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Original Research Article.

A Comparative Evaluation of Intrathecal Ropivacaine versus Ropivacaine Plus Fentanyl in Ambulatory Perineal Surgery: A Prospective Randomized Double Blind Study

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ABSTRACT

Aim: The aim of the present study was to evaluate intrathecal ropivacaine versus ropivacaine plus fentanyl in ambulatory perineal surgery.

Methods: This randomised, double-blind, prospective study was conducted among 100 patients between age group of 20-70 years undergoing perineal surgeries under spinal anaesthesia in the department of Anaesthesiology and Critical care, Government Medical College and Rajindra Hospital Patiala over the period of 2 years.

Results: In Group A , out of 50 patients 15 were from 15 to 24 years age group, 10 were from 25- 34 years age group, 11 were from 35-44 years age group and in group B, out of 50 patients, 7 were from 15 to 24 years age group, 15 were from 25-34 years age group, 7 were from 35-44 years age group. There were 37 male patients (74.0%) and 13 female patients (26.0) in group A, 42 male patients (84.0) and 8 female patients (16%) in group B. The difference was statistically non-significant in the sex distribution of the patients between the groups. Majority of the patients underwent Fistulectomy in both the groups. The heart rate mean value was measured every 2 min till 10 min and then at an interval of 10 min till 60 min and the difference between both the groups was statistically non-significant. The mean arterial blood pressure was non-significant throughout all time periods.

Conclusion: In this prospective, randomised, comparative, double blind study, we concluded that 0.75%(H) Ropivacaine 9mg provides adequate surgical blockade for perineal surgeries but addition of fentanyl 20mcg fentanyl to intrathecal 0.75%(H) Ropivacaine has added advantage in prolonging the postoperative analgesia, speeding up the onset and increasing the duration of the sensory block without impacting motor block recovery and time taken to unassisted ambulation. Thus, Ropivacaine with fentanyl may be a better choice in comparison to Ropivacaine alone for attaining enhanced recovery after perineal surgeries.

Keywords: Intrathecal Ropivacaine, Ropivacaine, Fentanyl, Ambulatory Perineal Surgery.

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INTRODUCTION

Spinal anaesthesia is popular and commonly used technique for ambulatory perineal surgeries. Spinal anaesthesia provides faster onset and effective motor and sensory blockage. It is simple, easy to perform and has got definite end point.[1] Spinal anaesthesia offers various advantages over general anaesthesia by reducing surgical stress responses, reducing intra-operative blood loss and also by providing analgesia in the early post-operative periods.[2] The advantage of an awake patient, rapid patient turnover and minimal drug cost has made this the method of choice for perineal surgeries.[1]

Spinal or intrathecal anaesthesia has a long history of success due to an increasing number of ambulatory procedures and interventions, for which the ideal spinal anaesthetic would provide rapid and adequate surgical anaesthesia together with early ambulation and ability to void to allow early discharge.[3] For outpatient surgery, an optimal intrathecal agent must induce rapid motor and sensory blockade, early return of cognition, minimal PONV(post-operative nausea and vomiting), are supposed to be more cost effective as compared to inpatient surgeries and also had less chance of iatrogenic infection and thromboembolism event due to early mobilisation, most importantly should have less stress and provide good comfort by early return to normal life to patients. In the past, to ensure a strong blockade followed by swift recovery, lidocaine was selected as the optimal agent in this case, yet the detection of a high prevalence of Cauda equine syndrome and neurologic symptoms of transient nature and has effectively excluded it from use.[4,5] Ropivacaine is a long-acting, amide local anaesthetic developed and promoted as a potential replacement

for Bupivacaine, citing reduced cardio- toxicity and neurotoxicity.[6] Ropivacaine is being extensively used for peripheral nerve blockade, epidural analgesia, and labor analgesia. In the European Union in February 2004, approval was granted for new route of application, the intrathecal use of Ropivacaine.[3] Ropivacaine is a enantiomerically pure (S-enantiomer) amide local anaesthetic. The influx of sodium ions is reversibly inhibited, resulting in the blockade of nerve impulse conduction.[7] This action is strengthened by dose- dependent potassium channel inhibition. Compared to Bupivacaine, Ropivacaine is less lipophilic and making it less likely to penetrate large, myelinated motor fibres; therefore, Ropivacaine has more selective effect on A δ and C fibres responsible for pain transmission but preserving motor function by minimizing effects on A fibres. The concentration in the bloodstream of Ropivacaine depends on the following factors, i.e the administered dose, patient's hemodynamics and the vascular characteristic of the site.

