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A comparative study of intrathecal Bupivacaine and Bupivacaine plus Fentanyl for major lower limb orthopedics surgery

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Abstract:
Background*: Spinal Anesthesia is the widely used process for lower limb orthopedic surgeries, giving a faster onset & effective motor & sensory blockade. It is easy to do and has got a definite end point. Intrathecal bupivacaine is widely used in spinal anesthesia over a long period of time. Fentanyl as an adjuvant to bupivacaine for intrathecal use has been found to improve the efficacy of Bupivacaine.*
Materials and Methods*: In this prospective randomised controlled study, 60 patients of ASA physical status I and II belonging to age group of 18-60years undergoing elective lower limb surgery under sub-arachnoid block were randomly allocated into 2 groups of 30patients each, Group A (Bupivacaine and Nalbuphine) and Group B (Bupivacaine and Buprenorphine). Group A received 2.8ml of 0.5% (H)Bupivacaine+[0.2 ml (2mg) of Nalbuphine (undiluted) taken in 1ml tuberculin syringe 1mg/0.1ml] and group B received 2.8ml of 0.5%(H)Bupivacaine+0.2ml(60µg) of buprenorphine for spinal anaesthesia. The onset and duration of sensory and motor blockade, 2 segment regression, duration of postoperative analgesia, side-effects and haemo dynamic parameters were compared between the groups.*
Results*: Onset of motor and sensory block in both the groups was comparable. Addition of fentanyl to hyperbaric bupivacaine prolongs the period of sensory block and the time for rescue analgesia requirement. The incidence of adverse effects was significantly lower in group B than in group A. Incidence of hypotension was seen in 10% of patients in group A while in group B 8% patients had hypotension. 6% patients of group A had nausea and vomiting when compared to group B where 2% patients had nausea and vomiting.*
Conclusion: *From the study it can be concluded that addition of 25 µg of fentanyl to 0.5% hyperbaric bupivacaine in subarachnoid block has proved to be a better adjuvant in prolonging sensory blockade, providing better hemodynamic stability intraoperatively and effective post-operative analgesia with reduced incidence of nausea/vomiting in elective lower limb orthopedic surgery under subarachnoid block.*
Key Word: *lower limb orthopedic surgeries; Bupivacaine; Fentanyl.*

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I. Introduction

For ages, mankind have struggled with pain and how to relieve it. Surgical trauma induces substantial tissue damage, and muscular spasm and visceral distension enhance surgical pain. For most lower limb orthopaedic procedures, regional anaesthetic is the recommended method.

James Leonard Corning accidently invented spinal anaesthesia using cocaine in 1885, and August Bier was the first to use it purposefully in 1898[1]. Over a lengthy period of time, intrathecal bupivacaine has been frequently used in spinal anaesthesia. Bupivacaine has four times the potency of lignocaine and lasts four times as long.. Despite the fact that bupivacaine has a lengthy duration of action, it does not cause long-lasting postoperative analgesia. As a result, various adjuvants are required for long-term surgery and prolonged post-operative analgesia. Yaksh and Rudy[2] were the first researchers to show direct opioid analgesia at the spinal cord level in 1976. Late and unexpected respiratory depression, postoperative nausea and vomiting, itching, and urine retention are all possible adverse effects of opioid analgesics. As an agonist, fentanyl is a synthetic phenylpiperidine opioid that acts on opioid receptors, especially the (mu) receptor[3]. Intrathecal fentanyl combined with bupivacaine has the capacity to increase the effects of local anaesthetics, hence prolonging analgesia and reducing analgesic intake postoperatively. It also has the capacity to extend the bupivacaine-induced motor blockage. Sedation and strong and long-lasting postoperative analgesia are achieved with high doses of intrathecal fentanyl without the use of local anaesthetics[4]. Our current study aimed at comparing the effects of intrathecal fentanyl (25 micrograms) as an adjuvant to intrathecal 2.5 ml hyperbaric bupivacaine (0.5 percent) and intrathecal 2.5 ml hyperbaric bupivacaine (0.5 percent) along with 0.5 ml of normal saline (0.9 %) in adult patients having lower limb orthopaedics surgeries.

II. Material And Methods

This prospective randomized interventional study was carried out on patients of Department of anaesthesiology, Katihar Medical College and hospital, Katihar, Bihar from March 2021 to March 2022. A total 40 adult subjects (both male and females) of aged ≥ 18, years were enrolled for in this study.

