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EVALUATION OF EPIDURAL LEVOBUPIVACAINE 0.125% AND ROPIVACAINE 0.125% WITH AND WITHOUT FENTANYL FOR POSTOPERATIVE PAIN RELIEF IN ABDOMINAL SURGERIES

Anaesthesiology

Dr. B. Jayalakshmi Assistant Professor, Dept. of Anaesthesiology, Kurnool Medical College, Kurnool.

Dr. P. S. Arunalatha.* Assistant Professor, Dept. of Anaesthesiology, Kurnool Medical College, Kurnool. *Corresponding Author

ABSTRACT

AIMS AND OBJECTIVES : The aim of this study is to compare the effectiveness of post operative analgesia, associated haemodynamic changes, side effects like hypotension, nausea, vomiting, pruritis, urinary retention and to assess for any residual motor blockade with continuous epidural infusion of ropivacaine 0.125%, ropivacaine 0.125% with 1 µg/ml Fentanyl, levobupivacaine 0.125%, levobupivacaine 0.125% with 1 µg/ml Fentanyl

METHODOLOGY : The study was conducted in 120 patients admitted in Government General Hospital, Kurnool undergoing elective or emergency abdominal surgeries from 2014-2015, who are aged between 18 and 60 years, and of ASA grade 1 and grade 2. After institutional ethical committee approval and with informed parental consent, 120 patients were randomly allocated into four groups of thirty each.

OBSERVATIONS AND RESULTS: Analgesia was superior in levobupivacaine with Fentanyl infusion and least in plain ropivacaine infusion. Differences in analgesia found in levobupivacaine, ropivacaine with Fentanyl and plain levobupivacaine was not clinically significant. Hemodynamic changes among groups were found not statistically significant throughout the study. Associated motor block was found in two patients in levobupivacaine with Fentanyl group and one patient in plain levobupivacaine group. Nausea, vomiting was distributed equally among four groups. Hypotension was reported in levobupivacaine with Fentanyl and ropivacaine with Fentanyl groups but not significant. Pruritis was not observed in any of the groups. Urinary retention was noted in ropivacaine with Fentanyl and levobupivacaine with Fentanyl groups but not statistically significant.

Conclusion: We conclude from present study that levobupivacaine with fentanyl is an attractive option for postoperative epidural analgesia. Ropivacaine with Fentanyl and levobupivacaine with fentanyl were of equianalgesic efficacy and plain 0.125% ropivacaine infusion is of lower analgesic efficacy probably due to the shorter duration of action and less potency of ropivacaine.

KEYWORDS

INTRODUCTION

Postoperative epidural analgesia is an effective and well accepted modality of pain relief techniques after abdominal surgeries. Postoperative epidural analgesia improve patient's outcome. Early mobilization and ambulation accelerate postoperative recovery. Analgesia delivered through indwelling catheter is a safe and effective method for management of acute postoperative pain .Epidural infusion of local anesthetics alone or combined with opioids may be used for postoperative analgesia. The location of action of local anesthetics in the epidural space includes spinal nerve roots, dorsal root ganglion or spinal cord itself.Ropivacaine was introduced in India in 2009. It is the monohydrate of the hydrochloride salt of 1-propyl-2′,6′-pipecoloxylidide and is prepared as pure S-enantiomer. Levobupivacaine was introduced more recently in India in 2012. It is the pure S-enantiomer of racemic Bupivacaine.Ropivacaine, structurally closely related to bupivacaine is a pure S (-) enantiomer with lower cardiac and central nervous system toxicity. The latest advance in local anesthetics has been levobupivacaine, the pure S (-) enantiomer of racemic bupivacaine. Levobupivacaine has better safety profile compared to racemic bupivacaine.

AIMS AND OBJECTIVES OF THE STUDY:

The aim of this study is to compare the effectiveness of post operative analgesia, associated haemodynamic changes, side effects and to assess for any residual motor blockade with continuous epidural infusion of ropivacaine 0.125%, ropivacaine 0.125% with 1 µg/ml Fentanyl, levobupivacaine 0.125%, levobupivacaine 0.125% with 1 µg/ml Fentanyl in patients undergoing abdominal surgeries

The parameters compared are :vas scoring at rest and during movement, heart rate, systolic blood pressure, diastolic blood pressure, complications like hypotension, nausea, vomiting, pruritis, urinary retention, residual motor blockade, total amount of consumed local anesthetic and number of boluses required.

