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Does high pneumoperitoneal pressure level has an impact on postoperative pain ? A prospective randomized trial

Seda Yuksel Simsek, Erhan Simsek, Gulsen Dogan Durdag, Safak Yilmaz Baran, Hakan Kalayci, Serdinc Ozdogan, Ferhat Samli, Songul Alemdaroglu, Esra Bulgan Kilicdag, Husnu Celik

Baskent University, Medical School Adana Dr. Turgut Noyan Teaching Hospital, Department of Obstetrics and Gynecology, Adana, Turkey

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Abstract

To investigate the postoperative pain intensity after laparoscopic gynecologic surgeries conducted with different pneumoperitoneal pressures. This study was designed as a single-blinded prospective randomized trial in a tertiary referral center. Patients who were scheduled to undergo laparoscopic surgery for benign gynecologic pathologies between dates August 2018 and December 2019 were included. Exclusion criterias were ; malign gynecologic diseases , lack of consent and conversion to laparotomy. Primary outcome measure was postoperative pain scores at 6th and 24th hour time point ; secondary outcome measures were shoulder tip pain and need for opioid type analgesic. The initial and intraoperative pressure for group 1 was 15 mm Hg, the initial pressure was 15 mm-Hg and intraoperative pressure was 12 mm Hg for group 2, and the initial and intraoperative pressure was 12 mm Hg for group 3. Visual analog score (VAS) surveys were performed in postoperative follow-ups for the 6th and 24th hours. The presence of shoulder tip pain and the postoperative opioid analgesic requirement was additionally evaluated. One hundred and seventy-one patients were investigated for per-protocol analysis. The mean 6th and 24th-hour VAS scores of the three study groups were 4.9;3.5; 5.0;4.1, and 5.3;4.3 respectively, for groups 1, 2, and 3 (p=0.506). The difference in shoulder tip pain rates was not statistically significant at each time point between the patient groups (p=0.829 and p=0.334, respectively). Opioid analgesic requirement was significantly higher in patients undergoing laparoscopic hysterectomy with 15 mm Hg intraabdominal pressure (p=0.004). Surgeons should take into account that high intraperitoneal pressures may cause more opioid analgesic requirement. Although pain scores and shoulder tip pain were comparable, opioid analgesic requirement is an important health issue.

Keywords: Laparoscopic CO_2 pressure, postoperative pain score, postoperative opioid analgesic requirement, shoulder tip pain

Introduction

Less postoperative pain is the main advantage of the laparoscopic approach compared with laparotomic surgeries from the patient's perspective. Although postoperative pain is less severe after minimally invasive surgeries compared with laparotomy procedures, it is known that the incidence of postoperative pain can be around 25-35% after discharge [1]. The somatic component of postoperative pain after laparoscopic surgeries is the result of tissue defects formed during abdominal wall penetration, and the visceral component is related to internal organ handling and the irritative and stretching effects of intraabdominal dissolved CO_2 on the peritoneum [2]. The use of nonopioid and opioid type analgesics is one of the most common ways of relieving pain [3,4].

The incidence of new-onset persistent opioid use after minor and major surgeries are similar and at similar rates around 6% in both groups [5]. The least possible opioid use is suggested in the scope of Early Recovery After Surgery (ERAS) [6,7]. In this context, the effects of modifications in intraoperative surgical techniques on the minimization of postoperative pain are gaining clinical importance.

The relation between active desufflation at the end of laparoscopic surgery, local anesthetic injections to trocar sites, the use of smaller trocars, and postoperative abdominal pain have been studied previously [8-10]. Researchers have also remarked on the benefits of such methods as pulmonary recruitment manoeuvre, intraperitoneal saline infusion, and surgery with low intraperitoneal pressure (IPP) on postoperative abdominal and shoulder tip pain [11-13].

