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Effect of Intraperitoneal Instillation of Bupivacaine on the Pain Scores post operation of Laparoscopic Cholecystectomy

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Abstract: Laparoscopic cholecystectomy is now an established form of treatment for patients with symptomatic gall stones as it is an excellent mean to minimize the trauma and agony of the patient following surgery, although recent studies have shown that patients still experience considerable pain after this surgery. In our current study, we aim to assess the effectiveness of intraperitoneal instillation of bupivacaine in the reduction of post-operative pain after laparoscopic cholecystectomy. 40 patients were randomly allocated in two groups; a study group that received 50 ml of bupivacaine (50%) instilled intraperitoneally into the gall bladder bed and under the surface of diaphragm, and control group which received 50 ml of 0.9% normal saline instilled in the same way. Data recorded from patients in pre-designed format and enrolled in a randomized double-blind prospective study showed a significant decline in post-operative pain scores in the study group between 1st and 4th hours as compared to the control group and, consequently, consumption of analgesics was lower in intergroup comparison. Discharge after surgery was significantly earlier in the study group (75%) one-day admission, while only (35%) of group B discharged after one-day hospitalization. We conclude that routinely intraperitoneal instillation of bupivacaine in laparoscopic cholecystectomy is a simple and safe method to minimize postoperative abdominal pain and analgesic requirements, which enhances early mobilization and discharge, and may become a routine practice.

Keywords: Postoperative pain; Bupivacaine, intraperitoneal; Laparoscopic cholecystectomy.

INTRODUCTION

Laparoscopic cholecystectomy is now an established form of treatment for patients with symptomatic gall stones. As it is an excellent mean to minimize the trauma and agony of the patient following surgery.

Although thought to result in less postoperative pain, recent studies have shown that patients may experience considerable pain after laparoscopic cholecystectomy procedures (Joris et al., 1992). However there still remains some challenges to minimize the post-operative pain in patients, the pain reaches a maximum level within 6 hours of the procedure and then gradually decreases over a couple of days (Bisgaard, Klarskov, Rosenberg, & Kehlet, 2001).

The etiology of pain is complex, including damage to abdominal wall structures, the induction of visceral trauma and inflammation, and peritoneal irritation because of CO2 entrapment beneath the hemidiaphragms, neuropraxia of the phrenic nerve caused by distention of the diaphragm during gas insufflation, and/or acid milieu created by the dissolution of CO2 (Alexander & Hull, 1987).

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Being a relatively new procedure there is no general agreement on effective postoperative pain control modalities have been proposed to relieve postoperative pain after laparoscopies like Non-steroidal anti-inflammatory drugs /opioids, intraperitoneal local anesthetics, and port site infiltration of local anesthetics.

Local anesthetics are widely used, have a good safety profile, and are available in long-acting preparations, they provide the benefit of anesthesia without the systemic side effects, local anesthetics block the generation, and propagation of action potentials in nerve and other excitable tissues in a reversible manner, probably at the level of the passive sodium channels.

Bupivacaine is a long acting amide-type local anesthetic, released for clinical uses in 1996. When ropivacaine is given intraperitoneally, it starts acting within 10 to 20 minutes, and the duration of action lasts for four to six hours. Intraperitoneal instillation of local anesthetics using 20 ml of 0.5% bupivacaine results in less postoperative pain as in some studies were carried out with variable results in patients undergoing laparoscopic cholecystectomy (Chundrigar, Hedges, Morris, & Stamatakis, 1993; Joris et al., 1992; Pasqualucci et al., 1996; Rademaker, Ringers, Odoom, Kalkman, & Oosting, 1992).

In our current study, we aim to assess the effectiveness of intraperitoneal instillation of bupivacaine in the reduction of postoperative pain after laparoscopic cholecystectomy.

MATERIALS AND METHODS

A total of (40) ASA I and II patients between 26- 45 years of age scheduled for laparoscopic cholecystectomy were enrolled in a randomized double-blind prospective study after taken written informed consent.

Inclusion Criteria the study included all patients regardless of gender, with chronic cholecystitis and in ages between 20 to 60 years.

