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Use of Intraperitoneal and Port Site Infiltration of Bupivacaine for Controlling Pain after Laparoscopic Cholecystectomy: A Prospective Study

Laparoskopik Kolesistektomi Sonrası Ağrı Kontrolü için Bupivakainin İntraperitoneal ve Port Alanı İnfiltrasyonunun Kullanımı: Prospektif Çalışma

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ABSTRACT

Purpose: Pain after laparoscopic cholecystectomy is less intense than after open cholecystectomy, some patients still experience considerable discomfort especially with coughing, respiratory movements and mobilization during initial few hours after surgery or during night after surgery.

Material and Methods: Study included 200 patients who underwent laparoscopic cholecystectomy. They were divided into two groups of 100 patients each. One group (experimental) received bupivacaine and other group (Control) received 30 ml of normal saline after completion pf laparoscopic cholecystectomy.

Results: Mean time of requirement of rescue analgesia in experimental group was 8.5 hours, whereas mean time of requirement of rescue analgesia in controls was 7.29 hrs. Total consumption of diclofenac in cases was 95mg whereas in controls it was 108.75mg (p=0.246), while as total consumption of tramadol in cases was 50 mg, whereas in controls it was 130mg (p<0.05). Postoperative abdominal pain as well as shoulder tip pain were less at all-time intervals (4h, 12h, and 24h) in cases compared to controls. Only 2 patients developed bradycardia and 1 patient developed mild drowsiness in experimental group in post-operative period. All the 3 patients required only monitoring and settled in 3-4 hours. Mean hospital stay in experimental group was 1.71 days, whereas in controls it was 1.93 days.

Conclusion: Intraperitoneal and port site bupivacaine significantly reduces both somatic and visceral components of pain in post-operative period in laparoscopic cholecystectomy. It decreases the requirement of rescue analgesia and expedites discharge of patient from hospital.

Key words: Laparoscopic cholecystectomy, pain, bupivacaine.

ÖZET

Amaç: Laparoskopik kolesistektomi sonrası ağrının, açık kolesistektomiden daha az yoğun olduğu, cerrahi sonrası ya da ameliyat sonrası gece boyunca ilk birkaç saat özellikle öksürük, solunum hareketleri ve mobilizasyonun bazı hastalarda halen önemli bir rahatsızlık olduğu görüldü.

Materyal ve Metod: Çalışma laparoskopik kolesistektomi olan 200 hastayı içerdi. Her biri 100 hasta olan 2 gruba ayrıldı. Tamamlama pf laparoskopik kolesistektomi sonrası ilk gruba (deney grubu) bupivakain ve diğer gruba (kontrol grubu) 30 ml serum fizyolojik verildi.

Bulgular: Kurtarma analjezi gereksiniminin ortalama süresi deney grubunda 8,5 saatken, kontrol grubunda bu süre 7,29 saattir. Deney grubunda diklofenakın toplam tüketimi 95mg iken, kontrollerde 108.75 mg'dır (p=0.246). Deney grubunda

tramadolun toplam tüketimi 50mg, kontrol grubunda 130mg'dır (p<0.05). Ameliyat sonrası karın ağrısıyla birlikte omuz ucu ağrısı tüm zaman aralıklarında (4 saat, 12 saat, 24 saat) kontrollerle karşılaştırıldı. Deney grubunda ağrı daha azdı. Ameliyat sonrası dönemde deney grubunda sadece 2 hastada bradikardi ve 1 hastada hafif uyuşukluk gelişti. Bu 3 hastanın sadece 3-4 saat sürekli izlenmesi istendi. Hastanede ortalama yatış kontrollerde 1.93 gün iken, deneylerde 1.71 gündü.

