

Transcatheter Closure of Atrial Septal Defects – Is Balloon Sizing Still Necessary?

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Abstract

Introduction: The device closure of atrial septal defects has evolved over the years. In the early days of transcatheter occlusion, balloon sizing was used to choose an appropriate sized device. We postulate that balloon sizing does not value-add to the procedure and is unnecessary. **Materials and Methods:** Patients who had balloon sizing, with (Group 1, n = 38) or without (Group 2, n = 21) atrial septal defect closure, were compared to another group (Group 3, n = 64) who had atrial septal defect closure without balloon sizing. Although the atrial septal defect size (mm) in those without balloon sizing (Group 3) compared to patients who had balloon sizing (Group 1) (18.3 ± 5.4 vs 14.8 ± 5.8 ; $P = 0.021$) was larger, the Amplatzer septal occluder size chosen (mm) (21.6 ± 6.3 vs 21.2 ± 8.1 ; $P = 0.693$) was similar. **Results:** We analysed the degree of absolute sizing, defined as [(Balloon or Amplatzer occluder size) – (transoesophageal echocardiography size)], versus relative sizing, which is defined as [(Balloon or Amplatzer occluder size) – (transoesophageal echocardiography size) / (Balloon or Amplatzer occluder size)]. It was evident that there was greater absolute and relative over-sizing (6.3 ± 4.4 mm vs 4.2 ± 2.1 mm; $P = 0.009$ and $28.3 \pm 15.4\%$ vs $20.0 \pm 7.0\%$; $P = 0.001$, respectively) in patients with balloon sizing (Group 1) compared to those who did not (Group 3). Even a greater degree of absolute (5.1 ± 3.9 mm vs 9.5 ± 4.7 mm; $P < 0.001$) and relative over-sizing ($24.8 \pm 15.6\%$ vs $33.0 \pm 13.6\%$; $P = 0.001$) was observed in patients who had balloon sizing but there was no closure (Group 2) compared to those who had balloon sizing and closure of their defects (Group 1). **Conclusion:** Our results showed that balloon sizing tended to over-size the atrial septal defect. This may have an important bearing in selecting a larger device than necessary, or even precluding transcatheter closure of the larger atrial septal defects. It is also associated with increased procedural, fluoroscopy time and cost. We suggest that balloon sizing may no longer be necessary in the protocol of device closure of an atrial septal defect.

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Introduction

Device closure of atrial septal defects through the transcatheter approach has now been well accepted as an option to surgical treatment. A range of devices has been developed for use over the years, with significant advances achieved in terms of profile and safety. These include the Cardioseal/Starflex,^{1,2} AngelWings,³ Amplatzer,¹ Helex⁴ and the more recent bioabsorbable⁵⁻⁶ devices. It has been demonstrated that device occlusion of atrial septal defects has led to significant improvements in cardiac form and function^{7,8} with good long-term outcomes.⁹ Of the many devices available in the market, the Amplatzer septal

occluder has been extensively deployed to close atrial septal defects and is now one of the very established devices for the transcatheter treatment of atrial septal defects worldwide.

One of the most important decision-making steps in the transcatheter closure of atrial septal defects has to be the precise sizing of the atrial septal defect and the choice of an appropriate device. Accepted practice in the closure of an atrial septal defect includes sizing done through a variety of methods, including balloon sizing,¹⁰ and echocardiographic guidance using transoesophageal,¹¹ 3-dimensional and intracardiac¹² echocardiography.

There have been numerous discussions as to which

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sizing method is superior but there has been no general consensus. Balloon sizing of atrial septal defects has been an established method in the protocol of atrial septal defect closure in many centres. As it was employed in the learning curve of many centres, it continues to be a practice today. However, with increasing experience, some cardiologists have done away with the need for balloon sizing and relied more on echocardiography alone. Our hypothesis is that therapeutic device closure of atrial septal defects can be carried out adequately with information obtained from transoesophageal echocardiography (TEE) alone. If so, this may potentially contribute to a shorter procedural time and lead to reduced costs.

