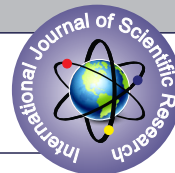


TO STUDY AND ASSESS THE EFFECTS OF INTRATHECAL HYPERBARIC ROPIVACAINE(0.75%)VERSUS HYPERBARIC ROPIVACAINE (0.75%) WITH FENTANYL IN LOWER ABDOMINAL SURGERIES: A PROSPECTIVE COMPARATIVE STUDY



Anaesthesiology

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ABSTRACT

Aims and Objectives: To study and assess the effects of intrathecal commercially available Hyperbaric Ropivacaine (0.75%) versus Hyperbaric Ropivacaine (0.75%) with fentanyl in lower abdominal surgeries. **Methodology:** 76 patients belonging to ASA I and II aged between 18-60 years undergoing elective surgeries will be randomly selected. Informed consent will be taken. Patients are randomly allocated into 2 groups, and receives one of the 2 study drugs mentioned above. Preanaesthetic check-up will be done with a detailed history, general physical examination and systemic examination. Preoperative routine investigations are done. Weight and height of the patients will also be recorded. Assessment of sensory and motor blockade, Assessment of intraoperative and postoperative analgesia is done. **Results:** Demographic data like age, sex, ASA classification are statistically insignificant. Post operative p-value is <0.0001 indicating a statistical significance and lesser VAS scores in group RF. In the present study, on comparison of pruritis and nausea of 2 groups, p value of 0.4933 is noticed which is not statistically significant. **Conclusion:** Group RF had significantly longer duration of action, longer time for rescue analgesia demand and had lesser VAS score. There is no statistically significant difference is seen in side effects between both the groups

KEYWORDS

hyperbaric ropivacaine, fentanyl, intrathecal

INTRODUCTION:

Postoperative pain control remains a major concern after abdominal surgery. Elective lower abdominal surgery can be performed effectively under general anesthesia (GA) or spinal anesthesia.¹

Lower limb procedures can be conducted using local, regional, or general anesthesia. Despite limitations such as shorter block length and inadequate postoperative analgesia, spinal anesthesia is still the favored treatment due to its early start, superior blockade, minimal risk of infection, lower failure rates, and cost-effectiveness.²

Ropivacaine, an amide local anesthetic licensed by the Food and Drug Administration (FDA) in 1997 but widely used in India since 2009. It may be a good choice for a long-acting local anesthetic because it is less cardiotoxic and has a much higher milligram threshold for central nervous system (CNS) toxicity than bupivacaine.³ Hyperbaric ropivacaine produces more predictable and consistent sensory and motor blockade, with a faster onset than a standard solution.⁴

The addition of fentanyl to ropivacaine to spinal anesthetic has been shown to extend analgesia in the early postoperative phase. As a result, it enhances anesthetic quality. However, few studies have been conducted on the use of intrathecal isobaric ropivacaine and fentanyl for postoperative pain management in lower abdomen and lower leg surgeries.⁵

As a result, the current study focuses on comparing the effects of intrathecal hyperbaric ropivacaine (0.75%) to hyperbaric ropivacaine (0.75%) with fentanyl in lower abdominal procedures.

AIMS:

To study and assess the effects of intrathecal commercially available Hyperbaric Ropivacaine (0.75%) versus Hyperbaric Ropivacaine (0.75%) with fentanyl in lower abdominal surgeries.

OBJECTIVES:

To compare the onset level and regression of sensory and motor block and to compare intraoperative and postoperative analgesic effect, haemodynamic stability, side effects if any between intrathecal commercially available Hyperbaric Ropivacaine(0.75%) versus Hyperbaric Ropivacaine(0.75%) with fentanyl in lower abdominal surgeries.

MATERIALS AND METHODS:

This prospective randomized comparative study included 76 patients, of ASA grade I and II, in the age group of 18-60 years, posted for elective surgeries under spinal anaesthesia procedures in Bapuji Hospital, Chigateri General Hospital and WCH, attached to J.J.M.

Medical College, Davangere.

Samples were randomly allocated into 2 groups

Group R received intrathecal Hyperbaric Ropivacaine (0.75%) 3ml (22.5mg).

Group RF received intrathecal Hyperbaric Ropivacaine (0.75%) 3ml (22.5mg) + Fentanyl 0.5ml (25mcg).

