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All correspondence should be directed to: Ziyad M. Hijazi, MD, Editor-in-Chief, Journal of Structural Heart Disease, PO Box 26999, Doha, Qatar. Tel.: +974-4003-6601, E-Mail: jshd@scienceinternational.org

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Left Atrial Appendage Closure

Where Do We Stand Now?

J. Mauricio Sánchez, MD[1*] and David R. Holmes, Jr., MD[2]

[1] Department of Cardiac Electrophysiology, The Heart Health Center, Mercy Clinic, St. Louis, Missouri, USA
[2] Department of Cardiology, Mayo Clinic, Rochester, Minnesota, USA

Abstract

Atrial fibrillation is the most common arrhythmia with significant morbidity and mortality. The most feared complication of atrial fibrillation remains stroke. While anticoagulation remains the cornerstone of stroke prevention in patients with atrial fibrillation, patients continue to be under treated due to misinformation, intolerance, as well as relative and absolute contraindications. The left atrial appendage has been implicated in thrombus formation in patients with atrial fibrillation. Left atrial appendage closure has been devised as an alternative strategy for decreasing stroke risk in patients with atrial fibrillation. Percutaneous left atrial appendage closure is currently being developed as a possible alternative to anticoagulation in patients at high risk for stroke especially among patients with relative or absolute contraindications to long-term anticoagulation. The PROTECT AF trials provides the first randomized, controlled trial data demonstrating proof of concept of left atrial appendage closure with the WATCHMAN device. Further data are explored in this review. Limited data are available with other devices. However, several devices are promising entries into the realm of left atrial appendage closure offering options to an under treated patient population.

Key Words

Atrial Fibrillation • Left atrial appendage • Left atrial appendage closure • Stroke • Thromboembolism • Bleeding

Introduction

Atrial fibrillation (AF) is the most common arrhythmia, with an overall incidence of 0.4% to 1% in the general population [1-3]. The prevalence of AF increases with age. Given an aging population, the number of patients with AF is likely to increase in the near future. The estimated prevalence in 2010 ranged between 2.1 million and 6.1 million. By 2050, this is projected to increase to between 5.6 and 12 million patients [4], which will present significant challenges for health care delivery. AF results in chaotic atrial contraction and subsequent loss atrial transport function, which impairs left ventricular filling and promotes stasis. The resultant symptoms can range from absent to severe. AF is associated with significant increase in morbidity including congestive heart failure [5], dementia [6], and significant increase in mortality. The most feared complication of AF is stroke from thromboembolism. Patients with AF are at a five times higher risk of stroke [7]. This risk increases with age [8]. Strokes in AF patients are often more severe than in non-AF related strokes [9].

Anticoagulation with vitamin K antagonists has been the cornerstone of stroke prevention in AF patients at high risk for embolic stroke. Vitamin K antagonists have been shown to decrease incidence of thromboembolic stroke in these patients as well as

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*Corresponding Author:
J. Mauricio Sánchez, MD
Department of Cardiac Electrophysiology
The Heart Health Center
West Wing, Suite 170, St. Louis, MO, 63141
Tel.: +1 314 991 6969; Fax: +1 314 997 6969; E-Mail: Jsanchez@Hearthealthcenter.com

decreasing the associated mortality from stroke [10]. In clinical practice however, patients who are warfarin eligible are often not treated [11]. In addition, approximately a quarter of patients who initiate therapy will discontinue its use at 1 year [12]. Novel oral anticoagulants (NOAC) have been shown to be non-inferior or superior compared to warfarin but also have discontinuation rates of between 17–25% at 2 years [13-15]. Complications from anticoagulation, including bleeding, intolerance, and falls, present challenges to traditional therapy and NOACs alike.

The left atrial appendage (LAA) is known play a significant role in thrombus formation and stroke in AF, with approximately 90% of thrombi located in the LAA in patients with nonvalvular AF based on echocardiographic and autopsy data [16]. Percutaneous LAA closure has emerged as an alternative strategy for reducing risk of thromboembolic stroke in patients with nonvalvular AF. Understanding the history of LAA closure and the emergence of current percutaneous technologies is imperative to the understanding of the developing field and future indications.

The Left Atrial Appendage

The LAA is a complex structure that is a remnant of the embryological left atrium. This pouch-like projection has a variety of morphologic appearances and anatomy with variable size, length, width, and number of lobes. In the setting of AF, poor atrial transport function results in stasis within the LAA. This can be documented by low Doppler inflow velocities on transesophageal echocardiography (TEE) and by spontaneous echo contrast, which are both associated with increased risk of stroke [17]. The walls can have a significant amount of trabeculations which may predispose to stroke [18]. Four main morphologies have been characterized based on appearance including: chicken wing, cactus, wind sock, and cauliflower. Non-chicken wing morphologies are significantly more likely to be associated with a thromboembolic event [19] even after controlling for traditional risk factors ($CHADS_2$ score.) Other factors such as endothelial dysfunction, inflammation, platelet activation, and hypercoagulable state have also been implicated in having a role the increased risk of thromboembolism [20, 21]. Assessment of stroke risk in AF remains of paramount importance. Utilization of the $CHADS_2$ score previously and now CHA_2DS_2VASc score [22] is recommended to determine patient risk per year of stroke and subsequent need for possible anticoagulation (Table 1).

Oral anticoagulation utilizes a systemic approach to decrease thrombus formation and subsequent thromboembolism. In contrast, LAA closure provides a local therapy to achieve a similar result. LAA closure is especially appealing in patients intolerant or with contraindications to systemic anticoagulation.

Table 1: $CHADS_2$ and CHA_2DS_2-VAS_C for ischemic stroke

$CHADS_2$			**CHA_2DS_2-VAS_C**		
	Risk Factor	Points		Risk Factor	Points
C	Congestive heart failure	1	C	Congestive heart failure	1
H	Hypertension	1	H	Hypertension	1
A	Age 75 years	1	A_2	Age 75 years	2
D	Diabetes mellitus	1	D	Diabetes mellitus	1
S_2	Previous stroke or TIA	2	S_2	Previous stroke or TIA	2
			V	Vascular disease	1
			A	Age 65–74 years	1
			Sc	Sex (female gender)	1
Maximum score		6			9

Surgical Closure

Surgical closure of the LAA has been performed for many years with mixed results. The first reported cases of LAA exclusion in the surgical literature was in 1949, in two patients with recurrent arterial emboli [23]. Since that time, surgical ligation has fallen in and out of favor. TEE assessment has shown surgical techniques to have a high occurrence of unsuccessful closure. Success is dependent on the surgical technique utilized with excision providing the best results [24]. Currently, LAA excision is performed usually as an additional procedure with cardiac surgery or as part of a surgical MAZE procedure. Thoracoscopic LAA excision is mainly performed with thoracoscopic surgical pulmonary vein isolation [25], though stand-alone procedures have been reported [26, 27]. There has been a lack of large, randomized, controlled trials with evaluation of long-term stroke risk after surgical LAA closure. Currently, the Left Atrial appendage Occlusion Study (LAAOS III) is being conducted to evaluate LAA occlusion during on-pump cardiac surgical procedures. It is a large-scale randomized controlled trial with an enrollment goal of 4,700 patients with AF. The end-point will be first occurrence of stroke or systemic arterial embolism over a mean follow up of 4 years.

Surgical clip devices have been developed in order to more predictably close the LAA during cardiac surgical procedures. The AtriClip system (AtriCure-USA, West Chester, Ohio, USA) and the Tigerpaw system (Maquet, Rastatt, Germany) are available in the United States [28, 29]. Advantages of use include utilization with live TEE guidance to evaluate position of the clip prior to final closure. While observational studies have demonstrated safety and feasibility of clip based LAA closure, there are no randomized, controlled trial data demonstrating efficacy with regard to stroke prevention. These devices are usually utilized in patients undergoing cardiac surgery, though stand-alone thoracoscopic implantation has been reported with the AtriClip [30]. Further data should help further delineate the effect on clinical outcome of surgical closure with these novel devices.

Transcatheter Closure

Percutaneous transcatheter approaches have been developed to close the LAA. The inherently less-invasive nature compared to surgical techniques has resulted in significant enthusiasm for transcatheter LAA closure as possible alternative to anticoagulation in patients with nonvalvular AF at high risk for stroke especially among patients with absolute or relative contraindications to long-term anticoagulation. A variety of devices and techniques have been developed with individual development histories and studies which dictate individual efficacy and safety outcomes. Below we discuss, the most frequently studied devices.

PLAATO

The PLAATO device was the first transcatheter LAA occlusion system developed and implanted in humans [31]. The device was a self-expanding nitinol cage covered with an occlusive expanded polytetrafluoroethylene membrane. It was delivered through a trans-septal access into the left atrium via femoral vein. Initial studies demonstrated that transcatheter closure of the LAA with the PLAATO device was feasible and safe in a nonrandomized study of patients at high risk for thromboembolism who were not able to receive warfarin therapy. When compared to expected event rates based on $CHADS_2$ score, the PLAATO device decrease events by 42–65% [32, 33]. The PLAATO system was withdrawn from the market in 2006 due to commercial reasons.

Amplatzer Cardiac Plug

The Amplatzer cardiac plug (St. Jude Medical, Minneapolis, Minnesota, USA) also known as ACP device was developed specifically for LAA closure. The ACP device is a self-expanding nitinol mesh connected to a polyester disk through a central waist (Figure 1). The soft lobe mesh is deformable and deploys distally with anchors that insert into the LAA. This maintains device stability within the LAA. The disk covers the ostium of the LAA sealing it. The development of this device followed the success of the AMPLATZER septal occluder device for patent formen ovale and atrial septal defects. The ACP device is delivered through the femoral vein into the left atrium via transseptal access and requires fluoroscopy and TEE guidance. Patients with the ACP device are maintained on dual

Figure 1. Amplatzer cardiac plug (ACP) device. The ACP device is a self-expanding nitinol mesh connected to a polyester disk through a central waist. The soft lobe mesh is deformable and deploys distally with anchors that insert into the LAA. This maintains device stability within the LAA. The disk covers the ostium of the LAA sealing it (image courtesy of St. Jude Medical, Inc.).

antiplatelet therapy for 1 to 3 months followed by aspirin alone for at least 5 months. Data for this device are limited and consist mainly of small, observational studies in patients not able to take anticoagulation. Initial trials in Europe demonstrated a high rate of procedural success, with 96% of patients successfully implanted in 137 patients [34]. Serious complications were reported in 10 patients (7%), including ischemic stroke, device embolization, and serious pericardial effusion. Data from the Asia Pacific experience and Canadian experience have demonstrated a similar high rate of implant success and similar rate of procedural complications [35, 36]. Thrombus formation on the device has been reported [37-39]. The ACP device has CE mark approval but is not approved in the United States at this time. The new ACP 2 device has been implanted with reported improvements in design including an imbedded threaded insert to decrease thrombus formation [40]. In the United States, a large, randomized, controlled trial of the ACP device compared to oral anticoagulation was recently halted in likely anticipation of still pending FDA approval of the WATCHMAN device [41].

WATCHMAN

The WATCHMAN device (Boston Scientific, Natick, Massachusetts, USA) is the most studied LAA closure device currently in use. It consists of a self-expanding nitinol frame with porous polyethylene terephthalate membrane on the face of the device (Figure 2). The device is delivered through the femoral vein into the left atrium via transseptal access. A 14 French access sheath is carefully maneuvered into the LAA body. The device is loaded into the distal sheath and unsheathed with removal of the access sheath while maintaining distal position of the WATCHMAN device within the LAA. The device is secured in position with fixation barbs present along the sides of the device which engage the endocardium.

This device has CE mark approval. It is the first and only LAA closure device to receive FDA approved in the United States. It was evaluated in a large, randomized, controlled trial in patients with nonvalvular AF who were eligible for warfarin therapy and high risk for thromboembolism. The WATCHMAN Left Atrial Appendage system for Embolic Protection in Patients With Atrial Fibrillation (PROTECT AF) enrolled 707 patients who were candidates for long-term anticoagulation and had nonvalvular AF [42]. The PROTECT AF study was a multicenter non-inferiority trial that randomized patients in a 2:1 fashion to either LAA occlusion with the WATCHMAN device or to warfarin therapy. Patients 18 years old or older with nonvalvular AF were eligible for enrollment with a $CHADS_2$ score greater than or equal to 1 (i.e., at least one of the following: congestive heart failure, hypertension, age greater than 75 years old, diabetes mellitus, previous stroke or transient ischemic attack [43]). Exclusion criteria for the trial included contraindication to aspirin or warfarin, comorbidities other than AF that required chronic warfarin use, LAA thrombus, patent foramen ovale with atrial septal aneurysm and a right-to-left shunt, mobile atheroma, and symptomatic carotid disease. Patients randomized to the device arm were placed on warfarin and aspirin for 45 days postimplantation. Device arm patients then underwent repeat TEE at 45 days of follow up. War-

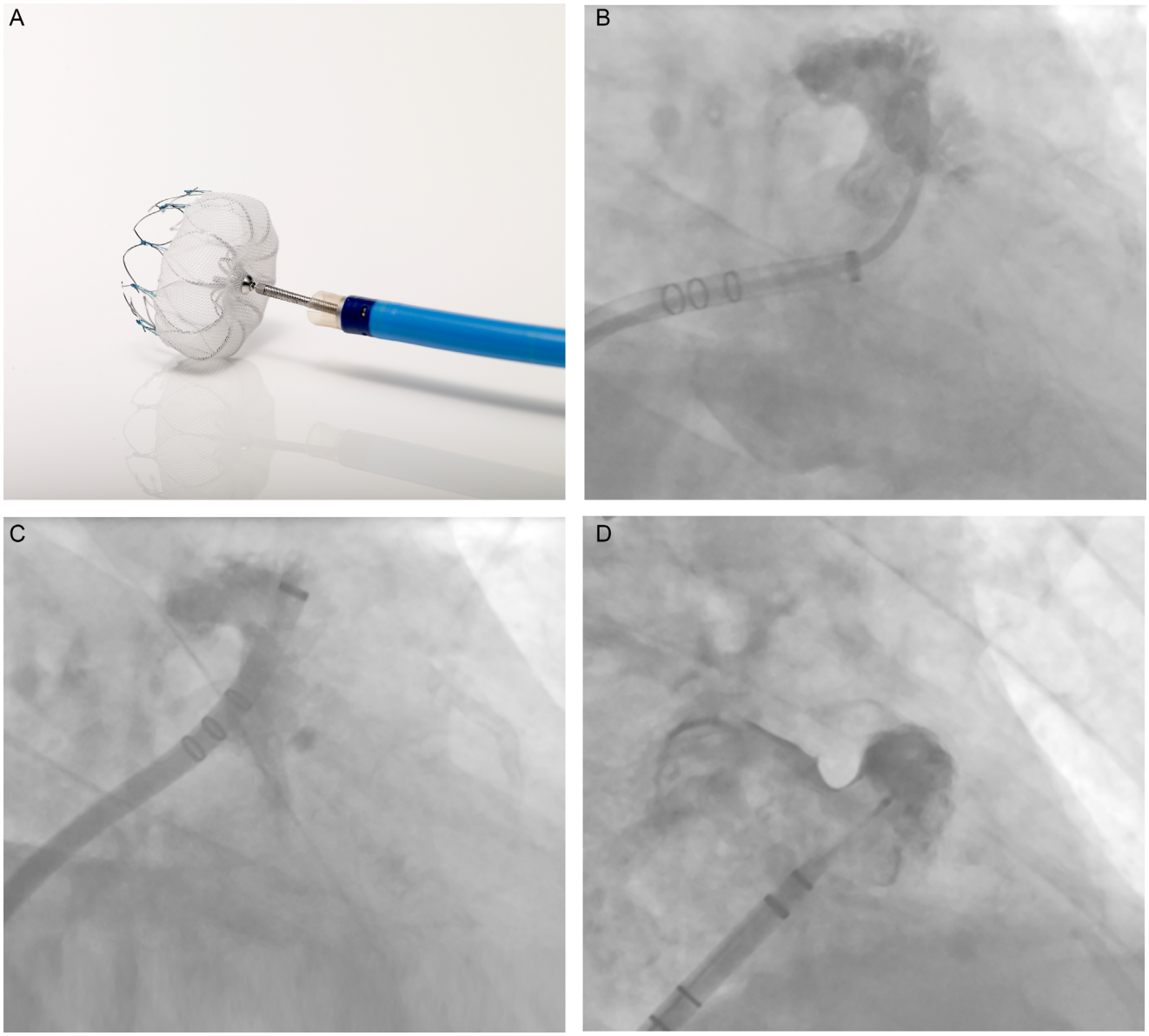

Figure 2. *Panel A*. WATCHMAN device. The WATCHMAN device consists of a self-expanding nitinol frame with fixation barbs. There is a porous polyethylene terephthalate membrane on the face of the device which endothelializes over time occluding the ostium of the appendage (image courtesy of Boston Scientific, Inc.). *Panel B*. Left atrial appendage (LAA) with pigtail catheter in place. A pigtail catheter is utilized to cannulate the LAA in an atraumatic fashion. Angiography of the LAA is performed to gain an understanding of the anatomy. The WATCHMAN 14 French sheath is placed over the pigtail into the LAA. *Panel C*. LAA with WATCHMAN sheath. The pigtail catheter is removed and the WATCHMAN 14 French access sheath is carefully maneuvered distally into the LAA. Marker bands which are visible under fluoroscopy allow for determination of where the device will land when access sheath is removed and device unsheathed. *Panel D*. LAA with WATCHMAN deployed. The device is loaded into the distal sheath and unsheathed with removal of the access sheath while maintaining distal position of the WATCHMAN device within the LAA. The device is secured in position with fixation barbs present along the sides of the device which engage the endocardium.

farin was discontinued in those patients who either had complete closure of the LAA or a small peridevice leak (jet < 5 mm in width). After discontinuation of warfarin, aspirin (81–325 mg) was continued with the addition of plavix (75 mg) until the 6-month follow up. At this point, plavix was discontinued. Aspirin

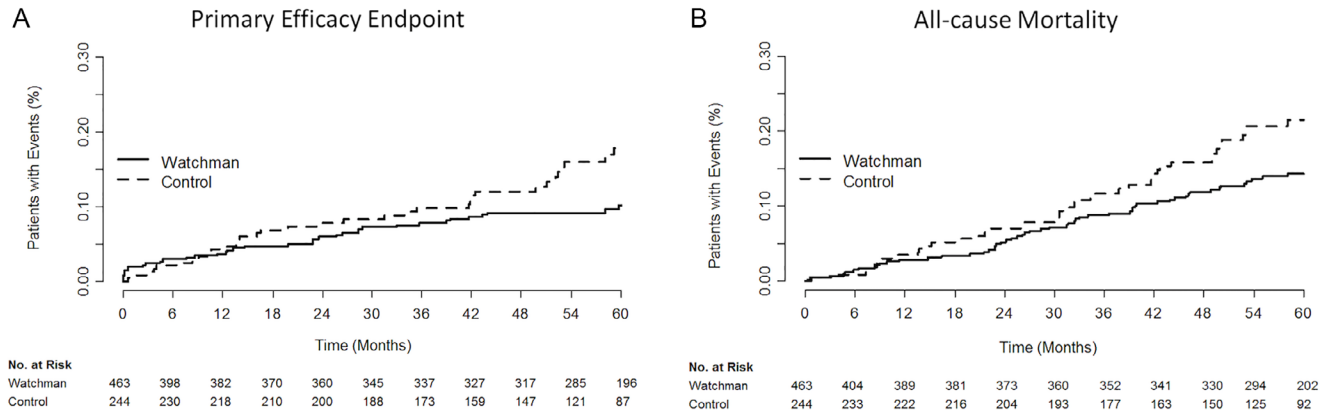

Figure 3. WATCHMAN efficacy data (PROTECT AF). *Panel A*. Primary efficacy. At 2621 patient-years of follow up, the WATCHMAN device met criterion for superiority compared to warfarin therapy for the combined endpoint of cardiovascular/unexplained death, stroke, or systemic embolism (2.3 events per 100 patient-years versus 3.8 per 100 patient years; RR 0.6; 95% CrI 0.41 to 1.05; posterior probability of 96%) [45]. *Panel B*. All-cause mortality. At 2621 patient-years of follow up, the WATCHMAN device was superior with regard to all-cause mortality (3.2% versus 4.8%; RR 0.66; 95%CrI, 0.45 to 0.98) and cardiovascular mortality (1 per 100 patient years versus 2.4 per 100 patient-years; RR 0.4; 95%CrI, 0.21 to 0.72) compared with warfarin [45].

alone was continued thereafter.

