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Original Research Article

Comparative Study of Intrathecal Fentanyl and Dexmedetomidine as Adjuvants to 0.5% Hyperbaric Bupivacaine for Lower Limb Orthopaedic Surgeries

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ABSTRACT

BACKGROUND
Spinal anaesthesia is the most common procedure for lower limb orthopaedic surgeries. Fentanyl, a synthetic opioid and dexmedetomidine, a selective α2 agonist have been used in this study as adjuvants to 0.5% hyperbaric bupivacaine for spinal anaesthesia in lower limb orthopaedic surgeries.

AIM
The main aim of the study is to compare the efficacy, analgesic effects, hemodynamic stability and side effects of intrathecal fentanyl and dexmedetomidine as adjuvants to 0.5% hyperbaric bupivacaine in lower limb orthopaedic surgeries.

MATERIALS AND METHODS
100 patients of ASA class 1 and 2 posted for lower limb orthopaedic surgeries were taken for this study. Patients were randomly allocated using sealed envelopes into 2 groups. Group F - 17.5mg of 0.5% hyperbaric bupivacaine with 25mcg fentanyl intrathecally and group D - 17.5mg of 0.5% hyperbaric bupivacaine with 10 mcg of dexmedetomidine intrathecally.

RESULTS
In patients who have received dexmedetomidine observed to have significantly longer analgesic effects than the other group who received fentanyl as adjuvant. Mean duration of sensory blockade for group D was 455.54 ± 43.09 mins when compared to Group F which was 283.32 ± 23.994 mins. Post operative shivering was more in Group F patients when compared to Group D patients.

CONCLUSION
Using dexmedetomidine as an adjuvant to hyperbaric bupivacaine for spinal anaesthesia in lower limb orthopaedic surgeries has longer duration of sensory and motor block and longer postoperative analgesia when compared to intrathecal fentanyl.

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KEY WORDS: Spinal Anesthesia, Fentanyl, Dexmeditomidine, Adjuvants, Bupivacaine.

INTRODUCTION

Spinal anaesthesia/sub arachnoid block is the most common mode of anaesthesia for lower limb orthopaedic surgeries, as it has effective motor and sensory blockade with rapid onset, cost effective, less chances of infections etc. But as it is given with local anaesthetic agent's duration of block wears off relatively faster. So, a number of adjuvants, such as clonidine, fentanyl, dexmedetomidine etc are added to local anaesthetics and have been studied to prolong the effect of spinal anaesthesia.[1,2]

Dexmedetomidine is widely used for anaesthesia and analgesic purposes. It has good sedative, anti-anxiety, analgesic and anaesthetic-sparing effects.[3]

Dexmedetomidine when added to local anaesthetics have been used to increase the duration of analgesia in subarachnoid, epidural and caudal blocks.[4,5]

Fentanyl is a synthetic opioid with central action, which is used widely for pain control. Intrathecal fentanyl is usually added to local anaesthetics as an adjuvant to increase duration of anaesthesia and analgesia. It improves the quality of spinal anaesthesia and reduces the opioid induced side-effects including pruritus, nausea and vomiting.[6]

Dexmedetomidine and fentanyl both have been used as an adjuvant to local anaesthetics in different surgeries to provide superior analgesia and to improve the duration of the spinal anaesthesia.[7-9]

Based on couple of previous studies we decided to inspect and explore wide uses and effects of dexmedetomidine along with fentanyl as adjuvants. So, we have conducted a comparative study between two groups who were posted for lower limb orthopaedic surgeries and evaluated them in terms of quality of block and post-operative span of effective analgesia.

MATERIALS AND METHODS

After obtaining permission from institutional ethical committee, the study was conducted on 100 ASA I and II patients undergoing elective lower limb orthopaedic surgeries under spinal anaesthesia.

Before including patients for the study, all patients were explained about procedure and a written informed consent were obtained.

Inclusion Criteria

- ASA I and II category
- Patients aged between 20 and 60 years
- Height between 150cms - 180cms
- Patients who are willing to participate in the study.

Exclusion Criteria

- Known allergy to bupivacaine or dexmedetomidine or fentanyl
- Pregnancy
- Lactation
- History of CVS Disorders
- Infection at puncture site
- Raised intracranial pressure
- Bleeding disorders

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Preoperative preparation

After preoperative assessment, vital parameters were recorded in the preoperative area. Intravenous line secured. The patients were randomly allocated into 2 groups of 50 each by using closed cover technique.

