Executive summary

Patient selection for transcatheter atrial septal defect closure

- Morphologic variation of atrial septal defect (ASD) is common and the shape of ASDs change dynamically during the cardiac cycle.
- In general, ASD of >10 mm in diameter is considered to account for a significant left-to-right shunt.
- In terms of accurate assessment of ASD morphology, including measurements of maximal diameter and surrounding rims, transesophageal echocardiography (TEE) is usually necessary, especially in most adult patients.
- Real-time 3D TEE allows for evaluation of ASDs of various shapes, especially in patients with complex-shaped ASD, such as multiple ASDs.
- Cardiac MRI and computed tomography can provide complementary information with a large field of view and low-operator dependency.

Real-time imaging during transcatheter ASD closure

- Either TEE or intracardiac echocardiography (ICE) and fluoroscopy are commonly used for guiding the procedure.
- Several portable consoles have become available recently and some TEE probes can be connected to these consoles.
- Comprehensible 3D TEE images contribute to a quick understanding of ASD morphology by interventionalists and echocardiographers, especially in patients with complex-shaped ASD.
- A downsized TEE probe will be a promising tool during guidance of the procedure for both pediatric and adult patients, although the spatial resolution of currently available micro-TEE probes is expected to evolve.
- Excellent ICE imaging, capability of manipulating the ICE catheter for interventionalists, and visualization and interpretation of images with local anesthesia have led to the spread of the ICE-guided procedure.
- Phased-array ICE imaging during transcatheter ASD closure can provide equivalent information compared with TEE imaging, including information on blood flow with color Doppler.
- Current limitations of ICE include cost, single plane imaging, sheath size and incapability of 3D imaging.
- Selection of TEE or ICE guiding as the tool depends on factors including the institution, patients and interventionalists.

Future perspective

- 3D ICE will greatly contribute to the field of structural heart interventions.
- Miniaturized TEE probe size may enable a transnasal approach in adult patients during the procedure, eliminating the requirement for general anesthesia.

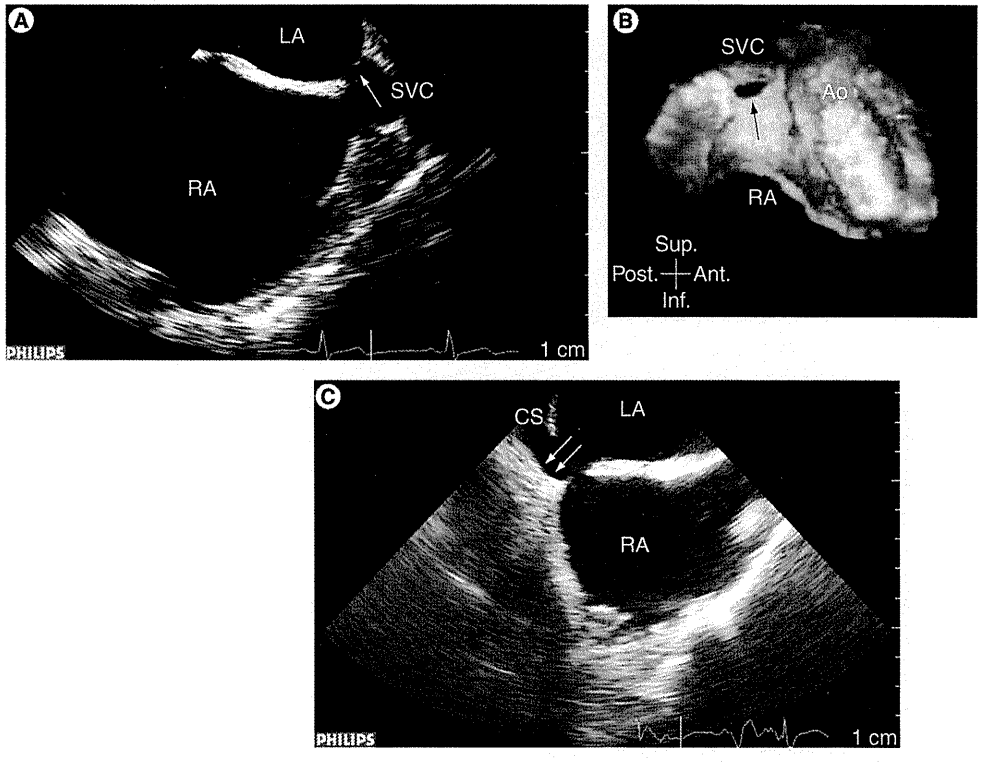


Figure 1. Transesophageal echocardiography image of superior form of a sinus venosus atrial septal defect and coronary sinus septal defect. (A) Sinus venosus atrial septal defect (superior) in biatrial view of 2D transesophageal echocardiography (TEE) (120°) and **(B)** 3D TEE image from right atrial view. White and black arrows indicate the defect. **(C)** CS septal defect in biatrial view of 2D TEE (90°). Double arrows indicate unroofed portion of the CS. Ao: Aorta; CS: Coronary sinus; LA: Left atrium; RA: Right atrium; SVC: Superior vena cava.

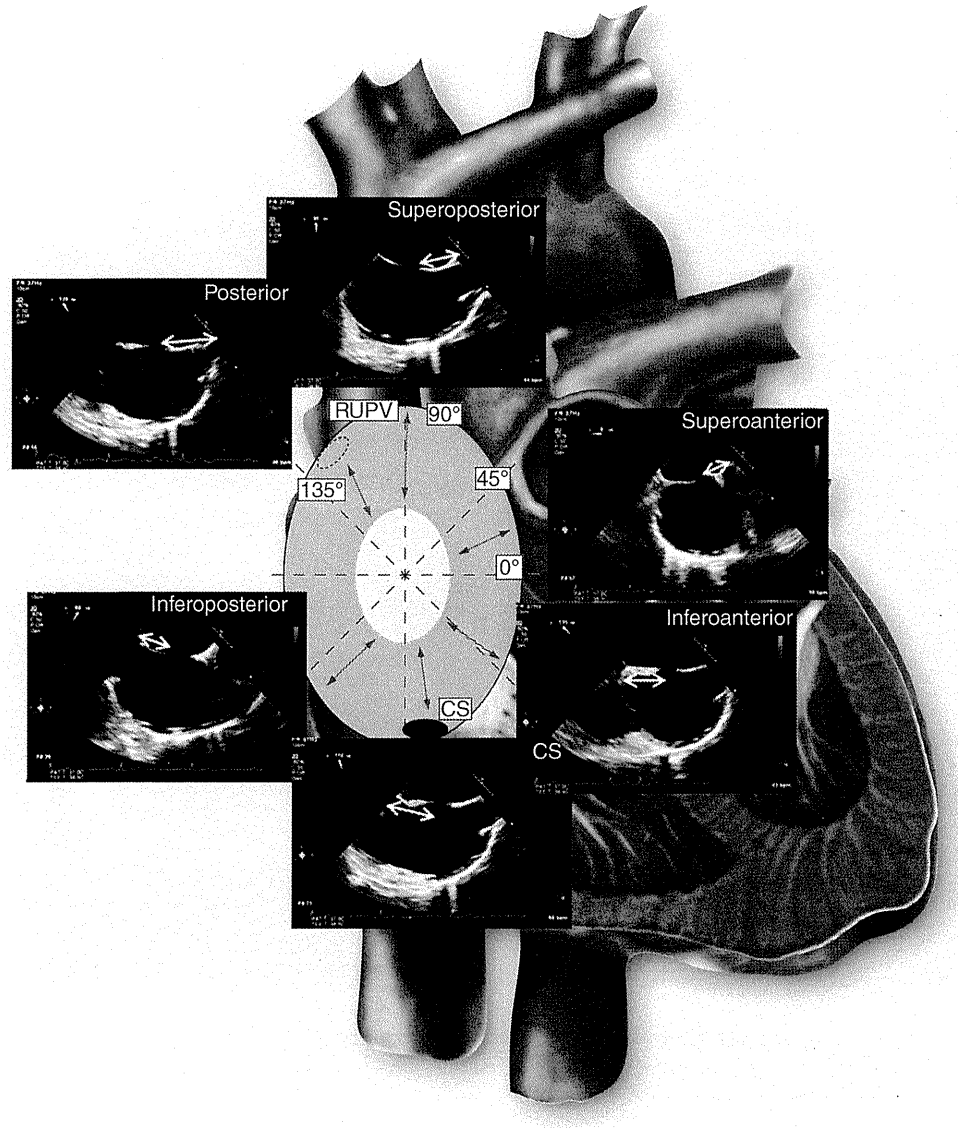


Figure 2. Assessment of surrounding rims using 2D transesophageal echocardiography.
Surrounding tissue rims and atrial septal defect (ASD) diameter should be measured in the phase of ventricular end systole with multiple cross-sectional transesophageal echocardiography (TEE) plane. Distances from the ASD to the aorta (superoanterior rim; 2D TEE view at 0–30°), superior vena cava (superoposterior rim; 2D TEE view at 90–120°), RUPV (posterior rim; 2D TEE view at 110–120°), inferior vena cava (inferoposterior rim; 2D TEE view at 60–90°), CS (2D TEE view at 100–120°) and atrioventricular valve (inferoanterior rim; 2D TEE view at 135–150°) are assessed.
CS: Coronary sinus; RUPV: Right upper pulmonary vein.

