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RESEARCH ARTICLE

Evaluation of Dexamethasone and Ondansetron as Intraperitoneal Adjuvants to Bupivacaine for Analgesia in Laparoscopic Cholecystectomy

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Abstract

Postoperative pain remains a significant concern following laparoscopic cholecystectomy (LC), necessitating a multimodal analgesic approach due to its multifactorial origins. Intraperitoneal instillation of local anesthetics over the diaphragmatic surface and gallbladder bed has emerged as an effective strategy to reduce visceral pain. While several adjuvants have been explored for enhancing analgesic efficacy, there is limited comparative evidence on their effectiveness when administered intraperitoneally with local anesthetics. This study aimed to compare the analgesic efficacy of dexamethasone versus ondansetron as adjuvants to 0.25% bupivacaine in patients undergoing elective LC. Ninety patients were randomly assigned into three groups to receive 2 ml of either dexamethasone, ondansetron, or normal saline, along with 30 ml of 0.25% bupivacaine, instilled intraperitoneally over the gallbladder bed. Postoperative pain was assessed using the Numeric Rating Scale (NRS) at 0, 1, 2, 4, 6, 12, and 24 hours, along with the time to first rescue analgesic and total number of rescue doses required within 24 hours. Incidence and severity of postoperative nausea and vomiting (PONV) were also evaluated using a 4-point scale. Results showed that the dexamethasone group had significantly lower NRS pain scores and reduced need for rescue analgesics compared to the ondansetron and control groups ($p<0.001$ and $p<0.05$, respectively). Additionally, patients in the dexamethasone group experienced significantly lower rates of PONV within the first 12 hours postoperatively ($p<0.05$). In conclusion, intraperitoneal dexamethasone as an adjuvant to bupivacaine provides superior analgesia and antiemetic effects compared to ondansetron in patients undergoing elective laparoscopic cholecystectomy, likely due to its potent local anti-inflammatory properties.
Laparoscopic cholecystectomy, Intraperitoneal instillation, Dexamethasone, Ondansetron, Postoperative pain, Postoperative nausea and vomiting

Key words: Laparoscopic cholecystectomy, Intraperitoneal instillation, Dexamethasone, Ondansetron, Postoperative pain, Postoperative nausea and vomiting

1 | INTRODUCTION

LC (Laparoscopic Cholecystectomy) is one of the most widely performed procedures as a treatment for cholelithiasis. It has now become the gold standard technique, replacing the open cholecystectomy procedure for symptomatic cholelithiasis. (1) Although LC has superiority with regard to outcome over open cholecystectomy, pain is still a major concern and challenge postoperatively. The pain experienced after laparoscopic procedures differs from that experienced after laparotomy. Patients experience visceral pain in laparoscopic surgeries, while laparotomy procedures cause parietal pain. (2–5)

Pain can be somatic pain from the incision site, vis-

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ceral pain from visceral structures, and referred pain to the shoulder tip from subdiaphragmatic region. (1) Visceral pain can be because of ruptured blood vessels due to rapid distension of the peritoneum, release of inflammatory molecules, abdominal wall trauma, nerve damage, pneumoperitoneum caused by the use of carbon dioxide for insufflation, high pressures maintained in the abdomen, and irritation of the phrenic nerve. (2)

Pain increases and reaches its maximum intensity in the first hour postoperatively. It is aggravated by coughing, mobility of the patient, and respiratory movements. (4) It usually gets relieved in 2 to 3 days postoperatively. It not only causes discomfort to the patient but also delays early ambulation and discharge from the hospital. (2)

Pain after LC has traditionally been managed by a multimodal approach as the causes are multifactorial. (5) Many approaches have been tried to reduce the pain after LC. Some of them are intravenous analgesics like nonsteroidal anti-inflammatory drugs, local infiltration of local anesthetic drugs, intermittent intramuscular opioids, epidural and intrathecal opioids, local anesthetics, intrapleural and intercostal nerve blocks. (2, 4) Intraperitoneal irrigation on the diaphragmatic surface and gall bladder bed using local anesthetics has been found to be a novel and effective way of reducing visceral pain. (2)

