*Cardiol Young 2002; 12: 352–356*

ISSN 1047-9511

*Original Article*

# Transcatheter closure of atrial septal defects in the oval fossa: is the method applicable in small children?

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**Abstract** We report our experience from 1996 through 1999, representing our initial experience with use of the Amplatzer device to close atrial septal defects. Of 46 patients taken to the catheter laboratory with the intention to close the defect, the device was permanently implanted in 40 (87%). They were aged between 1.4 and 71.8 years, with weights ranging from 7.8 to 90 kg. Both age and weight distributed into two peaks, demonstrating two different populations. The size of the devices, taking the biggest device if two were inserted, was between 9 and 30 mm. We underwent a short learning curve, but the time required for fluoroscopy, or the number of difficulties experienced, showed no connection with the size or age of the patient, nor the size of the defect itself. A suspicion that young age and small size would increase the risk and difficulties, and result in more interrupted procedures, could not be substantiated. In children no interruption was procedural. Our early experience, therefore, demonstrates that an experienced interventional team can use the Amplatzer occluder successfully to close atrial septal defects in patients of all ages and sizes, at least from 7.8 kg and up.

Keywords: Interventional catheterisation; secundum atrial septal defects; paediatrics; Amplatzer occluder

In selected cases, transcatheter closure of atrial septal defects in the oval fossa has now achieved general acceptance, with its efficacy and low risk being well documented.[1–4] Some, however, have pointed to the possibility of increased difficulties in smaller children,[5] while others have rather reluctantly accessed the area,[6] preferring to wait for the patient to grow. We started our implantations in humans in December, 1996.[7] We report here our experience over the first three years, until December 1999, providing a balance to the previously published data.

## Population studied

Our cohort comprises the first 40 patients undergoing interventional closure of an atrial septal defect in the oval fossa during the three years extending from December, 1996, to December, 1999. We selected this period because, over this time, the procedure was performed mainly by a single team, which had the same principal operator throughout. At first, we treated children only, and our first adult patient was the twentieth in the series. Following the first implantation in an adult, the two groups were equal in number. As to be expected, 29 of the 40 were female. The age of the patients ranged from 1.4 to 71.8 years, their weights varying from 7.8 to 90 kg (Table 1). Of the patients, three had a second significant defect outside the reach of the rim of the first device. A second device was implanted in these patients. In addition to these 40 patients, six further patients were taken to the catheterisation laboratory with the intention to treat. In three of them, no implantation was attempted. In another three patients, the attempted implantations did not succeed. These 6 patients will be reported separately. Two of the six failures were in children aged 15 years or less. Table 2 shows the patients grouped according to body weight, demonstrating that 17 of the patients (42.5%) had a body weight of 15 kg or less.

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Accepted for publication 22 April 2002

Table 1. The age in years (range, median and mean) in groups of 10 consecutive patients who had their atrial septal defect closed with an Amplatzer device. After the initial 20 patients there were equal numbers of adults aged beyond 16 years and children treated.

| Patient numbers | Children/adult ratio | Age range (years) | Median age (years) | Mean age (years) | Mean fluoroscopy time (min) | |
|---|---|---|---|---|---|---|
| | | | | | Children | Adults |
| 1–10 | 10/0 | 1.42–10.25 | 2.4 | 3.8 | 13.9 | – |
| 11–20 | 9/1 | 1.25–57.6 | 3.83 | 9.2 | 16.8 | 33.5 |
| 21–30 | 5/5 | 1.8–71.8 | 15.4 | 29.6 | 11.3 | 13.0 |
| 31–40 | 5/5 | 1.5–69.0 | 6.5 | 27.9 | 17.4 | 22.1 |

Table 2. The body weight of the treated patients (n = 40).

| Weight (kg) | Number |
|---|---|
| 7.8–9 | 3 |
| 10–12 | 7 |
| 13–15 | 7 |
| 16–20 | 6 |
| 21–30 | 4 |
| 31–50 | 2 |
| 51–70 | 7 |
| 71–90 | 4 |

## Methods

*Selection of patients*

It is the policy in our institution to treat a patient with an atrial septal defect electively, as soon as the diagnosis has been made. We have seen no advantage in postponing closure. Our criterion for recommending closure of an uncomplicated atrial septal defect is that there must be some indication of volume load, like increased size of the right-sided chambers or increased velocity of the blood stream, paradoxical septal movement, or signs in the electrocardiogram or chest X-ray. Only then do we assess if the transcatheter method for closure should be offered as an alternative to surgical treatment. This differentiation is made on the base of a detailed echocardiographic study of the walls surrounding the defect, establishing the distances to all relevant structures, and measuring the length of the septum relative to the probable size of the device. In children, we make these measurements using the transthoracic approach, transoesophageal echo being applied from the age of 14 to 16 years. Except for one parental couple, all accepted the transcatheter method when offered. During this period, the number of patients with such atrial septal defects undergoing surgical closure or treated by insertion of an Amplatzer occluder were almost equal.

