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Original Research Article

Study to compare the effect of Dexmedetomidine vs MgSo4 (50%) intrathecally as an adjuvant with bupivacaine (0.5%) for lower limb orthopedic surgery under subarachnoid block

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ABSTRACT

Background: Lower limb surgeries may be performed under local, regional (spinal or epidural) or general anesthesia, but neuraxial blockade is the preferred mode of anesthesia. Sub-arachnoid block or Spinal anaesthesia is the most common central block used in a surgical setting, which is being the most versatile and commonly used regional block. With increasing use of hyperbaric bupivacaine for sub arachnoid block, their limitations like prolongation of onset of sensory and motor blockage effect, short duration of action and early postoperative requirement of an analgesic agent, require an intrathecal adjuvant to these local anaesthetic agents for a complete satisfactory period of anaesthesia and patient satisfaction.
Aim: The aim of this study was to compare and evaluate the effect of Dexmedetomidine with MgSO4 (50%) intrathecally as an adjuvant for the characteristics of sensory and motor blockage for lower limb orthopedic surgery under subarachnoid block along with bupivacaine (0.5%).
Materials and Methods: Participants were randomly divided into two groups of 40 participants each. Group D (n=40) received Bupivacaine + dexmedetomidine, Group M (n=40) received Bupivacaine + MgSO4. Under strict aseptic and antiseptic precaution subarachnoid block was performed. Mixture of drugs according to group assign was injected. Assessment of sensory and motor characteristics was done.
Results: Inj. Dexmedetomidine as an adjuvant in spinal block, seems to be superior to intra-thecal MgSO4 as it has faster onset, longer duration of action, prolonged analgesia in comparison with Magnesium Sulphate without significant hemodynamic alterations.
Conclusion: Dexmedetomidine, as an adjuvant to Inj. Bupivacaine intra-thecally in sub-arachnoid block, has faster onset, longer duration of action, prolonged analgesia in comparison with Magnesium Sulphate.

1. Introduction

Lower limb surgeries may be performed under local, regional (spinal or epidural) or general anesthesia, but neuraxial blockade is the preferred mode of anesthesia. Sub-arachnoid block or Spinal anaesthesia is the most common central block used in a surgical setting, which is being the most versatile and commonly used regional block worldwide today, was introduced in 1885 by J. Leonard Corning.[1] The spinal technique is easy to perform and has a very high success rate. Spinal anaesthesia has been shown to blunt the stress response to surgery,[2] decrease intraoperative blood loss,[3] lower the incidence of postoperative thromboembolic events.[4] It can be used to extend analgesia into post-operative period, where its use has been shown to provide better analgesia than can be achieved with parenteral opioids. Orthopedic lower limb surgeries done under spinal anaesthesia have shown to reduce total blood loss by 30% to 50%.[5] Main

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advantage of regional anaesthesia is most evident in post operative phase. Residual block protects the patient from initial postoperative pain and requirement of opioids is reduced.[6] In lower limb orthopedic surgeries, post-operative pain management is a key area to be focused in a complete patient management plan for an anaesthetic. With increasing popularity of use of hyperbaric bupivacaine, ropivacaine intra-thecaly, for sub arachnoid block, their limitations like prolongation of onset of sensory and motor blockage effect, short duration of action and early postoperative requirement of an analgesic agent, require an intrathecal adjuvant to these local anaesthetic agents for a complete satisfactory period of anaesthesia and patient satisfaction. Various adjuvants like opioids (morphine, fentanyl and sufentanyl) and other drugs [such as dexmedetomidine (DXM), clonidine, magnesium sulfate (MgSO4), neostigmine, ketamine and midazolam] are tested as adjuvants to local anesthetics. Role of magnesium sulphate as an adjuvant to local anaesthetics in spinal anaesthesia is based upon potential anti nociceptive effect of magnesium through its voltage-dependent regulation of calcium influx into the cell, and non-competitive antagonism of N-methyl-D-aspartate (NMDA) receptors and has the potential to prevent central sensitization from peripheral nociceptive stimulation. Dexmedetomidine is intravenous sedative and co-analgesic drug. It potentiates the effect of local anaesthetics and allows a decreased dose without respiratory depression or hemodynamic instability and thus, it is used for prolonging duration of sensory, motor blockage and analgesic effect.[7] So this study was aimed to compare the effects of adding dexmedetomidine as an adjuvant to hyperbaric bupivacaine with magnesium sulfate to bupivacaine in subarachnoid block for lower limb orthopedic surgeries. The aim of this study was to compare and evaluate the effect of Dexmedetomidine with MgSO4 (50%) intrathecally as an adjuvant for the characteristics of sensory and motor blockage for lower limb orthopedic surgery under subarachnoid block along with bupivacaine (0.5%).

