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Original Research Paper

A randomized double blinded controlled study to compare the use of dexmedetomidine and dexamethasone intraoperatively to prevent post operative nausea and vomiting.

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ABSTRACT

Objective: Comparison of incidence of PONV between two groups of patients by verbal rating scale for nausea and by simple questioning. And secondary to the primary study to see the haemodynamic stability in dexmedetomidine group in the intraoperative period. As well as the comparision requirement of analgesia between the two groups of patient intraoperatively. **Material and Methods:** Present study was hospital based randomized, observer blinded, interventional study conducted in patients of age group of 18-60 years, ASA grade1/2, undergoing operation under general anaesthesia. 130 patients were divided into two groups 65 patients in each group. Group A (receiving dexmedetomidine infusion after induction) Group B (receiving single dose of dexamethasone). **Results:** The age, gender , duration of surgery, duration of analgesia between the two groups had no statistical significance. The heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure values at intubation and post intubation were comparable in both the groups. There was significant decrease in heart rate in group A. The requirement of fentanyl in group A was lower than in group B. Even the requirement of rescue anti-emetic was less in group A than in group B. But the decrease of vomiting in both the groups was not statistically significant. **Conclusion:** Dexmedetomidine has an effect similar to that of dexamethasone in reducing the incidence and severity of PONV and no significant difference was observed between the groups but rescue antiemetic was significantly lower in Group dexmedetomidine compared to Group dexamethasone. And the requirement of fentanyl is less in the dexmedetomidine group as compared to the dexamethasone group.

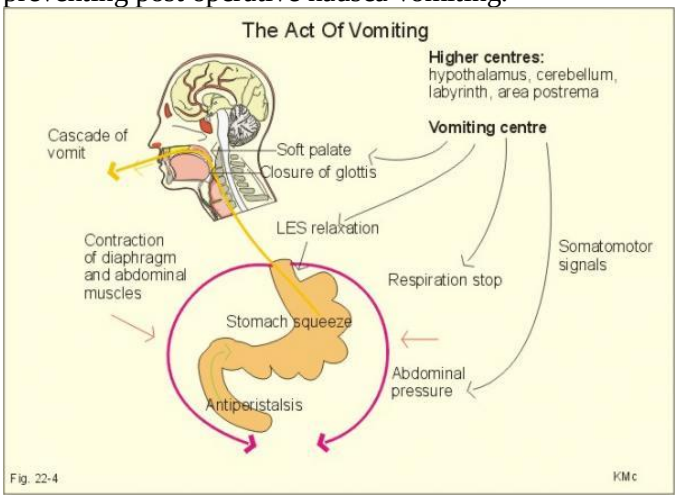
Keywords: PONV, dexmedetomidine, dexamethasone, nausea, vomiting

INTRODUCTION:

PONV constitutes a most common anaesthesia related undesirable event .Its incidence in the available literature is reported to vary between 20-80%.[1] PONV has significant adverse effects. It can cause profound distress to the patients. Oral administration of drugs, fluids and nutrients can be delayed and can lead to dehydration and alkalaemia. It may at times lead to serious complications like Mallory Weiss syndrome and esophageal rupture.[2]It is an important cause of delayed discharge. It may be associated with poor surgical outcome, vomiting can disrupt neck, abdominal and eye sutures. PONV is often severe on movement and may delay post-operative mobilization[3].The etiology of PONV is multifactorial[2] with increased incidence in paediatric patients, adult females, obese and in patients with a history of motion sickness. The surgery related factors are after strabismus surgery, orchidopexy, middle ear surgery, intra-abdominal and orthopaedic surgeries. Intravenous anaesthetic agents are associated with differing degrees of emesis. Newer agents like propofol are less emitogenic. Perioperative use of opoids is associated with an increased incidence of PONV. It is generally accepted that nitrous oxide is responsible for a significant degree of emesis. Inhalational agents like halothane and isoflurane also cause PONV, though to a lesser extent.[4]The postoperative course after the use of general anaesthesia is related to the operative procedure and the technique and agents used to manage the associated anaesthesia. Quite a few drugs are used to treat postoperative nausea and vomiting(PONV).These drugs are usually antihistaminics, anticholinergics, phenothiazine derivatives and dopamine receptor antagonist with side effects like extrapyramidal

symptoms, sedation, tachycardia, dysphoria, dry mouth and restlessness.[5,6,7]PONV may delay patient discharge from the post-anaesthesia care unit (PACU) and increase unanticipated hospital admissions in outpatients. Therefore, prevention of PONV will improve patient satisfaction and decrease overall health care costs.

