Balloon Interrogation of Intervening Tissue: A Novel Method to Decide Strategy for Closing Multiple Atrial Septal Defects

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BACKGROUND: Two separate ostium secundum atrial septal defects are a challenging substrate for device closure due to lack of a well-described strategy or an adequately evaluated protocol.

METHODS: This is a prospective study comprising 20 patients with 2 atrial septal defects who underwent device closure. All of them underwent balloon interrogation (BI) of the intervening tissue to decide 1- versus 2-device strategy. During BI, if the flow through both the defects could be stopped completely implying adequate mobility of the separating tissue, a single device strategy was used. The size of the device in this subset was determined by BI diameter. In case the flow persisted, 2 devices were used to close the defects separately.

RESULTS: The mean age was 24±17 years. The main defect size was (mean 14.5 mm±SD 2.69 mm), whereas the second defect measured (mean 8.5±SD 3.02 mm). The tissue separating the 2 defects was measured (mean 6.1±SD 2.6 mm). In 15 of them, based on the BI results, a single device was used successfully to close both the defects without a residual shunt. In the remaining 5 patients, 2 devices were used. There were no complications during the procedure or at follow-up period of 41.9±16.9 months.

CONCLUSIONS: BI in patients with 2 atrial septal defects is helpful in defining 1- versus 2-device strategies and in choosing the size of the device to be used. Nearly 3/4 of the patients may get away with a single device for closing both the defects successfully thereby decreasing the cost and complexity of the procedure.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: congenital heart defect ■ echocardiography ■ heart septal defects, atrial ■ septal occluder device

We wish to share our experience of balloon interrogation (BI) of the intervening tissue in patients having 2 ASDs to decide about the device number and size. To the best of our knowledge, this method has not been attempted till date for defining the strategy for closure of the defects in this subset of patients.

METHODS

The present cohort (N=20) comprises those patients in whom there were 2 distinct ostium secundum ASDs
WHAT IS KNOWN

- Multiple atrial septal defects can be closed using one or multiple Amplatzer septal occluders.
- Atrial septal defects separated by >7 mm require multiple devices.

WHAT THE STUDY ADDS

- Balloon interrogation of the intervening tissue in case of multiple atrial septal defects helps determine its mobility which in turn helps in deciding 1 versus 2-device strategy.
- The intervening tissue has differential mobility and therefore it is necessary to balloon interrogate from both the defects before abandoning a single device strategy.
- Based on this novel method of balloon interrogation, one may be able to close multiple defects separated by >7 mm with a single device.

Choosing the Device Size

In a single device strategy, the device size was chosen by adding 1 to 2 mm to the BID, whereas in 2-device strategy, devices 1 to 2 mm larger than BSD of each of the defects were used.

Device Deployment

In a single device strategy, it was considered mandatory to deliver and deploy the device through that defect from which BI was successful. In a 2-device strategy, the smaller device was delivered first followed by the delivery of the larger device, and the same sequence was followed during their release as well. In our early experience, we realized that when the large device was delivered first the large left atrial (LA) disc prevented the LA disc of the smaller device to abut against the interatrial septum on the LA aspect. One had to then recapture the LA disc of the larger device partially, push the device into the LA cavity, deploy the smaller device completely, and then deploy the larger device.

Before releasing the device, TEE was performed to confirm the device position with respect to the surrounding rims and to look for the presence of any residual shunt, obstruction to the pulmonary or systemic veins, occurrence of mitral regurgitation, and pericardial effusion. The patients were monitored in the intensive care unit for 24 hours looking for any complications and were discharged subsequently after confirming on the transthoracic echocardiography that the device(s) was/were in optimum position and there were no other complications as enumerated above. A predischARGE ECG was done to rule out any electrical abnormality. All the patients were followed at 6 weeks, 6 months, and every year thereafter for a period of 5 years with clinical evaluation, ECG, and transthoracic echocardiography. They received oral aspirin (5 mg/kg) once a day, up to a maximum of 150 mg/day for 6 months.

