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Comparing Levobupivacaine Alone and With Dexmedetomidine in Hernioplasty

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Abstract
Background and Aims: Spinal anaesthesia enjoys being the most popular anaesthetic technique for lower abdominal surgeries. Levobupivacaine is an amide type of long acting local anaesthetic agent which is an S (-) enantiomer of bupivacaine. Dexmedetomidine is a new addition to the class of alpha-2 agonist which has got numerous beneficial effects. Dexmedetomidine has the advantage of a lack of opioid-related side effects like respiratory depression, pruritus, nausea, and vomiting. Considering the merits of levobupivacaine and dexmedetomidine, study was conducted to know the influence of dexmedetomidine added to levobupivacaine on the characteristics of subarachnoid block, perioperative analgesia and side effects on patients undergoing hernioplasty. Methods: 60 patients were randomly allocated in two groups Group L receive 3 ml of 0.5% isobaric Levobupivacaine + 0.5 ml normal saline and Group L D receive 3 ml of 0.5% Levobupivacaine with 5µg Dexmedetomidine 0.5 ml. All statistical calculations were done using SPSS 21 version statistical program for Microsoft Windows. Result: Time to onset of sensory block achieved in Group L was longer than Group LD. Time to sensory regression to S1 segment was statistically significant p value <0.001. Time to onset of motor block (Bromage>0) was shorter in Group LD in comparison of Group L. However, time for complete motor block (Bromage > 3) was comparable in both groups. Regression to Bromage 0 was longer in Group LD than in Group L . Conclusion intrathecal levobupivacaine (0.5%) with dexmedetomidine have more effective block characteristics than intrathecal levobupivacaine (0.5%) for hernioplasty in spinal anaesthesia and better perioperative analgesia and slight better haemodynamic stability and adequate sedation.

Keyword: *Levobupivacaine, dexmedetomidine, bromage scale, intrathecal, enantiomers.*

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I. Introduction

Spinal block is still the first choice because of its rapid onset, superior blockade, less failure rate and cost effectiveness [1]. Regional techniques are the preferred anaesthetic procedure for surgeries involving lower abdomen and lower extremities. For potentiating the quality and duration of the subarachnoid block variety of drugs such as opioids, ketamine, midazolam and alpha-2 agonists, have been studied and tried. Most commonly drug used for spinal anaesthesia is bupivacaine it's side effects like cardio toxicity, neurotoxicity and more chances of hypotension has restricted it's use for certain cases. In such era luckily we have another safe option like levobupivacaine which has reduced risk of cardio-toxicity, neurotoxicity and rapid recovery of motor function. (S-) bupivacaine has been recognised as a lesser toxic of this compound's two enantiomers [2, 3]. It's less cardiovascular and central nervous system toxicity makes levobupivacaine a less toxic substitute for bupivacaine. [4, 5]

Levobupivacaine, the pure S (-) enantiomer of racemic bupivacaine, has been recently introduced in clinical studies, it is a new long -acting local anaesthetic .[6]

A newer prototype of alpha 2 agonists, dexmedetomidine is a highly selective prototype with α2:α1 selectivity of approximately eight times more in comparison to clonidine has been widely used because of its sedative , analgesic, and sympatholytic properties. It has central sympatholytic effect, which is useful in blunting hemodynamic responses in perioperative period. Intrathecal dexmedetomidine have its analgesic properties by inhibiting the release of C-fibre transmitters and by hyperpolarisation of post-synaptic dorsal horn neurons .Due to virtue of its effect on spinal alpha 2 receptors, dexmedetomidine produces its analgesic effects. Dexmedetomidine prolongs analgesia when used as an adjuvant to local anaesthetics for subarachnoid block, epidural and caudal epidural blocks effectively. [7]

In this study, the primary objective was to compare the block charactersticks between the levobupivacaine alone and levobupivacaine with dexmedetomidine by modified Bromage scale. The secondary objectives were to compare the haemodynamic changes, rescue analgesia requirement and other side effects in between the groups.

