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ORIGINAL ARTICLE

A comparative study of intrathecal 1mg nalbuphine as adjunct to 15mg of bupivacaine 0.75% versus 15mg of bupivacaine 0.75% alone in spinal anesthesia for infraumbilical surgery.

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ABSTRACT… Objective: To compare mean duration of analgesia when 1mg Nalbuphine is added to 15mg of Bupivacaine 0.75% versus 15mg of Bupivacaine 0.75% alone in spinal anesthesia for infraumbilical surgeries. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Anesthesia, Allied Hospital, Faisalabad. **Periods:** April 2024 to October 2024. **Methods:** Total 60 subjects undergoing elective infraumbilical surgery under spinal anesthesia were assigned to two groups; Group A received inj. 0.75% Bupivacaine 15mg along with inj. Nalbuphine 1mg (0.1ml) in subarachnoid space via 25 gauge Quinke type spinal needle and Group B received 0.75% bupivacaine 15mg alone in subarachnoid space using 25guage spinal needle. Analgesia duration (hours) was calculated from sensory block onset to first request of analgesia using VAS score. Analysis of data was done using SPSS.23, for statistical significance p-value ≤0.05 was taken. **Results:** Sensory and motor block onset in Group A vs B noted was 3.25 ± 0.41 minutes & 6.36 ± 0.66 minutes vs 4.31 ± 0.39 minutes & 7.90 ± 0.63 minutes (p<0.001). Duration of postoperative analgesia was longer in Group A 5.77 ± 0.57 hours vs 5.03 ± 0.29 hours in Group B (p < 0.001). **Conclusion:** These findings suggest that intrathecal Nalbuphine added to Bupivacaine can considerably prolonged the duration of analgesia versus when Bupivacaine used alone in spinal anesthesia for infraumbilical surgeries irrespective of age, gender, or comorbidity status.

Key words: Analgesia Duration, Bupivacaine, Infraumbilical Surgeries, Nalbuphine.

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INTRODUCTION

According to IASP, pain is defined as "an unpleasant sensory and emotional experience associated with, or resembling actual or potential tissue damage.[1]" Analgesics, or pain-relieving medications, are commonly used to manage pain and can be directed via various routes, depending on required level of pain relief.[2] However, limitations in pain control and undesirable side effects from high doses of these drugs have prompted ongoing efforts to find safer and more effective alternatives.[3] As a result, adjuvant medications have been introduced to enhance analgesic efficacy while minimizing drug-related adverse effects.[4]

Spinal anesthesia is commonly used for infraumbilical surgeries due to its effectiveness, rapid onset, and favourable safety profile.[5] Bupivacaine, a widely used local anesthetic in spinal blocks, offers dependable sensory and motor blockade.[6] Nevertheless, its duration of action is limited, often necessitating additional postoperative pain management, which can lead to increased patient discomfort and the need for supplemental analgesics.[7] Thus, improving the duration and quality of postoperative analgesia remains key area of interest in anaesthesiology.

Nalbuphine, synthetic opioid that is highly lipid-soluble and acts as kappa receptor agonist and mu receptor antagonist, providing effective analgesia particularly for visceral pain.[8] When used alongside bupivacaine, it has been shown to enhance postoperative pain relief while reducing side effects.[9]

This study aims to assess and compare effectiveness of 1 mg Nalbuphine added to 15 mg of 0.75% Bupivacaine versus 15 mg of 0.75% Bupivacaine alone in patients undergoing infraumbilical surgeries under spinal anesthesia. Several studies have examined the use of Nalbuphine with other

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anesthetics or as adjuvant in spinal anesthesia.[10] However, to date, no local study has evaluated combination of Nalbuphine with 0.75% Bupivacaine compared to Bupivacaine alone for infraumbilical surgeries. The rationale for using Nalbuphine as an adjunct in spinal anesthesia lies in its potential to extend sensory block duration and enhance postoperative pain control, while offering favourable side effect profile compared to other opioids making it a promising agent in regional anesthesia.

