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ORIGINAL RESEARCH

Comparison of duration of post operative analgesia after adding dexamethasone or ketamine as an adjuvant to hyperbaric bupivacaine in spinal anaesthesia for lower limb orthopedic surgery - A Prospective Randomized Single Blinded Control Study

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Abstract

Background: Spinal anaesthesiais being used most commonly worldwide for surgeries on lower part of the body since years. Different local anaesthetic agents with different adjuvants have been studied and are in use for spinal anaesthesia. Bupivacaine 0.5% heavy(hyperbaric) has been studied along with adjuvant drugs like opioids, vasoconstrictors, alpha 2 agonists, sedatives, steroids, neostigmine, magnesium sulphate and ketamine to enhance its duration of effect. Various studies have been carried out in which hyperbaric bupivacaine either alone or with different adjuvants had been used for spinal anaesthesia.

AIM: To study and compare the duration of analgesic effect of adjuvants with hyperbaric Bupivacaine in spinal anaesthesia and to delay rescue analgesic dose requirement and to study the duration of neurological recovery after surgery during postoperative period. After study of different literatures, we decided to compare effect of Dexamethasone and Ketamine as an adjuvant with Bupivacaine heavy0.5% in spinal anaesthesia.

Methods: We conducted study on total 64 patients and they were divided in two groups - Group A 32 patients and Group B 32 patients. Spinal anaesthesia was given with either bupivacaine0.5% heavy+ 4mg Dexamethasone in Group A patients or bupivacaine0.5% heavy+Ketamine25mg in Group B patients using standard spinal anaesthesia technique. We noted duration of sensory and motor block and time of requirement of first rescue analgesic. **Result:** Duration of sensory and motor block was significantly longer in Group A patients than Group B patients($p<0.05$). Time of rescue analgesic requirement was also significantly delayed in Group A than Group B.($p<0.05$). **Conclusion:** Addition Of Dexamethasone with hyperbaric Bupivacaine0.5% causes prolonged sensory and motor block and pain free period in comparison with addition of Ketamine with hyperbaric Bupivacaine0.5% in spinal anaesthesia.

Key words: Spinal anaesthesia, Bupivacaine, Dexamethasone, Ketamine, Pain, Rescue analgesia

Introduction

Spinal anaesthesia(1) is most commonly used mode of anaesthesia for surgery on the lower part of the body. It is easy to perform for any trained anaesthesiologist. Various local anaesthetics drugs are commonly used in spinal anaesthesia like Lignocaine5%, Bupivacaine

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0.5% , Ropivacaine 0.5% and 0.75%, Levobupivacaine 0.5% etc., with or without various adjuvants[2]. Bupivacaine 0.5% heavy has been studied combined with drugs like opioids, vasoconstrictors, alpha 2 agonists, sedatives, steroids, neostigmine, magnesium sulphate and ketamine to enhance its duration effect [2].Various types of studies have been carried out in which comparison of hyperbaric Bupivacaine either alone or with different adjuvants are used for spinal anaesthesia.

In our review of literature, we found numbers of studies available comparing- 1.Bupivacaine heavy alone with Bupivacaineheavy+Dexamethasone[3,4,8] and 2.Bupivacaine heavy alone with Bupivacaineheavy+Ketamine used intrathecally[5,6,7,8].

After study of available literature, we found that in the study of Manal et al[6], The result of study was adding ketamine to Bupivacaine heavy reduces the duration of spinal anaesthesia, while in another literature the result of study was that ketamine enhanced pain free period after Spinal anaesthesia [7]. So we decided to do further study using Ketamine as an adjuvant with Bupivacaine heavy and compare it with other adjuvant. After review of literatures available to us, we decided to compare duration of effect of Dexamethasone and Ketamine as an adjuvant adding to Bupivacaine heavy 0.5% in spinal anaesthesia.

