Ulster Med J 2016;**85(1):**18-22

Clinical Paper

High Risk Aortic Valve Replacement – The Challenges of Multiple Treatment Strategies with an Evolving Technology

Booth K[1], Beattie R[1], McBride M[1], Manoharan G[2], Spence M[2], Jones J M[1]

Accepted: 1st June 2015
Provenance: externally peer-reviewed

ABSTRACT

Objectives Deciding on the optimal treatment strategy for high risk aortic valve replacement is challenging. Transcatheter Aortic Valve implantation (TAVI) has been available in our centre as an alternative treatment modality for patients since 2008. We present our early experience of TAVI and SAVR (surgical Aortic Valve Replacement) in high risk patients who required SAVR because TAVI could not be performed.

Methods The database for Surgical aortic valve and Transcatheter aortic valve replacement referrals was interrogated to identify relevant patients.

Results Survival to hospital discharge was 95.5% in the forty five patients who had SAVR when TAVI was deemed technically unsuitable. One year survival was 86%.

Conclusion Defining who is appropriate for TAVI or high risk SAVR is challenging and multidisciplinary team discussion has never been more prudent in this field of evolving technology with ever decreasing risks of surgery. The introduction of TAVI at our institution has seen a rise in our surgical caseload by approximately by 25%. Overall, the option of aortic valve intervention is being offered to more patients in general which is a substantial benefit in the treatment of aortic valve disease.

Key Words: Transcatheter Aortic Valve Implantation (TAVI), Conventional Aortic Valve Replacement (AVR), High risk conventional Aortic Valve Replacement

INTRODUCTION

Transcatheter aortic valve replacement (TAVI) in humans was first described by Cribier et al.[1] Since then it has undergone a rapid technical evolution with promising results.[2-3] TAVI now offers an alternative to surgical aortic valve replacement (SAVR) when surgery is deemed high risk.[4] Considering aortic stenosis (AS) is more common in the elderly and those with cardiovascular risk factors and co-morbidities, surgical intervention is always going to be at a slightly higher risk of complication.[1,5] Despite the grave prognosis for patients with severe symptomatic AS not undergoing aortic valve replacement, the Euro Heart Survey found 33% of elderly patients did not have intervention due to this higher risk.[6,7] The Placement of Aortic Transcatheter Valves (PARTNER) trial demonstrated improved outcomes for patients with severe aortic stenosis randomised to TAVI or best medical care. This decreased mortality and increased functional capacity with good hemodynamic performance at 1- and 2-year clinical follow-up. 3 year results continue to show improved mortality with overall survival of 50% at three years.[8]

SAVR is still the gold standard in valve replacement in terms of haemodynamics. Post procedural complications such as aortic regurgitation, stroke, acute kidney injury, and vascular complications were seen in the PARTNER trial for TAVI. Residual para-valvular regurgitation after TAVI can lead to worsening left ventricular function and survival for patients. Cardiac causes were identified for 63% of all deaths at the three year follow up in the PARTNER trial. The optimal treatment strategy must be individualized when planning TAVI versus SAVR.

Crossover between the two interventions does occur and even in the PARTNER trial, crossover between medical treatment and TAVI was noted. D'Onofrio et al have shown that the development of TAVI caused an increase in the preoperative risk profile of patients scheduled for *all* aortic valve procedures without increasing hospital mortality.[9] Crossover between the two interventions occurs naturally as some patients decompensate and have their heart failure stabilised prior to intervention. Deciding which intervention is best can

[1] Department of Cardiothoracic Surgery and 2. Department of Cardiology, Royal Victoria Hospital, 274 Grosvenor Road, Belfast, BT12 6BA

Corresponding author: Karen Booth

E-mail: karen.booth@belfasttrust.hscni.net

be challenging but the wider range of options allows for more discussion on the best treatment course.

