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ORIGINAL ARTICLE

Assessment of a Combination of Clinical Maneuvers in Evaluation of Post-Laparoscopic Pain: A Randomized Clinical Trial

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Abstract

Background To assess the efficacy of the combined maneuvers in evaluation of post-laparoscopic pain.

Material and Methods A randomized controlled study was conducted. Sixty-four women were included in the study and were randomly divided into two groups. Intervention group received combined maneuvers such as intraperitoneal normal saline infusion, pulmonary recruitment maneuver and local bupivacaine instillation at port sites after laparoscopic surgery. Control group received routine care.

Main Outcome Measures Upper abdominal pain, shoulder pain and incision site pain were noted in both groups at 3, 6, 12, 24 and 48 h postoperatively.

Results The median interquartile range (in centiles) of upper abdominal pain score 3, 6 and 12 h postoperatively in the intervention group was 1.0 (0.25–1.0), 1.0 (0.0–1.0) and 0.50 (0.0–1.0), and in the control group, the values were 2.0 (2.0–1.0), 2.0 (2.0–1.0) and 1.0 (0–1.0) at 3, 6 and 12 h, respectively ($p < 0.000$). The median interquartile range of shoulder pain score 3, 6 and 12 h postoperatively in the intervention group was 0.0 (0.0–1.0), 0.0 (0.0–0.75) and 0.0 (0.0–1.0), and in the control group, the values were 1.0 (0.0–2.0), 1.0 (0.0–1.75) and 1.0 (0–1.0) at 3, 6, and 12 h. The upper abdominal pain and shoulder pain relief was significantly more in the intervention group than in the control group in the first 12 h of surgery.

Conclusion Combined maneuvers could significantly reduce post-laparoscopic upper abdominal and shoulder pain.

Clinical Trial CTRI Registration Number-CTRI/2017/07/0089, web address of CTRI—http://ctri.nic.in

Keywords Post laparoscopic shoulder pain · Upper abdomen pain · Pulmonary recruitment maneuver · Intraperitoneal normal saline infusion · Incision site pain · Local anaesthetics

Introduction

Laparoscopic surgery is common due to advances in technology, and it is less painful and has quicker recovery [1–4].

For pneumoperitoneum, carbon dioxide (CO_2) is most widely used. Post-laparoscopy residual CO_2 in peritoneum causes postoperative shoulder and upper abdomen pain. Pain may last for more than 72 h in some cases [5, 6]. The incidence of shoulder pain varies from 35 to 80% [7, 8]. Many methods were used to reduce pain but no reliable method has reported yet [9, 10].

Stretching of intra-abdominal cavity and peritoneal inflammation from carbon dioxide retention cause distension of diaphragm and upper abdomen pain [11]. CO_2 trapped between liver and right diaphragm irritates phrenic nerve and causes referred pain in C_4 dermatomes, namely shoulder pain [12–15]. The pulmonary recruitment maneuver and intraperitoneal normal saline infusion have been proposed to reduce post-laparoscopic shoulder and upper abdomen pain [16–20]. Both maneuvers assist in removal of residual abdominal CO_2. The pulmonary recruitment maneuver mechanically increases intraperitoneal pressure

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and facilitates removal of retained CO_2. The intraperitoneal normal saline infusion acts as physiologic buffer system to dissolve excess CO_2, and this helps to reduce delayed pain [21]. Incision site pain is mediated by peripheral sensory axons or central neurons. Local infiltration of anesthetics like bupivacaine blocks peripheral pain stimulus and somatovisceral components, thereby reducing incision site pain.

Materials and Methods

Study Design

This is a randomized controlled trial done in UCMS and GTB hospital, Delhi, India.

In this study, women of age 18–65 years, with American Society of Anaesthesiologists physical status classification of I or II and undergoing laparoscopic surgeries for benign gynecologic conditions and infertility evaluation, were included. Patients with cardiovascular or respiratory disease having malignancy, previous history of peritonitis, abdominal tuberculosis and more than three previous open abdominal surgeries were excluded.

Methodology

A detailed history and examination of women was done.

The selected patients underwent laparoscopic surgery during the study period. Patients were randomized into two groups using computer-generated random number tables. Randomization code was opened by surgeons. All operations were performed by the same surgeons. The postoperative assessment was performed by single evaluator.

