Conscious sedation for transcatheter implantation of atrial septal occluders with two- and three--dimensional transoesophageal echocardiography guidance — a feasibility and safety study

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Abstract

Background: General anaesthesia may have negative impact on patient mortality and morbidity, as well as overall procedure costs, in atrial septal occluder (ASO) implantation.

Aim: We sought to evaluate the safety, efficacy, and feasibility of conscious sedation for transcatheter implantation of ASOs.

Methods: A total of 122 patients referred for transcatheter implantation of ASO were included. Mean patient age was 51 ± 15 years, and 43 (35%) patients were male. The initial dose of midazolam was 2 mg and fentanyl dose was 25 μg. Additional doses of midazolam and fentanyl were administered, if necessary. Patient responsiveness was assessed every 10 min, and the sedatives doses were titrated in order not to exceed grade 3 sedation in the Ramsey scale.

Results: Atrial septal occluders were successfully implanted in the majority of patients (98.4%). In two (1.6%) cases the procedure failed because of too small patent foramen ovale (PFO) diameter (n = 1, 0.8%) or device instability (n = 1, 0.8%). The mean duration of procedure was 47.6 ± 28.4 min and was similar for ASD and PFO closure (p = 0.522). The overall mean dose of midazolam was 4.7 ± 2.2 mg (63.9 ± 32.5 μg/kg) and fentanyl was 30.0 ± 11.9 μg (0.43 ± 0.17 μg/kg). Median entrance dose of radiation at the patient plane was 25 (interquartile range: 16–57) mGy, and did not differ between ASD and PFO procedures (p = 0.614). The majority of patients were free of complications (91.0%). The following early complications were observed: transient ischaemic attack (n = 2, 1.6%), supraventricular arrhythmias (n = 4, 3.3%), left atrial thrombus formation (n = 1, 0.8%), symptomatic bradycardia (n = 1, 0.8%), and femoral venous bleeding (n = 5, 4.1%). After mean follow-up of 386 days residual shunt was observed in eight (6.6%) patients.

Conclusions: Conscious sedation for transcatheter implantation of ASO is a feasible, safe, and efficient technique, allowing successful PFO and ASD closure in the majority of patients.

Key words: atrial septal defect, patent foramen ovale, septal occluder device, feasibility studies, conscious sedation, transcatheter closure

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INTRODUCTION

Rapid technological and medical advancements have made interventional procedures like percutaneous atrial septal defect occluders (ASO), patent ductus arteriosus, and ventricular septal defect occluder implantation widely available and used. Since the first nonsurgical closure of an atrial septal defect (ASD) in 1976 [1], multiple devices and procedural approaches have emerged. Optimal sedation and anaesthesia strategies during these procedures are still actively being investigated. General anaesthesia or deep sedation is

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required for most transcatheter ASO implantation procedures to prevent patient pain and discomfort. However, it may have a negative impact on patient mortality and morbidity, as well as overall procedure costs. There is still no consensus regarding recommendations for anaesthetic management in interventional cardiology, and anaesthetic approaches during transcatheter ASO implantations procedures vary between different centres.

This study was designed to evaluate the safety, efficacy, and clinical feasibility of conscious sedation for transcatheter closure of atrial ASDs in adults, using two-dimensional/three-dimensional (2D/3D) transoesophageal echocardiography (TEE) guidance and presenting a single-centre experience.

METHODS

Our study was a retrospective, single-centre, observational study.

Study population

Patients with TEE confirmed ASD or patent foramen ovale (PFO) and prior episode of cryptogenic stroke/transient ischaemic attack (TIA) due to a presumed paradoxical embolism, as determined by a cardiologist and neurologist following an evaluation to exclude known causes of ischaemic stroke or right ventricle volume overload related to predominant left-to-right interatrial shunt, were eligible.

The following exclusion criteria were applied:

- anatomy other than ASD ostium secundum type or PFO or the presence of other congenital cardiac deformities requiring surgery;
- intracardiac mass, vegetation, tumour, or thrombus at the intended site of implantation;
- tissue rim other than aortic smaller than 5 mm in the case of ASD;
- active endocarditis or other untreated infection;
- documented severe, irreversible pulmonary arterial hypertension;
- contraindications for aspirin or clopidogrel;
- age < 18 years or > 65 years.