Sonuç: İntraperitoneal ve port alanı bupivakain, laparoskopik kolesistektomi ameliyatı sonrası dönemde ağrının somatik ve visseral bileşenlerini azaltır. Bu, kurtarma analjezi gereksinimini ve hastanın hastaneden taburcu olma hızını azaltır. **Anahtar kelimeler:** Laparoskopik kolesistektomi, Ağrı, Bupivakain

INTRODUCTION

Gallstone disease is one of the most common problems encountered in the surgical practice¹. Many patients remain asymptomatic throughout their life however some develop symptoms like biliary colic while others may progress to gall stone related complications like acute and chronic cholecystitis, choledocholithiasis with or without cholangitis, gallstone pancreatitis, fistula leading to gallstone ileus and gallbladder carcinoma². Surgery has been the mainstay of treatment for cholelithiasis. Langenbuch's open cholecystectomy remained the gold standard for symptomatic cholelithiasis for over a century with modification in length and disposition of incision. However in the last decade, the introduction of laparoscopic technique to perform cholecystectomy has revolutionized this procedure³. The procedure was standardized with passing years and ultimately became a gold standard for cholelithiasis. Laparoscopic cholecystectomy represents the most common laparoscopic procedure performed all over the world and has been performed as a day care procedure for over a decade^{4,5}. Although pain after laparoscopic cholecystectomy is less intense than after open cholecystectomy, some patients still experience considerable discomfort especially with coughing, respiratory movements and mobilisation during initial few hours after surgery or during first night after surgery. Laparotomy results mainly in parietal pain (abdominal wall), but patients complain more of visceral pain after laparoscopy⁶. Pain often results from the stretching of the intra-abdominal cavity⁷, peritoneal inflammation and phrenic nerve irritation caused by residual carbon dioxide in the peritoneal

cavity^{8,9}. Shoulder pain secondary to stretching of diaphragm as a result of CO₂ pneumoperitoneum is a frequent (60-70%) postoperative observation after laparoscopy. This can delay the patient's recovery, lengthen the hospital stay and increase morbidity and costs. Studies of local anesthetics infiltrated into the skin wounds report reduced postoperative pain only to a minor degree. Various modes of analgesia have been introduced which aim at avoidance of opioids and include use of NSAIDS, intraperitoneal local anesthesia, wound infiltration with local anesthetic, use of intraperitoneal saline, use of low pressure gas etc. The combination of techniques that take parietal, diaphragmatic, and visceral components of pain pain after into consideration may reduce laparoscopy. Bupivacaine a long acting amide linked local anaesthetic has been used as an acceptable analgesic for port sites and intraperitoneal instillation after performing laparoscopy. It acts by blocking sensory nerve endings which function through increased sodium permeability.

Present study was aimed to analyze the results of instillation of intraperitoneal and intraincisional bupivacaine in laparoscopic cholecystectomy at a single center in terms of: time to the administration of rescue analgesia in post operative period, total analgesic consumption in post-operative period, post-operative shoulder tip and abdominal pain, total duration of hospital stay and safety of bupivacaine.

MATERIAL and METHODS

This prospective randomized was conducted in the Postgraduate Department of Surgery,

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Government Medical College Srinagar over a period of two years from April 2011 – April 2013. The study included 200 USG documented cholelithiasis patients who underwent laparoscopic cholecystectomy. The criteria for exclusion of patients from the study was conversion to open surgery, acute cholecystitis, abnormal mental status or inability to understand and use the visual analogue scale (VAS), history of allergy to NSAIDs and/or LA. The trial was approved by local ethical committee and informed consent was sought from the patients before the surgical procedure.

Patients were randomized into 2 groups of 100 each.

Experimental Group (bupivacaine group):

In this group, patients were given 10 ml of 0.5% bupivacaine at the port sites in divided doses and 20 ml of 0.5% bupivacaine intraperitoneally.

Control Group (normal saline group):

In this group, patients were given 30 ml of 0.9% normal saline as placebo, 20 ml intraperitoneally and 10 ml at port sites.

On admission, a detailed history and thorough physical examination was done in every patient followed by routine baseline investigations like haemogram, complete urine examination, serum urea, serum creatinine, blood sugar (Random / Fast), serum Sodium and Potassium, Liver function tests, X-Ray Chest (P/A View), ECG all leads and USG Abdomen. Patients were explained the various components of pain they would experience in the post operative period and how to use visual analogue scale (VAS) in post-operative period. Visual Analogue Score of 0-10 was explained to the patients during preoperative visit as; 0 for no pain, 1-3 for mild pain, 4-7 for moderate pain and 8-10 for severe pain.

