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# To evaluate the effect of intrathecal 0.75% isobaric ropivacaine with fentanyl in two different doses - A comparative study in caesarean section.

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## Abstract

**Background and Aim:** Subarachnoid block is the technique of choice in Caesarean sections for which 0.5% hyperbaric solution of Bupivacaine is the most commonly used local Anaesthetic agent. However, newer local anaesthetics like Ropivacaine which produces relatively lower motor block and better sensory-motor differentiation with haemodynamic stability can also be used. The present study was aimed to compare two different doses of isobaric ropivacaine (0.75%) with fentanyl as adjuvant intrathecally, in patients undergoing elective caesarean section in terms of mean duration of postoperative analgesia, block characteristics, adverse effects and patient's satisfaction.

**Materials and Methods:** Sixty term parturients aged 18-45 years with ASA physical status II undergoing elective Caesarean section were included and randomised into two groups, Group A and Group B; with 30 patients in each group. In Group A, 2.5ml of Inj. 0.75% Isobaric Ropivacaine-1.8ml (13.5mg) + 0.5ml Fentanyl (25mcg) + 0.2ml 0.9% NS was injected intrathecally and in Group B it was 2.5ml of Inj 0.75% Isobaric Ropivacaine-2.0ml (15mg) + 0.5ml Fentanyl (25mcg).we assessed the onset and duration of motor and sensory blockade along with the duration of post operative analgesia. Haemodynamic variables were also compared and patients were observed for any side effects or complications related to the drug

and technique. Surgeon's and patient's satisfaction was also noted.

**Results:** The mean time to onset of both sensory and motor block was lesser in group B as compared to group A. Group B had longer mean duration of sensory and motor block. The mean time to first rescue analgesic was lesser in group A as compared to group B (p-value <0.001).

**Conclusion:** Low dose isobaric ropivacaine with fentanyl provides dense sensory block with early recovery of motor blockade and better haemodynamic stability.

**Keywords**: Block characteristics, Caesarean section, spinal anaesthesia, postoperative analgesia.

**Introduction**

Caesarean section is one of the most commonly performed surgeries in females of reproductive age group with subarachnoid block being the usual choice of Anaesthetic technique. It is safe, easy to perform, effective, has low failure rate, no systemic toxicity, inexpensive, prevents aspiration pneumonia and since the parturient remains awake during the surgery, she is able to ensure early breast feeding of the child thereby, strengthening the bond between mother and baby.[1]It inhibits the stress response to surgery, blunts the autonomic and somatic responses to pain which helps in early ambulation.[2] Efferent sympathetic blockade results in better wound healing due to increased blood flow to the blocked area and also minimises the risk of deep vein thrombosis and thromboembolism.

Bupivacaine is the most widely used local Anaesthetic agent for subarachnoid block, owing to its relatively safer neurotoxic profile as compared to other local anaesthetics and longer duration of action. However, this long duration of action delays recovery of motor function and prolongs Post Anaesthesia Care Unit (PACU) stay after surgery. Several studies have shown that bupivacaine is associated with a relatively higher incidence of cardiac toxicity, compared to other local anaesthetics. [3,4] This led to the need for newer local anaesthetics with a relatively safer cardiac profile. Ropivacaine, a long-acting amide local Anaesthetic agent, produces effects similar to other local anaesthetics by reversible inhibition of sodium ion influx and thereby blocking impulse conduction in nerve fibres.[5] It has reduced potential for cardiotoxicity and neuro toxicity as compared to bupivacaine and lignocaine. Ropivacaine is less lipophilic than bupi vacaine and less likely to enter large myelinated motor fibres, which in turn produces relatively lower motor block and hence has a better motor sensory-motor differentiation with haemo dynamic stability.[6]

The spread of the block is thought to be influenced more by the mass of the local Anaesthetic and the use of adjuvants rather than the concentration or volume of the drug alone. Therefore, the combination of intrathecal local anaesthetics with adjuvants, provides a dense sensory block with optimal pain control and decreases the incidence of adverse effects related to local ana esthetics.

