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Efficacy of dexmedetomidine and nalbuphine as an adjuvant to bupivacaine in lower limb surgeries done under subarachnoid block: a comparative study

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ABSTRACT

Background: Sub-arachnoid block is most commonly used technique in regional anaesthesia to conduct lower limb surgeries [1]. Wide variety of adjuvants have been used intrathecally to prolong post-operative analgesia. The aim of this study is to evaluate and compare the intra-operative block characteristics and duration of post-operative analgesia by using intrathecal dexmedetomidine (5µg) or nalbuphine(1mg) as an adjuvant to hyperbaric bupivacaine (12.5mg) in lower limb orthopedic surgeries.

Aims and objectives: This study is used to compare the effects of dexmedetomedine and nalbuphine when given as an adjuvant to hyperbaric bupivacaine in sub-arachnoid block.

Material and methods: This study was prospective, randomized, double-blind study. After obtaining ethical committees' clearance and informed consent, sixty patients of either sex, and ASA physical status I and II scheduled for sub-arachnoid block were included and categorized into two groups(n=30).

Result: Addition of dexmedetomedine with hyperbaric bupivacaine intrathecally when compared with nalbuphine result in faster onset of both motor and sensory blockade, with statistically significant longer duration of post-operative analgesia.

Conclusion: Both dexmedetomidine and nalbuphine can be used as adjuvant to hyperbaric bupivacaine in spinal anaesthesia but dexmedetomidine along with bupivacaine provide better quality of anaesthesia, and excellent post-operative analgesia when compared with nalbuphine.

Keywords: Bupivacaine, dexmedetomedine, nalbuphine, sub-arachnoid block

1. INTRODUCTION

Sub-arachnoid block is most commonly used technique in regional anaesthesia to conduct lower limb surgeries [1]. There are various options for anesthetist to conduct lower limb surgery like subarachnoid block, epidural anesthesia, general anesthesia etc. The advantages of providing regional anesthesia include prevention of airway

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manipulation, an awake and spontaneously breathing patient intraoperatively, effective postoperative analgesia and early ambulation and recovery [2,3]. It also lowers the incidence of venous thromboembolism.

Regional anaesthesia with sub-arachnoid block have been used for long time for various surgical procedures. The sub-arachnoid block has emerged as an effective and convenient method of anaesthesia, with intense motor and sensory blockade, good muscle relaxation, minimum physiological changes with few side effects [4].

Bupivacaine heavy 0.5% is the most commonly used local anaesthetic drug for sub-arachnoid block. When used alone for spinal anaesthesia it does not prolong post-operative analgesia. Therefore, research for the drug that subside the post-operative pain with lesser side effects is required. Wide variety of adjuvants have been used to prolong post-operative analgesia, these are opioids, clonidine, dexmedetomidine, nalbuphine, ketamine etc [5].

Addition of opioids to local anaesthetics is very commonly practiced. It reduces the toxicity and cardiovascular effects of local anaesthetics but it can cause various undesirable effects like itching, nausea and vomiting and / or respiratory depression.

Nalbuphine belongs to opioid family of phenanthrene series. It is a semi-synthetic opioid chemically related to oxymorphone and naloxone with agonistic action on k-receptor and antagonistic action at μ-receptor. It is equal in potency as analgesic to morphine, and one-fourth as potent as nalorphine as an antagonist. It provides analgesia and sedation due to its agonistic action on k-receptor and minimal side effects due to its antagonistic action on μ-receptor. Therefore, Nalbuphine produces minimal side effects like nausea, vomiting and pruritis compared to morphine [6]. It does not cause hemodynamic instability and respiratory depression. It does not cause any addiction due to its antagonistic action at μ-receptor.

