



Original Research Article

Evaluation of low dose hyperbaric bupivacaine with or without fentanyl in perianal surgeries: A prospective randomized double blind trial

Arti Kuldeep¹, Lalit Kumar Raiger², Swati Sharma¹, Krishan Gopal Jangir^{1,*}

¹Dept. of Anaesthesia, Pacific Medical College and Hospital, Udaipur, Rajasthan, India

²Dept. of Anaesthesia, RNT Medical College attached to MB Hospital, Udaipur, Rajasthan, India



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ABSTRACT

Background: Spinal anaesthesia should be ideal for perianal surgeries due to its quick onset, reliable anaesthesia with minimal supplies making it cost-effective technique with rapid turnover time.

Materials and Methods: 90 patients of ASA grade I-II scheduled for perianal surgeries divided into three groups of 30 each according to intrathecal dose of local anaesthetic: Group LB (Low dose bupivacaine): 0.6 ml of 0.5% hyperbaric bupivacaine (3mg), Group ULBF (ultralow dose bupivacaine plus fentanyl): 0.4 ml of 0.5% hyperbaric bupivacaine (2 mg) + 0.2 ml of fentanyl (10 µg) and Group ULB (ultra low dose of bupivacaine): 0.4 ml of 0.5% hyperbaric bupivacaine (2 mg) + 0.2 ml of normal saline. Three groups were compared in terms of success of block, time to first rescue analgesic from time of block, total rescue analgesic (tramadol) needed in 8 hours since time of block, visual analogue score (VAS) and patient satisfaction score.

Results: Successful saddle block was achieved in all patients in Group ULBF, 27 patients in Group LB and none in Group ULB. Group ULBF showed significantly lower mean VAS score when compared to Group ULB and Group LB, and Group LB when compared to Group ULB. Thus the group using fentanyl intrathecally had significantly lesser pain, so the requirement for the first dose of rescue analgesic was significantly earlier in Group ULB and delayed in Group ULBF. Patient satisfaction score was significantly higher in Group ULBF as compared to Group LB and Group ULB and in Group LB as compared to Group ULB.

Conclusion: Use of hyperbaric bupivacaine in dose of 3 mg and 2 mg with fentanyl (10 µg) in saddle block are an effective method of achieving successful surgical anaesthesia in patients undergoing perianal surgeries. Hyperbaric bupivacaine (2mg) with fentanyl (10µg) is better than other in providing postoperative analgesia.

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1. Introduction

Outpatient or ambulatory surgery is well accepted worldwide due to a number of benefits for the patient, hospital and community. An anaesthetic technique with a rapid and smooth onset of action, short recovery time without any side effects should be ideal. It should provide intraoperative analgesia and good surgical condition.¹ Ambulatory anorectal surgeries can be performed under general anaesthesia or central neuraxial block. Quick

onset, cost-effectiveness and shorter hospital stay with spinal anaesthesia makes it ideal for ambulatory surgery. Central neuraxial blockade provide added benefits of more alertness, less nauseated and more comfortable recovery to the patients when compared with those receiving general anaesthesia.²

In day case surgery, lidocaine was a popular local anesthetic for spinal anesthesia, but incidences of transient neurological symptoms (TNS)³ were highly reported for patients having surgery in the lithotomy position makes it unfeasible in anorectal day case surgeries.⁴ Bupivacaine has

* Corresponding author.

E-mail address: kg.jangir@gmail.com (K. G. Jangir).

low risk of TNS, but it is unsuitable for day case surgery due to its long duration of action.⁵ To avoid unusual long duration of action of bupivacaine, its use in low doses with intrathecal opioids can provide successful anesthesia and analgesia has been reported in different studies.^{3,6,7}

Selective spinal anaesthesia (SSA) has been providing sufficiently effective blockade with fewer side effects. It can be achieved with modification in local anaesthetic dose and by adding adjuvants.^{8,9} Intrathecal administration of a combination of opioids and local anaesthetics produces a well-documented synergistic effect without prolonged motor nerve block or delayed discharge.^{10,11} Intrathecal administration of fentanyl produces selective spinal analgesia (SSA) by acting on opioid receptors at substantia gelatinosa of dorsal horn of spinal cord.¹²

Hence, this study was carried out to assess the efficacy of ultra-low dose 0.5% hyperbaric bupivacaine 2 mg with low dose of fentanyl (10µg) versus 2 mg and 3mg of 0.5% hyperbaric bupivacaine for anorectal surgeries.

