Section: Anaesthesia

Original Research Article

COMPARATIVE ANALYSIS OF DEXMEDETOMIDINE AND PROPOFOL FOR CONSCIOUS SEDATION IN MIDDLE EAR SURGERIES UNDER MONITORED ANAESTHESIA CARE: AN INSTITUTIONAL BASED STUDY

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Abstract

Background: Tympanoplasty, stapedectomy, and mastoidectomy are frequently performed surgical procedures on the middle ear. The aim of the current investigation was to evaluate and contrast the efficacy of dexmedetomidine and propofol in providing conscious sedation during middle ear surgery while under monitored anaesthesia care. **Materials and Methods:** The current investigation was carried out on a study sample of 80 individuals of both genders. Prior to anaesthesia administration, all patients underwent a thorough pre-anesthetic evaluation, which included a detailed clinical history, a comprehensive general and systemic examination, as well as routine and specialised investigations. The variables of interest in this study include heart rate, mean arterial pressure, Aldrete score, patient satisfaction with the quality of sedation/analgesia, and surgeon satisfaction with patient sedation. The entirety of the qualitative data was subjected to analysis. A statistically significant result was determined by a P value of less than 0.05. **Result:** The group I patients exhibited a shorter duration of surgery, specifically 85.52±25 minutes. The group II patients demonstrated a shorter time to attain satisfactory sedation, with a mean of 10.54±2.8 minutes. The level of satisfaction reported by patients and surgeons was higher in group I. The group II participants demonstrated a shorter duration of time to attain an Aldrete Score of 10, with a mean of 39.49±5.68 minutes. A notable dissimilarity was observed between the two groups with respect to the Time required to attain satisfactory sedation and the Level of patient contentment. The hemodynamic stability of patients was maintained during the surgical procedure, with Group I exhibiting lower mean arterial pressure (MAP) and heart rate values compared to Group II. **Conclusion:** The research findings indicate that the utilisation of dexmedetomidine resulted in higher levels of satisfaction among both patients and surgeons. The hemodynamic stability of the patients was maintained during the surgical procedure, wherein the administration of dexmedetomidine resulted in a decrease in mean arterial pressure and heart rate.

INTRODUCTION

The auditory system holds significant importance in the realm of human sensory organs.[1] Middle ear disorders have the potential to manifest in individuals across all age groups, ranging from young children to the elderly. Various surgical interventions may be necessary to address certain medical conditions, such as stapedectomy, tympanoplasty for otosclerosis, tympanoplasty for reconstructive surgery of the tympanic membrane, and mastoidectomy for cholesteatoma.[2] Typically, the majority of middle ear surgeries are performed utilising local anaesthesia. Several benefits have been documented when surgeries are performed under local anaesthesia, including decreased bleeding, cost efficiency, prompt recuperation, and postoperative pain relief. In addition, the evaluation of auditory enhancement can be conducted intraoperatively in individuals who have undergone stapedectomy procedures. One of the primary sources of patient discomfort during local anaesthesia is anxiety

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induced by surgical noise, which can be exacerbated by the use of a burr for bone drilling. Additionally, patients may experience dizziness and discomfort due to the positioning of their head and neck during the procedure. The American Society of Anesthesiologists (ASA) has defined Monitored Anaesthesia Care (MAC) as a distinct anaesthesia service intended for diagnostic or therapeutic procedures performed under local anaesthesia with the addition of sedation and analgesia.[3,4] The standard practise of Monitored Anaesthesia Care (MAC) entails the concomitant administration of local anaesthesia and intravenous sedatives, anxiolytics, and/or analgesics.[5] Dexmedetomidine is a centrally acting alpha-2 agonist that exhibits analgesic and conscious sedative properties, while avoiding respiratory depression. Dexmedetomidine exhibits sympatholytic properties and has the ability to mitigate the stress response to surgical procedures, thereby preserving hemodynamic stability.[6,7] Propofol is a frequently utilised pharmacological agent for achieving sedation in the context of monitored anaesthesia care (MAC). Propofol is a sedative-hypnotic agent that has an ultrashort-acting nature, characterised by a rapid onset of action, high potency, and an extremely short recovery time. Patients tend to express high satisfaction levels with the drug due to its antiemetic and euphoric properties.8 The objective of the current investigation was to conduct a comparative analysis of dexmedetomidine and propofol in terms of their efficacy as agents for conscious sedation during middle ear surgery under monitored anaesthesia care.