A number of adjuvants have been studied to prolong the effect of spinal anaesthesia. Fentanyl is a potent, short acting, highly lipophilic synthetic opioid analgesic and acts primarily as an agonist at μ opioid receptors to enhance spinal analgesia.[7] It also allows finer titration of local Anaesthetic dose to ensure a better haemodynamic stability, dense sensory block and thus an improved quality of anaesthesia.

Since, there is paucity of literature on intrathecal ropivacaine -fentanyl combination for post operative analgesia in lower abdominal surgeries and caesarean sections; we did this study to compare the two different

doses of isobaric ropivacaine (0.75%) with fentanyl intrathecally, in patients undergoing elective caesarean section. The primary aim was to assess duration of post operative analgesia. Secondary objectives included block characteristics, adverse effects and patient satisfaction.

**2Materials and methods**

Following the institutional ethical committee approval (No.F.29(Acad)SPMC/2022/4771) and registering the trial in the Clinical Trials Registry of India (CTRI/ 2023/ 02/ 050029), the study was conducted at a tertiary centre after obtaining written informed consent from patients and relatives. Sixty term parturients aged 18-45 years with American Society of Anaesthesio logists (ASA) physical status II undergoing elective Caesarean section were included in the study. Patients with any history of bleeding diathesis, peripheral neuropathy, neurological disease, psychiatric disease, respiratory disease, acute or chronic liver or renal disease, patients on anticoagulant therapy, infection at the site of injection or any known allergy to the drugs were excluded. The principles of the Declaration of Helsinki were followed while conducting the study.

Participants were randomised using computer generated simple randomised numbers into two groups, with 30 parturients in each group. A detailed preanaesthetic check-up with a thorough physical examination was carried out for all the patients one day prior to surgery. They were advised Nil Per Oral (NPO) for at least six hours prior to surgery as per American Society of Anaesthesio logists (ASA) fasting guidelines. The entire procedure and visual analogue scale were explained to all the parturients.

On arrival of parturient in the operating room, a 20-gauge intravenous cannula was secured and IV infusion of Inj. Ringer's Lactate was started at the rate of 15ml/kg. The patients were connected with multi-parameter monitor to record heart rate (HR), non-invasive measurement of blood pressure, 5-lead electrocardiogram (ECG) monitoring and oxygen saturation ($Spo_2$). The baseline MAP, HR, $SpO_2$ were recorded. An anaesthesio logist not involved in the care or monitoring of the patient prepared the local Anaesthetic drug solutions. Both the patients and the observing anaesthesio logist were blinded to the study drug.

Under all aseptic precautions, with the parturients in sitting position, L3– L4 interspace was palpated and using 25-Gauge spinal needle, after confirmation of free flow of CSF either Inj. 0.75% isobaric ropivacaine-1.8ml (13.5mg) + 0.5ml fentanyl (25mcg) + 0.2ml 0.9% NS [Group-A] or Inj 0.75% isobaric ropivacaine-2.0ml (15mg) + 0.5ml fentanyl (25mcg) [Group-B] was injected. The patients were placed in supine position immediately after subarachnoid injection with a 15-degree wedge placed below right hip. Surgery was initiated only after the sensory level of the block reached up to T4 dermatome. Time to onset of the sensory block was assessed by pinprick method using a 3 point ordinal scale (0=Normal sensation,1=loss of sensation to pinprick,2=loss of sensation to touch) once in every two minutes till T4 level of the block was reached. The onset of motor block was assessed every two minutes for 10 minutes after injection of drug using Modified Bromage scale (Grade 0:The patient can move the hip, knee, and ankle (no motor block 0%); Grade 1**:**The patient is unable to move the hip but able to move the knee and ankle (partial motor block 33%); Grade 2**:**The patient is unable to move hip and knee but able to move the ankle (near complete motor block 66%); and Grade 3:The patient is unable to move hip, knee, and ankle.(complete motor block 100%). After 10 minutes if desired sensory/motor block was not achieved, then the block was declared to be failed and general anaesthesia was

