

Sedation with Dexmedetomidine or General Anaesthesia in Combination with Regional Anaesthesia in Mastoid Surgeries: A Comparative Study

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Abstract

Background and Aims: Mastoid surgery can be performed under general anaesthesia (GA) or sedation both combined with regional anaesthesia (RA). There are very few studies comparing both the techniques. Dexmedetomidine is the sedative agent of choice in modern era. Our primary aim was comparison of haemodynamic variation and bleeding under GA or sedation with dexmedetomidine and secondary being, adequacy of sedation and patient comfort under dexmedetomidine sedation, post operative analgesia and duration of stay in post anaesthesia care unit. **Methods:** 60 patients posted for mastoidectomy were randomly divided into two equal groups, GA or sedation. In GA after conventional technique of induction and intubation, anaesthesia was maintained with oxygen, nitrous oxide, isoflurane and propofol infusion. In sedation group dexmedetomidine 1 µg/kg was given over ten minutes followed by infusion at rate 0.2-0.8 µg/kg/hr. RA was given in both the groups. Intraoperative parameters were noted in both the groups. Statistical software version SPSS 19 was used. **Results:** Heart rate was lower in sedation group throughout surgery. Bleeding was less in both groups. None of the patients in sedation group were converted to GA. Maximum patients had discomfort to noise and neck position. Shifting of patients was earlier with sedation than in GA. There was longer post operative analgesia with dexmedetomidine sedation. **Conclusion:** Dexmedetomidine sedation with regional anaesthesia can also be a better choice for mastoid surgery. It maintains haemodynamic stability, minimal bleeding, adequate sedation and patient comfort. It also aids early ambulation of patients and has perioperative analgesic action.

Keywords: Mastoid Surgery; Dexmedetomidine Sedation; General Anaesthesia; Regional Anaesthesia for Middle Ear Surgery.

Introduction

Mastoidectomy is a procedure of removal of infected mastoid cells from mastoid with tympanoplasty [1]. Minimum haemodynamic variation, minimum bleeding, patient comfort with respect to pain, position, anxiety and noise are the prerequisites for a safe mastoid surgery. Mastoid surgery can be performed under sedation [2] or general anaesthesia (GA), both supplemented with regional anaesthesia (RA). Under GA there is more haemodynamic variation as a result of airway handling [3]. The rise in perioperative blood pressure and heart rate is more common, which may result in increased bleeding at the site of surgery.

Also use of Nitrous oxide which has 34 times more solubility in blood than Nitrogen can cause graft displacement if used continuously [1,4]. On contrary sedation without GA avoids endotracheal intubation, cessation of spontaneous respiration and hemodynamic variation associated with airway handling. There are very few studies comparing the difference of effects of GA and sedation in mastoid surgeries [5].

There are many drugs like benzodiazepines and Propofol that have been used for mastoid surgeries. Since these drugs produce respiratory depression, a drug without this side effect would be ideally suited for sedation. Hence Dexmedetomidine, which is a central presynaptic α_2 -adrenoceptor

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agonist, can be an appropriate choice. Its α -2: α -1 selectivity ratio is 1620:1. Its distribution half-life is 6 minutes and elimination half-life is 2-2.5 hours. It is popular for its unique conscious sedation (patient appears to be asleep but readily aroused), analgesia without respiratory depression [6]. It decreases BP, which is beneficial in reducing intraoperative bleeding.

Hence, it was hypothesized that sedation with Dexmedetomidine had better outcomes than GA [3]. The primary objectives of the present study were to compare haemodynamic stability, bleeding, sedation with Dexmedetomidine compared to GA, adequacy of sedation and extent of patient discomfort due to sedation. The secondary objectives were to compare, time to shift from post anaesthesia care unit (PACU) and post-operative analgesia.

