Journal Homepage: - www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/18191
DOI URL: http://dx.doi.org/10.21474/IJAR01/18191

RESEARCH ARTICLE

COMPARISON EFECTIVENESS OF DEXMEDETOMIDINE VERSUS DEXMEDETOMIDINE WITH KETAMINE FOR TYMPANOPLASTY SURGERY DONE UNDER MONITOREDANAESTHESIA CARE

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Manuscript Info

Manuscript History
Received: 16 November 2023
Final Accepted: 21 December 2023
Published: January 2024

Key words:-
Monitored Anaesthesia Care, Ear Surgeries, Dexmedetomidine, Anaesthetic Agent

Abstract

Background: Monitored Anaesthesia Care (MAC) has been widely used for patients undergoing middle ear surgeries. The use of dexmedetomidine in middle ear surgeries as a sole anaesthetic agent had many disadvantages owing to its insufficient sedative effect, increased recovery time and haemodynamic instability.

Aims and objectives: To evaluate the effectiveness of dexmedetomidine and ketamine combination in comparison with dexmedetomidine alone for tympanoplasty surgery under MAC.

Materials and Methods: In this cross sectional observational study, a total of 100 patients were included. Before the surgery, group D received 1 µg/kg dexmedetomidine followed by infusion of 0.2µg/kg/h to maintain 2 or 3 of modified observer's assessment of analgesia and sedation score. The patients in group DK received 1 µg/kg dexmedetomidine followed by infusion of 0.2µg/kg/h plus ketamine 0.5mg/kg 10 minutes before the start of the procedure.

Results: In the present study total of 100 patients were included, among which 66.0% were females and 34.0% were males. The mean age of 100 patients was 38.3±11.34 years. There were no differences in baseline measurements of HR, SBP and DBP between the two groups, but Group DK had significant fall in heart rate (5-10%) ($P < 0.001$). Average patients' and surgeon's satisfaction with sedation and analgesia was higher in Group DK than Group D ($P = 0.001$).

Conclusion: Dexmedetomidine and ketamine combination provides good haemodynamic stability, higher sedation score with safe and effective method of anaesthesia that provides good MAC for patients undergoing tympanoplasty surgery.

Introduction:-

The ideal anaesthetic agent for middle ear surgery is one that optimizes the surgical field without excessive arterial hypotension and allows for intraoperative monitoring of facial nerve function. In addition, it should minimize the chances of excessive coughing on emergence from anaesthesia and postoperative nausea and vomiting (PONV).[1] Some of middle ear procedures can be carried out under local anaesthesia with conscious sedation.[2] The local anaesthesia improves haemostasis and allowing the surgeon to perform an intraoperative hearing assessment.[3]

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Tympanoplasty involves reconstruction of perforated tympanic membrane with or without ossiculoplasty.[4] It is usually done under local anesthesia with sedation under monitored anesthesia care (MAC) or general anesthesia. MAC is also called conscious sedation. For this process, the vitals are maintained normally without using any intervention.[5] MAC is superior to local anaesthesia in terms of analgesia with sedation, comfort and satisfaction of both patient's and surgeon. However, in few developed countries surgeons prefer under general anaesthesia (GA). Reasons for using GA include patient and surgeon preference, avoidance of pain from local anaesthetic injections, and a reduced potential for sudden patient movements, which can compromise the surgery.[1]

Dexmedetomidine is a novel alpha-2 agonist sedative and analgesic introduced in December 1999 in clinical practice. Dexmedetomdine has multiple effects such as sedation, anxiolytic effect, analgesia, decreased sympathetic activity, decreased blood pressure and heart rate, vasoconstriction at high doses with minimal respiratory depression and patients are arousable with clear consciousness. It reduces opioid requirements and stress response to surgery ensuring a stable hemodynamic state.[6] Dexmedetomidine is increasingly being used as a sedative for MAC for various surgical procedures.[7]

Ketamine is a fast-acting general anesthetic agent causing blockage of N-methyl-D-aspartate (NMDA)-receptor which produces profound analgesia, maintains normal pharyngeal-laryngeal reflexes, and causes cardiovascular stimulation. The sympatho-inhibitory effects of dexmedetomidine are balanced with the cardio-stimulatory effects of ketamine, thereby maintaining a stable hemodynamic profile within normal physiological range.[8] The downside to its use is the high incidence of emergence agitation. Both the drugs offer analgesia via different modes and their effects appear additive. They are also known to preserve dose dependent airway reflexes and spontaneous breathing, thus useful in short duration surgeries where controlled ventilation can be avoided.[9] The emergence delirium likely to occur with ketamine is negated with the sedation of dexmedetomidine.

Hence, this study aimed to evaluate the effectiveness of dexmedetomidine and ketamine combination in comparison with dexmedetomidine alone for tympanoplasty surgery under monitored anesthesia care.

