

EVALUATION OF INTRA-OPERATIVE HAEMODYNAMIC CHANGES AND DEGREE OF POST-OPERATIVE ANALGESIA USING PRE-INCISIONAL PERIportal AND INTRA-PERITONEAL INJECTION OF LEVOBUPIVACAINE 0.25% IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

Sorabh Sharma¹, Vipin Kumar Goyal², Shashikala Chaturvedi³, Prakash Gupta⁴

¹Post Graduate Resident, Department of Anaesthesia, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan.

²Assistant Professor, Department of Anaesthesia, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan.

³Professor, Department of Anaesthesia, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan.

⁴Registrar, Department of Anaesthesia, Sir Gangaram Hospital, New Delhi.

ABSTRACT

Laparoscopic cholecystectomy is itself a lesser painful procedure.¹ but the various after-effects of pain such as difficulty in breathing and coughing, difficulty in moving around and various psychological and behavioural problems along with decreased secretion of Anti-Diuretic Hormone make good postoperative analgesia necessary. The various opioids, which are used for analgesia have various side effects like respiratory depression and also they increase the action of inflammatory mediators.

AIMS AND OBJECTIVES

The main aim of our study was,

1. To relieve the patients from postoperative pain and its adverse effects.
2. To decrease the amount of opioids administered and hence relieve from its side effects.²
3. To study the haemodynamic changes occurring intraoperatively.

METHODOLOGY

50 patients were taken in L group and another 50 patients were taken in NS group. All patients were of ASA grade I and II; 0.25% inj. Levobupivacaine was administered to L group patients and only normal saline administered to patients of NS group.

STATISTICAL ANALYSIS

Data analysis was performed using SPSS 20 (IBM SPSS Statistics) for windows. VAS score was compared between two groups by repeated measure of analysis of variance. P value <0.05 was considered statistically significant.

RESULT AND CONCLUSION

Patients in L group showed better postoperative analgesia and better protection from nausea and vomiting.

KEYWORDS

Levobupivacaine, Laparoscopic Cholecystectomy, Postoperative Analgesia, Postoperative Nausea-Vomiting, Systolic Blood Pressure, Diastolic Blood Pressure, Pulse Rate, Spo2%, Vas Score.

HOW TO CITE THIS ARTICLE: Sharma S, Goyal VK, Chaturvedi S, et al. Evaluation of intra-operative haemodynamic changes and degree of post-operative analgesia using pre-incisional periportal and intra-peritoneal injection of levobupivacaine 0.25% in patients undergoing laparoscopic cholecystectomy. J. Evolution Med. Dent. Sci. 2016;5(51):3272-3277, DOI: 10.14260/jemds/2016/759

INTRODUCTION

Effective pain control is essential for optimal care of surgery patients. Acute postoperative pain is a complex physiological reaction to tissue injury, visceral distension or disease. Its manifestations related to autonomic, psychological and behavioural responses results in unpleasant, unwanted sensory and emotional experience. Despite advances in knowledge of pathophysiology of pain, pharmacology of analgesics and effective techniques for post-operative pain control many patients continue to experience considerable discomfort.

Laparoscopic Cholecystectomy (LC) is one of the most frequently performed elective surgical operations.

The benefits of LC compared with open surgery are less postoperative pain and/or reduced analgesic consumption and more rapid return to normal daily activities.

However, postoperative pain remains the most prevalent complaint after this type of surgery and several studies have shown that visceral pain is the major component. Intra-peritoneal administration of Local Anaesthetic (LA) is a mode of multimodal analgesic techniques to provide adequate postoperative pain relief after LC.³

In many trials, intraperitoneal bupivacaine has been shown to be the most widely used LA because of its long duration of analgesic action and high potency.³

Levobupivacaine, an isomer of racemic bupivacaine, has been presented as a safer LA with a reduced risk of systemic toxicity and with long action.⁴

There is limited data regarding the use of levobupivacaine administered intraperitoneally. The purpose of the study is to compare the effects of pre-incisional infiltration and intraperitoneal instillation of levobupivacaine on postoperative pain of LC.⁵

Financial or Other, Competing Interest: None.

Submission 18-04-2016, Peer Review 11-05-2016,

Acceptance 18-05-2016, Published 25-06-2016.