2. Material and Methods

After getting approval from Institutional Review Board (IRB No 822/2019) and informed written consent from patients, this prospective, randomized, double blind study was carried out in the Department of Anaesthesiology, Govt. Medical College and Sir. T. Hospital, Bhavnagar, Gujarat. Trial was registered under Clinical Trial Registry India (CTRI registration No. CTRI/2019/07/027371). 80 patients of American society of anaesthesiology grade I, II and III, scheduled to undergo lower limb orthopaedic surgery were included in this study as per below mentioned inclusion and exclusion criteria.

2.1. Inclusion criteria

1. Age: 18 to 60 years.
2. Gender: Either gender.
3. Patients posted for lower limb orthopaedic surgery under subarachnoid block.

2.2. Exclusion criteria

1. Patients with psychiatric disorder.
2. Patients with neurologic disorder and deficit, Spinal cord and peripheral nerve diseases, poliomyelitis, multiple sclerosis.
3. Patients with allergy to local anaesthetic drug or study drug.
4. Drug/alcohol abuse.
5. Un-cooperative patients
6. Pregnant lady and lactating mother.

A detailed pre-anaesthetic examination was done comprising of history, clinical examination (general physical examination, systemic examination and airway examination), routine baseline investigations (complete haemogram, random blood sugar, renal profile, serum electrolyte and Electrocardiogram (ECG)) were done.

Monitoring was done which included recording of baseline vital parameters –heart rate (HR), noninvasive blood pressure (NIBP), peripheral arterial oxygen saturation (SpO2). Each patient was informed in detail regarding nature, course and purpose of the study. Patients were explained 0-10-point visual analogue scale (VAS) on a sheet paper where, (0) labeled as no pain and (10) as worst possible pain. Patients were randomly allocated to one of the two groups of 40 patients each by distributing computer generated random number sequence in sealed envelopes. Forty envelopes of each group were made with group mentioned inside and were mixed up. Patient was asked to pick one envelope in pre-anaesthetic room. One member (not assigned for recording outcome measures) from the team except from principle Investigator (PI), asked to open the envelope and filled up the drug as per group assigned to patient. PI was responsible for performing the procedure (SAB) and recording primary and secondary outcome measures of the study.

Group D: received 15mg hyperbaric Bupivacaine 0.5% + 0.1 ml (10μg) dexmeditomedine

Group M: received 15mg hyperbaric Bupivacaine 0.5% + 0.1ml (50mg) MgSO4 (50%)

Under strict aseptic and antiseptic precaution subarachnoid block was performed in left lateral position. Mixture of drugs according to group assign was injected. Immediately after the block, patient was turned supine. The time of injection was noted as time “0”. Assessment of sensory and motor characteristics was done at every 30 seconds interval till peak of the blockade achieved. The sensory block was assessed by skin sensation to pin prick,

using the sterile 23G hypodermic needle. The motor block was assessed according to Modified bromage scale.

Table 1: Modified bromage scale for motor block evaluation

Grade 0	The patient is able to move the hip, knee and ankle
Grade I	The patient is unable to move the hip, but is able to move the knee and ankle.
Grade II	The patient is unable to move the hip and knee but is able to move the ankle.
Grade III	The patient is unable to move the hip, knee and ankle.

Time of onset of sensory block at L1, T10 and maximum level attained were noted. Pulse rate, respiratory rate, non-invasive blood pressure and oxygen saturation were recorded at 1, 3, 5, 10, 15, 20, 30, 60, 90, 120 minutes till the completion of surgery and then at 1 hour interval till 4 hours post-operatively. After 4 hours, monitoring of pt. at 4 hours interval till 24 hours. Any supplementation required for inadequate block or side effects like haemodynamic disturbances, nausea, vomiting were recorded.

