The potential impact of percutaneous pulmonary valve stent implantation on right ventricular outflow tract re-intervention

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Abstract

Objective: To assess the impact of a percutaneous technique for pulmonary valve implantation on the conventional surgical valve/conduit approach to right ventricular outflow tract re-intervention. Methods: We have retrospectively reviewed our results following surgical or percutaneous re-intervention to the right ventricular outflow tract in both paediatric and adult groups. Between November 1998 and March 2004, 94 patients underwent surgical re-intervention to the right ventricular outflow tract. Percutaneous pulmonary valve implantation was introduced in October 2002 and 35 procedures were performed to March 2004. The median age was 26 years (6–65 years) in the surgical group and 16 years (9–39 years) in the percutaneous group. Tetralogy of Fallot was the commonest original diagnosis (64.9 and 62.9%, respectively). The predominant indication for re-intervention in the surgical group was pulmonary regurgitation (64.9%) compared to the percutaneous group in which it was homograft/conduit stenosis or a mixed lesion (68.6%). Results: There has been one (1.1%) early death reported in the surgical series and none in the percutaneous group. In the surgical group 9 (9.6%) experienced a procedural complication whilst 3 (8.5%) of those undergoing a percutaneous valve experienced a significant procedural event necessitating urgent surgery. Important early morbidity was 8 (8.5%) in the surgical group and 2 (5.7%) in the percutaneous group. Freedom from re-operation at 1 year was 100% in the surgical group and 86.1% in the percutaneous group due to late restenosis. Median hospital stay in the surgical group was 7 (4–114) days and 2 (2–22) days in the percutaneous group. Conclusions: Preliminary data suggests that percutaneous pulmonary valve implantation provides a promising additional and complementary approach to a successful surgical programme. Both approaches are safe with acceptable levels of morbidity and low mortality. With current technology the aneurysmal outflow tract remains a problem for the percutaneous approach. Follow-up remains too short, at present, to prove longevity of the percutaneous conduit.

Keywords: Congenital heart disease; Re-intervention; Right ventricular outflow tract surgery; Percutaneous pulmonary valve

1. Introduction

The current generation of patients with repaired congenital heart disease are exposed to increasing re-intervention rates, in part reflecting a discernible improvement in their life expectancy. Recognition of the deleterious long-term effects of the residual consequences of early repair has also contributed to a more aggressive surgical strategy.

In particular, those cardiac malformations which demand relief of right ventricular outflow tract (RVOT) obstruction or require restoration of continuity between the right ventricle and the pulmonary arteries are often subject to further revision of the right ventricular outflow tract at a later stage [1]. Tetralogy of Fallot (and its subtypes) remains the commonest defect in this category. Pulmonary regurgitation, patch aneurysm and valvar or conduit stenosis encompass many of the late complications seen following early intra-cardiac repair.

Questions regarding the ability of the right ventricle to recover fully following the chronic and progressive, functional decline resulting from pulmonary incompetence and, to a lesser extent, stenosis have motivated the growing inclinations for earlier re-intervention. Nevertheless, the optimal timing of re-intervention according to symptoms and cardiovascular indices remain unclear. Furthermore, this ‘earlier re-intervention’ strategy has been tempered by the risk of multiple re-operations implicit from the limited longevity of available conduits [2].
Percutaneous pulmonary valve implantation was originally developed by one of the authors, with the first case, a 12-year-old boy, reported in 2000 [3]. Nine further cases were performed in Paris before the programme moved to our centre in October 2002. The prospect of offering an alternative, less invasive approach to deal with right ventricular outflow tract dysfunction is clearly attractive both for the patient, the cardiologist and the surgeon.

To assess the potential impact of this new procedure on conventional surgical treatment we have retrospectively analysed all cases of re-intervention to the right ventricular outflow tract, eligible for consideration for either surgical or interventional approach, performed at our institutions between October 1998 and March 2004.

2. Methods

2.1. Patient selection

In the 5½-year-period between November 1998 and March 2004, 94 surgical re-interventions to the right ventricular outflow tract were performed in 93 patients at Great Ormond Street Hospital for Children, London and The Heart Hospital, London. Percutaneous pulmonary valve implantation was introduced in October 2002 and 35 procedures have been performed in 34 patients to March 2004 at our institutions.

Patients under the age of five or less than 20 kg in weight were not included in this analysis as they would not be eligible for consideration for a percutaneous procedure on account of their size alone.

