Cardiol Young 2001; 11: 521–525

ISSN 1047-9511

Original Article

Influence of the introduction of Amplatzer device on the interventional closure of defects within the oval fossa in children

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Abstract Since June 1998, we have used an Amplatzer device whenever considered appropriate in patients with isolated defects within the oval fossa. The aim of this study was to define the total cohort of patients with isolated defects in the oval fossa seen at this hospital, so as to assess the impact of this policy on contemporary management. In the two-year period commencing 1st June 1998, 116 patients older than 6 months were seen with an isolated septal defect within the oval fossa. Mean age at closure or last review was 5.8 years, with a range from 0.5 to 20 years. In total, 42 (36%) patients were assigned to surgical closure, 25 (22%) to closure using an Amplatzer device, and 49 (42%) remained under clinical follow up. Direct referral for surgical closure occurred in 24 (21%) patients, in whom transcatheter closure was considered not appropriate after transthoracic echocardiography. Transoesophageal echocardiography was performed in 45 (39%) patients to assess suitability for closure using the Amplatzer device. Of these, 20 (44% of the group undergoing transoesophageal echocardiography) were considered unsuitable for closure in this fashion. Of these, 8 were referred for surgery and 2 with small defects were considered not to require closure. Patients undergoing closure with the device were older than the group referred for surgical closure, having a median age of 7.8 versus 3.6 years, and stayed for a shorter period in hospital. Those closed using the device stayed for 2 days, as opposed to a median of 5 days, with a range from 4 to 10 days for those undergoing surgical closure. Closure was complete as assessed by echocardiography after follow up of 1–3 months in both groups. There were no recognised complications related to insertion of the device, whereas transient postoperative morbidity occurred in 38% of those closed surgically. Insertion of an Amplatzer device was considered to be appropriate in 37% of patients older than 6 months requiring closure of an atrial septal defect in the oval fossa.

Keywords: Secundum atrial septal defect; interventional catheterisation; surgery

PERCUTANEOUS CLOSURE OF DEFECTS IN THE oval fossa has gained increasing acceptance since introduction of the latest generation of devices. The Amplatzer device is now most frequently used in contemporary clinical practice, and short-term results have been good.[1–5] Studies to date have reported the results of the procedures performed during implantation rather than describing protocols based on the intention to treat, although there has been one report comparing results and complications after surgical closure as opposed to insertion of an Amplatzer device.[6]

Previous studies have included many, or predominantly, adults. Data are lacking regarding the proportion of children requiring closure who are suitable for insertion of an Amplatzer device. The number of patients investigated by transoesophageal echocardiography, cardiac catheterisation, or both, which are

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Research at the Institute of Child Health and Great Ormond Street Hospital for Children NHS Trust benefits from R&D funding received from the NHS Executive.

Accepted for publication 6 April 2001

required to establish the suitability of patients for insertion of an Amplatzer device, in comparison to the number undergoing insertion, is unclear. In addition, diagnosis of a defect within the oval fossa during infancy and early childhood is much more common in the present era than hitherto because of the sensitivity of modern echocardiography in detecting shunting at atrial level. We wished to estimate what proportion of children diagnosed to have a septal defect within the oval fossa required closure of the defect.

Patients

Retrospective review of hospital records identified 116 patients older than 6 months with an isolated defect within the oval fossa seen in the 2-year period commencing 1st June 1998, this being the date of insertion of our first Amplatzer device. Inclusion required identification of left-to-right flow within the oval fossa on transthoracic echocardiography with no other cardiac abnormalities. Infants aged less than 6 months were excluded in order to avoid confusion with patency of the oval foramen. Data were collected at the time of closure, or at latest review in patients not undergoing intervention. Retrospective comparison was made between the groups undergoing surgical closure as opposed to insertion of an Amplatzer device.

Results

The mean age of the entire cohort of 116 patients was 5.8 years, with a range from 0.5 to 20 years. The sequence of clinical management for the entire group is shown diagramatically in Figure 1.