2. Materials and Methods

After obtaining institutional ethical committee approval and written informed consent, a randomised, prospective, double blinded study was conducted on ninety patients of ASA grade I-II, age between 18 to 65 years, of both sex, scheduled for perianal surgeries (fistula in ano, fissure in ano, haemorrhoids) on ambulatory basis after getting a thorough pre anaesthetic check-up done atleast 24 hours before surgery.

2.1. Exclusion criteria

Contraindications to spinal anaesthesia (history of allergy to the study drugs, coagulation disorders, patients on anticoagulants), uncontrolled hypertension, diabetes, vertebral deformities, neurological disease, uncooperative patient and patient refusal.

2.2. Randomization and Group allocation

Patients were randomized by opaque sealed envelope technique into three groups of 30 patients each according to intrathecal dose of local anaesthetic as follows: Group LB (Low dose bupivacaine): 0.6 ml of 0.5% hyperbaric bupivacaine (3mg), Group ULBF (ultra-low dose bupivacaine plus fentanyl): 0.4 ml of 0.5% hyperbaric bupivacaine (2 mg) + 0.2 ml of fentanyl (10 µg) and Group ULB (ultra-low dose of bupivacaine): 0.4ml of 0.5% hyperbaric bupivacaine (2 mg) + 0.2 ml of normal saline. So, the net volume of intrathecal drug was 0.6 ml in all the three groups.

2.3. Blindness of the study

An anaesthesiologist, not involved in the study, prepared the spinal injection solution. The anaesthesiologist performing the block was blind to the solution administered and to the postoperative observations. All the data were recorded by one separate anaesthesiologist who was neither involved in drug preparation nor in performance of the block. Surgeon and patient both were not aware of group allocation.

2.4. Anaesthetic technique

On arrival in the operation theatre, routine monitoring was attached and baseline heart rate, NIBP, SpO₂ and respiratory rate were recorded. Intravenous line was secured with an 18 G peripheral intravenous cannula and preloading was done with 250 ml of 0.9% saline. Lumbar puncture was performed in sitting position under strict aseptic precautions between L₄ -L₅ or L₅-S₁ interspace with 25 gauge Quincke spinal needle by median route. After confirming free flow of CSF, the study drug (0.6ml) was injected with a 2ml syringe over 10 seconds duration. After that patients were kept in sitting position for 10 min (saddle block) and then placed in lithotomy position.

2.5. Data recording

Demographic data like age, sex, and weight of the patients; and surgical data like diagnosis, type of surgery, time of start of surgery and duration of surgery were recorded. Success of block.¹³ Assessed by recording sensory loss to pin prick in perianal region by using 24 Gauge hypodermic needle and was categorized as: Grade a - Complete absence of sensation, Grade B - Sensation of touch/ movement only, Grade C - Mild discomfort and Grade D - Discomfort recognised as pain. Another method was assessment of loss of sensation too cold in perianal region by using spirit swab and categorised as sensation “present” or “absent”. With the above assessment patients having sensory block of Grade C or D (according to pin prick sensation) was considered as ‘failure’ of anaesthesia and was given general anaesthesia. For that, patients were premedicated with inj. glycopyrrolate 0.2 mg and inj. midazolam 1mg intravenously and for induction inj. ketamine (1.5-2 mg/kg) intravenously slowly and inj. propofol @100-300µg/kg/min infusion; along with O₂ and N₂O (40:60 ratio) with the help of Bain’s breathing circuit using bag and mask were given. Grade A and Grade B were considered as ‘acceptable block’ (successful) and surgeon was allowed to start surgery. Degree of motor block: assessed by Bromage scale:¹³ 0 - Full flexion of knees and feet (no motor block), 1 - Just able to flex knees and full flexion of feet, 2 - Unable to flex knees, but some flexion of feet possible and 3 - Unable to move legs or feet (complete motor block). Vital parameters like: HR, SBP, DBP, Respiratory rate, SpO₂ were recorded at 0 min (immediately after performing saddle block), 5 min, 15 min,

