Corrected balloon occlusive diameter to determine device size during percutaneous atrial septal defect closure

Perkütan atriyal septal defekt kapaması esnasında cihaz boyutunu belirlemede düzeltilmiş balon okluziv çap

Şakir Arslan, M.D., Göksel Çağırcı, M.D., Nermin Bayar, M.D., Erkan Köklü, M.D., İsa Öner Yüksel, M.D., Selçuk Küçükseymen, M.D., Zehra Erkal, M.D., Çağın Mustafa Üreyen, M.D., Fuat Gündoğdu, M.D.,[#] Yekta Gürlertop, M.D.,[*] Mustafa Kemal Erol, M.D.,[†] Naci Ceviz, M.D.[‡]

Department of Cardiology, Antalya Training and Research Hospital, Antalya
[#]Department of Cardiology, Atatürk University Faculty of Medicine, Erzurum
[*]Department of Cardiology, Trakya University Faculty of Medicine, Edirne
[†]Department of Cardiology, İstanbul Kemerburgaz University Faculty of Medicine, İstanbul
[‡]Department of Pediatric Cardiology, Atatürk University Faculty of Medicine, Erzurum

ABSTRACT

Objective: The aim of this trial was to investigate the impact of corrected balloon occlusive diameter (cBOD) on successful performance of percutaneous atrial septal defect (ASD) closure.

Methods: The trial comprised 86 patients (60 female, 26 male; mean age 36.5±14.3) on whom percutaneous ASD closure was performed. Patients were evaluated using transesophageal echocardiography (TEE). Relation of the defect to surrounding tissues and size of rims was also investigated. Balloon sizing was performed intraoperatively on all patients. Size of device was ascertained according to both durability of rims and whether or not they formed significant indentation, both of which determine cBOD.

Results: The ASD closure device was successfully implanted in 84 (97.5%) patients. Mean maximum defect size was 17.4±5.9 mm, and mean color flow diameter was 16.8±5.4 mm. Mean maximum defect size at the moment of loss of shunt flow was 18.4±5.9mm with TEE, and 18.8±6.1mm with fluoroscopy. Mean size of Amplatzer occluder device was 20.0±6.5mm. Device embolization was observed in 2 patients. However, no death occurred during or after the procedure.

Conclusion: Percutaneous secundum ASD closure is a safe and effective treatment modality in experienced centers. Utilizing corrected balloon occlusive diameter may be of benefit in deciding the size of ASD occluder device.

ÖZET

Amaç: Bu çalışmada amacımız perkütan atriyal septal defekt (ASD) kapaması konusunda kliniğimizin deneyimlerini paylaşmak ve ayrıca 'düzeltilmiş balon okluziv çap'ın işlem başarısına etkisini araştırmaktır.

Yöntemler: Çalışmaya perkütan ASD kapaması yapılan 86 hasta (60 kadın, 26 erkek; ortalama yaş 36.5±14.3) alındı. Hastaların işlem öncesi transözofajiyal ekokardiyografi (TÖE) ile işleme uygunluğu, defektin komşu yapılarla ilişkisinin yanı sıra rimlerin boyutu ile floppy olup olmadığı değerlendirildi. Hastaların tamamına işlem esnasında balon sizing yöntemi uygulandı. Kullanılacak cihazın ölçüsünde, rimlerin sağlamlığına ve belirgin indentasyon oluşturup oluşturmamasına göre belirlenen düzeltilmiş balon okluziv çap dikkate alındı.

Bulgular: Hastaların 84'ünde (%97.5) başarılı olarak ASD kapama cihazı yerleştirildi. TÖE incelemesinde en yüksek defekt çapı ortalaması 17.4±5.9 mm, renkli akım genişliği ortalaması 16.8±5.4 mm saptandı. Perkütan işlem esnasında TÖE'de şant akımının kaybolduğu andaki ortalama defekt çapı TÖE ile 18.4±5.9 mm, floroskopik olarak 18.8±6.1 mm ölçüldü. Kullanılan Amplatzer occluder cihaz boyutu ortalaması 20.0±6.5 mm idi. İki hastada cihaz embolizasyonu oldu. İşlem esnasında veya takipte ölüm olmadı.

