Eight-French Intracardiac Echocardiography

– Safe and Effective Guidance for Transcatheter Closure in Atrial Septal Defects –

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Background: Intracardiac echocardiography (ICE) was introduced as a new guidance system for transcatheter closure of secundum atrial septal defect (ASD) with Amplatzer septal occluder® (ASO). The aim of this study was to investigate the clinical outcome of ICE-guided transcatheter closure of ASD compared with the trans-esophageal echocardiography (TEE)-guided method.

Methods and Results: From May 2003 to April 2010, 560 patients who underwent transcatheter closure of ASD using ASO in a single institute were analyzed retrospectively. In the TEE-guided group (n=237), all the patients underwent general anesthesia. The median age was 24.2 years (range, 14 months–63 years) and the average weight was 42.3±21.6 kg (range, 8.2–82 kg). One patient underwent surgery due to migration of device. The remaining 236 patients underwent the procedure successfully without significant complication. In the ICE-guided group (n=323), the median age was 30.5 years (range, 7 months–75 years). One patient underwent surgery because of mitral valve encroachment by left atrial disk after device placement. Another patient also underwent surgery due to device embolization. The remaining 321 procedures were performed successfully without major complications. Procedure time was 104.2 min and 87.7 min, respectively (P<0.001).

Conclusions: ICE-guided ASD occlusion with ASO is safe and effective and provides accurate anatomical information, sufficient to perform the procedure. In addition, there were benefits of avoidance of general anesthesia, and shorter procedure time. (*Circ J* 2012; **76**: 2119–2123)

Key Words: Atrial septal defect; Heart; Intracardiac echocardiography; Transcatheter closure

There have been many developments and changes in percutaneous interventional treatment of congenital heart disease.[1,2] In recent time, transcatheter closure of secundum atrial septal defect (ASD) using Amplatzer septal occluder® (ASO; AGA Medical, Golden Valley, MN, USA) has been reported as the standard treatment.[3–6] Transcatheter closure is usually carried out with trans-esophageal echocardiography (TEE).[7] TEE plays an important role not only in monitoring the procedure but also in evaluating anatomic characteristics of defects.[8–10] Intracardiac echocardiography (ICE) with 10-French (Fr), 5.5–10-MHz ultrasound-tipped AcuNav ICE catheter (Siemens, Mountain View, CA, USA) has been introduced as a new guidance system for transcatheter closure of ASD with ASO.[11–14]

Recently, a smaller 8-Fr, AcuNav ICE catheter has become available for clinical use, but there have been few reports comparing ICE guidance with TEE guidance during ASD closure with ASO. We investigated the clinical outcome of transcatheter closure of ASD under 8-Fr probe ICE guidance compared with TEE guidance.

