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A COMPARATIVE STUDY BETWEEN HYPERBARIC ROPIVACAINE (0.75%) ALONE AND HYPERBARIC ROPIVACAINE (0.75%) WITH DEXMEDETOMIDINE AS ADJUVANT FOR SPINAL ANAESTHESIA IN LOWER ABDOMINAL SURGERIES

Anaesthesiology

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ABSTRACT

Spinal anaesthesia in lower abdominal surgery with hyperbaric ropivacaine and hyperbaric ropivacaine with dexmedetomidine has been used now a days. This study was done to evaluate the efficacy and safety of dexmedetomidine as an adjuvant to intrathecal hyperbaric ropivacaine in spinal anaesthesia for lower abdominal surgeries, the onset of sensory and motor block, the duration of sensory and motor block, maximum cephalad spread, block height at 90 mins, hemodynamic stability, sedation using Ramsay sedation scale, Total 45 patients in group RN receiving 3.5 ml 0.75% intrathecal hyperbaric ropivacaine and 0.1ml NS and 45 patients in group RD receiving 3.5ml 0.75% intrathecal hyperbaric ropivacaine with 0.1ml (10 mcg) dexmedetomidine. Time for onset at T10 was prolonged in RN(5.27min) was as compared to RD (4.15min)group ($p < 0.001$). In group RN, mean of two dermatome regression duration is 102.20 ± 10.52 where in group RD is 120.78 ± 18.60 ($p<0.001$). In group RN, mean duration of pain sensation at S1 is 191.09 ± 14.08.where in another group RD it is is 238.09 ± 23.28. Addition of 10mcg of Dexmedetomidine to 0.75% hyperbaric ropivacaine 3.5mL in spinal anaesthesia significantly decreases the onset time, prolongs the duration of both sensory and motor blockade, improves the quality of postoperative analgesia without significant adverse effect.

KEYWORDS

INTRODUCTION

Spinal anaesthesia is most consistent block for lower abdominal surgeries which bypasses the risks associated with general anaesthesia such as aspiration of gastric contents, difficult airway management. It provides a good postoperative pain relief, reduces systemic analgesic requirements, permits early ambulation, and attenuates surgical stress response along with providing excellent muscle relaxation for surgeon.

Bupivacaine is widely used local anaesthetic agent to be administered in spinal anaesthesia for procedures of duration 90-120 minutes. Bupivacaine 0.5% heavy is commonly used for intrathecal use, having serious side effects such as hypotension and bradycardia if higher level is reached. Ropivacaine, a new amino-amide local anaesthetic agent, is similar in chemical structure to Bupivacaine[1], is 30-40% less potent [2,3]. The claimed benefits of these are reduced cardiac toxicity on overdose and more specific effects on sensory block and slightly less duration of motor block and also less incidence of hypotension.

However, hyperbaric ropivacaine has been little studied in intrathecal anaesthesia. Prior studies comparing hyperbaric ropivacaine and hyperbaric bupivacaine in same concentration that is 0.5%, have shown late onset and shorter duration of sensory and motor block with ropivacaine[4,5].

α_2 adrenergic receptor agonists Dexmedetomidine or Clonidine have been tried by many clinicians due to their sedative, anxiolytic, hypnotic, analgesic, perioperative sympatholytic and stable haemodynamic properties.[6].

Many reports have indicated that intrathecal administration of dexmedetomidine can prolong analgesia and reduce the side effects associated with the administration of opioids.[7]

AIMS AND OBJECTIVES:

To evaluate the efficacy and safety of dexmedetomidine as an adjuvant to intrathecal hyperbaric ropivacaine in spinal anaesthesia for lower abdominal surgeries.

To evaluate: the onset of sensory and motor block, the duration of sensory and motor block, maximum cephalad spread, block height at 90 mins, hemodynamic stability, sedation using Ramsay sedation scale.

MATERIALS AND METHODS:

It is an institution based prospective, comparative study performed in NRSMCH, Kolkata for patients planned for lower abdominal surgeries of age group of 18-60 years both male and female of ASA I, II.

Sample Size:

Sample size calculation was done using the following formula:

$$n = \frac{2SD^2(Z_{\alpha/2}+Z_{\beta})^2}{d^2} = 35.2$$

We add 15% more number of cases after deriving the value of n, rounding of 45. The total sample size required for this study is 90.

Inclusion:

Age group 18-60 yrs., ASA grade I AND II, BMI≤25,Patients planned to undergo lower abdominal surgeries, Patients who give a valid informed consent, Patients with intact anatomy of vertebral column.

