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A Comparative Analysis between Conventional-Dose and Low-Dose Bupivacaine & Fentanyl among Patients with Open Cholecystectomy under Spinal Anesthesia in a Tertiary Care Hospital: A Prospective Observational Study

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Abstract **Original Research Article**

Background: This prospective observational study aimed to compare the efficacy and safety of conventional-dose versus low-dose Bupivacaine combined with Fentanyl in patients undergoing open cholecystectomy under spinal anesthesia. ***Objectives:*** To compare the efficacy of conventional-dose versus low-dose Bupivacaine combined with Fentanyl in providing adequate anesthesia for open cholecystectomy under spinal anesthesia. ***Methods:*** This prospective observational study conducted at North Bengal Medical College Hospital between 2021 and 2023, the study included a sample size of 150 patients. Patients were divided into two groups: the conventional-dose group (Group A, n=75) received 15 mg of Bupivacaine with 25 µg of Fentanyl, and the low-dose group (Group B, n=75) received 7.5 mg of Bupivacaine with 25 µg of Fentanyl. Parameters such as hemodynamic stability, duration of analgesia, postoperative pain scores, and incidence of adverse effects were recorded and analyzed. ***Result****:* Group B demonstrated better hemodynamic stability with fewer episodes of hypotension and bradycardia compared to Group A. The duration of analgesia was slightly shorter in Group B, but postoperative pain scores were comparable between the two groups. Adverse effects, including nausea, vomiting, and pruritus, were less frequent in Group B. ***Conclusion:*** The study suggests that low-dose Bupivacaine combined with Fentanyl is a viable alternative to conventional-dose regimens for spinal anesthesia in open cholecystectomy, offering comparable analgesia with improved hemodynamic stability and fewer adverse effects. Further research is recommended to corroborate these findings and explore long-term outcomes.

Keywords: Open cholecystectomy, Spinal anesthesia, Tertiary care hospital.

INTRODUCTION

Laparoscopic cholecystectomy became the standard of care for symptomatic gallstone disease not long after it was introduced [1]. This was due to the procedure's clearly advantageous minimally invasive character, which is linked to shorter hospital stays, less discomfort following surgery, and an earlier return to normal activities. A prior study conducted at our facility showed that effective anesthesia for laparoscopic cholecystectomy was achieved using a conventional dose of spinal hyperbaric bupivacaine with fentanyl [2].

Additionally, it has been demonstrated that a low-dose spinal hypobaric lidocaine + fentanyl technique can effectively provide short-duration anesthesia for outpatient gynecological laparoscopy [3,4]. This method has the advantages of using less motor block, no hypotension, quicker sensory recovery, and early discharge compared to standard hyperbaric lidocaine anesthesia. Recently, 50 patients had magnetic resonance imaging to study the anatomy of the thoracic spinal canal.5. Research employing either a single puncture technique [8] or a combination spinal-epidural [6,7] approach has shown the safety of segmental spinal anesthesia at T10. It was shown in a recent study involving 300 patients that thoracic puncture with a pencil- or cut-point needle was linked to the same incidence of paresthesia as the lumbar method, and that there were no long-term effects [9]. The current study compared the intraoperative parameters, postoperative recovery, and complications of lumbar puncture using

conventional-dose bupivacaine + fentanyl with thoracic puncture using low-dose bupivacaine + fentanyl for laparoscopiccholecystectomy.

METHODOLOGY

This prospective observational study was conducted at North Bengal Medical College Hospital from 2021 to 2023, involving 150 patients undergoing open cholecystectomy under spinal anesthesia. The patients, aged 18-65 years and classified as ASA physical status I-II, were divided into two groups: Group A (conventional-dose) received 15 mg of Bupivacaine with 25 µg of Fentanyl, and Group B (low-dose) received 7.5 mg of Bupivacaine with 25 µg of Fentanyl. Exclusion criteria included contraindications to spinal anesthesia, hypersensitivity to study drugs, severe systemic diseases, coagulopathies, anticoagulant therapy, and pregnancy or lactation. Preoperative assessments included detailed history, physical examination, and baseline vital signs. Spinal anesthesia was administered at the L3-L4 or L4-L5 interspace. Intraoperative monitoring included heart rate, blood pressure, respiratory rate, and oxygen saturation, with treatments for hypotension and bradycardia as needed. Hemodynamic parameters were recorded at baseline and regular intervals during surgery, and postoperative data collection included the duration of anesthesia, postoperative analgesia, pain scores using the Visual Analog Scale (VAS) at various intervals, and the incidence of adverse effects. Patients were observed for at least 24 hours post-surgery, with analgesic requirements and patient satisfaction assessed. Statistical analysis was performed using SPSS, with continuous variables expressed as mean ± standard deviation (SD) and compared using the independent t-test, and categorical variables expressed as percentages and compared using the chi-square test or Fisher's exact test, with a p-value <0.05 considered statistically significant.