Patients may be deemed unsuitable for SAVR mainly based on risk profiling. This can include technical reasons such as a redo procedure or multiple comorbidities. TAVI also can be technically unsuitable due to 1) coronary artery disease (which is best treated by surgery), 2) the dimensions of the aortic root or 3) the anatomy of their peripheral vasculature. Contraindications are device, approach and institution specific.[10] The number of patients unsuitable for TAVI is naturally low and decreases as experience increases. However, the ever decreasing risks of open heart surgery is often ignored.[11] Studying a patient population who was deemed unsuitable for TAVI during the introduction of this procedure allowed us an opportunity to study high risk patients having SAVR. Other institutions in the United Kingdom have also found that the impact of offering TAVI has had a positive effect on the volume of SAVR carried out. We have found that the main factor in offering intervention to these patients is for symptomatic control as many are acutely ill inpatients and are prepared to accept a high risk intervention over medical therapy alone.[12]

METHODS

Data on all referrals for TAVI was prospectively collected between February 2008 and November 2012. This was cross-referenced against the electronic cardiac surgical database to create a list of patients who had been considered for TAVI before undergoing SAVR. Hospital charts and the surgical database were searched for perioperative, critical care and inpatient data.

Table 1.

Rationale behind TAVI refusal in the 33 patients undergoing surgical AVR.

Reason for TAVI refusal	Number (%)
Coronary anatomy unsuitable for PCI and/ or TAVI	18 (45%)
Peripheral vasculature unsuitable	6 (13.1%)
Concomitant non-valvular procedure required	6 (13.1%)
Annulus/native valve unsuitable	6 (13.1%)
MDT/patient decision	5 (11.1%)
Lack of funding	3 (6.7%)
Emergency procedure	1 (2.2%)

The national death registry was used for survival data, with the date of the search equating to the date of last follow up. Forty five patients were identified who had been discussed through the local heart team. This consisted of one non-interventional cardiologist, two interventional cardiologists who perform TAVI, one surgical consultant who performs TAVI and one surgical consultant who performs SAVR only. This review spans the evolutionary process from its introduction and it must be recognised that the rationale for unsuitability of TAVI (table 1) is mostly technical, so that new techniques such as; peripheral TAVI under local anaesthetic, direct aortic and trans-apical aortic valve replacement have modified unsuitability criteria as they have become available in our unit.

RESULTS

Of the 45 patients identified, 31 (69%) were male with a median age of 79.1 years. The numbers of patients who were offered surgical intervention, medical therapy and TAVI are listed in table 2. Preoperative data is displayed in table 3. Aside from the more common co-morbidities, two patients had liver cirrhosis and varices, one patient had multiple sclerosis and was wheelchair-bound having had a previous sternotomy, and four patients required inotropic support preoperatively.

Table 2.

Characteristics of 45 patients undergoing surgical AVR having been deemed unsuitable for TAVI.

Total patients	**45**
Male	31 (69%)
Median age (± SD)	79.1 (± 9.8)
Previous cardiac surgery	3 (6.7%)
Chronic renal failure (creat>200)	11 (24.4%)
COPD	15 (33.3%)
NYHA III-IV	28 (62.2%)
Diabetes Mellitus	9 (20%)
Previous CVA/TIA	5 (11.1%)
Urgent Procedure	23 (51.1%)
Median ejection fraction	50.1 (±17.74)
Median valve area, cm2	0.67 (±0.16)
Median peak gradient, cm2	75.7 (± 24.9)
Median logistic EuroSCORE	19.5 (± 12.9)

Table 3.

Intraoperative details of conventional AVR patients

Concomitant Coronary artery bypass grafts	23 (51.1%)
Concomitant Mitral valve Surgery	4 (8.8%)
Concomitant Tricuspid Valve Surgery	2 (4.4)
Via ministernotomy	1 (2.2%)
Median cross clamp time (mins)	110.7 (± 34.7)
Median CPB time (mins)	152.6 (55.27)

Concomitant mitral valve surgery was required in four patients (8.8%) (2 repairs, 2 replacements) and twenty three patients (51.1%) underwent coronary artery bypass grafting. Mean cross clamp and bypass times were 110.7 and 152.6 minutes respectively. Mean time to extubation was 6.8 days.