Statistical Analysis

The continuous variables were described as mean with SD. Tests of statistical significance were not applied in view of a small cohort size.
RESULTS

The demographic characteristics, defect sizes, width of the intervening tissue, BSD, BID, and number and size(s) of the device(s) used are summarized in the Table.

In 15 out of 20 patients, in whom the BI was successful, a single device was used to close both defects successfully without leaving behind any residual shunt. Among these 15, in 4 patients the initial BI was not

Figure 1. Assessment of balloon stretched diameter and balloon interrogated diameter.
A. Baseline transesophageal echocardiographic (TEE) short-axis view of the aorta (AO) showing 2 atrial septal defects (arrows) separated by a small strand of tissue (asterisk). B. TEE showing balloon stretched diameter (BSD; bidirectional arrow) by stop flow technique with residual flow through the anterior defect (arrow). C. Corresponding fluoroscopic image of B showing BSD (bidirectional arrow). D. TEE showing balloon interrogated diameter (BID) obtained by stretching the balloon beyond BSD to assess the mobility of the intervening tissue and is represented by the line drawn across the balloon (arrow). Note disappearance of the residual shunt through the anterior defect when the balloon was dilated beyond the BSD up to BID. E. Corresponding fluoroscopic image of D showing BID (bidirectional arrow). F. TEE post device deployment showing both the defects closed with a single device with no residual shunt. The device size was selected based on the BID. LA indicates left atrium; and RA, right atrium. (Continued)
successful but when the balloon position was changed from one defect to the other, the flow could be stopped through both the defects due to differential mobility of the intervening tissue in the 2 directions.

A single device strategy was successful universally if smaller defect was <10 mm, as seen in all the 14 patients. However, if size of smaller defect was >10 mm, only in 1 out of 6 patients, both the defects were closed using a single device. In the remaining 5 patients, 2 devices had to be deployed, one in each defect. The other morphological feature which determined success of a single device strategy was the width of the tissue separating these
2 defects (5.2±2.4 mm for 1 versus 8±1.1 mm for 2). Younger age was yet another determinant for successful BI and single device strategy (Mean age for successful BI 16.5±13 years versus unsuccessful BI 48±19 years).

When BI was successful, the BID was 35±14% more than BSD meaning correspondingly significant increase in the device size. In all these cases of single device strategy, ASO (Abbott Medical, 5050 Nathan Lane, North Plymouth, MN 55442) was used. In the remaining 5 patients, where 2-device strategy was used, 4 of them had ASOs, whereas 1 had Figulla Occlutech septal occluders (Occlutech Holding AG, Feldstrasse 228200, Schaffhausen, Switzerland).

**Figure 2.** Differential mobility of the intervening tissue separating the 2 defects.

A, Baseline transoesophageal echocardiographic (TEE) 4-chamber view showing 2 atrial septal defects shunting left to right (arrows) with a tissue (asterisk) separating them. B, TEE image of the balloon (*) passed through the defect close to the atrioventricular valves (AVV) and dilated beyond the balloon stretched diameter (BSD). There was incomplete displacement of the intervening tissue towards the atrial free wall with a persistence of residual shunt (Arrow head) through the other defect. C, Corresponding fluoroscopic image of B. D, TEE image in the same patient with the balloon (*) passed through the defect closer to the posterior atrial wall and dilated beyond the BSD. The intervening tissue was completely displaced towards the atrial free wall with a persistence of residual shunt (Arrow head) through the other defect. This balloon diameter was the balloon interrogated diameter (BID) represented by the line across the balloon. This is an example of the differential mobility of the intervening tissue only in the direction of the AVV but not in the direction of the posterior atrial wall. E, Corresponding fluoroscopic image of D showing BID (bidirectional arrow). F, TEE post device deployment showing complete closure of both the defects with a single device. The device size was selected based on the BID. LA indicates left atrium; RA, right atrium; and RV, right ventricle. (Continued)
In one patient (No. 20) initial device selected for closing 2 defects, based upon the BID, was a 26 mm ASO which required downsizing to 24 mm due to its bulky appearance, proximity to the anterior mitral leaflet, and excessive straddling on the aortic root. There were no intraprocedural or immediate postprocedural complications.