Group D: 17.5mg of 0.5% hyperbaric bupivacaine with 10mcg dexmedetomidine intrathecally

Group F: 17.5mg of 0.5% hyperbaric bupivacaine with 25mcg fentanyl intrathecally

On arrival of the patient in the operating room, ECG, Pulse oximetry and blood pressure base line values were recorded. Equipment's and drugs necessary for resuscitation and general anaesthesia administration were kept ready. Patients were preloaded with 10ml/kg of ringer lactate solution 15 mins prior to subarachnoid block.

Procedure of subarachnoid block

In sitting position, the skin over the lumbar region was prepared with antiseptic solution and draped with sterile towel. After palpation of L3-L4 space, subarachnoid block was performed with 25G Quincke needle using 0.5% hyperbaric bupivacaine + fentanyl/dexmedetomidine after aspirating CSF. Time of injection noted as 0 and all times were calculated from this point. The patients were made to lie supine immediately after the injection.

Parameters recorded

- Time of injection of subarachnoid block.
- Time of onset of sensory block till T8.
- Time to onset of motor block to modified bromage scale 3.
- Duration of sensory block.
- Duration of motor block.
- Heart rate, Systolic and diastolic blood pressure were recorded at 0 th, 5th, 10th, 15th, 20th, 30th, 45th, 60th, 90th, 120^{th} mins.

Outcomes measured in the study

Onset of sensory blockade

- Defined as the time from the injection of drug to lack of appreciation of cold sensation. Assessed by loss of sensation to pin prick using 26G sterile needle along the midclavicular line.
- The duration of sensory block was defined as the time from the injection of drug to regression of sensory blockade to S1.

Motor blockade

Assessed bilaterally using modified Bromage Scale

MODIFIED BROMAGE SCALE
0 Able to move hip, knee, ankle
1 Unable to move hip, but able to move knee and ankle
2 Unable to move hip and knee but able to move ankle
3 Unable to move hip, knee and ankle

- Onset of Bromage scale 1 was considered as onset of motor block.

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- Duration of motor block was taken from the time of intrathecal injection to return of Bromage score of 0.
- Duration of sensory blockade was taken from the time of intrathecal injection to the regression of sensory blockade to S1.

Observation and Statistical Analysis

- All 100 patients in two groups completed the study without any exclusion.
- The collected data were analyzed by chi square test and results obtained in the form of range, mean and standard deviation.
- The probability value 'p' of less than 0.05 considered statistically significant.
- Patient demographic data that includes hemodynamic variables, onset &duration of motor and sensory blockade and adverse effects between two groups were comparable.

RESULTS

Demographic Distribution of Patients

Features	Group D	Group F	P value
Age (mean /standard deviation)	42.33 ± 12.88	40.57 ± 13.22	0.875
Height (cms)	159 ± 7.36	157.89 ± 6.7	0.162
Weight (kgs)	64.4 ± 6.25	63.77 ± 6.58	0.617

Characteristics of Spinal Block

Variables	Group D	Group F	P value
Onset of sensory blockade (mins)	2.625 ± 0.563	2.795 ± 0.599	0.147
Time of onset to bromage 3(mins)	10.59 ± 1.003	10.38 ± 1.081	0.317
Duration of sensory block regression (mins)	455.54 ± 43.09	283.32 ± 23.994	0.000
Regression of motor blockade to bromage 0 (mins)	362.46 ± 7.382	283.32 ± 7.595	0.000

There was statistically no significant difference among 2 groups (p=0.147) in relation to onset of sensory blockade.

There was statistically no significant difference among 2 groups (p=0.317) in relation to mean time taken to achieve Bromage scale.

Duration of sensory blockade in group D was 455.54 ± 43.09 mins and in group F it was 283.32 ± 23.994 mins. So it was statistically significant.

Duration of regression to Bromage 0 in group D was 362.46 ± 7.382 mins and in group F it was 283.32 ± 7.595 mins. So it was statistically significant.

