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Research Article

Comparison of Hyperbaric and Isobaric Solution of Bupivacaine in Spinal Anaesthesia

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Abstract

Aims: The primary objective of the study was to compare the efficacy of administration of isobaric versus hyperbaric bupivacaine for spinal anaesthesia in patients undergoing lower abdominal and lower limb surgeries. Administering hyperbaric solution intrathecally is advisable for lower abdominal surgeries as the drug was found to produce a high sensory block when compared with isobaric bupivacaine. The longer duration of analgesia and the more gradual fall in blood pressure seen with isobaric bupivacaine are definite advantages over hyperbaric preparations. The isobaric preparation is of much help in perineal and lower limb surgeries.

Objectives: We tried to compare the efficacy of both hyperbaric and isobaric preparations of bupivacaine and if possible to replace hyperbaric with isobaric solution.

Methods: 80 patients in the age group 20-60 years undergoing elective surgery and belonging to ASA grade I& II were studied. These patients were divided into 2 equal groups of 40 each-Group I as those who received hyperbaric bupivacaine and group II as those who received isobaric bupivacaine. In the case of qualitative data, percentage were calculated and the association between the variables was tested statistically with the help of Chi-square test. The equality of the mean values of the two groups was tested by applying Student's t test.

Results: There was no statistical difference in outcome between the two groups in age, height, weight and sex. The mean number of segments blocked in the two groups appeared small, but it was statistically highly significant ($P < 0.001$). The isobaric group took 11.8 minutes as the time of latency of maximal spread compared to only 10.78 minutes in hyperbaric group ($P < 0.01$). While considering the duration of motor block, isobaric group necessitated 248.75 minutes whereas it was only 211.63 minutes in the hyperbaric group ($P < 0.001$). The duration of analgesia also was found to be greater with the isobaric group ($P < 0.001$).

Conclusion: The anaesthetic properties of isobaric and hyperbaric bupivacaine were compared after intrathecal injection undergoing lower abdominal, perineal and lower limb surgeries. Hyperbaric bupivacaine administered produced the highest spread of analgesia, up to T_7. Isobaric solution resulted in spread of analgesia to T_9 only. While motor block in the legs were good in both the cases, the onset was faster with the hyperbaric group. The longest duration of analgesia recorded was found to be greater with the isobaric group. The course of anaesthesia and recovery were uneventful in all patients of both the groups.

Keywords: Spinal Anaesthesia; Bupivacaine; Isobaric; Hyperbaric; Intrathecal

Introduction

Centrineuraxis blocks, both spinal block and epidural blocks are popular techniques of regional anaesthesia [1-4]. These are indicated whenever the surgical procedure can be accomplished with a sensory level of anaesthesia, without causing an adverse patient outcome. Drugs popularly used are Lignocaine 5% heavy and Bupivacaine 0.5% heavy [1]. Bupivacaine was first introduced in 1963 and used for subarachnoid block in the same year. Isobaric and hyperbaric solutions have been tried, mainly as 0.5%, 0.75% or 1% solution, with and without adrenaline. This agent has been used extensively abroad [5]; it is from Germany that large series of studies have appeared. Long-term follow-up of patients who had isobaric subarachnoid blocks has shown no major complications [6]. lsobaric bupivacaine still has not gained much popularity in India for subarachnoid blocks. Long duration of action and almost universal availability are its unique advantages. This drug is also known to produce less hypotension [7-9]. In addition, the popularity of bupivacaine for epidural analgesia raises the possibility that accidental subarachnoid injection that occurs fairly frequently is therefore important to know what effect might be expected should a small dose be given inadvertently [10,11].

Objectives of the Study

- **Primary:** To compare the anaesthetic properties of isobaric and hyperbaric bupivacaine in spinal anaesthesia, which includes time of onset of block and level and duration of block obtained (both sensory and motor)

- **Secondary:** To compare the effects of both the drugs on heart rate and blood pressure.