Sonuç: Sekundum tip ASD'lerin perkütan kapatılması tecrübeli merkezlerde güvenli ve etkili bir tedavi yöntemidir. Kapatma esnasında kullanılacak cihazın ölçüsünün belirlenmesinde düzeltilmiş BOD'nin kullanılması faydalı olacaktır.

Received: November 08, 2014 *Accepted:* January 16, 2015

Correspondence: Dr. Nermin Bayar. Öğretmenevleri Mah., 914. Sokak, 19ç Cadde, Fetih Konakları, B Blok, Daire: 5, 07100 Konyaaltı, Antalya.
Tel: +90 242 - 249 44 00 e-mail: dr.nermin@mynet.com

ASD is the most common congenital heart disease.[1] Due to potential long-term complications, treatment is recommended on diagnosis. Percutaneous ASD closure is a favorable alternative to surgery in appropriate patients. Selection of correct size of occluder device is vitally important for success of the procedure and long-term prognosis. B-mode diameter and color flow diameter measured with echocardiography and echocardiographic and fluoroscopic diameters during balloon sizing are used in determining device size.[2,3]

This trial shares the authors' experience concerning percutaneous ASD closure and outlines the results of using corrected balloon occlusive diameter in determining occluder device size.

METHODS

The trial included 86 patients aged >18 years from two separate centers between May 2008 and April 2014, and was approved by the local Ethics Committee. All procedures were performed using the Amplatzer occluder device by the same physician at the 2 centers. Patients were assessed for suitability for percutaneous closure using transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE). Cardiac dimensions, ventricular systolic functions and function of valves were evaluated, and Qp/Qs ratios and pulmonary artery pressures (4V2 + right atrial pressure) were measured. The type and size of ASD, size and mobility of rims and relevance of defect to surrounding tissues were appraised with apical four-chamber view, aortic short-axis and bicaval views of TEE. Maximal diameters were obtained from both B-mode and color flow views. The largest size was accepted as reference diameter.

Patients with pulmonary/systemic blood flow ratio ≥1.5 and right ventricular dilatation and pulmonary artery pressure/systemic arterial pressure <2/3 were included in the trial. ASD closure was not performed to patients with sinus venosus defect, primum ASD or additional cardiac disease necessitating surgery.

Cardiac catheterization was performed on all patients to measure intracardiac pressures and shunt ratio. The left femoral artery was catheterized with a 6F sheath, and the right femoral vein with a 7F sheath. Unfractionated heparin 100 unit/kg was administered to all patients. A 6F NIH catheter was advanced through the right atrium, right ventricle and pulmonary artery and pressure records of the right cardiac chambers were obtained. Blood gas samples were taken from the pulmonary artery and superior and inferior vena cava. The catheter was then advanced to the left atrium via the ASD and left atrial pressure was monitorized. The right upper pulmonary vein (RUPV) was then catheterized and a blood gas sample obtained. The shunt from left atrium to right atrium was visualized after injection of a contrast agent into the RUPV at the left anterior oblique position. Following detailed assessment, patients were given general anesthesia and the TEE probe was intubated. TTE was used in only 2 patients with local anesthesia. All others were administered general anesthesia. Defect diameter and rims were measured.

