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A prospective randomized trial of postoperative pain following different insufflation pressures during gynecologic laparoscopy

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ABSTRACT

Objective: To determine the effects of different intra-abdominal pressure values on visceral pain following gynecologic laparoscopic surgery in the Trendelenburg position.
Study design: This randomized, controlled prospective trial was conducted at a tertiary education hospital and included 150 patients who underwent gynecologic laparoscopy with different abdominal insufflation pressures. There were 54 patients in the 8 mmHg low pressure group (LPG), 45 in the 12 mmHg standard pressure group (SPG), and 51 in the 15 mmHg high pressure group (HPG). We assessed mean age, body mass index (BMI), duration of surgery, analgesic consumption, length of hospital stay, amount of CO_2 expended and volume of hemorrhage. Visceral pain and referred visceral pain were assessed 6, 12, and 24 h postoperatively using a visual analog scale (VAS).
Results: There was no significant difference in age, BMI, analgesic consumption or length of hospital stay among groups. The mean operative time and total CO_2 expended during surgery were higher in the LPG compared with the SPG and HPG. The mean intensity of postoperative pain assessed by the VAS score at 6 and 12 h was less in the LPG than in the SPG and HPG and was reduced significantly at 12 h. VAS scores at 24 h in the LPG and SPG were lower than in the HPG.
Conclusion: Pain is reduced by low insufflation pressure compared with standard and high insufflation pressure following gynecologic laparoscopic surgery in the Trendelenburg position. However, low insufflation pressure may result in longer operation times and increased hemorrhage.

Introduction

Laparoscopic surgery has several advantages over laparotomy, including decreased perioperative morbidity and mortality, smaller incisions, faster recovery, shorter hospital stays and earlier return to normal activities and work [1–4]. These advantages, coupled with technological advancements in endoscopy, have resulted in a preference for laparoscopy over laparotomy in the past two decades [5]. Although the overall recovery length and hospitalization stay tend to be shorter, postoperative pain is the most common complaint and still an important issue following laparoscopic surgery [6].

There are three forms of abdominal pain: parietal, visceral and referred visceral pain. Parietal pain is defined as sharp and well-localized due to unilateral innervation [7]. Visceral pain is defined as a diffuse, dull ache usually occurring in the midline because of the bilateral innervation of abdominal organs [7]. Referred pain is typically well localized and occurs when visceral afferents carrying stimuli from a diseased organ enter the spinal cord at the same level as somatic afferents from a remote anatomic location [7]. There are several causes of pain following laparoscopic surgery due to the effect of CO_2 pneumoperitoneum, peritoneal stretching, diaphragmatic irritation, diaphragmatic injury and shoulder abduction during surgery [8,9]. Postoperative pain components in laparoscopic surgery include incisional pain (parietal pain), deep intra-abdominal pain (visceral pain), and shoulder pain (approximately referred visceral pain) [6]. The pulmonary recruitment maneuver, continuous wound infiltration of local anesthetic, intraperitoneal normal saline infusion and low and high pressure pneumoperitoneum were found to reduce postoperative upper abdomen, shoulder and parietal pain [8,10–13].

In our experience, the use of the Trendelenburg position in gynecological operations results in increased pain, but we have found no studies addressing the relationship between

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intraperitoneal pressure and postoperative pain in gynecologic laparoscopy in the Trendelenburg position. The aim of our prospective study was to determine the effect of intra-abdominal pressure in the Trendelenburg position on visceral pain and referred visceral pain by examining different pressures in pneumoperitoneum.

Materials and methods

This prospective study was conducted at Zekai Tahir Burak Women Health Education and Research Hospital (Ankara, Turkey). Approval was obtained from the local ethics committee, and written informed consent was obtained from all participants. Female patients undergoing gynecologic laparoscopy were recruited from June 2013 to February 2014. The patients invited to participate in the trial had to meet the inclusion criteria, and included 150 consecutive adults with American Society of Anesthesiologists (ASA) physical status grade 1 or 2 who were undergoing gynecologic laparoscopic surgery (LS) (LS-tubal ligation, LS-cystectomy, LS-tubal ligation plus cystectomy, LS-diagnostic laparoscopy and LS-salpingectomy) under general anesthesia. To exclude variations in the anesthetic technique as a cause of differences among patients, a strict anesthetic protocol was used. Exclusion criteria were patients <18 years of age, those who refused to give consent, inability to understand the research questionnaire, pregnancy, and uncontrolled diseases such as severe hypertension, diabetes mellitus, and asthma.

The gynecologic LS in this study were performed by the same surgical team. Patients were randomized by computer into three different intra-abdominal insufflation pressure groups. There were 54 patients in the low pressure group (LPG), 45 in the standard pressure group (SPG) and 51 in the high pressure group (HPG).

