CLINICAL CASE REPORTS

EXPERIENCE WITH THE AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

Abbott

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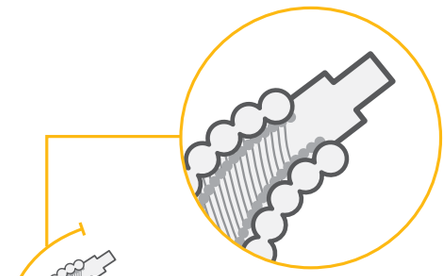
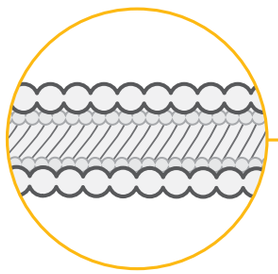
RELIABLE PRECISION
WHEN IT MATTERS MOST

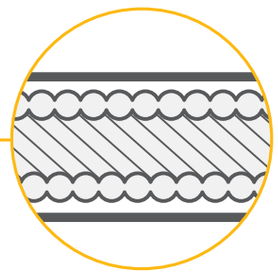
The Amplatzer™ Trevisio™ Intravascular Delivery System is an ultra-flexible delivery system enabling interventional cardiologists to perform their work with complete confidence. It leverages the one-piece cable design utilized by the Amplatzer™ TorqVue™ Delivery System, also know as the Classic Amplatzer™ Delivery System*. Trevisio is designed for no compromises on torque strength, sheath diameter and pushability.



ULTRA-FLEXIBLE TIP
- Improves assessment of device position before cable release.
- Reduces bias on the device.

FLEXIBLE TRANSITION SECTION
Maintains sheath position during deployment of the device.

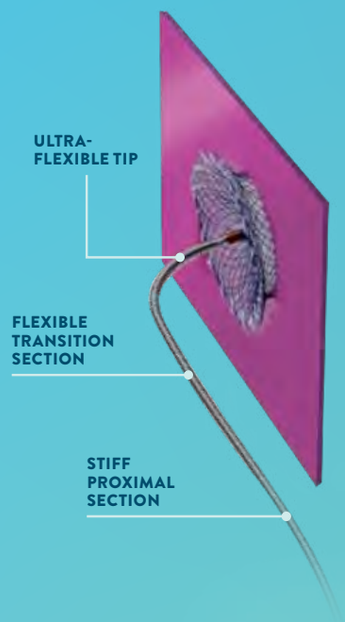




STIFF PROXIMAL SECTION
Maintains pushability of the delivery system.

CLASSIC AMPLATZER™ DELIVERY SYSTEM*

AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM



Flexible tip reduces the bias on the device and improves the assessment of device position prior to cable release.

* Amplatzer™ TorqVue™ Delivery System

IMPROVED DEVICE DELIVERY IN TRANSCATHETER ATRIAL SEPTAL DEFECT CLOSURE WITH THE NEW AMPLATZER™ TREVISIO™ SYSTEM

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ABSTRACT

Transcatheter interventional closure has become the preferred treatment of secundum type atrial septal defects (ASD). The Amplatzer™ Septal Occluder (ASO) is the most widely used device for ASD closure and has been demonstrated to be safe and highly effective in children and adults. However, in some cases technical success of device implantation may be limited by more complex ASD morphologies, such as large defects with floppy or deficient surrounding rims. The recently introduced Amplatzer™ Trevisio™ delivery system for the Amplatzer™ device family has a highly flexible delivery wire tip developed to improve device implantation. We report the first experience with the Trevisio™ delivery system in Europe employed in a successful transcatheter ASD closure in a child.

INTRODUCTION

During the past decades, transcatheter interventional closure has become the preferred treatment approach for secundum type atrial septal defects (ASD) with approximately 80-90% of isolated ASDs being closed percutaneously at present. The Amplatzer™ Septal Occluder (ASO) continues to be the most commonly used device for ASD closure and has been proven to be safe and highly effective in pediatric and adult patients. However, in some cases technical success of transcatheter device implantation may be limited by more complex ASD morphologies, such as large defects with floppy or deficient surrounding rims. Various modifications of delivery techniques have been described to prevent device embolization during the deployment and implantation in ASD with unfavourable rim morphologies.

The comparably stiff delivery wire of the ASO transfers considerable tension to the device and the atrial septum which may facilitate device embolization and technical failure of ASD closure in cases with suboptimal morphology. The recently introduced new Amplatzer™ Trevisio™ delivery system for the Amplatzer™ device family was developed with a highly flexible delivery wire tip to improve device implantation. Here, we report the first experience with the Trevisio™ delivery system in Europe employed during a successful transcatheter ASD closure performed in a child.

Prof. Dr. Felix Berger

CASE PRESENTATION

A 6-year old child (22.6kg, 116cm) was referred to our institution for closure of a large ASD. The diagnosis was established due to a heart murmur at the age of 2 years and she was since followed on a regular basis. Due to progressive enlargement of the right atrium and right ventricle as well as decreasing exercise tolerance the indication for ASD closure was made.

