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Clinical evaluation of Intrathecal dexmedetomidine and fentanyl as an adjuvant to isobaric bupivacaine for lower limb orthopedic surgery in patients from Bihar

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Abstract
Lower limb surgeries could be performed under local, neuroaxial and general anesthesia, but neuroaxial block is the preferred method. Spinal block has rapid onset, deep block, lower risk of infection and is cost effective. However, post-operative pain is an important problem as the used drugs have limited duration of effect; so the post-operative analgesic administration is necessary. Hence the present study was planned to evaluate the intrathecal Dexmedetomidine and Fentanyl as an adjuvant to isobaric Bupivacaine for lower limb orthopaedic surgery in patients from Bihar region.
The present study was planned in Department of Anesthesia, Nalanda Medical College and Hospital, Patna, Bihar. Total 30 cases of the patients of lower limb orthopaedic surgeries were enrolled in the present study. The Group I patients received the 2.5 mL volume of 0.5% hyperbaric bupivacaine and 5 µg dexmedetomidine in 0.5 mL of normal saline intrathecal (Dexmedetomidine (100 µg/mL) was diluted in preservative-free normal saline). The Group II patients received 2.5 mL volume of 0.5% hyperbaric bupivacaine with 25 µg fentanyl intrathecal. Intrathecal injection was given over approximately 10–15 s. immediately after completion of the injection patients were made to lie supine.
The data generated from the present study concludes that the dexmedetomidine appears to be an attractive alternative to fentanyl as an adjuvant to spinal bupivacaine in surgical procedures. It provides good quality of intraoperative analgesia, hemodynamically stable conditions, minimal side effects, and excellent quality of postoperative analgesia.

Keywords: lower limb orthopaedic surgeries, bupivacaine, dexmedetomidine, fentanyl, ETC

Introduction
Dexmedetomidine is most often used in the intensive care setting for light to moderate sedation. It is not recommended for long-term deep sedation. A feature of dexmedetomidine is that it has analgesic properties in addition to its role as a hypnotic, but is opioid sparing; thus, it is not associated with significant respiratory depression (unlike propofol). Many studies suggest dexmedetomidine for sedation in mechanically ventilated adults may reduce time to extubation and ICU stay. People on dexmedetomidine can be rousable and cooperative, a benefit in some procedures.
Compared with other sedatives, some studies suggest dexmedetomidine may be associated with less delirium [5]. However, this finding is not consistent across multiple studies. At the very least, when aggregating many study results together, use of dexmedetomidine appears to be associated with less neurocognitive dysfunction compared to other sedatives. Whether this observation has a beneficial psychological impact is unclear. From an economic perspective, dexmedetomidine is associated with lower ICU costs, largely due to a shorter time to extubation.
Dexmedetomidine can also be used for procedural sedation such as during colonoscopy. It can be used as an adjunct with other sedatives like benzodiazepines, opioids, and propofol to enhance sedation and help maintain hemodynamic stability by decreasing the requirement of other sedatives. Dexmedetomidine is also used for procedural sedation in children. There is weak evidence that it can be used for sedation required for awake fibreoptic nasal intubation in patients with a difficult airway [1].
Dexmedetomidine is a highly selective α2-adrenergic agonist. Unlike opioids and other sedatives such as propofol, dexmedetomidine is able to achieve its effects without causing respiratory depression. Dexmedetomidine induces sedation by decreasing activity of noradrenergic neurons in the locus ceruleus in the brain stem, thereby increasing the activity of inhibitory gamma-aminobutyric acid (GABA) neurons in the ventrolateral preoptic nucleus. In contrast [clarification needed], other sedatives like propofol and benzodiazepines directly increase activity of gamma-aminobutyric acid neurons.] Sedation by dexmedetomidine mirrors natural sleep. As such, dexmedetomidine provides less amnesia than benzodiazepines. Dexmedetomidine also has analgesic effects at the spinal cord level and other supraspinal sites [2]. Thus, unlike other hypnotic agents like propofol, dexmedetomidine can be used as an adjunct medication to help decrease the opioid requirements of people in pain while still providing similar analgesia.
Intravenous dexmedetomidine exhibits linear pharmacokinetics with a rapid distribution half-life of approximately 6 minutes and a terminal elimination half-life of approximately 2 hours. Plasma protein binding of Dexemedotomindine is about 94% (mostly albumin). Dexmedetomidine is metabolized by the liver via glucuronidation and cytochrome P450. As such, it should be used with caution in people with liver disease. The majority of metabolized dexmedetomidine is excreted in the urine

(~95%) [3].

