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SURGICAL ENDOSCOPY
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A prospective randomized trial on comparison of low-pressure (LP) and standard-pressure (SP) pneumoperitoneum for laparoscopic cholecystectomy

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Abstract
Aim: This study aimed to investigate the advantages and disadvantages of LP (7 mmHg) in comparison to SP (12 mm Hg) pneumoperitoneum in a prospective randomized clinical trial.
Materials and methods: 148 consecutive patients qualified for laparoscopic cholecystectomy (LC) due to uncomplicated symptomatic gallstones were randomized to either SPLC or LPLC. All the procedures were performed by the same experienced team of surgeons. The statistical analysis included sex, mean age, body mass index, ASA grade, operative time, complication rate, conversion rate, postoperative pain assessed by the Visual Analogue Scale of Pain (VAS) including the incidence of shoulder-tip pain, postoperative hospital stay, recovery time, and the quality of life (QOL) within 7 days following the operation. $p < 0.05$ was considered as indicative of significance.
Results: Neither conversion to an open procedure nor major complications occurred in either group. The operative time was similar in both groups (LP 55.7 ± 8.6 min vs SP 51.9 ± 8.3 min). The mean postoperative pain score was 6.18 ± 3.48 lower after LP than SPLC and the difference amounted to 22.2% ($p < 0.005$). The incidence of shoulder-tip pain was 2.1 times lower after LP than SPLC ($p < 0.05$). QOL within 7 days following the operation was remarkably better after LPLC than after SPLC ($p < 0.01$).
Conclusions: LP pneumoperitoneum is superior to SP pneumoperitoneum in terms of lower postoperative pain, a lower incidence of shoulder-tip pain, and a better QOL within 5 days following the operation. LP should be used for LC in cases of uncomplicated symptomatic gallstones as a recommended procedure as long as an adequate exposure is obtained with this technique.

Key words: Low-pressure pneumoperitoneum — Laparoscopic cholecystectomy

Each laparoscopic procedure requires the surgical team to achieve safe access to the abdominal cavity and to create therein an appropriately large working space. A good exposure of the operative field facilitates the technical performance and is a factor that affects the safety of a patient in the course of the procedure. Among the currently available methods of creating working space, the method of pneumoperitoneum-assisted access is the most popular. CO_2 is the most frequently employed medium; its pressure range is usually 12 to 15 mmHg. In view of the adverse effects of maintaining an increased intraabdominal pressure over longer periods, such as an impaired function of the circulatory system, respiratory problems, and renal dysfunction, a method has been developed aiming at creating a working space using abdominal integument lifting (e.g., Laparolift, Laparotensor) without the need of employing any gas. The method does not impair the cardiac function, and is particularly suitable in elderly patients with chronic conditions of the cardiovascular system [1, 10, 18]. In an attempt to minimize the adverse effects of pneumoperitoneum on cardiovascular function, a technique of low-pressure (7 mmHg) pneumoperitoneum has been developed that allows for an adequate exposure of the surgical field while affecting hemodynamic parameters only minimally in the course of the procedure [4–6, 9]. Some operators employ 4 mmHg pneumoperitoneum additionally combined with abdominal integument lifting [12].

The goal of the present authors was to compare the effectiveness of low-pressure (7 mmHg) and standard-pressure (12 mmHg) pneumoperitoneum in patients subjected to laparoscopic cholecystectomies (LC) investigated in a prospective, randomized trial, with the

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focus placed on the quality of surgical field exposure and the postoperative course (postoperative pain, the course of rehabilitation, and the perioperative quality of life).