We reviewed the records of all patients taken to the catheterisation laboratory with the intention to treat. We collected relevant data on the size of the patient and the defect, the time required for fluoroscopy, and the number of complications. The period of fluoroscopy was used as a measure of the ease of implantation, since all procedures had the same principal operator. We also assessed whether the reason to interrupt a procedure could be linked to the weight of the patient or the size of the defect, and if complications occurred more frequently in the smaller children. We searched the procedures with the longer fluoroscopy times for possible common denominators. In addition, we judged if the period of fluoroscopy identified a learning curve.

## Results

The main finding was that neither the size of the patient nor the size of the atrial septal defect had any consistent influence on the time required for fluoroscopy. The mean period of fluoroscopy was 16.1 min, the median being 14.2 min. The length of fluoroscopy in our consecutive series (Fig. 1) reveals a very short learning curve of 2 patients, and occasional later peaks of fluoroscopic screening above 20 min in 6 further patients. In these, three needed a second device because of an additional defect not closed with the first device. The longest fluoroscopic period, at 53.5 min, was in one of them. This girl, aged 6½ years and weighing 21.4 kg, needed two devices. The radioopaque marker on the delivery sheath disconnected and embolised during the implantation of the second device. Retrieval attempts were carried out. The peak in the 14th patient, representing a fluoroscopic period of 32.6 min, was encountered in a girl aged 2.3 years, weighing 11 kg, with a defect sized at 16 mm. The long fluoroscopy was caused by a technical problem with the device, the right-sided disc failing to flatten properly and remaining round. The problem was only solved with replacement of the device. In the 27th patient, a man of 71 years and 78 kg, the defect was sized with an old fashioned balloon to 18 mm. At implantation, it was clear that the device was undersized, and the defect had to be resized. Thereafter, a device of 24 mm was easily

https://doi.org/10.1017/S1047951100012956 Published online by Cambridge University Press

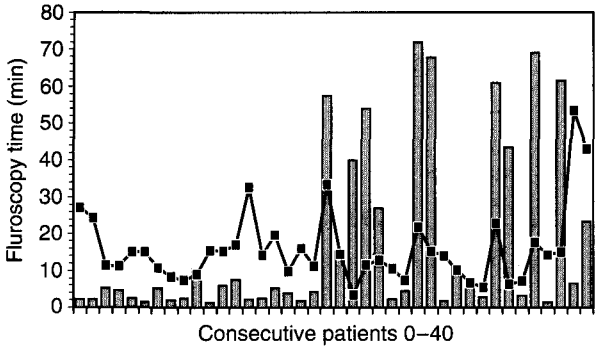


Figure 1.
*Age of the first consecutive 40 patients (■) and fluoroscopic time in minutes (-■-) used to close the atrial septal defect with Amplatzer plugs.*

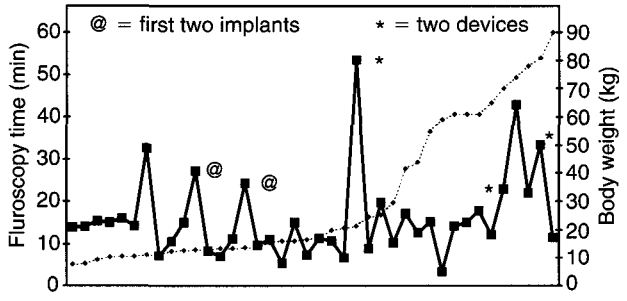


Figure 2.
*Relationship between fluoroscopic time in minutes (-■-) and body weight in kilograms (--■--) in 40 patients treated for atrial septal defect in the oval fossa. The figure is arranged with individual fluoroscopic time according to increasing weight.*

inserted. Finally, our 40th patient was an adult with a defect measuring 30 mm, and we experienced difficulties adjusting the device properly into it.

When examined by linear regression, we found no significant relationship between bodyweight and fluoroscopy time (Fig. 2, p = 0.290). Patients with a bodyweight below 25 kg, with four exceptions, all had fluoroscopic times below 20 min.

Similarly, we found no correlation between the size of the device and period of fluoroscopy (Fig. 3). Although there may be an optical impression that the longer fluoroscopic times are found in the larger patients, this is not statistically significant, linear regression revealing a p value of 0.251.

