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Original Research Article

A Clinical Prospective, Randomized Study to Compare Combined Spinal Epidural Bupivacaine – Fentanyl and Ropivacaine – Fentanyl for Lower Abdominal and Pelvic Surgeries

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Abstract

Aim: *We conducted this prospective, randomized, double blind study with an aim of comparing the effect of Combined Spinal Epidural Bupivacine with fentanyl and Ropivacaine with Fentanyl for post-operative analgesia in lower abdominal and pelvic surgeries.*

Methodology: *Eighty patients or lower abdominal & pelvic surgeries were studied after randomization into 2 groups with 40 patients in each group. Group BF– patients received 3 ml bupivacaine 0.5% for subarachnoid block and epidural top up 0.125% bupivacaine plus Fentanyl 25 µg diluted and made up to 8cc with Normal saline Group RF – Patients received 3ml ropivacaine 0.75% for subarachnoid block and epidural top up 0.125% ropivacaine plus Fentanyl 25 µg diluted and made up to 8cc with NS.*

The parameters observed included haemodynamic data, pain score by visual analogue scale scale, duration of surgery, Requirement of first dose of rescue analgesia. Side effects like nausea, vomiting shivering, hypotension and bradycardia were observed and managed symptomatically. times of recording were before administration of first epidural top up, 5,10 15,30 min after drug given,1,2,3,4,6,8,10& 12 hr after drug administration.

Results: *Haemodynamioc data and Pain score of patients of both groups were comparable at all time periods (p>0.05). Times for first dose of rescue analgesia and duration of surgery were comparable in both groups. No significant difference was found in both groups in respect to side effects (p>0.05).*

Conclusion: *We concluded that bupivacaine with fentanyl was eqully efficaceous to ropivacine with fentanyl in combined spinal epidural block for post-operative analgesics in lower abdominal and pelvic surgeries.*

Keywords: *Bupivacaine; Ropivacaine; Fentanyl, combined spinal epidural anaesthesia.*

Introduction

Lower abdominal and pelvic surgeries may be performed under local, regional or general anaesthesia. In recent years, regional blocks and a combination of neuraxial blocks with general anaesthesia have gained widespread popularity due to its minimal multisystem effects. Regional blocks, by lowering the side effects associated with general anaesthesia contribute in reducing the post-operative duration of hospital stay.

Combined Spinal Epidural block is one of the preferred choice for abdominal and pelvic surgeries because of its rapid onset, superior blockade; prolong analgesia, less failure rates and cost-effectiveness[i]. In neuraxial analgesia, the analgesics are injected or infused in close proximity to the spinal cord by using catheter, usually either intrathecally into the cerebrospinal fluid or epidurally into the fatty tissues around the dura, to block nerves that transmits pain signals to the brain[2,3].

Epidural administration of amide local anesthetics in combination with opioids is widely used for pain relief in lower abdominal and pelvic surgeries because of the dose minimizing and side effects reducing benefits[4,5]. Fentanyl, a low molecular weight, high potency and lipid soluble synthetic opioid, is a suitable analgesic drug which is in use for prolonging the analgesic effect of epidural anesthesia since a long time[ii].

Bupivacaine is one of the most common anesthetic agent used for abdominal and pelvic surgeries, however in recent years ropivacaine has increasingly replaced bupivacaine for the said purpose because of its similar analgesic properties, lesser motor blockade and decreased propensity of cardiotoxicity.[5,6]

This study was planned to compare the efficacy of Combined Spinal Epidural Bupivacine with fentanyl and Ropivacaine with Fentanyl for post-operative analgesia in lower abdominal and pelvic surgeries.

Material and Methods

After approval of ethical committee this prospective, randomized, comparative study was carried on 80 patients of ASA grade I & II**,** 18 to 55 years of either sex admitted for elective lower abdominal and pelvic surgery procedures under combined spinal epidural block. Patients with hepatic dysfunction, renal dysfunction, bleeding disorder, cardiopulmonary disease progressive neurological disorder, morbid obesity, and known history of allergy were excluded from study.

Preanaesthetic checkup of these patients were done with history, general examination and systemic examination. Routine investigations like cbc, blood sugar, urea, serum creatinin, chest X ray and ECG were done.