In our study we compared postoperative duration of analgesic effect of Ketamine v/s Dexamethasone added to bupivacaine heavy 0.5%, as an adjuvant in spinal anaesthesia. There are literatures of study available for each drug added to hyperbaric bupivacaine0.5% as an adjuvant in spinal anaesthesia to compare with hyperbaric Bupivacaine0.5% alone[3,4,5,6] .

Dexamethasone and Ketamine are commonly used drugs in operation theatre. Both drugs are easily available almost everywhere and are not expensive. Our aim is to evaluate easily available and affordable option to do comparative study of both the above mentioned drugs as an adjuvant to Bupivacaine heavy in spinal anaesthesia to prolong analgesic effect.

Bupivacaineheavy(Hyperbaric): Very commonly used long acting local anaesthetic agent in spinal anaesthesia.

Dexamethasone: It is a synthetic glucocorticoid which has anti-inflammatory effect and analgesic effect. Dexamethasone added with local anaesthetic drug in spinal anaesthesia alters prostaglandin production intrathecally. There are numbers of previous studies of adding dexamethasone to local anaesthetic agents in regional anaesthesia showing that it increases the duration of action of local anaesthetics and decrease requirement of post operative analgesics with various mechanisms of action locally as well as systemically[3,4,5,6].

Ketamine: It is phencyclidine derivative which produces dissociative anaesthesia. Despite this effect, ketamine is proven to be a desirable drug because of having short half-life and lack of clinically significant respiratory depression. Ketamine is also known for its analgesic, anti-inflammatory and antidepressant effect. Many studies have been done mentioning the use of ketamine intrathecally[5,6,7]. Ketamine is an anaesthetic agent with potent analgesic properties. Its mode of action includes non-competitive antagonism at N-methyl d-aspartate (NMDA) receptors and a local anaesthetic effect. We used inj. Ketamine preservative free intrathecally for our study in all patients.

This study is designed to assess and compare the postoperative analgesic efficacy of **Dexamethasone with bupivacaine 0.5% heavy (group A)**&**Ketamine with bupivacaine0.5% heavy (group B)** in spinal anaesthesia during and after lower limb orthopedic surgery at and bellow knee..

Methodology

Before starting study, we have achieved approval from institutional ethics committee and get registered our study to CTRI(clinical trial registry of India) reg. no. CTRI/2022/05/053980. The study was carried out at our institute DR. N. D. Desai Faculty of medical Science and Research, Dharmsinh Desai University, Nadiad, Gujarat.

The study was prospective randomized control single blind interventional study in which patient and observer didn't know about which adjuvant is added to hyperbaric bupivacaine in spinal anaesthesia. The study was conducted on total 64 patients of ASA risk I and II undergoing lower limb orthopedic surgery at and bellow knee. Sample size was calculated with Open Epi software after entering values from result of previous individual studies of Bupivacaine with Dexamethasone[3], and Bupivacaine with Ketamine[7] in spinal anaesthesia. Patients' randomization was done in Group A and Group B with rando software. 64 patients were divided in to two group of 32 each, **Group-A** and **Group-B**. 32 patients in Group A received Bupivacaine 0.5% heavy + Dexamethasone 4mg(1ml) in spinal anaesthesia and and 32 patients in Group B received Bupivacaine 0.5% heavy +Ketamine 25mg(0.5ml) preservative free+ NS 0.5 ml. in spinal anaesthesia. Total volume of intrathecal injection was 4ml in all 64 patients. Dose and volume of hyperbaric Bupivacaine 0.5% kept equal in both group for spinal anaesthesia which was 15mg(3ml)in both group of patients.

