Original Article

Comparative evaluation of two different doses of nebulized intraperitoneal dexamethasone on postoperative pain in laparoscopic surgeries

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Abstract

Background and Aims: Postoperative pain is a major cause of discomfort after laparoscopic surgeries and thus necessitates prevention and treatment. This study aims to evaluate and compare two different doses of intraperitoneally nebulized (aerosol size: 0.4–4.5 micrometers) dexamethasone for the prevention of postoperative pain.

Material and Methods: In this double-blind, randomized control study, 135 patients undergoing laparoscopic surgeries were randomly assigned to three groups after obtaining ethical committee clearance and CTRI registration. Intraperitoneal nebulization was performed using the Aeroneb device, with group A receiving 16 mg dexamethasone, group B receiving 8 mg dexamethasone, and group C receiving 0.9% normal saline. The primary outcome was assessed by measuring visceral, somatic, and referred pain using a visual analog scale (VAS) at 6 hours postoperatively. Secondary outcomes included VAS at 1 and 24 hours, the hemodynamic response to pneumo-peritoneum, 24-hour anti-emetics, and opioid consumption.

Results: VAS score at 6 hours was 0.9 ± 1.06 in group A, 1.7 ± 1.45 in group B, and 2.3 ± 1.87 in group C for referred pain; the values were statistically significant ($P = 0.01$). VAS score was 0.7 ± 0.76 in group A, 1.7 ± 1.82 in group B, and 2.2 ± 2.06 in group C for dull aching pain; the results were statistically significant at 24 hours ($P = 0.001$). None of the values at any time point were statistically significant ($P < 0.05$) for incisional pain. The rise in heart rate after 5 minutes of pneumoperitoneum was the least in group A compared to group C ($P = 0.01$). Group C had the highest consumption of anti-emetics and rescue analgesics ($P = 0.001$).

Conclusions: Intraperitoneal dexamethasone nebulization of 16 mg and 8 mg both are equi-effective in decreasing the severity of pain after laparoscopic surgeries compared to normal saline nebulization ($P = 0.001$).

Keywords: Dexamethasone, intraperitoneal, laparoscopic, nebulization, pain

Introduction

Laparoscopic surgeries are the most accepted technique compared to open surgeries, with advantages being decreased tissue damage, lesser hemorrhage, lesser postoperative pain, lesser time of recovery, hospital stay, and better cosmetic results.[1] Laparoscopic procedures need intraperitoneal insufflation of carbon dioxide. It causes peritoneal stretching, a change in intraperitoneal pH, diaphragmatic irritation, and postoperative retention of gas in the abdominal cavity.[2] These factors mainly irritate peritoneal nerves and thus visceral and shoulder pain occurs postoperatively. However, the pain experienced post-laparotomy is somatic pain in large incisions. Multimodal approaches have been used to treat postoperative pain, such as intravenous opioids, NSAIDS, regional blocks, intraperitoneal instillation of

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Access this article online

Quick Response Code:

Website: https://journals.lww.com/joacp

DOI: 10.4103/joacp.joacp_232_24

How to cite this article: Shrivastava N, Taneja R, Kumari M, Sood R, Grover N. Comparative evaluation of two different doses of nebulized intraperitoneal dexamethasone on postoperative pain in laparoscopic surgeries. J Anaesthesiol Clin Pharmacol 2025;41:250-6.

Submitted: 14-May-2024 **Revised:** 29-Oct-2024
Accepted: 30-Oct-2024 **Published:** 29-Jan-2025

local anesthetics, steroids, dexmedetomidine, and magnesium sulfate ($MgSO_4$).[3,4]

Intraperitoneal instillation has been used widely but provided limited pain relief. It may be attributed to the non-uniform distribution of drugs throughout the peritoneal surface where aerosol size is >5 μm. A newer technique of intraperitoneal nebulization by using a microvibration-based nebulization device (Aeroneb Pro® system, Aerogen, Ireland) delivers homogenous aerosols of size <5 μm and is more effective.[5]

The main cause of post-laparoscopic pain is attributed to peritoneal inflammation due to carbon dioxide, which can be relieved using steroids such as dexamethasone and hydrocortisone.[6] Dexamethasone has been used before for pain relief in intravenous and intraperitoneal instillation forms. Studies report that a dose of 16 mg dexamethasone in intraperitoneal instillation form is effective in decreasing the intensity of pain and opioid requirement postoperatively.[7] However, there is a paucity of literature on its use in the intraperitoneal nebulization form.