Exclusion Criteria the study excluded patients who received opioids or tranquilizers for more than one week prior, or when the operation was converted from Laparoscopic to open cholecystectomy. All patients were worked up with detailed history, clinical examination, and baseline pre-operative investigations,

The visual analogue scale (VAS) scoring system Figure1 (Breivik et al., 2008) was explained to all patients on the evening before surgery.

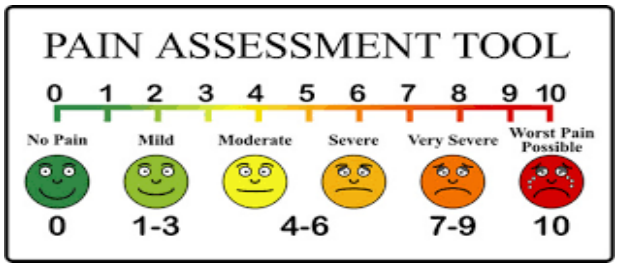

Figure (1). (VAS) The visual analogue scale of pain

The patients were randomly allocated in two groups A & B, by a lottery method.

Group A was a study group who received 50 ml of bupivacaine (50%) instilled intraperitoneally into the gall bladder bed and under the surface of the diaphragm. **Group B** was a control group and received 50 ml of 0.9% normal saline instilled intraperitoneally into the gall bladder bed and under the surface of the right diaphragm.

The visual analogue scale scoring system: was assessed at 1, 2, 4, 8, 12, 24 hours postoperatively, and blood pressure and heart rate were assessed at 120 min intervals as well as the need for analgesia frequency and dose were recorded precisely.

A conventional balanced general anesthesia was administrated,, the induction protocol was standard for all patients and anesthesia was maintained with a mixture of nitrous oxide and oxygen, ventilation was adjusted to maintain end-tidal carbon dioxide between 35 and 40 mmHg. Patients were placed in anti-

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Trendelenburg position during laparoscopy, and intraabdominal pressure was maintained between 12 and 14 mmHg. Patients were randomized into one of the two groups by the closed envelope technique.

A doctor, who had not participated in the surgery, prepared a drug solution and the drug was filled in preceded syringes and given to the surgeon. The surgeon and the assistants were unaware of the treatment for which the patient was randomized.

At the end of the procedure, those patients who were allocated to group A received 50 ml of bupivacaine (50%) intraperitoneally instilled on the operative site and inferior aspect of diaphragm via the lateral port site with patient in supine position (after peritoneal wash and suctioning), and those allocated to group B received 50 ml of 0.9% normal saline solution as (placebo), and was instilled in the same pattern. CO_2 was then evacuated from the peritoneal cavity and skin incision was sutured. Operative details such as bile, blood spilled, washout, drain, operation duration were recorded in predesigned patient format and the degree of postoperative pain was assessed at intervals 1, 2,4, 8, 12, 24 hours post-operative using the VAS score. When the score was high, patients were given an injection of Diclofenac sodium (75 mg Intramuscular), the time of the first analgesic and total analgesic requirements during the 24-hour post-op period were recorded, and the occurrence of adverse events was also recorded.

Statistical analysis: was done using SPSS software for Windows version 16.0. For non-continuous data, Chi-square test was used. The mean and the standard deviation of the parameters studied during observation period were calculated for the two treatment groups and compared using Student's t-test.

The critical value of 'p' indicating the probability of significant difference was taken as < 0.05.

RESULTS

The two groups were comparable for age, sex and preoperative vital signs (Table 1).

Table (1). Demographic data

Mean (SD)		
	Group A (n=20)	Group B (n=20)
Age (yrs.)	33.1±7.0	35.2+6.0
Sex (F: M)	18:2	18:2
PR (beats/min)	85.5(6.83)	88.30 (6.03)
SBP (mmHg)	121.50(8.84)	121.41(6.80)
DBP (mmHg)	81(7.18)	81.6(4.66)
MBP (mmHg)	94.5(7.03)	94.9(4.17)
RR (/min)	17.55(2.86)	16.50(2.82)

Abbreviation: PR pulse rate, SBP-systolic blood pressure DBP-diastolic blood pressure, MBP-mean blood pressure, RR-respiratory rate.

Inter group comparison of mean VAS scores showed a significant decline in A study group between 1st and 4th hour as compared to Placebo group and the pattern of change in mean VAS score overtimes was significantly different (P value <0.05) (Table 2).

