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Efficacy of Lignocaine versus Lignocaine + Butorphanol in Intravenous Regional Anaesthesia for Prolongation of Post-Operative Analgesia in Patients Undergoing Upper Limb Surgery-A Comparative Study

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ABSTRACT
Intravenous regional anaesthesia (IVRA) is a simple technique of regional anaesthesia where local anaesthetic is injected into exsanguinated vascular space with use of pneumatic tourniquet and injecting local anaesthetic as distal as possible to the tourniquet. In present study, we use inj. butorphanol 1 mg as additive to lignocaine. Butorphanol is a synthetic opioid an agonist-antagonist. It has low affinity for μ receptors to produce antagonism, moderate affinity for κ receptors. After obtaining approval from institutional ethical committee and consent of patients satisfying inclusion criteria, patients who are posted for elective upper limb surgeries lasting <1 hrs were assigned into two groups by randomization based on allocation sequence by computer generated random number tables. Group 1-0.5% lignocaine with 1 mg butorphanol of volume 40 mL Group 2-0.5% lignocaine alone of volume 40 mL patients were kept nil per oral status overnight and pre-medicated with capsule omeprazole 20 mg and Tablet alprazolam 0.25 mg the night prior to surgery and on the morning of surgery. We compared the duration of administration of rescue analgesic in postoperative period using SPSS software using paired t-test. Mean recovery time from sensory block, in group L was 85.08 mins and 111.4 mins in group LB. p-value is found to be statistically significant. Mean time for recovery from motor block is 64.04 mins in group L and 90.12 mins in group LB, p-value was <0.01 signifying statistically. Intravenous regional anaesthesia, butorphanol, post operative analgesia.

INTRODUCTION

Intravenous regional anaesthesia is a simple technique of regional anaesthesia, was invented by August Bier in.[1] It is used for short surgical procedures on upper extremities. Advantages of Bier's block include high indices of reliability, rapid onset of analgesia[2] effectiveness, economical for day care, safe for emergency surgery when patient is full stomach[3]. Limitations of Bier's block include tourniquet pain, poor muscle relaxation, minimal post-operative analgesia, local anaesthetic toxicity due to early tourniquet release[4]. This technique was largely forgotten until 1983, when Holmes used lignocaine instead of procaine in Bier's block[1-5] . To improve the quality of Intravenous regional anaesthesia block, various additives to local anaesthetics were used such as opioids, NSAIDS, neuromuscular blocking agents and also ketamine to improve the quality of the intra operative as well as the postoperative analgesia[6].

Butorphanol is a synthetic opioid an agonist antagonist that resembles pentazocine. It has low affinity for μ receptors to produce antagonism, moderate affinity for κ receptors to produce analgesia and anti-shivering effects, minimal affinity for sigma receptors so the incidence of dysphoria is low[4]. Side effects of butorphanol include sedation, nausea, respiratory depression which is reversible in healthy subjects with moderate dose of naloxone (up to 0.8 mg). Dizziness, confusion, headache and sweating also have been reported. Psychomimmetic reactions (feelings of floating or unreality, depersonalisation, hallucinations, euphoria) have been reported in some patients receiving butorphanol[6]. The incidence of some typical narcotic-like adverse effects (such as light-headedness, unusual dreams, feelings of fright) has been higher in cancer patients[7].

Objectives:

- To compare the effectiveness of "lignocaine" versus "lignocaine plus butorphanol" in Intravenous Regional Anesthesia in terms of Primary objectives
- Duration of post-operative analgesia

Secondary objectives:

- Time for first rescue analgesia
- Number of analgesic injections taken in the first 24 hrs
- Observing side effects related to butorphanol.

MATERIALS AND METHODS

Source of data: The study was a prospective double blinded randomized trial. Data was collected from patients who underwent upper limb surgeries in our institution under Department of Anaesthesiology, Mandya Institute of Medical Sciences, Mandya. Sixty patients were randomly allocated into two groups of thirty each.

Study design: Prospective double blinded randomised study

Sample size: 60

The sample size was calculated based on similar Intravenous Regional Anaesthesia studies conducted with lignocaine + butorphanol and is based on the number of Intravenous Regional Anaesthesia procedures performed in MIMS Mandya in last one year. Sample size taken for study is 60 patients.

Study period: 18 months

Sampling method: 60 patients who underwent upper limb surgeries and who had given consent to participate in the study and fulfilling the inclusion and exclusion criteria of our study will be given numbers continuously numbered from 1-60 (n = 60) and allocated in two groups randomly.