Transcatheter closure of the ASD was performed by our routine institutional protocol under conscious sedation by administration of midazolame and propofol. Cardiac catheterization was performed with continuous transesophageal echocardiography (TEE) monitoring while fluoroscopy was only used during device implantation and release (fluoroscopy time 59sec, dose area product 118mGy/cm^2, air kerma 2.42 mGy). TEE showed a 15-16mm centrally located ASD with deficient retro-aortic rim (Fig. 1A, B) but otherwise sufficiently present rims. After femoral access, a 0.035 inch guidewire was placed in the left upper pulmonary vein through the ASD using a 5F multipurpose diagnostic catheter (Cordis, Santa Clara, CA, US). The ASD was then sized with a 24mm Amplatzer™ sizing balloon (Abbott Medical, Plymouth, MN, US) measuring 16mm in diameter, stop flow was confirmed by TEE. For ASD closure, an 18mm ASO was chosen and the new Amplatzer™ Trevisio™ delivery system was used. After positioning the 9F delivery sheath in the left atrium via guide wire, the ASO was successfully positioned in the atrial septum in the first attempt. As visualized by TEE as well as fluoroscopy (Fig. 1 C, D), the tip of the delivery wire is highly flexible which allowed accurate positioning of the device with reduced tension on the atrial septum and resulting in a more favorable alignment of device and septum while still attached. After exclusion of residual shunt by TEE and confirmation of stable position with additional Minnesota maneuver, the device was released.

The patient had an uneventful post-interventional hospital stay and was discharged on the next day.

DISCUSSION

We present the first experience in Europe with the Amplatzer™ Trevisio™ delivery system for the Amplatzer™ device family which we used during successful transcatheter ASD closure in a child. From our experience, the newly developed Trevisio™ delivery wire provides improved device deployment and implantation performance compared to the previous delivery wire. The increased flexibility of the wire tip results in reduced tension of the delivery system on the device and the atrial septum which allows a more accurate and controlled positioning during the implantation procedure. Also anticipation of the final device position and orientation is facilitated. This might improve technical success in more complex ASD morphologies such as larger defects with floppy or deficient rims. Moreover, by providing increased flexibility and maneuverability the new delivery system may prove advantageous in other types of transcatheter interventions such as percutaneous closure of patent aterial duct or ventricular septal defect.

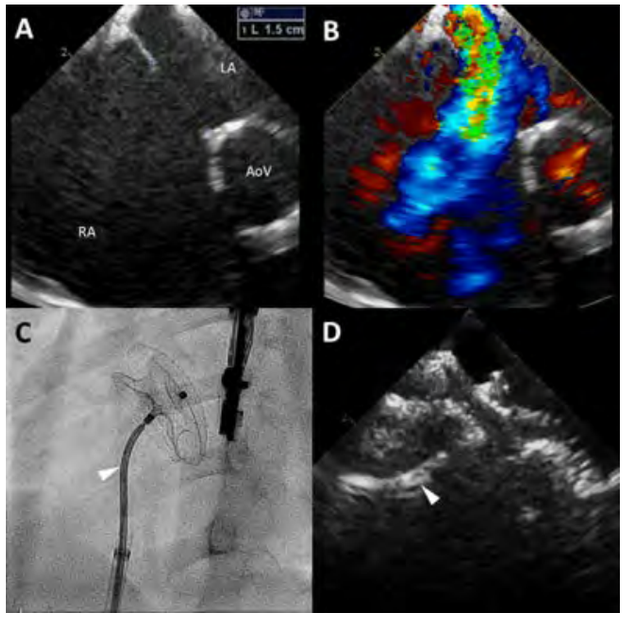

Figure 1:

A, B: Pre-procedural transesophageal 2D (**A**) and colour Doppler (**B**) echocardiograpy showing the large ASD with deficient retro-aortic rim.

C, D: Fluoroscopy (**C**) and transesophageal echocardiography (**D**) after device implantation before release. The flexible tip of the Trevisio™ delivery wire is clearly visualized (white arrowheads) resulting in less tension on the device and more favourable device orientation.

AoV - aortic valve; LA - left atrium, RA - right atrium.

CONCLUSION

The newly introduced Amplatzer™ Trevisio™ delivery system improves device delivery and implantation during percutaneous ASD closure with ASO by increased flexibility and tension-reduced positioning.

POST-INFARCTION VENTRICULAR SEPTAL DEFECT CLOSURE WITH THE NEW AMPLATZER™ TREVISIO™ SYSTEM

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ABSTRACT

Acute myocardial infarction (AMI) is a significant health problem. Delayed patient presentation and/or treatment increase the risk for mechanical complications including post-infarction ventricular septal defects (VSDs). Transcatheter closure of a VSD is a safe and effective alternative to surgical VSD closure. The Amplatzer PI Muscular VSD Occluder has been specifically designed for VSD closure in post-infarction patients. Device delivery can be improved with the recently introduced Amplatzer Trevisio delivery system which features an ultra-flexible tip. Here, we report the case of a post-infarction VSD, which we successfully closed using the Amplatzer Trevisio delivery system.