Dexmedetomidine is a potent α2-adrenergic agonist with potential applications in clinical anaesthesia because of its broad-spectrum effects, which include anxiolytic, sedative, analgesic, anaesthetic-sparing, sympatholytic, and hemodynamic-stabilizing properties.[8] The intra-operative use of dexmedetomidine as an anaesthetic adjuvant has led to significant reductions in the use of opioids and inhalation anaesthetics, reduction in the incidence of emergence agitation, a favourable recovery profile, and reduction of postoperative pain without adverse hemodynamic effects, and hence it may decrease PONV. A pre-induction single dose of dexmedetomidine of 0.6-2 µg/kg resulted in the reduction of both inhalational anaesthetic and opioid analgesic requirements during the intra-operative period.[9,10] Hence the present study was done at our tertiary care centre to compare the effect of intraoperative use of dexmedetomidine and dexamethasone on patients undergoing surgery under general anaesthesia in preventing post operative nausea vomiting.



MATERIALS AND METHODOLOGY:

A hospital based double blinded interventional study was conducted on 130 patients to evaluate effect of intraoperative use of dexmedetomidine and dexamethasone on patients undergoing surgery under general anaesthesia in preventing post operative nausea vomiting. Using SNOSE Method (sequentially number opaque sealed envelope), the patients were divided in the following two groups of 65 patients each:

Group A –Patients received intraoperatively dexmedetomidine after getting induced with propofol

Group B -Patients received intraoperatively dexamethasone after getting induced with propofol.

The study was conducted within a duration of 18 months (July 2019 to January 2021) at our tertiary care Topiwala National Medical College and B.Y.L Nair Charitable Hospital in the department of Anaesthesiology with the help of Department of Surgery and Department of Orthopaedics. With reference to the studies of Lwanga SK et al[98] and SeyamSameh H[96]and according to the rule of normal distribution, statistical parameters for all the groups like mean, standard deviation and coefficient of variation was calculated for the quantitative data and the sample size was calculated

Inclusion criteria: ASA 1 to ASA 2, Both Genders, BMI <30, Age 18-60 years, Apfel risk score <3

Exclusion criteria: Refusal of patients to participate in the study, ASA 3,ASA 4, BMI>30, Pregnant patients, Allergy to study drugs (Propofol and Dexmedetomidine), Patients with pre-operative respiratory and cardiac problems, Age <18 and >60, Patients with heart rate less than 60 beats/min., Apfel score >3. The study was done at our tertiary care centre in the department of Anaesthesiology on patients undergoing surgery under general anaesthesia after due permission from the Institutional Ethics Committee and Review Board and after taking Written Informed Consent from the patients. Division of patients was done with SNOSE METHOD (sequentially number opaque sealed envelope). Participants were made to pick an envelope after the pre anaesthetic check-up in which the group were mentioned .The patients presented the envelope in the morning of the study. The study drug was infused through a dedicated intravenous access. All the subjects were induced according to the standard protocol of pre medication first with glycopyrrolate 0.004mg/kg, midazolam 0.03mg/kg and fentanyl 2mg/kg and then induced according to the standardised general anaesthetic regime comprising of i.v propofol 2mg/kg and i.v atracurium 0.5mg/kg. After the induction patient were mechanically ventilated with intermittent positive pressure ventilation at tidal volume of 7-10 ml/kg and respiratory rate was adjusted to maintain end tidal volume CO_2 30-35mm Hg. The lungs were ventilated with air and O_2. After mechanical ventilation begins sevoflurane was started according to the need. MAC value of 1 was maintained thorough out the procedure and manipulated to maintain a mean arterial pressure and heart rate within 20% of baseline. After induction was done Group A received an infusion of dexmedetomidine of 0.5µg/kg/hr from the time of induction to complete till 30-45 minutes prior to extubation. Group B received single bolus of dexamethasone 8 mg after completion of induction. At the end of the surgery patients were allowed to breathe spontaneously. Patient were reversed and extubated with i.v Glycopyrrolate 0.008 mg/kg and Neostigmine 0.05 mg/kg. Patient were then shifted to the recovery room for post-operative observation. The

recovery anaesthesiologist were blinded to the group receiving the different drug. Post-operatively patient were questioned regarding post-operation nausea and vomiting and the need to give anti-emetic drug for 24hours. And later the patient were transferred to the surgical ward.

