The Study Isobaric 0.75% Ropivacaine 3.5ml (26.25mg) Intrathecally for Lower Limb Surgeries to Evaluate Perioperative Hemodynamic Stability

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Abstract

Background: The purpose of the study is Isobaric 0.75% Ropivacaine 3.5ml (26.25mg) Intrathecally for Lower Limb Surgeries to Evaluate Perioperative Hemodynamic. Fifty patients admitted to our hospital undergoing lower extremity surgeries under spinal anesthesia. Subjects and Methods: Pre-anesthetic assessment was done prior to the day of surgery which included past history of chronic illness and medication, drug therapy (especially corticosteroids, anti hypertensive, anti coagulant, anti diabetic, anti convulsant medications), drug sensitivity and past anesthetic experience along with routine investigations including, haemoglobin, random blood sugar, serum urea, serum creatinine, and serum electrolytes, chest X-ray, ECG. Fifty patients admitted to our hospital undergoing lower extremity surgeries under spinal anesthesia included in the study. Results: Patients in the age group 18 – 60 years were selected including 45 males and 5 females. Thirty-Nine patients had an ASA grade I and 11 patients had an ASA grade II. The duration of surgeries ranged from 45 to 270 minutes & there were no significant changes in the pulse rate perioperatively. Conclusion: A study was conducted in 50 patients belonging to ASA grade I and II posted for lower limb surgeries. They received 3.5ml of 0.75% isobaric Ropivacaine in L2-3 interspace. All patients were preloaded with 1000 ml of ringer lactate. Following institution of subarachoid block sensory characteristics such as onset of sensory block, maximum level achieved, duration of sensory block and request for first dose of rescue analgesics were studied. We found the requirement for postoperative analgesics was 218.97 minutes. Hemodynamic parameters were stable in most of the patients. Postoperative side effects included shivering, nausea. Thus we conclude that isobaric 0.75% ropivacaine 26.25 mg, 3.5 ml when administered intrathecally in L2-3 interspace provides an adequate sensory block for lower limb surgeries, which makes it a good choice for lower limb surgeries with benefits of early ambulation.

Keywords: Ropivacaine, Intrathecally, Lower Limb & Surgeries.

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Introduction

Bupivacaine aminoamide local anesthetic was first described by A Ekenstam in 1957. It has been used successfully for spinal anesthesia in either a glucose-free or a hyperbaric solution. It produces sensory and motor block for a longer duration. It is still widely used but has been associated with fatal cardiac and neurological toxicity when given intravascularly accidentally.[¹]

Ropivacaine is a long-acting regional anesthetic drug that is structurally related to Bupivacaine. Bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles. It provides long-lasting block. The reduced toxic potential is strongly supported by animal and volunteer studies, resulting not only in higher plasma concentrations and doses before signs of systemic toxicity but also in no cardiovascular toxicity or minimal signs of cardiac effects after CNS toxicity occurs.[²]

Ropivacaine shows a more reliable differentiation between sensory and motor block, making early mobilization possible. Extensive clinical data have shown that it has been used safely and effectively for local infiltration, epidural and peripheral nerve blocks. However, the experience of intrathecal anesthesia with ropivacaine is not documented. In vivo studies in dogs and mice have indicated that, at equal drug concentrations, ropivacaine was less potent and had a shorter duration of a motor block than bupivacaine after spinal administration.[³]

One of the most essential properties of long-acting local anesthesia is to reversibly inhibit the nerve impulses, thus causing a prolonged sensory or motor blockade appropriate in different types of surgeries. The acute pain relief obtained at lower doses in postoperative and labor patients due to sensory blockade is sometimes marred by accompanying
motor blockade, which serves no purpose and is quite undesirable.[5] The clinical efficacy and safety of 3.5 mL 0.75% (26.25 mg.) glucose-free ropivacaine as a local anesthetic for spinal anesthesia in patients undergoing lower limb surgeries.

