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Comparative study of 0.5% Isobaric bupivacaine(plain) and 0.5% Hyperbaric bupivacaine(Heavy) in Lower Limb/Lower abdominal and Pelvic surgeries

KEYWORDS: Isobaric,Hyperbaric, Bupivacaine,Bromage scale.

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ABSTRACT *BACKGROUND AND AIMS:*

The comparative study of 0.5% Isobaric bupivacaine and 0.5% Hyperbaric bupivacaine in lower limb/ lower abdominal and pelvic surgeries was studied to compare for the following aims

I) Onset of sensory and motor blockade
II) Duration of sensory and motor blockade
III) Intensity of motor blockade(assessed by bromage scale)
IV) Level of sensory block achieved
V) Pre-operative/intra-operative/post-operative haemodynamic changes(PR/BP/MAP)
VI) Any incidence of complications–
and inturn assess the role and usefulness of 0.5% Isobaric bupivacaine in clinical practice.

MATERIALS AND METHODS:

This study was conducted in two groups in 100 patients in the age group of 20-50Years of ASA-I status who weighted between 40-70Kgs and were of height 5'-3" to 5'-6" after pre-loading with one litre of ringer lactate.
A sterile 25G quinkie tip spinal needle, 3ml of 0.5% isobaric or 0.5% hyperbaric bupivacaine(15mg) and an autoclaved spinal pack was used.
Boyles anaesthetic machine with laryngoscope and endotracheal tubes were kept as standby before undertaking the procedure.

RESULTS:

With 0.5% hyperbaric bupivacaine,the onset of sensory/motor blockade was quicker with achievement of higher level and the duration of motor blockade was prolonged.
The degree of motor blockade was observed to be same in both the groups.
The haemodynamic/cardiovascular stability was better with 0.5% isobaric bupivacaine.

CONCLUSION:

As haemodynamic stability was seen better with 0.5% isobaric bupivacaine,it is prudent to use it in lower limb/lower abdominal and pelvic surgeries of less duration of time in patients with higher ASA status and 0.5% hyperbaric bupivacaine in surgeries where a higher level of sensory/motor blockade and more duration of time is required.

INTRODUCTION :

In certain surgical procedures, regional anaesthesia techniques have gained popularity.

Introduction of cocaine by Karl Koller in 1884 as a local analgesic was a stepping stone in the development of spinal analgesia.

Since the administration of first spinal analgesia by Sir August Bier on 16th August 1898, search is on for a new local analgesic drug to overcome the drawbacks of the existing ones and Arm the Anaesthesiologist with safe local analgesic drug.

Consequent to toxicity of cocaine the first local analgesic drugs as tropocaine(Giesel, 1891); amylocaine (Fourneau, 1904) and novacaine or Procaine (Einhorn, 1905) were discovered and used clinically for spinal analgesia.

For quite some years spinal analgesia was restricted only for surgery lasting about an hour; consequent to the short duration of action of the drugs available, Eisleb (1928) and Uhlman (1929) came out with amethocaine and percaine (cinchocaine, dibucaine or nupercaine) of which nupercaine had longer duration of action.

In recent times lignocaine (Lofgrain and Lindquist, 1943; and Gordh, 1949) was widely studied and used in clinical practice consequent to its properties like stability, rapid onset of action, low toxicity, good diffusibility and surface analgesic properties (Goldsby 1947, 1948, 1949, Bonica at al 1965).

Inspite of all the ideal properties possessed as compared to any local analgesic drug, its action was not sufficiently long, so as to give pain relief in the postoperative period.

Hence, search was continued to find out a local analgesic with sufficient duration of action for surgery and as well to spill over in the post-operative period to produce pain relief.

Mepivacaine (Egner, 1956) and prilocaine (Lofgren and Tegner, 1959) for sometime were used clinically until Bupivacaine was synthesized by Ekenstam (1959) and was clinically used by Telivuo (1963).

Over the years Bupivacaine has been used in various types

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of surgery clinically.A varied percentage of solutions as 0.5% , 0.75% and 1% were used to achieve spinal analgesia. Bupivacaine seems to be promising as far as the duration of action is concerned.

The Butyl group is present in place of methyl group in the piperidine ring of mepivacaine .

The hydrochloride salt of Bupivacaine is water soluble and stands autoclaving.

The striking feature of its duration of action would be its usefulness to spillover a good period of analgesia in the post-operative period.

