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Comparison between dexmedetomidine versus magnesium sulfate infusions for mitigating emergence agitation in obese adults undergoing nasal surgery

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Abstract

Background: Emergence agitation is a potentially serious post-anesthetic event occurring in the early phase of recovery from general anesthesia, characterized by anxiety, disorientation, violent, and irrational behavior. Many agents have been used as prophylaxis with varying degrees of success. The purpose of this study was to compare the efficacy and safety of dexmedetomidine to magnesium sulfate in mitigating emergence agitation. Patients were randomly allocated to one of three groups of 35 each. Dexmedetomidine group (D group) received intraoperative Dex 0.7 µg/kg/h infusion (no loading dose). The magnesium sulfate group (M group) received intraoperative magnesium sulfate 20 mg/kg/h infusion (no loading dose). The control group (C group) received equal volume of saline infusion as placebo.

Results: The total incidence of emergence agitation was significantly lower in group D, 5.6% and group M, 8.5% compared to control group, 54.2%. The median time to extubation was significantly longer in group D than C and M groups (13, 7, and 8, respectively) and was not significantly different between group C and M. During recovery, the number of patients who experience pain was significantly lower in D and M groups compared to patients in control group ($P < 0.002$). The total dose of rescue analgesic was also significantly lower in D and M group versus control group ($P < 0.001$).

Conclusions: Dexmedetomidine and magnesium sulfate infusion are both equally effective in reducing the incidence of emergency agitation in obese adults undergoing nasal surgery. Extubation time and post-operative anesthesia care time were rather longer in dexmedetomidine than other groups.

Trial registration: Registered with [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier: NCT04531371

Background

Agitation during emergence from general anesthesia is a potentially serious phenomenon that has not been studied in adults as often as in pediatric population (Yu et al., 2010).

When agitation, serious self-injury, or violence towards the medical team occur, with the risk of aspiration,

bleeding, hypoxia, arrhythmias, or simply pulling the endotracheal tubes, removal of drains or catheters (Hudek, 2009). Moreover, agitated patients are not only at risk of developing complications but also, they are labor-intensive as they require more medical attention, rescue drugs, and more attending staff till agitation attack safely subside (Veyckemans, 2001). Recognized risk factors to develop emergence agitation (EA) in adults include ear, nose, and throat (ENT) surgery, obesity, benzodiazepine pre-medication, sevoflurane anesthesia, endotracheal tube, and history of psychological illness (Kim et al., 2015). In

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adults, adjuvants have been co-administered with general anesthesia in order to negate or reduce the incidence of EA especially in patients with identified risk factors (Mason, 2017).

Magnesium sulfate is a drug that is familiar to anesthesiologists as it has been used for decades in the management of hypertensive diseases of pregnancy (pre-eclampsia and eclampsia), status asthmaticus, and arrhythmias (torsade's de pointes) (Do, 2013). Recently, published reports have shown that magnesium sulfate may enhance post-operative analgesia, sedation, minimize post-operative agitation, and provide smooth recovery after general anesthesia (Bujalska et al., 2017).

Likewise, dexmedetomidine (Dex), a highly selective α_2 sympatholytic, has been proposed as an attractive candidate for the prophylaxis of EA. By interacting with α_2 receptors in locus coeruleus of the pons, Dex exerts its unique anxiolytic, sedative and sympathetic antagonistic action with no respiratory depression. Moreover, it has pain-modulating effect due to interaction with α_2 receptor sites in the dorsal horn and supra-spinal regions (Lepouse et al., 2006).

Nevertheless, there have been conflicting data about Dex optimal dose and time of administration when used as prophylaxis against EA. Indeed, different dosing protocols are associated with over sedation, prolonged extubation time, and delayed PACU time (Zhu et al., 2015; Aldrete & Kroulik, 2007).

The main objective of our study was to compare both dexmedetomidine and magnesium sulfate as regards their efficacy in mitigating the incidence of EA in obese adults undergoing nasal surgery. Furthermore, hemodynamic changes, pain scores, extubation time, post-operative anesthesia care (PACU) time, and adverse events were compared.

