How to size ASDs for percutaneous closure

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ABSTRACT

Percutaneous closure is the treatment of choice for secundum type atrium septal defects (ASD). Since incorrect sizing may lead to complications adequate imaging is essential. Balloon sizing (BS) has been the method of choice for deciding on device size. With improved 2D- and 3D-transesophageal echocardiographic (TEE) imaging the necessity of BS is challenged.

Aim: BS was performed with 2 additional techniques to measure the stretched dimension of the ASD. The 1st method uses a stiff guide wire which stretches the ASD. This dimension is measured by 2D TEE. The second technique uses 3D TEE. We compared the results of ASD closure using these 3 sizing methods.

Methods and results: Two hundred thirty six patients with minimum 1 year follow-up were enrolled. The population was classified into 3 groups according to the sizing method: BS (group 1) n= 90, 2D-TEE (group 2) n=87 and 3D-TEE (group 3) n=59.

All groups showed a distinct correlation between the maximum baseline dimensions and the device size (R= 0.821). The relative expansion rate did not differ significantly between BS (32.50%) and 3D-TEE (32.80%). Group 2 (2D-TEE) showed a significantly lower expansion rate (14.38%). Procedural success and sizing-related issues did not differ between the 3 groups.

Conclusion: No difference in success-rate and sizing-related issues was seen. Moreover, 2D TEE sizing was the simplest method with comparable results and complications. The expected device size (compared to baseline) was lower for 2D TEE sizing. 3D sizing offers the advantage of accurate and fast shape assessment.

Key words: ASD - percutaneous closure – device – sizing – threedimensional – echocardiography

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Introduction

Percutaneous closure is the treatment of choice for most secundum type atrium septal defects (ASD) [1, 2]. Adequate measurement of the ASD size and assessment of the presence of sufficient rim are essential to avoid undersizing and oversizing [3, 4]. Embolisation and erosion are the most feared consequences of incorrect sizing [3, 5-7]. Initially balloon sizing (BS) was required [8, 9], but more recently, BS has been challenged as the golden standard for the accurate choice of the device size to be implanted [10, 11]. BS results in more oversizing, although less common with the stop-flow technique, increased risk of tearing of the septum and excess irradiation [8, 11-14]. Alternative sizing techniques using 2D or 3D echocardiography have been reported [10, 11, 13, 15-19]. In our own practice we moved from BS to 2D measurements and ultimately to 3D measurements. Therefore we decided to review our results and compare the 3 sizing techniques and assess procedural and long-term results and complications.

Population and Methods

The databases of Ghent University Hospital and Antwerp University Hospital were searched for percutaneous ASD closure procedures. All patients that underwent closure with the Amplatzer ASD occluder (ASO) (St Jude Medical, St Paul, Minnesota, USA) and the Occlutech Figulla ASD occluder (Occlutech, Helsingborg, Sweden) between 1999 and end of 2015 were identified. Design, delivery systems, sizing requirements and sizing issues of these 2 devices are comparable. After exclusion of patients with patent foramen, complex fenestrated ASD needing multiple or cribriform devices and ASD in complex congenital heart disease (CHD) or in CHD with right-to left shunt (total cavopulmonary anastomosis, right-

sided hypoplasia, Ebstein's disease, platypnoea-orthodexia syndrome), 236 patients were identified in whom the closure procedure was started after TEE screening for suitability. These patients were classified into 3 groups according to the sizing method of the ASD. Group 1 consisted of 90 patients in whom balloon-sizing was used, group 2 included 87 patients in whom the stretched-2D sizing method was used and 59 patients were included in group 3 using 3D echocardiography for sizing. Data were obtained at baseline ("maximum unstretched dimension") by 2D transthoracic echocardiography or TEE, after the procedure, at 6 months and 1 year follow-up or more. Complete and reliable follow-up (up to 1 year or more) was obtained in 208 patients (76 in group 1, 78 in group 2 and 59 in group 3). In the remaining 28 we included the pre-, per- and postprocedural data and used the follow-up data until available.

