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Research Article

Comparative study between dexmedetomidine/nalbuphine and midazolam/nalbuphine in monitored anesthesia care during ear surgery

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KEYWORDS

Dexmedetomidine;
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Monitored anesthesia care;
Ear surgery

Abstract *Background:* Monitored anesthesia care (MAC) is the practice of administrating local anesthesia in combination with IV sedatives, anxiolytics and/or analgesic drugs during certain surgical procedures. Most of ear surgeries can be done under monitored anesthesia care.
Methodology: This is a randomized, double blind, prospective study and 100 patients undergoing ear surgery under MAC were divided into two groups of 50 patients each. The patients in group (*D*) received dexmedetomidine 1 μg/kg IV over 10 min followed by 0.7 μg/kg/h + nalbuphine 100 μg/kg IV and in group (*M*) received midazolam 20 μg/kg IV followed by 20 μg/kg/h + nalbuphine 100 μg/kg over 10 min. Assessment of sedation by Ramsay sedation score, requirement of intraoperative rescue sedation, intraoperative VAS, intraoperative rescue analgesia, intraoperative hemodynamics, intraoperative bleeding, intraoperative complications, postoperative visual analogue score and postoperative rescue analgesia requirement, time to achieve full recovery and satisfaction scores of patients and surgeon were recorded.
Results: Group (*D*) showed more sedation by Ramsay sedation score than the midazolam (*M*) group. Fifty percent in group (*M*) needed more rescue sedation than 26% in group (*D*) ($p < 0.05$). Intraoperative VAS was significantly higher in group (*M*) than in group (*D*) that led to the use of more rescue analgesia in 60% of group (*M*). Intraoperative heart rate and mean blood pressure were significantly lower in group (*D*) than in group (*M*) ($p < 0.05$). There was no statistical difference between the two groups as regards respiratory rate or SpO_2. Intraoperative bleeding is less significantly less in group

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(*D*). Intraoperative hypotension was significantly higher in group (*D*) (30%) than in group (*M*) (20%). Bradycardia was insignificantly higher in group (*D*). As regards postoperative VAS, group (*D*) was significantly lower than group (*M*). This led to the use of more rescue analgesia in 94% of group (*M*). There was no statistically significant difference between the two groups as regards recovery time. Patient's satisfaction was significantly higher in group (*D*) (80%) compared with group (*M*) (60%) ($p > 0.05$). The same as regards doctor's satisfaction where satisfaction was significantly higher in group (*D*) (76%) than in group (*M*) (54%).

Conclusion: We concluded that the combination of dexmedetomidine/nalbuphine is a better alternative to midazolam/nalbuphine in MAC since it provides analgesia, amnesia and sedation with better intraoperative and postoperative patient satisfaction with better surgical field exposure.

1. Introduction

According to the American Society of Anesthesiologists (ASA), a monitored anesthesia care (MAC) is a planned surgical procedure during which surgery is performed under local anesthesia together with sedation and analgesia [1]. The 3 essential elements and purposes of a conscious sedation during a MAC are as follows: safe sedation, control of the patient anxiety and analgesia [2]. Most of ear surgeries can be done under monitored anesthesia care. It is essential for such delicate procedures to have a bloodless surgical field which can be provided by the addition of vasoconstrictor agent (usually epinephrine) to the local anesthetic infiltration and avoiding pain and anxiety [3].

Drugs that can be used during monitored anesthesia care should be chosen according to the type and time of surgical procedure, patient's medical and psychological conditions and experience of the anesthetic team [4]. Many drugs can be used for sedation during surgery under local anesthesia with monitored anesthesia care including opioids, benzodiazepines and propofol [5]. However, propofol may cause respiratory embarrassment [6]. Benzodiazepines may result in confusion and subsequent agitation, particularly in old age [7] and opioids are associated with increased risk of respiratory depression and oxygen desaturation [8]. Using combination of two agents can provide better patient control and allows the use of smaller doses of each single agent avoiding its undesirable effects.

Midazolam is a benzodiazepine which has sedative and anxiolytic activities, provides anterograde amnesia, and has anticonvulsant properties [9].

Alpha-2 adrenoreceptors agonists i.e. clonidine and dexmedetomidine are increasingly used for their sedative, analgesic, sympatholytic and cardiovascular stabilizing effects [10].

Nalbuphine is an agonist–antagonist opioid that is structurally related to oxymorphone and naloxone. Autoradiography studies indicate that nalbuphine binds to μ receptors as well as to $\hat{e}$ and $\ddot{a}$ receptors. Nalbuphine acts as an antagonist at the μ receptor and an agonist at the $\hat{e}$ receptor. Activation of supraspinal and spinal μ receptors results in limited analgesia, respiratory depression, and sedation [11].

2. Patients and methods

The study was conducted in Ain Shams University hospitals at the ENT surgical department. After institutional Ethics Committee approval, informed written consent was taken from each patient included. This study was designed as a randomized, double blind clinical trial.

Patients who were scheduled for elective ear surgeries under local anesthesia like tympanoplasty, myringoplasty or stapedectomies were included in this study. Exclusion criteria were hypertension, renal impairment, advanced liver disease, history of alcohol or drug abuse, or allergy to any of the study medications. Using a computer-generated program, 100 patients were randomly divided into two groups of 50 patients each to receive either dexmedetomidine/nalbuphine (group (*D*)) or midazolam/nalbuphine (group (*M*)) for sedation and analgesia during surgery. To follow the double blind nature of the study, drugs were prepared by an independent anesthesia technician and diluted to a fixed volume for every single drug used. The anesthesiologist who attended the surgery and recorded the data was also blind to both groups assigned.

Baseline heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), peripheral oxygen saturation (SpO_2) values were obtained using standard monitors. Intravenous cannula 22 gauge was inserted. Group (*D*) patients received dexmedetomidine 1 μg/kg IV over 10 min followed by 0.7 μg/kg/h + nalbuphine 100 μg/kg IV and group (*M*) patients received midazolam 20 μg/kg IV over 10 min followed by 20 μg/kg/h + nalbuphine 100 μg/kg. Local anesthetic infiltration was given by the operating surgeon, who was unaware of the group allocation, using lidocaine 1% with adrenaline 1:200,000. Paracetamol infusion 1gm was given to all patients.

After that, level of sedation was assessed using Ramsay Sedation Score (RSS). The desired sedation level was defined as RSS $\geqslant 3$. If RSS was less than 3, rescue sedation with propofol 100–200 μg/kg/h IV was given. Then surgeon proceeded to perform the surgery under local anesthesia. Intraoperative visual analogue scale (VAS) was measured. Whenever patient complained of pain during the surgery, the surgeon used an additional dose of local anesthetic.

Heart rate (HR), mean arterial pressure (MAP), respiratory rate(RR), and peripheral oxygen saturation (SpO_2) were recorded every 10 min till 60 min. Intraoperative bleeding was assessed by bleeding scale (0–4), acceptable bleeding score being 0–2, if bleeding score > 2 propofol was given.

All adverse events like bradycardia (HR < 55 beats/min), hypotension (MAP < 50 mmHg sustained for > 10 min), respiratory depression (respiratory rate < 10 bpm), oxygen desaturation (SpO_2 < 90%), nausea or vomiting were recorded.

After completion of the surgery patients were transferred to the recovery room where the following were done:

- Assessment of postoperative pain using Visual Analogue Scale (0–10 cm); if VAS was > 3, analgesia was provided with intravenous tramadol 0.5–1 mg/kg.