After obtaining written informed consent patients were subsequently randomized into 2 groups of 40 each by computer generated random numbers as follows:

Group BF (Bupivacaine Group)– Patients received 3 ml bupivacaine 0.5% for subarachnoid block and epidural top up 0.125% bupivacaine plus Fentanyl 25 µg diluted and made up to 8cc with preservative free Normal saline for post-operative analgesia

Group RF (Ropivacaine Group)– Patients received 3ml ropivacaine 0.75% for subarachnoid block and epidural top up 0.125% ropivacaine plus Fentanyl 25 µg diluted and made up to 8cc with preservative free Normal saline for post-operative analgesia.

All the patients in both groups were premedicated with Tab. Alprazolam 0.25 mg and Tab. Aciloc 150 mg in the night prior to surgery.

On the day of surgery, the patients were wheeled into the operation theatre and connected to all noninvasive monitors. Baseline parameters including pulse rate, arterial blood pressure (NIBP) and oxygen saturation were noted. ECG monitoring was also enabled.

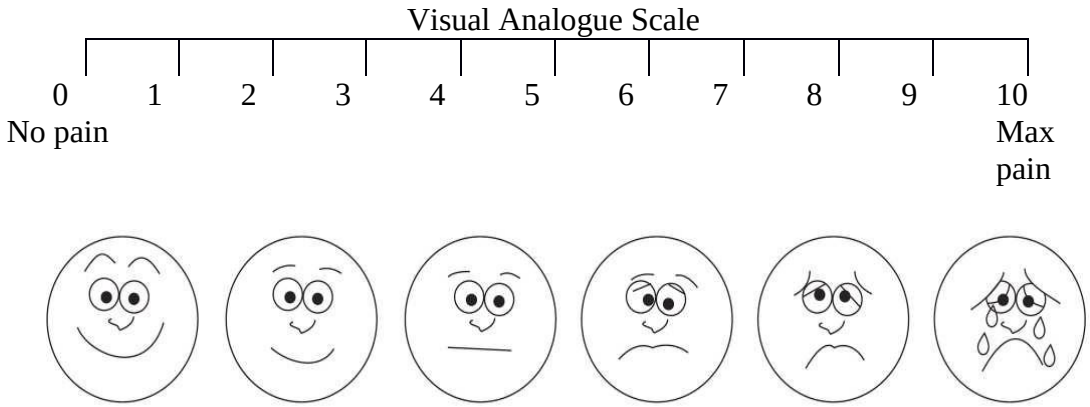
After IV access was established preloading was done with infusion of Ringer Lactate 10 ml/kg commenced. The epidural space was identified at L2-L3 or L3-L4 by midline approach using loss of

resistance technique. Dural puncture was performed by a needle-through-needle technique with a 26 G spinal needle and Group BF received 3 ml 0.5% bupivacaine while Group RF received 3 ml 0.75% Ropivacaine. 16 G epidural catheter was inserted into the epidural space and fixed. Routine intra-operative monitoring is done for all the patients.

At the time of closure of surgical wound, patients in Group BF received epidural top up 0.125% bupivacaine plus Fentanyl 25 µg diluted and made up to 8cc with preservative free Normal saline and Group RF received epidural top up 0.125% Ropivacaine plus Fentanyl 25 µg diluted and made up to 8cc with preservative free Normal saline. After 6 hr of first epidural top up patients of both Group received second epidural top up.

The anesthesiologist performing the block recorded the baseline value of vital signs (BP, HR, SpO_2,) before performing the procedure, and once in every 5 minutes inside the Operation Theatre, then in the Post Anesthesia Care Unit (PACU).

Pain was assessed by using 10 point Visual Analog Scale (VAS) in which a score of "0" indicated "no pain" and a score of "10" "worst pain imaginable".



Times for Recordings

- T0- Before administration of first epidural Top up
- T1- 5 mins after administration of the drug
- T2- 10 mins after administration of drug
- T3- 15 mins after administration of drug
- T4- 30 mins after administration of drug
- T5- 45 mins after administration of drug
- T6- 1 hr after administration of drug
- T7- 2 hr after administration of drug
- T8- 3 hr after administration of drug
- T9- 4 hr after administration of drug
- T10 - 6 hr after administration of drug
- T11 - 8 hr after administration of drug
- T12 - 10 hr after administration of drug
- T13 - 12 hr after administration of drug

At the above mentioned time periods HR, NIBP, RR, SPO_2 were also monitored. Adverse effects like nausea, vomiting and shivering were also documented and managed symptomatically. Hypotension was defined as decrease in MAP below 20% of baseline or SBP <90 mm Hg and was treated with Inj. Mephentermine 3 mg/ml. Bradycardia was defined as decrease in HR below 60/min and was treated with Inj Atropine 0.6 mg IV.

