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RESEARCH ARTICLE

COMPARATIVE STUDY OF UNILATERAL SPINAL BLOCK WITH 0.5% HYPERBARIC BUPIVACAINE AND CLONIDINE VERSUS 0.5% HYPERBARIC BUPIVACAINE ALONE FOR ANAESTHESIA AND PERIOPERATIVE ANALGESIA IN PATIENTS UNDERGOING LOWER LIMB ORTHOPAEDIC SURGERIES

Dr. Naveen Kumar Jindal[1], Dr. Harinder Pal Singh[2] and Dr. Jaspreet Singh[3]

1. Consultant, Department of Anaesthesia and ICU, Amar Hospital, Patiala, Punjab.
2. HOD, Department of Anaesthesia AND ICU, Amar Hospital, Patiala, Punjab.
3. Consultant, Department of Anaesthesia and ICU, Amar Hospital, Patiala, Punjab.

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Abstract

Introduction: Selective unilateral spinal anaesthesia is a useful approach for ambulatory lower limb surgery because it allows less hospital stay compared to bilateral block. Study done to compare the efficacy and safety of hyperbaric bupivacaine 0.5% and clonidine versus hyperbaric bupivacaine 0.5% alone for lower limb orthopedic surgeries under unilateral spinal anaesthesia.

Methods: Hundred patients were randomly divided into 2 groups of 50 each. In group 1 Patients received 3ml of 0.5% hyperbaric bupivacaine with 0.5 ml (50 micrograms) clonidine intrathecally and in group 2 Patients received 3ml of 0.5% hyperbaric bupivacaine plus 0.5 ml normal saline intrathecally.

Results and Conclusion: The addition of 50 µg of clonidine to bupivacaine for spinal anaesthesia leads to faster onset of sensory and motor blockade, increased duration of sensory blockade, increased duration of postoperative analgesia and reduced requirement of rescue analgesia in the postoperative period. However, there is increased incidence of episodes of bradycardia in first hour following sub arachnoid block requiring treatment in both groups.

Introduction:-

Spinal anaesthesia is an established method of anaesthesia since 1899 when August Bier first administered cocaine intrathecally to provide effective surgical anaesthesia.[1] it results in sympathetic block, sensory analgesia and motor block.[2]Selective unilateral spinal anaesthesia is a useful approach for ambulatory lower limb surgery because it allows more rapid home discharge compared to bilateral block. Infrequent use is due to the fact that obtaining selective unilateral block can be difficult, requiring attention to technique.(3)

Aims and Objectives:-

The aims of present study is to compare the efficacy and safety of hyperbaric bupivacaine 0.5% and clonidine versus hyperbaric bupivacaine 0.5% alone for lower limb surgery under spinal anaesthesia, to statistically analyze and compare the results, to compare both groups in term of onset time for maximum sensory and motor blockage and

Corresponding Author:- Dr. Naveen Kumar Jindal
Address:- Consultant, Department of Anaesthesia and ICU, Amar Hospital, Patiala, Punjab.

duration of effective analgesia, to study the adverse effect like hypotension, bradycardia, drowsiness, nausea and vomiting.

Material and Methods:-

The study conducted in 100 patients of age group 20 to 60 yrs of ASA grade I and II, undergoing lower limb and lower abdominal surgery under spinal anaesthesia in Department of Anaesthesiology and Intensive Care, Rajindra Hospital and Government Medical College Patiala. The patients was randomly divided into 2 groups of 50 each.

Patient's who refused**,** having abnormality of spine**,** Any skin infection or local cellulitis**,** Any coagulation defect**,** Recent myocardial infarction**,** Patients with neurological disorders**,** Unstable angina and significant aortic stenosis were not included in study.In group 1 Patients received 3ml of 0.5% hyperbaric bupivacaine with 0.5 ml (50 micrograms) clonidine intrathecally and in group 2 Patients received 3ml of 0.5% hyperbaric bupivacaine with 0.5 ml normal saline**.** Immediately after spinal injection, the patient was turned to operating side being dependent for 5 minutes and oxygen was administered via venturi mask with oxygen flow at 4 litres/min.

Observation:-

Following observations was made after giving subarachnoid block.

