IJMA

INTERNATIONAL JOURNAL OF MEDICAL ARTS

VOLUME 6, ISSUE 12, December 2024

P- ISSN: 2636-4174
E- ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Anesthesiology]

Original Article

Nalbuphine versus Fentanyl as Adjuvants to Bupivacaine in Spinal Anesthesia for Elderly Patient

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Article information

Received: 23-07-2024

Accepted: 11-12-2024

DOI: 10.21608/ijma.2024.306774.2005.

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Citation: Mohanna E, Mazy A, Farahat T. Nalbuphine versus Fentanyl as Adjuvants to Bupivacaine in Spinal Anesthesia for Elderly Patient. IJMA 2024 Dec; 6 [12]: 5153-5160 . doi: 10.21608/ijma.2024.306774.2005.

ABSTRACT

Background: Intrathecal adjuvant drugs are utilized with local anesthetics to relieve post-operative pain.

Aim of the study: Current study compared intra-and post-operative effects of Intrathecal nalbuphine versus fentanyl as adjuvants to bupivacaine during lower body surgeries in elderly.

Patients and Methods: Seventy subjects scheduled for elective lower body surgeries were randomly allocated to receive 2.5 ml of hyperbaric bupivacaine with either 0.8mg nalbuphine [group N], 20µg fentanyl [group F] intrathecally. Intra- and post-operative data collected and compared between groups. The first analgesic request as the primary outcome. Hemodynamic changes, total post-operative analgesic consumption, pain, sensory and motor blocks and associated adverse events were recorded as secondary outcome.

Results: Onset of sensory block was significantly delayed in N group [7.1±1.2 min] compared to F group [5.7±1.2 min] . Time to achieve maximum block height in group N was 12.7±2.2 min compared 10.3±1.8 min in group F . Mean time to two segment regression was significantly prolonged in N group [239.7±41.4 min] than F group [223.4±17.6] with [p=0.035]. The onset and duration of motor block were significantly faster in group F [7.6±1.15 min and 201 ± 17 min] compared to group N [8.7±0.86 min and 215 ± 26 min] .First analgesic request was significantly delayed in N group [267±25 min.] compared to F group [246±18 min.] . Total amount of ketorolac and Pethidine consumption in 24 h postoperatively was significantly lesser in N group compared to F group.

Conclusion: Nalbuphine intrathecally at a dose of 0.8 mg is as effective as fentanyl at a dose 20 µg when used as an intrathecal adjuvant to bupivacaine for lower body surgeries. The prolonged duration of analgesia and no adverse effects makes it a good choice in lower limb surgeries in elderly.

Keywords: Elderly; Fentanyl; Intrathecal; Nalbuphine.

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INTRODUCTION

During the antenatal period, the obstetrician is responsible for Spinal anesthesia is a well-established technique for lower body operations. It can be performed easily and it offers rapid onset and effective sensory and motor block [1].

The utilization of adjuvants with intrathecal [IT] local anesthetics [LA] improves the quality and duration of sensory block and postsurgical analgesia. Opioid drugs when given ***intrathecally,*** achieve synergistic effects when combined with LA, thus strengthening the sensory block with no increase in sympathetic block. Opioids are the most frequently used spinal adjuvant drugs that prolong post-surgical analgesia [2].

Fentanyl is an opioid that has fast onset following its injection intrathecally since it is lipophilic. Fentanyl improves quality of anesthesia and post-operative analgesia however; it causes nausea, emesis, pruritus, rigidity, and respiratory depression [3].

Nalbuphine provides analgesia and sedation as it is agonist at kappa receptors. On the other hand, it antagonizes mu receptors; thus causing less adverse effects compared with fentanyl, in particular less hemodynamic instability and respiratory depression [4]. Nonetheless, nalbuphine is not widely used an additive to IT local anesthetics. Few reports compared IT nalbuphine to other opioid drugs [5-8].

THE AIM OF THE WORK

The current study aimed at comparing intraoperative and postsurgical effects of IT nalbuphine to IT fentanyl as adjuvants to bupivacaine during lower body surgeries in elderly with the first analgesic request as the primary outcome. Hemodynamic changes [heart rate and blood pressure], total post-operative analgesic consumption, visual analogue scale [VAS] score for pain, sensory and motor block and associated adverse events were recorded as secondary outcomes.

PATIENTS AND METHODS

This prospective, randomized, double blinded study enrolled 70 elderly cases scheduled for elective surgeries in the lower abdomen and lower limbs surgeries from April 2021 to June 2022 at Mansoura University Hospital. It was approved by the Institutional Review Board, faculty of medicine, Mansoura University. Written consents were taken from all patients.