METHODOLOGY: 120 patients admitted in Government General Hospital, Kurnool undergoing elective or emergency abdominal surgeries from 2014-2015, who are aged between 18 and 60 years, and of ASA grade 1 and grade 2 were randomly allocated into four groups of thirty each

GROUP A: Thirty patients received 0.125% Ropivacaine infusion at rate of 8 ml per hour for 24 hours epidurally.

GROUP B: Thirty patients received 0.125% Ropivacaine with Fentanyl 1 microgram per ml at the rate of 8 ml per hour infusion for 24 hours epidurally.

GROUP C: Thirty patients received 0.125% Levobupivacaine infusion at the rate of 8 ml per hour for 24 hours epidurally.

GROUP D: Thirty patients received 0.125% Levobupivacaine with Fentanyl 1 microgram per ml at the rate of 8 ml per hour for 24 hours epidurally.

The study included different types of surgeries like Inguinal mesh hernioplasty, Appendicectomy, Incisional hernia repair, colostomy closure, ileostomy closure.

PREPARATION OF OPERATING ROOM:

Anaesthesia machine/Work station was checked. Appropriate size endotracheal tube, working laryngoscopes, stylet and working suction apparatus were kept ready before the procedure. Emergency drugs tray containing Atropine, Adrenaline, Ephedrine, Mephenteramine, Dopamine, hydrocortisone, antihistamines were kept ready.

EQUIPMENT:

The set for the procedure includes the following**:**

1) Sterile gloves.
2) Centrally fenestrated drape.
3) 18 gauge tuohy needle.
4) 2ml syringe.
5) 5ml syringe for loss of resistance.
6) 10ml syringe with 20G needle.
7) 2% lignocaine vial for local infiltration.
8) 23 G spinal needle.
9) 0.5% Bupivacaine ampoule.
10) 2 sponge holders.

11) 18G epidural catheter.

PROCEDURE:
On the day of surgery, preoperatively pulse rate, blood pressure and respiratory rate were recorded. An intravenous access was secured with 18gauge cannula before the procedure and 500ml of ringer lactate was infused to preload the patient.

MONITORING:
The monitors connected to the patients included non invasive BP, pulse-oximeter. Baseline PR, BP, SPo2 had been recorded. Three lead ECG with standard Lead II was used when necessary. After proper positioning and under strict aseptic precautions local infiltration of Lignocaine 2% 2 ml at the puncture site, 18 gauge Tuohy's needle was inserted into the L1 2 or L2-3 or L3-4 interspinal epidural space. Epidural space was confirmed by the loss of resistance method by 10 ml L.O.R. syringe. After negative aspiration for CSF and blood, institution of test dose of (3 ml injection lignocaine with adrenaline 2%) and subarchanoid injection was ruled out, epidural catheter was inserted and fixed. Subarachnoid block was achieved by injecting 3 cc of 0.5% hyperbaric Bupivacaine hydrochloride into L2-L3 or L3-L4 interspace. Surgery was performed under spinal anesthesia and the patients were randomly allocated into one of the four study groups. Post-operatively, the patient's vital signs were monitored continuously and analgesia was assessed every hour using the visual analogue scale (VAS) (0- no pain to 10- maximum pain). Epidural infusion was started only when the patient complained of pain with VAS of >3 and bromage score decreased to 0. All patients received an initial loading dose of 5 ml of the study drug. This was followed by an infusion of 8 ml/h with top ups of 5 ml as required for break through pain. VAS scores at rest and movement were recorded at initiation of infusion, 1 hour, 3 hours, 6 hours, 12 hours, 18 hours, and 24hours.

STATISTICALANALYSIS
In total 120 patients, 30 patients were allocated to each group.

At the end of study, all data was analyzed using Graphpad Prism Software version 6.03 (Graphpad Software Inc., USA).

Descriptive data presented as mean ± SD.

Quantitative data were analyzed by ANOVA followed by unpaired't' test.

