

Ketamine-Dexmedetomidine Combination for Monitored Anaesthesia Care in Tympanoplasty Surgery: An Observational Study

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ABSTRACT

Introduction: Monitored Anaesthesia Care (MAC) has been widely used for patients undergoing middle ear surgeries. Previous studies have shown that the use of local anaesthesia has many advantages over general anaesthesia in performing ear surgeries. The use of Dexmedetomidine as a sole anaesthetic agent had many disadvantages owing to its insufficient sedative effect, increased recovery time and haemodynamic instability. Hence, using a combination of low dose ketamine with Dexmedetomidine can prove to be useful in middle ear surgeries.

Aim: To evaluate the effects of Dexmedetomidine-Ketamine (DK) combination on the quality of sedation/analgesia and recovery profiles for MAC in tympanoplasty surgery.

Materials and Methods: In this observational study, a total of 20 patients were included. All the demographic data- including, age, sex and American Society of Anesthesiologists (ASA) grade were recorded before the surgery. Before the surgery, all patients received 1 µg/kg dexmedetomidine over 15 minutes followed by infusion of 0.2-0.7 µg/kg/h to maintain 2 or 3 of modified observer's assessment of analgesia and sedation score. Both the scores were checked every 10 minutes. Ketamine was infused at the rate of 10-15 mcg/kg/min, 10 minutes before the start of the procedure. The Heart Rate (HR), systolic and diastolic pressure, pain score and sedation score were monitored every 10 minutes

until 120 minutes of the preoperative condition after the nerve block was used. Statistical analysis was performed using IBM SPSS Version 25.0 (IBM, New York, United States). Continuous data values were shown in the form of mean±standard deviation. To compare the mean difference between the groups, student's t-test was used and p<0.05 was considered as statistically significant.

Results: The mean age of the population was 39.45±12.66 years; among which 15 patients (75.0%) were females. Out of 20 patients, 12 (60.0%) were in the ASA-I and 8 (40.0%) were in the ASA-II grade. The result of the study showed not a single instance of complication. All the patients were haemodynamically stable and HR was also found to be constant in both pre and postoperative instances. The pain score was found to be around 2 even after 120 minutes after the surgery (2±0.93). No rescue analgesia was required in any of the patients and all the patients recovered within 3-5 minutes after the infusion was stopped. No postoperative nausea and vomiting instances were also reported.

Conclusion: The present study showed that DK combination provides good haemodynamic stability, higher sedation score and lower pain score. In addition, this study also showed that for patients undergoing tympanoplasty surgery this is a safe and effective method of anaesthesia that provides good MAC.

Keywords: Haemodynamic stability, Pain score, Sedation score

INTRODUCTION

Usually, for ear surgeries, both local and general anaesthesia is used. Although both the method have their advantages and disadvantages, local anaesthesia is preferred by many physicians because of its capacity to improve haemostasis and allowing the physicians to perform an intraoperative hearing assessment [1]. MAC is also called conscious sedation. In this procedure, local anaesthesia is done along with analgesia and sedation. For this process, the cardiovascular and respiratory functions are maintained normally without using any intervention [2]. MAC is superior to local anaesthesia alone, since it provides sedation added to analgesia which makes surgeon comfortable and patient satisfaction is also more in the perioperative period.

Dexmedetomidine is a α_2 agonist and has analgesic and hypnotic effect. It has been shown that a dose of 3 µg of dexmedetomidine as additive prolongs the motor and sensory blockade effect of intrathecal bupivacaine [3]. A dose of 1 µg/kg dexmedetomidine is capable of extending the peripheral nerve blockade by 200 minutes [4]. Dexmedetomidine is capable of extending the effect of long-acting local anaesthetics which are used in the spinal blocks. In this meta-analysis the authors have also pointed out the different doses of dexmedetomidine used by different studies 1 µg/kg to 100 µg. Reversible bradycardia was reported in less patients in

less than 10% time [5]. But there are not many studies on use of dexmedetomidine with Ketamine in MAC.

