A RANDOMISED DOUBLE-BLIND CLINICAL TRIAL COMPARING ISOBARIC ROPIVACAINE 0.5% WITH DEXAMETHASONE AND 0.75% ROPIVACAINE ALONE IN SPINAL ANAESTHESIA IN TRANSURETHRAL RESECTION OF PROSTATE CASES

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ABSTRACT

BACKGROUND

This clinical study was designed to evaluate the clinical efficacy and safety of lower concentration of ropivacaine i.e. intrathecal 0.5% isobaric ropivacaine with dexamethasone for transurethral resection of prostate (TURP) in elderly patients. This combination should provide better haemodynamic stability and prolonged postoperative analgesia compared with 0.75% plain ropivacaine.

MATERIALS AND METHODS

Eighty patients were randomly divided into two groups, each comprising of 40 patients. Subarachnoid block was performed using 3.5 mL isobaric Ropivacaine 0.5% with 1 mL Dexamethasone (4 mg) in group I (RD) and 3.5 mL isobaric Ropivacaine 0.75% with 1 mL normal saline in group II (R). Haemodynamic parameters, onset and total duration of sensory and motor block, time to reach maximum sensory block, duration of sensory and motor block at T10, postoperative analgesic requirements and adverse effects were recorded.

RESULTS

Group RD shows longer onset of sensory blockade was 2.30 ± 0.56 minutes compared to 1.58 ± 0.64 minutes in group-R (P< 0.001) and motor blockade 2.23 ± 0.70 minutes compared to 1.68 ± 0.694 minutes in group-R (P<=0.001). The median time to reach the highest level of analgesia was 19.05 ± 6.02 minutes in group RD; 16.05 ± 4.68 in group R. The duration of sensory level at T10 dermatome was prolonged i.e. 90.60 ± 38.90 minutes in group-R compared to 47.45 ± 13.81 minutes in group-RD (P<0.001). Total duration of sensory block was prolonged in group R i.e. 188.75 ± 20.68 compared to 155.38 ± 28.10 in group RD (P<0.001). The duration of motor blockade in group-RD was 118.00 ± 13.24 minutes compared to 154.75±20.88 minutes in group-R (P<0.001). The time of first request of analgesics in group-RD was 293.08 ± 28.26 minutes compared to 267.95 ± 30.52 minutes in group-R (P = 0.000). The total opioid consumption within 24 hours following surgery in group-I was 77.50 ± 31.92 milligrams compared to 102.50 ± 35.72 milligrams in group-R (P<0.001).

CONCLUSION

Ropivacaine 0.5% with dexamethasone produces adequate surgical anaesthesia for TURP surgeries with negligible haemodynamic disturbances and prolongs the time to first request for analgesia and lesser opioid consumption following surgery.

KEYWORDS

Elderly Patients, Ropivacaine, Dexamethasone, Subarachnoid Block, Transurethral Resection of Prostate.

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BACKGROUND

This clinical study was designed to evaluate the clinical efficacy and safety of lower concentration of ropivacaine i.e. intrathecal 0.5% isobaric ropivacaine with dexamethasone for transurethral resection of prostate (TURP) in elderly patients. Low dose ropivacaine provides a high degree of haemodynamic stability and low incidence of hypotension and bradycardia.[1] Ageing and disease make elderly patients susceptible to hypotension during anaesthesia as these patients have a relatively high prevalence of coexisting systemic diseases. Benign prostatic hypertrophy frequently leads to symptomatic bladder outlet obstruction in older men. Recent clinical data have shown that ropivacaine is clinically effective and safe for regional anaesthetic techniques with good tolerability.[2] Ropivacaine could provide adequate surgical anaesthesia without compromising early ambulation and discharge.[2] Corticosteroids have been studied recently as adjuncts to local anaesthetics in regional block.[3]

Ropivacaine is less lipophilic than bupivacaine and is associated with decreased potential for central nervous system toxicity and cardiotoxicity.[4] Dexamethasone relieves pain by reducing inflammation and blocking transmission of nociceptive C-fibres and by suppressing ectopic neural

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discharge. It has been shown that the duration of post-operative analgesia was prolonged when dexamethasone is given as an adjunct for peripheral nerve blocks.[5]