After induction of anesthesia, pneumoperitoneum was induced in both groups using a Veress needle at the umbilicus, and CO_2 was insufflated at a rate of 1 L/min until abdominal pressures of 8, 12 and 15 mmHg were reached. Abdominal insufflation at these pressures was held constant by automatic regulation of the CO_2 inflow. The Trendelenburg position was held routinely at 30 degrees. In all cases, surgeries were achieved using three working ports, one 10-mm umbilical and two 5-mm lateral trocars. A gastric tube was administered routinely, but a Foley catheter was used in those cases who required bladder drainage, and no drain was inserted.

In all cases, residual CO_2 in pneumoperitoneum was evacuated at the end of the procedure by compressing the abdomen. All patients were prescribed postoperative analgesia, with 20 mg tenoxicam (Oksamen-L, Mustafa Nevzat, Istanbul, Turkey) administered intravenously (i.v.) during the first 6 h postoperatively by a ward nurse who did not know the details of the case. The same analgesic, 100 mg paracetamol (Perfalgan 10 mg/mL, Bristol-Myers Squibb S.r.l., Italy), was administered i.v. to all patients every 6 h if required.

The following study parameters were recorded: patient age, gravidity and parity, body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters), previous surgery, type and duration of surgery, quantity of bleeding during surgery, length of hospital stay and total amount of CO_2 used during surgery. Assessment of pain was performed postoperatively at 6, 12, and 24 h. We asked patients to ignore any sharp, well-localized pain around the incision of the trocar to exclude parietal pain. While at rest, the patients were then instructed by the resident physician to complete the visual analogue scale (VAS), ranging from 0 to 10 (0, no pain; 10, the most severe pain), to evaluate any diffuse, dull aching pains in the abdomen or shoulder, representing visceral and referred visceral pains. Both patients and resident physicians were blind to the intra-abdominal pressure used. The number of analgesic injections and i.v. paracetamol infusions required in each patient during the postoperative period was recorded, and the length of postoperative hospital stay was also noted.

The number of patients required for the study was calculated using power analysis based on 80% power to detect a 20–50% difference in the pain score at the 5% significance level. We required 38 experimental subjects and 38 control subjects to reject the null hypothesis, stating that the failure rates for experimental and control subjects are equally probable with a power of 0.8, and we created the smallest group with 44 participants. We used an uncorrected χ^2 statistic to evaluate this null hypothesis, which was associated with a type I error probability of 0.05. All data were analyzed statistically using one-way analysis of variance (ANOVA) followed by the Bonferroni test for multiple comparisons, using SPSS Version 11.0 for Windows (SPSS Inc., Chicago, IL). The data are expressed as means ± standard deviations (SD). P values <0.05 were considered to indicate significance.

Results

During an 8-month period from June 2013 to February 2014, 150 consecutive patients were randomized into three groups. The patients' demographic data are shown in Table 1. The average age, BMI and number of previous surgeries were similar among groups. Gravidity was significantly higher in the SPG than the HPG, and parity was significantly higher in the SPG than the LPG. There was no significant difference among the groups in terms of LS-tubal ligation, LS-cystectomy, LS-tubal ligation plus cystectomy, LS-diagnostic laparoscopy or LS-salpingectomy.

All laparoscopic surgeries were completed successfully using different intra-abdominal pressures. The mean volume of hemorrhage was significantly higher in the LPG than the HPG (Table 2). There were no major intraoperative complications in either group. The mean operative time and total CO_2 expended during the surgery were significantly higher in the LPG than the SPG or HPG ($P < 0.05$) (Table 2). All patients underwent LS for gynecologic indications, including tubal ligation, simple cyst excision, tubal ligation and cystectomy in the same session, diagnostic laparoscopy, and salpingectomy for ectopic pregnancy. These indications were similar among the groups ($P > 0.05$) (Table 2).

Table 1
Characteristics of patients.

	LPG (8 mmHg, $n = 54$)	SPG (12 mmHg, $n = 45$)	HPG (15 mmHg, $n = 51$)	P value
Age (years)	34.57 ± 7.2	33.06 ± 6.56	34.01 ± 6.79	0.55 (NS)
BMI (kg/m^2)	25.19 ± 4.18	24.87 ± 4.85	25.33 ± 3.86	0.23 (NS)
Number of gravidity	2.96 ± 1.4	3.33 ± 1.0[a]	2.78 ± 0.97	0.03
Number of parity	1.74 ± 0.99[b]	2.46 ± 0.66	1.96 ± 0.94	<0.001
Number of previous surgery	0.74 ± 0.80	0.62 ± 0.80	0.65 ± 0.75	0.47 (NS)

In SPG, the number of the gravidity was significantly higher than HPG and the number of the parity was significantly higher than LPG (Table 1). LPG: low pressure group, SPG: standard pressure group, HPG: high pressure group; data are expressed in mean ± SD; significant difference as $P < 0.05$; BMI: body mass index (kg/m^2), NS: not significant.

[a] SPG is significantly different from HPG ($P < 0.05$).

[b] LPG is significantly different from SPG ($P < 0.05$).