II. Methods

This was a randomized, prospective double blinded controlled clinical study over a period of 18 months. After approval of Ethical committee of institution & written informed consent, 60 patients aged 18-60 yrs , American Society of Anaesthesiologists (ASA) grade I and II of either sex undergoing elective surgery (hernioplasty) were enrolled in this study. Patients were randomized to two groups using sealed envelope technique. Patients allergic to either drug or standard contraindication of spinal anaesthesia were excluded. . Group L patients received premixed 3ml of 0.5% isobaric levobupivacaine and 0.5ml normal saline and Group LD patients received premixed 3ml of 0.5% levobupivacaine with 0.5 ml (5µg) dexmedetomidine . The sample size was calculated using the formula ($n = [z^{(1-\alpha/2)}]^2 \times SD^2 / d^2$) [8]
where $z^{(1-\alpha/2)}$ = standard normal deviation for 95% confidence = 1.96
SD = Population standard deviation of Bromage 0= 13 min
d = precision = 5%.

Patients were shifted to operating room after thorough preanaesthetic check up. The drugs were sealed in envelopes numbered 1-60 and were opened by the designated consultant just before administration of spinal anaesthesia. The drug was prepared using sterile technique and was handed over in a coded form to the attending anaesthesiologist who was unaware about the study design and groups. Observer was not present while subarachnoid block was administered. 25G spinal needle was used in all cases. Immediately after completion of the block, patients was made to lie in the supine position. Sensory testing was assessed by loss of pinprick sensation to 23 G hypodermic needle for onset and dermatomal levels were tested. Testing was then conducted until the point of two segment regression of the block. Data regarding the time to reach highest dermatomal level of sensory blockade from the time of injection, time for two segment sensory regressions was collected. . Motor testing was assessed by using Modified Bromage Scale [9]. Sedation was assessed and recorded by using Ramsay sedation scale [10] .Shivering was assessed during perioperative period.

Oxygen was administrated through a mask if the pulse oximetry reading decreased below 90%. Hypotension defined as a decrease in systolic blood pressure by more than 30% from baseline or less than 90 mm Hg was treated with incremental intravenous doses of ephedrine 6mg and further intravenous fluid as required. Bradycardia defined as heart rate less than 50 beats per minute was treated with intravenous atropine 0.6mg.

After the surgery, patients were shifted to the post anaesthesia care and recovery unit where they were kept until there is complete recovery of sensory and motor blockade. Post-operatively vital parameters were recorded and also any adverse events like nausea, vomiting, pruritus etc were noted. Pain score in postoperative period was recorded by using visual analog pain scale (VAS).[11] Diclofenac was given intramuscularly as rescue analgesia when VAS >4. A follow up was carried out post-operatively by the blinded anaesthesiologist, who asked about spinal associated neurological complications.

The observations are expressed as Mean ± one standard deviation. The baseline hemodynamic values and the post spinal hemodynamic changes at various time intervals were compared using SPSS Statistics17 version, using student't' test. P value less than 0.05 was considered statistically significant where p value is probability.

III. Result And Analysis

Demographic data such as age, sex, weight, height and duration of surgery were comparable in both groups [Table 1]. Differences in the block characteristics among these two groups are depicted in [Table 2] .Group LD has longer duration of two segment regression in comparison of Group L.Time to onset of motor block (Bromage>0) was shorter in Group LD (2.33±0.33 min) in comparison of Group L (3.65±0.44 min) which was statistically significant p value <0.001. However, time for complete motor block (Bromage > 3) was comparable in both groups. Regression to Bromage 0 was longer in Group LD (309.67±7.65 min) than in Group L (191.5±12.88) and was statistically significant p value <0.001.

Requirement for rescue analgesia is earlier in group L which was statistically significant at postoperative 3 hr and 4 hr with p value <0.001 in comparison of Group LD. There was statistically significant difference among two groups for time for rescue analgesia. On intergroup comparison there was no statistical difference in SBP, DBP, MAP, SpO2 and HR at all-time intervals. [Figure 1,2,3,4]. No statistically significant differences were found among the groups as regard each sedation grade. Group L & Group LD showed different number of patient for different grading of sedation score where p value was 0.775. Patient and surgeon

satisfaction scores were similar in both groups. There was no case of failed block or patchy block .None of the patients of either group's required supplemental analgesia or general anaesthesia.