Ropivacaine has a similar property to Bupivacaine with better safety profile. But the drawback is that postoperative analgesia duration is less than that of bupivacaine. This can be overcome by adding various adjuvant to Ropivacaine for spinal anaesthesia without compromising it's favourable characteristics like early mobilisation and early voiding.[5] To maintain the advantage of an intrathecal anaesthetic agent while improving intra and post-operative analgesia, an analgesic adjuvant can be used.[8,9] Variety of adjuvant drugs are added intrathecally to facilitate post-operative analgesia such as opioids, ketamine, clonidine, dexmedetomidine. However, opioid because of their motor sparing property are popular than others for the same thereby improving the quality and success of anaesthesia.[5,10] Various studies have been conducted and have shown that intrathecal opioids can greatly enhance analgesia from sub-therapeutic doses of local anaesthetic.[5,9]

The aim of the present study was to evaluate intrathecal ropivacaine versus ropivacaine plus fentanyl in ambulatory perineal surgery.

MATERIALS AND METHODS

This randomised, double-blind, prospective study was conducted among 100 patients between age group of 20-70 years undergoing perineal surgeries under spinal anaesthesia in the department of Anaesthesiology and Critical care, Government Medical College and Rajindra Hospital Patiala over the period of 2 years.

Inclusion Criteria

1. ASA physical status group I and II.
2. Patients planned for same day perineal procedures.
3. Both males and females were included
4. Patients between age group of 20-70 years.
5. Normal coagulation profile.
6. Patients who give consent for the surgery.

Exclusion Criteria

1. Patients with known contraindication of spinal anaesthesia such as abnormal coagulation profiles, skin infection, severe cardiac disease, abnormality of spine, neurological disorder etc.
2. Patients with a history of allergic reactions to amide type local anaesthetics.
3. Pregnancy.
4. Record of substance misuse.

Participants enrolled in this study were divided in a random manner into two groups by computer generated random numbers as follows:

GROUP A: Patients were given 1.2 ml of 0.75% hyperbaric of injection Ropivacaine(9mg).

GROUP B: Patients were given 0.8ml of 0.75% hyperbaric of injection Ropivacaine (6 mg) together with 0.4ml of injection fentanyl (20mcg).

The study was blinded properly wherein anaesthesiologist who prepared the drug and who performed the procedure was blinded of the group assigned. The data was recorded and analysed by other anaesthesiologist. Surgeon and patients were also unaware of allocation.

Anaesthetic Procedure

A signed informed consent was acquired from each patient after explaining the technique prior to their inclusion in this study in their own vernacular language. During pre-anaesthetic check up, a detailed history was taken. A thorough physical and systemic examination was done for all patients to detect any evidence of systemic disease and to determine the suitability of patient for spinal anaesthesia.

VAS (Visual Analogue Scale)

Patients were familiarised with the visual analogue scale (VAS) (0 – No pain, 10 - Worst pain) one day before surgery and asked to grade their pain on this scale in postoperative period. VAS is generally depicted as a 100 mm horizontal line in length. Patient marked their intensity of pain on the line which reflects their view of the current condition.

Patients were advised overnight fasting and tab Ranitidine 150 mg and Tab lorazepam 1 mg orally was given as pre-medications at 6 am in the morning at the surgical date with a sip of water. In the operation room, intravenous (i.v) was secured with 18 gauge cannula. A preload of 500 ml of Ringer lactate was administered to the patients. Noninvasive blood pressure monitoring, pulse oximetry measurement of blood oxygen saturation, and electrocardiography was done in each and every patient.

Under all aseptic precautions, cleaning and draping of back area was done in sitting position. L3 and L4 space were identified. lumbar puncture was done using 25/26 gauge quincke's spinal needle. Sub-arachnoid space was identified by clear and free passage of cerebrospinal fluid. Total volume of 1.2 ml of 0.75% of injection Ropivacaine (9 mg) was administered in patients of group A and 0.8ml of 0.75% of injection Ropivacaine(6mg) along with 0.4 ml of injection fentanyl (20mcg) was given in patients of group B. Patients were escorted to supine position after 5min and were given supplemental oxygen via venturi mask.