Materials and Methods:-

In this cross sectional observational study, a total of 100 patients were included that came to the study centre during the period from April 2021 to Oct 2022. 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 was also obtained. Adult patients aged 18-60 years of age, from either of the gender, belonging to ASA grade I and II category, undergoing tympanoplasty and having duration of surgery up to 90 mins were included in this study. Patients refuse to give consent, pre-existing cardiac, neurological or psychiatric illness, having known hypersensitivity to study drugs, had any history of sedative drugs use, morbidly obese, pregnant, obstructive sleep apnea were excluded from the study.

Pre-anaesthetic evaluations 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 heart rate (HR), non-invasive blood pressure including both systolic and diastolic pressures was recorded. Before the operation, all patients in group D received 1 μg/kg dexmedetomidine over 10 minutes followed by infusion of 0.2μg/kg/h to maintain 2 or 3 of modified observer's assessment of analgesia and sedation score. The patients in group DK received 1 μg/kg dexmedetomidine over 10 minutes followed by infusion of 0.2μg/kg/h plus ketamine 0.5mg/kg loading dose over 10 minutes. Both the scores were checked every 10 minutes. Both ketamine and dexmedetomidine were started before the surgery. During this period the patients were assessed every two minutes using ramsay sedation score (RSS) (1 = agitated, restless; 2 = cooperative, tranquil; 3 = responds to verbal command while sleeping; 4 = brisk response to gabellar tap or loud voice while sleeping; 5 = sluggish response to gabellar tap or loud voice; 6 = no response to gabellar tap or loud voice). The target end point was a patient having RSS = 3. If the target end point was reached before completing the loading infusion, then the infusion was stopped and noted.

The HR, systolic and diastolic pressure, pain score and Ramsay sedation score (RSS) 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 Injection fentanyl 1 mcg/kg IV if required when pain score (VAS) was more than 5, in spite of dexmedetomidine and ketamine infusions. Intraoperative Hypotension (more than 30% of decrease in pre-operative BP) was treated with Crystalloids at 200 mL bolus and Injection mephenteramine 3 mg. Bradycardia (20% drop from the baseline reading) if at all occurred, was treated with Injection 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).

The data was been entered into MS-Excel and statistical analysis was done by using IBM SPSS Version 22.0. 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 100 patients were included, among which 66 (66.0%) were females and 34 (34.0%) were males. The mean age of 100 patients was 38.3±11.34 years with a range of 18 to 60 years. Out of 100 patients, 62 patients (62.0%) were in the ASA-I and 38 (38.0%) were in the ASA-II grade. 42 patients (42.0%) were scheduled for left tympanoplasty surgery, 39 (39.0%) patients for right tympanoplasty and 19 (19.0%) patients were Bilateral Chronic Serous Otitis Media.

As shown in Table 1, there was no significant difference among the groups with respect to age and sex (P > 0.05).

Table 1:- Comparison of the patient's characteristics by age and sex.

Variable	Group D (n=50)	Group DK (n=50)	P value
Age			
<30	13 (26%)	15 (30%)	0.73
30-40	25 (50%)	22 (44%)	
40-50	9 (18%)	11 (22%)	
>50	3 (6%)	2 (4%)	
Sex			
Male	18 (36%)	16 (32%)	0.54
Female	32 (64%)	34 (68%)	

The descriptive statistics of HR, systolic and diastolic pressure are shown in [Fig-1-3]. There was no statistically significant difference between the preoperative and postoperative for systolic and diastolic pressure measurements (p>0.05).

There were no differences in baseline measurements of HR, SBP and DBP between the two groups, but Group DK had significant fall in heart rate (5-10%) (P < 0.001) from 5 min after start of infusion till the end of surgery. In contrast, Group D had no significant change from baseline till end of surgery (P > 0.05). Both the groups had significant reduction in SBP and DBP from their respective baseline values, however on analyzing the magnitude of decrease, patients in Group DK had a greater fall (10-15%) in comparison to Group D (5-10%) over a period of time [Figure 1 & 2]. Inter-group comparison of MAP at similar time intervals showed no significant difference between the two groups up to the 30th min after start of infusion, subsequent to which Group DK had a lower SBP and DBP till the end of surgery (P < 0.05).

Fig 1:- Changes in mean systolic blood pressure (mmHg) over a period of time.