IV. Discussion

The ease and long history of success has made subarachnoid block the anaesthetic procedure of choice for surgeries involving the lower abdomen / lower limbs. Various additives administered concomitantly with LA are fentanyl, morphine, clonidine, dexmedetomidine, and many more have shown to improve the quality of block and postoperative analgesia with varying degree of success

The aim of this prospective, randomized, comparative study is to evaluate and compare the influence of dexmedetomidine added to levobupivacaine on the characteristics of subarachnoid block, perioperative analgesia and side effects as shivering, pruritus, nausea, hypotension, bradycardia on patients undergoing hernioplasty. The clinical studies available on intrathecal anaesthesia with levobupivacaine suggest that it achieves satisfactory surgical anaesthesia. [12]

Esmaoğlu A et al [13] could reproduce similar results in transurethral endoscopic where sensory and motor block onset times were shorter in Group LD than in Group L ($p<0.001$). The regression of the sensory block to S1 dermatome and Bromage 0 were longer in Group LD than Group L ($p<0.001$). The two dermatome regression time was longer in Group LD than Group L ($p< 0.001$). Basuni et al [14], did same in knee arthroscopy patients which were randomized to receive plain levobupivacaine (4 mg) plus dexmedetomidine (3 µg) in group D or fentanyl (10 µg) in group F, intrathecal dexmedetomidine fastened the time to surgery (onset of neuraxial block) ($P = 0.002$), time to highest sensory level ($P = 0.001$), and time to highest Bromage score ($P < 0.001$), similarly we found Group LD show shorter onset time for sensory and motor block (p value <0.001) which was statistically significant. Tiwari J P et al [15] conducted a study on female patients which were scheduled for elective gynaecological surgery under spinal anaesthesia with similar group division and similar result in onset of sensory and motor block. Marothia K D et al [16] include total of 100 patients for lower limb orthopaedic surgeries, one of the group received dexmedetomidine in 1 µg/kg in epidural. The onset of analgesia (in minutes) at T10 dermatomal level was significantly earlier in the LD group (9.26±1.82) as compared to the group L (21.42±3.38) ($P<0.001$). Motor block, sensory block ,all these parameters showed highly significant difference in these two groups ($P<0.001$) .While we were conducted our study by using levobupivacaine and dexmedetomidine in spinal anaesthesia our results were comparable with early onset of sensory and motor block. Time to onset of motor block(Bromage>0) was shorter in Group LD (mean 2.33 min) in comparison of Group L (mean 3.65 min) which was statistically significant p value <0.001.

Ozyilkan N B et al [17] conducted study by comparing plain levobupivacaine and other group with adjuvant sufentanil and fentanyl intrathecally .The onset time of sensory block ,the onset time of the block reached theT10 level—the highest sensory block level and the onset time of motor block were significantly longer in Group C ($P <0.001$),whereas no significant differences were identified between Group S and Group F. VAS values for surgical incision, uterus incision, and skin closure, as well as intravenous fentanyl demand and sedation requirement were significantly higher in Group C ($P <0.05$ for each comparisons) our study show levobupivacaine with various adjuvants have better results. Gupta K et al [18] conducted study on patient for vaginal hysterectomy , randomized into two treatment groups, epidural 0.5% levobupivacaine with of 25 µg dexmedetomidine (Group LD) or 50 µg fentanyl (Group LF) .The difference in mean duration of sensory analgesia between groups was statistically highly significant and maximum ramsey sedation scores were higher (>3) inpatients of dexmedetomidine group In our study we observed statistically significant difference in time to onset of sensory block achieved but no statistically significant difference were found among the groups as regard each sedation grade. Intrathecal dexmedetomidine adjuvant effects are studied by Chattopadhyay et al [19] with low dose bupivacaine in transurethral resection of prostrate (TURP) patients which explains faster onset, prolonged sensory and motor block and reduced rescue analgesia .Das et al [20] explains role of dexmedetomidine as an anaesthetic adjuvant in a day care procedure because of its properties like analgesic, sympatholytic, sedative with haemodynamic stability. In our study other effects like nausea, pruritis, vomiting, shivering was statistically in insignificant similar to other studies.

V. Conclusion

From these observations and analysis of the study , it can be inferred that intrathecal levobupivacaine with dexmedetomidine have more effective block characteristics better perioperative analgesia ,slight better haemodynamic stability and adequate sedation than levobupivacaine alone. So we recommend the use of levobupivacaine plus dexmedetomidine in the mentioned doses to make patient more comfortable and to get the best results.

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Nil.

CONFLICTS OF INTEREST
There are no conflicts of interest.

