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

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ABSTRACT

BACKGROUND

Postoperative pain forms an acute category of non-malignant pain. Uncontrolled postoperative pain may produce range of detrimental acute and chronic effects. Postoperative epidural analgesia is an effective and well accepted modality of pain relief techniques after abdominal surgeries. The present study is to compare post-operative analgesia with epidural infusion of ropivacaine 0.125%, ropivacaine 0.125% with fentanyl, levobupivacaine 0.125%, levobupivacaine 0.125% with fentanyl for 24 hours in abdominal surgeries.

MATERIALS AND METHODS

The present study consists of 120 patients who got admitted in Viswabharathi Hospital, Kurnool and underwent abdominal surgeries during October 2014 to October 2015.

RESULTS

In this clinical study, 120 healthy patients of either sex belonging to ASA grade-I and grade-II were included. The patients were divided into four groups, group A, group B, group C and group D.

Group A- Thirty patients received 0.125% Ropivacaine infusion for 24 hours at rate of 8 ml per hour 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 was to compare quality of analgesia, haemodynamic changes, side effects, any associated motor block, amount of local anaesthetic consumed among 0.125% ropivacaine, 0.125% with fentanyl, 0.125% levobupivacaine, 0.125% levobupivacaine with fentanyl when administered as continuous epidural infusion for 24 hours.

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.

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. Studies with levobupivacaine for postoperative analgesia are limited unlike ropivacaine. 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 and less potency of ropivacaine.

KEYWORDS

Fentanyl, Levobupivacaine, Ropivacaine, Postoperative Pain.

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BACKGROUND

Postoperative pain forms an acute category of non-malignant pain. Uncontrolled postoperative pain may produce range of detrimental acute and chronic effects. Postoperative epidural analgesia is an effective and well accepted modality of pain relief techniques after abdominal surgeries. Postoperative epidural analgesia improves patient's outcome. Early mobilization and ambulation accelerate postoperative recovery. Epidural analgesia is often considered optimal postoperative analgesia after major lower abdominal or lower extremity surgery. Analgesia delivered through indwelling catheter is a safe and effective method for management of acute postoperative pain[1]. The high quality of postoperative pain relief is the main concerns for the patients. It is also the ultimate goal of

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both national health policy[2] and the specialty of anaesthesiology. Epidural infusion of local anaesthetics alone or combined with opioids may be used for postoperative analgesia. The location of action of local anaesthetics in the epidural space includes spinal nerve roots, dorsal root ganglion or spinal cord itself. The present study is to compare post-operative analgesia with epidural infusion of ropivacaine 0.125%, ropivacaine 0.125% with fentanyl, levobupivacaine 0.125%, levobupivacaine 0.125% with fentanyl for 24 hours in abdominal surgeries.

Aims and Objectives

1. To compare the effectiveness of post-operative analgesia 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.
2. To compare associated haemodynamic changes.
3. To compare side effects like hypotension, nausea, vomiting, pruritis, urinary retention.
4. To assess for any residual motor blockade.

MATERIALS AND METHODS

Source of Data: 120 patients admitted in Viswabharathi Hospital, Kurnool undergoing abdominal surgeries from 2014-2015

Inclusion Criteria

a. Patient belonging to ASA grade 1 and 2.
b. Patients of age between 18 and 60 years.
c. Elective or emergency lower abdominal surgeries

Exclusion Criteria

a. Patient refusal.
b. Patient belonging to ASA grade 3 and 4.
c. Infection at the site of injection.
d. Coagulation abnormalities.
e. Hypersensitive to local Anaesthetics.
f. Neurological or neuromuscular disease.

Methodology

Pre anaesthetic checkup was done one day prior to the surgery. Patients were evaluated for any systemic disease and laboratory investigations were recorded. Routine investigations like complete urine examination, complete blood picture, blood sugar, blood urea, serum creatinine, serum electrolytes, etc. ECG and chest X-ray in elderly patients and whenever indicated was undertaken to rule out the presence of systemic illness. The procedure of epidural block was explained to the patient and written informed consent was obtained. The patients were educated about the procedure of epidural analgesia i.e., about the position, the technique which is going to be performed, effects of the procedure and the parameters to be studied to gain the confidence and co-operation of the patients. All patients had intradermal sensitivity test, only those with normal response were included. Preparation of the patient included the period of overnight fasting. Premedication was done with oral tablet Alprazolam 0.25mg and capsule pantoprazole 20 mg.

120 patients were randomly allocated into four groups of thirty each-

- Group A- Thirty patients received 0.125% Ropivacaine infusion for 24 hours at rate of 8 ml per hour 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.