Preoperative PONV risk assessment tool based on Apfel's Simplified Risk Score are as follows

Female Gender

History of motion sickness or PONV

Non smoker

Postoperative opioids

Number of predictors presented Predictive PONV risk

Score and correlated PONV Risk

0=10%,1=21%,2=39%,3=61%,4=79%

0-1=Low Risk

2=Moderate Risk

3-4=High Risk

Each patient were given score according to the predictors for which the patient were positive and the total of the score tell us in which category to put the patient and if the Apfel score is less than 3 then the patient can be taken up for the study otherwise would not be included in the study.

Nausea was assessed by verbal rating scale(VRS)

0-represent no nausea

10-worst nausea

Vomiting was assessed by simple questioning for yes or no.

No was score 0

Yes was scored 1

Occurrence of emetic incidents, need for supplemental antiemetic medications, sedation, need for analgesia, or any adverse effects were recorded for 24 h (in ward) after operation. Rescue antiemetic (metoclopramide 0.2 mg/kg) was given slowly intravenously if more than two episodes of nausea, retching, and/or vomiting had occurred or the patient had persistent nausea.

RESULTS:

A hospital based double blinded interventional study was conducted with 130 patients to evaluate effect of intraoperative use of dexmedetomidine and dexamethasone on patients undergoing surgery under general anaesthesia in preventing post-operative nausea vomiting.

Group A –Patients received intraoperatively dexmedetomidine after getting induced with propofol**.**

Group B -Patients received intraoperatively dexamethasone after getting induced with propofol.

The mean age of the patients was 35.49 ± 10.10 years in group A and the mean age of the patients was 35.98 ± 9.88 years in group B. There was no statistical difference between the age groups as per Chi-Square test (p>0.05).Group A had 53 (81.5%) male and 12 (18.5%) female patients whereas Group B had 51 (78.5%) male and 14 (21.5%) female patients. There was no significant difference between the groups as per Chi-Square test (p>0.05).

Group A mean BMI of patients was 23.66 ± 1.87kg/m^2 and mean BMI of patients in group B was 24.29 ± 2.13kg/m^2. There was no significant difference between the groups as per Student t-test (p>0.05).

BMI (kg/m^2)	Group A		Group B		p Value
	N	%	N	%	
Normal (18.5-24.9)	47	72.3%	40	61.5%	>0.05
Overweight (25-29.9)	18	27.7%	25	38.5%	
Total	65	100%	65	100%	
Mean ± SD	23.66 ± 1.87		24.29 ± 2.13		

Group A had 54 (83.1%) and 11 (16.9%) patients with ASA Grade I and Grade II respectively, whereas Group B had 51 (78.5%) and 14 (21.5%) patients with ASA Grade I and Grade II respectively. The ASA Grading of the patients between two groups were comparable and statistically not significant as per Fisher test (p>0.05).

ASA Grading	Group A		Group B		p Value
	N	%	N	%	
I	54	83.1%	51	78.5%	>0.05
II	11	16.9%	14	21.5%	
Total	65	100%	65	100%	

The mean duration of surgery comparable in Group A and Group B was (74.40 ± 9.25 mins vs. 76.31 ± 5.99 mins) and the mean duration of analgesia comparable in Group A and Group B was (85.97 ± 8.77 mins vs. 91.63 ± 6.06 mins) which were statistically not significant as per Student t-test (p>0.05).

	Group A		Group B		p Value
	Mean	SD	Mean	SD	
Mean duration of Analgesia (mins)	85.97	8.77	91.63	6.06	>0.05
Mean duration of Surgery (mins)	74.40	9.25	76.31	5.99	>0.05

The heart rate values at intubation and post intubation were comparable in both the groups. At 15, 30, 45 and 60 mins interval post intubation, at extubation and post extubation there was significant decrease in the heart rate values in Group A compared to Group B as per Student t-test (**p<0.05**/). The systolic blood pressure values at intubation and post intubation were comparable in both the groups. At 15, 30, 45 and 60 mins interval post intubation, at extubation and post extubation there was significant decrease in the systolic blood pressure values in Group A compared to Group B as per Student t-test (**p<0.05**). The mean arterial pressure values at intubation and post intubation were comparable in both the groups. At 15, 30, 45 and 60 mins interval post intubation, at extubation and post extubation there was significant decrease in the mean arterial pressure values in Group A compared to Group B as per Student t-test (**p<0.05**).