Materials and methods

The investigations included 148 patients with uncomplicated, symptomatic cholelithiasis who were referred to the Third Department of Surgery, Collegium Medicum, Jagiellonian University, between 15 May 2000 and 15 December 2001, who met the inclusion criteria and granted their informed consent for the participation in the trial. All the investigated patients were managed by two experienced surgeons (MB, RMH). The study was approved by the Bioethics Committee of the Jagiellonian University. The exclusion criteria were as follows: age below 18 years of life, pregnancy and lactation, previous extensive abdominal surgery, ASA (American Society of Anesthesiology) grade of 3 or more, and prolonged administration of nonsteroid anti-inflammatory agents (NSAID) or other analgesics. The randomization was based on each patient receiving a sealed envelope containing a random number selected from the table assigning the given individual to one of two groups equal in size ($n = 74$): the LPLC group, where the low-pressure 7 mmHg pneumoperitoneum was employed, and the SPLC group, where standard 12 mmHg pneumoperitoneum was used. All the patients were hospitalized after the procedure for at least 24 h.

All the patients were anesthetized by one of two anesthesiologists (PK, KTB), who followed a strict protocol. All the individuals were premedicated with i.v. pethidine, midazolam, and paracetamol. Anesthesia was induced using fentanyl, thiopental, and pancuronium at the body-mass-dependent dose. Following an endotracheal intubation, all the patients were put on mechanical ventilation (isoflurane and oxygen mixture) and monitored by a capnograph to maintain the CO_2 level in the expired air within the range of 4.0–4.5% throughout the procedure. In the course of the operation, the patients received 1 L of Ringer's solution in an i.v. infusion. In each case a gastric tube was inserted for the duration of the procedure and removed prior to its termination. To prevent postoperative vomiting, i.v. metoclopramide was administered in each case prior to awakening.

The procedures were performed by two experienced surgeons involved in the study or by residents experienced in assisting in laparoscopic surgery and supervised by one of the above-mentioned surgeons. In the LPLC and SPLC groups, the surgeons performed 49/74 (66.2%) and 44/74 (59.5%) procedures, respectively.

In all the patients, access was achieved using four working ports (trocars). Pneumoperitoneum was created without visual control using a Veress needle inserted through a small skin incision in the umbilical region. Having created the 12 mmHg pneumoperitoneum, the surgeons proceeded to insert trocars. A Ternamian Endo-Tip 10-mm port was inserted through the umbilicus under visual control. Having introduced subsequent working ports, in the LPLC group the pressure of the pneumoperitoneum was decreased to 7 mmHg, while in the SPLC group the parameters were left unchanged. Throughout the trial, laparoscopic equipment manufactured by Storz GmbH, Tuttlingen, Germany, was employed.

The standard French surgical technique was used. In some cases the exposure of the surgical field was corrected placing the patient in the moderate (15–20°) reversed Trendelenberg position, and if that maneuver failed, the pneumoperitoneum pressure was increased up to 15 mmHg at the maximum or an additional 10-mm trocar was inserted, through which a fan retractor was passed down. Intraoperative cholangiography was performed in selected cases. The gallbladder was enclosed in an Endo Catch sac and excised through the umbilicus, in some patients with large cholecystoliths following a prior replacement of the trocar by an EndoPath 18-mm trocar (Ethicon Endo Surgery). Suction drainage of the subhepatic space was routinely employed in all the patients using the method developed by Redon (a 6Fr drain). Incisions through which 10-mm trocars had been inserted were closed with interrupted fascial sutures.

A detailed statistical analysis included the following factors: sex, age, BMI, ASA grade, medical history prior to operation, gallbladder wall thickness, the presence of adhesions in the vicinity of the gallbladder, the quality of surgical field exposure, the ability to use the LP pneumoperitoneum technique, the need for placing the patient in the reversed Trendelenberg position, increasing the pressure of the pneumoperitoneum and employing an additional trocar for retractor insertion, the duration of surgery, postoperative pain VAS score, and the course of rehabilitation and the QOL in the early postoperative period. The number of patients needed to treat was estimated based on the principle of detecting a 10% difference in pain intensity with a 90% probability at p assumed to be < 0.05. The statistical analysis was based on the chi-square and Student's t-tests.

