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A Comparative Study between Epidural Ropivacaine with Fentanyl and Levobupivacaine with Fentanyl for Postoperative Analgesia in Below Umbilical Surgeries

Dr. K. Kanakadurga[1], Dr. D. Sangeetha Rao[2]
[1](Department of Anaesthesiology, RIMS Medical College, Ongole, India
[2](Department of Anaesthesiology, RIMS Medical College, Ongole, India)
Corresponding Author : Dr. D. Sangeetha Rao

Abstract : *A double blind Randomized Controlled study to compare the Postoperative analgesia and degree of motor blockade between 0.2% Ropivacaine with Fentanyl 5mcg/ml and 0.125% Levobupivacaine with Fentanyl 5mcg/ml in below umbilical Surgeries. 100 patients in the age group of 35 – 75 years of either sex falling under ASA grade I & II were enrolled and allotted in to two groups A & B of 50 each. Group 'A' received Ropivacaine 0.2% with Fentanyl 5mcg/ml and group 'B' received 0.125% Levobupivacine with Fentanyl 5mcg/ml through epidural block in the Post operative period. Intraoperative Anesthesia was provided by General Anesthesia. After completion of surgical procedure, when patient complaint of pain, epidural infusion was activated and parameters were monitored as per planned intervals up to 48 hours. Pain score were monitored by using visual analog scale and degree of motor block was monitored by using bromage scale and observed that significant difference in onset of analgesia (group 'A' 6.46 min and group 'B' 5.8 min), (P value 0.008) and no significant difference in peak action of analgesia between both the groups both drugs are equally potent in analgesia and motor blockade.*

Keywords: *(Below umblical Surgeries – Epidural – Fentanyl – Levobupivacaine – Ropivacaine)*

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I. Introduction

One of the main objective of anaesthesia is analgesia. Pain is one of the most important factor that is responsible for many adverse outcomes during surgery and in postoperative period also. Control of postoperative pain is one of the main concern for both the patients and the surgical team. Advances in pharmacologic sciences and anaesthetic techniques have contributed to the development of the variety of therapeutic analgesics which are currently available.

Effective postoperative pain management not only increases the comfort and satisfaction of the surgical patient but may also enhance the postoperative recovery process by diminishing pain-related complications associated with delayed mobility and ineffective lung expansion[1].

The International Association for the Study of Pain[2] defines pain as, "the sensory and emotional experiences associated with actual or potential tissue damage". Pain has both physical and psychological facets. Physically surgery produces tissue damage and destruction and causes substances such as prostaglandins, substance P, and histamine to be released. These and other irritants stimulate free nerve endings located in the cutaneous and subcutaneous tissue[3]. These nerve endings, known as nociceptors, transmit the noxious stimuli to the central nervous system.

The psychological aspects of pain are influenced by many interacting factors which are dynamic and fluctuating. Pain is subjective in nature and there are no universally accepted means for its quantification. Pain responses and thresholds vary between individuals with fear and anxiety often accentuating the pain response[2]. In addition to the patient's perception and experience of pain, the healthcare provider's beliefs, biases, and attitudes must also be considered.

In major orthopaedic procedures, gynaecological procedures excruciating pain can occur and may result in bad prognosis. To decrease pain in the postoperative period there are many methods adopted. They are epidural analgesia either continuously or intermittently, regional nerve blocks like continuous or patient controlled continuous analgesia and Intravenous or Intramuscular agents.

If intravenous opioids are used as analgesic agents, they resulted in side-effects like nausea, vomiting, pruritis, respiratory depression, etc[4]. So now-a-days Anesthesiologists are not using opioids as sole agents. In regional techniques, people started using combination of opiods and local anaesthetic agents for providing better analgesia and good outcome.

With the introduction of Bupivacaine, the concept of differential blockade[5] came into limelight. Previous local anaesthetic agents like lignocaine cause both sensory and motor blockade.

Bupivacaine has got the capacity to produce only sensory block without effecting the motor activity. This unique feature is useful mainly in orthopaedic procedures where early movement is necessary for good prognosis and prevention of deep vein thrombosis(DVT)[8].

At 0.5% bupivacaine produces surgical anaesthesia, at 0.25% it provides analgesia with partial motor blockade. At 0.125% or 0.0625%, it provides only sensory blockade. This means patient can move his limbs and can start walking without any loss of muscle power[8].

