Starting out in minimally invasive aortic valve replacement in the UK

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Abstract

OBJECTIVES: Here we aim to describe in detail the logical procedure and philosophical approach to establish a minimally access aortic valve replacement programme in the current era.

METHODS: A real example of a National Health Service Trust in the United Kingdom has been described in a step-wise manner.

RESULTS: The outcomes of the new procedure established in this fashion are reported and the philosophical lessons learnt from the experiences are highlighted.

CONCLUSIONS: It is hoped that this paper will act as a template for newly established surgeons to embark onto a mini-AVR programme. An open-minded and enthusiastic team will undoubtedly be able to facilitate the introduction of this ‘new service’. A sensible approach will provide safe and sustainable outcomes.

Keywords: Minimally invasive • Aortic valve • Replacement • Programme

INTRODUCTION

Clinical effectiveness and patient safety is paramount when introducing a new procedure or technique in the current NHS climate. Here we describe in detail the logical procedure and philosophical approach to establish a minimally access aortic valve replacement programme in the current era. A real example of a National Health Service Trust in the United Kingdom has been described in a step-wise manner. The outcomes of the new procedure established in this fashion are reported and the philosophical lessons learnt from the experiences are highlighted. It is hoped that this paper will act as a template for newly established surgeons to embark onto a mini-AVR programme.

ESTABLISHING THE NEED

Minimally invasive aortic valve replacement (Mini-AVR) is now an established procedure. The first parasternal approach for mini-AVR was reported by Cosgrove and Sabik in 1996 [1] following the minimally invasive revolution in general surgery in the late 1980s. Further evolution has resulted in the upper mini-sternotomy and the right thoracotomy approaches to be currently the most popular ones [2]. Upper mini-sternotomy provides a window through which the aortic root is freely accessible [3, 4]. Without additional risk to the patient, the surgeon makes slight modification to already established familiar techniques. This offers the benefit of prompt recovery in appropriately selected patients and enhances patient choice and patient experience [4]. Although suited for isolated AVR in patients of all ages, mini-AVR is particularly applicable to the elderly, obese, recent smokers and those with impaired respiratory function [4]. When compared with a conventional sternotomy, the hemi-sternotomy leaves the sternum more stable. We believe that mini-AVR is particularly suitable for patients who may have a higher risk of sternal dehiscence but otherwise suitable for conventional AVR. Hence, these are not patients who would be considered for TAVI.

In a propensity score analysis comparing 233 patients with mini-AVR with 233 patients undergoing full sternotomy AVR, Sharony et al. [5] showed that the length of hospital stay was significantly shorter with mini-AVR. Similar outcomes have been reported by other authors as well [6-9]. With an increasingly elderly population in a tight fiscal climate, reducing the length of hospital stay after AVR, even by 1–2 days, could translate into better overall clinical outcomes and huge savings in the UK and worldwide. Applying this argument would be a key selling point when trying to set up a mini-AVR service in a cardiac surgical unit in Europe. A smaller scar, less pain and blood loss are other potential benefits. In centres where this procedure is well established, the referral base has significantly increased as mini-AVR is requested by both patients and cardiologists.
TRAINING

It is also important to establish any training needs, not only for the surgeon, but also for the whole team including anaesthetists, perfusionists and the scrub team. Before the first cases are performed, local departmental teaching should be organized (lectures, evidence, videos etc.) where all disciplines are invited. We used a combination of theoretical information and operative footage in order to familiarize the team with the procedure and its potential pitfalls. Visits to ‘mini-AVR centres’ and attendance at courses targeted at new centres are strongly advised. From the surgical perspective, at least two surgeons are required with an interest in minimal access surgery. An experienced aortic valve surgeon teaming up with a newly appointed surgeon would be the ideal combination. Enthusiasm and wisdom are the two key elements that are required to set up such a programme. In our unit, Jacek Szostek had performed hundreds of conventional AVR and had visited a UK centre to observe mini-AVRs. On the other hand, Hunaid A. Vohra had performed >100 conventional AVR but had spent time in fellowships, first learning minimal access surgery. An experienced aortic valve surgeon teaming up with a newly appointed surgeon would be the ideal combination. Enthusiasm and wisdom are the two key elements that are required to set up such a programme. In our unit, Hunaid A. Vohra in our case had performed five mini-AVRs independently during his fellowship.