There are many studies showing the efficacy of intraperitoneal irrigation of different local anesthetics like bupivacaine, ropivacaine, and lignocaine for reducing postoperative pain following LC. (1, 4, 6, 7) A few studies have evaluated the benefits of using either dexamethasone or ondansetron as adjuvants to intraperitoneal local anesthetics in comparison with local anesthetic alone in ameliorating postoperative pain following LC. (2, 5, 8)

There are however, no studies comparing the efficacy or superiority of one adjuvant over the other when used with bupivacaine through the intraperitoneal route. Hence, we wanted to compare the efficacy of intraperitoneal infiltration of ondansetron and dexamethasone as adjuvants to bupivacaine on reducing the postoperative pain following LC. PONV (Postoperative Nausea and Vomiting) is also a common complaint following laparoscopic surgeries, and its incidence ranges from 40-75%. (9, 10) As dexamethasone and ondansetron are also effective antiemetic agents, we also assessed the effect of these drugs in reducing the severity of PONV following LC. (5, 9)

2 | MATERIALS AND METHODS

This was a prospective double-blind randomized controlled study carried out over a study. 90 participants belong to ASA PS I-II, aged 18-60 years, of either sex, and scheduled for elective laparoscopic cholecystectomy under general endotracheal anesthesia, divided equally into 3 groups as follows.

- Group D: Received 2 ml 8 mg of dexamethasone with 30 ml of 0.25% bupivacaine.
- Group O: Received 2 ml 4 mg ondansetron with 30 ml of 0.25% bupivacaine.
- Group C: Received 2 ml of normal saline with 30 ml of 0.25% bupivacaine.

The intensity of postoperative pain was recorded using the NRS (Numerical Rating Scale), ranging from 0 to 10, where 0 indicated no pain and 10 represented the worst pain, at intervals of 0, 1, 2, 4, 6, 12, and 24 hours. If the NRS was 4 or higher, rescue analgesia with 50 mg of intramuscular Tramadol was administered, and the number of rescue doses given over 24 hours was recorded.

The intensity of PONV was recorded at 0, 1, 2, 4, 6, 12, and 24 hours postoperatively using a Four Point Scale.

0: No nausea and vomiting

1: Nausea only; no vomiting

2: Nausea and vomiting ($\leq$ 2 episodes of vomiting)

3: Severe nausea and vomiting (> 2 episodes of vomiting).

Data was analysed using SPSS version 22 software. Categorical data was displayed as frequencies and proportions, with the chi-square test employed to determine significance. Continuous data was presented as means and standard deviations, and an independent t-test was conducted to assess the mean difference between two groups. A p-value of less than 0.05 was considered statistically significant.

3 | RESULTS

The mean age of the study population was 38 years. Among the 90 patients studied, the majority of the subjects in our study were females (70%), and the rest were males (30%). The Shapiro-Wilk p-value for age was 0.005, indicating that the age data is not normally distributed. Therefore, we used the Kruskal-Wallis test to compare the mean age across the treatment groups. There was no significant difference in mean age across treatment groups, as indicated by the p-value of 0.205.

Table 1. Age Distribution

Age	Mean	SD	P -Value
Dexamethasone	36.6	12.2	
Ondansetron	38.5	12.3	**0.205**
Control	41.5	11.6	

Post-Operative Pain – Numerical Rating Scale

Postoperative pain was maximum during 0, 1, and 2 hours, which gradually declined over a period of 24 hours, as shown in Table 2.

Table 2. Post-Operative Pain – Numerical Rating Scale

Hours	Median	IQR	Minimum	Maximum
0 hr.	7	8-6	5	9
1hr.	6	7-6	4	8
2 hrs.	6	6-5	4	7
4 hrs.	5	5-4	0	6
6 hrs.	4	4-2	0	6
12 hrs.	3	4-2	0	6
24 hrs.	0	2-0	0	4

Comparison of Post-Operative Pain among 3 Groups

Since the NRS scores at various time points (0 hr, 1 hr, 2 hrs., 4 hrs., 6 hrs., 12 hrs., 24 hrs.) were not normally distributed (Shapiro Wilks p-values are <0.001), we used the Kruskal-Wallis test to compare these scores across the three treatment groups (dexamethasone, ondansetron, and control).

