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ORIGINAL ARTICLE

A Prospective Comparative Study of Intrathecal Low-dose Bupivacaine 5 mg (1 mL) plus Fentanyl 25 µg (0.5 mL) with Intrathecal Low-dose Bupivacaine 5 mg (1 mL) plus Normal Saline (0.5 mL) for Perineal Daycare Surgery

[1]M Vijay Anand, [2]Vanathi Nachimuthu, [3]Gurumoorthi Ramasamy

ABSTRACT

Aim: To compare the efficacy of intrathecal low-dose bupivacaine 5 mg (1 mL) plus fentanyl 25 µg (0.5 mL) with intrathecal low-dose bupivacaine 5 mg (1 mL) plus normal saline (NS) (0.5 mL) for perineal daycare surgery.

Materials and methods: Hundred patients in the age group 18 to 50 years of either sex with body weight of 40 to 100 kg and physical status American Society of Anesthesiologists (ASA) 1 and 2 undergoing daycare elective perineal surgery of duration less than 60 minutes under spinal anesthesia were randomly allocated into two groups with each 50 patients—group F, subarachnoid block with bupivacaine heavy 5 mg (1 mL) plus fentanyl 25 µg (0.5 mL) and group B, with bupivacaine heavy 5 mg (1 mL) with NS (0.5 mL). Subarachnoid block was performed in lateral position. Parameters including pulse rate, blood pressure, oxygen saturation with pulse oximeter, onset of anesthesia, block characteristics, and complications were noted and analyzed by independent author using Student's t-test.

Results: The mean duration of analgesia was significantly high in group F compared with group B ($p < 0.05$) with no difference in anesthesia characteristic, hemodynamic variables, and complications.

Conclusion: The intrathecal fentanyl with low-dose bupivacaine intensifies surgical anesthesia with extended postoperative analgesia without extending neurological deficit and complications.

Clinical significance: This method is a very effective and cheap anesthesia modality in daycare perineal surgery.

Keywords: Anesthesia, Bupivacaine, Daycare, Fentanyl, Low volume, Perineal, Spinal, Subarachnoid.

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[1,2]Assistant Professor, [3]Senior Resident

[1]Department of Anesthesiology, Velammal Medical College Hospital and Research Institute, Madurai, Tamil Nadu, India

[2]Department of Obstetric and Gynecology, Chennai Medical College Hospital & Research Centre, Trichy, Tamil Nadu, India

[3]Department of Anesthesiology, Chennai Medical College Hospital & Research Centre, Trichy, Tamil Nadu, India

Corresponding Author: Vanathi Nachimuthu, Assistant Professor, Department of Obstetric and Gynecology, Chennai Medical College Hospital & Research Centre, Trichy, Tamil Nadu India, e-mail: nvanathi2001@yahoo.co.in

INTRODUCTION

Central neuraxial block offers certain advantages that have made it a worthy alternative to general anesthesia in infraumbilical surgeries. Compared with general anesthesia, central neuraxial block is associated with advantages like conscious patient with normal airway reflexes, decreased incidence of deep vein thrombosis, reduced surgical and anesthesia stress resulting in decreased plasma catecholamine level, improved ambulation,[1] less blood loss, and fewer cardiorespiratory complications. The most common central neuraxial blockade performed at present is subarachnoid block. Local anesthetic agent was used with or without adjuvants in spinal anesthesia. Spinal anesthesia was used in daycare surgery but motor deficit and bladder bowel disturbance are main hindrance, especially in perineal surgeries compared with general anesthesia. Lot of work had been done on different local anesthetic drugs but in a country like India, which has only bupivacaine heavy available very commonly in all places, we had opted for it with very low volume of around 1 mL for spinal anesthesia.[2] The use of neuraxial opioids has increased dramatically in recent years, augmenting the analgesia produced by local anesthetics by binding directly to opiate receptors.[1-3] We had option of fentanyl and morphine for intrathecal use. Morphine having chance of delayed respiratory depression excludes its usage in daycare surgery in our study. We had opted for 25 µg fentanyl as adjuvant with 0.5% bupivacaine heavy and had compared with control (NS) for its synergetic action and complications.

AIM

The aim of the study was to compare the efficacy of intrathecal low-dose bupivacaine 5 mg (1 mL) plus fentanyl 25 µg (0.5 mL) with intrathecal low-dose bupivacaine 5 mg (1 mL) + NS (0.5 mL) for daycare perineal surgeries.