Inclusion criteria

- Age 18-60 years
- Surgery site- at and bellow Knee
- ASA risk 1 and 2 patients

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- Scheduled for planned Surgery
- Patients who could understand the nature of study and rate their pain on VAS scale (0-10) and able to provide written consent

Exclusion Criteria

- Patient's refusal
- Emergency surgery
- Pediatric patient
- History of Anaphylaxis and Allergy to any drug
- History of Bleeding Disorders
- History of Drug abuse
- Spine deformity
- Neurological and cardiac disease
- Infection at site of Spinal Anesthesia
- Inability to provide informed consent

After explanation to patients about nature of study, its advantages and disadvantages and consequences and probable complications, patients were selected for study and special consent for recruitment for study was taken along with anaesthesia consent.

64 patients recruited and divided in two groups, Group-A and Group-B as described previously. Randomisation was done with software and patients were allocated in Group A -32 patients and Group B -32 patients.

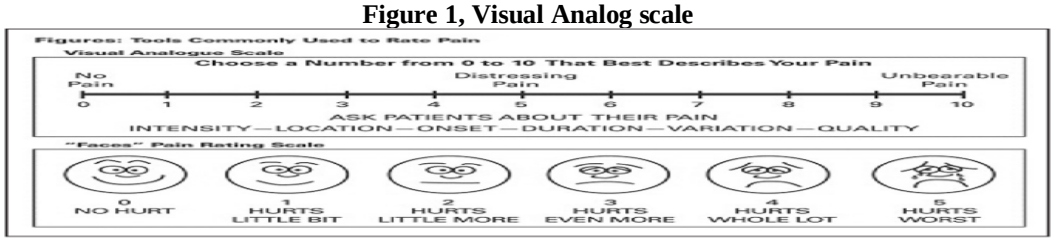
Group A received Bupivacaine 0.5% heavy 3 ml + Dexamethasone 4mg(1ml) and Group B received Bupivacaine 0.5% heavy 3ml +Ketamine 25mg(0.5ml) preservative free + NS 0.5 ml. Total volume of drug in either group was 4 ml in spinal and total dose of Bupivacaine was same in both groups as described earlier.

In our study we observed and noted many different parameters in both group of patients after spinal anaesthesia were - time of onset of sensory block, time of onset of motor block, time of achievement of complete sensory and motor block, duration of post operative analgesia, time of requirement of rescue analgesia and time of recovery of motor block.

Time of onset of sensory block was noted as initiation of decrease in touch sensation at T_{10} level. Time of onset of motor block was noted when patient was unable to rise leg without bending at knee.Time of complete sensory block noted when patient had no sensation at T_{10} level and time of complete motor block noted when patient was unable to move leg and foot.

We noted post operative duration of analgesia and onset of pain on operative site using Visual analog scale(VAS), and for motor recovery we used Modified Bromage score[9]. We also monitored and noted pulse, BP, SPO2, ECG during surgery and in post operative period.

Figure 1, Visual Analog scale



Modified Bromage Score (breen et al):

Scale 1 to 6

Grade 1- Complete block(unable to move feet and knees)

Grade 2- Almost complete block(able to move feet only)

Grade 3-Partial block(just able to move knees)

Grade 4-Detectable weakness of hip flexion(between score 3 and 5)

Grade 5-No detectable weakness of hip flexion while supine(full flexion of Knees)

Grade 6-Full flexion of hip

Result:

Our study carried out on total 64 patients of ASA Gr 1 and 2, out of which Group A-32 patients received inj. Bupivacaine heavy + Dexamethasone and Group B -32 patients received Inj. Bupivacaine heavy + Ketamine in spinal anaesthesia.

We noted the time of onset of sensory block, Onset of motor block, time of achieving complete effect of sensory and motor block after giving spinal block.(Table 2)

As shown in table 2, Time of onset of sensory block in both groups between 1 min to 4 min and time of onset of motor block in both group was between 3 min to 5 min. Onset of both sensory and motor block was rapid in group B(Mean time-sensory onset- 1.469 Sec, Mean time- motor onset 2.75 sec) than in group A(Mean time -sensory onset- 2.5625 sec, Mean time- motor onset 4.07sec).

