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COMPARISION OF FRACTIONATED VERSUS BOLUS DOSE INJECTION IN SPINAL ANAESTHESIA FOR LOWER LIMB SURGERIES

Anaesthesiology

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ABSTRACT

Introduction: To prevent hypotension various measures are followed such as preloading or co-loading with crystalloids and colloids, use of vasopressors such as mephentermine, phenylephrine etc. Dose of hyperbaric bupivacaine used for spinal anaesthesia depends various parameters like height, weight, anatomy of spine, type and duration of surgery. Usually the local anaesthetic is given intrathecally as a single bolus dose. The current study is done to compare the haemodynamic stability of a traditional bolus dose of bupivacaine and a fractionated dose of bupivacaine in divided doses of 2/3rd and 1/3rd calculated according to the height of the patient with a time gap of 90 seconds. Also characteristics of sensory and motor block were compared. **Methods:** After the Institutional Ethics Committee approval and written informed consent, the present study was carried out on sixty patients (thirty in each group) of the American Society of Anaesthesiologists physical status I–II, age from 15 to 60 years, height from 140 to 180cm **.**After aspiration of csf injection bupivacaine 3ml of 0.5% heavy was injected according to respective groups as bolus in one group and as fractionated in the other as divided doses of 2ml and 1ml with a gap of 90 seconds. Statistical Analysis**:** All the observations were recorded in MS-Excl, and all the results were analysed statistically using SPSS V17. Quantitative data were presented as mean ± standard deviation (SD) and analysed using the unpaired *t*-test. Qualitative data was represented with frequencies and percentages. Chi-square test was applied. *P* <0.05 was considered statistically significant. **Results:** The fractionated group patients were more haemodynamically stable compared to bolus group in view of episodes of hypotension and bradycardia. There was no significant difference in onset of either sensory or motor blockade . However the duration of sensory and motor blockade was significantly more in fractionated group compared to bolus group.The duration of analgesia was also significantly more in fractionated group compared to bolus group. **Conclusion:** Fractionated dose of spinal anaesthesia can be a valid alternative in patients to the regular bolus dose with a better haemodynamic stability and longer duration of sensory and motor blocks and duration of analgesia.

KEYWORDS

Fractionated, Bolus, Spinal Anaesthesia, Lower Limb Surgeries

INTRODUCTION

Since the "cocanization" of cerebrospinal fluid by AUGUST BEIR[1] on 16th august 1898 at the Royal surgical hospital of the University of Kiel as an alternative for General Anaesthesia for segmental resection of a tuberculosis infected ankle, the field of anaesthesia took rapid strides and underwent multiple changes in Central neuraxial blockade. However the complications still persist though adept recognition and multiple pharmacological agents has made life easy for the anaesthesiologist. Multiple local anaesthetics were used over a period of time with each making way for the other, bupivacaine being the most used one in recent past due to its longer duration of action[2]. The addition of adjuvants further increased the implications of spinal each causing differential increase in onset and duration of sensory, motor and analgesia. Also with that each group of adjuvants brought their own side effects.

Spinal anaesthesia acts by causing chemical sympathectomy thus blocking sensory and motor outflow of the lumbosacral plexus. However this also causes profound vasodilation of the involved segments which in turn will lead to hypotension and involvement of fibres above T4 may precipitate even bradycardia. These complications make it undesirable in scenarios where cardiovascular stability is of prime concern. Nausea ,vomiting, post puncture dural headache[3], urinary retention[4] are the other complications.

To prevent hypotension various measures are followed such as preloading or co-loading with crystalloids and colloids[5], use of vasopressors such as mephentermine, phenylephrine etc[6]. Dose of hyperbaric bupivacaine used for spinal anaesthesia depends various parameters like height, weight, anatomy of spine, type and duration of surgery[7,8,9,10].

Usually the local anaesthetic is given intrathecally as a single bolus dose. The current study is done to compare the haemodynamic stability of a traditional bolus dose of bupivacaine and a fractionated dose of bupivacaine in divided doses of 2/3rd and 1/3rd calculated according to the height of the patient with a time gap of 90 seconds. Also characteristics of sensory and motor block were compared.

AIMS AND OBJECTIVES

To compare bolus dose versus fractionated dose in spinal anaesthesia for haemodynamic stability and duration of analgesia in patients undergoing lower limb surgeries.