Materials and Methods

The study was conducted in 80 adults of The American Society of Anaesthesiologists (ASA score) 1 and II aged 20-60 years, involving both sexes, undergoing operations like herniorraphy, eversion of tunica vaginalis (TV sac), appendicectomy, varicose vein stripping, varicocelectomy, vaginal hysterectomy, incisional hernia repair and orthopaedic surgery of lower extremities.

The ASA score is a subjective assessment of a patient's overall health that is based on five classes (I to V).

- Patient is a completely healthy fit patient.
- Patient has mild systemic disease.
- Patient has severe systemic disease that is not incapacitating.
- Patient has incapacitating disease that is a constant threat to life.
- A moribund patient who is not expected to live 24 hour with or without surgery.

All patients were assessed in the pre-anaesthetic clinic and the following inclusion and exclusion criteria were applied.

Inclusion criteria

- Patients aged 20 - 60 years and weighing 50-75 Kg
- Patients with ASA grade I and II
- Patients who required elective surgery only.

Exclusion criteria

- Patients with ASA grade more than II
- Patients with spinal deformities
- Patients with known hypersensitivity to Bupivacaine.

Before the subarachnoid injection, normal saline 500 ml was administered by rapid intravenous (IV) infusion for preloading. Patients were then positioned horizontally in lateral decubitus position near the side of the table and lumbar puncture was performed under strict aseptic precautions. After local anaesthesia with 1% lignocaine (1ml), a midline puncture was performed at L3-4 with a 23 G spinal needle. The position of the needle was confirmed by free flow of CSF and 4 ml of the drug containing 5 mg I ml of bupivacaine was instilled. The speed of injection was 1 ml in 3 secs. Patients were then turned to supine position immediately after completion of injection.

Outcome measures

The onset and segmental spread of analgesia in the skin was studied by pin prick every 2 minutes. Analgesia during surgery was described as satisfactory or unsatisfactory. Motor blockade was assessed using Bromage score as follows:

- 0-No paralysis
- 1-inability to raise extended leg
- 2-inability to flex knee
- 3-inability to dorsiflex the knee.

Blood pressure and heart rate were measured periodically. The time elapsed between the administration of the spinal injection and the first need for post-operative analgesia was recorded. The quality of the block was assessed using the need for supplementation as a criterion of effectiveness. The Institutional ethics Committee approved the study.

Statistical analysis

The data collected were entered into a master sheet and statistical tables were prepared. In order to compare the quantitative data, the statistical constants like mean and standard deviation were computed. In the case of qualitative data, percentage were calculated and the association between the variables was tested statistically with the help of Chi-square test. The equality of the mean values of the two groups was tested by applying Student's t test. All statistical calculations were done by using computer packages (SPSS Chicago version 14.0).

Results

80 patients in the age group 20-60 years undergoing elective surgery and belonging to ASA grade I and II were studied. These patients were divided into 2 equal groups:

- Group I - Received Hyperbaric Bupivacaine.
- Group II - Received Isobaric Bupivacaine.

The results were tabulated in the following way.

Age (Years)	Hyperbaric		Isobaric	
	Group I		Group II	
	No.	%	No.	%
20 - 29	14	35	11	27.5
30 - 39	10	25	7	17.5
40 - 49	13	32.5	15	37.5
50+	3	7.5	7	17.5
Total	40	100	40	100

Table 1: Distribution according to age of patients.
χ^2= 2.63; d.f = 3; P >0.05 (Not significant-NS).

From table 1, it is observed that the percentage distribution of patients in group I (hyperbaric) and in group l (isobaric) was more or less identical. In both the groups more than 80% of patients were below 50 years. However in group II there were 7 patients (17.5%) in the '50 and above' age group, whereas there were only 3 patients (7.5%) in group I in this age group. Thus numerically the number of patients in the '50 and above' age was rather high in group II compared to group I, still the statistical test revealed that there were no significant difference between two groups according to age (χ^2 = 2.63; d.f = 3; P > 0.05) Thus it is inferred that the age of patients did not have any influence over the final outcome measures.