2.3. Statistical analysis

Sample size calculation assuming alpha error being 0.05 and beta error being 0.20 with a power of study 80% showed that 38 patients were required per group to detect difference of at least 30% in the median duration of sensory block between the groups, hence we included 40 patients per group. Data will be presented as Mean ± Standard Deviation (SD) or numbers. Comparison between two groups will be done (using software Instat) Mann-Whitney test (for non-parametric data) or unpaired- t test (for parametric data).

Level of significance
P is level of significance
P > 0.05: Not significant
P < 0.05: Significant
P < 0.01: Highly significant
P < 0.001: Very highly significant.

3. Results

The mean age was 41.75 ± 12.034 years in group M (MgSO4) and 44.7 ±13.282 years in group D (dexmedetomidine) with P value of 0.301 which was statistically not significant. Participants of both genders were distributed equally in the two groups with random allocation in which, on comparison, P value was 0.382 which was statistically not significant. Similarly, mean weight in group M was 65.85±11.59 kg, which was similar to group D with mean weight of 65.55±10.44 kg, and they were comparable with P value of 0.086 which was statistically not significant.

The onset of sensory blockade was delayed in magnesium group when compared to dexmedetomidine group. Addition of magnesium significantly delayed the onset of motor block when compared to dexmedetomidine group with P value <0.0001 which is statistically highly significant.

It was observed that duration to achieve max motor block is more when MgSO4 is added as adjuvant in comparison with dexmedetomidine which has faster achievement of maximum motor block. It was observed that duration to achieve max sensory block is more when MgSO4 is added as adjuvant in comparison with dexmedetomidine which has faster achievement of maximum sensory block.

Sensory block lasted longer in the dexmedetomidine group. Motor block lasted longer in the dexmedetomidine group. This difference was statistically significant (p=<0.0001).

The mean duration of analgesia was 7.375 ±0.723 hours in group D (dexmedetomidine) and 5.47±0.463 hours in group M (magnesium). This difference was statistically significant (p <0.0001). Analgesia lasted longer in the dexmedetomidine group.

Incidence of side effects such as nausea, vomiting, hypotension and bradycardia was more in dexmedetomidine (in 45% pts) group compared to magnesium group (in 10% pts). Incidence of bradycardia was 27.5% in dexmedetomidine group and 2.5% in group M (magnesium). Out of 40 patients 5 patients in dexmedetomidine group had an episode of hypotension (12.5%) whereas, incidence was 7.5% in group M. Incidence of vomiting was 5% in group D (dexmedetomidine). But none of the patients in group M (magnesium) had vomit.

4. Discussion

Efficacy of spinal anaesthesia in our study, was assessed in terms of onset and intensity of block, as well as duration of sensory and motor blockade. We also compared duration of analgesia, and occurrence of side effects such as hypotension, bradycardia, nausea and vomiting. We used magnesium sulphate (50%) as an adjuvant and the dose was 50mg based on studies by Sarika Katiyar et al.[8] They compared magnesium sulphate at dose of 50mg and 100mg added to intrathecal bupivacaine. They concluded the 100mg of magnesium sulphate prolonged the duration of analgesia without any significant side effects. The time of onset of sensory blockade at L1 for group D(dexmeditomedine) is 2.51 ± 0.448 min and for group M(magnesium sulphate) is 3.215±0.372 min with p value of <0.0001 which was statistically significant. Thus, addition of magnesium sulphate to bupivacaine delayed the onset of sensory blockade when compared to dexmedetomidine group. Arora et al[9] also observed similar delay in onset of sensory block. They found that it could be because of difference in pH and baricity of solution containing magnesium sulphate. Khezri et al[10]

Table 2: Time to onset of sensory and motor block upto L1 level in minutes

Type of onset of block	Group- D(Dexmedetomidine)		Group-M(Magnesium)		p-value
	Mean	SD	Mean	SD	
Sensory	2.51	0.448	3.215	0.372	<0.0001
Motor	2.774	0.381	3.416	0.407	<0.0001

Table 3: Time to achieve maximum motor and sensory block (according to levels) in minutes

Type of onset of block	Group-D (min) (Dexmedetomidine)		Group-M(min)(magnesium)		p-value
	Mean	SD	Mean	SD	
Motor	7.073	0.69	8.502	0.70	<0.0001
Sensory	9.815	1.192	11.58	1.44	<0.0001