The Kruskal-Wallis test revealed significant differences in NRS scores across the treatment groups at all time points ($p < 0.001$). The mean scores were consistently lowest in the dexamethasone group and highest in the control group, as shown in Table 3.

Table 3. Post-Operative Pain – Comparison among 3 Groups

Hours	Dexamethasone	Ondansetron	Control	P-Value
0 hr.	6.17 ± 1.01	7.2 ± 0.71	7.46 ± 0.5	<0.001
1hr.	5.66 ± 0.66	6.5 ± 0.5	6.96 ± 0.55	<0.001
2 hrs.	5.36 ± 0.66	5.8 ± 0.6	6.13 ± 0.62	<0.001
4 hrs.	3.83 ± 1.05	4.9 ± 0.3	5.2 ± 0.71	<0.001
6 hrs.	1.30 ± 1.26	3.53 ± 1.10	4.3 ± 0.83	<0.001
12 hrs.	1.23 ± 1.16	3.2 ± 1.09	3.63 ± 0.96	<0.001
24 hrs.	0 ± 0	0.86 ± 1.13	1.5 ± 0.93	<0.001

Comparison of Number of Rescue Analgesics Required among 3 Groups

The chi-square test revealed significant differences in the number of rescue analgesics required among the treatment groups ($p < 0.001$). The dexamethasone group had a significantly higher propor-

tion of patients requiring only one or two rescue analgesics compared to the ondansetron and control groups. The ondansetron group predominantly required three rescue analgesics, while the control group had similar requirements to ondansetron but also had a notable number of patients requiring four rescue analgesics. Overall, dexamethasone was associated with a lower need for multiple rescue analgesics, indicating better pain control compared to ondansetron and the control group.

Table 4. Number of Rescue Analgesics– Comparison among 3

	Dexamethasone	Ondansetron	Control	P-Value
1	8 (26.7%)	0 (0%)	0 (0%)	<0.001
2	22 (73.3%)	7 (23.3%)	0 (0%)	
3	0 (0%)	20 (66.7%)	20 (66.7%)	
4	0 (0%)	3 (10%)	10 (33.3%)	

In survival analysis, dexamethasone (D) demonstrated a gradual decline in the proportion of patients remaining pain-free over time. At 1 hour, approximately 81.8% of patients were still pain-free, but this proportion decreased to 22.7% by 3 hours, with a significant number requiring rescue analgesics after 2 hours. Ondansetron (O) initially had a high survival rate, with 93.8% pain-free at 0.5 hours, but this rate dropped sharply, with only 18.8% remaining pain-free by 1.5 hours and none by 2 hours. Control (C) started with 60% of patients pain-free at 0.5 hours, but this quickly dropped to 0% by 1 hour, indicating that all patients needed rescue analgesics by that time. Overall, the analysis showed dexamethasone provided a more gradual decline in pain relief compared to ondansetron and control (Table 5).

Table 5. Rescue Analgesics – Survival Table

Treatment	Time (hrs.)	Cumulative Proportion Surviving	No of Cumulative Events	No of Remaining Cases
Dexamethasone	1	0.818	4	18
	1.5	0.727	6	16
	2	0.409	13	9
	2.5	0.364	14	8
	3	0.227	17	5
Ondansetron	0.5	0.938	1	15
	1	0.25	12	4
	1.5	0.188	13	3
	2	0.000	16	0
Control	0.5	0.600	2	3
	1	0.000	5	0

The survival analysis showed that Dexamethasone provided the longest pain relief, with a mean survival time of 2.38 hours and a median survival time of 2.0 hours. This means patients experienced significant pain relief for an average of 2.38 hours, and at least half of the patients had pain relief for 2 hours or more. Ondansetron had a mean survival time of 1.18 hours and a median survival time of 1.0 hour, indicating that patients had moderate pain relief, but it was shorter compared to dexamethasone. Control had the shortest mean survival time of 0.80 hours and a median survival time of 1.0 hour, showing that pain relief was the least effective in this group. Overall, dexamethasone was the most effective at prolonging pain relief, making it a better option for managing postoperative pain compared to ondansetron and control.