MATERIAL AND METHODS

After the Institutional Ethics Committee approval and written informed consent, the present study was carried out on sixty patients (thirty in each group) of the American Society of Anaesthesiologists physical status I–II, age from 15 to 60 years, height from 140 to 180 cm **.**After aspiration of csf injection bupivacaine 3ml of 0.5% heavy will be injected according to respective groups.

STUDY DESIGN:

The study was prospective, randomized, controlled.

INCLUSION CRITERIA:

Age group 15-60 years of either sex, ASA 1 and ASA 2 patients, Patients undergoing elective lower limbsurgeries

EXCLUSION CRITERIA:

ASA 3 and ASA 4 patient, Pre-existing cardiovascular or cerebrovascular diseases, Known allergy or hypersentivity to local anaesthetic drugs, Height less than 140 or more than 180 cm, Weight less than 50 kgs or more than 100 kgs, Deformities of spine, Any other contraindication to spinal anaesthesia

Procedure:

Standard monitors including non-invasive blood pressure (NIBP), electrocardiogram (ECG) and pulse oximeter (SpO2) were attached to the patient, and baseline blood pressure and heart rate (HR) were recorded. Intravenous line was taken with 18 or 20 gauge IV cannula. Standard monitors like non-invasive blood pressure (NIBP), electrocardiogram (ECG) and pulse oximeter (SpO2) were connected to patient, and baseline blood pressure and heart rate were recorded. SA was given in sitting position with 23-gauge Quincke spinal needle in L3–L4 or L4–L5 interspace. After aspiration of cerebrospinal fluid, injection bupivacaine 0.5% heavy was injected according to respective

groups, B and F. Total dose of SA was 3ml in both groups. Group B patients received a single bolus of bupivacaine over 10 seconds. Group F patients received fractionated dose of bupivacaine with two-third of the total calculated dose given initially followed by one-third dose after 90 seconds, both doses given at a rate of 0.2 ml/s. After injection of initial two-third dose, the syringe was kept attached to the spinal needle for next 90 seconds, after which theremaining one-third was given.

To prevent observer's bias, patients were kept sitting for 90 s after completion of the spinal in Group B. Patients were then turned into the supine position. We supplemented oxygen with the face mask at 5 L/min.

The patients were randomly divided into two groups using computer-generated sequential number placed in envelopes and opened only before the starting of the study. The study designed in double-blind fashion such that the patient and the assessor were unaware of the group. The assessor was kept blinded during the administration of the drug. Only the attending anaesthesiologist administering the Spinal anaesthesia knew the group divison.

We noted time of onset, level and regression of motor and sensory block. Confirmation of sensory block was assessed by loss of pinprick sensation. Motor block was assessed by a modified Bromage scale. These tests were performed every 5 min untill the achievement of maximum sensory and motor block (Bromage scale 3) and every 30 min after surgery until the sensory and motor variables were back to normal. The onset time of sensory or motor blockade was defined as the interval between intrathecal injection and time to achieve maximum block height or a modified Bromage score of 3, respectively. Surgical incision was allowed when loss of pinprick sensation reached the T6 dermatome level bilaterally and when Bromage scale of three was achieved. Patients with inadequate sensory block and requiring conversion to general anaesthesia were excluded from the study. Intraoperatively, patients were monitored with continuous ECG, HR, NIBP and SpO2. Hypotension was treated when mean arterial pressure (MAP) decreased ≤20% of baseline with injection mephentermine 6 mg given IV and repeated when needed. The number of hypotensive episodes and mephentermine used were recorded for each patient. We treated bradycardia if any (HR of < 50 beats/min) with IV atropine 0.6 mg.

The duration of sensory blockade was defined as the interval from administration of spinal anaesthesia to S2 segment regression. The duration of motor blocka was defined as the time interval from the onset of motor block to the time of achievement of modified Bromage scale zero (0). Pain was assessed with the visual analogue scale (VAS) every 30 min post-operatively for the first 2 h then hourly up to 6 h. The duration of analgesia was defined as the time from intrathecal injection till the first demand for rescue analgesic when VAS was ≥4. The patient was given diclofenac sodium 75 mg intramuscular as rescue analgesic.

Statistical Analysis: All the observations were recorded in MS-Excl, and all the results were analysed statistically using SPSS V17. Quantitative data were presented as mean ± standard deviation (SD) and analysed using the unpaired *t*-test. Qualitative data was represented with frequencies and percentages. Chi-square test was applied. $P < 0.05$ was considered statistically significant.