INTRODUCTION

Acute myocardial infarction (AMI) remains a significant worldwide health problem that affects more than 15 million people every year. Historically, mechanical complications of AMI including free-wall ruptures, papillary muscle ruptures and ventricular septal defects (VSDs) occurred in up to 5 % of AMIs. Advances in establishing early reperfusion by thrombolytic therapy and percutaneous coronary interventions with stenting have led to a significant decrease in mechanical complications after AMI. However, especially in patients who present late or in whom there is a delay in therapy, the incidence may still be as high as 2 %. In addition, post-infarction VSDs are associated with a high mortality rate: 5 % of deaths after AMI can be attributed to VSDs. Surgical closure of post-infarction VSDs was long considered the gold standard; however, it is associated with high morbidity and mortality. Transcatheter closure has therefore become an attractive alternative to surgical closure in post-infarction VSD patients. The Amplatzer occluders are the most commonly used devices in VSD closure. They consist of two self-expanding nitinol discs which are connected by a thin waist; the discs are deployed on either side of the septum. Specifically designed for post-infarction (PI) VSD closure, the Amplatzer PI Muscular VSD Occluder can provide safe and highly effective occlusion. To improve device delivery, the second-generation Amplatzer Trevisio delivery system for the Amplatzer device family has recently been introduced. The new Amplatzer Trevisio delivery system now features an ultra-flexible tip, allowing for improved assessment of the device position prior to cable release and reducing bias on the device. In addition, the flexible Trevisio delivery system transition section facilitates maintaining of the sheath position during deployment of the device while the stiff proximal section ensures good pushability of the delivery system. Here, we report the case of a post-infarction VSD, which we successfully closed using the Amplatzer Trevisio delivery system.

Dr. Stanimir Georgiev

POST-INFARCTION VENTRICULAR SEPTAL DEFECT CLOSURE WITH THE NEW AMPLATZER™ TREVISIO™ SYSTEM

CASE PRESENTATION

This was a 71-year old patient who had a massive myocardial infarction. The patient underwent two bypass surgeries but remained unstable in spite of that, so he was put on extracorporeal membrane oxygenation (ECMO).

The reason for that instability could be clearly seen in echocardiographically (**Fig. 1**): there was a large VSD, which was in the apical septum. We measured the size of the VSD to be up to 18 mm.

We then took the patient to our congenital heart defects cardiac catheterization laboratory and aimed to close the defect. The femoral veins were already canulated for the ECMO and for dialysis, so we punctured the right jugular vein. We started there with a 6F sheath, which we ultimately upgraded up to a 12F Flexor‡ sheath. We also punctured the femoral artery with a 6F sheath.

As can be seen on the left ventricular angiogram, there was a massive left-to-right shunt over the VSD (**Fig. 2**). We put the coronary catheter into the VSD and entered the right ventricle and the pulmonary artery with a Terumo‡ wire, and over this Terumo‡ wire we advanced the catheter up to the pulmonary artery. Then we established an AV loop using a noodle wire and took the noodle wire out of the venous side; over this noodle wire, we advanced a delivery 12F Flexor‡ sheath to the VSD into the left ventricle.

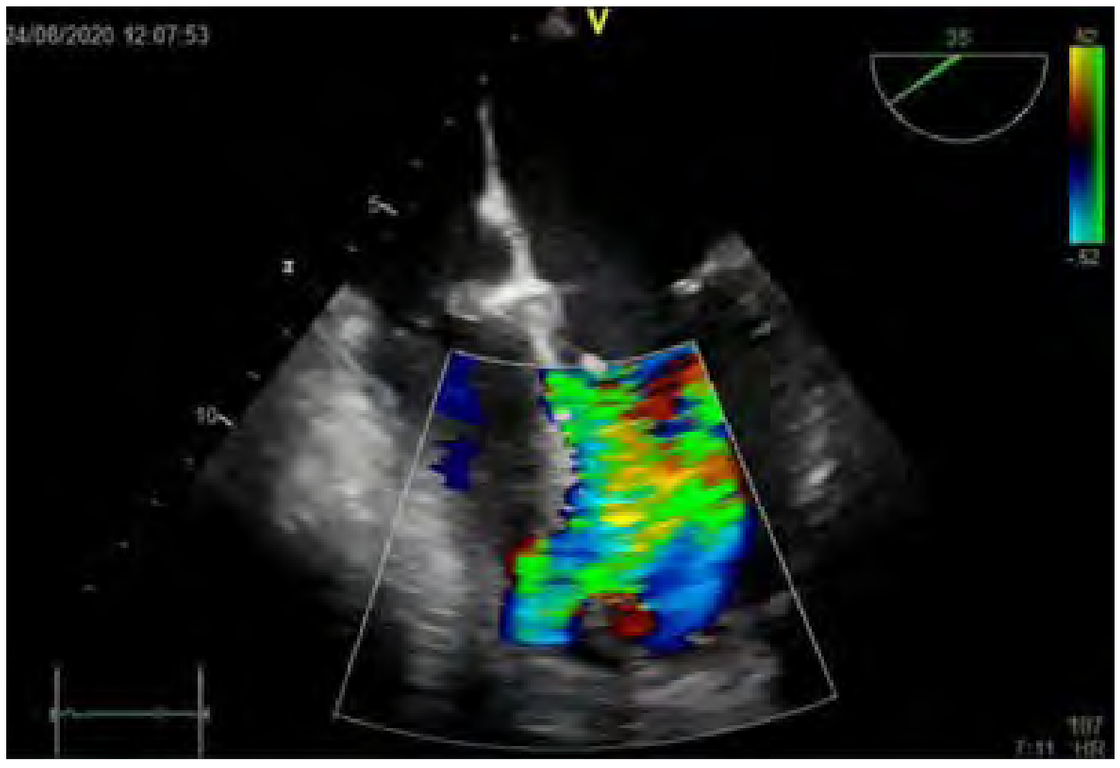

Figure 1: Pre-procedural color Doppler echocardiography showing a large VSD in the 71-year old patient.