MATERIALS AND METHODS

After getting approval from the ethical committee, 100 patients in age group 18 to 50 years of either sex with body weight of 40 to 100 kg and physical status ASA 1 and 2, undergoing daycare elective perineal surgery of duration less than 60 minutes under spinal anesthesia were randomly allocated using computer-generated numbers into two groups with each 50 patients—group F, subarachnoid block with bupivacaine 5 mg (1 mL) plus fentanyl 25 µg (0.5 mL) and group B, with bupivacaine 5 mg (1 mL) with NS (0.5 mL). Exclusion criteria include:

- Patients refusing for spinal anesthesia
- Patients belonging to ASA 3, 4, and 5 physical status
- Patients with evidence of any cardiovascular disease
- Patients with evidence of central and peripheral nervous system impairments
- Patients with history of convulsion
- Patients with history of bleeding diathesis or who were on anticoagulant therapy
- Patients with infection at the site of lumbar puncture
- Surgical duration expected more than 1 hour
- Baseline blood pressure systolic >140 mm Hg, diastolic >90 mm Hg, and pulse rate >100 beats/min
- Kyphoscoliosis

After getting informed consent, 0.5 mg of T. Alprazolam was given orally on the night before surgery and 2 hours before surgery. Patient was advised to void urine before entering the operating room. In the operating room electrocardiography, noninvasive blood pressure, and pulse oximeter were fixed to the patient and basal reading of pulse rate, systolic, diastolic and mean arterial blood pressures, and oxygen saturation were recorded. An intravenous (IV) line was established with 18G IV cannula and the patient was preloaded with 500 mL of Ringer's lactate. Drug for spinal anesthesia was prepared by primary investigator according to the randomization, and spinal anesthesia was administered by concerned anesthetist and both anesthetist and patient were unaware of the combination. The patient was placed in lateral decubitus position. The skin over the back was cleaned with 10% povidone iodine solution and draped with a central hole towel. By palpation, L3-4 or L4-5 interspinous space was identified and skin over the chosen space was infiltrated with 2 mL of 1% lignocaine. A 27G Whitacre spinal needle was introduced through skin puncture. Following free flow of cerebrospinal fluid respective drug was injected into subarachnoid space. The patient was made supine immediately and the following parameters were observed:

- Heart rate at 0/5/10/15/30/60/90 minutes after spinal anesthesia.
- Blood pressure at 0/5/10/15/30/60/90 minutes after spinal anesthesia.
- Oxygen saturation with pulse oximeter at 0/5/10/15/30/60/90 minutes after spinal anesthesia.
- Time for onset of sensory block at T12 was evaluated by pinprick test and a 4-point scale (0: normal sense; 1: reduced sense; 2: hypoesthesia; 3: no sense) was used. After 2 minutes of spinal anesthesia, sensory block is assessed every 15 seconds till we got score of 3 at T12. Highest sensory block level was assessed after 20 minutes using the same technique. Duration of two-segment regression of sensory block was assessed every 5 minutes after 30 minutes of anesthesia.
- Duration of motor block regression at hip was assessed every 10 minutes. Motor blockade was evaluated by the modified Bromage test and a 4-point scale (0: normal motor function in hip, knee, ankle, and toes; 1: motor blockade only in the hip; 2: motor blockade in the hip and knee; 3: motor blockade in the hip, knee, and ankle) was used.
- Time for urination.
- Complications.

A 20% decrease in mean blood pressure from baseline was considered as hypotension and was treated with a 500 mL infusion of Ringer's lactate. Heart rate below 45 bpm/min was considered as bradycardia and was treated with 0.6 mg of atropine, and oxygen was provided via a mask for cases with SpO_2 below 95%. The cases were monitored for pruritus, nausea and vomiting, allergic reactions, and respiration depression. We did not measure incidence of postdural puncture headache as both the groups undergo spinal anesthesia.

They were given data sheet which was filled intra- and postoperatively and was handed over back to primary investigator. Patient procedure was done in lithotomy position and Ringer's lactate was infused with 4 mL/kg in first hour and 2 mL/kg for next 3 hours. Data were collected and were analyzed by independent author using Student's t test to test the significance between two groups. Data were expressed as mean [±standard deviation (SD)] or median. Complications were expressed as relative risk with 95% confidence interval.