The effects of low, standard, and high IPP levels used in laparoscopic gynecologic surgeries on postoperative pain and

*Corresponding Author: Seda Yuksel Simsek, Baskent University, Medical School Adana Dr. Turgut Noyan Teaching Hospital, Department of Obstetrics and Gynecology, Adana, Turkey E-mail: dryukselseda@hotmail.com

shoulder pain have been investigated and remain a topic of interest for some authors [14-17]. Some prospective randomized studies propose that low IPP levels result in lower postoperative pain scores [14,16]. On the other hand, a prospective randomized clinical trial concluded that there was no significant difference between the pain scores of low, standard, and high IPP settings [18]. Furthermore, it is also indicated that visualization may be disturbed in low-pressure settings and the safety of the surgery might be compromised [18,19]. There are also scarce data about the effect of the initial pressure on postoperative pain.

The rationale behind this study is the lack of definite results on outcomes of intraoperative intraabdominal CO_2 pressures and their effects on postoperative pain scores. To the best of our knowledge, no study has compared the effect of 12-mm Hg and 15-mm Hg values alone, which are the most common values used in gynecologic laparoscopic surgeries, on postoperative pain. The aim of this study is to investigate the postoperative pain intensity after laparoscopic gynecologic surgeries conducted with different pneumoperitoneal pressures.

Materials and Methods

This study was designed as a single-blind, prospective randomized trial. Patients who underwent laparoscopic surgery for benign gynecologic etiologies between August 2018 and December 2019 in a tertiary referral center were included in the study. Patients diagnosed with malignant gynecologic diseases before or during surgery; who did not give consent or complete the assesment forms and patients converted to laparotomy were not included in the study.

The primary outcome measure was the effect of different initial and intraoperative pressures on postoperative pain scores and secondary outcome measures were shoulder tip pain existence and requirement of opioid analgesics after laparoscopic gynecologic surgeries. A randomized trial performed by Topçu et al was used to calculate the sample size [16]. Recruitment of 65 patients to each group was planned with a 95% confidence interval and 80% power. Planned loss to follow-up was allowed for in the recruitment numbers.

Enrolment in the study was performed by the surgeon who would perform the surgery. All patients were informed in detail and informed consent forms were signed by the patients. Closed envelopes that were prepared using a computer-generated simple randomization scheme were used just before the beginning of each surgery to determine the group of the patients. All patients were blinded as to which group they were randomized. The patients were divided into three groups. The initial pressure and intraoperative IPP was 15mm Hg for group 1. The initial pressure was 15mm Hg, and the intraoperative IPP was 12mm Hg for group 2. For group 3, the initial pressure and intraoperative IPP was 12mm Hg. After the group allocation, pressure levels were adjusted by the operating room (OR) technician under the supervision of the surgeon. A regularly calibrated electronic endoflator (Karl-Storz 26430520) device was used for the insufflation process. Predetermined pressure levels were checked every 15 minutes and recorded by the technician. Also, end-tidal CO_2 levels and Paw values were recorded every 15 minutes by the anesthesiologist. The initial pressure levels were changed to the intraoperative IPP levels 3 minutes after the beginning of the procedure. Entry to the abdomen was noted as the operation starting time and the withdrawal of trocars was recorded as the operation ending time.

The surgery was performed by five surgeons who were specialized in gynecologic laparoscopic surgeries. Tramadol hydrochloride (2mg/kg) (0.2 morphine milligram equivalent/day/kg) and 1g paracetamol were administered intravenously to all patients before leaving the operation room. Procedures such as pulmonary recruitment manoeuvre and intraabdominal saline infusion were not performed on the patients. A visual analog scale (VAS) for postoperative pain was used in all patients at the postoperative 6th and 24th hours who were in a resting position, by a study nurse. The study nurse was also blinded to the group allocation of the patients. Patients were asked to localize their pain and score it from 0 to 10 (0: no pain, 10: maximal pain). The presence of shoulder tip pain was also inquired at each time point and recorded as present or absent. After the 6th-hour VAS evaluation, patients were asked if they required analgesic administration. Diclofenac sodium was administered intramuscularly (IM) as the first-line nonsteroidal antiinflammatory drug (NSAID). In cases of the persistence of pain, 50-mg meperidine hydrochloride IM (6.67 morphine milligram equivalent) was given as an opioid analgesic.

