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	Coloby * Holo	Anaesthesiology COMPARING THE EFFICACY OF FENTANYL VS. BUTORPHANOL AS ADJUVANTS IN LUMBAR SUBARACHNOID BLOCK WITH BUPIVACAINE FOR PATIENTS UNDERGOING LOWER LIMB SURGERIES
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(ABSTRACT) Spinal anesthesia is the most commonly used technique for lower abdominal and lower limb surgeries. Intrathecally, administered local anaesthetics and opioids have been shown to have a synergistic analgesic effect, hence requiring relatively lower dosage. Neuraxial opioids also allow prolonged analgesia in the postoperative period and faster recovery from spinal anaesthesia. Adjuvants used include Fentanyl, morphine, buprenorphine, butorphanol, sufentanil. A prospective observational study was conducted in 354 patients of age group (20 – 60yrs) and ASA grade 1 and 2. A total of 177 patients received 25 mcg Fentanyl along with 3ml 0.5% Bupivacaine (H) and remaining 177 received 250 mcg Butorphanol along with 3ml 0.5% Bupivacaine (H). Duration of analgesia (sensory block), onset of sensory and motor blockade, duration of motor blockade, hemodynamic changes and adverse effects were compared. From the study it was found that Butorphanol was significantly better than Fentanyl in providing longer duration of analgesia. Butorphanol as adjuvant to hyperbaric 0.5% Bupivacaine 3ml in itrathecal route for lowerlimb surgeries offered better hemodynamic stability and provided effective and relatively safe anaesthesia.

KEYWORDS : fentanyl,butorphanol,adjuvant,bupivacaine,intrathecal

INTRODUCTION

Neuraxial anaesthesia is commonly performed for all surgical procedures carried on lower abdomen, pelvis and lower limbs to provide adequate surgical anaesthesia and analgesia. Spinal anaesthesia, despite providing a satisfactory surgical exposure, with just a small amount of local anaesthetic, has a drawback due to unpredictable perturbations in the haemodynamic parameters as a result of sympatholysis. These effects are proportional to the level of sympathetic blockade. Intrathecally, administered local anaesthetics and opioids have been shown to have a synergistic analgesic effect, hence requiring relatively lower dosage. Neuraxial opioids also allow prolonged analgesia in the postoperative period and faster recovery from spinal anaesthesia. Adjuvants used include Fentanyl, morphine, buprenorphine, butorphanol, sufentanyl etc. Intrathecal opioids have been used in treating intraoperative, post-operative, and chronic cancer pain. This technique of intrathecal opioid administration along with local anesthetics has been studied extensively. In our institution, Fentanyl and Butorphanol are the commonly used adjuvants, potent narcotic analgesics with rapid onset and short duration of action. The principal actions of therapeutic value are analgesia and sedation. Butorphanol is a proven intravenous analgesic, effective in intra muscular route in labour analgesia, and has also been safely used in epidural anaesthesia. So to enlighten further, we will be comparing the efficacy of Fentanyl Vs Butorphanol as adjuvants in lumbar subarachnoid block with 0.5% bupivacaine for patients undergoing lower limb surgeries.

OBJECTIVES PRIMARY OBJECTIVE

To compare the duration of analgesia (sensory blockade) between Butorphanol and Fentanyl as adjuvants to intrathecal hyperbaric 0.5% Bupivacaine in patients undergoing lower limb surgeries.

SECONDARY OBJECTIVES

To compare the onset of sensory and motor blockade between Butorphanol and Fentanyl as adjuvants to intrathecal hyperbaric 0.5% Bupivacaine in patients undergoing lower limb surgeries.

To compare the duration of motor blockade between Butorphanol and Fentanyl as adjuvants to intrathecal hyperbaric 0.5% Bupivacaine in patients undergoing lower limb surgeries.