Methods

All procedures were performed by or under direct supervision of the same interventional cardiologist (DDW). The ultimate decision on the device size was made by the same interventional cardiologist (DDW) based on the sizing method. The closure procedures were done under general anesthesia with TEE guidance and fluoroscopy. After puncture of the femoral vein a Gensini-type catheter is positioned through the ASD into the left upper pulmonic vein and replaced by a long Mullins-type delivery sheath after assessment of the ASD dimension by one of the 3 sizing methods. 2D TEE was performed with a Vivid 7 or Vivid S6 phased-array scanner (GE, Chicago, USA) with an adult or pediatric transoesophageal transducer. 2D TEE and 3D TEE were performed with an iE33 phased-array scanner (Philips Medical Systems, Andover, MA, USA) with a transoesophageal extended frequency range transducer. The maximal and minimal dimensions of ASD were assessed online in different planes from four-chamber (0°), short-axis (20-30°) and bicaval (110°)

planes at midoesophageal level. A 180° sweep was also performed to assure that we indeed measured the maximal dimension. Real-time threedimensional images of the interatrial septum were acquired from these views and the ASD was also directly measured in the three-dimensional view.

The first method consists of BS the defect by manually inflating a soft PTS sizing balloon (B Braun, Melsungen, Germany) with radiopaque markers until the color flow over the ASD stops as assessed by TEE monitoring ("stop-flow" technique) in all planes. The device size was chosen according to the measured "stretched" dimension, with 1-2 mm added in case of a floppy septum. The second method used 2D TEE in multiple planes. The largest ASD dimension irrespective of the cardiac cycle was measured while the ASD was stretched with an extra-stiff 0.035" Amplatz wire (Cook Medical, Bloomington, IN, USA). The dimension of the color flow signal through the ASD was also measured and the largest dimension of both measurements (wire or color) was chosen as the stretched dimension (figure 1). In case of a floppy septum, a device with a size at least 4 mm larger than the baseline dimension was chosen.

The third method used 3D imaging, with direct measurement of the ASD on the 3D image, or by measuring the ASD on 2D with the plane adjusted according to the largest dimension on 3D TEE irrespective of the cardiac cycle. 3D ASD dimensions were measured in the multi-planar reconstruction mode available in the 3DQ plugin for QLab software for direct 3D measurements (Philips Medical Systems, Andover, MA, USA). We sized the ASD using 3D TEE without the extra-stiff wire in order to avoid interference of wire artefacts with the measurements (figure 2). Two to four mm was added to the largest 3D dimension for the eventual device size, because we took into account that we did not really measure a"stretched

dimension" of the ASD with direct 3D measurements . In case of an oval ASD, the largest dimension of the ASD determined the device size.

The device was introduced through the sheath, deployed in the atrial septum and released after confirming a stable position. If the position of the device was unsuitable or unstable, if there was an important residual leak or if the ultimate shape of the device after deployment suggested oversizing or if arrhythmias not disappearing after a short delay appeared, the device was retrieved and replaced by a larger or smaller device as judged appropriate or the procedure was stopped.

At the end of the procedure the sheath was removed and the puncture site closed by a figure 8 skin suture.

Follow-up consisted of clinical evaluation, ECG, chest X-ray and transthoracic echocardiography 1 day post procedure and an outpatient visit with ECG and transthoracic echocardiography at least after 6 weeks, 6 months and one year. Longer follow-up was included if available.

For statistical analysis we used the SPSS Statistics 22 package (IBM, Armonk, New York, USA). Wilcoxon signed rank test and Kruskal-Wallis test were used for comparisons between groups. Undesired effects and complications were analyzed by the Chi-square crosstab. The relationship between baseline ASD dimension, "stretched" dimension and device size was done with Spearman's rank correlation coefficient.

The studies complies with the Declaration of Helsinki, and the research protocol is approved by the locally appointed ethics committee of UZ Gent and UZA.

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Results

Two hundred thirty six patients were identified in whom we attempted to close the ASD with an ASO or Figulla device (table 1). In 208 of them, follow-up was complete, (range 1 to 17 years). In the remaining 28 patients, some of the follow-up data were lacking during the first year of follow-up. The data of these 28 patients were used for the evaluation of the immediate results of the procedure only. The overall population was classified in 3 groups: group 1 (BS) n = 90, group 2 (stretched 2D) n = 87 and group 3 (3D) n = 59 (table 1). We had twice as much female (n=153) patients as male patients (n =83). The median age for the overall population was 13 years (range 0-80 years). The median age for group 1 was 24 years, 4 years for group 2 and 51 years for group 3.