Corresponding Author:

Dr. Sorabh Sharma,

Department of Anaesthesia,

Mahatma Gandhi Medical College and Hospital,

Jaipur, Rajasthan.

E-mail: sorabh.sharma13@gmail.com

DOI: 10.14260/jemds/2016/759

METHODS

This prospective randomized double blind study is conducted at our gastro-intestinal surgery unit between December 2013 and August 2014. Hundred patients of American Society of Anaesthesiologist (ASA) grade I and II between 18-60 years of age of either sex, scheduled for elective laparoscopic cholecystectomy under general anaesthesia with endotracheal intubation were included.

After obtaining Institutional Ethical Committee approval and written informed consent, patients were randomly divided into two groups of 50 each according to a computer generated table of random numbers.

Group NS (n=50): received 20 mL of normal saline.

Group L (n=50): received 20 mL of 0.25% levobupivacaine.

Patients with history of acute cholecystitis, hypersensitivity to local anaesthetics and morbid obesity were excluded during selection process at the time of preoperative check-up.

On preoperative anaesthesia check-up, patients were advised to take tablet Lorazepam 1 mg and tablet Pantoprazole 40 mg with sip of water night before the surgery and 6 AM next morning. Also patients were informed about postoperative pain and its assessment using a Visual Analogue Scale (VAS) ranging from 0=no pain to 10=worst pain imaginable.

On arrival at operation theatre, Multipara monitor with standard anaesthesia monitoring including Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Pulse oximeter were attached and baseline values were recorded. Peripheral line was secured with 18G Intravenous (IV) cannula and hydration started with ringer lactate.

Patients were pre-medicated with glycopyrrolate 0.2 mg, midazolam 0.02 mg/kg and fentanyl 3 mg/kg intravenously. Anaesthesia was induced with 2 mg/kg of IV injection of propofol followed by intubating dose of vecuronium (0.1 mg/kg). Patients were connected to anaesthesia ventilator after successful tracheal intubation and fixation of endotracheal tube. Nasogastric tube was placed and confirmed as a routine in all patients. Oxygen and air (50:50) in isoflurane along with additional boluses of vecuronium, as required were continued throughout surgery. Ventilator was adjusted to a target End Tidal Carbon Dioxide (EtCO₂) value of 32-35 mmHg.

All trocar ports were infiltrated with 10 mL of normal saline in group NS and 0.25% levobupivacaine in Group L before trocar insertion and same amount was instilled intraperitoneally at the end of surgery. All laparoscopic procedures were done via standard four trocar technique. Paracetamol 1 gm IV infusion was given to all patients before closure of ports. At the end of surgery, the residual neuromuscular block was reversed with intravenous neostigmine (50 µg/kg) and glycopyrrolate (10 µg/kg). At the end of the surgery, the intra-abdominal drain (put by the surgeon) was kept closed for 15 minutes after its placement.

All vital parameters including Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure

(MAP), heart rate, oxygen saturation, ECG were monitored throughout surgery. Postoperative pain was assessed 0, 0.5, 1, 2, 4, 8 and 24 hours after shifting the patient to postoperative ward. Injection tramadol 100 mg IV was administered as rescue analgesic to patients with VAS score >4. Adverse effects in perioperative period were recorded, if any.

Statistical Analysis

Data analysis was performed using SPSS 20 (IBM SPSS Statistics) for windows. Data are expressed as mean±standard deviation. Patient's characteristic data were analysed with one-way ANOVA for continuous variables and chi-square test for categorical variables. VAS score was compared between two groups by repeated measure of analysis of variance. P value <0.05 was considered statistically significant.

RESULTS

During the study period of nine months, total 109 patients were enrolled for clinical evaluation for study. Nine patients were excluded during evaluation on basis of refusal to consent (Seven patients) and obesity (Two patients). Remaining hundred patients were randomized in two groups (Fig. 1).

Demographic variables (age, sex) were comparable in both groups (P>0.05). [Table 1] Pre-operative vitals (HR, SBP, DBP and MAP) were comparable in both groups with no statistically significant differences (P>0.05).

Even the intraoperative and postoperative haemodynamic changes related to all vital parameters were comparable (P>0.05) between both the groups.

