INTRODUCTION

Laparoscopic surgeries are becoming more attractive because of early recovery.\(^1\) Pain is one of the most common medical causes of delayed discharge after ambulatory surgery. Unfortunately, prevention and treatment of postoperative pain continues to be a major challenge.\(^2\)

Pain after laparoscopy is considered to arise from the incision site, the pneumoperitoneum, and the procedure site. Pneumoperitoneum can result in referred shoulder pain from the subdiaphragmatic region which might stay for twenty-four hours. Incisional pain is highest directly postoperative and subsides with time.\(^3\) Passive exsufflation of carbon dioxide (CO\(_2\)), intraperitoneal instillation of drugs like hydrocortisone\(^4\) and the pulmonary recruitment manoeuvre (PRM) are some of the several methods that have been used to relieve laparoscopic postoperative pain.

The pulmonary recruitment manoeuvre will automatically wash away residual carbon dioxide (CO\(_2\))
after laparoscopic surgery, reduce phrenic nerve irritation, and consequently reduce post-laparoscopic shoulder and upper abdominal pain.[5] Although PRM and intraperitoneal hydrocortisone are reported to be effective, no head-to-head comparison of the two methods was done. Therefore, we designed this study to investigate the hypothesis that PRM is superior to intraperitoneal hydrocortisone instillation as regards postoperative pain reduction in patients who have undergone laparoscopic gynaecological surgery. The primary outcome of our study was the first 24 h total analgesic consumption, while time to first request for analgesia is a secondary outcome.

**METHODOLOGY**

After approval of the Department of Anesthesia and the local ethics and research committee N-29-2018, with clinicaltrials.gov Identifier NCT03845608 and obtaining informed patient consent, this prospective, randomized, controlled study was conducted during the period between February 2019 and June 2019. Female patients of American Society of Anesthesiologists (ASA) physical status I and II, aged between 20 and 45 years, scheduled for diagnostic laparoscopic gynaecological surgeries done as a part of infertility management were enrolled to participate in this study. Patients refusing to participate in the study, patients with a history of chronic pain, those with chronic respiratory disease, advanced renal, hepatic or cardiac diseases, and patients on opioids, tranquilisers, or steroids were excluded from the study.

The day before surgery, all patients had pre-anesthesia check-up with routine and subjective investigation as per requirement. The visual analogue score (VAS) was explained to the patients (where 0 = no pain and 10 = worst imaginable pain). A written valid informed consent was obtained from the patients.

In the pre-anaesthesia room 1 h before the procedure, a 20 gauge cannula was inserted peripherally and the patients were premedicated with intravenous (IV) midazolam 0.02 mg/kg, pantoprazole 40 mg, 10 mg metoclopramide before induction of general anaesthesia. After preoxygenation with 100% oxygen (O₂) for 3 min, anaesthesia was induced with IV propofol 2 mg/kg, 1 µg/kg of fentanyl followed by 0.5 mg/kg of atracurium to facilitate endotracheal intubation. Anaesthesia was maintained with isoflurane 1-1.5% in 100% O₂ and a state of muscle relaxation was maintained by IV atracurium 0.1 mg/kg every 30 min with volume-controlled mode of mechanical ventilation and adjusted parameters to keep end-tidal CO₂ between 35 and 40 mm Hg. All patients were continuously monitored by electrocardiogram (ECG), repeated non-invasive arterial blood pressure measurement every 5 min, and continuous end-tidal CO₂ and arterial oxygen saturation (SpO₂) by pulse oximetry. IV paracetamol 1g in 100 ml infusion over 15-20 min, was given 30 min before the end of surgery.

Laparoscopy was done using CO₂ as a distension medium. First, the Veress needle was introduced through the lower border of the umbilicus. A water test was done to confirm intraperitoneal placement. Then, the correct distension pressure was ensured when no dullness was felt over the lower border of the liver. The intraabdominal pressure was maintained between 12 to 14 mmHg. The patient was placed in the Trendelenburg position to provide optimum conditions for the laparoscopic view. A 10 mm laparoscopic trocar was introduced with 45 degrees towards the pelvis and a zero camera was introduced through the cannula trocar. The second puncture could be done through the right or left iliac fossae.

By the end of the operation, using a computer-generated randomization schedule, patients were randomly assigned into three equal groups:

Group (A) (hydrocortisone group), in which patients received intraperitoneal 100mg hydrocortisone in 150 ml normal saline in addition to routine method to remove CO₂.

Group (B) (pulmonary recruitment group), in which CO₂ was exsufflated by pulmonary recruitment maneuver performed manually using five positive pressure ventilation at a maximum pressure of 40 cmH₂O. The fifth positive pressure inflation was held by anaesthesiologist for approximately 5 s with the valves on the operative ports opened fully at end of surgery in addition to the routine method to remove CO₂.