30 min, 60 min, 4 hrs and 8 hrs. Pain score: Post-operative pain in the perianal region was assessed by Visual Analogue Scale (VAS score) of 0 – 10 cm; considering '0' as no pain and '10' as worst possible pain at 0 hour (end of surgery); 1 hour, 4 hour and 8 hour post operatively.

2.6. Rescue Analgesia

Whenever patient complained of pain or the VAS score was ≥ 3 , the rescue analgesic in the form of injection tramadol 50 mg intravenously was given. Time to first rescue analgesic and total rescue analgesic requirement in the first 8 hours were recorded. Other data: First time of voiding urine post operatively and time of ambulation were recorded. Complaint/complication: Headache, nausea, vomiting, pruritis, hypotension (systolic BP < 90 mmHg), bradycardia (pulse rate < 50 min), urinary retention, etc. were recorded. Patient satisfaction score: assessed after 8 hour and was graded as 0 – poor; 1- fair; 2 – good; 3 – excellent.¹⁴

2.7. Statistical analysis

Data were entered using MS Excel and Epi Info 6 System. Based on an effect size of 0.45% with a Type 1 (α) error of < 0.05 and a Type 2 (β) error (power) of 80%, we concluded that a minimum of 75 patients were required for the study. To accommodate for dropouts, we included 90 patients distributed equally in 3 groups. The data related to patient distribution according to sex, ASA grade, type of surgery, loss of pin prick sensation, loss of cold sensation, success of saddle block, motor blockade and complications were presented as number (percentage) and compared using Pearson Chi square test. Data related to age, weight, duration of surgery, hemodynamic parameters, VAS score, requirement of rescue analgesia and patient satisfaction score were expressed as 'Mean $\pm$ SD' and compared using student 't' test and analysis of variance (ANOVA). Statistic results, $p < 0.05$ was considered as significant.

3. Results

All the three groups were comparable regarding demographic parameters and statistically not significant ($p > 0.05$), (Table 1). Sensory block in the perianal region was assessed 10 min after saddle block using pin prick and loss of sensation to cold. 28 patients in Group LB and all 30 patients in Group ULBF showed acceptable sensory loss (grade A and B). 2 patients in Group LB were considered as unacceptable (grade C and D). 19 patients in Group LB and 18 patients in Group ULBF showed sensory loss to cold, whereas none of the patient in Group ULB showed sensory block to pin prick and cold. Acceptable sensory block to pin prick and cold were achieved by significantly higher number of patients in Group ULBF and Group LB, compared to none in Group ULB which was statistically

significant, $p < 0.001$. Group LB and Group ULBF were statistically comparable, $p = 0.14$ and $p = 0.79$ respectively. [Group ULBF $\approx$ Group LB $>$ Group ULB]. (Figure 1, Table 2)

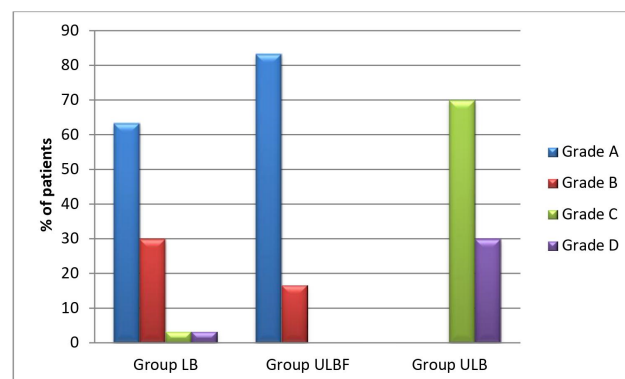


Fig. 1: Comparison of patients according to response to pin sensation in the perianal 10 min after performing block

Successful saddle block was achieved in 27 patients in Group LB and all patients in Group ULBF. All 30 patients in Group ULB required institution of general anaesthesia before the start of surgery, implicating failure of saddle block. The difference was statistically significant, ($p < 0.001$) [Group ULBF $\approx$ Group LB $>$ Group ULB]. (Table 2)

Bromage Score in all patients of the three groups was grade '0' as assessed from 10 min after performance of saddle block and upto 8 hours postoperatively; and there was no statistical difference between the three groups ($p > 0.05$).

