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A COMPARATIVE STUDY OF 0.5 % BUPIVACAINE WITH FENTANYL VERSUS 0.75% ROPIVACAINE WITH FENTANYL IN EPIDURAL ANESTHESIA FOR ABDOMINAL HYSTERECTOMY

Anaesthesiology

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ABSTRACT

INTRODUCTION Abdominal hysterectomy (AH) is a quite common gynaecological surgical procedure and electively done under central neuraxial blockade. AH is performed for malignant as well as benign indications such as uterine leiomyoma, persistent vaginal bleeding, or pelvic organ prolapse.

AIMS AND OBJECTIVES Compare the onset of motor and sensory block. Find out the duration of the sensory and motor blockade. Observe intraoperative hemodynamic changes and assess post-operative analgesia requirements in 24 hour. Duration of analgesia assessed by requirement of first rescue analgesic. Observe any untoward incident during intraoperative and post-operative period and managed accordingly

MATERIALS AND METHODS

Study Area: Department of Anesthesiology & critical care, DARBHANGA MEDICAL COLLEGE AND HOSPITAL.

Study Population: Adult patients (30- 65 years) undergoing elective abdominal hysterectomy with regional anaesthesia were included for this study.

Study Period: January 2019 to March 2020

Sample Design: Subjects were divided into two groups (n=35) equal in numbers and they sampled as per computerized randomization chart. These patients were divided into two groups, group B (with epidural 0.5% bupivacaine and 100 g fentanyl) and group R (with epidural 0.75% ropivavaine and 100g fentanyl).

Study Design: Prospective, open, randomized, controlled study.

RESULTS: In Our study showed that 3.38kg/m2 and 24.86 3.60 kg/m2in group B and R respectively. The duration of surgery was 100.86 9.35minutes and 98.86 8.32 minutes and the duration of stay, was4.86 0.81days and 4.60 0.914 days in group B and group R respectively. Now with comparison of both groups, time to onset of sensory block (uptoT6) has significant variation. But the other parameters namely, time to onset of motor block, two segment regression or duration of sensory block, rescue analgesia timing and complete motor recovery time were comparable and not significant statistically in both groups.

SUMMARY & CONCLUSIONS To conclude that in the present study using 0.5% bupivacaine with fentanyl and 0.75% ropivacaine with fentanyl epidurally, ropivacaine produced an earlier onset but similar duration of sensory block. The onset, quality and duration of motor block werecomparable in both the groups. It is important that new local anaesthetics with lower cardiotoxic property are adopted to ensure that regional techniques using large amounts of local anaesthetics remain safe with minimal complications. The recovery profile of ropivacaine may be useful where prompt mobilization is required.

KEYWORDS

0.5 % Bupivacaine, Fentanyl Versus, 0.75% Ropivacaine, Fentanyl In Epidural And Abdominal Hysterectomy

INTRODUCTION

Abdominal hysterectomy (AH) is a quite common gynaecological surgical procedure and electively done under central neuraxial blockade. AH is performed for malignant as well as benign indications such as uterine leiomyoma, persistent vaginal bleeding, or pelvic organ prolapse.

Innervation of the urogenital tract is complex and made up of somatic, sympathetic and parasympathetic components, found along the lateral walls of the pelvis. The nerves and nerve plexuses in the pelvis innervate the organs of the pelvis through the ligaments that anchor the various organs to the pelvis. Innervation to the uterus, ovaries, and vagina is derived from the superior hypogastric, pelvic, and utero-vaginal plexus.[1]

A sensory level extending to T4 or T6 provides sufficient anaesthesia for procedures involving uterus. Either epidural catheter insertion in the lumbar region with high volumes of local anaesthetics (LA) to raise the sensory level or low to mid thoracic placement is appropriate.

Epidural anaesthesia for open procedures like lower abdominal surgeries, as abdominal hysterectomy has the advantages of providing prolonged postoperative analgesia, decreasing the incidence of post-operative nausea vomiting (PONV) and perioperative thromboembolic events, and potentially influencing perioperative immune function and, relatedly, the recurrence of cancer in patients undergoing hysterectomy for ovarian or related carcinoma. The proposed pre-emptive analgesia effect provided by neuraxial blocking during abdominal hysterectomy requires further investigation.[2]

