International Journal of Scientific Reports
Gandhi P et al. Int J Sci Rep. 2021 Jan;7(1):1-5
http://www.sci-rep.com

pISSN 2454-2156 | eISSN 2454-2164

DOI: https://dx.doi.org/10.18203/issn.2454-2156.IntJSciRep20205451

Original Research Article

Comparative study of clinical efficacy and safety of intrathecal isobaric ropivacaine 0.75% with fentanyl versus isobaric ropivacaine 0.75% alone for caesarean

Pushpal Gandhi, Mahendra Agrawal*, Bhavika Agrawal, Simarn Behl

Department of Anesthesiology, Sri Aurobindo Medical College and Postgraduate Institute, Indore, Madhya Pradesh, India

Received: 26 November 2020
Accepted: 08 December 2020

***Correspondence:**
Dr. Mahendra Agrawal,
E-mail: drmk_aga@yahoo.co.uk

ABSTRACT

Background: Compare the clinical efficacy and safety of intrathecal isobaric ropivacaine 0.75% with fentanyl, 10 mcg vs isobaric ropivacaine 0.75% alone for caesarean section.
Methods: Two hundred patients were considered eligible for the study of which one hundred and sixty-eight patients undergoing caesarean section under spinal anesthesia and were included in the study. Parturient to ASA physical status I-II scheduled for caesarean section were randomly selected for the study and are divided into group of 84 each.
Results: There was significant difference in sensory block duration at T_{10} (min) and total duration of analgesia (min) in both groups. This difference between two group's was not significant. Adverse Effects in group RF 5 (5.9%) patients had hypotension and 2 (2.3%) bradycardias in group R 3 (3.5%) patient had hypotension.
Conclusions: Hemodynamic parameters were comparable in both the groups. Total duration of analgesia and sensory block duration at T_{10} was significantly shorter with ropivacaine (with saline) compared to ropivacaine with fentanyl.

Keywords: Spinal anesthesia, Cesarean section, Ropivacaine with fentanyl, Ropivacaine with normal saline, Intrathecal

INTRODUCTION

Spinal anesthesia is a very older and popular anesthetic technique with a good safety profile and a high success rate. Spinal anesthesia is unparalleled in the way in which a small quantity of drug can produce profound surgical anesthesia. New analgesic additives and local anesthetics are being investigated for different applications. As the practice of medicine focuses increasingly on out-patient care and spinal anesthetics should provide adequate anesthesia and short acting without compromising early ambulation and discharge from the day surgery unit. Ropivacaine is one local anesthetic that could have probable in this area.[1] Ropivacaine, an amide local anesthetic, has been introduced recently and used successfully to provide epidural analgesia for laboring women, caesarean delivery and post-operative analgesia.[2] Intrathecally it has been used for day care procedures as it provides adequate sensory block with early motor recovery.[3] The addition of adjutants to ropivacaine has shown to improve the quality of intra-operative and postoperative analgesia without compromising its benefits such as early mobilization and early voiding.[4] Ropivacaine blocks nerve fibers involved in pain transmission (Aδ and C fibers) to a greater degree than those controlling motor function (Aβ fibers) sub arachnoid block (SAB) a regional anesthesia techniques is safe and gold standard for caesarean section.[1] The presently used drug bupivacaine 0.5% is highly cardio-toxic and also produces prolonged motor blockade for prolonged duration. The newly drug ropivacaine being produces minimal motor blockade of shorter duration which relieves the psychological distress of patient being immobile for a longer period of time after caesarean

section. Hence a study was conducted to assess the duration of sensory and motor blockade of intrathecal ropivacaine and fentanyl to increase the duration of analgesia and toxic side effects if any compared to intrathecal ropivacaine alone duration caesarean section also comparative less cardio-toxic. Ropivacaine is a long acting enantiomerically pure amide, local anesthetic with a low lipid and high protein kinase a solubility. Is considered to block the sensory nerves to a greater extend then the motor nerves. It has similar local properties to bupivacaine but with a decreased potential for both neurotoxicity and cardio toxicity. The purposes of this study compare the clinical efficacy and safety of intrathecal isobaric ropivacaine 0.75% with fentanyl, 10 mcg vs isobaric ropivacaine 0.75% alone for caesarean section.

