Conscious sedation using dexmedetomidine for percutaneous transcatheter closure of atrial septal defects: A single center experience

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Objective: The aim of this study is to determine safety and feasibility of conscious sedation using dexmedetomidine for transcatheter atrial septal defect (ASD) device closure. Materials and Methods: A retrospective institutional review of transcatheter ASD device closure without endotracheal intubation over 18 months. The protocol included topical oropharyngeal anesthesia using lignocaine followed by dexmedetomidine bolus 1 µg/kg intravenously over 10 min and maintenance dose 0.2–0.7 µg/kg/h. Ramsay sedation score 2–3 was maintained. Patients were analyzed regarding demographic profile, device size, procedure time, anesthesia time, recovery time, hospital stay, and any hemodynamic or procedural complications. Results: A total of 43 patients with mean age 31.56 ± 13.74 years (range: 12–56 years) were analyzed. Mean anesthesia duration was 71.75 ± 21.08 min. Mean recovery time was 7.6 ± 3.01 min. 16 females and one male patient required additional propofol with a mean dose of 30.8 ± 10.49 mg. No hemodynamic instability was noted. No patient required general anesthesia with endotracheal intubation. The procedure was successful in 93.02% of patients. Four patients developed atrial fibrillation. All patients were satisfied. Conclusion: Conscious sedation using dexmedetomidine is a safe and effective anesthetic technique for percutaneous ASD closure.

Key words: Amplatzer device; Atrial septal defect; Dexmedetomidine; Sedation; Transcatheter

INTRODUCTION

Atrial septal defect (ASD) is the most common congenital heart disease in adults which if untreated, may result in pulmonary hypertension, paradoxical embolism, and Eisenmenger syndrome. Even though surgical closure is the gold standard, transcatheter closure has gained popularity because of high success rates, greater patient comfort; reduced morbidity and mortality, shorter hospital stay, superior cosmetic results, decreased cost, and less postoperative pain. Percutaneous ASD closure is performed under transesophageal, transthoracic or intracardiac echocardiographic (TEE/TTE/ICE) guidance. During TEE-guided procedure, general anesthesia (GA) with endotracheal intubation is preferred to protect airway with TEE probe in situ which is uncomfortable and has to be tolerated by the patient for a prolonged period. However, GA is associated with a stress response, delayed recovery, and decreased patient turnover in catheterization laboratory. Conscious sedation can overcome these drawbacks, and hence, we report our experience of using conscious sedation using dexmedetomidine for TEE-guided transcatheter ASD device closure.
MATERIALS AND METHODS

After Institutional Ethics Committee approval, retrospective analysis of patients who underwent ASD device closure under conscious sedation during January 2014 to June 2015 period was conducted. Totally 43 patients including adolescent and adults were analyzed regarding demographic profile, device size, procedure time, anesthesia time, recovery time, hospital stay, and any hemodynamic or procedural complications.

Before procedure, the technique of conscious sedation with topical oropharyngeal anesthesia was explained and written informed consent was taken. Since all patients had previous experience of diagnostic TEE for ASD under topical lignocaine spray without sedation in an echo suite at our institute; they were counselled easily. Careful medical history of gastroesophageal reflux disease, gastrointestinal bleed, dysphagia, esophageal varices, and peptic ulcer was obtained to prevent complications of TEE. After confirming adequate starvation, all patients received topical oropharyngeal anesthesia using 2% viscous Lignocaine gargles 15–20 min before procedure followed by lignocaine 4% (2 ml) nebulization in recovery area under observation. Inj glycopyrrolate 0.2 mg intravenous (IV) was given before gargles to improve its efficacy. Aspiration prophylaxis with injection pantoprazole 40 mg and injection ondansetron 4 mg IV was given. Endocarditis prophylaxis using injection cefazolin 1 g was provided. Standard monitoring included an electrocardiogram, noninvasive blood pressure, pulse oximeter, and capnography. Just before insertion of TEE probe, additional 2 puffs of 10% lignocaine were sprayed onto the posterior pharyngeal wall to prevent gag reflex. All patients received injection midazolam 0.05 mg/kg and injection fentanyl 2 mcg/kg before vascular access. The maximum dose of lignocaine 5 mg/kg was not exceeded. Meanwhile, injection dexmedetomidine was started with 1 µg/kg IV bolus over 10 min followed by 0.5–0.7 µg/kg/h throughout the procedure till the removal of the vascular sheath. Sedation level was titrated to Ramsay sedation score[6] 2–3, i.e. sleeping but responding to verbal commands or light glabellar tap. Injection propofol 0.5 mg/kg IV bolus was supplemented if the patient remained uncooperative. All patients received supplemental oxygen at 2 L/min via nasal cannula having the facility to measure EtCO\textsubscript{2}. Heparinization was done with 100 IU/kg to prevent thromboembolism. Amplatzer septal occluder device was used in all patients [Figure 1]. Anesthesia time was considered from the administration of sedative-analgesic till the removal of the vascular sheath. The time from vascular access till the removal of the vascular sheath was recorded as procedure time. Recovery time was considered from the endpoint of anesthesia time till achievement of Ramsay sedation score 1, i.e., calm and composed. All patients were monitored in the recovery area. Before shifting, all patients were asked about satisfaction regarding the quality of anesthesia as compared to their previous experience of diagnostic TEE.