There was no statistically significant difference in heart rate (HR) among the three groups ($p > 0.05$) at 0 min, 5 min, 60 min and 8 hour. At 15, 30 min and 4 hr HR was significantly higher in group ULB as compared to Group LB and Group ULBF, $p < 0.05$; whereas in Group LB and Group ULBF were statistically comparable, ($p > 0.05$). There was no significant difference in other hemodynamic parameters in the three groups throughout the study, ($p > 0.05$).

Postoperative pain in the perianal region as shown by mean VAS score remained < 4 throughout the study period of 8 hours, indicating acceptable pain control in all the three groups. The mean VAS score was lowest in Group ULBF (0.61 ± 0.42) as compared to Group ULB (1.41 ± 0.62), $p < 0.001$ and Group LB (0.86 ± 0.63), $p < 0.05$; and in Group LB as compared to Group ULB, $p < 0.001$. [Group ULBF $<$ Group LB $<$ Group ULB], (Figure 2) (Table 2). Time to requirement of first analgesic was significantly delayed in Group ULBF as compared to Group LB and Group ULB, $p < 0.001$; and in Group LB as compared to Group ULB, $p < 0.001$. [Group ULB $>$ Group LB $>$ Group ULBF] (Table 3).

The cumulative dose of rescue analgesic was significantly lower in Group ULBF (32 doses) as compared to Group LB (56 doses), $p < 0.001$ and Group ULB

Table 1: Comparison of age, weight, sex, ASA grading, duration of surgery and type of surgery in three groups

	Group LB (n=30)	Group ULBF (n=30)	Group ULB (n=30)	p Value
Age (yrs)	38.50±10.32	41.23±13.62	41.97±12.73	p=0.51
Weight (Kg)	57.60±7.82	56.17±7.85	57.13±7.40	>0.05
Sex n (%)				
Male	22 (73.33%)	21 (70.00%)	23 (76.67%)	>0.05
Female	8 (26.66%)	9 (30.00%)	7 (23.33%)	
ASA Graden (%)				
I	24 (80.00%)	22 (73.33%)	22 (73.33%)	0.66
II	6 (20.00%)	8 (26.66%)	8 (26.66%)	
Duration of surgery (mins)	23.67±6.94	23.17±11.92	23±6.90	p=0.95
Type of surgery n (%)				
Fistulotomy	6 (20.00%)	5 (16.67%)	7 (23.33%)	
Fistulectomy	5 (16.67%)	6 (20.00%)	5 (16.67%)	p=0.80
Haemorrhoidectomy	9 (30.00%)	4 (13.33%)	5 (16.67%)	
Ligation of Haemorrhoids	5 (16.67%)	6 (20.00%)	4 (13.33%)	
Lords Dilatation	5 (16.67%)	9 (30.00%)	9 (30.00%)	

Data are presented as mean ± SD

Table 2: Comparison of success of block, time of ambulation, time to first voiding of urine, mean VAS and patient satisfaction score