Patients in the L group show a better postoperative VAS score (P<0.001) and better profile against postoperative nausea and vomiting (P<0.002 and <0.003 respectively).

Variable	Group L	Group NS	P value
Sex (Female: Male)	30:20	27:23	0.686
Age (Years) Mean±S.D	46.36±12.79	48.90±8.99	0.253
ASA grade (1:2)			
Duration of surgery (Min)	53.25±17.51	58.13±15.09	0.13

Table: Demographic Data of Patients (P>0.05)

Age						
Group	N	Mean	SD	Min	Max	P Value LS
Group A	50	46.36	12.79	21	78	0.253NS
Group B	50	48.90	8.99	30	70	
Total	100	47.63	11.07	21	78	

Table 1: Age Wise Distribution of the Cases

Sex	Group A		Group B		Total
Female	30	60	27	54	57
Male	20	40	23	46	43
Total	50	100	50	100	100

Table 2: Sex-Wise Distribution of the Cases

Chi-square = 0.163 with 1 degree of freedom; P = 0.686 NS

Duration of Surgery (min.)				
Group	N	Mean	Std. Deviation	P Value LS
Group A	50	53.25	17.516	0.13NS
Group B	50	58.13	15.091	
Total	100	55.69	16.450	
Table 3: Distribution of the Cases According to Duration of Surgery (min.)				
Rescue Analgesia				
Group	N	Mean	Std. Deviation	P Value LS
Group A	50	9.8758	11.05555	<0.001S
Group B	50	1.7084	1.50921	
Total	100	5.7921	8.85820	
Table 4: Distribution of the Cases According to Duration of Rescue Analgesia (hrs.)				

Baseline Vital Parameters						
Group		SBP	DBP	MAP	Pulse	SPO2%
Group A	N	49	49	50	50	50
	Mean	129.82	80.39	96.64	83.28	99.92
	Std. Deviation	12.681	7.337	8.113	15.873	.340
Group B	N	50	50	50	50	50
	Mean	128.80	77.80	93.44	86.10	100.00
	Std. Deviation	13.812	8.154	8.543	12.134	0.000
P value LS		0.75NS	0.1NS	0.058NS	0.32NS	0.1NS
Table 5: Distribution of the Cases According to Baseline Vital Parameters						

Post-Operative SBP (mmHg)								
Group		Just after Extubation	30 min after Extubation	After 1 Hour	After 2 Hours	After 4 Hours	After 6 Hours	After 8 Hours
Group A	N	48	49	49	49	49	49	49
	Mean	134.27	118.16	116.5	114.6	116.76	118.4	119.18
	SD	9.51	16.82	16.50	17.10	9.10	5.99	6.24
Group B	N	50	50	50	50	50	50	50
	Mean	134.10	121.70	118.30	118.3	118.40	118.6	120.00
	SD	7.19	9.88	7.40	8.61	8.23	7.22	6.70
P Value LS		0.92	0.20	0.49	0.18	0.35	0.86	0.53
		NS	NS	NS	NS	NS	NS	NS
Table 6: Postoperative Systolic Blood Pressure at Different Time Interval								

Post-Operative Diastolic Blood Pressure (mmHg)								
Group		Just after Extubation	30 min after Extubation	After 1 Hour	After 2 Hours	After 4 Hours	After 6 Hours	After 8 Hours
Group A	N	49	49	49	49	49	49	49
	Mean	87.35	80.35	78.27	77.55	76.12	75.20	77.86
	Std. Deviation	10.562	9.98641	6.254	5.962	6.146	4.996	7.217
Group B	N	50	50	50	50	50	50	50
	Mean	91.00	79.00	77.00	77.30	76.40	77.50	76.40
	Std. Deviation	8.452	8.081	7.626	6.867	7.494	6.409	5.628
P Value		.060	.313	.369	.847	.841	.050	.265
Significance		NS	NS	NS	NS	NS	NS	NS
Table 7: Postoperative Diastolic Blood Pressure at Different Time Interval								