Duration of complete sensory and motor block achievement was 4 min to 8 min in both group but in Group A Mean time was 7.16sec. and Group B Mean time was 5.53 sec.

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We also noted time of recovery of motor block according to Modified Bromage score[9] and Time of onset of pain on VAS.(Table 3)

Approximate time of completion of all surgeries in our study after spinal block given in both the groups was 1 to 3 hours. We started counting post operative period from 3 hours after spinal anaesthesia given because all surgeries were completed within 1 to 3 hrs after spinal anaesthesia. So we noted time of Modified Bromage score and time of VAS at time started from 1 hour post operative and up to maximum 4 hours post operative because all patient recovered from motor block completely and had experienced pain within this time duration(Total time after spinal anaesthesia given was 3+4=7 hrs).

In both groups patients were hemodynamically stable during and after surgery.

Table 1: Comparison of baseline vitals

Parameter	**Group A (n= 32) (Mean ± SD)**	**Group B (n= 32) (Mean ± SD)**
Pulse (beats/min)	82.76 ± 12.91	78.73 ± 14.72*
Systolic Blood pressure (mm of Hg)	139.35 ± 14.95	134.5 ± 15.23*
Diastolic blood pressure (mm of Hg)	86.02 ± 7.64	84.11 ± 8.13*
Spo_2(%)	98.73 ± 1.18	99.14 ± 0.78*

*p>0.05 (not significant)

Table-2: Comparison of onset of anesthesia

Anesthesia onset time (in minutes)	**Group A (n= 32) (Mean ± SD)**	**Group B (n= 32) (Mean ± SD)**
Sensory	2.70 ± 0.57	1.47± 0.56*
Motor	4.05 ± 0.64	2.73 ± 0.56*
Complete	7.35 ± 0.73	5.47 ± 0.82*

*p<0.05 (Significant)

Table-3: Comparison of VAS & MBS during postoperative period

Score		**Group A (Mean ± SD)**	**Group B (Mean ± SD)**
Post op 1 hr	MBS	1.5 ± 0.56	2.35± 1.09*
	VAS	0 ± 0	0.41± 0.095
Post op 2 hrs	MBS	3.20 ± 1.06	4.30± 1.18*
	VAS	0.17 ± 0.57	1.63± 1.45*
Post op 3 hrs	MBS	4.94± 1.07	5.55± 0.64*
	VAS	1.35 ± 1.27	3.18± 1.14*
Post op 4 hrs	MBS	5.70 ± 0.78	5.90 ± 0.30**
	VAS	2.58 ± 1.28	3.63 ± 0.80*

*p<0.05 (Significant), ** p>0.05 (Not significant)

Table: 4 mean time (in minutes postoperatively) after which rescue analgesia required

Group A (n= 32) (Mean ± SD)	**Group B (n= 32) (Mean ± SD)**
391.47 ± 44.73	305.35 ± 48.47*

P<0.05 (significant)

Discussion:

Manal et al[6] found in their study that addition of ketamine in hyperbaric bupivacaine(Group 2)causes shorter time of onset and duration of spinal block than with bupivacaine heavy alone (Group 1) given in spinal anaesthesia. They used Bupivacaine heavy 0.5% 3ml in Group1 and Bupivacaine heavy 0.5% 2 ml with 25 mg ketamine in Group2. The doses of Bupivacaine heavy 0.5% were different- 3ml in Group 1 and 2ml in Group 2 in their study. In the study of Marzeih and colleagues [7], they had given equal dose of bupivacaine heavy 0.5% 10 mg (2ml) in both group of patients and they observed that in group of patients who received ketamine along with bupivacaine heavy0.05% had

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prolonged time of pain free period as well as requirement of 1st post operative rescue analgesia than in group of patients who received bupivacaine heavy 0.05% alone.