Study Design: Prospective randomized interventional study

Study Location: At Department of anaesthesiology, Katihar Medical College and hospital, Katihar, Bihar.

Study Duration: March 2021 to March 2022.

Sample size: 40 patients.

Subjects & selection method: The study population was drawn from patients undergoing lower limb surgeries and getting spinal anesthesia. They were randomely allocated in two interventional groups as follows;
Group A(N=20 patients) - 2.5 mL intrathecal Bupivacaine and 0.5 mL 0.9 percent normal saline were given.;
Group B (N=20 patients) - 2.5 mL intrathecal Bupivacaine and 0.5 mL (25 mcg) preservative-free fentanyl were given.

Inclusion criteria:

Patient posted for elective lower limb orthopaedic surgery

1. Age Group 20-60 years of Male and Female
2. ASA Grade I & II

Exclusion criteria:

1. Patients refusal
2. Local infection of the back
3. Coagulopathy or anticoagulant therapy
4. Bleeding disorders or patient on Anticoagulant therapy.
5. Unstable cardiovascular disease • Increased intracranial tension
6. Pre-existing neurological disease & severe deformity of the spine
7. Pregnant Female

Procedure methodology

The pain was assessed by visual analogue score (VAS) A linear visual analogue scale (VAS) on a scale of 0-10 cm (where 0 states no pain & 10 states worst pain) was explained to each patient. An informed & written consent was obtained from the parents or legal guardian after explaining the anesthetic procedure & the risk involved. First advocated by Revill & Robinson in 1976, VAS consists of a 10cm line anchored at one end labeled as 'No pain' & at the other end labeled as 'Worst pain imaginable' or 'Pain as Bad as may Be'. The patients simply mark the line to indicate the pain intensity then measure the length of the line to mark a point scale. All the patients were instructed about the VAS & to point out the intensity of pain on the scale. 0 = No pain 10 = Worst pain

All patients were given standard premedication Tab. Alprazolam 0.25 mg the night before the surgery. Patients was kept nil orally for 6 hours before surgery. PROCEDURE An anaesthesiologist who was not involved in the trial prepared pre-filled labelled syringes with the medicines. The contents of the syringes and the group assignment were unknown to the anaesthesiologist who performed the intervention and observation. When the patient arrived in the operating room, an IV was inserted, a Multipara monitor was attached, and 10 ml/kg of RL was preloaded, as well as baseline parameters such as EGG, NIBP, and SPO2, Under aseptic conditions and with antiseptic precautions, appropriate painting and draping were completed, and the skin was infiltrated with 2% lidocaine before a 25G Quincke's needle was inserted via the L2-L3/ L3-L4 interspace in the midline, with the patient seated. The free flow of cerebrospinal fluid indicated placement of needle in subarachanoid space, and 3.0 ml of the study medication was delivered over 10 seconds before the patient was laid supine.

Primary parameters: Spinal block characteristics – • Time taken to acvhieve peak sensory level T10 - Pinprick test • Time taken to achieve peak motor block -Bromage scale grade3 • Two segments sensory block regression time period • Time taken to motor block regression to Bromage scale grade 1 • Complete time Duration of analgesia Post –operative period – • Time taken to first analgesic request (VAS > 4)

Secondary parameters: • Heart rate (< 50 /min -bradycardia) • Hypotension if SBP or DBP fall is > 20 % from baseline SBP or DBP respectively • SpO2 • Pruritus • Nausea • Vomiting • Shivering

Statistical analysis

Data was tabulated in Excel spreadsheet with a sample size of 100 patients. All the data were analyzed using the SPSS 23.0 version for windows. The data were presented as descriptive statistics for continuous variables & percentage for categorical variables & were subjected to Chisquare test, t-test & Anova test. Other values were represented in number, proportions (%) & mean ± SD. Univariate analysis: of the dichotomous variables encoded was performed by means of the Chi square test with Yates correction if required.