Subjects and Methods

This study was conducted at Gajira Raja Medical College, Gwalior from Jul 2018 to June 2019, after approval from the ethical committee. Fifty patients admitted to our hospital undergoing lower extremity surgeries under spinal anesthesia included in the study. Pre-anesthetic assessment was done prior to the day of surgery which included past history of chronic illness and medication, drug therapy (especially corticosteroids, anti hypertensive, anti coagulant, anti diabetic, anti convulsant medications), drug sensitivity and past anesthetic experience along with routine investigations including, haemoglobin, random blood sugar, serum urea, serum creatinine, and serum electrolytes, chest X-ray, ECG.

Inclusion Criteria
1. Age- 18-60 years
2. ASA Grade – I and II
3. Lower limb surgeries
4. Valid informed consent

Exclusion Criteria
1. Hematologic disease.
2. Bleeding and coagulation abnormalities
3. Cardiac and respiratory diseases
4. History of allergy to local anesthetics
5. Pregnancy, Pediatric age group, Geriatric age group
6. Local infection in the lumbar region

The pre-anesthetic assessment was done before the day of surgery which included in the history of chronic illness and medication, drug therapy (especially corticosteroids, anti hypertensive, anti coagulant, anti diabetic, anti convulsant medications), drug sensitivity and past anesthetic experience along with routine investigations including, haemoglobin, random blood sugar, serum urea, serum creatinine, and serum electrolytes, chest X-ray, ECG. Informed and written consent after explaining the process to the patients. A thorough general, physical examination of all systems was carried out. The nature of the procedure was explained to the patients, informed and written consent.

Results

Table 1: Demographic data

| Parameters          | No. of patientsn = 50 (100%) |
|---------------------|------------------------------|
| Age (mean)          | 45 (90.10)                   |
| Sex (M/F)           | 45:5 (90:10)                 |
| ASA Grade (I/II)    | 39:11 (78:22)                |
| Duration of surgery (in mins) | 45-270(114.66 mins)(S.D. 49.33) |

Patients in the age group 18 – 60 years were selected including 45 males and 5 females. Thirty-Nine patients had an ASA grade I and 11 patients had an ASA grade II. The duration of surgeries ranged from 45 to 270 minutes.

Perioperative hemodynamic monitoring

Table 2: Perioperative pulse rate changes

| Time (in mins) | Pulse rate (Mean) | S.D. |
|----------------|-------------------|------|
| 0              | 92.86             | 17.50|
| 2              | 95.08             | 17.84|
| 5              | 92.14             | 15.57|
| 10             | 90.54             | 14.58|
| 15             | 89.86             | 15.88|
| 20             | 86.88             | 15.11|
| 25             | 86.28             | 15.98|
| 30             | 85.46             | 14.26|
| 45             | 85.36             | 14.60|
| 60             | 86.14             | 15.31|
| 120            | 84.82             | 12.94|
| 180            | 86.79             | 12.50|
| 240            | 85.23             | 12.23|
| 300            | 86.84             | 13.44|
| 360            | 80.37             | 8.9  |

There were no significant changes in the pulse rate perioperatively.

Eight patients had intraoperative hypotension was managed by mephentermine 6mg. Bradycardia occurred in 3 patients, they were given atropine sulfate 0.6mg IV. None of the patients had hypotension or bradycardia in the post-operative period. Two patients had intraoperative shivering. Postoperatively complications like shivering, nausea and headache were reported in one patient each.