Data collection: After we obtained approval from the Institute Ethics Committee and written informed consent from patients, 60 patients were included aged between 18-65years of either sex who belong to ASA PS I and II and who underwent elective upper limb surgeries which lasted for <1 hrs. Patients with coagulation disorders, sickle cell disease, Raynaud's disease and who denied consent, morbidly obese patients (BMI- >40kg m^2) any known allergy to study drugs and patients posted for emergency surgeries and pregnant women were excluded from the study.

Method: Patients were assigned into two groups (with 30 patients in each group as Group 1 and Group 2) by simple randomization. Group 1-0.5% lignocaine with 1 mg butorphanol of volume 40 mL Group 2-0.5% lignocaine alone of volume 40 mL According to ASA starvation guidelines patients were kept nil per oral status overnight and pre-medicated with capsule omeprazole 20 mg and Tablet alprazolam 0.25 mg the night prior to surgery and on the morning of surgery. Starvation status and surgical consent confirmed in the preoperative room before the patient was shifted inside the operating room. Pre-induction monitors were connected and baseline readings noted. The syringes were loaded by the investigator in the study. Two intravenous cannulas were secured according to the universal aseptic precautions-one on the dorsum of operative hand as distal as possible to field of surgery

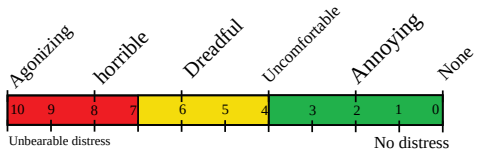

Fig 1: 24-11 point VAS scale

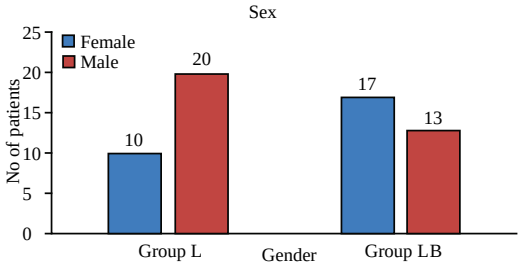

Fig 2: Sex distribution in both the groups

Table-1 Mean age distribution in both the group

Parameter	Group		p-value- Student t test
	Group L	Group LB	
Age	38.12(±12.42)	37.88(±9.96)	0.94

Table 2: Sex distribution in both the groups

Sex	Group		Total
	Group L	Group LB	
Female	10(33%)	17(57%)	27(45%)
Male	20(67%)	13(43%)	33(55%)
Total	30(100%)	30(100%)	60(100%)

Table 3: Mean BMI distribution in both the group

Parameter	Group		p-value Student t-test
	Group L	Group LB	
BMI	22.74(±1.71)	23.28(±1.56)	0.25

Table 4: Pulse rate during intra operative period

Group	Group L	Group LB	p-value student t-test
PR 0 min	83.12(±10.58)	79.92(±10.74)	0.29
PR 10 min	84.68(±10.16)	80.28(±10.93)	0.15
PR 20 min	82.64(±8.31)	80.36(±10.63)	0.40
PR 30 min	82.32(±10.88)	81.2(±10.74)	0.72
PR 40 min	80.84(±9.5)	81.24(±10.64)	0.89
PR 50 min	80.2(±9.26)	80.56(±11.72)	0.91
PR 60 min	104.37(±6.12)	80.33(±11.74)	0.01
PR 90 min	97.67(±6.6)	83.00(±12.15)	0.009
PR 120 min	84.67(±8.8)	83.83(± 11.8)	0.53
PR 150 min	84.36(±7.27)	80.04(±11.48)	0.12
PR 180 min	83.64(±9.71)	78.96(±10.82)	0.11
PR 240 min	82.24(±8.29)	79.08(±10.79)	0.25
PR 300 min	82.36(±9.14)	79.92(±10.68)	0.39
PR 360 min	81.44(±8.27)	80.4(±10.4)	0.70
PR 480 min	80(±8.01)	79.92(±9.44)	0.97
PR 600 min	84.4(±8.74)	78.96(±9.14)	0.54
PR 720 min	83.72(±9.8)	78(±10.43)	0.05
PR 1440 min	80.68(±7.43)	79.12(±7.43)	0.09

for IVRA (22 G) and another on the non-operative hand for crystalloid infusion (20 G). The double pneumatic tourniquet a proximal cuff and distal cuff, were applied to the operative limb after padding the limb. The operative arm was elevated for 2 min and exsanguination was aided with an esmarch bandage. The proximal cuff was inflated to 100 mm Hg above patient's systolic blood pressure. Circulatory isolation of arm was verified by inspection, absence of radial pulse and a loss of the pulse oximetry tracing. Under aseptic precautions 2% Preservative free lignocaine 10 mL diluted with normal saline to a total volume of 40 mL or with 2% preservative free lignocaine 10 mL +1 mg butorphanol diluted with normal saline to a total volume of 40 mL was given after inflating proximal tourniquet by the primary investigator.

