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A COMPARATIVE STUDY OF EFFECTS OF INTRATHECAL 4.0 CC OF 0.75% ISOBARIC ROPIVACAINE AND 3.5 CC OF 0.50% ISOBARIC ROPIVACAINE WITH 30 MCG CLONIDINE PLUS 0.3 CC OF STERILE NORMAL SALINE IN BENIGN PROSTATE HYPERPLASIA PATIENTS UNDERGOING TRANS URETHERAL RESECTION OF PROSTATE

Anaesthesiology

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ABSTRACT

Introduction: Spinal anaesthesia is a popular and common technique used worldwide. A newly introduced long acting amide linked local anaesthetic called `ROPIVACAINE, produces less motor blockade and is of shorter duration than bupivacaine. Intrathecal clonidine is being extensively evaluated as an alternative to neuraxial opoids for control of pain and has proven to be a potent analgesic. A very important advantage of ropivacaine over bupivacaine is less cardiovascular toxicity.

Aims and objectives: present study was planned to investigate the effects, (onset of action, duration of action, quality of sensory and motor block, haemodyamic stability and post-operative analgesia) of intrathecal 4.0 cc of 0.75% isobaric ropivacaine and 3.5 cc of 0.50% isobaric ropivacaine with 30 mcg clonidine plus 0.3 cc of sterile normal saline in benign prostate hyperplasia patients undergoing trans uretheral resection of prostate.

Materials and methods: this Prospective, randomized, double blind, comparative study was conducted at the Department of anaesthesiology and Critical Care, Government Medical College and Associated Group of Hospitals, Kota in patients posted for elective trans urethral resection of prostate with benign prostate hyperplasia. We made two groups of cases i.e. Group R (ROPIVACAINE) and Group RC (ROPIVACAINE WITH CLONIDINE). sample size was 80, which was divided into two groups of 40 each. Standard protocol followed to administering spinal anaesthesia. All data were collected and analysed with the help of suitable statistical parameters.

Results: Our study results in that combination of clonidine (30 mcg) as an adjuvant with 0.50% isobaric ropivacaine (17.5 mg) in subarachanoid blockade for trans urethral resection of prostate results in prolonged duration of sensory blockade and extended postoperative analgesia compared to plain 0.75% isobaric ropivacaine (30 mg).

KEYWORDS

spinal anaesthesia ropivacain, clonidine, benign prostate hyperplasia

INTRODUCTION:

Nowadays, Anesthesia is given not only to prevent pain but also to make the operation easier, faster and non-complicated for the patient. Due to significant progress in the safety of anesthesia, spinal anesthesia and other regional techniques are frequently used in lower extremity operations [1]. Spinal anaesthesia is a popular and common technique used worldwide The advantages of it an awake patient, simple to perform, offers rapid onset of action, minimal drug cost, relatively less side effects and rapid patient turnover has made this the choice of many surgical procedures[2]. Central neuraxial opoids, intrathecal as well as epidural, offer the benefit of analgesia but however the related side effects include sense of dizziness, nausea, vomiting, pruritis, urinary retention and even cases of respiratory depression have been reported[3].

Intrathecal clonidine is being extensively evaluated as an alternative to neuraxial opoids for control of pain and has proven to be a potent analgesic, free of atleast some of the opoid related side effects[4]. Intrathecal clonidine at the dose of 1 to 2 mg/kg was regularly reported to significantly improve the intensity and increase the duration of sensory and motor block provided by local anesthetics[5,6] and reduces the amount or concentration of local anaesthetic required to produce postoperative analgesia[7,8]. However, it was inevitably associated with bradycardia, relative hypotension, and sedation.

Bupivacaine, available as a racemic mixture of its enantiomers dextrobupivacaine and levoupivacaine, has been the gold standard for intrathecal use in spinal anaesthesia for many years[9]. Bupivacaine has been in clinical use since 1963 [10]. It has been classified as an agent of high anaesthetic potency and long duration of action, which like all amide anaesthetics has been associated with cardiotoxicity. Cardiovascular toxicity manifests as hypotension, bradycardia, conduction abnormalities, ventricular arrhythmias such as torsades pointes and finally cardiac arrest [11].