III. Result

All 40 patients with ASA physical status I/II involved in the study who satisfied all inclusion criteria were randomly separated into two groups in the Department of Anaesthesiology, Katihar Medical College & Hospital, Katihar , Bihar. All the patients completed the study without any exclusion. The collected data were analyzed. The following observations are as follows:

Table no 1

	Group	N	Mean	Std. Deviation	Std. Error Mean	p-value
Age	A	20	41.85	14.368	3.213	.895
	B	20	41.30	11.658	2.607	
weight (in kg)	A	20	61.75	7.966	1.781	.221
	B	20	64.35	4.902	1.096	
Height (in cm)	A	20	166.05	3.953	.884	.167
	B	20	164.50	2.929	.655	

Table 1: Comparison of baseline characteristics of study participants

Table no 1 shows the mean age of participants in Group A was 41.8 years and in group B it was 41.3 years. There was however, no statistically significant difference between them. Similarly, weight and height was also similar in both the groups. In group B, there were equal number of male and female participants, but in Group A, males were three fourths and females were one-fourth.

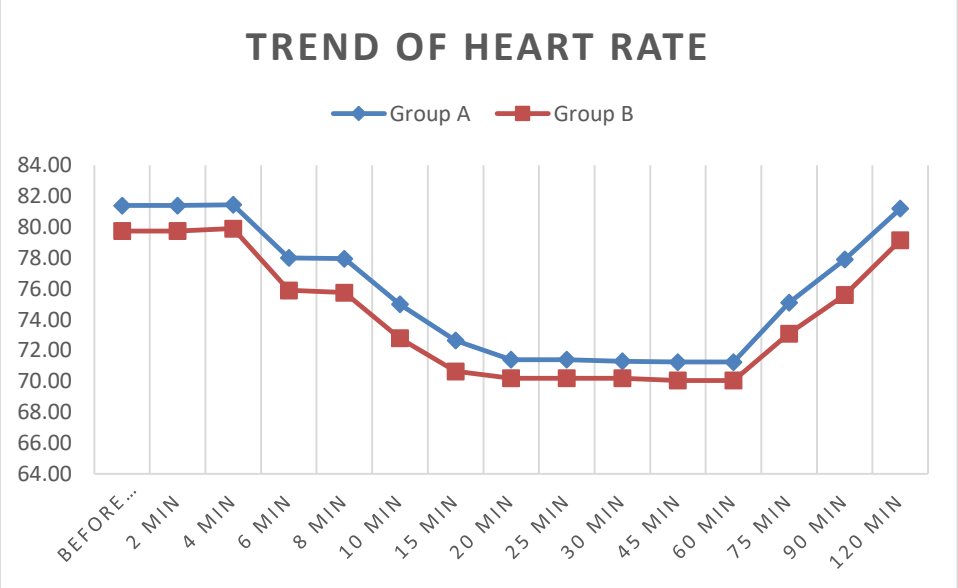

Figure 1: Line diagram showing trend of heart rate (mean) in both groups over 2 hours.

The mean heart rate in both the groups was within physiological range at all the times during the study. The mean heart rate was also statistically similar in both the groups during the study period (p-value>0.05) (Figure 1).

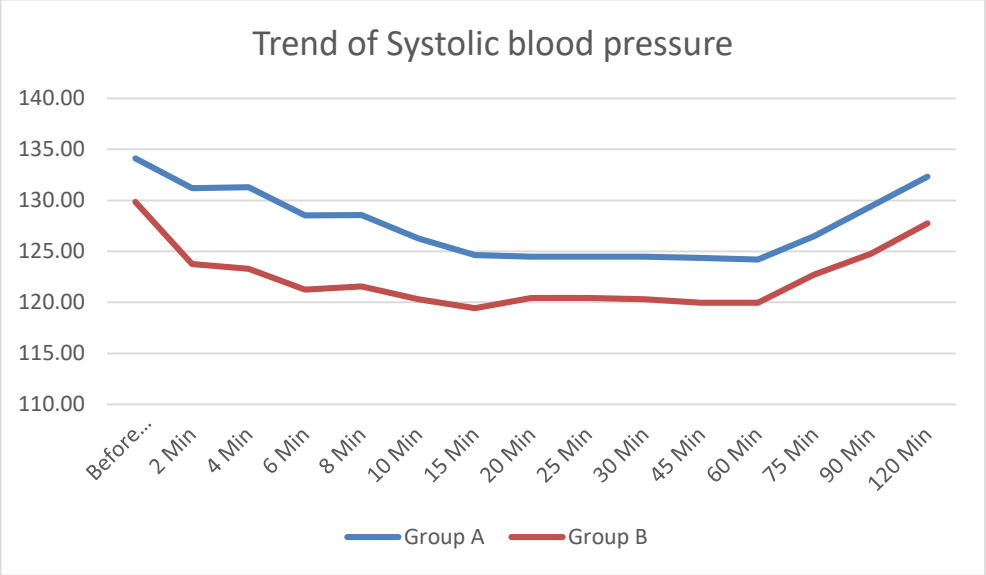

Figure 2: Line diagram showing trend of Systolic blood pressure (mean) in both groups over 2 hours.