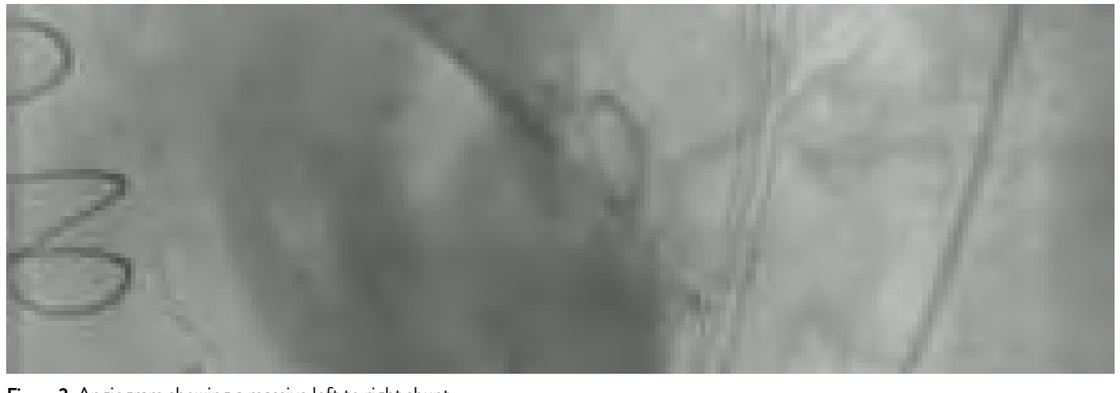

Figure 2: Angiogram showing a massive left to right shunt.

We chose a large 24 mm muscular Amplatzer™ VSD Occluder, because evidently this was a large hole. We then performed the implantation of the occluder using the Trevisio™ delivery system. What is so nice about this delivery system is that the tip of the wire is really soft and flexible, so it gives you really good control during implantation. In this case, too, the device implantation was very controlled; the device could be configured very nicely and there was practically no tension between the wire and the proximal disc of the device.

In the angiogram with the device still on the wire (**Fig. 3A**), one can see that the septum is placed nicely between the discs, so we were pretty happy with this position. We confirmed this, of course, by transoesophageal echocardiography, and we saw a nice position there as well (**Fig. 3B**), so we decided to release the device. And because this delivery system is very soft at the tip, there was really minimal or no tension at all between the wire and the proximal disc of the device. Therefore, when we released the device, we didn't see the typical jumping of the proximal disc, which one sees with the old Amplatzer delivery systems.

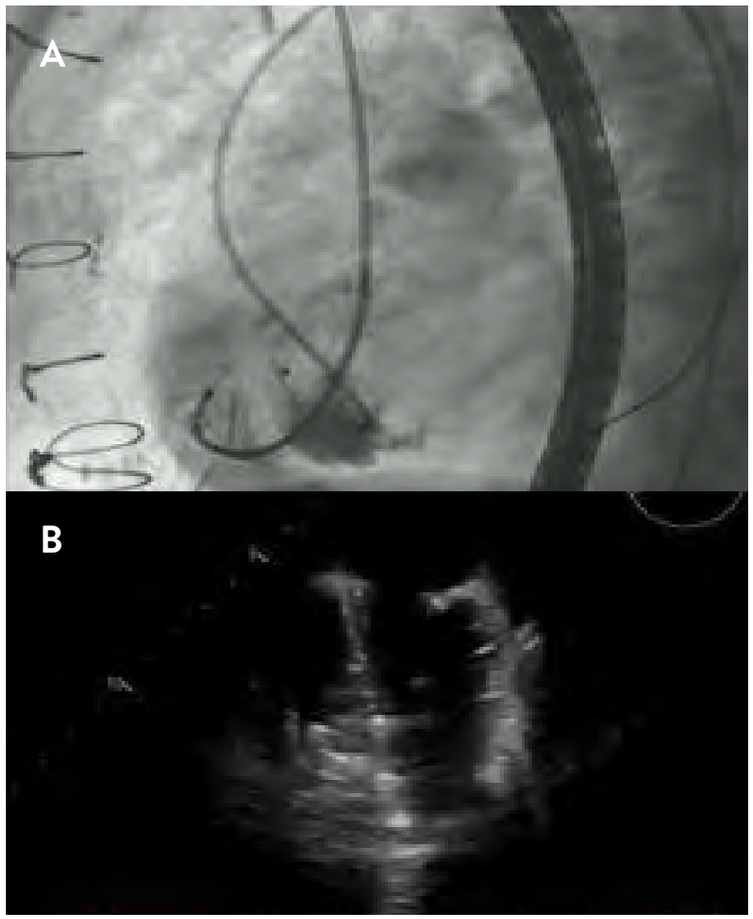

Figure 3 A, B: Angiogram (**A**) and transoesophageal echocardiography (**B**) showing device deployment before release.

