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ЕДНОЦЕНТРОВО РЕТРОСПЕКТИВНО ПРОУЧВАНЕ НА БАЛОН-АСИСТИРАНА ТЕХНИКА ПРИ ТРАНСКАТЕТЪРНО ЗАТВАРЯНЕ НА ГОЛЕМИ ДЕФЕКТИ НА ПРЕДСЪРДНАТА ПРЕГРАДА

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A SINGLE CENTRE RETROSPECTIVE STUDY ON BALLOON ASSISTED TECHNIQUE IN TRANSCATHETER CLOSURE OF LARGE ATRIAL SEPTAL DEFECTS

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Резюме.

Въведение: Данните за балон-асистираните техники (BATs) за транскатетърно затваряне (TCC) на ostium secundum атриален септален дефект (ASD) са по-малко. Целта на представеното изследване е да се проучат резултатите от BATs за TCC на ostium secundum предсърден септален дефект. Проведено е едноцентрово ретроспективно проучване на пациенти с ostium secundum ASD, претърпели TCC с помощта на балон-асистирана техника. **Резултати:** 33-ма от 36 пациенти с ostium secundum ASD и сложни морфологични характеристики са претърпели успешна BAT TCC. Нашата група пациенти имаше високо разпространение на неадекватни аортни, горни и задни ръбове. BAT беше успешен при 33-ма от 36 пациенти (91,6%). Средният размер на успешно третираните с BAT ASD е 27 mm. BAT е неуспешен при 3-ма от 36 болни. Тези пациенти са насочени за извличане на устройството и хирургично затваряне на дефекта на предсърдната преграда. **Заключения**: Затварянето на ASD с балонно устройство има 90% успех. BAT е безопасна и ефективна техника. Той позволява контролирано доставяне на устройство и подравняването на устройството е възможно с тази техника в ASD, когато конвенционалните техники не дават нужния резултат.

Ключови думи: балон-асистирана техника, устройство за транскатерърно затваряне, ostium secundum предсърден септален дефект

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Abstract.

Background: Data on balloon-assisted techniques (BAT) for transcatheter closure (TCC) of ostium secundum atrial septal defect (ASD-II) is scarce. The objective was to study the outcomes of the balloon-assisted technique (BAT) for transcatheter closure (TCC) of ostium secundum atrial septal defect. A single-centre retrospective study of patients with ostium secundum ASD who underwent balloon-assisted TCC. **Results:** This study included 36 patients. Thirty-three out of 36 patients with ASD-II and complex morphological features underwent successful BAT TCC. Our cohort of patients had a high prevalence of inadequate/floppy Aortic (90%), Posterior (40%) and Superior/Right upper pulmonary vein (25%) rims. Procedural success was defined as stable device position on post-procedure echocardiogram at 24-48 hours with no residual shunt. BAT was successful in 33 out of 36 patients (91.6%). The mean ASD size with BAT success was 27 mm. BAT was unsuccessful in 3 out of 36 patients. The combined deficiency and floppy nature of the Aortic, Superior, and Posterior rims was the reason for the failure of the Balloon-assisted technique along with the large size of ASD-II. BAT-failed patients were referred for emergent surgical device retrieval and closure of the atrial septal defect. No procedure-related mortality was encountered. **Conclusions:** Balloon-assisted device closure of ASD had a 90% success rate. BAT is a safe and effective technique in patients with large ASD-II. This technique enables controlled device delivery and alignment when conventional techniques fail.

Key words: balloon assisted technique, transcatheter device closure, ostium secundum atrial septal defect

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Background

Secundum Atrial septal defects (ASD-II) represent about 10% of congenital heart disease [1]. Surgical closure is a safe and effective procedure for all types of ASDs (ostium secundum, ostium primum, sinus venosus, and coronary sinus [2]. Transcatheter closure (TCC) for ASD-II has been a valid and common alternative treatment for more than two decades for adults and children [3]. Different studies have commented on what constitutes a large ASD-II ranging from ≥ 25 mm along the long axis [4-6]. Sometimes, we encounter very large defects (≥ 35 mm). Management of such large and very large ASD can pose a significant challenge.

ASD-II with more than 25 mm size are considered a risk factor for transcatheter closure [5]. However, data exist on large and very large ASDs that were successfully dealt with using the transcatheter route by employing modified techniques [5, 6]. Balloon-assisted technique (BAT) is one such technique that would increase the likelihood of successful outcomes for TCC of very large ASDs compared to conventional techniques (CT).