MAP (mm Hg)	Group A		Group B		p value
	Mean	SD	Mean	SD	
Intubation	88.47	7.54	88.79	7.55	p>0.05
Post Intubation	87.81	6.99	89.17	5.41	p>0.05
15 mins later	101.56	5.56	115.55	9.16	**p<0.05**
30 mins later	94.97	4.59	110.45	9.75	**p<0.05**
45 mins later	89.44	3.18	104.16	8.43	**p<0.05**
60 mins later	80.92	5.04	100.33	6.15	**p<0.05**
Extubation	81.46	5.24	97.45	8.16	**p<0.05**
Post extubation	80.83	6.44	97.64	8.27	**p<0.05**

The requirement of fentanyl in Group A and Group B patients were 2 (3.1%) and 9 (13.8%) respectively and this difference was statistically significant as per Chi-Square test (**p<0.05**).The requirement of rescue antiemetic was significantly lower in Group A compared to Group B as per Chi-Square test (**p<0.05**).The Verbal Rating Scale (VRS) was comparable at 0, 2, 6, 12 and 24 hours post-operative period between study groups.

Post-operative period (hours)	Group A		Group B		p Value
	Mean	SD	Mean	SD	
0 hour	5.92	1.27	6.35	1.34	>0.05
2 hours	6.05	1.40	6.28	1.43	
6 hours	4.98	1.30	4.78	1.62	
12 hours	4.12	1.43	4.23	1.30	
24 hours	3.38	0.74	3.32	1.46	

Comparison of post-operative Verbal Rating Scale (VRS) between groups

Vomiting was noted in 3 (4.6%) and 4 (6.1%) patients in Group A and Group B respectively. There was no significant difference between the groups as per Chi-Square test (p>0.05).

DISCUSSION:

PONV is an important issue after general anaesthesia and methods to prevent it need to be studied and in the present study we have tried to study the effect of the drugs in preventing the post of nausea and vomiting which would be helpful in early mobility and discharge of the patient and preventing any dyselectrolytemia. In the present study there was no statistical difference between the groups on the basis of age groups and gender as per Chi-Square test (p>0.05). This is similar to the studies of Modir H et al[12], Bakri MH et al[11] and Seyam SH[13]. Modir H et al[12] double-blind prospective clinical trial comparing the prophylactic effects of dexamethasone, ketamine, and dexmedetomidine versus normal saline on intra- and postoperative PONV found mean age of the patients was 25.6 ± 3.8 years, and there was no significant difference among groups regarding age. Bakri MH et al[11] randomized, controlled, double-blind study comparing the effects of a single dose of dexmedetomidine to dexamethasone for reducing PONV found no statistically significant difference between the two groups in age, gender, weight, ASA status, smoking, history of motion sickness, history of previous PONV, and duration of surgery or anesthesia. Seyam SH[13] prospective randomized single-blind study comparing the effects of a single dose of dexmedetomidine or dexamethasone found no significant differences among the three groups with regarding mean age, sex, height, BMI, type of surgical procedure, length of surgical procedures, or length of anaesthesia. In the present study that there was no significant difference between the groups on basis of BMI as per Student t-test (p>0.05). This is comparable to the study of Modir H et al[12].which is a double-blind prospective clinical trial which found mean of BMI in all patients was 28.9 ± 3.6 kg/m2 and showed some difference among studied groups. The BMI of dexmedetomidine was higher than the placebo group, while the other groups did not differ significantly. The ASA Grading of the patients between two groups were comparable and statistically not significant as per Fisher test (p>0.05). The mean duration of surgery was comparable in Group A and Group B (74.40 ± 9.25 mins vs. 76.31 ± 5.99 mins) and statistically not significant as per Student t-test (p>0.05). In the present study, the mean duration of analgesia was comparable in Group A and Group B (85.97 ± 8.77 mins vs. 91.63 ± 6.06 mins) and statistically not significant as per Student t-test (p>0.05). The heart rate values at intubation and post intubation were comparable in both the groups at 15, 30, 45 and 60 mins interval post intubation, at extubation and post extubation and there was significant decrease in the heart rate values in Group A compared to Group B as per Student t-test (**p<0.05**). This is concordant to the study of Modir H et al[12].Modir H et al[12] double-blind prospective clinical trial observed that a significant difference among four groups at all times except for initial HR and mean of HR was lower in dexmedetomidine group than other groups except at initial HR. In our study, the systolic blood pressure, diastolic blood pressure and mean arterial pressure values at intubation and post intubation were comparable in both the groups at 15, 30, 45 and 60 mins interval post intubation, at extubation and post extubation there was significant decrease in the systolic blood pressure values in Group A compared to Group B as per Student t-test (**p<0.05**). This is consistent with the studies of Bakri MH et al[11] and Seyam SH[13].Bakri MH et al[11] randomized, controlled, double-blind study showed mean arterial blood pressure and heart rate were significantly lower in the Dexmed group after administration of dexmedetomidine and on arrival at the PACU, but no significant changes occurred after that.Seyam SH[13] prospective randomized single-blind study found mean arterial blood pressure intraoperatively was ∼78.05–90.81 mmHg in the ondan–dexamed group, whereas it was 83.51–101.73 mmHg in the ondan and 83.59–98.23 mmHg in the ondan–dexa group and there was a significant difference between the ondan–dexamed group and the other two groups. It was observed in the present study that 2 (3.1%) and 9 (13.8%) patients in Group A and Group B respectively required fentanyl and this difference was statistically significant as per Chi-Square test (**p<0.05**).The mean dose of propofol was significantly lower in Group A compared to Group B (368.18 ± 16.18 mg vs. 452.18 ±12.80 mg; **p<0.05**). Also the mean average dosage of propofol required was significantly lower in Group A compared to Group B (4.17 ± 0.61 mg $kg^{-1}hr^{-1}$ vs. 5.45 ± 0.92 mg $kg^{-1}hr^{-1}$; **p<0.05**). This is in concordance to the studies of Bakri MH et al[11] and Seyam SH[13]. Bakri MH et al[11] randomized, controlled, double-blind study observed mean total amount of intra-operative fentanyl was significantly lower in the Dexmed group. Within the first 24 h postoperatively, the mean total amount of tramadol consumption was significantly lower in the Dexmed group. However, there was no significant difference in the mean total amount of ondansetron between the two groups. Seyam SH[13] prospective