Group (C) (control group), in which the routine method was performed by applying gentle abdominal pressure and removing CO₂ by passive exsufflation through the port site at the end of the surgery.

Residual neuromuscular block was antagonised with IV atropine 0.01 mg/kg and neostigmine 0.05 mg/kg.
and extubation was done according to the extubation criteria.

In the recovery room, patients were asked about post-operative shoulder and upper abdominal pain. Pain severity was assessed using the VAS. Pain with VAS score more than 3 was controlled using meperidine in increments of 20 mg every 20 min until the VAS is ≤3. Then, the patients were discharged to the ward according to the standard criteria.

In the ward, postoperative 24 h total analgesic consumption and time of first rescue analgesic request were recorded. Patients were also asked to fill a questionnaire at 1, 6, 12, and 24 h postoperatively using the VAS of pain severity. Vital measurements, (blood pressure and heart rate) were also recorded hourly for the first 24 h. The primary outcome was the first 24 h total analgesic consumption. The secondary outcomes were the time for the first request of analgesia in minutes, pain score (VAS), mean arterial blood pressure, heart rate in the first 24 h postoperatively and the incidence of postoperative nausea, vomiting, or abdominal distension.

The sample size was calculated considering a power of 0.8 and a P value of 0.05 to be statistically significant. The mean and standard deviation of the first 24 h total analgesic consumption was derived from a previous study[4] and was used to calculate sample size. Based on an assumption that the pulmonary recruitment manoeuvre will decrease total analgesic consumption about 20% more than intraperitoneal hydrocortisone, the total calculated sample size was 45 patients (15 in each group). To compensate for the possible dropouts, 60 patients were included (20 in each group). G-power software was used to calculate sample size.

Statistical Package for Social Sciences (SPSS) software was used for statistical analysis. Numerical data were presented as mean ± standard deviation or median (interquartile range). Categorical data were presented as frequency (percentage). Analysis of variance (ANOVA) test was used to compare the three groups regarding normally distributed numerical data. Chi-square test was used to analyse categorical data.

**RESULTS**

During the study period, 60 patients were enroled, of which 57 patients were included in the study [Figure 1].

The study groups were comparable with respect to the demographic profile baseline values of haemodynamic variables and surgical duration; there was no statistically significant difference between the three groups [Table 1].

There was a statistically significant difference between both the hydrocortisone and the pulmonary recruitment groups in comparison with the control group as regards 24 h postoperative total analgesic consumption, P value <0.001. Also, the first request for analgesia was less in both the hydrocortisone and the pulmonary recruitment groups as compared to the control group with a significant P value <0.001. There was no significant difference as regards the total analgesic consumption between the two intervention groups [Table 2].

Regarding pain scores, the VAS was used. The abdominal and shoulder pain scores were significantly lower in both the hydrocortisone and the pulmonary recruitment groups as compared to the control group, P value <0.001. But there was no statistically significant difference between the two intervention groups in the first 12 h postoperative. VAS 24 showed a significant difference between the two intervention groups, P value <0.001 [Figure 2].

The patients in the three groups were similar regarding the frequency of postoperative nausea and vomiting [Table 3].

Mean arterial blood pressure was higher during the first 4 h in the control group as compared to the hydrocortisone and the pulmonary recruitment groups with no significant difference after that [Figure 3].

**DISCUSSION**

In this study, both PRM and the intraperitoneal hydrocortisone installation significantly reduced the incidence and intensity of upper abdominal and shoulder pain after laparoscopic gynaecological surgeries without significant adverse effects; total analgesic requirements were less in the hydrocortisone and pulmonary recruitment groups during the first 24 h postoperatively as compared to the control group. However, the VAS score showed that the effect of intraperitoneal hydrocortisone is longer lasting.

Numerous factors affect pain after laparoscopic surgeries; the underlying disease, surgical factors, residual gas volume, and the pressure generated by the pneumoperitoneum.[6] Previous studies agree that
the post-laparoscopy pain consists of 3 components differing from each other in intensity, latency and duration; visceral pain (deep, dull pain that is hard to localise)\(^7\) from the operation itself, pain originating from the trauma to the diaphragm, peritoneal inflammation and neuronal rupture (shoulder-tip pain) as well as the incision pain itself (surface or wound-type pain).\(^{[8]}\) Several methods like local anaesthetics are being used for pain relief. It was found that intraperitoneal local anaesthetic administered immediately after capnoperitoneum creation decreases postoperative pain and helps to speed recovery.\(^{[9]}\) Addition of tramadol to local anaesthetics was reported to decrease postoperative pain and analgesic requirements.\(^{[10]}\)
Table 2: Post-operative total analgesic profile. Data expressed as mean ± standard deviation

| Postoperative analgesic profile | Group A (n=19) Hydrocortisone | Group B (n=19) Pulmonary recruitment | Group C (n=19) control | P        |
|---------------------------------|-------------------------------|-------------------------------------|-----------------------|----------|
| Total analgesic (meperidine) consumption (mg) | 21.8±12.5                     | 27.2**±12.9                         | 57.5±16.7             | <0.001*  |
| Time to first rescue analgesia (min)       | 46.7±7.7                      | 45.5**±8.1                          | 27.8±9.4              | <0.001*  |

P<0.05 was considered statistically significant. *Denotes significance between group A and Group C. **Denotes significance between Group B and Group C.