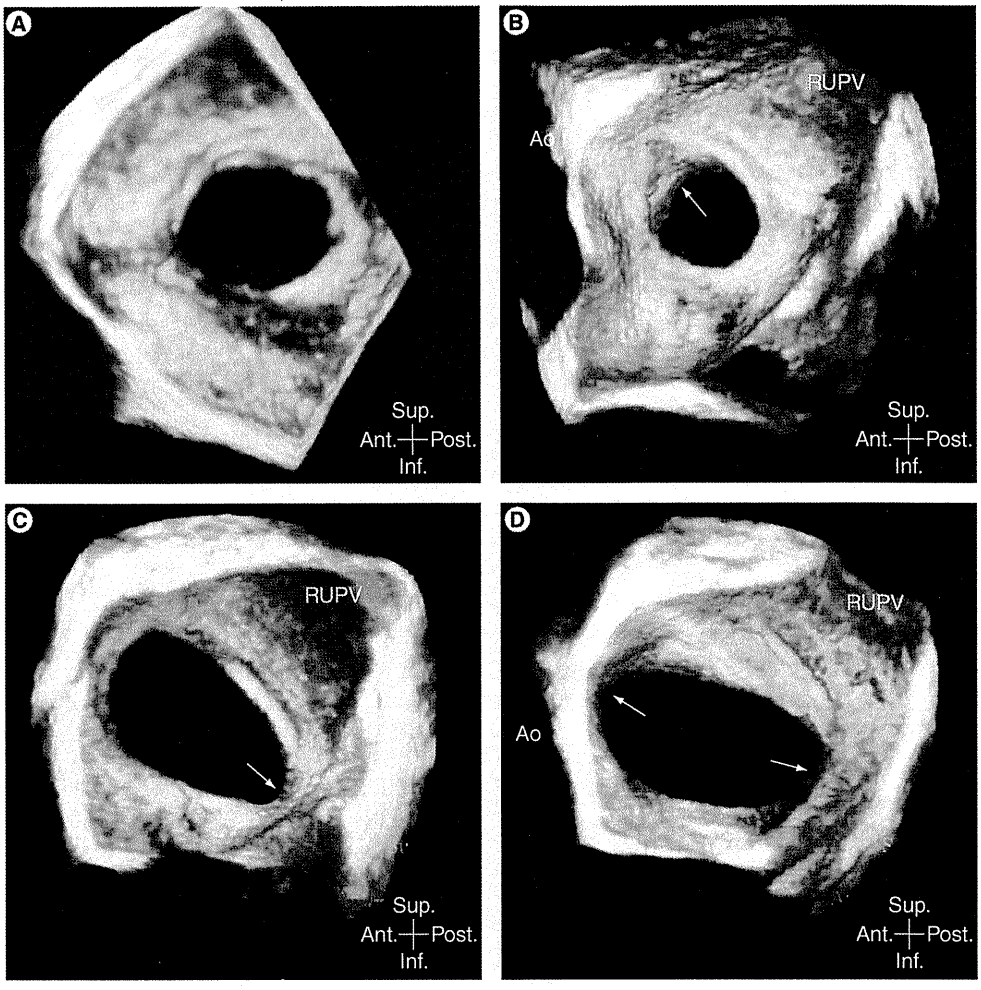


Figure 3. Various shapes of atrial septal defect visualized by 3D transesophageal echocardiography (left atrial *en face* view). (A) Sufficient rim, **(B)** deficient superoanterior rim, **(C)** deficient inferoposterior rim, **(D)** deficient superoanterior and inferoposterior rims. Arrows indicate the portion of rim deficiency.
Ao: Aorta; RUPV: Right upper pulmonary vein.

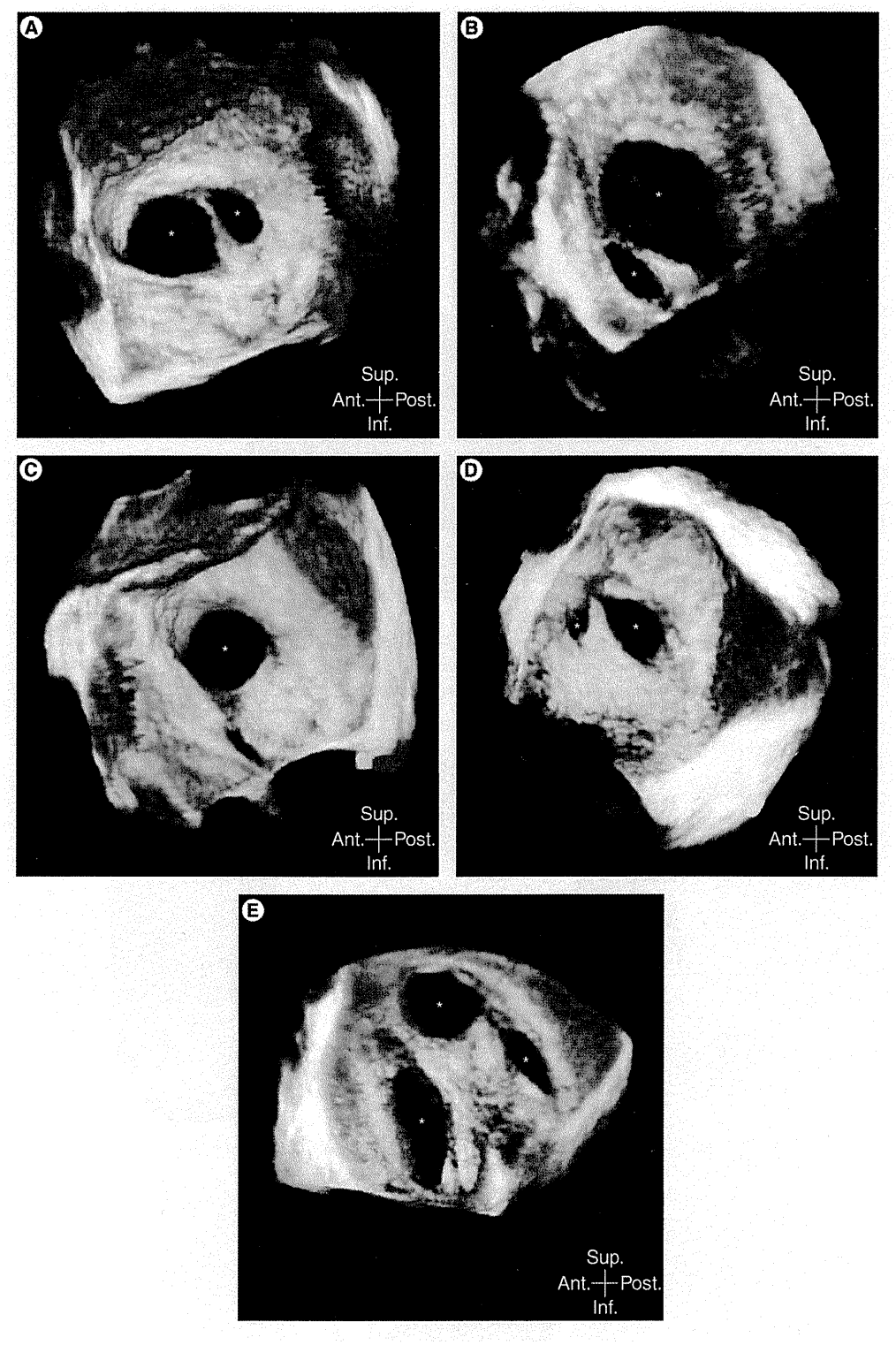


Figure 4. Multiple atrial septal defects visualized by 3D transesophageal echocardiography (left atrial *en face* view). Real-time 3D transesophageal echocardiography can provide important information on shapes and locations of defects in patients with multiple atrial septal defects. Asterisks indicate defects.

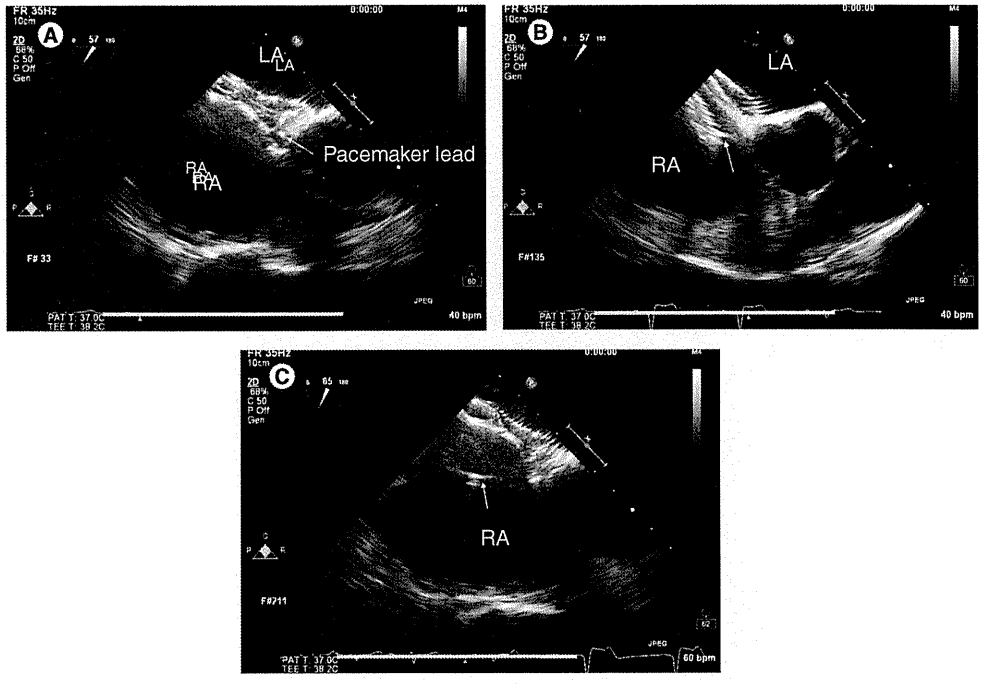
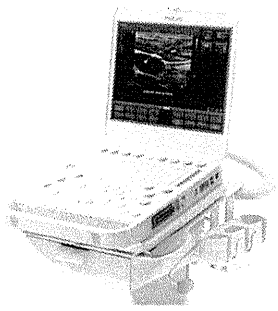


Figure 5. Pacemaker lead in the right atrium entrapped by the device. (A) Short axis view of 2D transesophageal echocardiography (60°). Arrow indicates pacemaker lead. **(B)** After pulling the right atrial disk. **(C)** The pacemaker lead was released. Arrow indicates pacemaker lead.
LA: Left atrium; RA: Right atrium.



