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Original Research Article

Assessment of effect of two different doses of dexmedetomidine infusion on emergence agitation and quality of recovery after nasal surgery

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ABSTRACT

Background: To evaluate two different doses of dexmedetomidine infusion on emergence agitation and measurement of hemodynamics, bispectral index, cortisol levels, and quality of recovery in patients who underwent nasal surgery under general anaesthesia.

Materials and Methods: 94 individuals of either sex between the ages of 18 and 65 who experienced nasal surgery under general anesthesia were split into two groups for this randomized experimental study. Before induction, each group received loading doses of dexmedetomidine (DEX) infusion at a rate of 1 μg/kg over a period of 10 minutes. Group B underwent a standard induction and then received an infusion of 0.4μg/kg/h of dexmedetomidine every hour until they were extubated, while group A received an infusion of 0.8μg/kg/h. Sevoflurane was employed for maintenance. During emergence, the frequency of agitation, cough hemodynamic parameters, and recovery traits were assessed. Patients received the Quality of Recovery (QoR-40) questionnaire 24 hours following surgery.

Results: The hemodynamic reaction to laryngoscopy and intubation was blunted and the intubating circumstances were improved by both doses equally well. Group A's intraoperative mean PR and MAP were significantly (P<0.05) lower than group B's. Coughing was more common among the subjects in group A. A statistically significant difference was found between groups in comparing emergence agitation. Cortisol levels were significantly higher postoperatively in the 0.4μg/kg dose of dexmedetomidine 0.8μg/kg/ group (p=0.001). Global QoR-40 score at 24 h after surgery showed a better global recovery profile in group A.

Conclusion: Although a greater dose of DEX may have more hemodynamic adverse effects, it may also reduce the incidence of emergent agitation, the surgical stress response, and a smoother recovery profile.

1. Introduction

When a patient emerges from general anesthesia, they may have emergence agitation (EA), which is characterized as a condition of mental disorientation, agitation, and disinhibition that shows up as hyperexcitation, restlessness, and hallucinations. It occurs between 30 to 60 minutes following emergence from general anaesthesia which may last up to 45 minutes in extreme cases.[1]

Occurrence in adults has been reported in a wide range of 4.7% or 21.3%.[2] It is disturbing to anaesthesiologists and recovery room staff and can lead to an increase in hospital staff. Emergence agitation can show deleterious sequelae such as deliberate removal of endotracheal tube, and catheter, and can lead to bleeding from the surgical site, injuries due to falling bed or operating room table.[3] Preoperative anxiety, postoperative pain, sevoflurane anesthesia, and post-traumatic stress disorder are regarded

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to be the triggers.[1] 55.4% patients experience agitation after otorhinolaryngology (ENT) surgery because of feel of suffocation caused by intranasal packing[4] using sevoflurane in high concentration to maintain bloodless field.[5]

DEX is a selective α2-receptor agonist and possesses hypnotic, sedative, anxiolytic, sympatholytic, and analgesic properties without causing marked respiratory depression. Dexmedetomidine causes sedation and a decrease in norepinephrine release by stimulation of alpha$_2$-receptors on pre-synaptic neurons by inhibiting the post-synaptic action thus decreasing the central nervous system excitation (CNS). It does not decrease respiratory drive and has sedative, analgesic, and anti-shivering properties. It attenuates stress and thus improves the recovery profile.[6]

We designed this study to administer two different doses (0.8μg/kg/hour vs 0.4μg/kg/hour) of dexmedetomidine for evaluation of intraoperative haemodynamic stability, bispectral index (BIS), EA, cortisol level, and quality of recovery in patients undergoing nasal surgeries under general anaesthesia.

2. Materials and Methods

After receiving authorization from the institutional ethics committee (SRHU/Reg./Inst/2019-83) and informed consent from the participants, this randomized trial was carried out in a tertiary care teaching hospital. The clinical investigation was undertaken in compliance with the December 2013 Helinski Declaration's ethical guidelines for medical research involving human patients.

A 12-month investigation was conducted on 94 patients, ages 18 to 65, of either sex who were undergoing nose surgery and were classified as grade I or II by the American Society of Anaesthesiologists (ASA).

Patients who refused surgery, belonging to ASA grade III, IV, patients with an anticipated difficult airway, with cognitive impairment, in whom supraglottic airway was introduced, uncontrolled hypertension, first-degree heart block, allergy to non-steroidal anti-inflammatory drugs or alpha 2 adrenergic agonists were not included.

