The combination of infiltrative bupivacaine with low-pressure laparoscopy reduces postcholecystectomy pain

A prospective randomized controlled study

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ABSTRACT

الأهداف: تقييم مدى فعالية الجمع بين البنج الموضعي النفاذ وتقليص الضغط داخل الصفاق في تخفيف الألم الناتج عن المنظار لدى المرضى الذين سيخضعون لعملية استئصال المرارة بالمنظار.

الطريقة: أُجريت هذه الدراسة العشوائية الاستطلاعية في قسم الجراحة والعناية المركزة التابعين لمستشفى الأم تيريزا، تيرانا، ألبانيا، واستمرت خلال الفترة من يناير 2006م إلى سبتمبر 2009م. شملت هذه الدراسة 473 مريض ممن سيخضعون لعملية استئصال المرارة بالمنظار، وقد قُسموا عشوائياً إلى المجموعات التالية: مجموعة 15 ملم زئبقي من الضغط داخل البطن من دون البنج الموضعي النفاذ (ج1، العدد:120)، ومجموعة 15 ملم زئبقي من الضغط داخل البطن و5 مل من البنج الموضعي النفاذ 0.5% في شق صغير (ج2، العدد:122)، ومجموعة الضغط داخل البطن تحت 10 ملم زئبقي ومن دون البنج الموضعي النفاذ (ج3، العدد: 110)، ومجموعة الضغط داخل البطن تحت 10 ملم زئبقي والبنج الموضعي النفاذ (ج4، العدد: 121).

النتائج: أشارت نتائج الدراسة إلى وجود اختلاف كبير من الناحية الإحصائية (p=0.003) بين المجموعات وذلك فيما يخص شدة الألم الناتج عن الشق، حيث كان هناك فرق بين ج1 وج4 (p=0.001)، وبين ج2 وج4 (p=0.037)، وبين ج3 وج4 (p=0.001). كما كان هناك اختلاف بين المجموعات فيما يخص شدة الألم في قمة الكتف (p=0.001)، حيث كان هناك فرق بين ج1 وج4 (p=0.001)، وبين ج2 وج4 (p=0.001)، وبين ج3 وج4 (p=0.031). ووجدنا اختلاف كبير من الناحية الإحصائية وذلك فيما يتعلق بوقت بداية الألم (اختبار أنوفا، p=0.027)، حيث كان هناك فرق بين ج1 وج4 (p=0.041)، وبين ج2 وج4 (p=0.031)، وبين ج3 وج4 (p=0.05).

خاتمة: أظهرت هذه الدراسة بأن الجمع بين البنج الموضعي النفاذ وتقليص الضغط داخل الصفاق له فعالية في تخفيف الألم بعد التنظير الجراحي وذلك بالمقارنة مع بقية الأساليب الأخرى.

Objectives: To evaluate the efficacy of combined infiltrative bupivacaine with low intraperitoneal pressure insufflation in reducing the post-laparoscopic pain in patients undergoing laparoscopic cholecystectomy (LC).

Methods: This randomized prospective single-blind study included 473 patients undergoing LC. The study took place at University Hospital Center "Mother Teresa," Tirana, Albania between January 2006 to September 2009. The patients were divided in 4 groups: Group 1 (n=120) with intra-abdominal insufflation pressure 15 mm Hg and no infiltrative bupivacaine (HPNBG); Group 2 (n=122) with intra-abdominal insufflation pressure 15 mm Hg and with 5 ml infiltrative bupivacaine 0.5% in abdominal minincisions (HPBG); Group 3 (n=110) with intra-abdominal insufflation pressure under 10 mm Hg and no infiltrative bupivacaine (LPNBG); and Group 4 (n=121) with intra-abdominal insufflation pressure under 10 mm Hg and infiltrative bupivacaine (LPBG).