This study was conducted to evaluate the effectiveness of intraperitoneal nebulized dexamethasone in a dose of 16 mg and 8 mg compared to placebo in decreasing the severity of pain after laparoscopic surgeries.

The primary objective of the study was to assess somatic, visceral, and referred pain using the visual analog scale (VAS) at 6 hours postoperatively. Secondary objectives were VAS at 1 and 24 hours postoperatively, the incidence of postoperative nausea and vomiting (PONV) in 24 hours, the need for the total amount of rescue analgesics or anti-emetics consumption, any attenuation of hemodynamic response to pneumoperitoneum, and any adverse effects of the drug.

Material and Methods

This double-blind randomized controlled study was approved by the institutional ethical committee, and CTRI registration (CTRI/2023/07/054843) was done. The confidentiality of subjects was maintained. The study was conducted in accordance with the principles of the World Medical Association Declaration of Helsinki, 1975, revised in 2013.

After obtaining the written informed consent, 135 patients aged between 18 and 60 years, ASA I and II, undergoing elective laparoscopic surgery under general anesthesia were recruited for the study. Patients were excluded if they had a BMI > 30 kg/m^2, were pregnant, were on chronic treatment with steroids, had cognitive impairment or communication problems, and if the surgical duration was less than 30 minutes and more than 2 hours.

Patients were kept fasting according to the ASA guidelines. In the preoperative period, patients were educated on the assessment of pain in terms of the type of pain, such as dull aching (visceral pain), incisional (somatic pain), and referred pain in the shoulder. VAS from 0 to 10 was used to assess the severity of pain, where 0 indicates no pain and 10 worst ever experienced pain.

Baseline heart rate (HR) and mean arterial pressure (MAP) were recorded in the preoperative room 30 minutes before shifting the patient inside the operation theatre (T_0). The patient and the observer were unaware of the interventional group being allotted. The primary investigator prepared and handed over the drug to the senior resident, who was unaware of the drug made and was supposed to administer the drug and handle that particular case along with the table consultant.

Patients randomized by computer-generated numbers were allocated by closed envelope method into three groups: group A (n = 45): intraperitoneal nebulization with dexamethasone 16 mg in normal saline diluted up to 4 mL; group B (n = 45): intraperitoneal nebulization with dexamethasone 8 mg in normal saline diluted up to 4 mL; and group C (n = 45): intraperitoneal nebulization with 0.9% normal saline 4 mL as placebo via AerogenPro-nebulizer system during pneumoperitoneum [Figure 1].

Patients were shifted to the operation theatre, intravenous fluid was started, and standard monitors were attached. A drug (4 mL) for intraperitoneal nebulization was handed over by the primary investigator to the concerned table anesthesiologist. All patients were preoxygenated and premedicated with IV fentanyl 2 μg/kg, induced with IV propofol 2–3 mg/kg titrated to loss of verbal response, after check ventilation, IV atracurium 0.5 mg/kg was administered. After 3 minutes of intermittent positive pressure ventilation, the ProSeal laryngeal mask airway was inserted and connected to a closed circuit system. Next, an oro-gastric tube and temperature probe were placed. Paracetamol 15 mg/kg IV was administered after induction, before the creation of pneumoperitoneum. Patients were maintained with O_2:Air 50:50, sevoflurane to achieve minimal alveolar concentration (MAC) of 1, and intermittent IV atracuronium 5 mg aliquots. Minute ventilation was adjusted to keep end-tidal carbon dioxide ($ETCO_2$) at 35–45 mmHg. The Aerogen pre-nebulizer unit was placed in series between the insufflator and the insufflation tubing. The drug was administered to the abdominal cavity by the insufflating gas through a 200-cm tubing connected to the