Patients who belonged to the ASA grades I and II in those aged from 65 to 85 years of both sexes and undergoing lower body surgeries expected to take a time less than 3 hours were enrolled. Patients who belonged to ASA grades III or IV, patients who are allergic to nalbuphine, fentanyl or bupivacaine, patients on mu agonists therapy for cancer pain, coagulopathies, cardiac or respiratory system failure, hepatic or renal impairment, as well as patient refusal or those with difficulty communication were not included.

Grouping:

Using computer-generated random sequence and sealed envelope technique, patients were allocated in 2 groups [35 each].

Group [N]: received 2.5 ml of 0.5% hyperbaric bupivacaine [12.5mg] [Marcaine spinal heavy 0.5% by Astra Zeneca, Yapi Kredi Plaza B Blok Kat: 3-4 Levent, turkey] and 800µg nalbuphine HCL intrathecally [Nalufin 20 mg/1 ml, manufactured by Amoun Pharmaceutical Co., Cairo, Egypt], in 0.5 ml sterile water.

Group [F]: received the same bupivacaine dose and 20 µg fentanyl [0.5 ml] intrathecally [Fentanyl Hameln 0.1 mg/2 ml, product of Sunny Pharmaceutical [100 Acre Industrial zone, Badr City, Egypt]. The anesthesiologist, surgeon and nurses were blind of randomization schedule and the injected medications of the two groups. The post-operative staff caring for patients was unaware of the purpose of the study.

Methods

Pre-operative general examination was conducted the day before the operation. Demographics including age, gender, and weight was recorded.

Routine investigations such as CBC, coagulation profile, liver function test, serum creatinine, blood glucose, chest X-ray, electrocardiogram and any other specific investigation wherever required was conducted.

The study design and spinal block approach was clarified to all patients. A linear visual analogue scale [VAS] on a scale 0-10 mm [0 indicates absence of pain while 10 indicates worst pain] was explained to all cases.

Anesthetic Considerations:

Each patient received an intravenous [IV] preload of 10ml/kg Ringer solution prior to subarachnoid blockade procedure. Furthermore, pulse, ECG, blood pressure [BP], and saturation of oxygen were reported. A 25-gauge spinal needle was used for lumbar puncture at L3-L4 or L4-L5 interspaces while the patient was in sitting position.

A midline or para-median approach was used for the puncture. After puncture, the premixed anesthetic solution was administrated after IT injection of local anesthetics, then the subject was turned into supine position and the O2 [four L/minute] was delivered via nasal prongs. Ringer's lactate solution was utilized to maintain and replace blood loss. The onset of drug injection was recorded and any observation was made using it as '0' min.

Intra- and post-operative sensory parameters were recorded. The onset of sensory block was the time required for subarachnoid block to reach T 10 segment. The time to highest block level was taken as the time from IT injection to the highest sensory level.

The sensory block's duration was the time taken for two-segment regression of sensory level. Motor block of lower limb muscles was assessed with Bromage Scale: [0= not blocked, able to raise hips, knees, and ankles. 1 = cannot raise extended legs, can move knees and feet. 2=cannot raise legs or move knees; can move feet. 3= cannot move the whole lower limb. Surgery was conducted following confirming Bromage score III.

Motor block duration was evaluated utilizing Bromage Scale following return to Bromage zero.

Measurements of pulse rate, mean arterial pressure [MAP], and skin temperature were obtained every five minutes in the first fifteen min and then every fifteen min for the rest of first hour and after 2 h post-operatively. The fall in BP of >20% of baseline was considered as hypotension. Intravenous bolus of Ephedrine 6 mg and IV fluids were used to treat hypotension. A 20% fall from baseline of pulse rate was considered as bradycardia and was managed with intravenous atropine [0.6mg].

Pain was evaluated at PACU postoperatively, then at 1st, 4th, 8th, 12th and 24 hours using the linear VAS. Duration of postsurgical analgesia is the time to the need for first rescue analgesic [intravenous Pethidine] after IT injection. If VAS ≥3 persisted after 30 minutes from Pethidine injection, intravenous Ketorolac was also administered.

During the post-operative 24 hours, each patient was observed for adverse effects such as low BP, slow hart rate, nausea, emesis, pruritus, shivering and respiratory depression. Hypotension: drop of systolic BP >25% from baseline measurement and was controlled with IV ephedrine5 mg. Bradycardia: pulse <60 beats/min and was treated using IV atropine 0.01 mg/kg. Intravenous antihistaminic [25 mg diphenhydramine] was administered for pruritus and if persisted or was severe, intravenous naloxone infusion [1µg/kg/h] was given. Shivering was treated by 25 mg Pethidine given intravenously.

Sample size:

The G Power program was used to calculate the power of the current study. Using a priory power analysis with accuracy mode calculation utilizing the 1st analgesic request as the primary variant and assuming type one error protection of 0.05 and an effect size convention of 0.8, a total sample of 70 subjects produced a power of 0.95.

