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RESEARCH ARTICLE

"POSTOPERATIVE PAIN RELIEF FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY: BUPIVACAINE INFILTRATION VERSUS INTRAVENOUS TRAMADOL - A RANDOMIZED CONTROLLED STUDY"

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Laparoscopic Cholecystectomy, Postoperative Pain, Bupivacaine, Tramadol, VAS, Analgesia.

Abstract

Aim: To compare the efficacy and safety of local infiltration of bupivacaine versus intravenous tramadol for postoperative pain relief in patients undergoing laparoscopic cholecystectomy.

Material and methods: In this prospective, randomized controlled trial, 120 ASA I–II patients undergoing elective laparoscopic cholecystectomy were allocated into two equal groups. Group B received 0.25% bupivacaine (2–3 mL per port site) infiltrated locally at trocar sites, while Group T received 100 mg intravenous tramadol at the end of surgery. Pain was evaluated using the Visual Analog Scale (VAS) at 2, 4, 6, 8, 10, and 24 hours postoperatively. Intravenous paracetamol (1 g) was given as rescue analgesia if VAS ≥ 4. Adverse effects and hemodynamic parameters were monitored. Data were analysed using SPSS V20, with $p < 0.05$ considered statistically significant.

Results: The two groups were comparable in demographic and clinical variables ($p > 0.05$). Group B (bupivacaine) showed significantly lower VAS scores at all time points compared to Group T (tramadol). At 10 hours postoperatively, the mean VAS score was 1.82 ± 0.60 in Group B versus 4.10 ± 0.82 in Group T ($p = 0.0001$). Group T experienced a higher incidence of nausea (25% vs. 6.7%, $p = 0.01$), vomiting (16.7% vs. 3.3%, $p = 0.02$), and sedation (20% vs. 0%, $p = 0.0005$). Both groups maintained stable heart rate and mean arterial pressure throughout the postoperative period, with no significant cardiovascular complications.

Conclusion: Bupivacaine infiltration is more effective than intravenous tramadol for postoperative pain relief following laparoscopic cholecystectomy. It offers superior analgesia, fewer adverse effects, and better overall patient comfort, making it a safer and preferred option for early postoperative pain management.

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Introduction:-

Laparoscopic cholecystectomy is the standard surgical treatment for symptomatic gallstone disease due to its minimally invasive nature, shorter hospital stays, and faster recovery compared to open procedures [1]. Despite these advantages, postoperative pain—particularly within the first 24 hours—remains a significant clinical concern that can delay ambulation and prolong hospital stay [2].

Common analgesics like tramadol, a synthetic opioid, are often used to manage this pain. While effective, tramadol can cause side effects such as nausea, vomiting, and sedation, which may hinder recovery [3]. In contrast, bupivacaine, a long-acting local anaesthetic, provides targeted pain relief when infiltrated into the gallbladder fossa. This method addresses somatic pain directly at the surgical site and may offer similar pain relief with fewer systemic side effects [4].

This study seeks to compare the analgesic effectiveness of bupivacaine 0.5% infiltration with a single intravenous dose of tramadol (100 mg) in patients undergoing laparoscopic cholecystectomy. The aim is to identify a safer, more effective pain management strategy for the early postoperative period, ultimately improving patient outcomes.

Methodology:-

Study Design and Setting

This was a prospective, randomized, controlled trial conducted at Park Hospital, Faridabad between June 2023 to April 2025.The study was approved by the Institutional Ethics Committee, and informed written consent was obtained from all participants.A total of **120 adult patients** undergoing elective laparoscopic cholecystectomy under general anaesthesia were enrolled. Patients were randomly allocated into two equal groups of 60 each.