Inclusion Criteria:

Age group 18-60 yrs, ASA grade I or II, Both sexes, Posted for elective lower abdominal surgeries (hernioplasty, appendicectomy, hysterectomy, ovarian cystectomy, hydrocele, circumcision, tubectomy, TURP, gynaecological surgeries).

Exclusion Criteria:

Previous history of allergy to anaesthetic medication, Any contraindications to spinal anaesthesia, Patients with pre-existing neurological disease, ASA III and IV, Patients on hypnotics, sedatives and other CNS depressant drugs, Patients with coagulopathies, infection at the local site of injection, Patient's refusal.

Preanaesthetic check-up was done with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination were done and preoperative routine investigations like complete Haemogram, Random Blood Sugar, Renal function test, ECG, HIV, HBsAg. Weight and height of the patients were recorded.

Preoperatively, Patients written informed consent was taken. Nil per oral status was confirmed. Procedure of subarachnoid was explained to the patient. They were premedicated with Tab. Alprazolam 0.5mg and Tab. Ranitidine 150 mg orally the night before the surgery.

Patient were shifted onto the OT table and intravenous access is established on the forearm with 18 or 20 G IV cannula and Lactated Ringers Solution 8-10 ml/kg infused intravenously before the block.

Procedure:

The monitors Pulse Oxymeter, NIBP, ECG were applied to the patient on arrival to the operation theatre. Maintenance of IV fluid continued. Following baseline parameters were recorded. Pulse rate, Respiratory rate, Blood pressure, Oxygen saturation, ECG.

Patient was placed in sitting or lateral position and under aseptic precautions patients back painted and draped. Lumbar puncture will be done by 23G Quincke Babcock needle at L3-L4 intervertebral space. Clear and free flow of CSF was confirmed.

Patients receives one of the two study drugs. Group R received intrathecal Hyperbaric Ropivacaine (0.75%) 3ml(22.5mg). & Group RF received intrathecal Hyperbaric Ropivacaine(0.75%)3ml(22.5mg) +Fentanyl0.5ml(25mcg).

After spinal anaesthesia, patient was made to lie in supine position. Oxygen at 4l/min with a facemask were administered to all the patients during the surgery.

After intrathecal drug administration, the following parameters were noted in the patients: assessment of motor block, assessment of sensory block, VAS scores, vital parameters like HR, SpO₂, MAP, assessment of analgesia.

Rescue analgesia with injection Diclofenac 75mg intravenous infusion was given for patients complaining of pain, clinically correlating with VAS score of more than 3. Following that side effects were recorded.

RESULTS:

In the present study, on comparison of age, ASA status, bromage score there is no significant difference between both groups. .

In the present study, mean onset of sensory block in group R is 4+0.69 min , and in group RF is 4.55+0.72min with a p value of 0.006 stating not statistically significant difference.

Duration of sensory block in group R is 151.03+6.458min, and in group RF is 196.58+8.391 min with a p value of <0.0001 stating statistically significant difference.

Onset of motor block in group R is 3.94+0.65min, and in group RF is 4.28+0.45min with a p value of 0.0082 stating not statistically significant difference.

Duration of motor block in group R is 149.08+6.335 min, and in group RF is 150.76+6.549 min with a p value of < 0.0001 stating statistically significant difference.

In the present study, there is no significant difference is noticed between mean heart rate, Spo₂, MAP between 2 groups.

On comparison of VAS scores between 2 groups, pre operatively p value is 0.7263 which is statistically in significant, whereas post operatively p value is < 0.0001 indicating a statistical significance and lesser VAS scores in group RF.

Table-1: Comparison Of Mean VAS Between The Group R And Group RF

Parameters	GroupR	GroupRF	P-Value
Preoperative VAS	6.89 +1.203	6.79 +1.277	0.7263
Postoperative VAS	4.26+0.644	1.92+0.882	<0.0001*

In the present study, on comparison of pruritis and nausea of 2 groups, p value of 0.4933 is noticed which is not statistically significant whereas on comparing presence of vomiting in both groups p value is 1 indicates not statistically significant.