The demographic characteristics of the patients, previous surgical histories, surgery types, and time information were extracted from the hospital record system. All patients were asked if they had any opioid-type analgesic addiction and none of them had this type of addiction. The weight, height, and waist circumference of the patients were measured before surgery and their body mass index (BMI) values were calculated and recorded. The details of the performed laparoscopic surgeries were obtained from surgical records. Drop-out reasons from the study were specified as the diagnosis of malignant disease intraoperatively, conversion to laparotomy, changing to different pressure values from predetermined pressure value, discharge before completion of the postoperative 24th hour, and refusal of patients to participate in the study. Approval of the study was obtained from the Instutional Ethics Committee (Project Number: KA18/145). The study was registered (Number: NCT03623399) under the name ‘Laparoscopic gas pressure and postoperative pain score.’

Statistical analysis was performed using the SPSS statistical package (Version 17.0, SPSS Inc., Chicago, IL, USA). For each continuous variable, normality was checked using the Kolmogorov-Smirnov and Shapiro-Wilk tests and with histograms. Categorical measurements are expressed as numbers and percentages, continuous measurements are expressed as mean values, standard deviations, and median, minimum and maximum values when needed. The categorical variables between the groups were analyzed using the Chi-square test or Fisher’s exact test. Comparisons between groups were made using Student’s t-test or one-way analysis of variance (ANOVA) for normally distributed data, and the Mann-Whitney U test or Kruskal-Wallis test were used for data that were not normally distributed.Multivariate logistic regression analysis used to determine significance of variables. P-values <0.05 were considered statistically significant.

Results

One hundred ninety-five patients were randomized, with 65 patients for each pressure group. After drop-outs, the data of 171 patients were

investigated for per-protocol analysis. Intended-to-treat analysis was not possible because VAS surveys could not be performed for drop-out patients. A flow diagram of the study is presented in Figure 1.

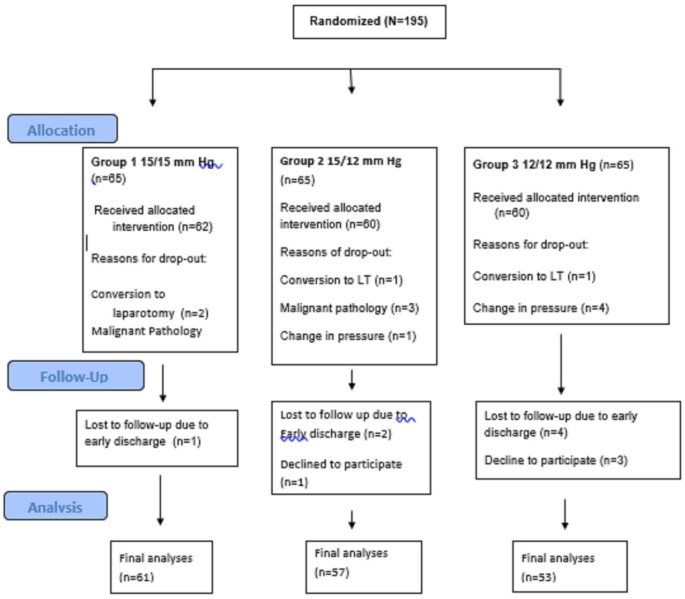

Figure 1. Flow diagram of the study

The mean age, BMI, waist circumference, previous surgeries, and surgical time data of each group are shown in Table 1. Mean operative time was significantly different between groups. And there were no statistically significant differences between the groups regarding other parameters.

The mean 6th and 24th-hour VAS scores were 4.9,3.5; 5.0;4.1, and 5.3;4.3, respectively, for groups 1, 2, and 3 (p=0.506;) (Figure 2).