The intensity of postoperative pain was assessed using a Visual Analog Scale of pain (VAS), with the evaluation done 4, 8, 12 and 24 h postoperatively and subsequently daily at 7:30 A.M., i.e., immediately after the morning toilet (or the morning mobilization of the patient) over 7 consecutive days. Neither the patients nor the nurses knew the relevant group assignment; thus the patients were not aware which pressure the pneumoperitoneum had been set at. Patients marked the intensity of pain with a vertical line on a 100-mm segment, with the left end described as "no pain at all" and the right end described as "insufferable pain." Each evaluation was marked by the patient on a separate evaluation form. For further analysis, data were treated as parametric. Nursing team recorded episodes of vomiting and nausea. All the patients received elective i.v. ketoprofen analgesia administered by an infusion pump over the initial 24 h postoperatively, the dose being dependent on body mass (2–4 mg/kg/day) and the reported pain intensity (VAS 20 or less, 2 mg/kg/day; VAS from 21 to 40, 3 mg/kg/day; VAS 41 or more; 4 mg/kg/day). Twenty-four hours postoperatively, oral analgesia was introduced (ketoprofen 2 mg/kg/day in three divided doses a day). Neither saline washout nor local anesthetic infiltration into the peritoneal cavity and wounds were used in this study. The patients were allowed to assume erect position, mobilized, and given oral diet 12 h after the surgery. Each patient was inquired with a standard QOL questionnaire on the seventh postoperative day. The instrument consisted of 30 items on a visual analog scale categorized into physical (15 items), psychological (10 items), and social (5 items) domains. All the subjects were seen by the surgeons involved in the study at follow-up visits at the outpatient surgical department 3 weeks after the operation.

Results

Between 15 May 2000 and 15 December 2001, 227 patients were admitted to the Third Department of Surgery, Collegium Medicum, Jagiellonian University, for surgical treatment of cholelithiasis and its complications. Of this group of 227 patients, 79 (34.8%) individuals were excluded from the study. Sixty-seven of them had acute cholecystitis requiring an emergency procedure at a time when none of the surgeons involved in the study was on call. Seven individuals had previous extensive abdominal procedures, while five others refused their consent to participate in the study. Randomization to two equal-sized groups ($n = 74$) included 148 patients. The groups were similar with respect to age, sex, BMI, ASA grade, and the mean duration and intensity of cholelithiasis-associated ailments (Table 1). The degree of technical difficulty of each operation was assessed by the operator based on the evaluation of gallbladder wall thickness and the presence of adhesions in the immediate area (Table 2).

Low-pressure laparoscopic cholecystectomies (LPLC) were successfully performed in 70 (94.6%) of 74 patients, while standard-pressure procedures (SPLC) were done in 73 (98.65%) of the group of 74 individuals. The difference was not statistically significant. No adequate exposure of the surgical field was achieved even following the placement of the patient in the reversed Trendelenberg position in four LPLC patients and in one SPLC individual (the likely causes included BMI

Table 1. Characteristics of the patients

	LPLC	SPLC
Sex (M:F)	9:65	10:64
Age (years)	48.15 ± 12.06	47.82 ± 12.58
BMI (kg/m^2)	27.52 ± 3.23	27.10 ± 3.29
Smokers (%)	22.97	27.02
ASA grade (I/II)	52/22	47/27
Mean history of biliary colics (years)	1.43 ± 1.29	1.38 ± 1.18

There were no significant differences between the groups. Values are means ± SD; ASA, American Society of Anesthesiology