Methods

After approval by ethical committee and obtaining informed consents, 105 American Society of Anesthesiologist (ASA) II, obese adults with body mass index (BMI) ≥ 30 aged 18–60 years, booked for elective nasal surgery, were included in this placebo controlled randomized double-blind study. Exclusion criteria included significant comorbidity like hepatic, renal, or cardiac disease; auditory impairment; cognitive dysfunction; substance abuse; allergy to the studied medicines; and planned intensive care admission right after the surgery.

Patients were randomly allocated to one of three groups of 35 each. Dexmedetomidine group (D group) received Dex 0.7 $\mu\text{g}/\text{kg}/\text{h}$ infusion (no loading dose). The magnesium sulfate group (M group) received magnesium sulfate 20 $\text{mg}/\text{kg}/\text{h}$ infusion (no loading dose). The control group (C group) received equal volume of saline infusion as placebo. The duration of the infusion was similar to the duration of anesthesia as all infusions

started with the induction and stopped when administration of general anesthetics was shut off.

Using website software, enrolled patients were randomized in a 2:1 ratio to one of three groups. Treatment allocation was assigned using randomized block design. The researcher, the surgical team, PACU team, and patients were masked to group allocation. The anesthesiologist who prepared the drugs in question was different from the one who administered it and collected clinical data.

Our primary end point was occurrence of emergence agitation. It was defined as Richmond Agitation Sedation Scale (RASS) of $\geq +1$ RASS monitored up to 5 min after extubation (during the time interval from turning off anesthetics to 5 min after extubation). RASS is a 10-point scoring system used to assess patient's level of agitation and sedation: 4 levels for agitation, 1 level for normal (alert and calm), and 5 levels of sedation. Midazolam 2 mg/iv was used as rescue medication for agitation, repeated incrementally.

Secondary end points included the following: hemodynamics, in the form of mean arterial blood pressure (MAP) and heart rates (HR) during the time interval from induction of anesthesia till discharge from post-anesthetic care unit (PACU); extubation time, defined as time interval between shutting off anesthetics to extubation; PACU time, time interval from admission to PACU till patient scored ≥ 9 on Aldrete scale (ready to discharge); pain, defined as numerical rating score (NRS) of ≥ 4 and was measured every 10 min; total amount of rescue analgesic, diclofenac 75 mg intramuscularly; and adverse events. PONV were monitored and ondansetron 4 mg was the rescue medication.

Premedication was achieved with midazolam 0.05/ kg IM and 0.2 mg of atropine i.v., 30 min and 5 min before the induction of anesthesia, in the mentioned order.

Basic general anesthesia monitoring included electrocardiogram, pulse oximetry, non-invasive arterial pressure, and capnography, were recorded every 5 min.

Preoxygenation with 100% oxygen for 5 min was performed before fentanyl 1 $\mu\text{g}/\text{kg}$ and propofol 1.5–2 mg/kg , were administered as induction agents. Intubation with facilitated with rocuronium bromide 0.6–0.8 mg/kg . The size of endotracheal tubes was 6.5–7.5 mm, for females and males, respectively. Mechanical ventilation was set on 8 ml/kg tidal volume, and respiratory rate was adjusted to keep end-tidal CO_2 between 35 and 40 mmHg , in 50% O_2/air . All patients at induction were given dexamethasone 4 mg i.v., ondansetron, 4 mg i.v., and metoclopramide 10 mg to prevent post-operative nausea and vomiting, plus Ringers lactate solution 6 mg/kg drip for basic volume maintenance. Blood loss was compensated for with Ringers lactate, intraoperatively.