Ethical considerations:

The Institutional Review Board of Mansoura University Hospital in Egypt gave their permission to the study [MS.18.10. 313]. Patients were interviewed, and their signed informed consents to participate in our study were obtained. All procedures in this study involving human participants were performed in conformity with the principles outlined in the Declaration of Helsinki, developed by the World Medical Association.

Statistical methods:

Data were analyzed by SPSSV 21.0., Chicago, Illinois, US. Quantitative data were represented as means ± standard deviations and 95% CI. Qualitative data were represented as frequencies and percent. Student's t-test was used to compare between means. Medians were compared with the independent samples median test. The proportions among 2 qualitative parameters underwent comparison by Chi-squared test. General linear model repeated measures ANOVA was utilized to compare serial measurements within each patient as within-subject effect and group as between subjects' effect. A significance of a result [p-value] was set at< 0.05 level.

RESULTS

In this trial, 70 patients planned for lower body surgeries were randomized to receive intrathecal Nalbuphine or intrathecal fentanyl [N group and F group, respectively] fig [1]. No significant differences existed among both groups regarding age, sex, weight, height, ASA, BMI, comorbidities, and duration of surgical procedures [Table 1].

Regarding the sensory block onset, it was significantly delayed [p <0.001] in N group [7.1±1.2 minute] in comparison to F group [5.7±1.2 minute].The mean times for maximum block height were 12.7±2.2 minute and 10.3±1.8 min in N and F groups, respectively [p <0.001]. Also, the mean time to two segment regression showed significant prolongation in N group [239.7±41.4 minute] than F group [223.4±17.6] with [p=0.035].

The onset and duration of motor block were significantly earlier in F group [7.6±1.15 minute and 201 ± 17 minute] compared to N group [8.7±0.86 minute and 215 ± 26 minute] with p<0.001and 0.009, respectively. As shown in table [2], intra-operative usage of ephedrine and intravenous fluid did not show significant difference among both groups [p>0.05] .

Regards to hemodynamic changes, basal and intra-operative pulse was comparable between N and F groups [Figure 2], while the MAP was statically significantly lower in F group in comparison to N group at 5, 10, 45 min and 1h [Figure 3]. Basal and intra-operative follow-up of skin temperature showed insignificant difference between N and F groups [Figure 4].

Meanwhile, there was an insignificant difference in VAS between N and F groups at any time of pain assessment in the post-operative 24 hours except at hour 24 was significantly lower [p= 0.001] in N group [Table 3].

Regarding the time of first requirement of analgesics [minutes], results demonstrated a significant delay in N group [267±25 minute.] compared to F group [246±18 minute.] [P <0.01] and the amount of ketorolac and Pethidine consumption in 24 h postoperatively was significantly less in the N group in comparison to F group [P <0.01] [Table 4].

Regarding complications, insignificant difference existed among both groups; 40.0% of patients in F group developed hypotension, 8.6% of patients developed bradycardia, 25.7% of cases reported nausea, 20% of patients reported vomiting, and 17.1% of patients developed shivering, whereas in N group, 14.3% of patients developed hypotension, no bradycardia was reported, 8.6% of cases reported nausea, 8.6% of patients had vomiting, and 5.7% of cases developed shivering. Pruritus occurred in 2.9% of patients in F group compared to no cases in N group. No respiratory depression was reported in the two groups [Table 5].