The patients were split into two groups at random utilizing a computer-generated number. During the pre-anaesthetic check-up, every patient was thoroughly examined, and all standard investigations were completed. The patients were kept nil / oral (NPO) for 6 hours before surgery. Before taking patients to operation theatre blood samples of the patients were taken for assessing cortisol levels. In the operation theatre intravenous (iv) line was established and all the monitors were attached and heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), bispectral index (BIS), were noted at the baseline, time of intubation and at every ten minutes interval till the end of the surgery. The drugs to be given in the research were prepared by anaesthesiologist who was not included further in the investigation 2ml (100 μg/ml) dexmedetomidine was diluted in 48ml of normal saline i.e., 4 μg/ml and infusion of DEX was started at loading dose of 1μg/kg/hour over 10 minutes followed by maintenance dose in Group A- 0.8μg/kg/hour and Group B- 0.4μg/kg/hour. (Diagram 1)

The anaesthetist who recorded the parameters was excluded from the study after being blinded to the type of medication delivery. Fentanyl injections at a dose of 2 mcg/kg were used to induce anesthesia in every individual. Propofol injections ranged from 1 to 1.5 mg/kg until verbal control was lost. Blockade of the neuromuscular response was achieved using 0.1 mg/kg of vecuronium. A cuffed endotracheal tube of appropriate size was used for endotracheal intubation. Maintenance of the mechanical ventilation with 6-8ml / kg tidal volume, frequency of ventilation was adjusted to maintain $EtCO_2$ between 30-35mmHg. 50% oxygen with air and sevoflurane, which was varied between age-adjusted minimum alveolar concentrations (MAC) of 1-1.5 to maintain BIS values of 40–60, were used to maintain anesthesia.[7] An intermittent bolus of injection fentanyl 1μg/kg and an injection of vecuronium 1mg were administered as deemed necessary by a consultant anaesthesiologist. Any change in BIS was maintained by the concentration of sevoflurane. I.V paracetamol 1 gm over 15min was given before the completion of the procedure. Once the surgery was completed dexmedetomidine and sevoflurane were discontinued in both the groups.

The neuromuscular blockade was reversed by injecting glycopyrrolate (0.01 mg / kg) and neostigmine (0.05 mg / kg) after oral suctioning and when the spontaneous effort occurred. The BIS value was also between 80 and 100. The timing of eye-opening, response to verbal command, and endotracheal tube removal after administration of reversal agent were noted.

When the patient was able to breathe and also responded to verbal commands Richmond Sedation Agitation Scale (RASS) was used to evaluate emergence agitation. 0= alert and calm; 1= restless (apprehensive or anxious but movements not aggressive or vigorous); 2= agitated (non-purposeful frequent movement); 3= very agitated (removes tubes or pulls on a catheter or having aggressive behaviour towards the staff) and 4= combative (overtly combative or violent, immediate danger to staff).[8] If RASS >5 then the patient was given 1mg midazolam. The grade of cough (GOC) during emergence was also evaluated using four points. Desaturation SpO_2 (<90%), laryngospasm, bronchospasm, tachycardia, hypertension, and other complications were also recorded if they emerged. Before shifting the patient to the PACU blood samples were taken to assess cortisol levels after surgery. Intravenous atropine 0.6mg was used to treat bradycardia (HR<60). I.V esmolol in 10mg increments was used to treat Tachycardia (HR > 110 beats/min). I.V ephedrine at 6mg increments was