METHODS

A prospective randomized controlled double-blind study conducted at department of anesthesiology, Sri Aurobindo medical college and postgraduate institute, Indore, M. P. and approval from the ethical and research committee. The duration of this study was April 2019 to May 2020. Two hundred patients were considered eligible for the study of which one hundred and sixty-eight patients undergoing caesarean section under spinal anesthesia and were included in the study. Parturient to ASA physical status I-II scheduled for caesarean section were randomly selected for the study and are divided into group of 84 each. drug to be given was mentioned inside the envelope. An envelope was randomly picked up just before the surgery. The envelope was opened by an anesthesiologist and the drug was loaded by that person.

Preoperative period

The anesthesia procedure was briefly explained to the patients. An informed written consent was from the patient. Routine investigation like pre-anesthesia examination including history, clinical examination of cardiovascular, respiratory and central nervous systems and examination of spine or deformity, infection was carried out.

Intra operative period

Once the patient was shifted to the operating room, the patient was connected to the routine monitors which included non-invasive blood pressure, pulse oximeter and continuous electrocardiogram. All resuscitation equipment's like intubation trolley with airways, laryngoscopes endotracheal tubes were kept ready. The anesthesia machine was also checked along with the oxygen delivery system. Patients were allocated into two groups group RF:84 patients received 2.25 ml of 0.75% isobaric ropivacaine and fentanyl 10 mcg (0.2 ml) intrathecally. Group R:84 patients received 2.25 ml of 0.75% isobaric ropivacaine normal saline 0.2 ml. Baseline pulse rate, respiratory rate, blood pressure, stands for peripheral capillary oxygen saturation, (SPO_2) were recorded. All patients were preloaded with 5 ml of Ringer's prior to spinal anesthesia. The patient was then put in lateral position. After spinal anesthesia, the patients pulse rate, systolic and diastolic and mean BP were recorded at 0, 5, 15, 30, 45 if the systolic arterial pressure decreased to less than 90 mm Hg, ephedrine in a small dose was given intravenously (IV). Bradycardia (heart rate <60 bpm) was treated with atropine sulphate, 0.3 mg IV. Onset of sensory motor block, duration of sensory block at T_{10} total duration of analgesia, duration of motor block and adverse effects were recorded.

Inclusion criteria

ASA physical status I and II parturient undergoing caesarean section of single babies at term. Valid informed explained consent.

Exclusion criteria

Exclusive criteria excluded the patients with neuromuscular, cardiac or hematologic disease, diabetes, eclampsia, bleeding or coagulation abnormalities or known fetal anomalies were excluded from the study.

Statistical analysis

Statistical analysis was done by SPSS version 18.0 (Chicago, IL, USA). Parametric data were recorded as arithmetic mean SD. Student t test was used for continuous variables and chi square test was used for discrete variables. $P<0.05$ was considered significant.

RESULTS

The mean age was in RF group 25.6±1.71 and 25.03±2.29 in R group. There was no significant difference in age, weight, height, ASA grade I and II between two groups. Apgar score at 1 minute in group RF was 8.48±0.49, in group R 8.64±0.47 and Apgar score at 5 minutes 9.48±0.49 in RF group, 9.38±0.48 in R group. The difference between two groups was not significant. Adverse effects in group RF 5 (5.9%) patients had hypotension and 2 (2.3%) bradycardias in group R 3 (3.5%) patient had hypotension (Table 1).

There was no significant difference in sensory block onset (min), maximum sensory block (min), motor block onset (min), complete motor block (min) and duration of motor block (min) between two groups. There was significant difference in sensory block duration at T_{10} (min) and total duration of analgesia (min) in both groups.

The changes in hemodynamic parameters like heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure at 0, 5, 15, 30, 45 minutes were comparable in both the groups with magnitude of fall in blood pressure being similar (Table 3).

Maximum sensory level in group RF was 34.5% at T4 level, in group R was 29.7%. In group RF at T6 level was 65.4%, in group R was 50% and in R group at T8 level 20.2% (Figure 1).

Table 1: Demographic variables.

Demographic variables	Group RF (n=84)	Group R (n=84)	P value
Mean age (year)	25.6±1.71	25.03±2.29	NS
Weight (kg)	59.45±3.91	59.39±3.36	0.934
Height	157.65±3.94	155.46±3.56	0.111
ASA Grade I (%)	59 (70.2)	62 (73.8)	0.606
ASA Grade II (%)	25 (29.7)	22 (26.1)	
Apgar score			
1 minute	8.48±0.49	8.64±0.47	0.106
5 minutes	9.48±0.49	9.38±0.48	0.315
Adverse effects			
Hypotension (%)	5 (5.9)	3 (3.5)	0.468
Bradycardia (%)	2 (2.3)	0 (0)	-

Table 2: Sensory level in both the group.