administered. Such cases were excluded from the study. Haemodynamic parameters were recorded at 0, 5, 10, 15, 30, 45 minutes, 1 hour then hourly till 6 hours, 12 hours and then at 24 hours. Hypotension (defined as BP<90 mm Hg or <20% of baseline BP) was treated with IV fluids initially (250 ml boluses repeated twice) followed by Inj. IV me phentermine in increments of 6 mg as and when required. Bradycardia (defined as heart rate of <60) was treated with 0.6 mg of Inj. intravenous atropine sulfate. After surgery parturients were shifted to recovery room. Post operatively VAS scores (where score 0= no pain, score 5 = distressing pain and score 10=unbearable pain) were assessed on scale of 0-10 hourly till first 6 hours and then at 12 hours and 24 hours. Duration of sensory block was defined as duration from the time of onset of sensory blockade till the patient complained of pain at the site of surgery. Rescue analgesia with Inj. diclofenac 75 mg IM was given when VAS score was more than three. Time for the first dose of rescue analgesic in the post operative period and the total number of rescue analgesics in the first 24 hours were noted down. Duration of motor blockade was defined as the time from the onset of motor blockade till the time for complete recovery of motor power. Patient satisfaction was assessed as- excellent (no discomfort or pain, good (mild pain or discomfort with no need for additional analgesics), fair (pain that required additional analgesics) and poor (moderate to severe pain). Any untoward incidents like nausea, vomiting, respiratory depression, bradycardia or hypotension, pruritus, any allergic reactions to study drugs were noted down as complications / side effects. The sample size was cal culated according to the formula: Sample size N =2($z_{\alpha}$ + $z_{1-\beta}$ )$^2$ $\sigma^2$ /$\delta^2$ using MEDCALC statistical software. It came out to be twenty-two cases for each group assuming 80% study power, 5%alpha error and 20%beta error. We did roundoff of 30 cases for each group for the present study expecting approximately 30% drops out.

A pre-structured Performa was used for data collection and statistical analysis was done with appropriate computer based statistical software SPSS version 26. Categorical data/results were presented as ratio or percentage, continuous data were presented as mean ± standard deviation or median (95% confidence interval). Chi-square test was used to analyse the categorical variables while intragroup comparison of mean changes in outcomes was evaluated by unpaired t test. The statistical significance was represented with p< 0.05 as significant and p< 0.001as highly significant. The entire methodology has been described in the consort diagram. [Figure 1]

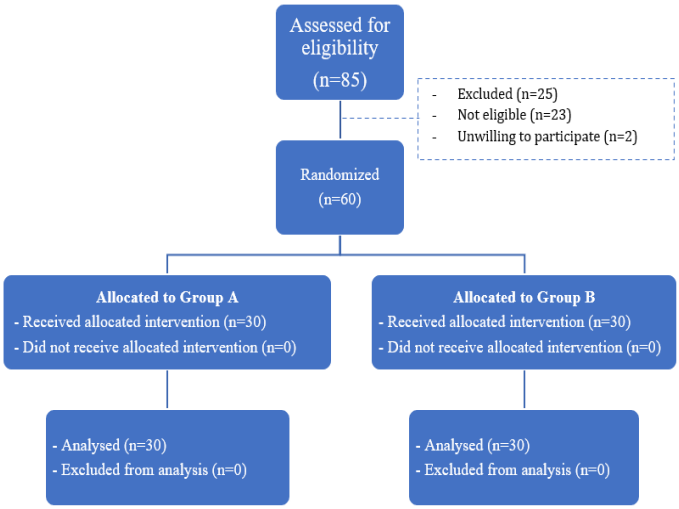



Figure 1: consort diagram of the study

**Results**

There was no drop out from our study and no case of failed spinal. Distribution of age, weight and height between the two groups of our study were comparable [Table 1]. Most of the patients in both the groups were from the age group of 22- 38 years.

