

## SCIENTIFIC LETTER

## Amplatzer device closure of atrial septal defects in mature adults: analysis of 76 cases

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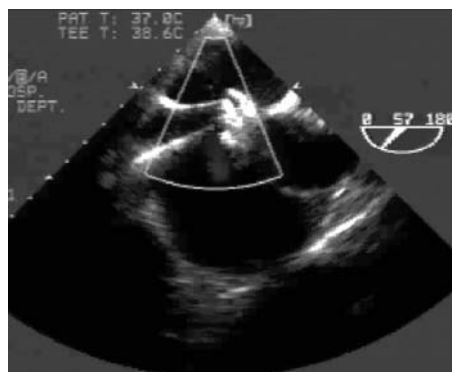
Ostium secundum atrial septal defects (ASDs) have been successfully closed surgically for over 30 years. The concept of percutaneous closure of such defects was proposed in the 1970s. In 1997, the self expanding Amplatzer nitinol prosthesis was first used in animals, with good results. Human studies soon followed and percutaneous closure of atrial septal defects is now standard treatment in the paediatric population. In exclusively adult populations there remains a relative lack of published data and only one series of any size.<sup>1</sup>

## METHODS

Adult patients with symptomatic atrial septal defects underwent transthoracic and transoesophageal echocardiography to assess defect location, size, and number, associated anomalies, and a more detailed assessment of the septal anatomy (particularly if aneurysmal) with respect to the inferior and superior rims. In the last five years, the waist diameter of the largest available device has gradually increased from 34 mm to 40 mm. The largest unstretched defect diameter on colour flow mapping likely to allow accommodation of a device has therefore risen from 24 mm to 30 mm during the same period.

All procedures were done under general anaesthesia with transeoesophageal echocardiography and fluoroscopy. Two sheaths (7 and 11 French) were introduced into the right femoral vein. The pulmonary to systemic shunt (Qp:Qs) was calculated. A multipurpose catheter was used to cross the ASD and was positioned in the left upper pulmonary vein. Intravenous heparin 5000 iu was given. The defect was sized with a 24 mm or 34 mm highly compliant sizing balloon. An Amplatzer ASD closure device corresponding to the stretched ASD diameter was then taken and de-aired under warm saline. An 8, 10, or 12 French delivery sheath was introduced according to defect size. The ASD closure device was withdrawn into the short connector sheath under saline and was introduced into the delivery sheath under a saline seal. In the left anterior oblique (LAO) 40° projection, the delivery cable was advanced into the left atrium until the left atrial disc emerged, spontaneously reshaping itself in the left atrium. The delivery system was withdrawn until the left atrial disc was flattened under tension on the left atrial side of the defect. The sheath alone was then withdrawn further over the delivery cable to allow the right atrial disc to emerge and reshape itself on the right atrial side of the defect (fig 1). The stability of the device was then vigorously tested. Once stability was assured, the delivery cable was unscrewed from the device and removed from the femoral sheath.

Following tracheal extubation, venous sheaths were removed after two hours. Patients were fully mobile four hours post-procedure. Repeat echocardiography was done the next morning to ensure good seating of the device and good reshaping where necessary. Patients were discharged on either warfarin, aspirin, or clopidogrel, depending on the



**Figure 1** Transoesophageal echocardiogram showing the Amplatzer closure device positioned across the defect. The delivery cable is still attached, tending to tilt the device caudally.

clinical indication for shunt closure and the presence or absence of atrial fibrillation.

## RESULTS

During the period under review, 76 patients aged 51 (18) years (range 16–80 years) were assessed for atrial septal defect closure; 51 (67%) were female. Seven patients had associated congenital heart defects: mitral valve prolapse in four, previous patent ductus arteriosus ligation in two and pulmonary stenosis in one. Patient's symptoms were graded as New York Heart Association (NYHA) functional class I (n = 9), II (n = 54), and NYHA III (n = 13). Sixty six (86%) were in sinus rhythm, 19 of whom had had documented episodes of paroxysmal atrial fibrillation.

At echocardiography, the ASD measured 17.1 (5.6) mm. In five patients, more than one defect was identified (this subsequently precluded defect closure in two). At catheterisation, the Qp:Qs ratio was 2.1 (0.6): 1.0. Pulmonary artery pressure was 31 (11) mm Hg systolic, 19 (5) mm Hg mean. Nine patients had significant associated left ventricular impairment on echocardiography. Average stretched ASD measured 22.2 (7.6) mm, and the average device size was 23 (7) mm (range 8–38 mm).