randomized single-blind study reported highly significant difference in tramadol dose during 24 h postoperatively between the three groups. The tramadol dose was 89.25±5025 in the ondan–dexmed group compared to 115.50±12.60 in the ondan group and 93.71±5.51 in the ondan–dexa group. There was highly significant difference in intraoperative fentanyl dose requirements among the three groups. The fentanyl dose was 99.75±11.55 in the ondan–dexmed group compared with 120.75±18.90 in the ondan group and 104.74±12.13 in the ondan–dexa group. It was observed in our study that the requirement of rescue antiemetic was significantly lower in Group A compared to Group B as per Chi-Square test (**p<0.05**). Bakri MH et al[11], Kim SH et al[16], Seyam SH[13] and Modir H et al[12] noted similar observations in their studies. Kim SH et al[99] in a randomized controlled trial observed that dexmedetomidine improved the quality of recovery (QoR-40), and reduced the rescue analgesic requirements during the first 24 h after surgery without prolonging recovery times or causing serious hemodynamic side effects. Seyam SH[13] prospective randomized single-blind study reported regarding the metoclopramide dose during 24 h postoperatively, there was a highly significant difference among the three groups. Metoclopramide dose was 0.12± 0.03in the ondan–dexmed group compared with 0.2±0.04 in the ondan group and 0.15±0.03 in the ondan–dexmed group. Analgesic request was after ~101.85±32.55 min postoperatively in the ondan–dexamed group versus 87.15±22.05 min in the ondan group and 106.94± 34.18 in the ondan–dexa group. Modir H et al[12] double-blind prospective clinical trial observed a significant difference in VAS scores between the dexmedetomidine group and the other groups. The VAS scores in dexamethasone group and ketamine groups showed of a similar trend but no statistical difference between the dexamethasone group and placebo group. In addition, the VAS scores gradually decreased in each time interval regardless of the patient. Significant differences were observed in Ramsey score at the 10th–110th min following administration of the study drugs. The Tukey post hoc test showed that the dexmedetomidine group (and then the ketamine group at the 10th min and the 60th–110th min) had a higher RSS than the other groups. The dexmedetomidine group had a higher RSS than the other groups. In the present study, the Verbal Rating Scale (VRS) was comparable at 0, 2, 6, 12 and 24 hours post-operative period between study groups. This finding was consistent with the study of Bakri MH et al[11]. In our study, vomiting was noted in 3 (4.6%) and 4 (6.1%) patients in Group A and Group B respectively. There was no significant difference between the groups as per Chi-Square test (p>0.05). Similar observations were noted in the studies of Bakri MH et al[11], Massad IM et al[17], Abdelmageed WM et al[18], Kim SH et al[16], Elhakim M et al[19], Wang JJ et al[20], Seyam SH[13], Modir H et al[12] and Myles PS et al[21]. Bakri MH et al[11] randomized, controlled, double-blind study observed incidence of PONV was 20.9% (9 patients) in the dexmedetomidine group compared to 27.9% (12 patients) in the dexamethasone group (P = 0.4) and neither nausea nor vomiting or retching was significant. Massad IM et al[17] study on balanced anesthesia with dexmedetomidine found that dexmedetomidine reduced the incidence of PONV in female patients undergoing elective diagnostic laparoscopic gynecological procedures and decrease in the overall consumption of anesthetic medications. Abdelmageed WM et al[18] study on analgesic properties of a dexmedetomidine infusion reported that PONV was significantly reduced in the dexmedetomidine group during the first 24h postoperatively and reduction of postoperative morphine consumption in the dexmedetomidine group. Kim SH et al[16] in a randomized controlled trial on Effects of single-dose dexmedetomidine on the quality of recovery found that the overall incidence of PONV during the 24 h after surgery showed a trend toward a lower incidence in the dexmedetomidine group, but it did not reach statistical significance and significantly reduced the incidence of severe PONV during the first 24 h after surgery. Elhakim M et al[19] suggested that dexamethasone might act as a serotonin receptor antagonist in the gastrointestinal tract. Wang JJ et al[20] proposed that dexamethasone might lead to a reduction in parasympathetic impulses to the brain by decreasing tissue inflammation around the surgery site. Seyam SH[13] prospective randomized single-blind study comparing the effects of a single dose of dexmedetomidine or dexamethasone observed nonsignificant differences between the three groups regarding the incidence of PONV during the 24 h postoperatively, with a slight difference in the ondan–dexmed group in relation to the other groups. Regarding the incidence of nausea, it was less in the ondan–dexmed group, with two (10.0%) episodes of nausea in comparison with five (25.0%) episodes in the ondan group and three (15.0%) episodes in the ondan–dexmed group (P=0.096). Regarding the incidence of retching, it was one (5.0%) episode in the ondan–dexmed group versus two (10.0%) episodes in ondan group and one (5.0%) episode in the ondan–dexa group (P=0.262). Regarding the incidence of vomiting, it was one (5.0%) episode in the ondan–dexmed group versus one episode (5.0%) in the ondan group and two (10.0%) episodes in the ondan–dexmed group (P=0.262). Regarding the overall incidence of PONV it was five (25.0%) episodes in the ondan–dexmed group in comparison with seven (35.0%) episodes in the ondan group and six (30.0%) episodes in the ondan–dexmed group. There was highly a significant difference among