The maximum ASD dimension at baseline was larger in group 3 (mean 20.86 mm, CI 19.03-22.68) compared to group 1 (mean 15.12 mm, CI 13.95-16.30) and group 2 (mean 14.70 mm, CI 13.63-15.76) (table 2 and 3). This difference was statistically significant ($p<0.01$). The atrial septum was considered floppy if the septum was thin with mobile edges of the ASD. Overall, 15% of the patients had a floppy septum. In group 1, the septum was labeled floppy in 19%, in group 2 in 7% and in group 3 in 22% of patients. The ASD was considered oval in 26% of patients overall and in 9 % of patients in group 1, in 18% in group 2 and 64% of group 3 patients. ASD's were fenestrated or multiple in 15% of the patients. Nineteen percent of patients in group 1 had a fenestrated ASD, 17% in group 2 and 7% in group 3. We only included patients in the study in whom we estimated that closure of all ASD's was possible with one overlapping device, or in whom only the largest ASD was closed and in whom a small residual ASD was considered acceptable. This meant essentially, that we only measured the largest ASD (-component) in these cases.

The stretched dimension was 18.13 mm in group 1 (CI 16.93-19.33), 15. 65 mm in group 2 (CI 14.53-16.76) and 22.03 mm in group 3 (CI 20.28-23.82)(table 2). In an attempt to correct

for the differences in distribution of age and baseline dimensions between the 3 groups, we analyzed the ratio of the difference between stretched/baseline dimensions (100x((stretched dimension-baseline dimension)/baseline dimension) in %)(table 3). This difference ratio was 23% for group 1, 19% in group 2 and 15% in group 3.

The device size chosen in group 1 was 19 mm, 16 mm in group 2 and 25 mm in group 3. The device/baseline dimension difference ratio was 32% in group 1, 14% in group 2 and 32% in group 3. The device/stretched dimension difference ratio was 10% in group 1, 7% in group 2, but 25% in group 3. The differences between baseline dimension and "stretched dimension and device size respectively were significant for the 3 groups ($p < 0.01$). The device size was also statistically different between the 3 groups ($p<0.01$), which is no surprise since there was already a significant difference in baseline ASD size between the 3 groups. However, the dimension difference ratio between baseline and device size was also statistically different between the 3 groups, due to the significant differences between group 2 and the other 2 groups.

The overall procedural success rate was 97% (99% group 1, 97% group 2, 97% group 3) (table 4). In 3 patients the device was oversized (arrhythmia after deployment, inadequate configuration of the device and/or conflict with surrounding tissues), retrieved and replaced by a smaller device (2 group 2 and 1 group 3). In 10 patients the device was undersized (unstable position, residual leak at the edges) and retrieved and eventually replaced by a larger device (3 patients group 1, 3 patients group 2 and 4 patients group 3). Six patients were referred for elective surgery (1 group 1, 3 group 2 and 2 group 3). We had 2 device embolisations (1 group 1 and 1 group 3). Three patients showed significant arrhythmia's (2 atrial fibrillation and 1 supraventricular tachycardia) which could be successfully terminated in all cases (2 group 1 and 1 group 3). We had one cardiac erosion a few months after the

procedure in group 2. Review of this case did not reveal any obvious measurement error or high device/baseline dimension ratio. In 5% of the cases a residual leak was present (none more than mild) (3% group 2, 4% group 2 and 11% group3). The number of undesired effects and complications did not differ significantly between the 3 groups.

If we focus on the sizing results, methodology, features of the atrial septum and eventual device size, we found a high correlation between the eventual device size and baseline dimension of the ASD if the septum was not classified as floppy and this for the 3 groups (R group 1 = 0.795, R group 2 = 0.855 and R group 3 = 0.928) (figure 3a). On the contrary, the correlation between baseline maximum ASD dimension and eventual device size was poor in case of a floppy septum and this was also true for the 3 groups (R group 1 = 0.580, R group 2 = 0.522 and R group 3 = 0.460) (table 5 and figures 3a and 3b).