Intrathecal dexamethasone may influence intraspinal prostaglandin production. Acute noxious stimulation of peripheral tissues leads to sensitisation of dorsal horn neurons of the spinal cord by the release of substances such as glutamate and aspartate.[6]

Ropivacaine is less lipid-soluble than bupivacaine and is reported to be 20% less potent than bupivacaine at equal doses.[7] Ropivacaine produces less motor blockade and is of shorter duration than bupivacaine.[8,9] This clinical study was designed to evaluate the clinical efficacy and safety of lower concentration of ropivacaine i.e. intrathecal 0.5% isobaric ropivacaine with dexamethasone for transurethral resection of prostate (TURP) in elderly patients. This combination should provide better haemodynamic stability and prolonged postoperative analgesia compared with 0.75% plain ropivacaine.

MATERIALS AND METHODS

This double-blind randomised clinical study was conducted on 80 male adult patients of physical status ASA grade I-II, aged 45-75 years with body weight 45-85 kg and height 145-180 cm, scheduled for TURP under subarachnoid block. After approval of Institutional Ethical Committee and written informed consent, all patients were subjected to preanaesthetic assessment. Patients with severe cardiac or pulmonary diseases, neurologic or renal dysfunction, bleeding or coagulation disorder, allergy to local anaesthetic amides, deformed spinal column, infection at site of lumbar puncture, or refusal to technique were excluded from the study. The patients were randomised into two groups, according to computer-generated numbers. Group RD receiving intrathecal Ropivacaine 0.5% 3.5 mL with Dexamethasone 4 mg 1 mL (Total volume = 4.5 mL) and Group R receiving intrathecal Ropivacaine 0.75% 3.5 mL with Normal Saline 1 mL. (Total volume = 4.5 mL).

All patients received tablet Diazepam 5 mg orally day before surgery for anxiolysis with sips of water. In the operating room, noninvasive blood pressure, SpO_2, ECG leads were connected to the patient. Pre-operative baseline systolic and diastolic BP, PR, SpO_2 and RR were recorded. Under aseptic precautions a midline lumbar puncture was performed at L3-L4 interspace using a 25G Quincke needle in lateral position. Following free flow of clear CSF, anaesthetic solution was injected slowly in both the groups. Then, the patient was placed in supine position.

The time of intrathecal injection was considered as 0 and following parameters were observed. After intrathecal injection, assessment started immediately and continued every 15 seconds till loss of pinprick sensation at T10 level. Assessment of sensory block was done by loss of sensation to pinprick using 23 G sterile needle. Onset time was taken from intrathecal injection to loss of pinprick sensation at T10. The maximum sensory level achieved following intrathecal injection of drug was measured when dermatomal level of sensory block remains same at successive two points of time. Time to achieve maximal sensory block i.e. time taken from intrathecal injection of drug to loss of pinprick sensation at highest dermatomal level was noted. Time taken from onset of sensory blockade till time of complete return of sensations at T10 level was noted as duration of sensory block at T10. Time from intrathecal injection of drug to complete return of sensations was noted as total duration of sensory block. Patients whose sensory block reached T10 were allowed to start the surgery. Motor block was assessed by Bromage score. [0 = No paralysis; 1 = Inability to raise extended leg; 2 = Inability to flex the knee; 3 = Inability to flex the ankle (complete motor block)]. Assessment started immediately after the intrathecal injection, tested every 15 seconds till Bromage score of 3. Onset of motor block was taken to achieve Bromage score 3 from the time of intrathecal injection. Duration of motor block was taken as time from intrathecal injection to return of Bromage score 0.

Haemodynamic parameters i.e. heart rate, arterial blood pressure, and SpO_2 were recorded before the intrathecal injection and thereafter at every 2 min. during the first 10 min., and then every 15 min. in the first hour and every 20 min. until the patient was transferred to the post-anaesthesia room. Tramadol was administered when the patient complained of pain. Time of first request for post-operative analgesia and total opioid consumption in first 24 hours by the patient was noted. The side effects like shivering, high spinal blockade, breathing difficulty, nausea and vomiting were looked for and occurrence of haemodynamic disturbances like hypotension, bradycardia were noted. Hypotension was defined as fall in systolic BP >30% from baseline or MAP <60 mm of Hg. This was managed with Inj. Ephedrine 6 mg IV increments. Bradycardia was defined as heart rate <60/min. and this was managed with Inj. Atropine 0.01 mg/kg IV. Respiratory depression defined as RR <8/min. and or SpO_2<85%. This was planned to be managed with bag and mask ventilation or intubation and IPPV if necessary.