Levobupivacaine is S-enantiomer of Bupivacaine, The majority of invitro, invovo, and human pharmacodynamic studies of nerve block indicate that levobupivacaine has similar potency to bupivacaine. However, Levobupivacaine had a lower risk of Cardiovascular and CNS toxicity than Bupivacaine in animal studies. In human volunteers, Levobupivacaine had less of negative inotropic effect and at intravenous dose >75mg produced less prolongation of the QT_C interval than Bupivacaine. Fewer changes indicative CNS depression of EEG were evident with Levobupivaine[6].

Levobupivacaine is long acting with a dose dependent duration of anaesthesia. The onset of action is <or=15 minutes with various anaesthetic techniques. In studies of surgical anaesthesia in adults, Levobupivacaine provided sensory block for upto 9hrs after epidural administration of <or=202.5mg[6].

Randomized, double blinded clinical studies established that the anaesthetic and analgesic effects of Levobupivacaine were largely similar to those of Bupivacaine at the same dose. Sensory block tend to be longer with Levobupivacaine than Bupivacaine, amounting to a difference of 23-45 minutes with epidural administration. With epidural administration Levobupivacaine produces less prolonged motor block[6].

Levobupivacaine is generally as effective as Bupivacaine for pain management during labour and is effective for the management of postoperative pain especially when combined with Clonidine, Morphine. Fentanyl. The most common adverse event associated with Levobupivacaine treatment is Hypotension[6].

Recently Ropivacaine was introduced. This agent also provides differential blockade. The intensity of analgesia is more than that of bupivacaine, Degree of motor blockade is less than that of bupivacaine. At 0.75% it provides surgical anaesthesia. At 0.2% it provides analgesia. Continuous epidural infusion of Ropivacaine postoperatively reduces postoperative pain in a dose related manner. Another advantage of ropivacaine over buypivacaine is less cardiac toxicity[7.8].

Levobupivacaine and Ropivacaine are two left enantiomeric molecules frequently used for peripheral nerve blocks because of their safe clinical profile. Levobupivacaine is more lipophilic and theoretically more potent than Ropivacaine, but clinical studies shows conflicting results in terms of anaesthetic and analgesic characteristics[9].

Aim of this study is postoperative analgesia and degree of motor blockade between Ropivacaine with Fentanyl and Levobupivacaine with Fentanyl.

II. Material and Methods

The present study was conducted in the Department of Anesthesiology, Rajiv Gandhi Institute of Medical Sciences, Ongole, Prakasam District, Andhra Pradesh, India. Approval of the Institutional ethical committee was obtained. Informed and written consent were taken from the patients after detailed explanations in their own languages regarding advantages, disadvantages, and monitoring up to 48 hours. 100 adult patients of class ASA I & II of either sex in the age group of 35-75 yrs, weighing 45-75kgs posted for below umblical surgeries were included in the study exclusion criteria of patients with progressive neurological, psychiatric and neuromuscular diseases, severe liver diseases, kidney diseases, history of drug allergy, severe cardiac and respiratory disorders and history of bleeding disorders. All the selected patients were undergone thourough pre-anaesthetic check-up and required investigations. Patients were randomly allotted to two groups A & B 50 of each. A group received ropivacaine 0.2% with Fentanyl 5 mcg/ml and B group received Levobupivacaine 0.125% with Fentanyl 5mcg/ml and blinding to the observer and patients was strictly maintained until results were analyzed. All the patients prior to the procedure preloaded with Ringer Lactate 10 – 20 ml/kg and basal vitals like Blood pressure, Pulse Rate, SPO_2 and ECG leads were monitored. As per the hospital protocol, under aseptic conditions in sitting position epidural space was identified in Lumbar space with 18 Gauze Tuohy needle using loss of resistance technique. After that, Epidural catheter was passed and fixed. Epidural test dose of 3ml of 1.5% Lignocaine (45mg) with 1 in 200000 adrenaline was given to all patients in both groups.

After placing Epidural Catheter, Intraoperative anaesthesia was provided by using Fentanyl 1-2 mcg/kg, Propofol 2-3 mg/kg, Atracurium 0.5mg/kg and Sevoflurane.