Maintenance of anesthesia was carried out with Sevoflurane, regulated at 2–3%, adjusted to minimal alveolar

concentration (MAC) at 1.75. Titrated incremental doses of atropine 0.5 mg, esmolol 10 mg, and ephedrine 6 mg were given i.v., when $HR \leq 45$, $HR \geq 120$ and $MAP \leq 60$, in the mentioned order. Diclofenac 75 mg was given I.M., at the time of nasal packing. When surgery was finished, gentle suction was attempted, and train of four using peripheral nerve stimulator was serially checked to monitor recovery of neuromuscular function and accordingly non-depolarizing muscle relaxant reverse with atropine, 0.5 mg and neostigmine 0.02 mg/kg was given. Next, sevoflurane was turned off together with studied infusions (saline, Dex and magnesium sulfate) and respiration was then converted back to manual ventilation with 100% oxygen at 7 L/min. The patients were not disturbed, except by continual verbal requests to open their eyes. All other stimuli were prevented. Extubation was done when patients were able to breathe spontaneously and interact with verbal demands. When patients were awake, calm, and sedated, they were transferred to the PACU. Patients were discharged from the PACU when their Aldrete score was ≥ 9 .

We calculated sample size based on the primary outcome of our trial, incidence of emergence agitation and we took in consideration prior publication, that reported the incidence of emergence agitation in adults undergoing ear, nose, and throat surgery was 55.4% (Kim et al., 2013). We assumed that the effect size would be 50% for Dex and magnesium sulfate (50% reduction of incidence). Thus, a minimum sample size of 105 patients (35 in each arm), were needed to obtain 80% power, considering α -error of 0.05 (statistically significant p value, using one-way ANOVA test). Continuous data was assessed using Shapiro–Wilk test and expressed as number (%), mean with 95% confidence interval and median with range. Independent t test was used to calculate parametric variables, and Mann–Whitney U test, for non-parametric variables. Categorical data were evaluated using the chi-square or Fisher's exact test. When statistically significant difference was detected among the three studied groups, post hoc calculation of comparisons between pairs of studied arms using Wilcoxon Mann-Whitney's U test, $P < 0.017$ was statistically significant. To counteract the problem of multiple comparisons, post hoc Bonferroni's corrected P value was applied ($p < 0.05/\text{number of comparisons}$). Intraoperative and post-operative adverse events were analyzed using chi-square test. Statistical analyses were calculated using SPSS software, version 23.

Results

Initially, we enrolled 145 patients to evaluate for eligibility and ended up with 105 patients, assigned randomly to 3 groups, 35 each. All patients received the allocated interventions and their data were analyzed

(Fig. 1). Patient characteristics data showed no statistical notable difference concerning: age, sex, BMI, height, duration of surgery, and anesthesia ($p > 0.05$) (Table 1). MAP and HR throughout anesthesia and emergence (Fig. 2), were compared among the studied groups. They showed similar trends intraoperatively; however, MAP in the D group demonstrated lower values, statistically insignificant though during and towards the end of operation and extubation, than C and M groups. Likewise, HR (Fig. 2) B showed stable fluctuating tendency among the groups, during the operation and towards extubation. D group demonstrated lowest value at extubation and emergence, statistically insignificant.