Operative Procedure

All patients were given general anesthesia with endotracheal intubation with intermittent positive-pressure ventilation under the effect of muscle relaxant. Intermittent positive-pressure ventilation was given in order to maintain end-tidal carbon dioxide concentration in the expired air ($EtCO_2$) at 35 ± 5 mm Hg. Laparoscopy was performed with three or four ports using CO_2 gas as the distension medium with the intra-abdominal pressure at 12–15 mm Hg.

Intervention Group

After laparoscopy, the upper abdominal cavity was filled evenly with isotonic normal saline (15-20 ml/kg body weight) and left. Then in trendelenburg position (30°), the anesthesiologist performed five manual pulmonary inflations at a maximum pressure of 40–45 cm of H_2O. Pulmonary recruitment maneuver was performed mechanically using positive-pressure ventilation to inflate the lungs and lower the diaphragm. During this, surgeons fully opened the port sleeve valves to allow the CO_2 to escape from abdomen. After that in supine position, the ports were removed. Two to three milliliters of bupivacaine (0.25%) was infiltrated locally at each port site and incisions closed.

Control Group

Routine method of releasing the abdominal gas, i.e., application of gentle abdominal pressure and removal of CO_2 by passive exsufflation, was through the port site after surgery.

Pain Assessment

Pain was measured by a visual analog scale (VAS). The VAS consisted of a nongraduated 10-cm line ranging from "no pain" to "worst pain." The patient was asked to indicate a score from 0 to 10 corresponding to pain. VAS ratings were obtained at 3, 6, 12, 24 and 48 h postoperatively for upper abdominal, shoulder and incision site pain.

Side effects like nausea, vomiting or abdominal distention and other complications were noted. Postoperative pain was managed with intravenous paracetamol as needed within 48 h. Intravenous infusion of paracetamol (15 mg/kg body weight) up to a maximum single dose of 1000 mg was given, whenever VAS score is 3 or more and maximum 4 doses in 24 h.

Statistical Analysis

Statistical analysis was performed using SPSS 20. As the data were not normally distributed, we applied nonparametric tests for analgesic. Mann–Whitney test was applied at each time point to compare the VAS score between the groups, and the p value was adjusted as Bonferroni correction, i.e., $0.05/5 = 0.01$. To compare the pain scores within a group at different time points with respect to baseline (3 h), Wilcoxon signed-rank test was applied with Bonferroni correction, and p value < 0.015 was taken as significant. Unpaired Students t test, Chi-squared tests or Fisher's exact test was performed to compare demographic and operative variables in two groups. Descriptive statistics were presented as the mean $\pm$ SD or numbers with percentage.

Primary outcome: To compare pain scores in the interventional group and control group at 3, 6, 12, 24 and 48 h.

Secondary outcome: To assess overall incidence of shoulder pain, upper abdomen and incision site pain, to analyze and compare requirement of analgesics in both groups and to assess the complication and side effects.

Observations and Results

The study was conducted in Departments of Obstetrics and Gynaecology and Anaesthesiology from November 2013 to October 2015. Sixty-four women were included and randomly divided into two groups, namely intervention ($n=32$) and control group ($n=32$).

The demographic characteristics like age, parity, socio-economic status, height, weight, body mass index (BMI) and symptoms were statistically studied. Parity, socio-economic status, height, BMI, duration of pneumoperitoneum, mean CO_2 volume were not statistically significant, but weight was found significant.

Symptoms

Majority of women in both groups presented with infertility. In the intervention, 68.75% ($n=22$) had primary infertility, while 59.37% ($n=19$) had primary infertility in the control group. 15.62% ($n=5$) in intervention and 25% ($n=8$) in control group had secondary infertility. 9.37% ($n=3$) in intervention and 12.5% ($n=4$) in control group had abdomen pain. Two women in the intervention group had abnormal uterine bleeding, and one patient in the control group had misplaced copper-T.

Operative Procedure

Indications

Majority of patients, who underwent laparoscopy, had infertility. Other indications of laparoscopy were dermoid cyst (7.81%, $n=5$), endometriosis (3.12%, $n=2$), abnormal uterine bleeding (3.12%, $n=2$) and missing copper-T (1.56%, $n=1$).