Indications for intervention were significant pulmonary regurgitation with evidence of increasing right ventricular size and/or impairment in exercise capacity or right ventricular outflow tract obstruction sufficient to cause right ventricular pressure to be at least 2/3 systemic. Selection for percutaneous valve implantation depended on the presence of favourable right ventricular outflow tract morphology, based on echocardiographic and MRI imaging. Potential suitability entailed identification of a safe anchoring site for stented valve implantation. Features of the conduit that were suggestive of this included a short axis diameter less than 22 mm, a gradient of greater than 30 mmHg across it, the presence of a discrete waist for implantation, the presence of calcification and the absence of pulsatility.

In the surgical group there were 63 males (67.0%) and 31 females (33.0%). The median age was 25 years (6–65 years). The commonest diagnosis was tetralogy of Fallot or subtype in 61 cases (64.9%). Patients had a history of a median of two (one-four) previous operations. The predominant lesion requiring intervention was pulmonary regurgitation in 61 cases (64.9%). Forty five patients (47.8%) had measurable tricuspid regurgitation on echocardiography.

In the percutaneous group there were 16 males (45.7%) and 19 females (54.3%). The median age was 16 years (9–38 years). The commonest diagnosis was tetralogy of Fallot or subtype in 22 cases (62.9%). Patients had a history of a median of three (one-five) previous operations. The predominant lesion

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Category</th>
<th>Surgical (n=94)</th>
<th>Percutaneous (n=35)</th>
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<tr>
<td></td>
<td></td>
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<td>n (%)</td>
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<tr>
<td>Gender</td>
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<td>16 (45.7)</td>
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<td>20–26 years</td>
<td>24 (25.5)</td>
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<td></td>
<td>With pulmonary atresia</td>
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<td>With absent pulmonary valve</td>
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TOF, tetralogy of fallot.
requiring intervention was homograft/conduit stenosis with or without pulmonary regurgitation in 24 cases (68.6%). Twenty eight patients (80.0%) had measurable tricuspid regurgitation on echocardiography. Patient characteristics are summarised in Table 1.

2.2. Surgical technique

Following the induction of general anaesthesia with invasive pressure monitoring and the placement of external defibrillator, redo sternotomy was undertaken with an oscillating saw and the lower table of the sternum was opened with Mayo scissors. Adhesions were divided with diathermy. Most cases were performed under routine cardiopulmonary bypass on the beating heart with ascending aortic and bicaval cannulation at 28-32 °C. In case of residual ventricular septal defect or other intra-cardiac lesion requiring attention, aortic cross clamping with cold blood cardioplegia was used.

Midline conduit and haemorrhage during redo-sternotomy warranted femoro-femoral bypass. The latter provides a controlled systemic hypothermic environment (28-32 °C) at low flow for a few minutes so that surgical access into the substernal space can be gained with a wider margin of safety.

Pulmonary homograft insertion was the preferred surgical option. The native main pulmonary artery was dissected out and circumferentially transected close to the ventriculo-arterial junction. The branch pulmonary arteries were sized, and dealt with if necessary. A longitudinal incision was made into the proximal outflow tract. Any hypertrophied muscular trabeculations in the subjunctional region would be divided to create a widely open pathway. In patients with aneurysmal RVOT patch, the akinetic thin area was excised leaving a small fibrous rim at the muscular margin, followed by plication with 4-0 Prolene to reconstruct the outflow tract. This infundibuloplasty aims to improve the distorted right ventricular outflow tract geometry and reduce the cavity size. The homograft was tailored in length to connect with the distal pulmonary artery using 5-0 Prolene. The proximal end of the homograft valve was inserted within the newly created muscular ‘sleeve’ for functional support. Patients with severe tricuspid regurgitation underwent concomitant valve repair. Patients with significant atrial or ventricular arrhythmia received anti-arrhythmic surgery using cryoablation.

2.3. Percutaneous technique

Percutaneous pulmonary valve (PPV) implantation was carried out under general anaesthesia with invasive blood pressure monitoring and biplane angiography. A full aseptic technique to surgical standards was used.