> 30 in two cases, adhesions in the vicinity of the gallbladder that required additional retraction in two patients, and rickets-associated chest deformities in one case). In two of these five patients, laparoscopic cholecystectomy was possible after the elevation of the pneumoperitoneum pressure to 15 mmHg, while in the remaining three individuals an additional trocar had to be inserted to retract the duodenum. The moderate reversed Trendelenberg position was employed in 36.48% LPLC and 21.62% SPLC patients ($p < 0.05$). The mean duration of the procedure was similar in both groups, i.e., 55.7 ± 8.6 min vs 51.9 ± 8.3 min in LPLC and SPLC patients, respectively ($p = 0.11$). Cholangiography was performed selectively when small concrements were seen within the gallbladder or a distended or relatively short cystic gall duct was encountered and involved 9.45% and 12.16% of LPLC and SPLC patients, respectively ($p = 0.45$). In both groups there was not a single case of choledocholithiasis that would require the bile duct exploration and no major intraoperative complications (apart from gallbladder perforation and the resultant escape of bile to the subhepatic space that occurred in the course of coagulation hook cholecystectomy in four LPLC and three SPLC patients, followed by a thorough rinsing of the subhepatic space with saline and subsequent suctioning). All the patients were routinely subjected to suction drainage using the Redon method (a 6Fr drain), and the drain was removed 18–24 h postoperatively. The mean hospitalization time after the surgery was similar in the LPLC and SPLC groups, amounting to 2.054 ± 0.43 and 2.108 ± 0.45 days, respectively.

Surgical wound infections were observed in three patients (two from the LPLC and one from the SPLC group). The infections involved the umbilicus, had a mild course, and were successfully treated with antibiotics. The difference was not statistically significant.

The mean intensity of postoperative pain assessed by the VAS scale was significantly lower (by the mean value of 22.2% throughout the entire postoperative period) in the LPLC group as long as day 5 postoperatively. The details are presented in Table 3. The most pronounced differences were seen between the second and fifth days after the operation (36.43% on the average), when the patients were returning to their normal daily activities and analgesics were gradually discontinued. In addition, the daily requirement for analgesics was significantly lower in LPLC than in SPLC patients (Table 4). The patients most often reported pain involving the abdominal integument (predominantly in the umbilical region). A marked difference was observed in the prevalence of postoperative shoulder-tip pain, which was reported by 10.81% and 24.32% of LPLC and SPLC patients, respectively ($p = 0.03$). In 7 individuals (2 and 5, respectively) the complaints were completely resolved after the drain had been removed from the subhepatic space, but the remaining 15 patients (5 and 10, respectively) complained of shoulder-tip pain of variable intensity persisting for the mean time of 2 days and required a single bolus of 0.25mg/kg of pethidine i.v. to improve pain control and facilitate early postoperative mobilization of the patients, which is crucial for decrease of possible postoperative pulmonary complications. Those cases were not complicated ones and they were not different from others except for older mean age of patients in that group (mean of 12.3 years older). Postoperative nausea and vomiting were noted in 27.02% and 16.21% of LPLC, as well as in 33.78% and 20.27% of SPLC patients, respectively, and the difference was nonsignificant.

QOL scores for SPLC group were comparable to those of LPLC group in the social and psychological domains, but were significantly different in the physical domain (78% vs 89% respectively; $p < 0.01$). SPLP patients reported higher level of abdominal pain and more frequent use of painkillers.

Discussion

Worldwide, laparoscopic cholecystectomy is most often performed by creating pneumoperitoneum by pumping CO_2 to the abdominal cavity using a pressure-regulating automatic insufflator. The maintenance of elevated intraabdominal pressure for the duration of the procedure is associated with numerous adverse effects involving the circulatory and respiratory systems, as well as the kidneys; some of these side effects result from a positive intraperitoneal pressure itself, while others are associated with carbon dioxide absorption from the peritoneal cavity to blood [3, 7, 8, 11].