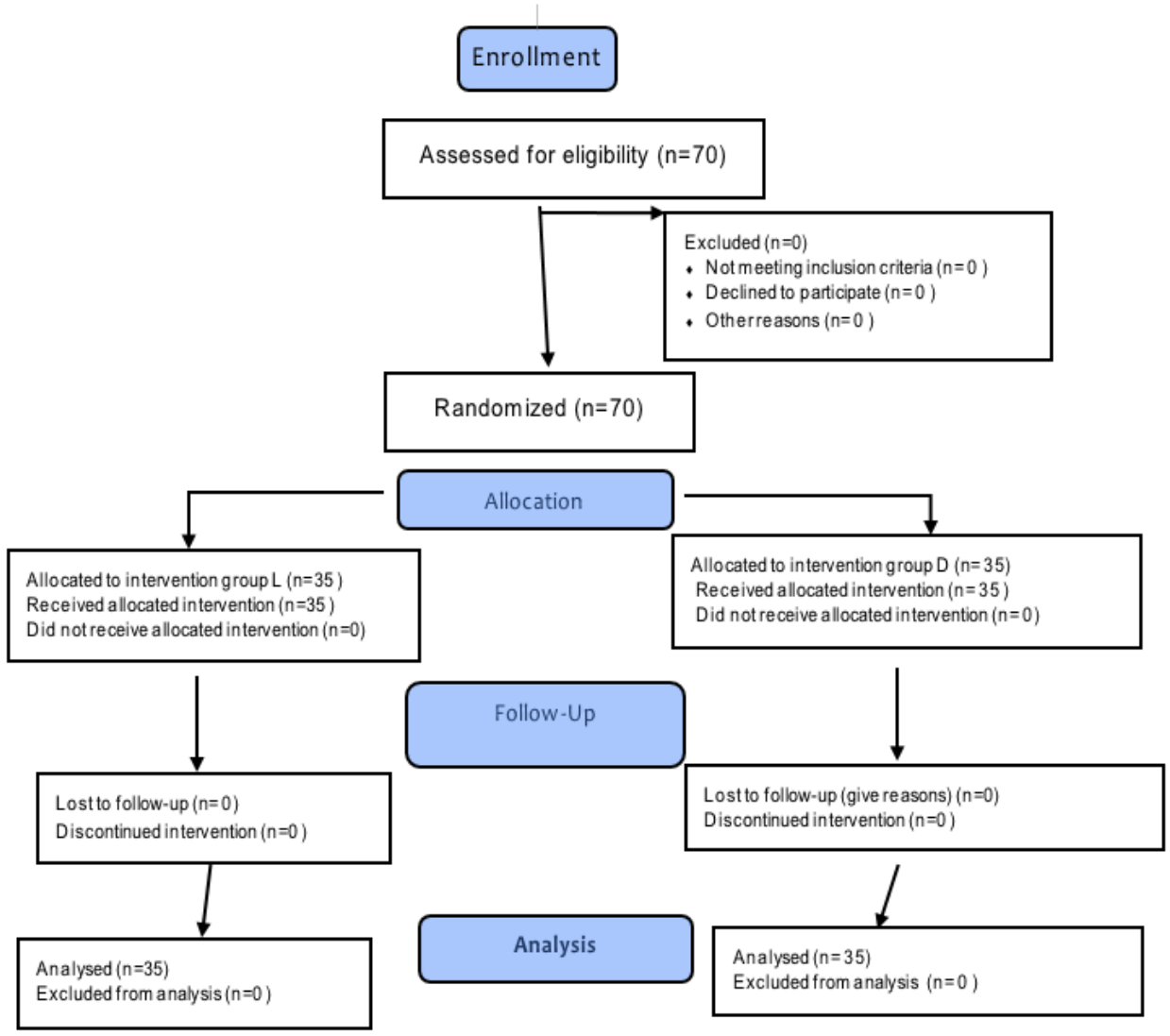

Figure [1]: Consort flow diagram of patient progress through the randomized trial

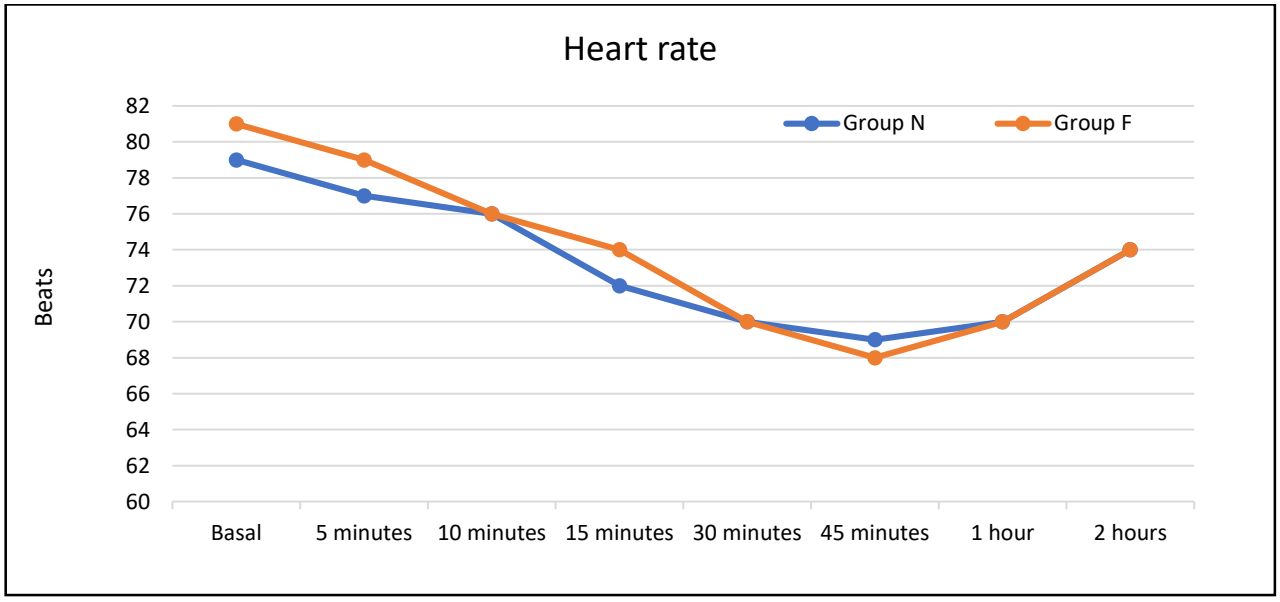

Figure [2]: Basal and intra-operative follow-up of pulse [beat/minute] in studied groups.