To compare hemodynamic changes and adverse events between Butorphanol and Fentanyl as adjuvants to intrathecal hyperbaric 0.5% Bupivacaine in patients undergoing lower limb surgeries

METHODOLOGY

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A prospective observational study conducted in 354 patients of age group (20 - 60yrs) and ASA grade 1 and 2. A total of 177 patients received 25 mcg Fentanyl along with 3ml 0.5% Bupivacaine (H) and

remaining 177 received 250 mcg Butorphanol along with 3ml 0.5% Bupivacaine (H). Duration of analgesia (sensory block), onset of sensory and motor blockade, duration of motor blockade , hemodynamic changes and adverse effects were compared between the two groups. Statistical analyasis was done using IMB SPSS Statistics version 20.0 and T-test and Mann Whitney U-test were done. Association analysed with Chi-square test and Fisher's exact test

RESULTS

354 patients satisfying inclusion criteria were enrolled into the study. After taking written informed consent for participation in the study, the patients were allocated to either 'Group 1' or 'Group 2' with equal allocation of 177 cases each. There was no patient lost to follow up and outcome was analysed for all the participants. Results on continuous measurements are presented on Mean \pm SD. Results on categorical measurements are presented in number and percentage. Significance is assessed at 5% level of significance. The collected data were coded and entered into the IBM SSPS Statistics, Version 20.0, a statistical package software program. The results are presented under the following headings: Section A: Socio demographic and clinical characteristics of study participants Section B: Outcome analysis: Comparison of Level of sensory blockade, Time to maximum sensory and motor blockade, Duration of motor blockade, Hemodynamic parameters at different time points between the groups

TABLE-1 COMPARISON OF AGE

AGE	GROUP - I	GROUP – II		
< 30	12	18		
31-40	18	24		
41 - 50	42	41		
51 - 60	59	54		
> 60	46	40		
Total	177	177		
Mean	52.531	50.356		
SD	11.392	12.346		
p'value	0.086 Not Sign	0.086 Not Significant		

Mean age of the group A is 52.53 and group B mean age is 50.36. There is no significant difference between both group regarding age. P value 0.086 not significant.



TABLE – 2 COMPARISON OF GENDER

GENDER	GROUP - I	GROUP - II
Male	119	128
Female	58	49
Total	177	177
p'value	0.355 Not significa	ant

There is no significant difference between both groups regarding gender. P value is 0.355 Not significant.



TABLE - 3 COMPARISON OF WEIGHT

WEIGHT	GROUP - I	GROUP - II		
Mean	70.19	68.70		
SD	8.008	7.477		
n'value	0.072 Not sign	0.072 Not significant		

There is no significant difference between both groups regarding weight of the patients. P value is 0.072 Not significant

COMPARISON OF WEIGHT



TABLE-4 COMPARISON OF HEIGHT

HEIGHT	GROUP - I	GROUP - II
Mean	163.41	160.29
SD	6.374	6.739
p'value	<0.001 Significant	

There is significant difference between both groups regarding height of the patients. P value is < 0.001 Significant

COMPARISON OF HEIGHT



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TABLE – 5 COMPARISON OF ASA					
ASA	GROUP - I	GROUP - II			
Ι	82	92			
II	95	85			
Total	177	177			
Mean	1.54	1.48			
SD	0.5	0.501			
p'value	0.289 Not signifi	cant			

There is no significant difference between both groups regarding ASA. P value is 0.289 Not significant



GROUP - I GROUP - II

TABLE – 6 COMPARISON OF MOTOR BLOCKADE TIME IN MINUTES

MOTOR BLOCKADE TIME in mins	GROUP - I	GROUP - II
Mean	120.48	128.26
SD	7.426	4.753
p'value	<0.001 Significant	

Motor blockade time is significantly higher in group II. P value is < 0.001 significant.

COMPARISON OF MOTOR BLOCKADE TIME



GROUP - I GROUP - II

TABLE – 7 COMPARISON OF ONSET OF MOTOR BLOCK IN MINUTES

Onset of Motor Block in minutes	GROUP - I	GROUP - II	
Mean	3.06	3.15	
SD	0.124	0.142	
p'value	<0.001 Significant		

Onset of Motor block is significantly higher in group II than group I. p value is < 0.001 significant.

COMPARISON OF MOTOR BLOCK IN MINUTES



TABLE – 8 COMPARISON OF ONSET OF SENSORY BLOCK IN MINUTES

Onset of Sensory Block in minutes	GROUP - I	GROUP - II
Mean	1.19	1.195
SD	0.15	0.153
p'value	0.895 Not Significat	nt
T1 1 1 10 1100 1		11 0

There is no significant difference between both groups regarding Onset of sensory block p value is 0.895 Not significant.

