

A Study on Haemodynamic Changes in Plain and Hyperbaric Solution of Ropivacaine for Spinal Anaesthesia

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Abstract

Background: Historically bupivacaine was used as it had a long duration of action, but subsequently it was found that “propyl derivatives” of pipercoloxylidides were less toxic than ‘butyl derivatives’ (bupivacaine). Thus ropivacaine was developed after bupivacaine was noted to be associated with significant number of cardiac arrests. **Subjects and Methods:** A comparative study of plain and hyperbaric solution of ropivacaine for spinal anaesthesia in minor gynaecological and urological procedures was undertaken in 60 patients. Patients were randomized in to two groups with 30 patients in Group H (2ml of 0.75% plain ropivacaine and 1ml of 25% dextrose) and 30 patients in Group P (2ml of 0.75% ropivacaine and 1ml of 0.9% normal saline). The onset and duration of sensory and motor blockade, sensory level achieved, and haemodynamic parameters were assessed. **Results:** The mean age of patients in group H was 45.83 ± 5.43 years compared to 45.76 ± 6.97 years in group P. In group H there were 11 males (37%) and 19 females (63%). In group P there were 10 males (33%) and 20 females (67%). The mean height of the patients in group H was 157.20 ± 5.06 cms and in group P was 159.70 ± 7.78 cms. The mean weight of the patients in group H was 56.63 ± 6.46 kgs and in group was 59.07 ± 7.53 . There was no statistically significant difference between the two groups with regard to age, sex, height and weight ($p > 0.05$). Both the groups were comparable with respect to age, sex, height and weight distribution. **Conclusion:** There was no significant change in systolic blood pressure following subarachnoid block in both groups. The systolic blood pressure values were comparable in both groups without any clinical or statistical significance.

Keywords: Haemodynamic Changes, Hyperbaric Solution of Ropivacaine, Spinal Anaesthesia.

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Received: July 2019

Accepted: July 2019

Introduction

Spinal anesthesia consists of the temporary interruption of nerve transmission within the subarachnoid space produced by injection of local anesthetic solution into CSF. Used widely, safely and successfully spinal anesthesia has many potential advantages over general anesthesia, especially for operations involving the lower abdomen, the perineum and the lower extremities.

These effects are due to sympathectomy that accompanies the technique and depends on height of the block, which typically described as extending from two to six dermatomes above the sensory level with spinal anesthesia.^[1]

This sympathectomy causes venous and arterial dilatation, but because of the large amount of the blood (75% of total blood volume) and limited amount of smooth muscles in the venous system venodilation effect predominates. In contrast smooth muscle tone on arterial side is retained to some extent. After neuraxial block if cardiac output is maintained, fall in peripheral vascular resistance is 15% to 18%, in elderly with cardiac disease vascular resistance may decrease 25%.

Heart rate during high neuraxial blockade typically decreases

as result of blockade cardioaccelerator fibers rising from T1 to T4. The heart rate may decrease because of a fall in right atrial filling, which decreases outflow from intrinsic chronotropic stretch receptors located in the right atrium and great veins.

Alterations in pulmonary variables in healthy patients during neuraxial block are usually of little consequence. Tidal volume remains unchanged during high spinal anesthesia, and vital capacity decreases a small amount 4.05 to 3.73L. This decrease in vital capacity is a result of a decrease in expiratory reserve volume related to paralysis of the abdominal muscles necessary for forced expiration rather than a decrease in phrenic or diaphragmatic function.^[2]

The rare respiratory arrest associated with spinal anesthesia is also unrelated to phrenic or inspiratory dysfunction but rather to hypoperfusion of the respiratory centers in the brainstem. This concept is supported by the evidence of disappearance of apnea as soon as pharmacologic and fluid therapies have restored cardiac output and blood pressure. This would not be the case if phrenic paralysis induced by high level of local anaesthetic was the cause of apnea.

Neuraxial block should be used cautiously in respiratory cripples because of paralysis of respiratory muscles. Except for severely compromised patients with respiratory failure,

inspiratory muscle function during neuraxial blocks should be adequate to maintain ventilator function.^[3]

Nausea and vomiting may be associated with neuraxial block in up to 20% of patients and are primarily related to gastrointestinal hyper peristalsis caused by unopposed parasympathetic activity. This gastrointestinal hyper peristalsis has the advantage of providing excellent surgical conditions because of a contracted gut. The decrease in hepatic blood flow during spinal anesthesia parallels the decrease in mean arterial blood pressure. When epidural analgesia is continued into post-operative period, there may be a protective effect on the gastric mucosa because intramucosal pH is higher during post-operative epidural analgesia than systemic analgesia.^[4]

Despite predictable decrease in renal blood flow accompanying neuraxial blockade, the decrease is of little physiologic importance. one aspect of genitourinary function that is of clinical importance is the belief that neuraxial blocks are a frequent cause of urinary retention, which delays discharge of outpatients and necessitates bladder catheterization in inpatients. Lower concentrations of local anaesthetics are necessary for paralysis of bladder function than for motor block in lower extremities.