CX50 (PHILIPS Medical System)

Vivid q (GE Healthcare)

ACUSON CypressPlus (SIEMENS Healthcare)

Figure 6. Portable consoles capable of connecting the transesophageal echocardiography probe. These portable consoles can contribute to making space around the head of the patient during transesophageal echocardiography-guided intervention in the catheterization laboratory. Images courtesy of Philips Medical Systems, GE Healthcare and Siemens Healthcare.

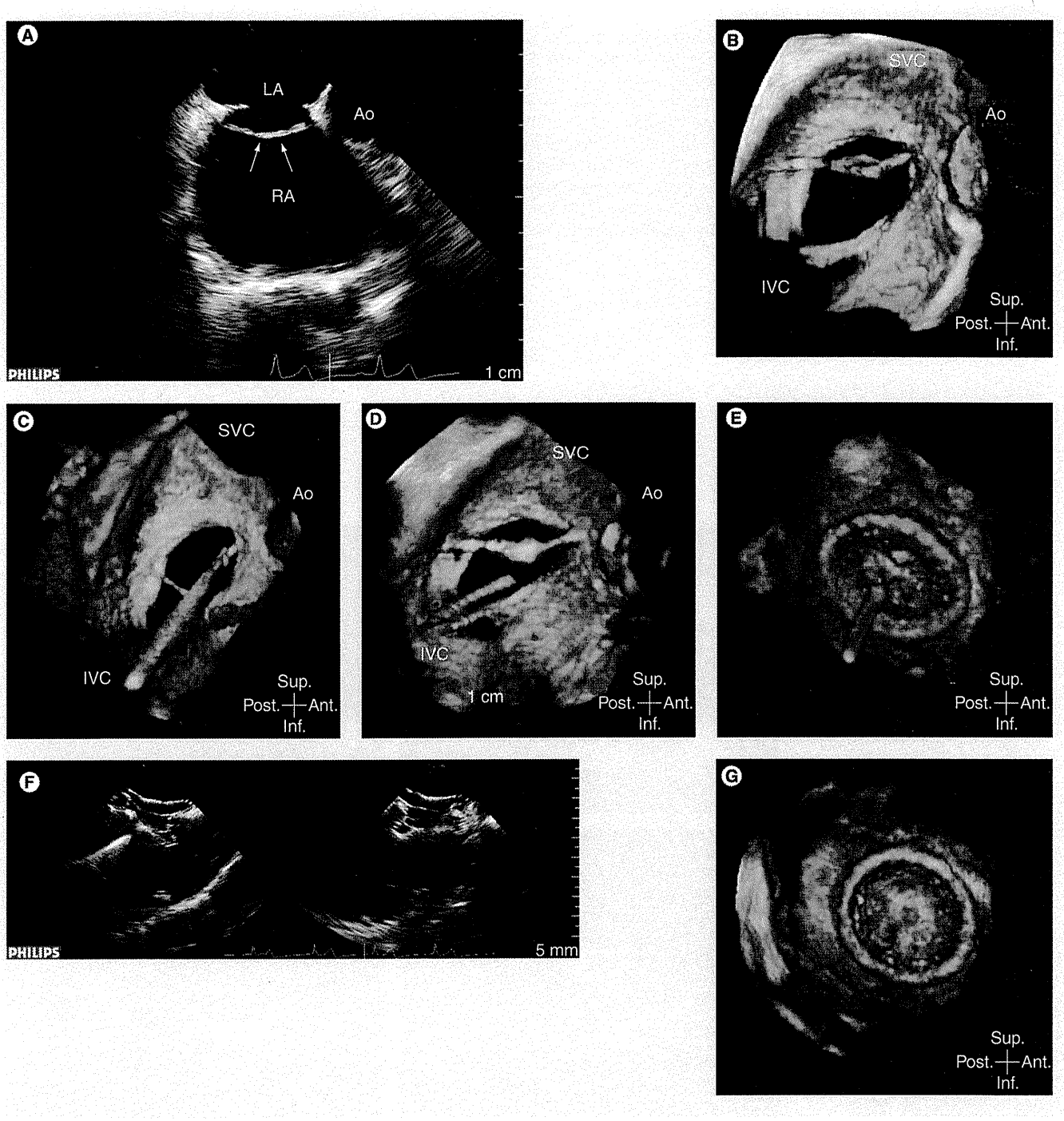


Figure 7. Real-time 3D transesophageal echocardiography-guided transcatheter atrial septal defect closure in patients with abnormal strand in the right atrium. This patient had an atrial septal defect with a maximal diameter of 28 mm and superoanterior rim deficiency. **(A)** Short axis view of 2D transesophageal echocardiography (TEE) (60°) demonstrated an abnormal string-like structure just below the defect in the right atrium (arrows), but it was not easy to estimate actual spatial location. **(B)** 3D TEE in right atrial *en face* view. It could clearly visualize the relationship between the abnormal structure and the defect. Based on this image, a strategy was made to cross the catheter from below the string-like structure and close the defect with single Amplatzer® septal occluder. **(C)** Right atrial *en face* view. The catheter was crossed from above the string-like structure against the interventionalist's wish. **(D)** Right atrial *en face* view. The catheter was crossed again correctly. **(E)** Right atrial *en face* view. The device was deployed appropriately. **(F)** Plane mode of 3D TEE. The position of the device was also confirmed with this mode. **(G)** Right atrial *en face* view after releasing the device.
Ao: Aorta; LA: Left aorta; IVC: Inferior vena cava; RA: Right aorta SVC: Superior vena cava.

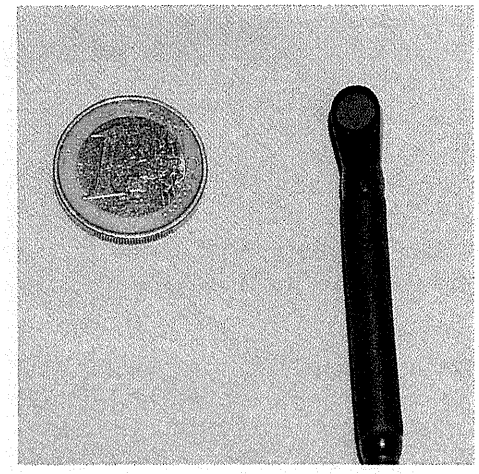


Figure 8. Microtransesophageal echocardiography probe. Microtransesophageal echocardiography (S8-3; Philips Medical Systems, Andover, MA, USA) has a tip length of 18.5 mm, tip width of 7.5 mm and tip height of 5.5 mm. The shaft size is 5.2 mm, which is approximately half of the shaft size for the standard transesophageal echocardiography probe for adults. M-mode, 2D, color Doppler, pulse-wave and continuous-wave Doppler are available.