CONCLUSION

What this case has shown is that it is possible to effectively close a large post-infarction VSD with the muscular Amplatzer VSD Occluder, and that the flexible tip of the Amplatzer Trevisio system allows for precise implantation with minimal position change of the device after release.

TRANSJUGULAR ATRIAL SEPTAL DEFECT CLOSURE WITH THE NEW AMPLATZER™ TREVISIO™ SYSTEM

Improved Adaptability and Accurate Positioning

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ABSTRACT

We report the first use of Amplatzer™ Trevisio™ Intravascular Delivery System for transjugular atrial septal defect closure in a 9-year-old congenital heart patient with interrupted inferior vena cava and azygos continuation. The device was uneventfully delivered from the right jugular vein and efficiently deployed, positioned, and released into proper position. The major advantage of device implantation with increased flexibility and pre-release accurate positioning was highly beneficial in this challenging approach of closure.

INTRODUCTION

Since the first device closure of secundum-type atrial septal defects (ASDs) in 1974, multiple devices were developed and tested in clinical studies. However, it was until the Amplatzer™ Septal Occluder (ASO) became available in the mid-1990s that percutaneous ASD closure became the treatment of choice with a low risk of complications and good long-term findings. In some patients, implantation may be challenging because of unusual access or complex anatomies with unfavorable rim morphologies. The recently introduced Amplatzer™ Trevisio™ intravascular delivery system for Amplatzer™ devices has an ultra-flexible delivery wire tip with promising technical advantages in terms of accurate device positioning and implantation. We report the first pediatric experience with the Amplatzer™ Trevisio™ delivery system in transjugular ASD closure.

CASE PRESENTATION

A 9-year-old child (39kg, 150cm) was referred to our institution for ASD closure. The patient had left isomerism, complete atrioventricular septal defect (AVSD) with interrupted inferior vena cava, and azygos continuation.

She had AVSD repair and 2 subsequent surgeries for regurgitation and stenosis of the right atrioventricular (AV) valve. She presented with exercise-induced oxygen desaturation (rest saturation of 98% dropping to 87%) and suffered from chronic migraines. Ultrasound showed a bidirectional shunt across a surgically created-ASD that was left initially for a residual mean 4mmHg gradient across the right AV valve. The indication of ASD closure was based on exercise intolerance and headache relief. Written informed consent was signed by the patient legal guardians to perform the procedure after they were provided with a comprehensive explanation about procedural details. The intervention was performed in a fully equipped biplane digital catheterization laboratory under general anesthesia, continuous transoesophageal echocardiography (TOE) guidance, and fluoroscopic control as per routine institutional protocol.

TRANSJUGULAR ATRIAL SEPTAL DEFECT CLOSURE WITH THE NEW AMPLATZER™ TREVISIO™ SYSTEM

Improved Adaptability and Accurate Positioning

TOE evaluation showed an 8mm centrally located ASD with all adequate rims (**Fig. 1A**). Intravenous cefazolin was given and the right jugular vein was accessed using a short 7-Fr introducer. Systemic heparinization was given and the ASD was crossed using a 5-Fr Judkins right coronary catheter (Cordis Corporation, FL, USA) in combination with a 0.035in x 180cm stiff-type angled Radifocus® Hydrophilic Guidewire M (Terumo Corp., Tokyo, Japan) that was positioned in the left ventricular outflow tract (**Fig. 1B**). As per institution protocol, a 12mm Amplatzer™ Septal Occluder (Abbott Medical, MN, USA) was chosen 4mm larger than the defect. The short introducer was upgraded into a 25cm-long 9-Fr Radiofocus® introducer II (Terumo Corp., Tokyo, Japan) that was advanced over the guidewire and positioned just across the ASD in the left atrium. A 7-Fr 45° angle curvature delivery sheath was inserted and the device was successfully delivered and deployed within the defect in the first attempt using the new Amplatzer™ Trevisio™ system. The improved flexibility of the wire helped in perfectly aligning the device with the atrial septum even before release allowing definitive assessment of the device's final position and residual leak. The released device maintained its identical pre-release shape, position, and orientation (**Fig. 1C, D**). No complication was recorded. Procedure time was 10 minutes and required 4.9 minutes of fluoroscopy (dose area product 77.5 µGy/m2 and air kerma 7.7 mGy). The patient was discharged after 24 hours of surveillance and aspirin therapy was prescribed for 6 months. Two-month-follow-up confirmed excellent outcomes.