After administering the drug, time of administration of drug and tourniquet application time was noted. The pin prick score was analysed by using a 25G sterile needle in median, ulnar and radial nerve innervated areas of the hand and forearm with intact skin on a three-point scale

2 = normal sensation
1 = blunted sensation
0 = absence of sensation[1]

Time of onset of sensory block was found out by using a pin prick method using a sterile needle at forearm or hand on intact skin every 30 sec from the time of injecting drugs till the pin prick score becomes 0. Onset of motor blockade was assessed by Modified Bromage Scale Grade 0-No block, total wrist and fingers

- Grade I partial block, wrist and fingers
- Grade II almost complete block, inability to flex wrist and fingers
- Grade III total block, inability to flex wrist and fingers[8]

After achieving complete sensory and motor blockade, the distal tourniquet was inflated to 100 mm Hg and surgery was started. Vitals including heart rate, blood pressure, respiratory rate and SPO_2, was recorded every 10 min till the end of procedure and the distal tourniquet was observed continuously for unintentional slow deflation. The proximal tourniquet was deflated after a minimum of 20 min from the time of injection of the solution. The distal tourniquet was not deflated till 30 min after the start of the procedure and was not inflated more than 2 hrs. The 11-point 100 mm visual analogue scale (VAS) was shown to all patients on pre-anaesthetic check-up after they are made familiar with it[9,10]. Recovery from sensory block was obtained by using the pin prick method every 2-3 min after tourniquet release, till the pin prick score returned to 0. This time interval was noted as the sensory block recovery time. Recovery from motor block was assessed by modified bromage Scale. Whenever the patient complained of pain in postoperative period, intensity was evaluated using VAS. Rescue analgesia in the form of inj. paracetamol

Table 5: Mean arterial pressure of both the groups

Group	Group L	Group LB	p-value student t-test
MAP 0 min	95.08(±8.78)	97.52(±9.59)	0.35
MAP 10 min	99.48(±10.1)	95.08(±22.08)	0.37
MAP 20 min	99.32(±13.42)	100.52(±13.77)	0.76
MAP 30 min	101.68(±14.61)	98.56(±13.61)	0.44
MAP 40 min	99.12(±9.36)	98.44(±13.53)	0.84
MAP 50 min	99.92(±8.73)	97.2(±11.7)	0.36
MAP 60 min	101.36(±8.24)	95.64(±10.43)	*0.04*
MAP 90 min	96.64(±5.98)	93.04(±5.78)	0.04
MAP 120 min	98.92(±1.26)	98.8(±0.91)	0.70
MAP 150 min	96.56(±6.78)	95.76(±7.4)	0.69
MAP 180 min	96.96(±8.1)	92.92(±8.1)	0.08
MAP 240 min	95.88(±8.57)	92(±6.53)	0.08
MAP 300 min	95.28(±6.83)	93.76(±8.9)	0.50
MAP 360 min	94.36(±7.45)	92.68(±8.06)	0.45
MAP 480 min	97.56(±8.35)	97.32(±10.18)	0.93
MAP 600 min	96.2(±5.02)	93.24(±6.72)	0.08
MAP 720 min	98.12(±7.92)	96.72(±7.31)	0.52
MAP 1440 min	94.28(±5.35)	91.48(±6.1)	0.09

Table 6: Respiratory rate during intra operative period

Group	Group L	Group LB	p-value- Student t-test
RR 0 min	21.56(±15.8)	17.96(±1.79)	0.26
RR 10 min	18.72(±1.81)	18.16(±1.95)	0.30
RR 20 min	18.52(±2.38)	18.6(±2.06)	0.90
RR 30 min	18.16(±2.12)	18.12(±2.15)	0.95
RR 40 min	18.28(±2.3)	18.2(±2.8)	0.91
RR 50 min	18.32(±2.79)	18.08(±2.29)	0.74
RR 60 min	18.2(±2.89)	17.84(±2.13)	0.62
RR 90 min	18.4(±3)	17.64(±2.27)	0.32
RR 120 min	18.32(±2.93)	18.04(±2.28)	0.71
RR 150 min	18.68(±2.43)	17.52(±1.76)	0.06
RR 180 min	19.12(±2.24)	18.12(±2.19)	0.12
RR 240 min	18.28(±2.3)	18.2(±2.8)	0.91
RR 300 min	18.96(±2.42)	17.8(±2.06)	0.08
RR 360 min	18.32(±2.12)	18(±1.94)	0.58
RR 480 min	18.04(±2.26)	18.24(±2.55)	0.77
RR 600 min	17.72(±2.07)	17.64(±2.27)	0.90
RR 720 min	17.88(±2.05)	18.04(±1.99)	0.78
RR 1440 min	17.88(±1.9)	17.72(±1.72)	0.76