Haemodynamic Parameters

Heart rate	Group D (mean ± SD)	Group F (mean ± SD)	P value
Basal	84.36 ± 13.715	82.68 ± 12.428	0.522
5 mins	83.36 ± 13.947	82.5 ± 12.704	0.487
10 mins	83.32 ± 14.329	73.4 ± 12.047	0.194
15 mins	83.02 ± 14.039	73.4 ± 11.596	0.120
20 mins	80.34 ± 12.514	73.4 ± 10.045	0.353

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30 mins	77.76 ± 10.310	73.4 ± 9.318	0.830
45 mins	76.26 ± 11.385	73.4 ± 8.142	0.936
60 mins	75.48 ± 11.202	73.4 ± 7.704	0.992
90 mins	74.98 ± 8.644	73.4 ± 7.572	0.624
120 mins	74.9 ± 7.490	73.4 ± 7.570	0.355

Table 1: Comparison of Heart Rate in Both Groups

In this study, the heart rate was recorded at frequent intervals as shown above in the table. There was not statistically significant difference in heart rate (P> 0.05).

SBP	Group D (mean ± SD)	Group F (mean ± SD)	P value
Pre op	124.94 ± 10.181	129.22 ± 11.689	0.054
5 mins	92.74 ± 5.386	96.88 ± 7.292	0.002
10 mins	114.24 ± 11.256	118.34 ± 12.555	0.074
15 mins	112.76 ± 10.843	115.24 ± 9.774	0.233
20 mins	110.92 ± 10.868	112.42 ± 9.047	0.455
30 mins	110.5 ± 10.504	110.22 ± 9.873	0.891
45 mins	109.38 ± 10.780	109.46 ± 9.702	0.969
60 mins	108.34 ± 10.575	107.66 ± 9.492	0.736
90 mins	107.82 ± 9.209	108.98 ± 9.747	0.542
120 mins	108.6 ± 8.885	111.24 ± 9.572	0.156

Table 2: Comparison of Systolic Blood Pressure in Both Groups

In this study, systolic blood pressure was monitored from preoperative period till 120th minute of the surgery at frequent intervals as shown at the above table. 2 intervals (preoperative and 5th min) were found to be statistically significant.

DBP	Group D (mean ± SD)	Group D (mean ± SD)	P value
Preop	78.34 ± 8.161	81.92 ± 9.180	0.042
5 mins	73.54 ± 9.355	77.38 ± 9.680	0.046
10 mins	70.5 ± 9.347	72.46 ± 8.570	0.277
15 mins	69 ± 9.337	69.04 ± 8.652	0.982
20 mins	67.74 ± 10.311	65.76 ± 7.875	0.283
30 mins	66.68 ± 10.314	62.3 ± 8.399	0.022
45 mins	65.12 ± 9.967	60.92 ± 9.236	0.031
60 mins	64.8 ± 9.664	60.92 ± 9.236	0.043
90 mins	65.16 ± 8.906	62.98 ± 8.791	0.221
120 mins	65.62 ± 8.308	65.76 ± 7.537	0.933

Table 3: Comparison of Diastolic Blood Pressure in Both Groups

In this study, diastolic blood pressure was monitored from preoperative to 120th minute of the surgery (10 intervals). 4 intervals (5min, 30min, 45min, 60 min) were found to be statistically significant.

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Complications	Group D	Group F
Bradycardia	4	2
Hypotension	4	4
Bradycardia + hypotension	1	0
Nausea and vomiting	1	2
Postoperative shivering	2	11

Table 4: Side Effects

DISCUSSION

In this study, we evaluated the efficacy of 2 adjuvants mixed with 0.5% bupivacaine heavy for lower limb orthopaedic surgeries. In this study, patient demographic factors like age, height and weight were standardized and there was no significant difference found within the groups.

Similar results were seen in study done by Sharma et al,[10] which showed no statistically significant differences in the demographic variables.

Onset of Sensory Block

Defined as the time from the injection of drug to lack of appreciation of pin prick sensation.

- In our study, the addition of 10mcg of Dexmedetomidine to 0.5% hyperbaric bupivacaine did not shorten the onset of sensory block when compared to addition of 25mcg offentanyl to hyperbaric bupivacaine. It is similar in both the groups.
- The mean time to onset of sensory block (in min) in group BD is 2.625 +/- 0.563 and in group BF is 2.7950 +/- 0.59909 min. there was statistically no significant difference among 2 groups.
- This result is similar to the study conducted by Sharma et al [10], where the onset of sensory blockade is similar in both the groups and found no statistically significance in both the groups.
- Similar study conducted by Gupta et al[11], found that there is no statistically significant between the two groups as regards to the onset of sensory blockade.

