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Original Research Article

To Compare Fentanyl versus Dexmedetomidine Added to Low Dose Bupivacine for Lower Limb Surgery: A Prospective Randomised Double Blind Study

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Abstract

Background and Aims: The usual dose of bupivacaine cause sympathetic block, prolonged and strong sensory and motor block, which may not be preferred in some patients. Low dose diluted bupivacaine reduces the spinal block's spread and promotes quick recovery, but it might not offer enough sensory blockage. Dexmedetomidine, a more selective 2 agonist, and short-acting lipophilic opioid fentanyl are used to lower the dosage of bupivacaine and its side effects. In this study, we sought to determine which combination of low dosage bupivacaine and fentanyl or low dose bupivacaine and dexmedetomidine produced a superior grade of anaesthesia.

Methods: Using the opaque sealed envelope approach, 60 patients were randomly divided into two groups for this prospective randomised double blind trial in a tertiary healthcare facility. Group 1 (n=30) received intrathecally bupivacaine 0.5% heavy (0.8 ml) in combination with fentanyl (25 mcg) and normal saline (0.3 ml), with the goal of achieving a final bupivacaine concentration of 0.25% (1.6 ml). Group 2 (n=30) received intrathecally 0.5%heavy bupivacaine in combination with 5mcg dexmedetomidine and normal saline (0.3ml) to achieve final concentration of 0.25% bupivacaine (1.6ml).Time to achieve highest level of motor blockade, highest level of motor blockade, time to achieve peak sensory block level, peak sensory block level (PSBL), time to achieve T10 block level, intra-operative vitals (SBP, DBP, MAP, HR, SpO2), VAS, time at first rescue analgesia, and post-operative adverse effects were all measured.

Results: The median time to reach PSBL (P=0.02), the highest level of sensory block (P=0.00), the highest degree of motor block (P=0.00), the VAS score, and the time to administer the first rescue analgesia (P=0.00) all showed statistically significant differences. The intra-operative vitals and side effects showed no statistically significant differences.

Conclusion: The anaesthesia administered by both groups was sufficient for lower limb procedures with stable hemodynamics. Dexmedetomidine is preferable to fentanyl because it promotes the distribution of block and extends the duration of post-operative analgesia for day care surgery such ambulatory knee operations.

Keywords: Dexmedetomidine, Fentanyl, Low Dose, Bupivacaine, Opioids, Spinal Anesthesia.

Introduction

In comparison to general anaesthesia, spinal anaesthesia has been found to lessen the endocrine-metabolic response to surgery. It has also been found to reduce blood loss and thromboembolic consequences, especially in complicated lower limb orthopaedic procedures. Spinal anaesthesia gives a quicker onset, more reliable analgesia, and a deeper level of surgical anaesthesia than epidural blocking. In contrast to epidural anaesthesia, spinal anaesthesia carries a higher risk of hypotension.[1,2]

The most commonly used local anaesthetic for spinal anaesthesia is bupivacaine hydrochloride. But regular dosages of bupivacaine can cause a severe sympathetic block, a protracted and intense sensory and motor block, and other undesirable effects for some people. So low-dose diluted bupivacaine has been used to restrict the spinal block's spread and speed up recovery. This strategy might not always offer a sufficient amount of sensory block, though.[3]

Different medications can be used as adjuvants for intrathecal injection to improve the quality of blocking, extend analgesia, and lower the necessary dose of local anaesthetics.[4] Due to its early onset of sensory and motor block and few side effects, fentanyl, a synthetic lipophilic opioid and pure mu receptor agonist, is routinely used with bupivacaine in spinal anaesthesia.

Dexmedetomidine, an alpha 2 receptor agonist, is thought to be a better adjuvant for local anaesthetics in neuraxial blocks because of its extremely selective alpha 2 action. Combining intrathecal injection of 2 receptor agonists with low-doses of local anaesthetics has been demonstrated to improve analgesia.[5]

The purpose of the study is to ascertain which combination of low-dose bupivacaine and fentanyl and low-dose bupivacaine and dexmedetomidine produces a superior grade of anaesthesia.