Sensory Block- Time elapsed until sensory block developed, maximum sensory level, time to reach highest sensory level was assessed by pin prick sensation. Sensory level was assessed every minute till maximum sensory level reached

Motor Block- Motor neural blockade was assessed by using the Bromage scale:

Motor block was assessed every 5 min till 20 min then every 20 min till recovery from motor block. The time taken for motor block develop was Bromage Scale ≥2. Time taken for motor block was defined as the time starting from the onset of motor block till the recovery from motor block (defined as Bromage Scale 0).

Surgery was allowed to start after obtaining adequate anesthesias (sensory blockade at T12). Noninvasive blood pressure was

recorded at 2-minute intervals over a 10- minute period after intrathecal injection and then every 10 minutes till 60 minutes. Drop in systolic blood pressure < 90mmHg or >20 % of fall from baseline value was taken as hypotension. It was treated with intravenous bolus dose of inj. ephedrine 5 mg. Heart Rate, ECG, RR and SpO2 were monitored continuously. Any pulse rate <60/ minutes was noted and was diagnosed with bradycardia and received 0.6 mg atropine via intravenous injection. A careful watch was kept on all the patients for any signs of toxic manifestations of local anaesthetic drug such as respiratory and cardiac depression.

Postoperative Pain: Postoperatively, assessment of pain was done with the aid of VAS score, every hour after sub-arachnoid injection, till 3 hrs. The effectiveness of analgesia was evaluated based on the time from subarachnoid injection of drug upto time when VAS is ≥4 or patient demanded rescue analgesia. Paracetamol 100ml. I.V. was administered to the patient as rescue analgesia. Time until the first dose of rescue analgesia was noted.

Monitoring Discharge of Patient

The selection to discharge the patent for home discharge following day care procedure is a crucial step in the ERAS (Enhanced recovery after surgery) pathway, as it is required to be attained without sacrificing care standard. Stable vital signs, early ambulation, pain, unassisted voiding, any complication etc. are the important factors for making the decision of discharge of patient. All these parameters were noted postoperatively.

Time to unassisted ambulation- After complete resolution of motor and sensory block, time for ambulation without assistance was noted. Time to voiding of urine- Time to return of voiding function was noted. If either walking or micturition is unsuccessful, then multiple attempts were made at 15 min intervals until these end-points are achieved. Time until the patient was eligible for home discharge- Time period from T0 to time when the criteria for home discharge was met, even if according to hospital procedures the patient was sending home later. Criteria for home discharge were within normal limits vital signs, ability to walking without help, void spontaneously and no nausea or pain.

Complications

Nausea, vomiting, urinary retention, headache, pruritus, respiratory depression and TNS was observed. The event of TNS was assessed 24 hours and one week post surgery using a standardised telephonic call questionnaire, asking patients about the presence of headache, backache, inability to void or presence of residual paraesthesia or dysesthesia in lower limbs or buttocks.

Data Analysis

Data collected was entered into MS-Excel 2013 spreadsheet. The collected data was analysed using IBM statistical package for social sciences (IBM SPSS) version 21 software (trail version)

Statistical Tests:

1. Continuous variables were reported as Mean ± Standard Deviation (SD) while categorical variables were expressed as absolute values and percentages.
2. Kolmogorov Smirnov and Shpiro-Wilk test was used to check the normality of the data.
3. Unpaired t test was used if the data is normal otherwise Mann Whitney U test was served for compare the means between the two groups.
4. Categorical variables were analysed using Chi Square/ Fisher Exact Test.
5. p-value less than 0.05 was taken as statistically significant.

RESULTS

In Group A, out of 50 patients 15 were from 15 to 24 years age group, 10 were from 25- 34 years age group, 11 were from 35-44 years age group, 8were from 45-54 years age group, 3 were from 55-64 years age group and 3 were from 65-74 years age group. In group B, out of 50 patients, 7 were from 15 to 24 years age group, 15 were from 25-34 years age group, 7 were from 35-44 years age group, 9 were from 45-54 years age group, 9 were from 55-64 years age group and 3 were from 65-74 years age group. Group A had a mean of 36.10 + 14.48 years in contrast; group B had mean age of 41.30+14.75 years. The difference was statistically non-significant (p value >0.05). There were 37 male patients (74.0%) and 13 female patients (26.0) in group A, 42 male patients (84.0) and 8 female patients (16%) in group B. The difference was statistically non-significant in the sex distribution of the patients between the groups. Majority of the patients underwent Fistulectomy in both the groups.