Sex	Hyperbaric		Isobaric	
	Group I		Group II	
	No.	%	No.	%
Male	31	77.5	26	65
Female	9	22.5	14	35

Table 2: Distribution according to sex of patients.
χ^2= 1.53; d.f=1; P > 0.05 (NS).

It was observed that 77.5% of patients in hyperbaric group and 65% in isobaric group happened to be males Thus males were more in both the groups and the percentage distribution according to sex is found to be identical in both the groups. The numerical difference groups noted in the percentage distribution according to sex turned out to be insignificant statistically (P > 0.05).

Height of patients	Hyperbaric		Isobaric	
	Group I		Group II	
	No.	%	No.	%
150 - 159	15	37.5	14	35
160 - 169	19	47.5	19	47.5
170 - 179	6	15	7	17.5

Table 3: Distribution according to height of patients.
χ^2= 0.11; d.f=2; P > 0.05 (NS).

It was also attempted to see whether the groups are similar with respect to height of patients. In both the groups 47.5% were having 160 - 169 cm of height and the distribution in 150 - 159 cm group and 170 - 179 cms group did not reveal an appreciable difference between the two groups. It appeared that both the groups are matched pairs when the height of patient was considered.

Weight	Hyperbaric		Isobaric	
	Group I		Group II	
	No.	%	No.	%
50 - 59	14	35	19	47.5
60 - 69	22	55	19	47.5
70 - 79	4	10	2	5.0

Table 4: Distribution according to weight of patients (in kg). χ^2= 1.26; d.f=2; P > 0.05 (N.S).

The weight of patients also revealed more or less similar findings that of the height of patient. In this case only marginal difference was observed between the two groups. In hyperbaric group 65% were having 60-69 Kg weight in place of 47.5% in other group. However the statistical test is found to be not significant. Hence it was assumed that the weight of the patients did not have any influence over the final outcome measures.

Group	Segment block		T value	P value
	Mean	S.D		
Hyperbaric	16.6	0.93	10.9	P < 0.001
Isobaric	14.1	1.13		

Table 5: Mean and S.D of number of segments blocked in Group 1/II and level of significance.

Figure a

In the present study it was attempted to see whether there was any difference in the mean number of segments blocked in the two groups. In the hyperbaric group, the mean number of segments blocked is computed to be 16.6, whereas the corresponding mean value in the isobaric was only 14.1. Even though numerically difference in the mean number of segments blocked in the two groups appeared small, it was statistically highly significant (t =10.9; d.f = 78; P < 0.001).

Group	Segment block		t value	P value
	Mean	S.D		
Hyperbaric	10.78	1.14	3.47	P < 0.01
Isobaric	11.88	1.65		

Table 6: Mean and S.D of time of latency of maximal spread (min) in group 1/II and level of significance.

From table 6 it is seen that isobaric group took 11.8 minutes as the time of latency of maximal spread compared to only 10.78 minutes in hyperbaric group. Thus group II have taken 1.l minutes more for attaining maximum spread compared to group I. The Student's 't' test showed the difference in the meantime taken was highly significant (P < 0.01).

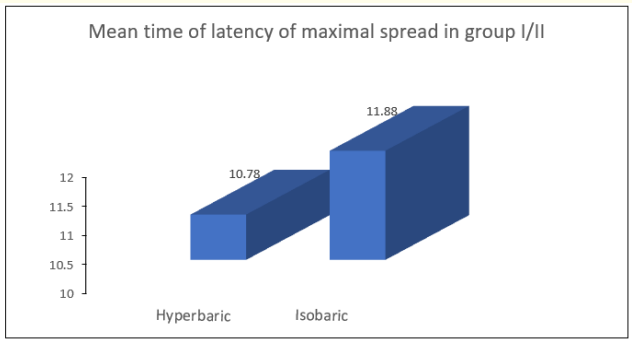

Figure b

Group	Duration of motor block (min)		t value	P value
	Mean	S.D		
Hyperbaric	211.63	18.79	6.12	P < 0.01
Isobaric	248.75	33.45		

Table 7: Mean and SD of duration of motor block (min) in group I/II and level of significance.