Methodology

Study Area: The study was conducted in the Trauma centre, Plastic Surgery OT and in Department of Anesthesiology and Critical Care at S.M.S. Medical College, Jaipur. Due permission from institution ethics committee was obtained.

Study Design: Hospital based Prospective Randomized double blind study.

Study Period: After approval of the plan from research review board, till the desired number of cases are complete.

Sampling Technique: Simple random method using a sealed, opaque envelope.

Sample Size: A sample of 30 cases in each group was adequate at 95% confidence and 80% power to verify the expected difference of 1.04±0.3098 in mean time to reach peak sensory block level in both groups receiving bupivacaine+ fentanyl and bupivacaine + dexmedetomidine intrathecally in lower limb surgeries.

Study Universe: Cases undergoing lower limb surgery.

Study Groups

Study Groups: The study was conducted on the following two patient groups. Each group had 30 patients (n =30/group). (N=30) Group 1 (Fentanyl Citrate Group): Intrathecally, patients received bupivacaine 0.5% (0.8 ml) + fentanyl 0.5 ml (25 mcg) + normal saline 0.3 ml for a total bupivacaine concentration of 0.25% (1.6 ml). Group 2 (Dexmedetomidine Group) (N=30): A 100 mcg ampule of dexmedetomidine was diluted in normal saline to achieve a dosage of 5 mcg in 0.5 ml. The patients were then given 0.5%

bupivacaine (0.8 ml) + dexmedetomidine 0.5 ml (5 mcg) + normal saline 0.3 ml for a total of 1.6 ml of 0.25% bupivacaine).

Eligibility Criteria

Inclusion Criteria:

- A patient who gave written and informed consent in vernacular language.
- Patients of either sex of age between 18 to 60 years
- ASA grade I & II
- Body weight 40 to 70 kg
- Patients undergoing lower limb surgeries.

Exclusion Criteria:

- Patients not willing to participate in the study.
- Cases with sepsis, bacteremia, or skin infection of local site
- History of spine surgery, spine deformities, severe hypovolemia, anemia, and compromised renal, cardiac, or respiratory status.
- Cases with raised intracranial tension and indeterminate neurological disease
- History of blood coagulopathies
- Patients allergic to drugs used for the study.
- Uncooperative patients
- ASA grade III / IV
- Failure of spinal anesthesia, cases in which general anesthesia was required.

Results

Table 1: Time to reach peak sensory block level

	N	Time [Minutes], Mean ± SD	P value
Group 1	30	5.733 ± 0.86	0.02
Group 2	30	4.560.56	

Table 2: The highest level of sensory block

Highest level of sensory block	Group 1, N[%]	Group 2, N[%]	P value
T10	7 [23]	0	0.00
T6	0	21 [70]	
T 8	23 [77]	9 [30]	
Total	30	30	

Table 3: Time to reach the T10 block level

	N	Time [Minutes], Mean ± SD	P value
Group 1	30	4.43 ± 0.93	0.01
Group 2	30	3.6 ± 0.49	

Table 4: Time to achieve the highest level of motor

	N	Time [Minutes], Mean ± SD	P value
Group 1	30	21.3 ± 3.2	0.00
Group 2	30	18.2 ± 1.6	

Table 5: The highest degree of motor blockade achieved

	The highest degree of motor blockade, N [%]		
	Motor block grade 3	Motor block grade 4	Motor block grade 5
Group 1	0	20 [66.7]	10 [33.3]
Group 2	23 [76.7]	7 [23.3]	0
Total	23	27	10
P value	0.00		

Table 6: Time at first rescue analgesia

Time at first rescue analgesia [Minutes]	Group 1, N [%]	Group 2, N [%]	P Value
150	0	14 [47]	
120	13 [43]	13 [43]	0.00
90	12 [40]	3 [10]	
60	5 [17]	0	
Total	30	30	

Discussion

Demographic data:

Patients' age, gender, ASA grade, height, and weight are comparable but not significantly different from one another.

Our study is analogous to those of Suresh G *et al*[7], Taher-Baneh N *et al*[6], and Nayagam H A *et al*.

