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A RANDOMIZED, PROSPECTIVE, COMPARATIVE STUDY COMPARING ROPIVACAINE 0.3%, 0.5% AND 0.7% WHEN USED FOR ULTRASOUND GUIDED CAUDAL EPIDURAL INJECTION FOR PATIENT UNDERGOING SURGERY OF ANORECTAL REGION (FISTULA IN ANO, ANAL FISSURE AND HEMORROIDECTOMY)".

Anaesthesiology

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ABSTRACT

Background For minor ano-rectal surgeries are spinal anaesthesia, caudal blockade, posterior perineal block and field block.Ultrasound guided caudal anaesthesia for adult anorectal surgeries is an attractive option for day care surgeries. Ultrasound sound (US) guided caudal injections demonstrate improved success rates, reduced numbers of attempts, blood aspiration, bone contact, and inadvertent subcutaneous injections in comparison with blind technique **Method And Material:** In the present comparative, prospective study we have included 90 patient of either sex of ASA grade 1 and 2 in three groups undergoing anorectal region surgery under caudal block. Patient were randomly allotted into three groups of 30 each Group A received Ropivacaine 0.3%, Group B received ropivacaine 0.5%and Group C received 0.75 % by caudal route. Patients were assessed for clinical efficancy by measuring duration of sensory block compared between the three groups S1 dermatome as an indicator of onset of sensory loss. **Result:** Durations of sensory block also depend upon dose of drug. In our study duration of sensory blockade among group A, group B and group C is 154.3±14.3, 178±15.6and 186±17 minutes respectively. Increase the duration of sensory block was observed with higher concentration of ropivacaine Upon subjecting these values to intergroup comparison, statistically significant difference was seen between groups A & group B and also between group A & group C. However no statistically significant difference was seen between group B and group C. **Conclusion:** We conclude 0.5 % ropivacaine is better choice with least side effect of local anaesthesia as compared to ropivacaine 0.75%, in terms of duration of blockade was statistically not significant between 0.75% and 0.50% of ropivacaine.

KEYWORDS

Ropivacaine, Ultrasound, Caudal

BACKGROUND

Many of the anorectal surgeries such as Hemorroidectomy, fistulectomy are now performed as day care surgeries. Anesthesia techniques commonly used for anorectal surgeries include local anaesthetic agent infiltration with or without sedation, central neuraxial blockade and general anesthesia. It is unclear whether any of these techniques are superior according to uniform outcome assessment. An optimal anesthetic technique for outpatient surgeries should provide excellent operating condition, low incidence of adverse events, high patient acceptance and rapid patient recovery and discharge from hospital[2]. Single-shot caudal epidural blockade is an ideal perioperative pain management strategy in patient undergoing hemorrhoidectomy, because of the ease of performing procedure, the reliable analgesia and the relaxation of anal sphincter it provides[3].

Caudal anesthesia was first described by two French physicians, Femand Cathelin and Jean-AnthanaseSicard. Sicard and Cathelin first described sacral approach to epidural anaesthesia 1901 but first published report of use of caudal anaesthesia in children was in 1933 by Campbell[5] Ultrasound guided caudal anaesthesia for adult anorectal surgeries is an attractive option for day care surgeries. Ultrasound sound (US) guided caudal injections demonstrate improved success rates, reduced numbers of attempts, blood aspiration, bone contact, and inadvertent subcutaneous injections in comparison with blind technique[6] The treatment effect, complication rates, and adverse events were comparable to fluoroscopic technique[7], while the time required for the procedure is lesser with ultrasound guidance.Therefore we conducted a randomized controlled trial (RCT) to compare injection ropivacaine in concentration 0.30%, 0.50% and 0.75% in ultrasound guided caudal epidural injection for patient undergoing anorectal region surgery in adult .

Purpose of this study is to find out an anaesthetic technique for outpatient ano-rectal surgeries that provides excellent operating conditions, absence of adverse events, high patient acceptance, and rapid patient recovery and discharge.

METHOD AND MATERIAL:

This study was carried out in Swaroop Rani Nehru Hospital associated with Moti Lal Nehru Medical College, Prayagraj over period of one year from July 2021 to June 2022 after approval of synopsis from Ethical Committee of the Institution and obtaining written and informed consent from all the patient.

Group allocation:

Total 90 patients were randomly allocated into any of the three groups using computer generated random number table (30 patients in each group).