In any case it is prudent to avoid administration of excessive volumes of crystalloid solutions under spinal anesthesia and to individualize the requirement for voiding before discharge in low risk ambulatory surgery patients after short acting spinal anaesthetics.

Spinal anesthesia have been shown to inhibit many endocrine metabolic changes associated with stress response, the effect is greatest with lower abdomen and lower extremity procedures than upper abdominal and thoracic procedures.^[5]

Ropivacaine is a new long acting local anaesthetic drug belonging to the amino amide group. Though it was synthesized by Ekenstam in 1957 and belongs to the same group as that of bupivacaine and mepivacaine, pipicoloxylidides local anaesthetics, ropivacaine was introduced to clinical practice in 1996.

Historically bupivacaine was used as it had a long duration of action, but subsequently it was found that “propyl derivatives” of pipicoloxylidides were less toxic than ‘butyl derivatives’ (bupivacaine). Thus ropivacaine was developed after bupivacaine was noted to be associated with significant number of cardiac arrests. Despite being in the market for close to three decades internationally, it was only introduced into the Indian market very recently in 2009.^[6]

It is the first local anaesthetic to be presented as an almost pure S-enantiomer (> 99% pure). It is used as local anaesthetic, including infiltration, nerve block, epidural and of late for intrathecal anaesthesia in adults and children over 12 years of age. It is also used for peripheral nerve blocks and caudal epidural in children 1 – 12 years of age for surgical pain relief.

Subjects and Methods

Source of data:

A randomized study was conducted on 60 patients admitted at Medical college, Hospital and Research Center, undergoing spinal anaesthesia for minor gynaecological and urological surgeries.

Inclusion Criteria

- ASA physical status I & II, patients undergoing spinal anaesthesia for minor gynaecological and urological surgeries.
- Valid informed/explained consent.

Exclusion criteria

- History of drug hypersensitivity to local anaesthetics.
- Active disease of central nervous system such as meningitis, poliomyelitis, intracranial haemorrhage, sub-acute combined degeneration of spinal cord.
- Spine deformities.
- Septicemia.
- Pyogenic infection of the skin at or adjacent to the site of lumbar puncture.
- Cardiogenic or hypovolumic shock.
- Coagulation disorders.

Method:

Sixty patients were randomly divided into two groups of thirty each.

Group P: Thirty patients received 3ml of injection 0.5% plain ropivacaine (2ml of 0.75% plain ropivacaine and 1 ml of 0.9% normal saline) intrathecally. Solution was prepared aseptically immediately before injection.

Group H: Thirty patients received 3ml of 0.5% hyperbaric ropivacaine (2ml of 0.75% plain ropivacaine and 1ml of 25% dextrose) intrathecally. Hyperbaric ropivacaine was aseptically prepared immediately before the injection.

Results

A comparative study of plain and hyperbaric solution of ropivacaine for spinal anaesthesia in minor gynaecological and urological procedures was undertaken in 60 patients. Patients were randomized in to two groups with 30 patients in Group H (2ml of 0.75% plain ropivacaine and 1ml of 25% dextrose) and 30 patients in Group P (2ml of 0.75% ropivacaine and 1ml of 0.9% normal saline). The onset and duration of sensory and motor blockade, sensory level achieved, and haemodynamic parameters were assessed.

Table 1: ASA distribution of patients studied

ASA grade	Hyperbaric ropivacaine	Isobaric ropivacaine	p-value
I	23	24	P=0.75
II	7	6	

ASA grade is statistically similar between both the groups (p=0.75).

Table 2: Demographic characteristics of the patients studied.

Variable	Hyperbaric ropivacaine	Plain ropivacaine	p-value
Age (year)	45.83 ± 5.43	45.76 ± 6.97	P=0.96
Sex (M/F)	11(37%) / 19 (63%)	10 (33%) / 20 (67%)	P=0.78
Weight (kg)	56.63 ± 6.46	59.07 ± 7.53	P=0.18
Height (cms)	157.20 ± 5.06	159.70 ± 7.78	P=0.14

The mean age of patients in group H was 45.83 ± 5.43 years compared to 45.76 ± 6.97 years in group P. In group H there

0 were 11 males (37%) and 19 females (63%). In group P there were 10 males (33%) and 20 females (67%). The mean height of the patients in group H was 157.20 ± 5.06 cms and in group P was 159.70 ± 7.78 cms. The mean weight of the patients in group H was 56.63 ± 6.46 kgs and in group was 59.07 ± 7.53 . There was no statistically significant difference between the two groups with regard to age, sex, height and

weight ($p > 0.05$). Both the groups were comparable with respect to age, sex, height and weight distribution.