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TABLE – 9 COMPARISON OF DURATION OF ANALGESIA IN HOURS

DURATION OF ANALGESIA (hrs)	GROUP - I	GROUP - II
Mean	6.59	7.49
SD	1.084	1.394
p'value	<0.001 Significant	

Mean duration of analgesia is 6.59 hrs for group I and 7.49 for Group II. This difference is statistically significant. p value is < 0.001 significant.

COMPARISON OF DURATION OF ANALGESIA IN HOURS



GROUP - I GROUP - II

$TABLE-10\,COMPARISON\,OF\,VERBAL\,NPRS\,SCORE$

	GROUP – I		GROUP - II			
Verbal NPRS Score in minutes	Mean	SD	Mean	SD	p'value	Significance
0 mins	0.412	1.025	0.232	0.497	0.035	Significant
30 mins	0	0	0	0	1	Not sig
60 mins	0	0	0	0	1	Not sig
90 mins	0	0	0	0	1	Not sig
120 mins	0.458	1.055	0.226	0.644	0.013	Significant
150 mins	0.927	1.327	0.898	1.061	0.825	Not sig
180 mins	3.412	0.719	3.548	0.91	0.121	Not sig
210 mins	3.333	0.54	3.379	0.562	0.441	Not sig
240 mins	4	0.707	4.023	0.639	0.753	Not sig
270 mins	4.864	1.13	3.808	1.577	< 0.001	significant
300 mins	6.588	0.678	6.554	0.698	0.643	Not sig



TABLE 11– 11COMPARISON OF MODIFIED BROMAGE SCALE

	GROUP	- I	GROU	JP - II		
Modified Bromage scale in minutes	Mean	SD	Mean	SD	p'value	Significance
0 mins	2.864	0.343	2.842	0.366	0.549	Not Significant
30 mins	4	0	4	0	1	Not Significant
60 mins	4	0	4	0	1	Not Significant

90 mins	4	0	4	0	1	Not Significant
120 mins	4	0	4	0	1	Not Significant
150 mins	2.571	0.519	2.333	0.496	< 0.001	Significant
180 mins	2.045	0.298	1.797	0.492	< 0.001	Significant
210 mins	1.949	0.307	1.684	0.49	< 0.001	Significant
240 mins	1.638	0.558	1.26	0.522	< 0.001	Significant
270 mins	2.051	1.174	0.944	0.796	< 0.001	Significant
300 mins	0.672	0.626	0.379	0.52	< 0.001	Significant

No significant difference between both groups regarding Bromage scale up to 120 minutes. After 120 minutes, upto 300 minutes there is significant difference between both groups. P value is < 0.001 significant.



TABLE-12 COMPARISON OF HEART RATE

	GROUP	- I	GROUP - II			
Heart Rate	Mean	SD	Mean	SD	p'value	Significance
0 mins	85.254	3.818	85.633	3.375	0.324	Not sig
30 mins	86.508	3.03	86.311	2.72	0.519	Not sig
60 mins	86.441	2.929	86.322	3.161	0.714	Not sig
90 mins	86.35	3.307	86.96	3.274	0.082	Not sig
120 mins	85.701	3.402	85.915	2.862	0.521	Not sig
150 mins	86.768	3.68	87.136	3.517	0.338	Not sig
180 mins	86.915	3.586	86.797	3.372	0.749	Not sig
210 mins	86.797	3.334	87.073	3.416	0.441	Not sig
240 mins	86.593	3.229	86.198	3.097	0.24	Not sig
270 mins	87.836	2.882	88.164	2.831	0.281	Not sig
300 mins	86.412	2.92	86.243	2.224	0.539	Not sig

No significant difference between both groups regarding regarding heart rate from 0 minutes to 300 minutes P value is not significant.