METHODS

This randomized trial was conducted at Department of Anesthesia, Allied Hospital Faisalabad, over six months period following approval of synopsis by CPSP. Prior to data collection ethical approval was also obtained from institution [No.48.ERC/FMU/2023-2024/394 Dated 02-02-2024]. Total 60 patients were registered using non-probability consecutive sampling. The sample size was with population mean taken was 348.33 and test value of population mean was 256.17, with pooled standard deviation of 56.6, 90% power of study, 5% level of significance, and 95% confidence level.[10] Calculated sample size was 60 (30 in each group).

Eligible participants included both male and female patients between 18 to 50 years, with ASA I or II, planned for elective infraumbilical surgeries under spinal anesthesia. Patients were excluded if they had any contraindications to spinal anesthesia, cerebral disease, bradycardia, morbid obesity, pregnancy, lactation, known hypersensitivity to study drugs, or were classified as ASA III or IV.

After obtaining written informed consent, participants were grouped using computer-generated random number table. Group A received intrathecal injection of 0.75% bupivacaine 15 mg combined with nalbuphine 1 mg (0.1 ml), while Group B received 0.75% bupivacaine 15 mg alone. All intrathecal injections were administered using 25-gauge Quinke-type spinal needle. Preoperatively, all patients received Tab alprazolam0.5 mg on night before surgery. In operating room, baseline parameters; heart rate, BP, and SpO_2 were recorded and preloaded with 500 ml Ringer's lactate. Time of intrathecal injection was considered as "0" minutes for study timeline. Sensory block level was assessed with 27G hypodermic needle every 2 minutes until two consecutive tests confirmed no sensation at the relevant dermatome. Hemodynamic parameters were monitored until complete recovery. Duration of analgesia was recorded from time of sensory block onset to first request for analgesia, defined as Visual Analog Scale (VAS) score >4.(11) VAS scores were assessed at different intervals postoperatively. The requirement and dose of rescue analgesia were also documented. All data were recorded by the principal investigator using standardized proforma.

SPSS v23 was used for data analysis. Categorical data represented by frequencies/percentages, and continuous variables by mean±standard deviation. Independent sample t-test/Mann-Whitney U test applied for normal and non-normal distributed data, respectively. Categorical variables were analysed using chi-square/Fisher's exact tests; p-value of less than 0.05 was deemed statistically significant. Stratification was used to control for effect modifiers in order to account for any confounding factors. Stratification was followed by reanalysis.

RESULTS

As shown in Table-I; mean age of group A and B patients noted was 37.33 ± 8.21 years and 35.97 ± 7.77 years, (p = 0.510). Group A comprised of males 63.3% and females 36.7%, whereas Group B included 56.7% males and 43.3% females; (p = 0.792). ASA physical status distribution showed that most patients in both Groups A and B, belongs to ASA Status I (66.7% and 53.3%; p = 0.430). BMI in Group A and B calculated was 27.07 ± 1.53 kg/m^2 and 27.43 ± 1.48 kg/m^2, p = 0.324. Regarding comorbidities, 17 patients (56.7%) in Group A and 13 patients (43.3%) in Group B were diabetic (p = 0.439), while 18 patients (60%) in Group A and 14 patients (46.7%) in Group B were hypertensive (p = 0.438). Total 13 patients (43.3%) in Group A and 10 patients (33.3%) in Group B were smokers (p = 0.596). No patients in either group reported a history of drug addiction. Baseline SpO_2 (%) and respiratory rate was similar in both groups; p 0.247 and 0.881, respectively. There was no statistically significant difference seen in baseline heart rate, (p = 0.155), systolic (p = 0.833), and diastolic BP (p = 0.656) among both groups. Time of spinal injection was also comparable between groups (p = 0.760).

Sensory block onset was faster in Group A (3.25 ± 0.41 minutes) compared to Group B (4.31 ± 0.39 minutes) p-value<0.001. Likewise, onset of complete motor block was significantly earlier in Group A (6.36 ± 0.66 minutes) than in Group B (7.90 ± 0.63 minutes) (p < 0.001). Duration of surgery was significantly shorter in Group A (98.43 ± 4.64 minutes) compared to Group B (102.30 ± 4.82 minutes); p = 0.002. Duration of postoperative analgesia was also significantly longer in Group A 5.77 ± 0.57 hours vs 5.03 ± 0.29 hours in Group B (p < 0.001). Median (IQR) values were 5.75 (0.92) for Group A and 5.05 (0.5) for Group B.