Methods

The study was conducted in tertiary hospital attached to a medical College and Research Institute; (October 2016 to March 2017). After obtaining approval from the institutional ethical committee and informed written consent from the patients, 60 patients were randomly selected, posted for mastoid surgery. Random selection was done by opaque closed envelope technique and divided into two equal groups: Group-GR or Group-SR with 30 patients in each. Inclusion criteria were: adult patients of either sex, aged between 18-60 years belonging to American society of Anesthesiologists (ASA) physical status class I or II. Exclusion criteria were patients with history of chronic use of analgesic or sedative agents, diabetes mellitus, alcohol or drug abuse, language barrier or psychiatric disorder, allergy to any of the study medications, history suggestive of obstructive sleep apnea, evidence of bradycardia with heart rate less than 60 or if patients were on beta blocker therapy.

Thorough preoperative evaluation was done for all patients and they were kept nil orally overnight. On the day of surgery, intravenous line obtained with 18 gauge cannula. Monitoring done using multi parameter monitor having electrocardiogram (ECG), capnography and non-invasive blood pressure (NIBP). Baseline heart rate (HR), mean arterial pressure (MAP) and pulse oximetry saturation (SPO₂) noted. They were premedicated 10 minutes before surgery with IV Ondansetron-4mg, IV Glycopyrrolate 2mg and IV Fentanyl 2 μ g/kg in both the groups.****

Group-GR: Patient induced with IV propofol 2mg/kg followed by IV muscle relaxant vecuronium 0.1mg/kg. After 3 minutes of ventilation with mask using oxygen (O₂) 40%, N₂O 60% and isoflurane 1%, patient intubated with endotracheal tube size 7.5 in females and 8.5 in males and tube secured. Patient ventilated with Bains circuit with O₂ 40% and N₂O 60%. Anaesthesia maintained with isoflurane at 1%. Propofol infusion started and titrated between 50-100 μ g/kg/min. 10ml of 0.25% bupivacaine with 10ml of 1: 200000 lignocaine with adrenaline was used for RA. 5 minutes after this infiltration, surgery was started. Intraoperative HR, MAP and SPO₂ monitored every 5 minutes. N₂O stopped during and after graft placement.

Beginning of skin suturing is considered to be end of surgery. 20 minutes before the end of the surgery propofol infusion was stopped. After skin suturing isoflurane was stopped. When patient developed slight efforts, he was reversed with IV neostigmine 0.05mg/kg and glycopyrolate 0.01mg/kg. Patient was extubated after adequate efforts.

RA was given in both the groups by injection of solution into the anterior meatal wall at the osteoarticular junction; injections at several points behind the auricle and over the mastoid process; injection of the periosteum at the anterior surface of the mastoid process and the skin of the floor of the meatus.

Group-SR: 1 μ g/kg bolus of dexmedetomidine given over 10 minutes under monitoring followed by maintenance infusion at the rate of 0.4 μ g/kg/hr. Rate titrated between 0.1-0.8 μ g/kg/hr to maintain Ramsay's sedation score (RSS) of 3. 10ml of 0.25% bupivacaine with 10ml of 1: 200000 lignocaine with adrenaline was used for RA. 5 minutes after this infiltration surgery started. Intraoperative HR, MAP, respiratory rate and SPO₂ monitored for every 5 minutes. RSS also monitored. If MAP was less than 60mmHg or HR drops below 50, it was considered as unwanted hypotension or bradycardia respectively, infusion was reduced to half rate. Ringer Lactate fluid bolus was given for hypotension followed by IV ephedrine if needed. IV Atropine 0.3mg was given for bradycardia and repeated as required. If RSS of the patient was 1, IV propofol infusion was given at the rate of 50-100 μ g/kg/min. If patient was dissatisfied or complained of severe pain, sedation was converted to GA. At the end of the surgery, infusion was stopped. Number of patients who received this additional sedation was noted to evaluate the adequacy of sedation with dexmedetomidine.