Variables	Group RF (n=84)	Group R (n=84)	P value
Sensory block onset (min)	2.7±0.51	2.7±0.91	1.000
Maximum sensory block (min)	8.02±0.67	8.22±0.78	0.172
Sensory block duration at T10 (min)	163.4±16.59	115.6±10.29	0.000*
Total duration of analgesia (min)	191.8±18.76	132.3±11.62	0.000*
Motor block onset (min)	2.36±0.73	2.42±0.62	0.654
Complete motor block (min)	7.84±0.89	8.64±1.49	0.112
Duration of motor block (min)	129. ±15.49	123.8±16.1	0.064

Table 3: Changes in hemodynamic parameters.

Time points	0 min	5 min	15 min	30 min	45 min
Heart rate					
RF group	84.82± 14.7	85.5±13.5	86.0±19.5	86.77±17.8	85.94±17.1
R group	84.52±14.76	85.78±13.44	85.62±16.88	84.1±15.74	83.36±15.94
SBP					
RF group	112.1±9.51	111.0±12.0	111.8±11.03	112.64±11.34	112.1±9.02
R group	112.03±9.40	109.75±12.03	112.57±9.95	112.8±11.56	111.8±9.64
DBP					
RF group	72.65±6.80	74.8±10.3	73.3±10.43	73.61±7.00	72.42±6.59
R group	73.07±6.48	74.3±9.77	73.46±9.03	73.62±7.40	72.26±6.81
Mean arterial pressure					
RF group	79.72±8.60	77.2±10.5	77.72±10.18	79.74±8.48	79.42±8.33
R group	80.36±8.31	77.8±8.86	77.82±9.21	80.5±8.50	79.22±8.20

SBP: systolic blood pressure; DBP: diastolic blood pressure.

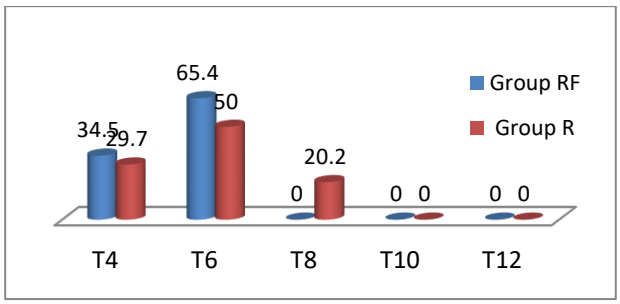

Figure 1: Maximum sensory level in both the group.

DISCUSSION

The patients studied across the groups did not very much with respect to age, weight and height. These parameters were kept identical in both the groups to avoid variations in the intraoperative in post-operative outcome of the patients.

In studies that evaluated intrathecal administration of 15-25 mg isobaric ropivacaine, the motor block time was shown to be related to the dose administered.[5-8] In

another study, incremental doses of ropivacaine were found to be responsible for a longer motor block time.[9] During a cesarean section, muscle relaxation is an important part of surgery, whereas a shorter motor block time facilitates early mobilization.[7]

The effective dose (ED50) 50% and the estimated effective dose (ED95) 95% of spinal plain ropivacaine alone for cesarean delivery were 16.7 and 26.8 mg, respectively.[10]

Apgar score at 1 min in group RF was 8.48±0.49 compared to 8.64±0.47 in group R which was statistically not significant. Apgar score at 5 min in group R 9.48±0.49 compared to 9.38±0.48 which was not statistically significant. Previous study has also observed that Apgar score were similar in both the groups.[11] In present study the changes in hemodynamic parameters were comparable in both the groups. Sensory block duration at T_{10} in group RF was 163.4±16.59 mins compare to 115.6±10.29 mins in R group which has statistically significant. By Yegin et al found that the sensory block duration at T_{10} was significantly prolonged in fentanyl group compare with saline group in a study of hyperbaric ropivacaine for TURP surgery.[12] In this study total duration of analgesia in group RF was 191.8±18.76 mins compare to 132.3±11.62 R group which has significant difference. Chung et al, have observed that the total duration of analgesia was better in the fentanyl group 143.2±34.2 as compare to ropivacaine alone group 101.4±21.4 ($p<0.01$).[13] Hypotension is an important maternal and fetal complication occurring after intrathecal administration of anesthetic agents.[7,8] In this study the systolic arterial pressure decreased to less than 90 mm Hg, ephedrine in a small dose was given intravenously (IV). Bradycardia (heart rate <60 bpm) was treated with atropine sulphate, 0.3 mg IV. There was no incidence of post-dural puncture headache and nausea in both the group. The clinical studies did not report neurological side effects associated with the intrathecal administration of ropivacaine.[6,14]

