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Original Research Article

Comparison of Isobaric and Hyperbaric Bupivacaine for Subarachnoid Block

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Abstract:

Objective: Aiming to compare the onset and duration of sensory block. Onset and duration of motor block. Quality of block. Post operative analgesia. Side effects and adverse effects of hyperbaric and isobaric bupivacaine in subarachnoid block. Duration of postoperative analgesia obtained with test drugs.

Methods: The patients included in the present study were scheduled for orthopaedic, general surgery and gynaecology requiring analgesia for below the level of umblicus. The patients were divided into two groups of 30 patients each .In group A patients hyperbaric bupivacaine and in group B patients isobaric bupivacaine 4ml 0.5% was injected. Vital parameters such as pulse, BP, pulse oximetry, RR, ECG where recorded throughout the procedure and in the post operative period. The onset and duration of sensory and motor block were recorded further the post operative analgesia, height of dermatomal level, muscle relaxation, complications and side effects were recorded in a predecided case proforma.

Results: The onset, duration, segmental spread of sensory and motor block is rapid with hyperbaric bupivacaine. Muscle relaxation was adequate in both the groups. The incidence of hypotension and bradycardia was seen more after hyperbaric bupivacaine whereas in isobaric bupivacaine, vomiting and shivering was seen. The analgesia produced with hyperbaric solution of bupivacaine is effective and satisfactory. The observations recorded where subjective to statistical analysis to discuss the finding with the available literature reviewed. On the basis of discussion, conclusions were drawn. Relevant bibliography of the articles reviewed is annexed.

Conclusion: The onset, duration, segmental spread of sensory and motor block is rapid with hyperbaric bupivacaine. Muscle relaxation was adequate in both the groups. The spinal subarachnoid block produced by hyperbaric bupivacaine is significantly better than by giving isobaric bupivacaine.

Keywords: Segmental spread, Sensory and Motor Block, Hyperbaric Bupivacaine, Muscle Relaxation, Isobaric Bupivacaine.

Introduction

Regional anaesthesia for lower abdominal and lower limb surgeries is safer than general anaesthesia. It avoids general anaesthesia related problems such as complications of poly-pharmacy, airway manipulation, hypo- hyper ventilation, vomiting and pulmonary aspiration. It

reduces surgical stress and attenuates increase in plasma catecholamines and other stress hormones. Regional anaesthesia gives intra and post operative pain relief with full preservation of mental status and normal protective reflexes.

The SAB is the common form of centrineuraxial blockade performed for lower abdomen and lower extremity surgeries. The ensuing sensory and motor block ensures analgesia for the patient, while motor block facilitates the surgeons work. Spinal anaesthesia is a reversible interruption of nerve impulses caused by injection of local anaesthetic in sub arachnoid space. The subarachnoid block has enjoyed more than 100 years of its success. It has proved to be safe, simple, efficient and cost effective anaesthesia. Contraindications both relative and absolute are there but are rare and therefore it is a preffered technique for lower abdominal and lower extremity surgeries since long time. [1]

The physiological effects of injecting local anaesthetic drug in sub arachnoid space on the cardio- circulatory system is primarily indirect and occurs through blockade of sympathetic nervous system and includes a reflex response to the primary cardiovascular effects. Most significant easily measurable effects of Spinal Anaesthesia is changed blood pressure and pulse. The aim of all anaesthesiologists is to perform the SA with the least deviation in blood pressure. Question arises as what Local Anaesthetic should be preffered, should we consider baricity; should we consider adjuvants and what consideration should be given for onset and duration of action and cardiovascular stability.

Many people calculates everything in terms of safety as day care surgery. It requires intense analgesia for a period of 2-3hrs with relatively early onset and offset of action and maximum cardiovascular safety and toxicity of drugs. Poorer motor block to allow early ambulation. Hyperbaric means that the specific gravity of drug is higher than CSF i.e the drug is heavier than CSF hence drug spreads with gravity towards dependent part obtained by positioning.