The mean systolic blood pressure was within physiological range during the study period in both the groups. There was statistically significant difference in mean systolic blood pressure at baseline, 8 minutes and 10 minutes (Figure 2).

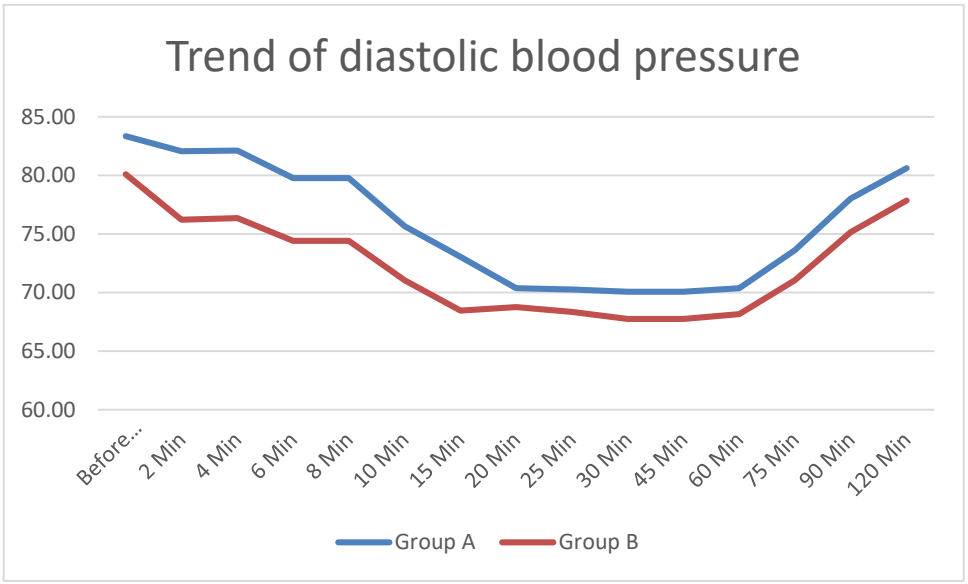

Figure 3: Line diagram showing trend of Diastolic blood pressure (mean) in both groups over 2 hours.

The mean diastolic blood pressure was lower in Group B at all the times as compared to Group A. However, statistically significant difference was seen till 15 minutes of our study (Figure 3).

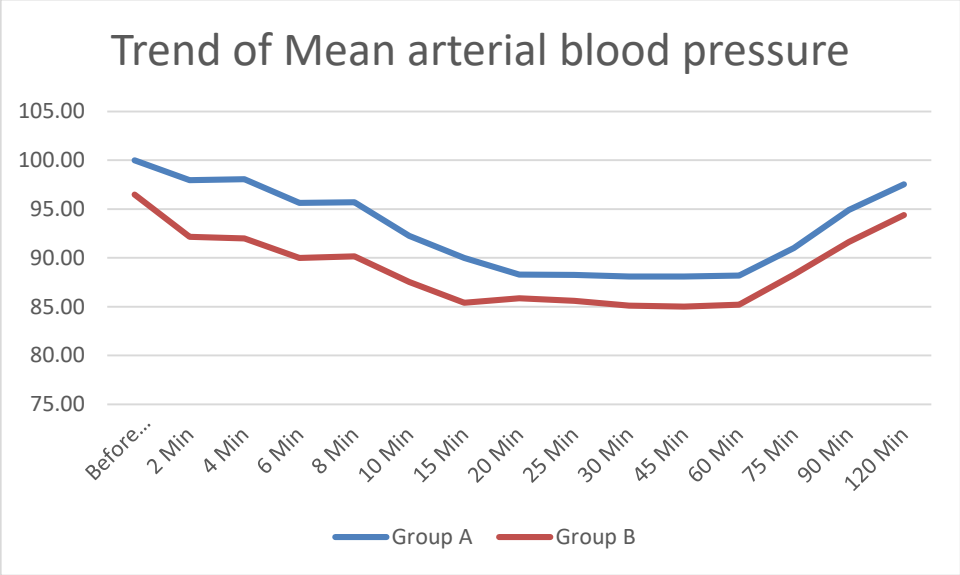

Figure 4: Line diagram showing trend of mean arterial blood pressure (mean) in both groups over 2 hours.