Access was usually obtained via the right femoral vein. Pressure measurements and angiography of the right ventricular outflow tract were performed at the outset to assess the proposed site for PPV implantation and to quantification pulmonary regurgitation. The PPV (Fig. 1), a bovine jugular venous valve stitched into a platinum-iridium stent (Numed, Hopkinton, USA), was prepared in three sequential saline baths (five minutes in each) to wash off the glutaraldehyde in which it was stored. The valve was crimped down over the barrel of a sterile 2 ml syringe and then front-loaded onto the delivery system (Numed, Hopkinton, USA). Further crimping of the stent was performed to mould it around the Balloon in Balloon (BiB) deployment system and it was then carefully retracted within the sheath of the delivery system.

The femoral vein was dilated to 22 French and under X-ray guidance the front loading delivery system was advanced directly into position over an ultra stiff exchange guide wire, which was secured in a distal pulmonary artery. The sheath was retracted from the valved stent and partial deployment was achieved by inflation of the inner balloon. Following final angiographic confirmation of the PPV position the outer balloon was inflated to complete deployment. The maximum balloon size is 22 mm.

Repeat angiography and pressure measurements were made to confirm a positive outcome (Fig. 2). Intravenous broad-spectrum antibiotics and heparin were administered at the time of the procedure.

2.4. Follow-up and data collection

All patients in the surgical group had physician review, 12-lead ECG and transthoracic echocardiography early, at 6 weeks, 6 months and thereafter at yearly appointments according to standard outpatient follow-up practice in our institutions. Additional appointments took place according to individual need.
Patients in the percutaneous group followed a strict follow-up protocol as approved by a local independent ethics review board. This consisted of physician review, 12-lead ECG, postero-anterior and lateral chest X-ray and trans-thoracic echocardiography early, 1 month, 3 months, 6 months, 1 year and thereafter at yearly intervals following valve implantation.

The severity of pulmonary regurgitation was assessed according to the appearance of the regurgitant jet on colour flow Doppler [4]. It was assigned an overall grade between 0 (absent), 1 (trivial), 2 (mild), 3 (moderate), 4 (severe).

2.5. Statistical analysis

Analysis has been performed on the basis of the number of procedures. A patient who had two procedures within the given time frame was counted twice. For categorical variables, the number and percentage of patients were provided. For continuous variables the mean and standard deviation were provided. For age at implant, number of previous operations, length of follow-up and hospital and ITU stay, the median and range were provided. For hospital and ITU stay, the day of intervention was counted as day 1. Early events were defined as less than 30 days and late events as greater than 30 days following intervention. The two-tailed paired t-test has been used to assess echocardiographic data before and after valve implantation. Statistical significance was inferred for a P value <0.05. Actuarial freedom from re-operation and pulmonary regurgitation were obtained using the Kaplan-Meier method.

3. Results

Following the introduction of the percutaneous technique, the total number of RVOT re-interventions being performed has increased (Fig. 3).

3.1. Surgical operative data

Revision of the right ventricular outflow tract was performed 94 times in 93 patients. Five of these operations were of an urgent nature: one for endocarditis, one for critical outflow tract obstruction, one following homograft rupture at attempted balloon valvuloplasty and two due to failed PPV implantation.

The predominant operation performed was homograft insertion in 72 cases (76.6%) with the size of the graft varying from 17 to 26 mm. Additionally, six patients (6.4%) had homograft insertion with goretex tube extension, 12 patients (12.8%) had a heterograft valved conduit placed, two patients (2.1%) received a biological prosthesis together with a outflow tract patch, and two patients (2.1%) had pulmonary valve repair.

![Fig. 2. Percutaneous pulmonary valve stent insertion. Severe pulmonary regurgitation (top) is absent following the deployment of the valve (bottom).](image1)

![Fig. 3. Number of RVOT re-interventions, surgical or percutaneous, performed at Great Ormond Street Hospital for Children, London and the Heart Hospital, London between October 1998 and March 2004.](image2)
Concomitant procedures to the RVOT included resection of hypertrophied muscular trabeculations in 32 patients (34.1%) and resection of a RVOT aneurysm, usually related to a previous outflow tract patch, in 25 patients (26.6%). Additional procedures performed at the time of surgery, included repair of residual ventricular septal defect (eight patients, 8.5%), tricuspid annuloplasty (eight patients, 8.5%) and cryoablation (four patients, 4.3%).

The mean cardiopulmonary bypass time was 98 ± 35 min. Twelve patients required cross-clamping of the aorta for between 7 and 95 min. The median temperature for cooling was 32 °C (range 18–34).

In terms of procedural complications, the right heart structure was entered expectedly or inadvertently in eight cases (8.5%) at the time of re-sternotomy necessitating elective or rapid instigation of femoral-femoral bypass. One patient (1.1%) sustained damage to a coronary artery, which was subsequently repaired.