Abbreviations:

ASD	*Atrial septal defect*
BOD	*Balloon occlusive diameter*
cBOD	*Corrected balloon occlusive diameter*
LUPV	*Left upper pulmonary vein*
RUPV	*Right upper pulmonary vein*
SBD	*Stretched balloon diameter*
TEE	*Transesophageal echocardiography*
TTE	*Transthoracic echocardiography*

A 6F Cournand catheter was advanced through the right femoral vein to the right atrium, from there to the left atrium via the ASD, and finally to the left upper pulmonary vein (LUPV). A super stiff exchange guide wire was then advanced to the LUPV via the catheter and the catheter retrieved. After removal of the sheath in the right groin, a balloon sizing catheter was forwarded to the ostium of the LUPV via a guide wire without a sheath. The sizing balloon was inflated with contrast agent diluted with saline at a ratio of 1/3, with this method, it was understood that the balloon markers on ASD. Balloon sizing was determined by means of TEE. The balloon was inflated to cessation of shunt flow in short-axis TEE view. An average of fluoroscopic and echocardiographic defect diameters was calculated, and this became balloon occlusive diameter (BOD). During the procedure, a 24 mm balloon was used if the reference defect diameter was 20 mm or less, and a 34 mm AMPLATZER® Sizing Balloon II was used if it was greater than 20 mm.

Corrected balloon occlusive diameter (cBOD), which was determined by durability of rims and formation of indentation, was of assistance in deciding device size. If indentation of the inflated balloon was bilateral, the measured diameter was used as device diameter. In the event of unilateral indentation or bi-

lateral minimal indentation, 2 mm was added to the measured defect size when the defect was smaller than 20 mm, and 4 mm added when the defect was 20 mm or larger. In instances, where unilateral complete indentation on one side and minimal indentation on the other, 1 mm was added to the measured defect size when the defect was smaller than 20 mm, and 2 mm added when the defect was 20 mm or larger. This correction of device size was called cBOD. An AMPLATZER® device was implanted to all patients. Determination of device size is demonstrated in Figure 1.

The balloon catheter was then retrieved. The delivery system, including sheath and dilatator, was advanced through the LUPV over the guidewire, and then dilatator and guidewire were withdrawn completely. The occluder device was loaded into the system and forwarded toward the end of the sheath with care taken to prevent an air embolism. The system was withdrawn slightly and the sheath withdrawn to open the left side of the device while keeping it fixed. The system was then withdrawn a little to rest the left wing of the device on the atrial septum. This position was confirmed by TEE, and the sheath was further retrieved to liberate the right wing of the device at the left anterior oblique cranial (left 35, cranial 35) position. After checking that the rims were inside the device, it was left on the septum. Patients were discharged after 24 hours of surveillance and control echocardiography. Acetylsalicylic acid of 300 mg and 75 mg of clopidogrel were prescribed for 6 months post-procedure. Patients were followed up with electrocardiogram, echocardiography and clinically at first and sixth month.

Statistical analysis

Data were analyzed with the SPSS software version 16.0 for Windows. Variables were presented as mean±standard deviation.