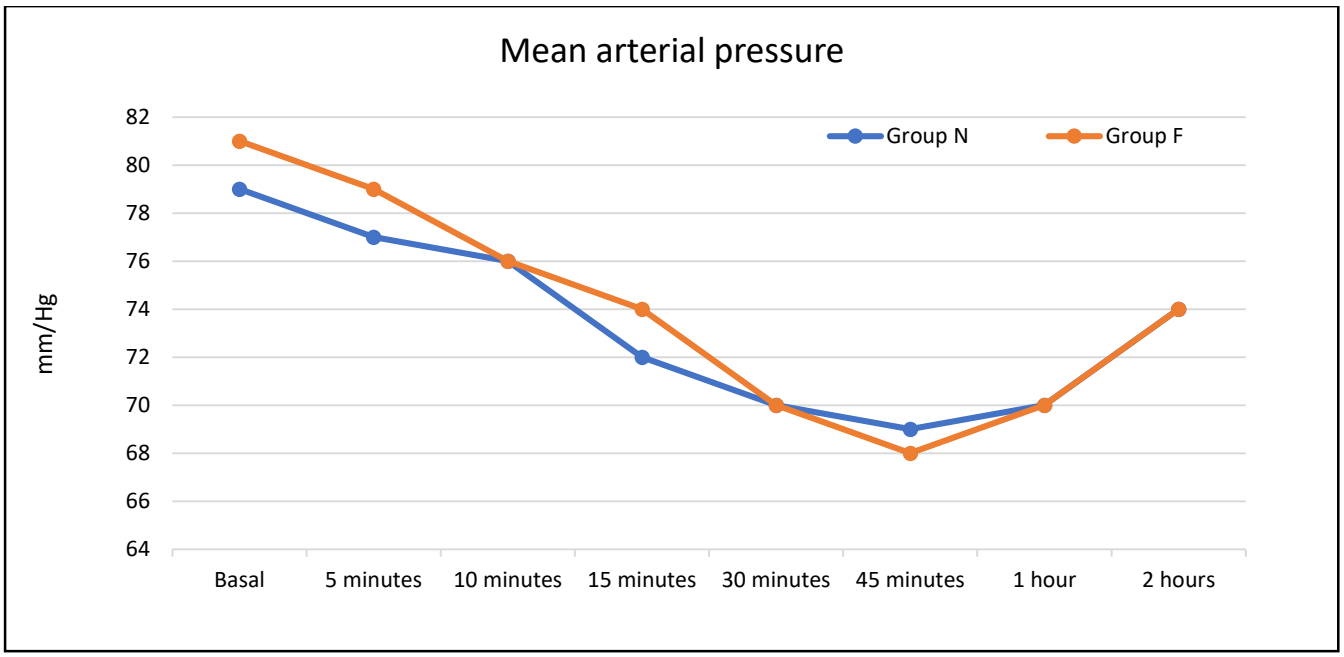

Figure [3]: Basal and intra-operative follow-up of MAP in studied groups

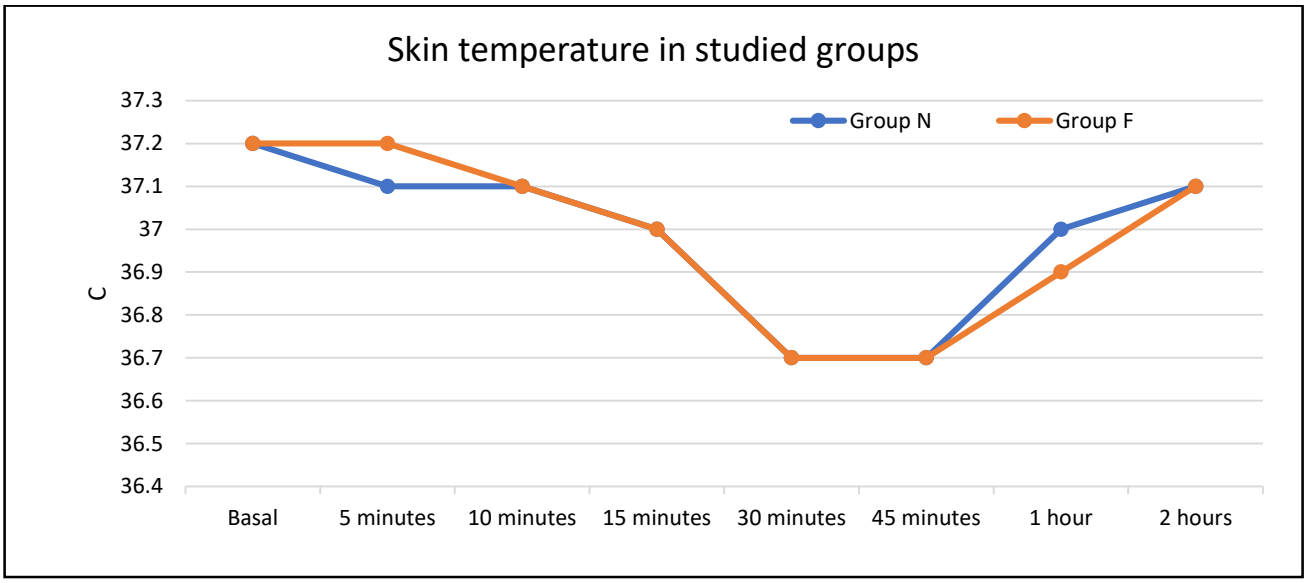

Figure [4]: Skin temperature follow-up of MAP in the studied group

Table [1]: Demographics, medical history, and operative duration of the study groups

		Group N [n= 35]	Group F [n= 35]	95% CI	P -value
Age [years]		71.8 ± 6.8	72.86 ±7.0	-2.23 to 4.35	0.522
Gender	**Male**	57.1% [20]	42.9% [15]	0.914	0.114
	Female	42.9% [15]	57.1% [20]		
Height [cm]		162.6±16.2	165.9±6.3	-2.56 to 9.16	0.265
Weight [kg]		83.3 ± 16.7	83.3 ± 7.3	-6.13 to 6.19	0.995
Body mass index [kg/m^2]		29.82 ± 4.4	30.34 ±2.9	-1.25 to 2.29	0.561
ASA	**I**	14.3% [5]	31.4% [11]	2.025	0.154
	II	85.7% [30]	68.6% [24]		
Diabetes		60.0% [21]	57.1% [20]	-0.26 to 0.2	0.808
Hypertension		62.9% [22]	51.4% [18]	-0.35 to 0.12	0.334
Ischemic heart disease		20.0% [7]	25.7% [9]	-0.14 to 0.25	0.569
Operative duration [min]		147 ± 35	154 ± 30	-8.5 to 22.5	0.372

Group N: Nalbuphine group, Group F: Fentanyl group

Table [2]: Sensory and motor block characteristics and intraoperative events of studied groups

		Group N [n= 35]	Group F [n= 35]	95% CI	P value