Table 2: Association Between Side Effects And Groups Of Study Subjects

Parameters	Group R	Group RF	P- Value
Pruritis and nausea	0	2	0.4933
Without pruritis and nausea	38	36	
Vomiting	0	1	1
Without vomiting	38	37	

DISCUSSION :

Ropivacaine is an amide local anesthetic that is less toxic to the CNS and cardiovascular system and has a faster recovery of motor function, making it a popular alternative. Intrathecal injection of plain ropivacaine caused a variable extent sensory block, and a significant number of patients required general anesthesia to complete surgery.⁵

Hyperbaric ropivacaine causes more predictable and consistent sensory and motor block, with a faster onset than a plain solution. The addition of fentanyl, clonidine, and dexmedetomidine was investigated to determine the influence on sensory and motor block characteristics associated with plain ropivacaine.⁵

In the present study hyperbaric ropivacaine is used as it was more

reliable than plain ropivacaine. Supporting our study, a study by Kim S. Khawet al., hyperbaric ropivacaine was found to be more reliable and disseminated cephalically than isobaric ropivacaine. Hyperbaric solutions spread due to gravity, whereas isobaric (plain) solutions do not. This results in increased concentration around the injection site.⁶

Similarly, Several studies Fettes *et al.*,⁷ Rajni Gupta *et al.*, Kim S. Khaw *et al.*,⁸ comparing hyperbaric and isobaric ropivacaine for spinal anaesthesia found that the isobaric group had a higher incidence of inadequate block, requiring general anaesthesia supplementation. In their investigation, group H had a shorter mean duration of sensory analgesia than group I.(p<0.05).

In the present study, Bromage score is similar score in both groups. This may be because of presence of same base drug in both the groups.

In the present study, onset of sensory block , Duration of sensory block , Onset of Motor block , Duration of motor block found no statistically significant difference between group R and group RF.

Similar to our study, study conducted by Ben David *et al.*, discovered that adding fentanyl increased the level and duration of sensory block without changing the motor block features. It resulted in the administration of lower doses of local anesthetic, which reduced the duration of motor block, the incidence of extremely high block, and hypotension.⁹

Similar to our study, Wai-Keung Lee stated that in his study, most patients experienced good pain relief with an epidural infusion of ropivacaine 0.1%, either with or without fentanyl. Motor block was minimal. The addition of fentanyl at 1 µg/mL considerably enhanced analgesia. Fentanyl caused side effects such as hypotension, nausea, and itching, although these were not statistically significant.⁷

In contrast to our study, Yoon Rho *et al.*, discovered that combining ropivacaine and fentanyl did not reduce sensory onset or result in an excessively prolonged sensory block level.¹⁰

In the present study on comparison of hemodynamic changes no statistical significant changes are seen between 2 groups.

Similar to present study, Revipati *et al.*, found no significant difference in heart rate after subarachnoid block in both the RD and RF groups. ⁵ Hypotension was also not statistically significant (P - 0.196). Contrary to the findings of Gupta *et al.* and El-Attar *et al.*⁵

On comparison of VAS scores between 2 groups, pre operatively p value is 0.7263 which is statistically insignificant, whereas postoperatively p value is <0.0001 indicating a statistical significance and lesser VAS scores in group RF

Similar to present study, Khanna A *et al.*, found that adding fentanyl to ropivacaine increased analgesia and was comparable to plain ropivacaine. Participants who received ropivacaine alone experienced more pain, consumed more PCEA, and needed more rescue analgesia than those in the "LA-fentanyl" combination groups.¹¹

In the present study, on comparison of pruritis and nausea of 2 groups, p value of 0.4933 is noticed which is not statistically significant where as on comparing presence of vomiting in both groups p value is 1 indicates not statistically significant value.

Similar to our study, In Revipati *et al.*, investigation, no patients in Group RD experienced pruritis. One patient in Group RF developed pruritis, accounting for 3.33%. This was not statistically significant (P - 0.313) and results were consistent with the research conducted by Gupta *et al.* and El-Attar *et al.*⁵

In contrast to our study, Wai-Keung Lee *et al.*, discovered that combining ropivacaine and fentanyl resulted in more sympathetic blocking, leading to hypotension in hypovolemic patients. Group RF patients reported higher rates of opioid-related side effects, including pruritis and nausea, as expected.⁷

CONCLUSION:

Both groups group R and group RF showed no statistical significant difference with respect to demographic parameters, onset of motor and sensory block and hemodynamic parameters whereas Group RF

showed longer duration of sensory and motor block and lesser VAS score compared to Group R, which are statistically significant concluding that addition of fentanyl to ropivacaine gives more acceptable results than plain ropivacaine.

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