Hyperbaric solutions of Bupivacaine containg 5% dextrose and 8% dextrose was used for spinal analgesia during abdominal surgery with good central neuronal blockade (Moore, 1980; Chambers at al, 1981).

Howard Jones (1930) and Etherington Wilson (1934) popularized their light spinal (Hypobaric) technique using various local anaesthetic drugs specially Nupercaine.

0.5% Isobaric Bupivacaine was given with good results for surgeries of the lower limbs / lower abdominal and perineum (Cambers WA et al, 1981).

The central Neuronal blockade produced was highly reliable and lasted between 2 to 4 hours with minimal circulatory disturbances.

This clinical study was done to compare the efficacy of 0.5% Isobaric Bupivacaine with 0.5% Hyperbaric Bupivacaine for spinal analgesia using a standard 3ml volume by injecting intrathecally between L3-L4 Lumbar inter-vertebral space with patient placed in right or left horizontal position.

MATERIAL AND METHODS :

The study was conducted in "100" patients undergoing lower limb/lower abdominal and pelvic surgeries at Nizam's Institute of Medical Sciences, Hyderabad after obtaining prior permission of the institute ethics committee and informed consent of every patient in the study and their near blood relatives.

Detailed history and clinical examinations was undertaken in all the patients such that patients with systemic disease as hypertension, diabetes mellitus and neurological problems were excluded and patients of only ASA-I status were included in the study.

All patients were investigated for complete blood picture, urine analysis, ECG and chest X-ray to rule out any organic disease and respiratory abnormality.

Patients selected were in the age group of 20-50 Years and weighed between 40-70 Kgs.

Patients below the height of 5'3" and over the height of 5'6" were excluded from the study to minimise the errors arising out of gross discrepancies in height.

No premedication was given to any of the patient in view of the fact that the premedication could alter the patients response to pin prick and assessment of the level of analgesia.

Patients were allocated to two groups each comprising of "50" patients.

In group-I 0.5% isobaric bupivacaine was used and in group-II 0.5% hyperbaric bupivacaine was used for subarchanoid block.

Before the start of the procedure, patients vital data such as pulse rate, blood pressure and respiratory rate were recorded and all patients were secured with "18 G" intravenous cannula at left dorsum of hand and were preloaded with one litre of ringer lactate prior to the subarchanoid block with 0.5% isobaric or hyperbaric bupivacaine at L3-L4 intervertebral space with 25G quinkie tip spinal needle.

EQUIPMENT – I :

Sterile 25G quinkie tip spinal needle
An autoclaved spinal tray consisting of the following-
Swab holder - one
Cotton swabs and gauze pieces
Fenestrated towel
Syringes – '2' CC - one - to give local
'5' CC - one - to give drug
File
2% Xylocaine for local infiltration
Betadine solution
Spirit
Gloves
Sterile gown
3ml of 0.5% isobaric or hyperbaric bupivacaine (15mg)

EQUIPMENT – II :

Boyles anaesthetic machine with laryngoscope and endotracheal tubes were kept as standby before undertaking the procedure.

TECHNIQUE :

Patients were explained about the procedure and were reassured and instructed not to move while performing the procedure.
All patients were placed in left lateral position with knees and head flexed to the abdomen
After scrubbing the hands thoroughly with betadine scrub and rinsing with surgical spirit, sterile gown and gloves were worn.
Patients back was thoroughly cleansed with betadine solution and followed up with surgical spirit from the angles of the scapula to sacral area and draped with sterile fenestrated towel.
The L3-4 intervertebral space is identified with the help of the imaginary line (line of tuffier) running across the highest point of iliac crests and 3 ml of 2% xylocaine is infiltrated in the space as local analgesia and then 25G quinkie tip spinal needle is introduced through this by midline approach.
Once the dura was pierced clear cerebrospinal fluid (CSF) flow was observed and the select drug 3ml of 0.5% isobaric or hyperbaric bupivacaine was injected intrathecally.
The lumbar puncture site was covered with a sterile gauze with an adhesive tape and thereafter the patient was placed in supine position immediately.
With the onset of sensory blockade to T10 level and grade-'3' motor blockade (assessed by Bromage scale) surgery was started.
The following parameters were noted →

1. Onset of sensory block as assessed by pin prick method every 30 seconds till it attained T10 level
2. Intensity and highest level of the sensory block after

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30 minutes
3. Intensity of motor blockade (as assessed by bromage scale)
4. Duration of analgesia (as assessed by two segment regression from the highest level of analgesia)
5. Duration of motor blockade (assessed by the ability of patient to move ankle and great toe)
6. Pulse rate, blood pressure and mean arterial pressure (MAP)
7. Any complications arising during the operative procedure.