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

The monitors connected to the patients included non-invasive BP, pulse-oximeter. Baseline PR, BP, SpO_2 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. O. R. syringe. After negative aspiration for CSF and blood, institution of test dose of (3 ml injection lignocaine with adrenaline 2%) and subarachnoid 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 Anaesthesia and the patients were randomly allocated into one of the four study groups. Post-operatively, the patients' 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 24 hours.

Statistical Analysis

In total 90 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 Bonferroni's correction.

P value <0.05 was taken as statistically significant.

P value <0.001 was taken as statistically highly significant.

RESULTS

A total of 120 patients were included in this study. Patients were divided into four groups. Group A, Group B, Group C and Group D each included 30 patients.

- Group A: 0.125% Ropivacaine.
- Group B: 0.125% Ropivacaine with fentanyl.
- Group C: 0.125% Levobupivacaine.
- Group D: 0.125% Levobupivacaine with fentanyl.

Demographic Data

The mean age, sex was comparable between the groups. The study was conducted with variable age in Group A, Group B, Group C and Group D with mean of 36.4667±9.8181, 37.00±9.1689, 36.7333±14.9619 and 39.900±10.246 respectively. The demographic data was comparable between the four groups as shown in the table 1 and graph 1.

Group	Number of Patients	Age	f Value	P Value
A	30	36.46±9.81	0.601	0.6151
B	30	37±9.16		
C	30	36.73±14.96		
D	30	39.9±10.24		

Table 1. Statistical Analysis of Age

Sex Distribution	Group A	Group B	Group C	Group D	Chi Square	p value
Male	24	25	25	25	0.17	0.98
Female	6	5	5	5		

Table 2. Statistical Analysis of Sex

Time	Group A	Group B	Group C	Group D	F Value	P Value	
	Mean±SD	Mean±SD	Mean±SD	Mean±SD			
0 hr.	7.10±0.54	7.16±0.37	7.00±0.26	7.10±0.48	0.71	0.54	NS
1 hr.	3.60±1.13	3.03±0.927	3.10±0.84	2.933±0.63	3.23	0.002	S
3 hrs.	2.43±0.85	1.83±0.87	2.10±0.99	1.70±0.74	4.11	0.008	S
6 hrs.	1.90±0.8	1.36±0.55	1.53±0.73	1.36±0.61	8.05	<0.0001	S
12 hrs.	1.80±0.76	1.40±0.67	1.43±0.72	1.30±0.59	2.98	0.003	S
18 hrs.	1.76±0.72	1.36±0.55	1.46±0.62	1.23±0.50	8.05	0.007	S
24 hrs.	1.66±0.66	1.30±0.53	1.36±0.614	1.1±0.40	5.23	0.002	S

Table 3. Statistical Analysis of Visual Analog Scale Scoring at Rest

	p Value						
Groups	**0 hr.**	**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

Table 4. Intergroup Comparison of Visual Analog Scale Scores at Rest

	p Value						
Groups	**0 hr.**	**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

Table 5. Statistical Analysis of Visual Analog Scale Score 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

Table 6. Intergroup Comparison of Visual Analog Scale Score

	Group A	Group B	Group C	Group D	F Value	p Value
	Mean±SD	**Mean±SD**	**Mean±SD**	**Mean±SD**		
0 hr.	79.16±8.11	79.96±9.56	76.20±7.56	79.60±8.00	1.27	0.28
1 hr.	77.96±7.74	78.06±8.99	73.96±7.18	77.50±8.16	1.76	0.15
3 hrs.	76.96±7.55	76.20±9.11	73.00±7.19	76.93±8.76	1.58	0.19
6 hrs.	77.53±7.16	74.76±8.77	73.13±7.53	74.13±9.10	1.59	0.19
12 hrs.	75.83±7.27	73.90±8.32	72.40±7.80	72.43±8.98	1.29	0.28
18 hrs.	75.93±7.16	72.90±8.09	71.60±6.67	72.13±8.86	1.875	0.13
24 hrs.	75.86±6.71	72.30±7.84	70.93±7.41	72.33±8.01	2.36	0.07

Table 7. Statistical Analysis of Heart Rate

	Group A	Group B	Group C	Group D	F Value	p Value
	Mean±SD	**Mean±SD**	**Mean±SD**	**Mean±SD**		
0 hr.	121±7.44	116±5.26	119±8.09	118±7.12	2.07	0.10
1 hr.	116.16±6.13	113.48±4.67	115.63±7.32	114.23±7.19	1.01	0.38
3 hrs.	114.46±6.81	111.58±4.84	113.23±7.14	113.23±7.55	0.86	0.46
6 hrs.	113.30±7.45	109.62±4.30	111.60±6.86	111.70±7.29	1.64	0.18
12 hrs.	112.96±7.29	109.27±4.82	111±6.58	109.43±7.20	2.05	0.10
18 hrs.	110.20±8.14	109.10±5.15	110.06±7.20	107.80±7.11	0.75	0.52
24 hrs.	110.33±6.21	107.86±4.83	109.56±6.88	107.40±6.75	1.48	0.22