Methods

Patients and Study Protocol

A retrospective analysis of patients within a 7-year period, from May 2003 to April 2010, was performed. A total of 562 patients underwent transcatheter closure of ASD at Severance Cardiovascular Hospital within this period. Two patients who underwent transcatheter closure of ASD with transthoracic echocardiographic guidance were excluded from this study. Transcatheter closure of the remaining 560 patients was performed under either TEE or ICE guidance. The patients were divided into 2 groups according to guidance modality: group 1, TEE; and group 2, ICE. Up until June 2006, all patients had TEE guidance; thereafter, ICE guidance was used. There was a total of 5 patients who underwent TEE before ASD device closure under ICE guidance. These patients were diagnosed as having
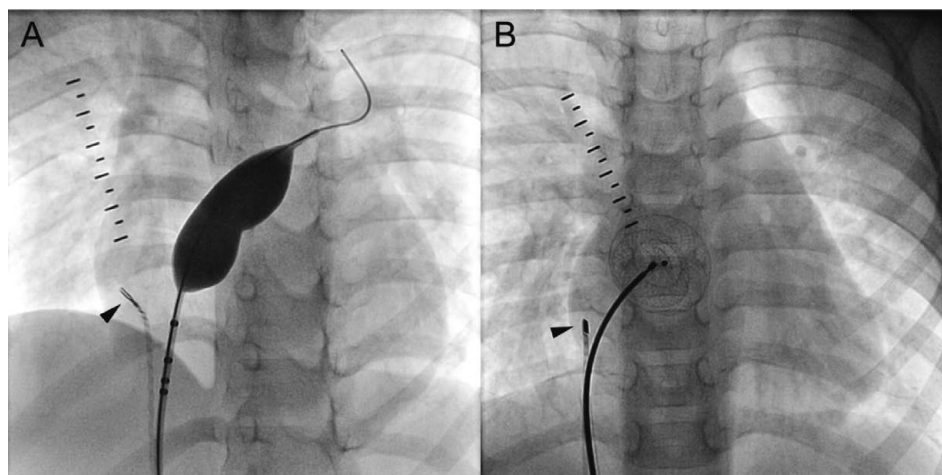
Figure 1. Fluoroscopy of intracardiac echocardiography (ICE) guidance during atrial septal defect closure. The ICE catheter (arrowheads) is placed at the right atrium. Through the different angulations of the ICE catheter, useful images are taken during (**A**) balloon sizing and (**B**) device deployment.

atrial fibrillation and TEE was used to rule out intracardiac thrombus. These patients were included in group 2. The medical records of these patients were retrospectively analyzed and the demographic data, treatment results, and complications were compared in each group.

TEE Guidance Protocol
For TEE, Philips® echocardiography equipment was used. Hemodynamic state was verified via diagnostic catheterization, and TEE was performed under general anesthesia with endotracheal intubation. All echocardiography was performed according to the recommendations of the American Society of Echocardiography.[15]

ICE Guidance Protocol
The ICE group, along with the TEE group, underwent diagnostic catheterization. If the patient was considered as a candidate for ASD closure, an ICE catheter was inserted and transcatheter closure of ASD was performed under ICE guidance. The ACUSON AcuNav™ 8-Fr ultrasound catheter (Issaquah, WA, USA) with an 8- or 8.5-Fr short sheath catheter introducer was used in all ICE group patients. In all patients, the short sheath catheter introducer was inserted through the left femoral vein. In patients weighing <10 kg, a 5-Fr short sheath catheter introducer was first used for femoral vein approach and then exchanged to an 8-Fr sheath to minimize damage to the femoral vein. The ICE catheter was placed at the right atrium through the femoral vein (**Figure 1**). After confirming the tricuspid valve at the home view position, the anatomical characteristics were confirmed, steering the probe rightward and posterior to bicaval view and long axis view. The ACUSON AcuNav™ 8-Fr ultrasound catheter, which was used in our catheterization laboratory, is a single-use, multifrequency (5–10-MHz), 64-element, linear phased array, ultrasound catheter, and this catheter is capable of tissue penetration of up to 10 cm and 4-way head articulation to allow multiple angle imaging. ICE views were acquired by guidance according to previously published basic ICE views (**Figure 2**).[5,16]

ASD Closure
All patients had diagnostic cardiac catheterization to verify hemodynamic state, and transcatheter closure of ASD was performed only when the ratio of pulmonary blood flow to systemic flow (Qp/Qs ratio) was >1.5. In order to select the most appropriate device size, echocardiographic imaging was used and, concurrently, balloon occlusive diameter or stop flow diameter was measured through balloon occlusion, and the surrounding rim lengths of the ASD were also measured. All the devices used in the current study were ASO. When the rim deficiency was too severe or when the stop flow diameter of the defect was >38 mm, device closure was declared impossible and the procedure was stopped.

Statistical Analysis
Statistical analysis was performed using SPSS version 18.0 (SPSS, Chicago, IL, USA). Continuous variables are expressed as mean±SD. Variables were compared using Student's T-test or Fisher's exact test.