RESULTS

The study was done in 60 patients divided into two groups of 30 between ages of 15 to 60 years and of ASA 1 and ASA 2 status posted under spinal anaesthesia. Patients from both groups were given a total dose of 3ml 0.5% bupivacaine heavy , as a bolus in one group and in two divided doses of 2ml and 1ml in another group with a time duration of 90 seconds.

Demographic data: The mean age in the Bolus group was 36±10.35 years as compared to 35.37±8.48 years in the control group and the difference was statistically not significant (P value-0.796). Both groups had 60% of male patients that is 18 in 30 and 40% of female patients that in 12 in 30. No statistical variation among both groups based on gender. Mean weight of patients in Bolus group was 75.97±7.08 and in fractionated group was 76.10 ± 6.09 . The P value was calculated to be 0.937 showing no significant difference. Mean height of patients in Bolus group was 162.67±7.47 and in fractionated group was 162.47±6.09 . The P value was calculated to be 0.834.

Types of Surgeries-

The procedure of spinal anaesthesia in both groups was performed in 5 surgeries namely Varicose veins stripping (VVS), Meniscectomy of knee for meniscal tears (MN), Proxiaml fibular osteotomy for osteoarthritis knee (PFO), Split skin grafting unhealed ulcers or post burns (SSG) and Implant removals (IR) of tibia. They were comparable in both groups.

Prosperities of Blockade

From Table-1: Sensory Blockade Onset snd Duration – The mean onset time of sensory blockade in the Bolus group was 4.90 ±0.80 and in Fractionated group was 4.90 ±0.76 with a P value of 1 ,drawing the conclusion that there is no significant time difference in onset of block. However the duration of sensory blockade in Bolus group was 125.77± 15.54 and in Fractionated group was 147.77± 14.38 with a P value of 0.0001 ,that is very significant statistically, meaning a prolonged duration of sensory block in the Fractionated group.

Blockade in the Bolus group was 7.17±0.95 and in Fractionated group was 6.93±0.87 with a P value of 0.324 ,drawing the conclusion that there is no significant time difference in onset of block. However the duration of motor blockade in Bolus group was 107.5± 13.24 and in Fractionated group was 118.5± 13.11 with a P value of 0.0019 ,that is very significant statistically, meaning a prolonged duration of motor block in the Fractionated group.

Duration of Analgesia –

The mean duration of analgesia in the Bolus group was 154.07±15.78 and in Fractionated group was 180.80 ±17.16 with a P value of 0.0001 ,that is very significant statistically, meaning a prolonged duration of analgesia in the Fractionated group.

Table-1: Comparison of Blockade between two group

Blockade	Time	Group-B	Group-F	P-value
Sensory	Onset time	4.90±0.80	4.90±0.76	1
	Duration	125.77±15.54	147.77±14.38	**0.0001**
Motor	Onset time	7.17±0.95	6.93±0.87	0.324
	Duration	107.5±13.24	118.5±13.11	**0.0019**
	Duration of Analgesia	154.07±15.78	180.80±17.16	**0.0001**

Haemodynamic Charecteristics:

From table-2: The mean heart rate was comparable between both the groups from baseline to 60 minutes though there were more episodes of bradycardia in bolus group compared to fractionated group at the time of 10 mins. However statistically there was no significant difference. Three patients in group B had bradycardia and one patient in group F had bradycardia and were promptly treated with atropine 0.6mg .

Table-2: Comparison of HR between two groups

HR	Group-B		Group-F		P-value
	Mean	SD	Mean	SD	
BASELINE	83.3	7.03	86	9.54	0.2173
5 MINS	94.17	11.67	89.8	10.6	0.1347
10 MINS	96.4	18.01	92.2	12.37	0.2969
15 MINS	93.77	9.46	88.4	11.48	0.0527
30 MINS	88	7.74	87.43	8.93	0.7937
45 MINS	83.8	6.22	84.27	7.85	0.7995
60 MINS	81.23	6.32	83.73	7.42	0.1656

From table-3: Mean aterial pressure at various points of time were noted from baseline to 60 minutes ,which showed significant difference at 45 minutes of time. There were episodes of hypotension in 10 patients in group bolus and 4 patients in fractionated group. They were treated with i.v mephentaramine 6mg .

