was 48 hours and total length of stay was 7.0 days. In terms of morbidity, seven patients (3.1%) required re-exploration.
18 developed pneumonia (8.0%), two had myocardial infarction (9%), and 10 had a stroke (4.3%). Thirty-day mortality was .4%. Mean residual mitral regurgitation (MR) on postoperative echo was 1.0 ± 0.85 and ejection fraction 54.2%.

LEARNING CURVES

The first description of a learning curve was made by T.P. Wright in 1936 when he published his thesis on airplane component production (9). He hypothesized that as the experience and skill of the workforce increased, the cost of production would decrease. Industry continues to use the concept of the “learning curve” and is benefitted by being able to assess outcomes using direct measures such quality control and cost. Medicine is unfortunately not granted with such direct measures of a clinician’s performance having to make do with indirect measurements such as procedural time, morbidity, and outcome measures such as survival and durability.

Despite significant literature reporting learning curves across all surgical specialties, the very concept of a learning curve is not universally accepted. Academics argue that conceptually there are so many variables in clinical practice that it just is not possible to attribute improvements in either surgical process or patient outcome to a measurable learning curve. In cardiac surgery, the most well-published discussion on learning curves came with the Bristol Royal Infirmary Inquiry in 2000. Gallivan in his report to the inquiry summarily dismissed the applicability of learning curves to cardiac surgical practice because the variables of clinical practice, learning measurement, and statistical analysis do not permit a learning curve to form (10). Despite this document, the final Bristol report adopted the concept and a key finding was that as far as patient safety is concerned, a learning curve should not exist.

For those who do accept the concept of an inherent learning curve in the introduction of new procedures, the logical thought progression must be how to overcome this. The Harvard Business School review of MICS in 16 institutions clearly identified the importance of teamwork (4). Out of a complex analysis of human performance and interaction they found a divergence of approach from the “surgical leader.” Those institutions whose surgeon adopted a “plug-in” approach to MICS failed to advance significantly up the learning curve despite adequate effort. Other hospitals whose surgeon took a “team innovation” approach where the surgeon became a partner to his anesthetists, perfusionists, and nurses rapidly progressed toward superior outcomes. 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 (11).

ROYAL ADELAIDE HOSPITAL LEARNING CURVE

We have analyzed our prospectively collected minimally invasive surgery database to try to identify if a learning curve exists and, if so, at what point was it overcome. The hypothesis was that a learning curve would be present and that a surgeon would require a significant mitral caseload to overcome it and maintain acceptable outcomes. We examined both surgical process measures such as crossclamp time and CPB time as well as patient outcome measures such as residual MR, morbidity, and mortality. Analysis was restricted to the mitral repair group to allow uniformity of the procedure.

There were 184 repairs in total with 121 (65.8%) being male. Preoperative factors such as comorbidities, left ventricular ejection fraction, and severity of MR or symptoms did not change significantly between earlier and later cohorts. In terms of process measures, CPB times and crossclamp time showed a significant reduction from the first to third terciles (140.5 and 91.1 minutes to 107.8 and 69.2 minutes, $p = .0001$). The repair rate for all degenerative disease improved from 88.1% to 92.2% but did not reach significance. The rate for isolated posterior leaflet prolapse was 95.7% overall with a significant improvement from the first to third terciles (95.2% vs. 98.4%). Morbidity remained stable with no significant changes when examined in either terciles or quartiles. There was also no change in mortality. The most important measurement of mitral repair is durability with residual MR on echocardiography assessed annually. At early follow-up (mean, 4.2 months), residual MR was significantly less in the third quartile than either the first or second (1.8 vs. 1.3, $p = .01$ and 1.6 vs. 1.3, $p = .002$). This continued at late follow-up with the third quartile again having significantly less residual MR than the first at mean follow-up of 24.2 months (2.0 vs. 1.6, $p = .03$). Despite the improvement in residual MR, left ventricular end-diastolic diameters did not significantly differ, largely thought attributable to a trend to elevated preoperative diameters.

THE DIFFICULTIES

Over the course of the program, several key problems were encountered and identified. They formed part of the learning curve and are likely pitfalls for any institution embarking on a MIMVS program.

Femoral Cannulation

Most cardiac surgeons and perfusionists will have limited experience with femoral cannulation, using this skill only for redo surgery and aortic dissections. When adding it to routine practice, the myriad of potential complications is highlighted. In our experience, complications have
included arterial cannula dislodgement, type B dissection, type A dissection, and embolic cerebrovascular accident. It is now routine practice to conduct preoperative computed tomography angiographic scans on all patients to assess for peripheral vascular disease.

Unilateral Lung Injury

Many centers have encountered patients requiring prolonged ventilatory support postoperatively for right lung edema and this was our experience in the early period. The accepted hypothesis is that single lung ventilation of the left lung when on bypass creates an inflammatory edema in the collapsed right lung, which is exacerbated by high positive end-expiratory pressure to re-expand it. Our solution to overcome this has been to abandon double-lumen intubation for single and go on bypass before opening the right chest, allowing ventilation to cease and removing any need for lung manipulation.

Repair Durability

As is now widely accepted in the literature, the strongest predictor of long-term durability of MR is residual MR on intraoperative TEE. This is seen in our series and certainly forms part of the learning curve because fewer patients in the latter tercile have had greater than trivial MR postbypass.

CONCLUSION

There exists a significant learning curve for minimally invasive mitral valve repairs. This is highlighted best when reviewing repair durability in the short- and midterm. From our results this curve is overcome after approximately 90–100 cases. Given the typical cardiac surgeon in Australia would only perform five to 20 mitral cases per year, this presents a significant challenge, because 5–10 years is not an acceptable learning curve period. This highlights the need for an adequate referral base and a concentrating of mitral procedures to surgeons with an interest in developing expertise.

The undertaking of a MIMVS program requires a degree of stamina to not only pursue training and resourcing, but also to work through the inherent difficulties that are present in the early period. A surgeon must also be able to ensure an adequate caseload that will allow the learning curve to be overcome within a reasonable period of time, and this is likely to be a significant challenge to many. We hypothesize from our results that a mitral workload of 40–50 cases per year is necessary to build experience rapidly enough to overcome the learning curve. Anecdotally there would be less than 10 cardiac surgeons in Australia who would currently perform this number of mitral procedures and therefore the further uptake of MIMVS should be limited. Undertaking a MIMVS program is not something to be done with flippancy, underresourcing, or singlehandedly. It requires the commitment of an entire surgical team to a long period of learning and development with each individual sharing the responsibility for achieving good outcomes. The surgeon must be a leader, not a dictator, and ensure he or she has the skills and support around them to undertake a minimally invasive program. Despite the Bristol enquiries demands that a learning curve not exist when considering patient safety, it is a real part of surgical advancement and the true onus has to be on risk minimization.

REFERENCES