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Low vs Standard Pressures in Gynecologic Laparoscopy: a Systematic Review

Esther B. Kyle, MD, Sarah Maheux-Lacroix, MD, FRCSC, Amélie Boutin, MSc, Philippe Y. Laberge, MD, FRCSC, Madeleine Lemyre, MD, FRCSC

ABSTRACT

Background: The optimal intraperitoneal pressure during laparoscopy is not known. Recent literature found benefits of using lower pressures, but the safety of doing abdominal surgery with low peritoneal pressures needs to be assessed. This systematic review compares low with standard pneumoperitoneum during gynecologic laparoscopy.

Database: We searched Medline, Embase, and the Cochrane Library for randomized controlled trials comparing intraperitoneal pressures during gynecologic laparoscopy. Two authors reviewed references and extracted data from included trials. Risk ratios, mean differences, and standard mean differences were calculated and pooled using RevMan5. Of 2251 studies identified, three were included in the systematic review, for a total of 238 patients. We found a statistically significant but modest diminution in postoperative pain of 0.38 standardized unit based on an original 10-point scale (95% confidence interval [CI], −0.67 to −0.08) during the immediate postoperative period when using low intraperitoneal pressure of 8 mm Hg compared with ≥12 mm Hg and of 0.50 (95% CI, −0.80 to −0.21) 24 hours after the surgery. Lower pressures were associated with worse visualization of the surgical field (risk ratio, 10.31; 95% CI, 1.29–82.38). We found no difference between groups over blood loss, duration of surgery, hospital length of stay, or the need for increased pressure.

Conclusion: Low intraperitoneal pressures during gynecologic laparoscopy cannot be recommended on the behalf of this review because improvement in pain scores is minimal and visualization of the surgical field is affected. The safety of this intervention as well as cost-effectiveness considerations need to be further studied.

Key Words: Laparoscopy, Artificial pneumoperitoneum, Gynecology, Pain, Safety.

INTRODUCTION

Intraperitoneal pressures at or above 12 mm Hg are usually used for intra-abdominal laparoscopy.[1,2] Some authors have postulated that reducing abdominal distention might be able to decrease postoperative pain and the risk of laparoscopy-related complications such as air embolism, pneumothorax, pneumomediastinum, arrhythmia, and ventilation issues.[3–8] A recent systematic review[9] has indeed concluded that lower intraperitoneal pressures during laparoscopic cholecystectomies were associated with reduced postoperative pain.

However, little data exist about the safety of performing abdominal endoscopic surgery with peritoneal pressures *below* the standard value of 12 mm Hg.[10,11] There is a concern of a poorer visualization of the operative field[12] and therefore an increase in the occurrence of complications. The optimal pneumoperitoneum pressure would allow proper visualization while having the fewest intra- and postoperative complications.[1] Furthermore, given the differences in patient positioning (Trendelenburg vs Fowler) and the nature of the surgeries in gynecologic laparoscopy, previous findings may not be applicable to this population.[13–15] Our systematic review aims to evaluate the benefits and safety of low versus standard (<12 mm Hg vs ≥12 mm Hg[1]) intraperitoneal pressures in gynecologic laparoscopy.

METHODS

This systematic review follows the methodology of the Cochrane Collaboration[16] and is presented according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses.[17] The protocol was registered in PROSPERO (CRD42015020231) and previously published.[18]

CHU de Québec – Université Laval Research Center (CHUL), Québec, QC, Canada (all authors)

Department of Obstetrics-Gynecology and Reproduction, Université Laval, Québec, QC, Canada (Drs Kyle, Maheux-Lacroix, Laberge, Lemyre)

Department of Social and Preventive Medicine, Université LavalQuébec, QC, Canada (Dr Boutin)

Abbreviations: PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses, CI: Confidence interval, mm Hg: Millimeter of mercury

Address correspondence to: Sarah Maheux-Lacroix, MD, MSc, Université Laval Quebec, QC, Canada; e-mail address: sarah.maheux.lacroix@gmail.com

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Eligibility and Criteria

We considered all randomized controlled trials comparing at least two intraperitoneal pressures during gynecologic laparoscopy and reporting data about complications or length of surgery or hospital stay. There was no restriction in terms of publication date or language. Any study in which more than 20% of laparoscopies were performed for malignant disease was excluded from the review because of the increased morbidity associated with more aggressive diseases and surgeries. Studies comparing only gasless laparoscopy with standard laparoscopy were also excluded.