the three groups regarding the severity of PONV. The PONV severity was 57.75±30.45 in the ondan–dexmed group compared with 68.25±23.10 in the ondan group and 60.64±31.97 in the ondan–dexa group. Modir H et al[12] double-blind prospective clinical trial observed two of patients in placebo group needed metoclopramide for control of nausea and vomiting. However, no significant difference was observed in need of metoclopramide among the groups. Dexamethasone immediately reduced the incidence of nausea and vomiting than placebo but was more effective with dexmedetomidine. Possible explanations for the lower incidence of PONV in the dexmedetomidine group may be related to the reduced consumption of intra-operative and postoperative opioids and inhaled anesthetics[22]. Also, dexmedetomidine decreases noradrenergic activity as a result of binding to alpha-2 presynaptic inhibitory adreno-receptors in the locus ceruleus, which may result in an antiemetic effect[23]. Lastly, it may be related to the overall reduction in sympathetic outflow and catecholamine release caused by dexmedetomidine. High sympathetic tone and catecholamine release may trigger PONV

CONCLUSION:

The hospital based interventional study which was conducted to prevent PONV made us to conclude thatDexmedetomidine has an effect similar to that of dexamethasone in reducing the incidence and severity of PONV and no significant difference was observed between the groups but rescue antiemetic was significantly lower in Group dexmedetomidine compared to Group dexamethasone. And the requirement of fentanyl is less in the dexmedetomidine group as compared to the dexamethasone group. And even the haemodynamic stability which was seen in the dexmedetomidine group compared to the dexamethasone group.

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