On the other hand, Ketamine is an N-methyl-D-aspartate (NMDA)-receptor antagonist that has shown to possess the local anaesthetic effect and affects nerve conduction significantly [6]. Studies have reported a high rate of adverse events including hallucinations, nausea and drowsiness in the group that received ketamine as an additive [6]. Interestingly, the studies conducted previously shown that this combination can be proved to be effective as dexmedetomidine prevent hypertension, tachycardia and salivation in patients commonly associated with ketamine. On the other hand, the adverse outcome associated with dexmedetomidine such as hypotension and bradycardia is prevented by ketamine [7].

Thus, this combination can prove to be useful in ear surgeries where it is necessary that the patient remains motionless throughout the surgery and can co-operate actively while the procedure is going on. However, till date, no such studies have been reported that have used this combination in tympanoplasty surgery. Hence, this study aimed to evaluate the effect of DK combination on the quality of sedation/analgesia. Moreover, this study will also access the recovery profiles for MAC in tympanoplasty surgery.

MATERIALS AND METHODS

In this observational study, a total of 20 patients were included that came to the study centre during the period from June 2019 to December 2019. Written consent was obtained from them before the start of the study. Before the beginning of the study approval of the Institution's Ethics Committee (09/ETC/2019) was also obtained.

Inclusion criteria: Adult patients, from either of the gender, belonging to ASA grade I and II category, undergoing tympanoplasty were included.

Exclusion criteria: Patients that were hypertensive, or had any history of allergy to either Ketamine or Dexmedetomidine, morbidly obese, alcoholics, pregnant, had some neurological or neuromuscular disease, with a history of using any type of sedative medications or opioids in the month before surgery or are not willing to take part in the study were excluded.

Pre-anaesthetic check-ups were conducted on all the patients and were done before the surgery. The patients were counselled for sedation, use of local anaesthesia and the details of the operative procedures.

On the day of the operation the HR, non-invasive blood pressure including both systolic and diastolic pressures was recorded. Before the operation, all patients received 1 µg/kg dexmedetomidine over 15 minutes followed by infusion of 0.2-0.7 µg/kg/h to maintain 2 or 3 of modified observer's assessment of analgesia and sedation score [8]. Both the scores were checked every 10 minutes. Ketamine was infused at the rate of 10-15 mcg/kg/min. Both Ketamine and Dexmedetomidine were started before the surgery. Ten minutes before the start of the operation Inj: Paracetamol 1 gm IV was given.

Surgeon, after cleaning and draping, infiltrated 10 mL of 2% lignocaine with 1 in 10000 adrenaline locally. The HR, systolic and diastolic pressure, pain score and sedation score were monitored every 10 minutes until 120 minutes of the preoperative condition after the nerve block was used. Oxygen was given throughout the surgery by nasal prongs at the rate of 2-3 ltr/min.

Rescue analgesia was given with Inj Fent 1 mcg/kg IV if required when pain score (VAS) was more than 5, inspite of Dexmedetomidine and Ketamine infusions. Intraoperative Hypotension (more than 20% of decrease in BP) was treated with Crystalloids at 200 mL bolus and Inj Mephenteramine 3 mg. Bradycardia (20% drop from the baseline reading) if at all occurred, was treated with Inj Atropine 0.6 mg IV. Postoperatively, Inj. Paracetamol was used as analgesic IV 8 hourly. Pain score was monitored in the postoperative period. Satisfaction score was assessed in the postoperative period from scoring of 1 (Poor), 2 (Fair), 3 (Good), 4 (Excellent).

STATISTICAL ANALYSIS

The data was been entered into MS-Excel and statistical analysis was done by using IBM SPSS Version 25.0. For categorical variables, the data values were expressed as number and percentages and for continuous variables, the data values were expressed as Mean±SD. To test the mean difference between the groups, student's t-test was used. The p-values <0.05 was considered as statistically significant.