Dexmedetomidine is a new alpha2-agonist that received FDA approval in 1999 for use as a short-term (less than 24 h) sedative, analgesic in the intensive care unit. It causes sedation without causing respiratory depression. It has sedative, analgesic, sympatholytic and anxiolytic effect that blunt many CVS responses in perioperative period. The elimination half-life is 2 hours and therefore discontinuing the infusion rapidly leads to a state of consciousness. It is used in treatment of symptoms of distress (intractable pain, agitation and delirium). [7-9] It is thought that intrathecal dexmedetomidine produces its analgesic effect by inhibiting the release of C fibers transmitters and by hyperpolarization of post-synaptic dorsal horn neurons. This antinociceptive effect explain the prolongation of sensory block when added to spinal anaesthesia. The prolongation of motor effect might be caused by direct impairment of excitatory amino acid release from spinal interneurons. Alpha 2 agonists produce sedative effect by acting on alpha 2-adrenergic receptors in locus ceruleus. Alpha 2 adrenoreceptors do not have an active role in the respiratory center, therefore, dexmedetomidine throughout a broad range of plasma concentration, has minimal effects on the respiratory system. Dexmedetomidine has been used in the epidural space in humans without any reports of neurological deficits. [10-12] Small doses of dexmedetomidine (2-5μg) used in combination with bupivacaine, in humans, for spinal anaesthesia, has been shown to produce a shorter onset of motor block and a prolongation in the duration of motor and sensory block with preserved hemodynamic stability and lack of sedation. Dexmedetomidine has a dose dependent effect on the onset and regression of sensory and motor block when used as an adjuvant to bupivacaine in spinal anaesthesia. [13,14]

The aim of our study is to compare the effect of dexmedetomidine and nalbuphine when given as an adjuvant to 0.5% bupivacaine heavy in subarachnoid block.

2. MATERIALS AND METHODS

The proposed study was conducted on either sex aged 60 years and above, (ASA physical status grade I and II) schedule for elective lower limb surgery under subarachnoid block at Nehru Hospital in B.R.D. Medical Collage, Gorakhpur after approval from ethical committee and obtaining informed written consent from all patients and their attendants on separate consent form. Study Period: November 2021-October 2022

Study Design: Prospective study

Sample Size: Total of 60 patients, with 95% Power of study, 95% confidence interval, 5% significance level/allowable error using appropriate software.

The study population was randomly divided into 2 groups with 30 patients (N=30) in each group.

GROUP I patients will receive 2.5ml of 0.5% hyperbaric bupivacaine and 5μg(0.5ml) dexmedetomidine comprising a total volume of 3.0ml.

GROUP II patients will receive 2.5ml of 0.5% hyperbaric bupivacaine and 1.0mg(0.5ml) nalbuphine comprising a total volume of 3.0ml.

Inclusion Criteria

1. Patients of any gender schedule for elective lower limb surgeries under subarachnoid block
2. Patients with ASA physical status I and II
3. Height between 150-170 cm
4. Weight between 50-80kg
5. Patient willing to undergo surgery under subarachnoid block

Exclusion Criteria

1. Patients who deny the consent

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2. Patients with ASA physical status III and IV
3. Patients with history of drug allergy
4. Patients with severe cardiac, pulmonary, hepatic, renal and neurologic disease
5. Patients physically dependent on narcotics

Careful pre-anaesthetic check-up was carried out in all patients with detailed clinical history, general and systemic examination. Preoperative assessment was done for each patient and written consents were taken. All patients were pre-medicated with tablet Alprazolam 0.25 mg and Tablet Rantac 150mg a night before surgery, fasted 8 hours for solid food and 2 hours for clear liquids. The baseline vitals were recorded. Intravenous (IV) fluid ringer lactate (R.L.) 5-10 ml/kg were preloaded before induction of spinal anaesthesia. Monitoring included electrocardiography, pulse oximetry, and non-invasive blood pressure. Under all aseptic conditions, the study drug was injected into L3–L4 subarachnoid space in sitting position using 27G Quincke's spinal needle after appearance of clear cerebrospinal fluid and the time of injection was recorded as 0 minutes.

Patients were monitored for occurrence of adverse events after spinal injection like nausea, vomiting, hypotension, bradycardia, shivering, pruritis, respiratory depression.

The following parameters were observed and recorded.

1. Onset of sensory blockade: Assessment of sensory block will be done by loss of sensation to pinprick at T10 level.

2. Onset of motor blockade: The time needed for the onset of motor block (Bromage 1). Quality of motor blockade was assessed by modified bromage scale[15].

Grade0- Full flexion of knees and feet.
Grade 1- Just able to flex knees, full flexion of feet.
Grade 2- Unable to flex knees, but some flexion of feet possible.
Grade 3- Unable to move legs or feet.
Grade 4-Complete paralysis.