OBSERVATION AND RESULTS :

From the study, following observations were made-

Out of total number of 100 patients, 50 cases received 0.5% isobaric bupivacaine (Group-I) and another 50 cases received 0.5% hyperbaric bupivacaine (Group-II) for subarchanoid block.

Drug used	No. of cases
Group-I – 0.5% isobaric bupivacaine	50
Group-II – 0.5% hyperbaric bupivacaine	50
Total	100

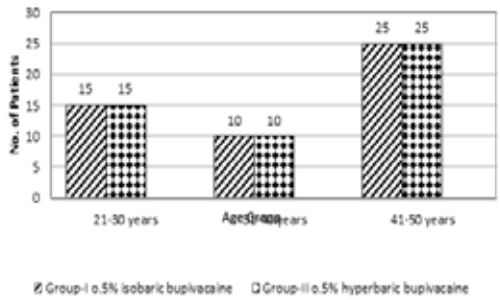
The type of surgeries performed for which 0.5% isobaric bupivacaine (Group-I) and 0.5% hyperbaric bupivacaine (Group-II) was administered is shown in the following table below-

Type of Operation	Group-I – 0.5% isobaric bupivacaine		Group-II – 0.5% hyperbaric bupivacaine	
	No. of cases	Percent	No. of cases	Percent
Orthopaedic surgeries				
Hemi-arthroplasty (AMP)	10	20.00	10	20.00
I.L Nailing tibia	10	20.00	10	20.00
Dynamic Hip Screw (DHS)	5	10.00	5	10.00
General Surgeries				
Inguinal Hernia	10	20.00	10	20.00
Appendicectomy	10	20.00	10	20.00
Hydrocele (EX and EV)	5	10.00	5	10.00
Total	50	100.00	50	100.00

The age incidence and the mean age noted in the two groups are shown in the following table and graph-

Age in years	Group-I - 0.5% isobaric bupivacaine		Group-II – 0.5% hyperbaric bupivacaine	
	No. of cases	Percent	No. of cases	Percent
21 – 30 years	15	30.00	15	30.00
31 – 40 years	10	20.00	10	20.00
41 – 50 years	25	50.00	25	50.00
Mean age	37		37	

Graph showing age distribution between Group-I and Group-II cases :



The following table and graph shows the distribution of cases in relation to their height and it was found that the mean height in both the Groups studied was comparable –

Graph showing the height distribution of Group-I and Group-II patients :

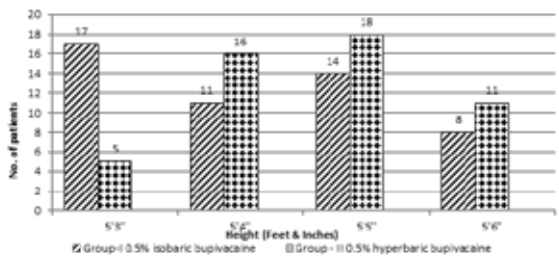


Table showing height wise distribution of cases :

Height in Feet	Group-I 0.5% isobaric bupivacaine		Group-II 0.5% hyperbaric bupivacaine	
	No. of cases	Percent	No. of cases	Percent
5′3″	17	34.00	5	10.00
5′4″	11	22.00	16	32.00
5′5″	14	28.00	18	36.00
5′6″	8	16.00	11	22.00
Mean height	5′42″		5′47″	

The following table and graph shows the distribution of cases studied in relation to weight and it was found that the mean weight in both the groups studied was comparable-

Table shows Weight wise distribution of cases :

Wright in Kgs	Group-I 0.5% isobaric bupivacaine		Group-II 0.5% hyperbaric bupivacaine	
	No. of cases	Percent	No. of cases	Percent
40-44	5	10.00	2	4.00
45-49	10	20.00	6	12.00
50-54	28	56.00	34	68.00
55-59	5	10.00	5	10.00
60-64	2	4.00	3	6.00
Mean weight (Kgs)	50.9		52.1	

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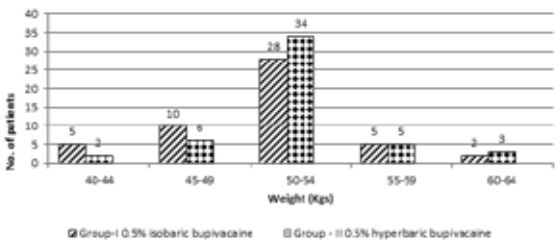
Graph showing weight distribution of Group-I and Group-II patients :



ONSET OF ANALGESIA :
In the Group-I (0.5% isobaric bupivacaine), the mean time for onset of analgesia was 13.15 minutes.