Results
Of the 560 eligible subjects, TEE guidance was used in 237 patients and they were categorized as group 1. Group 2, patients who had ICE guidance, included 323 patients. Two patients, who were not included in either group, had transthoracic echocardiographic guidance. There were no statistically significant differences in age, sex, weight, height, or body surface area between the 2 groups. The minimum weight, however, was 8.2 kg in group 1 and 7.3 kg in group 2, indicating that the patients in group 2 were smaller (**Table 1**).

There were no differences between the mean balloon occlusive diameter (or stop flow diameter), with the mean being 23.0±4.0 mm in group 1 and 22.0±7.7 mm in group 2. The device size also was not statistically significantly different between the 2 groups, with the mean being 22.4±2.9 mm in group 1 and 22.3±7.6 mm in group 2. Qp/Qs ratio (2.5±0.8 in group 1 vs. 2.4±0.7 in group 2, P>0.005), and the fluoroscopy time (14.8 min in group 1 vs. 14.3 min in group 2, P>0.005) was not different between the 2 groups. The total procedure time was
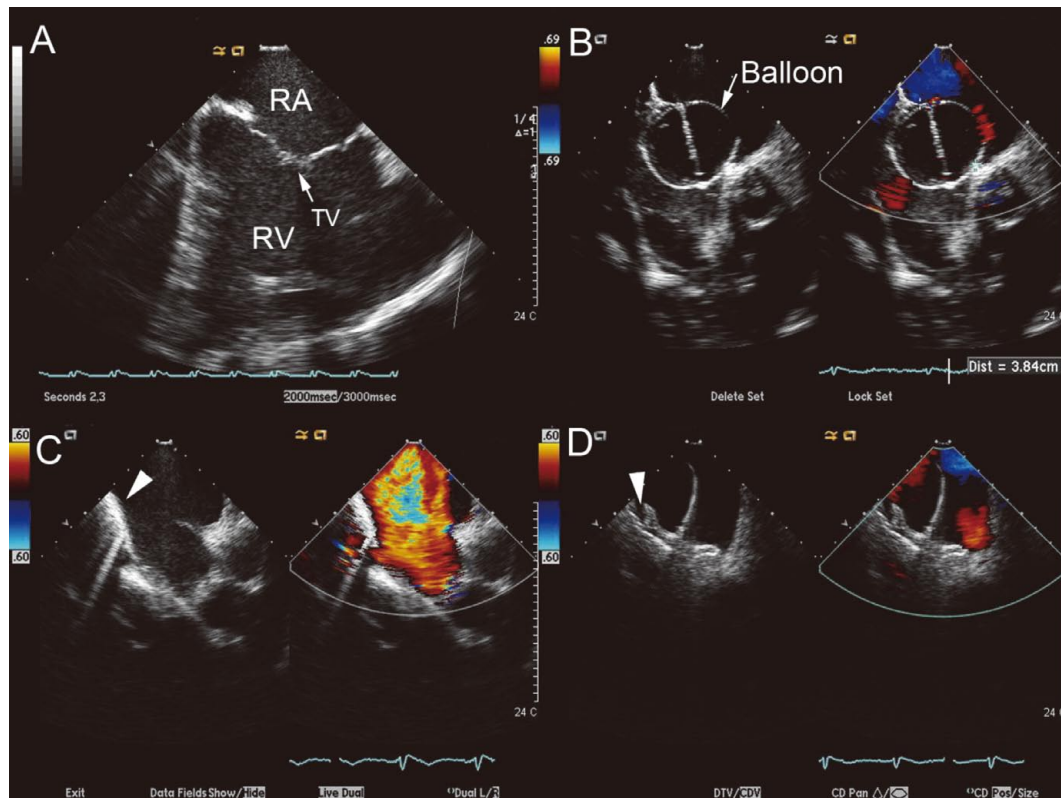
Figure 2. Various intracardiac echocardiography (ICE) views. (**A**) Home view: this view can be obtained by placing the ICE catheter in the right atrium. Therefore, this view is the standard view. RA, right atrium; RV, right ventricle; TV, tricuspid valve. (**B**) Balloon occlusion test; this can be performed successfully under ICE guidance. (**C**) Short axis view of ICE: by using ICE, anatomical characteristics of atrial septal defect (ASD) can be detected successfully. Even in patients with posterior rim deficiency (arrowhead), the procedure can be performed with sufficient imaging support. (**D**) ICE imaging has the advantage of being able to confirm the device position after transcatheter closure of ASD, especially in patients with posterior rim deficiency (arrowhead).