Sensory block characteristics	Time to achieve [T10] [minute]	7.1 ± 1.2	5.7 ± 1.2	-1.97 to -0.83	<0.001*
	Time to achieve maximum level [minute]	12.7 ± 2.2	10.3 ± 1.8	-3.36 to -1.44	<0.001*
	Time to 2 segment regression [minute]	239.7 ± 41.4	223.4 ± 17.6	-31.47 to -1.13	0.035*
Motor block characteristics	Onset [time to Bromage 3] [minute]	8.7 ± 0.86	7.6 ± 1.15	-1.58 to -0.616	<0.001*
	Duration [time to Bromage 0] [minute]	215 ± 26	201 ± 17	-24.5 to -3.5	0.009*
Intra-operative events	Ephedrine [mg]	13.1 ± 6.9	15.3 ± 9.1	-1.65 to 6.05	0.258
	IV fluids [ml]	1791 ±469	1914 ± 436	-93 to 339	0.259

* : Significant P value

Table[3]: Post-operative follow-up of median VAS score in the studied groups

visual analog scale score	Group N [n= 35]	Group F [n= 35]	95% CI	P value
At PACU	**1 [1,2]**	**1 [1,1]**	**-0.056 to 0.4**	**0.139**
1 hour	**2 [2,2]**	**2 [2,3]**	**-0.405 to 0.176**	**0.435**
4 hour	**4 [3,4]**	**4 [3,4]**	**-0.217 to 0.388**	**0.573**
8 hour	**3 [3,4]**	**4 [3,4]**	**-0.349 to 0.235**	**0.697**
12 hour	**4 [3,4]**	**4 [4,4]**	**-0.603 to 0.089**	**0.142**
24 hour	**4 [4,4]**	**5 [4,5]**	**-0.868 to -0.218**	**0.001***