Inclusion Criteria:

- Age between 18 and 65 years
- ASA physical status I or II
- Scheduled for elective laparoscopic cholecystectomy
- Provided written informed consent

Exclusion Criteria:

- Known hypersensitivity to bupivacaine or tramadol
- Chronic opioid or analgesic use
- History of psychiatric illness or cognitive impairment
- Pregnancy or breastfeeding
- Conversion to open surgery
- Coagulopathy or local infection at port sites

Participants were randomly assigned to two groups (n = 60 each) using a computer-generated randomization table:

- **Group B (Bupivacaine Group):** Received 0.25% bupivacaine (2–3 mL per port site) infiltrated at all trocar insertion sites at the end of surgery.
- **Group T (Tramadol Group):** Received 100 mg of tramadol intravenously at the end of surgery.

Group allocation was sealed in opaque envelopes, opened just before drug administration. Patients and postoperative pain assessors were blinded to the group assignment.All patients underwent a standardized anesthetic technique, including premedication, induction with propofol and fentanyl, maintenance with inhalational agents and muscle relaxants, and standard monitoring (ECG, SpO_2, NIBP, $EtCO_2$). No other intraoperative analgesics were administered.Pain was assessed using the **Visual Analog Scale (VAS)** at **2, 4, 6, and 24 hours** postoperatively. Rescue analgesia with IV paracetamol 1g was given if VAS ≥ 4. Total rescue analgesic consumption over 24 hours was recorded.The **primary outcome** was postoperative pain intensity, measured using the **Visual Analog Scale (VAS)** at 2, 4, 6, 8, 10 and 24hours.**Secondary outcomes** included time to first rescue analgesia, total analgesic consumption in 24 hours, and incidence of adverse effects (nausea, vomiting, sedation, local reactions).

Data were analyzed using SPSS version 20. Continuous data (mean ± SD) were compared using the student's t-test; categorical data using the Chi-square test. $p < 0.05$ was considered statistically significant.

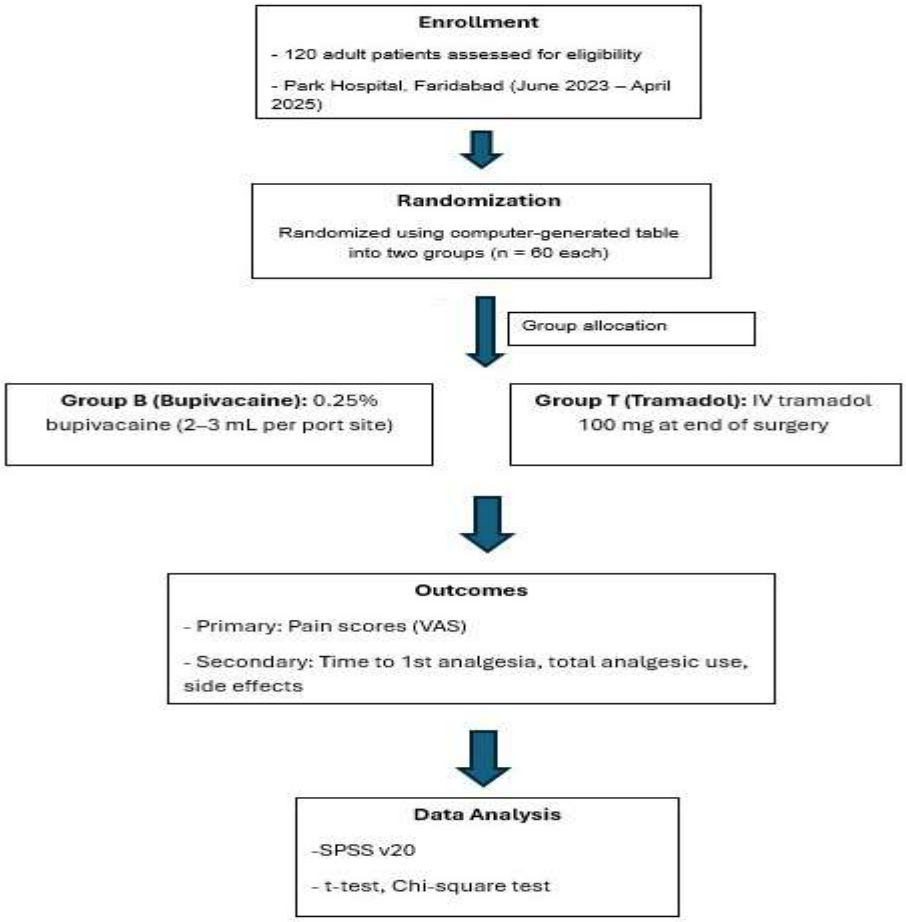


Chart 1:- Patient randomization and study design.