Materials and Methods

Between April 1997 and February 2008, 123 patients with atrial septal defect were subject to cardiac catheterisation with a view to closure with the Amplatzer septal occluder. These included children and adults with atrial septal defect, with age ranging from 3.1 to 75.6 years. We divided our patients into Phase I from April 1997 to June 2004 when balloon sizing was used, as it was in the earlier phase of our protocol. This included 59 patients. Of these patients, 38 successfully underwent device closure, and these were categorised as Group 1. Group 2 patients were those who did not successfully undergo atrial septal defect device closure. In the Phase II of our programme from June 2004 to February 2008, there were 64 patients who underwent atrial septal defect closure without balloon sizing. These 64 patients were placed in Group 3.

Balloon sizing was undertaken using the AGA balloon inflated with one-third contrast-filled saline to obliterate the atrial septal defect. The diameter was measured, using TEE and fluoroscopy, and the largest diameter was used

in selecting an AGA device that is about 1 to 2 mm larger than this size.

The echocardiographic measurement was performed using TEE. Sizing was carried out in 3 planes, 4 chamber view (0 degree), short axis (45 degrees) and long axis view (110 degrees). Based on the largest diameter of the atrial septal defect obtained, a device approximately 120% the size of the atrial septal defect was used to close the defect in the later group of patients who were not subjected to balloon sizing (Group 3).

Results

Patient demographics, atrial septal defect size and Amplatzer septal occluder size, together with outcomes of device closure, were available for between group comparisons. Our results are summarised in Table 1.

Although the atrial septal defect size (mm) in patients who did not have balloon sizing (Group 3) compared to those who had (Group 1) (18.3 ± 5.4 vs 14.8 ± 5.8 ; $P = 0.021$) was larger, Amplatzer septal occluder size chosen (mm) (21.6 ± 6.3 vs 21.2 ± 8.1 ; $P = 0.693$) was similar. We analysed the degree of absolute sizing, defined for Group 1 as (Balloon size – TEE size) and Group 3 as (Amplatzer occluder size – TEE size), versus relative sizing, which is defined as Group 1 as (Balloon size – TEE size)/Balloon size and Group 3 as (Amplatzer occluder size – TEE size)/Amplatzer occluder size). There was greater absolute and relative over-sizing (6.3 ± 4.4 mm vs 4.2 ± 2.1 mm; $P = 0.009$ and $28.3 \pm 15.4\%$ vs $20.0 \pm 7.1\%$; $P = 0.001$, respectively) in those patients who had balloon sizing (Group 1) compared to those who did not (Group 3) (Fig. 1). This was more so in terms of absolute (5.1 ± 3.9 mm vs 9.5 ± 4.7 mm; $P < 0.001$) and relative over-sizing ($24.8 \pm 15.6\%$ vs $33.0 \pm 13.6\%$; $P = 0.001$) in patients who had

Table 1. Comparison of Clinical Data, Atrial Septal Defect Size, Amplatzer Septal Occluder Size and Shunt Size

	Group 1 (n = 38) Mean $\pm$ SD Balloon sizing and closure	Group 2 (n = 21) Mean $\pm$ SD Balloon sizing only	Group 3 (n = 61) Mean $\pm$ SD Closure without balloon sizing
Age (y)	23.7 $\pm$ 18.9 ^d	11.5 $\pm$ 10.5 ^e	24.8 $\pm$ 20.7 ^p
Sex (Male/Female)	15/23	6/15	15/46
Weight (kg)	44.0 $\pm$ 22.6 ^f	30.6 $\pm$ 15.1 ^g	43.1 $\pm$ 20.8 ^q
ASD ^a size (mm)	14.8 $\pm$ 5.8 ^h	18.5 $\pm$ 3.6 ^j	18.3 $\pm$ 5.4 ^j
Balloon size (mm)	20.0 $\pm$ 7.2 ^k	26.8 $\pm$ 5.9 ^l	NA
ASO ^b size (mm)	21.2 $\pm$ 8.1	NA	21.6 $\pm$ 6.3
Qp/Qs	2.04 $\pm$ 0.84 ^m	3.07 $\pm$ 1.05 ⁿ	2.35 $\pm$ 0.72 ^r