There was no significant change in spo2 following subarachnoid block in both groups. The spo2 values were comparable in both groups without any clinical or statistical significance.

Table 3: Comparison of spo2 in two groups

SpO2 (In %)	hyperbaric ropivacaine	isobaric ropivacaine	Mean difference	95 % CI of difference	t-value	p-value
Pre op	98.60 ± 0.49	98.60 ± 0.49	0.00	-0.25 - 0.25	0.0	P=0.99
5	98.63 ± 0.49	98.70 ± 0.46	0.07	-0.31 - 0.18	0.54	P=0.59
10	98.60 ± 0.49	98.67 ± 0.47	0.07	-0.31 - 0.18	0.53	P=0.60
15	98.53 ± 0.51	98.70 ± 0.46	0.17	-0.42 - 0.08	1.32	P=0.19
20	98.70 ± 0.46	98.76 ± 0.43	0.07	-0.29 - 0.16	0.58	P=0.56
30	98.47 ± 0.51	98.50 ± 0.51	0.03	-0.29 - 0.23	0.25	P=0.80

Table 4: Comparison of pulse rate in two groups

Pulse Rate (beats/min)	hyperbaric ropivacaine	isobaric ropivacaine	Mean difference	95 % CI of difference	t-value	p-value
Pre op	78.23 ± 6.65	79.10 ± 7.23	0.86	-4.45 - 2.72	0.48	P=0.63
5	79.43 ± 6.71	76.63 ± 9.24	2.80	-1.38 - 6.98	1.34	P=0.18
10	79.20 ± 7.66	76.17 ± 9.66	3.033	-1.47 - 7.54	1.35	P=0.18
15	79.53 ± 6.65	75.90 ± 9.44	3.63	-0.59 - 7.86	1.72	P=0.09
20	78.07 ± 7.0	75.7 ± 10.8	2.33	-2.39 - 7.06	0.99	P=0.33
30	81.20 ± 7.48	77.2 ± 10.3	4.0	-0.67 - 8.67	1.72	P=0.09

Table 5: Comparison of systolic blood pressure in two groups

Systolic Blood Pressure (mmHg)	hyperbaric ropivacaine	isobaric ropivacaine	Mean difference	95 % CI of difference	t-value	p-value
Pre op	122.73 ± 8.03	123.43 ± 8.11	0.70	-4.87 - 3.47	0.34	P=0.74
5	113.53 ± 6.70	115.17 ± 6.78	1.63	-5.12 - 1.85	0.94	P=0.35
10	110.73 ± 6.16	112.70 ± 6.73	1.97	-5.30 - 1.36	1.18	P=0.24
15	112.03 ± 7.11	117.30 ± 7.89	5.23	1.38 - 9.15	2.72	P=0.009
20	112.87 ± 7.62	116.9 ± 10.5	4.03	0.72 - 8.79	1.70	P=0.09
30	114.40 ± 8.39	116.3 ± 11.5	1.90	-7.13 - 3.33	0.73	P=0.46

Table 6: Comparison of diastolic blood pressure in two groups

Diastolic Blood Pressure (mmHg)	hyperbaric ropivacaine	isobaric ropivacaine	Mean difference	95 % CI of difference	t-value	p-value
Pre op	78.47 ± 4.78	79.37 ± 4.92	0.90	-3.41 - 1.61	0.72	P=0.47
5	74.93 ± 4.95	76.37 ± 5.30	1.43	-4.08 - 1.22	1.08	P=0.28
10	72.60 ± 5.73	72.87 ± 5.22	0.27	-3.10 - 2.56	0.19	P=0.85
15	71.67 ± 4.67	73.37 ± 4.63	1.70	-4.10 - 0.70	1.42	P=0.16
20	71.80 ± 5.31	71.73 ± 4.95	0.07	-2.58 - 2.72	0.05	P=0.96
30	69.33 ± 6.98	68.80 ± 5.56	0.53	-2.73 - 3.79	0.33	P=0.74

Table 7: Comparison of mean arterial pressure in between two groups.