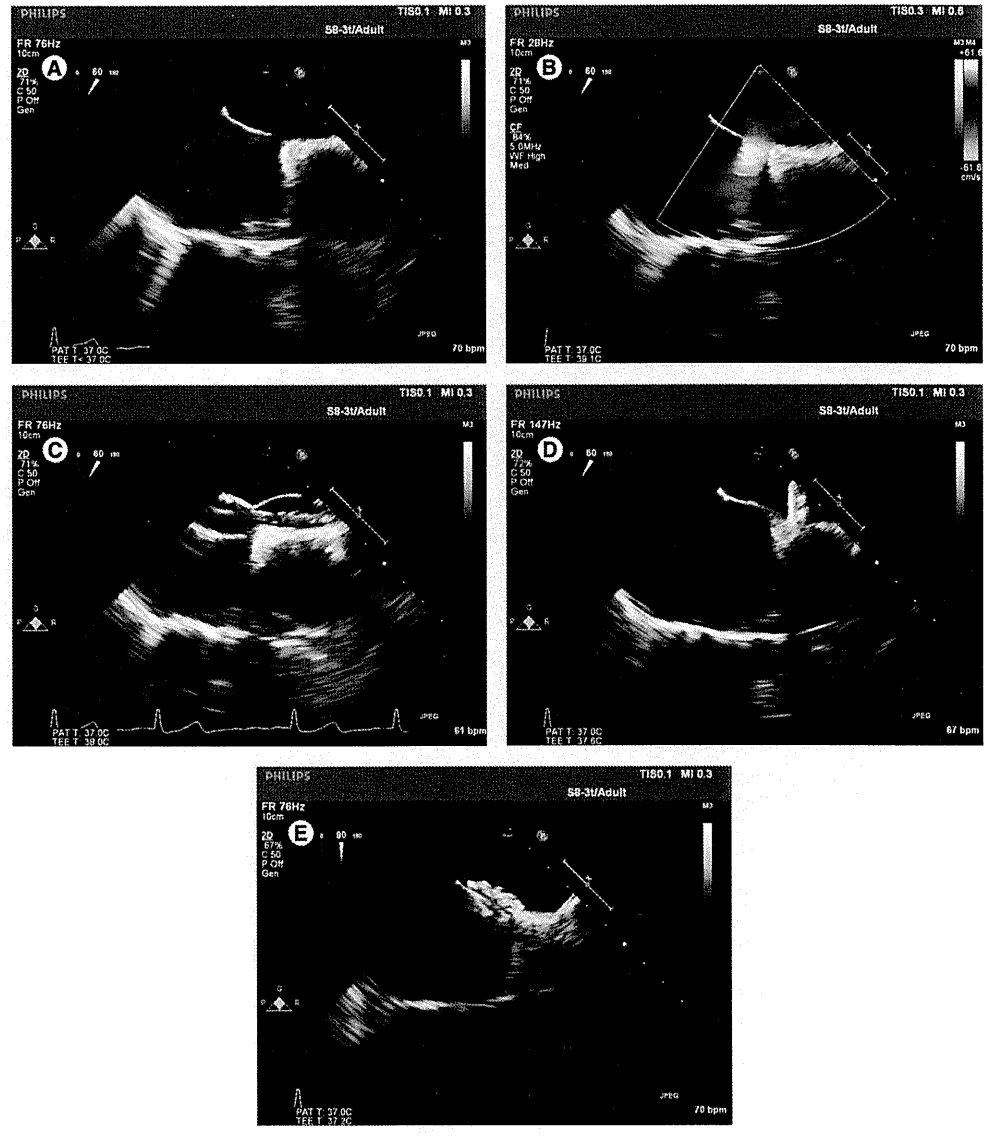


Figure 9. Microtransesophageal echocardiography-guided transcatheter atrial septal defect closure. (A) Short axis view (60°) of microtransesophageal echocardiography (TEE) before device closure. This patient had an atrial septal defect with maximal diameter of 9 mm and superoanterior rim deficiency. **(B)** Color Doppler of short axis view (60°). **(C)** Balloon sizing diameter was measured at 10 mm. **(D)** Micro-TEE short axis view for deploying the device. **(E)** Biatrial view (90°) after releasing the device.

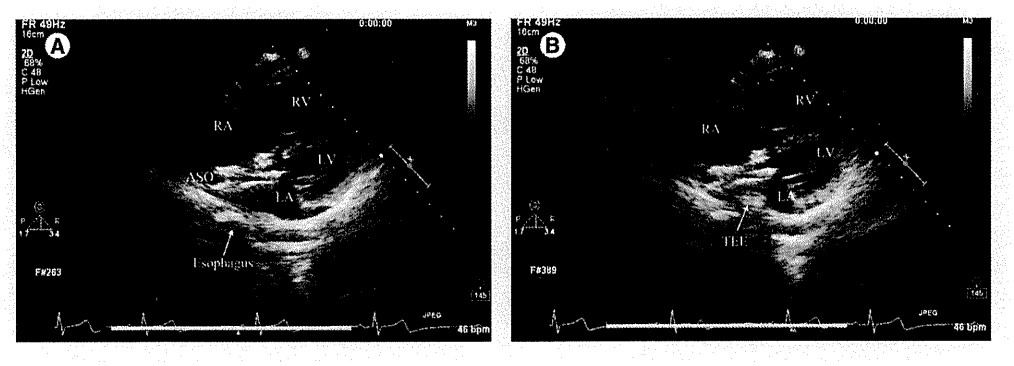


Figure 10. Extrinsic compression of the left atrium with transesophageal echocardiographic probe in a 17 year-old female with a small left atrium. Maximal atrial septal defect diameter of this patient was 30 mm. **(A)** transesophageal echocardiography (TEE) image before insertion of the TEE probe. **(B)** After insertion of the TEE probe, the probe pressed on the left atrium toward the interatrial septum from the outside of the heart.

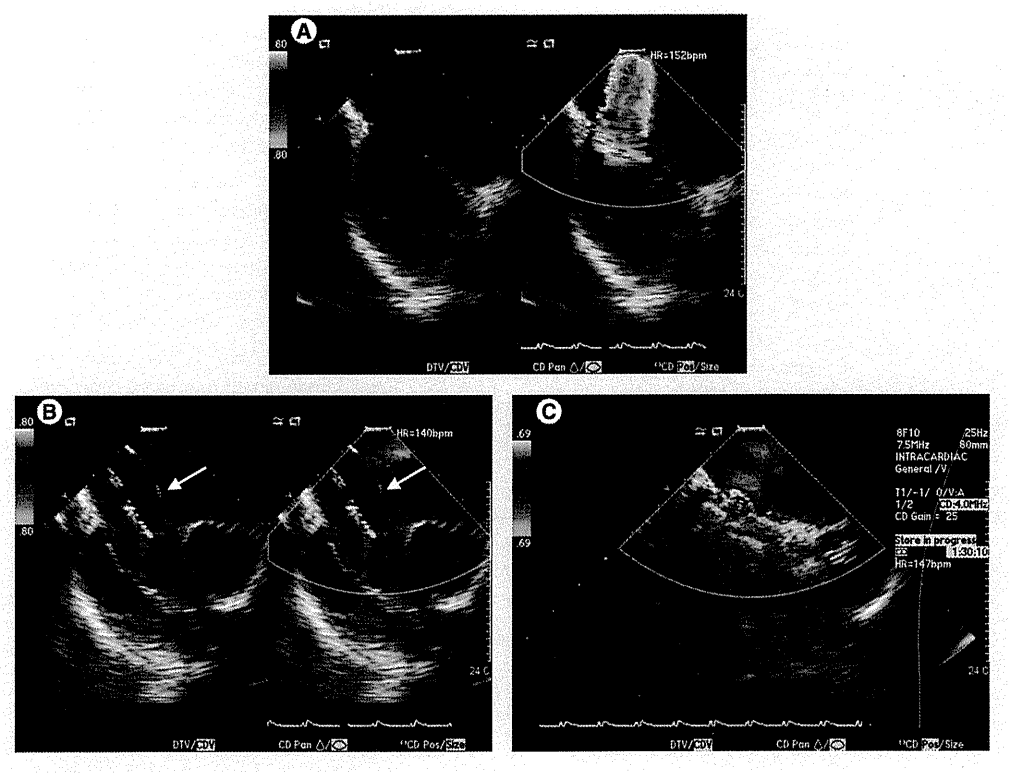


Figure 11. Intracardiac echocardiography-guided transcatheter atrial septal defect closure. (A) Short axis view of phased-array intracardiac echocardiography demonstrating inferoposterior rim deficiency before closure. **(B)** Maximal atrial septal defect (ASD) diameter was 15 mm and balloon sizing diameter was 18 mm. Arrows indicate the sizing balloon. **(C)** ASD was closed with an 18 mm device.
Courtesy of Jae Young Choi, Severance Cardiovascular Hospital, Yonsei University Health System, Seoul, Korea.

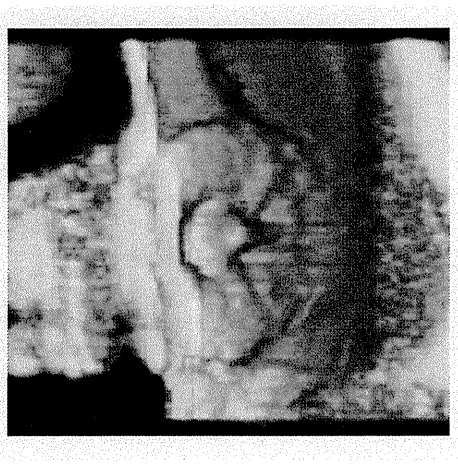


Figure 12. 3D/4D intracardiac echocardiography in transcatheter atrial septal defect closure. This 3D intracardiac echocardiography image was reconstructed using TomTec software (TomTec Imaging Systems GmbH, Unterschlessheim, Germany). Courtesy of Eustaquio Onorato, Policlinico Universitario Tor Vergata, Rome.