Epidural analgesia with a combination of local anaesthetic and opioid can provide complete dynamic analgesia. It obtunds the stress response to major surgery and reduce the incidence of postoperative pulmonary, thromboembolic and cardiac complications. As part of a multimodal recovery programme, epidural analgesia can enhance the quality of patient recovery from major surgery and shorten hospital stay. Epidural postoperative analgesia is a popular technique to improve patient outcome and comfort while reducing hospital costs.[3] Epidural opioids combined with local anaesthetics have been widely used for facilitation of central neuraxial blockade and post-operative analgesia. Multiple studies have shown that epidural analgesia is more effective when they are combined with local anesthetics.[4]

Epidural opioids work by crossing the dura and arachnoid membrane to reach the CSF and spinal cord dorsal horn. Lipophilic opioids such as fentanyl has higher partition coefficient into epidural fat and therefore are found in CSF in lower concentration than hydrophilic opioids(morphine). Fentanyl readily absorbed into systemic circulation and found as principal analgesic mechanism.

Local anesthetics(LA) block the generation and propagation of nerve impulses by inhibiting the sodium flux required for impulse conduction through the placement in proximity to neural tissue, diffusion of the anaesthetic molecules through the axon membrane and binding to voltage-gated sodium channels, preventing activation. Reversal of blockade requires the diffusion of molecules out of the nerve with subsequent metabolism.[5]

After recognition of acute life-threatening cardiotoxicity [6] following accidental intravenous injection of bupivacaine10 has encouraged to discover a local anesthetic agent with a high therapeutic ratio and lower cardiotoxicity resulting in a development of a new amide, ropivacaine. Ropivacaine [S-(-)-1-propyl-2',6'-pipecoloxylidide hydrochloride monohydrate] is an amide local anaesthetic that differs structurally from bupivacaine in having the butyl group substituted by a propyl group and S-isomer is produce rather than racemic mixture.

AIMS AND OBJECTIVES

1. To compare the onset of motor and sensory block.
2. To find out the duration of the sensory and motor blockade.

3. To observe intraoperative hemodynamic changes and assess post-operative analgesia requirements in 24 hour.
4. To find out the duration of analgesia assessed by requirement of first rescue analgesic.
5. To observe any untoward incident during intraoperative and post-operative period and managed accordingly

MATERIALS AND METHODS

Study Area: Department of Anesthesiology & critical care, DARBHANGA MEDICAL COLLEGE AND HOSPITAL.

Study Population: Adult patients (30- 65 years) undergoing elective abdominal hysterectomy with regional anaesthesia were included for this study.

Study Period: January 2019 to March 2020

Sample Size: Sample size for this study was calculated on the basis of duration of analgesia (interval between administration of study drug and first administration of rescue analgesia) as the primary outcome measure. It was estimated that 35 subjects are required in each group in order to detect the difference of 30 min in this outcome measure with 80% power and 5% probability of type 1 error. This calculation assumed a standard deviation of (SD) of 45min for the same duration of analgesia and two- sided testing. Sample size calculation was done using nMaster 2.0 (Dept. of Bio-statistics, CMC, Vellore) software.

Sample Design: Subjects were divided into two groups (n=35) equal in numbers and they sampled as per computerized randomization chart. These patients were divided into two groups, group B (with epidural 0.5% bupivacaine and 100 g fentanyl) and group R (with epidural 0.75% ropivavaine and 100 g fentanyl).

Study Design: Prospective, open, randomized, controlled study.

PARAMETERS TO BE STUDIED

I. Onset of sensory block at T6 dermatome by needle prick sensation andduration of sensory block till regression to T8 dermatome
ii. Onset and duration of motor block by modified Bromage scale
iii. Duration of analgesia assessed bytime to administration of first rescue analgesic according to visual analogscale (VAS)
iv. Vitals- heart rate, mean blood pressure, pulse oximetry, respiratory rate
v. Post-operative analgesia by VAS
vi. Post-operative total analgesic requirement in the first 24 hours

INCLUSION CRITERIA:

a) Adult female patients, aged between 30 to 65yrs, BMI 18.5 to 29.9 kg/meter^{2}with ASA physical status I&II.
b) Patients scheduled for elective abdominal hysterectomy under lumbar epidural anaesthesia.

EXCLUSION CRITERIA:

a) Patient refusal.
b) Any contraindication to epidural anaesthesia –
I. Infection at the site of injection
ii. Coagulopathy
iii. Neurological disorders and psychiatric disorder
iv. Haemodynamically compromised patients
v. Sepsis
vi. Gross anatomical abnormality of vertebral column.
vii. Known allergy to either bupivacaine or ropivacaine or fentanyl.
viii. Patients on chronic antiplatelet drugs and anticoagulants.