MATERIALS AND METHODS

The current investigation was carried out on a study sample of 80 individuals of both genders. Prior to the initiation of the investigation, authorization was procured from the institutional review board. The participants were required to provide a comprehensive written informed consent prior to their participation in the study. The study included individuals who met the following criteria: American Society of Anesthesiologists Grade (ASA) 1 or 2, aged between 18 and 60 years, and undergoing middle ear surgery while under local anaesthesia. Individuals who exhibit hypersensitivity to local anaesthetic agents, specifically lignocaine, propofol, or dexmedetomidine, as well as pregnant and lactating women, and those who have contraindications to regional anaesthesia, such as patients who refuse local anaesthesia, those with clotting abnormalities, and individuals with severe cardiac and pulmonary diseases, should be excluded from consideration for this procedure. The study excluded patients who had hepatic or renal insufficiency, endocrine and metabolic disorders, as well as those who had a history of using any sedative medication within one week prior to the surgery. Prior to anaesthesia administration, all patients underwent a thorough pre-anesthetic evaluation consisting of a detailed clinical history, comprehensive general and systemic examination, as well as routine and specialised investigations. The process of intravenous access was established and a solution of Ringers Lactate was initiated. A flow rate of 2 L/min was utilised to administer oxygen through a nasal cannula. The study involved performing regular monitoring using electrocardiogram, SpO2, and non-invasive blood pressure recordings. Premedication was administered to all patients in the form of injection glycopyrrolate 2mg and injection fentanyl 1 ug/kg. The study participants were allocated into two groups through a random stratification process, with each group consisting of an equal number of patients. The first group was assigned to receive dexmedetomidine. A loading dose of 1 microgram per kilogramme was administered to the subjects over a period of 10 minutes, followed by a continuous infusion at a rate of 0.4 micrograms per kilogramme per hour during the surgical procedure. The dexmedetomidine was diluted in 0.9% normal saline to achieve a target concentration of 4 micrograms per millilitre. The experimental group designated as Group II was administered propofol. The subjects were administered a loading dose of intravenous propofol at a rate of 75 micrograms per kilogramme per minute over a period of 10 minutes, followed by a continuous infusion at a rate of 50 micrograms per kilogramme per minute throughout the surgical procedure. Following the attainment of a Ramsay Sedation Scale score of 3, the surgical site was infused with a solution of lignocaine and adrenaline (1:200,000). The surgical procedure was initiated subsequent to verifying the adequacy of pain relief. The assessment of pain was conducted using a 10-point verbal scale. The following measures were assessed:

1. During the surgical procedure and subsequent postoperative period, the patient's heart rate and mean arterial pressure were monitored at 5-minute intervals and 15-minute intervals, respectively, until the patient was discharged from the Post Anaesthesia Care Unit (PACU).
2. The Aldrete score was evaluated at 10-minute intervals until the patient's discharge from the recovery room. Patients were deemed eligible for discharge upon achieving an Aldrete score of 10.
3. Prior to being discharged from the Post-Anesthesia Care Unit (PACU), patients were instructed to assess their satisfaction with the quality of sedation and analgesia provided using a seven-point Likert scale.

Following the completion of the surgical procedure, the surgeon was instructed to utilise the Seven Point Likert Like Verbal Rating Scale to assess their level of endorsement regarding patient sedation.

In cases where a patient's level of sedation was deemed insufficient and they reported experiencing pain, a rescue dose of fentanyl at a rate of 1 microgram per kilogramme of body weight was administered. Patients who required multiple doses of

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rescue analgesic were excluded from the study. A volume of 500 millilitres of Ringer Lactate solution was administered to all patients until the surgical procedure was concluded. Following the surgical procedure, an evaluation was conducted to determine the extent of bleeding in the surgical field. Following the surgical procedure, the administration of the investigational drug was ceased and the patients were subsequently transferred to the Post Anaesthesia Care Unit (PACU) for a minimum duration of one hour. Prior to discharge to the postoperative ward, the patients' Aldrete score was assessed to ensure that it reached a value of 10. The Chi Square Test was employed to analyse the qualitative data, while the students unpaired t test was utilised to analyse the quantitative data. The mean value along with the standard deviation (SD) was utilised to express the outcomes. A statistically significant result was determined by a p-value of less than 0.05.

RESULTS

The group I patients exhibited a shorter duration of surgery, specifically 85.52±25 minutes. The group II patients demonstrated a shorter time to attain sufficient sedation, with a mean of 10.54±2.8 minutes. The level of satisfaction reported by patients and surgeons was higher in Group I. The group II participants demonstrated a shorter duration of time to attain an Aldrete Score of 10, with a mean of 39.49±5.68 minutes. A notable disparity was observed between the two groups in terms of the Time to achieve adequate sedation and Degree of patient satisfaction.

The hemodynamic stability of patients was maintained throughout the surgical procedure, with Group I exhibiting a lower mean arterial pressure (MAP) as compared to Group II.

The hemodynamic stability of patients was maintained throughout the surgical procedure, with Group I exhibiting a lower heart rate than Group II.