At mean follow-up of 41.9±16.9 months, all devices were in place, and there were no complications like cardiac erosion, arrhythmias, stroke, mitral regurgitation or pulmonary or systemic venous obstruction. There was no residual shunt after 6 month follow-up in any of the patient.
DISCUSSION

Dealing with multiple ASDs during transcatheter closure is challenging due to variations in numbers, sizes, width and characteristics of the intervening tissue, and the anatomy of the interatrial septum. Patient’s age, weight, and presence of pulmonary hypertension also play a role in determining the strategy of closure which...
mainly revolves around the type of the device, number of devices, and the size of each device.

**Type of Device**

Strategies for successful closure of multiple ASDs without leaving any residual shunt involve use of ≥1 devices of different types and varying sizes in various combinations. This is, to a large extent, determined by the morphology of the defect. All patients with discrete (non cribriform) defects are closed using septal occluders of different makes. In the present study, 19 out of 20 patients received 1 or 2 ASOs, whereas in 1 patient 2 Figulla Occlutech septal occluders were used. For a combination of a discrete defect with multiple fenestrations in septum primum, usually one septal occluder is used along with a cribriform septal occluder, whereas those with multiple small fenestrations in the septum primum, with or without a septal aneurysm, are best dealt with by using ≥1 cribriform ASOs.18,20,24–26

**Number of Devices**

Most of the previous studies have used distance between the 2 defects to decide 1- versus 2-device strategy with a separation of ≥7 mm qualifying for the use of 2 devices.9,15 Others used a distance of >12 mm with inadequately mobile intervening tissue to consider a 2-device strategy by using devices with a 12 mm overhang of the LA disc.10 However, none of them defined a technique of assessing the mobility as was done in this study. These previous recommendations, therefore, appear empirical and an oversimplification of a much complex problem. In the present study, in 15 out of 20 patients (75%) had successful BI resulting in the stoppage of flow from both the defects when the balloon was inflated beyond the BSD with additional contrast. This, we believe, was due to the intervening tissue being mobile and therefore getting pushed all the way to compress the other defect completely. One can argue that during BI, the intervening tissue got torn thus creating a larger confluent defect. However, this was ruled out in our patients because in all of them with successful BI, the 2 defects with intact intervening tissue were seen even after the balloon deflation before device deployment. In 4 of these 15 patients, the BI was not successful when attempted through the first defect but when attempted from the second defect, the intervening tissue could be stretched all the way in the opposite direction. This clearly showed

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**Figure 4.** Schematic representation of 2 atrial septal defects in enface view explaining the concept of mobility of the intervening tissue separating the 2 defects. A, The baseline diameter of the larger defect. B, The balloon stretched diameter of larger defect. C, On further dilatation of the balloon, there is a shift in the intervening tissue between 2 defects resulting in the complete obliteration of the smaller defect. This was referred to as the balloon interrogated diameter.

**Figure 5.** Schematic representation of 2 atrial septal defects in short axis view at the level of the aorta explaining the concept of mobility of the intervening tissue separating the 2 defects. A, The baseline diameter of the larger defect. B, The balloon stretched diameter of larger defect. C, On further dilatation of the balloon, there is a shift in the intervening tissue between 2 defects resulting in the complete obliteration of the smaller defect. This was referred to as the balloon interrogated diameter.
differential mobility of the intervening tissue in the 2 directions. In 3 out of 4 patients, the initial BI done from a smaller defect was unsuccessful, but it was successful when attempted from the larger defect. While in the remaining one patient, it was vice versa. Therefore, it is recommended that even if BI fails through 1 defect, attempt should be made through other defect before committing the patient to a 2-device strategy. If the 2 defects are close to one another, it may not be possible to say with certainty whether the flow through both the defects stopped due to mobility of the intervening tissue or by the shoulders of the overinflated balloon. Irrespective of the mechanism, one device was able to close both defects without leaving behind any residual shunt in this subset of patients. In this study, young age of the patient, diameter of the smaller defect <10 mm, and the width of the intervening tissue of <8 mm were found to be more likely candidates for a successful single device strategy.