Material and methods

We conducted a retrospective study using BAT in TCC of large ASDs over the past 11-year period (January 2011 to December 2021) in our institution. Our study also looked at the different morphological features that may affect the successful outcomes of TCC. All patients who were referred for transcatheter closure were initially evaluated with a transthoracic echocardiography (TTE) followed by transoesophageal echocardiogram (TEE) if feasible. Thirty-six patients opting for TCC and who underwent balloon-assisted technique for transcatheter closure of ASD were included. This being a retrospective study consent for procedure had already been taken. These patients were included as per the prerequisites of device closure techniques and hence other patients were excluded.

Data collection was done after the institute's ethics committee approved it. This retrospective study included detailed TTE and TEE assessments of ASD and their morphological features in each patient based on hospital records. Cardiac catheterization findings were also noted. Follow-up data was analysed at the patients' last visit to the clinic, and data collected included the patients' clinical profiles and TTE studies.

TTE and TEE imaging of the defects has been done. TTE assessment of ASD includes size and rims of the atrial septal defect. Rims assessed were the Superior/Right upper pulmonary vein rim, Posterior rim, AV valve/Mitral rim, Aortic rim, Superior vena cava (SVC) rim and Inferior vena cava (IVC) rim. The nomenclature of rims was used as described in the 2015 American Society of Echocardiography guidelines (7). TEE assessment included sweeping from 0-120 degrees in addition to the standard imaging angles at 0, 30, 45 and 90 degrees. TEE was done by the interventionist in appropriate patients. TEE was deferred in paediatric patients. The procedure for adult patients was done under local anaesthesia and for paediatric cases under general anaesthesia. Heparin was administered at 100 U/kg and activated clotting time was maintained between 250-300 seconds during the procedure. Balloon sizing of atrial septal defect was done in 31 patients out of 36 patients (86%).

Conventional techniques (CT) were initially tried in all the 36 cases. Conventional techniques attempted in sequential order included deployment from the left atrium (LA), left pulmonary vein deployment and right pulmonary vein deployment. BAT was used as the last option in all the 36 cases when the above conventional techniques failed. Right femoral venous access was used as the primary access in all the cases. The same sizing balloon inflated partially was kept across the ASD from contralateral femoral vein access. The device was then delivered from the left upper/right upper pulmonary vein/left atrium with the inflated balloon in situ across the atrial septal defect. The LA disc was deployed, and the whole assembly was pulled back against the septum. By doing this, the use of a balloon prevents prolapse of the LA disc into the right atrium (RA), thereby allowing the RA disc to be deployed over the right side of the interatrial septum. After checking the position of the discs on their respective sides of the septum under TTE and fluoroscopy support, the operator deflates the balloon slowly. As the balloon is gradually deflated the discs realign themselves. The balloon is wholly and slowly pulled out of the septum, the wire is then gently removed, and the device position is reconfirmed. After confirming the device position by TTE and fluoroscopy, the stability of the device is ensured by gentle Minnesota wiggle before it is released. Following deployment, no or minimal shunt was considered a successful result. The LA disk, after deployment, used to transiently deform significantly, but as soon as the balloon was deflated, the LA disk assumed its shape (Figure 1).

The Amplatzer septal occluder (Abbott cardiovascular), Memopart ASD occluder (Lepu Medical), and Lifetech (Lifetech) ASD occluders were used, and the sizing balloon (Equalizer) from Boston Scientific was used for the BAT. The equalizer balloon is a 0.035 guide wire compatible double-lumen catheter with radio-opaque marker bands.

Post-procedure, all patients underwent a TTE 24 - 48 hours after the procedure to look for device position, presence of residual shunt, and improvement of