3. Maximum level of sensory blockade i.e., time taken from injection of study drug (0 minutes) till the patient attains loss of sensation at the highest dermatome attained. The time taken for the same was also recorded.

4. Total duration of sensory blockade: Time taken from maximum block height attained till regression of block to S1 dermatome.

5. Total duration of motor blockade: Time taken from maximum Bromage score attained to Bromage 0. It was tested at the end of surgery using modified Bromage scale.

6. Total duration of analgesia was noted.

7.Ramsay Sedation score was assessed using Ramsay sedation score which is as follows [15]:

1. Anxious, agitated, restless.
2. Cooperative, oriented, tranquil.
3. Responds to commands only.
4. Brisk response to light glabellar tap or loud noise.
5. Sluggish response to light glabellar tap or loud noise.
6. No response

8. Postoperative pain was assessed using Visual Analogue Scale (0 -10) at every 30 min till 2hour, then hourly for the next 4 hours, then 4 hourly till 12 hours and time to first rescue analgesic drug request was recorded. Rescue Analgesia was provided by inj. Fentanyl 1µg/kg IV

Hemodynamic changes - Hemodynamic parameters such as HR, SBP, DBP, mean arterial blood pressure (MAP) and Spo2 will be monitored every 2 min for the 10 min, every 5 min for next 30 min in, every 15 min up to 60 min half hourly up to 180 min and thereafter hourly till the 12th hrs. and every 3 hourly till 24 hrs. of surgery in both the groups.

Management of side effects:

Hypotension: Drop of mean arterial pressure by >20% from baseline or values <90mm/Hg was treated with intermittent doses of IV mephentermine 6mg/dose. Total vasopressor dose required was recorded.

Bradycardia: drop-in heart rate to <60bpm was be labelled as bradycardia and was treated with IV atropine 0.6mg.

Nausea / vomiting - Was treated with IV ondansetron 4mg stat.

Rescue Analgesia was provided by inj. fentanyl 1 µg/kg IV.

3. OBSERVATION AND RESULT

Our study is prospective comparative study in which we screened 60 patients, none of the screened patients were excluded from the study. The study period was from October 2021 to September 2022 (one year).

These 60 patients included in the study were posted for elective lower limb surgeries in Nehru hospital, BRD Medical college, Patients were divided into two groups with 30 patients in each group:

Randomization of the patients was done by chit and box method and were divided into two groups.

Group I: Patients receiving dexmedetomidine 5mcg (0.5 ml) with bupivacaine 12.5 mg (2.5ml)

Group II: Patients receiving nalbuphine 1mg (0.5 ml) with bupivacaine 12.5 mg (2.5ml)

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Table1: Distribution of patients into groups

		n	%
Group I	Dexmedetomidine	30	50.0
Group II	Nalbuphine	30	50.0

The onset of sensory block i.e., time taken for sensory block to reach T10 dermatome was significantly faster in group I i.e., (4.46 ± 0.90) minutes when compared to Group II (5.05 ± 0.91minutes), and was statistically significant(p=0.0143) as shown in table 2.

Table 2: Comparisons of mean onset(min) of sensory block (T10) in between

	Group I (n=30)		Group II (n=30)		t	p-Value
	Mean	±SD	Mean	±SD		
Onset of sensory block(T10) (min)	4.46	0.90	5.05	0.91	-2.52	0.0143

Time taken to reach the highest level of sensory block, as seen in table 3, was significantly(P=0.0137)) lower in group I (11.75 ± 0.97 min) as compared to group II (12.38 ± 0.95min).

Table3: Comparisons of mean time for max. sensory blockade (min) in each group.

	Group I (n=30)		Group II (n=30)		t	p-Value
	Mean	±SD	Mean	±SD		
Time for max sensory blockade (min)	11.75	0.97	12.38	0.95	-2.541	0.0137

The time for sensory regression to S_1 was longer in group I (286.4 ± 21.83min) as compared to group II (267.87 ± 19.71 min), and on statistical analysis found highly significant(P=0.001) shown in table 4.

Table 4: Comparisons of mean total duration of sensory block (regression to S1 level) in each group.