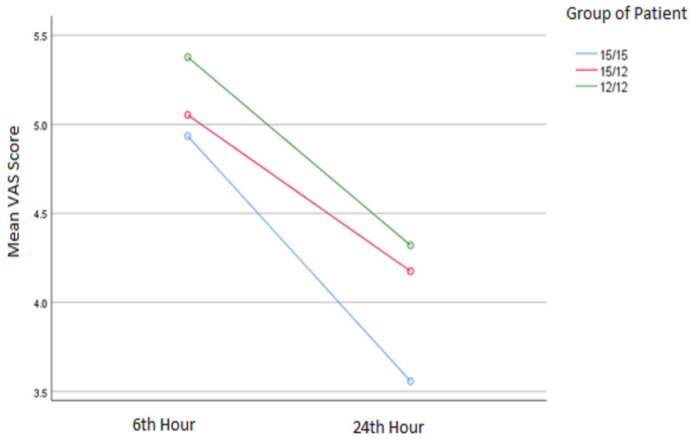

Figure 2. Mean 6th and 24th-hour VAS scores of the three groups

Table 1. General characteristics of the study group

	Group 1 15/15 mm Hg	Group 2 15/12 mm Hg	Group 3 12/12 mm Hg	P values
Age mean(range) years	47 (26-69)	49.2 (21-87)	46.6 (23-72)	0.405
BMI mean(range)	27.2 (19-42)	27.2 (19-44)	27.1 (19-39)	0.997
Waist circumference (mean)	98 cm.	98 cm.	95 cm.	0.444
Surgical duration (mean) min.	88.4 min.	102.7 min.	104.2 min.	0.016
Surgical history	**Group 1 (15/15 mm Hg)n**	**Group 2 (15/12 mm Hg)n**	**Group 3 (12/12 mm Hg)n**	
None	28	29	24	
Laparotomy	9	9	18	
Laparotomy 1<	15	12	9	0.103
Laparoscopy	2	3	2	
Laporoscopy+laporotomy	7	4	0	
Surgical procedures				
L/S hysterectomy +BS	21	17	20	
L/S hysterectomy +BSO	16	16	12	
L/S hysterectomy +USO	1	1	0	
L/S myomectomy	5	3	2	
L/S ovarian cystectomy	7	7	4	
L/S salphingectomy	3	2	1	
L/S USO	2	0	6	0.734
Diagnostic L/S	0	2	2	
L/S hysterectomy + BSO +sacrocolpopexy	3	6	4	
L/S sacrocolpopexy	1	1	1	
L/S cervical cerclage	1	0	0	
L/S hysterectomy +lateral suspension	1	1	0	
L/S lateral suspension	0	1	1	

Abbreviations: BMI: Body mass index; LS: Laparoscopic; BS: Bilateral salpingectomy; BSO: Bilateral salpingo-oophorectomy; USO: Unilateral salpingo-oophorectomy

The percentage and number of patients with shoulder tip pain at the 6th and 24th hour are shown in Table 2. There was no significant difference at either time point in terms of the existence of shoulder tip pain in the three groups (p=0.829 and p=0.334, respectively).

The distribution of patients in all pressure groups in terms of postoperative use of NSAIDs and opioid analgesic was the highest in group 1, but the difference was not statistically significant (p=0.175) (Table 3).

Table 2. Existence of shoulder tip pain at the postoperative 6th and 24th hours

Shoulder tip pain	6th hour n (%)	24th hour n (%)
Group 1 15 mm Hg / 15 mm Hg	18 (29.5)	23 (37.7)
Group 2 15 mm Hg / 12 mm Hg	14 (24.6)	18 (31.6)
Group 3 12 mm Hg / 12 mm Hg	14 (26.4)	24 (45.3)
p value	0.829	0.334

Table 3. Distribution of postoperative analgesic requirement of patients for each group

Postoperative analge-sic requirement	Group 1 15/15 mm Hg	Group 2 15/12 mm Hg	Group 3 12/12 mm Hg
None	1 (1.7)	0	0
NSAID only n (%)	29(47.5)	31(54.4)	35(66)
NSAID+opioid anal-gesic n (%)	31(50.8)	26(45.6)	18(34)
Total	61(100)	57(100)	53(100)
p-value			0.175

When patients were grouped in 10-year intervals in terms of age, there was no significant effect on VAS scores (p=0.27) (Figure 3). BMI values were grouped as <20, 20-25, 25-30, and >30kg/m2 and their relations with VAS scores were evaluated. Although patients with BMI values <20 had higher VAS scores, this difference was not statistically significant (p=0.552) (Figure 4). Waist circumference was also found to have a nonsignificant effect on 6th and 24th-hour VAS scores (p=0.283). The relation between waist circumference and shoulder tip pain was investigated using logistic regression analysis and it was detected that there was a 1.3% and 1.6% decrement in shoulder tip pain existence rates with a one-unit increment of waist circumference for the 6th hour and 24th-hour evaluation, respectively. The effects of parameters such as surgical time and history on VAS scores were also nonsignificant (p=0.623 and p=0.639, respectively).