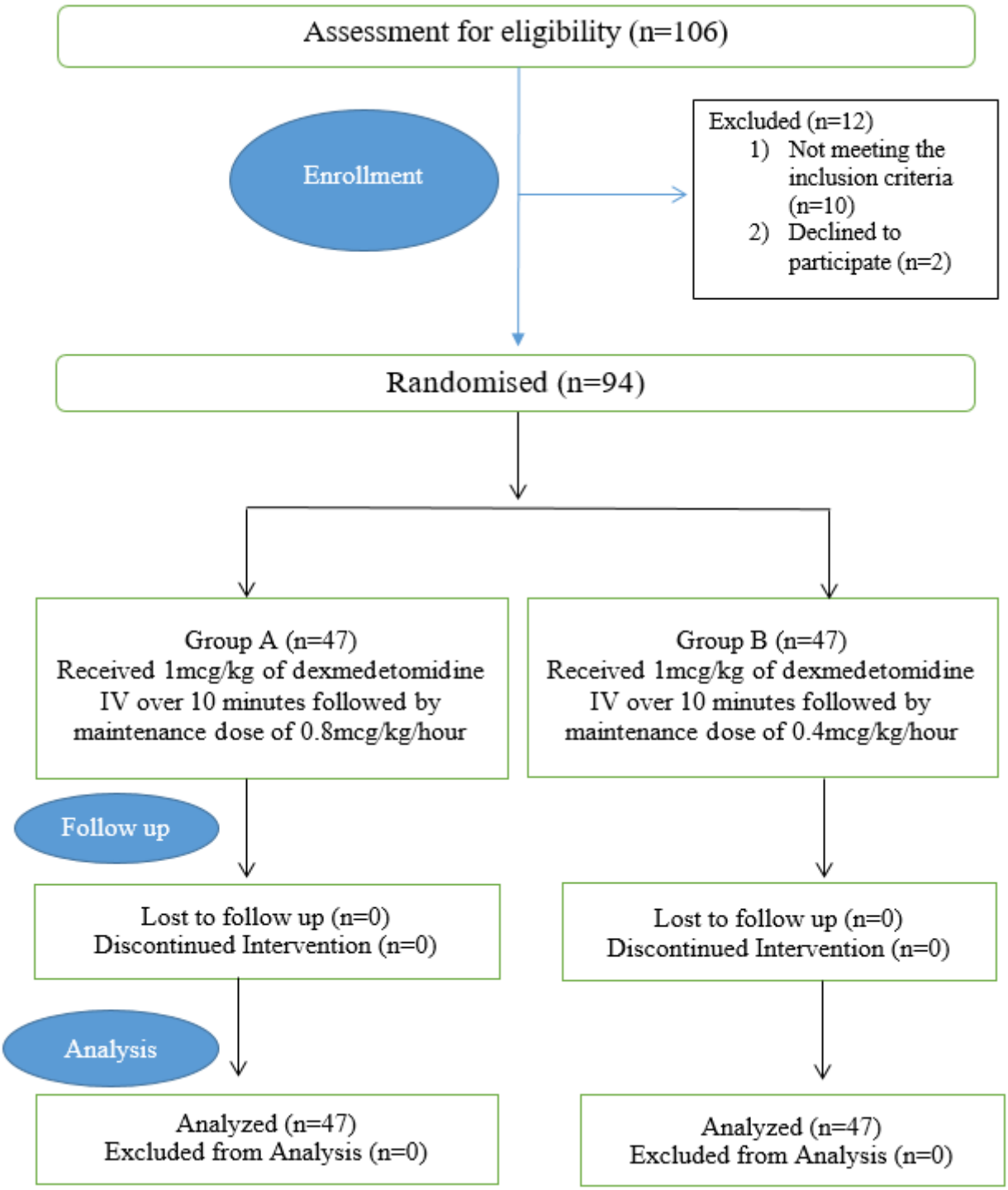

Diagram 1: Consort flow diagram of Group A and Group B

used for Hypotension when MAP<60 mm Hg.

The quality of recovery was evaluated after a 24-hour period using the QoR40 questionnaire. QoR-40 consists of five dimensions: pain (7 items), psychological support (7 items), physical independence (5 items), emotional state (9 items), and physical comfort (12 items).[9] Every item was assigned a five-point rating, with a global score ranging from 40 (very poor recovery quality) to 200 (very good recovery quality).

2.1. Statistical analysis

A minimum of 47 patients were included in each group for statistical purposes. 100% enumeration of cases was done for a duration of 12 months. The sample size for the study was calculated using the formula:

$$n = (Z_{1-\alpha/2}\sqrt{(p_1q_1)} + Z_{1-\beta}\sqrt{(p_2q_2)})^2/(p_1 - p_2)^2$$

Where:

- p1 - p2 = 20% (minimum difference assumed)
- Confidence Interval (CI) = 95%
- Power = 80%
- Unknown prevalence value = 50%

Using this formula, the calculated sample size was 47 in each group.

Statistical analysis was carried out using Microsoft Office Excel 2010 and Statistical Package for Social Sciences (SPSS) IBM version 22. The one-sample Kolmogorov-Smirnov test was employed to determine whether the data sets were different from a normal distribution. Normally distributed data was analysed using general linear model analysis of variance for more than two groups and comparison between two groups unpaired t-test was applied in normally distributed data whereas non-normally distributed data was analysed using Mann Whitney U test and the categorical data was analysed using Chi-square test. The level of significance is usually denoted as alpha as the following criterion: if p <0.05 then the hypothesis will be said to be significant.