The heart rate mean value was measured every 2 min till 10 min and then at an interval of 10 min till 60 min and the difference between both the groups was statistically non-significant.

The mean arterial blood pressure was comparable throughout the intra-operative period in both groups. The differences between the two groups were non-significant throughout all time periods.

The mean respiratory rate was comparable and the differences between the two groups were non-significant throughout all time periods. Onset of sensory block was taken from completion of injection of study drug till patient does not feel pin prick at T10 level. The mean time of onset for sensory block in group A was 3.70+1.80.min and in group B was 5.30+2.10 min and the difference between two groups was statistically non-significant. The mean onset of motor block in group A was 5.34 ±0.06 min and in group B, it was 5.33±0.03 min. Thus, the difference between two groups was statistically non-significant. Duration of analgesia was taken as the time from subarachnoid injection of drug upto time when VAS was > 4. Paracetamol 100ml i.v. was administered to the patients as rescue analgesia. Mean duration of analgesia in group A was 187.50±3.33 min and mean duration of analgesia in group B was 207.80±3.02 min. Thus, the difference between two groups was statistically highly significant.

The mean oxygen saturation was comparable and the differences between the two groups were non-significant throughout all time periods.

The motor block was assessed every 5 min till 20 min then every 20 min till recovery from motor block. Bromage scale was comparable in both the groups. There was no statistically significant difference between two groups at all time intervals.

In our present study, in group A 6 patients had nausea and vomiting, 5 patients had hypotension, 2 patients had bradycardia, 8 patients had shivering. In group B ,5 patients had nausea and vomiting, 4 patients had hypotension, 2 patients had bradycardia. The difference was statistically non-significant.

The mean heart rate was measured postoperatively every hour till 3 hours and the difference between both groups was statistically non-significant. The mean arterial pressure was measured postoperatively every hour till 3 hours. Mean arterial pressure in both the groups was measured at all the intervals and the difference between both the groups was statistically non-significant. The mean oxygen saturation (Spo2%) was measured postoperatively every hour till 3 hours. Mean oxygen saturation in

both the groups was measured at all the intervals and the difference between both the groups was statistically non-significant. Assessment of pain was done with the help of VAS score every hour after sub-arachnoid injection till 3 hours and the mean VAS score in both the groups was measured at all intervals. VAS score was >4 (moderate -severe) after the end of first hour and before starting of second hour. The difference between both the groups was found to be statistically non-significant.

Table 1: Baseline characteristics

Age (In yrs)	**Group A**		**Group B**	
	Number	**Percentage**	**Number**	**Percentage**
15 – 24	15	30.0	7	14.0
25 – 34	10	20.0	15	30.0
35 – 44	11	22.0	7	14.0
45 – 54	8	16.0	9	18.0
55 – 64	3	6.0	9	18.0
65 – 74	3	6.0	3	6.0
Total	50	100.0	50	100.0
Mean ± S.D	36.10 ± 14.48		41.30 ± 14.76	
Chi Square	7.857			
P value	0.164			
Sex				
Male	37	74.0	42	84.0
Female	13	26.0	8	16.0
Total	50	100.0	50	100.0
Chi Square	1.507			
P value	0.220			
Type of surgery				
Fistulectomy	25	50.0	26	52.0
Pilonidal Sinus excision	10	20.0	11	22.0
Haemorrhoidectomy	9	18.0	8	16.0
Lateral sphincter prong	6	12.0	5	10.0
Total	50	100.0	50	100.0
Chi Square	6.794			
P value	0.079			

Table 2: Mean Heart Rate (per min) over different time frames during intraoperative period

Time(min)	**Group A**		**Group B**		**P value**	**Significance**
	Mean	**S.D**	**Mean**	**S.D**		
Baseline	79.32	9.82	79.78	10.52	0.822	NS
0 Min	79.12	9.18	77.48	10.54	0.409	NS
2 Min	73.24	10.21	75.66	11.23	0.262	NS
4 Min	80.84	8.88	81.16	8.64	0.855	NS
6 Min	76.82	7.23	77.36	9.36	0.748	NS
8 Min	77.10	7.66	77.94	8.96	0.615	NS
10 Min	77.46	8.31	79.06	8.89	0.355	NS
20 Min	78.94	8.75	79.44	8.67	0.775	NS
30 Min	79.98	8.51	80.70	8.63	0.675	NS
40 Min	80.84	8.88	81.16	8.64	0.855	NS
50 Min	81.16	8.24	82.72	8.62	0.357	NS
60 Min	81.54	8.89	83.56	8.82	0.257	NS