No epidural topup doses were given to the patients intraoperatively. Epidural infusion bottle was filled with either Ropivacaine 0.2% with Fentanyl 5mcg/ml or Levobupivacaine 0.125% with Fentanyl 5mcg/ml and was connected to the Epidural catheter for giving continuous epidural analgesia at the rate of 5ml/hr postoperatively.

All parameters were measured for every 5 mins upto 20 mins, at 30mins, 1 hour, 2 hours, 4 hours, for every 4 hours upto 12 hours, for every 6 hours upto 24 hours and for every 12 hours upto 48 hours and values were noted in the proforma. Epidural infusion was stopped after 48 hours.
The observations were done as per the following parameters.
Speed of onset of analgesia in both the group
Time of peak of action
Pain scores
Any supplementation of analgesics
Degree of motor blockade
Blood pressure, pulse rate.

The time at which the epidural injection is completion was considered as zero(t0). Time of onset of analgesia was noted depending on the pain scales. When the patient is totally painfree, that means on painscale if the score is 0 or 1, that time was noted and considered as time for peak action. If the patient expresses a need for additional analgesia because of postoperative pain, Inj.Diclofenac sodium 75mg IM or IV in 100ml NS of Inj.Paracetamol 1g IV was given. Adverse effects such as pruritus, postoperative nausea and vomiting (PONV), headache, and low back pain were recorded and were treated accordingly.

Observations and Results

All the patient information was recorded on each patient's study proforma, and data collected as study outcomes measures was complied in a data spreadsheet in Excel and was kept confidential. Study data was analysed, to provide descriptive statistics on patient demographics, including age and gender for the two study groups.

Data was analysed to compare the efficacy of the epidural analgesic effects of the two study drugs, using the students test(unpaired), and also by to compare the continuous variables for the outcomes of interest (continuous variables) for the two groups with regard to the mean time of onset of action (in minutes), mean duration of analgesia (in minutes) and mean time to peak effect; Chi-Square t test for categorical variables (Requirement of additional supplementation, complications); Mann-Whitney Wilcoxon U test for Pain scores and modified bromage score.

For this study, a p value of <0.05 was considered significant.

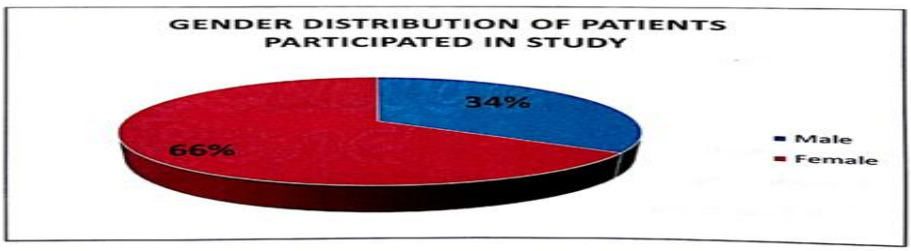
After analyzing the data the drugs were revealed by the third person.

Drug A is Levobupivacaine and Drug B is Ropivacaine.

Gender distribution :

SEX	NO.OF PATIENTS	PERCENTAGE
MALE	34	34%
FEMALE	66	66%
TOTAL	100	100%

TABLE 1: GENDER DISTRIBUTION

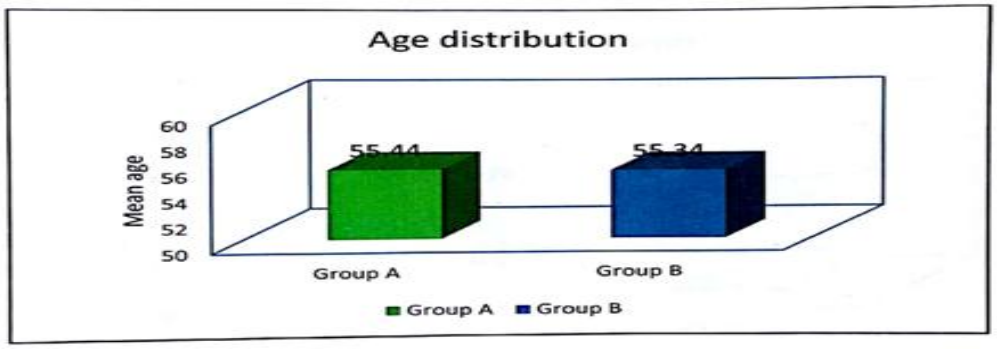


Out of 100 patients, 66 were Females and 34 were Males and the same was represented in the pie diagram.