Results: There were statistically significant differences (p=0.003) between groups regarding incisional pain intensity, between LPBG and HPNBG (p=0.001), between LPBG and HPBG (p=0.037), between LPBG and LPNBG (p=0.001), as well the shoulder-tip pain intensity (p=0.001); between LPBG and HPNBG (p=0.001), between LPBG and HPBG (p=0.001), and between LPBG and LPNBG (p=0.031). We found statistically significant differences related to pain beginning time (ANOVA test, p=0.027); between LPBG and HPNBG (p=0.041), between LPBG and HPBG (p=0.031), and between LPBG and LPNBG (p=0.05).

Conclusion: The combination of infiltrative bupivacaine with low intraperitoneal pressure insufflation shows to be more efficient in reducing the post-laparoscopic pain, compared with other regimens.

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Through the patients undergoing surgery every year, laparoscopic cholecystectomy (LC) is one of the most common procedures, which have been improved to reduce patient's trauma, morbidity, mortality, hospital stay and cost. Postoperative pain remains a major problem faced in the postoperative period.[1] Effective pain control is important for short and long-term patients' convalescence after surgery. Physiological responses to injury include pulmonary, cardiovascular, gastrointestinal, and urinary dysfunction, and neuroendocrine and metabolic effects as well. Aggressive postoperative pain treatment can attenuate all these responses. Less pain means early mobilization, reduced incidence of pulmonary complications (atelectasis, hypoxemia, pneumonia, respiratory failure, exacerbation of current respiratory diseases), reduced postoperative cardiac events, reduced risk for deep venous thrombosis and pulmonary embolism. Many of these consequences can be reduced by effective pain treatment.[1-3] Laparoscopic surgery offers less pain, early mobilization, and early hospital discharged. Laparoscopic cholecystectomy is a safe procedure associated with different pain intensity and types. Neck pain is a result of gas insufflations and distribution. The mini incisions' site can cause postoperative pain as well. The goal of this study is to evaluate the efficacy of the infiltrative bupivacaine combined with low-pressure pneumoperitoneum in reducing the post-laparoscopic pain in patients undergoing LC, because in the consulted literature we have not found such a combination.

Methods. The study was performed at the Department of Surgery by the Service of Anesthesiology and Intensive Care of the University Hospital Center "Mother Theresa", Tirana, Albania between January 2006 and September 2009. This single blinded, randomized, prospective cohort, case controlled study was approved by the Ethics Committee of the University Hospital Center "Mother Theresa" and the written informed consent was obtained from the patients as well.

Involved patients were classified ASA grade 1 and 2, scheduled to undergo general anesthesia for laparoscopic cholecystectomy. All the patients with severe pre-existing pulmonary and cardiac diseases, intracranial lesions, spinal and peridural anesthesia, local anesthetics' hypersensitivity, as well as pediatric patients, were excluded from the study. Based on the number of patients undergoing LC from the previous year (2005), we forecasted to include in our study 500 patients in 3 consecutive years. The patients were divided into 4 study groups: 125 patients each group. Our study was single-blind because the patients had the possibility to choose the blindly treatment group. The researcher put 4 balls (yellow, red, blue, white) into a non-transparent vase, which were extirpated by patients. This procedure continued until all groups were completed. The yellow ball mean high pressure/non-bupivacaine (HPNBG), the red ball mean high pressure/bupivacaine (HPBG), the blue one mean low-pressure/non-bupivacaine (LPNBG), and finally the white ball indicated low-pressure/bupivacaine (LPBG) group. During the surgery, some patients were excluded from the study because the surgical procedure was converted from LC to open, due to the consequences of surgical complications. The final number of studied patients was 473.

Figure 1 shows the scheme of the patients in the study. The applied method for each group was: Group 1: with intra-abdominal insufflation pressure 15 mm Hg and no infiltrative bupivacaine (HPNBG); Group 2: with intra-abdominal insufflation pressure 15 mm Hg and with 5 ml infiltrative bupivacaine 0.5% in abdominal mini incisions (HPBG); Group 3: with intra-abdominal insufflation pressure under 10 mm Hg and no infiltrative bupivacaine (LPNBG); and Group 4: with intra-abdominal insufflation pressure under 10 mm Hg and 5 ml infiltrative bupivacaine 0.5% (LPBG) (Astra-Zeneca, Willington, USA).