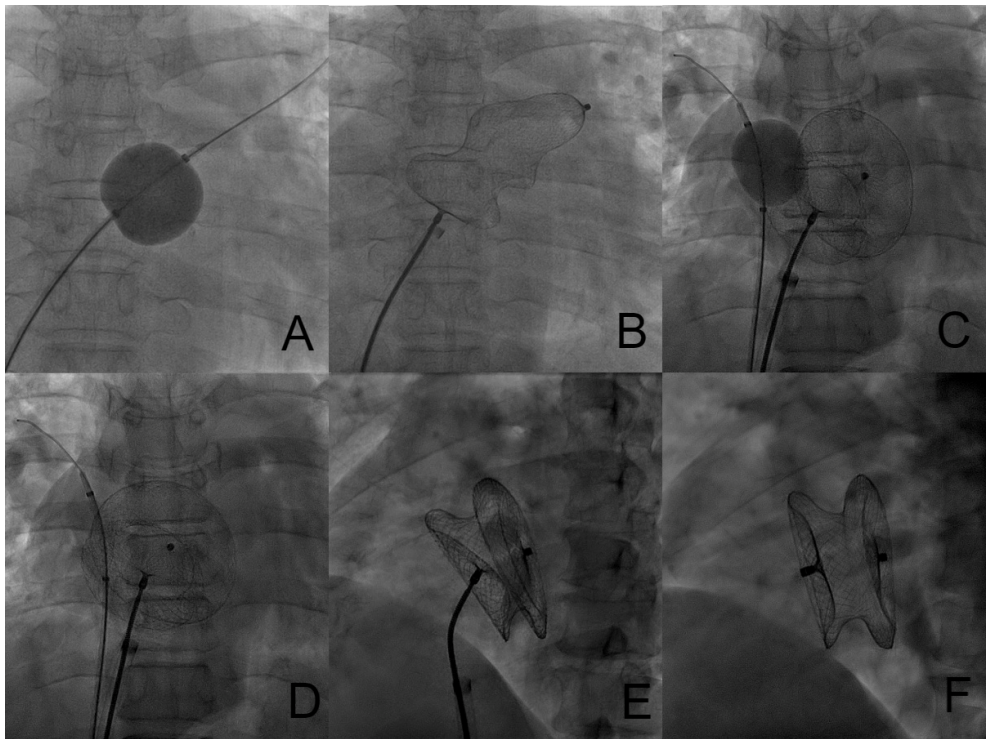

Fig. 1. Serial fluoroscopic images of balloon-assisted device closure of ASD-II. (A) Balloon sizing of the defect with balloon kept inflated across the defect; (B) Attempted left upper pulmonary vein deployment; (C) Balloon-assisted delivery of closure device; (D) The LA disk assumed its shape as the balloon was deflated; (E) Device in good position after complete deflation and withdrawal of the balloon; (F) Device deployed. Abbreviation: ASD-II, Ostium secundum atrial septal defect.

right ventricular systolic pressure and any complications. Procedural success was defined as stable device position on post-procedure echocardiogram at 24-48 hours with no residual shunt. Patients came for their first follow-up at 6 months, then on a yearly basis, with TTE done at each visit. Few patients have been lost to follow-up due to the COVID-19 pandemic.

Statistical analysis

Continuous data was reported as mean ± standard deviation (SD) or median interquartile range (IQR). For categorical data, the number of patients and percentage were presented. All analyses used the Statistical Package for Social Sciences (SPSS) software Version 21.0 (Armonk, NY: IBM Corp).

Results

Thirty-six patients who underwent Balloon-assisted TCC of ASD-II during the period from January 2011 to December 2021 were included in our study. Baseline characteristics of the patients are presented in Table 1. Of these 36 patients, 22 (61%) were females. The mean age was 29 (SD 13.5), 8 − 53 years. Four out of 36 patients (11.1%) were paediatric patients. Dyspnoea was the most common symptom, noted in 26 patients (72.2 %). Other symptoms noted were chest pain in 22.2%, palpitations in 38.9% and presyncope in 2.8% of patients. Five patients (13.9%) were asymptomatic.

Table 1. Baseline characteristics total number of patients = 36)

Characteristics	Number of patients (%)
Age (Mean)	29
Female gender	22 (61.1)
Dyspnoea	26 (72.2)
Chest pain	8 (22.2)
Palpitations	14 (38.9)
Presyncope	1 (2.8)
Asymptomatic	5 (13.9)
Diabetes Mellitus	0 (0)
Systemic Hypertension	1 (2.8)
CAD/CKD	0 (0)
Smoking	2 (5.6)
Drugs:	
Beta-blocker	1 (2.8)
Diuretics	2 (5.6)
Chest Xray:	
Cardiomegaly (RA, RV dilatation)	34 (94.4)
PA enlargement	34 (94.4)
Pulmonary plethora	36 (100)
Electrocardiogram:	
Right axis deviation	16 (44.4)
Normal axis	20 (55.6)
Right bundle branch block	33 (91.7)
Crochetage sign	30 (83.4)
Right atrial enlargement	29 (80.6)
Right ventricular hypertrophy	24 (66.7)

Chest X-ray (CXR) showed cardiomegaly in most patients with a mean cardiothoracic ratio of 56%. Two patients (5.6%) did not have cardiomegaly on CXR. Chamber enlargement (RA and RV) was noted in 34 (94.4%) of patients. Pulmonary artery (PA) enlargement was reported in 34 (94.4%) patients. Pulmonary blood flow was increased in all patients. An electrocardiogram (ECG) was done for all patients; right axis deviation was noted in 16 (44.4%) patients with right bundle branch block in 33 (91.7%) patients. Crochetage sign was seen in 30 (83.4%) patients. Right atrial enlargement and right ventricular hypertrophy were noted in 29 (80.6%) and 24 (66.7%) patients, respectively.

