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Intrathecal Levobupivacaine with Fentanyl Versus Levobupivacaine with Nalbuphine in Infraumbilical Surgeries

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Abstract:
Background*: Spinal anaesthesia is a temporary interruption of nerve transmission in the subarachnoid space that is produced by injecting local anaesthetic solution into cerebrospinal fluid (CSF). Levobupivacaine was commonly used in ambulatory surgeries with the advent of low-dose spinal anaesthesia technique. Opioids can provide most effective pain relief. Intrathecal opioids act synergistic with local anaesthetics and increase sensory block without influencing sympathetic block.*
Objective: *This study was done to know the efficacy of adding nalbuphine and fentanyl to isobaric levobupivacaine spinal anaesthesia in patients scheduled for infraumbilical surgeries.*
Materials and Methods: *This study was done at a tertiary care teaching institute in the Department of anaesthesia at Katuri Medical College, Andhra Pradesh, India, from July 2022 to December 2022. 50 patients were included as per the eligibility criteria. They were randomized into two groups (group N and group F), each group containing 25 patients. Age, gender, duration of analgesia, duration of sensory and motor blocks, side effects were assessed for all patients.*
Results: *There is no significant difference in the mean age and gender of patients between two groups. Most of the patients were males. Duration of analgesia and duration of sensory block was significantly more in group N patients. Duration of motor block was significantly more in group F patients. Mean sedation score was significantly more in group F patients. Shivering was the most common side effect followed by nausea and vomiting.*
Conclusion: *From our study, it is concluded that both the groups were almost equally efficacious with good intraoperative conditions but patients in Nalbuphine group had more duration of analgesia and more duration of sensory block with minimal side effects.*
Key Words: *Efficacy, Fentanyl,Infraumbilical SurgeriesLevobupivacaine, Nalbuphine*

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I. Introduction

Development of regional anaesthesia started with isolation of local anaesthetics like cocaine (the Spinal anaesthesia is a temporary interruption of nerve transmission in the subarachnoid space that is produced by injecting local anaesthetic solution into cerebrospinal fluid (CSF). Spinal anaesthesia has various advantages over general anaesthesia, mainly for surgeries of lower abdomen, perineum and lower extremities.[1]It is commonly used procedure forinfra-umbilical surgeries due to its cost-effectiveness, effective analgesia, good muscle relaxation and improved postoperative analgesia. Spinal block is ablock that has well-defined end points through which an anaesthesiologist can produce blocks using just a single injection. Absolute contraindications include increased intracranial pressure, which could be due to intracranial mass or infection at the site of procedure, patient refusal, coagulopathies.[2]Some of the side effects include backpain, post dural puncture headache, nausea, vomiting, hypotension etc. Distribution of local anaesthetic medications within the subarachnoid space affects the extent of neural blockade caused by spinal anaesthesia. Agents that are commonly used for spinal anaesthesia include local anaesthetics like lidocaine, tetracaine, bupivacaine, levobupivacaine, chloroprocaine, mepivacaine and ropivacaine. Levobupivacaine was commonly used in ambulatory surgeries with the advent of low dose spinal anaesthesia technique. To improve block characteristics of spinally given low dose local anaesthetics, adding adjuvant is compulsory.[3]Opioids can provide most effective pain relief. Intrathecal opioids act synergistic with local anaesthetics and increase sensory block without influencing sympathetic block. [4]Opioids forma vital component of postoperative pain management.

They decrease neuroendocrine stress response to pain. Giving opioids and local anaesthetic were previously studied to improve the quality of analgesia in various surgeries.[5,6]Combing opioids with local anaesthetics helps to decrease pain by action at 2 sites. Local anaesthetics act at axon of nerve and opioid at receptor of spinal cord.[7]All less studies were done on knowing the efficacy of combinational levobupivacaine in India, the current study was undertaken,

Objective: This study was done to know the efficacy of adding nalbuphine and fentanyl to isobaric levobupivacaine spinal anaesthesia in patients scheduled for infraumbilical surgeries.

II. Material And Methods

This comparative study was carried out at a tertiary care centre in India from July 2022 to December 2022.

Study Design: Comparative-randomized, single-blinded study

Study Location: This study was done at a tertiary hospital named Katuri Medical College & Hospital,Andhra Pradesh, India.