Search

We searched Medline, Embase, and the Cochrane library from their inception to May 18, 2015. Reference lists were also searched for relevant trials and systematic reviews on the subject. The search strategy used for Medline is available in our previously published protocol.[18] Keywords and index terms related to laparoscopy and artificial peritoneal pressures were used. Validated filters[19,20] were used to discriminate randomized controlled trials. We used EndNote X7.3 to manage the references and eliminate duplicates.

Study Selection

The title and abstract of all references, along with full text when required, were reviewed independently by two authors to assess eligibility. A third author was available to solve any disagreement. To avoid duplication, author names, sample sizes, and study results were compared.

Data Collection

Two authors independently extracted information from selected studies using a standardized data extraction sheet. If consensus was not reached, a third reviewer was consulted. From each included trial, we collected information about the study design, participant characteristics, intervention, and peri- and postoperative characteristics. Low intraperitoneal pressure was settled below 12 mm Hg, whereas standard intraperitoneal pressure was settled at greater than or equal to 12 mm Hg.[1,2] We contacted authors of the included trials and asked them for nonpublished data when needed.

Risk of Bias Assessment

The risk of bias in individual studies was determined using the Cochrane Collaboration's tool for assessing risk of bias in randomized trials[21] regarding the primary outcome. Two authors independently applied the tool on the selected trials, and a third author was available to solve any disagreement.

Statistical Analysis and Data Synthesis

Proportions of binary outcomes were compared using risks ratios, pooled with random effects models and the Mantel-Haenszel method. For continuous variables, mean differences and standardized mean differences were pooled with the inverse variance method. We provided 95% confidence intervals (CI). A consistency measure, I^2,[22] was achieved to determine heterogeneity between included trials. Sensitivity and subgroup analysis were planned a priori and conducted to explore sources of heterogeneity. All analyses were performed with the Cochrane statistical package RevMan5 software (Version 5.3; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

RESULTS

A total of 2251 studies were identified using our search strategy (**Figure 1**). Among them, 713 were duplicate records, 1514 did not meet the eligibility criteria based on title and abstract, and 16 did not meet the criteria based on full-text assessment. At the end of the process, 3 studies were included in the systematic review,[23–25] one of which reported infrequent malignant indications and so was deemed eligible.[24]

Table 1 provides the characteristics of the included studies. They were conducted in Italy, Korea, and Turkey, and reports were written in English. One study[25] compared low (8 mm Hg) with standard (12 mm Hg) to high (15 mm Hg) intraperitoneal pressures, whereas the others studied low (8 mm Hg) versus standard (12–13 mm Hg) pressures only. The three studies included in the systematic review were rated as having a low overall risk of bias.

Postoperative pain was measured specifically by two studies,[23,25] which represent 192 patients. Pooled results revealed that abdominal pain was diminished during the immediate postoperative period (last data entry ≤6 hours) with a standard mean difference of 0.38 based on an original 10-point scale (95% CI, −0.67 to −0.08) when using low intraperitoneal pressure of 8 mm Hg compared to pressures ≥12 mm Hg (**Figure 2**), and a standard mean reduction of 0.50 (95% CI, −0.80 to −0.21) at 24 hours after the surgery (**Figure 3**). Heterogeneity was low (I^2 = 0%) in both cases. A reduction in shoulder-tip pain was ob-