RESULTS

In the present study total of 20 patients were included, among which 15 (75.0%) were females and 5 (25.0%) were males. The mean age of 20 patients was 39.45±12.66 years with a range of 18 to 62 years. Out of 20 patients, 12 patients (60.0%) were in the ASA-I and 8 (40.0%) were in the ASA-II grade. Nine patients (45.0%) were scheduled for left tympanoplasty surgery, 07 (35.0%) patients for right tympanoplasty and 04 (20.0%) patients were Bilateral Chronic Serous Otitis Media [Table/Fig-1].

The descriptive statistics of HR, systolic and diastolic pressure sedation score and pain score are shown in [Table/Fig-2]. There were no complications reported after surgery. There was no statistically

significant difference between the preoperative and postoperative for systolic and diastolic pressure measurements (p>0.05).

Diagnosis	Frequency	Percent
Bilateral Chronic Serous Otitis Media	4	20.0
Chronic Otitis Media (Left) Inactive	7	35.0
Chronic Otitis Media (Left) Mucosal Inactive	1	5.0
Chronic Otitis Media Mucosal(Left)	1	5.0
Chronic Otitis Media Mucosal(Right)	5	25.0
Chronic Otitis Media (Right) Inactive	2	10.0
Patient satisfaction score (1-4)		
Excellent (4)	15	75.00
Good (3)	4	20.00
Fair (2)	1	5.00
Poor (1)	0	0.00

[Table/Fig-1]: Summary of the cases.

	Mean±SD (Min-Max)*				
	HR	SBP	DBP	Sedation score	Pain score
Pre-Op	70.90±10.10 (54-90)	112.2±8.8 (100-130)	70.8±5.67 (60-80)	pre-op	pre-op
Intra-Op	-	118.7±11.06 (100-142)	70.4±6.7	1.24±0.44 (1-2)	1.24±0.78 (0-2)
10 minutes	71.7±10.37 (56-86)	117.2±11.47 (98-138)	69.4±7.76 (52-88)	2.29±0.69 (1-3)	1.25±0.87 (0-2)
20 minutes	70.7±10.88 (52-86)	115±11.6 (96-136)	64.8±8.91 (50-78)	2.61±0.61 (1-3)	2.14±0.38 (2-3)
30 minutes	70±10.76 (52-84)	113.2±10.61 (98-136)	67.1±11.97 (50-90)	2.29±0.69 (1-3)	1.89±0.33 (1-2)
40 minutes	69.85±10.2 (52-84)	113±11.72 (96-136)	63.2±10.87 (40-88)	2.72±0.46 (2-3)	1.86±0.38 (1-2)
50 minutes	69.4±9.74 (52-84)	114.1±11.74 (96-136)	66.3±9.56 (60-90)	2.61±0.61 (1-3)	1.25±0.87 (0-2)
60 minutes	68.8±9.87 (52-86)	112.8±11.28 (98-140)	65.5±8.18 (52-78)	2.5±0.51 (2-3)	2.14±0.38 (2-3)
70 minutes	68.45±9.36 (54-84)	111.4±11.11 (96-140)	62.4±7.04 (50-72)	2.65±0.49 (2-3)	1.89±0.33 (1-2)
80 minutes	69.2±9.43 (56-84)	110.3±10.35 (94-132)	67.7±15.05 (40-90)	2.67±0.49 (2-3)	1.86±0.38 (1-2)
90 minutes	68.2±8.97 (54-82)	108.6±9.56 (96-128)	66.42±9.65 (50-90)	2.44±0.51 (2-3)	2.17±0.41 (2-3)
100 minutes	67.7±8.74 (54-82)	107.8±9.47 (96-128)	65.9±8.77 (52-78)	2.69±0.48 (2-3)	1.9±0.32 (1-2)
110 minutes	67.35±9.03 (52-84)	106.5±9.2 (90-124)	63.1±9.72 (40-80)	2.42±0.51 (2-3)	1.86±0.38 (1-2)
120 minutes	67.15±8.99 (52-82)	106.3±11.43 (88-138)	69.5±13.66 (40-90)	2.83±0.38 (2-3)	2±0.93 (1-4)

[Table/Fig-2]: Descriptive statistics of HR, systolic and diastolic pressure, sedation score and pain score.