The median ITU stay was two days (range 1–25) and the median hospital stay was 7 days (range 4–114).

3.2. Percutaneous procedural data

Percutaneous transcatheter valve implantation was attempted 37 times in 34 patients. Of these attempts, successful implantation of the valve was achieved on 35 occasions (94.6%). In the two failed procedures, the valved stent could not be manoeuvred into the outflow tract despite prolonged manipulation. All procedures were elective.

Thirty four implants were performed from a femoral approach, and one implant was performed via the right internal jugular approach. All procedures were performed under general anaesthesia. One patient had a second PPV implanted at a further procedure. The mean procedure time was 111 ± 50 min with a mean fluoroscopy time of 29 ± 20 min.

Following implantation of the PPV, there was a significant reduction in gradient across the right ventricular outflow tract from 37.8 to 27.4 mmHg (p < 0.01). This was associated with a drop in right ventricular systolic pressure from 60.7 to 51.0 mmHg (p < 0.01). There was no change in right ventricular end diastolic pressure. In addition the implantation of a competent valve saw a significant improvement in pulmonary artery diastolic pressure from 9.4 to 12.5 mmHg (p < 0.001) but no change in pulmonary artery systolic pressure.

Four additional procedures were performed at the time of PPV implantation: perimembranous VSD closure, closure of a para-valvular leak of a mechanical aortic valve, distal main PA stenting and second PPV implantation. One additional procedure, distal main PA stenting, was performed at the time of the second PPV implantation.

There were three (8.5%) procedural complications. In one case, instability and proximal dislodgement of the valve at the time of the procedure required urgent surgery and homograft replacement. A second patient developed cardiogenic shock a few hours after valve implantation. Echo demonstrated proximal dislodgement of the valve with obstruction to the RVOT and the patient proceeded to urgent surgery. In the third patient, homograft rupture during valve deployment led to haemothorax and urgent surgery. In this case, however, the valved stent was conserved in position and homograft replacement was not necessary.

The median ITU stay was zero days (range 0–9) and the median hospital stay was two days (range 2–22). The upper ends of these ranges represent the three patients who proceeded to urgent surgical intervention due to procedural complication.

3.3. Follow-up data

The follow up was 100% complete. The median follow-up in the surgical group was 10.0 months (range 0.1–59.5) and in the percutaneous group was 4.0 months (range 0.1–14.3).

3.3.1. Mortality

3.3.1.1. Surgical patients. In the surgical group there was one early death (1.1%) on day nine following operation. The patient suffered a terminal cardiac arrest in the context of severe right heart dysfunction and a moderate pericardial effusion. At post-mortem, there was no concern regarding the surgical repair, but significant cardiomyopathic changes were noted. There were no late deaths.

3.3.1.2. Percutaneous patients. There were no deaths in the percutaneous group.

3.3.2. Morbidity

3.3.2.1. Surgical patients. Early. In the surgical group, eight patients (8.5%) experienced major complications. Two patients had neurological events (one associated with long-term sequelae), two patients required tracheostomy and prolonged ventilatory support, one patient needed a permanent pacemaker for complete heart block, one patient required haemodialysis for acute renal failure and one patient experienced a systemic inflammatory response syndrome prolonging ITU stay.

Resternotomy was required in one patient on the intensive care unit within hours of the initial surgery, following sudden haemodynamic collapse. Partial dehiscence of the distal homograft anastomosis site was identified as the cause.

Thirty two patients (34.0%) experienced one or more moderate complications. There were 15 cases of pleural effusion (two requiring chest drains), four pericardial effusions, two episodes of pericarditis, nine chest infections, five pneumothoraces (one requiring aspiration), eight arrhythmias (five needing DC cardioversion), two vocal cord palsies, one episode of acute psychosis and one patient who required surgical intervention to treat a vascular complication (false aneurysm) of femoral cannulation for bypass.

Late. There were no complications arising after 30 days. There have been no confirmed cases of endocarditis. Homograft function is described later.

3.3.2.2. Percutaneous patients. Early. Two patients (5.7%) in the percutaneous group experienced complications. One patient had a prolonged temperature following valve implantation associated with a single blood culture yielding Candida albicans. This settled with medical management.
One patient developed early in-stent stenosis related to the 'Hammock effect'. This was associated with a design flaw in the PPV, which led to the prolapse of the venous wall into the lumen. The patient underwent a second procedure five days later to place a modified PPV within the first to good effect. Following this case, recognition of the problem led to the addition of extra stitches to the valve leaflets and no further cases have occurred following the change in design.