Balloon sizing of the ASD was done in 31 (86.1%) patients. In the remaining five patients, TCC was attempted based on TEE findings. A good correlation was noted between fluoroscopy waist measurement and stop flow echo. Complications related to BAT were not observed in our study. Right femoral vein access was used for TCC in all patients. Left femoral vein access was used for balloon support. PA pressure was normal in 23 (64%) patients, and elevated PA pressures due to increased pulmonary blood flow was noted in the remaining 13 patients (36%) (Table 3).

BAT-assisted device closure was successful in 33 out of 36 patients (91.6%). Table 2 shows the rims of ASD in 36 patients. More than 90% of the patients had floppy or inadequate (≤ 5 mm) Aortic rim, 40% had floppy or inadequate (≤ 5 mm) Posterior rim, and the Superior rim was floppy or inadequate (≤ 5 mm) in 25% of patients. The mean ASD size was 27.1 mm, and the mean device size was 33.4 mm. Table 3 shows the number of ASD devices deployed successfully with the balloon-assisted technique.

Table 2. ASD rims – TEE/TTE (total number of patients = 36)

Rims	Number of patients (%)
Superior (right upper pulmonary vein) > 5 mm ≤ 5 mm	 27 (75) 9 (25)
AV valve (Mitral) > 5 mm ≤ 5 mm	 35 (97.2) 1 (2.8)
Aortic > 5 mm) ≤ 5mm	 3 (8.4) 33 (91.6)
Posterior > 5 mm ≤ 5 mm	 21 (58.4) 15 (41.6)
Superior vena cava (SVC) > 5 mm ≤ 5 mm	 32 (88.9) 4 (11.1)
Inferior vena cava (IVC) > 5 mm ≤ 5 mm	 34 (94.5) 2 (5.5)

Table 3. BAT Procedure details (total number of patients = 36)

Variables	Number of patients (%)
PA pressure (mean/mmHg) < 20 – 20-40 – > 40 –	 23 (64) 11 (30.5) 2 (5.5)
Balloon sizing Yes	 31(86.1)
ASD occluder Amplatzer Lifetech Memopart	 8(22.2) 21(58.3) 7(19.4)

BAT failure

BAT was unsuccessful in three patients. The size of ASD-II in BAT-failed patients was 28mm, 38mm and 40mm. One patient developed palpitations 4 hrs after the procedure, an echocardiogram showed an embolised device across the Tricuspid valve. In the other two patients, embolised device was incidentally detected in the RVOT (right ventricular outflow tract) when a post-procedure echocardiogram was performed 24 hours after the procedure. Emergency surgical retrieval of the embolised device and patch closure were done within 6 hours in all three BAT-failed patients. In 2 out of 3 BAT failed patients, Aortic and superior rims were deficient, and the posterior rim was floppy. The posterior and aortic rims were deficient in the third patient, but the superior rim was floppy. We believe that the combined deficiency and floppy nature of the aortic, superior, and posterior rims was the reason for the failure of the Balloon-assisted technique along with the large size of ASD-II. Percutaneous device retrieval or upsizing the device was not considered as the operators were of the opinion that deficiency of the above rims would make it not amenable to closure even with a larger device. Hence these 3 patients were referred for device retrieval and surgical closure of atrial septal defect.

Complications

There was no procedure-related mortality. Coronary air embolism or cardiac tamponade were not encountered. As the patients were subsequently followed up, other complications, like late embolisation of the device or worsening of tricuspid regurgitation or aortic regurgitation, were not observed.

Follow-up outcomes

The follow-up period for the study was between 6 months – 5 years. Twenty out of 33 successful BAT patients came for follow-up. All patients who came for follow-up were clinically better and asymptomatic. Five out of 20 patients (25%) had only 6 months follow-up post-procedure, 12 out of 20 patients (60%) remained on follow-up at 1 year, and 3 out of 36 patients (15%)

remained on follow-up at 5 years. Echocardiography at follow-up showed that the device was stable in all these patients. Right ventricular systolic pressure in all patients was below 40 mmHg, and the grade of tricuspid regurgitation was either trace or mild at follow-up on echocardiograms in all these patients. None of them had any signs of erosion or progressive mitral regurgitation. No new arrhythmias or stroke were reported. Telephone follow-up was done for the remaining 13 patients, who were clinically better.