GROUP-A:	30 Patients	Patients will receive 20 ml of 0.3% Ropivacaine
GROUP-B:	30 Patients	Patients will receive 20 ml of 0.5% Ropivacaine
GROUP-C:	30 Patients	Patients will receive 20 ml of 0.75% Ropivacaine

Study Design –

This was a Prospective, Randomized, Interventional, Double blind and Non- Placebo study.

Total of ninety patients (90 patients in each groups) belonging to American Society of Anaesthesiologists (ASA) physical status I – II in the age group of 18-45 years of either sex posted for Elective scheduled for minor (estimated duration less than an hour) anorectal elective procedures (hemorrhoidectomy, perianal fistula, fissurectomy, polypectomy, etc.)

Inclusion criteria

- Adult patients of either sex
- Age between 18-45 year
- Patients of ASA grade I and grade II.
- Those scheduled for elective anorectal procedures of short duration.

Exclusion Criteria

- Patients refusal
- Bleeding diathesis, platelet count< 1, 00,000
- Prolonged surgeries (> 60 min)
- ASA physical status III or ≥ IV
- History of allergy to any study drugs, seizure disorders, Neurological and neuromuscular disorders.

- Anatomical malformation at puncture site.
- Failed Block

Technique:

Pre-anaesthetic visit:

In pre-anaesthetic visit one day prior to surgery, a detailed pre-anaesthetic examination including history, general examination, and systemic examination was done and examination of spine for any deformity or infection was noted. Airway assessment was done. Informed and written consent was obtained from each patient after the procedures were fully explained to patients in their own language. Age, weight, height, side of surgery were noted in all patients. Baseline parameters like pulse rate, blood pressure, SpO_2 respiratory rate was recorded during pre anaesthetic checkup. Baseline investigations like hemoglobin, blood sugar, blood urea, serum creatinine, platelet count, bleeding time, clotting time, chest X ray, ECG, were advised. All patients were kept nil per orally 6 - 8 hours. Tab. Ranitidine 150 mg and tab. Alprazolam 0.25 mg were given orally night before the surgery. Visual analogue score was explained to the patients.

In the operating room :

In the operation theatre, patient inquired for 8 hrs Fasting period and is being asked to void the bladder. On arrival, intravenous access was established using an 18-gauge cannula and patients were premeditated with midazolam 1 mg intravenously and a 10 ml/kg of intravenous Ringer Lactate was infused over 20 - 25 min prior to the Block. In the operation theatre standard ASA monitors like heart Rate (HR), arterial blood pressure, respiratory rate (RR) and peripheral oxygen saturation probe SpO_2 were attached and pre-operative parameters were recorded. Patients were then placed in the prone position. The sacral cornua are identified by palpation using the technique described in the section on anatomic landmarks. Sterile skin preparation and draping of the entire region are performed. After informing the procedure to the patient

a low frequency curvilinear probe, were placed in the transverse plane across the two sacral cornua. The sacral cornua can be visualized as two symmetric hyper echoic arches, with a hypo echoic shade underneath both lines, bridging these two structures. Traversing this hypo echoic area were two hyper echoic lines, the superficial one being the sacrococcygeal ligament and the deeper one line being the dorsal bony surface of the sacrum. At this point transducer was rotated 90° to examine the sonographic longitudinal view of the sacral hiatus, caudal canal were identified as a hypo echoic canal, tapering off caudally and bordered by dorsal and ventral hyper echoic bands.

The 21gauge echogenic needle was inserted into the space between the two cornua. A distinct “pop” were felt as the needle tip penetrates the sacrococcygeal ligament, a 21gauge echogenic needle appeared as a hyperechoic structure under sonography. The advancement of the 21-gauge echogenic needle between the two cornua to the sacral hiatus and into the caudal epidural space was observed as continuous and real-time sonographic images. As the 21gauge echogenic needle pierced through the sacrococcygeal ligament, the portion of the needle inside the caudal epidural space was no longer observed under sonography.

Under the transverse view, the spinal needle appeared as a small circular hyperechoic structure, resting between the two hyperechoic cornua, and within the two hyperechoic band-like structures. Once the needle was within the caudal canal, negative aspiration was done to ensure there is no CSF or blood. Once negative aspiration were confirmed, injection were carried out under real-time ultrasonography The needle tip was confirmed using a transverse view, and few milliliters of drug was injected in a pulsatile manner, The spread of the injectate drug can be visualized as turbulence within the caudal canal and the expansion of the epidural space were observed. A total volume of 20 mL of drug was injected.

The patients were turned into the supine position and put in lithotomy position following parameters were monitored.

1) Duration of sensory block by checking Hypoesthesia to pin-prick sensation was checked in S1 dermatome level.
2) Duration of surgery.