Table 1: Comparison of demographic data of both groups. (n=60)

| Variables | Group A (Mean±SD) | Group B (Mean±SD) | p-value |
|---|---|---|---|
| Age (years) | 26.03± 3.04 | 25.53±4.83 | 0.63 |
| Weight(kg) | 60.53±4.10 | 60.73±3.60 | 0.84 |
| Height (cm) | 158.33±2.68 | 157.43±3.19 | 0.24 |

*Unpaired t-test.

Mean Visual Analogue Scale (VAS) scores of parturients in group A was 3.44±0.28 whereas in group B was 3.32±0.0.45 [Table 2]. The overall difference was statistically insignificant (p-value = 0.11), even though individually it was found to be significant at 5 hours, 6 hours, and 12 hours.

Table 2: Comparison of Visual analog scale (VAS) of patients in Group A and Group B from 1 hour to 24 hours post operatively.

| Time | Group A (Mean±SD) | Group B (Mean±SD) | p-value |
|---|---|---|---|
| T7(1hr) | 0.00±.000[a] | 0.00±.000[a] | - |
| T8(2hr) | 1.13±0.34 | 1.07±0.45 | 0.522 |
| T9(3hr) | 2.30±0.46 | 2.30±0.46 | 1 |
| T10(4hr) | 3.40±1.45 | 3.00±0.98 | 0.217 |
| T11(5hr) | 5.97±1.42 | 4.97±1.06 | 0.003 |
| (T12) (6hr) | 5.73±1.57 | 6.93±1.28 | 0.002 |
| (13)12hr | 4.63±1.03 | 4.03±0.76 | 0.013 |
| (T14)24hr | 4.37±0.89 | 4.33±0.80 | 0.879 |
| Mean VAS | 3.44±0.28 | 3.44±0.25 | 0.11 |

*Unpaired t-test.

The mean time to first rescue analgesia in group A (309.33±33.90 min) was less than in group B (334±18.12 min) and was highly statistically significant (p-value <0.001) [Table 3].

Table 3: Comparison of Time to First Rescue Analgesia (Minutes)in Group A and Group B.

| Time | Group A (Mean±SD) | Group B (Mean±SD) | p-value |
|---|---|---|---|
| Time to first rescue analgesia (minutes) | 309.33±33.90 | 334.00±18.11 | 0.001 |

*Unpaired t-test.

Mean time to the onset of sensory block of parturients in group A was 2.419±0.42 min and in group B was 1.42 ± 0.23 min and thus difference was highly statistically significant (p-value < 0.001). The mean duration of sensory block of patients in group A was 243.50±22.40 min whereas in group B was 269.03±15.90 min and the difference was highly statistically significant (p-value < 0.001) between both the groups. The mean time to onset of motor block of patients in group A was 6.60±0.52 min whereas in group B it was 4.93±0.92 min and the difference was highly statistically significant (p-value < 0.001). Mean duration of action of motor block of patients in Group A was 196.67±22.45 min whereas in Group B it was 219.67±22.32 min and the difference was found to be highly statistically significant (p-value <0.001) [Table 4]