Statistical Analysis

For detecting a mean difference of 30 minutes with pooled standard deviation (SD) of 20 minutes in the duration of sensory block which we considered as clinically useful after conducting a pilot study, for alpha value of 0.01 and power 95%; the sample size calculated was minimum 16 per group. But, however, we included 40 patients in each group. The categorical factors are represented by the number and frequency (%) of cases. The continuous variables are represented by measures of central frequency (like mean, median and mode) and deviation (Standard Deviation and range).

SPSS 14.0 version was used for statistics. Independent student's t-test, Mann-Whitney test and Fisher's exact test, unpaired and paired t-test were used for quantitative nominal data (mean +/-). For repeated haemodynamic data, we used General Linear Model (GLM). Categorical data were compared by using χ^2 and Mann-Whitney U test where appropriate. P value of <0.05 was considered significant.

RESULTS

Patients studied across the group did not vary much with respect to age, height or weight (Table 1). Heart rate, systolic and diastolic blood pressure in both the groups did not vary significantly (Table 3). The onset of sensory blockade in group RD was 2.30 ± 0.56 minutes compared to 1.58 ± 0.64 minutes in group R which was statistically significant (P< 0.001). Similarly, the onset of motor blockade in group-RD was 2.23 ± 0.70 minutes compared to 1.68 ± 0.74 minutes in

group-R which was also statistically significant (P=0.001). The median time to reach the highest level of analgesia was less than 20 min. in both groups (ropivacaine 0.5% group, 19.05 ± 6.02 min.; ropivacaine 0.75% group, 16.05 ± 4.68 min.), the duration of sensory level at T10 dermatome in group-RD was 47.45 ± 13.81 minutes compared to 90.60 ± 38.90 minutes in group-R which was statistically highly significant (P<0.001).The total duration of sensory block was prolonged in group R; 188.75 ± 20.68 compared to 155.38 ± 28.10 in group RD, which was statistically significant (P<0.001).The duration of motor blockade in group-RD was 118.00 ± 13.24 minutes compared to 154.75 ± 20.88 minutes in group-R which was significant (P<0.001). (Table 2).

The time of first request of analgesics in group-RD was 293.08 ± 28.26 minutes compared to 267.95 ± 30.52 minutes in group-R statistically significant (P=0.003). Addition of dexamethasone to 0.5% Ropivacaine has increased its period of analgesia compared to 0.75% Ropivacaine and prolonged the time to first request of postoperative analgesia. The total opioid (Tramadol) consumption within 24 hours following surgery in group-RD was 77.50 ± 31.92 mg compared to 102.50 ± 35.72 mg in group-R (Table 4) which was statistically significant (P=0.001). This shows that requirement of opioid analgesia was significantly reduced due to addition of dexamethasone to 0.5% Ropivacaine compared to 0.75% Ropivacaine. In both the groups, surgery was accomplished without requisition for additional anaesthetic.

Six patients had shivering in group –RD as compared to 8 patients in group-R. One patient in each group had bradycardia. There were no incidences of post-dural puncture headache, nausea or vomiting in both groups.

Demographic Parameters	Group RD	Group R	Mean Difference	P value
Age	63.12 ± 7.56	60.3 ± 8.01	2.8	0.108
Height	162.25 ± 8.86	164.25 ± 8.84	2.0	0.315
Weight	64.40 ± 8.41	65.10 ± 7.07	0.7	0.688

Table 1. Comparison of Demographic Parameters in Two Groups of Patients Studied

Criteria	Group RD	Group R	Mean Difference	P value
Sensory Block				
Onset	2.30 ± 0.56	1.58 ± 0.64	0.72	<0.001
Time to Maximum Cephalad Spread	19.05 ± 6.53	16.05 ± 4.68	3.00	0.010
Duration at T10	47.45 ± 13.81	90.60 ± 38.90	43.15	<0.001
Total Duration	155.38 ± 28.10	188.75 ± 20.68	37.37	<0.001
Motor Block				
Onset	2.23 ± 0.70	1.68 ± 0.74	0.55	<0.001
Time to Maximum Degree Block	13.25 ± 4.79	12.83 ± 7.98	0.42	0.774
Total Duration	118.00 ± 13.24	154.75 ± 20.88	36.37	<0.001