RESULTS

There were no significant differences in age, weight, height, gender, or theater time between the two groups (Table 1). Demographic data and surgical history were similar for the two groups. All procedures were completed laparoscopically without violation of the present protocol.

Table-1: Age and Sex Distribution of the Patients

Characteristics	Group-A (Mean ± SD) n=75	Group-B (Mean ± SD) n=75	P-value
Age (years)			
<25	12	11	0.67
26-35	16	15	
36-45	20	20	
46-55	19	22	
≥56	8	7	
(Mean ± SD)	37.2(12.3)	36.4(10.3)	
Gender			
Male (n)	24	17	0.85
Female (n)	51	55	
Weight (Kg)	73.6(12.4)	71.0(13.1)	0.76
Height (cm)	164.3(8.3)	161.3(7.9)	0.47
BMI (Kg/m^3	28.3(4.3)	25.6(4.8)	0.85
Previous surgeries (n)	38	43	0.42

Table-2: Characteristics in both groups in perioperative period (mean ± standard deviation)

Parameter	Group-A (%) n=75	Group-B (%) n=75	P-value
Time until T3 (minutes)	7.0 (1.1)	2.7 (0.4)	<0.005
Surgical time(minutes)	58.8 (13.2)	55.5 (12.3)	0.12
Pneumoperitoneum(minutes)	34.4 (10.8)	32.8 (9.2)	0.13
Intravenous fluid (mL)	1000 (112)	1030 (100)	0.040
Shoulder pain (yes/no)	10/60	18/52	0.091
Nausea and vomiting (yes/no)	0/70	1/68	1.0
Doses of midazolam(mg)	3 (1)	2 (1)	0.23
Rescue fentanyl(yes/no)	10/56	12/58	1.0
Hypotension(yes/no)	27/41	9/56	0.64
Need for vasopressor(n)	0 (1)	0 (0)	<0.005
Bradycardia(yes/no)	0/68	40/26	<0.005

No significant difference was found in operative time between the groups (range 35–86 minutes, see Table 2). Conversion from spinal to general anesthesia was not required in any of the cases, and no major adverse intraoperative events occurred. There was no need to convert to open surgery in any patient. Twenty patients had dense adhesions of the omentum to the anterior abdominal wall, all of which were dissected successfully. Local washing of the right diaphragm with lidocaine solution 1% 10 mL was successful in preventing pain in 112 patients. Intravenous fentanyl 50 µg was needed in 22 patients due to severe right shoulder pain; surgery was continued and completed uneventfully after administration of rescue analgesic in all cases.

Table-3 Collateral effects during the postoperative period and duration of block (mean ± standard deviation)

Parameter	Group -A	Group-B	P-value
Shoulder pain (yes)	8/60	9/56	0.60
Nausea and vomiting (yes)	2/66	3/65	0.63
Urinary retention	0	0	
Sensitive block	4.14 (0.36)	2.30 (0.23)	<0.005
Motor Block	3.05 (0.25)	1.15 (0.15)	<0.005
Pruritus (yes)	7/60	10/56	0.32

Table 3 shows postoperative surgery-related and anesthesia-related events, including nausea, vomiting, urinary retention, right shoulder pain, and pruritus. The frequency of shoulder pain was similar in both groups. All patients were able to be discharged 24 hours after surgery and no patient required readmission. No patient complained of headache or other neurologic sequelae related to spinal anesthesia. Mean duration of motor block (3.05 [±0.27] hours vs 1.15 [±0.15] hours, respectively) as well as duration of sensory block were significantly (P< 0.005 for both) longer (4.14 [±0.36] hours vs 2.30 [±0:15] hours) with bupivacaine 15 mg than with bupivacaine 7.5 mg There was a reduction of 45.9% (±2.9%) with bupivacaine 15 mg and 33.6% (±2.1%) with bupivacaine 7.5 mg in the duration of motor block in relation to sensory block (P<0.005).