TABLE-13 COMPARISON OF NIBP SYSTOLIC

	GROUP	– I	GROUP - II			
NIBP[Systoli c] in mins	Mean	SD	Mean	SD	p'value	Significance
0 mins	129.576	3.273	128.96	3.072	0.069	Not Sig
30 mins	128.797	3.314	128.124	3.449	0.062	Not Sig
60 mins	126.836	3.265	126.271	3.43	0.113	Not Sig
90 mins	125.785	3.209	125.407	3.507	0.29	Not Sig
120 mins	123.814	3.481	123.424	3.576	0.299	Not Sig
150 mins	119.186	6.179	118.966	6.455	0.743	Not Sig
180 mins	116.096	5.114	116.243	5.15	0.788	Not Sig
210 mins	117.407	5.924	117.379	5.958	0.964	Not Sig
240 mins	115.977	6.239	115.927	6.249	0.939	Not Sig
270 mins	120.345	7.786	120.011	7.054	0.673	Not Sig
300 mins	119.469	6.904	118.797	5.572	0.314	Not Sig

No significant difference between both groups regarding regarding Systolic BP from 0 minutes to 300 minutes P value is not significant.

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TABLE - 13 COMPARISON OF NIBP SYSTOLIC

	GROUP	– I	GROUP	- II		
NIBP[Systolic] in mins	Mean	SD	Mean	SD	p'value	Significance
0 mins	129.576	3.273	128.96	3.072	0.069	Not Sig
30 mins	128.797	3.314	128.124	3.449	0.062	Not Sig
60 mins	126.836	3.265	126.271	3.43	0.113	Not Sig
90 mins	125.785	3.209	125.407	3.507	0.29	Not Sig
120 mins	123.814	3.481	123.424	3.576	0.299	Not Sig
150 mins	119.186	6.179	118.966	6.455	0.743	Not Sig
180 mins	116.096	5.114	116.243	5.15	0.788	Not Sig
210 mins	117.407	5.924	117.379	5.958	0.964	Not Sig
240 mins	115.977	6.239	115.927	6.249	0.939	Not Sig
270 mins	120.345	7.786	120.011	7.054	0.673	Not Sig
300 mins	119.469	6.904	118.797	5.572	0.314	Not Sig

No significant difference between both groups regarding regarding Systolic BP from 0 minutes to 300 minutes P value is not significant.



TABLE - 14 COMPARISON OF RESPIRATORY RATE

	GROUP - I		GROUP - II				
Respiratory Rate	Mean	SD	Mean	SD	p'value	Significance	
0 mins	12.282	0.612	12.226	0.644	0.398	Not sig	
30 mins	11.475	0.666	11.452	0.648	0.746	Not sig	
60 mins	11.486	0.595	11.514	0.7	0.683	Not sig	
90 mins	12.282	0.612	12.254	0.61	0.664	Not sig	
120 mins	11.475	0.666	11.463	0.666	0.873	Not sig	
150 mins	11.486	0.595	11.441	0.509	0.443	Not sig	
180 mins	12.282	0.612	12.249	0.608	0.601	Not sig	
210 mins	11.475	0.666	11.469	0.691	0.938	Not sig	
240 mins	11.486	0.595	11.486	0.623	1	Not sig	
270 mins	12.282	0.612	12.243	0.606	0.541	Not sig	
300 mins	11.475	0.666	11.446	0.629	0.682	Not sig	

No significant difference between both groups regarding regarding respiratory rate from 0 minutes to 300 minutes. P value is not significant.



TABLE-15	COMPARIS	ON OF SPO2
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	GROUP	– I	GROUP - II			
Spo2	Mean	SD	Mean	SD	p'value	Significance

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0 mins	98.972	0.842	98.994	0.829	0.799	Not Sig
30 mins	98.994	0.829	99.011	0.798	0.845	Not Sig
60 mins	99.011	0.798	99.028	0.808	0.843	Not Sig
90 mins	99.028	0.808	99.107	0.801	0.356	Not Sig
120 mins	99.107	0.801	99	0.819	0.213	Not Sig
150 mins	99	0.819	98.91	0.8	0.294	Not Sig
180 mins	98.91	0.8	99	0.833	0.298	Not Sig
210 mins	99	0.833	99.136	0.793	0.118	Not Sig
240 mins	99.136	0.793	99.537	0.594	0.561	Not Sig
270 mins	98.938	0.799	99.011	0.819	0.394	Not Sig
300 mins	99.011	0.819	98.972	0.842	0.654	Not Sig

No significant difference between both groups regarding regarding SPO2 from 0 minutes to 300 minutes. P value is not significant.