Study Duration: July 2022 to December 2022

Sample size: 50 Patients

Sampling procedure: Simple random sampling

Sample size calculation: The sample size was estimated from data of previous study done by, Girgan NK et al,[8] there is a standard deviation of 16.05 in duration of sensory block among patients scheduled for lower abdominal surgeries using levobupivacaine and fentanyl, using an errow of 4% and 85% confidence intervals, the minimum sample size came to be 43. Sowe included 50 patients in our study.

Subjects & selection method: The study population includes patients who were scheduled for infraumbilical surgeries at our tertiary care center under spinal anaesthesia.

Patients of Group N(n=25)received 15 mg isobaric Levobupivacaine (0.5%) with 0.8mg Nalbupine.
Patients in Group F(n=25)received 15 mg isobaric Levobupivacaine (0.5%) with 25mcg Fentanyl.

Eligibility criteria:

Inclusion criteria:

1. Patients aged above 18 years
2. Both males and females
3. ASA grade I and II patients scheduled for infraumbilical surgeries.
4. Patients who provided informed consent to participate in the study.

Exclusion criteria:

1. Pregnant and lactating women
2. Patients with coagulation abnormalities
3. Patients with allergies to opioids or local anaesthetics
4. Patients with spinal deformities
5. Patients with raised intracranial tension

III. Methodology:

Under strict aseptic precautions, spinal anaesthesia was given at L3-L4 interspace by 25 G Quincke needle in sitting position. Medication was injected into subarachnoid space after checing the free flow of CSF.
Hypotension, if noted, was treated with Ephedrine 6 mg. Bradycardia was treated with IV Atropine
Sensory testing was assessed using loss of pinprick sensation to 23 G needle.
Sedation was assessed using Ramsay sedation scale[9], which ranges from 1 to 6.
After completion of surgery, patient was shifted to post operative room. Postoperatively vital parameters vitals were recorded every 1 hour and also side effects were moted.
Motor block was assessed using modified bromage scale[10], which ranges from 0 to 3.

Parameters assessed:

- Age
- Gender
- Duration of analgesia
- Duration of sensory and motor blocks
- Time for rescue analgesia
- Sedation score
- Side effects

Ethical considerations:
Informed consent form was taken from every patient participated in the study.

Statistical analysis
Data was analyzed using SPSS software version 26.0 Results were expressed as percentages and mean with standard deviation. Students t test was used to compare numerical values between two groups and chi square analysis was used to compare categorical values between two groups. P value below 0.05 is considered significant.

IV. Results

The current study included 50 patients scheduled for elective infraumbilical surgeries.

Demographic features:
There is no significant difference in the mean age and gender of patients between two groups.

Table 1 shows demographic features of patients of both groups

Parameters	Group N	Group F	P value
Mean age	54.2±7.1 years	52.3±5.2 years	0.26
Gender- males (%)	64%	60%	0.33

Duration of analgesia:
There is significant difference in the duration of analgesia between two groups.

Table 2 shows duration of analgesia

Groups	**Mean duration of analgesia(min)**	**P value**
N	424.87 + 17.02	0.001
F	284.1 + 13.9	

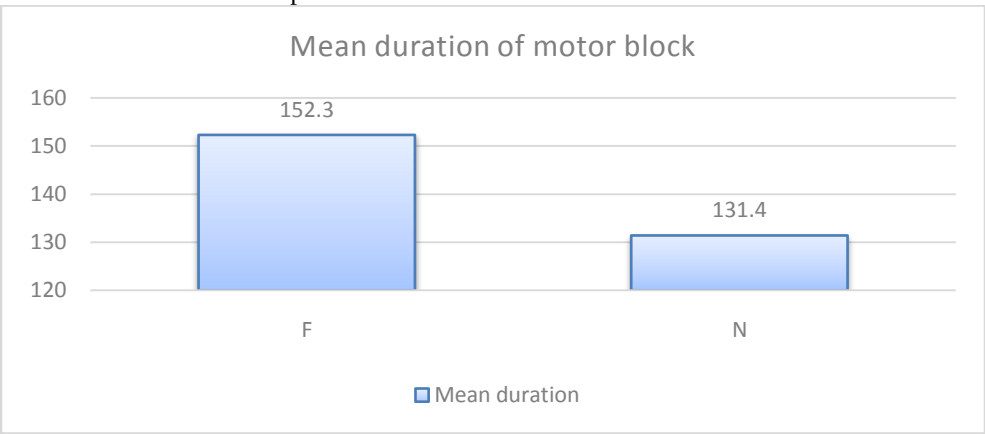
Duration of sensory block:
There is significant difference in the duration of sensory block between two groups. Mean duration is morein group D Natients.

