Study of intrathecal low dose bupivacaine plus fentanyl compared with intrathecal low dose bupivacaine for perineal surgeries

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Abstract

Background: The lipophilic opioids are more suitable for intraoperative use in the intrathecal space due to their rapid onset and modest duration. Additionally, with more timely clearance from the CSF, the risk of delayed respiratory depression from these drugs is much lower than Morphine. Addition of 10 to 25 mcg Fentanyl to low dose Lignocaine and Bupivacaine for spinal anaesthesia dramatically improves anaesthetic success, improves the quality of intraoperative and early postoperative block without delaying achievement of discharge criteria for ambulatory patients. Aim and **Objective:** Low dose intrathecal Bupivacaine facilitates short perineal surgical procedures, addition of Fentanyl extends analgesia even after wearing off of local anesthetic effect. The objectives of our study are, 1.To reduce the dosage of local anesthetic 2. To reduce the intra operative complications and early recovery. 3.To obtain intense analgesia extending into postoperative period. 4. To adopt such technique in high-risk patients. Methodology: 60 patients of both sexes scheduled for elective perineal surgeries under spinal anaesthesia, in the age group of 20 to 70 years and belonging to American society of Anaesthesiologists (ASA) Physical Status I and II were enrolled for the study. Results: 60 patients of either sex had participated in this study. In 57% of Group I patients the onset of action was within 6-8 minutes. In 97% of Group II the onset of action was in 5 minutes. On comparison of two groups, mean onset of time in Group I was 7 minutes and in Group II, 5 minutes. P<0.001 which is statistically highly significant but clinically not so significant. Inter group, intra-operative HR and BP was analyzed using "Student 't' Test" and the variation in HR and BP was found to be statistically insignificant, HR P = 0.265 and BP P= >0.05 Respectively. In Group I, majority of patients (83%) reached VAS > 6 in 5th hour while in Group II majority of patients (67%) reached VAS > 6 as early as 3rd hour. P value is < 0.001 which is statistically highly significant. Conclusion: Intrathecal Fentanyl in the dose of 25μg along with 1ml(5mg) Bupivacaine 0.5% heavy when compared with 1ml(5mg) Bupivacaine 0.5% heavy, in patients undergoing elective perineal surgeries, Reduces the dosage of local anesthetic required, Intensifies surgical anesthesia, Reduces intraoperative complications and early recovery, Maintains hemodynamic stability, Produces prolonged postoperative analgesia

Key Words: Intrathecal Anaesthesia, Bupivacaine, Fentanyl, Perineal surgeries

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INTRODUCTION

Spinal anesthesia is the most popular and most commonly used technique for lower abdominal surgeries as it is very economical and easy to administer. Postoperative pain control is a major concern because spinal anesthesia using only local anesthetics is associated with relatively short duration of action, and thus early analgesic intervention is needed in the postoperative period Bupivacaine is three to four times more potent than Lignocaine4 and has longer duration of action. Its disadvantages are slow onset of

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action and decreased motor block. Hyperbaric Bupivacaine 0.5% is extensively used in India for spinal anaesthesia. Though duration of action of Bupivacaine is prolonged, it will not produce prolonged post operative analgesia Hence another adjuvant is required for producing prolonged post operative analgesia. The lipophilic opioids are more suitable for intraoperative use in the intrathecal space due to their rapid onset and modest duration. Additionally, with more timely clearance from the CSF, the risk of delayed respiratory depression from these drugs is much lower than Morphine. Addition of 10 to 25 mcg Fentanyl to low dose Lignocaine and Bupivacaine for spinal anaesthesia dramatically improves anaesthetic success, improves the quality of intraoperative and early postoperative block without delaying achievement of discharge criteria for ambulatory patients. 1,2,3 This technique is still limited by dose dependent pruritus, nausea and urinary retention. Nevertheless, Fentanyl remains one of the most useful analgesic adjuvants for spinal anaesthesia. This study is designed to quantitatively examine the effects of adding Fentanyl to hyperbaric Bupivacaine for spinal anaesthesia on duration of surgery and recovery of sensory and motor block and postoperative analgesia for perineal surgeries.