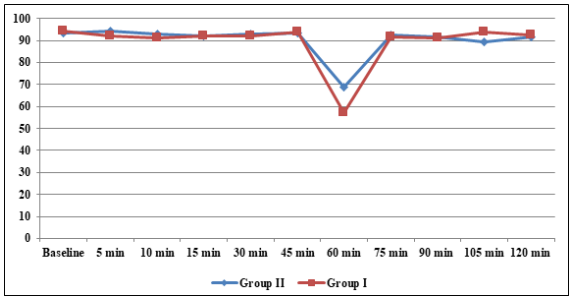

Figure 1: Mean Arterial Pressure intraoperatively and postoperatively

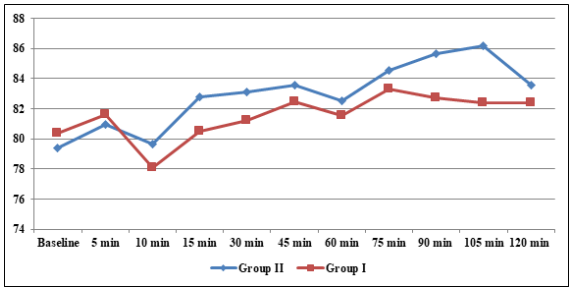

Figure 2: Mean Heart Rate intraoperatively and postoperatively

Table 1: Comparison of different parameters between two groups

Variable	Group I	Group II	p-value
Duration of Surgery (minutes)	85.52±25	91.4±34	>0.05
Time to achieve adequate sedation (minutes)	16.78±2.6	10.54±2.8	<0.05
Degree of patient satisfaction (7-point Likert Scale)	6.84+-1.34	5.5+-2.43	<0.05
Degree of surgeon satisfaction (7-point Likert Scale)	6.65±3.58	6.28±0.29	>0.05
Time to achieve Aldrete Score of 10 (minutes)	42.28±5.59	39.49±5.68	>0.05

DISCUSSION

Tympanoplasty and modified radical mastoidectomy procedures are typically performed on adult patients utilising either local anaesthesia or local anaesthesia in conjunction with sedation under monitored anaesthesia care (MAC). The application of MAC is relevant in diverse ENT surgical procedures where the provision of satisfactory sedation and analgesia, while avoiding respiratory depression, is crucial for the well-being of both the patient and the surgeon.[9,10]

The group I patients exhibited a shorter duration of surgery, specifically 85.52±25 minutes. The group II patients exhibited a shorter time to attain satisfactory sedation, with a mean of 10.54±2.8 minutes. The level of satisfaction reported by patients and surgeons was higher in group I. The group II participants demonstrated a shorter duration of time to attain an Aldrete Score of 10, with a mean of 39.49±5.68 minutes. A notable disparity was observed between the two groups with regards to the Time required to attain satisfactory sedation and the Level of patient contentment. The hemodynamic stability of patients was maintained during the surgical procedure, with Group I exhibiting lower mean arterial pressure and heart rate as compared to Group II.

The study conducted by Goel L et al revealed that both dexmedetomidine and propofol were effective in providing sufficient sedation. However, propofol was associated with a higher requirement for rescue analgesia and lower levels of patient satisfaction. The findings suggest that dexmedetomidine can offer satisfactory sedation and analgesia, while ensuring favourable outcomes for both the surgeon and patient, without any negative impact on patients undergoing middle ear surgery under local anaesthesia.[11]

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The study conducted by Nallam SR and colleagues determined that the administration of a combination of Nalbuphine and Dexmedetomidine is more effective than the combination of Nalbuphine and Propofol in inducing sedation and reducing Visual Analogue Scale (VAS) scores among patients undergoing monitored anaesthesia care during minor endoscopic surgeries. The administration of nalbuphine/dexmedetomidine was associated with enhanced surgical outcomes and increased patient satisfaction. The monitoring of haemodynamics is of paramount importance.[9]

According to the study conducted by Hembram B et al, Dexmedetomidine is a more effective sedative than propofol and can be administered safely during middle ear surgeries with minimal impact on the patients' hemodynamic stability. The administration of dexmedetomidine has been observed to yield analgesic effects, leading to a decrease in the need for additional analgesic interventions among patients. The majority of patients expressed contentment with the administration of anaesthesia utilising dexmedetomidine. The observed adverse reactions resulting from the interaction of the two drugs were deemed to be negligible. Hence, dexmedetomidine has the potential to serve as a viable substitute for propofol in the sedation of individuals undergoing middle ear surgical procedures.[12]

The study conducted by Eram SA et al demonstrated that the combination of Dexmedetomidine and midazolam was superior to the combination of nalbuphine and midazolam in terms of sedation, analgesic efficacy, and satisfaction of both the patient and the surgeon.[13]

CONCLUSION

The research findings indicate that the utilisation of dexmedetomidine resulted in a higher level of satisfaction among both patients and surgeons. The hemodynamic stability of the patients was maintained during the surgical procedure, wherein the administration of dexmedetomidine resulted in a decrease in mean arterial pressure and heart rate.

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