3. Results

The demographic parameters did not have any clinical implications on the recovery outcomes of patients. (Table 1) Baseline hemodynamic parameters were comparable in both groups. Intraoperative infusion of dexmedetomidine loading dose in both groups decreases hemodynamic parameters at induction and the maintenance dose of dexmedetomidine in both groups attenuates the intubation response. Throughout the intraoperative period, the hemodynamic response was lower than the baseline values in both groups which were clinically significant.

The intraoperative mean PR and MAP in dexmedetomidine group A were lower than group B and it was statistically significant (p < 0.05). (Figures 1 and 2) No intraoperative increase in PR, SBP, DBP, or MAP more than the baseline value was observed in either group. The incidence of 1(2.1%) hypotension, and 4(8.5%) bradycardia that required iv ephedrine treatment and iv atropine respectively was observed in group A whereas in group B none of the patients had hemodynamic instability requiring any intervention. Baseline BIS was comparable in both (P= 0.100). BIS values at any given time interval were between 40-60. (Figure 3)

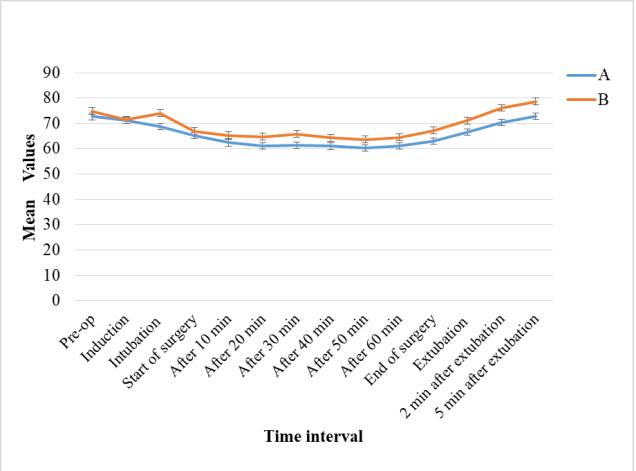

Figure 1: Intraoperative pulse rate at different time interval in Group A and B

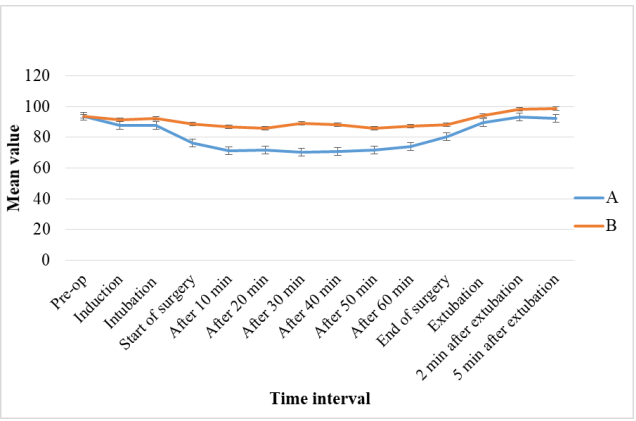

Figure 2: Intraoperative mean arterial pressure at different time intervals between Group A and B

Overall, 27(28.7%) subjects included in the study were alert and calm at the time of extubation out of which 16 patients (34%) belonged to group A and 11 patients (23.4%) to group B. Fourteen patients (29.7%) were restless in group A when compared to group B where 27 patients (57.4%) were restless.

4 patients (8.5%) in group A were agitated while in group B 9 patients (19.1%) were agitated. While five patients in group A were drowsy, six patients were lightly sedated, 1 patient was moderately sedated and 1 patient was in deep

Table 1: Demographic characteristics of study population

Demographic characteristics	Group A	Group B	P value
	Mean ± S.D.	Mean ± S.D.	
Age in years	34.28 ± 14.12	30.32 ± 12.74	0.162
Weight in kg	57.85±9.9	59.87 ±9.3	0.310
Height in cm	155.3±3.75	152.49±22.77	0.242
BMI in kg/m2	24.00 ± 4.13	25.18 ± 5.17	0.128
Sex (Male: Female)	26:21	35:12	0.052
ASA Grade I:II	25:22	35:13	0.05