While considering the duration of motor block, isobaric group necessitated 248.75 minutes whereas it was only 211.63 minutes in the hyperbaric group. Thus there is remarkable difference in the duration of motor block. The statistical test for equality of means showed the difference to be highly significant (P < 0.001).

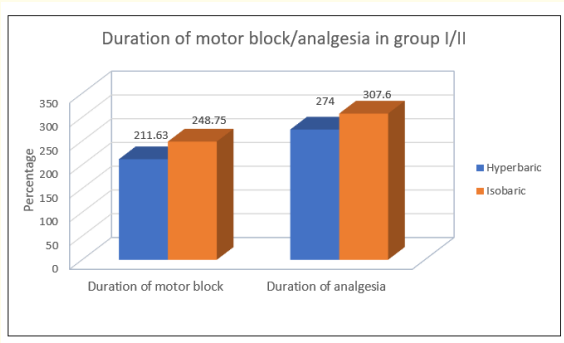

Figure c

Group	Duration of motor block (min)		t value	P value
	Mean	S.D		
Hyperbaric	274.0	32.2	4.2	P < 0.001
Isobaric	307.6	37.3		

Table 8: Mean and SD of duration of analgesia (min) in group I/II and level of significance.

In the present study it is also attempted to compare the duration of analgesia in the two groups. The mean duration of analgesia is recorded as 307.6 minutes in isobaric group in place of only 274.0 minutes in other group. In this case, the statistical test was highly significant (t=4.3; d.f = 78: P < 0.001).

Group	% of fall in BP (MAP)		t value	P value
	Mean	S.D		
Hyperbaric	25.5	5.5	3.42	P < 0.01
Isobaric	20.5	7.5		

Table 9: Mean and SD of percentage (%) of fall in blood pressure (MAP) of group 1/I and level of significance.

Figure d

Attempts were made to compare the mean arterial pressures of hyperbaric group with isobaric group. The percentage of fall in of blood pressure was rather high in hyperbaric group (mean=25.5) whereas the corresponding mean value in the other group was 20.5. As in other cases, the statistical test happened to be significant at 19% level (t=342. di - 78; P < 0.01).

Type of surgery	Group I	Group II
Herniorraphy	7	5
Eversion TV sac	4	3
Appendicectomy	7	4
Varicose vein stripping	1	1
Varicocelectomy	0	2
Vaginal hysterectomy	8	10
Abdominal hysterectomy	1	4
Incisional hernia repair	1	0
Orthopaedic surgery of leg	8	9
Split skin graft of leg and others	3	2

Table 10: Type of surgery in group I/II.

Side effects	Group I		Group II		Z value	P value
	No.	%	No.	%		
Headache	3	7.5	1	2.5	1.03	P > 0.05
Shivering	8	20	6	15	0.60	P > 0.05
Nausea	5	12.5	2	5.0	1.20	P > 0.05
Vomiting	2	5.0	1	2.5	0.60	P > 0.05
Back ache	2	5.0	3	7.5	0.46	P > 0.05

Table 11: Distribution according to side effects.

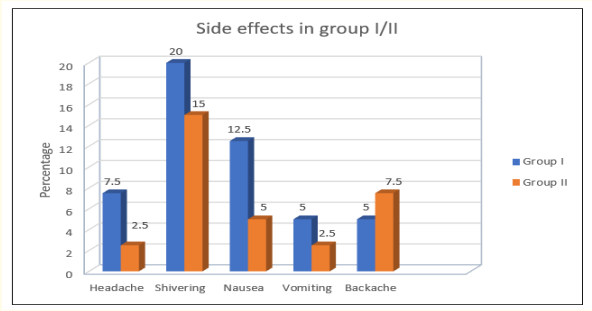

Figure e

Group I patients had comparatively more side effects than group II. Headache was reported by 7.5% of the patients in group I in place of only 2.5% in group II. Similarly the number of patients who had complaints of nausea was two times higher (12.5%) in group I compared to group II (5%). At the same time, the shivering, vomiting and backache showed only marginal difference between two groups. However, none of these differences proved to be significant statistically and therefore it is inferred that the chances of side effects are almost equally distributed in both the groups.