Time to reach peak sensory block and the highest level of sensory block:

In our study, the mean time to achieve the sensory block level differed in a statistically significant way. Patients in group 1 took 5.7 minutes, while those in group 2 only needed 4.5 minutes.

In our study, T 8 was the greatest level of sensory block attained by 77% of patients in group 1 (low dose bupivacaine with fentanyl), while T 6 was reached by only 70% of patients in group 2 (low dose bupivacaine with dexmedetomidine). P value is zero. Similar findings were made by Priya R. K. *et al*.[8], who found that the median times for patients receiving intrathecal dexmedetomidine and injectable fentanyl as adjuvants to reach peak sensory blockage were 2.23 and 4.12 minutes, respectively. In the dexmedetomidine group, the mean time to reach maximal sensory blockage was considerably shorter (P value 0.05).

The study by Nayagam H A *et al*.[9] revealed contradictory results. When compared to Group Fentanyl, Group Dexmedetomidine took longer to reach maximal sensory block (12.92 3.131 vs. 11.88 2.156: P 0.05), but there was no difference in the amount of time it took to reach T10 (Group F = 5.12 0.82; Group D = 4.96 0.92: P > 0.05). In the study by Suresh G *et al*. [7], group D took 6.37+1.06 min and group F took 6.52+1.90 min to reach the greatest sensory level, which was comparable but not statistically significant (p > 0.05).

According to this study, adding dexmedetomidine to low-dose bupivacaine enhanced the degree of sensory block and post-operative analgesic efficacy without causing noticeably negative side effects, but with a sizable motor blockade. In addition to reducing the spread of the block, the use of low-dose diluted anaesthetic helps speed up recovery from spinal anaesthesia. It might not, however, offer a sufficient amount of sensory block. Both the addition of dexmedetomidine (5 mcg) in conjunction with low-dose bupivacaine (4 mg) and the addition of fentanyl (25 mcg) to low-dose bupivacaine (4 mg) have been shown to improve the perioperative quality of spinal blocks with less cardiovascular side effects.[10]

The maximum level of sensory block in group 1 was T8, while in group 2 it was T6 in 70% of patients. The highest level of sensory block, T8, was present in nine patients in group 2. P value is zero. Peak Sensory Block Level was found by Nayagam H. A. *et al*.9 to be T4-T10 in Group D and T6-T10 in Group F, which was very significant (P = 0.000). It was statistically significant (P 0.05) for the

mean time to attain the peak sensory block level (Group F/Group D=11.88/12.92min).

According to the study by Suresh G *et al*.[9], group D and group F both obtained the maximum sensory levels in the sensory block at T6 (T4 to T8) and T8 (T6 to T10), respectively (p 0.005). When compared to fentanyl, Fyneface-Ogan *et al*.[11] who administered dexmedetomidine 2.5ug intrathecally found no significant difference in the amount of time needed to reach the greatest level of sensory block or the amount of time needed for regression to S1. Similar outcomes were discovered in the Mahdy *et al*.[12] investigation. The variable doses (volume and concentration) of bupivacaine, fentanyl, and dexmedetomidine that were employed could be the cause of the discrepancies in the outcomes.

Time to reach T10 level block, the highest level of motor block achieved, and time to achieve it:

In our findings, the mean time to reach the T10 block level differs in a statistically significant way. Patients in group 1 took 4.4 minutes, while those in group 2 only needed 3.6 minutes. The time to reach the T10 section (Group F/Group D = 5.12/4.96 min) was not statistically significant (P > 0.05), according to Nayagam H A *et al*. Compound density is thought to play a key role in regulating the degree of neuronal block.15 Fentanyl and dexmedetomidine have different densities, while sodium chloride has a density that is higher (0.9%). In our research, intrathecal dexmedetomidine prolongs the sensory block when paired with spinal bupivacaine by inhibiting the release of c fibre transmitters and by hyperpolarizing post-synaptic dorsal horn neurons..[14,13]

In the study by Fyneface Ogan *et al*.[11], the dexmedetomidine group had a noticeably shorter time to attain T10 levels.According to Priya R. K. *et al*.'s study[8], patients receiving intrathecal dexmedetomidine and injectable fentanyl as an adjuvant had motor blockage (modified Bromage scale) on average in 3.22 and 4.51 minutes, respectively. The dexmedetomidine group had a considerably shorter mean time to reach motor blockage (modified Bromage scale 3, p 0.05).