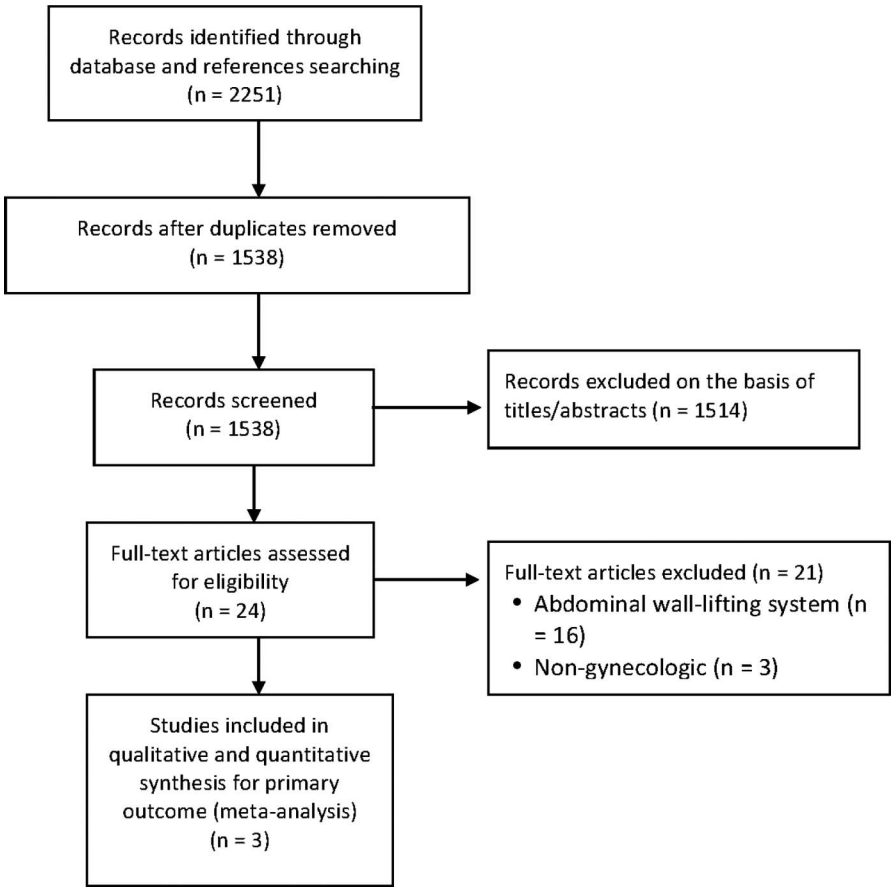

Figure 1. Flow diagram.

Table 1.
Characteristics of Included Randomized Controlled Trials

Study	Country	Participants (n)	Age (y)	BMI	Intervention(s)	Comparator	Surgery	Positioning
Bogani et al, 2014	Italy	42	48.05 (8.04)	25.16 (6.04)	8 mm Hg	12 mm Hg	Minilaparoscopic hysterectomy	Lithotomy or Trendelenburg at or under 25%
Kim et al, 2006	Korea	46	44.35 (9.9)	23.65 (3.15)	8 mm Hg	13 mm Hg	TLH ± BSO, BSO, USO, myomectomy, cystectomy, staging LSC, radical hysterectomy with LDN	Trendelenburg at 30%
Topçu et al, 2014	Turkey	150	33.93 (6.87)	25.14 (4.27)	8 mm Hg 15 mm Hg	12 mm Hg	TL, cystectomy, TL + cystectomy, diagnostic LSC, salpingectomy	Trendelenburg at 30%

BMI = body mass index, BSO = bilateral salpingo-oophorectomy, LDN = lymphadenectomy, LSC = laparoscopy, mm Hg = millimeter of mercury, mg = milligrams, TL = tubal ligation, TLH = total laparoscopic hysterectomy, USO = unilateral salpingo-oophorectomy.

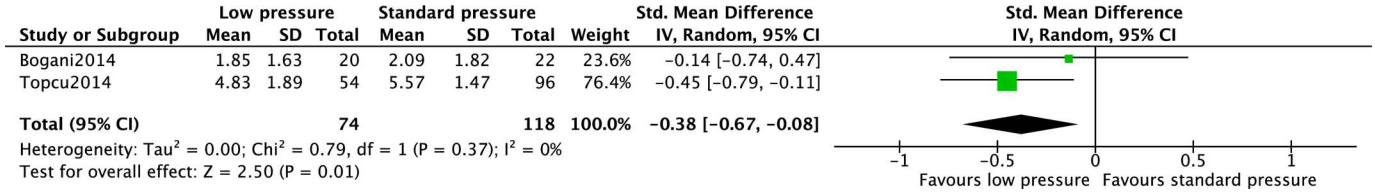

Figure 2. Abdominal pain ≤ 6 h after surgery.