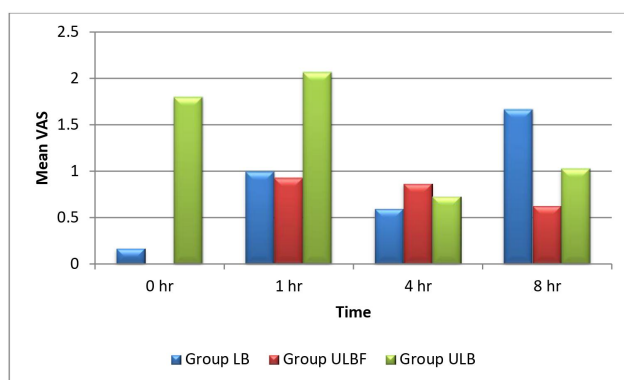
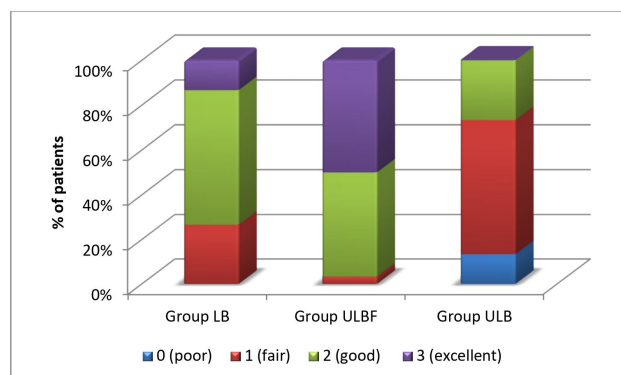
	Group LB(n=30)	Group ULBF (n=30)	Group ULB (n=30)	p Value by 't' test		
				LB/ ULBF	LB/ ULB	ULBF/ ULB
Response to pin prick						
A- Complete absence of sensation	19 (63.33%)	25 (83.33%)	0 (0.00%)	0.14	<0.001	<0.001
B-Sensation of movement/touch only	9 (30.00%)	5 (16.67%)	0 (0.00%)	0.35	0.003	0.061
C-Mild discomfort	1 (3.33%)	0 (0.00%)	21 (70.00%)	0.31	<0.001	<0.001
D-Discomfort requiring analgesic or anaesthetic supplementation	1 (3.33%)	0 (0.00%)	9 (30.00%)	0.31	0.015	0.003
Loss of Sensation to Cold in Perianal Region						
Yes	19 (63.33%)	18 (60.00%)	0 (0%)	0.79	<0.001	<0.001
No	11 (36.66%)	12 (40.00%)	30 (100%)			
Mean VAS±SD	0.86±0.63	0.61±0.42	1.41±0.62	<0.05	<0.001	<0.001
Success of Saddle Block						
Successful (S)	27 (90.00%)	30 (100%)	0 (0%)	<0.001		
Failure (F)	3 (10.00%)	0 (0%)	30 (100%)			
Time of Ambulation(hrs) Mean±SD	4.95±0.56	4.76±0.47	4.70±0.55	0.16	0.08	0.65
Time of Voiding Urine (hrs) Mean±SD	5.37±0.70	5.00±0.61	4.92±0.69		0.48	
Patients Satisfaction Score						
0 (poor)	0	0	4			
1 (fair)	8	1	18			
2 (good)	18	14	8			
3 (excellent)	4	15	0			
Mean ± SD	1.87±0.63	2.47±0.57	1.13±0.63	0.002	0.001	<0.001

VAS = visual analogue score, Data are presented as mean ± SD

Table 3: Comparison of requirement for rescue analgesia in postoperative period

	Group LB (n=30)	Group ULBF (n=30)	Group ULB (n=30)	LB/ ULBF	p value by 't' test LB/ ULB	ULBF/ ULB
No. of Doses in 8 hrs						
0	0	0	0			
1	4 (13.33%)	28 (93.33%)	1 (3.33%)			
2	26 (86.67%)	2 (6.67%)	29 (96.67%)			
Total no. of doses	56	32	59	<0.001	0.325	<0.001
Time of 1st rescue analgesic dose(min)	120.83 ±51.38 ≈2.01 hr	211.63 ±17.72 ≈3.52 hr	41.83 ±24.19 ≈0.69 hr	<0.001	<0.001	<0.001
Mean no. of doses for each patient during 8 hour	1.87±0.35	1.07±0.25	1.97±0.18	<0.001	>0.05	<0.001
Mean dose in mg for each patient during 8 hour	88.33 ±21.51	53.33 ±12.69	98.33 ±9.13	<0.001	>0.05	<0.001