When closure of a defect within the oval fossa was thought to be indicated clinically, assessment was made of its likely stretched diameter, taking into account the apparent rigidity or otherwise of the margins of the defect on transthoracic echocardiography in order to estimate the size of Amplatzer device which would be likely required to effect closure. Account was taken of the need for the margins of the atrial septal defect to accommodate the 6–7mm circumferential rim of the left atrial disc, and the 5mm right atrial disc. If it was thought by consensus at Unit Cardiology Conferences that an Amplatzer device could not be safely deployed without adequate separation of the device from right pulmonary veins, caval veins and mitral valve in particular, then direct surgical referral was recommended. If it was thought that closure might be appropriate using the device, transoesophageal echocardiography was recommended for further assessment.

Direct referral for surgical closure occurred in 24 patients. In 21 of these, this was because transthoracic echocardiographic assessment of the size of the defect in relation to somatic size, its location in relation to adjacent structures, or the presence of multiple defects, suggested surgical closure to be the preferred option. In three cases, parental preference was for surgical closure in the presence of defects which might otherwise have been suitable for closure using an Amplatzer device.

Transoesophageal echocardiography was performed in 45 patients in order to assess suitability for closure. Ten of these were considered unsuitable for closure using a device for the same reasons as noted above, and were referred for surgery. In two patients, the defects were sufficiently small that closure was not required, and a further 5 patients

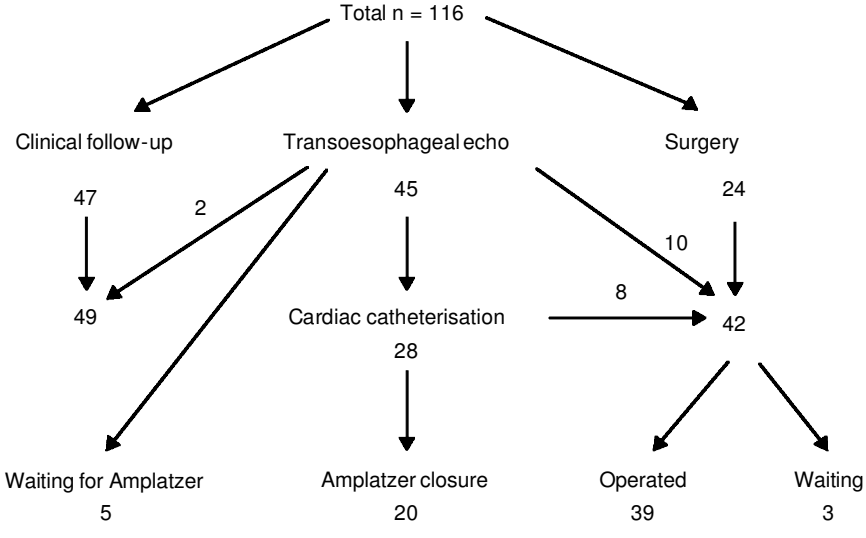

Figure 1.
Management of patients with defects in the oval fossa.

https://doi.org/10.1017/S1047951101000750 Published online by Cambridge University Press

had defects potentially suitable for closure, but it was thought advisable to defer this to allow somatic growth to occur before implantation of the device. The remaining 28 patients underwent cardiac catheterisation with a view to insertion of the device. Transcatheter closure was performed in 20 of these. The remaining 8 were referred for surgical closure. This was because the stretched dimensions of the defect were considered too large in relation to somatic size in 7 patients, and because previously unsuspected intrahepatic interruption of the inferior caval vein prevented deployment of the device in the other.

Table 1 gives clinical details of the groups undergoing surgical as opposed to interventional closure. The device was inserted using standard techniques with simultaneous transoesophageal echocardiography and single plane fluoroscopy. Successful delivery of a single device was achieved in all cases. There was a solitary atrial communication in 19 patients, and only 1 patient had a fenestrated defect. The sizes employed ranged from 8 to 26 mm, with a median of 17 mm. There were no vascular or other complications recognised. All patients were discharged from hospital on the day following the procedure. There was evidence of residual shunting on transthoracic echocardiography in 4 (25%) patients at 1 day after deployment, but no residual shunt was detected at follow up 1 to 3 months later. Aspirin was prescribed for 6 months, at an antiplatelet dosage.