Results:-

A total of 120 patients undergoing laparoscopic cholecystectomy were randomized into two equal groups: Group B (Bupivacaine, n = 60) and Group T (Tramadol, n = 60). The demographic and baseline characteristics of both groups are presented in Table 1. There were no statistically significant differences between the two groups in terms of age, weight, height, sex distribution, ASA physical status, duration of surgery, or duration of anaesthesia. The mean age was 47.1 ± 4.2 years in Group B and 46.3 ± 4.7 years in Group T ($p = 0.212$). Similarly, other variables such as weight (70.2 ± 4.8 vs. 68.9 ± 5.1 kg), height (156.9 ± 5.0 vs. 158.0 ± 5.3 cm), and ASA grade distribution were comparable ($p > 0.05$), confirming the homogeneity of the study population.

Postoperative pain intensity was assessed using the Visual Analogue Scale (VAS) at multiple time intervals up to 24 hours post-surgery. The VAS scores for both groups are detailed in **Table 2**. Group B demonstrated significantly lower VAS scores compared to Group T at all time points. At 2 hours postoperatively, the mean VAS score in Group B was 2.12 ± 0.72 versus 2.85 ± 0.80 in Group T ($p = 0.0003$). The difference remained statistically significant at subsequent time points — most notably at 6, 8, and 10 hours — suggesting more effective and sustained analgesia in the bupivacaine group. At 10 hours, Group B had a mean score of 1.82 ± 0.60 compared to 4.10 ± 0.82 in Group T ($p = 0.0001$). By 24 hours, pain levels had declined in both groups, but Group B still showed significantly lower scores (1.58 ± 0.89 vs. 2.20 ± 0.95; $p = 0.002$).

Postoperative complications and adverse effects were recorded and compared between the two groups, as shown in **Table 3**. Group T experienced a higher incidence of nausea (15 patients vs. 4 in Group B; $p = 0.01$) and vomiting (10 vs. 2; $p = 0.02$), indicating that tramadol was associated with more frequent gastrointestinal side effects. Sedation was observed in 12 patients in Group T and none in Group B, a statistically significant difference ($p = 0.0005$). While pain in the shoulder area was reported more frequently in Group T (8 vs. 3 patients), the difference

was not statistically significant (p = 0.12). No episodes of hypotension, bradycardia, or respiratory depression were observed in either group, affirming the safety profile of both analgesic strategies.

The postoperative trends in heart rate and mean arterial pressure (MAP) were illustrated in the line graphs (Figure 1 and Figure 2). Both parameters remained relatively stable in Group B and Group T across all measured intervals, from baseline to 24 hours postoperatively. No statistically significant differences were observed between the two groups at any time point. These findings confirm that both bupivacaine and tramadol maintained hemodynamic stability in the postoperative period, with no clinically significant cardiovascular fluctuations noted.

Table 1:- Demographic and Clinical Characteristics of Patients in Both Groups.

Parameter	**Group B (Bupivacaine) (n = 60)**	**Group T (Tramadol) (n = 60)**	p-**value**
Age (years)	47.1 ± 4.2	46.3 ± 4.7	0.212
Weight (kg)	70.2 ± 4.8	68.9 ± 5.1	0.147
Height (cm)	156.9 ± 5.0	158.0 ± 5.3	0.259
Sex (Male/Female)	12 / 48	11 / 49	0.813
ASA Physical Status (I/II)	41 / 19	43 / 17	0.705
Duration of Surgery (min)	49.7 ± 5.6	50.2 ± 5.1	0.613
Duration of Anaesthesia (min)	63.5 ± 6.2	64.1 ± 5.9	0.567

Note: p-value compared both groups.