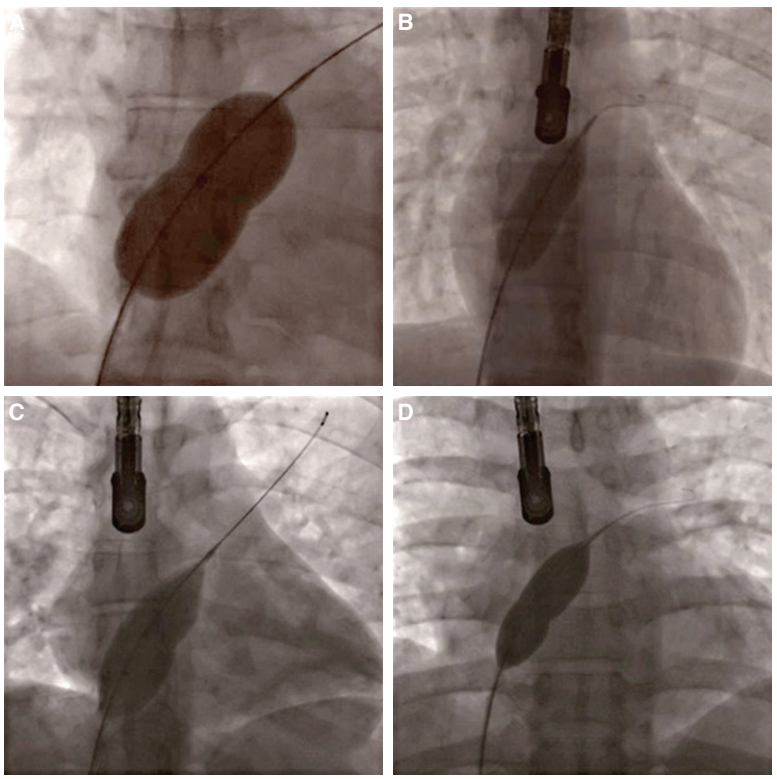

Figure 1. **(A)** Complete indentation was seen. BOD was measured as 24mm and 24 mm device was implanted. **(B)** Bilateral minimal indentation was demonstrated. BOD was 19.5 mm and 24 mm device was implanted. **(C)** Unilateral indentation was shown, on the contrary, any indentation on the contralateral side was not seen. BOD was 21.4 mm and 26 mm device was implanted. **(D)** Unilateral significant indentation and contralateral minimal indentation was demonstrated. BOD was 14 mm and 15 mm device was implanted.

RESULTS

Eighty-six patients (60 female, 26 male; mean age 36.5±14.3) were enrolled in the trial. Mean defect size measured with TEE was 15.8±5.8 mm in the four-chamber view, 14.6±6.1 mm in the aortic short-axis view, and 16.1±5.6 mm in the bicaval view. Mean maximum defect size was 17.4±5.9 mm and color flow diameter was 16.8±5.4 mm. Patients' demographics and echocardiographic parameters before procedure are shown in Table 1.

A single occluder device was implanted to all patients successfully, although one patient had 2, and a second had 3 defects. In these 2 patients, the central and largest defect was occluded, with peripheral defects also successfully occluded by the wings of the same device.

Despite all possible maneuvers being attempted, the device could not be implanted in 2 patients because the aortic rims were too short (1–2 mm) and the defects larger than 3 cm. These defects were repaired surgically. Overall success of the procedure was 97.5%.

No death occurred among the patients who underwent transcatheter-based closure of an ASD during hospital stay or after discharge. No complication arose except device embolization in 2 patients (2%). In the first of these, the posteroinferior rim was too floppy and short (4 mm). Device embolization to pulmonary artery after 2 hours of procedure was seen although defect size measured by sizing balloon was 28 mm and a 32 mm device had been implanted. The device was removed and the defect was repaired surgically owing to unstable hemodynamics in the patient. This patient has been under follow-up for 3 years without any complaint. In the second case of embolization,

Table 1. Demographic, echocardiographic and ASD characteristics of patients

	Cases (n=86)		
	n	%	Mean±SD
Age (years)			36.5±14.3
Female gender	60	69.7	
Ejection fraction (%)			62.8±3.9
Left ventricle end-diastolic diameter (mm)			44.3±4.0
Left ventricle end-systolic diameter (mm)			26.8±4.2
Left atrium diameter (mm)			35.1±5.1
Right atrium diameter (mm)			39.8±5.8
Right ventricle diameter (mm)			40.3±7.1
Pulmonary-to-systemic blood flow (Qp/Qs)			2.0±0.5
Pulmonary artery pressure (mmHg)			44.2±3.2
Left atrial pressure (mmHg)			6.6±3.0
Right atrial pressure (mmHg)			4.6±2.7
Transesophageal echocardiography-derived max defect size (mm)			17.4±5.9
Transesophageal echocardiography-derived mean defect size (mm)			15.5±5.4
Transesophageal echocardiography-derived defect size (4 chamber, mm)			15.8±5.8
Transesophageal echocardiography-derived defect size (aortic short axis, mm)			14.6±6.1
Transesophageal echocardiography-derived defect size (bicaval, mm)			16.1±5.6
Transesophageal echocardiography-derived max color flow diameter (mm)			16.8±5.4
Fluoroscopy-derived corrected balloon occlusive diameter (mm)			18.8±6.1
TEE-derived corrected balloon occlusive diameter (mm)			18.4±5.9
Device size (mm)			20.0±6.5