Table 1. Subject Characteristics

	TEE group (n=237)	ICE group (n=323)	P value
Age (years)	24.2±19.6 (1.1–63; median, 22)	28.4±21.5 (11–75; median, 35)	NS
M/F	65/172 (1/2.65)	52/111 (1/2.02)	NS
Weight (kg)	42.3±21.6 (8.2–85; median, 49)	44.6±22.4 (7.3–95; median, 53)	NS
Height (cm)	142.0±32.1 (76–185; median, 155)	140.0±32.9 (67–180; median, 155)	NS
BSA (kg/m²)	1.3±0.5 (0.31–2.02)	1.3±0.5 (0.38–2.20)	NS

Data given as mean±SD.
TEE, transesophageal echocardiography; ICE, intracardiac echocardiography; BSA, body surface area.

94.2 min in group 1 and 67.7 min in group 2, indicating that the total procedure time in group 2 was statistically significantly shorter than in group 1 (P<0.001). All the group 1 patients required general anesthesia, but none of the group 2 patients required general anesthesia with endotracheal intubation (**Table 2**).

There was no mortality in both groups, but a case of device embolism (group 1) and a case of deviant device placement (group 2), which required surgery afterwards, were noted as major complications. Two patients in group 1 and 3 patients in group 2 had mitral valve encroachment of left atrial disk after device placement. These patients were referred for surgery after

cessation of the procedure. Procedure success rate was 99.6% in group 1 and 99.4% in group 2, which was not statistically significantly different. There were 11 (4.6%) minor complications in group 1 and 12 (3.7%) in group 2. The complete defect closure rate immediately after the procedure in group 1 was 83.7%, and 84.2% in group 2. The complete defect closure rate at the latest follow-up in groups 1 and 2 was 99.0% and 98.7%, respectively (**Table 3**).

There were some minor complications, such as hematoma of catheterization site, migraine, and transient arrhythmia, but no statistical differences between the 2 groups. There was no oropharyngeal or esophageal damage by TEE probe in group 1,

Table 2. Procedure Parameters

	TEE group (n=237)	ICE group (n=323)	P value
BOD/SFD (mm)	23.0±4.0 (9–38)	22±7.7 (8–38)	NS
Device size (mm)	22.4±3.9 (10–38)	22.3±7.6 (9–38)	NS
Qp/Qs	2.5±0.8 (1.6–4.5)	2.4±0.7 (1.5–4.7)	NS
Fluoroscopy time (min)	14.8	14.3	NS
Procedure time (min)	94.2	67.7	<0.001
GEA	237	0	<0.0001

Data given as mean±SD.
BOD, balloon occlusive diameter; SFD, stop flow diameter; Qp, pulmonary blood flow; Qs, systemic blood flow; GEA, general endotracheal anesthesia. Other abbreviations as in Table 1.

Table 3. Treatment Outcome and Complications

	TEE group (n=237)	ICE group (n=323)	P value
Mortality (%)	0	0	NS
Complications, n (%)			
Major	1† (0.4)	1‡ (0.3)	NS
Minor	11 (4.6)	12 (3.7)	NS
Complete closure (%)			
At discharge	83.7	84.2	NS
Latest follow-up	99.0	98.7	NS

†Device embolization, ‡deviant device placement.
Abbreviations as in Table 1.