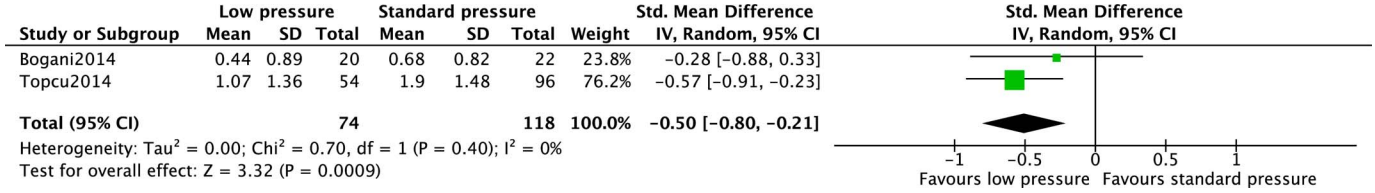

Figure 3. Abdominal pain 24 h after surgery.

served with lower pressures in the immediate postoperative period (standard mean difference, −0.51; 95% CI, −0.81 to −0.22; I^2 = 0%) but not at 24 hours after surgery (standard mean difference, −0.34; 95% CI, −0.90 to 0.21; I^2 = 62%).

Among 88 patients enrolled in two trials,[23,24] the low-pressure group was associated with worsened visualization of the surgical field (risk ratio of inadequate visualization, 10.31; 95% CI, 1.29–82.38; I^2 = 0%) compared with standard pressure. Three studies,[23–25] representing 238 women, assessed the incidence of complications related to the use of lower intraperitoneal pressures. Only one complication occurred (severe bradycardia) in the low intraperitoneal pressure group.[23] No statistically significant difference was observed.

Pooling results from included trials showed no significant difference in blood loss[23–25] (n = 238, 3 trials), duration of surgery[23–25] (n = 238, 3 trials), hospital length of stay, and the requirement for increased pressure[23,25] (n = 192, 2 trials) (**Table 2**). We found some important heterogeneity for these outcomes. However, the low number of studies available precluded subgroup analyses.

DISCUSSION

We found that low intraperitoneal pressures (<12 mm Hg) were associated with lower postoperative pain compared with standard pressure (≥12 mm Hg). However, lower pressures were also associated with poorer visualization of the surgical field, and no other outcomes differed significantly between the two groups.

We observed lower pain scores in the low-pressure group compared with the standard-pressure group at 6 hours and 24 hours after the surgery. The most significant difference was observed at 24 hours. Although statistically significant, this reduction could be considered of low amplitude from a clinical point of view, especially because we found no difference in the length of hospital stay between the two groups. Our results are in agreement with the systematic review of Hua et al[9] on cholecystectomies and of Ozdemir-van Brunschot et al[11] for abdominal laparoscopies, in which lower pressure was associated with a significant reduction in standardized mean pain measurement. Literature on general surgery[9,26] reported a slight reduction of 0.2 day in the hospital using lower-pressure pneumoperitoneum, a result for which clinical relevance can also be questioned. One possible factor of the comparability of both groups of our review could be the initial trocar insertion performed after inflation at standard pressures in two studies[23,24] included in our review. The initial peritoneal distention at standard pressures could have influenced the postoperative pain in the low-pressure groups. Furthermore, data on analgesic consumption were not available, rendering the exploration of the impact of pressure levels on this care parameter impossible.

One major concern about low-pressure pneumoperitoneum is the effect of lowering pressures on the quality of surgical exposure. Low pressures are already preferred in certain situations such as laparoscopy during pregnancy[27] or for patients with multiple comorbidities,[28] but its use during laparoscopy for the typical patient needs validation. In our review, we observed worse visual exposure (risk ratio, 10.31; 95% CI, 1.29–82.38; I^2 = 0%) with lower intraperitoneal pressures. The impression of poorer visualization might be explained by the usual practice of doing surgery under standard pressures of 12 mm Hg or