Post-Operative Pulse Rate (min.)								
Group		Just after Extubation Pulse Rate	30 min after Extubation	After 1 Hour	After 2 Hours	After 4 Hours	After 6 Hours	After 8 Hours
Group A	N	49	49	49	49	49	49	49
	Mean	95.31	82.14	79.90	77.57	78.27	78.67	79.82
	Std. Deviation	14.046	7.773	7.806	7.147	7.607	7.128	8.113
Group B	N	50	50	50	50	50	50	50
	Mean	97.50	83.70	80.60	80.30	81.20	80.60	95.40
	Std. Deviation	10.797	8.678	7.188	7.31	7.461	6.51	114.82
P Value		.385	.350	.643	.064	.056	.164	.346
Significance		NS	NS	NS	NS	NS	NS	NS

Table 8: Postoperative Pulse Rate at Different Time Interval

Post-Operative SPO2%								
Group		Just after Extubation	30 min after Extubation	After 1 Hour	After 2 Hours	After 4 Hours	After 6 Hours	After 8 Hours
Group A	N	49	49	49	49	49	49	49
	Mean	99.90	99.65	99.51	99.59	99.69	99.76	99.90
	Std. Deviation	.368	.663	.794	.814	.769	.778	.368
Group B	N	50	50	50	50	50	50	50
	Mean	99.80	99.58	99.44	98.94	99.58	99.78	99.92
	Std. Deviation	.606	.758	.884	2.668	.810	.616	.340
P Value		.335	.611	.679	.105	.475	.860	.758
Significance		NS	NS	NS	NS	NS	NS	NS

Table 9: Postoperative SPO2 (%) at Different Time Interval

Post-operative VAS								
Group		Just after Extubation VAS	30 min after Extubation	After 1 Hour	After 2 Hours	After 4 Hours	After 6 Hours	After 8 Hours
Group A	N	49	49	49	49	49	49	49
	Mean	3.04	2.78	2.82	2.78	2.63	2.76	2.92
	Std. Deviation	.789	.771	1.112	.896	.755	.969	.975
Group B	N	50	50	50	50	50	50	50
	Mean	3.86	3.84	3.88	4.06	3.88	3.24	3.96
	Std. Deviation	1.262	.976	1.081	1.058	1.003	.687	1.068
P Value		<0.001	<0.001	<0.001	<0.001	<0.001	0.005	<0.001
Significance		S	S	S	S	S	S	S

Table 10: Postoperative VAS at Different Time Interval

	Group A		Group B		Total	
	No	%	No	%	No	P value LS
Nausea	2	0	11	22	11	0.002S
Vomiting	1	0	10	20	10	0.003S
Hypotension	0	0	0	0	0	NA
Bradycardia	0	0	0	0	0	NA