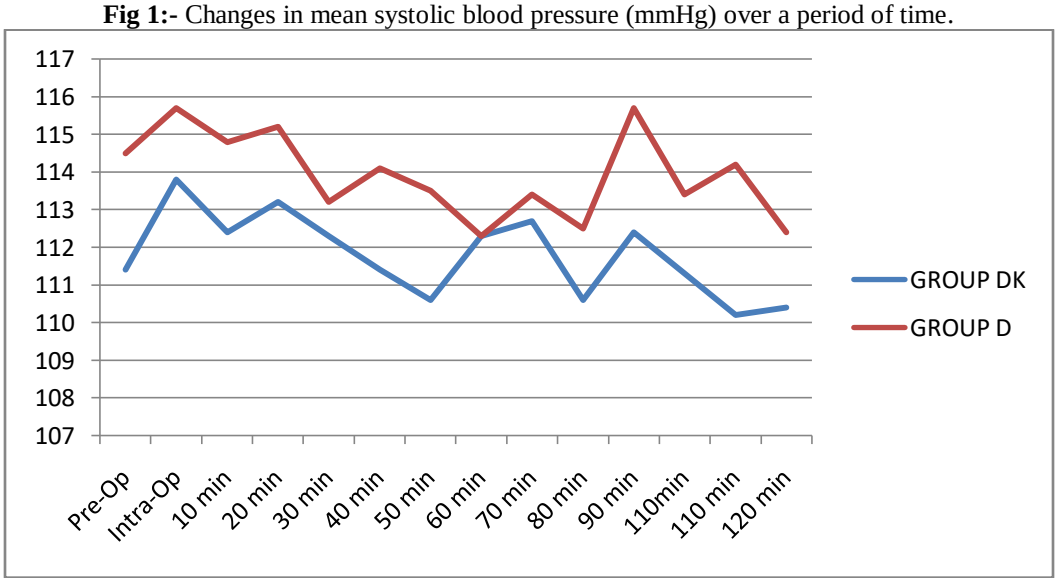
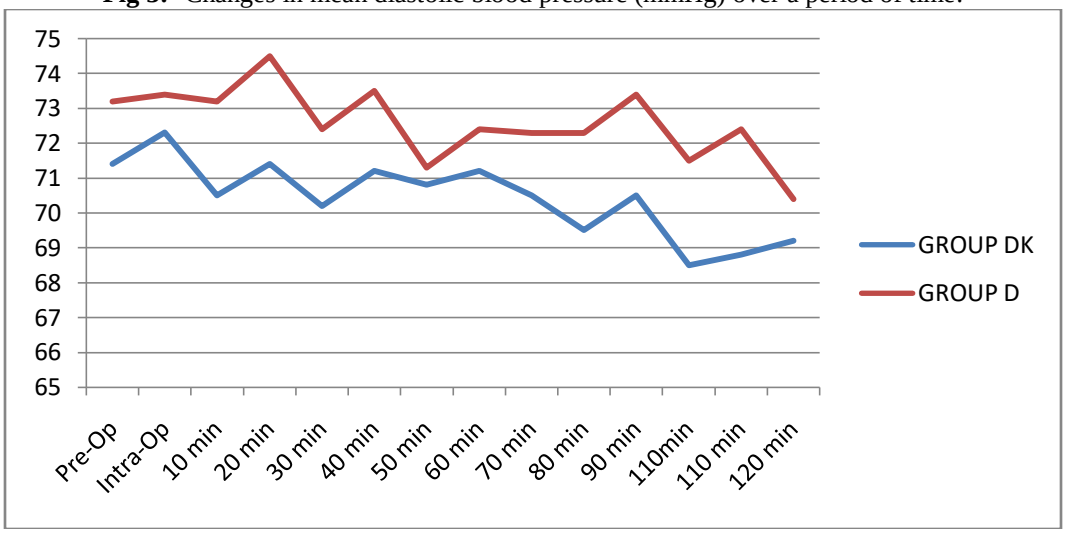


Fig 3:- Changes in mean diastolic blood pressure (mmHg) over a period of time.



The pain score was found to around 2 even after 120 minutes after the surgery (2±0.83). 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 95% of the patients. All the patients in both the groups reached RSS of 3 at the end of loading dose infusion, no additional supplementation was required. Five patients each in both the groups required stopping the loading dose infusion in the 10 minute as they had reached the target RSS of 3. No patient in either group had RSS >3 at any point during surgery. Ten patients in Group D required rescue local anesthetic infiltration in contrast to 20 in Group MF (P = 0.04). In Group D, significantly more number of patients required rescue fentanyl with 13 patients requiring one dose, four patients requiring two doses and one patient requiring three doses. In contrast only five patients in Group DK required rescue analgesic (four patients requiring one dose and one patient requiring three doses of fentanyl) (P = 0.01). The mean RSS score was significant higher in group DK (5.2±0.8) as compared to group D (4.7±0.7) (P<0.05).

Table 2:- Patient and surgeon satisfaction scores and time to postoperative rescue analgesics.