MATERIALS AND METHODS

The study was conducted by Department of Anaesthesia, Maharajahs Institute of medical sciences, Andhra Pradesh, India. It was an Observational cross sectional study. The study protocol was approved by Institutional ethics committee and the study period was 2 years. A total of 60 patients of both sexes scheduled for elective perineal surgeries under spinal anaesthesia, in the age group of 20 to 70 years and belonging to American society of Anaesthesiologists (ASA) Physical Status I and II were enrolled for the study. The enrolled 60 patients were randomized to one of the two groups of equal sized prospective, comparative study group using an open protocol design Group I 30 patients received Inj 0.5% hyperbaric Bupivacaine 5mg with Inj. Fentanyl 25 µg. The mixture was prepared freshly at time of procedure, by anesthetist and Group II 30 patients received Inj 0.5% hyperbaric Bupivacaine of 5mg. Routine pre-anesthetic checkup of all the patients was done to exclude coexisting medical conditions and to assess airway and spine. Routine investigations like hemoglobin%, blood group and typing, urine examination etc., were done.Adult patients belonging to ASA grade I and II were scheduled for elective perineal surgeries and the Exclusion criteria was ASA III, IV and V patients, Age <20 and >70 year, Pregnant females, Body weight more than 100 kg, Height less than 150 cm, Patients using alpha 2 receptor antagonists, calcium channel blockers and Angiotensin

convertase enzyme inhibitor, Heart block/Dysrhythmia by ECG, Contraindication to spinal anesthesia (patient refusal, allergic to drug, coagulation disorder, infection at puncture site, increased intracranial tension and hypotension), The use of any opioid or sedative in the week prior to surgery and Patients with psychiatric illness and neurologic disease. Standard pre operative procedure was done and All safety measures were taken for cardiovascular and pulmonary resuscitation and the Monitors were set. With the patient in sitting position the skin over the back was prepared with iodine containing sterilizing solution, spirit and draped with a sterile towel. The procedure was done under full sterile precautions, including gown, mask and gloves. As per protocol the interspace chosen was L3-L4. If the attempt at this level failed the L2-3 level was the next choice. A 25G Quincke spinal needle was introduced into the L2 – L3 or L3 – L4 intervertebral space gently in the midline until it reached the subarachnoid space. The position of the needle in the subarachnoid space was confirmed by dripping of cerebrospinal fluid through the needle freely. After aspirating 0.2ml of cerebrospinal fluid into the syringe, the respective drug was injected into the subarachnoid space slowly at the rate of 0.25ml/sec. with the bevel cephalad. The needle was withdrawn and the patient turned supine 3min after injection. 100% oxygen via face mask (at the rate of 4 L/min) was administered.

The following parameters were observed and recorded.

- 1. H.R, B.P and SpO2 every 5 min from beginning of the procedure till the end of surgery.
- 2. Level of sensory analgesia defined as loss of sensation to pin-prick, done with help of hypodermic needle at every 5 min interval for 30mins.
- 3. Intensity of motor blockade was assessed by Bromage scale
- 4. Intra operatively patients were sedated with Inj. Midazolam 1mg IV and additional analgesic of supplemented whenever necessary.
- 5. Side effects like hypotension, bradycardia, giddiness, nausea, vomiting, pruritus, shivering etc. noted, and appropriate therapeutic measures taken to correct it.
- 6. Postoperatively patients were monitored vital parameters for every 15 minutes in recovery room and every ½ hourly in the ward till they required rescue analgesic agent. Any complications and time of voiding were noted down.
- 7. Pain was assessed using "Visual Analogue Scale" advocated by Revill and Robinson in 1976. It is linear scale, consists of 10 cm line anchored at one end by a label such as "No pain"

and other end by "Worst pain imaginable". Patient simply marks the line to indicate the pain intensity. Supplemental analgesia was given for visual analogue score of more than 6. Time of supplemental analgesia was note

8. Following recovery parameters were observed a)Sensory level - Two dermatomal regression

time in (min) b)Motor level-Assessed by Bromage scale and c)Time of voiding of urine in minutes

The collected data analysed after the end of the study and statistical analysis was done with the help of Statistical Package for Social Sciences (SPSS).