In few patients (five) onset of analgesia was as late as 25 minutes.

Five patients had analgesia extending upto only T12 after 30 minutes.

In Group-II (0.5% hyperbaric bupivacaine), the mean time for onset of analgesia was 7.2 minutes.

In three patients the onset of analgesia was delayed as late as 10 minutes, whereas in one patient onset of analgesia was as early as five minutes.

The following table shows the mean values of onset of analgesia of both the groups-

Drug	Range (minute)	Onset of sensory blockade (minute)
Group-I 0.5% isobaric bupivacaine	6-30	13.15
Group-II 0.5% hyperbaric bupivacaine	5-10	7.20

LEVEL OF SENSORY BLOCKADE :
In Group-I (0.5% isobaric bupivacaine), most of the patients had analgesia upto T9 – T10 level whereas six patients had analgesia upto T12 level only.

None of the patients had patchy, unsatisfactory or incomplete block.

In Group-II (0.5% hyperbaric bupivacaine), most of the patients had analgesia upto T7 and T8.

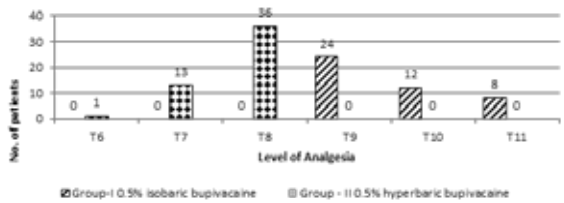
One patient had analgesia as high as T6 level.

All the patients studied in this group had level of analgesia extending beyond T10 level.

The following table and graph shows the level of analgesia in each of the groups-

Highest level of sensory block	Group-I 0.5% isobaric bupivacaine		Group-II 0.5% hyperbaric bupivacaine	
	No. of cases	Percent	No. of cases	Percent
T6	--	--	1	2.00
T7	--	--	13	26.00
T8	--	--	36	72.00
T9	24	48.00	--	--
T10	12	24.00	--	--
T11	8	16.00	--	--
T12	6	12.00	--	--

Graph showing levels of analgesia among Group-I and Group-II patients :



DURATION OF ANALGESIA :
In Group-I (0.5% isobaric bupivacaine), maximum duration of analgesia was upto 140 minutes and minimum duration was upto 60 minutes.

Mean duration of analgesia was 113 minutes.

In Group-II (0.5% hyperbaric bupivacaine), the maximum duration of analgesia was upto 160 minutes and the least duration was 100 minutes.

Mean duration of analgesia was upto 132 minutes.

The duration of analgesia was more in the Group-II when compared to Group-I

The following table shows the duration of analgesia achieved in each of the groups studied (2 segment regression)-

Drug	Range (minute)	Mean time (minute)
Group-I 0.5% isobaric bupivacaine	60-140	113
Group-II 0.5% hyperbaric bupivacaine	100-160	132

ONSET OF MOTOR BLOCKADE :
To Grade-3 was assessed by modified Bromage scale, which is as follows-

Grade-0 : no paralyses (full flexion of knees and feet)
Grade-1 : inability to raise, extend leg (just able to move knees)
Grade-2 : inability to flex knees (able to move feet)
Grade-3 : inability to flex the ankle joint (unable to move feet or knees)

This was taken as the time required from the time of injection till the patient had difficulty in moving the limbs (Bromage scale Grade-3)

In the Group-I (0.5% isobaric bupivacaine) the maximum time of onset of motor blockade was 12 minutes and maximum onset of time was 7 minutes with mean onset time of 9.16 minutes

In Group-II (0.5% hyperbaric bupivacaine) the maximum time taken for onset of motor blockade was 10 minutes and the earliest time was 5 minutes.

The Mean time of onset of motor blockade to Grade-3 was of 6.8 minutes.