Parameters	Group D	Group DK	P value
Patients satisfaction score (1-10)	8 (6.5-9.5)	9 (8-10)	0.001
Surgeon satisfaction score (1-10)	8 (6.75-9.25)	9 (8.5-9.5)	0.001
Time until need for postoperative rescue analgesic (min)	146.45 (109.78)	155.2 (89.76)	0.5

Immediately upon arrival into the recovery room, all the patients were able to obey commands. At the end of 30 min patients in both the groups had reached RSS of 2. Time until need for postoperative analgesic was comparable in both the groups (P = 0.5) [Table 2]. Average patients' satisfaction with sedation and analgesia was higher in Group DK than Group D (P = 0.001) [Table 2]. Similarly, surgeons' satisfaction with patients' sedation and surgical conditions was higher in Group DK than in Group D (P = 0.001).

In the postoperative period 5 patients in Group DK and 8 patients in D group had nausea and vomiting which was symptomatically treated. Four had shivering and seven patients in Group D (7.8%) had dryness of mouth in contrast to two patients in Group DK group (P = 0.005).

Discussion:-

The current study evaluated the effect of DK combination on the quality of sedation/analgesia in comparison with dexmedetomidine alone. The primary outcome measured in our study was the quality of sedation/analgesia, hemodynamic variables, and satisfaction scores of patients and physician.

Tympanoplasty is a common middle ear procedure performed under both general and local anaesthesia. However, sometimes due to longer duration of procedure and frequent manipulation of instruments, , surgeons do not feel comfortable using local anaesthesia for tympanoplasty.[10] Sympathetic stimulation and intraoperative movements may leads to bleeding and disturbance of field of vision which may even lead to graft failure. However, local anesthesia offers an advantage of intraoperative hearing assessment that detects complications immediately. Good patient selection, preoperative counseling and use of appropriate sedation are important factors for success of this surgery under local anesthesia.[11]

We found that combination of dexmedetomidine and ketamine offers better hemodynamic stability analgesia with good satisfaction to both patient and physician with lesser complications.

The present randomized controlled study comparing the effectiveness of dexmedetomidine plus ketamine combination against dexmedetomidine alone is unique as a thorough literature search could not find similar studies, though a randomized controlled study of the same for awake fiberoptic nasotracheal intubation is available.[12]

The Ramsay sedation score was higher in group DK (dexmedetomidine with ketamine) when compared to group D (dexmedetomidine alone) which was statistically significant (P = 0.01). Contrast to our findings in study by Sinha et al.[12] found no significant difference between dexmedetomidine group and group ketamine in terms of RSS values (P>.05) The sedative effects of the combination of ketamine and dexmedetomidine were found to be additive at the endpoints of hypnosis and anesthesia.[13] However, Shimabukuro et al.[14] study used Ramsay sedation scale and their patients were sedated in the scale of 2-4 and were very cooperative during the procedure, which is similar to the sedation levels achieved by our study subjects.

Previous studies have shown that MAC is a good method in surgeries that requires intraoperative evaluation of patients.[15,16] 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.[15]

In our study, we found that the heart rate and blood pressure was lower in group DK as compared to group D. This could be explained by the markedly decreased sympathetic activity in these patient group.[17] Our results suggest that dexmedetomidine with ketamine has clinical advantage over dexmedetomidine alone in providing a better operative field for microscopic surgery. Durmus et al.,[18] have evaluated this property of dexmedetomidine for providing controlled hypotension in general anesthesia for tympanoplasty cases and concluded that it is a useful adjuvant to decrease bleeding when a bloodless surgical field is required.

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. Our study reported that the average patients' and surgeons' satisfaction with sedation and analgesia was higher in Group DK than Group D (P = 0.001). This study also reported a better sedation score and higher patient satisfaction scores among the patients who had received ketamine and dexmedetomidine combination.[19] In accordance with this study present study also reported higher patient satisfaction among the study participants. The lower HR and BP in these patients could have probably resulted in a

better surgical field thus attributing to better surgeon satisfaction. Moreover, surgeons are satisfied if there is no patient movement during surgery.

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.[20] Similar findings have been reported by K. Karaaslan et al.,[21] where Group dexmedetomidine used significantly less rescue tramadol in comparison to Group midazolam when both the drugs were compared in FESS and nasal septoplasties.

A possible limitation of this study could be that amnesia scoring and cognitive function testing for psychomotor impairment was not done as early discharge of the patients was not a concern of this study. Another limitation could be that the effects of the drugs were seen only in ASA I/II patients. The effects of α2 agonists on the vitals may be beneficial in high-risk patients.

Conclusion:-

Dexmedetomidine in combination with ketamine offers an advantage of better sedation and hemodynamic stability in tympanoplasty surgery under monitored anesthesia care as compared to dexmedetomidine alone. It is associated with better patient and surgeon satisfaction and lesser complications. However hemodynamic parameters need to be closely monitored.

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