RESULTS

Around 145 patients had been preliminarily selected for study. After getting detailed history and examination, 100 patients with 50 patients in each group were selected according to computer-generated number and there was no dropout from study as patient was posted for surgery on next day of assessment. Patients in both groups were comparable with age, sex, weight, height, type of surgery, and duration ($p > 0.05$). There was no difference in baseline blood pressure, pulse rate, and oxygen saturation among the groups ($p > 0.05$). Even after spinal anesthesia,

Table 1: Blood pressure, pulse rate, and oxygen saturation

Time (min)	*Parameters*	*Group B Mean ± SD*	*Group F Mean ± SD*	*p-value*
0	SBP	114.40 ± 09.16	115.20 ± 10.04	>0.05
	DBP	71.60 ± 06.24	71.60 ± 06.87	>0.05
	MBP	85.72 ± 07.21	85.96 ± 08.33	>0.05
	PR	81.12 ± 10.05	80.36 ± 09.28	>0.05
	SpO_2	98.43 ± 01.24	98.76 ± 01.52	>0.05
05	SBP	112.40 ± 07.78	114.80 ± 07.70	>0.05
	DBP	70.00 ± 06.45	70.80 ± 07.02	>0.05
	MBP	84.44 ± 06.04	85.24 ± 07.35	>0.05
	PR	81.56 ± 09.35	80.32 ± 09.48	>0.05
	SpO_2	98.90 ± 01.06	98.60 ± 01.41	>0.05
10	SBP	109.20 ± 05.71	108.80 ± 07.25	>0.05
	DBP	70.40 ± 04.54	70.80 ± 05.71	>0.05
	MBP	84.04 ± 04.79	84.24 ± 06.21	>0.05
	PR	82.16 ± 10.99	80.16 ± 10.32	>0.05
	SpO_2	98.86 ± 01.12	98.62 ± 01.34	>0.05
15	SBP	110.64 ± 08.95	110.40 ± 09.78	>0.05
	DBP	70.80 ± 06.40	70.80 ± 05.71	>0.05
	MBP	84.64 ± 06.65	84.68 ± 06.69	>0.05
	PR	82.32 ± 10.60	80.08 ± 10.17	>0.05
	SpO_2	98.88 ± 01.33	98.10 ± 01.50	>0.05
30	SBP	112.80 ± 06.78	112.80 ± 07.37	>0.05
	DBP	71.20 ± 06.00	71.20 ± 05.25	>0.05
	MBP	84.56 ± 05.69	85.08 ± 05.98	>0.05
	PR	81.96 ± 10.10	79.12 ± 10.05	>0.05
	SpO_2	98.80 ± 01.24	98.86 ± 01.39	>0.05
60	SBP	112.00 ± 06.45	112.80 ± 07.91	>0.05
	DBP	70.80 ± 06.40	71.20 ± 06.00	>0.05
	MBP	84.56 ± 05.30	85.72 ± 06.15	>0.05
	PR	82.16 ± 10.15	79.52 ± 10.60	>0.05
	SpO_2	98.76 ± 01.23	98.80 ± 01.32	>0.05
90	SBP	111.30 ± 06.35	112.60 ± 07.51	>0.05
	DBP	71.10 ± 06.40	71.28 ± 06.24	>0.05
	MBP	84.59 ± 05.28	85.38 ± 06.14	>0.05
	PR	82.36 ± 10.20	79.57 ± 10.50	>0.05
	SpO_2	98.77 ± 01.24	98.58 ± 01.49	>0.05

SBP: Systolic blood pressure; DBP: Diastolic blood pressure; MBP: Mean blood pressure; PR: Pulse rate; SpO_2: Oxygen saturation

there was no difference in systolic blood pressure, diastolic blood pressure, mean blood pressure, pulse rate, and oxygen saturation ($p > 0.05$), which was measured at 5, 10, 15, 30, 60, 90 minutes (Table 1).

Regarding anesthesia parameters, mean duration for sensory block to reach thoracic nerve 12 (T12), which was assessed by pinprick test, was comparable ($p > 0.05$) among the two groups. Highest sensory block reached in both group was in the range of T9 to T11 with median of T10. Time taken for two-level sensory block regression, motor block regression at hip, bladder recovery had no significance ($p > 0.05$) among the groups. The mean duration of analgesia was significantly high in group F than group B ($p< 0.05$) (Table 2).