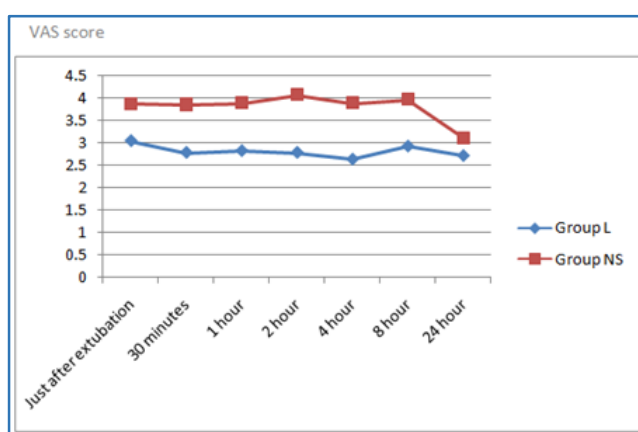
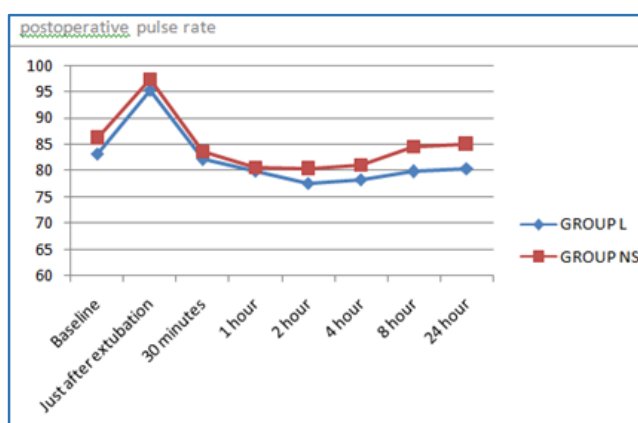
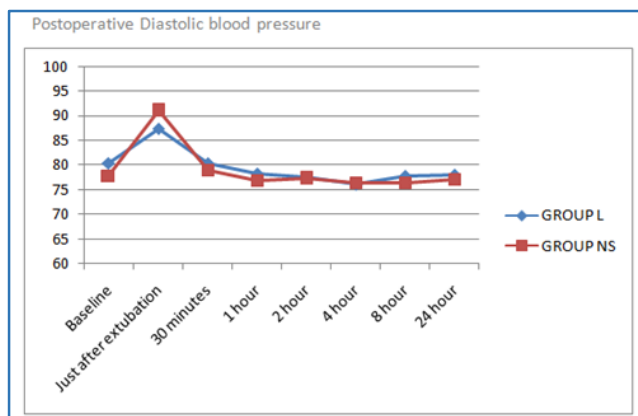
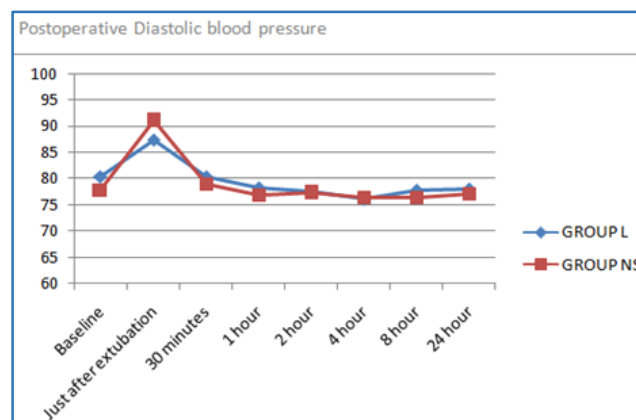
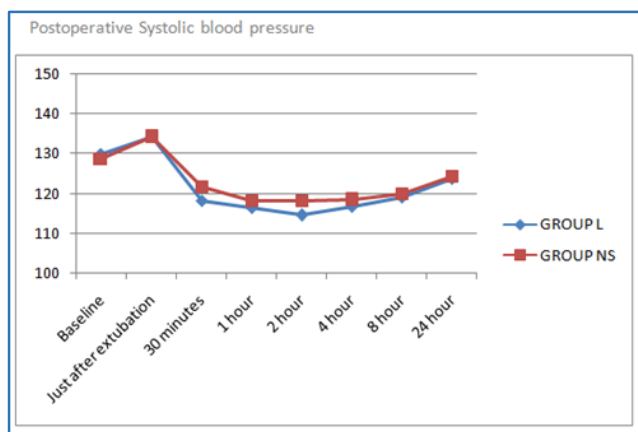
Table 11: Distribution of the Cases According to Complications

Rescue Analgesia	Group L	Group NS	P value
Time (hours)	9.88±11.05	1.71±1.51	0.001

Table 12: Time of First Rescue Analgesia

Postoperative Pulse		
	Group L	Group NS
Baseline	83.28	86.1
Just after Extubation	95.31	97.5
30 minutes	82.14	83.7
1 hour	79.9	80.6
2 hours	77.57	80.3
4 hours	78.27	81.2
8 hours	79.82	84.6
24 hours	80.5	85

