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Prior analgesic dosage during gynecologic laparoscopy: A randomized trial

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Abstract
Objective: To evaluate the efficacy of intraoperative infusion of Levobupivacaine solution for the relief of pain after operative gynecologic laparoscopy.
Design: Double-blind, randomized, controlled trial.
Materials & method: Ninety females aged 18 to 60 years who underwent gynecologic laparoscopic surgery from October 2018 through October 2019. The patients were divided into three groups, Group A (n =30): Intraperitoneal infusion of a mixture of 10 ml of 0.5% Levobupivacaine (50 mg) with epinephrine (1:500) in 40 ml of Ringer's lactate solution postoperatively. Group B (n = 30): the same mixture solution infusion preoperatively and postoperatively (total 100 mg Levobupivacaine). Group C (n = 30): Control.
Statistical analysis and results: Shoulder tip pain (STP), abdominal parietal pain (APP), and abdominal visceral pain (AVP) were recorded on a visual analog scale at 2, 4, 8, 16, and 24 hours postoperatively. A total of 79 patients fulfilled the study criteria. The overall incidence of STP was 61.5%. Abdominal visceral pain in group B was significantly less than in group C at 2 and 4 hours postoperatively (p =.011 and p = .010, respectively).
Conclusion: Intraperitoneal Levobupivacaine administration both immediately after placement of trocars and at the end of surgery was found to be effective in reducing the intensity of AVP but not in reducing STP, APP, or postoperative analgesia consumption after gynecologic laparoscopic procedures.

Keywords: Intraperitoneal, levobupivacaine, gynecologic laparoscopy, pain, visual analog score

1. Introduction
Laparoscopic surgeries are considered as a safe and conservative method of surgery especially in the field of Gynecology. However, many of the patients indeed experience pain which is usually postoperative. It has been reported that 35% to 63% of patients undergoing laparoscopic surgery suffer pain, such as shoulder tip pain (STP) and abdominal pain [1, 2]. Abdominal pain & that from shoulder tip after a gynecologic laparoscopic procedure remain largely unresolved which require attention. It is believed that laparoscopic surgery induced pain is of the referred type and is secondary to peritoneal stretching and diaphragmatic irritation. Thus, administration of intraperitoneal analgesics might minimize this pain.
A preemptive analgesic, which achieves an afferent block before nociceptive stimuli are triggered, can reduce or eliminate the onset of hyper excitability of the posterior horn neurons; therefore, it can significantly reduce both the intensity and duration of pain while also delaying its onset [3, 6]. One study found that intraperitoneal ropivacaine before and after laparoscopic cholecystectomy significantly decreased both shoulder and parietal pain [7]. Conversely, another study noted that neither preoperative nor postoperative intraperitoneal bupivacaine treatment alone significantly reduced abdominal pain, incisional pain, or shoulder pain following laparoscopic cholecystectomy [8]. In gynecologic laparoscopy, the association of intraperitoneal analgesic administration postoperatively with relief of pain remains controversial [9, 13].
There are very minimal data in the records regarding the effects of preemptive analgesia in gynecologic operative laparoscopy. In this study, we evaluated the efficacy of intraperitoneal Levobupivacaine solution administration immediately before and after gynecologic laparoscopy for the relief of STP, abdominal visceral pain (AVP), and abdominal parietal pain (APP).

2. Materials and methods
A double-blind, randomized, placebo-controlled study, approved by the ethics committee of Shri Shankaracharya Medical college and Hospital, Bhilai, Durg was conducted with 90 patients

between the ages of 18 and 60 who underwent gynecologic laparoscopic surgery in the Department of Gynecology & Obstetrics of the medical college from October 2018 through October 2019. Patients were randomly assigned in a 1:1:1 ratio to the A, B, or C group according to preprinted slips on sealed envelopes that had been prepared before the start of the study with a computer-generated randomization method. All of the patients were classified as either grade I or II under the American Society of Anesthesiologists Physical Status. The laparoscopic procedures included electrocautery for pelvic endometriosis, tubal sterilization, ovarian cystectomy, adhesiolysis, and tubal reconstructive surgery. The exclusion criteria were as follows: a history of abdominopelvic laparotomy, severe endometriosis (American Fertility Society score of greater than 40 points), extensive pelvic adhesions, an operative time of more than 3 hours, ruptured ectopic pregnancy with hemoperitoneum, active intraperitoneal infection with concomitant culdotomy, and insertion of a postoperative drainage tube. Preoperative informed consent was obtained.

2.1 Peritoneal analgesic

After induction of general anesthesia and before induction of the analgesic, patients were randomized into one of three groups. The patient, neither the surgeon nor the assessor of pain was aware of the solution administered. The laparoscopic technique and abdominal wall penetration locations were standardized.[14] Trocar insertion was limited to three punctures: one 10 mm trocar infra-umbilically and two 5 mm trocars suprapubically. After the patient was placed in the Trendelenberg position, one of three procedures was followed. Patients in group A received an intraperitoneal infusion of 50 ml of Ringer's lactate solution immediately after trocar insertion (preoperatively) and an intraperitoneal infusion of a mixture of 10 ml 0.5% Levobupivacaine (50 mg) with epinephrine (1:500) in 40 ml of Ringer's lactate solution at the end of surgery (postoperatively). Patients in group B received the same mixture of 10 ml of 0.5% Levobupivacaine with epinephrine (1:500) in 40 ml of Ringer's lactate solution as an intraperitoneal infusion preoperatively and postoperatively (total 100 mg Levobupivacaine). Patients in group C (control group) received an intraperitoneal infusion of 50 ml of Ringer's lactate solution preoperatively and postoperatively.