Table 6. Rescue Analgesics– Mean and Median for Survival Analysis

Treatment	Mean	SE	95% CI Lower	Upper	Median	SE	95% CI Lower	Upper
Dexamethasone	2.38	0.23	1.93	2.83	2	0.165	1.677	2.23
Ondansetron	1.18	0.11	0.97	1.40	1	0.079	0.846	1.15
Control	0.80	0.12	0.56	1.04	1	0.000	-	-

The log rank test showed a statistic of 24.65 with 2 degrees of freedom and a p-value of <0.001, indicating a significant difference in pain relief durations among the three treatment groups (dexamethasone, ondansetron, and control). This means that dexamethasone significantly outperformed both ondansetron and control in extending pain relief for patients undergoing laparoscopic cholecystectomy. The test confirms that dexamethasone is much more effective than the other treatments for managing postoperative pain.

Post-Operative Nausea and Vomiting

The chi-square tests indicated significant differences in the incidence of nausea and vomiting among the treatment groups at all-time points ($p < 0.001$). At 0 hours, the dexamethasone group had a higher proportion of patients with no nausea or vomiting compared to the ondansetron and control groups. By 1 hour, the dexamethasone group showed a substantial reduction in nausea and vomiting compared to both ondansetron and control groups. These differences persisted at 2, 4, and 6 hours, with the dexamethasone group consistently showing the lowest incidence of nausea and vomiting. In contrast, the control group had the highest rates of nausea and vomiting throughout the observation period.

4 | DISCUSSION

The current study aimed to compare the analgesic efficacy of intraperitoneal instillation of dexamethasone and ondansetron as adjuvants to 0.25% bupivacaine in patients undergoing laparoscopic cholecystectomy. A balanced distribution of 90 patients into three equal groups (33.3% each) receiving dexamethasone, ondansetron, or control treatment ensured unbiased comparisons. The sex distribution across the entire study population showed a higher proportion of female patients (63%) compared to male patients (27%). This is consistent with the epidemiological patterns observed in gallbladder diseases, which tend to be more prevalent in females. When comparing sex distribution across the treatment groups, there was no statistically significant difference ($p = 0.127$), suggesting that gender was evenly distributed across the three groups. The overall mean age of the study population was 38.87 years with a standard deviation of 12.10, ranging from 19 to 65 years. The control group had a slightly higher mean age of 41.5 years compared to the dexamethasone group at 36.6 years and the ondansetron group at 38.5 years. Despite these differences, the variation in age across the groups was not significant, ensuring that age-related factors did not influence the outcomes of the study. The distribution of comorbidities among the study population was relatively low, with the majority of patients (65.6%) reporting no comorbid conditions. The most common comorbidity was obesity (14.4%), followed by hypertension (8.9%) and hypothyroidism (7.8%). The presence of comorbidities such as diabetes mellitus (DM), seizures, smoking, and alcohol use was minimal, each accounting for a small percentage of the study population. The distribution of ASA classification was consistent across the groups, ensuring that the physical status of patients did not influence the comparative outcomes of the analgesic interventions.

The need for rescue analgesics in the first 24 hours postoperatively is a critical indicator of the efficacy of the primary analgesic intervention. In this study, the majority of patients required 2 to 3 doses of rescue analgesics (32.2% and 44.4%, respectively), while a smaller proportion required only 1 dose (8.9%) or 4 doses (14.4). Postoperative pain was assessed using a NRS at various time intervals. The median pain scores showed a gradual decrease over time, from a median score of 7 at 0 hours to a median score of 0 at 24 hours. The IQR (Interquartile Range) for pain scores also narrowed over time, indicating a reduction in the variability of pain experience among patients. This trend suggests that the analgesic interventions were effective in managing post-

operative pain, particularly as the immediate postoperative period progressed.

PONV is a common and distressing complication following laparoscopic surgery. In this study, the incidence of PONV was meticulously recorded at various time intervals postoperatively. At 0 hours post-surgery, 47.8% of patients experienced both nausea and vomiting, while 40% had nausea without vomiting. This high initial incidence decreased rapidly over time, with only 2.2% of patients reporting nausea and vomiting at 1 and 2 hours, and no cases of PONV observed at 4 hours and beyond. By 12 hours, all patients were free of PONV symptoms.

