BISMICS consensus statement: implementing a safe minimally invasive mitral programme in the UK healthcare setting

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ABSTRACT
Disseminating the practice of minimally invasive mitral surgery (mini-MVS) can be challenging, despite its original case reports a few decades ago. The penetration of this technology into clinical practice has been limited to centres of excellence, and mitral surgery in most general cardiothoracic centres remains to be conducted via sternotomy access as a first line. The process for the uptake of mini-MVS requires clearer guidance and standardisation for the processes involved in its implementation. In this statement, a consensus agreement is outlined that describes the benefits of mini-MVS, including reduced postoperative bleeding, reduced wound infection, enhanced recovery and patient satisfaction. Technical considerations require specific attention and can be introduced through simulation and/or use in conventional cases. Either endoballoon or aortic cross clamping is recommended, as well as femoral or central aortic cannulation, with the use of appropriate adjuncts and instruments. A coordinated team-based approach that encourages ownership of the programme by the team members is critical. A designated proctor is also recommended. The organisation of structured training and simulation, as well as planning the initial cases, is an important step to consider. The importance of pre-empting complications and dealing with adverse events is described, including re-exploration, conversion to sternotomy, unilateral pulmonary oedema and phrenic nerve injury. Accounting for both institutional and team considerations can effectively facilitate the introduction of a mini-MVS service. This involves simulation, team-based training, visits to specialist centres and involvement of a designated proctor to oversee the initial cases.

INTRODUCTION
In the current era of surgeon-specific outcome publication, cardiac surgery in the National Health Service has adopted a culture of evolutionary practice as opposed to revolutionary progression.1 The process of introducing new technologies and procedures is multifaceted, underpinned by the demonstration of both patient safety and clinical effectiveness. The innovation of techniques in minimally access mitral surgery (mini-MVS) has dominated the cardiothoracic community for the last two decades. Despite this, the penetration of this technology into clinical practice has been limited to centres of excellence, and mitral surgery in most general cardiothoracic centres remains to be conducted via sternotomy access as a first line. When compared with the conventional sternotomy approach, the procedure has implications for the surgeon, surgical team and postoperative healthcare staff with regard to surgical equipment, peroperative parameters and bedside adjuncts.2 These, in turn, requires a common agreement on the use of appropriate outcome metrics and benchmarking.

This consensus report will serve to comprehensively review the evidence for the practice of mini-MVS and use this to highlight the important considerations when initiating a new mini-MVS programme in a UK Healthcare Trust.

EVIDENCE FOR MINI-MVS
There are currently no adequately powered randomised controlled trial data comparing minimally invasive and conventional mitral valve surgery. However, mini-MVS has shown to have benefits demonstrated through specific metrics.

Reduced postoperative bleeding
One of the main worries of mini-MVS is the prospect for conversion to larger access owing to complications during surgery. However, mini-MVS has been found to reduce the need for re-exploration for bleeding.
compared with conventional sternotomy. Chitwood Jr and colleagues conducted a meta-analysis with 1535 participants showing reduced need for reoperation for bleeding with mini-MVS. Studies as early as 20 years ago also supported this notion, reporting 1.8 units fewer red blood cell transfusion in patients undergoing mini-MVS compared with conventional sternotomy.

Wound sepsis
A smaller area of disruption in skin integrity allows for less inoculation with commensal microbes, especially in patients with diabetes, immunosuppression and higher body mass index. In an observational study conducted by Grossi et al, the rates of septic wound complication in adult were 5.7% and 0.9% (p=0.05) in median sternotomy and mini-MVS groups, respectively. This benefit also continued to be evident in elderly patients.

Patient satisfaction (shorten)
Mini-MVS is associated with less postoperative pain and quicker return to normal activity. This translates to an improved quality of life in the early post-period. Glower et al showed that patients found that pain resolved more quickly and were able to return to activities of daily living up to 5 weeks earlier after mini-MVS compared with median sternotomy, perhaps a result of improved stabilisation of the thorax. Furthermore, several studies have reported a demonstrable cost saving with mini-MVS, which could be a result of shorter length of stay (LOS).

Benefits in redo surgery
Redo cardiac surgery is traditionally performed through a repeat median sternotomy. However, this procedure is technically challenging due to dense adhesions and has a considerable risk of injuries to cardiac and vascular structures, which are independent risk factors for mortality. In 2018, a meta-analysis with a total of 777 patients demonstrated mini-MVS as a valid alternative in redo MVS with significantly reduced rates in mortality, LOS and reoperation for bleeding.

TECHNICAL CHALLENGES TO OVERCOME
Mini-MVS is a technically demanding complex procedure. Considerations for new learning curves have been proposed in mini-MVS, namely altered incisions, reduced operative space, endoscopic instrumentation and aortic occlusion. The recommendations from this consensus statement are summarised in box 1.