PACU= post-anesthesia care unit; * : Significant P value

Table [4]: Post-operative analgesic consumption in studied groups

	Group N [n= 35]	Group F [n= 35]	95% CI	P value
Time to First analgesic request [minutes]	267 ± 25	246 ± 18	-31.4 to -10.6	<0.001*
24H total ketorolac consumption [mg]	43.7± 4.3	56.6 ± 6.4	10.3 to 15.5	<0.001*
24H total Pethidine consumption [mg]	31.14±6.76	43.71±10.6	8.32 to 16.81	<0.001*

* : Significant P value

Table[5]: Incidence of side effects of drug consumption in studied groups

	Group N [n= 35]	Group F[n= 35]	Chi-square test	P value
Hypotension	**14.3% [5]**	**40% [14]**	**2.368**	**0.066**
Bradycardia	**0% [0]**	**8.6% [3]**		
Respiratory depression	**0% [0]**	**0% [0]**		
Nausea	**8.6% [3]**	**25.7% [9]**	**2.083**	**0.149**
Vomiting	**8.6% [3]**	**20.0% [7]**	**0.900**	**0.342**
Shivering	**5.7% [2]**	**17.1% [6]**	**1.125**	**0.288**
Pruritus	**0% [0]**	**2.9% [1]**		

DISCUSSION

The combination of local anesthetics and opioid drugs decreases both the dose of both drugs and the incidence of adverse events of each of them. Such combination also provides a good quality of anesthesia, and extends the period of postsurgical analgesia [3].

Despite many good qualities of nalbuphine compared to fentanyl as adjuvants to IT local anesthetics, nalbuphine is not widely used. Few studies compared IT nalbuphine versus fentanyl in elderly patients scheduled for lower body surgeries. Our study compared 0.8 mg nalbuphine [N group] versus to 20 µg fentanyl [F group] as an additive to IT local anesthetics. VAS score for pain, sensory and motor block and associated adverse events were recorded. Regards to the sensory block onset, it showed a significant delay in N group [7.1±1.2 minute] in comparison with F group; [5.7±1.2 minute]. The mean times to maximum block height were 12.7±2.2 minute and 10.3±1.8 minute in N and F groups, respectively [p <0.001]. Also, the mean time to two segment regression was significantly higher in N group [239.7±41.4 minute] than F group [223.4±17.6] with [p=0.035]. Our findings agree **Sharma *et al.*** who reported that IT nalbuphine was associated with a significant delay in sensory block onset [9.27±1.45 minute] when compared with cases that received IT fentanyl [7.73±1.55 minute]. While the sensory block showed a longer duration in F group [122.05±10.65 minute] than in N group [114.55± 10.90 minute] [8].

Recently, **Jain *et al.*** revealed that the mean time of sensory block onset was 2.88 ± 0.0.65 minute in F group versus 3.43 ± 0.64 minute in N group. The mean durations of sensory blockade were 79.18±7.8 minute and 84.00 ± 7.61 minute in F group and N group, respectively. The mean times of motor block onset were significantly different among both groups [5.21±0.93 minute and 7.23±1.08 minute in F and N groups, respectively; P < 0.001] [3]. Several studies showed similar results with a highly significant increase in sensory block duration in N group compared with F group [6, 9, 10].

Our results disagree with **Deori *et al.*** study in which the duration of sensory block was a significantly longer in F group than in N and control groups [11]. Similarly, **Bindra *et al.*** studied 150 women scheduled for caesarean sections under spinal anesthesia, and revealed that the duration of sensory blockade was a significantly longer in F group in comparison to N and control groups [12]. **Naaz *et al.*** examined 90 cases scheduled for lower extremity operations under spinal anesthesia, and reported that the duration of sensory block was a significantly longer in F group than in N and control groups [13].

Compared to current findings, **Gomaa *et al.*** and **Geetha *et al.*** failed to find a significant difference between F and N groups as regards in sensory block onset [14, 15].

Regards to onset and duration of motor block in enrolled patients, it was significantly earlier in F group [7.6±1.15 min and 201 ± 17 min] compared to N group [8.7±0.86 min and 215 ± 26 min] with p <0.001and 0.009, respectively. Similar to current results, many studies reported a significant prolongation in motor block duration in N group than in F and control groups [6, 9, 10]. **Sharma *et al.*** showed that, the time for onset motor block in F group was 6.73 ± 0.98 minute which was significantly earlier than that in N group [8.18 ± 2.46 minute].But they found a significant prolongation of motor block duration in F group [197.73 ± 15.09 minute] as compared to N group [180.68±15.68 minute] [8]. Several studies studied nalbuphine and fentanyl without significant differences observed in onset of motor block [12, 16, 17]. In contrast, **Jain *et al.*** reported that mean durations of motor block were 99.92 ± 10.35 minute and 101.90±5.47 minute in groups F and N, respectively but without significant difference [P= 0.234] [3]. Similarly to current study, **Deori *et al.*** studied 100 patients scheduled for intra-abdominal surgeries under spinal anesthesia. They demonstrated that the IT fentanyl combined with bupivacaine produced more rapid onset of motor block than IT nalbuphine [11]. Also another study compared fentanyl vs. nalbuphine as IT adjuvant drugs to bupivacaine for women undergoing cesarean sections and reported the superiority of fentanyl over nalbuphine in enhancing the onsets of sensory block and motor block [18]. Other studies studied fentanyl and nalbuphine for lower abdominal, lower extremity and urological operations and reported comparable as regards the motor block duration [12, 14, 16, 17].