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MEAN ±SD

	GROUP L	GROUP LD
Age (years)	42.7 ± 13.1	42.6 ± 12.3
Weight (kg)	57.1 ± 6.0	58.8 ± 5.9
Height (m)	1.6 ± 0.1	1.6 ± 0.1
BMI	21.5 ± 1.8	22.3 ± 1.6
Sex(female)	1	1
ASA (1 & 2)	30	30
Duration of surgery (min)	67.5 ±7.2	68.8 ± 6.0

Data described as (mean±SD); p<0.05 is significant, ASA – American Society of Anesthesiologists.

TABLE 1 DEMOGRAPHIC DATA

MEAN ± SD

	GROUP L	GROUP LD	P value
Sensory onset(mins)	2.7 ±0.4	1.8 ±0.3	<0.001
Motor onset (mins)	3.7 ± 0.4	2.3 ± 0.3	<0.001
Two segment regression of sensory level (mins)	80.8± 2.7	110.3 ± 5.3	<0.001
Regression to modified bromage score to 0 (mins)	191.5 ±10.9	288 ± 8.7	<0.001
Time for rescue analgesia(hr)	4.3 ± 0.4	5.8 ± 0.3	<0.001

Data described as (mean±SD); where SD is Standard of deviation. p value above is <0.001 highly significant.