Table 4. Minor Complications

	TEE group (n=237), n (%)	ICE group (n=323), n (%)	P value
Hematoma	7 (3.0)	6 (1.9)	NS
Migraine	2 (0.8)	2 (0.6)	NS
Transient arrhythmia	2† (0.8)	3‡ (0.9)	NS

†One PVC and 1 atrial tachycardia; ‡1 PVC and 2 atrial arrhythmias.
PVC, pulmonary venous congestion. Other abbreviations as in Table 1.

and there was no vascular or intracardiac damage by ICE catheter in group 2 (**Table 4**).

Discussion

During interventional treatment for ASD, imaging support other than fluoroscopy, such as echocardiography, is essential for successful completion of the procedure.[7,17–21] It has previously been reported that in children with clear transthoracic echo-window, with only transthoracic echocardiographic guidance, successful device closure is possible, and advanced echocardiographic support such as TEE or ICE is unnecessary.[22] Also, there are some reports that in some circumstances, transcatheter closure of ASD can be achieved with only echocardiographic guidance and without fluoroscopy.[23] These reports assert that echocardiographic guidance plays a key role throughout the whole procedure.

TEE is seen as the gold standard for echocardiographic guidance in device closure of ASD.[9,17] Furthermore, TEE has continuously evolved and has established a solid foothold in the field of interventional cardiology for congenital heart disease. Through technical modifications, the inferior vena cava rim, once hard to visualize on TEE, can now be visualized.[24] Furthermore, 3-D TEE, which has become more popular in recent years, has provided abundant anatomical information during intervention.[25]

Rapid advances in 3-D TEE have dramatically reduced image analysis time and, as a result, even real-time 3-D TEE is now available. Real-time 3-D TEE can confirm the location of the ASD as well as the size of the defect, and also the associated anatomical structures surrounding the defect.[26] In particular, if there are multiple defects, it can visually confirm the relative location of the defects as well as the different sizes, and it can clearly demonstrate the relative location of the multiple devices during the interventional procedure.[24,25] Although there has been vast improvement in TEE technology, 1 large disadvantage is the need for endotracheal intubation during TEE-guided transcatheter closure of ASD. Consequently, additional personnel are required, including anesthesiologists, echocardiologists, and associated nurses. The procedure time will be prolonged and additional equipment will be needed for endotracheal intubation and general anesthesia. Furthermore, it can also affect hospitalization duration, resulting in a higher number of hospital days in TEE-guided patients than ICE-guided patients.

Although intravascular ultrasound was developed in the early 1970s, active clinical use has been delayed until the 21st century.[27] Currently used ICE systems are the AcuNav catheter (Biosense Webster, CA, USA), the ViewFlexcatheter (EP Medsystems, NJ, USA) and the Ultra ICE catheter (Boston Scientific, Boston, MA, USA). Among these different ICE systems, the AcuNav catheter system, which was developed from

a single-array TEE prototype probe, is most frequently used for ASD device closure. The benefits and usefulness of ICE guidance have already been reported in previous studies.[13,14,20] Recently, an 8-Fr catheter, with a 33% smaller cross-sectional area than the existing 10-Fr catheter, has been developed for clinical use with the AcuNav catheter system. With this new catheter, it is now possible to use ICE more safely in smaller children. A previous study has confirmed that in patients weighing <15 kg, a 10-Fr ICE catheter can be successfully used for intervention, with adequate image acquisition.[28] The present study also showed that compared to the already established 10-Fr catheter system, the new 8-Fr catheter system can be used in smaller patients, the smallest weighing 7.3 kg, with good image quality acquired safely and effectively. In the present study, 33 patients (10.2%) of 323 in group 2 weighed <10 kg, and all of the patients had successful procedures under ICE guidance. Also, this study has shown that although the 8-Fr ICE catheter is longer than the 10-Fr catheter, the handling of the catheter was not more difficult than that for the 10-Fr ICE catheter in acquiring sufficient images for procedure success. The single-use ICE catheter still has some disadvantages, especially with regard to cost, in percutaneous ASD closure, but the avoidance of general anesthesia reduces the need for associated personnel such as anesthesiologists and nurses, and also reduces the need for ventilation and associated equipment and space. Echocardiologists are also not needed, avoiding the need for the presence of another doctor during the procedure. Considering all these facts, the cost of hospitalization for percutaneous ASD closure with ICE is not much higher than that for TEE.[29,30] Given the regional and social characteristics, ICE guidance is possibly more efficacious, safe, and reasonably priced than TEE guidance. Furthermore, radiation exposure in the ICE-guided group was noticeably lower, which may be an advantage for both the patient and the operator.[31]