Age distribution :

Group	Age		P Value
	Mean	SD	
A	55.44	10.48	0.961
B	55.34	10.05	

t test for independent samples



The mean age in Group A was 55.44± 10.48 with a range of 35 – 75 years, where as in Group B it was 55.34± 10.05, with a range of 35 – 75 years. There was no statistically significant difference between the two groups when compared by student's t-test.

Weight distribution :

Group	Weight (kg)		P Value
	Mean	SD	
A	62.22	5.52	0.336
B	61.2	5.01	

t test for independent samples

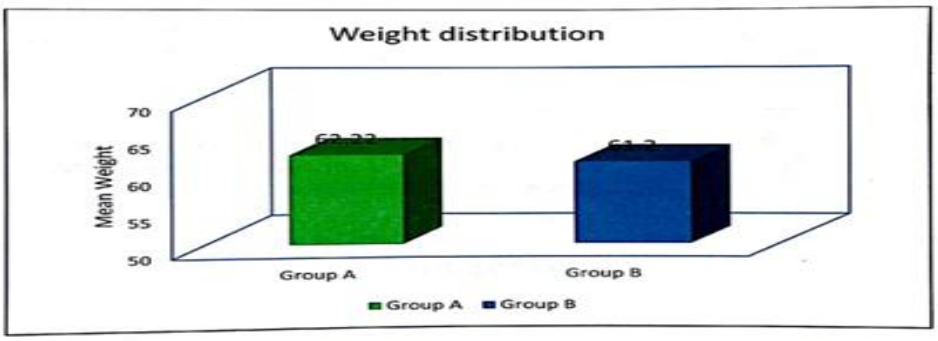


FIGURE 10: WEIGHT DISTRIBUTION

Among the population selected the mean weight was 62.22 ± 5.52kg in group A & 61.20 ± 5.01 kg in group B. The difference between the two groups was not significant by student's t – test. (p value is 0.336)

Study outcomes on epidural analgesic effects :

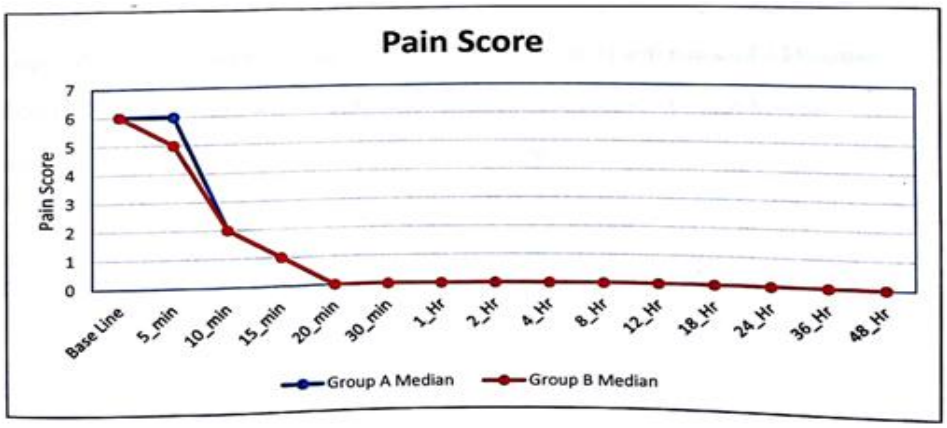
Pain Score :

Group	A			B			P Value
Pain Score	Group A Median	Mean	SD	Group A Median	Mean	SD	
Baseline	6	6.26	0.44	6	6.12	0.63	0.111
5_Min	6	5.06	1.72	5	4.22	1.98	0.023*
10_Min	2	2	0.64	2	1.98	0.71	0.878
15_Min	1	1.08	0.60	1	1.12	0.75	0.697
20_Min	0	0.24	0.48	0	0.3	0.46	0.402
30_Min	0	0.22	0.42	0	0.3	0.46	0.364
1_Hr	0	0.22	0.42	0	0.3	0.46	0.364
2_Hr	0	0.22	0.42	0	0.3	0.46	0.364
4_Hr	0	0.22	0.42	0	0.3	0.46	0.364
8_Hr	0	0.22	0.42	0	0.3	0.46	0.364
12_Hr	0	0.22	0.42	0	0.3	0.46	0.364
18_Hr	0	0.22	0.42	0	0.3	0.46	0.364
24_Hr	0	0.22	0.42	0	0.3	0.46	0.364
36_Hr	0	0.22	0.42	0	0.3	0.46	0.364
48_Hr	0	0.22	0.42	0	0.3	0.46	0.364