RESULTS

Table 1: AGE DISTRIBUTION

Tuble 1: AGE DISTRIBUTION					
	Gr	Group I		oup II	
Age in years	No of pts	No of pts Percentage		Percentage	
20-30	9	30%	10	33%	
31-40	7	23%	9	30%	
41-50	10	33%	5	17%	
51-60	2	7%	3	10%	
61-70	2	7%	3	10%	
Total	30	100%	30	100%	

P value > 0.05 Not Significant

Table No. 1 shows age distribution in each group. The patients who took part in this project were in the age group of 20 to 70 years. On statistical comparison, P value is found to be > 0.05. Hence the two groups were comparable

Table 2: SEX DISTRIBUTION

	Table 21 SEX BISTRIBOTION						
Sex	G	Group I		Group II			
	No. of pts	Percentage	No. of pts	Percentage			
Male	22	73%	25	83%			
Female	8	27%	5	17%			
Total	30	100%	30	100%			

P>0.05 Not Significant

Table 2 shows sex distribution of both the groups. 60 patients of either sex had participated in this study. Both groups has predominantly male patients 73% in Group I and 83% in Group II.

Table 3: HIGHEST LEVEL OF SENSORY BLOCK

Group I		рl	Group II			
Sensory level —	No. of pts	Percentage	No. of pts	Percentage		
T12	3	10%	0	0%		
L1	20	67%	15	50%		
L4-5	7	23%	15	50%		
Total	30	100%	30	100%		

Table 3 shows level of sensory blockade achieved in both groups. Sensory level L1 was seen in most of the patients (67% in Group I) and 50% in Group II, this was found to be comparable between the two groups. (P > 0.05)

As there was no paralysis observed and Bromage scalegrade was O in all patients, Motor blockade was assessed by anal sphincter relaxation and relaxation was adequate in all patients

TABLE 4: ONSET OF ACTION IN MINUTES

Onset Action Time	Group I			
	No of pts	Percentage	No of pts	Percentage
3-5 min	10	33%	29	97%
6-8	17	57%	1	3%
9-10	3	10%	0	0%
Total	30	100%	30	100%

Table 4 shows onset of action in minutes of both groups. In 57% of Group I patients the onset of action was within 6-8 minutes. In 97% of Group II the onset of action was in 5 minutes. comparison of two groups, mean onset of time in Group I was 7 minutes and in Group II, 5 minutes. P < 0.001 which is statistically highly significant but clinically not so significant.

Table 5: TYPES OF SURGERIES

Surgary	Group I		Group II	
Surgery	No of pts	Percentage	No of pts	Percentage
Haemorrhoidectomy	12	40	14	47
Lateral anal sphincterotomly	9	30	10	33
Perineal abscess landD	3	10	0	0
Fistulectomy	6	20	6	20
Total	30	100	30	100

Table 5 shows the types of surgeries performed in our study. Haemorrhoidectomy and Lateral anal sphinterotomy were the commonest surgeries in both the groups.

Table 6: DURATION OF SURGERY

Direction of congony	Grou	Group I		Group I	
Duration of surgery	No of pts	Percentage	No of pts	Percentage	
30-45	18	60	26	86	
46-60	8	27	2	7	
61-75	4	13	2	7	
Total	30	100	30	100	

Table 6 shows the duration of surgeries in minutes of both the groups and it was found that most of the surgeries were done within 30-45 minutes.