Exclusion:

Uncontrolled hypertension,Uncontrolled diabetes mellitus,Renal or hepatic impairment,Pregnant or lactating mothers.Obese or malnourished ,Chronic alcoholics,Local infection at the site of injection,Rheumatoid arthritis,Coagulopathies,neurological disorders,IHD, partial or complete heart block,Hypersensitivity to any of the drug used,Known contraindications to regional anaesthesia, Psychiatric and mentally retarded patient.

Precedure:

Preoperative check-up IV canulation with 18 G needle Patient was made to sit leaning forward and relaxing the back in such a way that lumber vertebra is prominent Antiseptic dressing and draping was done. Highest point of iliac crest was palpated both side and an imaginary line joining those two points was drawn. The intervertebral space lying closest or above the imaginary line was marked as L3-L4 junction 25G Quincke's Spinal needle was inserted in the intervertebral space either L3-L4 junction or L2-L3 junction and inserted till loss of resistance felt due to dura puncture and entry in the sub arachnoid space Free flow of CSF was ensured Now in group RN intrathecal hyperbaric 0.75% ropivacaine 3.5 ml with 0.1 ml NS in a single syringe being given was observed and in group RD intrathecal hyperbaric 0.75% ropivacaine 3.5 ml with 0.1 ml(10mcg)dexmedetomidine in a single syringe being given was observed Patient was made to lie down with foot end raised 10-15 degree and wait for 5-10 minute Surgery was allowed to start and Intraoperative hemodynamic parameters, characteristics of sensory and motor blockade were then observed.

Spinal Anaesthesia Given

Total 45 patients in group RN receiving 3.5 ml 0.75% intrathecal hyperbaric ropivacaine and 0.1ml NS and 45 patients in group RD receiving 3.5ml 0.75% intrathecal hyperbaric ropivacaine with 0.1ml

(10 mcg) dexmedetomidine.

Monitoring after having the intrathecal injection, patients made supine immediately and observed for vitals, Onset of sensory block (pinprick and cold sensation loss at T10) noted. Onset of motor block (M.B.S=3), time to maximum degree(M.B.S=4) observed and noted. Height of sensory block (highest dermatome involved) (maximum dermatome where pin prick and cold sensation were lost) was tested.

Heart rate, systolic, diastolic blood pressure, mean arterial pressure, oxygen saturation rhythm recorded every 5 minutes for 30 minutes, thereafter 15 minutes till 1 hour then every 30 min till the 2 hours. Sensory block- measured every 5 minutes for the first 30 minute and then at 15 min interval till the end of the surgery and hourly there after till complete sensory recovery. Duration of sensory block calculated from onset (pinprick and cold sensation loss at T10) to pin-prick and cold sensation at S1 dermatome. Two-dermatome regression from peak block height, time taken for regression up to T10 level was monitored for each patient. Measurements were performed at 5,10 and 15 minutes after intrathecal injection and then every 15 minutes after completion of surgery until motor blockade regressed to sacral dermatome. Duration of motor block was calculated till the modified Bromage score reached 0 for each patient.Sedation score will assess every 15 minutes intraoperatively, using Ramsay sedation scale and maximum sedation score was noted.Strict monitoring was done regarding any adverse effect like nausea, bradycardia, hypotension throughout the intraoperative period. Hypotension defined as when MAP <65mmHg, treated with inj. Phenylephrine, bradycardia was there when heart rate was less than 60 beats /min and treated with inj. Atropine.

Postoperatively- vitals were recorded 2, 6,12 hourly. Duration of complete analgesia (from onset to requirement of rescue analgesia) will be noted and rescue analgesia (drugs that will be given to both the groups are paracetamol 1 gm iv infusion injection) will be given when NRS score was >3. Monitoring was done for any adverse effect.

RESULT:

The continuous variables are presented with mean and standard deviation. The categorical variables are presented with frequency and percentage. Independent t test and chi square test are used for the statistical analysis. The p value ≤0.05 is considered statistically significant.

Time for onset at T10 was prolonged in RN(5.27min) was as compared to RD (4.15min)group ($p < 0.001$). In group RN, mean of two dermatome regression duration is 102.20 ± 10.52 where in group RD is 120.78 ± 18.60. . ($p<0.001$). In group RN, mean of regression at T10 duration is 148.71 ± 16.20.

In group RD, it is 183.29 ± 16.30 ($p<0.001$). In group RN, mean duration of pain sensation at S1 is 191.09 ± 14.08.where in another group RD it is is 238.09 ± 23.28. In group RN, mean time of motor onset is 5.20 ± 1.05, in RD is 4.47 ± 1.29. In group RN, mean duration of pain sensation at S1 is 191.09 ± 14.08.where in another group RD it is is 238.09 ± 23.28. In group RN, mean time of motor onset is 5.20 ± 1.05, in RD is 4.47 ± 1.29.