SD: Standard deviation.

defect size was 1 cm. However, the interatrial septum was severely aneurysmatic. After leaving the device on the atrial septum, it was realized that it was not covering the septum completely and attempts were made to attach the device again. However, it embolized to the left atrium and then to the distal of the left subclavian artery. It was eventually withdrawn with a snare using a 10F delivery system via the contralateral femoral artery. Percutaneous ASD closure was attempted in another session and complete occlusion was obtained successfully.

One patient suffered from left arm weakness after the procedure. Detailed assessment showed that the patient's left arm had been placed under his head during general anesthesia and mild damage to the brachial plexus had occurred. At 3 months follow-up, the patient had recovered completely.

Thrombus was demonstrated in the device during implantation by means of TEE. Additional intravenous heparin was administered to the patient and the device was retrieved. After flushing with saline and washing the thrombus away, the device was implanted. No thrombus was observed at 24 hour control and first month visits, at which control TEEs were free of thrombus. No clinical embolic event occurred during 2 years follow-up.

Minimal residue was ascertained in only 2 patients. However, no residue was observed on TEE performed 1 month after the procedure.

Hematoma was seen in the groins of 2 patients at arterial entry, and in one patient's groin at venous entry. However, none necessitated surgery and recovered with medical follow-up.

Mean patient follow up duration was 14±2 months. Frequent atrial extrasystoles leading to symptoms were observed in four patients and treated with beta blockers. No additional antiarrhythmic drug was needed. Rashes were observed in 4 patients owing to acetylsalicylic acid and in one patient due to clopidogrel. Single, instead of dual, antiaggregant therapy was continued in these patients. One patient, who was implanted with a 24 mm occluder device, complained of positional chest pain until the 3rd month. His echocardiographic findings were all normal, and his complaint resolved.

Balloon sizing was performed on all patients. Mean defect size at the moment of loss of shunt flow was 18.4±5.9 mm with TEE and 18.8±6.1 mm with fluoroscopy. Mean size of Amplatzer occluder device was 20.0±6.5 mm. The smallest device size was 9 mm and the largest device size was 38 mm.

DISCUSSION

This trial shares long-term data on 86 patients who underwent percutaneous ASD closure performed by the same physician in 2 different centers. The most important features of the trial are that septal defect size was measured with balloon sizing by means of TEE and fluoroscopy in all patients, the most convenient device size was chosen according to rim durability and cBOD, and that long-term data is reported.

Selection of proper size of device is very important for successful ASD closure. If too large a size is chosen, it may result in erosion of surrounding tissues and perforation, while too small a device can cause instability, embolization or residual shunt.[4–7]

Because of the 3-dimensional structure of the atrial septum, sizing the defect from different cross sections with TEE is important to specify the size of device. TEE is vitally important to evaluate the morphology, size and rims of an ASD.[8,9] Device erosion risk is higher in patients with shorter aortic and/or superior rims.[5] Nevertheless, Li et al. reported successful ASD closures in patients with insufficient superior-anterior rim (<4 mm). In this trial, TTE was used instead of TEE and a similar complication ratio was observed, except for a mild increase in risk of device malposition. Thus, Li et al. stated that TTE might be safe, particularly in patients with a central small secundum ASD.[10] In our trial, TEE was performed before the procedure on all except 2 patients, whose ASDs were small and central and therefore closed by means of TTE.