Data are presented as mean ± SD

**Fig. 2:** Comparison of mean VAS score at various time intervals postoperatively in the three groups**Fig. 3:** Comparison of patient satisfaction score

(59 doses), $p < 0.001$. Group LB and Group ULB were comparable, $p = 0.325$. The mean number of doses and the mean dose (in mg) of rescue analgesic for each patient were significantly lower in Group ULBF as compared to Group LB, $p < 0.001$; and Group ULB, $p < 0.001$. Group LB and Group ULB were comparable, $p > 0.05$. [Group ULB ≈ Group LB > Group ULBF] (Table 3).

Postoperatively, the mean time of ambulation and voiding of urine were comparable in all the three groups and statistically not significant ($p > 0.05$), (Table 2). The number of complications were higher in Group ULB (20%) as compared to Group LB (10%) and Group ULBF (6.67%), though it could not reach statistical significance, ($p = 0.262$). 2 patients in Group ULB and 1 patient in Group LB had complained of headache. Nausea was seen in 2 patients in Group ULB, 1 patient in Group LB and 1 patient in Group ULBF which was treated with injection ondansetron 4mg iv. Pruritus was seen in only 1 patient in Group ULBF which was treated with antihistaminics.

The mean patient satisfaction score was significantly higher in Group ULBF as compared to Group LB, ($p < 0.05$) and Group ULB, ($p < 0.001$); and in Group LB as compared to Group ULB, ($p = 0.001$). (Table 2) [Group ULBF > Group LB > Group ULB] (Figure 3)

4. Discussion

Among adult population, 4-5% harbour minor anorectal diseases of which approximately 10% require surgical management.¹⁵ Currently, 90% of anorectal surgeries are performed on an ambulatory basis.¹⁶ Spinal anaesthesia provides the benefits of rapid onset and offset, easy administration, minimal expense for ambulatory surgeries

with minimal side effects and complications.¹⁷ Regional anaesthesia provides preemptive analgesia. Complications of general anaesthesia like sore throat, airway trauma and muscle pain can be avoided with spinal anaesthesia.¹⁸ Spinal anaesthesia provides an alternative approach for patients with comorbidities that predispose them to higher perioperative risk.¹⁹

Analgesic property of subtherapeutic doses of local anesthetics enhances with the simultaneous administration of Intrathecal opioids. So, combining intrathecal opioids with low doses of local anaesthetics will achieve successful spinal anaesthesia which otherwise would be inadequate.^{20,21} Simultaneously low doses of local anaesthetics might shorten the block duration and its recovery without any undesired hemodynamic adverse effects.²²

Intrathecal opioids opens up presynaptic K⁺ channels to inhibit transmitter release and reduces calcium influx which in turns inhibit nociceptive afferent synaptic transmission via A δ and C fibers.²³ Lipophilic opioids, like fentanyl, had shown a better clinical profile with rapid onset of action, moderate duration (1–4 h) and low risk of delayed respiratory depression. The recommended safe effective dose of intrathecal fentanyl is 10–25 μ g. multiple studies had shown that duration of motor blockade did not get prolonged with intrathecal fentanyl.^{24,25} Mysliwy P et al. (2009)²⁶ concluded that 1 ml of 0.5% heavy bupivacaine alone may be insufficient to produce a block suitable for surgery; the addition of fentanyl 10 μ g can enhance the sensory block while leaving motor function relatively unchanged.

In view of low incidence of TNS with bupivacaine and keeping in validation with the previous studies, the present study was conducted with a primary aim of evaluating the efficacy of low dose (3mg) bupivacaine (Group LB), and ultra-low dose (2 mg) bupivacaine with low dose fentanyl (10 μ g) (Group ULBF) or without fentanyl (Group ULB); and a secondary aim to compare the three regimens regarding postoperative pain and satisfaction of the patients.

HR was significantly higher in Group ULB as compared to other groups at 15 min, 30 min and 4 hr interval after the subarachnoid block. This significant rise in HR at 15 min and 30 min was attributed to institution of glycopyrolate and ketamine based general anaesthesia in all cases due to failure of saddle block. However, at 4 hr it was attributed to onset of post-operative pain.