Data so obtained was subjected to analysis using SPSS version 15.0 or above. Independent samples 't'-test, paired 't'-test, chi-square test, Mann-Whitney U test and Wilcoxon signed rank test were used for the purpose of analysis of data. The confidence level of the study was kept at 95%.

Results

Both groups were comparable for age and statistically insignificant ($p>0.05$). All the patients included in the study were females and all the patients had undergone Total Abdominal Hysterectomy.

Table- 1: Demographic profile of 2 groups

S.no.	Parameters	Group R		Group RC	
		Mean	±SD	Mean	±SD
1.	Age (yrs)	**46.45**	**5.38**	**47.12**	**5.17**

Baseline hemodynamic parameters were comparable in both groups. When we compare both groups, No significant difference was found in these parameters during study periods.

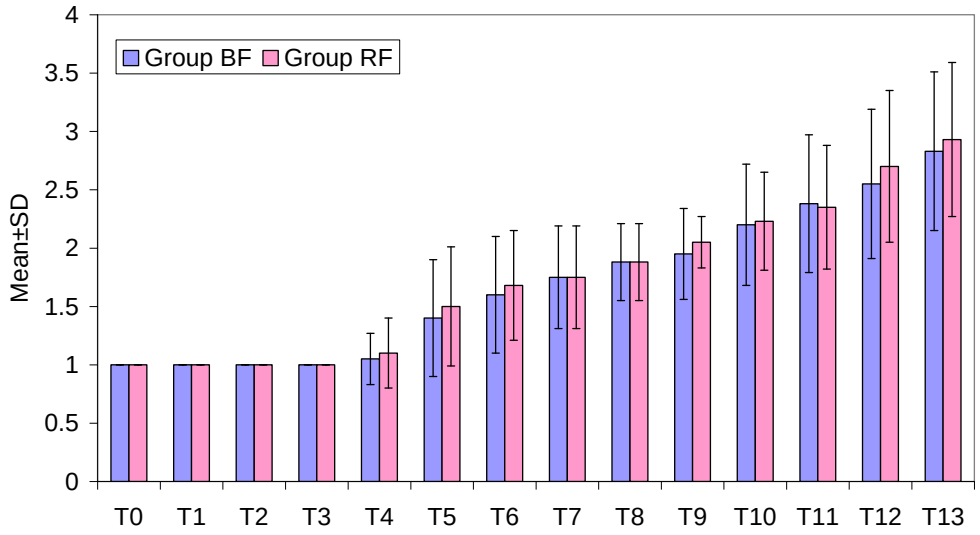
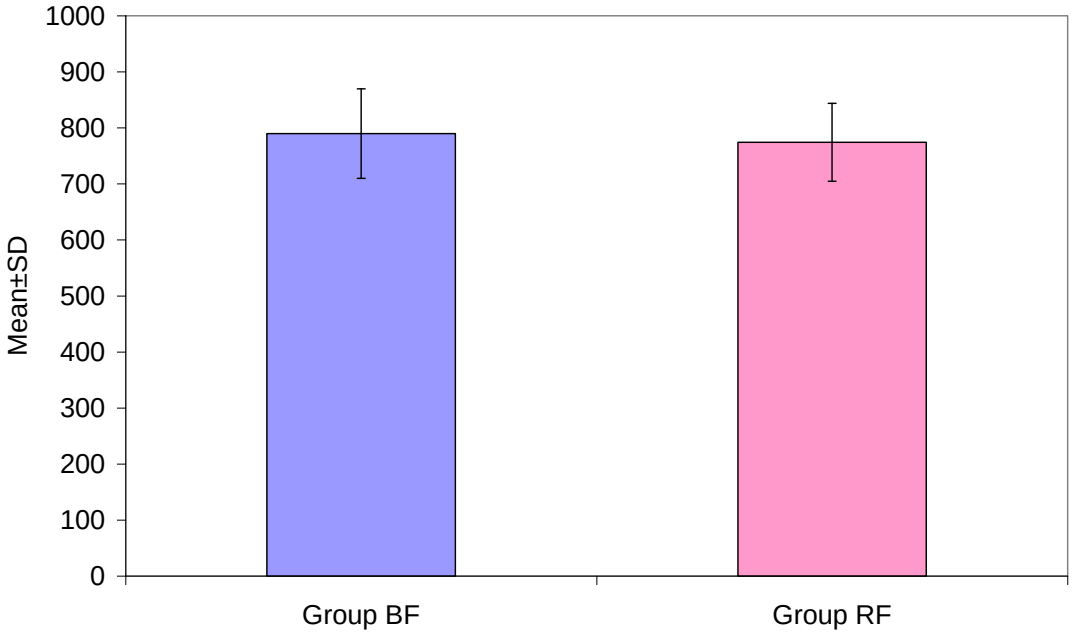


Fig. 1: Between Group Comparison of Pain (VAS Score) at different time intervals

During T1-T3 (Up to 15 min of admin of drug) pain score of patients of both the groups was 1.00±0.00. After T4 (30 min after admin of drug) increase in pain score of patients of both groups started. Pain score of patients of both the groups (Group BF and RF) were comparable at all the periods of observation.