The initial 1065 patient-years follow-up demonstrated WATCHMAN as noninferior to warfarin for the combined efficacy primary endpoint of cardiovascular/unexplained death, stroke, or systemic embolism. The primary efficacy endpoint event rate was 3.0 per 100 patient-years (95% credible interval [CrI] 1.9–4.5) in the WATCHMAN group and 4.9 per 100 patient-years (95% CrI 2.8–7.1) in the warfarin group (rate ratio [RR] 0.62, 95% CrI 0.35–1.25). Analysis at 1588 patient-years confirmed the noninferiority of WATCHMAN compared to warfarin with regard to the primary efficacy endpoint of cardiovascular/unexplained death, stroke, or systemic embolism (RR 0.71, 95% CrI 0.44 to 1.30) [44]. At 2621 patient-years of follow up, the WATCHMAN device met criterion for superiority compared to warfarin therapy for the combined endpoint (2.3 events per 100 patient-years versus 3.8 per 100 patient years; RR 0.6; 95% CrI 0.41 to 1.05; posterior probability of 96%) [45]. Additionally, the WATCHMAN device was superior with regard to all-cause mortality (3.2% versus 4.8%; RR 0.66; 95%CrI, 0.45 to 0.98) and cardiovascular mortality (1 per 100 patient years versus 2.4 per 100 patient-years; RR 0.4; 95% CrI, 0.21 to 0.72) compared with warfarin (Figure 3). Hemorrhagic stroke rates were significantly lower in the WATCHMAN group (0.2% versus 1%; RR 0.18; 95% CrI, 0.04 to 0.6).

The PROTECT AF study demonstrated that the WATCHMAN device could be successfully implanted. It was successfully implanted in 88% (408/463) of patients randomized to the WATCHMAN group and in 91% (408/449) of patients in whom implant was attempted. At the 45-day TEE, 86% (349/408) of patients were able to discontinue warfarin. At the 6-month TEE, 92% (355/408) of patients were able to discontinue warfarin. While long-term follow up of PROTECT AF has demonstrated sustained efficacy and confirmed long-term safety, acute safety events in PROTECT AF were an initial concern. Primary safety events at 18 months occurred at a higher rate in the WATCHMAN group compared to the warfarin group (RR 1.69, 95% CrI 1.01–3.19). The majority of safety events in the WATCHMAN group (55%, 27out of 49) occurred on the day of the procedure. This contrasts to the warfarin group, which had half (8 out of 16) occur between day 45 and 1 year. The most frequent primary complications were directly procedure related including serious pericardial effusion and procedure-related ischemic stroke. No peri-procedural death or long-term disability occurred within this or in any WATCHMAN clinical trial. In further analysis, there was a significant decline in procedure related safety events within 7 days of the procedure between the first and second halves of the PROTECT AF trial and the Continued Access Protocol Registry (CAP)

[46]. This suggested a significant improvement in safety with operator experience and technical refinement of the procedure.

The Prospective Randomized Evaluation of the Watchman Left Atrial Appendage Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy (PREVAIL) trial was the second randomized, controlled trial conducted to further evaluate safety and efficacy with the WATCHMAN device in response to U.S. Food and Drug Administration concerns over selection criteria and acute safety events [47]. The PREVAIL trial randomized patients 18 years old or older with nonvalvular AF with a $CHADS_2$ score greater than or equal to 2 or 1 with an additional high-risk characteristic (female age ≥ 75 years, baseline ejection fraction ≥ 30 but < 35%, age 65 to 74 years and either diabetes or coronary disease, and age ≥ 65 years old with congestive heart failure). This was meant to include higher risk patients than were evaluated in PROTECT AF. A total of 407 patients were randomized in a 2:1 fashion with 269 patients in the WATCHMAN group and 138 patients in the warfarin group. The WATCHMAN device was successfully implanted in 95.1% of patients in whom implant was attempted, an improvement from PROTECT AF (p = 0.04). Furthermore, 39.1% of implants were performed by new implanters with no statistically significant difference in success or in complications compared to experienced implanters demonstrating improvements in physician education and the evolution of the procedure. All 7-day complications after attempted implantation including pericardial effusion requiring surgery, pericardial effusion requiring pericardiocentesis, procedure-related strokes, and device embolization occurred at significantly lower rate in PREVAIL compared to PROTECT AF (4.5% versus 8.7%, p = 0.004). This data was consistent with data from CAP registry demonstrating procedural complications as infrequent and significantly improved (Figure 4).

The PREVAIL composite 18 month efficacy endpoint (stroke, systemic embolization, and cardiovascular/unexplained death) failed to achieve the noninferiority prespecified criteria. Event rates in the WATCHMAN arm and the warfarin arm were similar (0.064 versus 0.063). The 18-month rate ratio of 1.07 had a 95% CrI of 0.57 to 1.89, which failed to meet the prespecified upper bound

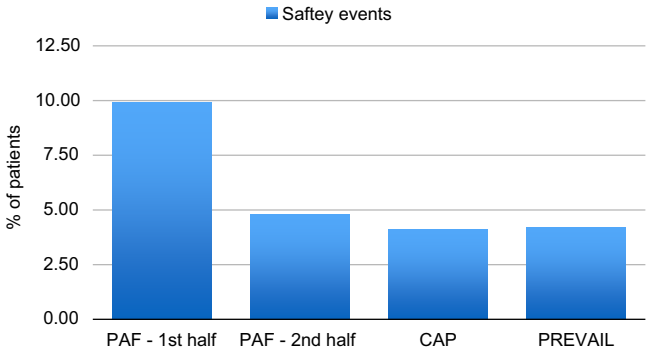

Figure 4. WATCHMAN safety events: PROTECT AF(PAF), Continued Access Protocol Registry (CAP), Prospective Randomized Evaluation of the Watchman Left Atrial Appendage Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy (PREVAIL). Safety data from PROTECT AF and CAP registry were compared by Reddy et al. [45]. Results of PREVAIL [47] demonstrated consistent reduction in safety events. All 7-day complications after attempted implantation including pericardial effusion requiring surgery, pericardial effusion requiring pericardiocentesis, procedure related strokes, and device embolization occurred at significantly lower rate in PREVAIL compared to PROTECT AF (4.5% versus 8.7%, p = 0.004).

of 1.75. The rate of stroke after 7 days after randomization was 0.0253 in the WATCHMAN arm and 0.0273 in the warfarin arm meeting prespecified criteria for noninferiority. Importantly, the warfarin arm ischemic stroke rate per patient years in PREVAIL (0.70) was significantly lower than all other recent AF studies involving NOACs [i.e. RE-LY (1.7) [13], ARISTOTLE (1.6) [14], and ROCKET AF (2.2) [15]].

While PROTECT AF, CAP, and PREVAIL included warfarin eligible patients, the group in most need of alternatives to anticoagulation include those nonvalvular AF patients who are unable to be treated with anticoagulation. While there are no randomized trial data, the ASA Plavix Registry (ASAP) study evaluated such patients [48]. A total of 150 nonvalvular AF patients who were ineligible for warfarin were prospectively enrolled in this observational study. Prior bleeding was the main reason for inability to be treated with warfarin. Patients were placed on with clopidogrel for 6 months after implantation of the WATCHMAN device and with aspirin indefinitely thereafter. Patients were followed up for a mean of 14.4±8.6 months. The observed event rate for stroke or systemic embolism was 2.3% per year. The expected event rate based

on a mean $CHADS_2$ score of 2.8 was 7.3% per year. This demonstrated an association with significant event rate reduction. Of note, laminar thrombus formation has been reported with the WATCHMAN device. The ASAP trial had six cases of thrombus formation (4%) on the device with only one resultant clinical event (ischemic stroke). This was similar to PROTECT AF, which had a 4.2% (20 of 473) thrombus formation rate with three having ischemic strokes. The thrombus-associated annualized stroke rate was 0.3%. While ASAP was a prospective, observational trial, the totality of data involving the WATCHMAN device remains critical to establishing the LAA as focal source of thromboembolus and that closure of the LAA decreases stroke rate. Data from various studies support WATCHMAN as an alternative to anticoagulation in both warfarin eligible and warfarin ineligible patients.

Lariat

The Lariat device (SentreHeart, Redwood City, California, USA) is a transcatheter LAA ligation system that utilizes both endocardial and epicardial approach to place a preformed surgical knot around the ostium of the LAA and approximate all walls thus excluding the LAA [49]. Epicardial access ("dry tap") is performed through a subxyphoid approach with a micropuncture needle or 17-gauge epidural needle. Access is obtained in the anterior aspect of the pericardial sac with angulation toward the LAA. Dilation up to a 14 French sheath is required. The 14 French epicardial sheath is placed over a stiff guidewire. Femoral venous access is obtained and a transseptal puncture is performed to gain left atrial access. A magnet tip wire is then placed in the LAA endocardially. An epicardial magnet wire is advanced into the pericardial space toward the LAA until a connection is made between the endo- and epi-magnet wires. The Lariat loop snare is then carefully advanced over the epicardial wire while holding the wires in place until the device is placed over the LAA and closed (Figure 5). TEE guidance is utilized to visualize LAA closure and assess adequacy of closure. A preformed surgical knot is deployed. A tensioner is used to tighten the knot before cutting the suture. The procedure is limited to patients with LAA less than 40 mm due to loop snare size. Unfavorable orientation of the appendage determined on the required preoperative CT may exclude the patient from this procedure. It is also limited to patients who have not had previous cardiac surgery. The device currently has FDA 510k approval for tissue approximation. While initial data has demonstrated a high rate of success in terms of closure and leaks, most studies have been small, observational studies. Bartus et al. [49] prospectively enrolled 92 patients who were not warfarin eligible or were poor candidates for warfarin. Presence of pericardial adhesions excluded three patients. The remaining 89 patients underwent attempted Lariat closure of the LAA. Successful closure ($<$ 1 mm residual leak) was performed in 96% of the patients. Of patients undergoing TEE at one year, 98% (64 of 65) had complete closure. Complications occurred in five patients with three having pericardial effusions and two having pericarditis. An additional patient developed a late effusion, 2 weeks after LAA closure. More recently, Price et al. [50] retrospectively evaluated the results of Lariat procedures in 154 patients at eight different centers. While procedural success was high (86%), major complications occurred in 15 patients (9.7%). Significant pericardial effusion occurred in 16 patients (10.4%). There were 14 (9.1%) major bleeds with 4.5% of all patients needing transfusion. Death, myocardial infarction, or stroke occurred in 4 patients (2.9%). Thrombus formation at the endocardial site of LAA closure has also been reported [51, 52]. Given the limited data, a large, randomized, controlled trial is needed not only to confirm the apparent high procedural success but also better understand the clinical efficacy of the procedure as well as the procedural risks involved with this technique.

Wavecrest

The Wavecrest LAA occluder device (Coherex Medical, Salt Lake City, Utah, USA) is an umbrella shaped device designed to cover the LAA at the ostium. It is constructed with a nitinol frame and covering material with anchoring barbs which are deployed after the covering face is first positioned into place at the osmium (Figure 6). The covering material consists of nonpermeable, Teflon material at the face and a foam

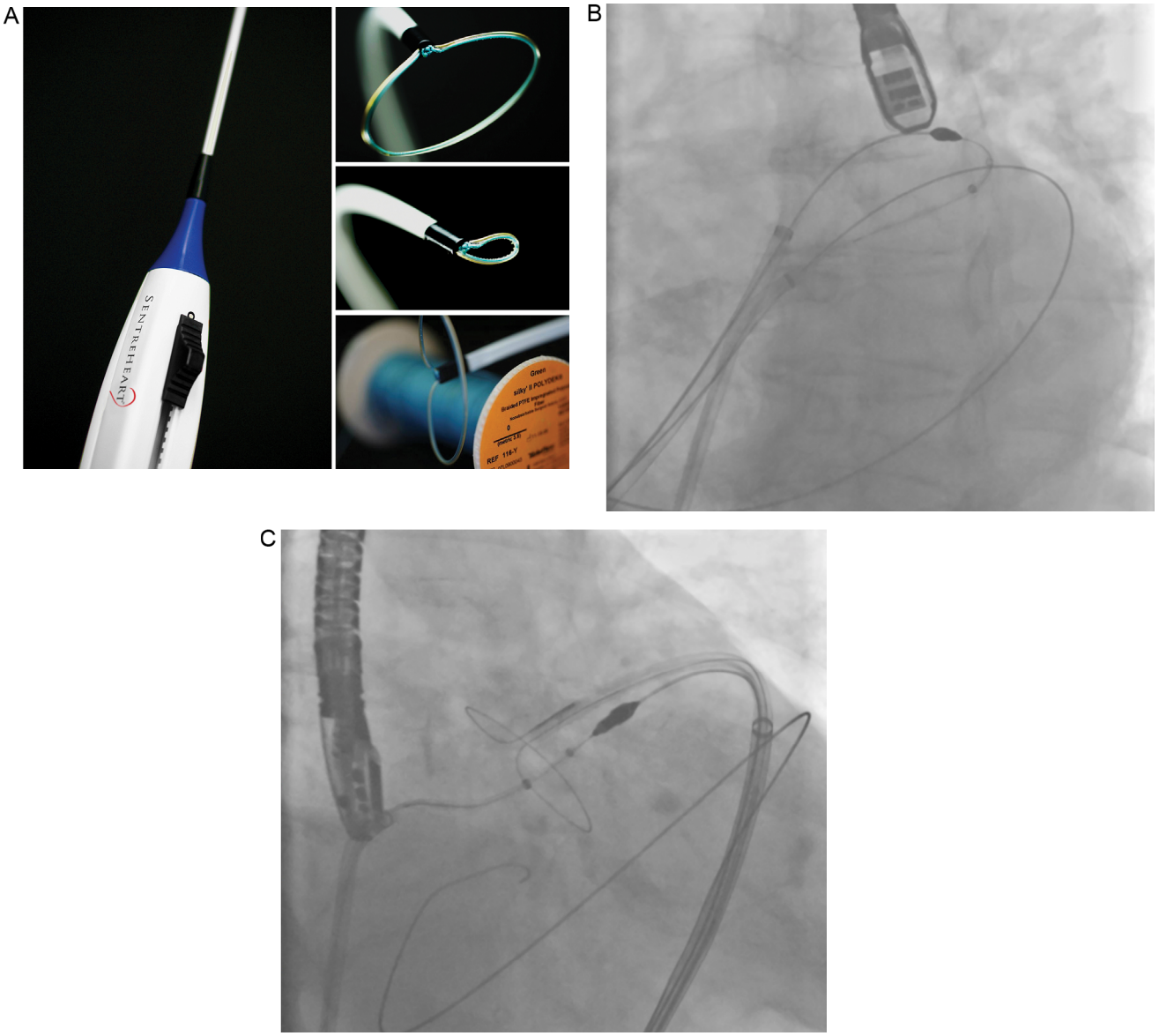

Figure 5. *Panel A.* LARIAT image courtesy of SentreHeart, Inc. *Panel B.* This left anterior oblique projection demonstrates epicardial and endocardial magnet wires connected at the tip of the left atrial appendage (LAA). An additional wire for maintained pericardial access is also seen. *Panel C.* This right anterior oblique fluoroscopy image demonstrates the LARIAT snare being placed over the appendage while the endocardial and epicardial magnet wires function as a rail. Once over the base of the LAA, the snare will be closed.

cuff around the face for direct contact with the endocardium. The device is delivered through the femoral vein into the left atrium via trans-septal access and requires fluoroscopy and TEE guidance as with other LAA occluder devices. The Wavecrest device differs from others in that the occluding atraumatic face of the device is deployed first into the LAA at the ostium and advanced outside of the delivery sheath without requiring delivery sheath placement into the LAA itself. Once in position, the deployment anchors are advanced into the LAA body. Currently, dual antiplatelet therapy is recommended after implantation. This device has received CE mark approval. There is limited data concerning clinical outcomes with this device at this time.

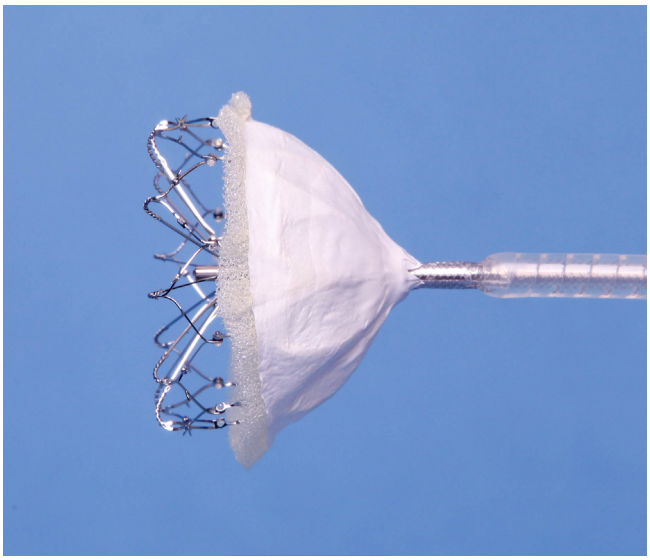

Figure 6. WAVECREST. The Wavecrest is an umbrella shaped device constructed with a nitinol frame and covering material with anchoring barbs which are deployed after the covering face is first positioned into place at the ostium. The covering material consists of non-permeable, Teflon material at the face, and a foam cuff around the face for direct contact with the endocardium (image courtesy of Coherex Medical, Inc.).

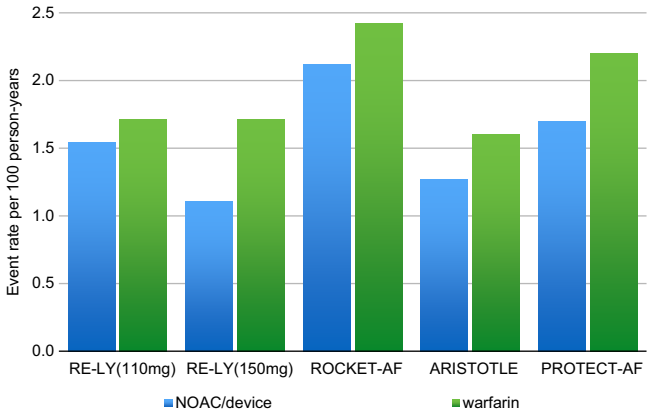

Figure 7. Comparison of stroke or systemic embolism event rate per 100 person-years. RE-LY [13], ARISTOTLE [14], ROCKET-AF [15], and PROTECT AF [45] trials demonstrating event rates of stroke or systemic embolism per 100 person-years.