In case of isobaric solution drug mixes equally in CSF without any change in spread with change of position after injecting the drug. Hypobaric drug floats in CSF and effect is localised. For subarachnoid block in 0.5% bupivacaine 80mg/ml dextrose has been added to make it hyperbaric. Due to its prolonged effect, hyperbaric bupivacaine is most commonly used for spinal anaesthesia however its cardiovascular and neurotoxicity is not favourable. The incidence of hypotension and bradycardia is also associated when heavy bupivacaine is used for subarachnoid block.

The isobaric solution of bupivacaine due to its limited spread seems to be safer, especially for lower abdominal and lower limb surgeries with adequate duration of action and less incidence of bradycardia and hypotension. Height of block is affected by many factors but baricity and position of patient after injection of drug is very much important. [5] The sitting position is frequently used for induction of spinal anaesthesia. Hyperbaric solutions, under the influence of gravity, would be expected to spread caudally, whereas isobaric solutions would be expected to distribute rostrally. [2, 3, 4].

Although level of block is affected by many factors but baricity is very important in determining spread of drug and consequent extent of block. It has been therefore taken into consideration to study hyperbaric and isobaric bupivacaine in subarachnoid block in the present study. The aim of all anaesthetists is to perform spinal anaesthesia with least changes in blood pressure and pulse rate- baricity plays important role. In this study therefore both isobaric and hyperbaric solution of bupivacaine has been compared in spinal subarachnoid block.

Materials and Methods

The present study entitled "Comparison of Isobaric and Hyperbaric Bupivacaine for Spinal Subarachnoid Block" was carried out in the Department of Anaesthesiology RKDF Medical College Bhopal, after approval of hospital ethics committee on 60 patients admitted in surgical and orthopaedics wards undergoing surgery on lower abdomen and lower limb under intrathecal block.

Inclusion Criteria

- A.S.A. grade I and II.
- Age between 20 – 60 years, both sexes.
- Weight between 40-70kgs, both sexes.
- Patient scheduled for elective surgery like surgery of ilioinguinal region, lower extremities and Hip under regional anaesthesia.
- Written and informed consent of patient for inclusion in study.

Exclusion Criteria:

- Patient not willing to get operated awake.
- Patients sensitive to local anaesthetic drug.
- History of allergic reaction or abnormal response during previous exposure.
- Patient on anticoagulation therapy.
- Abnormal bleeding or coagulation profile.
- Infection at the site of injection.
- Spinal abnormality like kyphosis, scoliosis, lordosis, previous spine surgery.

Procedure:

"Patient's selection and procedures will be done by consultant, researcher will make observe observations on patient".

Group A: Inj. Hyperbaric Bupivacaine – 4.0 ml + 1 ml.

Group B: Inj. Isobaric Bupivacaine – 4.0 ml.

After subarachnoid injection of drug according to assigned group, patients were observed for –

- Time of onset of sensory block
- Time of onset of motor block
- Highest dermatomal level of sensory block achieved
- Quality of motor block
- Duration of sensory block
- Duration of motor block

Using multi parameter monitor, vital parameters Pulse, B.P, ECG, R.R and SpO_2 were continuously observed. Heart rate, NIBP, R.R & SpO2 were recorded before intrathecal injection and after intrathecal injection at 1, 3, 5, 15, 20, 25 and 30 minute and then at every fifteen minutes till the end of the operation. Incidence of hypotension (M.A.P $\leq$ 70 mmHg) was treated with 500ml IV fluid bolos and incremental doses of ephedrine 6 mg and bradycardia (heart rate $\leq$ 60/min) was treated with atropine 0.6 mg I. The level of sensory block was assessed by loss of pinprick sensation using hub of 20-gauge hypodermic needle bilaterally at L1, T12, T10, T8, T6 & T4 level. For sensory block assessment reference point was T12 level. Motor block was assessed using 3 point modified Bromage scale (0 = no motor block, 1 = inability to raise extended legs, 2 = inability to flex knees, and 3 = inability to flex ankle joints). The maximum Bromage scores reached were recorded. These tests were performed every 2 min till maximum score after spinal anesthesia and postoperatively every 15 min until the sensory and motor functions were back to normal. The maximum level of sensory block, the onset time & duration of sensory and motor block was recorded. The occurrence of adverse events, that includes bradycardia, hypotension, shivering and vomiting were recorded as number of patients exhibiting these.