A newly introduced long acting amide linked local anaesthetic congener structurally similar to bupivacaine called `ROPIVACAINE` has been introduced since 1996. Ropivacaine, the S-(-)-enantiomer of 1-propy-l,2,6-pipecolo-xylidide, is a new amino- amide local anaesthetic, structurally related to bupivacaine and mepivacaine[12]. This drug which is currently under clinical investigation, appears to be an effective local anesthetic with a long duration of action when given epidural. Sensory block characteristics after epidural administration of ropivacaine 0.5% are similar to those of bupivacaine 0.5% [13]. However, ropivacaine 0.5% is less potent than bupivacaine 0.5% in terms of producing motor block. Ropivacaine produces less motor blockade and is of shorter duration than bupivacaine[14,15]. The reduced lipophilicity of Ropivacaine is also associated with decreased potential for central nervous system toxicity and cardiotoxicity [11]. Thus it is a favorable local anaesthetic for day care surgeries and associated with earlier post operative mobilization than bupivacaine. A very important advantage of ropivacaine over bupivacaine is less cardiovascular toxicity but the duration of action of ropivacaine in intrathecal anaesthesia is approximately 50% to 67% than that of the bupivacaine. However, each drug has its own limitations and a need for alternative methods or drugs always exist.

So the present study was planned to investigate the effects, (onset of action, duration of action, quality of sensory and motor block, haemodyamic stability and post-operative analgesia) of intrathecal 4.0 cc of 0.75% isobaric ropivacaine and 3.5 cc of 0.50% isobaric ropivacaine with 30 mcg clonidine plus 0.3 cc of sterile normal saline in benign prostate hyperplasia patients undergoing trans uretheral resection of prostate.

MATERIAL AND METHODS:

The present study was conducted at the Department of anaesthesiology and Critical Care, Government Medical College and Associated Group of Hospitals, Kota in patients posted for elective trans urethral resection of prostate in patients with benign prostate hyperplasia. This study was done after ethical committee approval and written informed consent obtained from all the patients included in this study.

Study design:

Prospective, randomized, double blind, comparative study.

Source of data:

Patients in the age groups (46-75yrs) with American Society of Anesthesiologists (ASA) I & II and scheduled to undergo trans uretheral resection of prostate under spinal anesthesia Eighty(80) adult patients, satisfying inclusion criteria, were randomly divided into two

groups of forty each, randomization were done by closed envelope technique.

Group R (n=40) - 4.0 cc of 0.75% isobaric **Ropivacaine** alone.

Group RC (n=40) - 3.5 cc of 0.50% isobaric **Ropivacaine** in combination with 30 mcg (0.2cc) **Clonidine** combination plus 0.3 cc of normal saline to make the volume 4.0cc.

Procedure for double blinding-
In our study the technical aspect of procedure was conducted by one anaesthesiologist and the observational part were analysed by a different anaesthesiologist.

Pre anaesthetic evaluation:-
patients included in this study were undergo thorough standard preoperative evaluation Patients who was satisfy the inclusion criteria were explained about the nature of the study and the anaesthetic procedure. Written informed consent were obtained from all patients included in the study. Patients were advised to be nil orally from 10 p.m. onwards on the previous day of surgery. The standard procedure of subarachnoid block was explained and the patient was informed to communicate to the anesthesiologist about perception of any pain or discomfort during the surgery. During surgery, Patients were monitored continuously using non invasive blood pressure, pulse oximeter and ECG. After spinal anaesthesia, oxygen (4L/min) by facemask was given.

Parameters studied:-
The following parameters was observed and recorded.

Vital parameters:-
HR, SBP, DBP, MAP, RR and SpO2 monitored at baseline, after drug injection for every 2 mins for first 10 mins, then every 10 mins for next 30 mins and 20 mins thereafter till end of the surgery and transfer of patient.

Sensory blockade:
- Time to onset at T10-defined as loss of pin prickatT10.
- Maximal sensory level.
- Time taken to achieve maximal sensory block.
- Duration of sensory block at T10- defined as time to two segment regression.
- Duration of sensory block till regression- defined as time to complete regression of sensory block.

Motor blockade:
- Time taken to complete block.
- Duration of block.
- Duration of effective analgesia

Post-operative analgesia: Total opioid (tramadol) consumption in first 24 hrs following surgery

Motor block will be assessed by Modified Bromage Score as used by Breen et al.

Score	Criteria
1	Complete block (unable to move feet or knees)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

RESULTS:
(A) Observation made during induction of spinal block

Table 1 Comparison of maximal sensory block level in group R and group RC

Maximal Sensory Level	Group R	Group RC
	No. of patients	No. of patients
T4	2(5%)	2(5%)
T6	14(35%)	10(25%)
T8	12(30%)	10(25%)
T10	12(30%)	18(45%)
Total	40	40

Table 2 Comparison of duration (min) of sensory block at T10 in group R and group RC

Variables	Group R	Group RC
Mean ± SD	108.35±12.54	119.50±20.37
Mean difference	11.15	
p value	0.04 (significant)	

(B) Observation made during recovery of spinal block

Table 3 Comparison of duration (min) of sensory block till regression in group R and group RC

Variables	Group R	Group RC
Mean ± SD	205±26.31	255.5±65.47
Mean difference	50.5	
p value	0.0001 (significant)	

Table 4 Comparison of duration (min) of motor block in group R and group RC

Variables	Group R	Group RC
Mean ± SD	173.50±25.57	176±53.316
Mean difference	2.5	
p value	0.9 (insignificant)	

Table 5 Comparison of time to first request for post operative analgesia (min) by patients in group R and group RC

Variables	Group R	Group RC
Mean ± SD	336±76.18	403.45±89.03
Mean difference	67.45	
p value	0.005 (significant.)	