The comparison of NRS scores across the dexamethasone (D), ondansetron (O), and control (C) groups at various time points revealed significantly lower scores in the dexamethasone group compared to the others at all measured intervals ($p < 0.001$). At baseline (0 hours), the mean NRS score for dexamethasone was 6.17±1.01, while the control group had the highest score of 7.46±0.5, suggesting that dexamethasone provides immediate analgesic effects. At 1 hour postoperatively, the scores were 5.66±0.66 for dexamethasone, 6.5±0.5 for ondansetron, and 6.96±0.55 for control, indicating that dexamethasone continued to effectively reduce pain levels shortly after surgery.

By 2 hours, the dexamethasone group maintained the lowest score of 5.36±0.66, with the control group again having the highest at 6.13±0.62, reinforcing dexamethasone's efficacy. At 4 hours, the scores were 3.83±1.05 for dexamethasone, 4.9±0.3 for Ondansetron, and 5.2±0.71 for control, suggesting that dexamethasone may provide prolonged analgesic effects. At 6 hours, there was a dramatic drop in pain scores for dexamethasone (1.30±1.26) compared to ondansetron (3.53±1.10) and control (4.3±0.83), indicating a strong and increasing analgesic effect of dexamethasone over time. At 12 hours, the scores were 1.23±1.16 for dexamethasone, 3.2±1.09 for ondansetron, and 3.63±0.96 for control, showing sustained pain relief with dexamethasone. Finally, at 24 hours, the dexamethasone group reported no pain (0±0), while the ondansetron and control groups had scores of 0.86±1.13 and 1.5±0.93, respectively, highlighting the superior long-term pain relief provided by dexamethasone compared to the other treatments.

These findings are consistent with several other studies that have investigated the analgesic efficacy of intraperitoneal dexamethasone and ondansetron in patients undergoing laparoscopic cholecystectomy. A study by Basim Herez Ali et al., (11) also found that intraperitoneal instillation of dexamethasone or ondansetron combined with bupivacaine reduced postoperative pain intensity compared to bupivacaine alone, as assessed by VAS scores. Similarly, Doaa H. Abdelaziz et al., (12) reported that intraperitoneal ondansetron had an additional role in controlling postoperative pain alongside its antiemetic effect. Another study by Nazemroaya B et al., (13) demonstrated that intraperitoneal administration of 8 mg dexamethasone was associated with a significant reduction in postoperative pain compared to the control group. Vandana et al., (14) also found that administering 16 mg of dexamethasone with bupivacaine intraperitoneally during laparoscopic cholecystectomy significantly decreased postoperative pain and the need for rescue analgesia compared to bupivacaine alone. In comparison, other studies have explored the effectiveness of various analgesic strategies. Elnoury et al., (15) highlighted that both 4 mg and 8 mg doses of intraperitoneal dexamethasone with bupivacaine delayed the need for rescue analgesia and reduced pain significantly.

Celik et al., reported that combining bupivacaine with dexamethasone led to significantly lower pain scores and reduced opioid consumption compared to bupivacaine alone or saline. (16) Dogan et al., similarly found that the combination of bupivacaine and dexamethasone resulted in superior pain relief and reduced opioid use compared to bupivacaine alone. (17) Hsieh et al., demonstrated that combining ondansetron with bupivacaine not only improved pain control but also reduced nausea and vomiting more effectively than either agent alone. (18) These findings collectively support the robust analgesic and antiemetic benefits of dexamethasone, particularly when combined with other agents, providing a comprehensive approach to managing postoperative discomfort and improving patient outcomes.

The analysis of PONV over a 24-hour period demonstrated that dexamethasone consistently results in a higher proportion of patients experiencing no nausea or vomiting at various time points, particularly right after surgery, at 1 hour, and at 6 hours. At