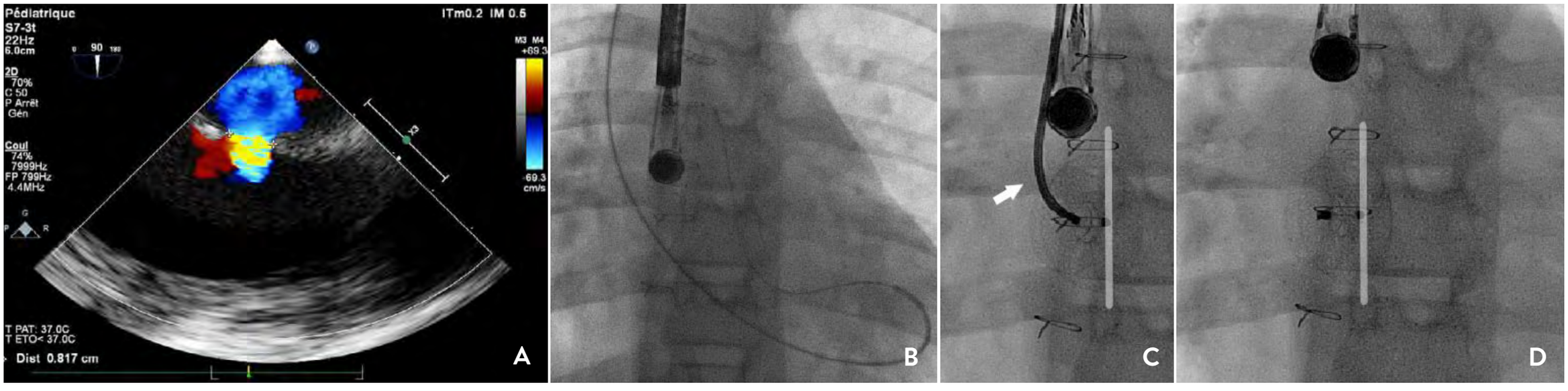

Figure 1: Pre-procedural transoesophageal 2-dimensional and color Doppler echocardiography showing an 8mm centrally located and bidirectionally shunting ASD with all adequate rims (**A**). Fluoroscopic views of transjugular access (**B**) and deployment of an Amplatzer™ Septal Occluder using the new Amplatzer™ Trevisio™ intravascular delivery system (**C**). The recently introduced flexible tip of the cable is visualized (white arrow) resulting in reduced tension and increased accuracy in device positioning. Note the identical position, shape, and orientation of the device before (**C**) and after (**D**) release.

DISCUSSION

The ASO continues to be the most frequently used device for ASD closure. However, the original stiff delivery wire transfers significant tension to the device increasing the risk of procedure failure especially in patients with suboptimal anatomies. Based on our preliminary experience, the recently designed Amplatzer™ Trevisio™ intravascular delivery system will ease the procedure in complex ASD cases with improved performance and safety. This system offers reliable precision where it matters the most. The increased flexibility on the wire tip decreased the tension created by the delivery cable on the device and subsequently on the atrial septum, allowing efficient positioning of the ASO and minimizing any unwanted drag or pull on the implant (**Fig. 2**). We noticed that the device was perfectly aligned with the septum without the use of a steerable introducer. The perpendicular orientation of the delivery system to the atrial septum was easily obtained with the ultra-flexible wire. Most importantly, this new system offers the major advantage of precise evaluation of definitive device position with better visualization of the venous margins prior to release and therefore a more reliable assessment of the presence of residual para-prothetic leak on TOE. We believe that these aforementioned promising technical advantages might improve procedure success in complex ASD anatomies or patients with unclassical access and will also prove beneficial in other types of percutaneous interventions.

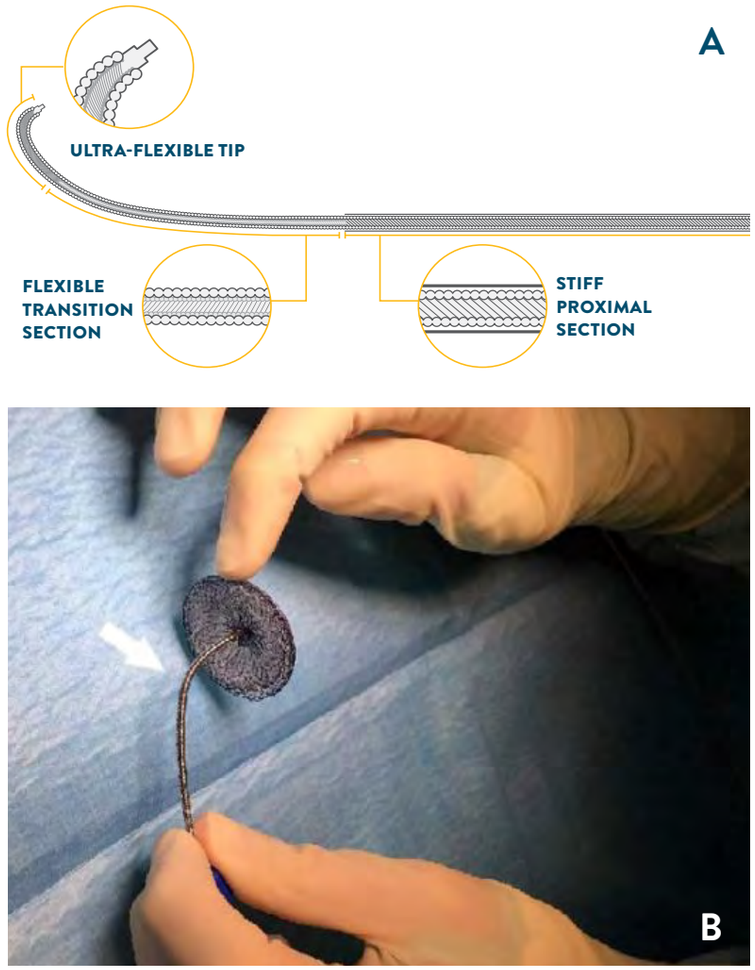

Figure 2: Detailed schematic presentation of Amplatzer™ Trevisio™ intravascular delivery system with recently added features (**A**). Note the Flexible tip (white arrow) of the Trevisio™ delivery wire connected to an Amplatzer™ Septal occluder (**B**).