Table 3: Mean MAP (mmHg) at several time frames during intra-operative period

Time(min)	Group A		Group B		P value	Significance
	Mean	S.D	Mean	S.D		
Baseline	94.26	6.35	94.96	6.46	0.586	NS
0 Min	91.14	5.19	91.28	6.00	0.901	NS
2 Min	81.46	8.02	84.28	8.99	0.101	NS
4 Min	92.36	2.38	92.00	4.97	0.645	NS
6 Min	93.04	3.33	93.56	2.98	0.413	NS
8 Min	89.42	3.69	88.28	5.48	0.226	NS
10 Min	90.46	3.30	90.68	5.81	0.816	NS
20 Min	91.24	3.73	91.62	5.29	0.679	NS
30 Min	92.36	2.38	92.00	4.97	0.645	NS
40 Min	92.38	2.51	93.08	4.02	0.299	NS
50 Min	93.04	3.33	93.56	2.98	0.413	NS
60 Min	91.24	3.73	94.20	3.80	<0.001	HS

Table 4: Mean oxygen saturation (SpO2%) at different time intervals during intra-operative period

Time(min)	Group A		Group B		P value	Significance
	Mean	S.D	Mean	S.D		
Baseline	97.98	2.68	98.58	1.05	0.646	NS
0 Min	99.12	0.96	98.90	0.97	0.218	NS
2 Min	99.52	0.65	99.40	0.78	0.536	NS
4 Min	99.48	0.58	99.24	1.00	0.560	NS
6 Min	99.10	0.99	99.06	1.10	0.935	NS
8 Min	99.36	0.78	99.28	0.78	0.535	NS
10 Min	99.32	0.77	99.34	0.92	0.528	NS
20 Min	99.48	0.65	99.28	0.78	0.219	NS
30 Min	99.26	0.78	99.46	0.68	0.179	NS
40 Min	99.48	0.58	99.24	0.87	0.255	NS
50 Min	99.22	0.82	99.24	0.77	0.998	NS
60 Min	99.44	0.58	99.58	0.57	0.185	NS

Table 5: Mean Respiratory Rate (per min) at different time intervals during intra-operative period.

Time (min)	Group A		Group B		P value	Significance
	Mean	S.D	Mean	S.D		
Baseline	19.50	2.04	19.72	1.31	0.079	NS
0 Min	19.70	1.11	20.00	1.95	0.587	NS
2 Min	19.70	1.11	20.00	1.95	0.587	NS
4 Min	19.76	1.12	20.14	2.02	0.944	NS
6 Min	19.74	1.08	20.00	1.95	0.459	NS
8 Min	19.56	0.97	20.16	2.13	0.640	NS
10 Min	19.96	1.05	20.14	2.14	0.287	NS
20 Min	19.48	0.93	20.16	2.13	0.467	NS
30 Min	19.34	0.87	19.80	1.82	0.930	NS
40 Min	19.06	1.15	19.54	1.53	0.288	NS
50 Min	19.74	1.16	20.00	1.95	0.544	NS
60 Min	20.02	1.77	20.12	2.08	0.674	NS

Table 6: Mean Onset of sensory block (min), Mean onset of motor block (min) and Mean duration of analgesia (min)

	Mean	S.D	P value	Significance
Sensory block				
Group A	3.70	1.80	>0.05	NS
Group B	5.30	2.10		
Motor Block	Mean	S.D		
Group A	5.34	0.06	0.947	NS
Group B	5.33	0.03		
Analgesia	Mean	S.D		
Group A	187.50	3.33	<0.001	HS
Group B	207.80	3.02		

Table 7: Motor Blockade Assessment

Time (min)	Group A		Group B		P value	Significance
	Mean	S.D	Mean	S.D		
5 Min	2.88	0.33	2.82	0.39	0.403	NS
10 Min	2.24	0.43	2.20	0.40	0.631	NS
15 Min	2.20	0.40	2.18	0.39	0.800	NS
20 Min	2.08	0.27	2.08	0.27	1.00	NS
40 Min	1.96	0.20	1.94	0.24	0.648	NS
60 Min	1.10	0.30	1.08	0.27	0.728	NS
80 Min	0.00	0.00	0.00	0.00	-	-