Patients belonging to both the groups were then kept in PACU for monitoring. Any side effects like PONV or facial nerve paresis were looked for. Surgeons were asked to grade the intraoperative bleeding as 0: no bleeding, no suction; 1: minimum bleeding, sporadic suction; 2: diffuse bleeding, repeated suction; 3: troublesome bleeding, continuous suction.

Patients of Group-SR were asked to rate their discomfort score to pain, noise, position and anxiety via questionnaire; from 0 to 4 where 0- no discomfort; 1-mild discomfort; 2-moderate discomfort; 3- severe discomfort and 4- extreme discomfort. Patients were shifted to the ward after the modified Aldrete score (MAS) >8. Duration of stay in the PACU noted. Postoperative analgesia

assessed via visual analogue score (VAS). Duration to attain VAS > 4 noted and rescue analgesia with IV paracetamol was given.

Ramsay Sedation Scale is as Follows

1. Anxious, agitated or restless
2. Cooperative, oriented and tranquil
3. Responds to command
4. Asleep but has a brisk response to light glabellar tap or loud auditory stimulus
5. Asleep has a sluggish response to a light glabellar tap or loud auditory stimulus
6. Asleep no response

Post Anaesthesia Recovery Score (Modified Aldrete Score)

Parameter	2	Score 1	0
Activity	Moves all extremities voluntarily or on command	Moves two extremities voluntarily or on command	Unable to move extremities
Respiration	Breathes deeply and coughs freely	Dyspnoeic, shallow or limited breathing	Apnoeic
Circulation	BP ± 20 mm of preanaesthetic level	BP ± 20-50 mm of preanaesthetic level	BP ± 50 mm of preanaesthetic level
Consciousness	Fully awake	Arousable on calling	Not responding
Oxygen saturation	SpO ₂ >92% on room air	Supplemental O ₂ required to maintain SpO ₂ >90%	SpO ₂ <90% with O ₂ supplementation
Total Score=10			

Visual Analogue Scale: VAS (0-10cm)

0	2	4	6	8	10
No pain			worst pain		

The study was started after the pilot study involving 16 patients with 8 patients in each group. Sampling will be purposive sampling, done using the formula $S = z^2 pq / d^2$ where z is constant, p is prevalence, q is (1- p) and d is significance level. In this study, considering hospital prevalence of 4% and confidence interval of 95%; z will be 1.96 and d will be 0.05. Applying this formula, sample size (S) will be 60 patients.

Statistical analysis was done using SPSS statistical software version 19 for windows. Data were presented as mean and standard deviations (SD). Comparison was done using Independent sand paired samples t tests, Cramer’s V & repeated measure ANOVA tests. P values below 0.05 were considered statistically significant.