	Group L	Group NS
Nausea	2	11
Vomiting	1	5
Bradycardia	0	1



DISCUSSION

- In our study, we have found that levobupivacaine is a better analgesic drug in comparison to opioid drugs and diclofenac.
- Szem JW et al (1996), reported that intraperitoneal 0.1% Bupivacaine 100 mL administered before surgery offered advantages with respect to postoperative pain after Laparoscopic Cholecystectomy for the first 6 hours.⁶
- Furthermore, Pasqualucci et al (1996) showed that the timing of administration of 0.5% Bupivacaine 40 mL with epinephrine before surgery was important with respect to postoperative pain relief and analgesic consumption.⁷
- In a meta-analysis by Mehta S et al (2006) including intraperitoneal administration of Bupivacaine, Lidocaine, Ropivacaine and Levobupivacaine in Laparoscopic Cholecystectomy, 12 out of 24 trials reported a significant improvement in pain during the early postoperative period without a significant effect on total amount of analgesia delivered.⁸
- The administration of Local Anaesthetic immediately after pneumoperitoneum has been previously shown to be especially more effective than administration before the removal of trocars in Laparoscopic Cholecystectomy. According to the meta-analysis by Mehta S et al (2006), it was suggested that administration of local anaesthetic at the beginning of operation served as pre-emptive analgesia via suppression of central neural sensitization before the nociceptive stimulus triggered the activation of pain pathways.⁸
- A Papadima et al (2009) concluded that 2 separate doses of intraperitoneally administered levobupivacaine in laparoscopic cholecystectomy significantly decreased postoperative pain and the need for opioids compared with placebo. This technique is simple, safe and without adverse effects.
- According to Lee IO et al, the local anaesthetic effect persists for only 3 postoperative hours.⁹
- According to Uzunkoy A et al, local anaesthetic injection at site of incision was effective and it reduced the need of Diclofenac postoperatively.¹⁰
- According to Sarac AM et al, injecting local anaesthetic after the surgery at the site of incision was effective more as compared to its administration before skin incision.¹¹

CONCLUSION

In our study, we have found the efficacy of periportal and intraperitoneal infiltration of Levobupivacaine 0.25% with respect to its haemodynamic effects and postoperative analgesia (duration and side effects).

Study population consisted of 100 ASA I/II patients posted for Laparoscopic Cholecystectomy surgery who were randomly divided into two cases and controls.

Age, sex, intraoperative haemodynamic changes and duration of surgery were equivalent in the two groups, but the duration of analgesia was prolonged in the cases group in comparison to the control group.

We found that use of Injection Levobupivacaine for postoperative analgesia in laparoscopic cholecystectomy caused prolonged analgesia and it led to decreased consumption of other analgesic drugs.

REFERENCES

1. Squirrell DM, Majeed AW, Troy G, et al. A randomized, prospective, blinded comparison of postoperative pain, metabolic response, and perceived health after laparoscopic and small incision cholecystectomy. *Surgery* 1998;123(5):485-95.
2. Hasaniya NW, Zayed FF, Faiz H, et al. Preinsertion local anaesthesia at the trocar site improves perioperative pain and decreases costs of laparoscopic cholecystectomy. *Surg Endosc* 2001;15(9):962-4.
3. Joris J, Thiry E, Paris P, et al. Pain after laparoscopic cholecystectomy: characteristics and effect of intraperitoneal bupivacaine. *Anaesth Analg* 1995;81(2):379-84.
4. Papagiannopoulou P, Argiriadou H, Georgiou M, et al. Preincisional local infiltration of levobupivacaine vs ropivacaine for pain control after laparoscopic cholecystectomy. *Surg Endosc* 2003;17(12):1961-4.
5. Louizos AA, Hadzilia SJ, Leandros E, et al. Postoperative pain relief after laparoscopic cholecystectomy. *Surg Endosc* 2005;19(11):1503-6.
6. Szem JW, Hydo L, Barie PS. A double-blinded evaluation of intraperitoneal bupivacaine vs saline for the reduction of postoperative pain and nausea after laparoscopic cholecystectomy. *Surg Endosc* 1996;10(1):44-8.
7. Pasqualucci A, de Angelis V, Contardo R, et al. Preemptive analgesia: intraperitoneal local anesthetic in laparoscopic cholecystectomy. A randomized double blind, placebo controlled study. *Anesthesiology* 1996;85(1):11-20.
8. Mehta S. The effect of intraperitoneal local anaesthetic in laparoscopic cholecystectomy-a systematic review and metaanalysis. *Anaesthesia and analgesia* 2006;103(3):682-8.
9. Lee IO, Kim SH, Kong MH, et al. Pain after laparoscopic cholecystectomy: the effect and timing of incisional and intraperitoneal bupivacaine. *Can J Anaesth* 2001;48(6):545-50.
10. Uzunkoy A, Coskun A, Akinci OF. The value of preemptive analgesia in the treatment of postoperative pain after laparoscopic cholecystectomy. *Eur Surg Res* 2001;33(1):39-41.
11. Sarac AM, Aktan AO, Baykan N, et al. The effect and timing of local anaesthesia in laparoscopic cholecystectomy. *Surg Laparosc Endosc* 1996;6(5):362-6.