Table 3: Perioperative systolic pressure changes

| Time (in mins) | Systolic pressure (Mean) | S.D. |
|----------------|--------------------------|------|
| 0              | 123.78                   | 13.12|
| 2              | 124.4                    | 14.23|
| 5              | 118.26                   | 12.95|
| 10             | 115.82                   | 12.63|
| 15             | 115.44                   | 13.02|
| 20             | 117.04                   | 14.51|
| 25             | 114.76                   | 12.76|
| 30             | 115.46                   | 14.65|
| 45             | 115.86                   | 14.25|
| 60             | 116.74                   | 12.48|
| 100            | 116.82                   | 11.78|
| 180            | 117.79                   | 10.64|
| 240            | 119                      | 7.21 |
| 300            | 119.69                   | 8.0  |
| 360            | 117.75                   | 7.36 |

Table 4: Perioperative diastolic pressure changes

| Time (in mins) | Diastolic pressure (Mean) | S.D. |
|----------------|---------------------------|------|
| 0              | 76.72                     | 10.34|
| 2              | 76.16                     | 9.19 |
| 5              | 73.3                      | 10.19|
| 10             | 71.96                     | 12.68|
| 15             | 73.12                     | 10.80|
| 20             | 72.82                     | 10.19|
| 25             | 71.72                     | 10.60|
| 30             | 70.6                      | 11.06|
| 45             | 72.76                     | 10.21|
| 60             | 73.26                     | 8.9  |
| 120            | 75.12                     | 7.5  |
| 180            | 75.54                     | 7.13 |
| 240            | 75.31                     | 6.60 |
| 300            | 77.07                     | 5.07 |
| 360            | 76.62                     | 4.43 |
Discussion

Mc Namee et al.[5] found both intrathecal ropivacaine and bupivacaine produced an initial moderate fall in the arterial pressure keeping with the expected sympathetic block produced by spinal anesthesia. Intraoperative hypotension requiring ephedrine occurred in 12% and 26% respectively of patients. Two patients in the ropivacaine group also required atropine. Hemodynamic changes were similar, no significant difference in the hemodynamic parameters was observed in the first 15 minutes.[5] Various other authors like Helena et al., Ph E. Gautier et al., Y.Y Lee et al. in their respective comparisons between the isobaric preparations of the drugs found no significant difference in the incidences of hypotension and bradycardia.[6-8] It was found that these effects were related to the level of sympathetic block produced rather than the drug characteristic. J.B. Whiteside et al.[9] found significant differences (p = 0.001). In their comparative study of 0.5% hyperbaric ropivacaine with hyperbaric 0.5% bupivacaine with hypotension occurring in the bupivacaine group as compared to 15% in the ropivacaine group.[9]

Table 5: Number of Patients with Intraoperative and postoperative complications

| Complications       | Intraoperative (n=50) | Postoperative (n=50) |
|---------------------|-----------------------|----------------------|
| Hypotension         | 8                     | 0                    |
| Bradycardia         | 3                     | 0                    |
| Nausea and Vomiting | 0                     | 1                    |
| Shivering           | 2                     | 1                    |
| Headache            | 0                     | 1                    |

Lopez-Soriano et al. in comparative study found fewer episodes of hypotension (0% vs 17.7%) and bradycardia (4.4% vs 8.8%) in hyperbaric 0.5% ropivacaine in comparison to 0.5% hyperbaric bupivacaine.[10] In our study 8 patients were hypotension was seen intraoperatively which was treated a single dose of phentamine sulfate 6mg, Bradycardia in 03 patients, they were given 0.6mg. atropine sulfate IV.

Conclusion

A study was conducted in 50 patients belonging to ASA grade I and II posted for lower limb surgeries. They received 3.5ml of 0.75% isobaric Ropivacaine in L2-3 interspace. All patients were preloaded with 1000 ml of ringer lactate. Following institution of subarachnoid block sensory characteristics such as onset of sensory block, maximum level achieved, duration of sensory block and request for first dose of rescue analgesics were studied.

We found a requirement for postoperative analgesics was 218.97 minutes. Hemodynamic parameters were stable in most of the patients. Postoperative side effects included shivering, nausea. Thus we conclude that isobaric 0.75% ropivacaine 26.25 mg, 3.5 ml when administered intrathecal in L2-3 interspace provides an adequate sensory block for lower limb surgeries, which makes it a good choice for lower limb surgeries with benefits of early ambulation.

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