All of the laparoscopic procedures were performed by surgeons of Department of Gynecology & Obstetrics of Shri Shankaracharya Medical College & Hospital, Bhilai. Intra-abdominal pressure was maintained by insufflations of CO_2 at 15 mm Hg. Intraperitoneal local administration of analgesic or placebo solution was left in situ for at least 5 minutes. Under direct vision, the surgeon used an irrigator to infuse 30 ml of solution into the sub-diaphragmatic space (15 ml on the right and 15 ml on the left) and 20 ml into the pelvic cavity. At the conclusion of the procedure, as much CO_2 as possible was removed from the peritoneal cavity. Laparoscopic entrance wounds were not infiltrated with any of the local anesthetic solution.

2.2 Postoperative management

Blood pressure, heart rate, and respiratory rate after surgery were recorded at 4-hour intervals. Postoperative analgesia was prescribed: meperidine 50 mg intramuscularly every 4 hours as needed immediately after surgery and oral acetaminophen 500 mg four times a day, 6 to 8 hours postoperatively. In cases of severe nausea and/or vomiting, prochlorperazine 5 mg intramuscularly every 4 hours was prescribed. The degree of postoperative STP, AVP (defined as deep in the abdomen with poor localization), and APP (defined as abdominal wall, incisional pain with a fixed pattern) was assessed using a visual analog pain scale (VAS) with the patient resting in the supine position at 2, 4, 8, 16, and 24 hours postoperatively. The VAS, with scores ranging from zero (no pain) to 10 (unbearable pain), was constructed without numeration, allowing patients to mark a point along the scale that best represented their pain at that time. Postoperative pain was assessed in a double-blind manner. Neither the patients nor the postoperative caregivers were aware of the solution administered.

3. Statistical analysis

Data were collected as the mean ±1 SD for demographics, pain score, and meperidine consumption. The statistical package Sigmastat (Jandel Corporation; San Raphael, CA) was used for data analysis. Demographic values, length of hospitalization, and meperidine consumption were assessed using one-way ANOVA analysis. The STP, APP, and AVP were compared within and among groups by using repeated measures of ANOVA.

4. Results

Demographic data were similar among the three groups (Table 1). From the 90 patients recruited into the study, 79 subjects fulfilled the study criteria. A total of 11 subjects were excluded from the study (four in group A, four in group B, and four in group C) because of non-fulfillment of inclusion criteria. The overall incidence of STP was 61.5%. No significant statistical differences were found in preoperative and postoperative systolic/diastolic blood pressure, heart rate, and respiratory rate both among and within the groups.

4.1 Postoperative pain scores

Postoperative pain scores are shown in Table 2. The incidence of STP during the first 24 hours was 61.5% (49 of 79 patients), with 42% reporting unilateral and 58% bilateral shoulder pain. Because many patients (28/79) were discharged less than 24 hours postoperatively, the analysis of pain at 24 hours was omitted for the consideration of small sample. Repeated measures of ANOVA on the time by- treatment interaction showed: (1) For STP, neither time ($p = .144$) nor group ($p = .115$) was a significant factor; (2) For APP, time ($p = .001$) rather than group ($p = .282$) was a significant factor. Post hoc multiple comparisons revealed that significant differences existed between 2 hours and 8 hours ($p = .022$) and 2 hours and 16 hours ($p = .005$); (3) For AVP, time ($p = .031$) and interaction between time and group ($p = .024$) were significant factors but group ($p = .100$) was not. Post hoc multiple comparison revealed that AVP was significantly less in group B than in group C at 2 and 4 hours postoperatively ($p = .034$ and $p = .031$, respectively). Comparison of the need for postoperative meperidine during the first 24 hours in the three groups revealed that there was no statistically significant difference (Table 3). Among the groups, no statistically significant difference in operative time, blood loss, or length of hospitalization was found.

4.2 Postoperative complications

Statistically significant difference was not found in the groups regarding nausea, vomiting, dizziness, epigastric pain, fever, urinary frequency, urinary retention, abdominal distension, diarrhea, headache, or back pain. The most common complaint was nausea and/or vomiting; it occurred 46.1% in group A, 34.6% in group B, and 40.7% in group C.