***indicates value is statistically significant.**

Mann whitney wilcosin U test

Table :Variation in Pain scores



The pain score was assessed using Visual analogue scale. The mean value for Group A in VAS was 0.22 where as in group B in VAS scale was 0.3. when compared using Mann-Whitney Wilcoxon U Test, there was no significant difference between two groups with VAS(p value = 0.364) except at 5 mins interval pain score in Group A was 5.06 and in Group B was 4.22(p value=0.023). Variation in pain scores from base line to 48 hrs after surgery was also mentioned and represented in the diagram.

Requirement of additional analgesia :

Group	Additional supplementation		Total
	Yes	No	
A	1	49	50
B	1	49	50
Total	2	98	100

Table : Additional Supplementation

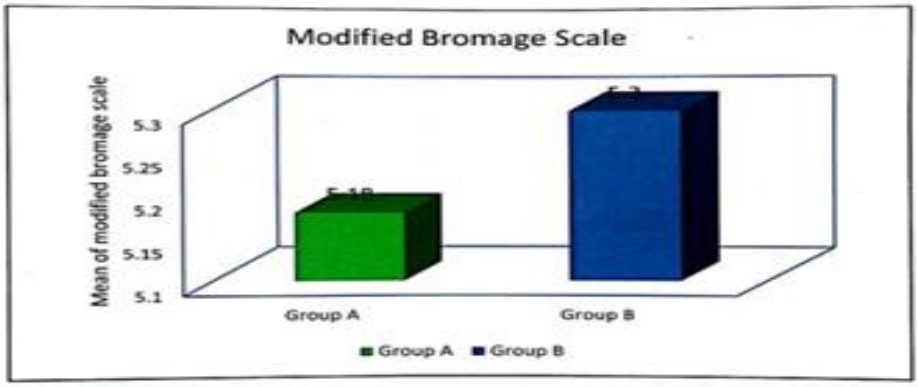
Among the 100 patients studied in each group, in group A one patient required additional supplementation and in group B one patient required additional supplementation. There was no statistical difference between the two groups as assessed by Chi-Square Test. (Tabla)(p value = 0.999).

Modified bromage scale for motor block :

Group	Modified bromage scale			P Value
	Median	Mean	SD	
A	5	5.18	0.39	0.162
B	5	5.3	0.46	

Mann-Whitney wilcoxon U test

Table : Modified **Bromage Scale**



The mean of the peak Modified Bromage score in group A was 5.18(SD ± 0.39) and in group B was 5.3 (SD ± 0.46). by Mann-Whitney wilcoxon U test, there ws no significant difference between the two groups (p=0.162).

Time of onset of analgesia :