Pressure values that are most often employed in association with pneumoperitoneum range between 10 and 15 mmHg and as a rule provide a good exposure of the surgical field while the adverse effects are still acceptable. When pneumoperitoneum is created, the diaphragm is elevated upward as a consequence of abdominal stretching, lung volume and compliance are decreased, the venous blood return from the inferior vena cava is impaired and the stroke volume decreases, the visceral vascular bed shrinks, and the renal blood flow decreases. In addition, the vascular bed shrinkage results in an increase of the mean arterial pressure [13, 14, 17]. In order to minimize the adverse effects of pneumoperitoneum, the clinical practice was extended to include low-pressure pneumoperitoneum (5–7 mmHg) and the gasless technique based on abdominal integument lifting [some surgeons prefer supplementing the gasless technique with low-pressure pneumoperitoneum (4 mmHg) to achieve a better exposure of the

Table 2. Results

	LPLC	SPLC	*p*
Completed successfully	94.6%	98.65%	0.172[a]
Gallbladder wall			
Thin	82.43%	79.73%	0.674[a]
Thickened	10.81%	9.46%	0.785[a]
Thickened and inflamed	6.75%	10.81%	0.383[a]
Adhesions			
None or light	89.18%	87.83%	0.796[a]
Moderate	10.82%	12.16%	0.796[a]
Dense	0%	1.35%	0.315[a]
Reverse Trendelenberg	36.48%	21.62%	0.046[a]
Increase of pressure to 15 mmHg	5.40%	1.35%	0.042[a]
Additional port	2.70%	1.35%	0.559[a]
Operating time (min)	55.7 ± 8.6	51.9 ± 8.3	0.110[b]
Shoulder-tip pain	10.81%	24.32%	0.030[a]
Cholangiography	9.45%	12.16%	0.450[a]
Mean hospital stay (days)	2.054 ± 0.43	2.108 ± 0.45	0.461[b]
Wound infection	2.7%	1.35%	0.559[a]

[a] Chi^2 test
[b] Student *t*-test

Table 3. Postoperative pain scores (mean ± SD)

Time after operation	LPLC	SPLC	p^a
4 h	27.62 ± 7.32	31.78 ± 9.21	0.003
8 h	28.54 ± 7.23	32.93 ± 9.15	0.001
12 h	27.50 ± 6.65	30.86 ± 6.46	0.002
24 h	31.79 ± 5.17	36.54 ± 6.62	< 0.001
2nd day	29.94 ± 4.74	41.10 ± 11.17	< 0.001
3rd day	28.82 ± 5.07	39.32 ± 7.71	< 0.001
4th day	25.18 ± 6.73	34.28 ± 8.43	< 0.001
5th day	22.60 ± 6.77	24.91 ± 6.98	0.043
6th day	19.87 ± 8.02	21.36 ± 7.78	0.254
7th day	15.75 ± 6.59	17.50 ± 6.67	0.112

Pain scores assessed in Visual Analogue Scale
[a] Student *t*-test

Table 4. Analgesic consumption (mean daily values of ketoprofen in mg ± SD)

Time after operation	LPLC	AR	SPLC	AR	p^a	p^b
1st day	170.27 ± 43.79	93.24%	208.10 ± 60.83	94.59%	< 0.001	0.112
2nd day	179.05 ± 46.08	87.83%	216.89 ± 61.53	90.54%	< 0.001	0.097
3rd day	139.86 ± 38.80	66.21%	187.16 ± 46.12	79.73%	< 0.001	< 0.001
4th day	96.62 ± 53.84	39.19%	119.59 ± 41.22	71.62%	0.004	< 0.001
5th day	25.00 ± 46.24	12.16%	37.83 ± 56.01	17.56%	0.130	0.170
6th day	10.13 ± 23.37	6.76%	16.89 ± 41.60	9.46%	0.225	0.275
7th day	6.08 ± 29.78	4.05%	14.18 ± 44.19	6.75%	0.192	0.225

AR, Analgesia request (% of patients who required pain medication)
[a] Student *t*-test
[b] Chi^2-test

surgical field] [3, 15, 19]. Although each of these techniques has its advantages and disadvantages, the rational approach seems to be to strive to employ minimum pneumoperitoneum pressure values that allow for a good exposure of the surgical field rather than to routinely employ only one technique in all patients, what has been reflected in the recommendations of EAES [12]. The greatest benefit from low-pressure techniques or abdominal lift methods is observed in patients with diseases of the cardiovascular system and the kidneys. LP pneumoperitoneum results in decreasing the adverse hemodynamic effects in comparison to standard pneumoperitoneum (12–15 mmHg) [3, 19].