We performed the induction in all patients with Fentanyl 3 mcg.kg (Janssen-Cilag, Beerse, Belgium), Thiopenthal 6 mg.kg (RotexMedica, Tritau, Germany), and the patients' tracheas were intubated using Pancuronium 0.08 mg.kg (RotexMedica, Tritau, Germany). No additional drugs were necessary. Karl Storz thermoflator (Karl Storz GmbH & Co, Tuttligen, Germany) was used to create pneumoperitoneum. The device was set to maximal intra-abdominal CO2

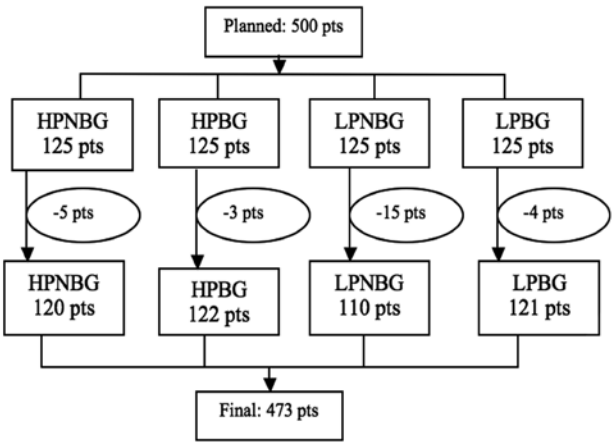

Figure 1 - The included scheme of the patients in the study. HPNBG - with intra-abdominal insufflation pressure 15 mm Hg and no infiltrative bupivacaine, HPBG - with intra-abdominal insufflation pressure 15 mm Hg and with 5 ml infiltrative bupivacaine 0.5% in abdominal mini incisions, LPNBG - with intra-abdominal insufflation pressure under 10 mm Hg and no infiltrative bupivacaine, LPBG - with intra-abdominal insufflation pressure under 10 mm Hg and 5 ml infiltrative bupivacaine 0.5%, pts - patients

pressure of 15 mm Hg for the 2 first groups and 10 mm Hg for the second 2 groups. After that, the CO2 insufflation and laparoscopic procedure was started. Infiltrations with 5 ml Bupivacaine 0.5% (Astra-Zeneca, Willington, USA) were made approximately 1 cm depth. The surgeon infiltrated first the periumbilicus zone, and then a mini incision was performed. After that, the surgeon predicted the suitable sites in order to make the other incision. After drawing using dermatograph, he infiltrated the other sites as well. Finally, the other instruments were placed and pneumoperitoneum was created. The following parameters were recorded: intra-abdominal pressure, onset of the pain, incisional and shoulder-tip pain intensity measured with visual analogue score (VAS) 1-10/10, and daily morphine consume. We considered VAS over 4/10 as a threshold for postoperative pain treatment, and morphine administration. Morphine was used until the VAS less than 4/10.

The collected data were elaborated statistically according to analysis of variance (ANOVA) and Chi square tests. The continuous data were presented as mean and standard deviation. Categorical data were presented in absolute numbers. One-way analysis of variance was used to test the significance of differences between 3 or more sampling means, and Chi-square test was used to analyze differences between groups (for categorical data). P-value ≤5% was considered significant. Statistical Package for Social Sciences for Windows, Version 16.0 was used for statistical analysis.

Results. The demographic data is presented in **Table 1**. Using ANOVA test, there were no statistically significant differences between groups regarding age (p=0.533) and surgery duration (p=0.177). Using Chi-square test, no statistically significant difference between groups related to gender (df=7, p=0.437). The data recorded in 4 groups are presented in **Table 2**.

Table 1 - Demographic data of patients and groups classified as ASA grade 1 and 2 and scheduled to undergo general anesthesia for laparoscopic cholecystectomy.