Sixty two (82%) of the 76 patients underwent successful percutaneous closure of the ASD. Of the other 14, in nine patients the defect was too large for the largest available device at the time; in two patients there were separate defects which would have required implantation of two devices, and in one patient an additional sinus venosus defect was identified. Defect closure was therefore attempted in 64

**Abbreviations:** ASD, atrial septal defect; LAO, left anterior oblique; NYHA, New York Heart Association;  $\dot{V}O_2$ max, maximum oxygen consumption

patients, and was successful in 62 of these (97%). Technical failure occurred in two cases, in both of which a large device could not be seated across a defect > 28 mm without partially overhanging the atrial septum. These devices were therefore not deployed and were resheathed without incident.

Procedure duration was 64 (25) minutes, with a screening time of 12 (9) minutes and a diameter of 42 (18) CGy. Immediately after device deployment, there was a small central jet of residual flow in five patients in keeping with device design.

Of the 62 patients who underwent successful ASD closure, 59 were discharged the next day. Three patients remained a further night, two for social reasons and one following a pericardial effusion (see below). Patients were discharged on either aspirin (n = 27), warfarin (n = 22), aspirin and warfarin (n = 10), clopidogrel and warfarin (n = 2), or clopidogrel (n = 1).

Complications were infrequent. One patient developed a pericardial effusion noted on echocardiography shortly after successful device implantation; 150 ml of oxygenated blood was aspirated by immediate pericardiocentesis and there were no haemodynamic sequelae. The assumption was that there had been left atrial wall damage at the time of device implantation. The blood did not re-accumulate and no further action was required. This patient was discharged on the second post-procedural day and remains well. One patient developed transient inferior ST segment elevation during seating of the device in the defect. This has been noted before with a variety of interventional procedures<sup>2</sup> and relates either to a vagally mediated phenomenon or to preferential passage of small air emboli into the right coronary sinus when the patient is in the supine position. The patient was treated with intravenous atropine with rapid resolution of the ECG changes.

During our early experience, two patients developed sizeable haematomas post-procedure, related in both cases to removal of the femoral sheaths before tracheal extubation.

Follow up was for 20.5 (15) months. Patients were seen post-implant in the outpatients clinic. Some were discharged at this stage, while others continue under review. Information was therefore obtained both from medical records and by telephone review. Nine patients were lost to follow up; for the remaining 53 patients, information was gathered regarding current NYHA status, minor and major complications, and overall clinical condition and satisfaction. NYHA status improved in 29 patients, remained the same in 21 and deteriorated in three. Patients were found to be NYHA I (26); II (18); III (8); and IV (1).

Major complications during follow up occurred in two patients. One patient aged 80 years had two transient ischaemic attacks in quick succession three months after the device was implanted. Transoesophageal echocardiography demonstrated a suspicion of thrombus formation on the left atrial disc. No cerebral abnormality was seen on computed tomographic scan. Aspirin was restarted (there were relative contraindications to warfarin) and the patient has had no recurrence of symptoms in the three years since. One patient had a large gastrointestinal haemorrhage thought likely to be caused by aspirin treatment. Minor complications included eight patients (15%) with significant

bruising during the first week post-procedure and three patients with atypical chest pain.

## DISCUSSION

Percutaneous closure is now accepted treatment for ostium secundum ASDs. Publications however remain modest on this topic, particularly in adults. Our implantation and follow up data suggest that the technique is safe and effective in the short to medium term. Longer term data are awaited with interest.

Chessa and colleagues recently published a large series on young adults.<sup>1</sup> This involved 417 patients (258 of whom had Amplatzer closure) whose average age was 26 years. Our group, with an average age of 51, is the oldest series thus far reported. The study reported a 9% overall complication rate, with device embolisation requiring surgical retrieval in 2%. There were two late complications: one late device embolisation to the leg and one sudden death one and a half years post-procedure, unfortunately without postmortem data. More recently, there have also been reports of thrombus immediately after implant and late aortic erosion, which are of concern.

Post-procedure anticoagulation requirement is currently unclear. Most operators use aspirin 300 mg daily for three months from the time of device implant. Pre-treatment with aspirin may also be useful, as would a longer duration of treatment as the device endothelialises.

One frequent dilemma is whether or not to close a defect in patients with few or no symptoms with a Qp:Qs of approximately 2:1. Brochu and colleagues recently looked at a cohort of such patients.<sup>3</sup> Maximum oxygen consumption ( $\dot{V}O_2\text{max}$ ) increased from 23 ml/kg/min pre-closure to 27 ml/kg/min six months later. Interestingly, the degree of improvement in  $\dot{V}O_2\text{max}$  was just as great in patients with Qp:Qs in the range 1.2 to 2.0:1.0, and in patients over the age of 40.

The Amplatzer septal defect occluder can be safely and successfully used to close ostium secundum ASDs in adults. Morbidity is low and discharge within 24 hours is routine. Long term safety and efficacy data are awaited.

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