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Transcatheter Closure of a Large Atrial Septal Defect under Microprobe Transesophageal Echocardiographic Guidance

Manabu Taniguchi, M.D.,* Teiji Akagi, M.D.,* Yasufumi Kijima, M.D.,† Hiroshi Ito, M.D.,† and Shunji Sano, M.D.*

*Division of Cardiac Intensive Care Unit, Okayama University Hospital, Okayama, Japan; †Department of Cardiovascular Medicine, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama, Japan

We present a case of an atrial septal defect (ASD) in a 59-year-old man with an indication for ASD closure who also had a history of chronic obstructive pulmonary disease. Because of his decreased respiratory function with multiple bullae in his lungs, the procedure was performed without general anesthesia under the guidance of fluoroscopy and two-dimensional (2D) transesophageal echocardiography (TEE) using a transesophageal echocardiographic microprobe (micro-TEE) (S8-3t; Philips Medical Systems, Andover, MA, USA). The micro-TEE probe was inserted into the esophagus smoothly and easily in the supine position without sedation. It revealed a deficient superior-anterior rim and adequate rims elsewhere, and the maximal diameter of ASD was measured to be 25 mm. Balloon sizing resulted in a stretched defect diameter of 29 mm using the stop-flow technique. A 30-mm AMPLATZER Septal Occluder (AGA Medical, Plymouth, MN, USA) was deployed. The micro-TEE demonstrated that both disks were on the appropriate sides of the interatrial septum and the device was not interfering with surround cardiac structures. Residual shunt flow was not detected with color Doppler. The device was released successfully without any complications. Recently introduced multiplane micro-TEE can provide adequate information about a large ASD with a less invasive procedure in adult patients. Micro-TEE has a potential to become a novel imaging option for interventions of the interatrial septum. (Echocardiography ****;**:E1-E3)

Key words: transesophageal echocardiography, atrial septal defect, transcatheter closure device

A 59-year-old man with a history of chronic obstructive pulmonary disease who presented with progressive exertional dyspnea was found to have a secundum-type atrial septal defect (ASD) and a dilated right ventricle on transthoracic echocardiography (TTE). He was referred to our hospital for evaluation and transcatheter ASD closure.

Right heart catheterization demonstrated a pulmonary-to-systemic flow ratio of 1.8:1. His respiratory function was decreased due to multiple bullae in his lungs. And an intracardiac echocardiography was unavailable in our hospital. Therefore, transcatheter ASD closure was performed without general anesthesia under the guidance of fluoroscopy and two-dimensional (2D) transesophageal echocardiography (TEE) using a transesophageal echocardiographic microprobe (micro-TEE) (S8-3t; Philips Medical Systems, Andover, MA, USA) (Fig. 1). No sedatives were used, and local pharyngeal anesthesia was induced with oral liquid containing lignocaine. The micro-TEE probe was inserted into the

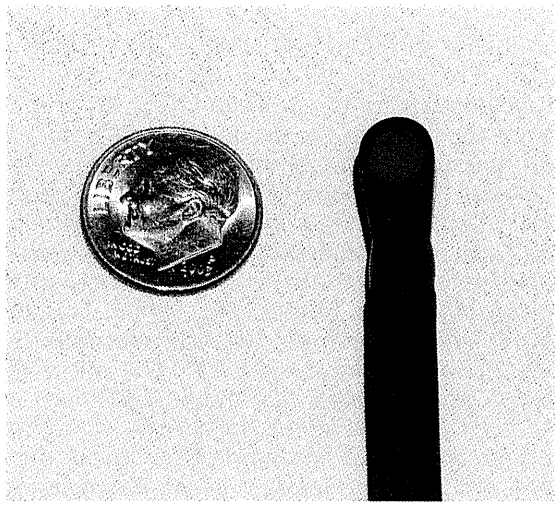

Figure 1. Miniaturized micro-TEE probe.

There are no disclosures about this report.

Address for correspondence and reprint requests: Manabu Taniguchi, M.D., PHD 2-5-1 Shikata-Cho, Okayama Kita-ku, Okayama 700-8558, Japan. Fax: 81-86-235-7353; E-mail: tmnb@md.okayama-u.ac.jp

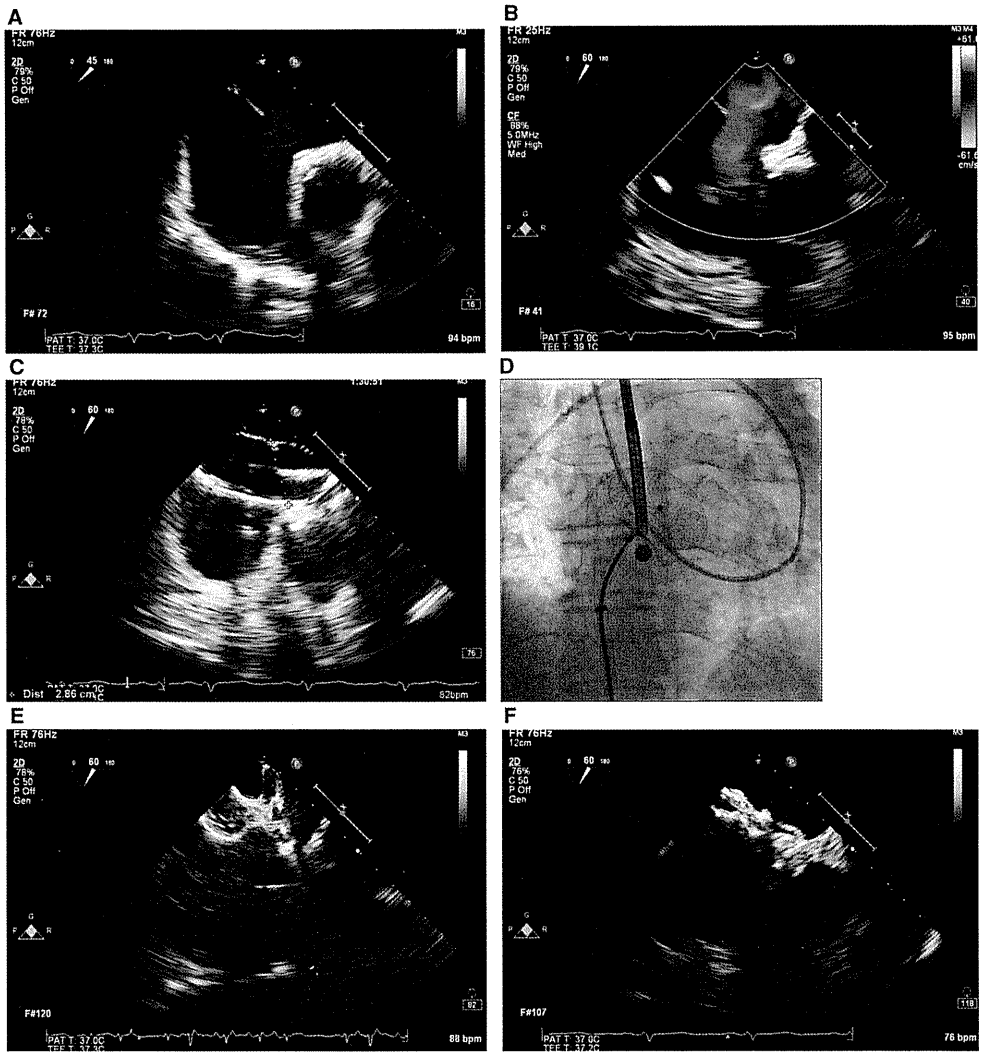

Figure 2. Transcatheter atrial septal defect closure under micro-TEE and fluoroscopic guidance. **A.** Micro-TEE demonstrates a large atrial septal defect (ASD) and a deficient superior-anterior rim. **B.** With color Doppler image, left-to-right shunt flow is recognized. **C.** Balloon sizing using the stop-flow technique **D.** Fluoroscopic view and **E.** micro-TEE view deploying a 30-mm AMPLATZER Septal Occluder **F.** Device is deployed successfully.

esophagus smoothly and easily in the supine position. It revealed a deficient superior-anterior rim and adequate rims elsewhere (Fig. 2A and B, movie clip S1), and the maximal diameter of ASD was measured to be 25 mm. Balloon sizing with a 34-mm AGA balloon (AGA Medical, Plymouth, MN, USA) resulted in a stretched defect diameter of 29 mm using the stop-flow technique (Fig. 2C). A 12-French AGA sheath was used to deliver the device. A 30-mm AMPLATZER Septal Occluder (AGA Medical, Plymouth, MN, USa) was deployed (Fig. 2D and E, movie clip S2). The micro-TEE clearly demonstrated that both disks were on the appropriate sides of the interatrial septum and the device was not interfering with surround cardiac structures. Residual shunt flow was not detected with color Doppler. The device was released successfully without any complications (Fig. 2F).

The extremely miniaturized multiplane micro-TEE has 18.5 mm of tip length, 7.5 mm of tip width, and 5.5 mm of tip height. The shaft size is 5.2 mm which is about a half size of the standard TEE probe for adults. The transducer consisted of 32 elements and has frequency from 3.2 MHz to 7.4 MHz. 2D, as well as M-mode, color Doppler, pulse-wave wave Doppler, and continuous-wave Doppler are available.

Echocardiography plays a pivotal role in guiding interventions of structural heart diseases. There are several imaging tools of echocardiographic guidance for structural heart interventions including 2D TTE, 2D TEE,[1] intracardiac echocardiography,[2,3] and recently introduced

real-time three-dimensional (3D) TEE.[4,5] From the standpoint of echocardiographic options for transcatheter closure of an interatrial septum in the catheterization laboratory, the small size of the micro-TEE probe may be better tolerated without general anesthesia for a prolonged procedure such as ASD closure, as compared to a standard TEE probe. In addition, micro-TEE has some advantages compared to intracardiac echocardiography in terms of capability of multiplane, reusability, avoiding vascular complications and cost effectiveness. However, image quality of the current micro-TEE probe is inferior to that of a conventional adult TEE probe, and inability of 3D imaging by a micro-TEE probe can also be a limitation.