Stratified analysis of duration of analgesia revealed that Group A (receiving nalbuphine with bupivacaine) consistently showed longer median duration of analgesia compared to Group B (receiving bupivacaine alone) across various subgroups as shown in Table-II. When analyzed by age, patients in the 31–40 and 41–50 year groups in Group A had significantly longer analgesia than those in Group B (p = 0.001 and p = 0.002, respectively), while difference in 20–30year group was not statistically significant (p = 0.165). Gender-based comparison showed significantly prolonged analgesia in both males and females in Group A compared to Group B (p < 0.001 and p = 0.001, respectively). Among patients with/without diabetes Group A demonstrated significantly longer duration of analgesia than Group B (p = 0.009 and <0.001, respectively). Similarly, hypertensive and non-hypertensive patients in Group A experienced significantly longer analgesia (p < 0.001 and p = 0.029, respectively). Group A again showed significantly longer duration of analgesia compared to Group B (p < 0.001) among smokers and non-smokers.

TABLE-I

Patients characteristics in study groups

		Group-A	Group-B	P-Value
		30	30	
Age (years) mean±SD		37.33±8.21	35.97±7.77	0.510(t)
Gender	Male n(%)	19(63.3%)	17(56.7%)	0.792(c)
	Female n(%)	11(36.7%)	13(43.3%)	
ASA Status	I n(%)	20(66.7%)	16(53.3%)	0.430(c)
	II n(%)	10(33.3%)	14(46.7%)	
BMI (kg/m2) mean±SD		27.07±1.53	27.43±1.48	0.324
Diabetes n(%)		17(56.7%)	13(43.3%)	0.439(c)
Hypertension n(%)		18(60%)	14(46.7%)	0.438(c)
Smoking n(%)		13(43.3%)	10(33.3%)	0.596(c)
Drug addict n(%)		0(0%)	0(0%)	-
SpO2(%)		97±0.79	97.23±0.82	0.247(ζ)
Respiratory Rate (B/min)		14±0.85	14±0.87	0.881(ζ)
Heart Rate (BPM)		74±1.62	75±1.37	0.155(ζ)
Systolic Blood Pressure (mmHg)		121±4.56	121±5.16	0.833(t)
Diastolic Blood pressure (mmHg)		77±3.67	78±4.35	0.656(ζ)
Time of Spinal Injection (HH:MM)		9.11±0.27	9.09±0.27	0.760(ζ)
Time of Onset of Sensory block (Min)		3.25±0.41	4.31±0.39	<0.001(ζ)*
Time of Onset of Motor Block complete		6.36±0.66	7.90±0.63	<0.001(ζ) *
Duration of surgery (Min)		98.43±4.64	102.30±4.82	0.002(t) *
Duration of Analgesia (Hours)	Mean±SD	5.77±0.57	5.03±0.29	<0.001(ζ) *
	Median(IQR)	5.75(0.92)	5.05(0.5)	

Note: (c): Chi Square test, (t): independent sample t-test (ζ): Mann Whitney u test (*): statistically significant (p-value<0.05)

Table-II

Duration of analgesia (hours) stratified for various variables

		Duration of Analgesia		P-Value(ζ)
		Group-A	Group-B	
		30	30	
		Median (IQR)	Median (IQR)	
Age (Years)	20-30	5.70(1.50)	5.30(0.30)	0.165
	31-40	5.70(1.13)	5.00(0.60)	0.001*
	41-50	6.00(0.80)	4.90(0.45)	0.002*
Gender	Male	5.70(0.90)	5.00(0.50)	<0.001*
	Female	6.10(1.00)	5.10(0.55)	0.001*
DM	Yes	5.70(1.20)	5.20(0.55)	0.009*
	No	6.10(0.70)	4.90(0.55)	<0.001*
HTN	Yes	6.10(0.70)	4.95(0.63)	<0.001*
	No	5.60(1.15)	5.15(0.47)	0.029*
Smoking	Yes	6.10(0.90)	4.90(0.35)	<0.001*
	No	5.70(1.10)	5.20(0.58)	0.001*