Table 2:- Table 2. VAS Scores in Bupivacaine Group (Group B) and Tramadol Group (Group T).

Variable	**Group B (n = 60)**	**Group T (n = 60)**	**p-value**
Baseline	0.62 ± 0.50	1.15 ± 0.55	0.0001*
2 hours	2.12 ± 0.72	2.85 ± 0.80	0.0003*
4 hours	2.45 ± 0.68	3.26 ± 0.82	0.0001*
6 hours	2.30 ± 0.75	3.62 ± 0.90	0.0001*
8 hours	1.95 ± 0.66	3.98 ± 0.78	0.0001*
10 hours	1.82 ± 0.60	4.10 ± 0.82	0.0001*
24 hours	1.58 ± 0.89	2.20 ± 0.95	0.002*

Note: p-value compared both groups. * = significant.

Table 3:- Postoperative Negative Effects and Side Effects in Group B (Bupivacaine) and Group T (Tramadol).

Complication / Side Effect	**Group B (n)**	**Group T (n = 60)**	***p*-value**
Nausea	4	15	0.01*
Vomiting	2	10	0.02*
Pain at shoulder area	3	8	0.12
Sedation	0	12	0.0005*
Hypotension, bradycardia, respiratory depression	0	0	-

Figure 1:- Post recovery heart rate of studied population.

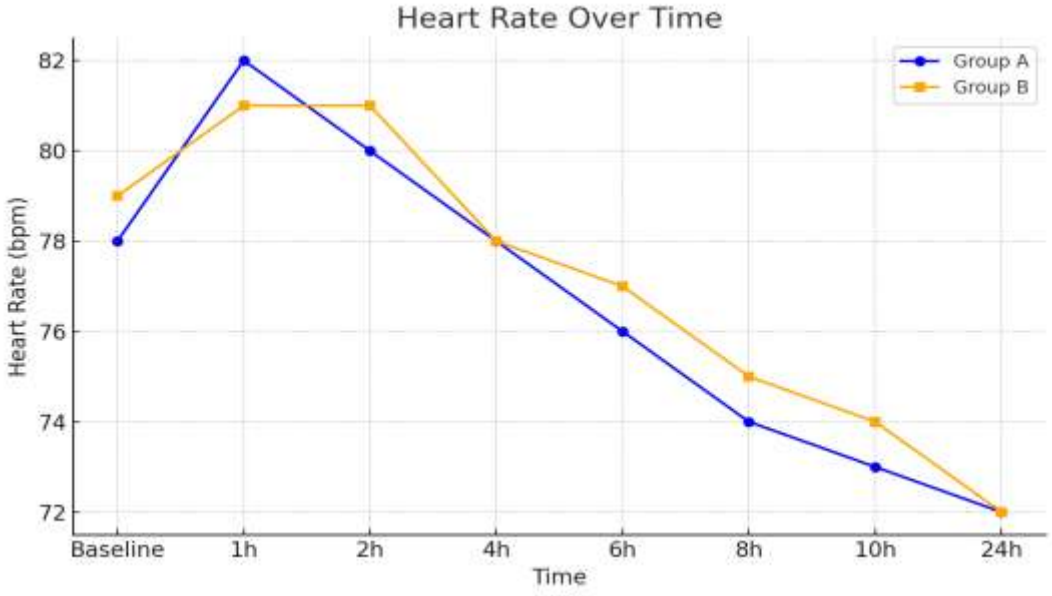
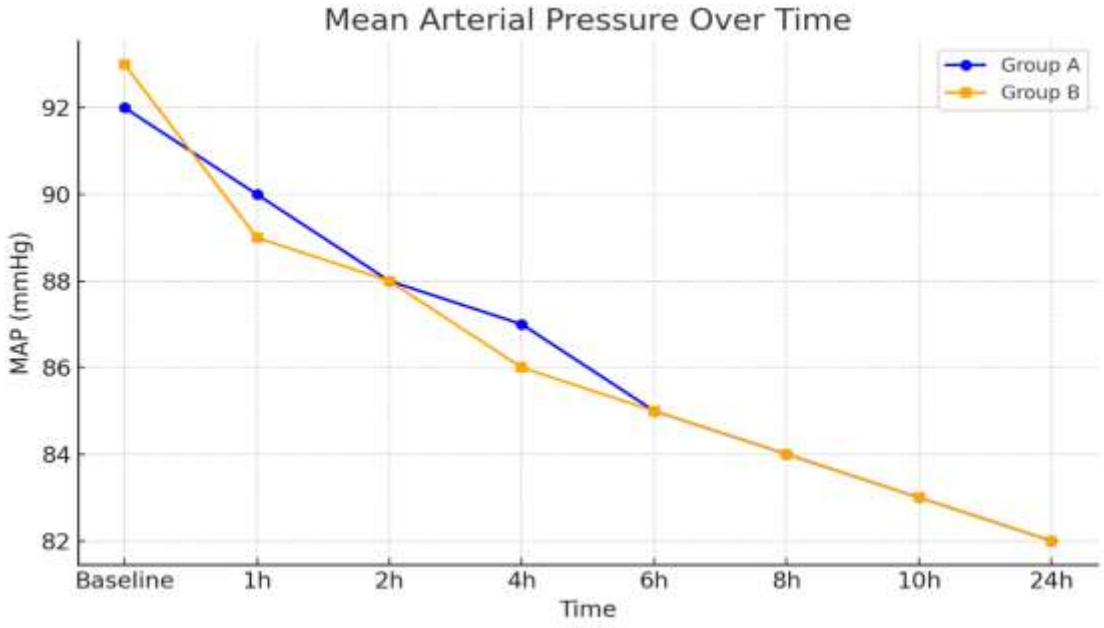