Observation Chart and Results

The present study entitled **"**Comparison of isobaric and hyperbaric bupivacaine for spinal subarachnoid block" was carried out after permission of Ethics committee with an aim to compare the onset and duration of sensory block, onset and duration of motor block, quality of block, hemodynamic changes occurring after administration of subarachnoid block, duration of post operative analgesia, side effects and adverse effects of hyperbaric and isobaric bupivacaine in subarachnoid block.

Table 1: Mean onset time of sensory block

OSB	Mean Time (seconds)	S.D	t	P	Significance
Group A (n=30)	90.46	9.82	9.314 (Group A & B)	0.005	(p<0.05) Highly Significant
Group B (n=30)	110.80	6.80			

The mean onset time of sensory block was 90.46±9.82 seconds in group A patients; 110.80±6.80 seconds in group B patients. The onset time of sensory block to T 12 level was assessed by pin prick method defined as time interval between injection of the drug in subarachnoid space and loss of sensation to pinprick at T 12 level. The onset time was faster in group B than in group A respectively and its highly significant (P <0.05).

Table 2: Mean duration of sensory block

Groups	Mean Time (minutes)	S.D	t	P	Significance
Group A (n=30)	294.60	30.85	-2.635	0.01	(p<0.05) Highly Significant
Group B (n=30)	271.63	36.43			

Table shows the duration of sensory block. The time interval from intrathecal administration of the drug to the point of a regression of sensory block from T12 to S1, recorded in minutes. In group A patients block regressed in 294.60±30.85 minutes, and in group B block regressed in 271.63±36.43 minutes. Statistical analysis revealed that the changes observed are highly significant (P<0.05).

Table 3: Mean onset time of motor block

OMB	Mean-Time (Seconds)	S.D	T	p	Significance (p<0.05)
Group A (n=30)	106.30	5.79	13.24	0.00	Highly Significant
Group B (n=30)	127.90	6.80			

Table shows the mean onset time of motor block in each group & is time interval between the injection of local anaesthetic solution with or without study drug till inability to move ankle, knee or flex hip (Bromage Score 3). It was recorded in seconds. Time for onset of motor block in group A patients was 106.30 ± 5.79 seconds; where as in group B patients it was 127.90 ± 6.80 seconds. The time for onset of motor block was found statistically highly significant between group A and group B.

Table 4: Mean duration of motor block

GROUPS	Mean Time (minutes)	S.D	t	P	Significance
Group A (n=30)	256.0	31.9	-1.827	0.07	(p>0.05) Not Significant
Group B (n=30)	241.1	31.3			

The duration of motor block defined as the time interval from intrathecal administration to the point at which the Bromage score was back to zero and was recorded in minutes. The mean duration of motor block was found to be 256.03 ± 31.96 minutes in group A, and in group B it was found to be 241.10 ± 31.35minutes. It was not significantly prolonged (P > 0.05) among group A and B of patients.

Table 5: Comparison of post operative analgesia

Groups	Mean Time (minutes)	S.D	T	P	Significance
Group A (n=30)	352.26	33.92	-5.008	0.005	(p<0.05) Highly Significant
Group B (n=30)	307.26	35.64			

The duration of postoperative analgesia and is defined as time interval from intrathecal administration of drug till demand of first rescue dose of analgesic, recorded in minutes. In group A patients remained pain free for 352.26 ± 33.92 minutes and in group B patients 307.26 ± 35.64 minutes. Statistical analysis revealed that the changes produced were highly significant in between group A and B.