	Group I (n=30)		Group II (n=30)		t	p-Value
	Mean	±SD	Mean	±SD		
Total duration of sensory block (regression to S1 level) (min)	286.4	21.83	267.87	19.71	3.3408	0.001

The onset motor blockade (bromage 1) was earlier in group I (2.15 ± 0.51min) as compared to group II (2.17 ± 0.46min), the difference is insignificant(P=0.879) on statistical analysis as shown in table 5.

Table 5: Comparisons of mean Onset(min)of motor block (bromage 1) in between group I and group II

	Group I (n=30)		Group II (n=30)		t	p-Value
	Mean	±SD	Mean	±SD		
Onset of motor block (bromage 1) (min)	2.15	0.51	2.17	0.46	-0.153	0.879

Time for maximum motor blockade (bromage 4) shown in table 6 was also faster in group I (12.28 ± 2.09 min) when compared to group II (15.17 ± 1.76 min) which were significant on statistical analysis(P<0.1).

Table 6: Comparisons of mean time for max motor block (bromage 4 (min) in between group I and group II

	Group I (n=30)		Group II (n=30)		t	p-Value
	Mean	±SD	Mean	±SD		
Time for max motor block (bromage 4 (min))	12.28	2.09	15.17	1.76	-5.790	<0.001

Recovery of motor block i.e., regression of motor blockade to bromage 0 in each group were given in table 7. The mean time to regression to bromage 0 (min) was significantly(P=0.0023) higher in group I (279 ± 24.31 min) as compared to group II (259.87 ± 22.0 min).

Table 7: Comparisons of mean time for regression to bromage 0 (min) in each group

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	Group I (n=30)		Group II (n=30)		t	p-Value
	Mean	±SD	Mean	±SD		
Time for Regression to bromage 0 (min)	279.00	24.31	259.87	22.00	3.195	0.0023

Pain was measured using VAS (Visual analogue score) rated from 0 to 10 subjectively with 0 for no pain and 10 for maximum pain. The VAS score was better in dexmedetomidine (group I) patients with mean at 4hr of (1.56), at 6hr of (2.46), at 8hr of (2.43) and 12hr of (1.9) as compared to the VAS score of Nalbuphine (group II) with mean at 4hr of (2), at 6hr of (2.23), at 8hr of (2.2) and at 12hr of (2.5) respectively, Shown in table 8. The difference found was statistically insignificant on intergroup comparison.

Table 8: Showing mean VAS score in each group

VAS	Group I (n=30)		Group II (n=30)	
	Mean	±SD	Mean	±SD
30min	0.00	0.00	0.00	0.00
1hr	0.10	0.31	0.24	0.44
2hr	0.13	0.45	1.7	0.43
3hr	0.63	0.41	2.40	0.50
4hr	1.56	0.35	2	0.45
6hr	2.46	0.50	2.23	0.50
8hr	2.43	0.50	2.2	0.43
12hr	1.9	0.97	2.5	0.96

Table 9 shows the sedation score, was higher in Group I (2.9 ±0.90) as compared to Group II (2.43±0.130), the difference found was statistically highly significant(P<0.001).

Table 9: Showing mean Ramsay Sedation Score in each group

	Group I (n=30)		Group II (n=30)		t	p-Value
	Mean	±SD	Mean	±SD		
Ramsay Sedation Score	2.9	0.90	2.43	0.130	-2.830	0.0064

The time for rescue analgesia i.e., the time when patients demanded first dose of analgesic. It was prolonged in Group I (333.17 ± 21.64min) as compared to Group II (281.17 ± 18.92min) which was found to be statistically significantly higher (P<0.001), as shown in table 10.

Table 10: Shows the comparisons of mean time for rescue Analgesia (min) perioperatively in each group.