ASD^a: atrial septal defect by transoesophageal echocardiography; ASO^b: Amplatzer septal occluder; ^cBS: balloon sizing; Qp/Qs: left to right shunt

$P = 0.05$: m vs. r;

$P < 0.02$: d vs. e, f vs. g, g vs. q, h vs. j, n vs. r;

$P < 0.01$: h vs. l, e vs. p;

$P < 0.005$: m vs. n;

$P < 0.001$: k vs. l

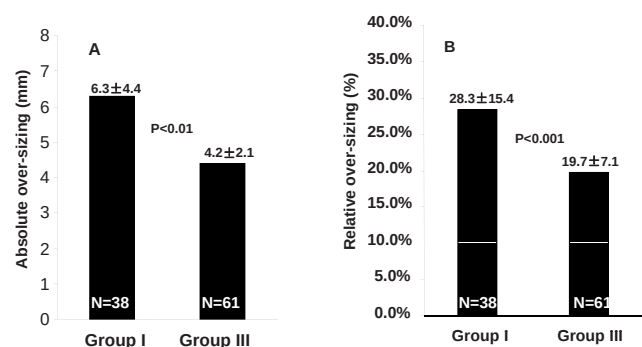


Fig. 1. Over-sizing of atrial septal defect in patients with device closure using balloon sizing (Group 1) versus transoesophageal echocardiographic sizing (Group 3).

balloon sizing but did not go on to receive the occluder (Group 2) compared to those who had balloon sizing and device closure (Group 1) (Fig. 2).

After exclusion of 4 patients who were judged not suitable for device closure, 11 out of the remaining 17 patients (64.7%) who had undergone balloon sizing but did not receive the occluder (Group 2) were deemed suitable for device closure, if balloon sizing had not been used. Finally, fluoroscopy time (FT) and procedural time (PT) were significantly shorter in patients who did not undergo balloon sizing (Group 3) (12.34 ± 8.44 minutes and 69.92 ± 30.69 minutes, respectively) compared to those who did (Group 1) (20.79 ± 47 minutes and 95.71 ± 31.15 minutes, respectively) ($P < 0.001$).

From our results, we have found that 21 out of 59 (35.6%) patients in Phase I did not have device closure, compared to 3 out of 64 (4.7%) in Phase II ($P < 0.0001$). There were 4 patients (6.8%) in Phase I who were excluded from device closure because of the following reasons (small atrial septal defect and left to right shunt = 1.1:1; double atrial septal defect; deficient inferior vena caval rim; and deficient inferior vena caval rim and superior vena caval rims) and the remaining 17 were judged not suitable for device closure after balloon sizing. In comparison, for Phase II, only 3 patients (4.7%) were judged to be unsuitable for device closure because of inadequate rims in 2, and atrial septal defect larger than the available Amplatzer septal occluder size in another. This figure of 4.7% is far smaller than the 35.6% in Phase I. Put in another way, in applying the current criteria based on TEE sizing for selection of Amplatzer septal occluder, 11 out of 17 (64.7%) of those patients who underwent balloon sizing but where the occluder was not implanted (Group 2) may have been suitable for device closure, if balloon sizing was not used. Only 6 out of the 17 patients truly did not have adequate atrial septal length to accommodate the device appropriate for the size of the defect. It is plausible therefore, that balloon sizing tended to over-size the atrial septal defect, necessitating