Group	Onset Time(min)		P Value
	Mean	SD	
A	6.46	1.199	0.008*
B	5.8	1.245	

t test for independent samples
indicates value is statistically significant

Table : Time of onset of Analgesia

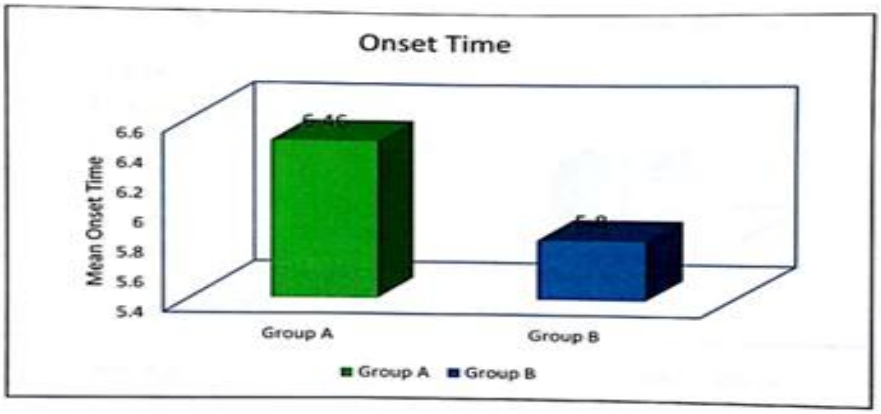


Figure : Time of onset of Analgesia

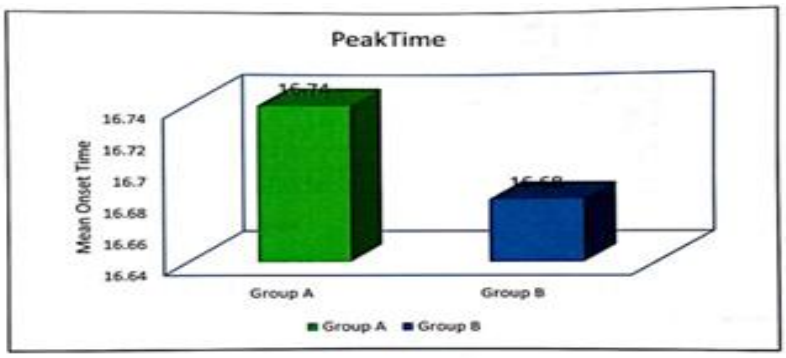
The mean time of onset of analgesia in group A was 6346min (SD ± 1.199) when compared to group B which was 5.8min (SD ± 1.245) mean. This is statistically significant when compared with student's t-test (p value 0.008) (p value <0.05).

Peak time of analgesia :

Group	Peak Time (min)		P Value
	Mean	SD	
A	16.74	1.998	0.874
B	16.68	1.778	

t test for independent samples

Table : Time of peak action of Alalgesia



The peak of action that is "0-1" on pain score was 16.74min(SD ± 1.998) in Group A and 16.68min (SD±1.778) in Group B (p Value=0.874). peak of action is not significant when compared with student's t-test.

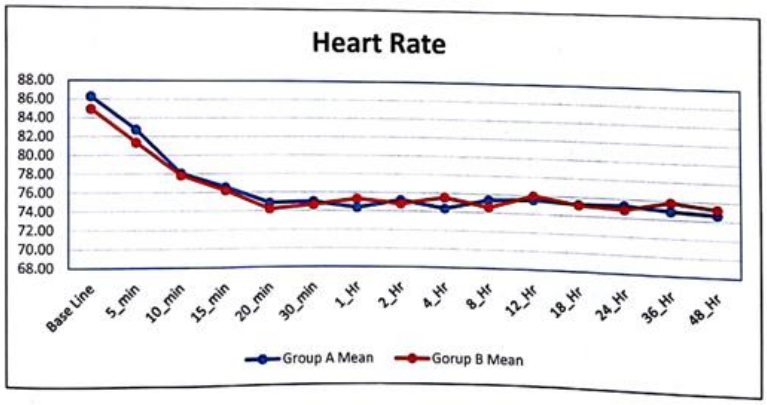
Comparison of Hemodynamic parameters :

Heart rate :

Group	A		B		P Value
Heart Rate	**Group A Mean**	**SD**	**Group B Mean**	**SD**	
Baseline	86.30	7.29	84.96	9.53	0.432
5_Min	82.74	7.20	81.34	9.59	0.411
10_Min	78.06	6.85	77.84	8.27	0.885
15_Min	76.56	6.78	76.22	8.55	0.826
20_Min	74.86	6.57	74.22	7.41	0.649
30_Min	75.00	6.92	74.66	7.87	0.819

1_Hr	74.38	6.34	75.32	7.60	0.504
2_Hr	75.22	6.03	74.80	7.64	0.761
4_Hr	74.36	6.54	75.54	7.43	0.369
8_Hr	75.38	6.46	74.60	7.42	0.576
12_Hr	75.54	6.55	75.96	8.20	0.778
18_Hr	75.24	6.59	75.16	7.92	0.956
24_Hr	75.32	6.53	74.88	7.08	0.307
36_Hr	74.90	5.91	75.82	7.65	0.503
48_Hr	74.66	6.44	75.24	7.07	0.669