Figure 3: Map over 24 hours

Similar to our results, Güngördük K et al.\(^1\) reported that the PRM effectively and safely reduced postoperative shoulder and upper abdominal pain levels in patients undergoing laparoscopic gynaecological oncologic surgery. Also, in accordance with the present study, Liu H et al.\(^1\) investigated the efficacy of combining local anaesthetic infiltration of ropivacaine with pulmonary recruitment manoeuvre on postoperative pain following diagnostic hysteroscopy and laparoscopy. It was so effective that there were more patients without shoulder pain and fewer requiring tramadol. A study done by Khanna et al.\(^1\) investigated simple pulmonary recruitment maneuver to reduce pain after laparoscopic cholecystectomy and found that it is a simple and safe technique that can be implemented routinely after abdominal laparoscopy. The manoeuvre was different to ours, such that only two manual inflations to a maximum pressure of 60cm H\(_2\)O were done and each was held for 5 s. Tsai H et al.\(^1\) compared the effect of intraperitoneal normal saline instillation and pulmonary recruitment for shoulder and upper abdominal pain using VAS score for 48 h and concluded that the effect of intraperitoneal normal saline instillation (INSI) was longer-lasting and more persistent than that of PRM. INSI had an additional buffer system. In contrast to PRM, the effect of INSI is long-lasting, continuous, and physiological until the normal saline is absorbed. Several studies investigated the use of intraperitoneal local anaesthetics and other drugs as a method to decrease postoperative shoulder pain. In the study done by Jain S et al., it was found that intraperitoneal instillation of high-volume local anaesthetic was effective in decreasing shoulder pain in a good number of patients because this volume covers effectively a larger area of sub-hepatic space together with the surrounding peritoneum.\(^1\)

In the present study, the use of intraperitoneal 100 mg hydrocortisone at the beginning of the procedure significantly reduced shoulder pain and analgesic requirement in comparison to the control group. Among corticosteroids, dexamethasone has been used widely to reduce postoperative pain. Steroids decrease the pain through various mechanisms, like suppression of bradykinin, neuropeptides release, suppression of phospholipase enzymes, thus decreasing cyclooxygenase and lipoxygenase inflammatory pathways, and also inhibition of other mediators of inflammation as TNF, interleukin 6 and 12.\(^1\) Sarvestani et al.\(^1\) used intraperitoneal 100 mg of hydrocortisone in 250 mL of normal saline before intraperitoneal insufflation of CO\(_2\) and found that the pain scores decreased significantly by using intraperitoneal hydrocortisone in the postoperative period as well as the analgesics used without any effect on the postoperative nausea and vomiting. Sharma et al. reached similar results by using 100 mg hydrocortisone plus 100 mg bupivacaine compared with 100 mg bupivacaine alone with shorter hospital stay time and early oral intake for liquids and semisolids for the hydrocortisone and bupivacaine combination group.\(^1\) Amini et al. in 2014 also used intraperitoneal 100 mg of hydrocortisone in 250 mL of normal saline with the same technique as in comparison to intraperitoneal 100 mg bupivacaine in 250 mL normal saline and they found that there was no difference between the patients as regards pain scores compared to the bupivacaine group. The patients were similar regarding postoperative analgesic requirements, return of bowel function, nausea, and vomiting.\(^1\) In a similar study, Zahra Asgari et al. studied the effect of dexamethasone added to intra-peritoneal bupivacaine on postoperative pain after gynaecological surgery and concluded that combination to be more effective than bupivacaine alone.\(^1\)

Our study has some limitations. Incisional infiltration of local anaesthetic was not done, and we recommend that it be used in future studies to abolish the incisional element of postoperative pain. Also, different surgical
In conclusion, both intraperitoneal hydrocortisone installation and the pulmonary recruitment maneuver could effectively reduce pain after laparoscopic surgery, but intraperitoneal hydrocortisone might give a longer pain-free time following gynaecological laparoscopies.