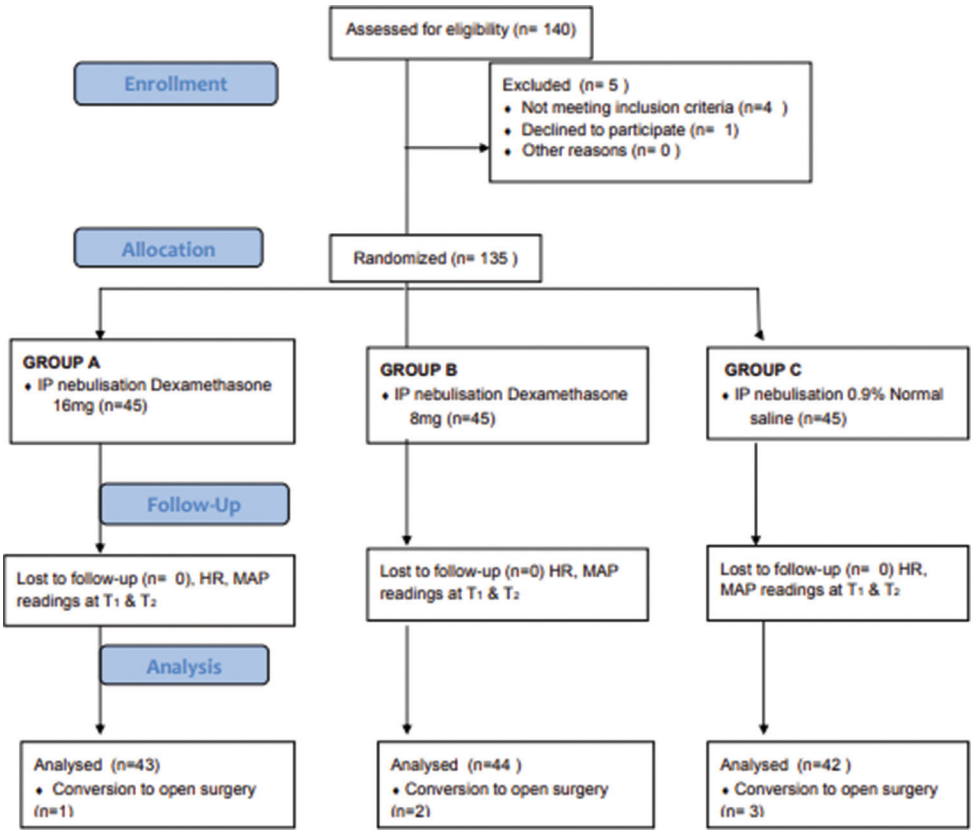

Figure 1: CONSORT diagram

Veress needle. The time of withdrawal of the Veress needle for insertion of the first trocar was considered the end point of pneumoperitoneum creation. Heart rate and MAP were recorded at 5 minutes (T_2) and 10 minutes (T_3) after creation of the pneumo-peritoneum. Intra-abdominal pressure was maintained between 12 and 15 mmHg throughout the surgery. The surgeon was requested to wait for the mist to clear if at all it was present due to nebulized drug.

Any fall in HR < 50/min was treated with IV atropine 0.6 mg, and any fall in systolic blood pressure (SBP) <20% from the baseline was treated with IV mephentramine 3 mg aliquots. Patients out of muscle relaxant during pneumoperitoneum and surgical duration of more than 2 hours were excluded from the analysis. IV ondansetron 0.16 mg/kg and IV tramadol 50 mg were administered half an hour before reversal. Inj. bupivacaine 0.25% 8–10 mL was used for local infiltration at the port sites. Patients were reversed with IV glycopyrrolate 0.01 mg/kg and IV neostigmine 0.05 mg/kg, The airway device was removed after adequate return of tone, power, and reflexes and shifted to the recovery room. All the patients received IV paracetamol 15 mg/kg thrice a day for postoperative analgesia.

Patients were assessed for pain by using the VAS for visceral, somatic, and referred pain at 1 hour (T_3), 6 hours (T_4), and 24 hours postoperatively (T_5) on rest and deep breathing. At T_5, VAS was assessed at movement also. VAS >3 was treated with IV tramadol 50 mg after antiemetic as a rescue analgesic.

Patients were assessed for postoperative nausea and vomiting (PONV); scoring was done from 0 to 3, with 0 for no symptoms, 1 for nausea, 2 for retching, and 3 for vomiting, at T_3, T_4, and T_5. In case of the presence of symptoms, IV metoclopramide 10 mg was administered.

The total amount of rescue antiemetics or analgesics/opioids required was recorded at T_5, 24 hours postoperatively. Adverse events due to dexamethasone if witnessed during surgery or surgical follow-up, such as hyperglycemia, delayed wound healing, or infection, were recorded.

Sample size calculation was based on a pilot study conducted by us, which reported the mean pain score in 16 mg and 8 mg intraperitoneal dexamethasone on a 10-point VAS scale. VAS was compared for both groups' mean ± SD: 1.29 ± 1.14 and 2.11 ± 1.57. To achieve 80% power at 5% level of significance and 95% confidence interval, the minimum sample size required was 41 in each group (total: 123). However, on account of exclusion from the study, a total of 45 patients were recruited per group.