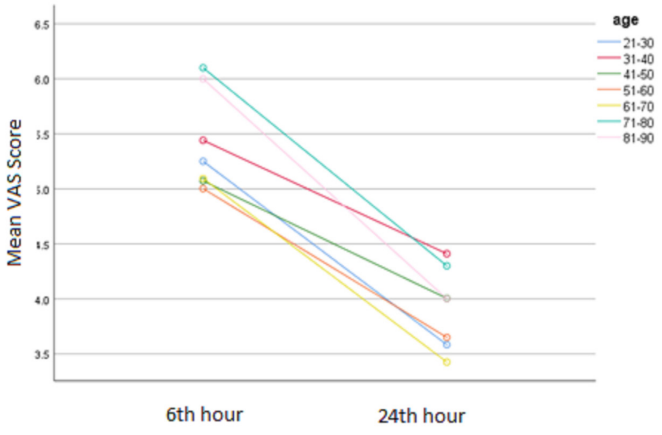

Figure 3. Mean 6th and 24th-hour VAS scores of different age groups

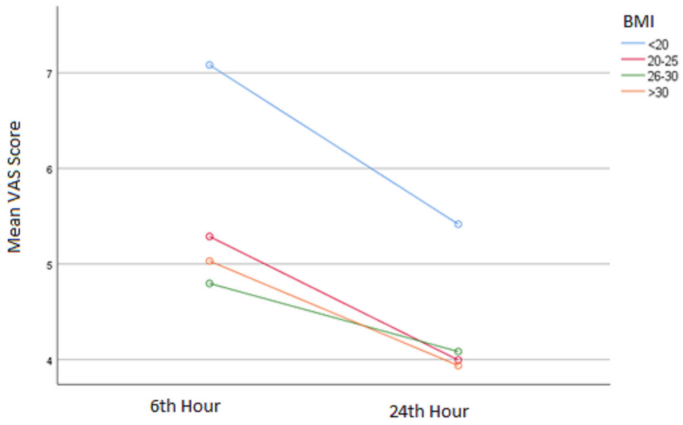

Figure 4. Mean 6th and 24th-hour VAS scores of different BMI groups

The most frequently performed surgery was laparoscopic hysterectomy in the entire study population. Laparoscopic hysterectomy+bilateral salpingectomy /salpingo-oophorectomy/ unilateral salpingo-oophorectomy procedures were considered collectively as laparoscopic hysterectomy and there were 104 patients in this group. The intraoperative IPP was 12mm Hg for group 2 and 3, so these groups were also considered as the standard IPP group and their outcomes were compared with group 1, which was regarded as high IPP. Additionally, the outcomes of standard and high IPP were evaluated under the laparoscopic hysterectomy subgroup. Primary outcomes were also analyzed for these subgroups.

The mean 6th and 24th-hour VAS scores of groups 1, 2, and 3 were 4.9;3.3, 4.7;4.2, and 5.2;4.6, respectively, for the patients of the laparoscopic hysterectomy subgroup (p=0.105).

Table 4. Shoulder tip pain in laparoscopic hysterectomy patients and high and standard IPP groups

TOTAL STUDY GROUP(n:171)	High IPP (15 mmhg)	Standard IPP (12 mmhg)		P value
Shoulder tip pain (+) 6th hour n (%)	18(29.5)			0.735
Shoulder tip pain (+) 24th hour n (%)	23(37.7)			0.737
LS HYSTEREC-TOMY SUBGROUP (n:104)				
Shoulder Tip Pain (+) 6th hour n (%)	10(26.3)	18(27.3)		0.910
Shoulder tip pain (+) 24th hour n (%)	14(36.8)	33(50)		0.190
	15/15 mmhg	15/12 mmhg	12/12 mmhg	
Shoulder Tip Pain (+) 6th hour n (%)	10 (26.3)	11 (32.4)	7 (21.9)	0.628
Shoulder tip pain (+) 24th hour n (%)	14 (36.8)	15 (44.1)	18 (56.3)	0.264

Table 5. Postoperative analgesic requirement of laparoscopic hysterectomy patients, high IPP and standard IPP patients