Note: (ζ) Mann Whitney u test (Normality assumption was not fulfilled) (*): statistically significant (p-value<0.05)

DISCUSSION

According to current study findings, sensory block onset in Group A and B noted was 3.25 ± 0.41 minutes and 4.31 ± 0.39 minutes; p-value <0.001. Motor block onset was 6.36 ± 0.66 minutes in group A and 7.90 ± 0.63 minutes in group B (p < 0.001). Duration of postoperative analgesia was also significantly longer in Group A 5.77 ± 0.57 hours vs 5.03 ± 0.29 hours in Group B (p < 0.001). Likewise, in study by Naik et al, addition of 1.6 mg nalbuphine to bupivacaine significantly increased mean duration of analgesia from 175.8 minutes to 303.8 minutes.[12] Similarly, Niharika et al, reported notable extension of analgesia duration with nalbuphine (4.65 hours) compared to bupivacaine alone (3.21 hours) and also reported quicker sensory block onset of 1.93 minutes with nalbuphine versus 3.30 minutes with bupivacaine alone.[13] Our results are further supported by Raut Dessai et al, who observed mean analgesia duration of 264.97 minutes with nalbuphine, which was significantly longer than 198.50 minutes in bupivacaine-only group, p<0.001.[14] In addition to prolonged analgesia, onset of both sensory and motor blocks was found to be faster when nalbuphine was used as adjuvant. When used as an adjunct in spinal anesthesia, nalbuphine was also hemodynamically safe in study by Mehdi et al.[15] In contrast, Shah et al, compared three groups (2 groups with different doses of nalbuphine (1.6mg and 2.4mg) in combination with bupivacaine and one group received only bupivacaine and found similar onset of sensory and motor blocks among groups (p > 0.05). However, analgesia duration found to be highest in group with injection nalbuphine 2.4mg, p <0.001.[16] As reported by Bachula et al, intrathecal nalbuphine 0.8mg to bupivacaine in spinal block significantly enhances onset of sensory and motor block and extends the duration of postoperative analgesia, in patients undergoing cesarean section. Although higher proportion of patients in bupivacaine-only group achieved maximum sensory block, group receiving nalbuphine experienced longer duration of sensory regression and analgesia.[17] Nalbuphine is associated with favorable profile, as multiple studies have shown no significant occurrences of common opioid-related complications such as respiratory depression or urinary retention, which are often seen with agents like fentanyl.[18,19] Furthermore, its use does not negatively impact hemodynamic stability. Compared to other opioids, nalbuphine has demonstrated superior efficacy by providing longer-lasting analgesia while also minimizing side effects, making it more suitable option for managing postoperative pain.[18] In current study nalbuphine 1mg dose was given. Recent evidence suggests intrathecal nalbuphine 1.2mg is most effective

dose when used as adjuvant to bupivacaine for postoperative pain relief. While lower doses such as 0.8 mg also offer moderate analgesia (around 247 minutes).[20] On the other hand, although higher doses like 1.6 mg may extend analgesia duration, they are more likely to cause side effects. Thus, 1.2 mg strikes best balance between efficacy and safety, offering prolonged analgesia with minimal adverse effects.[19] These findings suggest that nalbuphine is safe and effective adjuvant to bupivacaine, offering improved analgesic outcomes with minimal adverse effects, making it viable alternative to traditional intrathecal opioids.

This study has certain limitations. We did not compare different doses of nalbuphine to determine the optimal effective dose. Additionally, nalbuphine was not compared with other adjuvant drugs, limiting broader applicability. The safety profile, including long-term or rare adverse effects, was also not thoroughly assessed.

CONCLUSION

These findings suggest that intrathecal Nalbuphine added to Bupivacaine can significantly prolonged the duration of analgesia versus when Bupivacaine used alone in spinal anesthesia for infraumbilical surgeries irrespective of age, gender, or comorbidity status.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Ammarah Aslam:** Manuscript writing.
2	**Humaira Ahmad:** Literature search.
3	**Mohsin Riaz Askri:** Study design, data analysis.
4	**Shumyala Maqbool:** Data interpretation.
5	**Ijaz Ahmad:** Statistical analysis, proof reading.
6	**Arfa Rauf:** References, proof reading.