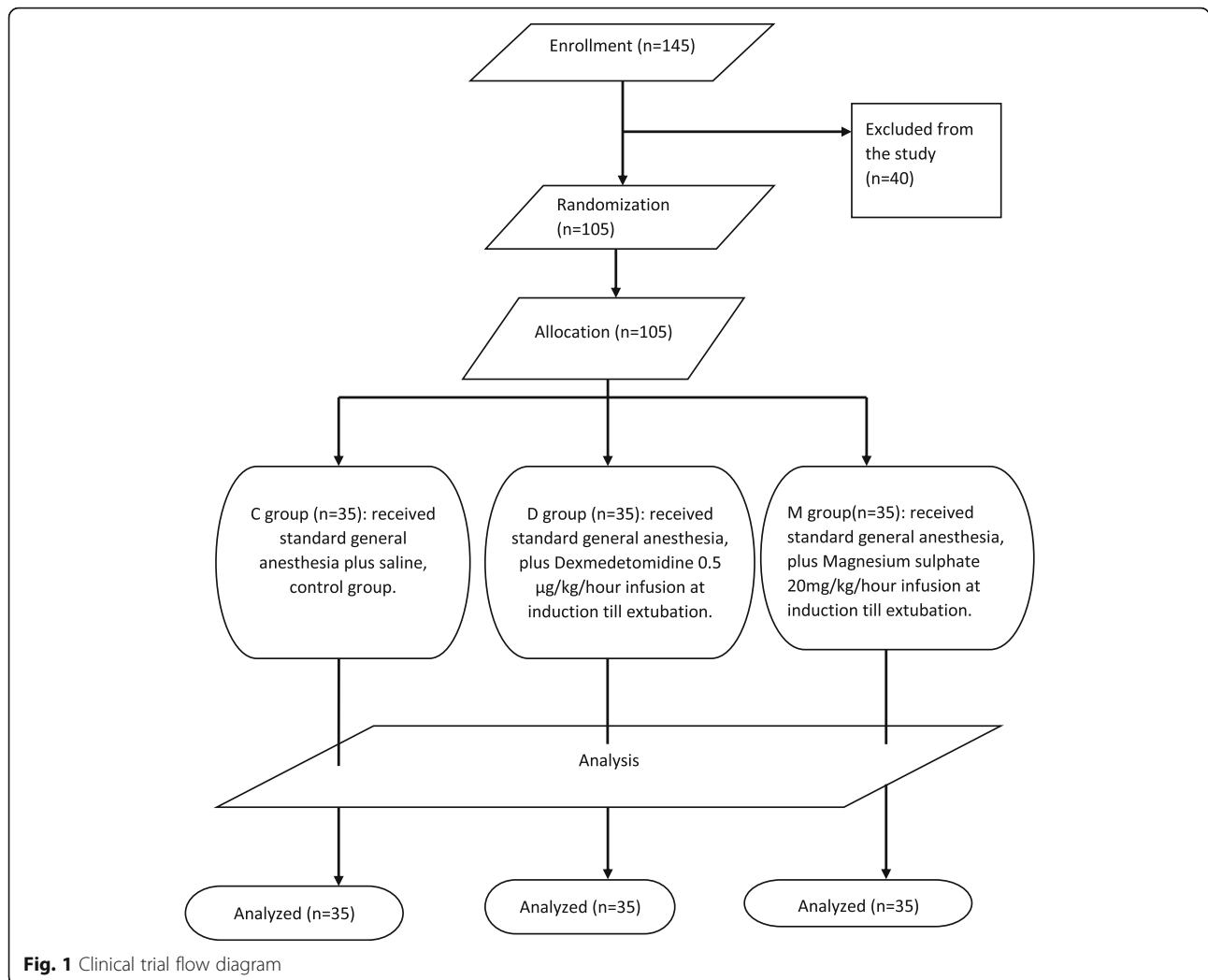
Table 2, group analysis of RASS levels, shows that the total incidence of emergence agitation was significantly lower in group D, 5.6 % and group M, 8.5 % compared to control group, 54.2%. RASS levels in the control group were distributed as follows: level + 4, combative agitated 2.85 % ($n = 1$); level + 3, very agitated 5.7% ($n = 2$); level + 2 agitated, 20% ($n = 7$), and level + 1 restless, 25% ($n = 19$). Between-group analysis of RASS agitation levels reveal that, the incidence of RASS levels + 1, + 2, and + 3 were statistically lower in D (2.85%, 2.85%, and 0%, respectively) and M groups (5.6%, 2.85%, and 0%, respectively) versus control group. Incidence of RASS level + 4 was not significantly different among studied groups.

Table 3 shows that during recovery, the number of patients who experience pain was significantly lower in D and M groups compared to patients in control group ($P < 0.002$).

As with the incidence of pain, the total dose of rescue analgesic was also significantly lower in D and M group versus control group ($P < 0.001$). Five patients in control group required rescue midazolam compared to none in group D or M ($P < 0.001$).