Table-3: Comparison of MAP between two groups

MAP	Group-B		Group-F		P-value
	Mean	SD	Mean	SD	
BASELINE	95.04	10.4	97.83	7.8	0.392
5 MIN	102.73	9.18	103.53	7.86	0.718
10 MIN	96.9	10.6	98.93	7.82	0.401
15 MIN	101.43	9.04	99.13	8.66	0.318
30 MIN	102.67	18.39	101.83	6.76	0.816
45 MIN	89.67	6.24	103.03	5.36	0.0001
60 MIN	106.6	4.97	104.37	5.42	0.101

Oxygen Saturation – There was no significant difference in spo2 in both of the groups. No desaturation episodes were present.

DISCUSSION

Hypotension and cardiovascular instability are still the two major concerns post spinal anaesthesia[11]. In view of prolonging a surgery increased dosage of the local anaesthestic further increases the chance of these complications.

The addition of adjuvants dates back long and have undergone a wide range of research and metamorphosis. Trail and testing was done on a number of groups including opioids, NMDA blockers, Alpha 2 agonists, benzodiazepine like midazolam, neostigmine etc[12,13,14,15]. Research on each group showed varying results on onset of sensory and motor blockade ,duration of block and analgesia. Also each group of them had their own complications[16] .Opioids were associated with rash, nausea, vomiting, rarely respiratory depression too[17]. Alpha 2 agonists are notorious for profound bradycardia and hypotension. Intrathecal neostigmine caused severe headache, vomiting and bradycardia[18].

Fahmy et al[19] compared the circulatory and anaesthetic effects of bolus versus fractionated administration of bupivacaine. They found that fractionated dose of bupivacaine prolonged the duration of action and was associated with more circulatory stability.

Favarel *et al*[20]. studied sixty elderly patients undergoing surgery for hip fracture for haemodynamic tolerance of titrated doses of bupivacaine versus single dose SA and concluded that titrated doses of bupivacaine was safe, efficient and provided better haemodynamic stability than single dose SA.

Badheka et al[21], Compared fractionated dose versus bolus dose injection in spinal anaesthesia for patients undergoing elective caesarean section, for haemodynamic stability and duration of analgesia. They concluded the fractionated group had more haemodynamic stability and also a prolonged motor and sensory blockade.

All the the above and others were conducted in view of using fractionated dose of spinal as a safe alternative for cases requiring prolonged blockade and thus more dose or an adjuvant without causing more haemodynamic variations or the side effects due to adjuvants.

This study differs from other studies conducted byv Badheka et al, and Monika et al, in that they were done in pregnant women and this study was done in study group having both male and female patients posted for lower limb surgeries. The aforementioned studies calculated the dose of spinal anaesthesia in patients depending on the height ,that is 0.07mg/cm height of the patient[22]. However in our current study we took a fixed dose of 3ml in patients from both groups as the dose taken in those studies was not adequate in non-pregnant population. The mean height in both groups was comparable and showed an insignificant P value.

The salient findings of this study were the prolongation of both sensory (147.77 mins) and motor blockade (118.5 mins) in the group receiving fractionated dose in comparison to the sensory (125.77) and motor (107.5) blockade in bolus group. Also analgesia in the fractionated group (180.80) was significantly more than the bolus group (154.07) .These findings were in support of the studies done by badeka et al, and manjula et al[23], and others.

	Current study		Badheka et al		Monika et al		Bina patel et al[24]	
	B	F	B	F	B	F	B	F
Duration of sensory blockade	125.7	147.7	161	236	150.8	169.3	176	216
Duration of sensory blockade	107.5	118.5	145	204	132.3	150.8	130	155
Duration of analgesia	154.1	180.8	231	273	156	190.2	-	-
Vasopressor Requirement	10	3	14	5	39	15	11	4

However none of the studies had a possible explanation for prolonging of sensory and motor blockades and also analgesia which were statistically significant with the same amount of drug and with all other demographic parameters being comparable.

Limitations of our study; Fixed dose of drug was given in all patients without calculating dose according to weight or height. No possible explanation for better blockade and haemodynamic stability in the fractionated group despite giving same volume of drug. Done is ASA 1 and ASA 2 patients only ,so haemodynamic stability in cardiovascular unstable cases or patients with other comorbidities could not be evaluated.

CONCLUSION

The fractionated group patients were more haemodynamically stable compared to bolus group in view of episodes of hypotension and bradycardia. There was no significant difference in onset of either sensory or motor blockade. However the duration of sensory and motor blockade was significantly more in fractionated group compared to bolus group. The duration of analgesia was also significantly more in fractionated group compared to bolus group.

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