TRUST APPROVAL

New Interventions and Procedures Advisory Group application

In our trust, all new procedures need prior approval from the New Interventions and Procedures Advisory Group (NIPAG). These groups or committees exist in one form or the other in most hospitals. It is crucial that the team endeavours to gain approval from such committees before embarking onto a mini-AVR programme. This ensures patient safety, highlights clinical governance and maintains quality control. The NIPAG application requires description and indications of the proposed procedure, intended benefits, possible complications, summary of evidence base, estimated number of annual procedures to be performed, names of supporting colleagues, names of performing colleagues and letter of support from the lead clinician.

Support from colleagues

Ideally, the proposed procedure should be discussed with all Consultant surgical colleagues formally and their support sought, even if all of them would not be performing the new procedure. The names of the surgeons performing the operation in the ‘setting-up’ phase should be specified. Once this phase has passed and the final approval from NIPAG granted, other surgeons may also be able to embark onto the programme with appropriate in-house training.

Proctor

It should be considered compulsory to have a named proctor (Christopher Young in our case) with considerable experience and reputation in the field to provide training and supervision in the first cases performed. The ideal proctor is one with whom at least one of the operating surgeons has worked or trained with before (Hunaid A. Vohra in our case).

Patient information leaflet

NIPAG also requires that a patient information leaflet (see Supplementary material) is devised in a language easily understood by the patients where it is clearly stated that this is a new procedure to the trust but the surgeons involved are adequately trained and will be initially supervised to perform this. The leaflet informs the patient of the potential benefits and that this operation would not put the patients at higher risk of harm when compared with conventional surgery. Reassurance should also be provided that, in case of a serious complication, the incision will be made bigger to control the situation. The leaflet is intended to educate the patient with respect to the ‘new technique’ and provides them with an option they may wish to consider.

Audit

NIPAG also requires that individual patient audit and a summative audit is provided after the first 20 cases are performed. Any untoward serious event must be reported and copied to NIPAG. This provides the foundation for the final trust approval. Regardless, once the procedure becomes well established, 6–12 monthly audits with morbidity and mortality figures would be recommended as best practice.

Cost

Although new additional costs can be involved, mini-AVR can generally be performed without the requirement for any special equipment. The Trust Management should be reassured that extra funding would not be required for starting a mini-AVR programme.

TAKE-OFF

Communicate

Before the programme commences, every effort must be made to encourage open discussion in a relaxed environment, to exploit every opportunity to highlight concerns regarding equipment and training and to facilitate team-work and boost morale. This becomes paramount if previous experiences have not been positive. Frequent informal dialogues in corridors and coffee rooms as well as formal discussions at regular Consultant, Monthly Audit and other Clinical Governance meeting should not be underestimated.

Patient selection

In the initial period (first 20 cases), patient selection is the key. Avoid very elderly, grossly obese, current smokers and high-risk patients. Once the programme is ‘up and running’, it is these very patients who might benefit from mini-AVR. At the outset, the skin incision can be made slightly longer as it is the mini-sternotomy.
and not the skin incision that provides clinical benefit. A flow chart of patient selection for mini-AVR is provided (Fig. 1).

Proctor contract

As the proctor is likely to be working in another trust, he will require a local contract to be able to assist with surgery. To avoid last-minute disappointment, ensure that this is organized beforehand. Although sounds tedious, but this can be easily and quickly done by the communication between the Human Resources Departments of the two NHS Trusts (if applicable).

Team briefing

Prior to the first case, the whole team must be extensively debriefed (with the proctor present) and ensure that all equipment required is available. It is important that all members of the team are encouraged to ask questions at this point to provide further opportunity to highlight issues and promote team involvement.