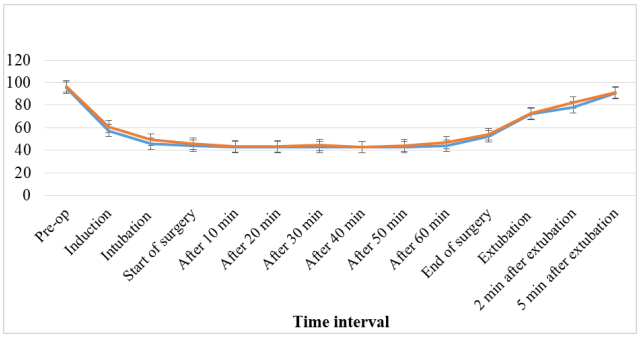

Figure 3: Intraoperative bispectral index (BIS) at different time interval in group A and group B

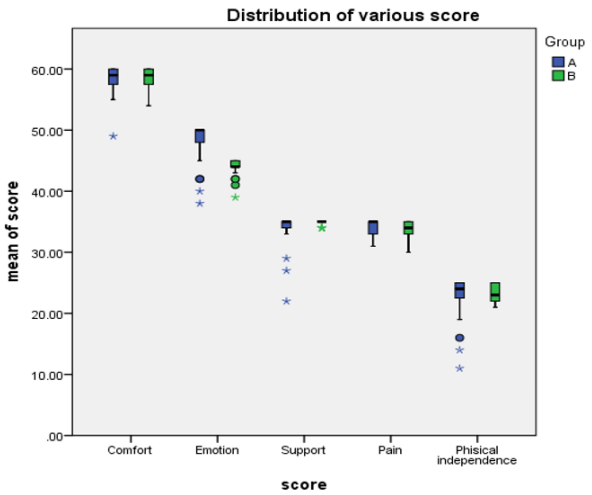

Figure 4: Comparison of postoperative QoR 40 at 24 hours between Group A and B

sedation. When compared to group B where no patient was sedated after extubation. Statistically significant differences were seen in RASS amongst the 2 groups (p=0.001). (Table 2)

Global QoR-40 scores were significant when compared between both groups. Among all dimensions in the QoR40, the emotional state was significantly improved in group A patients. While other dimensions were higher in the A group than the B group but were insignificant. (Figure 3)

4. Discussion

ENT surgeries are among the most challenging procedures requiring proper anaesthetic management for many reasons including the need for immobility, maintaining haemostasis, and especially smooth emergence from anaesthesia.[10] The requirement of deliberate hypotension to provide a relatively clear field while using an operating microscope has gained popularity. Most anaesthetic agents have a hypotensive effect.[11] Several pharmacological agents like magnesium sulphate, vasodilators, nitro-glycerine, and high doses of potent inhaled anaesthetics along with beta-adrenergic antagonist have helped in achieving controlled hypotension. Some of the disadvantages reported because of these agents are late recovery from inhaled anaesthetics, vasodilator resistance, cyanide toxicity from nitroprusside, and tachyphylaxis.[12]

Inhalational anaesthetic owing to potent vasodilator effect at high concentration is required to achieve a bloodless field, and these concentrations led to the high incidence of EA, liver and kidney injury with delayed recovery from general anaesthesia.[13]

Maintenance with dexmedetomidine provides more stable anaesthesia, and promotes quality of recovery following major surgeries such as nasal surgeries. Because dexmedetomidine affects central alpha 2 receptors in the locus coeruleus, its effectiveness in preventing epilepsy following nose surgery has been demonstrated.[1] Dexmedetomidine's sympatholytic feature maintains a steady hemodynamic during both surgery and extubation.

The relative safety of the lower dose with respect to these side effects, such as hypotension (2.1% vs. 0) and bradycardia (8.5% vs. 0), appears to provide a clear clinical advantage, which is consistent with earlier studies, given the sufficiency of both the low and high doses in blunting the hemodynamic response.[14,15]

Group A needed more time to achieve BIS 90 thus delaying recovery. The strength of our study is that we used BIS to assess patient awareness and also guide us to know the depth of sedation during emergence. These findings are in accordance with the investigation /formed by Yacout A.G et al.[16]

Table 2: Comparison of recovery data, Richmond sedation-agitation score (RASS) in Group A and Group B

Time (in minutes)	A (Mean ± SD)	B (Mean ± SD)	p-value
T1	2.04±1.27	1.70±0.81	0.322
T2	2.08±1.56	1.46±0.67	0.062
T3	47.55±07.51	51.10±8.73	0.046
RASS			
Mean ± S.D.	0.96±0.66	-0.04 ±1.35	0.001
Median	1(0-2)	0(-4-2)	
Cough grading 0:1:2	41:6	38:4:3	0.206
Cortisol levels			
Preoperatively	117.40 ±63.77	108.37± 98.73	0.599
Postoperatively	94.67 ± 66.6	80.43 ± 90.91	0.001
Complications PONV	1(2.1%)	0	1.00
Bradycardia	4(8.5%)	0	0.117
Hypotension	1(2.1%)	0	1.00

*Mann - Whitney test
T1= Time to verbal response.
T2= Time to extubation
T3 = Length of recovery staff.
The cough grading during emergence was also assessed using 4 points (0 = no cough; 1 = single cough; 2 = persistent cough lasting < 5 seconds and 3 = persistent cough lasting >5 seconds or bucking).