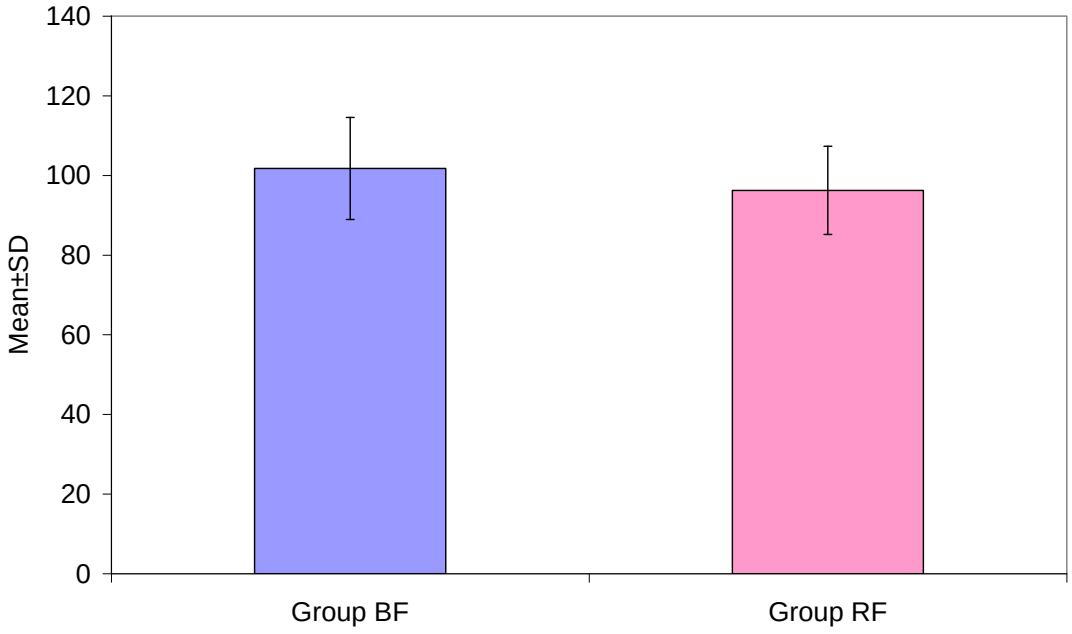


't'=0.915; p=0.363

Fig. 2: Between Group Comparison of Time for first dose of rescue analgesia

Requirement of first dose of rescue analgesia was earlier in Group RF (774.30±69.52 minutes) as compared to Group BF (789.62±79.85 minutes) but this difference was not found to be statistically significant (p=0.363).

Duration of surgery among patients of Group BF (100.88±12.24 min) and RF (96.25±11.08) was comparable.



't'=1.772; p=0.080

Fig. 3: Between Group Comparison of Duration of Surgery (minutes)

Table 2: Between Group Comparison of Adverse Effects in the Study Population

Adverse Effects	Total (N=80)		Group BF (n=40)		Group RF (n=40)	
	No.	%	No.	%	No.	%
No adverse effect	72	90.00	36	90.00	36	90.00
Pruritis	1	1.25	1	2.50	0	0.00
Nausea & Vomiting	7	8.75	3	7.50	4	10.00
			p=0.565			

Difference in adverse effects among patients of Group BF and Group RF was not found to be statistically significant.

Incidence of nausea and vomiting was more common in Group RF as compared to

Group BF while that of Pruritis was more common in Group BF as compared to RF

Discussion

Inadequately controlled pain negatively affects quality of life, function, and functional recovery, the risk of post-surgical complications, and the risk of persistent postsurgical pain[9]. For this purpose, preemptive measures to reduce the post-operative pain have emerged as a strategy to reduce the patient discomfort. Post-operative regional anesthetic techniques have emerged as one of the good strategies to reduce the burden of post-operative pain.