Results

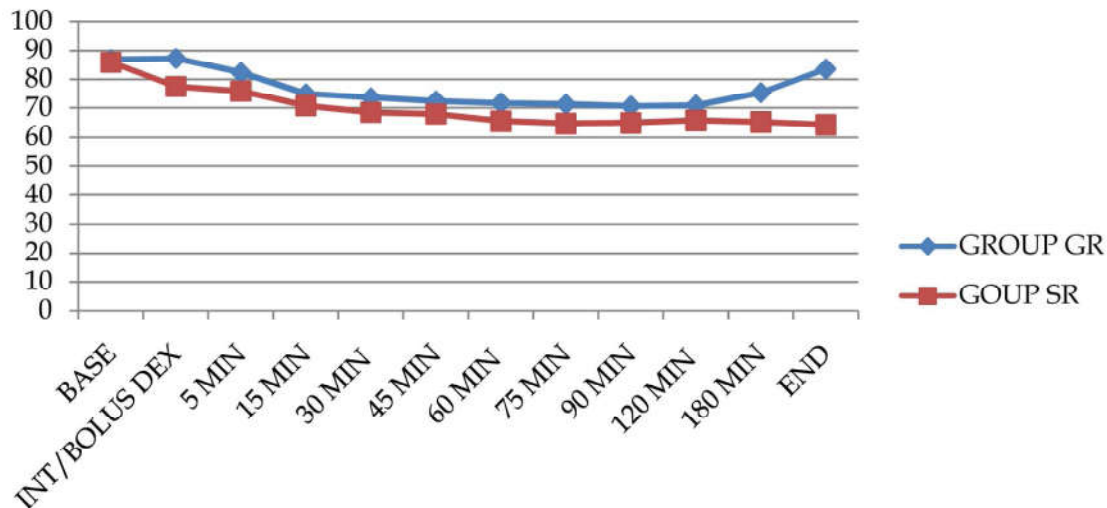
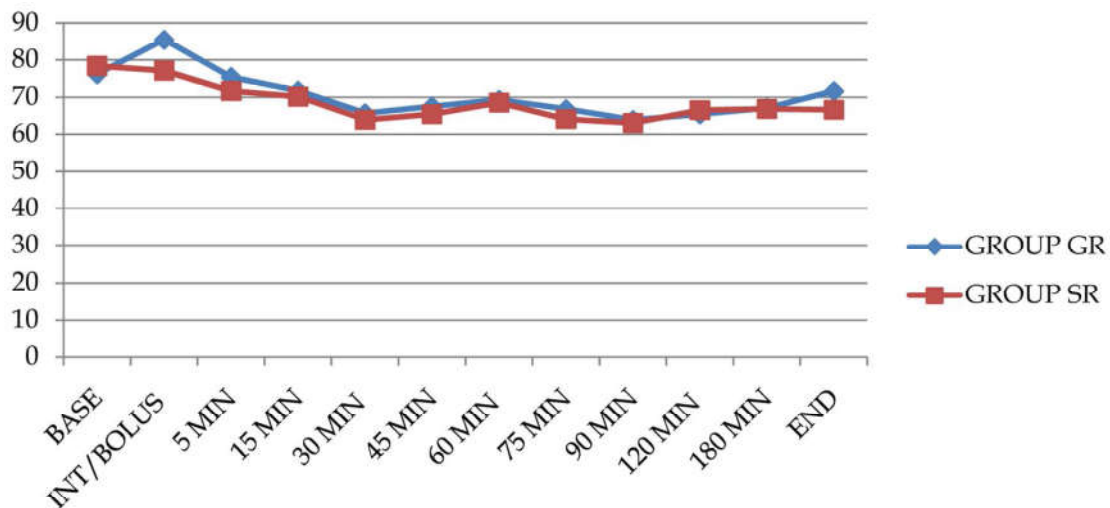
In our study, both the groups were comparable in their demographic characters, duration of surgery and mean baseline HR and MAP (Table 1)

Intraoperative HR was lesser in group SR compared to group GR throughout the surgery. However there was a statistically significant increase of HR in the first 15 min and the last 10 minutes in Group GR compared to Group SR (Figure 1).

Intraoperative MAP had maximum difference at first 15-20 minutes and last 15-20 minutes. It was significantly higher in group GR compared to group SR. Throughout the surgery the difference was not statistically significant (Figure 2).

Table 1: Demographic characters, duration of surgery and mean baseline Heart Rate (HR) and Mean Arterial Pressure(MAP)

	Group GR	Group SR	P value
Age(years)	34.46 +/- 10.5	30.63 +/- 8.53	0.126
Weight (kg)	58.23 +/- 6.04	57.9 +/- 5.86	0.829
Sex (male: female)	13:17	17:13	0.302
ASA grade (I : II)	15:15	21:9	0.114
Duration of surgery	2.61 +/- 0.32	2.64 +/- 0.32	0.736
Mean baseline HR	86.93 +/- 13.45	85.9 +/- 14.77	0.778
Mean baseline MAP	76.26 +/- 8.87	78.43 +/- 7.79	0.319

**Fig. 1:** Heart Rate variation at different time intervals in both the groups**Fig. 2:** Mean Arterial Pressure (MAP) changes at various time intervals between the Groups

Bleeding score as graded by surgeons was 1.5 +/- 0.62 in Group GR and 1.4 +/- 0.62 in Group SR. (P value-0.538). It is not statistically significant. Maximum grading of the bleeding score was 2.