Table: Demographic data, duration of surgery and hospital stay:

	Group B (mean SD) (n=35)	Group R (mean SD) (n=35)	p value
Age (year)	51.09 5.10	51.83 7.62	0.633
Weight(kg)	58.54 10.62	61.66 13.18	0.285
Height(cm)	149.14 7.31	145.41 8.51	0.470
BMI(kg/m2)	26.07 3.38	24.86 3.60	0.152
Duration of Surgery (minutes)	100.86 9.35	98.86 8.32	0.348
Duration of Stay (day)	4.86 0.81	4.60 0.914	0.423

RESULTS:

In Our study showed that 3.38kg/m2 and 24.86 3.60 kg/m2in group B and R respectively. The duration of surgery was 100.86 9.35minute and 98.86 8.32 minutes and the duration of stay, was4.86 0.81days and 4.60 0.914 days in group B and group R respectively. Now with comparison of both groups, time to onset of sensory block (uptoT6) has significant variation. But the other parameters namely, time to onset of motor block, two segment regression or duration of sensory block, rescue analgesia timing and complete motor recovery time were comparable and not significant statistically in both groups.

In comparison to both groups, as shown in table 2 and fig. 2,time to onset of sensory block upto the level of sixth thoracic dermatome[p=0.005] and less in groupR than in group B.It was revealed that onset of sensory block was(11.34 1.75 min)and(10.06 1.95 min) in group B and Respectively. 95% confidence interval of this standard error of difference (0.443) was [-2.16808 to -0.40192]. Other variables namely, onset of motor block was (11.93 1.12 min)and (12.74 1.11 min) in group B and group R respectively. The duration of analgesia or rescue analgesia time was(348.86 23.10 min) in group B and (358.29 29.95 min) in group R. The two segment regression time (duration of sensory block) was (147.43 12.56 min)and (148.76 11.92 min)in group B and group R respectively. The time to complete motor recovery was(329.14 29.54 min)in group B and (331.71 27.17 min) in group R.

We found, the total drug dose in mg, the total post-operative drug dose (mg) and fixed dose of fentanyl used during epidural anesthesia were described. In table 3, the primary epidural drug (mg) and post-operative epidural drug in 24hour (mg) were significantly less in bupivacaine group than ropivacaine group. The primary epidural drug was (117.29 5.47 mg)in group B and(176.05 6.12 mg)in group R. Total 24hour post-operative drug was (42.29 5.47 mg) and (63.09 6.65 mg)in group B and group Respectively. The bromage score and sedation score were comparable. The bromage score was (2.83 0.382)in both group without any statistical significant value. The sedation score(Ramsay) was (2.11 0.323)in both groupand no significant variations were noted.

Our study showed that the RAM(%) was (24.0 2.14) in group B and (22.85 2.21) in group R and no significant variation in p value was seen. In table 4,Mann-Whitney U test was applied to find out the p-values between groups to assess U value and Z score. In comparison to both groups, Z-score and p-value of duration of stay in hospital were 1.081 and 0.245 respectively. In table 5, heart rate between groups was slowly decreasing after the epidural drug administration and comparable throughout the study in every point of measurement and there was no significant value when compared at every point statistically. The (mean SD) was (87.37 3.97) per minute in group B and(87.46 4.00) per minute in group R, when compared at the base point. The mean SD of heart rate at the point of 120 minute was (79.51 4.63) per minute in group Band(79.26 4.36) per minute in group R.

It was observed that, the values of SBP were decreasing slowly after the epidural drug administration (marked zero time, SBP 0). After 20 minute of epidural injection through lumbar route, a significant change was noted and a lower level of SBP was shown in group B than group R. These values were statistically significant. The SBP at base was (125.49 8.06 mmHg) in group B and (125.6 7.89 mmHg) in group R. It was also noted that SBP were comparable in both groups till 15th minute of epidural drug administration. In comparison to both group, 20th minutes onwards in group B less values of SBP were recorded than group R till the end of the operation. The SBP at 120min was (109.86 6.01mmHg) in group B and (115.69± 5.63 mmHg)in group R. All values were significant statistically.

These graphs clearly depicted the significant changes of SBP from 20th minute after drug administration and continued till the end of surgery(120minute). Ropivacaine group has less episode of fall in SBP than bupivacaine group. In table 7, diastolic blood pressure (DBP) in both groups was decreasing slowly after the injection of epidural drug as marked zero time(DBP 0). The DBP at base was 80.94 3.62 mmHg in group B and 81.71 3.61 mmHg in group R respectively and till 15th minute after epidural drug administration the DBP were comparable in both groups. After 20 minute of drug injection through epidural route, a significant fall in DBP was seen in group Bthan group R and was continued till the end of surgery. The DBP at 120min was 68.14 2.50 mmHg in group B and 76.17± 2.38 mmHg in group R. All of these values were statistically significant.