The most important complication of the procedure was the embolised marker. It embolised to the right middle cerebral artery, from where it could not be retrieved, but was turned so that the ring aligned to the circumference of the artery. No sequels have occurred. Early in our series, 3 patients had minor and transient elevations of the ST segments after introduction of the delivery sheath, most likely

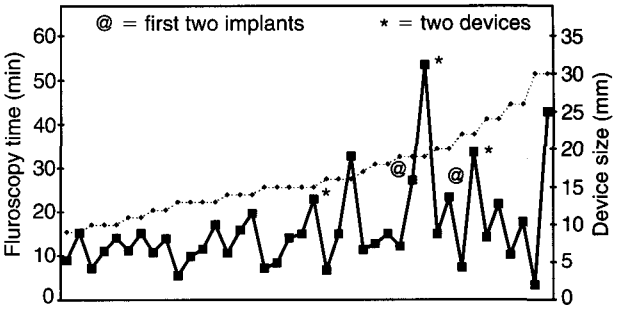


Figure 3.
*Relationship between fluoroscopic time in minutes (-■-) and size in millimetres of the device implanted (--■--) in 40 patients treated for atrial septal defect in the oval fossa. The figure is arranged according to increasing defect size. In cases with two devices implanted, the size of the biggest device is shown. Note the different scales for fluoroscopy (left) and size of the device (right).*

because of air embolism. The formation of a thrombus on the left-sided disc was observed by echo during implantation in one patient, but it resolved immediately after giving additional heparin.

In 6 patients (13%), implantation was either not attempted or was unsuccessful, with three instances each. No attempt was made in a girl aged 1 year and 4 months in whom one anomalously connected right-sided pulmonary vein had not been discovered prior to angiocardiography. In a 61-year-old woman, we measured the defect at 38 mm, and a device of this size was not available at that time. In a 2-year-old girl, azygos continuation of the inferior caval vein prohibited access to the defect. We interrupted the attempted closure in two women aged 65 and 35 years, respectively, failing to seat a device of 30 mm in one and of 34 mm in the other. In the final patient, a 32-year-old woman, the device turned around in the septum after having been released, resulting in unrestricted flow on both sides, fortunately without embolising. The screw of the device was caught with a snare and the device was removed.

## Discussion

Increased numbers of complications, and a reduced rate of success, have been reported in smaller patients undergoing attempted transcatheter closure of atrial septal defects using the Amplatzer® device.[5] The exact weight of the patients, however, is not given. In contrast to our series, that cohort included two patients in their first year of life. The procedures were not interrupted in these patients, however, but in the oldest one and in another patient just over one-year-old. We interrupted two procedures in children, both because of anatomical reasons not detected

https://doi.org/10.1017/S1047951100012956 Published online by Cambridge University Press

prior to the catheterisation, azygos continuation of the inferior caval vein in one, and an anomalously connected pulmonary vein in the other. We did not experience misplacement of the device in small children as reported by the group from Berlin,[5] but we had to retrieve one device in an adult, where we had implanted it between two strings of an open fibrous network rather than into the defect itself. In our experience, there were no greater problems in judging the correct positioning of the device prior to release in children as compared to the adults. We strongly agree with the statement that transoesophageal examination is the echocardiographic method of choice,[5] and we consider echo to represent a very important part of the implantation procedure.

The report from Rastegari and colleagues suggested a reluctance to use catheter techniques to close atrial septal defects in smaller patients.[6] Hence, in their series of 28 patients, implantation was achieved in only 20 (71%), partly because, for unexplained reasons, it was thought advisable to defer closure to allow growth. Based on our experience, we cannot support their suspicion of increased difficulty in smaller patients. Others have also failed to encounter such problems.[2,4]

If small size, or low age, of the patients would complicate the procedure, the fluoroscopic time would increase if the circumstances otherwise were constant. We chose the fluoroscopic time as a parameter, therefore, because it probably is the only measurable variable likely to reflect the ease or difficulty of the procedure, provided that the setting and personnel are constant. In our series, prolongation of the fluoroscopy time beyond 20 min in children represented either the learning curve or was caused by the need to implant two devices, a problem with the device, or attempts to retrieve an embolised marker. We found that 11.6 min was the shortest regular period required for implantation in adults, but a shorter period was used in 14 out of 29 children.