Table (2). the pattern of change in mean VAS score over postoperative times

VAS post-operative pain score overtimes

Post-operative time in hours	VAS Pain Score Bupivacaine group	VAS Pain Score Placebo group	P value
1st	2.42 ± 0.71	3.78 ± 1.18	0.010
2nd	1.73± 0.71	4.08 ± 1.05	0.008
4th	2.13 ± 0.56	4.12 ±1.13	0.005
8th	3.27 ± 0.78	3.52 ± 1.22	0.055
12th	3.88 ± 0.85	3.85 ± 0.88	0.488
24th	2.61 ± 1.08	2.55 ± 1.33	0.744

Consumption of analgesics was also lower in patients of group A (20%) 4 patients out of 20, while it was (85%)17 patients out of 20 in-group B. (Figure2)

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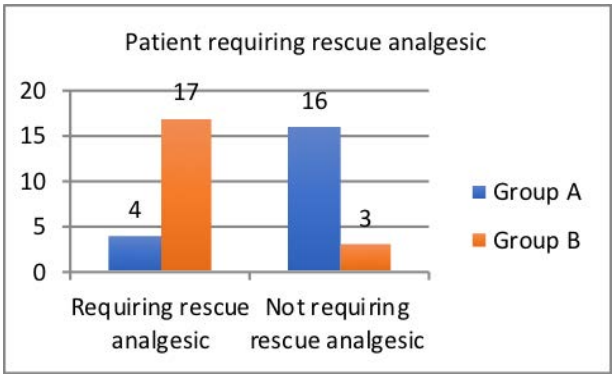

Figure (2). Patient requiring rescue analgesic

Discharge after surgery was significantly earlier in-group A (75%) one-day admission while only (35%) of group B discharged after one-day hospitalization (Figure3).

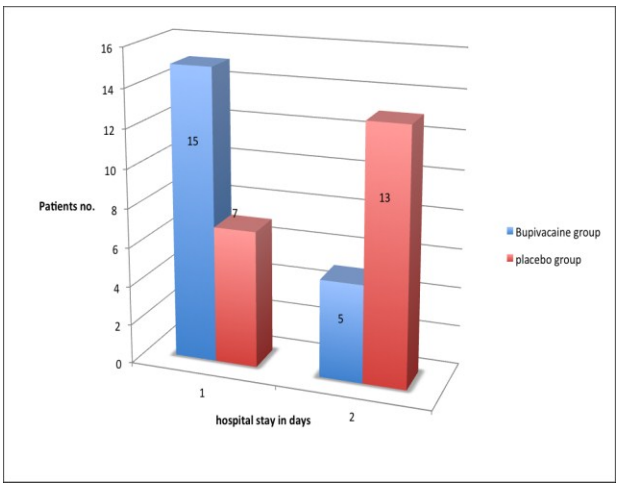

Figure (3). Hospital stay in the two groups

DISCUSSION

Although laparoscopic cholecystectomy pain is less intense and lasts for a short amount of time than open surgery, it remains a problem and may delay discharge of the patient. Therefore, adequate early postoperative relief of pain after LC is an essential goal to enable the patient to go home early with little pain and in stable condition (Lepner & Goroshina, 2003; Refaie & Khatab, 2005).

In this study, intraperitoneal instillation of bupivacaine was found to be beneficial in reducing the intensity of abdominal pain in the early few hours after the operation, which may enhance mobilization and early discharge after surgery, likewise reduction of analgesic requirement in comparison with the control group in patients underwent LC. Our findings are in agreement with other studies done by (Elhakim, Elkott, Ali, & Tahoun, 2000; Refaie & Khatab, 2005) who found a reduction in the intensity of pain and analgesic requirements, by using bupivacaine after LC.

On the other hand, there were studies that failed to demonstrate any pain reduction with intraperitoneal instillation bupivacaine in patients undergoing LC as (Rademaker et al., 1992; Ure et al., 1993).

The difference between our study and these studies may be attributed to the different responses of patients to the bupivacaine, or differences in its amount or concentration used in these studies or may be attributed to variations in patient selection criteria, some intraoperative events, or techniques used in each study.

In the present study, we compared bupivacaine group with the control group and found that bupivacaine group had good control of abdominal pain in early postoperative before 6 hours as compared with the control group. These results are consistent with that of (Lepner & Goroshina, 2003).