Mitral valve repair
Surgeons should be comfortable with the techniques of repair by operating on an adequate number of sternotomy access mitral procedures. The buildup to mini-MVS should also be graduated, ensuring that the 20 initial cases are straightforward, commonly P2 prolapse cases, which could be considered the simplest mitral procedure.

Incision size
The goal of a thoracotomy incision is to make it less than 5 cm in length, which has numerous patient benefits. For the initial cases, the skin incision can be made slightly longer to assist visualisation as it is the avoidance of sternotomy or no rib-spreading which provides clinical benefit. Beyond this, the relationship between volume and outcome remains true in mini-MVS, and it would not be unreasonable that the time to be considered an expert in mini-MVS may take a few years. Overcoming the challenges of operating in a reduced space is perhaps the largest challenge for the surgeon.

Aortic occlusion
Aortic occlusion is achieved currently by two techniques available to surgeons: (1) transthoracic clamp (TTC);
and (2) endoaortic balloon occlusion (EABO). The TTC technique is simpler and involves inserting a clamp through the intercostal spaces to clamp the ascending aorta. The EABO technique is associated with a longer learning curve as the procedure requires more monitoring and experience. It involves accessing the aorta through a catheter inserted either in the femoral artery or directly through the ascending aorta with an inflatable balloon at its tip. This is guided by transoesophageal echocardiography (TOE), the balloon is inflated and the aorta occluded. In a recent meta-analysis, the only advantage of TTC over EAOB was the reduction in aortic dissection complications (risk ratio 0.33, 95% CI 0.12 to 0.93; p = 0.04) 23.

The use of aortic occlusion method currently remains entirely down to surgical preference and newer adjuncts for aortic occlusion are yet to penetrate surgical practice. Importantly, occluding the aorta through aortic cross-clamp time or EABO is a learning curve that the surgeons can only ascend during minimally invasive procedures. A useful option for TOE-guided cannulation would be gaining the patient’s consent to practise percutaneous femoral cannulation on sternotomy or hemisternotomy cases could be a viable method for improving the surgeon’s familiarity with this alternative strategy.

### Endoscopic mini-MVS

Thoracoscopes have been implemented in mini-mitrval surgery for over two decades helping to reduce complications via improved visualisation, 24 although familiarity for their use is required and mainly specialised centres advocate performing mini-MVS totally endoscopically. 25 In 2008, Chitwood and colleagues described levels of mini-MVS based on the size of the incisions and progressive use of video-assisted or robotic-assisted surgery 26 (table 1).

Robotic-assisted mini-MVS techniques, although safe and effective, are associated with more difficult learning curves. Robotic surgery provides ergonomic gains which improve the surgical process and the smaller incision sizes are favoured by patients. Current evidence is mostly based on observational studies, and therefore randomised trials may be required in order to definitively assess the advantages and disadvantages of these techniques. 27

### IMPLEMENTING THE FIRST FEW CASES

#### Early engagement with hospital and patients

In most hospitals, all new procedures need prior approval from a hospital committee, which has ethical, cost, patient outcome and management considerations. This ensures patient safety, highlights clinical governance and maintains quality control. The hospital committee may have a specific application process and ask for prerequisite information prior to issuing favourable support. Usually, this involves description and indications of the proposed procedure, intended benefits, possible complications, summary of evidence base, estimated number of annual procedures to be performed and names of supporting colleagues.28

Evidence suggests that patients prefer detailed explanations of their treatment and decisions made surrounding it. 29, 30 Written material explaining why the department is employing the new procedure, evidence surrounding its use, as well as what patients should expect following the procedure should be offered containing visual aids and diagrams. Risks of mini-MVS should be explained openly and helps avoid confusion or anxiety.

#### Selecting the initial cases

In the initial period (first 20 cases), appropriate patient selection is key. This ensures patient safety and allows the surgeon and team to ‘break in’ to the novel procedure.
with as minimal complications as possible. In the early stages, should avoid
1. Very elderly.
2. Grossly obese.
3. current smokers.
4. High risk (high Euroscore).
5. Complex repairs (stick to straightforward annuloplas-
   ty±P2 resection).

In actual fact, it is these very patients who may benefit
from mini-MVS the most. However, in the initial stages
of implementation, the complication rate may be higher.
Other contraindications to mini-MVS that would persist
beyond the initial cases should also be described and
made clear in the institution’s protocol. Although not
absolute contraindications, each patient should be
considered on an individual basis via a risk-benefit anal-
ysis and through the consideration of the multidisci-
plinary process. The contraindications to be considered
have been outlined in table 2.