Fentanyl, also spelled fentanil, is an opioid used as a pain medication and together with other medications for anesthesia. Fentanyl is also used as a recreational drug, often mixed with heroin or cocaine. It has a rapid onset and its effects generally last less than two hours. Medically, fentanyl is used by injection, as a patch on the skin, as a nasal spray, or in the mouth. Common side effects include vomiting, constipation, sedation, confusion, hallucinations, and injuries related to poor coordination. Serious side effects may include decreased breathing (respiratory depression), serotonin syndrome, low blood pressure, addiction, or coma. Fentanyl works primarily by activating μ-opioid receptors. It is around 100 times stronger than morphine, and some analogues such as carfentanil are around 10,000 times stronger [4].

Intravenous fentanyl is often used for anesthesia and analgesia. During anaesthesia it is often used along with a hypnotic agent like propofol. It is also administered in combination with a benzodiazepine, such as midazolam, to produce sedation for procedures such as endoscopy, cardiac catheterization, and oral surgery, or in emergency rooms. It is also used in the management of chronic pain including cancer pain [5].

Fentanyl is sometimes given intrathecally as part of spinal anaesthesia or epidurally for epidural anaesthesia and analgesia. Because of fentanyl's high lipid solubility, its effects are more localized than morphine, and some clinicians prefer to use morphine to get a wider spread of analgesia. However, it's widely used in obstetrical anesthesia because of its short time to action peak (about 5 min), the rapid termination of its effect after a single dose, and the occurrence of relative cardiovascular stability. In obstetrics, the dose must be closely regulated in order to prevent large amounts of transfer from mother to fetus. At high doses, the drug may act on the fetus to cause postnatal respiratory distress [6].

Bupivacaine, marketed under the brand name Marcaine among others, is a medication used to decrease feeling in a specific area. In nerve blocks, it is injected around a nerve that supplies the area, or into the spinal canal's epidural space. It is available mixed with a small amount of epinephrine to increase the duration of its action. It typically begins working within 15 minutes and lasts for 2 to 8 hours. Possible side effects include sleepiness, muscle twitching, ringing in the ears, changes in vision, low blood pressure, and an irregular heart rate. Concerns exist that injecting it into a joint can cause problems with the cartilage. Concentrated bupivacaine is not recommended for epidural freezing. Epidural freezing may also increase the length of labor. It is a local anaesthetic of the amide group [7].

Bupivacaine is indicated for local infiltration, peripheral nerve block, sympathetic nerve block, and epidural and caudal blocks. It is sometimes used in combination with epinephrine to prevent systemic absorption and extend the duration of action. The 0.75% (most concentrated) formulation is used in retrobulbar block. It is the most commonly used local anesthetic in epidural anesthesia during labor, as well as in postoperative pain management. Liposomal formulations of bupivacaine are no more effective than plain solutions of bupivacaine [8].

In human anatomy, the lower leg is the part of the lower limb that lies between the knee and the ankle. The thigh is between the hip and knee and makes up the rest of the lower limb. The term lower limb or "lower extremity" is commonly used to describe all of the leg. This article generally follows the common usage. The leg from the knee to the ankle is called the crus or cnemis. The calf is the back portion, and the tibia or shinbone together with the smaller fibula make up the front of the lower leg.

Evolution has provided the human body with two distinct features: the specialization of the upper limb for visually guided manipulation and the lower limb's development into a mechanism specifically adapted for efficient bipedal gait. While the capacity to walk upright is not unique to humans, other primates can only achieve this for short periods and at a great expenditure of energy. The human adaption to bipedalism is not limited to the leg, however, but has also affected the location of the body's center of gravity, the reorganisation of internal organs, and the form and biomechanism of the trunk. In humans, the double S-shaped vertebral column acts as a great shock-absorber which shifts the weight from the trunk over the load-bearing surface of the feet. The human legs are exceptionally long and powerful as a result of their exclusive specialization for support and locomotion — in orangutans the leg length is 111% of the trunk; in chimpanzees 128%, and in humans 171%. Many of the leg's muscles are also adapted to bipedalism, most substantially the gluteal muscles, the extensors of the knee joint, and the calf muscles [8].

The sensory and motor innervation to the lower limb is supplied by the lumbosacral plexus, which is formed by the ventral rami of the lumbar and sacral spinal nerves with additional contributions from the subcostal nerve (T12) and coccygeal nerve (Co1). Based on distribution and topography, the lumbosacral plexus is subdivided into the lumbar plexus (T12-L4) and the Sacral plexus (L5-S4); the latter is often further subdivided into the sciatic and pudendal plexuses.