Discussion

Percutaneous transcatheter LAA closure provides an alternative in the treatment of patients with nonvalvular AF at high risk for stroke. Warfarin alone has been the mainstay of therapy until recently with the introduction of NOAC agents. While these agents provide some advantages over warfarin, they are not without risk of bleeding. While risk of intracranial bleeding is less with these agents, overall risk of bleeding is similar to warfarin with the exception of apixaban. Gastrointestinal bleeding is higher with both dabigatran and rivaroxaban compared with warfarin [13, 15]. Currently, there are no approved antidotes for these agents presenting challenges for management. These agents also do not fully address the issue of noncompliance and intolerance with significant discontinuation rates of all oral anticoagulants. Currently, the European Society of Cardiology guidelines for the management of atrial fibrillation support consideration of transcatheter closure of the LAA in patients with a high stroke risk and contraindications for long-term oral anticoagulation [53]. The American Heart Association/American College of Cardiology/Heart Rhythm Society guidelines for the management of patients with atrial fibrillation discuss percutaneous LAA closure but do not provide any recommendations with regard to its use [54]. Though WATCHMAN has demonstrated noninferiority and superiority compared to warfarin eligible patients, no direct comparison to NOACs is currently available. Indirect comparisons of relative reduction in mortality between NOACs and WATCHMAN compared to warfarin favor LAA closure with WATCHMAN (Figure 7). Indirect comparisons with regard to stroke rate or rate of systemic embolism also appear similar (Figure 8). The debate continues whether the WATCHMAN device should be used as alternative to anticoagulation as in PROTECT AF, CAP and PREVAIL trials or indicated only for those patients with relative or absolute contraindications to anticoagulation as in ASAP. There is a paucity of data with other devices with no other randomized trial data to support LAA closure as an alternative to anticoagulation with such devices at this time. Such devices should be limited to patients with contraindications to anticoagulation until further data are available.

The patients who stand to benefit most from LAA closure include those at highest risk for bleeding. Interestingly, these patients are also at the highest risk of thromboembolic stroke. Continued understanding of risks of transcatheter LAA closure techniques is needed to allow for more accurate risk assessment for patients facing the choice of being at high risk for bleeding com-

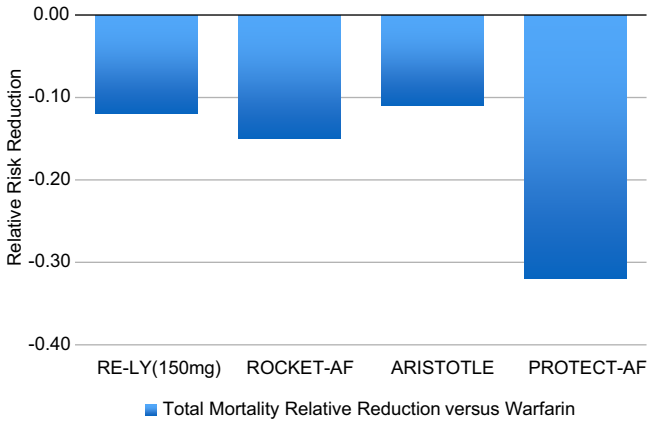

Figure 8. Indirect comparison of total mortality reduction from major trials. RE-LY [13], ARISTOTLE [14], ROCKET-AF [15], and PROTECT AF [45] trials demonstrating relative risk reduction in total mortality.

plications, at high risk for thromboembolic stroke, or at risk of complications from a percutaneous procedure. Tools such as CHA_2DS_2VASc score allow for such determination of CVA risk in nonvalvular AF patients. Assessment of bleeding risk is equally important. The HAS-BLED score [55] has been validated and can be used to determine risk of bleeding among patients who have an indication for anticoagulation (Table 2). The risk of each individual transcatheter technique must be established to accurately determine at what point LAA closure is indicated and the risks acceptable. Consideration of both procedure risks and long-term risks of the device themselves must be evaluated. It is important to note that bleeding and stroke risk continue yearly with life-long anticoagulation, while procedural risks of device implantation are usually short term and should be weighed as such. None the less, there is a large population of patients at this time in need of alternatives especially those with relative and absolute contraindications to anticoagulation use who are also at high risk of thromboembolic stroke from AF.

Conclusion

LAA closure is a rapidly developing area of cardiology with significant promise. Transcatheter LAA occlusion has shown that local therapy can reduce systemic thromboembolism. The individual techniques and devices involved require continued prospective study to demonstrate each device's efficacy and safety as well as to determine specific anticoagulation or antiplatelet regimens that may or may not be necessary. While data from the only randomized, controlled, trials available compared LAA closure to anticoagulation eligible patients, it is likely that this technology will be limited until further confirmatory data are available. It is clear that a large percentage of patients are currently unable to be treated with oral anticoagulation of any kind. Another option is needed for patients. Further study may expand the indications as technologies continue to develop and more data are available.

Table 2: HAS-BLED

HAS-BLED	Score
Hypertension (systolic blood pressure > 160 mm Hg)	1
Abnormal renal and liver function (1 point each)	1 or 2
Stroke	1
Bleeding tendency/predisposition	1
Labile INRs (if on warfarin)	1
Elderly (age > 65 years)	1
Drugs or alcohol (1 point each)	1 or 2
Maximum score	9

Conflict of Interest

Sánchez reports having received consulting fees from Boston Scientific, the manufacturer of the Watchman device. Dr. Holmes has received research grant support from Atritech/Boston Scientific. In addition, the Watchman LAA closure technology has been licensed to Atritech, and both Mayo Clinic and David Holmes have contractual rights to receive future royalties from this license. To date, no royalties have been received.

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Atrial Septal Defect: Step-by-Step Catheter Closure

Shreepal A. Jain, MD[1], Bharat V. Dalvi, MD[2*]

[1] Department of Pediatric Cardiac Sciences, Sir H N Reliance Foundation Hospital, Mumbai, Maharashtra, India

[2] Department of Cardiology, Glenmark Cardiac Center, Mumbai, Maharashtra, India

Abstract

Transcatheter device closure of ASD has come a long way since the first experimental closure in dogs by Kings and Mills in 1972. However, unlike earlier devices, the current generation is easier to deploy and retrieve. The secret to a successful procedure includes meticulous planning and execution. It involves comprehensive evaluation from the point of appropriate case selection, detailed pre- and intra-procedural imaging, knowledge of various techniques of device deployment, and anticipating complications and ways to deal with them. In this paper, we describe the step-by-step procedure for transcatheter closure of an atrial septal defect using the Amplatzer Septal Occluder.

Key Words

Atrial Septal defect • Amplatzer Septal Occluder • Catheter closure • Balloon assisted technique • Pulmonary vein deployment technique

Slide Descriptions

Slide # 1:

Title slide

Slide # 10:

Typical electrocardiogram findings [4]:
1. Right axis deviation
2. Incomplete right bundle branch block (rsR' in V1)
3. Right atrial and ventricular enlargement

Slideshow. Click on the presentation above to view the presentation online. Please be aware that the presentation has many embedded videos so there is a long load time (90.4MB). You may download the file at http://dx.doi.org/10.12945/j.jshd.2016.007.14.ppt.01.

Slide # 11:

Chest radiogram findings [4]:
1. Cardiomegaly due to right heart dilatation
2. Dilated main pulmonary artery
3. Pulmonary plethora

Slide # 13:

The device size is chosen based on the largest dimension recorded in any of the standard views (details in subsequent slides).

Fax +1 203 785 3346
E-Mail: jshd@scienceinternational.org
http://structuralheartdisease.org/

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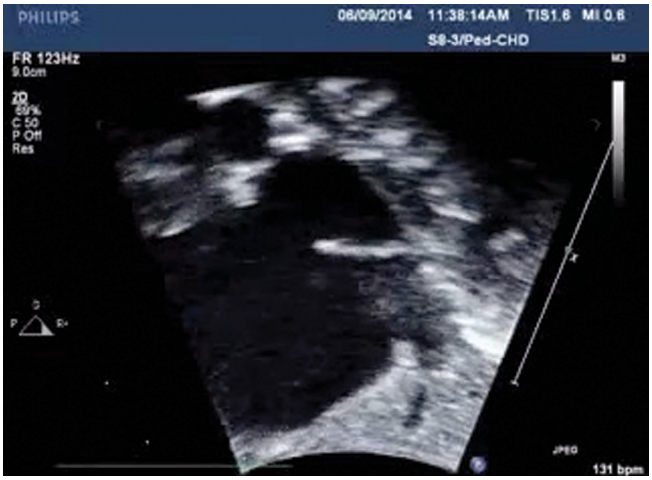
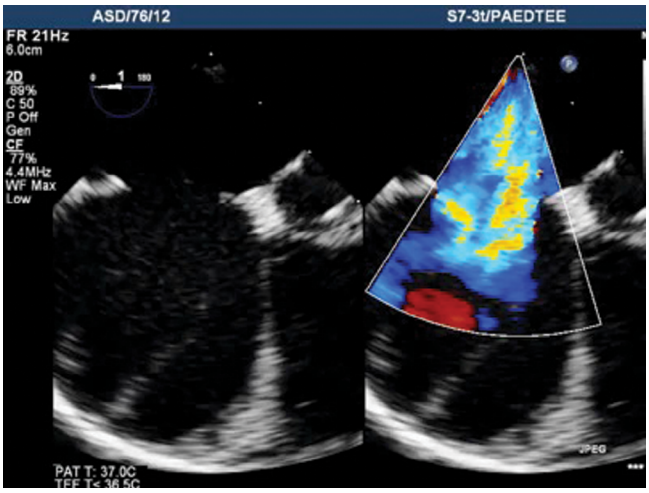
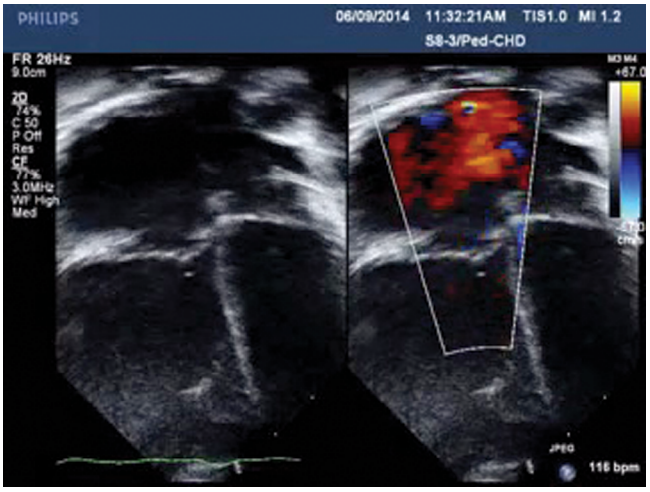
* Corresponding Author:
Bharat V. Dalvi, MD
Glenmark Cardiac Center
Department of Cardiology
First Floor, Flat No.101&102, Opp. Swami Samarth Math & Dhanwantari Hospital
D L Vaidya Road, Behind Shivsena Bhavan, Dadar (West), Mumbai, Maharashtra 400028
Tel. +91 98 21210188, Fax: +91 22 24335058, E-Mail: bharatdalvi@hotmail.com



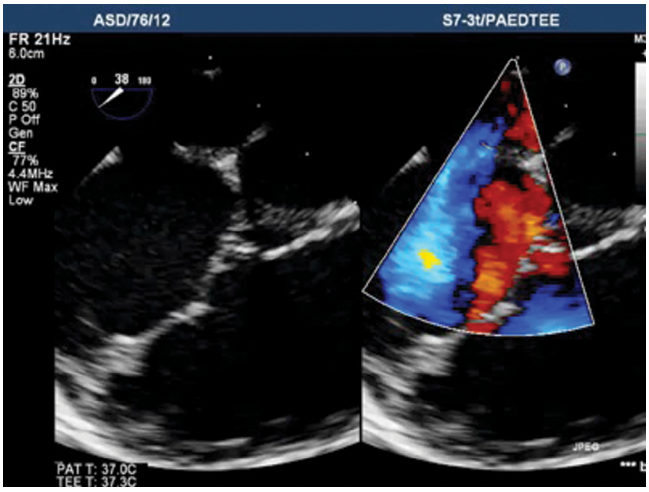
Video 1. Subcostal bicaval view, documenting adequacy of superior vena caval (SVC) and inferior vena caval (IVC) margins. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.01.



Video 3. TEE at 0 degrees (4-chamber view), showing the AV valve (or mitral) and the posterior margins. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.03.



Video 2. Skewed Apical 4 chamber view with color compare showing the atrio-ventricular (or mitral) margin and the posterior margin. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.02.



Video 4. TEE at 40 degrees (aortic short axis view), depicting the retroaortic and the posterior margins. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.04.

Slide # 14:

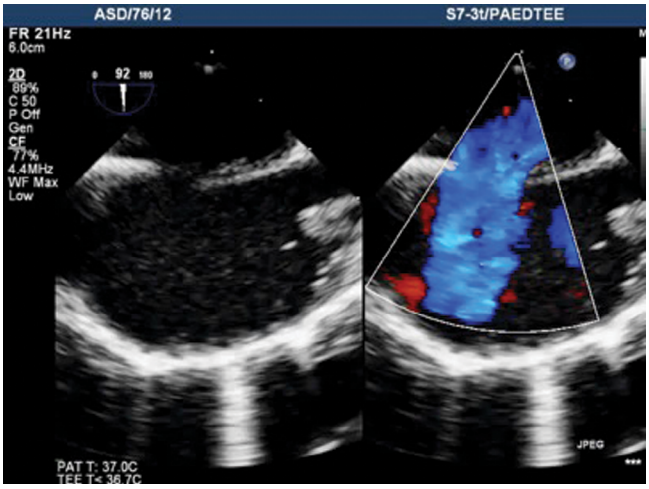
Left frame: Subcostal bicaval view, documenting adequacy of superior vena caval (SVC) and inferior vena caval (IVC) margins (Video 1).

Right frame: Skewed Apical 4 chamber view with color compare showing the atrio-ventricular (or mitral) margin and the posterior margin (Video 2).

Slide # 16:

TEE imaging in different views to confirm adequacy of surrounding margins for device closure of the ASD.

Top left: TEE at 0 degrees (4-chamber view), showing the AV valve (or mitral) and the postero-inferior margins (Video 3).



Video 5. TEE at 90 degrees (bicaval view) demonstrates the superior vena caval and inferior vena caval margins. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.

Figure 1. Panel A. When fully deployed, the occluder assumes a double disc configuration that bridges the septal defect to prevent shunting of blood between the right and left atria. Panel B. Device release is a two staged process, firstly locking of the device by the lock loop and then removal of the retrieval cord.

Top right: TEE at 40 degrees (aortic short axis view), depicting the retroaortic and the postero-superior margins (Video 4).

Bottom: TEE at 90 degrees (bicaval view) demonstrates the superior vena caval and inferior vena caval margins (Video 5).

Slide # 19:

ICE: Intracardiac echocardiography
TTE: Transthoracic echocardiography
TEE: Transesophageal echocardiography

Slide # 25:

Stop-flow technique: The sizing balloon is placed across the ASD and inflated until there is stoppage of flow across the defect on color-flow Doppler imaging. The maximum width of the balloon is then measured on TTE/TEE/ICE as well as fluoroscopy.

Waist measurement technique: The sizing balloon is placed across the ASD and inflated until there is a waist formation noted along both the margins of the balloon on fluoroscopy. This waist is then measured on fluoroscopy.

Slide # 26:

The HELEX^{R} Septal Occluder (W.L: Gore & Associates, Flagstaff, Arizona, USA) is a soft and compliant, non-self-centering device made from a single-length nitinol wire shaped into the left and right atrial discs covered by a polytetraflouroethylene (ePTFE) membrane. The membrane is treated with a hydrophilic coating to facilitate echocardiographic imaging of the occluder during implantation. When fully deployed, the occluder assumes a double disc configuration that bridges the septal defect to prevent shunting of blood between the right and left atria (Figure 1: Panel A). The HELEX^{R} Septal Occluder received FDA clearance in 2006. The HELEX^{R} Septal Occluder, a new device, is the result of an extended development and improvement of the HELEX^{R} Septal Occluder. The wire frame is formed from five wires shaped into the right and left atrial discs, the eyelets, and the lock loop. The five-wire design provides conformability, allowing each individual wire within a right or left atrial disc to conform to the heart anatomy. Device release is a two staged process, firstly locking of the device by the lock loop and then removal of the retrieval cord (Figure 1: Panel B). A 2:1 ratio between the device size and the defect size "balloon-stretched diameter" is used for optimal results, and the device diameter should not exceed 90% of the measured septal length. The device is available in sizes of 15, 20, 25, 30, and 35 mm.

Advantages:

1. No reported incidence of device erosion or cardiac perforation.
2. Even after locking the device in position after optimal position is confirmed, it can still be retrieved with the help of retrieval cord attached to the right atrial disc.
3. The HELEX^{R} Septal Occluder is a non-self-centering device having a narrow mid portion that makes it suitable for closure of multifenestrated defects.
4. The device can easily be seen on fluoroscopy and echocardiography.

Disadvantages:

1. Defects larger than 18 mm cannot be closed with this device.
2. Wire frame fracture has been reported with the HELEX^{R} Septal Occluder, especially the larger sizes, occurring in 6.4–8.0% after 1 year [12].
3. In a United States multicentre study of the HELEX^{R} Septal Occluder, used in 143 patients for closure of ASDs, there was a rate of residual leaks of 25.7% at 12 months [13].
4. There is a fixed right angle between the tip of the delivery catheter and the device. In some cases, especially in children, this distorts the anatomy and orientation of the atrial septum, making it difficult to decide whether the occluder position is optimal. With release of the device there is a pronounced repositioning when the force from the delivery system is taken away from the septum.

Slide # 27:

The Occlutech Figulla Flex II (Occlutech GmbH, Jena, Germany) is a self-expanding nitinol wire mesh, very similar to the Amplatzer device in shape, but with a different design that eliminates the left atrial microscrew (left figure). The device, developed using a unique patented braiding technique, consists of a nitinol wire mesh to create a smooth and flexible outer layer. Two retention discs allow for a single central pin on the right atrial side. Two polyethylene terephthalate (PET) patches assure complete closure after implantation. Available sizes range between 4 to 40 mms.

Advantages:

1. There is a 50% reduction of meshwork material on the left atrial side along with elimination of the left atrial disc microsrew, minimizing both the risk of thrombus formation and damage to the distal wall of the left atrium during implantation.
2. The delivery cable mechanism is different and allows pivoting of the device (up to 50^{0}), which facilitates positioning across the septum; an advantageous feature especially in large defects and borderline length of rims (right figure).
3. The device is fully recapturable and repositionable.

Slide # 28:

The Amplatzer Septal Occluder device (St. Jude, Plymouth, Minnesota, USA) is a self-expandable double-disk device made of a nitinol (55% nickel; 45% titanium) wire mesh. The ASO device is constructed from a 0.004–0.0075-inch nitinol wire mesh that is tightly woven into two flat disks. There is a 3–4-mm connecting waist between the two disks, corresponding to the thickness of the atrial septum.

Slide # 29:

*This will be in context of Amplatzer Septal Occluder (St. Jude, Plymouth, Minnesota, USA).

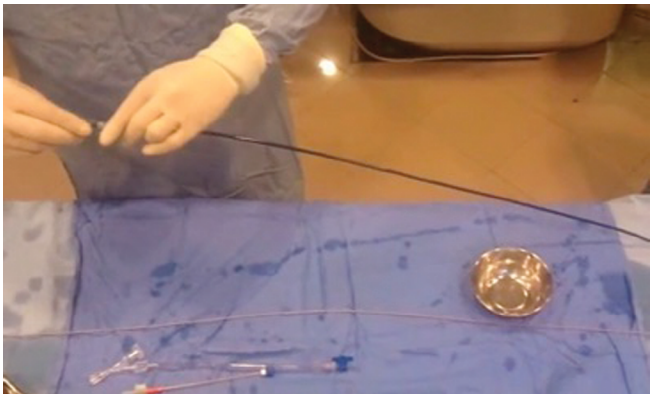
Slide # 30:

These sheath sizes are recommended by the manufacturer depending on the size of the device. Our practice is to use a sheath 1 Fr larger than the recommended size excepting in children weighing less than 15 kg in whom we use the same size as per the recommendations.