*SD: Standard deviation; Min: Minimum; Max: Maximum

Similarly, HR was also found to be constant in both pre and postoperative instances. The pain score was found to around 2 even after 120 minutes after the surgery (2±0.93). No rescue analgesia was required in any of the patients and all the patients recovered within 3-5 minutes after the infusion was stopped. The patients were continuously monitored in the post-anaesthesia care unit for one hour after they were shifted from the operation theatre. The complete analgesia or sedation was achieved in 92% of the patients. The outcome parameter which indicates the quality of analgesia-sedation score revealed that 75% of patients had excellent score of satisfaction which is shown in [Table/Fig-1]. No postoperative nausea and vomiting instances were reported.

DISCUSSION

The present study evaluated the effect of DK combination on the quality of sedation/analgesia. The primary outcome measured in

this study was the quality of sedation/analgesia, cardiorespiratory variables, and satisfaction scores. Secondly, this study also measured the recovery parameters including the time to spontaneous eye-opening and the length of the recovery room stay.

Tympanoplasty is a common middle ear surgery that can be performed under both general and local anaesthesia. However, in maximum cases, surgeons do not feel comfortable using local anaesthesia for tympanoplasty surgery because of the long duration of such surgeries and the requirement of greater manipulation of instruments [9]. However, in a recent study Sarmento KM and Tomita S have shown that in retroauricular tympanoplasty, local anaesthesia can be successfully used in patients. This study reported that sedation and the use of local anaesthesia can be tolerated by the patients undergoing this surgery. Noise discomfort had the lowest mean score [10].

Previous studies have shown that MAC is a good method in surgeries that requires intraoperative evaluation of patients [11,12]. In this technique for optimum analgesia and sedation, local anaesthesia was combined with parenteral drugs. For this type of anaesthesia, the most used agents are ketamine, midazolam, sevoflurane and propofol [11].

In the present study, 20 patients undergoing tympanoplasty surgery were included. The study results showed no change in the preoperative, intraoperative and postoperative HR, systolic and diastolic pressure values. Lower pain score was reported by the patients in the first 30 minutes of the operation. After that, the pain score increased a bit and even after 60 minutes of the operation, the pain score remained in the range of 2-4.

In a previous study by El Sharkawy R, it was reported that in patients undergoing awake fiber-optic intubation, a low dose of ketamine administered concomitantly with dexmedetomidine had a better intubation time compared to a combination of low dose ketamine and propofol. This study also reported a better sedation score and higher patient satisfaction scores among the patients who had received ketamine and dexmedetomidine combination [13]. In accordance with this study present study also reported higher patient satisfaction among the study participants.

In another study, where the efficacy of DK combination was compared with Dexmedetomidine-Midazolam-Fentanyl (DMF), it was reported that both the groups have comparable efficacy, recovery time and spontaneous eye-opening time. Moreover, the onset time and the analgesia were also comparable between both the groups [14].

Limitation(s)

In spite of various new findings described in this study, this suffers from several limitations. This study included 20 patients and the study group should have been larger. Firstly, no elderly patients were included in this study. Therefore, the effect of this drug combination on elderly patients is not clear. Secondly, no control group was employed in the study. Thus, further large cohort studies that recruit appropriate control groups are warranted to confirm the study findings. Moreover, more studies are also required to determine the

best combination and appropriate drug doses for elderly patients so that unwanted adverse events can be avoided.

Although an array of studies was conducted where ketamine and dexmedetomidine combinations were used for conducting various surgeries, not a single study was conducted in the field of middle ear surgeries. Hence, this study is one of its kind and provides great knowledge in this field.

CONCLUSION(S)

The present study showed that DK combination provides good haemodynamic stability, higher sedation score and lower pain score. In addition, this study also showed that for patients undergoing tympanoplasty surgery this is a safe and effective method of anaesthesia that provides good MAC.

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