Micro-TEE could provide adequate information with a less invasive procedure even in patients with a large ASD. Micro-TEE has the potential to become a novel imaging option for interventions of the interatrial septum.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Movie clip S1: Short-axis view with micro-TEE shows a large atrial septal defect (ASD) and a deficient superior-anterior rim.

Movie clip S2: The micro-TEE shows that both disks are on the appropriate sides of the interatrial septum.

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原　著

成人期心房中隔欠損に対するカテーテル閉鎖術と外科的閉鎖術の臨床成績比較：単一施設における後方視的非ランダマイズ化検討

藤井　泰宏[1)]，赤木　禎治[2)]，谷口　　学[2)]，中川　晃志[2)]
木島　康文[2)]，大月　審一[3)]，富井　奉子[1)]，岩崎　達雄[4)]
五藤　恵次[4)]，戸田雄一郎[4)]，岡本　吉生[3)]，新井　禎彦[1)]
笠原　真悟[1)]，佐野　俊二[1)]

岡山大学病院心臓血管外科[1)]，循環器疾患治療部[2)]，小児科[3)]，
麻酔蘇生科[4)]

Key words:
atrial septal defect, adult, catheter intervention, cardiac surgery

Comparison of Clinical Outcomes of Catheter and Surgical Closures in Adult Patients with Atrial Septal Defect: A Single-institution Retrospective Non-randomized Study

Yasuhiro Fujii,[1)] Teiji Akagi,[2)] Manabu Taniguchi,[2)] Koji Nakagawa,[2)] Yasufumi Kijima,[2)] Shin-ichi Otsuki,[3)] Tomoko Tomii,[1)] Tatsuo Iwasaki,[4)] Keiji Goto,[4)] Yuichiro Toda,[4)] Yoshio Okamoto,[3)] Sadahiko Arai,[1)] Shingo Kasahara,[1)] and Shunji Sano[1)]

[1)]Department of Cardiovascular Surgery, [2)]Department of Cardiac Care Unit, [3)]Department of Pediatrics, and [4)]Department of Anesthesiology and Resuscitology, Okayama University Hospital, Okayama, Japan

Background: The purpose of this study was to compare the outcomes of surgical closure and catheter closure of atrial septal defects (ASDs) using an Amplatzer Septal Occluder in patients 40 years of age or older.

Methods: Seventy-three patients underwent catheter closure (group D), and 27 patients underwent surgical closure of ASDs (group S). The echocardiogram, catheter, and electrocardiogram data were compared.

Results: The patients in group D were older at the time of closure (P=0.004) and had smaller ASD diameters (P<0.001) than the patients in group S. There was no mortality due to cardiac events in either group. The group D patients had significantly shorter hospital stays (P<0.001). The incidence of postoperative atrial arrhythmias was significantly lower in group D (P=0.015).

Conclusions: Despite the implantation of a foreign body inside the heart, catheter closure contributed to a lower incidence of postoperative atrial arrhythmias. These findings may influence the long-term clinical outcomes of adult patients with ASDs.

要　旨

背景：心房中隔欠損症(ASD)に対するカテーテル閉鎖術が国内に導入され4年が経過したが，成人期のASDに対する治療経験は限られている．また，外科的治療とカテーテル治療で治療成績にどのような違いが生じるのか不明である．本研究の目的は，成人期ASDに対するカテーテル治療と外科治療の臨床成績を，単施設の後方視的検討として比較することである．

方法：対象は1991年3月から2008年12月までに当院にてASD閉鎖術を施行した40歳以上の成人症例100例．27例が手術閉鎖(外科的閉鎖群)，73例がカテーテル閉鎖(カテーテル閉鎖群)であった．術前術後のエコー所見，カテーテル検査所見，心電図記録を比較検討した．

結果：外科的閉鎖群はカテーテル閉鎖群に比べ，有意に低年齢(平均52歳 vs. 58歳，P=0.004)で，大きいASD径(平均31 mm vs. 19 mm，P<0.001)を有していた．両群間で治療に関連する死亡，重篤な合併症は認めなかった．外科的閉鎖群は術後在院日数が有意に長かった(P<0.001)．単変量解析で外科的閉鎖群は，有意に術後の上室性不整脈発生率が高かった(9/27 vs. 9/73，P=0.015)．

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別刷請求先：〒700-8558　岡山県岡山市北区鹿田町2-5-1
岡山大学病院心臓血管外科　藤井　泰宏

結論：成人期ASDに対するカテーテル治療の導入によって，術後遠隔期の上室性不整脈発生頻度が低下する可能性があり，本疾患患者の長期予後を改善させる可能性がある．

はじめに

心房中隔欠損症(ASD)に対するカテーテル治療(カテーテル閉鎖術)がわが国に導入されてから4年が経過し，その症例数は1500例を超えた．ASDのカテーテル閉鎖は人工心肺を必要とせず，術後の良好な心室リモデリングが期待されるため，今後も本疾患の第一選択の治療となっていくことが期待される．経皮的ASD閉鎖は低侵襲であることが大きなメリットであるが，外科的閉鎖術も近年の手術，体外循環，周術期治療面の進歩により，多くの施設では死亡，重大な合併症なく実施可能である[1, 2]．実際，当院でも1996年から2008年にかけて，134例の外科的ASD閉鎖術を施行し，死亡，重大な神経学的合併症は発生していない．一方，カテーテル閉鎖術も外科的閉鎖術と同様に，完全に安全な手技であるとはいえない．デバイスが誘因の血栓塞栓症，デバイス塞栓，心びらん・穿孔，不整脈，重大な大血管損傷などが報告され，時にはそれらが致命的となる症例がある[3]．また，心房内の大きな異物であるデバイスは長期的に不整脈源となるのではないかという懸念もある．ASDに対する治療としてカテーテル閉鎖術と外科的閉鎖術の有効性と安全性を比較した研究がいくつか報告されている．アメリカの多施設研究によるとカテーテル閉鎖術は外科的閉鎖術に比べ，有効性は同等であるが，合併症の発生率が有意に低いと報告している[4]．一方，Bergerらはカテーテル閉鎖術と外科的閉鎖術で合併症発生率は同等であったと報告している[5]．ところが，これらの報告はすべて小児例を中心とした検討である．ASDは加齢によって臨床症状，合併症の頻度が大きく異なる特徴がある．40歳以上で手術を行った症例では，健常人と比べ生命予後が有意に低下し[6]，さらに，40歳以上で手術を行うと術後上室性不整脈の発生頻度が有意に高い[2]ことも広く知られている．このため，40歳以上の症例においてカテーテル閉鎖術と外科的閉鎖術の有効性と安全性を比較することは大変重要と考えられる．本研究の目的は40歳以上成人例において，ASDのカテーテル閉鎖術と外科的閉鎖術で臨床上の有効性・安全性の比較を行い，成人期ASDに対するカテーテル閉鎖術の治療戦略上の有用性を明らかにすることである．

方　法

1. 対　象

1991年3月から2008年12月までに当院にて中心窩型ASDを閉鎖した40歳以上の症例を対象とした．診療記録，カテーテル記録，心エコー記録を後方視的に検討した．カテーテル閉鎖術が導入される以前は，外科的閉鎖術のみ行われていた．2005年8月以降，当院における成人ASD閉鎖の第一選択はカテーテル閉鎖である．外科的閉鎖術を施行された患者はASD閉鎖単独もしくはASD閉鎖＋僧帽弁もしくは三尖弁形成術を施行した患者に限定しており，そのほかの追加手技を要した患者は除外した．ただし，術中心房のアブレーションを施行した症例は手術群に含んでいる．卵円孔開存の患者は除外した．

2. カテーテル閉鎖手技

全例，Amplatzer Septal Occluder(AGA Medical Corporation, Golden Valley, Minnesota)を使用してASDを閉鎖した．原則として，術前に経胸壁および経食道エコー(TEE)を施行した．カテーテル閉鎖の適応はDuらの報告に準じて決定した[7]．治療は，カテーテル室で全身麻酔，人工呼吸管理下，経食道エコーモニター下に施行した．肺体血流比を評価下後，サイジングバルーンを使用して欠損孔の伸展径をTEEで計測し，測定された同一径もしくは1～2 mm大きなデバイスを使用した．デバイスは附属のデリバリーシース，もしくはHausdorf Sheethを使用して留置した．留置後はアスピリン(100 mg/day)を6カ月間使用した．

3. 外科的閉鎖手技

ASDのカテーテル閉鎖導入前の外科的閉鎖の適応は，肺体血流比(Qp/Qs)が2.0以上，肺高血圧の進行，不整脈等の症状の出現のいずれかを満たし，かつ肺血管抵抗が8 U·m^{2}より小さい症例である．手術は全身麻酔下に胸部正中切開もしくは前側方開胸を行い，人工心肺を使用し，軽度低体温もしくは常温下にて施行した．大動脈遮断後，blood cardioplegiaにて心停止を得，右房切開を加え，ASDは自己心膜パッチもしくはGore-Tex patch(W.L. Gore & Associates, Inc, Flagstaff, Arizona)でパッチ閉鎖，もしくは非吸収糸にて直接閉鎖した．

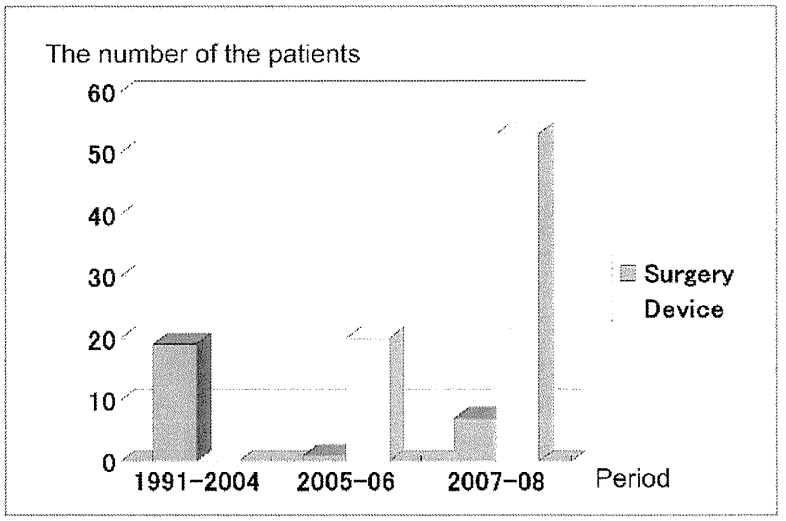

Fig. 1 Distribution of the number of patients during the study period.
Device closure has been the first-line strategy for ASD closure since 2005.