Procedure details on 2D/3D TEE-guided occluder implantation

The whole implantation procedure was monitored using 2D/3D-TEE guidance with the E9 Vivid (GE Vingmed, Norway) and iE33 (Philips Health Systems). Device sizing was done using 2D and 3D measurements, according to the manufacturer's instructions and echocardiographic guidelines [2, 3]. No additional balloon device sizing was performed.

The loading dose of 300 mg of clopidogrel was administered prior to procedure. Initial bolus of 5000 IU of unfractionated heparin (UFH), followed by adequate UFH dosing intravenously, was administered to keep the activated clotting time greater than 200 s throughout the procedure.

The right femoral vein access was used to perform standard right heart catheterisation.

Implantations protocols differed in their details between the occluders producers. In general, the guidewire was introduced into the left atrium via ASD/PFO under TEE guidance. The delivery sheath was then advanced over the guidewire through the communications into the left upper pulmonary vein. The correct position of the delivery sheath was verified by TEE. Then, the guidewire was removed and the device was advanced into the delivery sheath by pushing the delivery cable. Under TEE and fluoroscopic guidance, the left atrial disc was deployed with its proper position controlled by the device gently pulling against the atrial septum, which could be felt and also observed in TEE as atrial septum tenting. Subsequently, the right atrial disc was delivered. A secure position of the occluder across the ASD or PFO was assured using gentle motions with the delivery cable along with TEE control. The delivery cable was released from the device only if there was no device interference with any adjacent cardiac structure (such as superior vena cava, pulmonary vain, mitral valve, coronary sinus, aorta).

Figure 1A and B present the intra-ASD before and after occluder implantation with the use of 3D TEE.

During the procedure and up to 6 h after procedure, haemodynamic and respiratory parameters (blood pressure [BP], heart rate, electrocardiogram [ECG], SpO_2 with the use of continuous pulse oximetry, and respiratory rate with the use of transthoracic impedance continuous measurement with electrocardiography) were monitored.

Primary sedation safety outcomes were defined as adverse sedative effects such as: respiratory depression (SpO_2 < 90% for at least 20 s) or persistent hypotension (systolic BP < 90 mmHg). In safety analysis the need for endotracheal intubation or consultation of an anaesthesiologist because of spontaneous ventilation problems or cardiovascular instability were evaluated.

Total procedure time, entrance dose of radiation at the patient plane (EFD), and overall dose of analgesics and sedatives were calculated for each procedure.

Procedure details on conscious sedation

All patients received conscious sedation. The loading dose of midazolam was 2 mg and loading fentanyl dose was 25 μg intravenously in slow infusion over several minutes. Additional doses of midazolam and fentanyl were administered during procedure course, if necessary. Midazolam and fentanyl were administered gradually to maintain amnesia and analgesia. The patient's responsiveness in Ramsay Sedation Score was assessed every 10 min with sedation kept at the Ramsey Sedation Scale not deeper than grade 3 in the Ramsey score. The administration of analgesic and sedative medication