Patients will be asked to grade the procedural comfort according to the verbal response scale (no pain, mild, moderate, and severe pain).

Any discomfort either during positioning and surgery will be noted and if significant, supplemental analgesia or general anesthesia will be planned to be administered according to the anesthesiologist's preference.

Hypotension was defined as 20% fall in mean arterial pressure from the baseline and was treated with injection. Mephentermine Sulphate and fluids.

Bradycardia was defined as pulse rate less than 60 beats / minute and was managed with Injection. Atropine 0.6mg.

Rescue analgesia was given when VAS more than 4. Injection. Pentazocine 0.5 mg/kg was given intravenously.

Other complications like local anaesthetic toxicity were also noted.
There are various scale using for assessing the pain score in post-operative

RESULT:

Durations of sensory block depend upon dose of drug. In our study duration of sensory blockade among group A, group B and group C is 154.3±14.3, 178±15.6and 186±17 minute respectively. Increase the duration of sensory block was observed with higher concentration of ropivacaine.

Upon subjecting these values to intergroup comparison, statistically significant ($P<0.05$)difference was seen between groups A & group B and also between group A & group C. However no statistically significant difference was seen between group B and group C($P>0.05$).

Table 1: Mean (SD) of duration of sensory block (in minutes) and its significance

Group	Mean (SD) Duration of sensory block	ANOVA p-value & Significance	p-value Group A Vs Group B	p-value Group B Vs Group C	p-value Group C Vs Group A
Group A	154.3(14.3)	0.00000000005 (Signi.)			
Group B	178.6(15.6)		0.00000007 (Signi.)	0.0586 (Not Signi.)	0.00000000002 (Signi.)
Group C	186.2(17)				

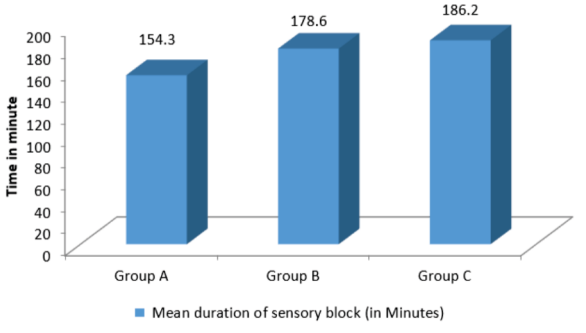

Fig 1: Mean duration of sensory block of patients among groups

The mean duration of sensory block is depicted in Fig 1. It can been seen that the average duration of sensory block is greater than in Group C than Group B and Group A. The ANOVA and group-wise comparisons are given in Table-1. The ANOVA has p-value less than 0.05 hence it is significant also all the group-wise comparisons are significant except that the comparison between Group B and Group C.

DISCUSION

In the study done by ***Su Y et el. (2015)***[8],they used 0.25%,0.50 and 0.75 concentration of drugs and compared their efficacy, onset and duration sensory blockade in patient posted for inguinal hernioplasty and found 0.50% optimal effective with least side effect.

Our study was also supported by ***Finucane BT et al. (1996)***[10], who studied to investigate the dose-response relationship of increasing doses of ropivacaine on the quality of anaesthesia and the duration of both motor and sensory blockade. In their study they found least consistent difference between ropivacaine 0.75% and 0.50%. Similar

results were observed in our study that in with increasing dosage of ropivacaine was associated with an increased clinical effect. However the increase in clinical effect was statistically not significant between 0.75% and 0.50% of ropivacaine

Similar study was conducted by ***Sharma S et al.(2021)*** [9] , they compared hemodynamic changes associated with different doses of ropivacaine and they found that both ropivacaine 0.75% and 0.5% are equal efficient in providing anesthesia .

CONCLUSION:

In our study it was found that injection ropivacaine in concentration 0.75% has longer duration of action but more side effect of local anaesthesia then 0.50% and 0.30%. where as comparing 0.50% and 0.75% concentration, it was found that 0.30% concentration has shorter duration as compared 0.50% . so we conclude that injection ropivacaine 0.50% is better than 0.30% and 0.75% concentration in caudal epidural block in anorectal region surgerys.

Limitations

1) Our study, one was the small sample size and hence future studies need to be undertaken with a large size population
2) Ultrasoundguided caudal block is the difficulty in identifying intrathecal or intravascular injection. Contrast fluoroscopy is still the best technique to rule out inadvertent intrathecal or intravascular injection
3) USG longer learning curve and so results are user dependent

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