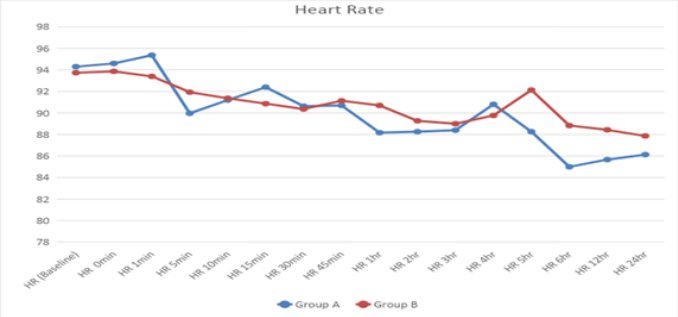
Table 4: Comparison of block characteristics of both groups

| Time | Group A (Mean±SD) | Group B (Mean±SD) | p-value |
|---|---|---|---|
| Onset of sensory block (minutes) | 2.41±0.42 | 1.41±0.23 | 0.0001 |
| Duration of sensory block (minutes) | 243.50±22.40 | 269.03±15.90 | 0.0001 |

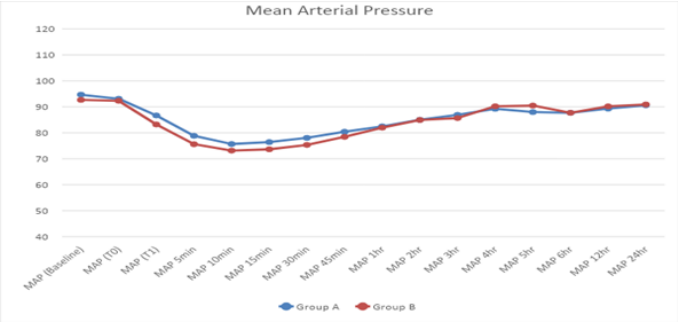
| | | | |
|---|---|---|---|
| Onset of motor block (minutes) | 6.60±0.52 | 4.93±0.92 | 0.0001 |
| Duration of motor block (minutes) | 196.67±22.45 | 219.67±22.32 | 0.0001 |

*Unpaired t-test.

Incidence of variations in the haemodynamic variables have been depicted in Graph 1 and 2. Although, mean baseline heart rate in both the groups was comparable (p-value = 0.87) but the difference in heart rate between group A and group B was found significant at 5 hours (p-value=0.03) and 6 hours (p-value = 0.02).

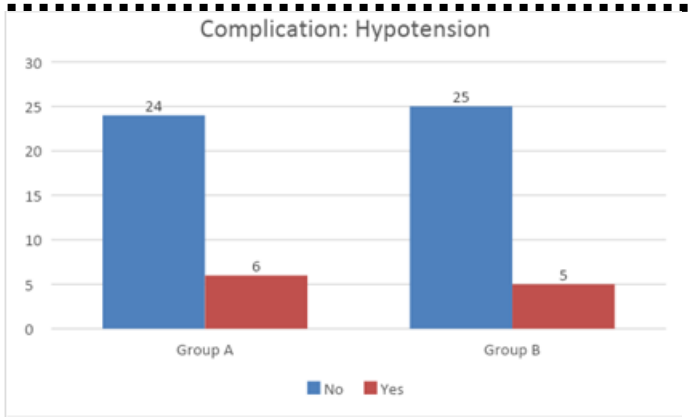



Graph 1: Heart rate trend from 0 min to 24 hours in Group A and Group B.



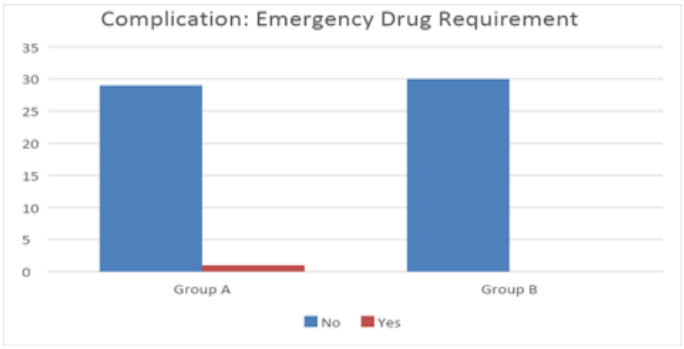

Graph 2: Trend of mean arterial pressure from 0 min to 24 hours in Group A and Group B.