In the previously reported studies, 2-device strategy was used only after one device failed to close both the defects, that is, when single device left behind a hemodynamically significant residual shunt. In these studies, the incidence of residual shunt is found to be as high as 20% to 65%. This may be partly related to using an ad hoc method to decide 1 versus 2 devices as well as to empirical choice of the device size. However, in the present study, there were no residual shunts probably due to BI of the intervening tissue to decide the strategy of using 1 or 2 devices apriori and to use a device size based on BID rather than using an approximate size based on the TEE measurements of the defect. The other reason for the higher incidence may have been the difference in the morphology of the defect between these studies. Using 2 devices instead of 1, increases complexity of the procedure, prolongs the procedural time and more importantly increases the cost of the procedure, which has significant implications in the developing countries. Also, there are some possible inherent risks of accommodating 2 devices in a small septum while dealing with younger children. Whether immediate risk of device embolization increases with the increase in number of devices is difficult to say, however, the same has been reported. Complications like cardiac perforation, pericardial effusion are also reported with increasing frequency when multiple devices are used, and therefore, must be specifically looked for as it is difficult to predict the interplay between multiple devices themselves as well as between these devices and the surrounding cardiac tissue. Fortunately, in this study, no such complications were reported in those where 2 devices were used. Sometimes when second defect is very small and hemodynamically insignificant, it is left open if there is no previous history of paradoxical embolism. Such small defects are known to close during the follow-up period. In this cohort, none of the defects was considered small to be left unattended.

| Table. Baseline Demographic Parameters and Transoesophageal Echocardiographic Findings of the Study Population |
|-------------------------------------------------|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Age/ gender | Weight, kg | Diameter of ASD1, mm | Diameter of ASD2, mm | Separation between 2 ASDs, mm | Balloon stretch diameter ASD1, mm | Balloon stretch diameter ASD2, mm | Balloon interrogation diameter, mm | No. of devices | Size of device, mm |
|-------------|------------|----------------------|----------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|----------------|-------------------|
| 1           | 5/F        | 21                   | 14                   | 5                             | 3                             | 15                           | 19                           | 1              | 20                |
| 2           | 21/F       | 57                   | 10                   | 8                             | 7                             | 13                           | 22                           | 1              | 22                |
| 3           | 8/F        | 26                   | 13                   | 7                             | 4                             | 15                           | 20                           | 1              | 20                |
| 5           | 12/F       | 37                   | 12                   | 6                             | 4                             | 14                           | 18                           | 1              | 18                |
| 6           | 14/F       | 42                   | 15                   | 7                             | 3                             | 16                           | 22                           | 1              | 24                |
| 7           | 17/F       | 48                   | 18                   | 8                             | 8                             | 20                           | 26                           | 1              | 26                |
| 8           | 9/F        | 27                   | 14                   | 6                             | 4                             | 15                           | 19                           | 1              | 20                |
| 9           | 11/M       | 32                   | 16                   | 8                             | 3                             | 18                           | 25                           | 1              | 26                |
| 10          | 16/F       | 36                   | 14                   | 7                             | 5                             | 15                           | 21                           | 1              | 22                |
| 11          | 45/F       | 54                   | 18                   | 8                             | 8                             | 21                           | 27                           | 1              | 28                |
| 12          | 5/F        | 17                   | 16                   | 3                             | 4                             | 16                           | 18                           | 1              | 19                |
| 13          | 44/F       | 64                   | 14                   | 7                             | 11                            | 18                           | 23                           | 1              | 24                |
| 14          | 3/M        | 11                   | 8                    | 8                             | 3                             | 12                           | 16                           | 1              | 16                |
| 15          | 22/M       | 54                   | 13                   | 14                            | 7                             | 14                           | 22                           | 1              | 24                |
| 16          | 40/F       | 55                   | 18                   | 12                            | 7                             | 21                           | 13                           | 21 and 13      | 22 and 14        |
| 17          | 52/F       | 71                   | 16                   | 13                            | 8                             | 19                           | 16                           | 19 and 16      | 21 and 18        |
| 18          | 67/F       | 65                   | 15                   | 12                            | 10                            | 16                           | 13                           | 16 and 13      | 17 and 13        |
| 19          | 83/F       | 62                   | 18                   | 12                            | 9                             | 19                           | 14                           | 19 and 14      | 20 and 15        |
| 20          | 18/M       | 50                   | 14                   | 12                            | 8                             | 15                           | 14                           | 15 and 14      | 16 and 15        |