Regarding complications, patient had only shivering and nausea in both groups. Three patients in both

Table 2: Anesthesia parameters

Parameters	*Group B Mean ± SD*	*Group F Mean ± SD*	*p-value*
Time for onset of sensory block at T12 (min)	04.75 ± 01.80	04.50 ± 01.65	>0.05
Highest sensory block level	T9-11 T10 (median)	T9-11 T10 (median)	
Duration of two segment sensory regression (min)	52.40 ± 08.50	54.20 ± 07.50	>0.05
Duration of motor block regression at hip (min)	68.10 ± 06.50	67.10 ± 08.50	>0.05
Time for rescue analgesia	144.60 ± 27.30	162.00 ± 30.73	<0.05
Time for bladder recovery	248.40 ± 26.90	256.20 ± 30.50	>0.05

Table 3: Complications

Complications	*Group B Number (%)*	*Group F Number (%)*	*Relative risk (95% confidence interval)*
Pruritus	0 (0)	0 (0)	–
Nausea	2 (4)	3 (6)	1.5 (0.26–8.60)
Vomiting	0 (0)	0 (0)	–
Shivering	3 (6)	3 (6)	1.0 (0.21–4.72)
Hypotension	0 (0)	0 (0)	–
Bradycardia	0 (0)	0 (0)	–
Respiratory depression	0 (0)	0 (0)	–

groups had shivering, which was not significant. Three patients in fentanyl group had nausea compared with two patients in control group but none of the patients had vomiting (Table 3).

DISCUSSION

Subarachnoid block is the commonest anesthetic technique for perineal surgeries because of its simplicity, rapid onset of actions, and intense analgesia. However, low levels of subarachnoid block in perineal surgeries reduce the intraoperative complication of subarachnoid block. Addition of opioid (fentanyl) to low dose of bupivacaine is expected to provide good surgical anesthesia and extended period of analgesia.[2,4,5] Thus, the synergism of intrathecal opioid with low-dose bupivacaine has been studied extensively in recent years.[1] In our study design, group B received 0.5% of hyperbaric bupivacaine 5 mg with 0.5 mL of NS, and group F received 0.5% of hyperbaric bupivacaine with 25 µg fentanyl, injected intrathecally to 50 patients in each group undergoing perineal daycare surgery.

Irrespective of the combination, highest sensory block had reached T9 with median value of T10. For perineal surgeries, blocking sacral nerves is adequate for surgery

but in our study it had blocked even lumbar and lower dorsal nerves. Patra et al[6] observed that the peak height of sensory blockade achieved in both bupivacaine 10 mg and bupivacaine 7.5 mg with 25 µg fentanyl was T7. It may be due to larger dose used compared with our study. For perineal surgery, there was less chance of vagal stimulation, which needs block upto T4 and hence keeping to minimum needed dermatome possibly to sacral nerve is enough. But motor block is needed upto lumbar level for positioning the patient especially in lithotomy. Whether reducing dose further can avoid dorsal segment block needs more study.

Both groups had stable hemodynamic parameters throughout the procedure. It may be due to low volume of drug used, which was comparable to all other studies done with low-volume bupivaine.[7,8] In our study, all patients were in lithotomy posture, which would have contributed further to hemodynamic stability.[9] This technique can even help patients with cardiac dysfunction to undergo these procedures safely but it needs further study to confirm it. Time required for rescue analgesia is prolonged in group F than in group B and it was due to synergetic action of fentanyl with bupivacaine and central opioid action.[1-3,7,8]

Regarding complications, there was no incidence of hypotension, bradycardia, and decreased saturation in both groups, thereby confirming this technique and drugs are very safe. Adding fentanyl does not cause delayed respiratory depression that confirms 25 µg as quiet safe dose. Among the complications, they had shivering and nausea without vomiting. There was no difference among the groups. Shivering may be explained by redistribution of core body temperature and operation theater temperature.[10] Fentanyl group had three patients with nausea compared with two patients in group B but it was not significant. In our study, we found that adding fentanyl intrathecally cannot increase chance of nausea and vomiting, which can be explained by the low dose used. There was no incidence of pruritus in both groups. It shows that 25 µg fentanyl can be added to low-volume bupivacaine (1 mL) to increase duration of analgesia without side effects and complications related to opioids.

CONCLUSION

From our study we conclude that intrathecal fentanyl with low-dose bupivacaine intensifies surgical anesthesia by extending postoperative analgesia without causing systemic and local opioid complications. This method is the most effective and cheap anesthetic modality in daycare perineal surgery.

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