Hypotension was found to be the most common adverse effect but the difference between both the groups was not statistically significant (p-value = 0.74) [Graph 3].




Graph 3: Comparison of Complication: Hypotension in Group A and Group B.

Six patients in group A and five patients in group B developed hypotension. However, while in group A, only one patient required use of emergency drug, in group B, no patient needed emergency drug and the overall difference was statistically insignificant across both groups (p-value = 0.31) [Graph 4].




Graph 4: Comparison of Complication: Emergency Drug Requirement in Group A and Group B.

**Discussion**

Choice of local Anaesthetic for subarachnoid block in caesarean section is based on need for longer duration of sensory block and shorter duration of motor block along with reduced maternal and foetal toxicity. Thus, ropivacaine is nowadays being preferred widely due to less CNS and cardiac toxicity, early ambulation and good quality of post operative analgesia as compared to other local anaesthetics. Moreover, addition of adjuvants to

local anaesthetics prolongs the duration of sensory block and provides better haemodynamic stability.

In our study, VAS score was significantly less and the mean time to first rescue analgesia was significantly longer in group B as compared to group A for first 24 hours[Mean VAS score 3.44+-0.28 Vs 3.32+-0.45];Time to first rescue analgesia was 309.33+-33.90 Vs 334.18+-18.12.These findings are similar to the study conducted by Vasanti P. Kelkar et al who compared two different doses of intrathecal isobaric ropivacaine (20 mg and 15 mg) in caesarean section and found that 20mg isobaric ropivacaine had longer duration of analgesia as compared to 15mg isobaric ropivacaine group[152+-14.5 Vs 130+-17.4][8].The reason for prolonged duration of analgesia in our study as compared to Vasanti .P. Kelkar et al may be because we used fentanyl as adjuvant which not only prolongs duration of analgesia but also provides dense sensory block and the above said study used only plain ropivacaine .

The mean time to onset and mean duration of both sensory and motor block was significantly less in Group B as compared to group A. Our results are in con cordance with a study by Sawant K B et al who com pared hyperbaric ropivacaine and isobaric ropivacaine with fentanyl as adjuvant in caesarean section. Duration of surgical analgesia in hyperbaric group was 218. 37±28.74min and 239.30±28.28min in isobaric group thereby, concluding that isobaric Ropivacaine provides excellent muscle relaxation and surgical analgesia. [9] Gandhi P et al compared plain isobaric ropivacaine and isobaric ropivacaine with fentanyl in caesarean section and observed that duration of onset of sensory block and total duration of analgesia was 2.7±0.91vs2.7±0.51min and 132.3 ± 16.62 vs 191.8 ± 18.76min respectively. Ropivacaine with fentanyl accelerated the onset and duration of sensory block.[10] MA nazir Athar et al also observed that mean duration of onset of motor block and duration of sensory block with ropivacaine-fentanyl combination in caesarean section were 5.1±1.3 min and 236.3±12.4 min respectively [11].

In our study there was decrease in mean arterial blood pressure after administration of drug in both the groups. However, the overall variations in blood pressure was statistically insignificant between both the groups. A study conducted by Nishat Akthar et al**,** also showed no significant difference between the two groups in terms of systolic BP, diastolic BP and MAP [12]. The difference in heart rate between both the groups was although found significant only at 5 hours and 6 hours but none of the patients developed bradycardia, Multiple studies show that isobaric Ropivacaine in combination with different adjuvants provides overall haemodynamic stability [12- 14]

One patient in group A developed hypersensitivity reaction in the form of pruritis and it was duly managed by Inj. ondansetron 0.15mg/kg [15]. However, no such reaction was reported in group B. Limitations of this study where that it was conducted in a single centre service hospital, thus, results cannot be generalised to the population of other countries and study population included only ASA II patients. Therefore, a multi centre model with a longer duration of study is further validating the outcomes. Effect of drugs on pregnancy associated disorders / co morbidities and critically ill patients also need further study. Moreover, pain is a subjective sensation, thus its quantification was difficult.