While Mostafa MF et al. studied dexmedetomidine different doses and their effects on recovery response after surgery and reported no statistical difference among the three groups.[17]

The Richmond Agitation Sedation Scale was employed. In our investigation, bias was eliminated by using adult patients with a statistically negligible gender ratio and treating all patients in both the A and B groups with the same inducing and maintenance agents (apart from the study drug's dosage). Every patient had nasal surgery, and none of them required the insertion of a catheter. Instead, all patients were intubated using a normal anesthesia procedure.

Numerous studies have assessed a number of risk factors for EA, such as age, gender, use of inhalational anesthetics, type of surgery, postoperative discomfort, presence of tracheal tube, and presence of urine catheter.[18]

Surgery elevates the level of inflammatory and stress markers such as cytokines and cortisol as previously documented. The biomarker of the stress response is cortisol levels. Endocrine, metabolic, and/or inflammatory responses can lead to postoperative complications. Reduction in postsurgical fatigue can be done by modulation of these responses and can also shorten the postoperative convalescence period. Elevation of cortisol immediately after surgery occurred. Dexmedetomidine causes a reduction in intraoperative stress response (cortisol level) and thus, enhances recovery.[19]

Our study shows significantly higher cortisol levels postoperatively in 0.4μg/kg dose of dexmedetomidine than postoperative cortisol levels of 0.8μg/kg/ group (p=0.001).

In accordance with our study Mostafa. M.F. et al studied cortisol levels pre-incision and 2 hours after the end of surgery in three groups of different dexmedetomidine doses (1μg/kg vs 0.75 μg/kg vs 0.5μg/kg). It was found that there was no statistical difference between the three study groups. After surgical skin incision and at the end of surgery levels of stress markers were increased. Although the increased dosage of dexmedetomidine decreases the stress response related to surgery.[17]

In accordance with our study, Kim S.Y et al studied that there was no difference between the DEX group vs placebo group in cough during emergence with p=0.46.[19] The effect of intraoperative dexmedetomidine infusion on recovery profile has been investigated in a few studies. In the study of Kim S.Y et al QoR-40 scores were significantly more in the D-dexmedetomidine group than in the C-control group with p=0.041. The most significant dimension among group D patients was the pain dimension.[19]

In a study Tufanogullari B et al. used a nine-item questionnaire in laparoscopic procedures for quality of recovery, (0.2-0.8 μg / kilogram / hour) DEX did not correlate with better recovery quality.[20]

Bekker et al. study in spinal surgery, 0.5μg / kg / hour of dexmedetomidine resulted in a better quality of recovery as assessed by a 40-questionnaire in contrast to the placebo group (p<0.001).[6]

Limitations of the study were: Firstly, all the patients belonging to ASA grade I & II the safety or efficacy of dexmedetomidine on ASA grade III and patients more than 60 years were not studied. Secondly, the dexmedetomidine effect was not evaluated over inhalational agent dose. Sevoflurane was estimated for maintaining a specific BIS range, the inhalational anaesthetic consumption with the study drugs was not compared.

Lastly, the control group was lacking in our study so, the intensity and severity of cough and pressure response

without the drug were not known, only two doses (0.4 μg and 0.8 μg / kg) selection, thus it may be a possibility that most desired dose lie between two doses. For these aspects, further trials are needed to investigate.

5. Conclusion

Nasal surgery under sevoflurane may increase the incidence of emergence agitation which may have deleterious effects. Dexmedetomidine infusion after a loading dose of 1μg/kg/hour over 10minutes before inducing and maintenance dose was followed as 0.8μg/kg/hour in A group and 0.4μg/kg/hour in group B offers a multitude of advantages. The higher dose may decrease the incidence of emergence agitation, surgical stress response, smoother recovery profile, and an improved recovery profile but may have more hemodynamic side effects than the lower dose.

6. Sources of Funding

None.

7. Conflict of Interest

None.

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