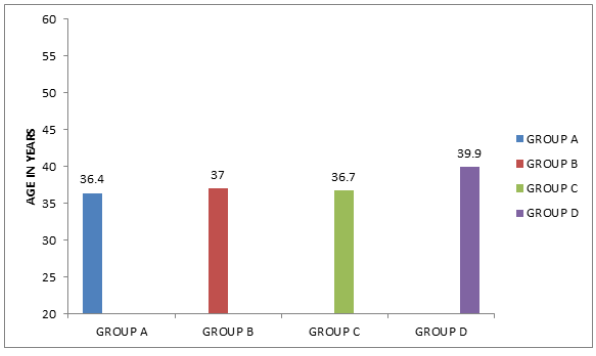
Qualitative data were analyzed using chi square test.

Inter group comparisons of percentage change of hemodynamic parameters compared to baseline were done by repeated measure ANOVA followed by unpaired't' test with Bonferoni's correction.

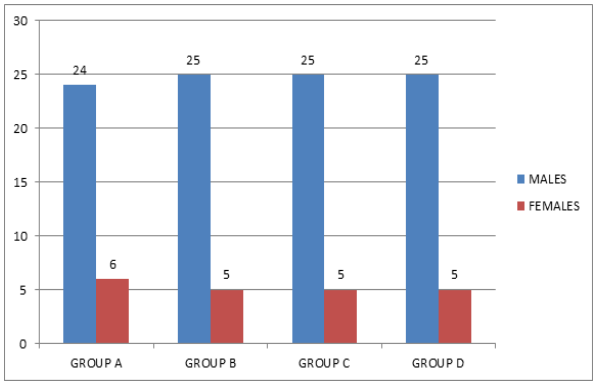
P value < 0.05 was taken as statistically significant.
P value <0.001 was taken as statistically highly significant

OBSERVATION AND RESULTS
DEMOGRAPHIC DATA:
The demographic data is given in the below table. The data was comparable between the four groups.

AGE DISTRIBUTION:
GRAPH 1: GRAPHICAL REPRESENTATION OF AGE:



SEX DISTRIBUTION:
GRAPHICAL REPRESENTATION OF SEX: GRAPH 2



VAS SCORING AT REST:
Pain intensity was assessed by VAS scoring.

GRAPHICAL REPRESENTATION OF VAS SCORING AT REST: GRAPH 3

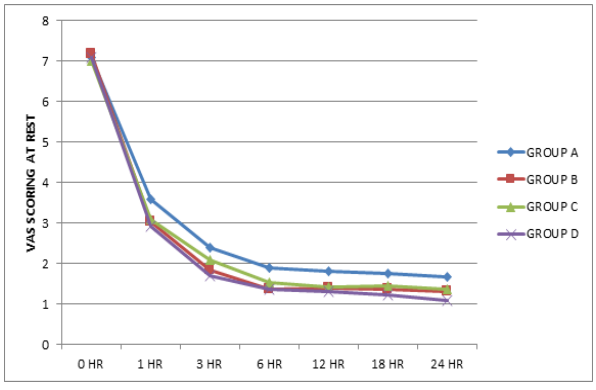


TABLE -4 INTERGROUP COMPARISON OF VAS SCORES AT REST:

	p value						
Groups	**0 hrs**	**1 hr**	**3 hrs**	**6 hrs**	**12 hrs**	**18 hrs**	**24 hrs**
A and B	NS	S	S	S	S	S	S
A and C	NS	NS	NS	NS	NS	NS	NS
A and D	NS	S	S	S	S	S	S
B and C	NS	NS	NS	NS	NS	NS	NS
B and D	NS	NS	NS	NS	NS	NS	NS
C and D	NS	NS	NS	NS	NS	NS	NS

VAS SCORING ON MOVEMENT:

TABLE-5 STATISTICAL ANALYSIS OF VAS SCORING ON MOVEMENT:

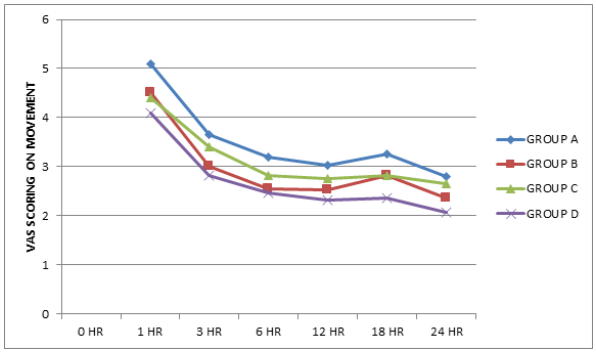
Time	Group A	GroupB	Group C	Group D	P value	
	Mean±SD	Mean±SD	Mean±SD	Mean±SD		
1 hr	5.1±1.12	4.5±0.93	4.4±0.93	4.1±0.74	0.002	S
3 hrs	3.66±1.06	3.0±0.64	3.4±0.89	2.83±0.87	0.0014	S
6 hrs	3.2±1.08	2.56±0.72	2.83±0.69	2.46±0.57	0.001	S
12 hrs	3.03±0.92	2.53±0.89	2.76±0.89	2.33±0.54	0.0102	S
18 hrs	3.26±1.04	2.83±1.08	2.83±0.87	2.36±0.76	0.002	S
24 hrs	2.8±0.71	2.36±0.55	2.66±0.60	2.06±0.44	<0.0001	S

TABLE-6 INTER GROUP COMPARISON OF VAS SCORING ON MOVEMENT:

	p value					
Groups	**1 hr**	**3 hrs**	**6 hrs**	**12 hrs**	**18 hrs**	**24 hrs**
A and B	S	S	S	S	S	S
A and C	S	NS	NS	NS	NS	NS
A and D	S	S	S	S	S	S
B and C	NS	NS	NS	NS	NS	NS
B and D	NS	NS	NS	NS	NS	NS
C and D	NS	S	S	S	S	S

S: Significant NS: Non-significant

GRAPHICAL REPRESENTATION OF VAS SCORING ON MOVEMENT: GRAPH 4

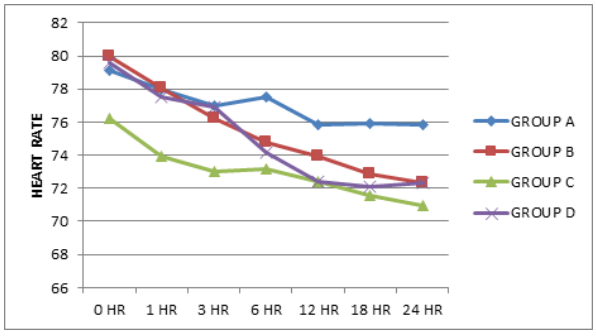


HAEMODYNAMIC CHANGES:

HEART RATE:

No significant difference was found among four groups after 1 hour, 3 hours, 6 hours, 12 hours, 18 hours and 24 hours of infusion as shown in the graph 5.

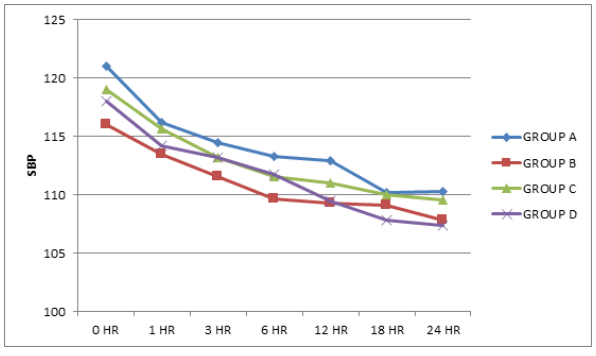
Graphical representation of heart rate changes: graph 5



SYSTOLIC BLOOD PRESSURE:

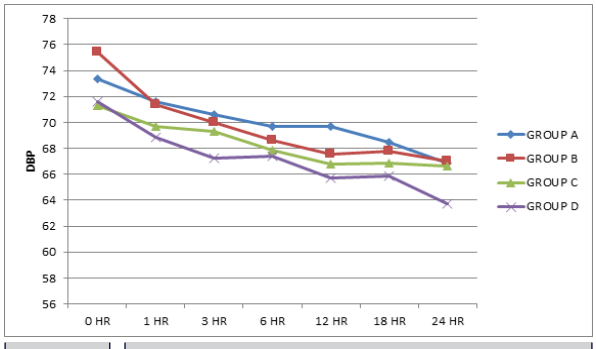
Results are displayed in the following graph 6.on comparion, difference was statistically not significant