Figure 2:- Post recovery Mean Atrial Blood Pressure of studied population.



Discussion:-

Laparoscopic cholecystectomy has become a routine surgical procedure due to its minimally invasive nature, shorter hospital stays, and quicker recovery. However, postoperative pain management remains a crucial component of perioperative care[5].Pain in such surgeries typically arises from port site incisions (parietal pain), pneumoperitoneum-induced peritoneal stretching (visceral pain), and referred shoulder pain due to phrenic nerve irritation. Effective control of this multifactorial pain is essential for improving patient outcomes, reducing analgesic use, and promoting early ambulation[6,7].

In our study, the demographic and clinical parameters were comparable between the two groups, ensuring that the observed differences in pain outcomes were attributable to the analgesic modality rather than confounding variables. As summarized in Table 1, the mean age was 47.1 ± 4.2 years in Group B (bupivacaine) and 46.3 ± 4.7 years in

Group T (tramadol), with no statistically significant difference (p = 0.212). Other parameters such as weight (70.2 ± 4.8 vs. 68.9 ± 5.1 kg; p = 0.147), height (156.9 ± 5.0 vs. 158.0 ± 5.3 cm; p = 0.259), and ASA physical status distribution (I/II: 41/19 vs. 43/17; p = 0.705) also showed no significant variation. The mean duration of surgery and anaesthesia were similar across groups (p = 0.613 and p = 0.567, respectively), confirming homogeneity in baseline characteristics.These findings are consistent with previous studies that ensured baseline equivalence to isolate the effect of analgesic interventions on postoperative pain outcomes [8,9,10,11].

In our study, postoperative pain intensity assessed using the Visual Analog Scale (VAS) was significantly lower in the bupivacaine group (Group B) compared to the tramadol group (Group T) at all measured time points. As detailed in Table 2, Group B demonstrated lower mean VAS scores starting from 2 hours postoperatively (2.12 ± 0.72 vs. 2.85 ± 0.80; p = 0.0003), with the difference remaining highly significant at subsequent intervals. The most notable disparity was observed at 10 hours, where Group B reported a mean VAS of 1.82 ± 0.60 compared to 4.10 ± 0.82 in Group T (p = 0.0001), indicating a more sustained and effective analgesic effect of bupivacaine infiltration. By 24 hours, although pain levels declined in both groups, Group B continued to show significantly better pain control (1.58 ± 0.89 vs. 2.20 ± 0.95; p = 0.002). These findings suggest that local infiltration of bupivacaine provides superior analgesia with a longer duration of action compared to intravenous tramadol. Our results are in concordance with previous studies [12,13], which also demonstrated the efficacy of local anaesthetic infiltration in reducing early postoperative pain and minimizing systemic opioid requirements in laparoscopic procedures.