Table 8. Statistical Analysis of SBP

Time	Group A	Group B	Group C	Group D	F value	p value
	Mean±SD	**Mean±SD**	**Mean±SD**	**Mean±SD**		
0 hr.	73.36±6.33	75.41±5.62	71.26±7.54	71.60±5.76	2.47	0.06
1 hr.	71.63±6.20	71.34±4.83	69.70±7.56	68.83±7.05	1.22	0.30
3 hrs.	70.63±4.70	69.96±6.16	69.30±7.46	67.23±5.47	1.75	0.15
6 hrs.	69.66±6.92	68.65±5.51	67.86±6.82	67.36±5.26	0.77	0.50
12 hrs.	69.70±6.12	67.58±5.72	66.80±6.75	65.70±5.35	2.37	0.07
18 hrs.	68.43±4.57	67.79±5.44	66.83±6.36	65.90±5.04	1.26	0.28
24 hrs.	66.90±4.94	67.03±4.95	66.60±6.49	63.76±5.96	2.28	0.08

Table 9. Statistical Analysis of DBP

Amount of local Anaesthetic 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 following table

Amount of Local Anaesthetic	Group A	Group B	Group C	Group D	F Value	p Value
Mean	209.833	202.83	205.16	202.16	9.33	HS
SD	8.77	4.74	6.22	4.04		

Table 10. Total Amount of Consumed Local Anaesthetic

Complications	Group A	Group B	Group C	Group D
Nausea and Vomiting	2	2	2	1
Pruritis	-	-	-	-
Urinary Retention	0	1	0	2
Hypotension	O	1	0	2

Table 11. Complications

Associated lower limb weakness was seen in 1 patient in group C and 2 patients in group D as displayed in the following table 13 and graph 11.

	Group A	Group B	Group C	Group D
Motor Block	0	0	1	2

Table 12. Associated Motor Blockade

DISCUSSION

Demography

In the present study all the four groups A, B, C, D were comparable in regard to the demographic variables and was statistically not significant

Dosing of Drugs

R Whiteside et al[3] conducted a study on the effect of volume and concentration of epidural ropivacaine with fentanyl in treating postoperative pain following gynaecological oncology surgery. They found that low concentration ropivacaine 0.1% with low dose fentanyl 1 microgram/ml appears satisfactory compared with ropivacaine 0.2% with fentanyl (2 microgram/ml). So in the present study we chose the concentration of ropivacaine as 0.1%.

VAS Scoring

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.

Wai-Keung Lee et al.[4] did a randomized double blinded comparison between Ropivacaine 0.1 % with and without fentanyl for epidural post-operative analgesia. They observed that Visual analogue scale score for pain relief with epidural infusion of 0.1% ropivacaine (Group R) was higher compared to 0.1% ropivacaine with fentanyl ($p<0.05$) was statistically significant similar to our present study.

Heart Rate

Changes in heart rate were similar in all the groups and no statistically significant difference was found.

This may be due to the sub Anaesthetic concentration of local Anaesthetics and low dose fentanyl used in the present study. Ansari et al found no statistically significant difference in heart similar to present study.

Blood Pressure

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[5] found no significant difference in systolic and diastolic blood pressures during infusion of ropivacaine and levobupivacaine.

Complications

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 were 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.

Paraskevi et al.[6] reported nausea, prurutis which is not statistically significant between three groups similar to the present study. Decosmo et al,[7] observed minor side effects with similar incidence among Ropivacaine with sufentanil and levobupivacaine with sufentanil similar to the present study.

Motor Block

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. Paraskevi et al.[6] 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[8] observed significant motor block in patients receiving 0.1% levobupivacaine with fentanyl compared with 0.0625% plus fentanyl.

CONCLUSION

From the present study, it can be concluded that-

1. Analgesia was more effective with levobupivacaine with fentanyl.
2. The amount of local anaesthetic consumed was more with ropivacaine group.
3. The number of bolus doses required was also more with ropivacaine group.
4. Motor weakness was observed but was not clinically significant.
5. Pruritis was not observed in any of the groups.
6. Very few side effects were seen.

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. Though few complications were observed with levobupivacaine with fentanyl infusion, they were not clinically significant. Studies with levobupivacaine for postoperative analgesia are limited unlike ropivacaine. 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 and less potency of ropivacaine.

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