The following table shows onset of motor blockade to Grade-3 (Bromage scale)-

Drug	Range (minute)	Mean time (minute)
Group-I 0.5% isobaric bupivacaine	7-12	9.16
Group-II 0.5% hyperbaric bupivacaine	5-10	6.8

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DURATION OF MOTOR BLOCKADE :
The duration of motor blockade which is taken as the time interval from the commencement of Grade-3 (Bromage scale) motor blockade to till the patients was able to move ankle and great toe.

In Group-I (0.5% isobaric bupivacaine) the duration of motor blockade was of the range between 150-260 minutes in all the patients with the mean value of 226.8 minutes.

In Group-II (0.5% hyperbaric bupivacaine) the maximum duration of motor blockade was between 210-260 minutes with mean duration of 229 minutes.

In both the groups there was no significant difference in the duration of motor blockade.

The following table shows the duration of motor blockade of both the groups-

Drug	Range (minute)	Mean time (minute)
Group-I 0.5% isobaric bupivacaine	150-260	226.8
Group-II 0.5% hyperbaric bupivacaine	210-260	229

HAEMODYNAMIC CHANGES IN BOTH THE GROUPS :
In Group-I (0.5% isobaric bupivacaine) cases, the average fall in the systolic blood pressure was of the order of 13.75%, whereas in Group-II it was 20.32%

In Group-I cases, the average fall in diastolic pressure was of 14.6% whereas in Group-II the diastolic pressure fall was to an average of 18.1% .

The calculated mean arterial pressure reduced by an average of 12.3% in Group-I, whereas it was reduced to 14.48% in Group-II.

The following table shows systolic, diastolic and mean arterial pressure before and after subarchanoid block-

Blood pressure	Group-I 0.5% isobaric bupivacaine			Group-II 0.5% hyperbaric bupivacaine		
	Before block	Lowest	Percent fall	Before block	Lowest	Percent fall
Systolic pressure (mm Hg)	128.0	110.4	13.75	125.6	110.2	12.26
Diastolic pressure (mm Hg)	79.6	67.92	14.6	80.0	65.52	18.1
Mean arterial pressure (mm Hg)	96.49	84.62	12.3	95.83	81.95	14.48

COMPLICATIONS :
Two patients in Group-I and three patients in Group-II had vomiting and nausea in post-operative period.

DISCUSSION:
The study was undertaken in "100" selected patients undergoing lower limb/lower abdominal and pelvic surgeries and were allotted to two groups of "50" patients each.

In Group-I patients, 0.5% isobaric bupivacaine was used and in Group-II patients 0.5% hyperbaric bupivacaine was used to produce subarchanoid block with a standard 3ml volume injected intrathecally between L3-4 space in right or left lateral position in all the patients of both the groups.

The mean age of the patients studied in both the groups were same (37 years) such that age was not a criteria for any variation of the parameters studied and as well the type of surgeries were almost identical in both the groups.

Mean height was also identical (5'4.2" in Group-I and 5'4.7" in Group-II) so as to avoid variation in the levels of analgesia achieved.

In both the groups the mean weight (50.9 in Group-I and 52.1 in Group-II) was identical such that weight of patient did not have any effect on the levels of the subarchanoid block.

ONSET OF SENSORY BLOCKADE:
In our study onset of cephalad spread of analgesia to T10 levels was taken as the criteria.

In 0.5% isobaric bupivacaine group (Group-I) mean onset of time was 13.5 minutes whereas the mean onset of time of analgesia in the 0.5% hyperbaric bupivacaine group (Group-II) was 7.2 minutes.

The study revealed a significant difference in the time of onset of sensory blockade between 0.5% isobaric and hyperbaric bupivacaine groups.

Inspite of lower spread of pinprick analgesia in Group-I cases with 0.5% isobaric bupivacaine, sufficient sensory blockade was obtained for lower limb/lower abdominal and pelvic surgeries.

MAXIMUM LEVEL OF SENSORY BLOCKADE:
In our study with 0.5% isobaric bupivacaine (Group-I), it was found in 80% of patients, the level of analgesia increased one to two segments higher than what was noted (T12 level), at the end of 30 minutes (T10 levels).

In 20% of patients, the level of block was only upto T12.

Maximum spread of analgesia was with 0.5% hyperbaric bupivacaine (Group-II) and the level of sensory block extended to two to four segments higher after 30 minutes (T6-T8) in this group also.