The median of 14.2 min for our fluoroscopic time in our series is within reasonable limits, more than the 8.7 min quoted by Berger and associates,[1] but less than the 19 min reported by Rastegari and colleagues.[6] It has to be considered, though, that the cohort of Berger and colleagues[1] includes atrial septal defects, persistent oval foramens and fenestrated Fontan procedures. Indeed, in some cases the implantation procedure had been preceded by an earlier diagnostic and sizing procedure. The mean fluoroscopic time reported by Vogel and colleagues[5] was 12.8 min, comparable to ours. We opine that the fluoroscopic time is a sensitive marker of the difficulties experienced during the catheterisation. Obviously, it also may reflect the different skill and practice of different operators, particularly if trainees are involved, but such factors can be excluded in our series, since the principal operator was the same throughout. We were unable to demonstrate any increased difficulty in the smaller patients, whether judged by fluoroscopic time or by analysis of the detailed reports of the procedures. Statistical calculations also showed no such connection, in spite of three patients being less than 10 kg, and another ten below 13 kg.

Neither the size of the patient nor the defect was a reason for failure in children. At the other end of the size range, we encountered technical difficulties in seating the device in three patients. This seems to be caused by the smaller ratio between the left-sided disc and the core of the bigger devices, the spatial relation of the sheath coming from the inferior caval vein and the atrial septum, and the reduced possibility of angulating the distal sheath. The problem of passing the left-sided retention disc through the cranial portion of the defect, as reported by Vogel,[5] was not encountered in our children, but was experenced in our adults and was the reason for aborting two of the procedures.

Thus, our findings lend no credence to earlier claims that implantation may be more difficult in small children.[5,6] On the other hand, there will certainly be a lower limit where the left-sided disc will not be able to move freely in the left atrium due to the ratio of the disc to the core approaching 2½ or more in smaller sized plugs. Inevitably, the smaller the atrium and the bigger the device will, at a certain point, influence movements. We certainly approach borderline situations in small hearts, but we have not experienced any technical problems in our patients with a body weight down to 7.8 kg. Maybe a redesign of the plug, with a smaller retention disc in the smaller sized defects, would allow its use in even smaller patients. Although the ratio of children to adults in our cohort undergoing successful implantation is 29 to 11, the same ratio in the six patients in whom we were unable to insert a device is 2 to 4. The reason for failure in these children was anatomical and not technical.

The complications occurring in children were not caused by their size, since the improper reshaping of the device and the embolisation of the distal sheath marker could have happened in any patient. Air embolism only occurred early in the series. These events occurred only in children since the first patients were all children. Later, when adults were included, we had learned how to avoid this complication.

Although not statistically significant, we think we see a tendency towards more technical problems and more interrupted implantations, in adults. This is certainly in part due to the ratio between the diameter of the core of the device and the size of the left-sided

disc. The smaller the device, the higher is this ratio, making it easier for the left-sided disc to align on the left side of the septum rather than passing in part through the defect. In children, however, device-related technical problems, rather than the size of the patient, cause prolongation of the procedure.

Closure of atrial septal defect in the oval fossa with the Amplatzer technique, therefore, is a safe and efficient technique. With a short learning curve, it can be used in patients of all ages and sizes, at least down to 1 year of age and 8 kg body weight. We encountered no increased rates of complications nor procedural problems in children. The small size of the patient does not influence the ease or the safety of the procedure, nor does it lead to increased fluoroscopic times. Even the size of the defect cannot be demonstrated as a significant risk factor for failure, although some big defects in adults caused technical difficulties during implantation.

## References

1. Berger F, Ewert P, Bjornstad PG, et al. Transcatheter closure as standard treatment for most interatrial defects: experience in 200 patients treated with the Amplatzer septal occluder. Cardiol Young 1999; 9: 468–473.
2. Fischer G, Kramer HH, Stieh J, Harding P, Jung O. Transcatheter closure of secundum atrial septal defects with the new self-centering Amplatzer septal occluder. Eur Heart J 1999; 20: 541–549.
3. Berger F, Vogel M, Alexi-Meskishvili V, Lange PE. Comparison of results and complications of surgical and Amplatzer device closure of atrial septal defects. J Thorac Cardiov Sur 1999; 118: 674–678.
4. Walsh KP, Maadi IM. The Amplatzer septal occluder. Cardiol Young 2000; 10: 493–501.
5. Vogel M, Berger F, Dahnert I, Ewert P, Lange PE. Treatment of atrial septal defects in symptomatic children aged less than 2 years of age using the Amplatzer septal occluder. Cardiol Young 2000; 10: 534–537.
6. Rastegari M, Redington AN, Sullivan ID. Influence of the introduction of Amplatzer device on the interventional closure of defects within the oval fossa in children. Cardiol Young 2001; 11: 521–525.
7. Bjornstad PG. Interventional closure of atrial septal defects with the Amplatzer device: first clinical experience. Cardiol Young 1997; 7: 277–283.