CONCLUSION

The newly developed Amplatzer™ Trevisio™ intravascular delivery system improves the efficacy of percutaneous ASD closure by increasing procedural flexibility with reliable precision and tension-reduced implantations.

PATENT FORAMEN OVALE CLOSURE
WITH THE NEW AMPLATZER™ TREVISIO™ SYSTEM

with the aid of transnasal micro-TEE probe

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INTRODUCTION

Percutaneous closure of patent foramen ovale (PFO) has become routine practice in selected patients in order to reduce the risk of recurrent stroke due to paradoxical emboli. The technical aspects of PFO closure vary between institutions and operators. Many centers prefer closure to be performed under transoesophageal echocardiography (TEE) to reliably visualize the procedure. Some centers have reported routine PFO closure using only fluoroscopic imaging. In our experience, general anesthesia (GE) is required while using ordinary transoesophageal TEE imaging during the PFO procedure, and it is thus subject to the availability of GE. To improve the workflow we have used a micro-TEE probe inserted transnasally in conscious sedated patients. Doing this, the anesthesia team is available for other procedures, and our procedural times have been reduced by 23 minutes per procedure.

Here we report four cases of PFO closure using the new Amplatzer Trevisio delivery system with imaging performed with a micro-TEE probe.

CASE REPORT

All patients were diagnosed with stroke verified on imaging (MRI/CT) and they were qualified for PFO closure with imaging proven PFO (TEE bubble study) and no significant other factors associated with stroke.

Patient 1. 56 years old male with hypertension. Acute stroke in March 2019 in the occipito-temporal region. TEE bubble study revealed a PFO with significant shunting during the Valsalva maneuver.

Patient 2. 41 years old female with no cardiovascular risk factors. Cortical stroke with multiple point-like in-farctions on MRI. Treated with thrombolysis. In etiological assessment a grade IV flow at rest through the PFO on TEE bubble study.

Patient 3. 41 years old female patient with no significant cardiovascular risk factors. Presented with symp-toms of stroke and on imaging an arterial thrombus in the left P1 area treated with thrombolysis and mechanical thrombectomy. TEE bubble study was positive for PFO related shunting especially during the Valsalva procedure.

Patient 4. 64 years old female patient with multiple strokes a few months apart. On MRI infarctions in the right cerebellar hemisphere and the posterior area of the insular cortex. At rest, there was a left to right flow on color Doppler in the PFO.

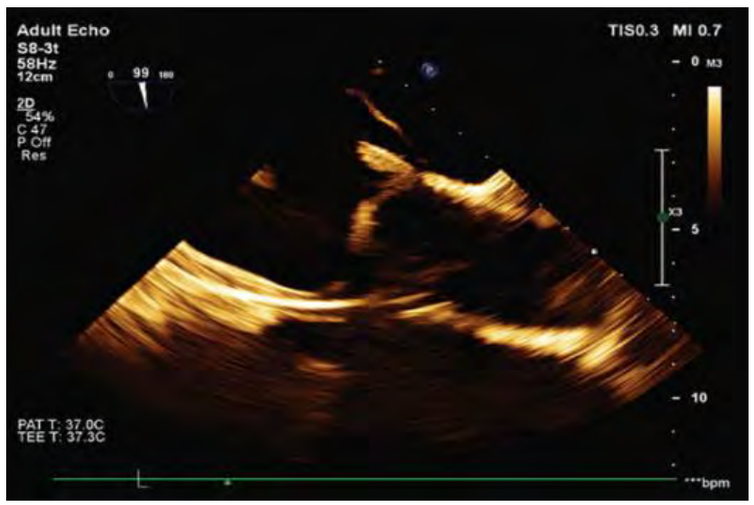

Figure 1: Visualization of the floppy septum and the PFO by transnasal Micro-TEE probe. With optimization of the image quality, sharp images are achieved with quality close to the ordinary TEE images.

PATENT FORAMEN OVALE CLOSURE
WITH THE NEW AMPLATZER™ TREVISIO™ SYSTEM
with the aid of transnasal micro-TEE probe

PROCEDURE WITH MICRO-TEE PROBE

Our standard practice is to insert the micro-TEE probe transnasally under conscious sedation at the beginning of the procedure in the cath lab. After confirmed insertion of the probe and adequate acoustic windows, the patient is prepared for the procedure. PFO closures were perfomed using standard protocol via the right femo-ral vein and with adequate anticoagulation using i.v. heparin. We routinely assess the PFO with balloon sizing and measure the defect under by fluoroscopy and ultrasound. All of the four patients had relatively normal PFO sizes ranging from 8 – 15 mm, and Amplater PFO Occluder devices ranging in size from 18 mm to 35 mm were used. The procedural results were adequate and there were no significant postprocedural complications.