Discussion

For achieving successful percutaneous closure of ASD's, accurate imaging and sizing is important. Underestimating the real size of the ASD can lead to undersizing the device chosen and may result in significant residual leaks or embolization of the device after release [3, 5]. Oversizing could cause arrhythmia's, distortion of the device or erosion [3, 7]. BS of the ASD was hitherto the method of choice recommended by manufacturers and literature [8, 9]. However, BS has been reported to cause oversizing of the implanted device, is inaccurate for the sizing of large ASD's, causes additional costs and results in more fluoroscopy time and hence irradiation [8, 11-14]. Several reports questioned the necessity of BS and proposed sizing of the ASD by the use of 2D echocardiography or 3D echocardiography [10, 11, 20-22].

Therefore we compared 3 methods of ASD sizing: BS with the stop-flow technique, 2D TEE sizing and 3D (guided) TEE sizing. The sizing of the ASD was done in order to choose the appropriate size of an ASD occluder with central waist, type ASO or Figulla [23, 24].

These 3 methods gave comparable success rates and did not result in significantly more undesired effects or complications.. If we analyse the stretched/baseline dimension difference ratio (designed in attempt to correct for the differences in baseline dimensions of the ASD's between the 3 groups), the differences between baseline and "strectched" dimensions were largest for the BS group. The lowest ratio was found in the 3D group. Normally, this should also result in a relatively lower device size for the 3D and 2D groups (also expressed as difference ratio). However, we found that the ultimate device size to baseline ASD size ratio was comparable for the BS and 3D sizing groups The larger size of the device chosen in the 3D group can only be explained by a more cautious choice of the device size. Indeed as already mentioned in the methodology, we systematically chose a device 2 to 4 mm larger than the largest dimension on 3D as a kind of safety margin, as we estimated that the largest 3D dimension was not a real stretched dimension (although categorized as such for the analysis of the result). In fact, the relative device size/"stretched"dimension was 25% for the 3D group, and only 8% and 7% in the 2 other groups. This safety margin is probably unnecessary if the septum is not floppy and could be avoided, certainly if the configuration of the ASD is oval. In the 3D group 64% of the ASD's were classified as oval compared to 9% and 18% in groups 1 and 2. This has probably nothing to do with a real difference of configuration between the 3 groups. In other series, depending on imaging mode and definition of oval configuration (shortest dimension < 0.75 of the largest dimension), 35 to 42% of ASD's were oval [20, 25]. We used eyeballing, which probably explains the higher percentage in our series. Essentially this means that 3D echocardiography is able to identify

the largest dimension in any anatomical configuration of ASD's which makes the measurement of the largest dimension more accurate than with 2D sizing. This should allow less oversizing of the device if one does no add 2-4 mm to the 3D measurement as we did now in this series. We adjusted our practice accordingly: if we assess the ASD size with 3D imaging, we now use the largest dimension of the ASD measured on the 3D image directly as the ultimate size of the device, especially if the ASD is oval. This adjustment in our device choice for oval ASD is supported by data in another study in which the differences between the maximal 3D diameter of an oval ASD and the stretched balloon diameter and implanted device were small [26]. If the ASD is round, we add 2 mm to choose the device size, and only in case of a floppy septum, we remain more cautious and add up to 4 mm, unless the ASD is extremely oval (short axis ≤ 50% of the long axis) . Of course, this concept has to be validated in other studies.

We looked at the relationship between baseline dimension of the ASD and the device chosen and found that in case of a firm septum, a linear relationship was found between the baseline dimension and the device chosen, meaning that no other measurement than baseline is necessary to choose the device. On the other hand, no such relationship was found in case of a floppy septum. Consequently, meticulous assessment of ASD size, variation of ASD size over the cardiac cycle, ASD anatomy (oval configuration or not), and stretching potential by wire or sizing of the color flow width in multiple planes is particularly important for the accurate choice of the device size. Overall, 2D sizing resulted in the choice of the smallest devices compared to baseline measurements without significantly more undesired effects nor complications. BS does not seem to add any advantage nor safety to the procedure and is probably unnecessary. Only for training purposes, cautious BS could be of any benefit. At first sight 3D echocardiography does not add any advantage to 2D sizing. This is particularly

important for children for whom appropriate 3D TEE probes are not widely available yet. On the other hand, 3D imaging allows accurate and fast assessment of the ASD shape (oval or fenestrated) and variations of size during the procedure. As this information also affects device choice and manipulation during deployment, 3D imaging is probably the method of choice if feasible and available.