Table 4.

Post operative course in 33 patients undergoing conventional AVR.

Post op	
Median blood loss (ml) (+ SD)	794 (+585)
Median Transfusion PRC units	1.6 (+ 1.7)
Median hours to extubation	6.8 (+9.4)
Requiring IABP	3 (6.7%)
LRTI	21 (46.7%)
New AF	11 (24.4%)
Dialysis	7 (15.5%)
PPM insertion	2 (4.4%)
Resternotomy for bleeding	7 (15.5%)
Prosthetic valve endocarditis	2 (4.4%)
Mean critical care stay (days)	8.3 (+5.0)
Mean LOS post operatively(days)	17.9 (+10.3)
30 day mortality	2 (4.4%)
1 year survival	86% (SE + 5.3)
Mean follow up in months	27.9 (+ 16.3)

Table 5.

Changes in referral patterns since the introduction of TAVI

	2006-2007 (2 years preceeding TAVI)	2009-2010 (2 years after TAVI)	p
Total number of AVRs	381	476	<0.01
Mean Age (sd)	65.9	67.8	0.03
Mean Euroscore	6.3	6.9	0.04

Mean blood loss in the initial 24 hours post operatively was 794 mls and seven patients (15.5%) required resternotomy for bleeding (see Tables 4&5).

One patient developed prosthetic valve endocarditis and underwent a successful redo procedure 2 months after the initial surgery. Two patients died before discharge, one from a Cerebrovascular Accident (CVA) on post-operative day 27 and the other died following unrecoverable cardiac arrest on post-operative day 2 from which post mortem examination revealed hypertensive heart disease. Forty-three (95.5%) patients survived to discharge. On follow up, 6 patients died within the first year, one from metastatic ovarian cancer, one from CVA, one from congestive cardiac failure, one from end stage renal failure, one from bronchopneumonia and one from peritonitis following bowel perforation and underlying ulcerative colitis. One year survival was 86% (see figure 1).

Since the introduction of TAVI we have seen an increase in SAVR caseload by 25%. Looking at 2006-2007 (2 years preceding the introduction of TAVI) we performed a total of 381 AVR's, in contrast from 2009-2010 we performed 476 operations.

DISCUSSION

The new joint ESC/EACTS guidelines on the management of valvular heart disease based mainly on the results of the PARTNER trials published in 2012, give a Class I B recommendation for the use of TAVI in patients with severe symptomatic AS who are not suitable for aortic valve replacement as assessed by the heart team, and a Class IIa for high-risk patients with severe symptomatic AS who may still be suitable for surgery but in whom TAVI is favoured by the heart team based on the individual risk profile and anatomic suitability.[13]

UK institutions such as the National Institute for Health and Clinical Excellence (NICE) recommend TAVI for patients with AS who are considered to be unsuitable for SAVR as the evidence on the efficacy of TAVI is adequate. For these patients, TAVI may be used with normal arrangements for clinical governance, consent and audit. Details of all patients should be entered into the UK Central Cardiac Audit Database.[14]

The National Health Service clinical commissioning policy recommend that patients should be considered by a multidisciplinary team (including 2 surgeons and 2 interventional cardiologists) with assessment of the balance of the risk/benefit ratio of open heart surgery versus TAVI. The usual "high risk" patient will have a logistic Euroscore of >20 or a Society of Thoracic Surgeons (STS) score of >10.[15] We accept that in this cohort our median logistic Euroscore was 19.5 and by definition 50% of this study group had a logistic Euroscore less than the accepted definition. This suggests that logistic Euroscore alone is not enough when deciding who is suitable for TAVI. For example, our cohort included a young patient with a life expectancy of less than 5 years from metastatic breast cancer. Another 2 patients had liver cirrhosis and varices. One patient had multiple sclerosis and was wheelchair-bound. Intervention may not have been considered in the past but with the advent of TAVI, patients' individual needs are now discussed at heart team meetings.