INTRA OPERATIVE PARAMETERS

1. **Heart Rate:** Intra group, intra operative HR was analyzed using "Anova test" and the variation in HR was found to be statistically not significant. (Group I, P = 0.246 and Group II, P = 0.862)

Table 7: MEAN HEART RATE						
Intra Operative -	Group	o I	Group	o II	P Value	Remarks
ilitra Operative –	Means	SD	Mean	SD	P value	Remarks
Heart Rate/min	82.24	<u>+</u> 24.40	86.52	<u>+</u> 10.50	>0.05	N.S

Table 7 shows mean HR per minute in both groups. Inter group, intra-operative HR was analyzed using "Student 't' Test" and the variation in HR was found to be statistically insignificant, P = 0.265.

INTRA OPERATIVE SYSTOLIC BLOOD PRESSURE

Intra group, intra operative BP was analyzed using "Anova test" and the variation in BP was found to be statistically not significant. (Group I, P = 0.881 and Group II, P = 0.805) when statistically compared within each group there was no significant difference in the systolic BP.

Table 8: MEAN SYSTOLIC BLOOD PRESSURE

Group	ρl	Grou	Group II P VALUE REM		REMARKS
Mean	SD	Mean	SD	— P VALUE	KEIVIAKKS
110.80	<u>+</u> 10.50	112.32	<u>+</u> 8.45	>0.05	NS

Table 8 shows mean systolic Blood Pressure in both groups. Inter group, intra operative BP was analyzed using "Student 't' Test" and the variation in BP was found to be statistically insignificant P > 0.05

Table 9: Recovery Parameter

		.,			
Recovery	Group I		Group II		
Parameter	Mean SD	N	/lean SD	Р	Remark
2 dermatomal regression time (min.)	83.57 <u>+</u> 8.26	67.83	<u>+</u> 7.79	<0.001	HS
Sensory recovery time (min.)	115 <u>+</u> 28.48	100.9	<u>+</u> 6.38	< 0.001	HS
Time to voiding (min.)	381.63 <u>+</u> 29.49	255.46	<u>+</u> 28.86	< 0.001	HS

Table 9 shows recovery parameters of both groups. Sensory two dermatomal regression time was 83.5 min. in Group I and 67 min. in Group II which is statistically highly significant. Sensory recovery time was 115 min. in Group I and 100 min. in Group II which is statistically highly significant. The time for voiding was 381 min. in Group I and 255 min. in Group II statistically highly significant.

Table 10: TIME OF ONSET OF PAIN AS ASSESSED BY VAS > 6

VAS score		Group I		Group II
VAS SCORE	No. of pts	Percentage	No. of pts	Percentage
1 st hr	0	0	0	0
2 nd hr	0	0	0	0
3 rd hr	0	0	20	67
4 th hr	5	17	9	33
5 th hr	25	83	0	0
Total	30	100	30	100

Table 10 shows the time of onset of pain in both groups. In Group I, majority of patients (83%) reached VAS > 6 in 5th hour while in Group II majority of patients (67%) reached VAS > 6 as early as 3rd hour. P value is < 0.001 which is statistically highly significant.

Table 11: TIME FOR RESCUE ANALGESIA					
Group I	Group II	P Value	Remarks		
Mean SD	Mean SD				
245.769 + 20.1	143.83 + 18	< 0.001	HS		

Table 11 shows time for rescue analgesia in both the groups. Patients in Group I required rescue analgesia at mean time of 245 min. while in Group II patients required rescue analgesia as early as 143 minutes.

Table 12: INTRA OPERATIVE ANALGESIA REQUIREMENS

Group	Total No of pts		No of pts requiring intra op. analgesia		No of pts notrequiring intra op. analgesia	
		No of Pts	Percentage	No of Pts	Percentage	
Group I	30	0	0%	30	100%	
Group II	30	3	10	27	90%	

Table 12 shows intra operative analgesia requirement of both the groups. Analgesia was adequate in all patients in Group I, and 10% of Group II patients required intra operative supplementary analgesia which is statistically significant.