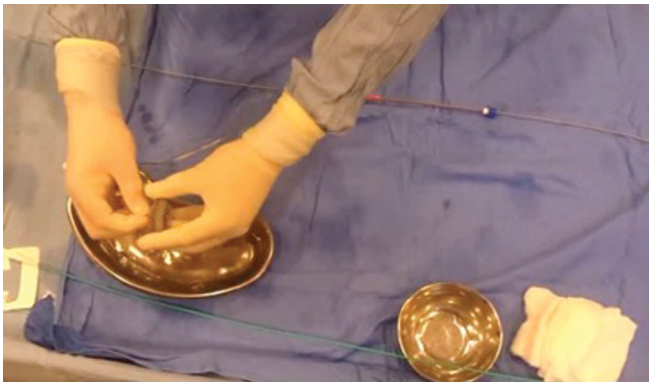
*A 40-mm device is not available in the US.

Slide # 31:

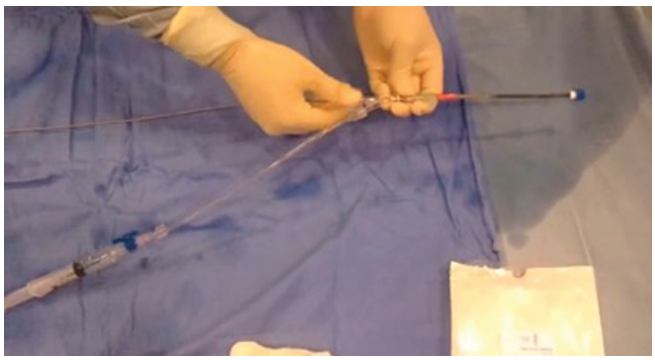
A. Loader – used to introduce the Amplatzer Septal Occluder into the delivery sheath.
B. Hemostatic valve with extension tube and stopcock – allows flushing the delivery system and controls back-bleeding.
C. Delivery sheath – provides a pathway through which a device is delivered.



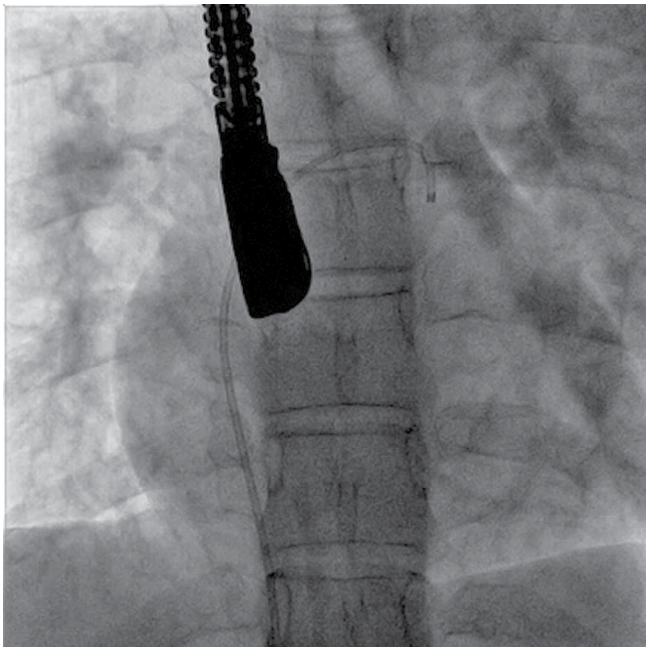
Video 6. All the components of the delivery system are thoroughly flushed and wiped from outside with heparinized saline solution. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.06.



Video 7. It is necessary to load the device after gently messaging it in heparinized saline so as to get rid of the air that might have been trapped in the Dacron patches. It is always a good habit to double check that the device is screwed onto the cable securely. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.07.



Video 8. The ASO is slenderized within the loader followed by thorough flushing to get rid of the air within the system. View supplementary video at http://dx.doi.org/10.12945/j. jshd.2016.007.14.vid.08.



Video 9. Crossing the defect with a Judkin's right coronary artery catheter. The catheter tip is positioned in the left superior pulmonary vein (LSPV). View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.09

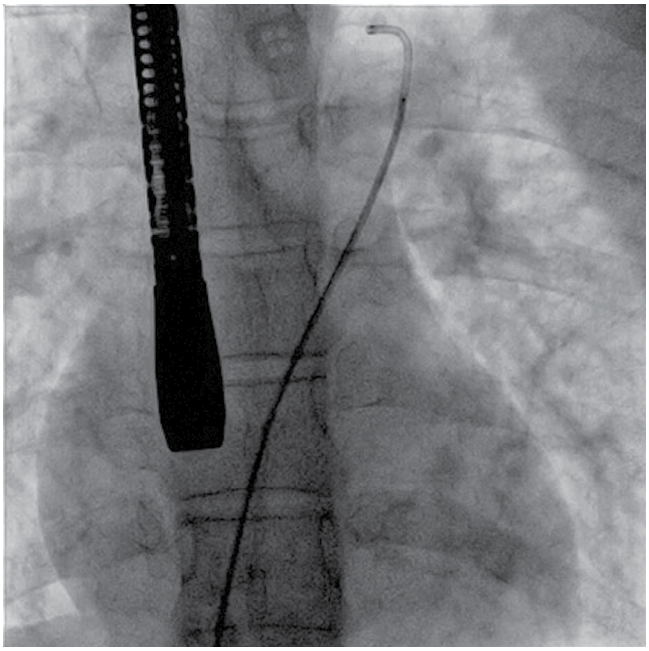
D. Dilator – used to ease penetration of skin and the subcutaneous tissue.
E. Delivery cable – the device is screwed onto the distal tip of the delivery cable, which allows for placement (and if necessary, retrieval) of the device.
F. Plastic vise – attached to the delivery cable, serving as a "handle" for detaching (unscrewing) the delivery cable from the device.

Slide # 32:

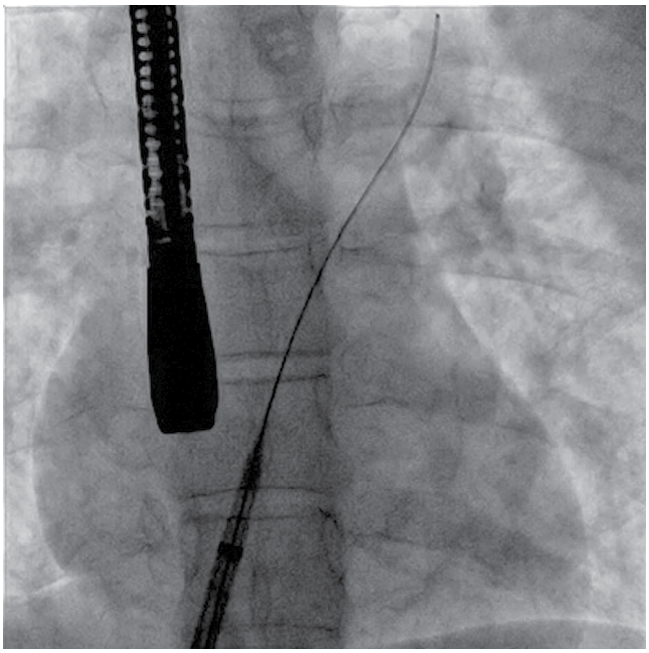
All the components of the delivery system are thoroughly flushed and wiped from outside with heparinized saline solution (Video 6).

Slide # 33:

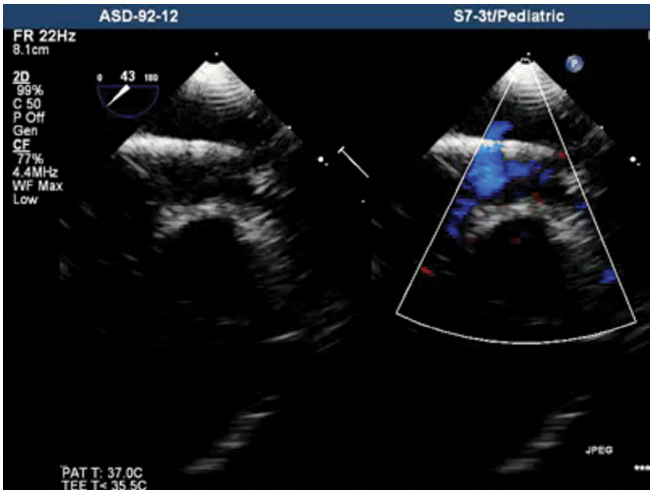
It is necessary to load the device after gently messaging it in heparinized saline so as to get rid of the air that might have been trapped in the Dacron patches. It is always a good habit to double check that the device is screwed onto the cable securely (Video 7).



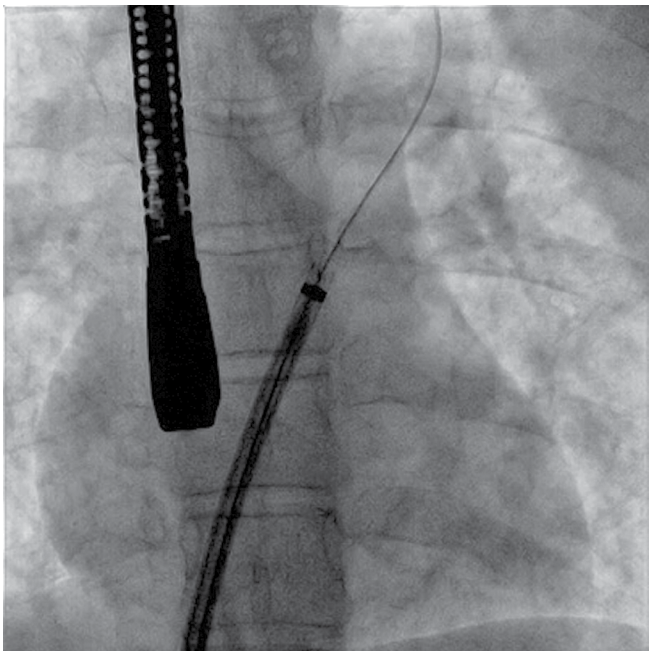
Video 10. A floppy tip Amplatz Superstiff™ guide wire (Boston Scientific, Marlborough, Massachusetts, USA) being placed in the LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.10.



Video 11. An Amplatzer TorqVue™ 45° delivery sheath (St. Jude, Plymouth, MN, USA) being passed over the Superstiff wire into the mouth of the LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.11.



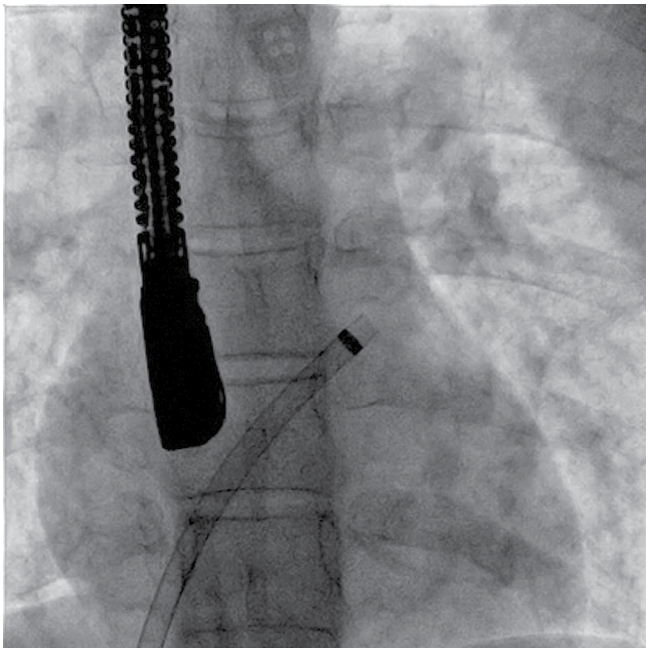
Video 12. Corresponding TEE loop depicting the delivery sheath positioned in the LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.12.



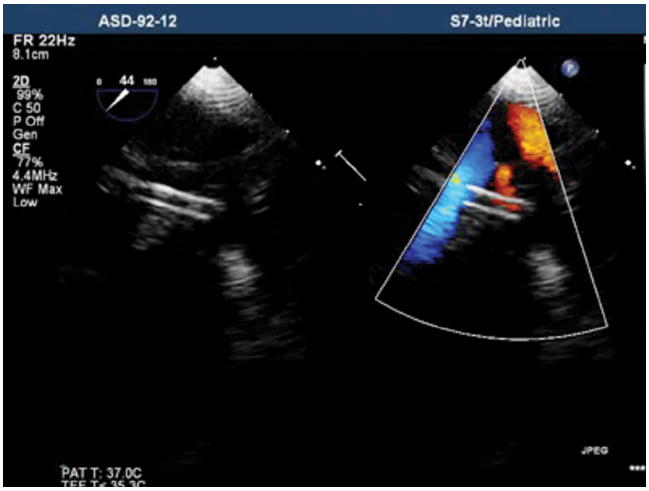
Video 13. Delivery sheath is being advanced over the dilator into the mouth of LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.13.

Slide # 34:

The ASO being slenderized within the loader followed by thorough flushing to get rid of the air within the system (Video 8).



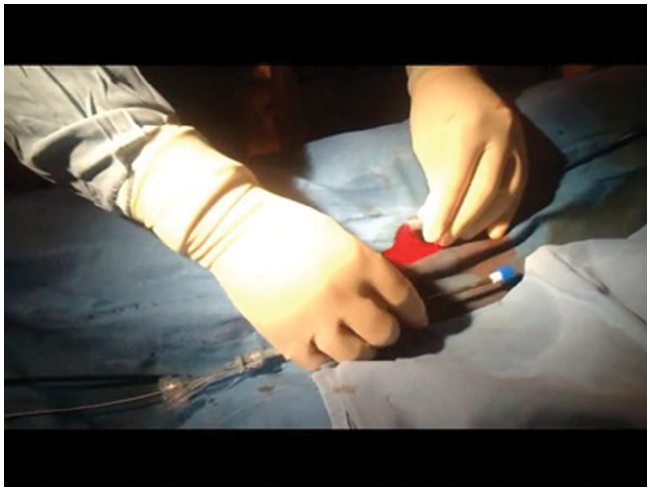
Video 14. The delivery sheath positioned in the left atrium just outside the LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.14.



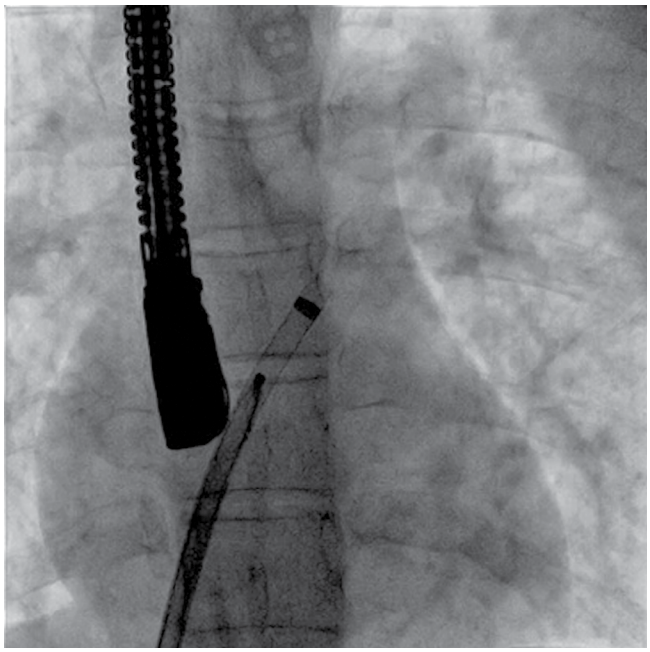
Video 15. Corresponding TEE loop showing the sheath in the left atrium near the opening of the LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.15.

Slide # 35:

Left frame: Crossing the defect with a Judkin's right coronary artery catheter. The catheter tip is positioned in the left superior pulmonary vein (LSPV) (Video 9).

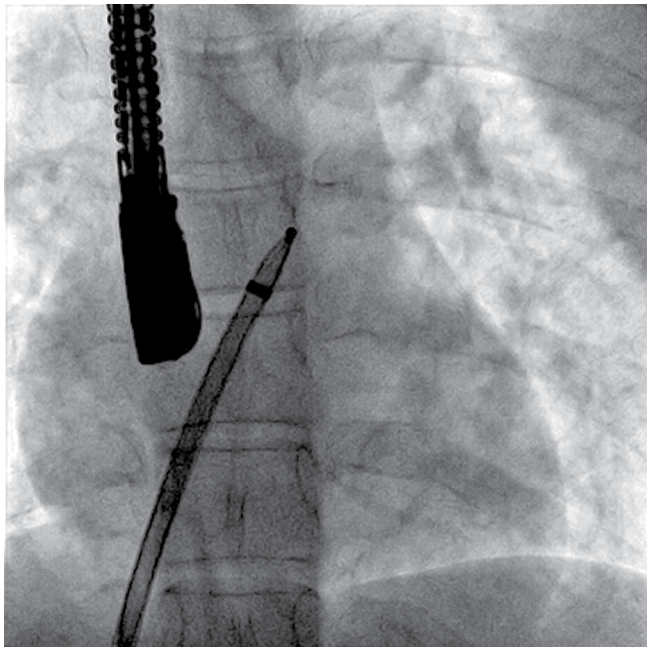


Video 16. Dilator is removed from the sheath to allow back bleed and prevent air embolism. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.16.

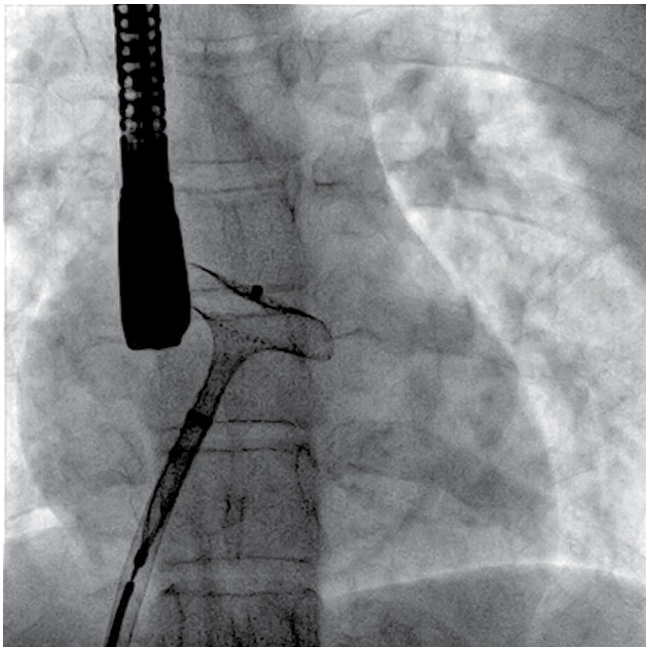


Video 17. Amplatzer septal occluder (ASO) is being passed through the delivery sheath. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.17.