The pain score for both groups has the highest intensity after 6 hours postoperative, with the biggest difference between the two groups at before 6hours intervals, after that it declined to a comparable VAS values up to 24 hours.

Therefore, the main effect of bupivacaine in this study seems to reduce the pain during the early few hours after LC. (Kucuk, Kadiogullari, Canoler, & Savlı, 2007). This is the period in which the pain is in its highest intensity and the patients need adequate pain relief (Sharan et al., 2018).

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Although the half-life of bupivacaine is approximately 2.7 hours, its beneficial effect in soft tissue is up to 12 hours (Refaie & Khatab, 2005).

CONCLUSION

Routinely intraperitoneal instillation of bupivacaine in laparoscopic cholecystectomy is a simple and safe method to minimize postoperative abdominal pain and analgesic requirements, which enhances early mobilization and discharge, and may become a routine practice.

ACKNOWLEDGEMENT

The total budget was at our expense and since we get approval from Derna hospital administration, we would like to extend our appreciation to all hospital staff for the great help and offering facilities used in this study.

ETHICS

All patients involved in this study were pre-informed about the nature and steps of the study and signed a written consent that was taken from each without cognizance about which group he/she belongs to (double-blind trial) and were attached to each patient format sheath.

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تأثير تقطير المخدر الموضعي (البوبيفاكين) داخل الغشاء البريتوني (الصفاق) على الشعور بالألم بعد الجراحة في حالات استئصال المرارة بالمنظار

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المستخلص: يعتبر الآن استئصال المرارة بالمنظار العلاج الافتراضي والخيار الأول للمرضى الذين يعانون من حصوات بالحويصلة المرارية وبالرغم من أنه وسيلة ممتازة للحد من معاناة المريض بعد الجراحة إلا أن الدراسات الحديثة قد أظهرت أن المرضى لا يزالون يعانون من آلام ملحوظة حتى مع هذا النوع من الجراحات الحديثة. في هذه الدراسة نهدف إلى تقييم فعالية تقطير عقار البوبيفاكايين داخل الصفاق في الحد من الآلام ما بعد عملية استئصال الحويصلة المرارية بالمنظار، حيث تم تحديد أربعين مريضا قسموا عشوائيا إلى مجموعتين متماثلتين في العدد والعمر والجنس والحالة الصحية الأولى، مجموعة الدراسة تشمل أولئك الذين تلقوا 50 مل من عقار بوبيفاكايين (50 ٪) داخل الصفاق والثانية مجموعة الشاهد وتشمل أولئك الذين تلقوا 50 مل من المحلول الملحي المشابه بنسبة (0.9 ٪) بنفس الطريقة للتمويه. أظهرت البيانات المسجلة من المرضى في النموذج المعد مسبقًا وتحليلها من خلال دراسة استطلاعية عشوائية مزدوجة التعمية انخفاضًا ملحوظًا في درجات الألم بعد العمليات الجراحية في مجموعة الدراسة وبخاصة بين الساعة الأولى والساعة الرابعة مقارنةً بمجموعة الشاهد وبالتالي كان استهلاك المسكنات أقل عند المقارنة بين المجموعتين ونتج عن كل ذلك أن الخروج من المستشفى بعد الجراحة أصبح بعد يوم واحد من الإيواء لـ (75 ٪) من المرضى في مجموعة الدراسة مقارنة لـ (35 ٪) في مجموعة الشاهد بذلك من الممكن أن نخلص إلى أن تقطير عقار البوبيفاكيين داخل الصفاق في عملية استئصال الحويصلة المرارية بالمنظار هو طريقة بسيطة وآمنة لتخفيف الألم بعد الجراحة وتحد بشكل كبير من طلب المريض للعقاقير المسكنة في فترة النقاهة وبالتالي لعدم التعرض إلى آثارها الجانبية، كل ذلك يعزز من إمكانية العودة المبكرة للبيت والعمل قد يصبح تقطير عقار البوبيفاكايين داخل الصفاق ممارسة روتينية شرط خضوعها للمزيد من الدراسة والبحث.

الكلمات المفتاحية: الألم بعد العملية الجراحية، بوبيفاكين، داخل الصفاق، استئصال المرارة بالمنظار.

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