Studies have been done to investigate the necessity of balloon sizing in percutaneous closure since the first years of the procedure.[2,11–15] Quek et al. reported that balloon sizing does not give extra information and may lead to oversizing of ASD diameter.[11] On the other hand, Vinijarnsorn et al. stated that while balloon sizing does not cause oversizing, it does not enhance success of the procedure. Estimated device size was calculated as defect size + 4.2 mm in their trial.[12] None of these trials concerned themselves

with rim structure when, in fact, one of the most important determinants of device stability, presence of residue flow or device embolization is the floppy or stiff structure of the rim. Therefore, this structure should be kept in mind while specifying device size.

Balloon occlusive diameter (BOD) and stretched balloon diameter (SBD) have been used via echocardiography and fluoroscopy for balloon sizing.[2,13,16] BOD is the balloon diameter when the shunt flow is over on echocardiography without any deformity to the sizing balloon, while SBD is the balloon diameter when indentation is present on the sizing balloon. Residue may be detected or embolization of device may occur if device size is chosen to match BOD in patients with floppy rims. On the other hand, if SBD is used, the defect may become enlarged or an oversize device may be implanted, which may lead to erosion in the long term. Therefore, to overcome these complications, BOD should be corrected according to rim durability.

Balloon sizing has been performed for many years. However, it may have some disadvantages such as arrhythmias, oversizing the defect, hypotension owing to deterioration of diastolic filling, particularly when indentation is seen or SBD is measured.[17] The aim is not to stretch the septum, which may expand the defect, and to implant the correctly sized device. Balloon sizing with cBOD was performed on all patients in this trial, and no complication due to balloon sizing was encountered.

Currently, percutaneous ASD closure can be performed with high success and low complication rates in experienced centers. Major complication rates are reported as 3–5% in various trials.[12,18–21] Our complication rate was 2%, which is compatible with the literature. There was no death resulting from the procedure. However, device embolization was detected in 2 patients, the probable cause of which were severe septal aneurysm in one and inadequate posteroinferior rim in the second. Occurrence of device embolization is known to be high, particularly in patients with a scanty posteroinferior rim.

The authors consider it advantageous to use corrected BOD during ASD closure to determine device size.

Conflict-of-interest issues regarding the authorship or article: None declared

REFERENCES

1. Chen QH, Lu L, Xu XL, Wang Q, Zhao GQ, Hu L, et al. Epidemiological survey of congenital heart disease among people aged from 4 to 18 in Haidong area of Qinghai province. [Article in Chinese] Zhonghua Yu Fang Yi Xue Za Zhi 2009;43:319–21. [Abstract]
2. Rao PS, Langhough R, Beekman RH, Lloyd TR, Sideris EB. Echocardiographic estimation of balloon-stretched diameter of secundum atrial septal defect for transcatheter occlusion. Am Heart J 1992;124:172–5. CrossRef
3. Wang JK, Tsai SK, Lin SM, Chiu SN, Lin MT, Wu MH. Transcatheter closure of atrial septal defect without balloon sizing. Catheter Cardiovasc Interv 2008;71:214–21. CrossRef
4. Divekar A, Gaamangwe T, Shaikh N, Raabe M, Ducas J. Cardiac perforation after device closure of atrial septal defects with the Amplatzer septal occluder. J Am Coll Cardiol 2005;45:1213–8. CrossRef
5. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand WE, Kleinman CS. Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects: review of registry of complications and recommendations to minimize future risk. Catheter Cardiovasc Interv 2004;63:496–502. CrossRef
6. Crawford GB, Brindis RG, Krucoff MW, Mansalis BP, Carroll JD. Percutaneous atrial septal occluder devices and cardiac erosion: a review of the literature. Catheter Cardiovasc Interv 2012;80:157–67. CrossRef
7. Du ZD, Cao QL, Rhodes J, Heitschmidt M, Hijazi ZM. Choice of device size and results of transcatheter closure of atrial septal defect using the amplatzer septal occluder. J Interv Cardiol 2002;15:287–92. CrossRef
8. Hellenbrand WE, Fahey JT, McGowan FX, Weltin GG, Kleinman CS. Transesophageal echocardiographic guidance of transcatheter closure of atrial septal defect. Am J Cardiol 1990;66:207–13. CrossRef
9. Boutin C, Musewe NN, Smallhorn JF, Dyck JD, Kobayashi T, Benson LN. Echocardiographic follow-up of atrial septal defect after catheter closure by double-umbrella device. Circulation 1993;88:621–7. CrossRef
10. Li GS, Li HD, Yang J, Zhang WQ, Hou ZS, Li QC, et al. Feasibility and safety of transthoracic echocardiography-guided transcatheter closure of atrial septal defects with deficient superior-anterior rims. PLoS One 2012;7:e51117. CrossRef
11. Quek SC, Wu WX, Chan KY, Ho TF, Yip WC. Transcatheter closure of atrial septal defects-is balloon sizing still necessary? Ann Acad Med Singapore 2010;39:390–3.
12. Vijarnsorn C, Durongpisitkul K, Chanthong P, Chungsomprasong P, Soongswang J, Loahaprasitiporn D, et al. Transcatheter closure of atrial septal defects in children, middle-aged adults, and older adults: failure rates, early complications; and balloon sizing effects. Cardiol Res Pract 2012;2012:584236.
13. Hajizeinali A, Sadeghian H, Rezvanfard M, Alidoosti M, Zoroufian A, Volman MA. A comparison between size of the