TABLE 2 BLOCK CHARACTERSTICKS

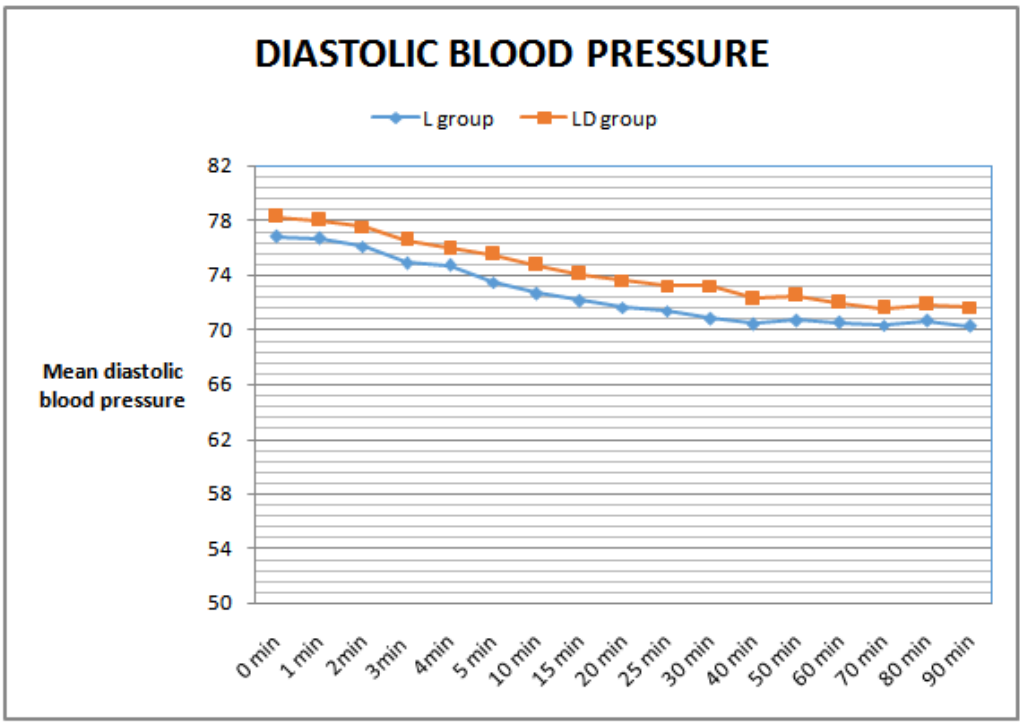

FIGURE 1 Mean diastolic pressure comparison between groups

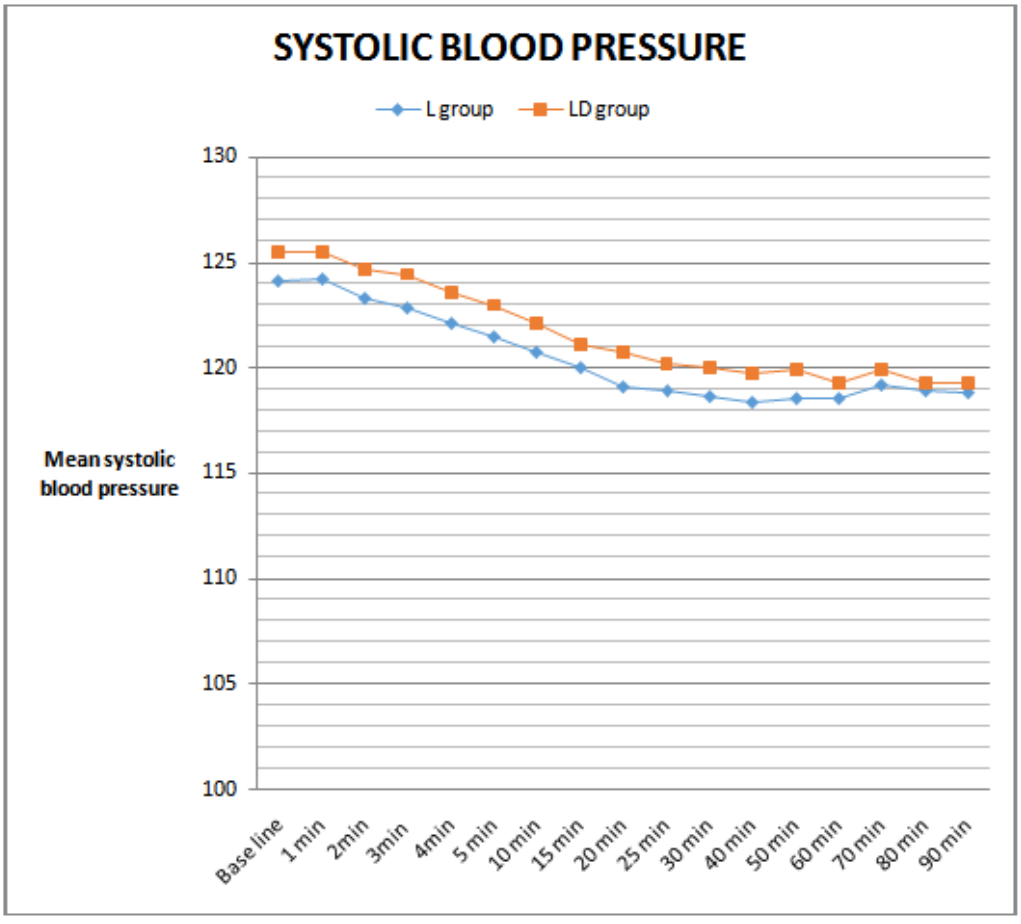

FIGURE 2 Mean systolic blood pressure comparison between two groups .