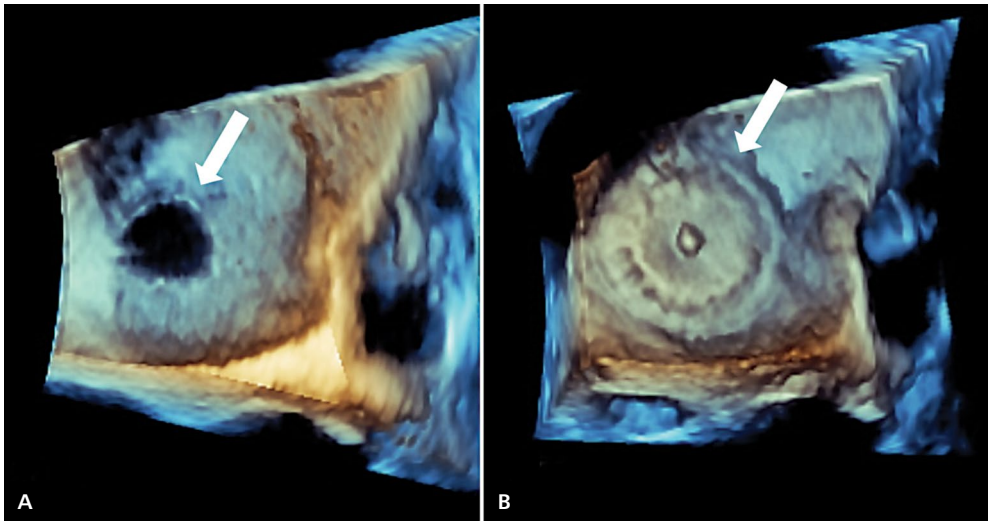

Figure 1. Three-dimensional transoesophageal echocardiography before (A) and after (B) atrial septal defect closure

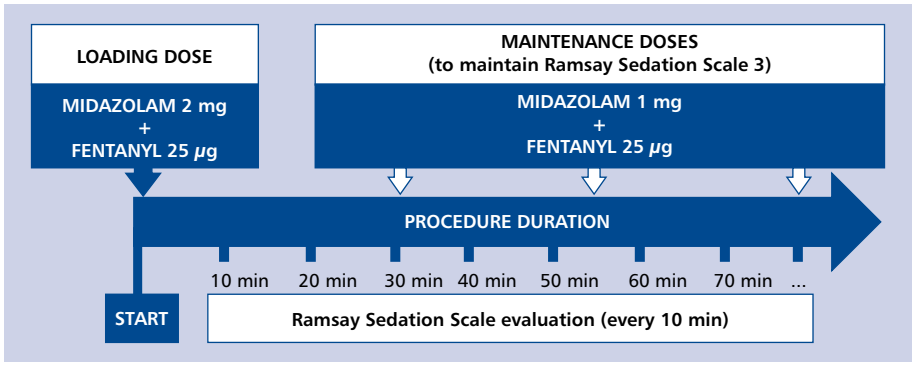

Figure 2. Procedural conscious sedation protocol

were performed under the instruction and supervision of the cardiologist performing the occluder implantation procedure.

Figure 2 presents the conscious sedation protocol.

Post-procedural care

All patients were transferred to the intensive cardiac care unit and monitored after the procedure for up to 6 h — BP (every 5 min), heart rate, ECG, respiratory rate, SpO_2 (continuously) with appropriate sound alarms. If no adverse respiratory (desaturation, apnoea) and haemodynamic (hypotension) events occurred, they were transferred to the general ward. The patient remained supine for up to 2 h until the venous sheath was removed.

Aspirin (75 mg daily) and clopidogrel (75 mg daily) are were prescribed for six months (or longer and in different dose according to device characteristics).

The patients were discharged from the hospital the day after the procedure, in the case of no local vascular complications and if appropriate device position was confirmed one day post-implant transthoracic echocardiography (TTE).

The appropriate endocarditis prophylaxis for six months following device implantation was recommended. All patients were instructed to avoid strenuous activity for a minimum of one month post-device implant to avoid device erosion.

Echocardiographic follow-up

After the procedure patients were followed-up for 12 months. TTE was performed before hospital discharge, as well as at three, six, and 12 months after the occluder implantation procedure. Follow-up TEE was performed three to six months after the procedure. Clinical follow-up with a cardiologist annually thereafter was also recommended.

Efficacy of PFO/ASD closure was defined as the absence of residual shunt (at rest and post-Valsalva) in the control TTE or TEE.