ASD indicates atrial septal defect; F, females; and M, males.
Size of the Device
The stretchability of the intervening tissue in patients with multiple ASDs is an unexplored territory in ASD device closure. Apart from deciding the number of devices to be used, it also determines the size of the single device or size of each of the 2 devices to be deployed depending on 1 or 2 device strategies respectively. As stated earlier, in 15 out of 20 (75%) of the patients, the intervening tissue could be stretched all the way to stop the flow through both the defects during BI. In this group of patients, the device size was determined based on the BID. The BID on an average was found to be 33% larger than the BSD but the device profile was not found to be bulky. In only one of the patients, this estimate was found to be a little larger and the device had to be down sized from 26 mm to 24 mm since it was found to be touching the base of the anterior mitral leaflet. Some may argue about inflating the balloon beyond the BSD will result in significant oversizing of the device and is against the instruction for user. However, it is important to realize that the instruction for user does not take into consideration multiple defects and has not made any recommendations for dealing with them. In the earlier studies, the operators have oversized the device by 6 to 9 mm (which is 25%–40% more than the defect size) to cover both the defects.9,10 In that sense, oversizing in the present study is not significantly different from the one previously reported. On the contrary, we believe, that not attempting to stretch the intervening tissue and going by the BSD using stop flow technique may result in significant under sizing of the defect with high chances of device embolization and without a chance to adopt a single device strategy. Despite using a device size based on BSD which was much larger than the one estimated on BSD, there were no immediate or delayed complications of systemic or pulmonary venous obstruction, atrioventricular valve injury, cardiac tachyarrhythmias, atrioventricular blocks, or cardiac erosion in this study. However, in view of the device, oversize concern about cardiac erosion cannot be overlooked.

In the remaining 5 patients in whom BI was unsuccessful and 2 device strategy was used, the size of the device was chosen based on the BSD of each of the defect.

Role of 2D-TEE
Because 3-dimensional TEE (3D TEE) was not available, we relied entirely on 2D TEE for determining the number of devices to be used as well as the size of the individual device. Although, 3D TEE is strongly recommended for the closure of multiple ASDs,30–32 it is not mandatory. In all our patients, 2D TEE was used effectively for planning and executing the closure of multiple defects. Although 3D TEE displays the defects in en face view and gives accurate information about the size, shape, and relationship of the defects to each other, in some cases the intervening tissue is too thin to be displayed on 3D TEE especially when there is an aneurysm of the interatrial septum.19,30–32 Also, in children <30 kg, it cannot be used due to the large probe size.32 In none of our patients, the procedure had to be abandoned for the want of 3D TEE.

Limitations
It is a single center study with limited number of patients. As a result, no definite recommendations can be made regarding the strategy for approaching this complex subset of patients with multiple ASDs. Given the small sample size of the current study, the risk of cardiac erosion from the use of large devices based on the BID (35% larger than BSD) will need close consideration. Multicentric study with a larger cohort and with a longer duration of follow-up will help in overcoming these limitation.

Conclusions
Tissue separating 2 ASDs can be stretched significantly during the BI thereby stopping the flow through both the defects without tearing the intervening tissue. This may help in deciding the number and size of the septal occluders to be used in a given patient.

It is important to be aware of the differential stretchability of the intervening tissue in various directions. Hence, it is essential to do the BI through both the defects separately and sequentially before deciding on the number and size(s) of the device(s).

BID rather than BSD should be used for deciding the size of the device in those where single device strategy is adopted. Deciding the device size based on BID probably helps in optimum sizing. Choosing the device size based on the BSD may result in significant undersizing of the device with a potential for embolization and residual shunt.

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