We did not measure the reduction of irradiation in the procedures without BS, since we rely heavily on echo guidance during the procedure anyhow and have mean fluoroscopy times of about 2 minutes, but of course even tiny reductions in irradiation are of benefit. The cost and procedure time reductions depend on the technique and the type of sizing balloon and were not assessed in this retrospective study.

Limitations of the study

This is a retrospective study and the patients were not randomly assigned to the different groups. Indeed, over the years our measurement mode changed from BS to 2D and at last 3D consecutively. We left the BS technique as we became more experienced, and felt that we could choose the appropriate device size on the 2D measurements alone. We used 3D sizing from the moment it became available to us, but initially combining it with the 2D stretched technique as a control. Once we got confident enough, we used 3D sizing as our method of choice, except for smaller children. This means that patients were not individually selected to be assigned in one of the 3 groups.

Since the study was aimed at comparing sizing methods only, the groups were not really matched for age and ASD size. We tried to overcome the differences in median ASD size by focusing on the relative differences between “stretched” dimension, device size and baseline dimension by using percentages instead of absolute values. The reason for the differences in

age and ASD size between the 3 groups are quite simple: our 3D echocardiography probes are adult size probes, unsuitable for children below 35 kg. Therefore, in recent years the majority of our small children were included in group 2 (a mixture of children and adults) and group 3 was almost exclusively reserved for adults and older children.

The methodology described and assessed is only valid for devices with a central waist as is the case for ASO and Figulla devices.

Strength of the study

To our knowledge, this is the first study comparing 3 methods of measuring ASD's and assessing outcomes in a relatively large population. The number of patients assessed in this study is relatively large compared to other series and all procedures were done or directly supervised by the same interventional cardiologist (DDW) assuring comparable technique and methodology for all patients studied.

Conclusion

In experienced hands, simple 2D sizing of ASD's is a reliable method for choosing the appropriate device size in percutaneous ASD closure procedures, especially if the interatrial septum is not floppy. If the configuration of the ASD is more complex, oval or fenestrated, 3D echocardiography can offer a faster assessment of the anatomy and the largest dimension. The use of BS and ensuing increased procedure time, increased cost and increased irradiation thus can be avoided.

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Table 1

	TOTAL POPULATION	GROUP 1	GROUP 2	GROUP 3
DEMOGRAPHIC DATA				
N	236 (100%)	90 (35.9%)	87 (34.7%)	59 (23.5%)
MALES	83 (35.2%)	39 (43.3%)	31 (35.6%)	13 (22.0%)
FEMALES	153 (64.8%)	51 (56.7%)	56 (64.4%)	46 (78.0%)
AGE AT PROCEDURE (YEARS)	13 (0-80)	24 (0-74)	4 (0-60)	51 (18-80)
LENGTH (CM)	143 (52-198)	136 (61-182)	103 (52-198)	166 (147-196)
WEIGHT (KG)	35.50 (3.5-132)	30.50 (7.0-115.0)	16.50 (3.5-91.0)	72.50 (48.0- 132.0)
FIRM SEPTUM	200 (84.7%)	73 (81.1%)	81 (93.1%)	46 (78.0%)
FLOPPY SEPTUM	36 (15.3%)	17 (18.9%)	6 (6.9%)	13 (22.0%)
ROUND ASD	138 (59.5%)	65 (72.2%)	56 (64.4%)	17 (28.8%)
OVAL ASD	62 (26.3%)	8 (8.9%)	16 (18.4%)	38 (64.4%)
FENESTRATED ASD	36 (15.3%)	17 (18.9%)	15 (17.2%)	4 (6.8%)