Discussion and Conclusion

Both hyperbaric and isobaric preparations of bupivacaine 0.5% were found to be suitable agents for lower abdominal and lower limb surgeries [12-16]. In operations lasting longer than three hours no supplementation was required. In this study, 4ml of isobaric and hyperbaric bupivacaine 5mg/ml was administered to induce spinal anaesthesia in 80 patients.

Here 40 patients were given hyperbaric bupivacaine and 40 patients received isobaric bupivacaine for spinal anaesthesia. It was found that the hyperbaric drug produced a higher level of blockade than the same dose of isobaric bupivacaine. The maximum level of analgesia following intrathecal injection of isobaric bupivacaine 5 mg/ml was found to be T_9, and that following hyperbaric drug was T_7. It has been shown that hyperbaric solutions tended to produce higher levels of the block more rapidly [17-19]. The sensory level obtained in the hyperbaric group was significantly higher than in isobaric group in another study [20].

Duration of analgesia was found to be 307.6 minutes in isobaric group compared to 274 minutes in the other group. Another study noted that the duration of perioperative analgesia with the hyperbaric preparation is, however, shorter than isobaric preparation [21]. At the same time, hyperbaric bupivacaine blocks a greater number of spinal segments.

In another study it was found that the duration of analgesia and motor blockade was more with isobaric bupivacaine solution than hyperbaric group [22].

Motor block was adequate in both the groups. It was shown that when a higher concentration of bupivacaine (0.75%) was given, the motor blockade lasted longer [23]. In older men (over 50 years) the motor blockade tends to occur earlier when compared to younger subjects, but recovery of motor blockade does not appear to be age dependent [24]. Decreased number of axons, and substantial demyelination may explain the rapidity of the total motor blockade by bupivacaine in older patients [23]. In this study, the duration of motor block in isobaric group was 248.75 minutes compared to 211.63 minutes in hyperbaric group. Here the statistical test for equality of means showed the difference to be highly significant ($P < 0.001$).

The degree of arterial hypotension during spinal anaesthesia has been said to be related to the magnitude of the sensory blockade. In a study with hyperbaric and isobaric bupivacaine 0.5% found that blood pressure dropped in both the groups. The decrease in blood pressure was so severe in hyperbaric group that vasopressors were required in 70% of cases [7,8].

This fall in mean arterial pressure was rather high in hyperbaric group which was found to coincide with the increased level of sensory block in hyperbaric group [7,8]. The maximal fall in the

systolic blood pressure occurred between 20 and 45 minutes after the induction of spinal anaesthesia. Hemodynamic changes during this study may be regarded as modest. This may be attributed to the administration of sufficient normal saline solution prior to and during the induction. The need to use mephentermine occurred only in five patients, to correct hypotension.

Side effects like shivering, nausea and vomiting were only transient. Post dural puncture headache was probably the result of using 23 gauge needles. Backache is known to occur after spinal anesthesia and needling cannot be blamed as the cause for this. Since it is known to occur after general anaesthesia with relaxation, the reason for backache may be undue strain on the ligaments of lower back owing to the completely relaxed muscles [25,26].

The anaesthetic properties of isobaric and hyperbaric bupivacaine (4 ml) 5mg/ml were compared after intrathecal injection in 80 patients undergoing lower abdominal, perineal and lower limb surgeries. Hyperbaric bupivacaine administered produced the highest spread of analgesia, up to T_7. Isobaric solution resulted in spread of analgesia to T_9 only. While motor block in the legs were good in both the cases, the onset was faster with the hyperbaric group. The longest duration of analgesia recorded was found to be greater with the isobaric group. The course of anaesthesia and recovery were uneventful in all patients of both the groups.

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