Table 13: POST OPERATIVE COMPLICATIONS

Complications	Group I		Group II	
	No of pts	Percentage	No of pts	Percentage
Pruritus	5	17%	0	0%
Nausea and Vomiting	1	3%	0	0%
No of complications	24	80%	30	100%
Total	30	100%	30	100%

Table 13 shows post operative complication observed in both groups. In Group I , pruritus was most common complication (17%) followed by Nausea and Vomiting (3%). On statistical analysis the incidence of pruritus was significant. P < 0.05.

DISCUSSION

Subarachnoid block is commonest anesthetic technique for perineal surgeries because of its simplicity, rapid onset of action and intense analgesia. Perineal surgeries demand low level of SAB, thereby intraoperative complications of SAB are also reduced. In our Present study, Group I received 0.5% heavy hyperbaric Bupvacaine 5mg with Fentanyl 25µg and +Group II received 0.5% heavy hyperbaric Bupivacaine 5mg, injected ntrathecally to the patients undergoing perineal surgeries. SAB was performed in sitting position. In our study, the mean time of onset of action was 7 minutes in Group I and in Group II, 5 minutes. This variation in onset of action is clinically insignificant though statistically significant. Neerja Bharti *et al*⁴., in their study

concluded that the onset times and the duration of motor blockade were comparable among 3 groups while the time to sensory block regression was longer in Bupivacaine-Fentanyl group as compared to Bupivacaine group (p< 0.001). The duration of postop analgesia was significantly prolonged in the Bupivacaine-Fentanyl group. The study result is comparable to our study. Mehtap Honca *et al*⁵, in their study concluded that addition of Fentanyl intrathecally provided good quality spinal anesthesia in anorectal surgery without affecting the motor functions and hemodynamic stability. It increased duration of sensory analgesia with longer first analgesic requirement time without prolonging time to void or intensifying the motor blockade. Their results are found comparable to our study. Otokwala *et al*⁶, have

found out that the combination of Bupivacaine with Fentanyl provided much more prolonged pain relief, the results of which are very much consistent and comparable to our study Gurbet et al, have concluded that 25 µg intrathecal Fentanyl added to low dose Bupivacaine prolonged the duration of sensory spinal block and reduced the analgesic requirement during the early postoperative period without increasing the incidence of opioid related side-effects, except pruritus, or delaying hospital discharge in patients undergoing ambulatory surgery. In our study, rescue analgesia was required after 245 minutes in the Fentanyl-Bupivacaine group compared to 143 minutes in the Bupivacaine group. These results are comparable to the studies done by Mehtap Honca et al⁵,Otokwala et al⁶, Gurbet et al⁷. Respiratory depression is a known complication of spinal opioids; this may be problematic with higher doses. In the present study, however, there were no clinical manifestations of respiratory depression with a Fentanyl dose of 25 µg. Urinary retention is a significant side effect of hydrophilic spinal opioids, however lipophilic opioids such as Fentanyl appear to have a more favourable urinary profile as evident by no increase in time to first void in our study Most of the patients in both groups achieved upper limit of sensory blockade at level of L1 which was adequate to perform the surgery. Kristiina et al8, evaluated effects of 25µg of Fentanyl with Bupivacaine 5mg and achieved the sensory level up to T7. In their study, the final volume of intrathecal injection was adjusted to 2.5ml with sterile distilled water. This difference in volume is probably responsible for high level of sensory blockade in their study. All our patients in both groups were able to lift the legs and Bromage scale grade was O, hence we assessed motor blockade by anal sphincter relaxation. Kristiina et al8 in their study found no motor blockade after administration of intrathecal Bupivacaine 5 mg with 25 µg Fentanyl .Thus our study result are consistent with above study. The cardiovascular profile of our patients was found to be remarkably stable throughout the intraoperative period. In Group I and Group II the mean systolic BP was comparable. Similarly there was not much of a difference in the HR between the two groups and mean HR of both group were comparable. Catherin O. Hunt et al9., evaluated the effect of different doses of intrathecal Fentanyl with Bupivacaine 10 mg and found no significant changes in hemodynamic status. H. Singh et al^{10} , in their study administered Fentanyl 25 µg with Bupivacaine 13.5 mg in patients undergoing urological procedures. They observed that cardiovascular profile of their patients were stable and hemodynamic stability maintained. Our study results were similar to above studies done by Catherin O. Hunt et al 9 ., H. Singh et