In the study of Nadia Bani Hashem and colleagues[3] they added Inj. Dexamethasone in Bupivacaine heavy 0.5% and found significantly prolonged duration of sensory block and requirement of 1st rescue analgesic dose was delayed than bupivacaine heavy alone used in spinal block. Subrata Dutta[4] and others in their study also found prolonged sensory block after addition of dexamethasone with bupivacaine heavy in spinal anaesthesia.

According to result of our study (table 2), sensory block onset time after spinal anaesthesia given was 1.47±0.56 min in group B whereas sensory block onset time was 2.7±0.57 min in group A ($p<0.05$). Onset of motor block time after spinal anaesthesia given was 2.73±0.56 min in group B whereas in group A the time was 4.05±0.64 min ($p<0.05$). Time of complete block was achieved after spinal anaesthesia given in group B was 5.47±0.82 min and in group A it was 7.35±0.73 min ($p<0.05$). Thus complete spinal block was achieved significantly faster in group B than group A. Which shows that in our study, onset of sensory, motor and complete block were faster in group B than group A.

In both group duration of completion of surgery was 1 hour to less than 3 hours after spinal anaesthesia given. Because all surgery was completed in less than 3 hours, we have started to count post operative period after 3 hrs of spinal anaesthesia given to maintain uniformity to count time for recovery and time of 1st rescue analgesia in all patients. For reference, 1 hour after surgery was counted as 4 hours after spinal anaesthesia given. After surgery we noted time of recovery of sensory and motor block(according to Modified Bromeg scale-MBS) as well as we noted time of onset of pain according to Visual analog scale-VAS on 1 to 10 scale (Table 3). We have given recue analgesic when patient had VAS scale 4 or more (Table 4).

After one hour post surgery, MBS in group B was 2.35±1.09 and in group A was 1.5±0.56 ($p<0.05$), thus motor recovery was faster after 1 hour in group B where as VAS in group B was 0.41±0.095 and in group A was 0. Thus there was no pain after 1 hour post operatively at all in patients in both groups (not significant). Two hours after surgery MBS was 4.30±1.18 in group B and 3.20±1.06 in group A, thus partial motor recovery in both groups was present but more significant in Group B. VAS was 1.63±1.45 in group B whereas VAS 0.17±0.057 in group A thus in group B, few patients had mild pain whereas in group A patients had still no pain. After 3 hours post operative MBS was 5.55±0.64 in group B and 4.94±1.07 in group A which shows that there was little difference in motor recovery in both group 3 hours after surgery completed but motor recovery was still faster in group B than group A. VAS scale after 3 hours post surgery was 3.18±1.14 in group B and 1.35±1.27 in group A, suggesting that few numbers of patients were having pain in group B and required rescue analgesia during this period and not a single patient from group A required recue analgesia. Rescue analgesia required earliest in one patient 1 hour after surgery in Group B, whereas first rescue analgesia required in Group A was after three hours in post operative period was in three patients. All patients in group B received rescue analgesia within 4 hours postoperatively. In group A patients, all patients received analgesia 7-8 hours after spinal block given. Mean time for rescue analgesia given in group B was 305.35±48.47 and in group A was 391.47±44.73 ($p<0.05$), time of requirement of rescue analgesia was significantly earlier in Group B than group A.

Our study shows that in group B onset of sensory, motor and complete block was achieved faster than group A. Recovery of sensory, motor block and requirement of rescue analgesia was significantly earlier in group B patients than in group A patient. The total duration of sensory block, motor block and time of requirement of 1st dose of rescue analgesia was significantly delayed in group A (Dexamethasone) than group B(Ketamine).

Conclusion:

Adding Inj. Dexamethasone 4mg with Inj. Bupivacaine 0.5% heavy in spinal anaesthesia causes more prolonged sensory and motor block and longer pain free period after surgery than adding Inj. Ketamine 25mg with inj. Bupivacaine 0.5% heavy.

Sponsership:

There is no sponsorship

Conflict of interest:

There is no conflict of interest.

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