Diagnostic hystero-laparoscopy was performed in 34.37% ($n=11$) women in the control and 65.6% ($n=21$) in the intervention group. Diagnostic and operative laparoscopy with hysteroscopy was performed in 43.75% ($n=14$) women in control and 12.5% ($n=4$) women in intervention group. Laparoscopic ovarian cystectomy was performed in 12.5% ($n=4$) in intervention and 12.5% ($n=4$) in control group. Diagnostic hystero-laparoscopy with resection of uterine septum was performed in two women in control group. Laparoscopic-assisted vaginal hysterectomy with bilateral salpingo-oophorectomy was performed in three women in intervention group.

Primary Outcome Measures

Upper abdominal pain, shoulder pain and incision site pain were noted in both intervention and control groups at 3, 6, 12, 24 and 48 h.

1. Upper abdominal pain

The median interquartile range (in centiles) of upper abdominal pain score 3, 6 and 12 h postoperatively in the intervention group was 1.0 (0.25–1.0), 1.0 (0.0–1.0) and 0.50 (0.0–1.0), respectively. In the control group, the values were 2.0 (2.0–1.0), 2.0 (2.0–1.0) and 1.0 (0–1.0) at 3, 6, and 12 h, respectively. There was a significant difference in the VAS scores at all three points ($p<0.000$). The median interquartile range of upper abdominal pain score 24 h postoperatively in the intervention and control groups was 0.0 (0.0–1.0) and 1.0 (0.0–1.0), respectively, the difference being not significant ($p=0.015$). The difference in the pain scores was not significant at 48 h ($p=0.068$). The values are summarized in Table 1.

The pain relief was significantly more in the intervention group than in the control group in the first 12 h of surgery.

2. Shoulder pain

The median interquartile range (in centiles) of shoulder pain score 3, 6 and 12 h postoperatively in the intervention group was 0.0 (0.0–1.0), 0.0 (0.0–0.75) and 0.0 (0.0–1.0), respectively. In the control group, the values were 1.0 (0.0–2.0), 1.0 (0.0–1.75) and 1.0 (0–1.0) at 3, 6, and 12 h, respectively. The median interquartile range of shoulder pain score 3, 6 and 12 h postoperatively was significantly low in the intervention group as compared to control group ($p=0.003$, 0.002, 0.009 at 3, 6, and 12 h, respectively). However, there was no significant difference in the shoulder pain between the intervention and control group at 24 and 48 h postoperatively. The values are summarized in the Table 2.

Table 1 Comparison of upper abdominal pain at various time points between intervention and control

Variables (h)	Median (IQR) 50th percentile (25th–75th)		*p* value
	Intervention	Control	
3	1.0 (0.25–1.0)	2.0 (1.0–2.0)	<0.000 (S)
6	1.0 (0.0–1.0)	2.0 (1.0–2.0)	<0.000 (S)
12	0.50 (0.0–1.0)	1.0 (0–1.0)	<0.000 (S)
24	0.0 (0.0–1.0)	1.0 (0.0–1.0)	0.015 (NS)
48	0.0 (0.0–1.0)	1.0 (0.0–1.0)	0.068 (NS)

Table 2 Comparison of shoulder pain at various time points between intervention and control

Variables (h)	Median (IQR) 50th percentile (25th–75th)		*p* value
	Intervention	Control	
3	0.0 (0.0–1.0)	1.0 (0.0–2.0)	0.003 (S)
6	0.0 (0.0–0.75)	1.0 (0.0–1.75)	0.002 (S)
12	0.0 (0.0–1.0)	1.0 (0.0–1.0)	0.009 (S)
24	0.0 (0.0–1.0)	1.0 (0.0–1.0)	0.054 (NS)
48	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.110 (NS)

Table 3 Comparison of incision site pain at various time points between intervention and control

Variables (h)	Median (IQR) 50th percentile (25th–75th)		*p* value
	Intervention	Control	
3	2.0 (2.0–2.0)	2.0 (2.0–3.75)	0.017 (NS)
6	2.0 (2.0–3.0)	2.0 (2.0–3.0)	0.693 (NS)
12	2.0 (1.0–2.0)	2.0 (2.0–3.0)	0.141 (NS)
24	1.0 (1.0–2.0)	2.0 (1.0–3.0)	0.348 (NS)
48	1.0 (1.0–2.0)	1.0 (1.0–2.0)	0.982 (NS)

3. Incision site pain

The median interquartile range (in centiles) of incision site pain score 3, 6, 12, 24 and 48 h postoperatively in the intervention group was 2.0 (2.0–2.0), 2.0 (2.0–3.0), 2.0 (1.0–2.0), 1.0 (1.0–2.0) and 1.0 (1.0–2.0) and in control group was 2.0 (2.0–3.75), 2.0 (2.0–3.0), 2.0 (2.0–3.0), 2.0 (1.0–3.0) and 1.0 (1.0–2.0), respectively. The difference between the two groups was not significant. The values are summarized in the Table 3.