Statistical analysis

All analyses were performed using the IBM, Statistical Package for the Social Sciences (SPSS) version 16.0 (Chicago, USA) software. Continuous data were summarized as the mean ± standard deviation whereas categorical data as percentage.

RESULTS

Totally 43 patients including adolescents and adults between 12 to 56 years of age underwent procedure [Table 1].

The procedure was successful in forty patients (93.02%). Mean recovery time was 7.6 min despite prolonged anesthesia and procedure time [Table 2].

Sixteen females and one male patient required additional propofol with a mean dose of 30.8 ± 10.49 mg. No hemodynamic instability was noted [Table 3].

Figure 1: (a) Amplatzer sheath crossing atrial septal defect. (b) Bicaval view showing undeployed Amplatzer device. (c) Three-dimensional transesophageal echocardiographic showing Amplatzer device across atrial septal defect
The procedure was abandoned in 3 patients due to inadequate/flimsy rims around ASD. None of the patients required general anesthesia with endotracheal intubation. Four patients developed atrial fibrillation. Three patients responded to injection diltiazem while one required direct current cardioversion [Table 4]. There was no mortality.

DISCUSSION

Transcatheter device closure has undergone a lot of improvement since the first description by King et al.[7] However, only ostium secundum ASDs are amenable to the transcatheter closure which is done under continuous TEE/TTE or ICE guidance. ICE probe is inserted into the femoral vein and advanced directly into the right atrium to obtain two-dimensional (2D) and color Doppler views. It is performed under sedation only. However, ICE probes are expensive and good quality imaging is difficult to acquire which limits its use.[2] Use of TTE during this procedure also avoids the need for GA and in expert hands, it provides accurate information albeit with a poor resolution as compared to TEE. Live 3D TTE provides real-time imaging of the heart and an en face view of an interatrial septum. However, a good 2D image is a prerequisite for proper 3D imaging and that is why TEE is superior to TTE in this aspect. TEE being in proximity to the heart; provides an excellent image resolution and unlike TTE there is no need to keep echo probe stable to acquire an image. TTE is also limited by the suboptimal acoustic window in obese and supine patients. Most importantly, poor subcostal view during TTE does not reliably delineate inferoposterior inferior vena cava (IVC) rim of ASD, which anchors device and stabilizes it.[8]

TEE, on the other hand, overcomes the limitation of poor acoustic windows in adult patients and its midesophageal bicaval view 90–110° beautifully delineates IVC rim too. It also makes sure appropriate placement of the device, confirms unobstructed superior vena cava, IVC, pulmonary venous inflow, evaluates valve competence, allows detection of early thrombus and provides confirmation of device stability after placement.[2]

However, this continuous TEE monitoring is required for a prolonged period which makes airway control and manual ventilation using facemask; a challenge. For this reason, GA with endotracheal intubation becomes necessary.[5] Anesthesia is also required for pain and general discomfort during the procedure with the need to provide an immobile patient for a significant period (usually more than 1 h). However, GA prolongs recovery; thereby reducing patient turnover in the catheterization laboratory. Hypothermia during GA with endotracheal intubation also contributes to delayed recovery. Stormy extubation too may lead to increased risk of device embolization, especially in cases with borderline atrial septal rims due to increased transthoracic pressure which may cause rise in right atrial pressure. In this context, therefore, a balanced anesthesia technique of conscious sedation with short-acting drugs might be helpful. Conscious sedation is also advantageous in early detection of neurologic signs and symptoms of complications like stroke during the procedure. In conscious and sedated patient, esophageal/gastric perforations are evident from signs of subcutaneous emphysema, dyspnea, and

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**Table 1: Demographic data**

| Parameter                  | Mean±SD          |
|----------------------------|------------------|
| Age range (years)          | 12-56            |
| Mean age (years)           | 31.56±13.74      |
| Sex                        | 36 females, 7 males |
| Weight (kg)                | 46.86±14.34      |
| ASD size (mm)              | 22.34±5.15       |
| Amplatz device size (mm)   | 27±4.67          |

ASD: Atrial septal defect, SD: Standard deviation

**Table 2: Recovery and miscellaneous data**

| Parameter                  | Mean±SD          |
|----------------------------|------------------|
| Anesthesia time (min)      | 71.75±21.08      |
| Procedure time (min)       | 61.02±23.84      |
| Recovery time (min)        | 7.64±3.01        |
| Procedure success rate (%) | 93.02            |
| Hospital stay (days)       | 1.48±0.51        |
| Patient Satisfaction (%)   | 43/43 (100)      |

**Table 3: Hemodynamic characteristics**

| Parameter | Baseline | Post-TEE insertion | Post-TEE removal |
|-----------|----------|--------------------|------------------|
| HR (min)  | 86.34±6.39| 98.82±4.66        | 81.02±9.52       |
| MAP (mmHg)| 88.62±6.74| 94.66±9.23        | 84.44±5.78       |