Statistical analysis

Collected data were analyzed using SPSS 13. Quantitative data were shown as mean and standard deviation, and qualitative data were shown as frequency. Qualitative data were compared between the two groups by using the Chi-square test, and quantitative data were compared between the two groups by using a *t*-test for normal distribution. When the distribution was not normal, non-parametric tests were used. A P value < 0.05 was considered significant.

Results

A total of 135 patients were enrolled, and 129 were included in the data analysis; two patients from group A, one patient from group B, and three patients from group C were excluded from the analysis due to conversion to open surgery. There was no significant difference among the groups with respect to age, weight, gender, and duration of surgery [Table 1].

A total of three patients (one in each group) were operated for laparoscopic appendicectomy, and the other 132 patients were posted for laparoscopic cholecystectomy.

Table 1: Demographic variables

Measured variable	Group A (n=45)	Group B (n=45)	Group C (n=45)	P
Age (years)	36.6±12.2	38.1±13.6	36.7±12.3	0.82
Sex (F:M)	34:11	29:16	32:13	0.81
Weight (kg)	59.1±9.1	60.4±8.6	56.5±10.0	0.13
ASA I: ASA II	30:15	34:11	28:17	0.09
Duration of surgery (min)	55	58	52	0.10

Dull aching pain at both 1 and 6 hours was similar in all the groups, at 24 hours P value between group A and B was 0.02 and between group A and C 0.007 between B and C 0.4. Thus, 16 mg dexamethasone was found to be more effective in decreasing VAS score at 24 hours than 8 mg dexamethasone as compared to placebo [Table 2].

Shoulder/referred pain was minimal in group A at all time points, which was statistically significant than the VAS in group C ($P < 0.05$). However, the VAS score was less for group A as compared to group B, but the results were not significant statistically ($P = 0.5$). Thus, 16 mg and 8 mg dexamethasone both were found to be more effective in relieving shoulder pain than placebo [Table 3].

Incisional pain was similar in all three groups at 1, 6, and 24 hours on movement. No statistically significant difference was found between VAS scores in groups A, B, and C [Table 4].

A statistically significant increase in the heart rate ($P = 0.01$) was seen in group C as compared to groups A and B after 5 minutes of pneumoperitoneum creation. There was no statistically significant difference in mean arterial pressure at any time point in all three groups [Table 5].

A statistically significant difference ($P = 0.001$) was found for total rescue analgesic dose consumption in group A compared to group C. Tramadol consumption was higher in group B than group A, but the results were not statistically significant. Total anti-emetic consumption in the first 24 hours was less in group A as compared to groups B and C, and the difference was statistically significant between groups A and C ($P = 0.001$) [Table 6].

Table 2: Assessment of visceral pain on rest, deep breathing, and movement at different time points

Postoperative VAS	Group A (n=43)	Group B (n=44)	Group C (n=42)	P
At Rest at 1 hour ($DAPR_1$)	2.1±1.99	2.4±1.94	2.8±1.96	0.24
At Deep Breathing at 1 hour ($DAPD_1$)	1.5±1.50	1.7±1.43	2.0±1.81	0.32
At Rest at 6 hours ($DAPR_6$)	1.1±1.10	1.3±1.05	1.4±1.15	0.42
At Deep Breathing at 6 hours ($DAPD_6$)	1.5±1.27	1.6±1.17	1.7±1.375	0.75
At Rest at 24 hours ($DAPR_{24}$)	0.5±0.66	1.2±1.20	1.8±2.04	0.001
At Deep Breathing at 24 hours ($DAPD_{24}$)	0.7±0.76	1.7±1.82	2.2±2.06	0.001
At Movement at 24 hours ($DAPM_{24}$)	1.3±1.03	1.6±1.65	2.6±2.07	0.001

Table 3: Assessment of referred pain on rest, deep breathing, and movement at different time points

