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Role of Dexmedetomidine as monitored anaesthesia care in ENT local surgeries

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Abstract
Analgesia and sedation are usually required for the comfort of all patients and surgeons during any surgery, particularly ENT surgery done under local anesthesia.
We conducted study on 30 adult ASA grade I/II patients of either sex posted for various elective ENT surgeries under LA and monitored anesthesia care. Patients received IV dexmedetomidine infusion of 1mcg/kg over 10 min followed by 0.2mcg/kg/h during surgery. Sedation was maintained to keep Ramsay Sedation Score (RSS) to 3. Surgery was performed under LA. Intra operatively, if required, patients were given rescue analgesic fentanyl 1mcg/kg and rescue sedative midazolam 0.01mg/kg. Patients' vital parameters (PR, BP, SPO2, ECG), VAS and sedation scores were recorded every 10 min. Post operatively all patients were interviewed to assess their satisfaction score about the technique. Surgeons were also asked for their opinion to assess their satisfaction about sedation technique.
We found that:
1. Surgeons' and patients' satisfaction score were better
2. 8 patients required rescue LA infiltration.
3. Number of patients requiring rescue analgesic and rescue sedative medication was 4 and 1 patient respectively.
4. None of the patients in both the groups had any complications requiring active treatment.

Keywords: Surgeries, dexmedetomidine, ENT surgery

Introduction
Majority of ENT surgeries in adults are done under local anesthesia (LA) [1] supplemented with intravenous (IV) analgesia and sedation and monitored anesthesia care (MAC) The types of surgeries which can be done by this anesthetic technique are

- Tympanoplasty
- Mastoidectomy
- Septoplasty
- Functional endoscopic sinus surgery (FESS)

Some of the patients may require general anesthesia (GA) or in some cases LA technique may have to be converted in to GA if patient is uncooperative on the operation table. If surgery is done only under LA without any sedation and analgesic supplement patient may feel discomfort due to surgical pain, noise of suction, manipulation of surgical instruments, and application of traction and head-neck position necessary for adequate exposure of surgical site [2].
Commonly used drugs for IV sedation and analgesia during surgery are [3]
Opioids - fentanyl, sufentanil.
Benzodiazepines - midazolam.
IV anesthetic drugs – propofol.
Non-opioids – ketamine in analgesic doses.
Use of these drugs is associated with side effects, for example, midazolam has quick onset of action but if it is administered repeatedly can cause prolonged sedation due to its relatively long half-life. If it is combined with opioids there is a risk of respiratory depression and even apnea leading to hypoxemia. Propofol can cause cardio-respiratory depression especially if it is combined with opioids and midazolam [4]. Over sedation during MAC can cause harm to the patient in many ways.

Recently dexmedetomidine hydrochloride has been added to the armamentarium of anesthesiologist. It is a highly selective alpha-2 adrenergic agonist. It has analgesic, sympatholytic and sedative property without any respiratory depression [5] which is commonly seen with combination of opioids and midazolam [4]. Dexmedetomidine also reduces opioid requirement and stress response to surgery ensuring hemodynamic stability [6]. Therefore this drug is being increasingly used as a sedative for MAC for various surgical procedures such as eye surgery, dental surgery, upper gastro intestinal endoscopy and FESS etc. [7]. We therefore decided to undertake this study to compare efficacy of dexmedetomidine for IV sedation during MAC with that of commonly used combination of midazolam – fentanyl for IV sedation during MAC for ENT surgery.

Materials and Methods

The study was conducted on 30 adult patients posted for elective Ear, Nose and Throat (ENT) surgery belonging to either sex and in the age group of 20 to 60 years. Only those patients belonging to American Society of Anesthesiologists (ASA) grade I/II were accepted for this study. Prior approval of medical ethics committee of the institute was obtained. All patients were subjected to thorough pre anesthetic evaluation including relevant essential investigations. They were then explained about use of Visual Analogue Score (VAS) for purpose of recording their pain score. Informed consent was obtained from all the patients.

Inclusion criteria

- Patients between 20 to 60 years age.
- Both males and females.
- Patients of ASA physical status I and II.
- Patients posted for elective ENT surgery.