TOTAL STUDY GROUP n:171	High IPP (group 1)	Standard IPP (group 2+3)		P value
NSAID n (%)	29(47.5)	66(60)		0.103
NSAID+Opioid n (%)	31(50.8)	44(40)		
LS HYSTEREC-TOMY SUBGROUP (n:104)				
NSAID n (%)	14(36.8)	38(57.6)		.04
NSAID+Opioid n (%)	24(63.2)	28(42.4)		
LS HYSTEREC-TOMY SUBGROUP	15/15 mmhg	15/12 mmhg	12/12 mmhg	
NSAID n (%)	14(36.8)	18(52.9)	20(62.5)	0.09
NSAID+Opioid n (%)	24(63.2)	16(47.1)	12(37.5)	

The mean 6th-hour VAS score for high IPP was 4.93 and 3.55 for the 24th hour. These scores were 5.21 and 4.25, respectively, for standard IPP (p=0.26) (Figure 5).

The presence of shoulder tip pain and postoperative analgesic requirement of these subgroups are summarized in Tables 4 and 5.

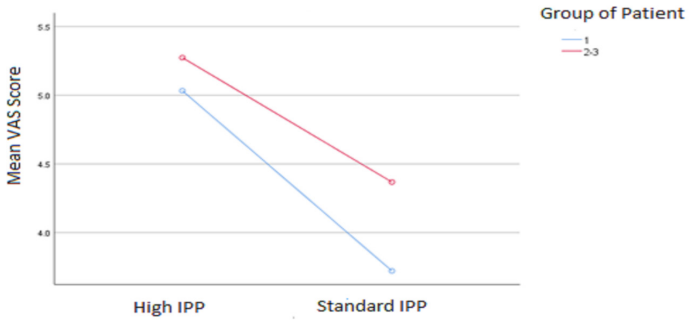

Figure 5. Mean 6th and 24th-hour VAS scores of high IPP and standard IPP patients

Discussion

The primary outcome of this study was to detect the postoperative pain scores of different intraperitoneal pressure levels in benign laparoscopic surgeries. We found no significant difference between the different pressure study groups. However, one of the important results was the enhanced opioid requirement of patients at higher pressure levels. When we consider the presence of shoulder tip pain, we detected that the shoulder tip pain rate was higher at the 24th-hour time point compared with the 6th-hour time point in the entire study group. Although the difference was not significant in the 12 mm Hg group, the pain rate was higher than the 15 mm Hg group.

Bogani et al. showed that low IPP groups had less shoulder tip pain compared to standard IPP patients, but this difference was not observed at the 24th hour. They also noted that there was no significant difference in terms of abdominal pain between those groups [14].

In another study by Bogani et al. on patients who underwent laparoscopic hysterectomies, the low IPP group was seen to be related to less abdominal and shoulder tip pain compared with standard and high IPP patients [15]. In a meta-analysis performed by the same author, it was concluded that there were higher pain scores at the 24th postoperative hour in the high IPP group, and that low IPP was associated with a mild reduction in postoperative pain compared with higher IPP values [20].

Similarly, in their randomized prospective study, Topçu et al. also found that 6th-hour VAS scores were lower in the low IPP group compared with standard and high IPP groups, and the 24th-hour VAS scores were lower in the low and standard IPP groups compared with the high IPP group [16]. A meta-analysis comprising the previously mentioned randomized trials (230 patients) also supported the argument that laparoscopic pelvic surgeries with a

low-pressure setting caused less postoperative pain [20]. However, Kyle et al. remarked that the decrement of postoperative pain was minimal at these pressure values compared with higher pressures, and drew attention to poor visualization of the surgical field in lower IPP values [19].

The results of this study showed that neither abdominal pain scores nor shoulder tip pain were lesser in the lower IPP group, contrary to the results of the aforementioned studies. One of the possible explanations for this situation could be that the studied groups' pressure values were different but close to each other. As mentioned under the 'results' title, opioid type analgesics are more frequently used in patients with high IPP, so this factor may also affect the pain scores of patients at least at 24th hour time point.