DISCUSSION

Epidural anaesthesia and analgesia is considered by most of anaesthesiologist as the gold standard technique for major lower abdominal surgery. Epidural techniques are specifically effective at providing dynamic analgesia and improves the intraoperative as well as post-operative outcome. It attenuates the physiologic response to surgery, in particular, significant reduction in pulmonary complication, thrombo-embolic episode, ileus, acute renal failure and blood loss. Bupivacaine is an excellent drug for epidural anaesthesia but it is associated with higher incidence of cardiotoxicity when high volume epidural drug is used. Ropivacaine are S(-) enantiomers of bupivacaine developed as an alternative to bupivacaine for its lesser incidence of potential toxicity.

The Rastogi et al [7] (2013) showed the contrast result. In their study, the onset of sensory block was shorter in bupivacaine group (12.4 6.9) min than ropivacaine group (17.5 3.7) min whereas the duration of sensory block was significantly more in bupivacaine group (175.8 8.6) min than ropivacaine (130.6 10.2) min.

It is well established that ropivacaine is less potent than bupivacaine but the effects may vary when opioids are added to it. Cherng et al[8] (2005), showed that onset of sensory block (T10) was 13.0 3.0 min when 15ml 1% epidural ropivacainemixed with 100 g fentanyl in contrast to16.2 3.5 min when epidural ropivacaine was combined with intravenous 100 g fentanyl. They commented that this effect was due to synergistic interaction between local anesthetics and opioids with epidural administration. Fentanyl might enhance the nerve conduction block of spinal roots. Similarly, Field (1980) et al[9] showed that primary afferent tissues (dorsal roots) contain opioid binding sites; thus fentanyl might act directly on the spinal nerve or penetrate the dura and act at the spinal roots.

Rao et al[10] (2016) showed thatepidural administration of the mixture of fentanyl and ropivacaine solution accelerated the onset of sensory and motor blocks during epidural ropivacaine anaesthesia without significant fentanyl related side effects. Fentanyl is a useful adjunct to local anaesthetic ropivacaine for epidural anaesthesia.

In the present study, similar findings were also noted due to the synergistic effect of epidural fentanyl with ropivacaine.

The study of the median onset and duration of motor block between two groups were comparable. Median duration of motor block in 1% ropivacaine group was 294 min and 318 min in 0.75% bupivacaine group. Similarly, the onset and duration of motor block were indistinguishable in both ropivacaine and bupivacaine group. Korula (2013) et al[11] found that the duration of motor block was comparable in both groups which supported well the findings of present study regarding duration of motor block.

Morrison (1994) et al[12] found that the motor block produced by ropivacaine was less intense and comparable in duration than that produced by bupivacaine which goes well in similarity with present study.

In contrast, the study stated that the duration of motor block in ropivacaine group (112.5 45) min and bupivacaine group (165.3 26) min was statistically significant. Demonstrated that hypotension was frequent with high levels of epidural anesthesia because of blockade of the preganglionic sympathetic nerve fibers leading to relative hypovolemia and decreased venous return.

Simon (2002) et al shows the hemodynamic changes and neural blockade occured after ropivacaine epidural anesthesia and postulated that splanchnic nerve blockade (T6- L1) will result in pooling of the blood in capacitance vessels of the splanchnic bed, contributing to the observed hypotension in patients with high level of analgesia.[13]

SUMMARY & CONCLUSIONS

Bupivacaine and ropivacaine are long acting local anesthetics used widely as regional anesthesia solely or with additives. Ropivacaine, have been developed as an alternative to bupivacaine after the evidence of its severe cardiac toxicity.

In hemodynamics, heart rate was comparable in both groups but blood pressures (SBP, MAP, DBP) was decrease significantly in bupivacaine group after 20min of administration of the epidural study drug.

To conclude that in the present study using 0.5% bupivacaine with fentanyl and 0.75% ropivacaine with fentanyl epidurally, ropivacaine produced an earlier onset but similar duration of sensory block. The onset, quality and duration of motor block werecomparable in both the groups. It is important that new local anaesthetics with lower cardiotoxic property are adopted to ensure that regional techniques using large amounts of local anaesthetics remain safe with minimal complications. The recovery profile of ropivacaine may be useful where prompt mobilization is required.

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