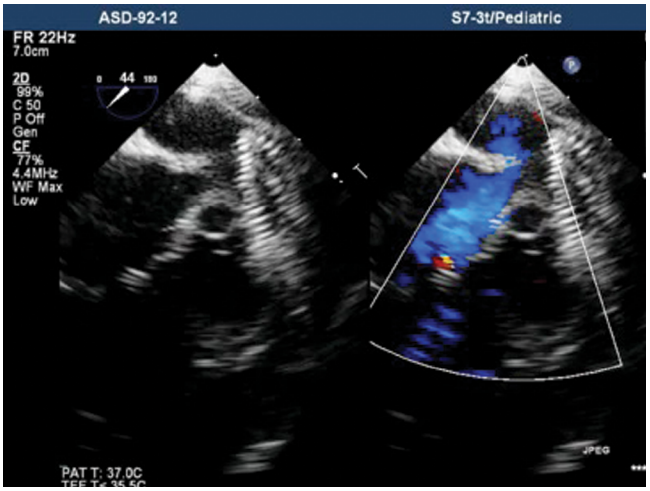
Right frame: A floppy tip Amplatz Superstiff™ guide wire (Boston Scientific, Marlborough, Massachusetts, USA) being placed in the LSPV (Video 10).



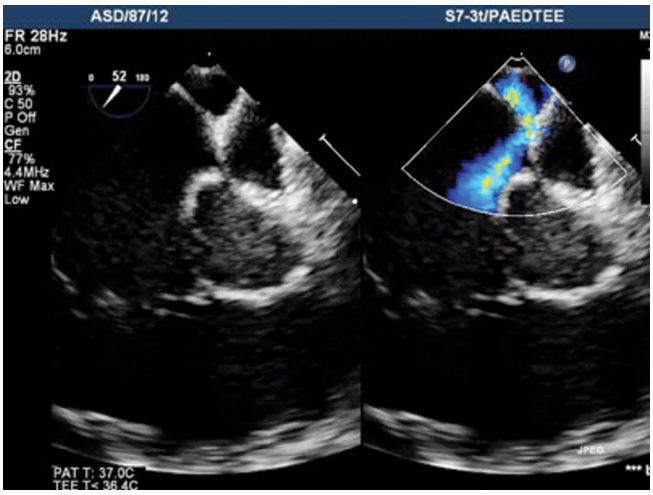
Video 18. Left atrial disk of the ASO being extruded in the left atrium. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.18.



Video 20. The left atrial disk of the ASO being pulled back against the interatrial septum. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.20.



Video 19. Corresponding TEE loop showing left atrial disk in the left atrium. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.19.



Video 21. Corresponding TEE loop depicting the same. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.21.

Slide # 36:

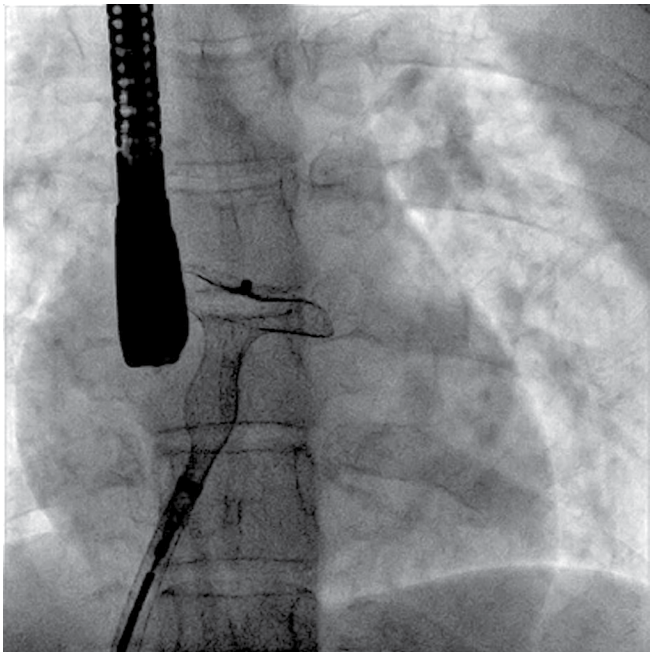
Left frame: An Amplatzer TorqVue™ 45° delivery sheath (St. Jude, Plymouth, MN, USA) is passed over the Superstiff wire into the mouth of the LSPV (Video 11).

Right frame: Corresponding TEE loop showing the delivery sheath positioned in the LSPV (Video 12).

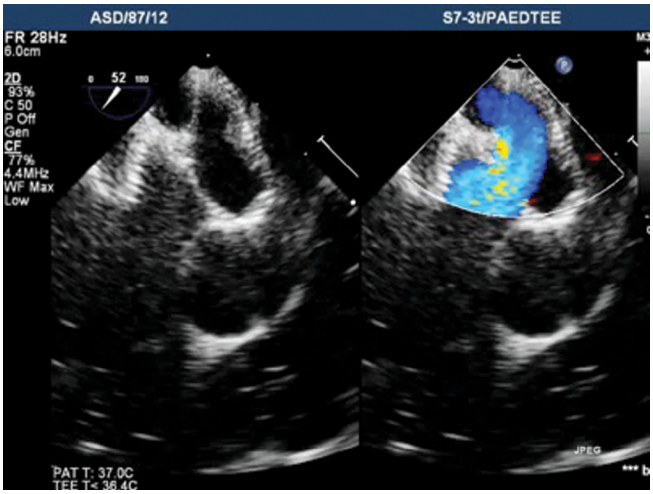
Slide # 37:

Top left frame: Delivery sheath is advanced over the dilator into the mouth of LSPV (Video 13).

Top right frame: The delivery sheath positioned in the left atrium just outside the LSPV (Video 14).

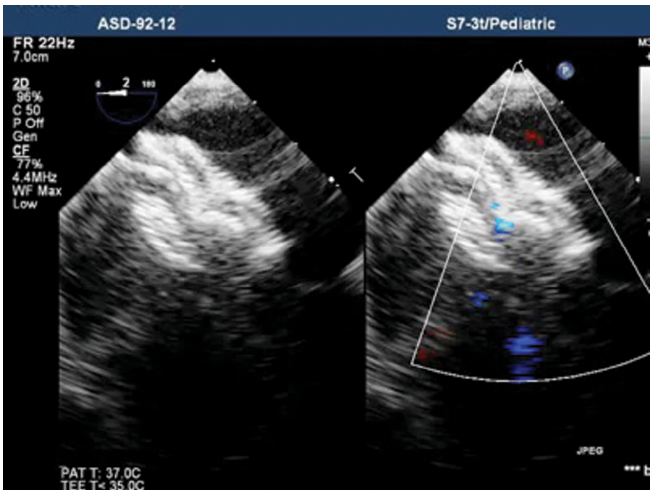


Video 22. Delivery sheath "peeled" back over the loading cable to allow release of the waist and the right atrial disk and deployment of device. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.22.

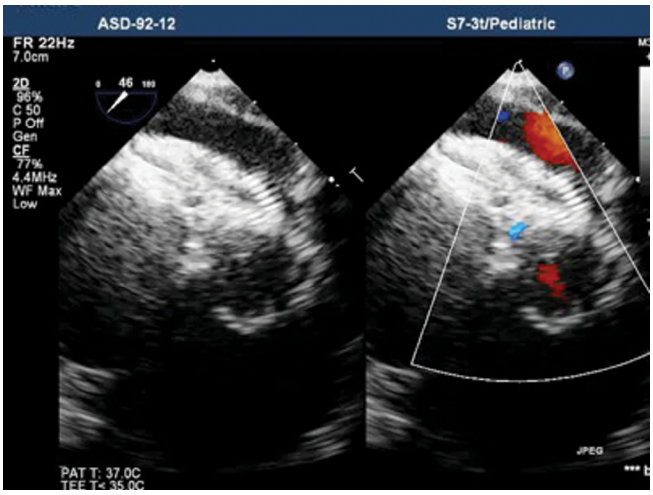


Video 23. Corresponding TEE loop depicting deployment of the ASO across the defect. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.23.

Bottom frame: Corresponding TEE loop showing the sheath in the left atrium near the opening of the LSPV (Video 15).



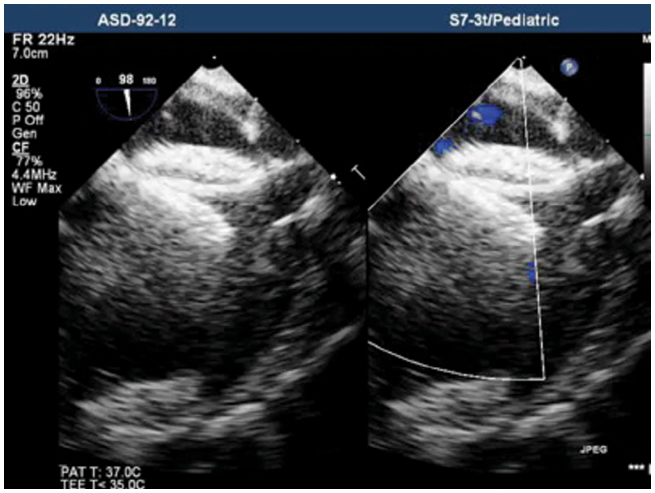
Video 24. TEE loops at 0, confirming adequate capture of all margins before releasing the device from the loading cable. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.24.



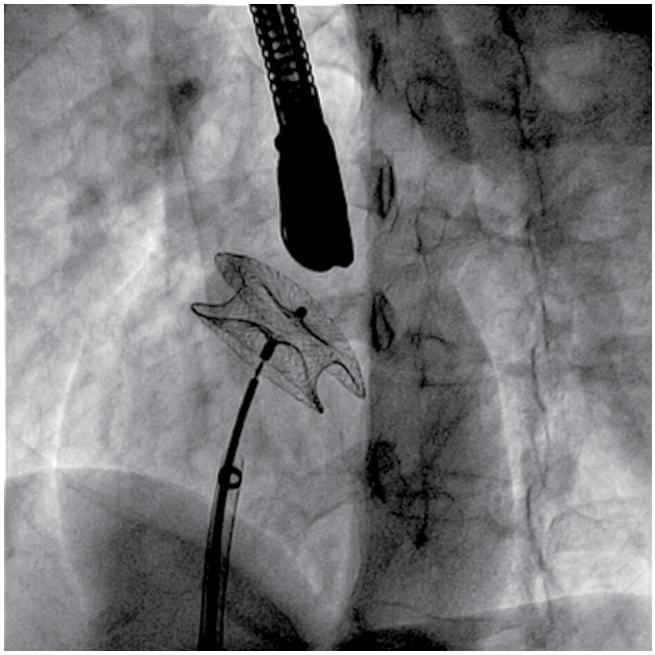
Video 25. TEE loops at 45, confirming adequate capture of all margins before releasing the device from the loading cable. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.25.

Slide # 38:

Dilator is removed from the sheath to allow back bleed and prevent air embolism. If the patient is under GA with positive-pressure ventilation, one can back bleed as shown in this movie; but if the patient is breathing spontaneously, it is better to back bleed by holding the sheath below the level of the heart in a saline bowl. This helps in preventing inadvertent sucking of air into the sheath resulting in air embolism (Video 16).



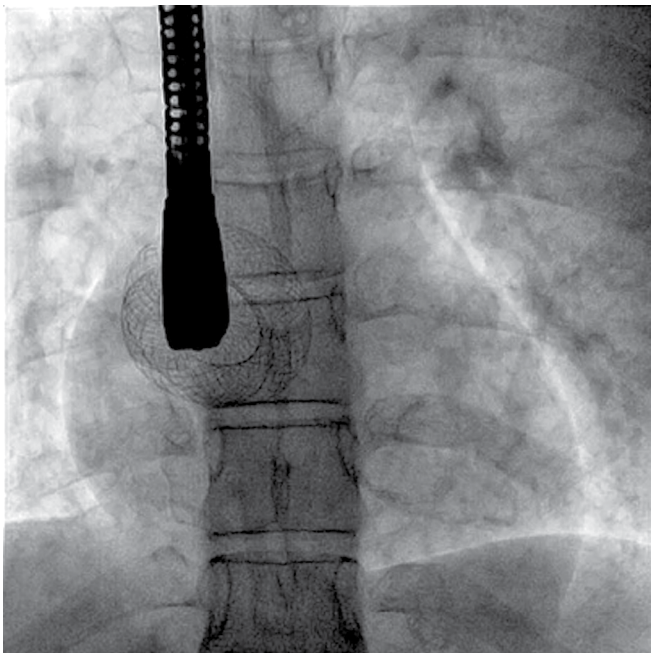
Video 26. TEE loops at 90 degrees, confirming adequate capture of all margins before releasing the device from the loading cable. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.26.



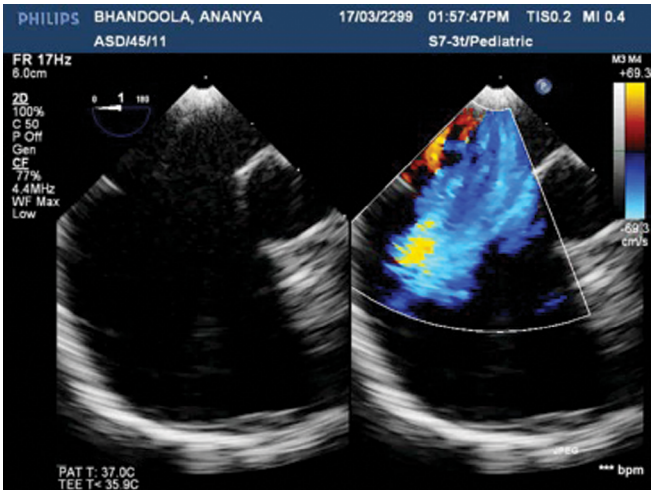
Video 27. Release of the ASO from loading cable in left anterior oblique (LAO) view. Note the well-separated disks of the ASO in LAO view confirming a well-positioned device. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.27.

Slide # 39:

Top left frame**:** Amplatzer septal occluder (ASO) is passed through the delivery sheath (Video 17).



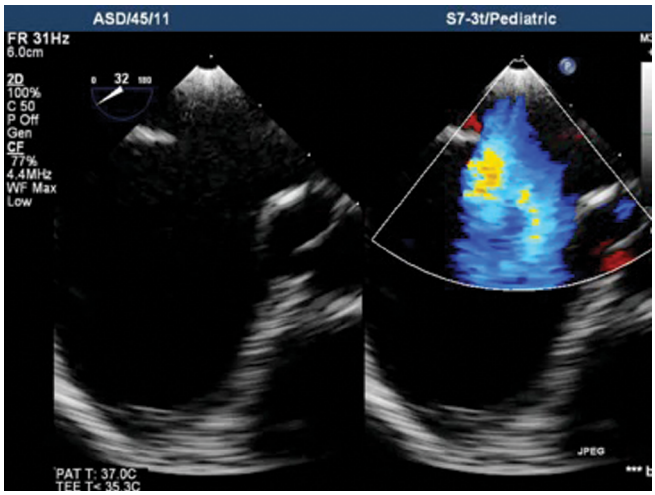
Video 28. Final position of the device in anteroposterior projection; fluroscopic "fingerprinting" of the device. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.28.



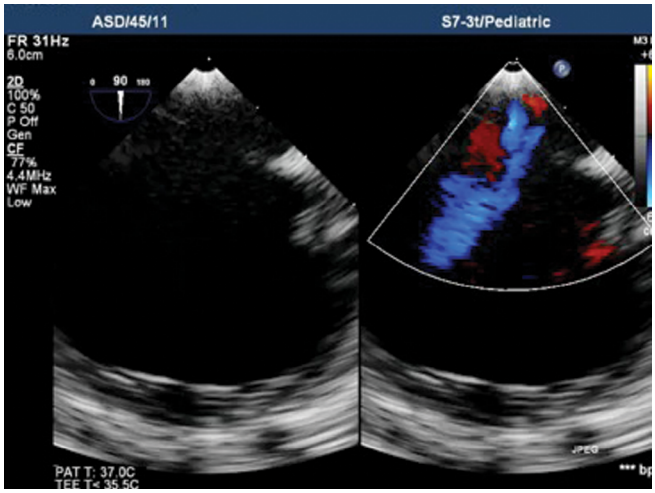
Video 29. TEE loops depicting a large ASD in a small child. The left atrium is relatively smaller compared to the right atrium. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.29.

Top right frame: Left atrial disk of the ASO is extruded in the left atrium (Video 18).

Bottom frame: Corresponding TEE loop showing left atrial disk in the left atrium (Video 19).



Video 30. TEE loops depicting a large ASD in a small child. The left atrium is relatively smaller compared to the right atrium. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.30.

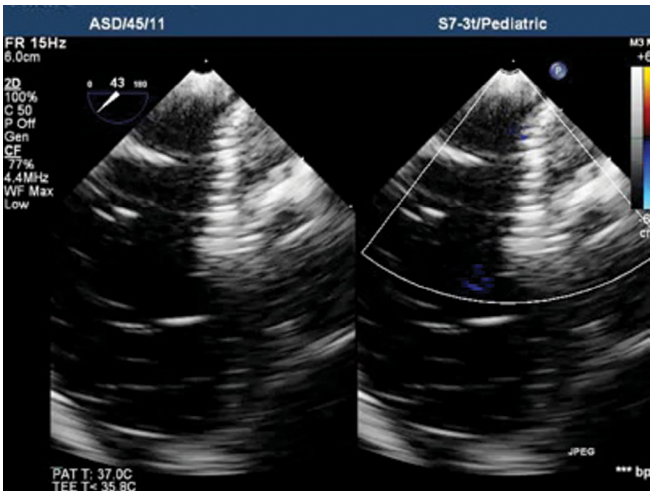


Video 31. TEE loops depicting a large ASD in a small child. The left atrium is relatively smaller compared to the right atrium. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.31.

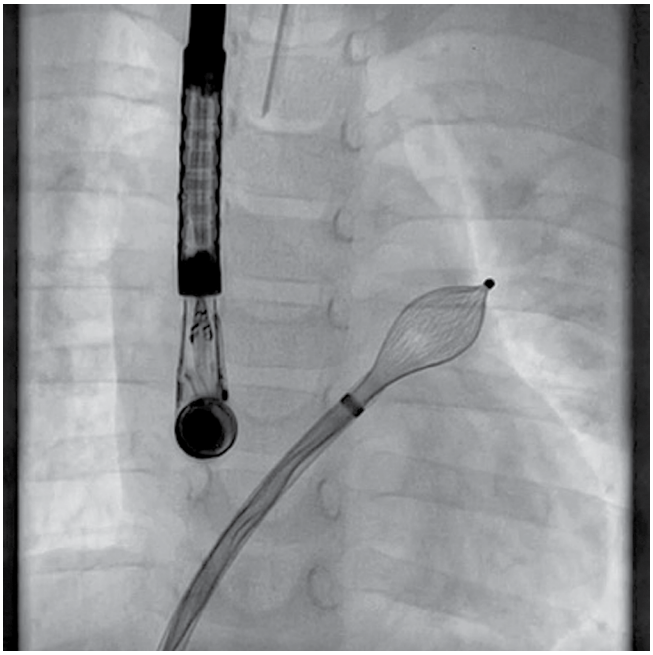
Slide # 40:

Left frame: The left atrial disk of the ASO is pulled back against the interatrial septum (Video 20).

Right frame: Corresponding TEE loop depicting the same (Video 21).



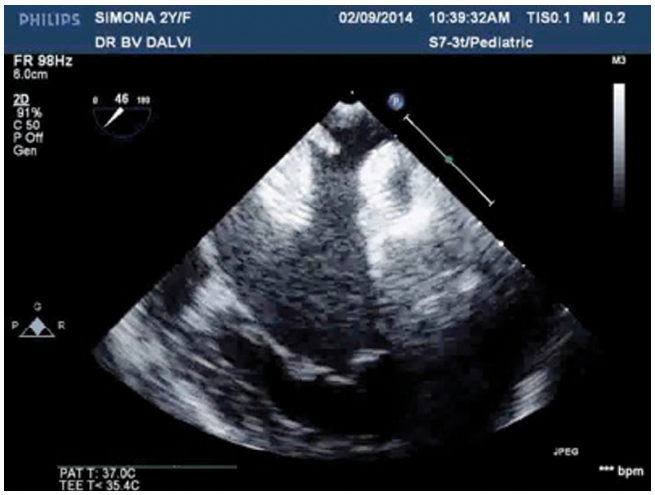
Video 32. TEE depicting the left atrial disk lying perpendicular to the atrial septum due to inability to accommodate the disk in the left atrium. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.32.