**Equipment needs**

An important recommendation for familiarisation with
mini-MVS technology is to make use of them during estab-
lished open procedures. This includes the thoracoscope,
knot pusher and TOE-guided cannulation (table 3). Space
will be less restricted and safety for their use in these
scenarios would not be compromised. Local depart-
mental teaching attended by all involved personnel and
team members from different specialties should also be
delivered. This allows for the following opportunities:
1. Invited speakers from specialised centres or equip-
   ment companies.
2. Watching operative videos of the procedure
3. Exploring the rationale of the new technology.
4. Group discussion.
5. Handling of specialised instruments and discussion
   surrounding their use.
6. Agree to one case per day for the whole team to allow
   adequate time for a full debrief where each member of
   the team has a voice.

**Trainees and surgical assistants**

Establishing the new service should have a long-term
vision that includes transferring the knowledge and
skills to junior colleagues who can lead and participate
in the service in subsequent years. Including trainees in
visits to specialised centres, teaching sessions and group
discussions surrounding the new procedure should be

### Table 2 Contraindications for minimal access mitral surgery

<table>
<thead>
<tr>
<th>Contraindication</th>
<th>Implications for mini mitral surgery</th>
<th>Methods to circumvent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior right chest surgery or radiation</td>
<td>Patients are at increased risk due to pleural adhesions</td>
<td>Preoperative CT scan can allow for operative planning with specific adjuncts and techniques to avoid damage to major structure</td>
</tr>
<tr>
<td>Severe peripheral atherosclerosis or chronic peripheral arterial occlusive disease. Descending aorta aneurysm, aortic dissection, aortic thrombus.</td>
<td>Peripheral cannulation for CPB can be particularly challenging for these patients</td>
<td>Alternate routes of cardiopulmonary bypass to be considered or full sternotomy</td>
</tr>
<tr>
<td>Prominent ascending aorta calcifications or ascending aorta aneurysm/dilation (&gt;4.5 cm)</td>
<td>Aortic clamping and antegrade cardioplegia administration are challenging in these patients</td>
<td>Consider endo-balloon or percutaneous mitral valve repair</td>
</tr>
<tr>
<td>Moderate to severe aortic regurgitation (AR)</td>
<td>Difficulties with cardioplegia administration</td>
<td>Conventional sternotomy</td>
</tr>
<tr>
<td>Significant chest wall deformity (particularly severe pectus excavatum)</td>
<td>Challenging access to all intrathoracic structures</td>
<td>Conventional sternotomy</td>
</tr>
<tr>
<td>Severe mitral annular calcification</td>
<td>Extensive decalcification of the mitral annulus and reconstruction with a pericardial patch is very challenging through a minimal invasive approach</td>
<td>Conventional sternotomy or percutaneous mitral valve replacement</td>
</tr>
</tbody>
</table>

### Table 3 Technical aspects of minimal access mitral surgery and relevant ways to introduce into a new unit

<table>
<thead>
<tr>
<th>Attemps on sternotomy mitral cases</th>
<th>Wetlab</th>
<th>Team-based simulation</th>
<th>Visit to specialist centre</th>
<th>Visit from proctor to unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mini thoracotomy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOE-guided aortic cannulation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Aortic occlusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knot pushing</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Thoracoscopic adjunct</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

TOE, transoesophageal echocardiography.
encouraged. Assisting in the initial cases is also recommended. The use of high-fidelity virtual reality simulation training has demonstrated benefit in many fields of minimally invasive surgery, including thoracoscopic surgery. This helps shorten the learning curve outside the operating theatre and hence improve patient safety while new procedures are being implemented.

Staff considerations
The importance of team concordance and communication surrounding these new process entities are paramount. In this light, the need for simulation is highly recommended. Scheduling a visit to a customised simulation centre with specialised assessment equipment and simulated theatres is extremely useful. Specialised audio-visual equipment can allow for unique playback and feedback opportunities to allow team members to improve on personal aspects of communication. Promoting positive relations and trust between the team members play an important role in ensuring the efficient running of complex procedures. Studies in many surgical specialties have shown that the familiarity of team members is key to minimise operative-related complications, reduce operative time and improve patient outcomes.

Devising one to two mini mitral-specific checklists is also highly recommended. This will help reduce untoward error related to equipment, staff or theatre processes. This may be used to benefit specific staff, or groups of staff, members, for example, scrub nurses when checking equipment preparation and theatre operating department practitioners when checking theatre and patient readiness.

It is important to note that initiating a novel mini-MVS service has significant benefits for the institution. For the staff, this can be a catalyst for improving team morale, self-belief and skill progression. Becoming a unit that collectively leads in the implementation of new technology and techniques will carry both staff and patient benefit.