Bupivacaine is one of the most commonly used drug in regional anesthesia however, in the recent years its use has been limited owing to toxic reactions reported in studies[6,7]. Ropivacaine, the S-enantiomer of the amide local anesthetic, produces differential neural blockade, with less motor blockade, cardiovascular and neurological toxicity, has emerged as a possible alternative to bupivacaine with similar anesthetic and analgesic

properties sans the toxic effect of bupivacaine[7,8] , and has been shown to be effective in combination with fentanyl for different infraumbilical surgeries[10,11,12], primarily in women undergoing cesarean section .

Hence, present study was carried out with an aim to evaluate and compare the efficacy of Combined Spinal Epidural Bupivacaine plus Fentanyl with Ropivacaine plus Fentanyl in post-operative pain control among patients undergoing abdominal and pelvic surgeries.

Ropivacaine is less potent than bupivacaine and levobupivacaine at lower doses, such as those used for epidural or intrathecal analgesia[13]. As we were using lower concentrations of both the drugs, hence it was decided to use ropivacaine with 1.5 times higher concentration as compared to bupivacaine for subarachnoid block. As far as concentration of two drugs at the time of top up is concerned, in present study we used same concentration of bupivacaine and ropivacaine (0.125%), hence the concentration difference of two drugs if any was limited to the time of initial anesthetic dosage of two drugs.

In a previous study too, 0.5% bupivacaine has been compared with 0.75% ropivacaine[14] for post-operative analgesia. Both the drugs were hemodynamically similar and did not have any significant change in hemodynamics throughout the study period. In a previous study, comparing 0.5% isobaric ropivacaine to 0.5% isobaric bupivacaine too, no significant difference in hemodynamic variables was observed between the two groups

However, Gautam *et al.* (2014)[14] in their study showed a high incidence of hypotension and bradycardia in both the groups, but more so in bupivacaine group using a similar concentration of drug. These findings suggest that the safety of drug not only depends on the concentration of drug being used but is also dependent on the total dosage of drug being used.

However, as far as analgesic activity was concerned, in present study, the VAS scores in two groups also showed a comparable profile throughout the study period. The median VAS scores were 1 till 30 min postoperative interval and remained as 2 from 2 hr to 12 hr follow-up interval in both the groups. Thus, for time interval upto 12 hr post-operative interval both the drugs showed excellent efficacy for the analgesic effect without having any cardiotoxic effect. In present study, first analgesic need was 789.62±79.85 minutes in Bupivacaine plus Fentanyl group as compared to 774.30±69.52 minutes in Ropivacaine plus Fentanyl group, thus showing no significant difference between two groups.

Gautam *et al.* (2014)[14] did not find a significant difference in block quality between two groups. Murali and Laxmi (2016)[15] who used 0.75% ropivacaine with 25 µg of Fentanyl as adjuvants for pre-operative analgesia reported the mean time for first analgesic request to be 462.4±38.42 min. Meister *et al.* (2000)[16] who compared 0.125% ropivacaine to 0.125% bupivacaine both in combination with fentanyl found bupivacaine to be more effective as compared to ropivacaine as far as their analgesic effect was concerned.

This study was mainly focused on intraoperative anesthetic role of ropivacaine and bupivacaine and did not concern with the post-operative pain. This implies that the anaesthetic role and analgesic role of drugs may vary and should not be viewed to follow a similar trend. As such studies using equal concentration of ropivacaine and bupivacaine for post-operative analgesia had shown bupivacaine to be better as compared to ropivacaine[17], thus stressing upon the need of equipotent rather than equiconcentration combinations.

In one such study Owen *et al.* (2002)[18] who used 0.075% ropivacaine or bupivacaine, each with fentanyl 2 µg /mL as a patient-controlled epidural infusion for post-operative pain management found both the combinations to hold equivalent analgesic and hemodynamic effect. Girard *et al.* (2006)[19] using much lesser yet equal concentrations (0.125%) in epidural labour analgesia, no significant difference between bupivacaine and ropivacaine as far as motor blockade and analgesic outcome was concerned.

The present study did not have any significant side effects.

Conclusion

0.5% bupivacaine for subarachnoid block and epidural top up 0.125% bupivacaine plus Fentanyl 25 µg was equipotent to ropivacine 0.75% for subarachnoid block and epidural top up 0.125% ropivacaine plus Fentanyl 25 µg as post-operative analgesics as combined spinal epidural anesthesia without jeopardizing the hemodynamic stability in either of two groups. Both the groups had similar efficacy of postoperative analgesia and there was no advantage of one group over the other group. Further studies to substantiate the findings of present study are recommended.

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