Table 3 shows duration of sensory block

Groups	**Mean duration of sensory block(min)**	**P value**
F	240.6 + 10.1	0.001
N	388.57 + 14.2	

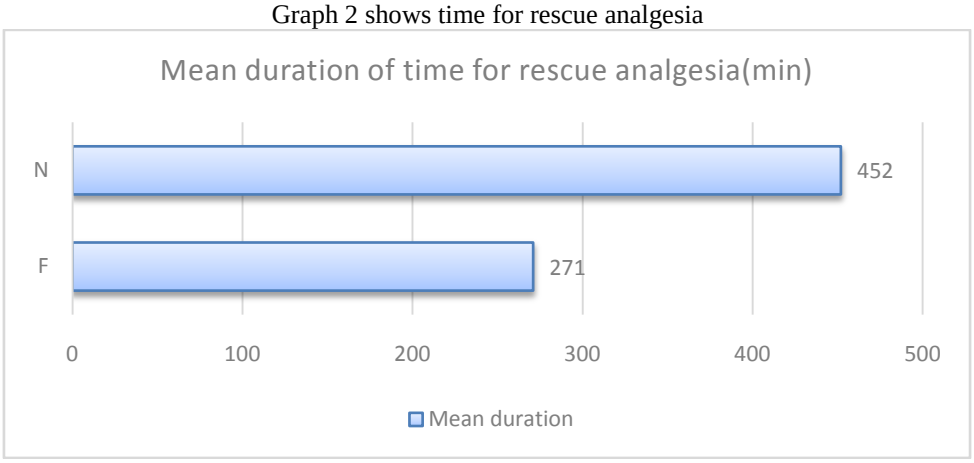
Duration of motor block:
There is significant difference in the duration of motor block between two groups(p=0.001).

Graph 1 shows mean duration of motor block



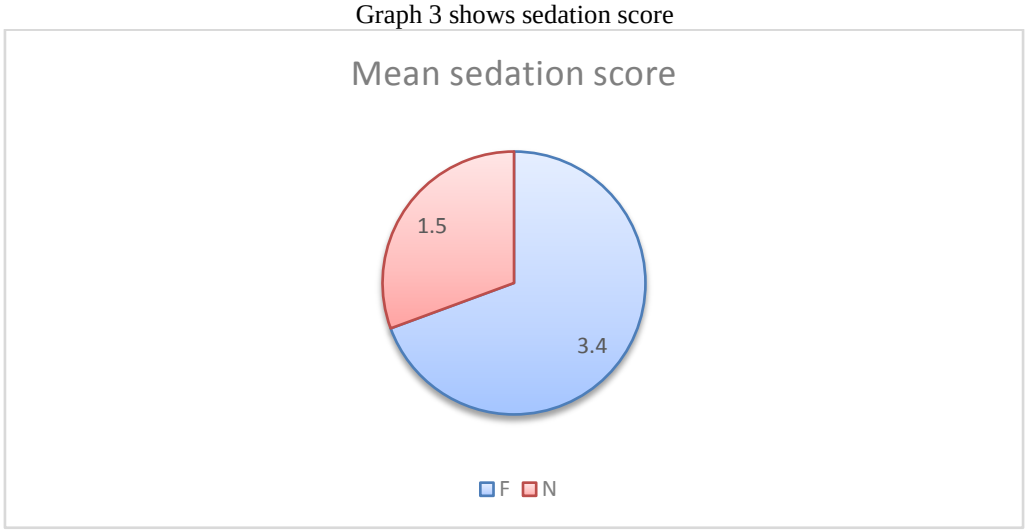
Time for rescue analgesia:
Time for rescue analgesia was significantly more in group N patients(p=0.001).