Table 6 Comparison of total opioid (tramadol) consumption (mg) in first 24 hours following surgery by patients in group R and RC

Variables	Group R	Group RC
Mean ± SD	96.25±39.85	77.50±39.14
Mean difference	18.75	
p value	0.03(significant.)	

DISCUSSION:
Subarachnoid block is a very well accepted and an excellent anesthetic technique in this modern era with a high success rate and a good safety profile. Hence, the search is always on for a drug which is safer, efficacious and less toxic with an early recovery profile. Our study design consisted of eighty patients, ASA physical status I, II undergoing elective trans urethral resection of prostate for benign prostate hyperplasia under spinal anesthesia, they were randomly divided into two groups after taking informed consent. In our study we evaluated the effects of intrathecal 4 cc of 0.75% isobaric ropivacaine (30 mg) and 3.5 cc of 0.50% isobaric ropivacaine(17.5 mg) with 30 mcg clonidine combination.

Baseline hemodynamic parameters did not show any difference between the groups. 57.1% of patients in Group R had a maximum sensory level of T6in comparison with Group RC in which 68.6% achieved a level of T6. The level T4was achieved in 20% of the patients in Group R and 31.4% of the patients in Group RC. A maximum sensory level of only up to T8 was achieved in 22.9% of patients in Group R. The upper extent of the sensory block was higher in Group R, when compared with Group RC, which was statistically significant.

Onset sensory block
A study conducted by Ogun C et al [16] concluded that the mean onset sensory block in group R was 5.6±2.7 and in group RC was 6.5±4.7. In our study the mean onset sensory block in group R was3.57±1.37 and in group RC was 4.12±1.38. The difference is non-significant as the p value is >0.05.

Maximal sensory level
A study conducted by Kleef VJ et al [17] concluded that the upper level of analgesia was obtained at T10-11 (L4-T4) and T11 (L4-T5) respectively, maximal sensory level was higher for 0.75% ropivacaine. In our present study, maximal sensory level in group (R) was T6(T4-T10) and in group (RC) was T10(T4-T10). This showed maximal sensory level in group (R) was higher by 4 segmental level than in group (RC).

Duration of sensory block till regression
A study conducted by Kock D et al [18] concluded that duration of sensory block in group R is 112±11.1 min and in group RC is 123±19.5

min. In our study, duration of sensory block till regression was considerably prolonged in group (RC) with 255.5±65.47min and in group (R) it was 205±26.31 min which was statistically significant as the p value is <0.05. (Table 3)

Duration of motor block

A study conducted by Ogun C et al [16] concluded that Duration of motor block in group A was 144±12.5 min and in group B was 153±19.9 min. In our study, Duration of motor block in Group R was 173.5±25.57 min compared to Group RC 176±53.31 min which was statistcally non-significant as the p value is >0.05.

Time to first request for post-operative analgesia

A study conducted by Ogun C et al [16] concluded that Time to first request for post-operative analgesia in group A was 3.5±1.2 hours and in group B was 6.8±2.2 hours. In our study, time to first request for post operative analgesia (min) was considerably prolonged in group RC with 403.45±89.03 min and in group R it was 336±76.18 min which was statistically highly significant (p value 0.0005).

Total opioid

A study conducted by Shah Z et al [19] concluded that Total opioid injections given in post operative period for group R was 1.47± 0.57 and for group RC was 2.30± 0.60, in this study the requirement of analgesia was lesser in group R.

In the present study, total opioid (tramadol) consumption (mg) in first 24 hours following surgery was lower in group RC 77.50±33.87 mg when compared to group R 96.25±38.20 mg which was statistically significant (p value 0.03).

CONCLUSION:

On the basis of the present clinical comparative study, we concluded that combination of clonidine (30 mcg) as an adjuvant with 0.50% isobaric ropivacaine (17.5 mg) in subarachanoid blockade for trans urethral resection of prostate results in prolonged duration of sensory blockade and extended postoperative analgesia compared to plain 0.75% isobaric ropivacaine (30 mg).

Conflict of interest: there is no conflict of interest between authors

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