In conclusion, ICE-guided ASD occlusion with ASO is safe and effective and provides accurate anatomical information, sufficient to perform the procedure. In the ICE-guided group, there were no significant complications or limitations of information and procedure, compared with the TEE-guided group. In contrast, there were benefits of avoidance of general anesthesia, endotracheal intubation, and shorter procedure time in the ICE-guided group.

References

1. King TD, Thompson SL, Steiner C, Mills NL. Secundum atrial septal defect: Nonoperative closure during cardiac catheterization. *JAMA* 1976; **235:** 2506–2509.
2. Wang J, Wu M, Lin M, Chiu S, Chen C, Chiu H. Transcatheter closure of moderate-to-large patent ductus arteriosus in infants using Amplatzer duct occluder. *Circ J* 2010; **74:** 361–364.
3. Du ZD, Hijazi ZM, Kleinman CS, Silverman NH, Larntz K. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults: Results of a multicenter nonrandomized trial. *J Am Coll Cardiol* 2002; **39:** 1836–1844.
4. Le Gloan L, Mercier L, Dore A, Marcotte F, Ibrahim R, Mongeon F, et al. Recent advances in adult congenital heart disease. *Circ J* 2011; **75:** 2287–2295.
5. Park S, Kim NK, Kim JO, Yoo BW, Choi JY, Sul JH. Morphologic characteristics and relating factors to the need of technical modification in transcatheter closure of large atrial septal defect (≥25 mm). *Korean Circ J* 2010; **40:** 191–196.
6. Spies C, Hijazi ZM. Transcatheter closure of secundum atrial septal defects in the elderly. *Korean Circ J* 2009; **39:** 47–51.
7. Elzenga NJ. The role of echocardiography in transcatheter closure of atrial septal defects. *Cardiol Young* 2000; **10:** 474–483.
8. Cooke JC, Gelman JS, Harper RW. Echocardiologists' role in the deployment of the Amplatzer atrial septal occluder device in adults. *J Am Soc Echocardiogr* 2001; **14:** 588–594.
9. 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:** 207–213.
10. Tanoue Y, Morita S, Ochiai Y, Masuda M, Tominaga R. Impact of atrial septal defect closure on right ventricular performance. *Circ J* 2006; **70:** 909–912.
11. Hijazi Z, Wang Z, Cao Q, Koenig P, Waight D, Lang R. Transcatheter closure of atrial septal defects and patent foramen ovale under intracardiac echocardiographic guidance: Feasibility and comparison with transesophageal echocardiography. *Catheter Cardiovasc Interv* 2001; **52:** 194–199.
12. Koenig PR, Abdulla R, Cao Q, Hijazi ZM. Use of intracardiac echocardiography to guide catheter closure of atrial communications. *Echocardiography* 2003; **20:** 781–787.
13. Mullen MJ, Dias BF, Walker F, Siu SC, Benson LN, McLaughlin PR. Intracardiac echocardiography guided device closure of atrial septal defects. *J Am Coll Cardiol* 2003; **41:** 285–292.
14. Bartel T, Konorza T, Neudorf U, Ebralize T, Eggebrecht H, Gutersohn A, et al. Intracardiac echocardiography: An ideal guiding tool for device closure of interatrial communications. *Eur J Echocardiogr* 2005; **6:** 92–96.
15. Douglas PS, DeCara JM, Devereux RB, Duckworth S, Gardin JM, Jaber WA, et al. Echocardiographic imaging in clinical trials: American Society of Echocardiography Standards for echocardiography core laboratories: Endorsed by the American College of Cardiology Foundation. *J Am Soc Echocardiogr* 2009; **22:** 755–765.