occluder device and two-dimensional transoesophageal echocardiographic sizing of the ostium secundum atrial septal defect. Cardiovasc J Afr 2013;24:161–4. CrossRef

14. Gupta SK, Sivasankaran S, Bijulal S, Tharakan JM, Harikrishnan S, Ajit K. Trans-catheter closure of atrial septal defect: Balloon sizing or no Balloon sizing - single centre experience. Ann Pediatr Cardiol 2011;4:28–33. CrossRef
15. Tzifa A, Gordon J, Tibby SM, Rosenthal E, Qureshi SA. Transcatheter atrial septal defect closure guided by colour flow Doppler. Int J Cardiol 2011;149:299–303. CrossRef
16. Zhu W, Cao QL, Rhodes J, Hijazi ZM. Measurement of atrial septal defect size: a comparative study between three-dimensional transesophageal echocardiography and the standard balloon sizing methods. Pediatr Cardiol 2000;21:465–9. CrossRef
17. Harikrishnan S, Narayanan NK, Sivasubramonian S. Sizing balloon-induced tear of the atrial septum. J Invasive Cardiol 2005;17:546–7.
18. Huang TC, Hsieh KS, Lin CC, Lee CL. Clinical results of percutaneous closure of large secundum atrial septal defects in children using the Amplatzer septal occluder. Heart Vessels 2008;23:187–92. CrossRef
19. Abdi S, Kiani R, Momtahen M, Basiri HA, Maadani M, Abdolrahimi S, et al. Percutaneous device closure for secundum-type atrial septal defect: short and intermediate-term results. Arch Iran Med 2012;15:693–5.
20. Chen CY, Lee CH, Yang MW, Chung HT, Hsieh IC, Ho AC. Usefulness of transesophageal echocardiography for transcatheter closure of ostium secundum atrial septum defect with the amplatzer septal occluder. Chang Gung Med J 2005;28:837–45.
21. Yüce M, Ozer O, Cakıcı M, Sarı I, Davutoğlu V, Doğan A, et al. Closure of secundum atrial septal defects by the Amplatzer occluder device. [Article in Turkish] Turk Kardiyol Dern Ars 2011;39:35–40.

Key words: Angioplasty, balloon; atrial septal defects; corrected balloon occlusive diameter; echocardiography.

Anahtar sözcükler: Anjiyoplasti, balon; atriyal septal defektler; düzeltilmiş balon oklüziv çap; ekokardiyografi.