Table 6: Incidence of side effects

Side Effects	Group A (n=30)	Group B (n=30)
Hypotension	05	00
Bradycardia	04	00
Shivering	02	03
Vomiting	01	0

Table 7: Changes in heart rate

GROUPS	Preoperative HR	After 15 min	After 30 min	After 45 min	After 60 min
Group A (n=30)	82.26±16.84	76.66±14.79	76.03±12.86	76.70±11.50	77.46±14.79
Group B (n=30)	84.46±8.23	74.66±9.93	75.56±9.40	75.90±10.0	75.10±9.91

In all patients mean heart rate (according to the paired t-test) did not change significantly. 4 patients from group A had bradycardia that is pulse rate less than 60 bpm. All patients responded to injection atropine 0. 6 mg intravenously. The changes produced in all the groups are not significant.

Table 8: Changes in mean arterial pressure.

GROUPS	Preoperative MAP(in mm Hg)	After 15 min(in mm Hg)	After 30 min(in mm Hg)	After 45 min(in mm Hg)	After 60 min(in mm Hg)
Group A (n=30)	93.33± 12.28	87.33 ±17.65	83.00± 7.28	83.16 ±8.00	86.23± 10.94
Group B (n=30)	95.86± 15.33	85.10±10.26	83.50± 10.98	83.86± 10.94	85.30± 11.19

Table no.8 shows changes observed in mean arterial pressure in group A and B patients. In 5 patients hypotension was observed in group A. It was treated when the mean arterial pressure value was lower than 70 mmHg. Patients responded to intravenous fluid bolus and injection ephedrine 6-12 mg given intravenously. The changes produced in all the groups are not significant.

Table 9: Changes in respiratory rate

GROUPS	Preoperative RESPIRATORY RATE	After 15 min	After 30 min	After 45 min	After 60 min
Group A (n=30)	12.96±0.44	12.86±0.89	13.00±0.90	12.96±0.66	12.83±O.83
Group B (n=30)	13.33±1.53	13.20±1.24	12.93±1.59	13.00±1.43	12.90±1.34

Statistical Analysis:

Study Type: Clinical observational study.

Sample Size: 60 adult patients of ASA I & II status.

Method of Randomization: Block randomization. First thirty patients received 0.5% Hyperbaric Bupivacaine 4.0 ml and Next thirty patients received 0.5% Isobaric Bipivacaine 4.0 ml. Thus two groups of patients shall be created named as A and B. Data on onset and offset characters, pulse rate, blood pressure (mean arterial pressure), postoperative pain free period, incidences of complications and other demographic details of the subject shall be recorded in pre-designed Proforma. At the end of study, data were compiled and analyzed using software SPSS version 16. P value of < 0.05 was considered significant.

Data type: The data on onset and offset character and on post operative pain free period, intraoperative hemodynamic parameters will be continuous numeric type and shall be subjected to statistical calculations by Mean and standard deviation test. In situations of wider range of observations interquartile range was quoted because standard deviation provided clinically unacceptable data.

Discussion

Martin R et al saw that onset of spinal block is more rapid with isobaric than hyperbaric bupivacaine. They were undergoing urological, gynecological, orthopedic, gastro-intestinal or vascular surgery. Using a double blind technique, the followings parameters were measured: cutaneous analgesia to pinprick, motor blockade, time for two segment regression, time for complete regression of the motor block, quality of anesthesia. They concluded that the block developed more rapidly in the isobaric group, but both isobaric and hyperbaric 9.75 mg bupivacaine produced adequate upper levels of analgesia for surgery. [6]