Secondary Outcome Measures

Reduction in pain at various time points (6, 12, 24 and 48 h) was compared in a single group taking 3 h as a baseline value. The results are as follows:

Upper Abdominal Pain

In intervention group, there was a significant decrease in pain at 24 h and 48 h ($p=0.002$, $p=0.001$). In the control group, a significant decrease was noted at 12 h ($p=0.003$), 24 h ($p=0.00$) and 48 h ($p=0.00$) (Fig. 1).

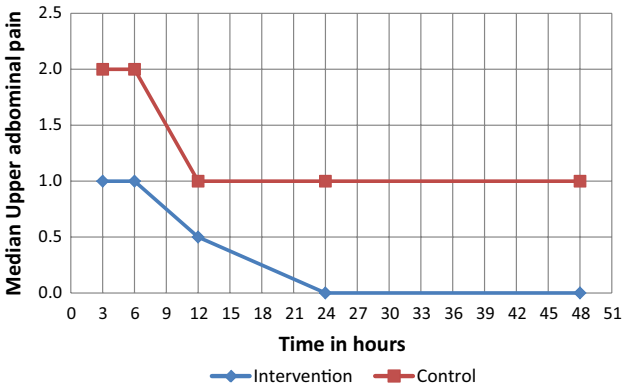

Fig. 1 Median interquartile range of upper abdominal pain at various time points in both groups

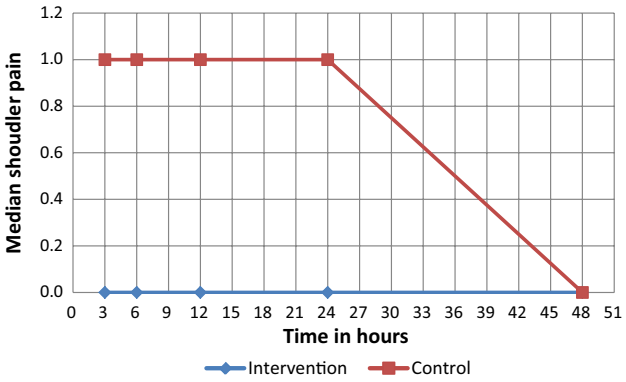

Fig. 2 Median interquartile range of shoulder pain at various time points in both groups

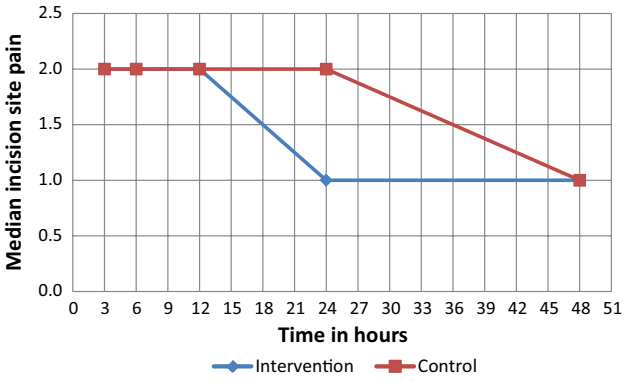

Fig. 3 Median interquartile range of incision site pain at various time points in both groups

Shoulder Pain

In intervention group, there was no shoulder pain at all time points. In the control group, a significant decrease in pain occurred only after 48 h ($p=0.002$) (Fig. 2).

Incision Site Pain

In intervention group, there was a significant decrease in pain at 24 and 48 h ($p=0.005$, $p=0.000$). In the control group, there was a significant decrease in pain observed at 48 h ($p=0.000$) (Fig. 3).

Total Paracetamol Infusion Used

Paracetamol infusion was given to women postoperatively, who had a VAS score ≥ 3. Seventeen cases of intervention group required paracetamol infusion (53.12%) compared to 23 in control group (71.87%). The difference of total paracetamol used in both groups was not statistically significant ($p=0.078$).

Side Effect

No side effect like nausea, vomiting and abdominal distension was noted in the postoperative period.