4. Follow-up と不整脈の評価

術後，すべての患者は外来にて診察，心電図検査，胸部X線検査，経胸壁ドプラ心エコー検査を定期的に施行された．動悸を訴えた場合 Holter 心電図を施行した．術後上室性不整脈を3通りの場合にわけて分析した．1)すべての患者を対象にした術後上室性不整脈発生，2)術前慢性心房細動を有する患者を除いた患者を対象にした術後上室性不整脈発生，3)術前不整脈を合併していない患者を対象にした術後上室性不整脈発生．

5. 外科的閉鎖とカテーテル閉鎖の比較

すべての患者を外科的閉鎖群とカテーテル閉鎖群にわけ，統計学的に術前，術後データを比較検討した．

6. 統計学的検討

2値データは chi-square test，連続値は正規分布の場合は Student t-test を非正規分布の場合は Welch's modified t-test を用いて比較検討した．僧帽弁，三尖弁逆流は Mann Whitney-U test を用いて比較検討した．左心室の駆出率の術前術後の変化の比較は Two-way ANOVA を用いた．在院日数の比較には Logistic regression models を用いた．術後不整脈の発生率の比較には Cox proportional hazard model を用いた．術後上室性不整脈保有率の分析には年齢，ASD 径，術前上室性不整脈保有の有無を，新規術後上室性不整脈発生率の分析と術前上室性不整脈改善率の分析には年齢と ASD 径を多変量解析に投入した．以上の統計学的検討は SPSS 10.0 for Windows software package(SPSS Inc., Tokyo, Japan)を用いて行われた．データは mean±SD もしくは median で表記した．$P<0.05$ を統計学的に有意であると判断した．

結　果

1. 術前状態の比較検討と閉鎖手技

1991年3月から2008年12月までの間に ASD の外科的閉鎖もしくはカテーテル閉鎖を施行した378例中，40歳以上成人患者は100例であった．Fig. 1 に本研究期間の40歳以上成人患者の patient distribution を示した．カテーテル閉鎖導入後成人 ASD 閉鎖術の90%(73/81)がカテーテル閉鎖であった．Table 1 に術前の患者データの詳細を示した．1991年3月から2008年12月までの間に27例の外科的 ASD 閉鎖術を施行した(外科的閉鎖群)．内，8例がカテーテル閉鎖導入後の手術症例である．この8例が手術を選択した理由は ASO が留置できない large ASD が2例，aortic rim 以外の rim 欠損が3例，floppy rim が2例，比較的大きい ASD(最大径 35 mm)でかつ左房が小さく ASO が留置できない症例が1例であった．2005年11月から2008年12月までの間に78例に対してのべ80回のカテーテル閉鎖を施行した．この内，73例で初回もしくは再試行のカテーテル閉鎖で ASD 閉鎖に成功した．この73例を本研究のカテーテル閉鎖群とした．カテーテル閉鎖非成功の5例中2例に対し，手術による閉鎖が行われた．この2例は外科的閉鎖群に含まれている．残りの3例は外科的閉鎖待機中もしくは経過観察中である．

Table 1 Comparison of the patient's preoperative demographics

	Device (N=73) Mean±SD (range)	Surgery (N=27) Mean±SD (range)	P
Period	Nov 2005–Dec 2008	Mar 1991–Dec 2008	<0.001
Age (years)	52.4±7.7 (40–84)	58.4±12.0 (42–73)	0.004
Female:Male	43:30	19:8	0.256
ASD diameter (mm)	18.7±6.7 (6–37)	31.1±10.6 (14–50)	<0.001
CTR	53±7 (39–75)	57±7 (44–75)	0.030
Qp/Qs	2.48±0.62 (1.38–4.00)	2.78±1.04 (1.64–6.39)	0.181
mPAP (mmHg)	16±6 (8–38)	19±8 (9–47)	0.039
PAR (Wood unit m^2)	1.72±0.90 (0.55–6.20)	2.19±1.32 (0.51–5.30)	0.158
LVEF (%)	70±7 (44–84)	66±11 (48–84)	0.083
Cr (mg/dl)	0.73±0.21 (0.43–1.99)	0.73±0.26 (0.45–1.78)	0.987
HT	19% (14/73)	7% (2/27)	0.154
HL	12% (9/73)	0%	0.056
DM	15% (4/73)	4% (1/27)	0.718
Atrial arrhythmia	22% (16/73)	33% (9/27)	0.242
Chronic Af	14% (10/73)	7% (2/27)	0.390
Paf/PAF/PAT	8% (6/73)	26% (7/27)	0.019
Paradox IVS	49% (36/73)	56% (15/27)	0.579
LVDd (mm)	41±5 (31–55)	40±6 (31–55)	0.377
LVDs (mm)	25±4 (18–38)	25±5 (16–35)	0.583
TR	2.1±0.6 (1–4)	2.0±0.8 (1–4)	0.427
MR	1.1±0.6 (0–3)	0.7±0.9 (0–3)	0.006
Embolic event	8% (6/73)	4% (1/27)	0.432

Af, atrial fibrillation; ASD, atrial septal defect; CTR, cardio-thoracic ratio; Cr, serum creatinine level; DM, diabetes mellitus; GFR, glomerular filtration rate; HL, hyper lipidemia; HT, hypertension; IVS, interventricular septum; LVDd, left ventricular end-diastolic diameter; LVDs, left ventricular end-systolic diameter; LVEF, left ventricular ejection fraction; mPAP, mean pulmonary arterial pressure; MR, mitral regurgitation; Paf, paroxysmal atrial fibrillation; PAF, paroxysmal atrial flutter; PAR, pulmonary arterial resistance; PAT, paroxysmal atrial tachycardia; TR, tricuspid regurgitation

外科的閉鎖は5例で直接閉鎖，21例で自己心膜によるパッチ閉鎖，1例でゴアテックスパッチによるパッチ閉鎖が施行された．平均人工心肺時間61±33分，平均大動脈遮断時間は29±22分であった．同時施行手術は，僧帽弁形成術2例，三尖弁形成術5例，心房のアブレーション4例であった．不整脈手術施行例はすべてカテーテル閉鎖導入後(2006年以降)の症例であり，肺静脈孤立化の予防的施行1例(術後心房細動は出現しなかったが，上室性頻拍が出現した)，心房粗動に対する右房Maze手術1例(術後改善)，右房Maze手術の予防的施行1例(術後不整脈出現せず)，慢性心房細動症例に対する肺静脈孤立化＋右房Maze手術1例(術後改善)であった．右房Maze手術は凍結凝固で，肺静脈の孤立化は高周波通電を用いて施行した．

一方，73例のカテーテル閉鎖で76個のASDを閉鎖した．1例でデバイスを2個使用し，1例でデバイスを3個留置した．Amplatzerデバイスの平均径は22±7 mm(6 mm～38 mm)であった．

カテーテル閉鎖群は外科的閉鎖群と比較して，有意に高年齢であり，ASD径は小さく，低い肺動脈圧，大きい心胸郭比(CTR)，高度な僧帽弁逆流，高い術前上室性不整脈保有率であった．Qp/Qs，肺血管抵抗，左心室駆出率，血清クレアチニン濃度，左室拡張末期圧，左室収縮末期径，三尖弁逆流，高血圧・糖尿病・高脂血症の保有率，慢性心房細動保有率，心室中隔の奇異性運動保有率，塞栓症の既往保有率に有意差を認めなかった．

2. 術後成績の比較検討

Table 2に両群の術後成績を示した．カテーテル閉鎖群は外科的閉鎖群に比し，短い観察期間であった．カテーテル閉鎖群のすべての患者で6カ月以上の観察

Table 2 Comparison of the postoperative outcomes except for outcomes of the atrial arrhythmia