Video 33. ASO being deployed via LSPV technique that is engaging the LA disk into LSPV. The LA disk disengagement was spontaneous. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.33.

Slide # 41:

Left frame: Delivery sheath "peeled" back over the loading cable to allow release of the waist



Video 34. Corresponding TEE loop depicting the LSPV technique. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.34.

and the right atrial disk and deployment of device (Video 22).

Right frame: Corresponding TEE loop depicting deployment of the ASO across the defect (Video 23).

Slide # 42:

TEE loops at 0 (top left), 45 (top right), and 90 degrees (bottom), confirming adequate capture of all margins before releasing the device from the loading cable (Videos 24, 25, and 26, respectively).

Slide # 43:

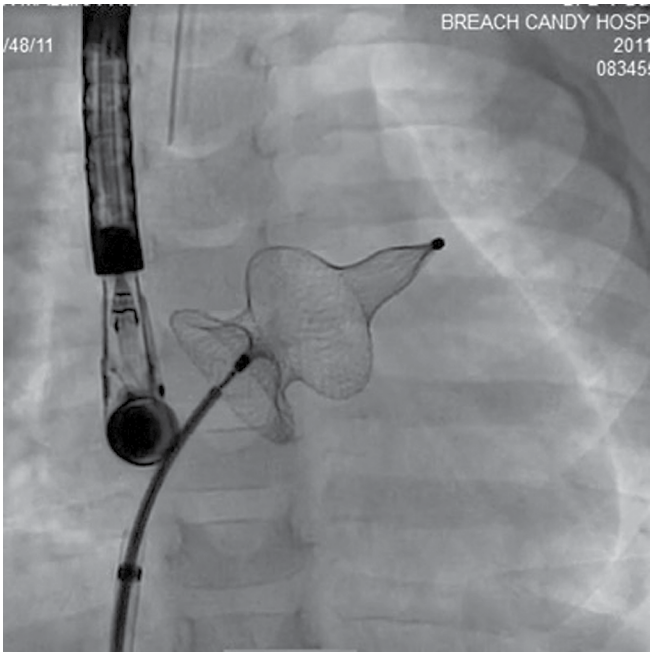
Left frame: Release of the ASO from loading cable in left anterior oblique (LAO) view. Note the well-separated disks of the ASO in LAO view confirming a well-positioned device (Video 27).

Right frame: Final position of the device in anteroposterior projection; fluroscopic "fingerprinting" of the device (Video 28).

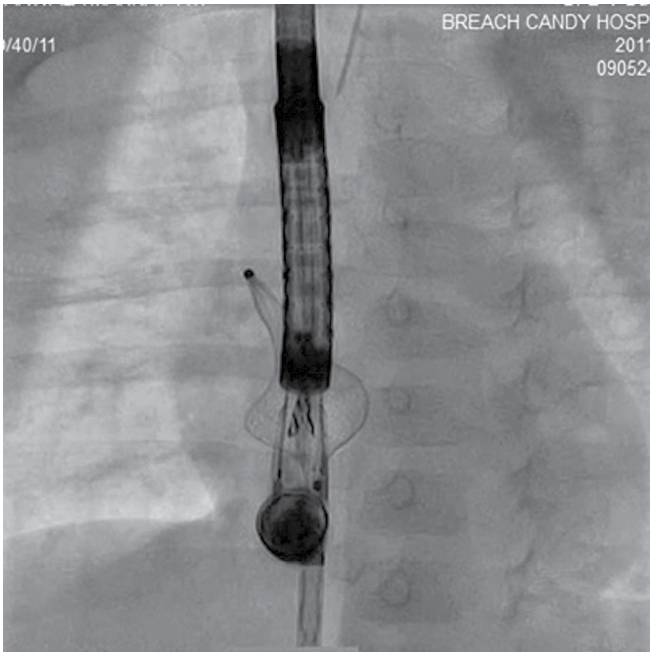
Slide # 46:

Top frames and bottom left frame: TEE loops depicting a large ASD in a small child. The left atrium is relatively smaller compared to the right atrium (Videos 29, 30, and 31).

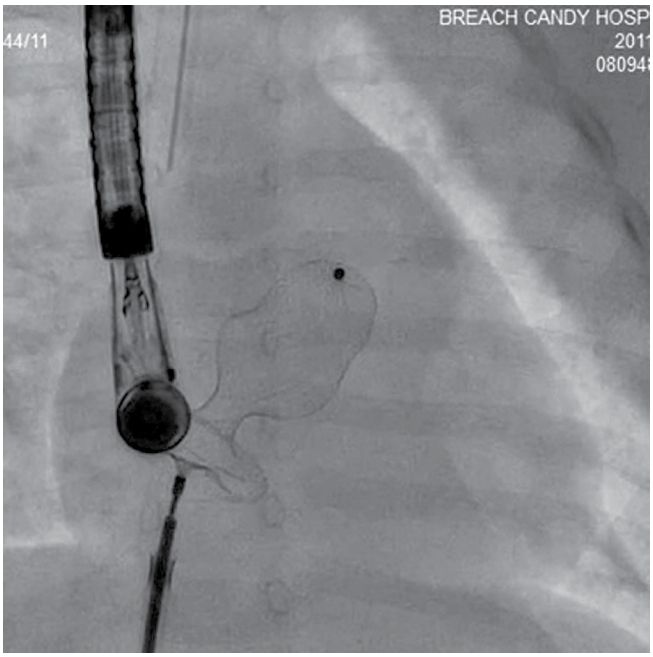
Bottom right frame: TEE depicting the left atrial disk lying perpendicular to the atrial septum due to



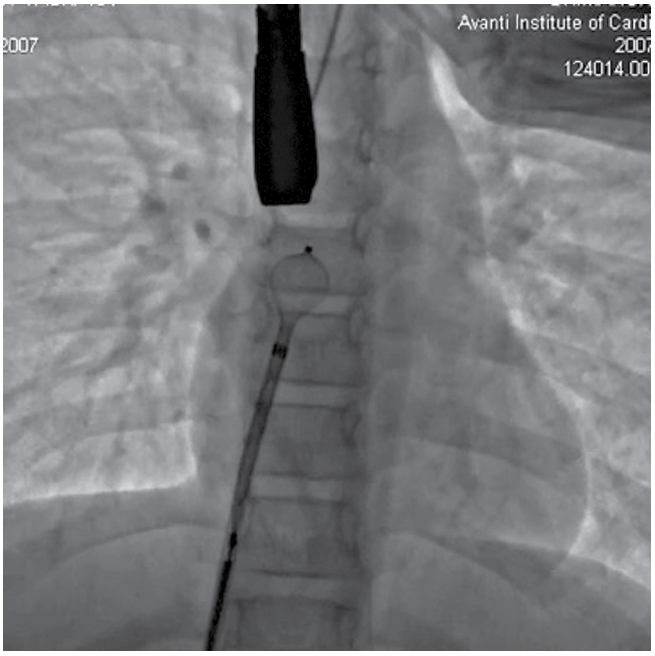
Video 35. A contrarian technique of pushing on the cable rather than pulling, to disengage the LA disk. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.35.



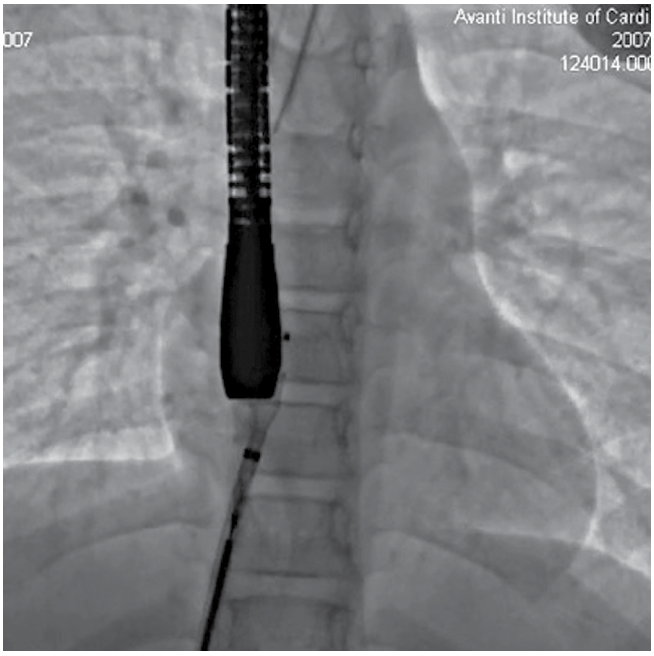
Video 36. ASO is deployed with the left atrial disk being engaged into the right superior pulmonary vein. Loading cable is pushed to disengage the let atrial disk from the RSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.36.



Video 37. ASO is deployed with the left atrial disk engaged in the left atrial appendage. Similar to the previous case, the LA disk has been disengaged from the LA appendage by pushing the loading cable. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.37.



Video 38. The delivery sheath has been positioned outside the right superior pulmonary vein instead of LSPV to prevent malalignment of the device disks with the interatrial septum. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.38.



Video 39. The ASO device being deployed by this technique. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.39.

inability to accommodate the disk in the left atrium (Video 32).

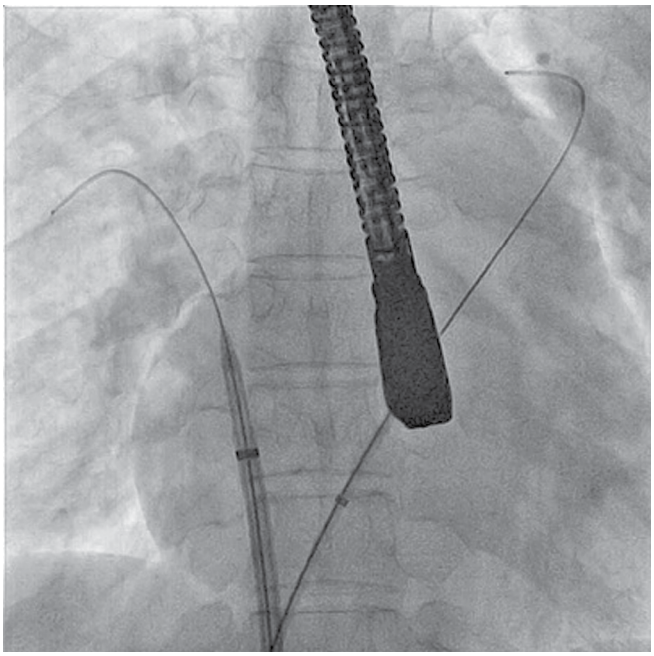
Slide # 48:

Left frame: ASO being deployed via LSPV technique that is engaging the LA disk into LSPV. The LA disk disengagement was spontaneous (Video 33). Similarly the left atrial disc can be engaged in the right superior pulmonary vein or the left atrial appendage.

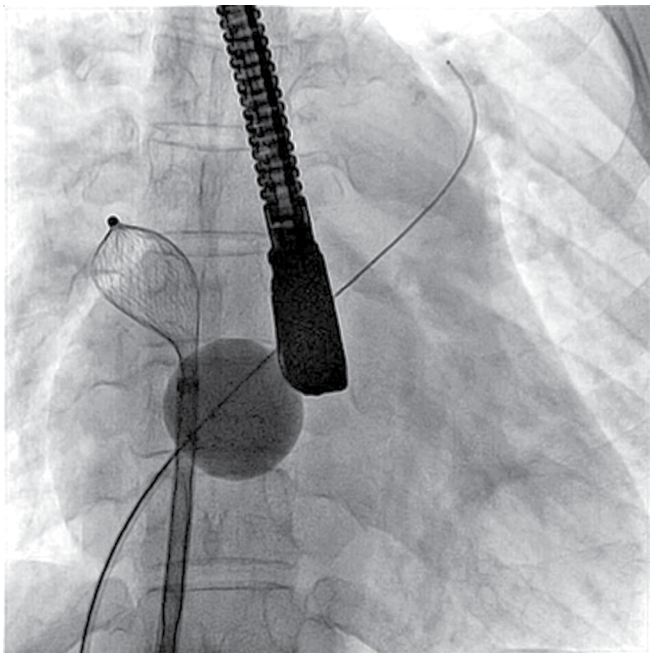
Right frame: Corresponding TEE loop depicting the LSPV technique (Video 34).

Slide # 49:

Left frame: If the LA disk does not disengage spontaneously, there is a tendency to pull on the loading cable to disengage the disk. In doing so, the RA disk tends to lose its alignment with the IAS and the LA disk tends to fall through the defect in the RA. We have used a contrarian technique of pushing on the cable rather than pulling, to disengage the LA disk. This creates a secondary torque on the LA disc, resulting in its disengagement from the LSPV while maintaining the alignment of the right atrial disk with the interatrial septum (Video 35).



Video 40. An Occlutech balloon is positioned in the right atrium and pushed against the interatrial septum over a Superstiff wire positioned in the LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.40.



Video 41. The balloon is inflated followed by sequential release of the left atrial disk, waist and the right atrial disk. Superstiff wire positioned in the LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.41.

Middle frame: ASO is deployed with the left atrial disk engaged into the right superior pulmonary vein. Loading cable is pushed to disengage the let atrial disk from the RSPV (Video 36).

Right frame: ASO is deployed with the left atrial disk engaged in the left atrial appendage. Similar to the previous case, the LA disk has been disengaged from the LA appendage by pushing the loading cable (Video 37).

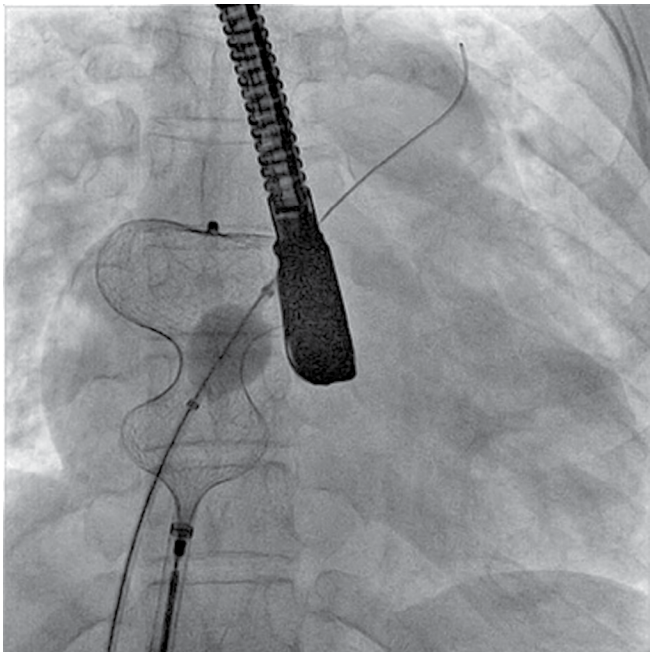
Slide # 51:

Left frame: The delivery sheath has been positioned outside the right superior pulmonary vein instead of LSPV to prevent malalignment of the device disks with the interatrial septum (Video 38).

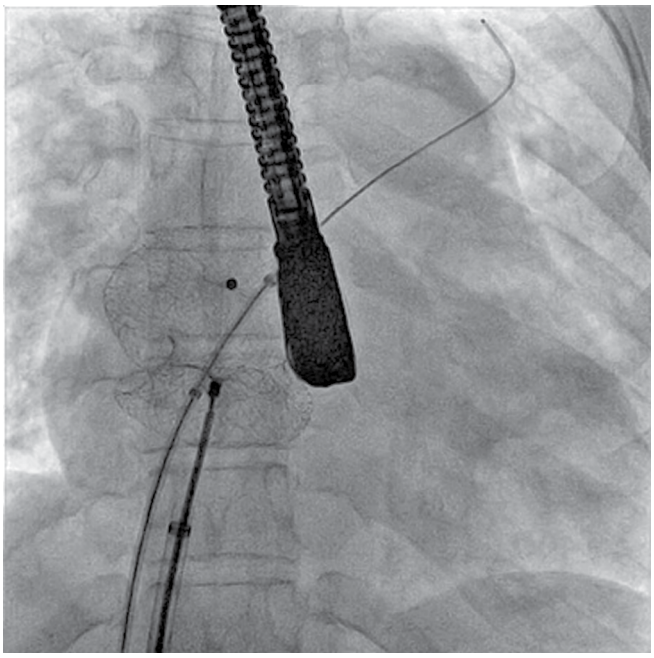
Right frame: The ASO device is deployed by this technique (Video 39).

Slide # 52:

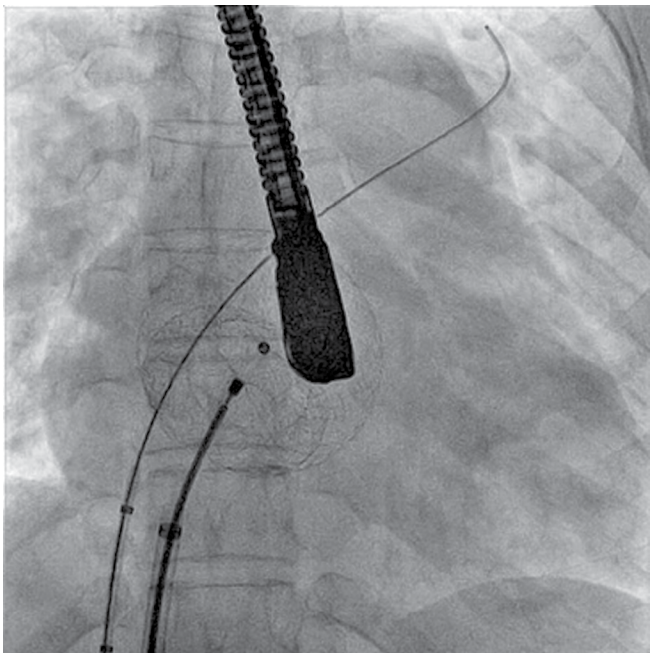
Left frame: Hausdorf sheath (Cook, Bloomington, Indiana, USA) is a specially designed long sheath with two posterior curves at its end, allowing for a



Video 42. The balloon is gradually deflated to allow deployment of the device across the ASD. Superstiff wire positioned in the LSPV. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.42.



Video 43. The balloon catheter is pulled back into the inferior vena cava before releasing the device. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.43.



Video 44. The Superstiff wire now pulled back into the inferior vena cava before releasing the device. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.44.

better alignment of the left atrial disk parallel to the septum [16].

Right frame: Sidecutting sheath is a modified Mullins sheath with the creation of a bevel at the inner curvature, also allowing a more parallel alignment of the left atrial disk to the interatrial septum [17].

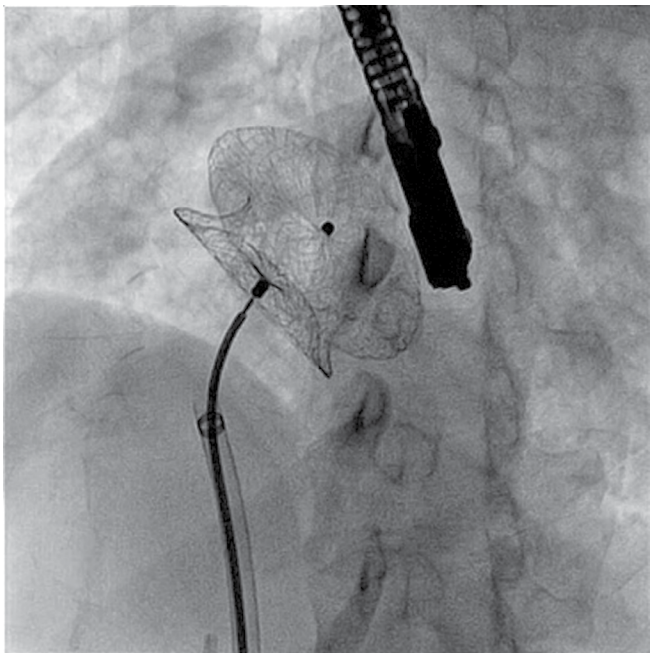
Slide # 53:

Wahab technique (Dilator-assisted technique): Following deployment of the left atrial disk, a long dilator is advanced into the left atrium, holding the anterosuperior part of the left atrial disk to prevent it from prolapsing [18].