Table 2. Comparison of Sensory Block and Motor Block Characteristics in Two Groups of Patients Studied

Haemodynamic Parameter	Heart Rate		Systolic BP	
Time Interval	**Group RD**	**Group R**	**Group RD**	**Group R**
Baseline	76.45 ± 13.82	75.48 ± 8.28	126.25 ± 9.68	126.30 ± 13.29
2 minutes	77.48 ± 14.51	77.58 ± 9.78	125.43 ± 8.87	125.45 ± 10.50
5 minutes	76.88 ± 11.16	72.58 ± 8.48	125.88 ± 10.47	122.10 ± 11.40
10 minutes	77.03 ± 12.54	72.53 ± 10.01	123.63 ± 10.44	119.55 ± 12.73
15 minutes	75.45 ± 14.77	73.25 ± 11.29	119.95 ± 10.68	114.85 ± 10.25
20 minutes	70.08 ± 13.12	72.13 ± 13.31	121.65 ± 14.89	114.03 ± 9.56
30 minutes	70.08 ± 9.48	67.63 ± 9.81	119.88 ± 11.88	113.08 ± 10.24
45 minutes	72.58 ± 9.81	68.13 ± 9.10	121.60 ± 9.18	114.18 ± 11.14
60 minutes	71.95 ± 10.62	69.68 ± 9.06	120.33 ± 9.25	114.93 ± 10.55

Table 3. Comparison of Haemodynamic Parameters in Two Groups of Patients Studied

Group	Time of First Request for Post-op Analgesia	Total Opioid (Tramadol) Consumption (mg) in 24 hours after Surgery
Group RD	293.08 ± 28.26	77.50 ± 31.92
Group R	267.95 ± 30.52	102.50 ± 35.72
Mean Difference	25.13	25.00
	P<0.001	P< 0.001

Table 4. Comparison of Postoperative Analgesic Requirements in Two Groups

DISCUSSION

Although dexamethasone has been used intrathecally for many years, it has not been evaluated when it was given in conjunction with ropivacaine intrathecally. This double-blind randomised study was conducted to compare two different concentrations of intrathecal ropivacaine in TURP cases and that low concentration of ropivacaine (0.5%) 3.5 mL in combination with 4 mg dexamethasone**.** This double-blind randomised study was conducted to compare two different concentrations of intrathecal ropivacaine in TURP cases, and low concentration of ropivacaine (0.5%) 3.5 mL in combination with 4 mg dexamethasone 1 mL is enough to produce sufficient surgical anaesthesia in the patients comparable to 0.75% ropivacaine 3.5 mL (total volume 4.5 mL by adding Normal Saline 1 mL). Dexamethasone added to 0.5% ropivacaine prolonged the time to first analgesic request. It also reduced total opioid (Tramadol) consumption postoperatively as compared to plain ropivacaine 0.75%.

Perioperative Cardiovascular Parameters

Heart rate, systolic and diastolic blood pressure in both the groups did not vary significantly. Cardiovascular changes were unremarkable throughout, and similar in the two groups, as were the volumes of fluid administered. Kim S Khawet al[10] in 2001, found that the incidence of hypotension were similar in a comparison of different doses of plain ropivacaine. John On-Nin Wong et al[11] in 2004, have observed the same that there are no major cardiovascular changes in

the two groups receiving plain ropivacaine in different doses compared to each other.

Changes in the Onset of Sensory and Motor Blockade

In our study, the onset of sensory blockade in group-RD was 2.30 ± 0.56 minutes compared to 1.58 ± 0.64 minutes in group-R with mean difference of 0.72 minutes which was statistically significant (P< 0.001). Similarly, the onset of motor blockade in group-RD was 2.23 ± 0.70 minutes compared to 1.68 ± 0.74 minutes in group-R with mean difference of 0.55 minutes which was also statistically significant (P=0.001). The median time to reach the highest level of analgesia was less than 20 min. in both groups with mean difference of 3.00 minutes. Ying Y. Lee et al[12] in 2007 found that the onset of motor blockade was more reliable with 0.75% ropivacaine.