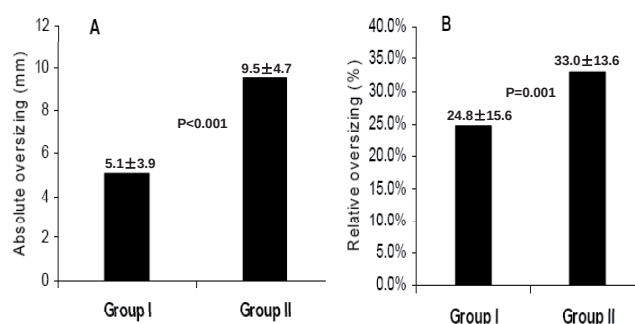


Fig. 2. Over-sizing of atrial septal defect in patients with balloon sizing and device closure (Group 1) versus those without device closure (Group 2).

the use of a larger Amplatzer septal occluder and possibly precluding closure due to inadequate atrial septal length in some children.

There were no major complications or embolisation observed in the patients who had undergone transcatheter atrial septal defect treatment.

Discussion

Transcatheter closure of atrial septal defect with Amplatzer septal occluder¹³ has produced good results in the majority of patients, and remains a widely acceptable option to surgery in most centres today. However, there are a significant number of interventional cardiologists who rely on balloon sizing in selecting an appropriate Amplatzer septal occluder size for closure. The protocol varies among centres, and even within centres, the use of balloon sizing may not be always carried out. There is currently very little literature available comparing the use of balloon sizing versus closure without, except for one. Wang et al¹⁴ reported a series of their patients whose atrial septal defects were closed without balloon sizing. However, their methodology was significantly different from ours. In their study, device sizes were chosen based on a fixed, but different and arbitrary, “upsized” number that depended on whether the atrial septal defect was larger or smaller than 14 mm. They concluded that there was no difference in success or complication rate between those with or without balloon sizing and suggested that balloon sizing was not necessary. Our comparative evaluation of results by the 2 methods yielded a similar conclusion, although our method for determining device size was very different. We further highlight that it potentially leads to prolonged PT and FT, and results in increased cost of procedure. Additionally, there may be significant problems associated with its use. Balloon sizing may oversize the actual atrial septal defect. This is especially so if a waist is obtained during the balloon sizing or in atrial septal defect with thin rims, leading to the deployment of a larger Amplatzer septal occluder than is

necessary. Recent reports of erosion¹⁵ have been associated with large Amplatzer septal occluders, and even if the risk is small, it would be arguably better to have a smaller device than a larger foreign body than is necessary to do the same work. Potentially, it may prevent some atrial septal defects from being closed with a device in oversizing the larger defects. To address the issue of over-sizing, the concept of “stop-flow”¹⁶ technique is now being advocated. While this is meant to preempt the tendency of over-sizing, the issue of costs needs to be addressed. This could well translate to a lower radiation dose¹⁷ as well, and is an important consideration in a small child. However, there remains a role of using the “stop-flow” method of balloon sizing, such as in centres where there is limited TEE experience and equipment or support, and in ASD lesions with aneurysmal septum where there is a risk of undersizing.

Limitations of Study

Our study was not a randomised, controlled trial. It was our experience in our atrial septal defect closure programme using 2 methods. This was based on a series of patients who had undergone catheter closure performed sequentially by the same team of operators. We acknowledge the initial learning phase of the curve which may have contributed to longer PT and FT. We may also have “oversized” the atrial septal defect with balloon sizing in patients where the “stop-flow” technique was not used. Based on our TEE sizing of the atrial septal defect without balloon sizing, we now do not upsize more than 20%. This is an arbitrary figure used and is well served. We are aware that the atrial septal defect may not be round, but frequently elliptical or oval, and the upsizing helps to overcome this and possible thin rims surrounding the defect, without over-estimating the device size.

Conclusion

While atrial septal defect can be safely and effectively occluded using the Amplatzer septal occluder, our experience suggests that atrial septal defect balloon sizing does not value-add to the procedure. In fact, the transcatheter closure of the atrial septal defect may well be achieved without balloon sizing, as we have shown in our study despite some limitations. A randomised study to more accurately compare the present recommended balloon sizing (“stop-flow”) technique versus our description of no balloon sizing is useful in addressing this basic but interesting question.

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