Slide # 54:

*Balloon assisted technique [19]:

Left frame: An Occlutech balloon (Boston Scientific, Watertown, Massachusetts, USA) is positioned in the right atrium and pushed against the interatrial septum over a Superstiff wire positioned in the LSPV. The ASO delivery sheath is positioned in the right superior pulmonary vein (Video 40).



Video 45. Device position confirmed in left anterior oblique view and released. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.45.

Middle frame: The balloon is inflated followed by sequential release of the left atrial disk, waist and the right atrial disk (Video 41).

Right frame: The balloon is gradually deflated to allow deployment of the device across the ASD (Video 42). The advantages of BAT are that it is a simple and safe procedure, is effective across all ages, has a short learning curve and is predictable. Its limitations include requiring an additional venous access, additional hardware (cost), need for additional personnel, large venous access and problems pertaining to hemostasis.

Slide # 55:

Left frame: The balloon catheter is pulled back into the inferior vena cava before releasing the device (Video 43).

Middle frame: The Superstiff wire now pulled back into the inferior vena cava before releasing the device (Video 44).

Right frame: Device position confirmed in left anterior oblique view and released (Video 45).

Slide # 57:

BAT modification by Kammache et al. [20]:

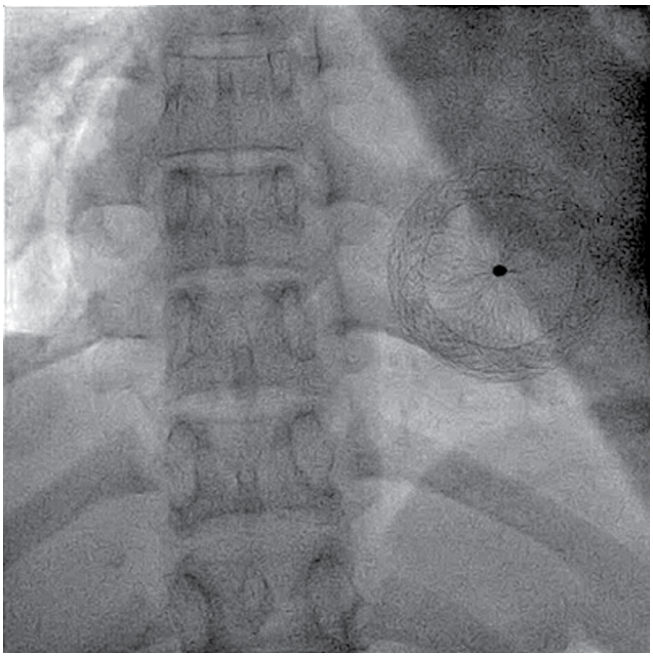
Major differences in this modified technique include:

1. The sizing balloon (Meditech, Boston Scientific, Watertown, Massachusetts, USA) is positioned in the septal defect or even within the left atrium in order to use it as a rim to anchor the device.
2. The left atrial disk is delivered in the left atrium rather than just outside the superior pulmonary vein.
3. The authors recommend gentle tug on the delivery cable (Minnesota wiggle) to ascertain secure device position since the balloon, and not the rim, is used as a support during device deployment.

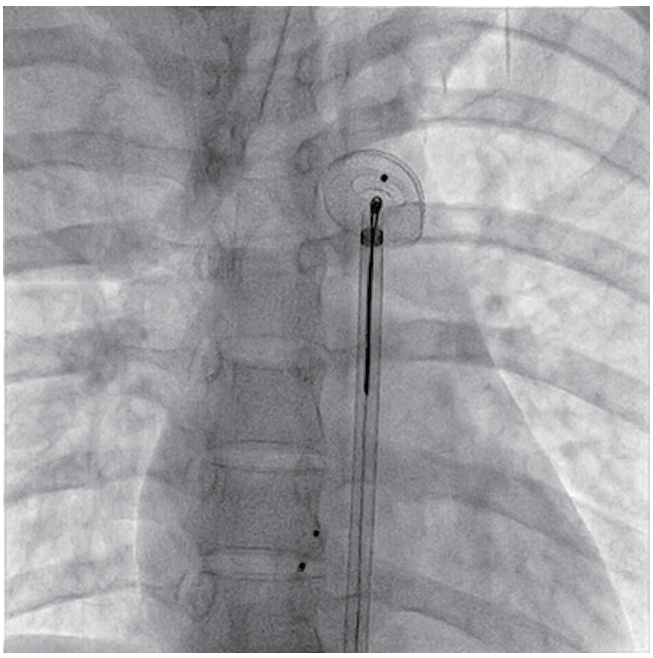
Slide # 58:

BAT modification by Wahab et al. [21]:

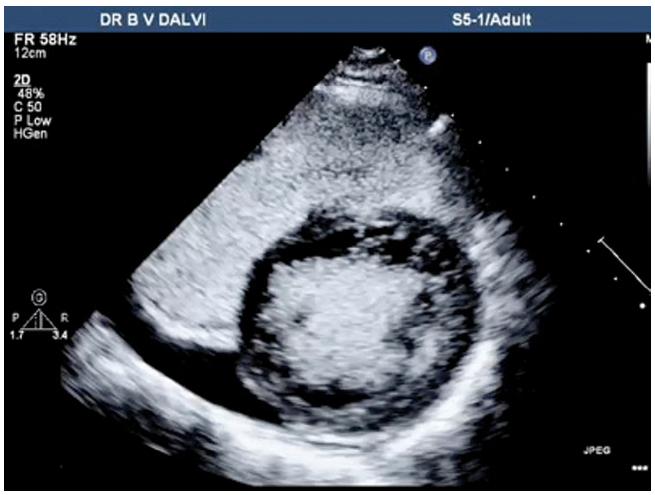
This technique utilizes a regular sizing balloon that is positioned across the atrial septal defect to prevent prolapse of the left atrial disk.



Video 46. ASO embolized to the right ventricle. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.46.



Video 47. ASO being retrieved from the descending thoracic aorta. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.47.



Video 48. Absence of leak of contrast agent into the pericardial space after appearing in all the four cardiac chambers. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2016.007.14.vid.48.

Slide # 61:

Air embolism:
- Evident by ST segment changes (left frame).
- Usually transient (right frame)
- Can be avoided by consciously avoiding injecting air through peripheral lines and checking for adequate back flow of blood from catheters and sheaths placed in the left atrium/pulmonary vein.

Slide # 65:

Device embolization:
- Rare complication (0.55%) [24]
- Usually occurs in those with large ASD and deficient rims. Can embolize to either side of the atrial septum (left frame: ASO embolized to the right ventricle; Video 46)
- Majority do not cause acute hemodynamic collapse
- Most can be snared and retrieved percutaneously (right frame: ASO being retrieved from the descending thoracic aorta; Video 47); principles of percutaneous device retrieval have been well described in the literature [25]

Slide # 68:

Use of ultrasound contrast agent during echocardiography can help diagnose cardiac erosion. The above video depicts absence of leak of contrast agent into the pericardial space after appearing in all the four cardiac chambers (Video 48). Patient was managed medically with close supervision to observe for any evidence of hemodynamic compromise or increase in the amount of pericardial effusion. The effusion reduced gradually followed by complete disappearance on medical management.

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Conflict of Interest

Bharat Dalvi is a consultant for St. Jude Medical.

Comment on this Article or Ask a Question

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Current Status of Percutaneous Pulmonic Valve Therapies: The Melody Valve

Marc Gewillig, MD, PhD, FAEPC, FESC, FACC

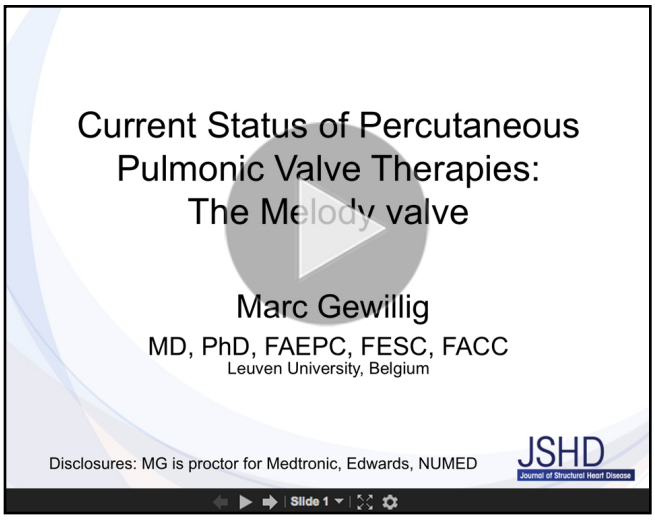
Pediatric Cardiology, Leuven University, UZ Leuven, Herestraat 49, Leuven, Belgium

Abstract

Transcatheter percutaneous pulmonary valve implantation (PPVI) was first described in 2000 by Philip Bonhoeffer et al 1 as an alternative to open-heart surgery to prolong survival of a right ventricular outflow tract (RVOT) valve conduit.
Since then multiple studies have documented the short term benefits of PPVI implantation using the Melody™ valved stent (Medtronic Inc, Minneapolis, USA) for dysfunctional right ventricle to pulmonary artery (RV-AP) conduits.
This review discusses the development, current status and future endeavors of the Melody valve in the pulmonic position.

Key Words

Pulmonic valve therapy • Melody valve



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Conflict of Interest

The author is proctor for Medtronic, Edwards, NuMed.

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Fax +1 203 785 3346
E-Mail: jshd@scienceinternational.org
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* Corresponding Author:
Marc Gewillig, MD, PhD, FAEPC, FESC, FACC
Pediatric Cardiology
Leuven University
UZ Leuven, Herestraat 49, Leuven, Belgium
Tel.: +32 16 343865; Fax: +32 16 343981; E-Mail: marc.gewillig@uzleuven.be

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Low Incidence of Rhythm Disturbance Following Percutaneous Closure of Ventricular Septal Defects Using the Amplatzer Device at Immediate-to-Long-Term Follow Up

Muhammad Dilawar, MD[1*], Muhammed Riyas K Rahmath, MD[2], Assad Al-Hroob, MD[3], Howaida G. El-Said, MD[4], Amal El Sisi, MD[5], Salwa Morcos, MD[6], Mohammed Numan, MD[7]

[1] Division of Pediatric Cardiology, Hamad General Hospital, Doha, Qatar
[2] Division of Pediatric Cardiac Surgery, Hamad General Hospital, Doha, Qatar
[3] University of Texas, Health Science Center, San Antonio, Texas, USA
[4] Division of Cardiology, Rady Children's Hospital, University of California, San Diego, USA
[5] Cairo University Pediatric Hospital, Cairo, Egypt
[6] Division of Pediatric Cardiology, Rush University Hospital, Chicago, USA
[7] Division of Pediatric Cardiology, University of Texas, Houston, Texas, USA

Abstract

Background: **There have been concerns of heart block and rhythm disturbances following transcatheter closure of VSD. Our aim in this study is to evaluate rhythm and conduction disturbances following percutaneous device closure of ventricular septal defects at immediate and long-term follow up.**

Methods: **A retrospective review of all patients who underwent transcatheter VSD closure using an Amplatzer device from January 2003 to September 2012 at Hamad General Hospital in Qatar was performed, including catheterization data, echocardiograms, and EKGs at latest follow up.**

Results: **Of 49 patients, 45 (35 perimembranous and 10 muscular) were successfully closed. Median age was 8.5 years and median weight was 24 kg. The median VSD size was 6 mm. Median pulmonary to systemic blood flow was 1.4:1, and the median Amplatzer device size was 8 mm. There was no immediate or late mortality, and the closure rate was 91.8%, whereas the procedure was unsuccessful or abandoned in 8.2% of cases. At a mean follow up of 54.5 months, echocardiography revealed complete ventricular septal defect closure in 41 (91%) patients, and 4 (9%) patients had a small residual shunt. An electrocardiography median follow up of 61.9 months revealed normal sinus rhythm in 37 (84%) cases, incomplete right bundle branch block in 1 (2%) case, complete right bundle branch block in 4 (8%) cases, and left bundle branch block in 2 (4%) study group cases. However, complete atrioventricular block was observed in one (2.9%) of the perimembranous VSD patients.**

Conclusions: **Transcatheter closure of perimembranous and muscular ventricular septal defects is a safe and effective procedure. Rhythm disturbance at late follow up is comparable with surgical closure rhythm disturbances and is less frequent than previously found in some transcatheter closure reports.**

Key Words

Congenital heart defects • Perimembranous VSD • Muscular VSD • Complete atrioventricular block • VSD device closure • Amplatzer VSD device

Fax +1 203 785 3346
E-Mail: jshd@scienceinternational.org
http://structuralheartdisease.org/

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*Corresponding Author:
Muhammad Dilawar, MD
Pediatric Cardiology
Hamad General Hospital & Weill Cornell Medical College at Qatar
PO Box 3050, Doha,Qatar
Tel.: +00974 55916554, Fax: +00974 44391622, E-Mail: dilawarmd@yahoo.com

Introduction

Ventricular septal defect (VSD) is the most common congenital heart disease (CHD), constituting 30–40% of all congenital heart diseases [1]. Symptomatic patients need medical management and probably surgical closure if medical therapy fails. Although advances in surgical, anesthetic, and postoperative care have made surgical closure of VSD safer, morbidities like cerebrovascular accidents, seizures, chorea/athetosis, lung collapse, phrenic nerve injury, and junctional ectopic tachycardia are still concerns following open heart surgery [2, 3]. One of the serious complications of surgery is complete atrioventricular block (CAVB), which has been reported from 0.7% to 3.1% for membranous and outlet VSDs [4, 5]. Transcatheter approach to close such VSDs has been an attractive option to avoid these morbidities. Ten years after the initial transcatheter closure, in 1998, the Amplatzer muscular occluder had revolutionized the percutaneous VSD closure with favorable outcomes [6, 7]. Approximately two-thirds of VSDs are in the perimembranous (pmVSD) location, and there have been growing concerns about complete heart block at late follow up of percutaneous membranous VSD closure. A special Amplatzer membranous VSD device with an eccentric left ventricular disc was designed for the closure of pmVSDs with good initial results [8–10]. Occasionally, pmVSD with aneurysmal tissue can be closed with an Amplatzer duct occluder (ADO) [11, 12]. The aim of this study is to evaluate rhythm disturbances caused by transcatheter VSD devices at immediate and long-term follow up.

Materials and Methods

This is a retrospective observational study to assess immediate to long-term rhythm follow up of percutaneous closure of muscular VSD (mVSD) and pmVSD with different types of Amplatzer occluders. All patients who were taken to the catheterization laboratory for attempted VSD closure using an Amplatzer device during the period of January 2003 and September 2012 at Hamad General Hospital, Doha, Qatar, were included. Inclusion criteria for percutaneous VSD closure was a muscular or pmVSD with clinical and or echocardiographic evidence of significant left to right shunt or a significant residual VSD after surgical repair. Exclusion criteria for percutaneous VSD closure was a body weight less than 7 kg, right to left shunt across the VSD, a pmVSD with less than 2-mm subaortic rim on long axis echocardiographic view, VSDs associated with complex heart lesions, and or contraindication to antiplatelet therapy.

Hospital IRB approval for the study was obtained. Data collected included patient's demographics, echocardiographic and cardiac catheterizations data (Tables 1 and 2). Electrocardiographic (EKG) data was collected and analyzed to evaluate the rhythm disorders in this cohort (Tables 3 and 4).

Previously described technique for VSD closure was used [14]. Echocardiogram and EKG on the first post-catheterization day and at 1, 3, 6, and 12 months, and then yearly were reviewed for any conduction abnormality, residual VSD shunt, aortic regurgitation (AR), or tricuspid regurgitation (TR).

The data were initially entered into an Excel spread sheet and subsequently imported into the JMP Statistics Package v8.0.1 (SAS Corp., USA). All statistical analyses were carried out within JMP. In addition to basic descriptive statistics (mean, medians, ranges, standard deviations, and counts of missing data), both Pearson's and Spearman's correlation coefficients (and their associated p values) were calculated to explore the linear correlations between specific pairs of variables, and the correlations quoted here are Spearman's rho. Potential outliers were identified by eye (based on JMP scatter plots) and aided by the superimposition of a 95% bivariate normal density ellipse generated by JMP. The statistical significance of the differences between the means of continuous variables was explored using the *t* test (for equal or unequal variances as applicable) and Wilcoxon's test, and the p values quoted here are for Wilcoxon's. The alpha-level for statistical significance was set to be 0.05 for all tests.

Results

VSD device closure was attempted on 49 patients with successful closure achieved in 45 patients (success

Table 1: Patient demographics, VSD size, device size, Qp:Qs, RVSP, fluoro time, and procedure time

	Mean	Median	Range
Age (years)	11.2	8.5	2–36.7
Weight (kg)	35.5	24	10–106
VSD size (mm) by TTE	7.2	7	3–14
VSD size (mm) by TEE	7.5	6	4–15
VSD size (mm) by LV angiography	6.2	6	3–14
Device size (mm)	8.7	8	4–18
Qp:Qs	1.5	1.4	1– 3
RVSP (mm Hg)	31.5	28.5	20–50
Fluoro time (min)	47.11	41.5	17–138
Procedure time (min)	145	132.5	46–310

TTE = transthoracic echo; TEE = transesophageal echo; Qp:Qs = pulmonary to systemic blood flow ratio; RVSP = right ventricular systolic pressure.

Table 2: Comparison of muscular and membranous VSD groups and their mean values

Type of VSD	Age (years)	Wt (kg)	VSD TEE (mm)	Qp:Qs	Device Size (mm)	Proc. Time (min)	Fluoro Time (min)	Follow Up (months)
Muscular	13.2	46.5	6.67	1.65	8.25	159.16	61	54.78
Membranous	12.43	36.35	6.66	1.4	8.14	137.81	43.93	64.03
P value	0.31	0.11	0.49	0.11	0.71	0.67	0.21	0.51

Wt = weight; TEE = transesophageal echo; Qp:Qs = pulmonary to systemic blood flow ratio; Proc time = procedure time.

rate of 91.8%); the female to male ratio was 1.14. Among these 45 VSD closure cases, 35 were perimembranous (78%) (34 native and 1 surgical residual) and 10 muscular (9 native and 1 surgical residual) defects. The pmVSDs were closed using 23 pmVSD devices, 6 muscular VSD devices, and 6 Amplatzer duct occluders (ADO), whereas the muscular VSDs were closed with nine muscular VSD devices and one ADO device. The ADO devices were used only in tunnel shape aneurysmal VSDs. Ten (22%) patients had associated cardiac anomalies including patent ductus arteriosus in one, pulmonary valve stenosis in four, mild mitral stenosis in one, additional small muscular VSDs in two, and bicuspid aortic valve in two.

In two out of four unsuccessful cases, the VSD delivery sheath could not be advanced through VSD due to aneurysmal tissue; in one case, there was device related aortic regurgitation and the device was retrieved with no residual regurgitation, and in another case, there was transient complete heart block that reverted to normal sinus rhythm after device removal. All four patients who failed device closure were referred for surgical closure.