ΔII the Patients were operated by conventional four port laparoscopic surgery. included Procedure the creation of pneumoperitonium by veress needle, insertion of 10mm camera port at umbilicus and 10mm epigatric port and two 5mm ports, one in midclavicular line and second in anterior axillary

line. After diagnostic laparoscopy, dissection at calots triangle was done followed by dissection of gall bladder from liver bed and extraction via epigatric port. Following complete haemostasis and suction irrigation if required, a feeding tube was inserted through subcostal port and a grasper through epigastric port was used to hold tip of feeding tube and it was directed towards gall bladder fossa. 10 ml of bupivacaine and normal saline was instilled in gall bladder fossa in bupivacaine group and control respectively and 10 ml of bupivacaine/normal saline was instilled in sub-diaphragmatic space. The port sites were infiltrated with bupivacaine or normal saline in bupivacaine group and control group, each 5mm port with 2 ml of 0.5% bupivacaine/normal saline and each 10 mm ports with 3ml 0f 0.5% bupivacaine/normal saline.

After surgery patients were given I/V fluids, Antibiotics (ceftriaxone 1gm i.v. bid) and in addition to vital signs (pulse, BP, respiratory rate, temperature, urine output), pattern of pain (parietal/visceral/shoulder tip) and pain score as per VAS were monitored at 4 hour, 12 hour and 24 hours after surgery. Patients with a pain score greater than 6 on VAS were given a dose of rescue analgesia (IM 75 mg diclofenac and or tramadol), which was titrated with the requirement of patients. Total amount of analgesia intake was noted. Patients were put on light orals after 6-8 hours of surgery, if tolerated and discharged after tolerating orals. Follow up was done at one week then every four weeks for three months. Data were analyzed using word excel and SPSS 11 for windows. Independent samples T test and Chisquare test were used for inter-group comparison. Results were reported as mean ± standard deviation. The p value of <0.05 was taken as statistically signicant difference.

RESULTS

A total of 200 patients were selected for the study which were divided into two groups, experimental (bupivacaine) group and control (normal saline) group of 100 patients each. Females predominated in both the groups and comprised of 63% in bupivacaine group and 65% in control group while as there were 37% males in bupivacaine and 35% in control group. The mean age of patients was 40.52 years in bupivacaine group and 38.96 years in normal saline group respectively. All patients underwent laparoscopic cholecystectomy by conventional 4 port technique. In bupivacaine group, patients were given 10 ml of 0.5% bupivacaine at the port sites in divided doses and 20 ml of 0.5% bupivacaine intraperitoneally and in control group, patients were given 30 ml of 0.9% normal saline as placebo, 20 ml intraperitoneally and 10 ml at port sites. 60 patients among bupivacaine group and 75 patients in normal saline group required analgesics (diclofenac sodium and or tramadol) in postoperative period. Mean time of requirement of rescue analgesia in bupivacaine group was 8.5 hours, whereas mean time of requirement of rescue analgesia in controls was 7.29 hrs (Table 1).

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|----------------------|-----------------------|------------------------|--------------------------|
| | requirement or rescue | : מוומועכסומ ווו טעטוע | |
| | | | |

| Group | Number of patients | Mean time (hours) | Std. Deviation | Std. Error Mean | p-value |
|----------------------|-----------------------|----------------------|----------------|--------------------|---------|
| Bupivacaine group | 60 | 8.15 | 1.459 | .188 | 0.008 |
| Control group | 75 | 7.29 | 2.072 | .239 | |

P value=0.008 (significant)

Mean consumption of diclofenac in bupivacaine group was 95 mg, whereas in controls, it was 108.75mg (p=0.246). Postoperative abdominal pain as well as shoulder tip pain was less at all time intervals (4h, 12h, 24h) in bupivacaine group compared to controls (Table 2).

| Postop assessment time | GROUP | MEAN | STANDARD DEVIATION | STD ERROR MEAN | P VALUE |
|-----------------------------|-------------|------|-----------------------|----------------|----------|
| Abuominai pam. Voo 4 bro | Bupivacaine | 2.96 | 1.247 | .125 | ≤0.0001* |
| | CONTROL | 4.88 | 1.008 | .101 | |
| Abuuminai pam. Maa 126ma | Bupivacaine | 3.66 | 1.545 | .155 | 0.008* |
| | CONTROL | 4.17 | 1.101 | .110 | |
| Abuummai pam | Bupivacaine | 3.60 | 1.917 | .192 | ≤0.0001* |
| | CONTROL | 4.49 | 1.210 | .121 | |
| | Bupivacaine | 2.72 | 1.147 | .115 | ≤0.0001* |
| | CONTROL | 4.75 | 1.184 | .118 | |
| | Bupivacaine | 3.07 | 1.350 | .135 | ≤0.0001* |
| | CONTROL | 4.18 | 1.086 | .109 | |
| Shoulder tip pain. | Bupivacaine | 3.15 | 1.500 | .150 | ≤0.0001* |
| | CONTROL | 4.49 | 1.087 | .109 | |