GRAPH 6: GRAPHICAL REPRESENTATION OF SBP:



DIASTOLIC BLOOD PRESSURE: On comparison difference was statistically not significant.Results are displayed in the following graph 7

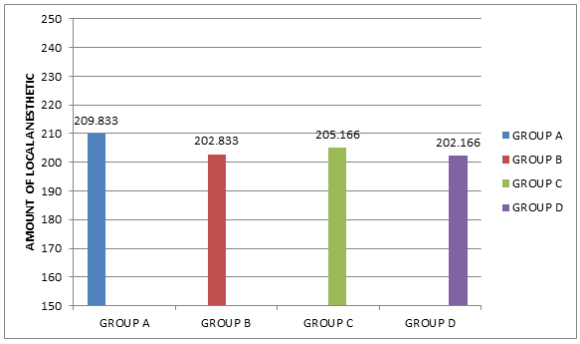
Graphical representation of DBP: Graph 7



TOTAL AMOUNT OF CONSUMED LOCAL ANESTHETIC:

Amount of local anesthetic consumed was more in Group A(209.83) and least consumed in group D (202.16). When compared, difference was found to be statistically significant as displayed in the graph 8.

Graph 8: Graphical representation of amount of local anesthetic consumed

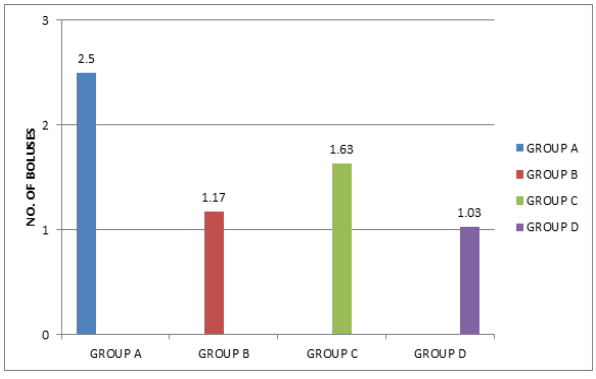


TOTAL NO. OF BOLUSES REQUIRED:

The average number of boluses required in group A was 2.5. The average number of boluses required in group D was 1.03. The number of boluses required in group B and C was respectively 1.17 and 1.633. When compared results were statistically significant.

Results are displayed in the graph 9.

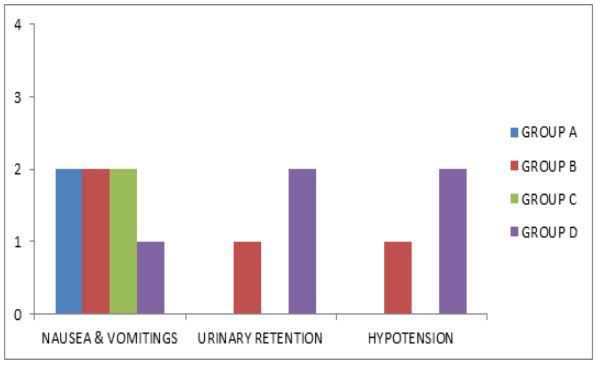
Graph 9: Graphical representation of number of boluses



COMPLICATIONS:

Nausea and vomiting was noted in two patients in each of groups A, B, C and one patient in group D. The difference was found to be statistically not significant. Urinary retention was observed in one patient in group B and two patients in group D. On comparison, difference was statistically not significant.Hypotension was found in two patients in group D and one patient in group B. Difference was statistically not significant.Results are displayed in the following graph 10.

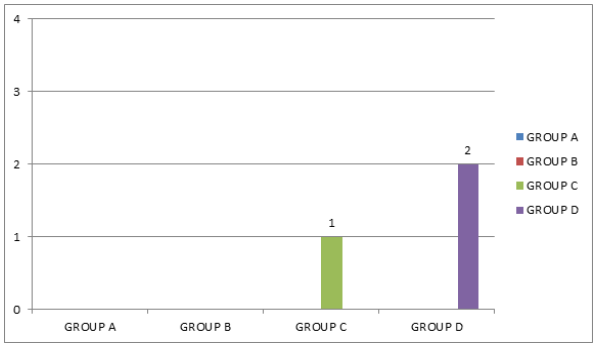
Graphical representation of complications: graph 10



ASSOCIATED MOTOR BLOCKADE:

Associated lower limb weakness was seen in 1 patient in group C and 2 patients in group D as displayed in the following graph 11.