Graph 2 shows time for rescue analgesia



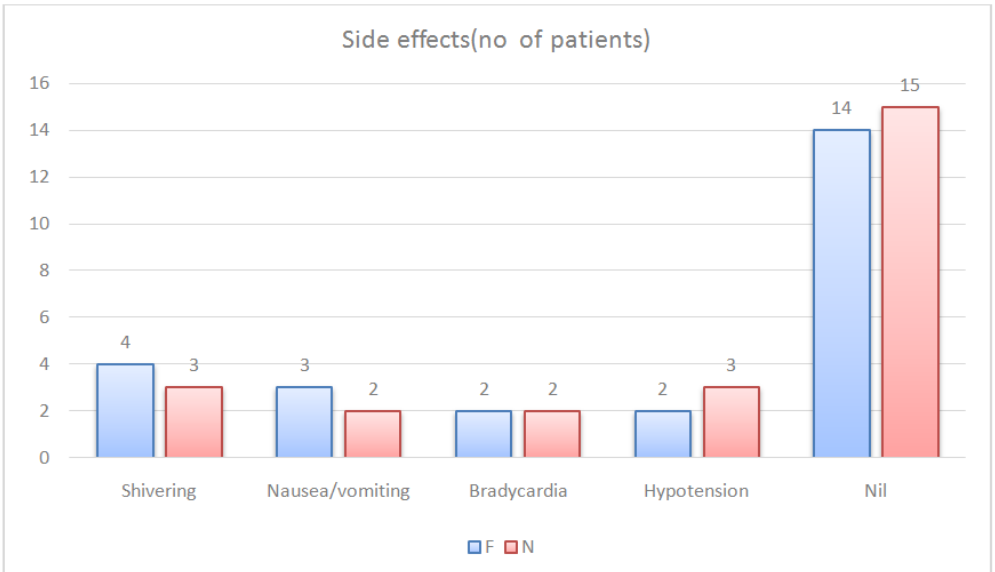
Sedation score:
Sedation score was significantly more for F group patients at 6 hours after surgery(p=0.001).

Graph 3 shows sedation score



Side effects:
Shivering was the most common side effect seen followed by nausea and vomiting.

Graph 4 shows side effects among two groups of patients



V. Discussion

The current study was done at a tertiary care teaching institute in the Department of anaesthesia at Katuri Medical College, Andhra Pradesh, India, from July 2022 to December 2022. 50 patients were included as per the eligibility criteria. They were randomized into two groups (group N and group F), each group containing 25 patients. Results showed that there is no significant difference in the mean age and gender of patients between two groups, which indicates that there is no age and gender-related bias. Most of the patients were males. Duration of analgesia and duration of sensory block was significantly more in group N patients. Duration of motor block was significantly more in group F patients. Mean sedation score was significantly more in group F patients. Shivering was the most common side effect followed by nausea and vomiting. Previous authors[11-13] in their studies, have chosen 25 micrograms of fentanyl to be added to hyperbaric bupivacaine given as spinal anaesthesia. So, we have chosen 25 micrograms of fentanyl in our study.

In the study of **Gomaa et al**[14] authors compared postoperative analgesia of nalbuphine with fentanyl added to bupivacaine and found that the duration of post-operative analgesia as more in nalbuphine group, similar to our study findings. There is significant difference in duration of sensory and motor blocks between two groups, similar to our study. Side effects were less commonly seen in nalbuphine group, similar to our study.

Naaz et al.[15]did a study on nalbuphine and fentanyl on 90 patients scheduled for elective orthopaedic surgeries of lower limb. Results showed thatthe duration of analgesia was more in nalbuphine group compared to fentanyl group, similar to our study. Analgesic requirement was less in nalbuphine group compared to fentanyl group.

Gurunath et al.[16] did a study on 124 patients to compare efficacy of nalbuphine with fentanyl given as adjuvants to spinal anaesthesia and found that theonset of sensory block as quick in Fentanyl group patients.

Bisht et al.[17]compared the efficacy of intrathecal 0.5% hyperbaric bupivacaine with fentanyl 25mcg and hyperbaric bupivacaine with nalbuphine among patients scheduled for total abdominal hysterectomy and found that time for 1st analgesic requirement is quick and earlier in fentanyl group compared to nalbuphine group. This implies that nalbuphine has more efficacy as postoperative analgesia, similar to our study results.

Study limitations:

1. Small sample size
2. Hemodynamic parameters were not measured.

V. Conclusion

Both the groups were almost equally efficacious with good intraoperative conditions but patients in Nalbuphine group had more duration of analgesia and more duration of sensory block with minimal side effects.

The study is self-sponsored. There were no conflicts of interest.

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