Mean arterial pressure (mmHg)	hyperbaric ropivacaine	isobaric ropivacaine	Mean difference	95 % CI of difference	t-value	p-value
Pre op	93.39 ± 5.39	93.97 ± 4.82	0.58	-3.22 - 2.06	0.44	P=0.66
5	87.97 ± 4.55	89.11 ± 4.19	1.14	-3.39 - 1.12	1.01	P=0.32
10	85.14 ± 5.26	86.09 ± 4.62	0.95	-3.51 - 1.61	0.75	P=0.46
15	85.25 ± 4.87	87.65 ± 4.11	2.40	0.07 - 4.73	2.06	P<0.04
20	85.37 ± 5.70	87.20 ± 4.83	1.83	-4.56 - 0.90	1.34	P=0.18
30	84.16 ± 6.35	84.76 ± 5.47	0.60	-3.66 - 2.46	0.39	P=0.69

[Table 4] There was no significant change in heart rate following subarachnoid block in both groups. The heart rates were comparable in both groups without any clinical or statistical significance.

[Table 5] There was no significant change in systolic blood pressure following subarachnoid block in both groups. The systolic blood pressure values were comparable in both groups without any clinical or statistical significance.

[Table 6] There was no significant change in diastolic blood pressure following subarachnoid block in both groups. The diastolic blood pressure values were comparable in both

groups without any clinical or statistical significance.

There was no significant change in mean arterial pressure following subarachnoid block in both groups. The mean arterial pressure were comparable in both groups without any clinical or statistical significance.

Discussion

Spinal anaesthesia is a safe, inexpensive and easy-to-administer technique which also offers a high level of post-anaesthesia satisfaction for patients. Spinal anaesthesia consists

of the temporary interruption of nerve transmission within the subarachnoid space produced by injection of a local anesthetic solution into cerebrospinal fluid. The risk of general anesthesia, including mishaps due to airway management and side effects due to multiple drugs can be avoided by this technique. Spinal anesthesia has many potential advantages over general anesthesia, especially for operations involving the lower abdomen, the perineum and the lower extremities.

Ropivacaine is an *s*-enantiomer of bupivacaine is being used for spinal anaesthesia in,^[7] lower abdominal and perineal surgeries, lower limb surgeries including caesarean section. Major advantage is shorter duration of motor block compared to bupivacaine.^[8,9] Thus it minimizes the psychological discomfort of being immobile for long time. And also Ropivacaine is less cardiotoxic than bupivacaine.^[10]

These advantages made ropivacaine a better alternative to bupivacaine in day care surgeries. However, there are only few data comparing the actions of plain and hyperbaric solutions of this drug. Hence the current study was designed to compare the plain and hyperbaric solution of ropivacaine for spinal anaesthesia in minor gynaecological and urological surgeries and to prove their usefulness in day care setting.

A prospective randomized controlled double blind study was conducted involving 60 patients belonging to ASA grade I & II coming for minor gynaecological and urological surgeries. They were randomly divided into 2 groups of 30 each. Group P received 3ml of injection 0.5% plain ropivacaine (2ml of 0.75% plain ropivacaine and 1 ml of 0.9% normal saline) intrathecally, Group H received 3ml of 0.5% hyperbaric ropivacaine (2ml of 0.75% plain ropivacaine and 1ml of 25% dextrose). All patients were premedicated and preloading was done with 500 ml of ringer lactate. Following institution of subarachnoid block sensory characteristics such as onset of sensory block, duration of sensory block were studied. Motor blockade characteristics such as onset of motor block, duration of motor block were studied. Hemodynamic parameters like heart rate, NIBP and SpO₂ were monitored at 0,5,10,15,20,30 min.

Demographic parameters in both groups were comparable. Onset of sensory and motor blockade is faster in Group H compare to Group P. Whereas, total duration (S1 regression) of sensory block and motor block were significantly shorter in Group H compared to Group P. Hemodynamic parameters were comparable in both the groups with magnitude of fall in blood pressure being similar.

Fettes,^[11] and colleagues in their study found that Cardiovascular changes were unremarkable throughout, and similar in the two groups. McNamee,^[12] and colleagues

compared 0.75% isobaric ropivacaine versus 1% isobaric ropivacaine in patients undergoing total hip arthroplasty and found that in terms of safety, both doses of intrathecal ropivacaine provided a high degree of cardiovascular stability with a low incidence of bradycardia. In our study also there is no significant difference found in the haemodynamic parameters in between two groups.

Conclusion

Hemodynamic parameters were comparable in both the groups with magnitude of fall in blood pressure being similar.

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How to cite this article: Waris I, Khan KDI. A Study on Haemodynamic Changes in Plain and Hyperbaric Solution of Ropivacaine for Spinal Anaesthesia. *Acad. Anesthesiol. Int.* 2019;4(2):48-51.

DOI: dx.doi.org/10.21276/aan.2019.4.2.12

Source of Support: Nil, **Conflict of Interest:** None declared.