The median time to extubation was significantly longer in group D than C and M groups (13, 7, and 8, respectively) and was not significantly different between group C and M. Indeed, the median time to staying in PACU was also longer in group D than in C and M groups (93, 61, 63, respectively) and was not significant between C and M groups.

The complications observed during the study were less in groups D and M compared to C group (14.2%, 5.6%, and 28.5%, respectively). The incidence of coughing, desaturation, and PONV were significantly lower in D and M groups than C group ($P < 0.001$). However, the incidence of bradycardia was significantly more in group D versus C and M groups (5.6%, 2.8%, and 2.8, respectively), but was not different between group C and M. There was no statistical difference in laryngospasm between groups.



Discussion

The results of this study showed that in obese adults, anesthetized with sevoflurane undergoing nasal surgery, intraoperative dexmedetomidine 0.5 µg/kg/h infusion till extubation was as equally effective as magnesium sulfate infusion 20 mg/kg/h till extubation, in reducing the

incidence of emergence agitation compared to placebo (5.6%, 8.5%, and 54.4, respectively, $p = 0.001$). Published data, addressing emergence agitation in adults, reported conflicting array of incidences, ranging from as low as 20% up to 60% (Patel et al., 2010). Indeed, there are factors associated with increased risk of developing

Table 1 Patient characteristics

Parameter	Control (n = 35)	D group (n = 35)	Mg group (n = 35)	P value
Age (years)	41.77 ± 5.05	40.04 ± 2.45	41.03 ± 3.66	0.433
Sex (male/female)	10/25	12/23	11/24	0.09
BMI (kg/m ²)	83.46 ± 12.47	82.16 ± 9.32	81.19 ± 11.44	0.476
Height(cm)	159.14 ± 10.74	162.14 ± 10.74	161.11 ± 12.33	0.522
Duration of surgery (min)	78.61 ± 5.18	76.61 ± 5.18	79.83 ± 4.97	0.195
Duration of anesthesia (min)	85 ± 0.21	84 ± 0.21	86 ± 0.21	0.235