Late. Six patients (17%) developed RVOT restenosis. Three patients developed in-stent re-stenosis related to the 'Hammock Effect' at late follow-up. One patient underwent surgical explantation, one patient had a second PPV implanted and one patient is awaiting further percutaneous intervention. Three further patients had residual stenosis unrelated to the 'Hammock Effect'; one underwent surgical explantation, one had balloon dilatation of the PPV and the other is awaiting further percutaneous intervention.

There was one case of endocarditis reported occurring at 143 days. The causative organism was staphylococcus aureus. The patient responded to a prolonged course of intra-venous antibiotics and did not require further percutaneous or surgical intervention. One patient was found to have stent fractures at routine follow-up. This was not associated with any clinical sequelae.

3.3.3. Late reoperation
3.3.3.1. Surgical patients. In the surgical group, one patient developed degeneration of their homograft with free pulmonary regurgitation necessitating re-intervention. The patient proceeded to percutaneous valve implantation at 1675 days, however the attempt was unsuccessful complicated by severe distal RVOT obstruction and resulted in urgent surgery, as described earlier. The actuarial freedom from re-operation at 1 year was 100.0% and at 5 years was 95.2%.

3.3.3.2. Percutaneous patients. Two patients underwent late explantation of the PPV at 101 and 373 days. Indications for late re-operation were in-stent stenosis related to the 'Hammock Effect' and external compression of the PPV by the sternum. The actuarial freedom from re-operation at 1 year was 86.1%.

3.3.4. Homograft/percutaneous pulmonary valve function
3.3.4.1. Surgical patients. There was a significant reduction in pulmonary regurgitation from a mean grade of 3.8–1.0 ($p<0.001$) in the early post-operative period. This was sustained at latest follow-up with a mean grade of 1.3 ($p<0.001$). There was a small, but significant, early reduction in velocity across the right ventricular outflow tract from 3.7 to 3.1 m/s ($p<0.001$); however, this was not sustained at latest follow-up, in part due to the impact of the 'Hammock Effect'. At 1 year the actuarial freedom from moderate or severe pulmonary regurgitation was 96.6%. (Fig. 4)

4. Discussion
Currently, no 'ideal' conduit exists for reconstruction of the right ventricular outflow tract. All are susceptible to degeneration and loss of function, according to the conduit, the patient and the circumstance of re-operation [2].

Perhaps surprisingly, the impact of the percutaneous pulmonary valve programme on our institutions has been an overall increase in the numbers of right ventricular outflow tract re-interventions performed. In part, this may reflect external referral practises incumbent on the availability of a new procedure. However, in the context of an expanding adult congenital heart patient population, the availability of a less invasive approach for the management of pulmonary valve dysfunction has highlighted our recent increasing inclination for earlier surgical re-intervention in these patients due to the fact that chronic right ventricular dysfunction may not be recoverable [5].

A direct comparison should not be made between these two groups as the percutaneous approach is not available to all patients with an indication for reintervention to the right ventricular outflow tract and follow up is limited in the group who do receive a valved stent. This is an important limitation to our study. At this stage our observation can only be that a percutaneous approach provides a complementary approach to the existing surgical strategy.

Although the percutaneous group may represent a more severe spectrum of disease (on the basis of median number of previous operations), the lower median age heralds a general tendency to offer re-intervention at an earlier age and we believe this will be mirrored in the surgical population with time.
Additionally, it seems likely that sequential percutaneous pulmonary valve implantation is feasible and theoretically could delay the need for surgery indefinitely, thus overcoming concerns regarding conduit longevity and risks associated with recurrent re-operation. However, only time will corroborate this. It is important to appreciate that the combination of pulmonary valvar competency without significant residual RVOT stenosis is important in terms of sustained right ventricular recovery, which in turn reduces the likelihood of reintervention, either surgical or percutaneous.

Equally important, with current technology, the dilated outflow tract remains unsuitable for a percutaneous mode of pulmonary valve replacement. In the percutaneous group 11.4% had a transannular patch or native outflow tract compared with 67.0% of the surgical group. The calcification and varying degrees of stenosis inferred from a degenerated homograft provide a more suitable environment for secure stent implantation than the often, aneurysmal transannular patch repair. A right ventricular outflow tract diameter of greater than 24 mm currently precludes a percutaneous approach on account of the diameter of bovine jugular vein/valve. Recent development of an infundibular-reducing device is encouraging and may facilitate a percutaneous approach for such patients in the future [6].