	Device (N=73) Mean±SD (range)	Surgery (N=27) Mean±SD (range)	P
Follow (y)	1.8±0.9 (0.5–3.6)	4.8±4.8 (0.1–18.3)	0.003
Mortality	1.3% (1/73)	0%	0.541
Major morbidity	0%	0%	
CTR (%)	51±7 (39–74)	51±5 (40–62)	0.626
LVEF (%)	72±5 (60–83)	67±10 (34–83)	0.011
Cr (mg/dl)	0.75±0.39 (0.44–3.73)	0.71±0.37 (0.35–2.27)	0.701
Paradoxical IVS	10% (7/73)	15% (4/27)	0.458
Paradox IVS improvement	81% (29/36)	73% (11/15)	0.746
Residual≤mild	11% (8/73)	0%	0.073
Residual≤moderate	0%	0%	
Hosp stay (days)	3±1 (2–8)	15±7 (6–31)	<0.001
LVDd (mm)	46±5 (29–58)	42±5 (30–52)	<0.001
LVDs (mm)	27±4 (18–38)	26±5 (16–39)	0.683
TR	1.6±0.6 (0–3)	1.2±0.7 (0–2)	0.017
TR deterioration	0%	0%	
MR	1.4±0.7 (0–3)	0.8±0.9 (0–3)	<0.001
MR deterioration	32% (23/73)	26% (7/27)	0.589
Embolic event	0%	0%	

CTR, cardio-thoracic ratio; Cr, serum creatinine level; GFR, glomerular filtration rate; Hosp stay, postoperative hospital stay; IVS, interventricular septum; LVDd, left ventricular end-diastolic diameter; LVDs, left ventricular end-systolic diameter; LVEF, left ventricular ejection fraction; mPAP, mean pulmonary arterial pressure; MR, mitral regurgitation; TR, tricuspid regurgitation

Table 3 Comparison of outcomes on the atrial arrhythmias

			Univariate	Multivariate		
	Device	Surgery	P	P	HR	CI
Atrial arrhythmia	12% (9/73)	33% (9/27)	0.015	0.153	0.004	0.0–7.9
New onset atrial arrhythmia	0% (0/57)	11% (2/18)	0.011	0.266		
Arrhythmia improvement	44% (7/16)	22% (2/9)	0.256			
Chronic Af improvement	10% (1/10)	50% (1/2)	0.166			
Paf/PAF/PAT improvement	100% (6/6)	14% (1/7)	0.002	0.255	0.015	0.0–20.7

Af, atrial fibrillation; Paf, paroxysmal atrial fibrillation; PAF, paroxysmal atrial flutter; PAT, paroxysmal atrial tachycardia

期間を有した．カテーテル閉鎖群の1例は前立腺癌で死亡した．両群で外科的処置を必要とする合併症，血栓塞栓症，治療を要する心不全などの，侵襲的治療や集中治療室管理を要する合併症を認めなかった．カテーテル閉鎖群は外科的閉鎖群に比べて，良好な左室駆出率，短い在院日数，大きい左室拡張末期径，高度な三尖弁もしくは僧帽弁逆流を認めた．しかしながら，左室駆出率の変化は両群で改善傾向であった．CTR，血清クレアチニン濃度，心室中隔奇異性運動保有率，左室収縮末期径，僧帽弁逆流に両群間の有意差は認められなかった．三尖弁逆流が悪化する症例は認めなかった．

Table 3に術後上室性不整脈の結果を示した．カテーテル閉鎖群は外科的閉鎖群に比し，低い術後上室性不整脈発生率，低い新規上室性不整脈発生率，高い術前上室性不整脈改善率を示した．多変量解析ではこれらに有意差は認めなかった．ASO導入以降の外科的閉鎖群8例の術後上室性不整脈発生率は25%(2/8)であった．Fig. 2にestimated postoperative atrial tachyarrhythmia free survivalを示した．これは両群間で同等の上室性不整脈発生率であった．しかしながら，Fig. 3

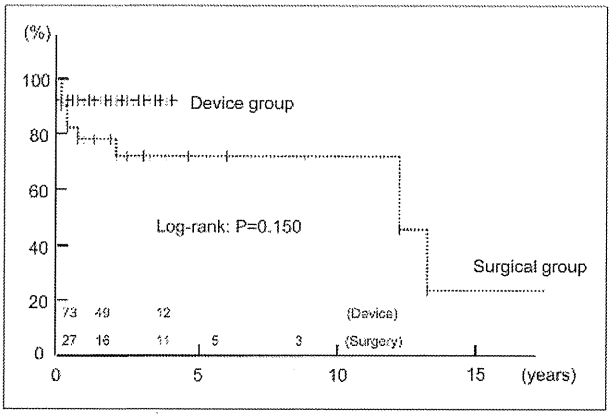

Fig. 2 Estimated postoperative atrial tachyarrhythmia-free survival.
No difference was observed. The mean follow-up periods of the device group and of the surgical group were 1.8±0.9 and 4.8±4.8 years, respectively.

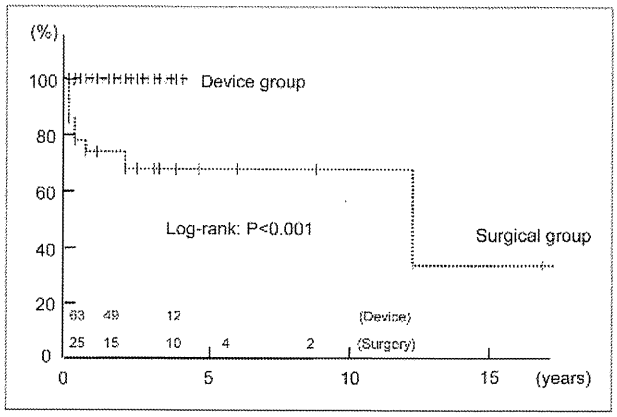

Fig. 3 Estimated postoperative atrial tachyarrhythmia-free survival in patients without preoperative chronic atrial fibrillation.
The incidence of postoperative atrial tachyarrhythmia was significantly lower in the device group than in the surgical group in patients without preoperative chronic atrial fibrillation. The mean follow-up periods of the device group and of the surgical group were 1.8±0.9 and 4.5±4.3 years, respectively.

に示されるように，術前に慢性心房細動を有さない患者に限った場合，estimated postoperative atrial tachyarrhythmia free survival はカテーテル閉鎖群が外科的閉鎖群に比し，有意に高かった(Fig. 3，P<0.001)．さらに，術前上室性不整脈を持たない患者の上室性不整脈新規発生はカテーテル閉鎖群で外科的閉鎖群に比べて有意に低かった(Fig. 4，P=0.011)．

また，外科治療群内でカテーテル治療導入前(2005年10月以前，n=19)と導入後(2005年11月以降，n=8)で不整脈発生に変化がないかどうか検討したが，術後上室性不整脈発生率(7/19 vs. 2/8，P=0.551)，新規上室性不整脈発生率(1/13 vs. 1/5，P=0.457)に有意差は認められなかった．術前の上室性不整脈改善率は上昇した(0/6 vs. 2/3，P=0.023)．

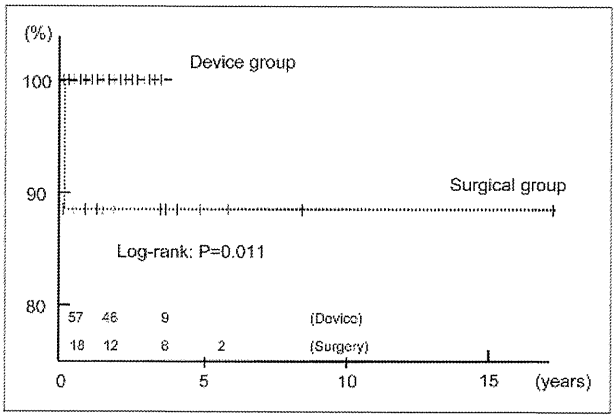

Fig. 4 Estimated postoperative new onset atrial tachyarrhythmia-free survival in patients without preoperative atrial arrhythmia.
The incidence of postoperative atrial tachyarrhythmia was significantly lower in the device group than in the surgical group in patients without preoperative atrial tachyarrhythmia. The mean follow-up periods of the device group and of the surgical group were 1.8±0.9 and 3.3±4.3 years, respectively.

討　論

ASD は加齢に伴って臨床像の変化する疾患である．本研究に認められたように，40歳以上の成人例においても無症状の患者は決して少なくない．Attie らはランダマイズ化比較臨床試験を実施し，40歳以上のASD患者では外科的閉鎖群が薬物治療群に比し，重大な心合併症発生率，死亡率両面で優れていると報告しており[8]，40歳以上でも積極的に ASD は閉鎖すべきと考えられる．現在では多くの症例が手術より低侵襲なカテーテルによるカテーテル閉鎖が可能となり，第一選択となりつつある．本研究は40歳以上患者における，ASD のカテーテル閉鎖と外科的閉鎖を比較検討した最初の研究である．筆者の調べたところ現在までに ASD のカテーテル閉鎖と外科的閉鎖を比較検討した研究は4つの研究のみである[4, 5, 7, 9]．しかし，これらの研究はすべて小児と成人両方を含んでいる．ASD 閉鎖後の上室性不整脈発生率は成人例の方が小児例に比し明らかに高い[6]．特に，40歳以上での ASD 外科的閉鎖例では，術後上室性不整脈の発生率が極めて高いことが知られている[1]．

本研究では，ASD の外科的閉鎖とカテーテル閉鎖はともに手技が原因の死亡および重大な合併症を認めず，その安全性は同等であった．カテーテル閉鎖で1