**Conclusion**

Low dose isobaric ropivacaine with fentanyl provides sufficiently dense sensory block with early recovery of motor blockade and equivalent hemodynamic stability. This leads to early ambulation postoperatively leading to early maternal and foetal bonding.

**References**


1. Dharmalingam TK, Ahmad Zainuddin NA. Survey on maternal satisfaction in receiving spinal anaesthesia for caesarean section. Malays J Med Sc,20,51-4(2013).
2. Roofthooft E, Van de Velde M. Low-dose spinal anaesthesia for caesarean section to prevent spinal-induced hypotension. Curr Opin Anaesthesiol,21,259-62. (2008).
3. Bernhard M. Graf, Ingo Abraham, Nicole Eberbach, Gudrun Kunst, David F. Stowe, Eike Martin; Differences in Cardiotoxicity of Bupivacaine and Ropivacaine Are the Result of Physicochemical and Stereoselective Properties. Anesthesiology,96,1427–1434.(2002).
4. Nalini A, Uma Kuragayala, Bhimeswar MV. A comparative study of intrathecal 0.5% isobaric Ropi vacaine Vs 0.5% isobaric bupivacaine in lower ab dominal surgeries. International Journal of Contemporary Medical Research.,3(11):3124-3127(2016).
5. Mohta M. Ropivacaine: Is it a good choice for spinal anesthesia? J Anaesthesiol Clin Pharmacol,31(4):457-8 (2015).
6. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. Indian J Anaesth, 55, 104-10(2011).
7. Sonya K, Davies CV. A prospective randomised double blind study of the comparison of two opioids-fentanyl and buprenorphine – as adjuvant to spinal bupi vacaine in caesarean sections. Int J Clin Trials, 4 (1): 45-8(2017).
8. Vasanti P. Kelkar, Prabha P. Nayak et al : Intrathecal Isobaric Ropivacaine for Cesarean Section: A comparison of 15 mg and 20 mg Dose. International Journal of current Medical and Applied sciences,8(2),46-50(2015).
9. Sawant K B, Patel H, Intrathecal ropivacaine with fentanyl for LSCS Comparison of hyperbaric and iso baric solution. Indian J Clin Anaesth , 2 (3), 156-160 (20 15).
10. Gandhi P, Agrawal M, Agrawal B, Behl S. Comparative study of clinical efficacy and safety of intrathecal isobaric ropivacaine 0.75% with fentanyl versus isobaric ropivacaine 0.75% alone for caesarean. Int J Sci Rep ,7(1):1-5(2021).
11. Athar M, Haleem S, Fatima N, Khan D, Ozair E, Varshney VK. Does Ropivacaine Causes less Spinal Induced Hypotension than Bupivacaine in Caesarean Section: A Randomised Study. Ann. Int. Med. Den. Res, 2, 328-32(2016)
12. Akhtar N, Quadir A, Athar M, Singh N. Recovery profile of intrathecal ropivacaine with or without fentanyl: A randomized double-blind controlled trial in equivalent doses. Int J Health Allied Sci,5,158-63(2016).
13. Ateser R Y, Kaya can N. Intrathecal ropivacaine in cesarean delivery. Niger J Clin Pract,20,1322-7(2017).
14. Satyanarayana, P., Sreedevi, P., Lakshmi, M. B., & Abbaiah, P. Comparative study of intrathecal isobaric and hyperbaric ropivacaine in cesarean delivery. International Journal of Health Sciences ,6(S2),6728–36 (2022).
15. Kumar K, Singh SI. Neuraxial opioid-induced pruritus: An update. J Anaesthesiol Clin Pharmacol, 29 (3): 303-7(2013).