In these procedures, a new Amplatzer Trevisio delivery system was used. The system has a new flexible tip section and a shorter end-screw. The flexible tip is designed to reduce the tension between the occluder device and the cable when the device is deployed in the defect. The flexibility gives more freedom of movement to the occluder and the deployed position is closer to the final result after release. No problems were encountered during these procedures with the new introducer.

DISCUSSION

In our initial experience of > 90 PFO closures using the transnasal micro-TEE probe, the technique has adequate imaging quality and shortens the procedural times without any significant patient discomfort. Most significantly, this has obviated the need for general anesthesia. In our experience we have had a few patients in whom the transnasal route was too narrow for safe insertion of the probe and postprocedurally we have had a few minor nasal bleeds that have been well controlled. Overall, we find the transnasally inserted micro-TEE probe to be safe and its benefits significantly outweigh the minor complications we have encountered thus far.

The Trevisio delivery cable performed well in our initial experience in these four patients. The alignment of the occluder device during deployment was more natural and closer to the final result, than with the previous de-livery system. Although PFO closure in routine practice is usually quite straightforward, there are cases where the benefits of the flexible tip should come into play. Especially in complex cases or in ASD closure.

Micro-TEE used for nasal approach

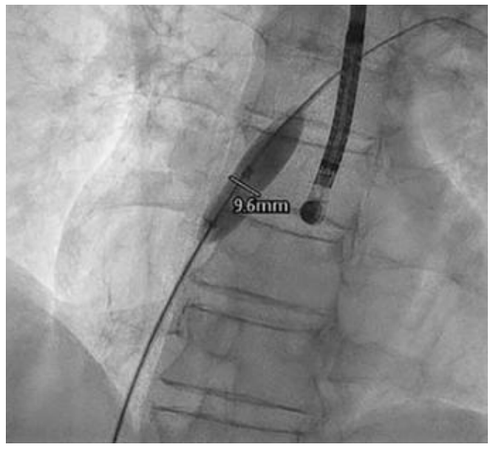

Figure 2: Balloon sizing of the PFO by fluoroscopy. A thin TEE probe can be appreciated on the right side of the sizing-balloon.

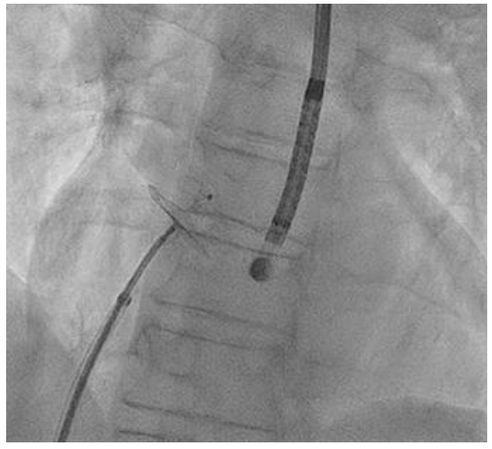

Figure 3: Deployment of the PFO occluder under fluoroscopic guidance.

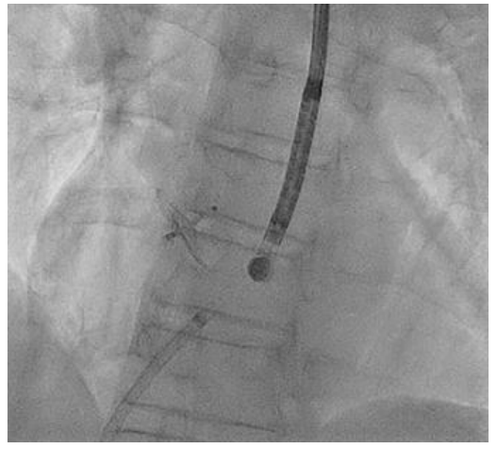

Figure 4: Final result after release of the PFO occluder.

DELIVERY SYSTEM DIMENSIONS

DELIVERY SYSTEM (SHEATH SIZE)	INNER DIAMETER OF SHEATH	OUTER DIAMETER OF SHEATH	MODEL NUMBER/ DELIVERY SYSTEM SIZE
6 Fr	2.11 mm (0.08 in)	2.79 mm (0.11 in)	9-ATV06F45/60
7 Fr	2.44 mm (0.10 in)	3.18 mm (0.13 in)	9-ATV07F45/60
7 Fr	2.44 mm (0.10 in)	3.18 mm (0.13 in)	9-ATV07F45/80
8 Fr	2.69 mm (0.11 in)	3.45 mm (0.14 in)	9-ATV08F45/60
8 Fr	2.69 mm (0.11 in)	3.45 mm (0.14 in)	9-ATV08F45/80
9 Fr	3.00 mm (0.12 in)	3.81 mm (0.15 in)	9-ATV09F45/80
10 Fr	3.30 mm (0.13 in)	4.14 mm (0.16 in)	9-ATV10F45/80
12 Fr	3.99 mm (0.16 in)	4.80 mm (0.19 in)	9-ATV12F45/80
13 Fr	4.32 mm (0.17 in)	5.13 mm (0.20 in)	9-ATV13F45/80

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