	Group I (n=30)		Group II (n=30)		t	p-Value
	Mean	±SD	Mean	±SD		
Time for rescue Analgesia(min)	333.17	21.64	281.17	18.92	9.909	<0.001

4. DISCUSSION

Sub-arachnoid block has been commonly used for lower limb surgeries because of its simplicity, speed, reliability and minimal exposure to depressant drugs. The aim of good postoperative analgesia is to produce a long lasting, effective analgesia with minimum side effects. Adding, an intrathecal adjuvant to local anesthetics forms a reliable method to prolong the duration of anaesthesia. A number of adjuvants to local anesthetics for spinal anaesthesia like opioids (Fentanyl and Nalbuphine), benzodiazepines (midazolam), ketamine and neostigmine have been used. Intrathecal opioid administration along with local anesthetic was first introduced in 1979 with intrathecal morphine as a forerunner. Neuraxial administration of opioids along with local anesthetic improves quality of intraoperative analgesia and also provides postoperative pain relief for longer duration. However intrathecal opioids can produce a number of side effects like nausea, vomiting, pruritis and/ or respiratory depression depending on the dose used.

Dexmedetomidine, a newer α_2-agonist, also having analgesic effects is being used intrathecally. Their analgesic action is a result of depression of C-fibers transmitters release and hyperpolarization of postsynaptic dorsal horn neurons. The prolongation of sensory effect may be due to synergism between local anesthetics and $\alpha_2$receptor agonists while prolongation of motor blockade is due to binding to motor neurons in dorsal horn.

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The present study "Efficacy of dexmedetomidine and nalbuphine as an adjuvant to bupivacaine in lower limb surgeries done under subarachnoid block": comparative study, is aimed to study the sensory and motor blockade characteristics, the duration of post operative analgesia provided by nalbuphine and dexmedetomidine, and to know the hemodynamic variation and side effects.

The onset of sensory block (table 2) i.e., time taken for sensory block to reach T10 dermatome was significantly(p=0.0143) faster in group I i.e. (4.46 ± 0.90 minutes) when compared to Group II (5.05 ± 0.91minutes), and the onset of motor blockade (bromage 1) is 2.15±0.51 minutes in group I and 2.17±0.46 minutes in group II. The time for maximum motor blockade (bromage 4) was 12.28±2.09 minutes in group I and 15.17±1.76 minutes in group II which is almost similar to study done by Bhargav Vishnu Gantasala et al [16]. where they found sensory onset 4.42±2.02 minutes in group Dexmedetomedine and 4.60±1.20 minutes in nalbuphine group. Similar study was also conducted by Bindu Nagraj et al. [17] in order to found out the efficacy of Dexmedetomedine and nalbuphine as an adjuvant to intrathecal bupivacaine where they observed early onset of sensory block (1.85minutes) compared to nalbuphine group(2.1minutes), the result is incongruence with our study, this could be due to dose variation in our study.

The result of our study is also in correlation with study conducted by Kanazi GE. et. al. (13) where they found the mean time for motor blockade (bromage 3) was 13.2±5.6 minutes in dexmedetomedine group. Bhalavat et al [18], Jahnabee sarma et al [19] concluded that intrathecal dexmedetomidine in a dose of 5µg when given as an adjuvant to bupivacaine, significantly(P<0.001) decreases the mean onset of sensory and motor blockade.

The maximum level of sensory blockade achieved in our study is T6 in both the groups and these findings was also supported by study conducted by Kanazi GE et al [13] where the median range of the peak sensory level reached were T6 in group Dexmedetomedine. These findings also correlate with study done by Bindu Nagraj et.al [17].

Time taken to reach the highest level of sensory block, as seen in table 3, was significantly(P=0.0137)) lower in group I (11.75 ± 0.97 min) as compared to group II (12.38 ± 0.95min). Our study is in accordance to study done by Kumar et.al [20]. where he concluded that time taken to reach maximum level of sensory block was 12.3±1.8 minutes in dexmedetomidine group.

The time for sensory regression to S1 in our study was longer in group I (286.4 ± 21.83 minutes) as compared to group II (267.87.07 ± 19.71 minutes), and it was found to be statistically significant(P=0.001) shown in table 4. Our study was comparable to studies conducted by Mahmoud MM AL Mustafa et. al. [21] where duration of sensory blockade in dexmedetomedine group was 277.10±23.2 minutes, similarly R Kumar et al [20]. found 306±13.32 minutes of total sensory block duration in dexmedetomedine group. Shagufta Naaz et al [22]. in a randomized, double blinded study in a patient undergoing lower limb surgeries studied the efficacy of nalbuphine as an adjuvant to hyperbaric bupivacaine found duration of sensory blockade to be 248±40.22 minutes which is comparable to our study.