Postoperative VAS	Group A (n=43)	Group B (n=44)	Group C (n=42)	P
At rest at 1 hour (SPR_1)	0.6±1.39	1.1±1.42	1.8±2.34	0.007
At deep breathing at 1 hour (SPD_1)	0.7±1.30	1.4±1.76	2.2±2.30	0.001
At rest at 6 hours (SPR_6)	0.3±0.67	1.4±1.23	1.5±1.40	0.001
At deep breathing at 6 hours (SPD_6)	0.9±1.06	1.7±1.45	2.3±1.87	0.001
At rest at 24 hours (SPR_{24})	0.5±0.50	1.3±1.40	1.4±1.87	0.004
At deep breathing at 24 hours (SPD_{24})	0.5±0.50	1.3±1.74	1.3±1.27	0.004
At movement at 24 hours (SPM_{24})	0.5±0.69	1.3±2.30	1.4±1.65	0.023

Table 4: Assessment of incisional pain on rest, deep breathing, and movement at different time points

Postoperative VAS	Group A (*n*=43)	Group B (*n*=44)	Group C (*n*=42)	*P*
At rest at 1 hour (IPR_1)	1.23±0.61	1.39±0.95	1.51±0.3	0.14
At deep breathing at 1 hour (IPD_1)	1.22±0.6	1.39±0.76	1.67±1.5	0.11
At rest at 6 hours (IPR_6)	1.22±0.42	1.27±0.50	1.39±0.58	0.63
At deep breathing at 6 hours (IPD_6)	1.33±0.47	1.53±0.9	1.55±0.75	0.28
At rest at 24 hours (IPD_{24})	1.20±0.51	1.32±0.52	1.44±0.51	0.08
At deep breathing at 24 hours (IPD_{24})	1.25±0.51	1.30±0.51	1.44±0.50	0.18
At movement at 24 hours (IPM_{24})	1.23±0.5	1.33±0.47	1.46±1.09	0.34

Table 5: Assessment of response to pneumoperitoneum (heart rate, mean arterial pressure) in 3 groups

	Heart rate			Mean arterial pressure		
	T_0	T_1	T_2	T_0	T_1	T_2
Group A (*n*=45)	86.0±12.8	75.6±13.7	74.2±14.9	100.6±11.4	95.5±14.3	94.9±16.2
Group B (*n*=45)	84.2±15.3	78.8±14.9	80.8±13.7	96.7±9.5	97.5±16.2	95.7±15.1
Group C (*n*=45)	82.7±7.4	83.9±12.6	78.6±9.5	98.7±5.3	99.0±20.1	99.1±14.6
P	0.44	0.01	0.05	0.13	0.62	0.38

Table 6: Total analgesic and anti-emetic consumption in postoperative 24 hours

Total consumption	Group A (*n*=43)	Group B (*n*=44)	Group C (*n*=42)	*P*
Tramadol (mg)	50±33.7	65.8±41.1	85.1±46.9	0.001
Metoclopramide (mg)	1.21±3.31	4.65±6.3	6.66±9.53	0.001

All three groups showed no evidence of hyperglycemia at any of the time points. No adverse effects were reported in post-surgery follow-up.

Discussion

According to the results in this study, dexamethasone nebulization using Aerogen pre-nebulization system significantly reduces referred pain as well as dull aching pain in the first 24 hours postoperatively compared with placebo. Postoperative 24-hour consumption of metoclopramide and tramadol was reduced, which was statistically significant. The use of dexamethasone has been shown to decrease some stress responses to pneumoperitoneum. There was no statistically significant difference in pain scores in incisional pain.

The nebulization system used in this study consists of a commercially available high-frequency vibrating mesh nebulizer which is reusable and easy to assemble. It can be placed in series with insufflating tubing, requiring no extra tubing, injection system, or driving gas, and can be sterilized using plasma sterilization. It allows simultaneous and efficient delivery of drugs along with surgical procedures being performed.[8] Because the particle size generated by the Aerogen nebulization device is small (mass median diameter: 5 mm), it was found that the drug spreads uniformly throughout the peritoneal surface.[9,10] This nebulizer has been used for pain relief in various studies with effective results.[8,11,12] Studies have compared intraperitoneal nebulization and peritoneal instillation of ropivacaine and found nebulization to be superior to the instillation of ropivacaine.[13-15] However, this nebulization technique forms droplets of small size creating a foggy environment, which may interfere with the surgeon's vision. Aeroneb Pro can deliver 3 mL of solution in 5–6 min.[12] In our study, we used a volume of 4 mL, which took 5–7 minutes to clear the mist.