Parameters	Intra-abdominal pressure 15 mm Hg		Intra-abdominal pressure 15 mm Hg		ANOVA	Chi-square
	HPNBG group	HPBG group	LPNBG group	LPBG group		
Patient's number	120	122	110	121		
Age (years)	45 ± 9.2	43.5 ± 8.7	46.7 ± 6.3	44.3 ± 7.1	p=0.533	
Gender (M/F)	49/71	48/74	39/71	44/77		df=7 p=0.437
Surgery duration (min)	68.3 ± 12.5	65.7 ± 10.8	64 ±13.6	66 ±11.4	p=0.177	

HPNBG - with intra-abdominal insufflation pressure 15 mm Hg and no infiltrative bupivacaine, HPBG - with intra-abdominal insufflation pressure 15 mm Hg and with 5 ml infiltrative bupivacaine 0.5% in abdominal mini incisions, LPNBG - with intra-abdominal insufflation pressure under 10 mm Hg and no infiltrative bupivacaine, LPBG - with intra-abdominal insufflation pressure under 10 mm Hg and 5 ml infiltrative bupivacaine 0.5%. ANOVA - analysis of variance, df - degree of freedom

Table 2 - Recorded data of 4 groups classified as ASA grade 1 and 2 and scheduled to undergo general anesthesia for laparoscopic cholecystectomy.

Parameters	Intra-abdominal pressure 15 mm Hg		Intra-abdominal pressure 15 mm Hg	
	HPNBG group	HPBG group	LPNBG group	LPBG group
Patient's number	120	122	110	121
Incisional pain (VAS 1-10/10)	7.2 ± 1.8	2.5 ± 1.2	6.9 ± 2.1	4.8 ± 1.3
Shoulder-tip pain (VAS (1-10)	7.4 ± 2	6.9 ± 1.4	5.7 ± 1.6	4.5 ± 1.5
Pain beginning time (hour)	2.3 ± 0.6	2.9 ± 1.1	3.2 ± 0.9	4.7 ± 0.5
Daily morphine consume (mg)	13 ± 1.5	10 ± 2	9.5 ± 1.5	7.5 ± 0.5

HPNBG - with intra-abdominal insufflation pressure 15 mm Hg and no infiltrative bupivacaine, HPBG - with intra-abdominal insufflation pressure 15 mm Hg and with 5 ml infiltrative bupivacaine 0.5% in abdominal mini incisions, LPNBG - with intra-abdominal insufflation pressure under 10 mm Hg and no infiltrative bupivacaine, LPBG - with intra-abdominal insufflation pressure under 10 mm Hg and 5 ml infiltrative bupivacaine 0.5%, VAS - Visual Analogue Scale

Using ANOVA test, there were statistically significant differences (p=0.003) between groups regarding incisional pain intensity (VAS); between LPBG and HPNBG (p=0.001), between LPBG and HPBG (p=0.037), and between LPBG and LPNBG (p=0.001). There were statistically significant differences between groups regarding shoulder-tip pain intensity (VAS), p=0.001; between LPBG and HPNBG (p=0.001), between LPBG and HPBG (p=0.001), and between LPBG and LPNBG (p=0.031). We found statistically significant differences between groups related to pain onset (ANOVA test, p=0.027); between LPBG and HPNBG (p=0.041), between LPBG and HPBG (p=0.031), and between LPBG and LPNBG (p=0.05). There were statistically significant differences between groups regarding daily postoperative morphine consume (p=0.033); between LPBG and HPNBG (p=0.024), between LPBG and HPBG (p=0.031), and between LPBG and LPNBG (p=0.05).