t test for independent samples **Table : Variation in Heart Rate**



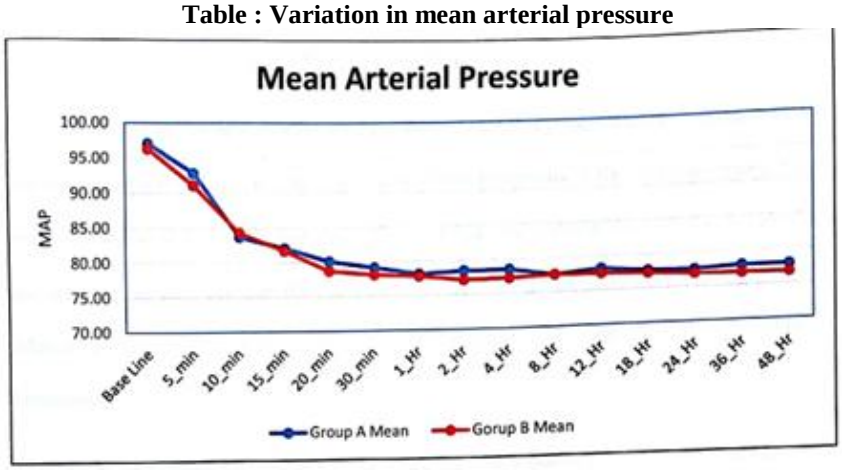
The mean basal heart rate (at time 0) was compared between the two groups. There was no significant statistical difference between the two groups (p=0.432). The mean values of the heart rate calculated thereafter also showed no significant difference throughout the procedure.

Mean arterial pressure (MAP) :

Group	**A**		**B**		**P Value**
Heart Rate	**Group A Mean**	**SD**	**Group B Mean**	**SD**	
Baseline	97.08	8.16	96.32	10.65	0.69
5_Min	92.84	8.25	91.08	10.45	0.352
10_Min	83.72	12.65	84.28	14.39	0.837
15_Min	82.04	5.98	81.66	8.31	0.794
20_Min	80.08	5.36	78.68	7.27	0.276
30_Min	79.14	5.25	78.10	6.43	0.378
1_Hr	78.12	5.38	77.80	6.72	0.793
2_Hr	78.48	4.55	77.16	5.69	0.204
4_Hr	78.52	5.62	77.26	6.93	0.32
8_Hr	77.54	4.85	77.52	5.83	0.985
12_Hr	78.16	5.21	77.46	6.07	0.538
18_Hr	77.62	5.07	77.24	6.25	0.739
24_Hr	77.52	4.76	76.90	5.72	0.557
36_Hr	77.88	5.05	76.78	6.16	0.331
48_Hr	77.86	5.11	76.74	6.05	0.32

t test for independent samples

Table : Variation in mean arterial pressure



The mean value of baseline pressure (MAP) before giving the topup/bolus in both the groups was calculated. There was no significant difference in both the groups P value=0.69. Then mean values of mean arterial pressure in both groups there after also found insignificant throughout the procedure.

Comparision of complications :

Group	Complication		Total
	Yes	NO	
A	1	49	50
B	1	49	50
Total	2	98	100
Chi – Square Test (Yates Correction)	0.999		

Table : Comparision of Complications

Out of 100 patients, one patient in group A had nausea and one patient in group B had nausea. There was no statistically significant difference between two groups as per Chi-Square Test. (p value = 0.999)

III. Discussion

In major orthopaedic procedure, gynaecological procedure excruciating pain can occur and may result in bad prognosis. Effective postoperative pain management not only increases the comfort and satisfaction of the surgical patient but may also enhance the postoperative recovery process by diminishing painrelated complications associated with delayed mobility and ineffective lung expansion.

In this series of studies, we compared 0.2% Ropivacaine with 5mcg/ml of fentanyl with 0.125% Levobupivacaine with 5mcg/ml of Fentanyl. The selection of the concentration, these drugs selectively block the sensory nerve fibers sparing the motor fibers totally or partially. This selective blockade of sensory fibers is called differential blockade.

A sample size of 100 was selected for this study which is small according to statistical formula based on previous studies outcomes. But this sample size is comparable to other previous studies by Senard etal.. in 2004 with 50 sample size, Koch etal in 2008 with 88 sample size, Fournier R etal.. in 2010 with 80 sample size.

When time of onset is compared, there is significant difference between the two groups. Mean value of Time of onset of action in Levobupivacaine with fentanyl is 6.46min (SD±1.199) whereas in Ropivacaine with Fentanyl is 5.8min (SD ± 1.245) (p value=0.008).

When time of peak action is compared, there is no significant difference between the two groups. Mean value of time of peak action in Levobupivacaine with Fentanyl is 16.74min(SD±1.998) whereas in Ropivacaine with Fentanyl is 16.68min (SD±1.778) with p value 0.874.