Table 2.
Outcome Measures

Outcome	Studies (reference number)	No. of patients/Total no. in the cohort		Effect estimate (95% CI)	I^2
		Low pressure	Standard pressures		
Complications	3 (23–25)	1[a]/97	0/141	RR, 3.29 (0.14, 76.33)	NE
Postoperative pain (scale from 1 to 10)					
≤6 h	2 (23, 25)	74	118	SMD, –0.38 (–0.67, –0.08)	0%
Visceral vs abdominal					
≤6 h	2 (23, 25)	74	118	SMD, –0.51 (–0.81, –0.22)	0%
Visceral vs Shoulder-tip					
24 h	2 (23, 25)	74	118	SMD, –0.50 (–0.80, –0.21)	0%
Visceral vs abdominal					
24 h	2 (23, 25)	74	118	SMD, –0.34 (–0.90, 0.21)	62%
Visceral vs shoulder-tip					
Blood loss	3 (23–25)	97	141	MD, 29.73 (–20.78, 80.24)	90%
Duration of surgery (days)	3 (23–25)	97	141	MD, 9.50 (–10.52, 29.51)	78%
Hospital stay (days)	2 (23–25)	74	118	MD, –0.01 (–0.18, 0.16)	65%
Inadequate exposure	2 (23–24)	13/43	0/45	RR, 10.31 (1.29, 82.38)	0%
Need to raise pressures	2 (23–24)	3/43	0/45	RR, 7.00 (0.38, 128.33)	NE

CI = confidence interval, MD = mean difference, NE = not evaluable, RR = risk ratios, SMD = standard mean difference.
[a]Severe bradycardia during insufflation.

above. However, reducing visibility might increase the technical difficulty, and there is concern of an increase in complication rate. Unfortunately, our review did not attain sufficient statistical power to determine the safety of lowering the peritoneal pressure. Most surgeries in included studies represented simple cases, but some oncologic surgeries were also compiled. In fact, only one complication occurred over 238 patients, which is expected in gynecologic laparoscopic surgeries.[29] Thereby, further well-designed trials with sufficiently large sample sizes would be necessary to assess safety issues, as was also highlighted by other authors.[10,11]

Surprisingly, despite the difference in exposure, operative time was comparable in both groups. This is consistent with previous reports in general surgery in which low-pressure peritoneum was only two minutes longer in the low-pressure group than in the standard pressure group.[9,26] There was also no difference in blood loss, need to increase pressure, and conversion to laparotomy. These results support the fact that lowering the pneumoperitoneum pressure is feasible. In fact, laparoscopic surgeries using low pressure were successfully completed in approximately 90% of cases in a previous review.[10]

tk;4Our study has strengths and limitations. The systematic review of the literature grouped data from three studies including 238 patients measuring the impact of different pressures in gynecologic laparoscopy. Even though they are considered of good methodological quality, the small number of patients did not allow us to achieve sufficient statistical power to draw conclusions. Furthermore, despite additional analyses being planned a priori, sources of heterogeneity could not be explored because of a paucity of data. Further data have to be collected to detect differences over complications, and both intra- and postoperative complications should be collected and reported methodically in future researches.

In counterpart, our review was rigorously conducted and our search was extensive and included major databases of medical references and the references of each included study. We used validated methods to conduct our searches and analyses.[17,19–21] We included all randomized controlled trials comparing at least two different intraperitoneal pressures during gynecologic surgery without regard to language, date of publication, or the characteristics of the patients, enhancing the validity, precision, and generalizability of our results. Our systematic review was conducted according to our previously published protocol,[18] which confers enhanced validity to our methodology.

In conclusion, we observed a small reduction in postoperative pain using low- compared with standard-pressure pneumoperitoneum, but lower pressures were also associated with poorer visualization of the surgical field. Based on the quality of the design (randomized controlled trials only) and the quality of the studies (low risk of bias), we consider the general evidence from moderate to high quality. However, we found no evidence in the current literature to support the use of low-pressure pneumoperitoneum.

The use of lower intraperitoneal pressures during gynecologic laparoscopy cannot be recommended based on this review. Cost-utility considerations could be examined in future studies, because limited gains in postoperative pain, even in the absence of operative complications, might not be correlated with shorter hospital stay or reduced usage of pain medication.[9] Further well-designed research is essential to ascertain the gains and prejudice of this approach and needs to concentrate on specific gynecologic interventions.

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