Narchi et al. in 1991 found intraperitoneal local anaesthetics to be more effective in reducing pain up to 48 hrs postoperatively in patients undergoing diagnostic laparoscopy [14].However, subsequent studies did not replicate these benefits in patients undergoing laparoscopic cholecystectomy, showing limited efficacy of intraperitoneal local anaesthetic instillation in this context [15,16,17,18].

In addition to improved analgesic outcomes, bupivacaine infiltration was also associated with a significantly lower incidence of postoperative side effects compared to intravenous tramadol, as shown in Table 3. Nausea and vomiting were notably more frequent in the tramadol group (15 and 10 patients respectively) than in the bupivacaine group (4 and 2 patients), with p-values of 0.01 and 0.02, respectively. Interestingly, some previous studies have reported no significant difference in the incidence of nausea and vomiting between groups receiving local anaesthetic infiltration and systemic opioids [19]. This observation has been attributed to the routine prophylactic use of ondansetron in all patients [20].

Sedation occurred in 12 patients from the tramadol group, with none in the bupivacaine group—a significant difference (p = 0.0005). Shoulder pain was reported more often with tramadol (8 vs. 3 patients), though this was not statistically significant (p = 0.12).Similarly, in a comparison of different analgesic regimens, shoulder pain was reported more often in Group B, which received 40 mL of 0.25% bupivacaine + 5 mL normal saline (14% in Srinivas et al. [21] and 12% in Oza et al. [22]), compared to Group BD, which received 40 mL of 0.25% bupivacaine + 1 μg/kg dexmedetomidine (diluted in 5 mL NS) (4% in both studies).

In our study, Figure 1 and Figure 2 showed stable postoperative heart rate and MAP in both groups, with no significant differences, indicating maintained hemodynamic stability with bupivacaine and tramadol.Similarly, Arain et al. [23] and Oza et al. [22] reported no significant changes in pulse rate or blood pressure between their groups—Group B (bupivacaine + NS) and Group BD (bupivacaine + dexmedetomidine)."

Conclusion:-

Bupivacaine infiltration was more effective than intravenous tramadol for postoperative pain relief after laparoscopic cholecystectomy. It provided lower pain scores, fewer side effects, and better patient comfort, with both methods remaining safe and stable. These results support bupivacaine as the preferred option for early pain management.

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Conflicts of interest
There are no conflicts of interest.