al10., In our study, duration of surgery was near normal in both the groups as most of the surgeries were done within 30-45 minutes. Kristiina S et al8., in their study found no incidence of bradycardia during intraoperative period. Their finding correlates with our study results. In our study, we found that the time for two segmental regression was prolonged in Fentanyl group, 83 minutes when compared to 67 minutes in Group II. This indicates that Fentanyl increases intensity of sensory blockade and also prolongs its duration. This is significant both clinically and statistically. H. Singh et al¹⁰., and Ben. David et al⁹ in their study concluded that addition of 25 ug of Fentanyl to Bupivacaine provided an enhancement and increased duration of sensory analogesia without intensifying motor blockade. Our study results were similar to the above studies. The sensory recovery time after SAB was prolonged in Fentanyl group 115 min compared to 100 min in Group II, which is highly significant. Ben. David et al9 ,and H. Singh et al10, in their studies observed that total sensory recovery time was prolonged up to 140 minutes and 146 minutes in Fentanyl groups. These results were consistent with our study results. It is essential to have bladder sensation for patient to void urine. Whenever there is delay in sensory regression, correlating delay in voiding is also observed. In our study Group I patients took longer duration to void. Mean voiding being 380 minutes in Group I where as in Group II mean voiding time was of 255 minutes. It was both clinically and statistically significant. Though voiding time was delayed by more than an hour none of required catheterization or experienced discomfort due to bladder distention. A.Gupta et al¹¹, in their study found that 17% of patients needed to be catherized and 2% of patients had retained catheter over night.In study done by A.M Korhonen¹²,none of patients required catheterization and took almost 3 hours to void. The study result correlated with our study. Respiratory depression is one of the major side effect of intrathecal opioid. None of our patients experienced respiratory depression and maintained SpO2 of 99-100% in the both groups. Varrassi et al13, studied the ventilatory effects of different dosages of intrathecal Fentanyl on elderly patients and concluded that the patients who received 50 μg Fentanyl had respiratory depression and recommended 25 µg as only dose with out respiratory depression. Pruritus is a frequent complication (49-100%) of intrathecal Fentanyl. In our study, in Group I, pruritus was seen in 17% of patient during postoperative period. It was mild and self-limiting. Buvanendran et al14, found that addition of small dose of Bupivacaine to intrathecal Fentanyl reduces the incidence of pruritus from 95% to 36%, on all parts of body except the face. The mechanism by which the combination of local anesthetic with opioid

may result in a reduced incidence of pruritus may be either due to neuronal blockade or direct modulation of opioid receptors, probably inhibiting receptor action and increasing opioid binding to delta and kappa receptors. Kristiina S. K. et al⁸, in their study observed pruritus in 22.5% of patients with Fentanyl group. It was mild and well tolerated. Our study results were similar to above study. In all our patients in Group-I the analgesia lasted as long as 245+20 minutes and rescue analgesia was delayed when compared to Group-II, where analgesia lasted up to 130+ 20 minutes and the requirement of analgesia was as early as 143 minutes. H. Singh et al¹⁰.,in their study concluded that intrathecal Fentanyl reduced requirement of analgesic in early post operative period and the time for first analgesic dose requirement was prolonged. Catherin O. Hunt et al⁹, and Varrassi et al¹³ found that intrathecal Fentanyl increases mean duration of postoperative analgesia. Our results were similar to above studies. Thus 25 µg of Fentanyl along with low dose of Bupivacaine, 5 mg, provides good surgical anesthesia for perineal surgeries and provides postoperative analgesia without any major side effects.

CONCLUSION

With the present study, we can conclude that intrathecal Fentanyl acts synergistically to potentiate Bupivacaine induced sensory spinal blockade. Fentanyl added to 0.5% hyperbaric Bupivacaine intrathecally prolongs the duration of sensory block and extends analgesia into early post operative period

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