Number of patients with acceptable sensory loss to pin prick and 'loss of cold' sensation in the perianal region were significantly higher in Group LB and Group ULBF. Gurbet A et al. (2008)²⁷ found no significant difference in sensory blockade by using pin prick testing after giving saddle block with 5 mg of 0.5% hyperbaric bupivacaine (Group B) and 2.5 mg of 0.5% hyperbaric bupivacaine with 25 μ g fentanyl (Group BF) for anorectal surgeries. 2 mg of 0.5% hyperbaric

bupivacaine was insufficient to achieve successful saddle block. Thus surgery was started by institution of general anaesthesia in all patients of Group ULB. Carron M et al. (2007)²⁸ concluded that efficacy of bupivacaine is dose dependant. Efficacy is only 20% with 2 mg, near maximal 90% with 3 mg and maximal 100% at doses higher than that. All patients in Group ULBF and 27 patients in Group LB achieved successful saddle block. Thus, the addition of 10 μ g fentanyl to Group ULBF increased the efficacy of 2mg bupivacaine. Ben David et al. (1997)²⁹ demonstrated that the use of 3 ml of 0.17% bupivacaine for spinal blockade is inadequate to provide reliable anaesthesia for surgical arthroscopy but the addition of 10 μ g of fentanyl is sufficient to make it a reliable anaesthetic.

All patients in the present study showed ability to full flexion of knees and feet throughout the study. Mean time of ambulation and voiding of urine were comparable in all three groups. In present study urinary retention was not seen in any of the three groups. Gurbet A et al. (2008)²⁷ found that addition of 25 μ g of fentanyl to ultra-low dose not prolonged the discharge time for anorectal surgery in ambulatory setting.

In the present study, the requirement of rescue analgesic was taken as one of the clinical end points in determining the efficacy of saddle block for postoperative analgesia in all groups. In Group ULBF, overall mean VAS score was significantly lower and there was delayed requirement of first dose of rescue analgesic. The total no. of doses, mean number of doses and the mean dose in mg of rescue analgesic required in 8 hours postoperatively were also significantly lower in Group ULBF as compared to other Groups. Thus in our study it was found that addition of fentanyl to intrathecal bupivacaine significantly prolongs postoperative analgesia with reduced requirement of rescue analgesic. Gurbet A et al (2008)²⁷ demonstrated that 25 μ g intrathecal fentanyl along with ultra-low dose (2.5 mg) bupivacaine provides better spinal anaesthesia and reduces requirement for post-operative analgesics in anorectal outpatients. All three groups had lesser side effects and complications. The most common amongst them were headache, nausea and hallucinations. Pruritus was seen in only 1 patient in Group ULBF. Ben David et al. (1997)²⁹ had shown that pruritus after adding 10 μ g fentanyl was much less prominent.

In our study patient satisfaction score was higher in Group ULBF which was due to the addition of fentanyl that provides better postoperative analgesia. Patient satisfaction was better in Group LB as compare to Group ULB as none of the patient achieved successful saddle block in Group ULB and required more no. of rescue analgesic doses post operatively.

5. Conclusion

The present study concludes that low dose hyperbaric bupivacaine (3 mg) and ultra-low dose bupivacaine (2 mg) with fentanyl (10 µg) in saddle block provide successful surgical anaesthesia for perianal surgeries with shorter discharge time and better patient satisfaction. Addition of 10 µg fentanyl provides better postoperative analgesia with longer first analgesic requirement time. Ultra low dose bupivacaine (2 mg) alone failed to achieve surgical anaesthesia as well as postoperative analgesia in any of the patients and hence we do not recommend this dose in anaesthetic technique for perianal surgeries.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare that there is no conflict of interest.

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Author biography

Arti Kuldeep, Assistant Professor

Lalit Kumar Raiger, Senior Professor

Swati Sharma, Assistant Professor

Krishan Gopal Jangir, Assistant Professor

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