Heart Rate:

Rate and rhythm was recorded after every 5 minutes for 30 minutes after intrathecal injection, thereafter every 10 minutes throughout the surgery and every 15 minutes postoperatively till full regression of subarachnoid block. Heart rate less than 60 per minute was taken as bradycardia and was treated with intravenous injection atropine 0.3mg.

Arterial Blood Pressure:

Systolic, diastolic and Mean Blood pressure was recorded every 5 minutes for 30 minutes after intrathecal injection and then every 10 minutes throughout the surgery and every 15 minutes postoperatively till full regression of subarachnoid block. Fall in systolic blood pressure less than 90mmHg or more than 20 percent of fall from baseline value was taken as hypotension and was treated with intravenous bolus dose of mephentermine 5 mg. Time of onset of sensory and onset of motor blockade measured as first Visual Analogue Score of 1 or less and modified bromage score of III respectively.

Vital parameters including arterial blood pressure, Heart rate and SpO_2, Post-operative analgesia was assessed using a Visual Analogue Scale for pain measurement. Intra-operative complications like nausea, vomiting, hypotension, bradycardia, respiratory depression, pruritis, urticaria, shivering, post-spinal headache, urinary retention was recorded. Any episode of vomiting was treated with injection ondansetron 4mg given intravenously.

Results:-

Descriptive and inferential statistical methods were used to analyze the data. In descriptive statistics, calculation of means, standard deviation and differences in average blood pressure and heart rate were done with the help of Microsoft Excel windows 7 on SPSS (Statistical Package for the Social Sciences) software version.In inferential statistics, Student's t-test of difference between two means was used to analyze the difference in proportion of males and females in both the groups.In our study, we have used 0.5% hyperbaric bupivacaine with or without clonidine for surgeries under spinal anaesthesia. The patients were randomized into two groups and were compared in terms of onset and duration of sensory and motor blockade as well as postoperative VAS scores. Heart rate, blood pressure, respiratory rate and SpO_2 were recorded at various time intervals intraoperatively and postoperatively up to 24 hours. Rescue analgesia was given using injection diclofenac 75mg and the total number of doses of rescue analgesics were calculated and compared between the two groups. Various side effects such as pruritis, dry mouth, nausea, vomiting, shivering, bradycardia and hypotension were also evaluated.

Intraoperative Hemodynamic Parameters:

Heart rate:

TIME	**MEAN HEART RATE (bpm)**		**P Values (Unpaired t test)**	
	Group 1	**Group 2**		
Baseline	79.1	78.4	0.651	**NS**

5 mins	77.7	80.9	0.154	**NS**
10 mins	73.8	85.2	0.0001	**S**
15 mins	72.9	86.2	0.0000	**S**
20 mins	74.2	86.2	0.0002	**S**
25 mins	85.3	85	0.978	**NS**
30 mins	74.7	82.1	0.002	**S**
40 mins	75.7	81.1	0.011	**S**
50 mins	73.9	79.6	0.002	**S**
60 mins	75.9	80.4	0.026	**S**
70 mins	74.9	79.6	0.113	**NS**
80 mins	76.6	78.5	0.572	**NS**
90 mins	78	81	0.597	**NS**
100 mins	74.9	79.6	0.113	**NS**
110 mins	76.6	78.5	0.572	**NS**
120 mins	78	81	0.597	**NS**

On inter group comparison, the heart rates were significantly lower in group 1 especially in the first hour of intrathecal injection ($p<0.05$). The baseline mean heart rate of both the group was comparable (p value >0.05). However, there was statistically significantly lower mean heart rate at 10, 15, 20, 30, 40, 50 and 60 minutes recorded in group 1 (p value <0.05). But at baseline, 5, 25 and after 60 minutes, the difference in mean heart rate in both the groups was statistically non-significant.

Our results correlates to Klimscha W et al [(4)] and H Saxenaet al[(5)]who also found lower heart rates in the clonidine group with more incidence with higher dose.