Duration of Sensory Block

In our study, the duration of sensory level at T10 dermatome in group-RD was 47.45 ± 13.81 minutes compared to 90.60 ± 38.90 minutes in group-R with mean difference of 43.15 minutes which was statistically significant (P<0.001). The total duration of sensory block was prolonged in group R; 188.75 ± 20.68 compared to 155.38 ± 28.10 in group RD, with mean difference of 37.37 minutes which was statistically significant (P<0.001). Jack W van Kleef et al[4] in 1994, found that the duration of analgesia at the level of T12 was significantly longer in the 0.75% group as compared to 0.5% group. However, the total duration of analgesia was clearly dose-dependent (P<0.002), lasting longer with the more concentrated solution. This shows that ropivacaine 0.75% has a more reliable duration of analgesia.

Duration of Motor Blockade

In our study, the duration of motor blockade in group-RD was 118.00 ± 13.24 minutes compared to 154.75 ± 20.88 minutes in group-R with mean difference of 36.37 minutes which was significant (P<0.001). Ropivacaine 0.75% solution resulted in longer duration of motor block. Van Kleef, Jack W et al[4] in 1994 observed that the greater propensity to produce a complete motor block, and the longer duration of analgesia and motor block produced by the 0.75% ropivacaine solution, should be suitable for orthopaedic and vascular surgical procedures of intermediate duration, requiring an intense motor block. On the other hand, the 0.5% ropivacaine solution with its shorter duration of analgesia and often relatively moderate motor block could be useful for transurethral procedures where the degree of motor block is not of critical importance.[4]

Time of First Request of Analgesics

In our study, the time of first request of analgesics in group-RD was 293.08 ± 28.26 minutes compared to 267.95 ± 30.52 minutes in group-R with mean difference of 25.13 minutes which was significant (P = 0.003). Jack W. van Kleef et al,[4] in 1994, found that the time of first request for analgesia was significantly longer in the 0.75% group as compared to group RD. This shows that there was significantly longer period of analgesia with 0.75% ropivacaine. Our study has found that addition of dexamethasone to 0.5% ropivacaine has increased its period of analgesia compared to 0.75% ropivacaine and prolonged the time to first request of post–operative analgesia.

Total Opioid (Tramadol) Consumption in 24 hours following Surgery

In our study, the total opioid (Tramadol) consumption within 24 hours following surgery in group-RD was 77.50 ± 31.92 mg compared to 102.50 ± 35.72 mg in group-R with mean difference of 25 mg which was statistically highly significant (P=0.001). This shows that requirement of opioid (Tramadol) analgesia was significantly reduced due to addition of dexamethasone to 0.5% ropivacaine compared to 0.75% ropivacaine.

Elzayyat N et al[13] in 2014 found that compared to bupivacaine with dexmedetomidine, bupivacaine with dexamethasone had significantly longer duration of sensory block (P = 0.025) and longer duration of postoperative analgesia (P < 0.001). Compared with plain bupivacaine, bupivacaine with dexamethasone had significantly longer duration of sensory block (P < 0.001) and longer duration of postoperative analgesia (P < 0.001).

Biradar et al[14] found that addition of dexamethasone to 1.5% lidocaine with adrenaline in supraclavicular brachial plexus block speeds the onset and prolongs the duration of sensory and motor blockade.

Adverse Effects

Six patients had shivering in group RD as compared to 8 patients in group R. One patient in each group had bradycardia. There were no incidences of post-dural puncture headache, nausea or vomiting in both groups. Wong J. et al[11] al in 2004 found that the incidence of shivering was more in the group receiving 33.75 mg plain ropivacaine than the group receiving 26.25 mg of plain ropivacaine. We found no major differences clinically in the adverse effects of both drugs.

CONCLUSION

Although intrathecal administration of 0.75% isobaric ropivacaine produces longer duration of sensory and motor block compared to isobaric 0.5% ropivacaine with dexamethasone; 0.5% ropivacaine with dexamethasone produces adequate surgical anaesthesia for TURP surgeries with negligible haemodynamic disturbances and found to prolong the time to first request for analgesia and lessen opioid consumption following surgery.

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