There was statistically significant difference in average mean arterial blood pressure till 15 minutes of the study period (Figure 4).

Table 2: Mean distribution of onset of sensory and motor blockade, grade of motor blockade and duration of blockade in both the groups during surgery and post operatively.

	Group	N	Mean	Std. Deviation	p-value
Onset of Sensory Block at T10 (min)	A	20	2.54	.21	.324
	B	20	2.47	.19	
Onset of Motor Block Bromage-3 (min)	A	20	2.75	.19	.368
	B	20	2.69	.23	
Duration of Sensory Blockade(min)	A	20	165.70	3.197	0.00
	B	20	198.55	7.53	
Duration of Motor Blocked (min)	A	20	149.10	4.87	0.00
	B	20	179.70	9.02	
Duration of Analgesia (min)	A	20	205.4	3.43	0.00
	B	20	250.75	5.91	

Table 2 shows that the onset of sensory block was similar in both the groups, however, onset of motor block was significantly faster in Group B as compared to Group A. Grade of motor blockade was same in both the groups. Duration of sensory blockade, motor blockade and analgesia was higher in Group A as compared to Group B (p-value <0.00).

Table 3: Distribution of side effects in both the study groups

SIDE EFFECTS	Group A	Group B	p-value
Hypotension	0	2 (10%)	0.30
No side effects	18 (90%)	17 (85%)	
Vomiting	2 (10%)	1 (5%)	
Total	20 (100%)	20 (100%)	

Table 3 shows that the 90% of patients in group A and 85% in Group B had no side effects in the study. 10% in group A and 5% in group B had complaints of vomiting. 10% in group B had hypotension.

IV. Discussion

The goal of the current study was to assess the effectiveness and duration of anaesthesia and analgesia with intrathecal fentanyl (25 micrograms) as an adjuvant to intrathecal 2.5 ml hyperbaric bupivacaine (0.5%) in 40 patients with ASA physical status I/II of both sexes undergoing elective lower limb orthopaedic surgery under subarachnoid block at Katihar Medical College & Hospital. Group A participants received Fentanyl and Group B received saline with bupivacaine in our study. The mean age of participants in Group A was 41.8 years and in group B it was 41.3 years. There was however, no statistically significant difference between them. Similarly, weight and height was also similar in both the groups. In group B, there were equal number of male and female participants, but in Group A, males were three fourths and females were one-fourth. The mean heart rate in both the groups was within physiological range at all the times during the study. The mean heart rate was also statistically similar in both the groups during the study period (p-value>0.05).The mean systolic blood pressure was within physiological range during the study period in both the groups. There was statistically significant difference in mean systolic blood pressure at baseline, 8 minutes and 10 minutes. The mean diastolic blood pressure and mean arterial blood pressure was lower in Group B at all the times as compared to Group A. The mean SpO_2 level in both the groups was similar during the study period. The onset of sensory block was similar in both the groups, however, onset of motor block was significantly faster in Group B as compared to Group A. Grade of motor blockade was same in both the groups. Duration of sensory blockade, motor blockade and analgesia was higher in Group A as compared to Group B (p-value <0.00). 90% of patients in group A and 85% in Group B had no side effects in the study. 10% in group A and 5% in group B had complaints of vomiting. 10% in group B had hypotension.

The mean age, weight, height were comparable across the studies with our findings. The age ranged between 27.63 years in study by Routray SS et al[5] and 67 years in study by Zode at al[6]. The mean SBP was 127 in our study similar to previous studies[5,7,8]. Similarly the mean DBP was around 77 in study by Sabertanha A[7] and Chakraborty K[8]. Heart rate was low in study by Unal D et al[9] as compared to our study, however rest all the previous literature[5,7,8] has shown mean heart rate ranging between 77-85 bpm.