The lumbar plexus is formed lateral to the intervertebral foramina by the ventral rami of the first four lumbar spinal nerves (L1-L4), which all pass-through psoas major. The larger branches of the plexus exit the muscle to pass sharply downward to reach the abdominal wall and the thigh (under the inguinal ligament); with the exception of the obturator nerve which pass through the lesser pelvis to reach the medial part of the thigh through the obturator foramen. The nerves of the lumbar plexus pass in front of the hip joint and mainly support the anterior part of the thigh [8].

The iliohypogastric (T12-L1) and ilioinguinal nerves (L1) emerge from the psoas major near the muscle's origin, from where they run laterally downward to pass anteriorly above the iliac crest between the transversus abdominis and abdominal internal oblique, and then run above the inguinal ligament. Both nerves give off muscular branches to both these muscles. Iliohypogastric supplies sensory branches to the skin of the lateral hip region, and its terminal branch finally pierces the aponeurosis of the abdominal external oblique above the inguinal ring to supply sensory branches to the skin there. Ilioinguinalis exits through the inguinal ring and supplies sensory branches to the skin above the pubic symphysis and the lateral portion of the scrotum [8].

Lower limb surgeries could be performed under local, neuroaxial and general anesthesia, but neuroaxial block is the preferred method. Spinal block has rapid onset, deep block, lower risk of infection and is cost effective. However, post-operative pain is an important problem as the used drugs have limited duration of effect; so the post-operative

analgesic administration is necessary [11].
Hence the present study was planned to evaluate the intrathecal Dexmedetomidine and Fentanyl as an adjuvant to isobaric Bupivacaine for lower limb orthopaedic surgery in patients from Bihar region.

Methodology

The present study was planned in Department of Anesthesia, Nalanda Medical College and Hospital, Patna, Bihar. Total 30 cases of the patients of lower limb orthopaedic surgeries were enrolled in the present study. The Group I patients received the 2.5 mL volume of 0.5% hyperbaric bupivacaine and 5 µg dexmedetomidine in 0.5 mL of normal saline intrathecal (dexmedetomidine (100 µg/mL) was diluted in preservative-free normal saline). The Group II patients received 2.5 mL volume of 0.5% hyperbaric bupivacaine with 25 µg fentanyl intrathecal. Intrathecal injection was given over approximately 10–15 s. immediately after completion of the injection patients were made to lie supine.
All the patients were informed consents. The aim and the objective of the present study were conveyed to them. Approval of the institutional ethical committee was taken prior to conduct of this study.
Following was the inclusion and exclusion criteria for the present study.
Inclusion Criteria: Patients with Anesthesiologists (ASA) physical status I or II, either sex, age 18–50 years, presenting for lower abdominal surgeries.
Exclusion Criteria: Patient allergic to drug, heart block/ dysrrhythmia, or on therapy with adrenergic receptor antagonist, calcium channel blocker, and/or ACE inhibitor

Results and Discussion

Administrating the combinations of other classes of analgesics with local anesthetics has used to increase the duration and reduce side effects of analgesia [3]. Some drugs have been used as adjuvants in spinal anesthesia to prolong intraoperative and postoperative analgesia [1, 2] including opioids, α2 agonists, neostigmine, vasoconstrictors, etc. Clonidine and dexmedetomidine are two α2 agonists affecting via pre- and post-synaptic α2 receptors [4]. Dexmedetomidine has been widely used for anesthesia and analgesic purposes. This drug has sedative, anti-anxiety, analgesic, neuroprotective, and anesthetic-sparing effects [5]. Dexmedetomidine along with other drugs have been used to increase the duration of analgesia in subarachnoid, epidural and caudal blocks [12, 13].
Fentanyl is a synthetic opioid with central action, which is used widely for pain control. Intrathecal fentanyl is usually added to other local anesthetics to increase anesthesia and analgesia. It has improved spinal anesthesia and reduced the anesthetic drug related side effects including pruritus, nausea and vomiting [14].
Dexmedetomidine and fentanyl have been used as adjuvant to local anesthetics in different surgeries to provide superior analgesia and to improve the duration of the block [15]. One study on lower limbs surgery showed a better efficacy with dexmedetomidine [16, 17].