One hundred four laparoscopic hysterectomy procedures were performed and the results of this subgroup were also analyzed separately. Again, there was no significant difference either between the three pressure groups or between the standard and high IPP groups. In a prospective study conducted by Radosa et al. on 178 patients undergoing laparoscopic hysterectomy, significantly less postoperative abdominal and shoulder tip pain was reported in the 8-mm Hg group compared with the 15-mm Hg group [21]. Although the present study lacks such a low IPP group (8 mm Hg), we can remark that the postoperative pain scores and the existence of shoulder tip pain of patients undergoing laparoscopic hysterectomy were similar between 12- mm Hg and 15-mm Hg groups.

The postoperative opioid analgesic requirement was significantly higher in the 15-mm Hg group and this increment in analgesic requirement was significant for the laparoscopic hysterectomy subgroup. Radosa et al. also found similar results regarding opioid analgesics. In their study, patients undergoing laparoscopic hysterectomy with 8-mm Hg and 15-mm Hg IPP were compared [21]. In the present study, we showed different opioid use rates for even closer pressure groups.

In our study, it was also found that patient age, surgical duration, and surgical history were not significantly related to VAS scores and shoulder tip pain. Although the mean VAS scores of patients with no surgical history were the lowest (4.2) and for patients with one previous laparotomy it was highest (5.3), the difference was not significant. In contrast to our findings, Kundu et al. showed significant effects of age, surgical duration and history on VAS scores, remarking that the VAS scores of patients at advanced ages were lower, whereas longer surgical duration and a history of two or more laparotomies were related to higher pain scores [18]. We also revealed that patients with no surgical history tended to have lower pain scores, but this effect was minimal.

As a result of our clinical observations, we found that patients with low BMI indexes and waist circumference might experience more severe postoperative pain. The results of the present study revealed that the highest 6th and 24th-hour mean VAS scores belonged to patients with BMIs lower than 20 kg/m², but the difference was not significant. Every one unit increment of waist circumference caused an approximately 1-2% decrement in shoulder pain existence. Based on this outcome, it can be speculated that the increase of peritoneal surface or volume of the intraabdominal cavity may give rise to a reduced stretching force of intraabdominal gas on the peritoneal surface. To make a definite conclusion, these presumptions must be evaluated on larger patient groups.

There are some limitations of this study . We compared three different initial and intraoperative pressure groups, the values quite close to each other. This proximity of pressure values may affect the results. Forthcoming studies may be planned with more discrete pressure values to better delineate the differences Lowest IPP used in the surgeries of this study group was 12 mm Hg so it is not possible to comment on lower IPP pressures than 12 mmhg. We are also unable to make comments on long-term postoperative outcomes and objective intraoperative visualization scores because we lack such data. Shoulder tip pain assessment was made as present or absent. If we used an objective grading scale the results might have been different. All of the operations undertaken were benign gynecological laparoscopic procedures but heterogenous in between. This factor may also effect the result. Laparoscopic hysterectomy was the mostly performed operation , so a subgroup analysis for these patients . Main powerful aspect of this study was the prospective randomized nature of the study and inclusion of a large patient group. To the best of our knowledge, similar studies in the literature have compared the effects of low, standard, and high IPP values. However, in this study, we only evaluated the effects of standard and high IPP values. The number of patients undergoing laparoscopic hysterectomy in this trial is also one of the largest in the literature.

Conclusion

In conclusion, this study revealed that standard IPP values are not superior to high IPP regarding postoperative pain scores and the existence of shoulder tip pain. High IPP values may be mandatory for clear visualization for some groups such as patients with obesity [22].We can say that performing surgery at high pressure when needed will not cause higher pain scores compared with standard pressure. Postoperative opioid requirement increased in parallel with the increment of IPP and this was statistically significant. Surgery performed with IPP at the lowest possible levels should be the aim because contemporary literature supports less use of opioid analgesics for early recovery.

Parameters such as age, BMI, surgical duration and history are potentially effective on postoperative pain scores. These parameters should also be investigated thoroughly to clarify the results. More detailed studies on larger patient groups are required to anticipate the effects of these parameters on postoperative pain.

Conflict of interests
The authors declare that they have no competing interests.

Financial Disclosure
All authors declare no financial support.

Ethical approval
This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Baskent University Medical School. (Date: 06/06/2018 / Number: KA18/145).

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