Blood pressure:

TIME	**MEAN SBP (mm of Hg)**		**P Value**		**TIME**	**MEAN DBP (mm of Hg)**		**P Value**		**TIME**	**MEAN MAP (mm of Hg)**		**P Value**	
	Group 1	**Group 2**	**(Unpaired t test)**			**Group 1**	**Group 2**	**(Unpaired t test)**			**Group 1**	**Group 2**	**(Unpaired t test)**	
Baseline	125	125	0.753	**NS**	**Baseline**	78.8	79.3	0.653	**NS**	**Baseline**	94.3	94.7	0.703	**NS**
5 mins	120	122	0.211	**NS**	**5 mins**	74	76.1	0.081	**NS**	**5 mins**	89.2	91.3	0.066	**NS**
10 mins	112	114	0.29	**NS**	**10 mins**	67.6	69.5	0.175	**NS**	**10 mins**	82.4	84.3	0.17	**NS**
15 mins	107	110	0.174	**NS**	**15 mins**	63.3	66.1	0.12	**NS**	**15 mins**	77.9	80.8	0.119	**NS**
20 mins	107	111	0.147	**NS**	**20 mins**	63	66.2	0.1	**NS**	**20 mins**	77.8	81.2	0.097	**NS**
25 mins	110	112	0.377	**NS**	**25 mins**	65.5	66.8	0.467	**NS**	**25 mins**	80.4	81.9	0.398	**NS**
30 mins	113	114	0.621	**NS**	**30 mins**	67.2	67.4	0.891	**NS**	**30 mins**	83	83	0.759	**NS**
40 mins	115	114	0.821	**NS**	**40 mins**	68.3	69.2	0.578	**NS**	**40 mins**	83.8	84.3	0.776	**NS**
50	115	115	0.859	**N**	**50**	70.4	68.4	0.267	**N**	**50**	85.4	84	0.388	**N**

mins				**S**	**mins**				**S**	**mins**				**S**
60 mins	115	115	0.917	**NS**	**60 mins**	69.5	69.8	0.853	**NS**	**60 mins**	81.8	83.8	0.593	**NS**
70 mins	117	115	0.503	**NS**	**70 mins**	71.3	69	0.414	**NS**	**70 mins**	86.6	84.5	0.366	**NS**
80 mins	118	120	0.652	**NS**	**80 mins**	71.7	70	0.724	**NS**	**80 mins**	79.8	86.7	0.427	**NS**
90 mins	118	113	0.566	**NS**	**90 mins**	71.3	64.7	0.158	**NS**	**90 mins**	76	80.9	0.686	**NS**
100 mins	107	110	0.174	**NS**	**100 mins**	70.4	68.4	0.267	**NS**	**100 mins**	80.4	81.9	0.398	**NS**
110 mins	107	111	0.147	**NS**	**110 mins**	71.3	69	0.414	**NS**	**110 mins**	83	83	0.759	**NS**
120 mins	110	112	0.377	**NS**	**120 mins**	71.7	70	0.724	**NS**	**120 mins**	83.8	84.3	0.776	**NS**

In our study we found that systolic, diastolic and mean blood pressurestart decreasing after administration of spinal anaesthesia in both the groups. However on the intergroup comparison, results have been statistically non-significant ($p>0.05$).

Block Characteristics:

	Group 1	**Group 2**	**P Value (Unpaired t test)**	
Mean Onset of Sensory block (Minutes)MEAN ±SD	4.92±1.103612	6.8±1.355262	0.0000	**HS**
Mean Onset of Motor block (Minutes) MEAN ±SD	6.61 ±1.340119	10.12±1.451811	0.0000	**HS**
Mean Duration Post op Analgesia (Minutes) MEAN ±SD	175.48 ± 43.82583	75.68 ±23.83313	0.0000	**HS**
Number of Rescue Analgesics given MEAN ±SD	1.54±0.705951	3.16±0.680936	0.0000	HS

Sensory Blockade

Onset of sensory block:

The time taken for the loss of sensation to pin prick at T_{10} level after intrathecal injection was considered as time of onset of sensory block. On comparing both the groups, we found that the mean onset time of sensory block was 6.8 minutes in bupivacaine group (group 2) and 4.92 minutes when clonidine was added (group 1). The difference was statistically highly significant thereby showing that clonidine shortens the time of onset of sensory block. The current results concur with those previously reported by Strebel Set al[10] (2004) who concluded that intrathecal clonidine added to bupivacaine for spinal anaesthesia shortened the sensory block onset time.[10] Similar results were obtained by Kanazi et al[6] by adding clonidine to bupivacaine for urological surgeries