Discussion. Pain remains a common problem after LC. Neck and shoulder pain (resulting from diaphragmatic irritation by CO2 insufflation) is reported in majority of patients during the first 24 hours.[8] The upper abdomen surgery can reduce vital capacity, tidal volume, residual volume and capacity, and forced first second expiratory volume (FEV1). These changes are a consequence of decreased diaphragmatic function,[4] resulting in increased risk for atelectasis, hypoxemia, hypercarbia and postoperative pneumonia. Pain increases heart rate, myocardial oxygen consumption, augmenting the risk for myocardial ischemia and infarction.[5] The physical activity is also reduced when the fear of aggravating pain results, increasing the risk of deep venous thrombosis, and pulmonary embolia.[6] Pain can also decrease the urinary bladder motility and postoperative paralytic ileus. Pain causes the rise of sympathetic response, hypothalamic stimulation, increasing systemic catecholamines and catabolic hormones such as cortisol, antidiuretic hormone, glucagon, aldosterone and also decreasing insulin secretion. This result in catabolic state, salt and water retention and hyperglicemia.[7] Neck and shoulder pain (resulting from diaphragmatic irritation by CO2 insufflation) is also reported in the majority of patients in the first 24 hours.[8] Laparoscopy allows a significant reduction in postoperative pain and analgesic consumption.[8-10] Post-laparoscopic pain syndrome is well recognized and characterized by abdominal and particularly shoulder-tip pain; it occurs frequently following LC and several studies have reported different pain management strategies.[11] Postoperative shoulder pain is minor from the usage of low-pressure CO2 pneumoperitoneum compared to the open technique.[12,13] These studies demonstrated that low-pressure pneumoperitoneum was superior to standard pressure pneumoperitoneum in terms of lower postoperative pain, and lower incidence of shoulder-tip pain. Other studies confirm that lower than usual pneumoperitoneum pressure, reduces both the frequency and intensity of shoulder-tip pain following laparoscopic cholecystectomy.[14] Our data confirm these findings; the low-pressure group had significantly lesser shoulder pain intensity. However, conflicting data are reported in the literature. Another study[15] demonstrated that reducing the pressure of the pneumoperitoneum to 7 mm Hg tended to produce lower incidence of postoperative shoulder-tip pain (27.9% versus 44.3%), and lower intensity of shoulder-tip pain. Chok et al[16] studying the use of low-pressure pnuemoperitoneum in out-patients undergoing to LC, enrolled in their study only 40 patients. They reported less pain in low-pressure group, but not statistically significant.

Study limitation. This conclusion can be explained by the small number of the enrolled patients. The authors stated that the study was not double blind, further confusing the conclusions. Celik et al[17] conducted a prospective study, including 64 patients. The small number of the included patients, can explain the lack of the significance. Another limitation may be the fact that high-pressure group had statistically significant short duration than low-pressure group. Probably greater insufflation time, more diaphragm irritation, and greater neck and shoulder pain can equalize the pain intensity between groups.

Kanwer et al[18] concluded that low-pressure pneumoperitoneum does result in some benefit to the patient in the form of lower intensity of postoperative pain. Intravenous tramadol showed to provide superior postoperative analgesia in the early postoperative period after LC compared with an equivalent dose of tramadol administered intraperitoneally.[18] Intraperitoneal administration of local anesthesia is often used to improve pain relief after LC. In a meta-analysis,[19] the authors conclude that the use of intraperitoneal local anesthesia is safe, and it results in a statistically significant reduction in early postoperative abdominal pain. Intraperitoneal local anesthetics have been investigated in other laparoscopic procedures as well, but no clinical significance was demonstrated.[20] Another study[21] confirms significantly lower benefits of intraperitoneal irrigation of bupivacaine. Thus, the intraperitoneal irrigation does not reduce the intensity pain. We applied local anesthetic drug in peri-incisional skin infiltration, and evaluated the effect of its combination with low-pressure pneumoperitoneum on both incisional and shoulder-tip pain. In the consulted literature, we have not found other studies describing such a mentioned

combination. The data of our study shows statistically significant difference between the LPBG and other groups regarding the measured parameters. The onset of the pain was extended, while its intensity (including shoulder-tip and incisional pain) and morphine consumption were significantly reduced in LPBG. Due to limited number of patients involved in the study, a multi-centric trial is required in order to enhance the reliability of our data.

As a conclusion, based on our results, we recommend the combination of low-pressure pneumoperitoneum and local infiltration, in order to postpone the onset and to reduce the intensity of the pain, as well as to reduce the postoperative morphine consume after laparoscopic cholecystectomy procedures.

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Related topics

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