DISCUSSION

In our study, 354 patients undergoing elective lower limb surgeries were observed. The patients who received Fentanyl were included under Group 1 - 177 cases and those patients who received Butorphanol were included under Group 2 - 177 cases. Sociodemographic data of Group 1 and Group 2 were comparable. The age of the patients ranged from 26 years to 68 years. The mean age for Group 1 was 52.53 ± 11.39 years and that of Group 2 was 50.35 ± 12.34 years. Of the total study populationin each group, 70% were males and 30% were females. The demographic characteristics of two groups (Fentanyl and Butorphanol) showed no statistically significant associations as p values are >0.05, except for height. Similar observations were made by Bhandari et al, Sandip Roy Basunia et al regarding the demographic data (5,3). In our study population, 46% patients of group 1 and 52% patients of group 2 belonged to ASA class 1 and rest belonged to ASA class 2. Distribution of ASA class 1 and 2 between Group 1 and 2 were tested using Chi-squaretest and P value was calculated which was not statistically significant. The time of onset of sensory block was 1.19 ± 0.15 minutes in group 1 and was 1.195 ± 0.15 minutes in Group 2 and showed no statistical significance. A faster onset of sensory blockade was demonstrated by studies done by Bhandari et al and Binay kumar et al (5,1).

Motor blockade characteristics were also compared between the two groups in our study. Time to maximum motor block in Group 1 was 3.06 ± 0.12 minutes and 3.15 ± 0.14 minutes in Group 2. Duration of motor blockade was 120.5 ± 7.43 minutes in group 1 and 128.3 ± 4.75 minutes in group 2. Independent t' test was conducted to find out the statistically significant differences in the time of maximum motor blockade and duration of motor blockade between two groups (Fenatanyl and Butorphanol) and they showed that there is a statistically significant differences between the groups as p <0.001. According to studies done by Binay kumar et al in 77 parturients epidural volume expansion (EVE) is better than epidural or spinal in terms of level of motor blockade, time taken for motor recovery and with comparable incidence of side effects(1). This is supported by studies done by Kaur et al with similar results (13). The studies done by Binay kumar et al and Kishnani et al also observed faster motor recovery in patient undergoing epidural volume extension (1,2).The hemodynamic parameters including the HR, RR and SPO2 were recorded in both groups from the time of administration of anaesthesia every 30 minutes to till 300 minutes. The mean baseline HR in group 1 was 85.25 ± 3.82 and group 2 was 85.63 ± 3.37 . and at 300 minutes 86.4 in group 1 and 86.24 in group 2, both P values obtained on comparing between two groups were statistically insignificant. The mean baseline SPO2 group 1 was 98.97 ± 0.84 and of group 2 was $98.97 \pm 0.83.$ Independent t' test was conducted to find out the no statistically significant differences during and after the surgery with two groups (Fenatanyl and Butorphanol) and they showed that there were no statistically significant differences from 0 minutes to 300 minutes as P values are >0.05. Comparative studies between butorphanol and fentanyl or other pure mu receptor agonists, or even

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butorphanol vs plain bupivacaine heavy, as adjuvants to spinal anaesthesia are relatively fewer in number. The study by Upasna B et al., was the only contemporary study on comparison of intrathecal Fentanyl and Butorphanol as adjuvants to spinal anaesthesia in different varieties of infraumbilical surgeries comparable to this study [4]. Hence, this study was undertaken to compare these two drugs in a variety of infraumbilical surgeries to get a better idea regarding their perioperative analgesic and anaesthetic efficiency as opposed to only one variety of surgery. There was also a controversy on the optimal intrathecal dose of butorphanol with variations in the range of 25 µgm -200 µgm in the above referred studies. The studies conducted by Gupta K et al., and Reddy NG et al., both of them being based on lower limb orthopaedic surgery [7,9], used a dose of 200 µgm intrathecal butorphanol along with bupivacaine heavy. Similar dose was also used by Singh SN et al., in abdominal and vaginal hysterectomies under spinal anaesthesia without any significant side effects [12]. Thus, a dose of 25 µgm Fentanyl and 250 µgm of Butorphanol as adjuvants with Bupivacaine heavy 3 mL, in subarachnoid block was used in this study with an intention of testing the perioperative efficacy, especially that of butorphanol as against a relatively fixed and already established dose of fentanyl. The other major concern was whether this dose of butorphanol was associated with an increase in adverse effects in comparison with other studies.