Table 8: Complications

Complication	Respiratory Rate	Group A		Group B		P value	Significance
		Mean	S.D	Mean	S.D		
Nausea/ Vomiting	**Yes**	6	12.0	5	10.0		
	NO	44	88.0	45	90.0	0.749	NS
Hypotension	**Yes**	5	10.0	4	8.0		
	NO	45	90.0	46	92.0	0.727	NS
Bradycardia	**Yes**	2	4.0	2	4.0		
	NO	48	96.0	48	96.0	1.00	NS
Pruritus	**Yes**	0	0.0	0	0.0		
	NO	50	100.0	50	100	-	NS
Shivering	**Yes**	8	16.0	8	16.0		
	NO	42.0	84.0	42	84.0	1.00	NS
Urinary Retention	**Yes**	0	0.0	0	0.0		
	NO	50	100.0	50	100.0	-	-
Headache	**Yes**	0	0.0	0	0.0		
	NO	50	100.0	50	100.0	-	-
Respiratory Depression	**Yes**	0	0.0	0	0.0		
	NO	50	100.0	50	100.0	-	-
TNS	**Yes**	0	0.0	0	0.0		
	NO	50	100.0	50	100.0	-	-

Table 9: Mean heart rate (per min), Mean arterial pressure (mmHg), Mean oxygen saturation (SpO2%), Mean VAS score at different time interval during postoperative period

Mean heart rate Time (hrs)	Group A		Group B		P value	Significance
	Mean	S.D	Mean	S.D		
1 hrs	82.32	7.83	80.70	8.63	0.328	NS
2 hrs	82.32	7.83	80.70	8.63	0.328	NS
3 hrs	82.88	8.19	83.56	8.82	0.690	NS
Mean arterial pressure Time(hrs)						
1 hrs	95.30	3.20	95.16	3.11	0.825	NS
2 hrs	94.28	3.57	94.20	3.58	0.911	NS
3 hrs	94.12	3.93	93.96	3.60	0.832	NS
Mean oxygen saturation Time (hrs)						
1 hrs	99.66	0.48	99.72	0.45	0.519	NS
2 hrs	99.66	0.48	99.72	0.45	0.519	NS
3 hrs	99.66	0.48	99.72	0.45	0.519	NS

DISCUSSION

The present prospective randomised double blind study aimed to compare 0.75% hyperbaric Ropivacaine and 0.75% hyperbaric Ropivacaine using 20 mcg fentanyl administered as a supplemental agent among 100 patients between age group of 20- 70 years for perineal surgeries under spinal anaesthesia. Within this study, the primary objective was to compare both the groups in terms of the length of pain relief and time to unassisted ambulation. Secondary objectives were onset and length of sensory and motor impairment, maximum height of sensory block, time for 2-segment regression, hemodynamics parameters, voiding time, time until the patient met discharge criteria and any side effects. In our study, the groups were matched in term of age, sex, weight, type of surgery and mean duration of surgery.

Pulse rate, diastolic blood pressure, systolic blood pressure, Respiratory rate, mean arterial pressure (MAP), and SpO2 were monitored preoperatively, intra-operatively, and postoperatively and were comparable across both groups. Our findings are consistent with the study done by Singh P et al who compared the evaluation of low dose Ropivacaine and Levobupivacaine in patients for inguinal herniorrhaphy under walking spinal anaesthesia as day care surgery and the difference in HR, BP, RR, and SPO2 was statistically non-significant in both groups during the preoperative period.[6] The primary finding of this study is that the supplement of fentanyl alongside Ropivacaine delayed the period of analgesia effect without lengthening the motor block. In present study, the analgesia lasted for 87.50+3.33 minutes in group A compared to 107.80+3.02 min in group B. The difference was statistically highly significant, p value < 0.01. This can be linked to the addition of fentanyl. The results of the extension of sensory block and postoperative analgesia are consistent with experimental as well as clinical synergistic interaction between spinal opioids and local anaesthetics. Ours finding are also similar to those obtained with the study conducted by Gupta k et al[11] who conducted the prospective study to assess the effectiveness of intrathecal fentanyl as an supplement to isobaric Ropivacaine (0.75%) for surgery below umbilicus under subarachnoid block and group RF (Ropivacaine with fentanyl) has delayed the period of analgesia effect in early post- operative period in comparison to group RC (Ropivacaine control group). The difference in total analgesic effect time on sensory function between groups was statistically highly significant.