Exclusion criteria

Patient's unwillingness to participate in the study.
Patients with known sensitivity to local anesthetics and sedative/analgesic drugs to be used for study.
Patients who are unable to understand use of VAS.
Pregnant females and lactating mothers.
Patients suffering from renal and hepatic disease.
Patients who are on opioids, benzodiazepines and alpha 2 receptor agonists.
Patients having bradycardia, intra cardiac conduction defects and low ventricular ejection fraction (EF <30%).
Patients who are hypotensive and hypovolemic due to any cause.

Materials required

- Anesthesia machine with Bain's breathing system.
- Source of oxygen.
- All resuscitation equipment-laryngoscope with different sizes of blades, endotracheal tubes of different sizes, stylets, local anesthetic jelly, Ambu bag, ventilator, oro pharyngeal airways, Laryngeal mask airways (LMAs).
- IV fluids –Ringer lactate (RL), dextrose normal saline (DNS), normal saline (NS), and colloids.
- IV cannulae 20 and 18 G size.
- IV infusion sets.
- Drugs
- Drugs for pre-anesthetic medication-glycopyrrolate, ondansetron, metoclopramide, ranitidine.
- Drugs for sedation and rescue-midazolam 10 ml vial (1 mg/ml), fentanyl 2 ml ampoule (50 mc/ml), dexmedetomidine ampoule 1 ml [100 mcg/ml].
- Syringes 2ml/5 ml/10 ml.
- Syringe infusion pump.
- Drugs for resuscitation –adrenaline, noradrenaline, atropine, mephentine, dopamine, dobutamine

Procedure

On the operation table patient's pulse rate (PR), Mean Arterial Pressure (MAP), peripheral arterial oxygen saturation (SPO2), respiratory rate (RR) and electro cardiogram (ECG) were recorded.
Venous cannulation was done on dorsum of left hand or other suitable site using 20 G venous cannula and slow IV infusion of ringer lactate (RL) was started at the rate of 2 ml/kg body weight.
A loading dose of dexmeditomidine IV infusion was given at the rate of 1 mcg/kg over 10 min followed by maintenance infusion at the rate of 0.2 mcg/kg/hr. throughout surgery.
During this 10 min period the patients were closely observed and assessed every 2 min for sedation using Ramsay Sedation Score (RSS) as follows.
Score Assessment

- 1 Patient agitated
- 2 Patient cooperative and tranquil
- 3 Patient sleeping but responds to verbal command
- 4 Brisk response to gabellar tap or loud voice
- 5 Sluggish response to gabellar tap or loud voice
- 6 No response

RSS 3 was taken as the target end point. In patients in whom the target end point was achieved before completing the loading dose the infusion was stopped and the dose of sedative drug administered was noted. In patients in whom sedation score was less than 3 then additional IV bolus dose of midazolam 0.01 mg/kg was given and was subsequently repeated if necessary to achieve RSS 3.
Immediately after the loading dose was completed maintenance infusion was started in patient and surgeon was requested to administer local anesthesia with 2% lignocaine-adrenaline (1:200000) 6-7 ml and proceed with surgery.
During surgery patient's clinical parameters such as PR, MAP were recorded initially every 2 min during loading dose infusion and then every 10 min and ECG, SPO2 monitored continuously. In addition RSS was monitored every 10 min. In case RSS was noted to be <3, then midazolam 0.01mg/kg was administered IV as a rescue sedative.
Intra operatively pain intensity was also assessed every 10 min using VAS as follows.

- VAS 0 no pain
- 1-3 mild pain
- 4- 6 moderate pain
- >7 severe pain
- 10 worst imaginable pain

If pain was more than 6-7 on VAS then surgeon was asked to give local infiltration of the same local anesthetic at surgical site. In spite of this in the event of patient still complaining of pain rescue analgesia was given in form of fentanyl 1 mc/kg.

During surgery all the patients were observed for following adverse events-

- Bradycardia (PR<50 /min)
- Hypotension (SBP fall > 20% below base line)
- Hypertension (SBP increase > 20% above base line)
- Respiratory depression (RR < 8 breaths/min)
- Peripheral O2 desaturtion (SPO2<90%)
- Any other adverse event.

In case of such adverse events following treatment was given immediately. For bradycardia-atropine 0.3 mg IV and repeated if required. For hypotension rate of RL infusion was increased and IV ephedrine 3-5 mg was given. For respiratory depression oxygen flow was increased to 6 lit/min and bag- mask ventilation was used.