The group undergoing surgical closure were younger and smaller than those in whom it proved possible to insert a device. The median weight at surgery was 14.3 kg, only a little heavier than the smallest patient undergoing closure with a device. Surgery was performed before the age of 2 years in 7 patients, all with large left-to-right shunts and poor weight gain. Fenestrated atrial defects were confirmed in 6 patients. The defects were closed by direct suture in 16 patients, and by insertion of a pericardial or Goretex patch in 23. Transient postoperative morbidity was encountered in 15 of the 39 patients (38%). This consisted of pericardial effusion in 7, right pleural effusion in one, retrosternal bleeding in 2, one of whom required reoperation, prolonged pyrexia in 2, and pneumonia and pneumothorax, supraventricular tachycardia requiring intravenous adenosine for termination, and sternal instability requiring reoperation each in one further patient. Median hospital stay was 5 days, with a range from 3 to 10 days. There was residual shunting on transthoracic echocardiography 1–2 days postoperatively in 8 (21%), but this had resolved at reassessment 1–3 months later.

Table 1. Clinical details of patients undergoing closure of a defect within the oval fossa.

	Amplatzer (n = 20)	**Surgery (n = 39)**
Age (years)	7.8 (3.3–20)	3.6 (0.5–14.5)*
Weight (kg)	20.7 (11.5–77.4)	14.3 (5.2–46.9)*
Gender f : m	11 : 9	20 : 19
Size of defect (mm)		
TOE	14 (8–25)	
Stretched	16 (8–27)	
Size of device (mm)	17 (8–26)	
Fluoroscopy (min)	19 (8–47)	
Cross clamp (min)		13 (4–28)
Bypass time (min)		31 (19–75)
Hospital stay (days)	2	5 (3–10)

*$p < 0.01$, Numeric data expressed as median (range)

The remaining 47 patients remain under clinical follow up, having neither undergone closure nor investigation by transoesophageal echocardiography during the period of observation. The ages of the patients in this group cover a wide range from 0.5 to 15.8 years, with 29 aged less than 3 years. The dimension of the defect as measured on transthoracic echocardiography ranged from 4 to 20 mm. Allocation to this group was at the discretion of the Consultant Cardiologist, who did not consider that closure was (yet) indicated. In 7 of these patients, the Consultant Cardiologist had indicated that closure would be advisable after further somatic growth, but there were no stated plans to consider closure in the remainder.

Discussion

The natural history of atrial septal defects within the oval fossa is poorly defined. Attrition rates calculated using data from 121 reported necropsies, and 167 patients followed clinically, demonstrated high rates of mortality in middle adult life.[7] This has led to consensus that an isolated defect with left-to-right shunting sufficient to cause right ventricular enlargement justifies closure in childhood on prognostic grounds. Surgical closure is safe and effective, with virtual absence of mortality, but perhaps greater morbidity than is sometimes supposed.[6,8] Any catheter interventional procedure must be compared to the surgical alternative, and the efficacy of surgery has meant that transcatheter closure of defects within the oval fossa has gained wide acceptance only with the development of the latest generation of devices. It should be remembered that improvements in the design of occlusive devices have been accompanied by progress in surgical techniques. The diminishing size of surgical scars, and reduction in postoperative hospital stay, are of particular relevance in the comparison of techniques used for closure.

At first sight, our data seem to contradict those contained in a previous report detailing a consecutive series of patients undergoing closure in whom

https://doi.org/10.1017/S1047951101000750 Published online by Cambridge University Press