Both surgical and percutaneous pulmonary valve replacement have been accomplished with almost no mortality and excellent early survival. In the surgical group, the actuarial freedom from re-operation is broadly consistent with previously reported series [7,8]. In the percutaneous group a somewhat lower, but still acceptable, figure reflects the inevitable 'learning curve' associated with the introduction of a new device and technique.

Surgical morbidity remains significant and unsurprisingly contributes to restrained patient enthusiasm for re-operation. Morbidity in the percutaneous series has proved mainly device or procedure related and can occur late after implantation. Any subsequent high re-intervention rate might render the initial percutaneous procedure less cost effective. With attention to device design and growing experience in terms of patient selection and procedural execution the complication rate should diminish considerably. The potential cost implications associated with a reduced ITU and hospital stay cannot be ignored although should not be the sole driving force behind change.

The early evidence indicates that percutaneous pulmonary valve replacement offers a promising alternative to the conventional surgical strategy. At present, it is not suitable for all patients and does not address the problems of RVOT patch aerysmus or sub-valvar hypertrophied muscle bundles. In addition, surgery would still be required for severe tricuspid regurgitation and intra-operative cryoablation can decrease the incidence of pre-existing atrial or ventricular tachy-arrhythmia [9]. On the other hand, residual ventricular septal defect can be closed by device, and distal pulmonary artery stenosis can be dealt with by catheter intervention. In our opinion, with evolving device design and prospective data collection, including cardiopulmonary exercise testing and magnetic resonance imaging, the answers to questions regarding how and when re-intervention should be performed is beginning to emerge.

Failure to recognise an extensive surgical experience led to misjudgement in the early development of interventional techniques for the treatment of coronary artery disease. With patient preference now firmly tending towards minimally invasive alternatives, it is imperative that we do not repeat the errors of the past. The management of patients with complex congenital heart disease requires a 'lifet ime strategy' with co-operation between the cardiologist and the surgeon. The impact of this innovative technique has uncovered our strong predilection for earlier intervention to protect against possibly irreversible cardiac functional deterioration. To achieve this goal in a longer-lived population, it is clear that the surgeon’s approach to early intra-cardiac repair and subsequent re-operation must lie in optimizing the potential for a future minimally invasive approach.

Acknowledgements

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References

Appendix A. Conference discussion

**Mr J. Pepper** (London, UK): What is the limit to the upper size of graft that you could use from a percutaneous approach? If it is 23 mm, an alternative approach for larger valves might be, like a closed pulmonary valvotomy, to introduce it via the apex of the right ventricle. You would still avoid cardiopulmonary bypass. Of course, it would be an operation but the procedure would be in the hands of the surgeons. What do you think?

**Mr Tsang**: The largest percutaneous device is 22 mm. The MRI imaging we are using at the moment would offer us a lot of objective data how we decide which way we are going, and in the foreseeable future we can undertake a randomized control trial to find out which is really better in the longer term.

Your second point, in the hands of the surgeon. I find that concept rather strange. The patients are not in the hands of anybody. What we try to do is to create the best way forward for these patients when they require reoperations.

**Dr A. Bhan** (New Delhi, India): What is concerning me is if these patients come back and you are to explant these devices, it is so much of metal, is it going to be technically a difficult job? Because redoing a conduit is not such a big affair.

**Mr Tsang**: The answer is no.

**Mr J. Monro** (Southampton, UK): One possible approach is if you have too big an RV outflow tract for your size 22 valve would be to put one in each of the individual pulmonary arteries. Have you been doing that?

**Mr Tsang**: I think that stent valve needs to be anchored. I am not the expert to talk about this. Professor Bonhoeffer would be able to give you the answer. But my feeling is too big an outflow tract would not offer the anchorage to support the stent. That is why a lot of the stent patients, had a previous homograft and with some calcification that provides a very strong platform for the valve to stay very neatly without movement. And your concept of using two stents together, my concern is that one stent would compress the other. However, following on your concept of using two stents is sequential stenting. One stent may last, say, 5 years and another stent can be put inside that pre-existing stent to offer valve competency, but the underlying aetiology would determine whether it would work or not.