Most of the patients maintained RSS of 3 in Group SR. None were converted to GA.

Patient discomfort score was assessed in Group SR. Patients show maximum discomfort to noise and neck position compared to pain and anxiety (Table 2).

Intraoperative, 3 patients in group SR had bradycardia with HR < 60/min and corrected by IV Atropine 0.6mg. None of the patients in either of

Table 2: Patient discomfort score in Group SR

Patients in Group SR	Pain	Noise	Anxiety	Neck Position
Mean discomfort score	1.2 +/- 0.4	2.2 +/- 0.66	1.6 +/- 0.71	2.1 +/- 0.79

Table 3: Perioperative Haemodynamic complications and post-operative parameters in both the Groups

	Group GR	Group SR	P value
Bradycardia	0	2	
Hypotension	1	3	
Facial paresis	1	1	
PONV	3	1	
Mean PACU shift time (min)	40.1 +/- 7.39	31.9 +/- 7.09	<0.005
Mean Post op Analgesia duration (hrs)	4.5 +/- 0.67	5.1 +/- 0.68	0.002

the Groups had PR < 50/minute. 2 patients had hypotension in Group SR. It improved after administering fluid bolus and IV ephedrine 6 mgs. Incidence of PONV was not significant in both the Groups. One case of facial paresis was noted in each group, in group GR it was noted postoperatively whereas it was detected intraoperatively in group SR. The paresis was transient and disappeared within 24 hours.

Time to shift from PACU was early in group SR (40.1±7.39 minutes) than group GR (31.9±7.09 minutes) as they attained MAS >8 early. Post-operative duration of analgesia in Group SR was longer than Group GR (Table 3).

Discussion

Studies comparing GA versus sedation for mastoid surgeries are lacking. In our study we compared sedation with Dexmedetomidine and conventional endotracheal GA, both combined with RA in mastoid surgeries to assess haemodynamic variations, perioperative bleeding, patient comfort under sedation, adequacy of sedation, any adverse effects, recovery and duration of analgesia.

Andreassen [5] compared local anaesthesia (LA) verses GA for middle ear surgery (MES), and found out that MES with LA is advantageous as it was acceptable to majority of the patients.

Dogan et al. [3] showed that LA with dexmedetomidine sedation resulted in a more stable haemodynamic state, less surgical bleeding compared to GA alone. In studies conducted by J. A. Alhashemi et al [7] and Taqhinia AH et al [8] there was a lower HR and MAP with dexmedetomidine sedation patients. Durmus et al [9] studied haemodynamic responses in tympanoplasty and septoplasty, with

dexmedetomidine infusion when used intraoperatively along with GA. HR and MAP were lower intraoperatively with the infusion compared to placebo. Similarly in our study there was significant reduction in HR from the baseline throughout the surgery in dexmedetomidine sedation.

Our study has shown that MAP and HR increase was only during the first and last 15-20 minutes in GA group which coincided with laryngoscopy, intubation and extubation respectively. However there was no increase of MAP or HR in Group SR through-out. Intraoperatively in both the groups the haemodynamic changes were not statistically significant. In studies conducted by Ghali et al [10] and Reetu Verma et al [11], there was reduction of MAP from baseline with both propofol and dexmedetomidine sedation. In studies by Arain et al [12] and Ebert et al [13] using Propofol infusion for sedation, MAP was lower with propofol sedation. In the above mentioned studies we notice that MAP decreases with propofol sedation, which has got an additive effect of isoflurane in GA as in our study. Hence MAP was lower from baseline intraoperatively in group GR where anaesthesia was maintained with propofol infusion and isoflurane 1%. It was also lower in group SR and the variation in both the groups had no statistical significance. This can be explained by the powerful inhibitory effect of propofol on sympathetic outflow [13]. Dexmedetomidine also has sympathetic inhibitory effect causing fall in BP [14]. The rise in MAP in group GR during first and last 15-20 minutes is due to intubation and extubation response. Hence there was more haemodynamic stability in HR and MAP with dexmedetomidine compared to GA in our study though the variation in MAP was not much intraoperatively.