Table 1. Clinical characteristics of the study group

Demographic characteristics	
Male	43 (35.2%)
Age [years]	50.6 ± 15.0
Body weight [kg]	73.3 ± 16.0
Height [cm]	168.2 ± 9.4
BMI [kg/m^2]	25.8 ± 4.3
SBP [mmHg]	121.6 ± 10.2
DBP [mmHg]	74.4 ± 7.5
Comorbidities	
Diabetes mellitus	15 (12.3%)
Hypercholesterolaemia	48 (39.0%)
Arterial hypertension	55 (45.1%)
Heart failure	20 (16.4%)
Coronary artery disease	9 (7.3%)
Indications for ASD/PFO closure	
Right heart volume overload	32 (26.2%)
Secondary stroke/TIA prevention	90 (73.8%)
Occluder implantation procedure	
Occluder implantation successfully completed	120 (98.4%)
Total procedure duration [min]	47.6 ± 28.4
Entrance dose of radiation at the patient plane [mGy]	25 (16–57)
The diameter of implanted device [mm]	22.5 ± 5.8
Drugs	
Midazolam total dose [mg]	4.7 ± 2.2
Midazolam total indexed dose [μg/kg]	63.9 ± 32.5
Fentanyl total dose [μg]	30.0 ± 11.9
Fentanyl total indexed dose [μg/kg]	0.43 ± 0.17

The data are presented as mean ± standard deviation, median with interquartile range or number (percentage); ASD — atrial septal defect; BMI — body mass index; SBP — systolic blood pressure; DBP — diastolic blood pressure; PFO — patent foramen ovale; TIA — transient ischaemic attack

Statistical analysis

Data is presented as percentages for categorical variables and as mean with standard deviation (SD) or median with interquartile range (IQR) for continuous variables depending on their distribution. The normality of distribution was analysed using the Shapiro-Wilk's test. Intergroup analysis was performed using the Student t-test for independent variables or the Mann-Whitney U-test depending on the variable distribution. The χ^2 test or Fisher exact probability test were applied for the categorical variable analysis. P-values less than 0.05 were considered statistically significant. The overall statistical analysis was performed using MedCalc version 12.0 and STATISTICA version 10.0.

RESULTS

A total of 122 consecutive patients with either a significant ostium secundum ASD (n = 67, 54.9%) or PFO (n = 55, 45.1%) were referred for transcatheter implantation of atrial septal occluders between 7/05/2009 and 20/11/2015. Mean patients' age was 50.6 ± 15.0 years, and 43 (35.2%) patients were male. The main indications were: secondary stroke and/or TIA prevention (n = 90, 73.8%) and significant shunting (n = 32; 26.2%). The detailed characteristics of the studied group is presented in Table 1.

Devices

The following devices were implanted in ASD group: Occlutech (Occlutech International AB, Helsingborg, Sweden) Figulla Flex™ ASD Occluder (n = 7); Cardia Ultrasept™ ASD (n = 1); Cardia Atriasept™ II-ASD (n = 16); MemoPart™ (PFM Medical) ASD Occluder (n = 16); Nit-Occlud™ (PFM Medical) ASD-R (n = 2); AMPLATZER™ (St. Jude Medical) Septal Occluder (n = 27). Patients with PFO received the following devices: Occlutech™ (Occlutech International AB, Helsingborg, Sweden) Figulla Flex™ PFO Occluder (n = 2); Cardia Atriasept™ II-PFO (n = 19); Cardia Ultrasept™ PFO (n = 9); MemoPart™ (Lupu Medical) PFO Occluder (n = 10); Nit-Occlud™ (PFM Medical) PFO (n = 12); AMPLATZER™ (St. Jude Medical) PFO Occluder (n = 1).

Procedure efficacy

Atrial septal occluders were successfully implanted in the majority of patients (n = 120, 98.4%). In two (1.6%) cases the procedure failed because of too small PFO diameter (inability of catheter to passage through the interatrial septum) in one (0.8%) case and device instability in one (0.8%) patient. The diameter of implanted devices ranged between 9 and 35 mm (mean occluder diameter 22.5 ± 5.8 mm). The mean duration of procedure was 47.6 ± 28.4 min, and was similar for ASD and PFO closure (48.1 ± 22.3 vs. 47.0 ± 34.4 min, p = 0.522; Fig. 3A). Median entrance dose of radiation at the patient plane (EFD) was 25 (IQR 16–57) mGy and did not differ between ASD and PFO procedures (p = 0.614).