5. Discussion

The overall incidence of postoperative STP in this study was 61.5% and is comparable with those in the two previous studies (35% and 63%) [1, 2]. This study demonstrated that AVP at 2 and 4 hours postoperatively in patients receiving both preoperative and postoperative intraperitoneal Levobupivacaine infusion (Group B) was significantly less than it was in the Group C. However, a statistically significant difference was not found between the group that received only a postoperative infusion of Levobupivacaine (Group A) and the control group. APP & STP were not significantly different among the groups. The above observation is compatible with the hypothesis that an afferent block with local anesthetics performed before nociceptive stimuli are triggered can reduce or eliminate the onset of hyperexcitability of posterior horn neurons and subsequently reduce both the intensity and duration of pain while also delaying its onset [3]. The postoperative pain induced by laparoscopy has a considerable visceral component (due to surgical manipulation and diaphragmatic irritation from CO2) and a lesser component somatic in origin (due to abdominal puncture wounds). In previous studies, some investigators reported a benefit of intraperitoneal anesthetic infusion at the conclusion of gynecologic laparoscopy [9, 12, 15]. However, others did not find it efficacious in reducing postoperative pain [13, 16] Some of the studies [3] stressed that the timing of administration of local anesthetic is essential for the reduction of postoperative pain.

VAS scores and consumption of analgesics were significantly lower in patients receiving an intraperitoneal Levobupivacaine infusion both immediately after establishing pneumoperitoneum and at the conclusion of surgery than it was when the infusion was given only at the conclusion of surgery. One research stated that although a combination of somatovisceral local anesthetic treatment before or after surgery did not reduce abdominal visceral pain or shoulder pain, preoperative incisional infiltration with a local anesthetic was effective in reducing incisional somatic pain [8] Another study used a large (150 mg) dose of bupivacaine, administered to the right sub diaphragmatic space, and was unable to demonstrate an analgesic effect [17]. Other researchers employed a direct multiple visceral infusion of ropivacaine and did not find an analgesic effect [18] These results suggest that the dosage of local anesthetic (100 mg Levobupivacaine) used in our study may not be the reason for lack of efficacy. The VAS scores of STP, APP, and AVP tended to be lower in the patients receiving Levobupivacaine (group A and group B) at 2, 4, and 8 hours than in the placebo group (Group C). However, none of these differences was statistically significant. This may be explained by the pharmacokinetic characteristics of Levobupivacaine: 3.5-hour half-life and 3- to 10-hours duration of action.

The results of this study are not in complete agreement with some of the researches [3]. Some studies have reported that intra-abdominal bupivacaine infusion before and after surgery significantly reduced postoperative pain and analgesic requirement; however, type of pain were not described, (i.e., APP or AVP). The reason for the lack of a statistically significant difference in postoperative meperidine administration in our study may be due to our routine oral acetaminophen given 6 or 8 hours postoperatively, which may have covered the difference in the parenteral analgesic requirement. That there was no statistically significant difference in postoperative blood pressure, heart rate, respiratory rate, and side effects between the study and control groups implies that the Levobupivacaine dose used intraperitoneally (100 mg) is within a safe therapeutic range.

6. Conclusion

Intraperitoneal Levobupivacaine administration both immediately after placement of trocars and at the end of surgery was found to be effective in reducing the intensity of AVP but not STP or APP, nor did it reduce postoperative analgesia consumption after non-advanced gynecologic laparoscopic procedures. The duration of the analgesic effect of Levobupivacaine instilled into the peritoneal cavity did not exceed 8 hours and probably was not dose related.

7. Tables

Table 1: Patient Characteristics

Characteristic	Group A (n=26)	Group B (n=26)	Group C (n=27)	p
Mean Age (In yrs)	31.1 ±10.6	31.6±7.9	35.1±11.0	0.213
Mean Body Mass Index	21.3±2.9	22.8±3.5	21.5±3.7	0.724
Mean Parity	0.80	0.73	1.14	0.121

Table 2: Intensity of shoulder tip pain, abdominal parietal pain, and abdominal visceral pain recorded on a visual analog scale.

Pain site	Group A mean VAS score (95% CI) (n= 26)	Group B mean VAS score (95% CI) (n = 26)	Group C mean VAS score (95% CI) (n =27)	p
STP				
2 Hr	0.31	0.34	0.55	0.764
4 Hr	0.50	0.51	1.56	0.149
8 Hr	0.88	0.61	1.23	0.566
16 Hr	0.56	0.68	1.68	0.125
APP				
2 Hr	1.63	2.23	3.18	0.220
4 Hr	1.39	2.00	2.43	0.325
8 Hr	1.11	1.68	1.74	0.507
16 Hr	1.17	1.27	1.16	0.964
AVP				
2 Hr	1.94	1.40	3.57	0.031
4 Hr	1.83	1.38	3.26	0.030
8 Hr	1.94	1.41	2.21	0.442
16 Hr	1.82	1.27	1.35	0.672

Table 3: Intraoperative and postoperative variables.

Variable	Group A (n = 26)	Group B (n = 26)	Group C (n = 27)	p
Mean operation duration in min (95% CI)	96.43	101.8	88.96	0.367
Mean blood loss in ml (95% CI)	12.95	6.15	26.65	0.194
Mean hospitalization in hrs (95% CI)	41.28	34.14	36.56	0.293
Mean meperidine consumption in mg (95% CI)	21.13	23.18	31.46	0.484

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