| Table 2. Mean | pain score in ex | perimental (I | bupivacaine) | group and | control aroup |
|---------------|------------------|---------------|--------------|-----------|---------------|
| | | | sapiratanit, | gioup ana | oona or group |

P<0.05 at all-time intervals (significant)

Only 2 patients developed bradycardia and 1 patient developed mild drowsiness in bupivacaine group in postoperative period. All the 3 patients required only monitoring and settled in 3-4 hours. Mean hospital stay in cases was 1.71 days, whereas in controls it was 1.93 days.

DISCUSSION

In less invasive procedures pain is less intense than after open surgeries but some patients still experience considerable pain postoperatively which can be further aggravated by coughing, respiratory movements and mobilisation during initial few hours after surgery or during night after surgery. This can delay the patient's recovery, lengthen the hospital stay and increase morbidity and costs. Various techniques have been used to reduce pain after laparoscopic procedures10, 11. The combination of techniques that takes parietal, diaphragmatic, and visceral components of pain into consideration may reduce pain after laparoscopy. . Bupivacaine a long acting amide linked local anaesthetic has been used as an acceptable analgesic for port sites and intraperitoneal instillation after performing laparoscopy. It acts by blocking sensory nerve endings which function through increased sodium permeability. Onset of action of bupivacaine is 4-10 min and duration of action is 1.5 - 8.5 hours. Its maximum dose is 400 mgs in 24 hours. It is metabolized in liver and excreted in urine. Adverse effects are mild and include, feelings of drowsiness, nausea and vomiting. These adverse effects tend to subside quickly. A major cause of adverse reactions to amide group of local anesthetics is excessive plasma levels, which may be due to over dosage, inadvertent intravascular injection, or slow metabolic degradation in patients with liver disease5, 7.

In this study we evaluated the role of bupivacaine in controlling postoperative pain after laparoscopic cholecystectomy when used intraperitoneally and as infiltration at the port site. As our study was a prospective one, overall we encountered more number of female patients in our study. This preponderance of females has also been reported by previous workers12. Mean time to the requirement of rescue analgesia in study group was 8.15 hours, whereas mean time to the requirement of rescue analgesia in controls was 7.29 hrs (statistically significant, p value=0.008). This observation in our study is supported by Kum et al10 who reported similar results. In their study, they observed time to requirement of rescue +/-57.2 minutes in analgesia was 426.8 bupivacaine group and 109 +/- 46.5 min in normal saline group. Present study revealed significant reduction in consumption of tramadol in study group (50 mg), whereas in controls it was 130mg (statistically significant p=0.016). This significant difference in requirement of narcotic analgesic was in consistent with the findings of Uri et al and Tsimoyiannis et al.13, 14 On comparison of pain scores at different assessment times, we found a significant variation in pain scores at each of the assessment times between bupivacaine group and control group. We did detect differences in mean pain scores between the bupivacaine and control group during 4 ours, 6 hours and 12 hours postoperative assessment. Mean pain scores at these time intervals were found to be statistically significant. Similar findings have been reported by many workers who found lesser VAS values for pain at 2h, 4h, 8h, 12h and 24hrs in patients in whom local anaesthetic was used compared to controls.13, 14, and 15

CONCLUSION

Intraperitoneal and port site bupivacaine significantly reduces both somatic and visceral components of pain in post operative period in laparoscopic cholecystectomy. It decreases the requirement of rescue analgesia and expedites discharge of patient from hospital. We conclude that intraperitoneal and port site bupivacaine should be used in carefully selected patients in laparoscopic cholecystectomy, as it further decreases morbidity associated with minimally invasive procedures and expedites return of patient to normal activities, thus decreasing overall cost.

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