First 20 cases

The first case in our programme was performed by the more experienced surgeon (Jacek Szostek) with the proctor (Christopher Young) as the first assistant and the other surgeon (Hunaid A. Vohra) as the second assistant. The second case was again performed by Jacek Szostek with Hunaid A. Vohra as the first assistant whilst the proctor observed the case unscrubbed in theatre. During these cases, there were frequent technical points discussed which helped enormously. Thereafter, another 3 cases (unproctored) were performed by the 2 surgeons scrubbed together and then the rest of the first 20 cases were performed by one surgeon individually with the other surgeon on backup within the hospital, if required. After the first 20 cases, the audit was submitted to NIPAG and final approval granted. The results for the first 35 cases performed after starting a mini-AVR programme in the above fashion are presented in Table 1. Currently, 90% of the patients undergoing AVR in our practice are undergoing this via the minimally invasive route. On an average, in our hands, the cross-clamp time is 10 min longer and the whole procedure takes 30 min longer compared with conventional AVR. Hence, the surgical time of mini-AVR is comparable with conventional AVR.

**Flow chart for patient selection for mini-AVR**

 Patients with severe symptomatic aortic stenosis or aortic regurgitation requiring surgery

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Referral by cardiologist

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Seen by cardiac surgeon in the out-patient clinic

↓

Confirm need for surgery and discuss risks/benefits of AVR

↓

Suitable for mini-AVR (diabetic, obese, immuno-compromised, patient choice)

↓

Standard AVR full explanation about mini-AVR/PIL provided in OPD

↓

Patient refuses

↓

Patient discussed at aortic MDT

Consensus for mini-AVR

↓

Patient consents to mini-AVR

↓

Patient undergoes mini-AVR

Figure 1: Patient selection flow chart. AVR: aortic valve replacement; PIL: patient information leaflet; OPD: out-patient department; MDT: multi-disciplinary team.
Examples of technical difficulties

Although not the subject of this paper, below are some examples of technical difficulties that we experienced in the initial phase of the programme with a brief explanation of how they were solved.

**Difficult access.** By increasing the length of the skin incision and/or changing from a J to a T hemi-sternotomy or sternotomy into the fifth intercostal space instead of the fourth space.

**Right atrial venous pipe ‘in the way’.** Use a flat venous cannula and pass it under the retractor before connecting to CPB circuit.

**Blocked drain.** Using two drains of two sizes smaller instead of one big drain.

**Difficulty in placing ventricular pacing wires.** Insert while the heart is arrested before removing the cross-clamp.

Key lessons learnt

- Work together with an experienced surgeon
- Proctor is essential
- Always have backup
- Do not be afraid to convert
- It is not as difficult as it sounds

### Table 1: Postoperative characteristics of the first 35 patients undergoing mini-AVR

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of mini-AVRs</td>
<td>35</td>
</tr>
<tr>
<td>Mean follow-up</td>
<td>16 ± 6.2 weeks</td>
</tr>
<tr>
<td>Mean cross-clamp time</td>
<td>59.6 ± 10.1 min</td>
</tr>
<tr>
<td>Cardiac-related deaths</td>
<td>0</td>
</tr>
<tr>
<td>Conversion to open</td>
<td>0</td>
</tr>
<tr>
<td>Re-exploration</td>
<td>1 (blocked drain)</td>
</tr>
<tr>
<td>Wound infection</td>
<td>0</td>
</tr>
<tr>
<td>Sternal dehiscence</td>
<td>0</td>
</tr>
<tr>
<td>Permanent pacemaker</td>
<td>0</td>
</tr>
<tr>
<td>Valve reoperation</td>
<td>0</td>
</tr>
</tbody>
</table>

AVR: aortic valve replacement.

### CONCLUSION

The universal adoption of mini-AVR in contemporary cardiac surgery seems inevitable in the foreseeable future. It is a safe and logical option from the data provided so far from studies and registries. An open-minded and enthusiastic team will undoubtedly be able to facilitate the introduction of this ‘new service’. The ‘starting-up’ period can be daunting for a newly appointed surgeon. However, a sensible approach will provide safe and sustainable outcomes.

### SUPPLEMENTARY MATERIAL

Supplementary material is available at ICVTS online.

### Conflict of interest: none declared.

### REFERENCES