Phelan et al did a comparison of hyper-and isobaric solutions of bupivacaine for subarachnoid block. The comparative efficacy of two solutions of bupivacaine, 0.5% plain isobaric, and hyperbaric in 4% dextrose, for spinal anaesthesia was studied in 67 patients. Hyperbaric bupivacaine blocks a greater number of spinal segments ($p < 0.01$), causes a more rapid fall in blood pressure ($p < 0.05$), and is more predictable in effect with regard to the number of segments blocked and to the lateralisation of the block. The duration of perioperative analgesia with the hyperbaric preparation is, however, shorter — 3.8 hours as opposed to 5.8 hours ($p < 0.01$) — but this was likely to be due to the smaller total dosage of bupivacaine used in the hyperbaric group. It was concluded that either solution may be used satisfactorily in clinical practice. The isobaric solution, however, despite its ready availability, is less satisfactory than the hyperbaric because its effect with regard to the extent of blockade is less predictable. [7]

Uppal et al did a systematic review and meta-analysis for adult patients undergoing noncesarean delivery surgery using hyperbaric versus isobaric bupivacaine for spinal anesthesia. The aim of this study was to systematically review the comparative evidence regarding the effectiveness and safety of the 2 formulations when used for spinal

anesthesia Both hyperbaric bupivacaine and isobaric bupivacaine provided effective anesthesia with no difference in the failure rate or adverse effects. The hyperbaric formulation allows for a relatively rapid motor block onset, with shorter duration of motor and sensory block. The isobaric formulation has a slower onset and provides a longer duration of both sensory and motor block. Nevertheless, the small sample size and high heterogeneity involving these outcomes suggest that all the results should be treated with caution. [8]

Etemadi S et al did evaluation effectiveness and safety of hyperbaric and isobaric bupivacaine for spinal anesthesia in a systematic review and meta-Analysis. Finally, four studies required for this systematic review. Meta-analysis showed, there was no statistically significant difference between two groups about incidence of hypotension. Duration of the motor block was longer in HB group and the duration of sensory block was significantly higher with the IB vs HB with significant inverse correlation .Conclusion derived was that due to the low quality of the existing studies, sufficient evidence could not be provided and results should be treated with caution. [9]

Kokki H et al did a double-blind, randomized, parallel group, prospective comparison of isobaric and hyperbaric bupivacaine. Spread and duration of sensory block showed a similar wide scatter in both groups. The highest median level of sensory block was T4 (range T1-12) in the isobaric group and T4 (T1-7) in the hyperbaric group. Times to two segment regression of block were similar: 80 (55-190) min in the isobaric and 80 (30-190) min in the hyperbaric group. Cardiovascular stability was good. Similar study was done by Solakovic N et al.

Cameron et al used bupivacaine 0.5% plain solution was used to produce spinal analgesia on 63 occasions. In 33 patients a fixed dose of 4 ml injected at the L2/3 interspace at 0.5 ml/second produced an extent of analgesia which was directly related to patient age ($P < 0.005$). The latency was 17·3 minutes (SD 8.4) and duration of action was 286 minutes (SD 62). A second group receiving only 1 ml of solution had a much shorter duration of action (mean 154 minutes, SD 30). In 90% of patients the analgesia obtained was fully sufficient for surgery to be performed and no form of analgesic supplementation was given. On two occasions no analgesia occurred at all. Bupivacaine 0.5% plain proved to be an effective agent for subarachnoid block. The extent of analgesia was, however, poorly predictable, and even with low doses unacceptably high levels of block were sometimes achieved.

Conclusion

The onset, duration, segmental spread of sensory and motor block is rapid with hyperbaric bupivacaine. Muscle relaxation was adequate in both the groups. The incidence of hypotension and bradycardia was seen more after hyperbaric bupivacaine whereas in isobaric bupivacaine, vomiting and shivering was seen. The analgesia produced with hyperbaric solution of bupivacaine is effective and satisfactory. The spinal subarachnoid block produced by hyperbaric bupivacaine is significantly better than by giving isobaric bupivacaine.

Declarations:

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Code availability: Not applicable

Consent to participate: Consent taken

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Consent for publication: Consent taken

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