Motor Blockade:

Onset of motor block:

Motor blockade was assessed using modified bromage scale.[7] This is a simple tool to apply in clinical settings. Modified bromage scale is a qualitative measure of intensity of block that analyses movements in various muscle groups. On comparing both the groups, we found that the mean onset time of motor block was 10.12 minutes in

bupivacaine group (group 2) and 6.6 minutes when clonidine was added(group 1). Our study indicated statistically significant faster onset of motor blockade when clonidine was added to intrathecal bupivacaine

Result is consistent with the results obtained byAnil Thakur et al who concluded that intrathecal clonidine added to bupivacaine for spinal anaesthesia shortened the motor block onset time.[9] Kanazi et al[6] andSaptate M et al(2014)[11] also showed similar results with addition of clonidine to bupivacaine.

Duration of Postoperative analgesia:
The mean duration of postoperative analgesia in group 1 was 175.48 minutes ± SD 43.826 and in group 2 it was 75.68 minutes ± SD 23.833. Thereby showing **highly significant** increase in the duration of postoperative analgesia in patients receiving clonidine (p value< 0.001)

Number of Rescue Analgesics:
The mean number of rescue analgesics given in the postoperative period was less in group 1 i.e. 1.54 ± 0.706 as compared to group 2 i.e 3.16 ± 0.681. The difference was **highly significant** (p values<0.001).

Duration of Sensory Block & VAS Score:
The intensity of postoperative pain has been assessed using a visual analog scale (VAS).[10] Each patient was asked to point to the position on the line between 0-10cm to indicate the severity of pain. The rescue analgesia was given for pain score of 4 or more in form of intramuscular diclofenac 75mg. the mean postoperative VAS Scores were lower in group 1 as compared to group 2 at 4,8,12 and 24 hrs. The difference was **significant** (p values<0.05) thereby indicating that the patients receiving clonidine (group 1) had lesser pain in the first 24 hours postoperative period.

The mean duration of sensory blockade, defined as the time interval between the onset of analgesia till the time of giving first rescue analgesia, in group 1 was 250.58 minutes ± SD 27.302 and in group 2 it was 150.38 minutes ± SD 12.325 thereby showing **highly significant** increase in the duration of sensory blockade in group 1 as compared to group 2 (p value<0.001).

Postoperative Hemodynamic Parameters:
The difference in the postoperative heart rate and the blood pressures of the two groups at all times was statistically non-significant (p>0.05). This is in accordance with the results obtained by Singh R et al[10] who found no significant difference in the postoperative vitals when clonidine was added to intrathecal bhupivacaine.

Side Effects:
The incidence of pruritis, dry mouth, nausea, shivering, bradycardia and hypotension was statistically non-significant in both groups. In our study, there was same incidence of bradycardia and hypotension in patients receiving clonidine as an adjuvant to intrathecal bupivacaine, which responded well to intravenous bolus dose of 0.3 mg atropine and 5 mg mephentermine respectively. We found bradycardia occurred in 12 patients (24%) of clonidine containing for which atropine administration was required compared to 7 patients (14%) in the group 2 developing bradycardia. The difference was statistically non-significant (p value<0.05). The incidence of bradycardia and use of atropine has been same in clonidine group (group 1) and group 2 and the difference is statistically non-significant.

Conclusion:-

We observed that the groups were comparable with respect to the demographic data (age, gender, weight, BMI, ASA grades and duration of surgery. The mean onset of sensory and motor blockade was observed to be significantly reduced with the addition of clonidine to bupivacaine. The results showed statistically significant increase in the duration of postoperative analgesia and reduction in the requirement of postoperative rescue analgesia after addition of clonidine .Adverse effects like pruritis, dry mouth, nausea, vomiting, shivering, bradycardia and hypotension has no effect in a statistically significant number of patients receiving clonidine. However, the episodes of bradycardia requiring treatment were increased after the addition of clonidine in first hour .The addition of 50 µg of clonidine to bupivacaine for spinal anaesthesia leads to faster onset of sensory and motor blockade, increased duration of sensory blockade, increased duration of postoperative analgesia and reduced requirement of rescue analgesia in the postoperative period. However, there is increased incidence of episodes of bradycardia in first hour following sub arachnoid block requiring treatment.

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