The present prospective randomized trial has confirmed earlier observations, also demonstrating a significant decrease in postoperative pain intensity and in the demand for analgesics in patients in whom the LP technique was employed as opposed to those in whom

SP pneumoperitoneum was created. This is true not only in the case of a decreased intensity of pain involving the abdominal integument (22.2%, on the average) within 5 days postoperatively, but in particular in the case of a decrease in the prevalence of shoulder-tip pain from 24.32% in the SPLC group to 10.81% in LPLC patients ($p < 0.05$). The origin of pain after LC is multifactorial, with pain arising from the incision sites, the pneumoperitoneum, and the cholecystectomy [20]. The exact mechanism of pain related to pneumoperitoneum after laparoscopy has yet to be clarified. Proposed mechanisms include diaphragmatic stretching, chemical irritation of peritoneum by carbonic acid formed from carbon dioxide, and sympathetic nervous system activation derived from hypercarbia and leading to amplification of local tissue inflammatory response as well as splanchnic mucosal ischemia [7, 17]. The authors believe that the use of the LP technique during LC results mostly in a remarkable reduction of pain arising from pneumoperitoneum. However, the fact that shoulder-tip pain subsided in some patients immediately following the removal of a peritoneal drain favors the supposition that the pain was caused by the mechanical irritation inflicted by the drain and not only by the stretching of the diaphragm and diaphragmatic nerve endings by pneumoperitoneum [2, 16]. Use of continuous 24-h i.v. analgesia following the LC was to reduce the variability of ketoprofen serum level dependent on malabsorption in cases of postoperative nausea and vomiting. In the present trial, the authors have failed to find differences in the duration of postoperative hospitalization in view of the strict economic rules of a 2-day minimum hospitalization after the procedure of cholecystectomy that are enforced in Poland by particular Sickness Funds.

It is commonly believed that a higher pressure of pneumoperitoneum results in a better exposure of the surgical field. Yet, personal observations of an animal model have demonstrated that the largest volume of gas is pumped into the peritoneal cavity until the pressure value of 7–8 mmHg is achieved. A further increase of pressure leads to a geometrically decreasing increment of the pneumoperitoneum volume.

In the present trial, LP pneumoperitoneum has been proven to be sufficient for performing laparoscopic cholecystectomies in as many as 94.6% of patients (as compared to 98.65% of individuals subjected to the same procedure employing standard-pressure pneumoperitoneum). When LP pneumoperitoneum is used, the necessity of improving the exposure of the surgical field through placing the patient in the reversed Trendelenberg position occurs significantly more frequently (36.48% in LPLC vs 21.62% in SPLC patients; $p < 0.05$). When the maneuver fails to cause the desired effect, some improvement may be achieved by employing an additional port to insert a duodenal retractor before a decision is reached to increase the pneumoperitoneum pressure up to 12–15 mmHg. In patients with well-developed muscles, LP peritoneum requires adequate relaxation. No significant differences have been noted in the duration of the procedures performed by surgical staff and senior residents.

Summing up, the use of LPLC as compared to SPLC significantly decreases the intensity of pain and the demand for analgesics for 4–5 days after laparoscopic cholecystectomies, at the same time improving the QOL in the early stage of postoperative rehabilitation. The low-pressure technique may be employed in the majority of patients subjected to laparoscopic cholecystectomies and it should be more extensively employed in clinical practice. Only when no adequate exposure of the surgical field is achieved employing LP pneumoperitoneum should a surgeon consider elevating the pneumoperitoneum pressure to the lowest value providing a good exposure.

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