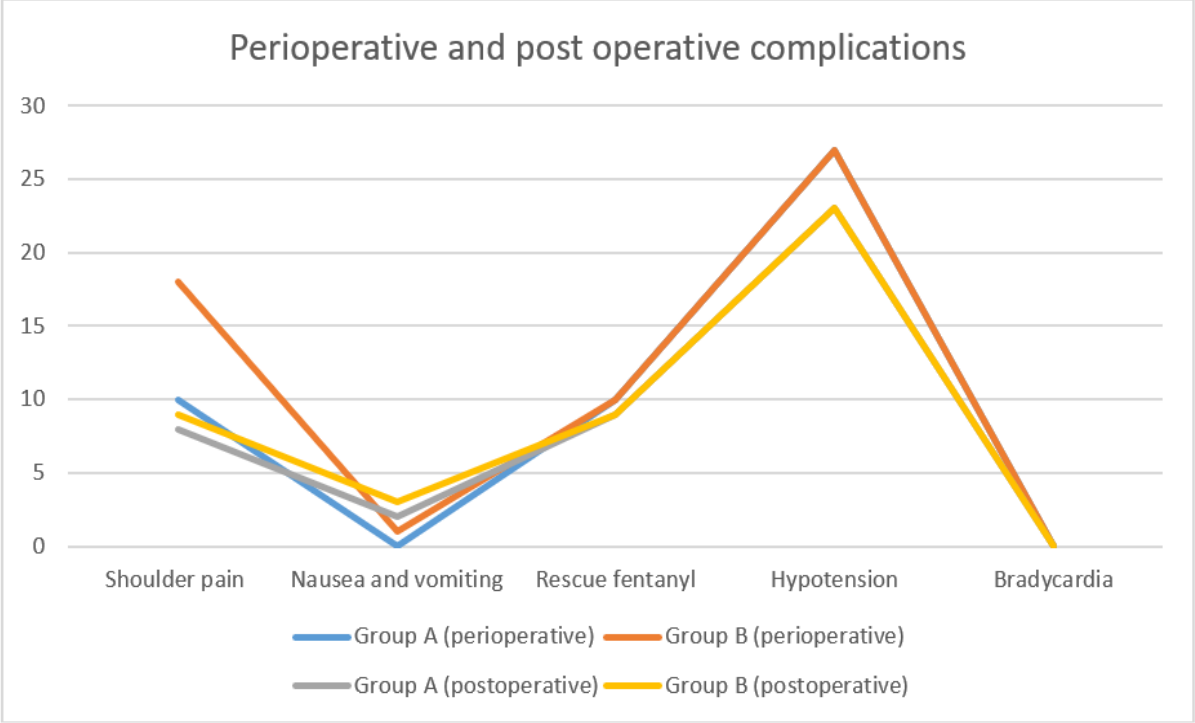

Figure: Perioperative and post operative complication with 15 mg of Bupivacaine with 25 µg of Fentanyl and 7.5 mg of Bupivacaine with 25 µg of Fentanyl

There is increase in shoulder pain and decrease in nausea and vomiting and rescue with fentanyl gradually increase and hypotension gradually increases with sudden decrease in bradycardia.

One hundred and twenty-three patients reported that they were highly satisfied with the procedure, with seven patients reporting being dissatisfied because of experiencing longer motor block. All patients reported that they would definitely recommend spinal anesthesia for laparoscopic cholecystectomy. No late complications were detected at the 3-month follow-up.

DISCUSSION

A single dose of 25 µg of fentanyl combined with a 7.5 mg hyperbaric bupivacaine reduction dosage was sufficient to achieve appropriate spinal block for laparoscopic cholecystectomy. Compared to the traditional-dose hyperbaric bupivacaine + fentanyl combination, low-dose spinal anesthesia produced improved hemodynamic stability, less hypotension, and a shorter duration of both sensory and motor block. In every patient, the block was sufficient. The limited requirement for vasopressor assistance was indicative of hemodynamic stability.

This tenth interspace, which is located in the middle of the surgical area, can be easily used to perform the combination spinal epidural block approach at the lower thoracic level [10]. We used the same space in this investigation without using the combination spinal epidural set. During the initial insertion of the pencil tips spinal needle, no patient suffered paresthesia. This is in contrast to a prior report that used the identical needle and found a 5% incidence of paresthesia. [10]

Laparoscopic cholecystectomy is thought to be a more affordable method for treating symptomatic cholelithiasis and has quickly gained popularity as an alternative to open cholecystectomy. In comparison to general anesthesia, spinal anesthesia has a few benefits [2,11], such as allowing the patient to awaken and regain consciousness sooner after the procedure, causing less discomfort thereafter, and enabling them to walk around sooner than patients under general anesthesia.