Approximately 15 to 20 minutes prior to end of surgery maintenance infusion of the study drug was stopped and patient was allowed to recover. The patients were then shifted to post anesthesia unit (PACU) for further observations and management. After surgery surgeon was asked to grade surgical condition and satisfaction with this sedation technique on numerical rating scale (NRS) in which 0 on this scale meant least satisfaction and score of 10 meant maximum satisfaction. Patients were also asked to grade their level of satisfaction on first postoperative day. This was the primary end point of our study.

Statistical analysis

For statistical analysis SPSS version 16.0 was used

Sample size was calculated based on population standard deviation of 1.1 80% power and 5% alpha error.

Hemodynamic and respiratory data was evaluated using unpaired t test for inter group and paired t test for within group comparison. P value < 0.05 was considered significant.

Results

Types of ENT surgeries performed are FESS, ttmpanoplasty, septoplasty and mastoidectomy. Mean duration of surgery was 77.33+-4.53 minutes Base line vital parameters (PR, MAP, and SPO2) were recorded. Loading dose of Dexmedetomidine was given over 10 min and during this period sedation score (RSS) was recorded every 2 min. Out of 30 patients 5 patients were cooperative and tranquil (RSS=2) and 25 patients were comfortably sleeping, responding to verbal command (RSS=3).In patients having RSS=2, midazolam 0.01mg/kg was administered IV.

During surgery PR, MAP were recorded every 10 min till the end of surgery is shown in Tables 1. In all these patients SPO2 was monitored continuously from commencement of loading dose of the study drug till the end of surgery. There was no fall in SPO2 below 97% any time during surgery.

Table 1: Comparison of pulse rate and mean BP at various time interval in study group.

Time (mins)	Pulse		Mean BP	
	Mean	SD	Mean	SD
0	79.26	1.80	98.16	3.01
5	76.76	1.82	96.16	2.63
10	68.46	2.46	79.5	3.10
20	73	2.12	78.46	3.05
40	76.3	2.20	77.1	2.13
60	77.06	2.56	77.9	1.89
80	80.93	1.94	80.93	1.68

Mean VAS recorded at 10 min interval intra operatively is shown in Table 2. Eight patients required rescue local anesthetic (LA) infiltration by the surgeon. Out of these patients only 4 patients in needed rescue fentanyl (one top-up dose in 3 patients and top-up doses in 1 patient) and one of these patients required one rescue dose of midazolam as RSS in this patient was 2.

Table 2: Comparison of mean of VAS score at different time intervals in groups.

Parameter Time (MINS)	VAS Score	
	Mean	SD
0	0	0
5	1.34	0.80
10	1.34	0.80
20	1.41	1.00
40	1.62	1.35
60	1.68	1.24
80	1.89	1.35

There were no major complications or side effects due to drugs used for sedation. Majority of patients had bradycardia between 48-55 beats/min which could be easily treated with atropine 0.2-0.3 mg IV. However, none of the patients developed hypotension requiring any active treatment. Eight patients complained of dryness of mouth.

In recovery room all the patients were observed and closely monitored with pulse oximeter and non-invasive BP monitor for one hour. All patients were quiet and were able to obey commands. They were then shifted to postoperative ward. On the next day, all the patients were interviewed for their overall experience about sedation for surgery and they were asked to rate their satisfaction score using Numerical Rating Score (NRS). The operating surgeons were also asked about their experience and level of comfort during surgery. NRS expressed by patients and surgeons is given in Table no 3 Patients' as well as surgeon's level of satisfaction was significant in dexmedetomidine.

Table 3: patient & surgeon satisfaction score & time to post-operative rescue analgesics.