16. Asrress KN, Mitchell ARJ. Intracardiac echocardiography. *Heart* 2009; **95:** 327–331.
17. Van Der Velde ME, Perry SB. Transesophageal echocardiography during interventional catheterization in congenital heart disease. *Echocardiography* 1997; **14:** 513–528.
18. Latiff HA, Samion H, Kandhavel G, Aziz BA, Alwi M. The value of transesophageal echocardiography in transcatheter closure of atrial septal defects in the oval fossa using the Amplatzer septal occluder. *Cardiol Young* 2001; **11:** 201–204.
19. Figueroa MI, Balaguru D, McClure C, Kline CH, Radtke WAK, Shirali GS. Experience with use of multiplane transesophageal echocardiography to guide closure of atrial septal defects using the amplatzer device. *Pediatr Cardiol* 2002; **23:** 430–436.
20. Koenig P, Cao Q, Heitschmidt M, Waight DJ, Hijazi ZM. Role of intracardiac echocardiographic guidance in transcatheter closure of atrial septal defects and patent foramen ovale using the Amplatzer device. *J Interv Cardiol* 2003; **16:** 51–62.
21. Baglini R. Intracardiac echocardiography in monitoring atrial septal defect percutaneous closure: Initial experience in an adult laboratory. *Int J Cardiol* 2007; **114:** 274–276.
22. Zaqout M, Suys B, De Wilde H, De Wolf D. Transthoracic echocardiography guidance of transcatheter atrial septal defect closure in children. *Pediatr Cardiol* 2009; **30:** 992–994.
23. Ewert P, Berger F, Daehnert I, van Wees J, Gittermann M, Abdul-Khaliq H, et al. Transcatheter closure of atrial septal defects without fluoroscopy: Feasibility of a new method. *Circulation* 2000; **101:** 847–849.
24. Kwak J, Andrawes M, Garvin S, D'Ambra MN. 3D transesophageal echocardiography: A review of recent literature 2007–2009. *Curr Opin Anaesthesiol* 2010; **23:** 80–88.
25. Georgakis A, Radtke WA, Lopez C, Fiss D, Moser C, VanDecker W, et al. Complex atrial septal defect: Percutaneous repair guided by three-dimensional echocardiography. *Echocardiography* 2010; **27:** 590–593.
26. Lodato JA, Cao QL, Weinert L, Sugeng L, Lopez J, Lang RM, et al. Feasibility of real-time three-dimensional transoesophageal echocardiography for guidance of percutaneous atrial septal defect closure. *Eur J Echocardiogr* 2009; **10:** 543–548.
27. Bom N, Lance CT, Van Egmond FC. An ultrasonic intracardiac scanner. *Ultrasonics* 1972; **10:** 72–76.
28. Patel A, Cao Q, Koenig PR, Hijazi ZM. Intracardiac echocardiography to guide closure of atrial septal defects in children less than 15 kilograms. *Catheter Cardiovasc Interv* 2006; **68:** 287–291.
29. Alboliras ET, Hijazi ZM. Comparison of costs of intracardiac echocardiography and transesophageal echocardiography in monitoring percutaneous device closure of atrial septal defect in children and adults. *Am J Cardiol* 2004; **94:** 690–692.
30. Budts W, Troost E, Voigt J, Gewillig M. Intra-cardiac echocardiography in atrial septal interventions: Impact on hospitalization costs. *Acta Cardiol* 2010; **65:** 147–152.
31. Rigatelli G, Cardaioli P, Roncon L, Giordan M, Bedendo E, Oliva L, et al. Impact of intracardiac echocardiography on radiation exposure during adult congenital heart disease catheter-based interventions. *Int J Cardiovasc Imaging* 2007; **23:** 139–142.