Data are represented as absolute number or mean ± SD

P value < 0.05 is considered significant

BMI Body mass index

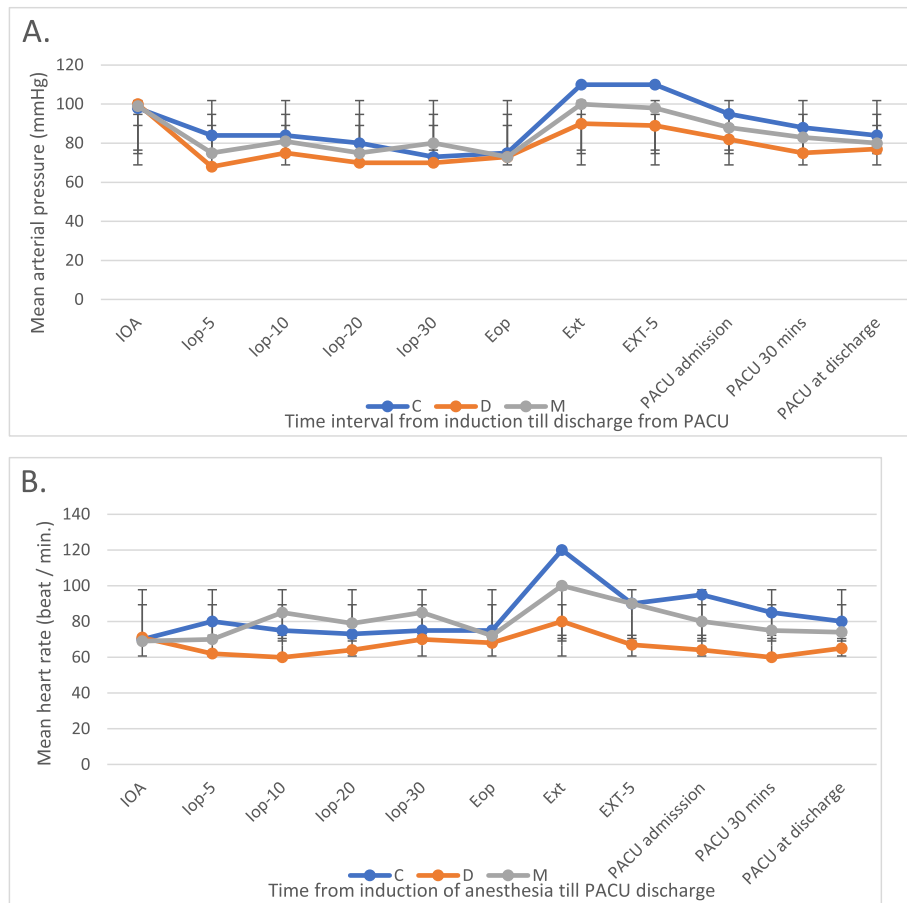


Fig. 2 Hemodynamic trends throughout anesthesia and emergence. **A** Mean arterial pressure. **B** Heart rate. IOA, induction of anesthesia; IOP-5, 5 min intraoperative; IOP-10, 10 min intraoperative; IOP-20, 20 min intraoperative; IOP-30, 30 min intraoperative; Eop, end of operation; Ext, extubation; EXT-5, 5 min after extubation; PACU admission, post-anesthesia care unit admission; PACU 30 min, 30 min in the post-anesthesia care unit; PACU at discharge, post-anesthetic care unit when the patient is ready to leave. C, control group; D, Dex group; M, magnesium sulfate group; linear C, trendline based on control group. Data shown as mean ± standard deviations

emergence agitation: male gender, BMI > 30, benzodiazepine premedication, sevoflurane inhalational anesthetics, tracheal tubes, and ear, nose, and throat surgery (Radtke et al., 2010).

In our clinical trial, we anticipated high incidence of emergence agitation as our inclusion criteria included patients who were obese BMI > 30; nasal surgery with nasal packing; endotracheal tubes were used; sevoflurane

Table 2 Incidence of emergence agitation among studied groups

RASS level		C group (n = 35)	D group (n = 35)	M group (n = 35)	P values
Level	Terms	n (%)	n (%)	n (%)	
+ 4	Combative	1 (2.85)	0 (0)	0 (0)	0.132
+ 3	Very agitated	2 (5.6)	0 (0) †	0 (0) †	0.041
+ 2	Agitated	7 (20)	1(2.85) †	1(2.85) †	0.031*
+ 1	Restless	9 (25)	1 (2.85) †	2 (5.6) †	0.012*
Total		19 (54.2)	2 (5.6) †	3 (8.5) †	0.001*

Abbreviations: n Number of patients, RASS Richmond agitation sedation score, C Control, D Dexmedetomidine, M Magnesium sulfate
Notes: Our primary end point was occurrence of emergence agitation. It was defined as Richmond Agitation Sedation Scale (RASS) of ≥+ 1 during the time interval between turning off anesthetics till the patient was eligible to leave the PACU (Aldrete score of ≥ 9). Agitation is defined as ≥+ 1 RASS level. *P value is < 0.05, among the groups using one-way ANOVA test; †p < 0.017 is significant compared to C group using Wilcoxon Mann-Whitney U test; values are presented as number of patients (%) or absolute number (N)

Table 3 Recovery features

	C group n = 35	D group n = 35	M group n = 35	P value
Incidence of pain (NRS \geq 4)	19 (54.28)	6 (17.1) †	8 (22.84) †	0.002*
Total rescue analgesic dose (mg)	1425	450 †	600 †	0.001*
Incidence of midazolam rescue	5 (4.28)	0(0) †	0(0) †	0.001*
Extubation time (min)	7 (5–10)	13(8–17) † ‡	8(4–12)	0.002*
PACU time (min)	61 (40–100)	93 (60–160) † ‡	63 (50–110)	0.001*
Adverse events				
Laryngospasm	1(2.8)	0(0)	(0)	0.214
Coughing	3 (8.5)	0(0) †	1(2.8) †	0.001
Desaturation	3(8.5)	1(2.8) †	1(2.8) †	0.001
Bradycardia	1(2.8)	4 (5.6) †‡	1 (2.8)	0.002
PONV	2 (5.6)	0(0) †	0(0) †	0.001
Total	10 (28.5)	5 (14.2) †‡	2(5.6) †	0.001*