Discussion

In the present study, a combination of maneuvers, namely intraperitoneal normal saline infusion and pulmonary recruitment maneuver, was used for pain relief as hypothesized by Tsai HW et al. [22]. Both the maneuvers had different mechanisms of action. In addition to this, in this study, to offer complete pain relief, infiltration of bupivacaine was added postoperatively to reduce port sites pain. The mean age in the present study was lower as compared to the study by Tsai HW et al. (28.34 ± 5.3 vs. 39.7 ± 9.04) as majority of women had infertility and underwent either diagnostic or operative laparoscopy, while in the latter study mainly laparoscopic hysterectomies for various reasons were done. The mean BMI of women in the present study was higher (25.38 ± 5.05) than (22.7 ± 3.94) in the study by Tsai HW et al., showing that women in our study were overweight. However, patient profile in the present study with respect to mean age and BMI was similar to the one studied by Radke OC et al. [23]. In a study of Radke et al. [23], the type of operative procedures was almost similar to our study, while other surgeries were ovarian cystectomy, salpingo-oophorectomy and ablation of endometriotic lesion.

As compared to our study, in the other two studies by Tsai et al. and Suginami et al. [22, 24], more laparoscopic hysterectomy and myomectomy were performed. On comparing operative time, the mean operative time in our study was longer as compared to Radke OC et al. (91.72 ± 36.024 v/s. 41.8 ± 2.9 min) as the number of operative laparoscopic procedures for infertility was higher. Hence, mean volume of CO_2 used in our study was higher as compared to Radke et al. (112.91 ± 83.315 v/s 19.6 ± 2.51) [23].

In the study of Tsai et al. and Suginami et al. [22, 24], the operative time was much higher than the present study due to major indications being hysterectomy and myomectomy. However, the total CO_2 consumption has not been mentioned in their results.

In the present study, the incidence of laparoscopic-induced upper abdominal and shoulder pain was significantly lower in the intervention group in the first 12 h of surgery, while Tsai HW et al. showed upto relief of pain at 12 h which is similar to the present study [22]. However, the latter did not evaluate pain in the first 12 h post-surgery. Similar to our study, they demonstrated a relief of upper abdominal pain for 48 h. The incidence of laparoscopic-induced upper abdominal pain was 50%, 44%, 31% at 12, 24 and 48 h, respectively, in our study as compared to 78%, 72% and 58%, respectively, in the study by Tsai et al. [22]. The increased pain in the latter study could be explained by difference in indications of laparoscopic surgery. Significant reduction in shoulder pain was seen in first 12 h in the present study which continued till 48 h, similar to study by Radke OC et al. which reported significant relief at 48 h after a single maneuver (five positive pulmonary ventilation) [23]. Long-lasting shoulder pain relief up to 48 h was also reported by Tsai et al. [22] although they had used a combination of positive pulmonary ventilation and intraperitoneal normal saline infusion. They had hypothesized that pulmonary recruitment maneuver is effective but short acting, while saline infusion due to physiologic buffer mechanism offers a prolonged pain relief. However, the present study confirms with the hypothesis. Although we have not studied positional pain, but a significant reduction has been observed from 63% to 31% by Phleps et al. [17].

No study has evaluated pain with the first 12 h of procedure; however, this is an important parameter which reflects the amount of analgesic requirement and immediate postoperative patient comfort.

There was no significant relief of incision site pain in the intervention group. This is in contrast to the results of Pavlidis et al. [25] who demonstrated a significant pain relief in cases of laparoscopic cholecystectomy and laparoscopic hernia repair in the intervention group. Also, they used ropivacaine, while we had used bupivacaine. No side effects of intervention were observed in the present study which is similar to the studies by Radke et al. and Tsai et al. Hence, the combined maneuver is a safe intervention. As suggested by Tsai et al. [22], the risk of pneumothorax is negligible by positive pulmonary ventilation at 45 cm H_2O pressure, as coughing and sneezing increase intrapulmonary pressure

to 80–130 cm H_2O. Combined maneuvers are effective and inexpensive and can be easily implemented in daily clinical practice. The strength of the study is the prospective and randomized design. Also, the pain was evaluated at 3, 6, 12 h interval which was not done in the other studies.

The main limitations were that majority of cases required short-duration surgeries for infertility; in future, more studies need to be done for long procedures like hysterectomy and myomectomy.

Compliance with Ethical Standards

Conflict of interest The authors report no conflict of interest.

Informed Consent Informed written consent was taken from the patients.

Ethical Approval Taken from UCMS and GTB Hospital Institutional ethical committee.

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