The onset of sensory block in fentanyl group was 2.48 in our study which was similar to the findings of Zode at al[6] and Devi A[10]. The rest of studies had onset of sensory block in fentanyl group in 7.4 (Routray SS et al[5] and Sabertanha A[7]), 8.6 in study by Mahendru V et al[11], and 12.1 in study by Gupta R[12].

The onset of motor block in our study was 2.7 similar to Srinivasgam K et al[13] and Zode A et al[6]. In rest of the previous literature, the onset of motor block was delayed from 5.05 (Rahimzadeh P[14]) to 14.3 (Alghanem SM et al[15]). However, the onset of motor and sensory blocks varied across the studies because of the dosage of fentanyl, the mode of administration and the criteria for asserting the blocks.

Ram C[16] et al in 2019 compared the effects of intrathecal bupivacaine with adjuvants like clonidine, and fentanyl in lower limb studies. They studied over 40 patients in each group. They observed that duration of sensory block in fentanyl group was 199.6 min while motor block was 151.7 min. in our study, the duration of sensory block was 198.55 min and motor block was 179.7 which was more the findings of Ram C et al. Mahendru V[11] et al found that mean sensory block regression in bupivacaine was 102 in bupivacaine saline group and 119 in in bupivacaine fentanyl group. This was lower than our observation. The duration of motor block was however, compatible with 161.5 min in saline group and 196 min in fentanyl group.

Fentanyl inhibits the release of substance P, a nociceptive transmitter, by binding to opioid receptors in the brain and spinal cord. Combining fentanyl with local anaesthetics not only extends the time of the regional block but also improves its quality[17]. The interaction of intrathecal fentanyl with opioid receptors in the dorsal horn of the spinal cord is what causes its effects[18].

The duration of sensory block in our study was 198.55 min which was similar to findings of C Ram et al[16], Kaur H[19], Zode at al[6] and Routray SS et al[5]. The shorter duration of sensory blocks were found in studies by Mahendru V et al[11] (119 min), and Chakraborty K[8] (96 min). Most of the studies reported the duration of sensory block ranging between 170 min-205 min.

The duration of motor block in our study was 179.7 min which was similar to Routray SS et al[5], Reddy IR et al[20] , Rahimzadeh P[14] and Zode at al[6]. Fewer studies like studies by Mahendru V et al[11], Devi A[10] and Chakraborty K[8] had higher duration of motor blocks (>190 min) in their studies.

Different volumes, concentrations, and bariticities of the local anaesthetic solutions used may be the cause of the disparity in data on the onset of motor block recorded by various authors.

The most prominent side effects of fentanyl observed across the studies are hypotension ranging from 6.66%[12] to 30%[16]. In our study the prevalence of hypotension was 105 in fentanyl group which was similar to findings of Thada B[21], Rahimzadeh P[14], Sabertanha A[7], and Devi A[10].

The next common side effect seen in fentanyl group was vomiting or nausea which was 5% in our study similar to C Ram et al[16], Thada B[21], and Sabertanha A[7]. The nausea and voimiting was seen in around 10% of study population in rest of the studies[10,12,19] .

When used with local anaesthetics, intrathecal fentanyl lessens somatic and visceral pain. No subject in group A of our study had visceral pain.

When administered intrathecally, fentanyl may also work by spreading to the supraspinal region and interacting with opioid receptors in the dorsal horn of the spinal cord. It has been used as an adjuvant to local anaesthetics in Subarachnoid block lowers both visceral and somatic pain, but its usage is currently restricted because of its dose-dependent side effects[23].

Bradycardia was seen in around 3.3%[10] to 10%[14] of the study populations in other studies. Shivering was seen in 5%[6] to 10%[22] of the participants. However, the side effects were found to be limited in our study. The fentanyl was observed to be a superior adjuvant to intrathecal bupivacaine in terms of depth, duration and quality of anaesthesia and hemodynamic stability. Few limitations of our study were small sample size due to feasibility which will impact the generalisability of its findings. The follow up duration was also less. The study was not blinded due to procedural reasons

V. Conclusion

According to the results, 25 mcg of fentanyl to 0.5 percent hyperbaric bupivacaine was found to be a better adjuvant in elective lower limb orthopaedic surgery under subarachnoid block, improving haemodynamic stability intraoperatively, increased sensory block, motor block, duration of analgesia and providing effective postoperative analgesia with a lower incidence of nausea and vomiting.

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