Legend: data expressed as median (minimum - maximum) or mean (CI: '95% confidence interval')/ N (percentage total), Group 1 = BS, Group 2 = 2D-TEE, Group 3 = 3D-TEE

Table 2

	total population	Group 1	Group 2	Group 3
SIZING-RELATED DATA				
BASELINE DIMENSION ASD (MM)	16.41 (CI:15.60-17.23)	15.12 (CI:13.95-16.30)	14.70 (CI:13.63-15.76)	20.86 (CI:19.03-22.68)
'STRETCHED' DIMENSION ASD (MM)	18.20 (CI:17.38-19.01)	18.13 (CI:16.93-19.33)	15.65 (CI:14.53-16.76)	22.03 (CI:20.28-23.82)
SIZE DEVICE (MM)	19.60 (CI:18.72-20.49)	19.06 (CI:17.84-20.30)	16.29 (CI:15.09-17.48)	25.23 (CI:23.51-26.96)

Legend: data expressed as mean (CI: '95% confidence interval')/ N (percentage total), Group 1 = BS, Group 2 = 2D-TEE, Group 3 = 3D-TEE

table 3: percentage differences between device size and “stretched dimension”

	GROUP 1	**GROUP 2**	**GROUP 3**
difference: between stretched’ and baseline dimensions	22.97%	18.87%	15.50%
difference between device size and ‘stretched’ dimension	7.96%	7.31%	25.50%
difference between device size and baseline dimension	32.50 %	14.38%	32.80%

Legend: ‘differences in percentage between 3 groups’; Group 1 = BS, Group 2 = 2D-TEE, Group 3 = 3D-TEE

table 4

	Total population	Group 1	Group 2	Group 3
UNDESIRED EFFECTS AND COMPLICATIONS				
SUCCESS RATE	230 (97.5%)	89 (98.9%)	84 (96.6%)	57 (96.6%)
UNDESIRED EFFECTS	31 (14.9%)	9 (11.8%)	10 (12.8%)	12 (22.2%)
OVERSIZING	3 (1.4%)	0 (0%)	2 (2.6%)	1 (1.9%)
UNDERSIZING	10 (4.8%)	3 (3.9%)	3 (3.8%)	4 (7.4%)
CONVERSION TO SURGERY	6 (2.9%)	1 (1.3%)	3 (3.8%)	2 (3.7%)
ARRHYTHMIA'S	3 (1.4%)	2 (2.6%)	0 (0.0%)	1 (1.9%)
EMBOLISATION DEVICE	2 (1.0%)	1 (1.3%)	0 (0.0%)	1 (1.9%)
CARDIAC EROSION	1 (0.5%)	0 (0.0%)	1 (1.3%)	0 (0.0%)
RESIDUAL LEAK	11 (5.3%)	2 (2.6%)	3 (3.8%)	6 (11.3%)

Legend: data expressed as N (percentage total), Group 1 = BS, Group 2 = 2D-TEE, Group 3 = 3D-TEE

Table 5: correlation between baseline dimension and device size depending on the firmness of the septum

	TOTAL POPULATION	GROUP 1	GROUP 2	GROUP 3
ALL SEPTA	0.821	0.755	0.858	0.832
FIRM SEPTUM	0.873	0.795	0.855	0.928
FLOPPY SEPTUM	0.536	0.580	0.522	0.460

legend: 'spearman correlatiecoefficient (baseline dimension- size of the devicedevice)'; Group 1 = BS, Group 2 = 2D-TEE, Group 3 = 3D-TEE

legends and captions figures

Figure 1: 2D stretched dimension sizing. Twodimensional transoesophageal view with color flow mapping showing stretched dimension by stiff wire (arrows) of secundum type atrial septum defect. (LA: left atrium, RA: right atrium).

Figure 2: 3D oval ASD. Threedimensional left atrial view of large secundum type oval atrial septum defect allowing measurement of smallest and largest dimension

Figure 3a: ‘scatterplot : correlation baseline/ size device for the overall population in case of a firm septum’

Figure 3b: floppy septum: correlation baseline dimensions and device size. ‘scatterplot : correlation baseline/ size device for the overall population in case of a floppy septum’