Abbreviations: PACU Post-operative anesthesia care unit, PONV Post-operative nausea and vomiting

Notes: *P values of < 0.05, among groups, are significant using one-way ANOVA test. †P < 0.017 is significant comparing pairs of groups: D to C and M to C, using Wilcoxon Mann-Whitney U test. ‡P < 0.17 is significant comparing between group D and M using Wilcoxon Mann-Whitney U test. Values are shown as number of patients (%) for incidence of pain, incidence of midazolam rescue sedative, adverse events as number for total rescue analgesic dose, extubation time, and PACU time; and median (interquartile range) for total sedative dose. Recovery: time interval from turning off anesthetics till let out of PACU. Extubation time: the time interval between turning off anesthetics and extubation. PACU time: the time interval from admission to PACU till patient scored \geq 9 on Aldrete scale (eligible to discharge). Rescue analgesic: diclofenac 75 mg, IM. Rescue sedative: midazolam 2 mg incremental dose

inhalational anesthesia was given. As anticipated, the incidence of emergence agitation in the control group in our study was 54.2% which was in consistent with other previous reports (Kang et al., 2020).

Dexmedetomidine, a selective central α 2 adrenergic agonist effect, has sympatholytic, anxiolytic, sedative, and analgesic action without respiratory depression. In comparison to other sedatives, Dex is associated with less neurocognitive dysfunction and least delirium (Hauber et al., 2015; Shukry et al., 2010). Therefore, it is potentially good candidate to prevent emergence delirium in high-risk adults. In this trial, Dex reduced the incidence of emergence agitation by 48.6% which is consistent with reports from other researches (Kim et al., 2013; Patel et al., 2010; Radtke et al., 2010; Kang et al., 2020).

Magnesium sulfate is the 4th most abundant blood cation and has pivotal roles in key physiological pathways in humans (Taheri et al., 2015). Recently, it has been a focus of interests in literatures for its antinociceptive, anticonvulsant, and cellular membrane-stabilizing properties (Gallagher et al., 2015). It antagonizes N-methyl d-aspartate receptor in non-competitively and inhibits Ca-ATPase gated and Na-K-ATPase gated ion exchange channels, leading to cell membrane stabilization (Ryu et al., 2008). In addition, it inhibits angiotensin-converting enzyme activity and stimulates prostacyclin synthesis resulting in vasodilation (Ryu et al., 2009). Moreover, magnesium sulfate has analgesic action and it decrease post-operative pain scores and opioid requirements (Song et al., 2011). Owing to its calcium channel blocking action, magnesium reduces acetylcholine release at the presynaptic clefts, which decreases muscle fibers excitability and

diminishes the amplitude of action potential, leading to augmentation muscles relaxation (Teymourian et al., 2015). It might be worth mentioning that magnesium sulfate minimize non-depolarizing muscle relaxants requirements and enhances their onset in patients' under general anesthesia (Borazan et al., 2012). In our study, magnesium sulfate infusion resulted in significantly decreasing the incidence of emergence agitation by 51.7%, when compared to control group. However, the incidence was not significant between Dex and magnesium groups.

Pain is a key factor to the development of EA although, a direct relationship has not been found, yet. In our trial, both Dex and magnesium sulfate groups, showed statistically significant lower pain scores in the post-operative period compared to control group. This is reflected on the consumption of the total amount of rescue analgesics. Patients in D and M groups needed less analgesics compared to patients in the control group, in the post-operative PACU period. Indeed, we can stipulate that the pain modulating effect of either Dex or magnesium sulfate might have contributed to the observed low EA incidence in both groups. This in consistency with other data claiming that adequate analgesia may reduce the incidence of EA (Borazan et al., 2012). Nevertheless, concerning the analgesic efficacy, none of the tested drugs (Dex vs magnesium sulfate) was superior to the other.