Onset of Motor Blockade

- The mean onset of motor blockade (in mins) in dexmedetomidine group is 10.590+/1.0035 and group fentanyl is 10.380+/1.0812 there was statistically no significant difference among 2 groups.
- Similar study conducted by Gupta et al,[11] where the onset of motor blockade indexmedetomidine group is 11.6+/1.8 min and in fentanyl group is 11.2+/-1.3 and there was no statistically significance among 2 groups.

Duration of Sensory Blockade (Regression of S1)

- Duration of sensory blockade was taken from the time of intrathecal injection to the regression of sensory level S1. In our study, mean duration of sensory blockade in group BD is 455.54 +/- 43.090 min and group BF is 283.22 +/- 23.994 min and there is statistically significance among 2 groups.
- According to Poupak Rahimzadeh et al,[12] he observed that mean duration of sensory blockade in dexmedetomidine group is 560.53 +/- 81.86 and in group fentanyl is 329.83 +/ 44.10 min.

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Duration of Motor Blockade (Regression to Bromage 0)

- In our study, mean duration of motor blockade in dexmedetomidine group is 362.46 +/-7.382 and in fentanyl group is 283.32 +/- 7.48.
- According to Gupta et al,[11] they observed that mean duration of motor blockade in dexmedetomidine group is 421+/-21min and in fentanyl group is 149.3+/-18.2min and it was significantly longer in dexmedetomidine group.
- Poupak Rahimzadeh et al,[12] found a significant difference between 2 groups with respect to duration of motor block.

Haemodynamic Parameters

Heart Rate

- In this study, Heart rate was recorded in 10 intervals, including basal heart rate.
- Difference in heart rate was not statistically significant at all the above intervals.

Systolic Blood Pressure

- In this study, systolic blood pressure was monitored from preoperative to 120th minute of procedure (10 intervals).
- 2 intervals (preop and 5th min) are statistically significant.

Diastolic Blood Pressure

- In this study, diastolic blood pressure was monitored from preoperative to 120th minute of procedure (10 intervals).
- 4 intervals (5min, 30min, 45min, 60min) are statistically significant.
- Khan et al[13] found that heart rate to be lower in the dexmedetomidine group than fentanyl group except at 35min, 40min, 120min after intrathecal injection. SBP lower in dexmedetomidine group than fentanyl group except at baseline and 5min after intrathecal injection.
- DBP was lower in dexmedetomidine group than fentanyl group except baseline and 5min after intrathecal injection.

Adverse Effects

- In our study, the incidence of bradycardia is 4% in the fentanyl group and 8% in the dexmedetomidine group. They were managed successfully with use of atropine 0.6mg IV.
- The incidence of hypotension is 8% in dexmedetomidine group and 8% in the fentanyl group. They were managed with iv. Mephentermine 6mg incremental doses and intravenous fluids.
- The incidence of nausea and vomiting is 2% in dexmedetomidine group and 4% in fentanyl group.
- The incidence of postoperative shivering is 2% in dexmedetomidine group and 22% in the fentanyl group.
- No incidence of pruritis seen in this study. This correlated with following studies.
- Rajini Gupta et al[11] found that hypotension was more in the dexmedetomidine group than fentanyl group but it was not statistically significant.
- Khan et al[13] found that hypotension was more in the dexmedetomidine group than fentanyl group. But it was not statistically significant.

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SUMMARY AND CONCLUSION

The present study "Comparative Study of Intrathecal Fentanyl and Dexmedetomidine as Adjuvants to Hyperbaric Bupivacaine for Lower Limb Orthopaedic Surgeries": The above study was carried out to study and compare intrathecal fentanyl and dexmedetomidine as adjuvants in spinal anaesthesia. This study was conducted on 100 ASA I and II patients in the age group 18 to 60 years belonging to both sexes. After comparing various parameters, we concluded that:

1. The onset of sensory and motor blockade were not statistically significant between the 2 groups.
2. The duration of both sensory and motor blockade were prolonged in dexmedetomidine group compared to fentanyl group and it was statistically significant.
3. Among hemodynamic variables, heart rate changes were not significant in dexmedetomidine as compared to fentanyl.
4. The SBP and DBP were not significant in dexmedetomidine as compared to fentanyl.
5. Significant difference was found in adverse effects like postoperative shivering, were high in fentanyl group and was statistically significant.

Therefore, it is concluded that, the addition of dexmedetomidine intrathecally to hyperbaric bupivacaine significantly prolonged the duration of sensory and motor block in comparison to fentanyl.

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