Table 4: Time to regression of sensory and motor block (in hours)

Type of onset of block	Group-D(Dexmedetomidine)		Group-M(Magnesium)		p-value
	Mean(Hrs)	SD	Mean	SD	
Sensory	3.57	0.37	2.925	0.253	<0.0001
Motor	3.905	0.356	3.335	0.426	<0.0001

Table 5: Duration of analgesia in hours

Group-D(Dexmedetomidine)		Group-M(Magnesium)		p- value
Mean(hrs)	SD	Mean	SD	
7.375	0.723	5.47	0.463	<0.0001

Table 6: Side effects

Side Effects	Group-D(Dexmedetomidine)		Group-M(Magnesium)	
	Number	%	Number	%
Nil	22	55	36	90
Bradycardia	11	27.5	01	2.5
Hypotension	5	12.5	3	7.5
Vomiting	2	5	00	00
Total	40	100	40	100

found that increase in metabolism of bupivacaine due to activation of cytochrome P450 by magnesium may be responsible for delayed onset of sensory block. Aamir Laique Khan, Raj Bahadur Singh observed in their study that adding intrathecal dexmeditomedine to bupivacaine in spinal anaesthesia which reduces the time for onset of sensory blockage and prolongs the duration of action similar to this study.[11] The time to achieve maximum sensory block for the level was comparable in both the groups where time for Group D was 9.815±1.192 min and for group M was 11.58±1.44 min with P value of <0.0001, which was highly statistically significant. So it was observed that duration to achieve max sensory block is more when MgSO4 is added as adjuvant in comparison with dexmedetomidine which has faster achievement of maximum sensory block. This result was similar with the study of Zameer Faruque and Neha Gupta[12] who studied MgSO4 and dexmedetomidine effects by adding them as an adjuvants intrathecally to bupivacaine. The mean time to onset of motor blockade with Bromage score 1(inability to flex the hip) showed dissimilarity in both groups. The mean time to onset of motor blockade in group D is 2.774±0.381 min and in group M is 3.416±0.407 min with P value <0.0001 which is statistically highly significant. Addition of dexmedetomidine fasters the onset of motor block compared to MgSO4 as an adjuvant. The mean time to regression of sensory block to L1 was 3.57 ±0.37 hours in group D (dexmeditomedine) and 2.925±0.253 hours in group M (magnesium). This difference was statistically significant (p=<0.0001). Sensory block lasted longer in the dexmeditomedine group. The mean duration of analgesia was 7.375 ±0.723 hours in group D (dexmeditomedine) and 5.47±0.463 hours in group M (magnesium). This difference was statistically significant (p <0.0001). Analgesia lasted longer in the dexmeditomedine group. It was similar to study by Aamir Laique Khan, Raj Bahadur Singh where dexmeditomedine at dose of 5 microgram increased the duration of analgesia and decreased postoperative analgesic requirement in comparison with fentanyl intrathecally in subarachnoid block with bupivacaine. Incidence of

side effects such as nausea, vomiting, hypotension and bradycardia was more in dexmeditomedine group (45%) compared to magnesium group (10%). Incidence of bradycardia was 27.5% in dexmeditomedine group and 2.5% in group M (magnesium). Out of 40 patients 5 patients in dexmeditomedine group had an episode of hypotension (12.5%) whereas, incidence was 7.5% in group M. Incidence of vomiting was 5% in group D (dexmedetomidine). But none of the patients in group M (magnesium) had vomiting.

5. Conclusion

Dexmedetomidine, as an adjuvant to Inj. Bupivacaine intrathecally in sub-arachnoid block, has faster onset, longer duration of action, prolonged analgesia in comparison with Magnesium Sulphate. Dexmedetomidine increases the total duration of analgesia and reduces the need for analgesic supplementation post-operatively in comparison with MgSO4. Both, dexmedetomidine and MgSO4 shows incidence of bradycardia and hypotension but was treated pharmacologically. Thus, inj. Dexmedetomidine as an adjuvant in spinal block, seems to be superior to intrathecal MgSO4 as it has faster onset, longer duration of action, prolonged analgesia in comparison with Magnesium Sulphate without significant hemodynamic alterations.

6. Source of Funding

None.

7. Conflict of Interest

None.

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