Spinal anesthesia is used to prevent certain potential issues with the general anesthesia technique, such as sore throats, damage to teeth and oral cavity during laryngoscope insertion, and pain from intubation and/or extubation [12]. This is done for specific patients undergoing laparoscopic interventions. When 7.5 mg of bupivacaine was used, the recovery period from sensory and motor block was significantly shortened, and 60% of patients were able to transfer to the stretcher by themselves. With the standard dose of 15 mg, none of the patients could transfer to the stretcher without assistance.

In our investigation, low-dose spinal anesthetic did not necessitate any changes to surgical technique, with the exception of a low insufflation flow rate to prevent bradycardia and vagal reflexes. Limiting the total volume of CO2 used for peritoneal insufflation to a maximum of 4 L and administering analgesic and/or sedative by parenteral injection helped patients tolerate laparoscopy under spinal anesthesia. The 8 mmHg intra-abdominal pressure is in line with other reports [2].

It would be ideal to offer regional anesthesia as a choice to patients undergoing laparoscopic cholecystectomy. There have been instances of using both traditional2,11 and low-dose10 epidural12 bupivacaine spinal anesthesia. Severe right shoulder pain is one of the main issues with laparoscopic cholecystectomy performed under spinal anesthesia [2,11].

A modification to the methodology from a prior series2 involved the intraperitoneal injection of lidocaine 1% (10 mL) as soon as the camera was introduced. This made it possible to significantly lower the frequency of shoulder discomfort from 47% to 20% and to lower the usage of rescue analgesics from 29.4% to 15% [2]. A significant and protracted hypotension can occur after spinal anesthesia because of the quick extension of sympathetic block. Another issue with laparoscopic cholecystectomy under spinal anesthesia is intraoperative hypotension [2,10]. According to different reports, hypotension on the standard dose of hyperbaric bupivacaine is between 41% and 59% [11].

In this trial, 38.5% of patients receiving conventional-dose bupivacaine experienced hypotension severe enough to necessitate noradrenaline medication, while only ten patients (14.2%) in the low-dose group experienced hypotension. For the repair of hip fractures in older patients, a lower dose of hyperbaric bupivacaine (7.5 mg) combined with 5 µg of sufentanil gives a dependable spinal anesthetic with few hypotensive episodes and minimal requirement for vasopressor support [12]. Our study's minimal demand for vasopressor support shows that patients undergoing laparoscopic cholecystectomy benefit from better hemodynamic stability and fewer adverse events when hyperbaric bupivacaine 7.5 mg is administered in addition to fentanyl at a similarly reduced dose. The authors of a previous study involving 3492 patients came to the conclusion that spinal anesthesia, which has several advantages over general anesthetic and does not necessitate any changes in technique, should be the preferred method of anesthesia for laparoscopic cholecystectomy [13].

To summarize, this study has demonstrated that sufficient spinal anesthesia for laparoscopic cholecystectomy can be achieved with a minimal dose of hyperbaric bupivacaine 7.5 mg combined with fentanyl 20 µg. This low-dosage combination results in less hypotension and less need for noradrenaline to sustain blood pressure than the standard 15 mg dose of hyperbaric bupivacaine with 20 µg fentanyl. With regard to ambulatory individuals, the low-dose approach would be more advantageous due to the earlier restoration of motor and sensory function and the earlier release.

Limitations of the study

The present study was conducted in a very short period due to time constraints and funding limitations. The small sample size was also a limitation of the present study.

CONCLUSION

In this study has shown that a small dose of hyperbaric bupivacaine 7.5 mg in combination with fentanyl 25 µg provides adequate spinal anesthesia for laparoscopic cholecystectomy. This low-dose combination, in comparison with the conventional 15 mg dose of hyperbaric bupivacaine with 20 µg fentanyl, causes less hypotension and fewer requirements for noradrenaline to support blood pressure. The low-dose strategy may have an advantage in ambulatory patients because of the earlier recovery of motor and sensory function and earlier discharge.

RECOMMENDATION

This study can serve as a pilot to much larger research involving multiple centers that can provide a nationwide picture, validate regression models proposed in this study for future use and emphasize points to ensure better management and adherence.

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