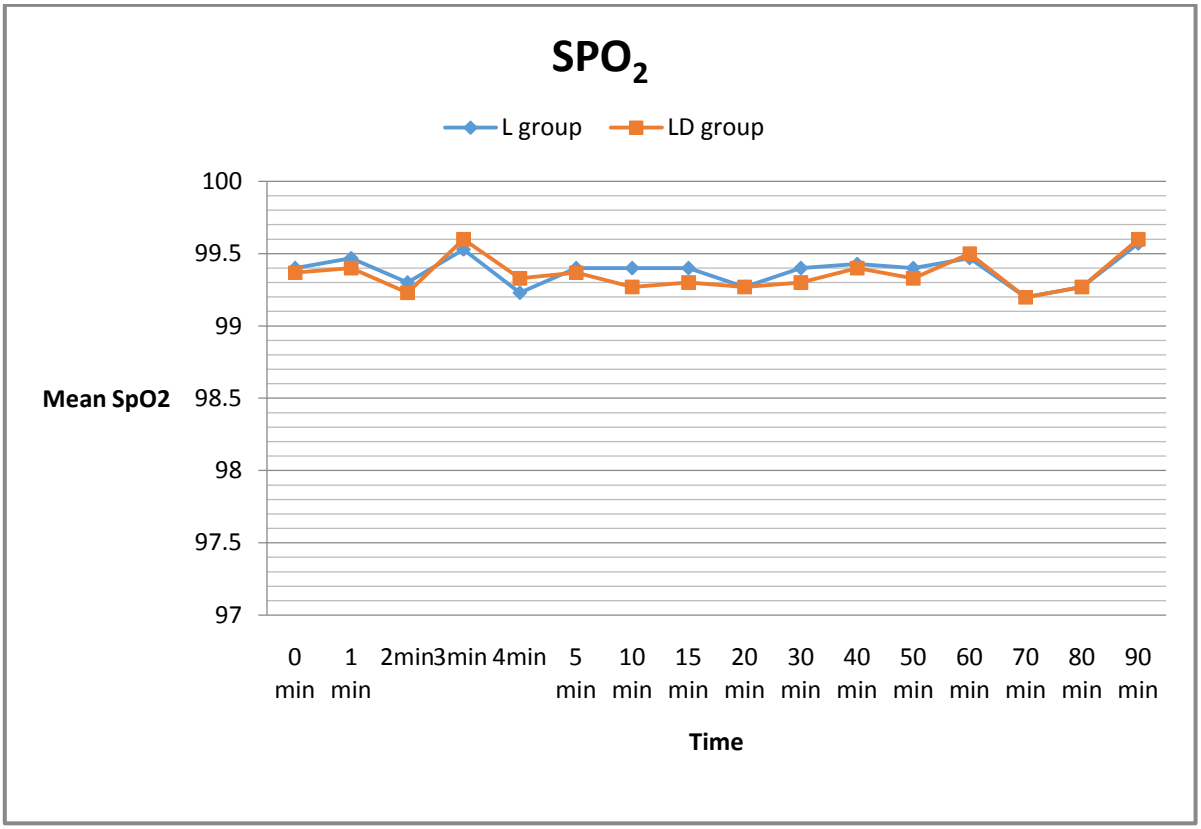

FIGURE 3 Comparison between SpO2 between two groups

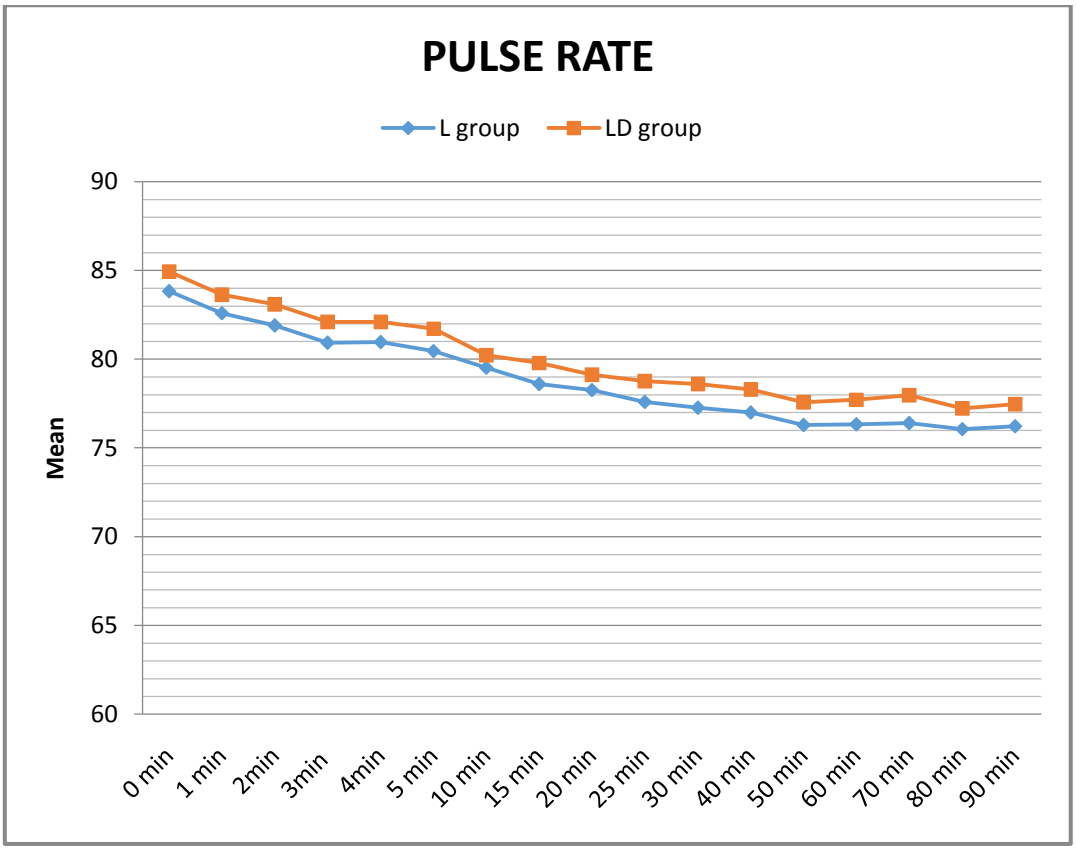

FIGURE 4 COMPARISON OF PR OF BOTH GROUPS .