When potencies are compared, in this study in both groups, both drugs are equally potent except at 5mins interval where Ropivacaine is more potent than Levobupivacaine. Mean VAS score for Levobupivacaine at 5mins interval was 5.06(SD±1.72) and for Ropivacaine VAS score was 4.22(SD±1.98) with P value 0.023. Visual analogue scale in Levobupivacaine group is 0.22(SD±0.42) whereas in Ropivacaine group it is 0.3(SD±0.46) indicating that both drugs are equally potent (p value=0.364). This was supported by other studies, Senard etal in 2004 reported that there is comparable analgesia between Ropivacaine with Morphine group and Levobupivacaine with Morphine group and by Koch etal.. in 2008 who concluded that Levobupivacaine is comparable with Ropivacaine in analgesic effect.

When degree of motor blockade is compared, in this study using Modified Bromage scale, the score is 5.18(SD±0.39) in Levobupivacaine group and the score in Ropivacaine group i.e. 5.3(SD±0.46) indicating that both groups produces equal motor blockade which is statistically insignificant (p value = 0.162). This was supported by Koch etal.. in 2008 who concluded that Levobupivacaine is comparable with Ropivacaine in motor blockade.

On comparing hemodynamic parameters like mean arterial pressure and heart rate, both Ropivacaine and Levobupivacaine were comparable at all time points in this study. The mean value of mean arterial pressure at baseline in Group Levobupivacaine is 97.08mmHg(SD±8.16) and in Group Ropivacaine it is 96.31mmHg(SD±10.65) with p value equal to 0.69. the mean value of Heart rate at baseline in Group Levobupivacaine is 86.30 per min(SD±7.29) and in Group Ropivacaine is 84.96 per min(SD±9.53) with p value equal to 0.432.

When hypotension is compared, there is no statistical significant difference present between the two groups, throughout the procedure, in mean arterial pressures at baseline and thereafter for 48hrs after surgery. The mean value of mean arterial pressure at baseline in Group Levobupivacaine is 97.08mmHg (SD±8.16) and in Group Ropivacaine it is 96.32mmHg(SD±10.65) with p value equals to 0.69. When complications like bradycardia, nausea, vomiting, pruritis, etc are compared, there is no statistically significant difference between the two groups. This was supported by other studies, Senard etal in 2004 reported that there was comparable results in hemodynamic parameters and complications between Ropivacaine with Morphine group and

Levobupivacaine with Morphine group and by Koch etal.. in 2008 who concluded that Levobupivacaine is comparable with Ropivacaine in relation to hemodynamic parameters and complications.

IV. Conclusion

When comparing Levobupivacaine with Ropivacaine, an extremely significant diffierence in time of onset of action was noted.(6.46min for Group A and 5.8min for Group B and p value is 0.008(p value is less than 0.05).

On comparing the timing of peak action between Ropivacaine and Bupivacaine, no significant diffenences were noted. Timing of peak effect in Group A was 16.74min and in Group B it was 16.68min and p value equals to 0.874.

Both levobupivacaine and Ropivacaine were considered as equally potent analgesics. (Pain Score using Visual Analogue scale in Group A was 0.22 and in Group B it was 0.3, p value is equal to 0.364). it was noted that at 5mins interval Ropivacaine is more potent than Levobupivacaine. (Visual Analogue scale in Group A at 5mins interval was 5.06 and in Group B it was 4.22, p value is equal to 0.023).

When moto blockade using Modified Bromage Scale compared between Levobupivacaine and Ropivacaine, there is equal motor blockade in both Groups. (Modified bromage scale in Group A was 5.18 and in Group B was 5.3, p value is equal to 0.162).

On comparing hemodynamic parameters like mean arterial pressure and heart rate, both Levobupivacaine and Ropivacaine were comparable at all time intervals.

When complications, such as nausea, vomiting, pruritis, urinary retention, etc, were compared between Levobupivacaine and Ropivacaine, minimal complications were observed.(one patient in Group A and one patient in Group B Complained nausea, p value is equal to 0.999).

From this study results, Ropivacaine with Fentanyl appears to be more rapid in onset of action than Levobupivacaine with Fentanyl. Both drugs have equal potency in analgesia and equal motor blockade.

These study findings can be confirmed, explored further by increasing the sample size and to the patients undergoing other surgical procedure.

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