Initiation of sensory blockade was taken from completion of sub-arachnoid injection of study drug till patient is insensitive to pin prick sensation at the T10 Dermatomes level. In present study, mean time sensory block in group A began at 3.70+1.90 min and in group B began at 5.30+2.1 min. The difference in mean time to onset was statistically non-significant. Group B had a more rapid initiation of sensory anaesthesia in comparison to group A, which was due to the supplementation of fentanyl. Fentanyl additive to local anaesthetic leads to rapid onset of the sensory nerve block when administered intrathecally due to its lipophilic nature. Gupta K et al who showed initiation of sensory block at the T10 dermatome level was 3.2+1 min in group 1 (ropivacaine+ saline) and was 3.5+1 min in group II (ropivacaine + fentanyl), with the difference statistically non- significant.[11]

Sensory blockade was noticed by loss of pin prick sensation to 23 G sterile hypodermic needle at every 2 minutes for 10 min until the highest level (highest level of sensory blockade) was achieved and stabilised for four consecutive tests. Time required to achieve peak sensory block was noted, highest sensory block in group A was T10 (76%) and time taken to achieve to attain peak sensory block was 8.94+0.34 min, whereas in group B, time take to obtain the highest level of sensory block at T10 (86%) was 8.99+0.28 min. the statistically analysis showed a non-significant difference, as the p value was 0.368 ($p > 0.05$). Our results are in concordance with the study done by Gupta K et al. There was no statistically significant difference between group 1 (Ropivacaine control group) and group 2 (Ropivacaine with fentanyl) (p Value >0.05) in the meantime required for attaining the peak level of sensory blockade. Time takes to attain peak sensory level was 9.8+3.2 in group 1 and 8.13+1.92 in group 2.[11]

In the present study, duration of analgesia was defined as the time from subarachnoid injection of drug when VAS was >4. Paracetamol 100ml I.v was administered till the patients rescue analgesia. Mean duration of analgesia across group A was 187.50+3.33 min and 207.80+3.02 min across group B. Thus, the difference between two groups was statistically highly significant (p value <0.001). Our results are also similar to the study done by Yegin A et al who analysed the impact of fentanyl intrathecally

supplement to (H) Ropivacaine for endoscopic resection of prostate. The mean analgesic duration group S (Ropivacaine + saline) was 180+26 min and in group F (Ropivacaine + fentanyl) was 210+31 min. Times to the initial pain sensation and first analgesia requirement were significant delayed in the fentanyl groups as opposed to the saline group (p value 0.016).[12] Motor block was assessed every 5 min till 20 min then every 20 min till recovery from motor block. The time taken for motor block develop was Bromage Scale ≥2. Time taken for motor block was defined as the time starting from the onset of motor block till the recovery from motor block (defined as Bromage Scale 0).

In present study, onset of motor block was 5.34+0.06 across group A and 5.33+0.03 min across group B. The difference in length of motor function loss was statistically non-significant (p value 0.947). Our results are similar to the study done by Yegin A et al who analysed the clinical outcome of intrathecal fentanyl included to hyperbaric Ropivacaine for transurethral excision of the prostate and the mean initiation of motor function loss was 6.4+4.9 min in group S and 9.7+8.1 minute in group F. The difference of mean initiation of motor block was statistically non-significant.[12] In present study, length of motor block was 169.80+1.39 min within group A and 170.30+2.33 min within group B. The difference in onset and length of motor block was statistically non-significant (p value 0.704). Yegin A et al who analysed the clinical outcome of intrathecal fentanyl included to hyperbaric Ropivacaine during transurethral resection of prostate and demonstrated that, the mean time of motor function loss in group S (saline + ropivacaine) was 94.7+42.4 minutes whereas in group F (fentanyl + ropivacaine) was 97.7+31.4 min. The difference in mean onset of motor blockade was statistically non-significant.[12]

CONCLUSION

In this prospective, randomised, comparative, double blind study, we concluded that 0.75%(H) Ropivacaine 9mg provides adequate surgical blockade for perineal surgeries but addition of fentanyl 20mcg fentanyl to intrathecal 0.75%(H) Ropivacaine has added advantage in prolonging the postoperative analgesia, speeding up the onset and increasing the duration of the sensory block without impacting motor block recovery and time taken to unassisted ambulation. Thus, Ropivacaine with fentanyl may be a better choice in comparison to Ropivacaine alone for attaining enhanced recovery after perineal surgeries.

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