CONCLUSION

Hemodynamic parameters were comparable in both the groups. Total duration of analgesia and sensory block duration at T_{10} was significantly shorter with ropivacaine (with saline) compared to ropivacaine with fentanyl. Onset of sensory and motor blocked is similar in both the groups. Does not alter hemodynamic stability. Hence, we would recommend ropivacaine with fentanyl for caesarean section in view of its prolonged analgesic effect without increasing the duration of motor blocked.

ACKNOWLEDGEMENTS

Authors would like to thank Dr. Susmit Kosta, head, central research Lab, SAIMS, Indore for their comments on an earlier version of the manuscript, although any errors are our own and should not tarnish the reputations of these esteemed persons.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

REFERENCES

1. Wille M. Intrathecal use of ropivacaine: A review. Acta Anaesthesiol Belg. 2004;55(3):251-9.
2. Bang EC, Lee HS, Kang YI, Cho KS, Kim SY, Park H. Onset of labor epidural analgesia with ropivacaine and a varying dose of fentanyl: A randomized controlled trial. Int J Obstet Anesth. 2012;21(1):45-50.
3. Boztug N, Bigat Z, Ertok E, Erman M. Intrathecal ropivacaine versus ropivacaine plus fentanyl for out-patient arthroscopic knee surgery. J Int Med Res. 2005;33(4):365-71.
4. De Kock M, Gautier P, Fanard L, Hody JL, Lavand'homme P. Intrathecal ropivacaine and clonidine for ambulatory knee arthroscopy: A dose-response study. Anesthesiol. 2001;94(4):574-8.
5. McDonald SB, Liu SS, Kopacz DJ, Stephenson CA. Hyperbaric spinal ropivacaine: A comparison to bupivacaine in volunteers. Anesthesiol. 1999;90(4):971-7.
6. Bawdane KD, Magar JS, Teldonkar BA. Double blind comparison of combination of 0.1% ropivacaine and fentanyl to combination of 0.1% bupivacaine and fentanyl for extradural analgesia in labour. J Anaesthesiol Clin Pharmacol. 2016;32(1):38-43.
7. Gautier E, DeKock M, Van Steenberge A, Pont N, Lahaye-Goffart. Intrathecal ropivacaine for ambulatory surgery. Anaesthesiol. 1999;91(5):1239-45.
8. Malinovsky JM, Charles F, Kick O, Lepage JY, Lepage JY, Cozian A et al. Intrathecal anaesthesia: Ropivacaine versus bupivacaine. Anaesth Analg. 2000;91(6):1457-60.
9. Ayorinde BT, Buczkowski P, Brown J, Shah J, Buggy DJ. Evaluation of preemptive intramuscular phenylephrine and ephedrine for reduction of spinal anaesthesia induced hypotension during ceaserean section. Br J Anaesth. 2001;86(3):372-6.
10. Khaw KS, Ngan Kee WD, Wong ELY, Liu JYW, Chung R. Spinal ropivacaine for cesarean section. Anesthesiol. 2001;95:1346-50.
11. Sanli S, Yegin A, Kayacan N, Yilmaz M, Coskunfirat N, Karsli B. Effects of hyperbaric spinal ropivacaine for caesarean section: with or without fentanyl. Eur J Anaesthesiol. 2005;22(6):457-61.
12. Yegin A, Sanli S, Hadimioglu N, Akbas M, Karsli B. Intrathecal fentanyl added to hyperbaric ropivacaine for transurethral resection of the prostate. Acta Anaesthesiol Scand. 2005;49(3):401-5.

13. Chung CJ, Yun SH, Hwang GB, Park JS, Chin YJ. Intrathecal fentanyl added to hyperbaric ropivacaine for cesarean delivery. Reg Anesth Pain Med. 2002;27(6):600-3.
14. Mohta M. Ropivacaine: Is it a good choice for spinal anesthesia? J Anaesthesiol Clin Pharmacol. 2015;31(4):457-8.

Cite this article as: Gandhi P, Agrawal M, Agrawal B, Behl S. Comparative study of clinical efficacy and safety of intrathecal isobaric ropivacaine 0.75% with fentanyl versus isobaric ropivacaine 0.75% alone for caesarean. Int J Sci Rep 2021;7(1):1-5.