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Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Johnson N, Barlow D, Lethaby A, Lavender E, Curr E, Garry R. Surgical approach to hysterec- tomy for benign gynecological disease. Cochrane Database Syst Rev 2006;(2):CD003677.
2. Vadivelu N, Mitra S, Narayan D. Recent advances in postoperative pain management. Yale J Biol Med 2010;83:11-25.
3. Mitra S, Khandelwal P, Roberts K, Kumar S, Vadivelu N. Pain relief in laparoscopic cholecystectomy: A review of the current options. Pain Pract 2012;12:485-96.
4. Sarvestani AS, Amini S, Kalhor M, Roshanravan R, Mohammadi M, Lebaschi AH. Intraperitoneal hydrocortisone for pain relief after laparoscopic cholecystectomy. Saudi J Anaesth 2013;7:14-7.
5. Khanna A, Sezen E, Barlow A, Rayt H, Finch JG. Randomized clinical trial of a simple pulmonary recruitment maneuver to reduce pain after laparoscopy. Br J Surg 2013;100:1290-4.
6. Sandhu T, Yamada S, Ariyakachon V, Chakrabandhu T, Chongruskwit W, Ko-iam W. Low pressure pneumoperitoneum versus standard pneumoperitoneum in laparoscopic cholecystectomy: A prospective randomized clinical trial. Surg Endosc 2009;23:1044-7.
7. Dixon JB, Reuben Y, Halket C, O’Brien PE. Shoulder pain is a common problem following laparoscopic adjustable gastric band surgery. Obes Surg 2005;15:11-7.
8. Kim T, Kang H, Park J, Chang I, Park S. Intraperitoneal ropivacaine instillation for postoperative pain relief after laparoscopic cholecystectomy. J Korean Surg Soc 2010;79:130-6.
9. Putta PG, Pasupuleti H, Samantaray A, Natham H, Rao MH. A comparative evaluation of preemptive versus post-surgery intraperitoneal local anaesthetic instillation for postoperative pain relief after laparoscopic cholecystectomy: A prospective, randomized, double blind and placebo controlled study. Indian J Anaesth 2019;63:205-11.
10. Kumari A, Acharya B, Ghimire B, Shrestha A. Post-operative analgesic effect of intraperitoneal ropivacaine with or without tramadol in laparoscopic cholecystectomy. Indian J Anaesth 2020;64:43-8.
11. Güngördük K, Ağcaoğlu O, Özdemir İA. Effect of the pulmonary recruitment maneuver on pain after laparoscopic gynecological oncologic surgery: A prospective randomized trial. J Gynecol Oncol 2018;29:e92.
12. Liu H, Ma C, Zhang X, Yu C, Yang Y, Song X, et al. Combined incisional ropivacaine infiltration and pulmonary recruitment maneuver for postoperative pain relief after diagnostic hysteroscopy and laparoscopy. Chin Med J 2014;127:825-9.
13. Tsai HW, Chen YJ, Ho CM, Hseu SS, Chao KC, Tsai SK, et al. Maneuvers to decrease laparoscopy-induced shoulder and upper abdominal pain: A randomized controlled study. Arch Surg 2011;146:1360-6.
14. Jain S, Nazir N, Singh S, Sharma S. A prospective randomized controlled study for evaluation of high-volume low-concentration intraperitoneal bupivacaine for post-laparoscopic cholecystectomy analgesia. Indian J Anaesth 2018;62:109-14.
15. De Oliveira GS Jr, Almeida MD, Benzon HT, McCarthy RJ. Perioperative single dose systemic dexamethasone for postoperative pain: A meta-analysis of randomized controlled trials. Anesthesiology 2011;115:575-88.
16. Sharma M, Kharbuja K, Sharma N. Intraperitoneal hydrocortisone plus bupivacaine versus bupivacaine alone for pain relief after laparoscopic cholecystectomy. J Lumbini Med Coll 2016;3:34-41.
17. Amini S, Sabzi Sarvestani A. Comparing the impact of intraperitoneal hydrocortisone with bupivacaine on postoperative pain after laparoscopic cholecystectomy. J Lumbini Med Coll 2016;4:e17206.
18. Asgari Z, Mozafar-Jalali S, Faridi-Tazehkand N, Sabet S. Intraperitoneal dexamethasone as a new method for relieving postoperative shoulder pain after gynecologic laparoscopy. Int J Fertil Steril 2012;6:59-64.

Table 3: Postoperative nausea and vomiting (PONV). Data expressed as number and percentage

| Group A (n=19) hydrocortisone | Group B (n=19) Pulmonary recruitment | Group C (n=19) control |
|-----------------------------|-------------------------------------|-----------------------|
| Count | % | Count | % | Count | % |
| PONV | | | | | |
| Yes | 7 | 35 | 9 | 45 | 12 | 60 | 0.280 |
| No | 13 | 65 | 11 | 55 | 8 | 40 |

P<0.05 was considered statistically significant.