In this study, the extubation time was prolonged in patients in Dex group compared to other groups. This in accordance to other published data (Kim et al., 2013; Patel et al., 2010) and it could be due to its analgesic and sedative action. However, other studies claimed that

Dex shortens extubation time (Mason, 2017; Lepouse et al., 2006). The reason for these conflicting reports could be attributed to the dose and duration of Dex administration. In our study, Dex .7 µg/kg/h kept running throughout the whole operation, and was turned off just when we stopped administering general anesthesia. This dose is relatively higher than the usual infusion dose of 5 µg/kg/h and it might contribute to residual sedation and delayed extubation time. This residual sedation was continued in the PACU, and the PACU time was significantly delayed in patients received Dex compared to patients in magnesium and placebo groups. Although, the duration of magnesium sulfate infusion was similar to the duration of Dex infusion, patients in magnesium sulfate group did not show delayed extubation time or stayed longer in the PACU.

Comparing Dex and magnesium sulfate, it is hard to explain why magnesium did not affect the extubation and PACU times, while have comparable results with Dex in reducing the incidence of EA. This is could not be attributed solely to the dose we used in our protocol (20 mg/kg/h infusion, no loading dose), as other studies, used higher dose 30 mg/kg/h infusion and others used bolus doses with infusion without delay. It could be that magnesium is cleared out of the N-methyl-D-aspartate (NMDA) receptors to the extracellular fluid quickly, or may have decreased agitation by its calcium antagonistic effect and brain protective neuromodulation, rather than sedative effect.

Both dexmedetomidine and magnesium sulfate result in hemodynamic changes. Dex has biphasic effect on blood pressure, transient hypertension followed by hypotension and magnesium sulfate has hypotensive effect that makes him a useful adjuvant for hypotensive anesthesia. In our clinical trial, MAP and HR during anesthesia till discharge from PACU showed lower values in group D compared with group M and group C; however, there were no significant differences between the groups. Indeed, 4 patients in the D group suffered from bradycardia but it was transient and did not require atropine rescue.

Our study has limitations to be addressed. First, sample size was based on the incidence of emergence agitation in adults reported in previous publications. These reported incidences were varied and inconsistent. We cannot exclude confounding factors that might have attributed to reported incidences. Second, there is no consensus on the definition of emergence. We chose to define emergence as 5 min after extubation as most agitation occurred during this time (Kim et al., 2013). However, different definition would have resulted in different outcome. Third, the outcomes were evaluated based on subjective measuring scale (RASS and NRS). Nevertheless, our rationale was that these subjective scales were validated and used widely in clinical settings.

Conclusions

Dexmedetomidine and magnesium sulfate infusion are both equally effective in reducing the incidence of EA in obese adults undergoing nasal surgery. Extubation time and PACU time were rather longer in Dex than magnesium sulfate and control group patients.

Abbreviations

EA: Emergence agitation; D group: Dexmedetomidine group; M group: Magnesium sulfate group; C group: Control group; PACU: Post-anesthesia care unit; ENT: Ear, nose, and throat; Dex: Dexmedetomidine; ASA: American Society of Anesthesiologists; RASS: Richmond Agitation Sedation Scale; MAP: Mean arterial blood pressure; Co2: Carbon dioxide; MAC: Minimal alveolar concentration; NRS: Numerical rating score; PONV: Post-operative nausea and vomiting; HR: Heart rate; IM: Intramuscularly; IV: Intravenously; NMDA: N-methyl-D-aspartate

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Authors' contributions

OH has contributed with designing, recruiting, performing the interventions and writing the manuscript. HS analyzed and interpreted the patient data. He also shared in writing the manuscript. All authors have read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the Faculty of Medicine, South Valley University. Registration code: AIP027. Written consents were obtained from all participants. Registered with [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier: NCT04531371.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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