Haemodynamic parameters like mean HR, SBP and SPO2 were within acceptable limits. Both mean SBP and DBP were lower in the butorphanol group as compared to the fentanyl group, although it was not statistically significant, whereas there was no such trend on comparison of mean HRs between the groups, just like the study of Reddy NG et al., [9]. This was unlike the findings of Sandip Roy Basunia et al where both mean HRs and blood pressure were significantly lower in the butorphanol group between 45-90 minutes of intraoperative period [3]. Haemodynamic parameters were within acceptable limits in line with the study of Reddy IR et al., [6]. Time for onset of sensory block of the fentanyl group (1.19±0.15 min) was less than that of butorphanol group (1.195±0.15 min) but results were comparable (p>0.05). This was similar to the findings of Kumar A et al., where time to onset of sensory block in fentanyl group was 8±1.4 minutes, while it was 8±3.2 minutes in the butorphanol group [8]. The longer period in the latter study may be due to their much lower dosage of spinal drugs. The maximum sensory level achieved was T6 in both groups in this study much like Reddy NG et al., where they had used 200 µgm of intrathecal butorphanol and bupivacaine heavy 3 mL[9]

Both these adjuvant opioids did not cause any significant increase in onset of motor blockade which was consistent with the findings of Binay kumar et al and Kishnani et al.[1,2]. However in Group B, the mean duration of motor block was 120.45±7.43 minutes, which was significantly more than Group A at 128.3±4.75 minutes. These findings were quite consistent with Reddy IR et al., (butorphanol group 178.99±13.32 min as opposed to 168.8±9.18 min in fentanyl group) and Upasna B et al., (246±42.6 min in butorphanol group as opposed to 180±16.8 min in fentanyl group [6,4]. This was contrary to the findings of Kumar B et al., who found no statistically significant difference between duration of motor block between these groups [10]. One explanation may be, they had used 2.5 mL of 0.5% Bupivacaine and 25 µgm of butorphanol, while in this study 3 mL of 0.5% Bupivacaine and 250 µgm of Butorphanol was used instead. However, if mean duration of surgery in these groups are compared (73.27±14.69 min for Group A and 75.36±13.53 min for Group B), the motor block was not that inconvenient. Most significant finding of this study was that time for first request of rescue analgesia was prolonged in Butorphanol group $(7.49 \pm 1.39 \text{ hrs})$ compared to Fentanyl group $(6.59 \pm 1.39 \text{ hrs})$. Both fentanyl and butorphanol along with bupivacaine provided adequate analgesia and anaesthesia, but butorphanol was superior in delaying time of rescue analgesic which supports the result obtained from studies of Kumar B et al., time of consumption of rescue analgesia in fentanyl group was 308±14.9 minutes which was significantly less than in butorphanol group at 365.9±12.3 minutes [10]. Similar statistically significant findings were also observed in studies of Binay kumar et al and Kishnani et al [1,2].

Addition of fentanyl (20-25 μ g) to low-dose bupivacaine (4 mg) has been reported to increase the perioperative quality of spinal blocks with fewer cardiovascular changes in elderly patients. None of the groups had episodes of hypotension which means that butorphanol much like fentanyl has a scope of use as an adjuvant in spinal anaesthesia in elderly patients with cardiovascular morbidities. Delayed respiratory depression is more commonly associated with poorly lipid-soluble narcotic drugs, like morphine. The patients were continuously observed for respiratory depression and sedation in this study and no significant respiratory depression was noted much like Binay kumar et al and Kishnani et al., thus again pointing out that both these drugs in this route may have fewer side effects[1,2].

CONCLUSION

The conclusion of the study was that the Butorphanol was significantly better than Fentanyl in providing longer duration of analgesia. Butorphanol as adjuvant to hyperbaric 0.5% Bupivacaine 3ml in itrathecal route for lowerlimb surgeries offered better hemodynamic stability and provided effective and relatively safe anaesthesia.

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