TEE: Transesophageal echocardiogram, HR: Heart rate, MAP: Mean arterial pressure

**Table 4: Peri-procedural complications**

| Complication               | Incidence |
|----------------------------|-----------|
| Hypotension/bradycardia     | 0/43      |
| Nausea/vomiting             | 0/43      |
| Atrial fibrillation         | 4/43      |
| Procedure abandoned         | 3/43      |
pain. However under GA, this perforation usually goes unnoticed, ultimately resulting in mediastinitis, sepsis, and multi-organ failure.\textsuperscript{[9]}

Another potential advantage is the early recovery, reduced postoperative anesthetic complications and increased patient turnover in the catheterization laboratory which proves cost effective. The patient can resume routine activity much earlier than after GA. Authors also found an added advantage of reducing radiation exposure to anesthesia personnel in their institute because this technique avoids the need for manual bag ventilation within the proximity of the C-arm.

Respiratory depression becomes a challenge during TEE because of difficulty in manual ventilation with TEE probe \textit{in situ}. Most of the IV anesthetics carry the risk of apnea barring dexmedetomidine and ketamine.\textsuperscript{[10]} Dexmedetomidine is selective $\alpha_2$-adrenergic receptor agonist having sedative, analgesic properties without causing respiratory depression.\textsuperscript{[11]} It is also relatively cardio stable compared to other sedatives. These properties make it as an ideal agent for conscious sedation. Other sedatives such as midazolam, propofol, and ketamine carry some side effects such as respiratory depression, loss of airway reflexes, delirium like reactions, increased salivation, and sympathetic stimulation.

Studies comparing different sedatives have been carried out in the cardiac catheterization laboratory. However, authors could not find similar studies except one case report\textsuperscript{[12]} where dexmedetomidine provided effective sedation and hemodynamic stability despite bolus dose. A similar study was carried out using dexmedetomidine for providing adequate sedation and hemodynamic control for awake, diagnostic transesophageal echocardiography with satisfactory results.\textsuperscript{[13]} However, they included only diagnostic TEE, which is a very short procedure and 22 patients were studied in contrast to 43 in this study. Authors think that this prolonged tolerance to TEE probe was achieved due to combined usage of topical anesthesia and dexmedetomidine. Patient cooperation and proper counseling also played a significant role in this context. Karagoz et al.\textsuperscript{[14]} in their retrospective study of 106 adult patients undergoing percutaneous ASD closure under general anesthesia observed no major complications with propofol and fentanyl anesthesia. Other similar studies were carried out in pediatric patients where early recovery with propofol/dexmedetomidine combination was demonstrated in children undergoing transcatheter ASD closure under general anesthesia.\textsuperscript{[15]}

Concerns regarding bradycardia and hypotension following bolus dose of dexmedetomidine have been addressed in the recent literature. In fact, transient hypertension occurs during the loading dose due to activation of peripheral $\alpha$(2B)-adrenoceptors and its treatment has generally not been necessary.\textsuperscript{[16]}

Even, dexmedetomidine bolus of 2 $\mu$g/kg in pediatric patients undergoing computed tomography and magnetic resonance imaging have been shown to be safe and effective without pharmacologic intervention and any adverse events.\textsuperscript{[17,18]} Rapid IV bolus of either 0.25 or 0.5 $\mu$g/kg administered over 5 s in children having undergone heart transplants was clinically well tolerated too.\textsuperscript{[19]} This study also replicates excellent hemodynamics with bolus dose of dexmedetomidine.

Sedation without endotracheal intubation carries a risk of an unprotected airway. At the same time, sedation further improves patients’ tolerance to TEE probe insertion and reduces coughing, vomiting, and pain.\textsuperscript{[20]}

The incidence of anesthesia-associated fatal aspiration in NAP4 was very low - 1 in 350,000.\textsuperscript{[21]} It has been shown that incidence of aspiration increases with obesity, during emergency procedures, and in higher ASA status.\textsuperscript{[22-24]}

However, intact laryngeal and cough reflex and titrating sedation to moderate level prevented complications such as respiratory depression and aspiration in this study. Further, transgastric TEE views were not taken which maintained lower esophageal sphincter competency. Recently, ASE 2013 guidelines advocate the use of topical oropharyngeal anesthesia before giving sedation during TEE. It also does not mention about the incidence of vomiting and aspiration during diagnostic and intraoperative TEE because the risk is negligible in properly selected patients and expert hands.\textsuperscript{[25]}

Limitations of this study include lack of BIS monitoring due to its unavailability and its retrospective nature. Furthermore, comparing results with the control group would have highlighted results further.

\textbf{CONCLUSION}

Conscious sedation using dexmedetomidine for transcatheter ASD closure is a safe, effective, and
feasible anesthetic technique. However, utmost vigilance is required to avoid respiratory depression and tackle airway-related complications.

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**Conflicts of interest**
There are no conflicts of interest.

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