Conscious sedation

The overall mean midazolam used dose was 4.7 ± 2.2 mg (63.9 ± 32.5 μg/kg) and the overall mean fentanyl dose was 30.0 ± 11.9 μg (0.43 ± 0.17 μg/kg). There were no significant differences in used doses of midazolam (p = 0.797) and fentanyl (p = 0.247) between PFO and ASD groups, retrospectively (Fig. 3B, C).

None of the studied patients needed endotracheal intubation or consultation of an anaesthesiologist due to haemodynamic instability or ventilation problems. There were no adverse sedative effect such as a desaturation, apnoea episodes, or hypotension.

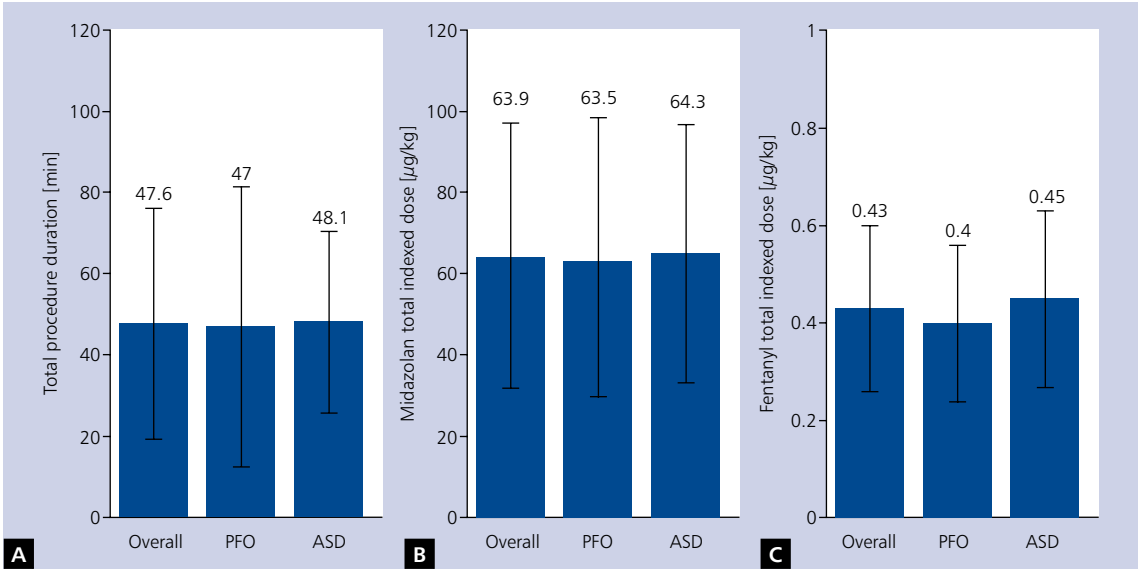

Figure 3. Comparison between patent foramen ovale (PFO) and atrial septal defect (ASD) morphology and total duration of procedure (**A**), total indexed midazolam dose (**B**), and total indexed fentanyl dose (**C**)

No procedure was terminated prematurely due to adverse effect of sedation.

Periprocedural complications

The majority of patients were free of any complications (n = 111, 91.0%).

The following early complications were observed: TIA (n = 2, 1.6%) with symptoms resolving within 24 h, supraventricular arrhythmias (n = 4, 3.3%), left atrial thrombus formation (n = 1, 0.8%), symptomatic bradycardia (n = 1, 0.8%), and femoral venous bleeding with haematoma formation without communication with femoral artery (n = 5, 4.1%). None of these access-site complications required specific treatment.

There were no device-related deaths.

Long-term results

TTE and/or TEE for diagnosing residual shunting was obtained in all 120 (100%) patients with successfully implanted ASD/PFO occluder. After a mean follow-up of 386 days, residual shunt (at rest or post-Valsalva) was observed in eight (6.6%) patients. The presence of residual shunt was more common in the ASD group than in the PFO group, but the difference did not reach statistical significance 2/55: 3.6% vs. 6/67: 9.0%, p = 0.292.

There were no cases of suspected or proven device erosion during the follow-up.

DISCUSSION

In this study we have demonstrated that percutaneous ASO implantation with 2D/3D TEE guidance, but without the use of general anaesthesia, is feasible and highly successful. The described procedure in a high-volume TEE and percutaneous procedure centre is also very safe.