DURATION OF SENSORY BLOCKADE:
The duration of analgesia, which is taken as two segments regression from the highest level of analgesia, was within a range of 60-140 minutes with a mean time of 113 minutes with 0.5% isobaric bupivacaine (Group-I).

In 0.5% isobaric bupivacaine group (Group-II) the duration of sensory blockade was within a range of 100-160 minutes with a mean time of 132 minutes.

ONSET OF MOTOR BLOCKADE:
In this study the time required for complete motor blockade (bromage scale Grade-3) was between 7-12 minutes with a mean time of 9.16 minutes in 0.5% isobaric bupivacaine group (Group-I) whereas in the 0.5% hyperbaric bupivacaine group (Group-II), the range was between 5-10 minutes and the mean time was 6.8 minutes.

DURATION OF MOTOR BLOCKADE:
In both the groups the degree of motor blockade was of Grade-3 (Bromage scale).

Mean duration of motor blockade in the 0.5% isobaric bupivacaine group (Group-I) was 226.8 minutes whereas

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in the 0.5% hyperbaric bupivacaine group (Group-II) it was 229 minutes.

HAEMODYNAMIC CHANGES:
The fall in blood pressure was found in both the groups but more in Group-II (0.5% hyperbaric bupivacaine group).

No significant hypotension (below 80mmHg) was observes in either of the groups.

In Group-I (0.5% isobaric bupivacaine), the fall of mean systolic blood pressure was 17.6 mmHg (13.75%) and in Group-II (0.5% hyperbaric bupivacaine), it was 25.3mmHg (20.32%).

The fall in mean diastolic pressure was 11.68 mmHg (14.6%) and 14.48 mmHg (18.1%) in the Group-I and Group-II respectively.

No significant bradycardia (i.e, below 60 per minute pulse rate) was observed.

SUMMARY AND CONCLUSSION:
A clinical study was undertaken in "100" patients of ASA-I status.

They were allotted to two groups of "50" patients in each group.

In Group-I patients received subarchanoid block with 3ml (15mg) of 0.5% isobaric bupivacaine and in Group-II patients were given 3ml (15mg) of 0.5% hyperbaric bupivacaine.

In both the groups the drug was injected intrathecally with 25G quinkie tip spinal needle at L3-4 space in right or left lateral positions.

This study was done to evaluate regarding usefulness of 0.5% isobaric bupivacaine in comparison to that of 0.5% hyperbaric bupivacaine.

Patients studied in each of the group were of similar mean age, weight and height, hence did not come in the way of comparison.

Onset of sensory and motor blockade was delayed with 0.5% isobaric bupivacaine when compared to 0.5% hyperbaric bupivacaine.

The level and duration of sensory blockade was lesser with 0.5% isobaric bupivacaine, whereas 0.5% hyperbaric bupivacaine gave a consistently higher level.

The onset of motor blockade was quicker and the duration of motor blockade was prolonged with 0.5% hyperbaric bupivacaine in comparison with 0.5% isobaric bupivacaine.

The degree of motor blockade was observed to be same in both the groups.

The cardiovascular effects were less with 0.5% isobaric bupivacaine than with 0.5% hyperbaric bupivacaine, but there was no significant hypotension in any of the groups, which could be due to preloading with one litre of ringer lactate prior to subarchanoid block and as well due to infusion of ringer lactate intraoperatively.

In conclusion when given for subarchanoid block, 3ml of 0.5% hyperbaric bupivacaine produces significantly higher cephalad spread of sensory and motor blockade compared to 3ml of 0.5% isobaric bupivacaine in which the level of analgesia was found to be unpredictable.

With 0.5% hyperbaric bupivacaine there was predictable levels of analgesia and a higher spread after 30 minutes there was complete motor blockade of the lower limbs in both the groups (0.5% isobaric and 0.5% hyperbaric groups).

The cardiovascular stability was more in 0.5% isobaric bupivacaine group than in 0.5% hyperbaric bupivacaine group, hence it is preferable to use 0.5% isobaric bupivacaine in lower limb/lower abdominal and pelvic surgeries of less duration of time, in patients with higher ASA status and 0.5% hyperbaric bupivacaine in surgeries were a higher level of sensory/motor blockade and more duration of time is required.

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CONFLICTS OF INTEREST:
There are no conflicts of interest

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