At the time of VSD closure, the median age of the study group was 8.5 years (range 2–36.7 years) and the median weight of 24 kg (range 10–106 kg). The median VSD size by transthoracic echocardiogram (TTE), TEE, and by LV angiogram was 7, 6, and 6 mm, respectively, and the device size was with a median of 8 mm (range 4–18). The median ratio of systemic to pulmonary blood flow (Qp:Qs) was 1.4 (range 1–3) and the median right ventricular systolic pressure was 28.5 mm Hg (range 20–50 mm Hg). The median fluoro and the median procedure times were 41.5 minutes and 132.5 minutes, respectively (Table 1).

There was no significant correlation between weight and VSD size with fluoroscopy time [when outliers were removed the correlation coefficient was 0.282 (p=0.11) and 0.066 (p=0.73), respectively].

Table 3: New onset rhythm disorders in the membranous VSD group

Rhythm Disorder & Patient Number	Age (years)	Weight (kg)	VSD Size (mm) by TEE	Device Size (mm)
CRBBB - 4				
1	17.5	57	12	12
2	9.4	18	14	16
3	5	18	8	10
4	5.7	14	4	4
CLBBB - 1	5	16	6	6
CAVB - 1	5	17	12	12
EAT - 1	27.2	54	4	4
V. Tach - 1	14.3	77	11	10

TEE = transesophageal echo; CRBBB = complete right bundle branch block; CAVB = complete atrio-ventricular block; EAT = ectopic atrial tachycardia; V. Tach = ventricular tachycardia.

Table 4: New onset rhythm disorders in the muscular VSD group

Rhythm Disorder & Patient Number	Age (years)	Weight (kg)	VSD Size (mm) by TEE	Device Size (mm)
ICRBBB - 1	10.5	37	6	6
CLBBB - 1	3.5	23	6	6
PVCs - 1	8	21	4	4

TEE = transesophageal echo; CLBBB = complete left bundle branch block; ICRBBB = incomplete right bundle branch block; PVCs = premature ventricular contractions.

Base line EKG

At baseline, all patients had 12-lead EKG prior to VSD closure. EKG was normal in 40 (89%) patients and abnormal in 5 (11%) patients [4 incomplete right bundle branch block (ICRBBB) and 1 complete right bundle branch block (CRBBB) (Figure 1)].

Latest EKG

During 8 year follow up, EKG findings were analyzed in all 45 subjects. At a median follow up of 61.9 months, EKG revealed one patient with muscular VSD had developed ICRBBB. There were total 5 patients with CRBBB at the latest follow up. Out of these 5 patients, 3 patients had new onset CRBBB, fourth patient had progression of base line ICRBBB to CRBBB and in the fifth patient the base line CRBBB persisted as it is at the latest follow up. All the patients with CRBBB were having pmVSD and they received a pmVSD Amplatzer device of mean size 10.5 mm at a mean age of 9.4 years and weight of 26.7 kg. There was no CRBBB observed in muscular VSD patients at follow up.

Complete left bundle branch block (CLBBB) was seen in two (4%) patients in this cohort, one had pmVSD and one had muscular VSD. Both patients received muscular VSD Amplatzer devices (6 mm size) and their mean age and weight were 4.3 years and 19.5 kg, respectively.

Complete atrioventricular block occurred in one (2.9%) of the patients in the perimembranous VSD group. This patient received a 12-mm membranous type Amplatzer device, and his age and weight were 5 years and 17 kg, respectively. He developed CRBBB immediately after the procedure, which persisted for 6 months; at 1 year follow up, he was found to have CAVB and underwent placement of a permanent pacemaker.

Other arrhythmias observed in the pmVSD group included 3 beats run of ventricular tachycardia in one patient and ectopic atrial tachycardia in another patient. Occasional premature ventricular contractions were observed in one of the cases from the muscular VSD group (Tables 3 and 4). All the patients who received ADO Amplatzer devices (six patients with pmVSD and one muscular VSD) had no arrhythmia or conduction abnormality at either immediate or long-term follow up.

Interestingly, we noted resolution of ICRBBB in two of the four who had it at baseline EKG before closure and both had normal EKG at all follow-up visits. Of the other two patients of ICRBBB at baseline, one progressed to CRBBB and one maintained the same after device closure.

For all groups at long-term follow up, no mortality, stroke or neurologic deficit, device migration, wire fracture, thromboembolism, endocarditis, or hemolysis was seen.

Discussion

Nonsurgical closure of VSD has been an attractive option to avoid artificial circulation and sternotomy scars. The Amplatzer muscular occluder has been successfully used to close muscular VSDs [6, 7] and a specially designed Amplatzer ventricular septal occluder has been used in perimembranous defects [8, 10, 14]. The Amplatzer duct occluder has been used successfully for the closure of tunnel-type VSDs with aneurysmal tissue [11, 12]; recently, ADO - II has been tried with good success rates and minimal rhythm disturbances [13]. One of the major drawbacks for membranous VSD closure is the significant incidence of heart block and rhythm abnormality. In one study, the CAVB was reported as high as 5.8% [17] with the need for pacemaker therapy. In other studies, the major adverse events have been reported as low as 0.6% in pmVSD patients under 3 years of age using symmetrical devices [15]. Late occurrence of CAVB also has been reported at 1 year follow up [20]. The junctional rhythm at early (within 48 hours) post-device pmVSD implantation indicates an inflammatory process around the atrioventricular node. Some studies showed occurrence of early post-implantation junctional rhythm up to 14% of their patients [15]. This can explain the observed benefit of steroid administration in some patients who developed CAVB early post-device implantation [15].

We showed a low incidence of CAVB in one (2.9%) patient in the pmVSD group with a mean follow up of 62 months. This patient developed CAVB between 6 and 12 months post-implantation, remained asymptomatic, and was diagnosed by routine EKG. This warrants the necessity of long-term follow up of all

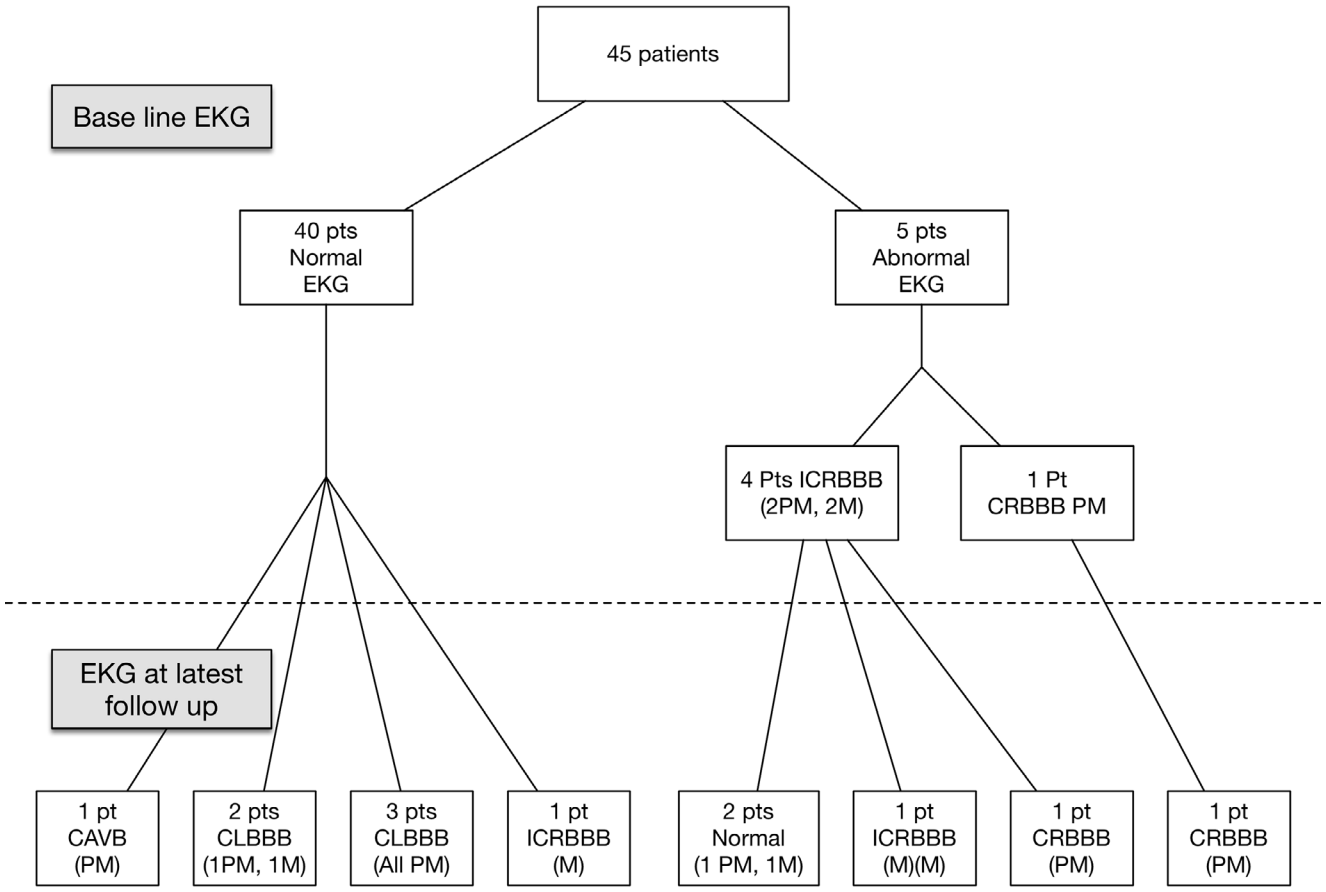

Figure 1. EKGs at baseline and at latest follow up. CAVB = complete atrioventricular block; CLBBB = complete left bundle brach block; CRBBB = complete right bundle branch block; ICRBBB = incomplete right bundle branch block; PM = perimembranous VSD; M = membranous VSD.

patients with VSD device closure. CAVB has been reported in up to 5.8% with an asymmetric Amplatzer device [17] and as low as 0.1% with symmetrical occluders [15]. Acute (within 48 hours) and late (at 5 and 12 months post-procedure) CAVB in pmVSD was noted by Carminati et al. [18]. Independent risk factors for CAVB include younger age, low body weight, oversized device, type of device, repeated maneuvers, and position of defects [17–19]. Butera et al. [20] reported two cases of late-onset CAVB at 4 and 12 months after the procedure. Up to 30 days after Amplatzer VSD device closure, recovery of various forms of arrhythmias and heart block with corticosteroid therapy was observed [21, 22]. CAVB has been recovered in 70% of the patients within 2 weeks post-procedure after being treated with steroids and isoprenaline [16].

We observed other "benign" conduction and rhythm disturbances in about 12% of the pmVSD group. Of those 12%, there was only one patient who developed LBBB, which is less frequent than that reported in other studies. This LBBB didn't progress during 5 years of follow up. The pmVSD patients with aneurysmal tissue (six patients) that were closed by ductal occluders (ADO) did not show any rhythm disturbances. This may encourage investigators to utilize this approach whenever possible to avoid rhythm complications. The other interesting finding in our study was the resolution of IRBBB post-device implantation in two out of four patients who had it at baseline. This observation could be secondary to the decrease in right ventricular volume overload after stopping the left-to-right shunt. Our reported benign conduction

disturbances in pmVSD are similar to another report of 12% CRBBB [10]. CLBBB has been reported at an incidence of 3.7% [16]; however, the incidence of CLBBB was lower at 1.1% using the symmetrical VSD occluder [15].

Overall, our reported incidence of CAVB post-pmVSD device closure is similar to that reported for surgical closure. Certainly the occurrence of "benign" conduction disturbances with device closure is far fewer than that seen in surgical closures.

At 54.5 months mean echocardiographic follow up, complete VSD closure was observed in 91.2% of patients, whereas a small (1–2 mm in size by transthoracic echo) residual shunt was found in 8.8% of patients. This is similar to other reports that noted a success rate of 92–97.6% [7, 9, 16].

Conclusion

Transcatheter closure of perimembranous and muscular VSDs has a high success rate with an adequate safety margin. Heart block following device closure is comparable to the surgical approach. Other rhythm disturbances in VSD device closure are far fewer than those of postsurgical closure. Rhythm disturbances at late follow up are uncommon but warrant close follow up.

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Conflict of Interest

The authors have no conflict of interest relevant to this publication.

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ANTITHROMBOTIC TREATMENT AFTER PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE: A DIFFICULT CHALLENGE IN PATIENTS AT HIGH RISK OF BLEEDING

Daniele Gemma[1], Guillermo Galeote García[1], Raúl Moreno Gómez[1], Javier De Juan Bagudá[2], Natalia Lorenzo Muñoz[3], Ignacio Plaza Pérez[2], Inés Ponz de Antonio[1], José Luis López Sendón[1]

[1] Hospital Universitario La Paz, Madrid, Spain
[2] Hospital Infanta Sofía, Madrid, Spain
[3] Hospital Infanta Cristina, Parla (Madrid), Spain

Background: Contraindication to oral anticoagulation (OAC) is the main indication for percutaneous left atrial appendage closure (PLAAC). This implies a challenge in deciding the adequate antithrombotic therapy after device implantation.

Objectives: The aim of our study is to assess whether the type of antithrombotic treatment is related to thromboembolic/bleeding risk after PLACC.

Methods: Retrospective observational study including patients with atrial fibrillation who underwent PLAAC with Amplatzer™ device for OAC contraindication in our centre, until April 2015. Major bleeding was defined as intracranial bleeding, decrease in Hb 2 g/L and/or transfusion requirement, and minor bleeding as any other kind of bleeding.

Results: 18 patients were included (mean age 75 years, HASBLED 4). After PLAAC, control transesophageal echocardiography was performed in 14 patients; 12 patients (66.6%) received dual antiplatelet therapy (DAPT), 3 (16.7%) single antiplatelet therapy (SAPT), 3 (16.7%) apixaban for 3 months. No device thrombosis was observed. Bleeding was observed in 5 cases (3 major, 2 minor), 4 of them in the first year, with an annual rate of major bleeding in the first year higher than expected by the HASBLED score (11.1% vs. 8.9%). 2 major bleedings occurred under DAPT, while the 2 minor bleedings occurred under SAPT. No bleeding was observed under apixaban. The only parameter associated with major bleeding was DAPT at discharge (p=0.001).

Conclusions: In our series DAPT after PLAAC was associated with a higher rate of bleeding complications. We didn´t observe device thrombosis. Further studies are needed to find the optimal ant thrombotic regimen after implantation.

Table 1.

	Kind of bleeding	Age	Gender	HAS-BLED score	Time from intervention (months)	Antithrombotic treatment
Major bleeding	Esophageal varices (Exitus)	82	M	5	30	Nothing
	Intracranial (Exitus)	65	M	5	2	M Acetylsalicylic acid 100 mg + Clopidogrel 75
	Intestinal (Transfusions)	74	M	4	1	Acetylsalicylic acid 100 mg + Clopidogrel 75
Minor bleeding	Haematuria	77	M	5	9	Acetylsalicylic acid 100 mg
	Epistaxis	93	F	3	6	Acetylsalicylic acid 100 mg

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http://structuralheartdisease.org/

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E-Mail: jshd@scienceinternational.org
http://structuralheartdisease.org/

IMPORTANCE OF CARDIAC CT PRIOR TO A SECOND GENERATION TRANSCATHETER AORTIC VALVE IMPLANTATION

Ines Ponz, Daniele Gemma, Elena Refoyo, Emilio Cuesta, Guillermo Galeote, Zorba Blazquez, Juan Caro, Mar Moreno, Raul Moreno, Jose Luis Lopez Sendon

Hospital Universitario La Paz, Madrid, Spain

Introduction: The LotusTM Valve (LV) is a second-generation transcatheter aortic prosthetic valve. Our aim was to identify predictors of potential complications related to its implantation.

Methods: Prospective study including patients submitted to LV implantation between May 2014 and February 2015. Transthoracic and transesophageal echocardiography and Cardiac Computerized Tomography (CT) was performed before the procedure.

Results: 16 patients underwent LV implantation: number 23 in 56.2%, 25 in 18.8% and 27 in 25% (62.5% female, mean age 80.5 years, mean EuroSCORE 9.65, Table1). After the procedure both mean and maximal gradient improved in all patients (p0.001), finding no predictors of such improvement.

We found a higher incidence of postprocedural complications among patients with a greater ascending aortic diameter by CT (37.9 vs. 32.6mm, p0.011), and with left ventricular dysfunction, particularly with renal failure (p0.001).

Pacemaker implantation (50%) was associated with a greater left ventricular outflow tract (LVOT) perimeter (73.6 vs. 65.2mm, p0.03) and calcification of the mitroaortic fibrosa (p0.001), which was also more frequent among patients developing bundel branch block (62.5%; p0.035).

12.5% suffered a cardiac arrest due to atrioventricular block, which was associated with a greater LVOT area (484 vs. 343mm2, p0.005) and perimeter (82 vs. 68.2mm, p0.002), measured by CT, and also with implantation of a bigger valve (p0.02).

Conclusion: Performing a Cardiac CT prior to a LV implant is useful to predict possible postprocedural complications. A greater LVOT with implantation of a bigger valve and the calcification of the mitroaortic fibrosa associate a greater risk of conduction disorders.

Table 1: Echocardiographic or tomographic/radiographic characteristics

	Mean value
Valvular área (3D planimtry)	0,65 cm2
Pre-procedure maximal gradient	65,2 mmHg
Pre-procedure mean gradient	20,3 mmHg
LVEF	62,3%
Aortic annulus area (CT)	442,4 mm2
Aortic annulus perimeter (CT)	78,9 mm
Calcium Score	3048,6

LOTUS, A NEWSECOND-GENERATION TRANSCATHETER AORTIC PROSTHETIC VALVE EFFICACY AND SAFETY

Daniele Gemma, Inés Ponz De Antonio, Raúl Moreno Gómez, Guillermo Galeote García, Elena Refoyo Salicio, José Luis López Sendón

Hospital Universitario La Paz, Madrid, Spain

Background: Lotus™ Valve (LV) is a second-generation transcatheter aortic prosthetic valve (TAVI), retrievable and repositionable, designed to minimize the risk of complications, particularly periprosthetic aortic regurgitation (AR). Experience with this new TAVI is still limited.

Objective: The aim of our study is to report the results of our initial experience with LV implantation, in terms of safety and efficacy.

Materials: Prospective study including patients with severe aortic stenosis who underwent LV implantation in our centre between May 2014 and February 2015. We report echocardiographic and clinical outcomes until hospital discharge.

Results: 16 patients underwent LV implantation (62.5% female, mean age 80.5 years, mean EuroSCORE 9.65). During the procedure, a patient suffered a thrombotic occlusion of the left main coronary artery, which was corrected by thromboaspiration, without sequelae. No prosthesis embolization was observed. Following LV implantation, both mean and maximal gradient and AR improved in all patients (p0.001), with no cases of periprosthetic AR post TAVI. Pulmonary systolic pressure was reduced in 50% of patients (see Table 1). 8 patients suffered complete atrioventricular block until eight days after the procedure, requiring pacemaker implantation. The average hospital stay was 5 days, without any exitus at discharge.

Conclusion: Lotus is an effective and safe alternative for the treatment of patients with severe aortic stenosis and high surgical risk, despite a relatively high incidence of conduction disorders in our initial experience. Studies are needed to better patient selection for this type of TAVI.

Table 1: Pulmonary Systolic Pressure

	Pre-Lotus	Post-Lotus	P
Maximal Gradient	65,2 mmHg	20,2 mmHg	p 0,001
Mean Gradient	4 20,3 mmHg	10,1 mmHg	p 0,001
Aortic regurgitation	68,8% grade I or II	18% grade I	p 0,001
Pulmonary Artery Systolic Pressure	51 mmHg	39,9 mmHg	p 0,01