Parameter	Group	Mean	SD	P value
Two dermatome regression duration (min)	Group RN	102.20	10.52	<0.001*
	Group RD	120.78	18.60	
Regression at T10 duration (min)	Group RN	148.71	16.20	<0.001*
	Group RD	183.29	16.30	
Pain sensation at S1 duration (lateral heel area) (min)	Group RN	191.09	14.08	<0.001*
	Group RD	238.09	23.28	
Time of onset (M.B.S.=3) (min)	Group RN	5.20	1.05	0.005*
	Group RD	4.47	1.29	
Duration of motor block (min)	Group RN	175.36	15.65	<0.001*
	Group RD	221	21.06	
Duration of analgesia (min)	Group RN	170.09	14.62	<0.001*
	Group RD	223.90	20.16	

DISCUSSION:

Nowadays, α-2-adrenoceptor agonists are frequently used in anaesthetic field for their sedative, analgesic, sympatholytic, anaesthetic-sparing and favourable haemodynamic properties. Dexmedetomidine, is one such agonist having a relatively high α2 / α1 -activity ratio (1620:1) as compared to clonidine (220:1). It's also unique that it lacks respiratory depressant action, thereby conscious sedation making it therapeutically a useful and safe adjunct.[8]. There was no block failure and requirement of general anaesthesia. So, the statistical calculations contained n=90 (45 in each group). We used student t test for quantitative data and chi square test for qualitative data.

In our study, both groups were comparable with respect to demographic profile (age, gender, height, weight, BMI, ASA grade), preoperative hemodynamic. Perioperative hemodynamics was maintained.

In the present study, there was statistically significant difference with regard to onset of sensory (at T 10) and motor block (time to reach M.B.S=3) between both the groups with faster onset in Dexmedetomidine group. Our results correlate with studies done by Al-Mustafa *et al* (2011). Deepika Shukla *et al.(*2013) ,Sisinti Sanjeeb Patro *et al.* (2016). [7,8,9]

However, maximum cephalad spread (which is observed at 15 minutes) and block height at 90 minutes were similar and statistically insignificant in both the groups.

The time for 2 segment regression was considerably prolonged in Group RD with 120.78±18.60 minutes and in Group RN it was 102.20±10.52 minutes which is similar with the findings of Sheriff GE Kanazi *et al*. (2006), Rajni Gupta *et al.*(2011) Sisinti Sanjeeb Patro *et al.* (2016). [7,8,10] Similarly there was significant increment of duration for regression to T10 in group RD (183.29±16.30) as compared to RN group (148±16.20),which was also accordance to the previous studies. The total duration of both sensory and motor blockade was significantly prolonged in Group RD which is similar with studies done by the above authors. Total duration of sensory block which we are observing as onset to pain sensation at lateral heel area (S1 dermatome) is significantly high in group RD which was 238.09 ± 23.28 as compared to group RN.

Al-Mustafa *et. al.*(2011) [11]found that the regression time to reach S1 dermatome was 338.9 +/- 44.8 minutes in group D10 (10 mcg of dexmedetomidine + bupivacaine 12.5 mg) and 165.5 +/- 32.9 minutes in group N (bupivacaine 12.5 mg + normal saline). Study by Sisinti Sanjeeb Patra *et al.* (2016) [11] found that total duration of sensory block as 317.70±16.16 minutes in Group II (bupivacaine + dexmedetomidine group) and 188±11.86 minutes in Group I (bupivacaine), so effects of adding dexmedetomidine is similar in both the study.

Patients were given rescue analgesia when N.R.S was more than 3. Duration till rescue analgesia was significantly prolonged in Group RD (223.90 min) as compared with Group RN (170.09 min) and addition of Dexmedetomidine to intrathecal ropivacaine significantly delayed the requirement of rescue analgesia in the postoperative period in accordance with the studies mentioned earlier.[7,12]

There was no significant difference between 2 groups regarding sedation which is measured by Ramsay Sedation scale, which is in accordance to similar with the findings of Sheriff GE Kanazi *et al*. (2006).[12] Kanazi *et al.* found that Dexmedetomidine (3 microg) or clonidine (30 microg), when added to intrathecal bupivacaine, there is a lack of sedation. Sisinti Sanjeeb Patra *et al.* (2016) [7] also did not found any sedative effect of intrathecal dexmedetomidine.

However, Rajni Gupta *et al.* (2011) [13] in their comparative study of intrathecal dexmedetomidine and fentanyl as adjuvants to Bupivacaine found that more sedation score was more in group D (dexmed. group) patients than group F (fentanyl group).

CONCLUSION:

Addition of 10mcg of Dexmedetomidine to 0.75% hyperbaric ropivacaine 3.5mL in spinal anaesthesia significantly decreases the onset time, prolongs the duration of both sensory and motor blockade, improves the quality of postoperative analgesia without significant adverse effect.

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