Graph 11: Graphical representation of motor blockade



DISCUSSION

The adequate management of post operative pain has been emphasized now days. Epidural analgesia with local anesthetics is one of the most effective techniques used for post-operative pain relief and may improve patient outcome.

In the present study VAS scoring was matched and was similar among four groups before the start of 24 hours epidural infusion. During 24 hours of infusion VAS scoring both at rest and on movement was found to be higher in patients receiving plain 0.1% ropivacaine infusion when compared with other groups. When compared between plain ropivacaine and ropivacaine with Fentanyl VAS score was found higher with plain ropivacaine. 0.1% Ropivacaine with Fentanyl provided better analgesia compared with plain ropivacaine. our study results are in accordance with Wai-Keung Lee et al.

Changes in heart rate were similar in all the groups and no statistically significant difference was found. This may be due to the sub anesthetic concentration of local anesthetics and low dose fentanyl used in the present study. Ansari et al13 found no statistically significant difference in heart rate similar to the present study.

In the present study, statistically significant difference was not found in both systolic and diastolic blood pressure during 24 hour infusion of ropivacaine, ropivacaine with Fentanyl, levobupivacaine, levobupivacaine with fentanyl. Ansari et al found no significant difference in systolic and diastolic blood pressures during infusion of ropivacaine and levobupivacaine

In the present study, hypotension was noted in one patient in group B and two patients in group D, which was statistically insignificant. Pruritis was not noted among 4 groups Nausea and vomiting was noted in 1 patient in group D and 2 patients in group A, B and C. The difference was statistically not significant in the present study Urinary retention was noted in one patient in group B and two patients in group D which was statistically insignificant. Paraskeviet al.9 reported nausea, prurutis which is not statistically significant between three groups similar to the present study. Decosmoet al, observed minor side effects with similar incidence among Ropivacaine with sufentanil and levobupivacaine with sufentanil similar to the present study.

In the present study, motor block was seen in one patient in group C and two patients in group D and no motor block in groups A and B. Contrary to the present study, Senard et al observed no patient had a motor block in levobupivacaine with morphine group, E.Sitsen et al found no motor block in 0.125% levobupivacaine with Fentanyl group and Decosmo et al8 found no motor block in levobupivacaine with Fentanyl group. Paraskevi et al observed motor weakness in lower limbs in patients receiving 0.15% levobupivacaine and no weakness in patients receiving 0.15% ropivacaine and 0.15% ropivacaine with Fentanyl supporting present study. Lin MC et al observed significant motor block in patients receiving 0.1% levobupivacaine with fentanyl compared with 0.0625% plus Fentanyl.

In the present study, more amount of local anesthetic was consumed in ropivacaine group (209.83) compared to ropivacaine with Fentanyl (202.83), levobupivacaine(205.16), levobupivacaine with Fentanyl (202.16). The amount of anesthetic consumed was similar in levobupivacaine with Fentanyl and ropivacaine with Fentanyl groups.More number of bolus doses was given in ropivacaine group when compared with other groups. Similar to the present study, Karis Bin Misiran et al observed the mean volume of ropivacaine was 13% greater than that of levobupivacaine. The boluses delivered/attempted ratio was also greater in ropivacaine group.Possible explanation for higher requirement of ropivacaine in that study may be due to shorter duration of action of ropivacaine

CONCLUSION

We conclude from present study that levobupivacaine with fentanyl an attractive option for postoperative epidural analgesia. Ropivacaine with Fentanyl and levobupivacaine with fentanyl were of equianalgesic efficacy. Though the few complications were observed with levobupivacaine with fentanyl infusion they were not clinically significant. From the present study it was found that plain 0.125% ropivacaine infusion is of lower analgesic efficacy probably due to the shorter duration of action andless potency of ropivacaine.

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