surgical closure was performed in patients older than those in whom a device was inserted.[6] That study from Berlin, however, described a series of patients who were much older than the subjects in our cohort. The median age at surgery was 20 years, whereas it was 12 years for patients undergoing closure using an Amplatzer device. It is also notable that in a subsequent publication detailing further experience at the same institution, the median age of patients treated with an Amplatzer device was as high as 31 years.[4] The bulk of the Amplatzer device has made us hesitate to deploy it in small hearts. In practice, the smallest patient in whom we used the Amplatzer device weighed 11.5 kgs. There were, however, also similarities between our experience and that of Berger and colleagues.[6] In their report, half of all consecutive patients undergoing closure were suitable for insertion of an Amplatzer device. Of patients undergoing cardiac catheterisation with a view to deployment of a device, 44% were considered unsuitable, and were referred for surgical closure. Blood products were not required in any patients undergoing closure with a device, which was also our experience, and there were no vascular complications, with the exception of a single patient, in whom the device embolised to the left ventricle. In this patient, surgical removal from the femoral artery was required after catheter retrieval from the heart.[6] The proportion of children deemed suitable for closure using the Amplatzer device in our series (37%) was a little less than we had forecast at the outset, but probably represents a reasonable baseline from an unselected series of children. Selection criterions were deliberately conservative so, for example, a device was inserted in only one patient with a fenestrated defect. This relatively rigid policy for selection probably also contributed to us achieving complete occlusion in all our patients. It seems quite likely that the indications for closure using an Amplatzer device will be slightly more liberal in the future with the benefit of experience gained to date. While insertion in patients aged less than 2 years may be technically feasible, this approach also seems to be associated with greater risk, even in experienced hands.[9] Thus, it would still seem appropriate to offer surgical closure to most young children in whom early closure is indicated when weighing less than about 12 kgs, who are symptomatic, or who have important volume overload of the right heart.[10]

Over one third of the patients in our series with the clinical and echocardiographic diagnosis of isolated defect in the oval fossa did not undergo closure during the period of observation. In the pre echocardiography era, it was argued that typical physical signs of such defects were sufficient to justify surgical closure on the basis that these patients would have merited inclusion in Campbell's natural history study.[7] The same cannot be said in the present era because of the ability to accurately diagnose smaller atrial septal defects with relatively modest left-to-right shunting. The severity of haemodynamic disturbance required to justify closure remains uncertain. In terms of risk benefit analysis, if the early encouraging results with regards to closure using an Amplatzer device are sustained with medium term follow up, it is likely that the threshold for intervention in patients with anatomically suitable defects will gradually diminish. Many of the patients with a borderline haemodynamic indication for closure will have defects which are anatomically suitable for closure using the device, being relatively small holes in reasonably large hearts. It is important to consider that the impedance to left ventricular filling increases with age during childhood, so that left-to-right shunting at atrial level may increase progressively. Hence, it would seem advisable to maintain occasional follow up in children with relatively modest left-to-right shunting which is thought not to justify closure of the defect in order to assess this possibility. The risk benefit assessment of closure in such patients needs to be updated periodically.

If the Amplatzer device is to be utilised to maximum advantage, it may be appropriate to defer closure of defects in patients aged less than 2 years with moderate left-to-right shunting in the absence of symptoms or impaired growth.[9,10] Such a policy contributes in part to the relatively large number of patients who remained in the clinical follow-up group during the observation period of this study. The logic was that, even if the size of the defect relative to the rest of the atrial septum did not become smaller with growth, the margins around the defect would be likely to become more extensive, and the atriums larger. It is likely that a complication during deployment, such as embolisation of the device, can be more easily resolved without permanent adverse sequels in a larger heart.

It would be desirable to minimise the number of transoesophageal echocardiography studies and cardiac catheterisation procedures undertaken in children who prove ultimately to be not suitable for insertion of an Amplatzer device. Subcostal echocardiographic windows are usually sufficiently good in small children that transthoracic echocardiography in a cooperative subject should be sufficient to identify most patients who are unsuitable for closure. Transoesophageal echocardiography, nonetheless, will inevitably be required in some subjects in whom the suitability for occlusion is uncertain, and biplane or multi plane imaging assist the delineation of proximity of the edges of the defect to the adjacent caval vein in particular.

https://doi.org/10.1017/S1047951101000750 Published online by Cambridge University Press

In summary, just over one-third of an unselected series of infants and children requiring closure of an isolated defect within the oval fossa were considered suitable for insertion of an Amplatzer device. Closure was complete and uncomplicated in this group, and compared favourably with surgery. Nevertheless, the patients referred for surgery were younger and smaller, with haemodynamically more important lesions, and it seems likely that surgical closure will remain the intervention of choice in many of this group for the foreseeable future.

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