Recovery of motor block i.e., regression of motor blockade to bromage 0 in each group were shown in Table 7. The mean time(min) to regression to bromage 0 was significantly(P<0.001) higher in group I (279 ± 24.31minutes) as compared to group II (259.27 ± 22 minutes). Sree Vidya Ramineedi et al [23] studied the efficacy of dexmedetomedine with hyperbaric bupivacaine in lower limb orthopaedic surgeries and concluded that duration of motor blockade (bromage 0) was significantly (P<0.001) higher i.e., 262±17.73 minutes as compared to bupivacaine alone (168.71±9.3minutes), which also concurs with our result. AL Mustafa MM et al [24] also found in their study that dexmedetomedine as adjuvant to spinal bupivacaine provide significantly longer duration of motor blockade (246.4±25.7 minutes). Our study is also in accordance with the study conducted by Bhargav Vishnu Gantasala et al [16], Jahnabee sarma et.al [19].

From above findings we can say that on intergroup comparison, addition of dexmedetomidine with hyperbaric bupivacaine intrathecally when compared with nalbuphine results in faster onset of both sensory and motor blockade and also longer regression time for motor and sensory block.

Hemodynamic parameters were observed perioperatively. One patient in group I had both hypotension and bradycardia, and in another 2 patients, one had bradycardia and other had hypotension which were easily managed without any untoward effect. Overall hemodynamic stability was good in both the groups. Similarly, in the study done by Gupta et al [15] in group dexmedetomidine, 6.6% had bradycardia and hypotension, respectively. Hence, the addition of dexmedetomidine as an adjuvant cause minimal variation in vitals parameters and is comparable with nalbuphine and safe to use as an alternative. In a similar study conducted by Bhalavat et al [18] also found that the incidence of hypotension and bradycardia in dexmedetomedine group was 6.67% and 6.67% respectively, which were comparable to our study.

We have also studied post-operative analgesia effect by VAS score (table 8). The VAS score was serially assessed till the patients complained of pain (VAS > 3). In most of the patients VAS score was <3 till 8th hour post-operatively, three patients in group I and two patients in group II required rescue analgesia in the form of Inj. fentanyl. Our study is comparable to study conducted by Kim JE et al [25] where they found VAS score 0.4 at 30 minutes, and at 6hrs the VAS score was 2.0 in dexmedetomidine group. Routray SS et al [26]. also found VAS score 0.00 at 1hr and at 2 hr and 3hr the VAS score was 1.0 and at 4th and 5th hr the VAS score was 2.0 in

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dexmedetomidine group. Pallavi Ahluwalia et al [27] conducted study on nalbuphine where they found VAS score 1.56 at 3hr, 2.01 at 3.5 hr, 2.56 at 4hr and 2.89 at 4.5hr which was comparable to our study.
The time for recue analgesia (table 10) was prolonged in Group I (333.17 ± 21.64min) as compared to Group II (281.17 ± 18.92min) which was found to be statistically significantly higher (P<0.001). Jahnabee sarma et al [19] concluded that supplementation of hyperbaric bupivacaine with dexmedetomedine (5µg) produces significantly(P=<0.001) longer duration of analgesia (336.80±50.56 minutes), which concurs with our result. Gurunath et al [28] studied effect of nalbuphine as an adjuvant to bupivacaine provides longer duration (268.3±44.44 minutes) of analgesia. These findings were also supported by studies done by Bindu Nagraj, Vinay BR et [17], Bhalavat et al [18], Shehla shakooh-et-al [29], Al Mustafa MM and Halaweh Abu et al [24].
Table 9 shows the sedation score, 2.9 ±0.90 in group I and 2.43±0.13 in group II, the difference found was statistically highly significant(P<0.001) which is in similarity with study conducted by Bhalavat-et-al [18].

5. CONCLUSION

The present study concluded that both dexmedetomidine and nalbuphine can be used as adjuvant to hyperbaric bupivacaine in spinal anaesthesia but dexmedetomidine along with bupivacaine provide better quality of anaesthesia, and excellent post-operative analgesia when compared with nalbuphine.

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