0 hours, 36.7% of patients in the dexamethasone group experienced no nausea or vomiting, compared to 0% in both the ondansetron and control groups ($p < 0.001$), highlighting dexamethasone's immediate effectiveness as an antiemetic. At 1 hour postoperatively, 93.3% of patients in the dexamethasone group reported no nausea or vomiting, significantly higher than 20% in the ondansetron group and 6.7% in the control group. By 2 hours, dexamethasone continued to demonstrate superior results, with 96.7% of patients free from nausea or vomiting, compared to 40% in the ondansetron group and 6.7% in the control group. At 4 hours, 100% of patients in the dexamethasone group reported no nausea or vomiting, compared to 90% in the ondansetron group and 33.3% in the control group, reinforcing the superior antiemetic effect of dexamethasone. This effectiveness persisted at 6 hours, with 100% of dexamethasone patients experiencing no nausea or vomiting, consistent with the results in the ondansetron group (90%) and the control group (33.3%), underscoring the prolonged action of dexamethasone in preventing PONV. This supports findings from a 2016 Cochrane review that highlighted dexamethasone's superior ability to reduce PONV and the need for additional antiemetics. The study by Eman A. Ismail et al., (19) also supports the effectiveness of intraperitoneal dexamethasone. While ondansetron, as shown in Zahra et al., (20) is effective, it doesn't match the level of dexamethasone, with higher rates of nausea and vomiting observed in this group, particularly at 0 and 1 hour after surgery. Overall, these findings indicate that dexamethasone is more effective than ondansetron and the control group in preventing nausea and vomiting right after surgery.

Patients receiving dexamethasone predominantly needed only one or two doses of rescue analgesics (26.7% and 73.3%, respectively), whereas those in the ondansetron and control groups mostly required three or more doses ($p < 0.001$). Eman A. Ismail et al., (19) demonstrated that dexamethasone effectively reduces postoperative pain and analgesic requirements, supporting our results. In contrast, ondansetron, typically used as an antiemetic, did not show similar efficacy in pain management, reflecting its primary role in preventing nausea rather than directly modulating pain pathways. The mean time to first rescue analgesia was 2.38 hours for the dexamethasone group, compared to 1.18 hours for the ondansetron group and 0.80 hours for the control group. The median survival times further supported these findings, with dexamethasone providing pain relief for at least 2 hours in 50% of patients, whereas ondansetron and control had shorter durations of pain relief. The log rank test confirmed the significant difference in pain relief durations among the three groups, with a statistic of 24.65 and a p-value < 0.001. This robust statistical result highlights that dexamethasone not only extends the duration of pain relief but does so with a statistically significant advantage over both ondansetron and the control group.

The evolving strategy of intraperitoneal instillation of dexamethasone represents an advanced approach to optimizing its benefits. Administering dexamethasone directly into the peritoneal cavity allows for localized effects at the surgical site, potentially enhancing its anti-inflammatory and analgesic actions more effectively than systemic administration alone. Research has shown that this method can significantly decrease postoperative pain and reduce PONV incidence by ensuring higher concentrations of the drug are available directly at the surgical site. This localized approach may offer improved outcomes compared to traditional methods of administration, reinforcing the value of dexamethasone as a valuable adjunct in the postoperative management of laparoscopic cholecystectomy patients.

The administration of dexamethasone via intraperitoneal instillation is an emerging strategy aimed at maximizing its therapeutic effects directly at the surgical site, enhancing both analgesic and antiemetic outcomes. Research supports the efficacy of intraperitoneal dexamethasone in reducing postoperative pain and PONV, highlighting its potential to improve recovery times and overall patient comfort.

The study demonstrated that intraperitoneal instillation of dexamethasone as an adjuvant to bupivacaine provides superior postoperative pain relief and better control of nausea and vomiting compared to ondansetron and a control group in patients undergoing laparoscopic cholecystectomy. Dexamethasone not only reduced pain more effectively but also decreased the need for additional pain medication and significantly minimized the incidence of post-

operative nausea and vomiting. These findings suggest that dexamethasone is a more effective option for enhancing patient comfort and recovery after surgery.

5 | CONCLUSION

In patients undergoing elective laparoscopic cholecystectomy under general anesthesia, intraperitoneal instillation of dexamethasone and ondansetron as adjuvants to 0.25% bupivacaine reduced postoperative pain, nausea, and vomiting. Between the two, dexamethasone significantly reduced postoperative pain, nausea, and vomiting when analysed over 0, 1, 2, 4, 6, 12, and 24 hours postoperatively. This effect is likely due to the local anti-inflammatory properties of dexamethasone.

Data Availability Statement

Data sharing is not applicable to this article as no data sets were generated or analyzed during the current study.

Conflicts of Interest The author declares no conficts of interest.

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