Table 4. Follow-up details (total number of patients = 20)

Variables	N (%) patients
Clinical follow up	
6 months-1 year	5(25)
1-5 years	12(60)
> 5 years	3(15)
Echocardiographic follow up	
Stable device	20(100)
Complications	0(0)

Discussion

Our study demonstrated marked success in managing TCC of ASD-II using BAT in more than 90% of the cases. The cases taken up for BAT were the ones where conventional techniques were unsuccessful. Our patients had a high prevalence of complex morphological features like deficient or floppy Aortic rim (90%), Posterior rims (40%), and Superior rim (25%). In most of the patients balloon sizing was done prior to choosing the device. The patients underwent imaging (TTE and TEE) in the presence of the interventionist. We excluded ASD-II with size of ≥ 44 mm. The mean defect size in our series was larger than the previously published series by Nazmi et al. (27 vs. 19 mm) and smaller than Dalvi et al. (27 vs. 33 mm) [6]. Cases with completely deficient IVC rims were not attempted in this series. BAT was unsuccessful in 3 patients and required surgical intervention and retrieval of embolised device. BAT with sizing balloon for large ASD have been published earlier [5, 6, 15]. The wire position for BAT was randomly chosen from either the left or right pulmonary vein or the left atrium. We used the balloon support from the left femoral vein and delivery sheath from the right femoral vein in all patients. In cases with large ASD-II with a small LA size, the LA disc often prolapses into the RA [6]. In such cases with small LA size, the pulmonary vein (either upper, middle left or right upper) deployment technique may be helpful, as a small LA with a large device ensures stretching of the device [8, 9]. In cases with a malaligned septum, the rims have different orientations when placing the device, and it may be difficult to position the device correctly. Hence, the pulmonary vein deployment technique is not always successful. The BAT helps in proper alignment in the malaligned septum by allowing the left atrial disc to remain open over the left side of the septum while the right atrial disc fans out over the right atrial side of the septum. This essentially helps the device to "stent" the defect. As the balloon is deflated slowly and withdrawn from the septum, the discs on either side tend to realign to seal the defect. Despite all the manoeuvres, the essence of a successful outcome lies in properly aligning the device with respect to the defect and surrounding structures. The device alignment and disc movement are facilitated by balloon [6]. Successful closure of a complex ASD is dependent on anatomical assessment with appropriate imaging techniques [8-11]. In patients having complex anatomical substrate it is better to delineate the anatomy prior to planning intervention [11]. In cases having deficient or absent retro aortic tissues along with deficient posterior rims positioning the device may prove challenging. Late device erosion has been reported [12, 13], but we did not come across erosion in our series. Our study did not report erosion, residual shunt, arrhythmia, or stroke on follow-up.

Our technique was different to the technique proposed in earlier published series. The balloon catheter used in our series was an equalizer balloon (circular balloon catheter), which is different from the Nazmi series [14] (Tyshak II balloon). In our series, the septal occluders used were different (Lifetech, Amplatzer and memopart). The procedural success rate was 90%, similar to the previously published series by Pillai et al. [15]. Follow-up cannot be compared to previous studies since we lost follow-up of a few patients due to the COVID-19 pandemic.

Limitations

Our study is not devoid of limitations, the major limitation being its retrospective design. Our study's small sample size and retrospective nature may be insufficient for identifying different morphological features associated with conventional techniques' failure where BAT could be useful. Follow-up data of all patients are not available partly due to the COVID-19 pandemic; hence, complications may have been missed. Therefore, prospective studies with good sample sizes are needed in future.

Conclusions

Balloon-assisted device closure of ASD had a 90% success rate. BAT is a safe and effective technique in

patients with large ASD-II. This technique enables controlled device delivery and alignment when conventional techniques fail.

List of abbreviations:

ASD-II – Ostium secundum Atrial septal defect
TCC − Transcatheter closure
BAT − Balloon-assisted technique.
CT − Conventional techniques
TTE − Transthoracic echocardiography
TEE − Transesophageal echocardiogram
SVC – Superior vena cava
IVC – Inferior vena cava
LA − Left atrium.
RA − Right atrium
IQR − Interquartile range
SPSS – Statistical Package for Social Sciences
SD – Standard deviation
CXR − Chest Xray
RV – Right ventricle
ECG − Electrocardiogram
CAD – coronary artery disease
CKD – chronic kidney disease
PA – Pulmonary artery

No conflict of interest was declared

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