Opioids have remained the mainstay of treatment for intraoperative sympathetic stimulation caused due to pneumoperitoneum and postoperative pain management, but it has many side effects such as delayed recovery, obstructive breathing in the immediate postoperative period, drug dependency, and urinary retention. Dexamethasone has an anti-inflammatory effect, which has a beneficial role in providing postoperative analgesia.[7]

Dexamethasone is a long-acting glucocorticoid with a half-life of 36–72 hours. Postoperative analgesia may be attributed to various mechanisms such as inhibition of prostaglandin production, suppression of bradykinin, release of neuropeptides from nerve endings, inhibition of cyclooxygenase isoform 2 synthesis, tumor necrosis factor alpha, and interleukins.[16] The referred pain in the shoulder may be due to residual CO_2, blood, or other materials (e.g. bile and amniotic fluid) below the diaphragm, irritating the afferent nerve fibers of the phrenic nerve supplying the diaphragm.[17] Thus, non-inflammatory agents such as corticosteroids may relieve shoulder pain severity via the reduction of inflammation after laparoscopy. It may also contribute to relieving visceral pain, which may be due to surgical manipulation and tissue destruction of the visceral organ during the surgical process.

A study by Srivastava *et al*.[4] compared intraperitoneal instillation of dexamethasone (8 mg), dexmedetomidine (1 μg/kg), and their combination to decrease the occurrence of PONV and analgesics requirement after laparoscopic hysterectomies. They concluded that dexamethasone alone and in combination with dexmedetomidine is useful in decreasing pain scores and PONV in comparison to placebo. This is similar to the results of our study, where dexamethasone alone can provide effective analgesia and relief from PONV. In a study by Asgari *et al*.,[7] the severity of shoulder pain was assessed in the first 24 hours after gynecology laparoscopy and showed the analgesic effect of 16 mg intraperitoneal dexamethasone on reducing postoperative shoulder pain, which is consistent with the results of the present study.

In this study, it was found that nebulized dexamethasone 8 mg was effective in decreasing postoperative pain compared to placebo. This finding aligns with the observation made by Nasr *et al*.,[18] who reported that patients receiving intraperitoneal bupivacaine with 8 mg dexamethasone had a significantly longer duration of analgesia (9.2 hours) as compared to bupivacaine alone (6.1 hours) following laparoscopic bariatric surgery. In the study conducted by Ismail *et al*.,[19] IP and IV dexamethasone were effective in reducing patients' pain and PONV in women undergoing gynecologic laparoscopy, which confirms the results of the present study. Nouri *et al*.[20] in a study inferred that intraperitoneal dexamethasone was effective in shoulder pain control and PONV after gynecological laparoscopy when compared to placebo.

Laparoscopic surgeries are notorious for a high incidence of PONV, with a mean incidence of 56.4%.[21] Untreated PONV can increase the risk of some postoperative complications, such as gastric aspiration, bleeding, wound dehiscence, dehydration, and electrolyte disturbances.[22]

Dexamethasone has been suggested as an effective prophylactic antiemetic in many surgical procedures which outweighs its adverse effect on wound healing; therefore, it is suggested as an effective and appropriate antiemetic to be preoperatively used. Its anti-emetic properties may be due to the involvement of the physiological transmission pathway of glucocorticoid receptors in vomiting, including serotonin neurotransmitter, neurokinin 1, 2 tachykinin protein receptors, alpha-adrenergic receptors, and regulation of hypothalamic pituitary adrenal axis.[16]

There are various studies where dexamethasone has been used intraperitoneally instilled form to decrease postoperative nausea and vomiting and has been found effective.[4,19,20] These findings are similar to our study where intraperitoneal nebulization of dexamethasone decreased the requirement of perioperative anti-emetics.

There are certain limitations of the study, such as a foggy environment interfering with the surgeon's vision. Furthermore, the time to request the first rescue analgesic and time to ambulation were not assessed. In addition, there was no possibility to evaluate the causal relationships between the study variables due to the nature of the study design. Moreover, the patients were only followed for 24 hours, and the studied outcomes and adverse effects after this period were not evaluated.

Conclusion

Intraperitoneal dexamethasone nebulization of 16 mg and 8 mg both are equi-effective in decreasing the severity of pain after laparoscopic surgeries compared to normal saline nebulization. Both decreased postoperative requirement of analgesia and anti-emetic consumption. Lower doses of dexamethasone (8 mg) can be used instead of 16 mg to obtain similar outcomes.

Financial support and sponsorship

ESIC medical college, NH-3, Faridabad.

Conflicts of interest

There are no conflicts of interest.

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