The mean time to reach the greatest level of motor block differed in a statistically significant way. Groups 1 and 2 each completed it in 21.3 and 18.2 minutes, respectively. It's possible that the propensity of agonists of the 2 receptor to bind with motor neurons in the dorsal horn of the spinal cord accounts for the greater motor inhibition observed in Group Dexmedetomidine (P = 0.00).[14]

In the study by Suresh G *et al*. [7] the degree of motor block obtained in terms of the time needed for Bromage 3 in groups D and F was 5.711.369min and 5.411.69min, respectively. These results were not statistically significant.

In our investigation, the degree of motor blockage obtained was compared between the two groups. On motor blockage, neither group exhibits much of an effect. Level 4 was the maximum block for Group 1 while Grade 3 was the maximum block for Group 2. With a p-value of 0.00, the difference was significant. The degree of motor block measured by the MBS [Modified Bromage Scale] in both groups in the study by Nayagam H A *et al*.[9] ranged from Grade 2 to Grade 4. However, there were more patients in Group D (16 vs. 5) who attained Grade 2 block than in Group F, with a statistically significant difference of 0.035.

Vital parameters:

A statistically negligible variation in the vitals was found in our investigation. Overall, there was no discernible difference between the two groups in terms of hemodynamics,

which is consistent with research by Ben-David *et al*.[15] and Atallah *et al*.[16]

VAS score and time to first rescue analgesia:

At 60 minutes, 90 minutes, 120 minutes, and 150 minutes, there was a statistically significant difference in the score on the visual analogue scale. The difference between group 1 [Fentanyl] and group 2 [Dexmedetomidine] had a higher mean score, and it was statistically significant. VAS was considerably lower in the BF and BD groups within 24 hours of surgery than in the BS group, according to Taher-Baneh N *et al*.[6] ($p = 0.016$).

In our trial, 5 of the 30 participants in Group 1 needed their first dosage of rescue analgesia within the first 60 minutes, 12 during the next 60 to 90 minutes, 13 within the first 120 minutes, and none within the following 150 minutes because the analgesia had already been administered.

In contrast to Group 2, none of the patients needed rescue analgesia in the first 60 minutes, only 3 out of 30 needed it in the next 60 to 90 minutes, 13 out of 30 needed it in the next 120 minutes, and 14 out of 30 needed it in the next 150 minutes.

According to Taher-Baneh N *et al*[6], there was no discernible difference between the three groups ($p = 0.092$) when meperidine was taken as a rescue medication for pain management over the course of 24 hours (23.27mg, 24.97mg, and 22.99mg in the BS, BD, and BF groups, respectively).

Time to rescue analgesia in the trial by Gupta *et al*.[17] was 251 minutes with dexmedetomidine and 168 minutes with fentanyl, and it was significant (p value 0.001). The time to rescue analgesia (measured in hours) was greater in Group D than in Group F (8.20 2.78 vs. 6.64 2.32; $P = 0.000$) in our investigation, which is consistent with Nayagama H A *et al*[9].

Post-operative adverse effects:

Shivering and pruritis were the two post-operative symptoms that affected the groups the most frequently. Between the groups, there was no statistically significant difference.

Conclusion

In conclusion, this study compared the quality of anesthesia between low doses of bupivacaine plus fentanyl and low doses of bupivacaine plus dexmedetomidine. Dexmedetomidine showed advantages over fentanyl, including shorter time to reach peak sensory and motor block levels, longer duration of sensory and motor blocks, and a lower need for rescue analgesia.

Dexmedetomidine helped the sensory block to spread and delayed post-operative analgesia for day surgery procedures such ambulatory knee operations on .The study however, have some drawbacks, including a limited sample size and the exclusion of individuals with serious comorbidities. To validate these results and investigate the advantages in more complicated procedures, additional research with bigger sample numbers and various patient populations are required.

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