Despite the fact that many different anaesthetic approaches have been reported for cardiac catheterisation, controversies between optimal conscious sedation, deep sedation, or general anaesthesia remain [4–13]. The advantages of conscious sedation are not only related to reduced procedural time and costs, but also with early detection of signs and symptoms of complications, especially neurological (stroke/TIA) [4]. The use of sedation improves patients' tolerance to TEE probe and reduces vomiting, coughing, and pain [14]. However, the sedation without endotracheal intubation carries a risk of unprotected airways [4].

In the study by Putra et al. [6] in 152 patients with ASD, the median device implantation procedure time under general anaesthesia was 115 min, whereas in our study the procedure duration was significantly shorter, with a mean procedure time 47 min. Also, in large study on ASO implantation by Omeish et al. [15] the median procedural time was substantially longer (80 min). In the recent study by Desai et al. [4] on conscious sedation using dexmedetomidine without endotracheal intubation during ASO implantation the procedure time was relatively short with a mean procedure duration time of 61 min and high procedural success rate (93%). The presented results suggest that the general anaesthesia prolongs the overall procedure duration and reduces patient turnover in the catheterisation laboratory.

Importantly, the success rate of ASO implantations in our centre was similar or even higher to that previously presented in large population studies, where general or deep sedation were applied (86.0% to 97.4%) [4–6, 10, 13, 15–17].

Although ASO implantation is a relatively safe procedure, it can be associated with some major complications including stroke, thrombosis, cardiac tamponade, bleeding, and minor complications like arrhythmias [9, 15]. Device-induced arrhythmias are usually transient and self-limiting. In our study, transient symptomatic bradycardia was encountered in one (0.8%) patient and treated successfully with atropine. Supraventricular arrhythmias were observed in four (3.3%) patients and in all cases they had terminated spontaneously before hospital discharge without the use of antiarrhythmic drugs or direct currant cardioversion. A similarly low incidence of periprocedural supraventricular arrhythmia (atrial fibrillation) was observed by Węglarz et al. [13] in a group of 149 PFO implantations, and also all of them have gone without any treatment.

Similarly to the study by Omeish et al. [15] of 3850 ASO device implantations, in our study no device-related deaths were observed and overall major complications were similar to the procedures performed under general anaesthesia. However, in our study access site bleeding with haematoma formation was the most common periprocedural complication (4.1%) and occurred more frequently as compared to the prevalence reported for procedures under general anaesthesia (0.2%). It may suggest that a full immobility and loss of motor reflexes under general anaesthesia can prevent local vascular complications, mainly related to the preserved patient mobility under conscious sedation and motor reaction to painful manoeuvres of the delivery sheath.

Proper patient counselling and patient cooperation during the procedure play a significant role. As we have previously reported in another study, appropriate preparation of patients to the TEE results in lower patient anxiety and discomfort, as well as improves comfort of the physician and reduces the dose of used sedatives [18]. Of note, none of the procedures performed by us were aborted due to lack of patient cooperation. It seems, that proper patient preparation to the procedure is crucial in achieving a high procedural success rate.

Another important aspect was the length of hospital stay — the majority of patients were discharged the day after the implant procedure. Therefore, along with no need of anaesthesiologist support during ASO implantation, this approach seems attractive given its favourable cost-effectiveness.

Limitations of the study

The main limitation of our study is that it represents a retrospective analysis of studies performed at a single centre. Moreover, we did not directly compare our conscious sedation protocol with other anaesthetic approach. Therefore, further case-control studies comparing conscious and deep sedation or general anaesthesia are warranted to confirm the non-inferiority of the protocol presented by us. Another limitation of our study is the variety of implanted devices; however, it could also be a strength of our report indicating that the type of device and delivery system do not affect the safety and efficacy of conscious sedation.

CONCLUSIONS

Transcatheter closure of ASD or PFO under conscious sedation with 2D/3D TEE guidance is feasible, safe, and efficient. The only concern is an increased prevalence of access-site complications, but they do not require specific treatment.

Conflict of interest: *none declared*

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