Patient satisfaction score: NRS (1 – 10)	9 (8 – 10)
Surgeon satisfaction score: NRS (1 – 10)	9 (8 – 10)

Review of literature

Monitored anesthesia care (MAC) is a specific anesthesia service for diagnostic or therapeutic procedures performed under local anesthesia along with sedation and analgesia titrated to a level that preserves spontaneous breathing and airway reflexes [American Society of Anesthesiologists (ASA) update 2008] [8]. MAC comprises of three basic components. A safe conscious sedation

- Measures to allay patient's anxiety.
- Effective pain control

The mechanism of action of dexmedetomidine is unique and differs from the currently used sedative drugs. It acts both centrally as well as peripherally. Centrally it acts on locus ceruleus in brain to activate alpha-2 receptors and inhibits sympathetic stimulation and decreases sympathetic outflow which provides analgesia and sedation without respiratory depression. At lower doses DEX is predominantly sympatholytic. On binding to alpha-2 receptors it reduces sympathetic outflow and augments cardiac vagal activity

resulting in decreased heart rate and cardiac output [9]. Despite higher cost, DEX appears to an attractive alternative and effective substitute of opioids, primarily due to its property of arousable sedation with analgesic sparing effect, preservation of better airway reflexes and ventilator drive.

Recently Gupta K and colleagues [10] evaluated the clinical effects of dexmedetomidine IV infusion during middle ear surgery using operating microscope under general anesthesia in 32 adult patients. They used a dose of 0.5mcg/kg/h after induction of GA till 20 min before completion of surgery. They concluded that DEX infusion was safe to provide oligaemic surgical field for better visualization under operating microscope for middle ear surgery keeping the hemodynamic variations within physiological range. It also reduced the requirement of isoflurane and recovery from anesthesia was complete and smooth.

Discussion

Dexmedetomidine has been safely and effectively used as sedative –analgesic for MAC in patients undergoing various surgical procedures under local anesthesia and for diagnostic procedures such as eye surgery, ENT surgery, dental surgery, gastro intestinal endoscopy and radiological investigations [6]. ENT surgery, particularly tympanoplasty, septoplasty, mastoidectomy and functional endoscopic sinus surgery (FESS) pose different challenges for the surgeon and anesthesiologist because most of the times these surgeries are done under local anesthesia supplemented with some kind of sedation and analgesia. Sympathetic stimulation and movements of patient due to pain, discomfort and excessive anxiety can cause bleeding and obscure the fine surgical field under microscope.

We have used this comparatively newer alpha-2 adrenergic receptor agonist for ENT surgeries as a component of MAC. We observed that dexmedetomidine was very effective and well tolerated by all the patients. Our results have shown that significantly less number of patients required supplemental midazolam and fentanyl for rescue sedation and analgesia.

We have selected a loading dose of 1mcg/kg body weight based on previous studies [11]. Various studies have shown that use of low or moderate dose of dexmedetomidine by slow infusion leads predominantly in alpha-2 agonist effects and not the alpha-1 effects [5]. Dexmedetomidine has a short distribution half- life of 5 minutes. So initial loading dose need to be followed by maintenance infusion. For this, we used maintenance infusion of 2mcg/kg/h. Surgery was essentially done under LA infiltration. So we maintained infusion of dexmedetomidine at a fixed rate and whenever patient was in distress due to pain or discomfort we administered additional dose of rescue fentanyl and midazolam. Dexmedetomidine possesses both sedative and analgesic properties and therefore it can be used as a single agent for MAC. In addition its central as well as peripheral sympatholytic action and anxiolytic property is an advantage during surgery under LA [7].

PR and BP were on the lower side compared to midazolam-fentanyl group which can be explained by marked inhibition of sympathetic activity. Our findings are similar to other studies where lower PR and BP were observed in dexmedetomidine group Dexmedetomidine is a unique drug in that it does not cause any respiratory depression and therefore hypoxia because its action is not mediated via gamaaminobutyric system [12].

In the present study patient and surgeon satisfaction scores were significantly higher with dexmedetomidine suggesting superior quality of sedation and analgesia with this drug. Lower PR and BP could have resulted in bloodless surgical field with better surgeon satisfaction. Also surgeons feel happy and satisfied if there is no patient movement during surgery. Lesser number of patients demanded rescue analgesic and sedative as compared to midazolam-fentanyl group. Similar findings have been reported by K Karaaslan et al [13] where group dexmedetomidine used significantly less rescue tramadol. Dexmedetomidine has analgesic and opiate sparing property which has been well documented and has been reported in studies conducted in GA with dexmedetomidine.

Conclusions

From the present study we can conclude that:

- Dexmedetomidine when used by continuous IV infusion for sedation-analgesia during ENT surgery for MAC is safe and better.
- Patient and surgeon satisfaction

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