On reflection, this is a cohort in a centre performing 100 TAVI procedures and 300-400 aortic valve replacements annually. TAVI funding was an initial hurdle which we no longer face. Unfavourable anatomy is also seen less frequently. Anatomy requiring multi-vessel PCI is associated with referral for conventional surgery and it is noted that a high percentage of our high risk patients had concomitant coronary disease. Twenty-three patients in this cohort required CABG x3 for revascularisation with comorbidities such as diabetes. There is an acceptance that even if a patient is high risk, if the long term outlook is better with conventional surgery, then it is the treatment of choice. This demonstrates the need for better scoring systems for this group of patients.

As one of the largest series published on this patient population, our results concur with another UK centre - in

the series from Dimarakis et al, there was also high morbidity with 15% resternotomy rate, 25% new atrial fibrillation and median intensive care stay of 8 days. The survival data is also comparable with 81% at 359 days for Dimarakis' group and 86% at a similar interval for our own.[12] Our resternotomy rate is certainly higher in this SAVR cohort than our unit average of 4.6% for all comers (including CABG). This high morbidity confirms that despite a median logistic Euroscore of less than 20, discussion in a high risk forum was necessary.

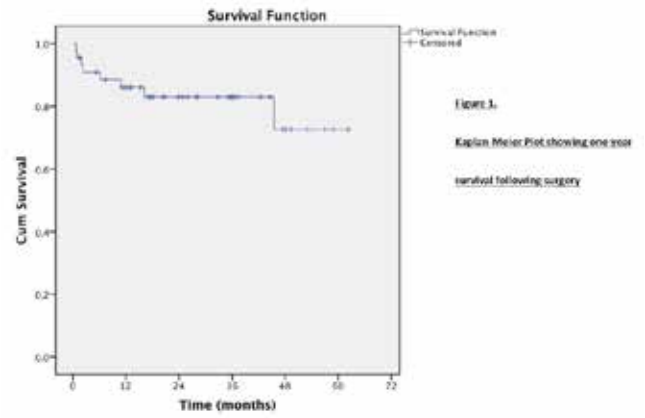

Figure 1.

Kaplan Meier Plot showing one year survival following surgery

The introduction and growth of TAVI has influenced the characteristics and outcomes of patients undergoing aortic valve procedures and in our own centre we have seen an increase SAVR caseload by 24.93%.

It is well established that symptomatic severe AS carries a grave prognosis if treatment is restricted to medical management only.[16] TAVI and SAVR confer better survival than medical management and with over 50% of our cohort being acute inpatients, it is reasonable to offer an intervention strategy for these patients despite the higher morbidity. The existing risk stratification models overestimate mortality and with the rapid evolution of TAVI, it has become pertinent to improve on these with some countries developing their own assessment tools.[17, 18, 19]

It is interesting to note cross over, mainly in one emergent patient. This patient initially was for TAVI procedure but due to an episode of pulmonary oedema and institution of heart failure supportive measures was reallocated to surgical treatment. This demonstrates that inpatients need daily reassessment and discussion with the heart team.

50% of this cohort underwent surgery on an urgent basis. This happened when the physicians at the MDM felt that overall, prompt intervention was appropriate but for various reasons, TAVI was unsuitable.

TAVI has been available in our unit for 5 years with differing valve systems and access routes. We have recently introduced a surgical arm to our TAVI programme to include more patients (although this does negate the benefit of a procedure under local anaesthetic). With the increase in our surgical case load and the availability of intervention to a wider patient population, multidisciplinary team discussion remains essential to ensure that the highest possible proportion of patients receive aortic valve intervention. New technology, such as the use of sutureless aortic valve replacement will add another valuable treatment modality.[20]

Our experience shows that with prudent MDM discussion involving surgeons and interventional cardiology, SAVR and TAVI can be offered to high risk patients with very acceptable mid-term morbidity and mortality. More importantly, it permits more patients to be considered for an increasing range of interventions.

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