Table 1: Basic Demographic Details

Group	**Group I**	**Group II**
Group of	**Bupivacaine with Dexmedetomidine**	**Bupivacaine with Fentanyl**
No. of Cases	**15**	**15**
Age	38 – 46	41 – 49
Sex		
Males	10	11
Females	5	4
ASA		
Class I	11	12
Class II	4	3
Weight in Kg	52 – 79	55 – 83
Duration of Surgery (min)	142 – 215	132 – 206

Table 2

Group	**Group I**	**Group II**
Group of	**Bupivacaine with Dexmedetomidine**	**Bupivacaine with Fentanyl**
No. of Cases	**15**	**15**
Highest sensory level	T4 – T8	T4 –T7
Time from injection to highest sensory level (min)	10.5 – 14.1	11 – 13.5
Time of two segment regression from the highest sensory level (min)	98 – 145	68 – 98
Time for sensory regression to S1 from highest sensory level (min)	430 – 486	172 – 196
Total analgesic dose in first 24 h (mg)	43 – 114	96 – 216
Time to rescue analgesia (min)	229 – 260	168 – 186
Onset to Bromage 3 (min)	9.5 – 12.9	10.1 – 12.5
Regression to Bromage 0 (min)	405 – 453	138 - 168

Table 3: Side Effects

Group	**Group I**	**Group II**
Group of	**Bupivacaine with Dexmedetomidine**	**Bupivacaine with Fentanyl**
No. of Cases	**15**	**15**
Nausea	1	2
Vomiting	0	1
Pruritus	0	1

Respiratory depression	0	0
Hypotension	2	1
Bradycardia	0	0
Urinary retention	1	1

Peak level of sensory block attained in the fentanyl group was T4 and the peak level of sensory block in dexmedetomidine group was T6 and in the saline group peak level was T8. So the highest sensory block was attained in the fentanyl group. Curvas *et al* in 2010 [18] found the difference in the sensory block and this can be explained by the difference in the baricity of the solutions ;.opioids are hypobaric and when added to the hypobaric local anaesthetic make the mixture more hypobaric thus altering the density of the resulting solution which affect the direction and extent of spread. Al Ghanem M Subhi *et al* [19] found out that highest sensory level was T6 in the Dexmedetomidine group and in the fentanyl group it was around T8 level.

Mantouvalou *et al*. [11] and Ogun *et al*. [9] found a similar cephalad extent of sensory block after isobaric bupivacaine or ropivacaine subarachnoid anesthesia. Marret *et al*. [20] who compared equal doses (10 mg) of isobaric bupivacaine with the isobaric ropivacaine also found a similar range of block height. But Malinovsky *et al*., [21] found a lower cephalad extent (median dermatome level T9) of anesthesia associated with less intense anesthetic blockade in the ropivacaine group, resulting in requirement of supplemental analgesia to perform surgery. This difference can be explained by use of fentanyl as adjuvant in our study which improves the quality of the block as well as the increased drug volume could have led to a higher cephalad extent of the local anesthetic solution.

In our study, we did not found any incidence of bradycardia in any patient. Though McNamee *et al*., [24] in their study found 2 patients among 32 in the ropivacaine group to have bradycardia and required atropine to treat the same; they had used a higher dose of ropivacaine that is, 3.5 ml 0.5%, total of 17.5 mg. The result of our study is comparable with a study done by Koltka *et al*., [22] 2009, who also did not found statistically significant difference in HR and arterial blood pressure in their study. Though McNamee *et al*. [24] found intraoperative hypotension requiring treatment with ephedrine in 12% patients in ropivacaine group and 26% patients in bupivacaine group, they had used a continuous intravenous infusion of 1% propofol after giving spinal anesthesia. They also later attributed the hypotension was due to propofol infusion rather than the institution of spinal anesthesia as the incidence of hypotension started only after starting the propofol infusion [23].

Ayman Eskander *et al* in 2017 [25] found that the postoperative analgesic requirement in first 24 hr was significantly lower in the dexmedetomidine and the fentanyl group compared to the control group and it was significantly lower in the dexmedetomidine group than fentanyl group ($p < 0.05$).

Side effects may occur by using any anesthesia medications. The best medication is the one with the highest efficacy and lowest side effects. We observed no significant difference in the rate of hypotension, bradycardia, nausea and vomiting and chilling between groups. Previous studies have reported different rate of side effects. Similar to our findings, Ravipati [26] observed pruritus only in fentanyl group while nausea and vomiting was more common in dexmedetomidine, with no significant difference between groups. There is also only one study reporting increase in hemodynamic side effects, bradycardia and hypotension, in dexmedetomidine [27].

Another important side effect of anesthesia medications is respiratory system suppression. However, we observed no respiratory suppression. First, fentanyl compared to other opioids is less likely to cause respiratory suppression. Second, this complication is not common in dexmedetomidine.

Conclusion

The data generated from the present study concludes that the dexmedetomidine appears to be an attractive alternative to fentanyl as an adjuvant to spinal bupivacaine in surgical procedures. It provides good quality of intraoperative analgesia, hemodynamically stable conditions, minimal side effects, and excellent quality of postoperative analgesia.

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