Reem Hamdy Elkabarity et al. concluded that there was near bloodless field during MES with

dexmedetomidine surgery [15]. Fazilet Sahin et al [16] observed that there was no difference in the amount of bleeding in MES when dexmedetomidine sedation was compared to alfentanil. In Our study there was no statistical significant difference in bleeding. It might be due to the non-significant variation in MAP which was high only during the beginning and at the end of the surgery in group GR. However in both the groups the surgeons did not grade bleeding more than 2. This indicates similar extent of bleeding can be caused by GA with propofol infusion and sedation with dexmedetomidine infusion.

Hence dexmedetomidine sedation can also be preferred for controlled bleeding in mastoid surgery.

Raul et al [17] studied dexmedetomidine sedation in MES. They evaluated the degree of sedation wherein maximum had achieved RSS of 2 and 3. Adequate sedation was achieved successfully with the mean infusion rate of 0.27 µg/kg/hr. Goksu et al [18] study results showed that dexmedetomidine gives adequate sedation without any discomfort in functional endoscopic sinus surgery. Their results are consistent with the results of our study. Most of the patients had RSS of 2, 3 or 4 without any hemodynamic or respiratory untoward changes in our study. None of the patients were converted to GA.

Yungs [19] observed in his study of MES with LA that maximum discomfort was to noise and anxiety. Whereas Sormento et al [20] study patients had more discomfort to neck position when intramuscular promethazine was used. Caner G [2] observed that patients had most discomfort to noise and patients were irritable. Our study also showed increased discomfort to noise and neck position compared to anxiety and pain. This may be because of anxiolytic and analgesic property of dexmedetomidine. This entire discomfort score was assessed at the end of the surgery by questionnaire. Despite of this discomfort neither the surgeons nor the patients interrupted surgery.

Bradycardia and hypotension more associated with dexmedetomidine could be explained by its central α -2 adrenergic blockade which eventually decreases sympathetic outflow [14, 21].

In Dogan et al [3], Arian SR et al [11] and Reetu Varma et al [12] study there was better pain relief in dexmedetomidine group post operatively in MES. McCutcheon CA [22] also noted there was lesser requirement of post-operative rescue analgesics in patients undergoing carotid endarterectomy with

dexmedetomidine sedation. This explains the analgesic feature of dexmedetomidine which is also observed in our study with long duration of post-operative analgesia.

Dogan et al [3] who compared dexmedetomidine sedation with GA in septoplasty also observed faster recovery in dexmedetomidine group as in our study.

Some of the limitations of our study are as follows: RSS was not assessed frequently as it would interrupt the surgery. It was done for every 15 minutes for 1st hour and then hourly. This might made us to miss if there was inadequate sedation level attended by the patient. Other limitation was the lack of facility of bispectral index for delineating the end point of sedation. In our study it was assessed via RSS where the target level was 3. There was subjective assessment of bleeding by surgeons as there was no definitive objective method of detecting the bleeding. This is another limitation of our study.

Conclusion

Mastoid surgery can be performed either under GA or sedation with RA. Sedation can be preferred over GA as there is less hemodynamic variation and equal bleeding rate in both the groups. With infusion rate of dexmedetomidine 0.1-0.8 µg/kg/hr, adequate sedation can be attained intraoperatively. Surgery can be performed by assessing hearing and facial nerve function. There will be tolerable discomfort to noise and position. The recovery of patient in sedation is earlier than with GA; less PONV and longer duration of analgesia. As there are many advantages of Dexmedetomidine sedation with RA, mastoid surgeries can be safely performed with the same.

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