DEALING WITH ADVERSE EVENTS
Establishing a culture of objectivity is critical for the audit process. This involves the leading members of the service and team in promoting an ethos of openness, honesty and devoid of blame. Moving to a mini-MVS approach does expose the surgeon and his team to a different set of complications related to alternative cannulation strategies and new incisions. All adverse outcomes need to be clearly documented and each can be virtually eliminated by constant improvements in technique and technology used. Regular conversations with a mentoring surgeon or team helps understand specific complications and leads to a lower incidence.

Bleeding and re-exploration
One of the underlying causes of conversion from mini-MVS to median sternotomy is bleeding. Although literature has shown that mini-MVS leads to a reduction in bleeding and re-exploration compared with sternotomy. Management of postoperative bleeding should adhere to strict standards as with other cardiac surgical procedures. The need for adequate surgical re-expansion for severe haemorrhage should not be overshadowed by the desire to maintain the integrity of minimal access. In the first instance, hypothermia and acidosis should be closely monitored, and crystalloid administration should be minimised to avoid haemodilution. Additionally, excessive hypertension should be avoided, and mean arterial pressure levels should not be allowed to run higher than 90 mm Hg and timely transfusion with blood products is required.

Dense pulmonary adhesions are another cause of conversion to sternotomy. This is associated with patients with a background of pulmonary diseases. Hence, a detailed preoperative CT scan with anatomical consideration and detailed multi-disciplinary team discussion should be carried out in these patients.

Pulmonary oedema
There have been reports of unilateral pulmonary oedema (a rare but life-threatening complication) occurring after mini-MVS, with the pathophysiology thought to be inflammatory related. The cause–effect relationship is yet to be established, as many cases of severe pulmonary oedema can also be observed following sternotomy access for cardiac procedures. Two landmark trials found a role for perioperative intravenous steroids in sternotomy cardiac patients for the significant reduction in the incidence of pulmonary oedema. Although this has not been formerly trialled in mini-MVS. Retrospective studies in mini-MVS have found that the introduction of perioperative steroids in mini-MVS may lead to a reduced incidence of clinical and radiological pulmonary oedema. Careful ventilatory strategies may also need to be employed to reduced volume and barotrauma-related lung injury.

Phrenic nerve palsy
The risk of phrenic nerve palsy with mini-MVS has been reported to increase by 3% compared with conventional sternotomy. This can have adverse implications as patients may experience respiratory distress and prolonged ventilation. It is speculated that phrenic nerve palsy results from excessive pull on pericardial traction sutures which are used for better visualisation of the left atrium. Therefore, measures to incise the pericardium further away from the phrenic nerve (preferably >3 cm) and avoid retraction sutures near the nerve to prevent extensive pull are advocated. It is important to note that phrenic injury is an avoidable complication, which gives emphasis to the importance of rigorous attention to this part of the procedure when training surgeons in mini-MVS.

Pain
Although mini-MVS confers a smaller incision, chronic pain can develop as a result of intercostal nerve damage. Randomised controlled studies are lacking in this area,
although the use of various analgesic techniques has been reported. The use of a catheter inserted in close proximity to intercostal space before skin closure with administration of 75 mg of 0.75% ropivacaine has been shown to eliminate early postoperative pain.\textsuperscript{38} Alternatively, intercostal nerve blockade combined with general anaesthesia has also been reported,\textsuperscript{39} which was achieved by the administration of 0.5% ropivacaine from T3 to T7 prior to anaesthesia induction. Intractable cases of chronic pain secondary to intercostal nerve traction is likely to require input from neuropathic pain specialists to employ patient-specific therapy. Most cases of pain tend to resolve within 12 months, and many lessons can be drawn from thoracic surgical practice whose patients frequently have pain related to the intercostal nerve.

**CONCLUSION**

This consensus statement has outlined the important considerations and processes for establishing a workable, effective and sustainable mini-MVS service in a modern UK healthcare system. The aim of the authors is to promote standardised practice to allow the effective and safe dissemination of novel technology in healthcare for the betterment of patients requiring mitral surgery.

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**Correction notice**

This article has been corrected since it was first published. ‘Massimo Caputo’ has been added as the 4th author and a funding statement has now been included.

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**REFERENCES**


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Co-author Massimo Caputo was previously omitted from the author list and has now been added as the 4th author. Additionally, the following funding statement has been added since the article was first published: “The British Heart Foundation, Cardiovascular theme of NIHR Bristol Biomedical Research Centre, supported this work. The funders played no role in the design of the study, in the collection, analysis and interpretation of data, or in the decision to submit the manuscript for publication.”

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