Regarding hemodynamic changes, basal and intra-operative heart rate demonstrated no significant difference, while MAP was statistically significantly lower in cases receiving fentanyl compared to cases receiving nalbuphine at 5, 10, 45 min and 1h. Baseline and intra-operative follow-up of skin temperature was comparable in the two groups. Compared to current results, several reports revealed insignificant differences in hemodynamic profile among fentanyl and nalbuphine groups [6, 12, 14, 19]. Recently three studies found insignificant difference in pulse, BP, or MAP between fentanyl and nalbuphine groups during intra-operative or post-operative periods [3, 20, 21].

Against to our results, **Saiyed *et al.*** revealed significant differences in hemodynamic parameters, with higher pulse rate and BP in cases receiving nalbuphine than in controls [22]. Lower VAS scores in post-operative period are clinically important as they provide longer and good analgesia to the patient. In our trial, VAS score for pain was decreased in both groups; meanwhile, it is insignificantly different between the two groups up to 24 h postoperatively. At 24 h postoperatively, the median VAS score in N group 4 was lower than F group. In a line with current results, AL- Morsy et al. demonstrated that in 1st post-operative hour, insignificant difference in VAS score existed between studied groups. At 7th postoperative hour, VAS scores were lower in N group than in F and control groups [10]. Also, other authors reported a significant decrease in pain scores in N group in comparison to F group [13, 16, 23, 24, 25]. Recently, **Jain et al.** revealed a significant difference in mean VAS scores at 1, 2, 3 and 12 hours post-operatively; however at 4, 6, 18 and 24 hours, no significant difference in VAS scores was observed [3].

The time to the first rescue analgesic among enrolled patients was significantly prolonged in N group [267±25 minute] than in F group [246±18 minute] and the required amounts of ketorolac and Pethidine in 24 h postoperatively was significantly lesser in N group. Similarly, several studies, revealed that, the mean duration of effective analgesia was significantly prolonged [P < 0.001] in N group [214.34± 9.31 minute] than in In F group [195.00 ± 9.18 minute] [3, 6, 9, 10, 23, 26].

Our results are against that concluded by **Gomaa *et al.*** and **Sabry *et al.*** who did find a significant difference in the time to the first rescue analgesia between N and F groups [14, 20]. Others reported that the mean analgesia duration in F group was significantly longer than in N group [7, 11], which was also against our results. This might be because of that fentanyl might have increased the synergistic action with increasing dose of bupivacaine in their studies.

Our results revealed that the incidence of side effects of used adjuvant drugs [hypotension, sloe heart rate, nausea, emesis, and shivering] was comparable between studied groups. Pruritus developed in 2.9% of cases in F group compared to no cases in N group. No respiratory depression was recorded in both groups. In addition, numerous reports didn't observe a significant increase in the incidence of nalbuphine-related adverse effects [8,14,20,23,27,28]. **Raghuraman** found that adding nalbuphine for subarachnoid block improved the quality and prolonged duration of postsurgical analgesia. Nalbuphine has anti-shivering and anti-pruritic effects and it is associated with lower rates of nausea and emesis [4].

Against current findings, **Ahmed FI,** examined 80 women scheduled for cesarean sections under spinal anesthesia, and reported significantly higher rates of pruritus and shivering in F group in comparison to N group [18]. Recently **Srinivasaiah *et al.*** revealed that hypotension and bradycardia did not develop in any of patients in both groups. The incidence of pruritus was higher in F group however without a significant difference [21].

Limitation: Limitation of this study include difficulty to find elderly patients with no or less comorbidities and fewer number of cases in single center study.

Conclusion: Nalbuphine as IT adjuvant to hyperbaric bupivacaine, in spinal anesthesia, was superior to fentanyl in prolonging the duration of sensory and motor blockade and in enhancing the postsurgical analgesia in lower body surgeries with few adverse events.

Financial support: None.

Conflict of interest: No conflict of interest to be declared.

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IJMA

INTERNATIONAL JOURNAL OF MEDICAL ARTS

VOLUME 6, ISSUE 12, December 2024

P- ISSN: 2636-4174
E- ISSN: 2682-3780