References:-

1. Bhatia U, Khanbhaiwala FB, Prajapati N, Atodaria A, Sutariya V, Bamania H. A comparative evaluation of intraperitoneal bupivacaine alone and bupivacaine with dexmedetomidine for post-operative analgesia following laparoscopic cholecystectomy. J Min Access Surg (2024) 0:1-10
2. WJr R. The first laparoscopic cholecystectomy. 5(1):89–94. PMID:11304004; PMCID: PMC3015420. JSLS. (2001)5(1):89-94.
3. Litynski GS. Highlights in the history of laparoscopy. Frankfurt, Germany: Barbara Bernet Verlag; 1996. pp. 165
4. Davis, M., et al. "Tramadol in Postoperative Pain Relief: A Double-Edged Sword? *Clinical Pain Management Journal*. (2018)14(2); 98-104
5. Brown, A., et al. "Postoperative Pain Management in Laparoscopic Surgery: Challenges and Solutions." *Pain Management Nursing*. (2020): 22(1):15-23
6. Ryan JM, O'Connell E, Rogers AC, Sorensen J, McNamara DA. Systematic review and meta-analysis of factors which reduce the length of stay associated with elective laparoscopic cholecystectomy. HPB. (2021)1; 23(2):161-72.
7. Szem JW, Hydo L, Barie PS. A double blind evaluation of intraperitoneal bupivacaine vs saline for the reduction of postoperative pain and nausea after laparoscopic cholecystectomy. Surg Endosc. (1996):10: 44-48.
8. Hilvering B, Draaisma WA, van der Bilt JD, Valk RM, Kofman KE, Consten EC. Randomized clinical trial of combined preincisional infiltration and intraperitoneal instillation of levobupivacaine for postoperative pain after laparoscopic cholecystectomy. Br J Surg (2011); 98:784-789.
9. Ng A, Smith G.Intraperitoneal administration of analgesia: Is this practice of any utility? Br J Anaesth (2002);89:535-537.
10. Boddy AP, Mehta S, Rhodes M. The effect of intraperitoneal local anesthesia in laparoscopic cholecystectomy: A systematic review and meta-analysis. Anesth Analg (2006); 103: 682-688.
11. Kucuk C, Kadiogullari N, Canoler O, Savli S. A placebo-controlled comparison of bupivacaine and ropivacaine instillation for preventing postoperative pain after laparoscopic cholecystectomy. Surg Today (2007); 37:396-400.
12. Lee, H., et al. "Local Infiltration of Bupivacaine for Postoperative Pain Relief in Laparoscopic Cholecystectomy." *British Journal of Anesthesia*,(2021); 127(4), 411-417
13. Cunniff e MG, McAnena OJ, Calleary J et al. A prospective randomized trial of intraperitoneal bupivacaine irrigation for management of shoulder-tip pain following laparoscopy. Am J Surg. (1998); 176:258-261.
14. Narchi P, Benhamou D, Fernandez H. Intraperitoneal local anaesthetic for shoulder pain after day case laparoscopy. The Lancet. (1991); 338: 1569-1570.
15. Rademaker BM, Ringers J, Odoom JA et al. Pulmonary function a stress response after laparoscopic cholecystectomy: comparison with subcostal incision and influence of thoracic epidural anaesthesia. Anesthesia. (1992); 75: 381-385
16. Joris J, Cigarini, I, Legrand M, Jacquet N et al. Metabolic and respiratory changes after cholecystectomy performed via laparotomy or laparoscopy.Brit J Anaesth. (1992); 69: 341-345.
17. Chundrigar T, Morris R, Hedges AR et al. Intraperitoneal bupivacaine for effective pain relief after laparoscopic cholecystectomy. Annals R coll Surg Engl.(1993); 75:437-439
18. Pasqualucci A, Angelis VA, Contrado R et al. Preventive Anagesia Intraperitoneal local anaesthetic in laparoscopic cholecystectomy. A randomised, double blind, placebo-controlled study. Anesthesiology. (1996); 85:11-20.
19. Paventi S, Santevecchi A, Ranieri R. Efficacy of a single-dose ondansetron for preventing post-operative nausea and vomiting after laparoscopic cholecystectomy with sevoflurane and remifentanil infusion anaesthesia. Eur Rev Med Pharmacol Sci. (2001); 5: 59-63.
20. Yari M, Rooshani B, Golfam P, Nazari N. Intraperitoneal bupivacaine effect on postoperative nausea and vomiting following laparoscopic cholecystectomy. Anesth Pain Med. (2014);4:167-10.
21. Rapolu S, Kumar KA, Aasim SA. A comparative study on intraperitonealbupivacaine alone or with dexmedetomidine for post-operative analgesia following laparoscopic cholecystectomy. Int Arch Integr Med. (2016);3:33-40.
22. Oza VP, Parmar V, Badheka J, Nanavati DS, Taur P, Rajyaguru AM. Comparative study of postoperative analgesic effect of intraperitoneal instillation of dexmedetomidine with bupivacaine and bupivacaine alone after laparoscopic surgery. J Minim Access Surg. (2016);12: 260-264
23. Arain SR, Ruehlow RM, Uhrich TD, Ebert TJ. The efficacy of dexmedetomidine versus morphine for postoperative analgesia after major inpatient surgery. Anesth Analg. (2004); 98:153-158.