Table 8: Oxygen saturation during intra operative period

Group	Group L	Group LB	p-value student t-test
SPO2 0 min	99.04(±1.21)	99.2(±1.04)	0.62
SPO2 10 min	98.96(±1.24)	98.88(±0.73)	0.78
SPO2 20 min	98.92(±1.26)	98.6(±0.96)	0.32
SPO2 30 min	98.88(±1.24)	98.56(±1.08)	0.34
SPO2 40 min	98.84(±1.25)	98.52(±1.12)	0.35
SPO2 50 min	98.84(±1.25)	98.68(±1.11)	0.63
SPO2 60 min	98.92(±1.19)	98.84(±0.9)	0.79
SPO2 90 min	98.92(±1.26)	98.68(±1.03)	0.46
SPO2 120 min	98.92(±1.26)	98.76(±0.97)	0.62
SPO2 150 min	98.92(±1.22)	98.8(±0.87)	0.69
SPO2 180 min	98.96(±1.17)	98.96(±0.84)	1.00
SPO2 240 min	98.92(±1.26)	98.92(±0.91)	1.00
SPO2 300 min	98.92(±1.26)	98.8(±0.91)	0.70
SPO2 360 min	98.88(±1.3)	98.72(±0.98)	0.63
SPO2 480 min	98.92(±1.22)	98.56(±0.96)	0.25
SPO2 600 min	98.92(±1.22)	98.6(±0.96)	0.31
SPO2 720 min	98.88(±1.27)	98.68(±0.99)	0.54
SPO2 1440 min	98.92(±1.22)	98.52(±1)	0.21

1 gram IV was given to the patients when VAS was more than 4 and time to first analgesic (TTFA) was noted. Patients were monitored up to 6 hrs after procedure, every 30 min and for post-operative analgesia every 2 hrs and followed up for pain assessment upto 24 hrs. Total number of analgesic requirement in 24 hrs was also calculated.

Statistical analysis: Data were entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data were represented in the form of Frequencies and proportions. Chi-square was the test of significance. Continuous data were represented as mean and standard deviation. Independent t-test was the test of significance to identify the mean difference between two groups. $p<0.05$ was considered as statistically significant.

Sample size estimation: Sample size was estimated by using the difference in mean time for first analgesia between Lignocaine group and Lignocaine butorphanol from the study Abhishek Bansal *et al*. as 73.63±61.32 min and 169.5±99.25 min. Using these values at 99% Confidence limit and 80% power sample size of 23 was obtained in each group by using the below mentioned formula and Med calc sample size software. With 20% non-response sample size of 23+4.6 = 27.6 ≈ Rounded off to 30 cases were included in each group.

The sample size calculation:

$$N = 2 \left(Z\alpha/_2 + Z_{1-\beta} \right)^2 S^2 \over d^2$$

Note:

N = Sample size.
P = Prevalence/proportion.
q = (100-P) or (1-P).
e = Allowable error (Absolute/relative error).
S = Standard deviation from previous studies
d = Clinical significant difference between 2 groups (expected /actual).
$Z = Z_\alpha = 1.96$ (type I error) two way hypothesis.
$Z_{1-\beta}$ = Power of the study (80%) = 0.84.

Applying formula

$Z\alpha/2 = Z_{0.05/2} = Z_{0.025} = 1.96$ (From Z table) at type 1 error of 5%
$Z_{1-\beta} = 0.842$ (From Z table) at 80% power
d = effect size = difference between mean values
So now formula will be

$$\text{Sample size} = N = 2 \left(1.96 + 0.84 \right)^2 S^2 \over d^2$$

N = 27.6 ≈ Rounded off to 30 cases were included in each group.

OBSERVATION AND RESULTS

In our study, total 60 patients were selected after considering the inclusion and exclusion criteria. Consent was obtained from all the 60 patients and were divided into 2 groups with 30 patients in each group.

Group L: received 0.5% of lignocaine (preservative free (PF)) of volume 40 mL

Group LB: received 0.5% Lignocaine (preservative free

Table 8: Mean time for sensory block onset

	Group		
Parameter	Group L	Group LB	p-valuestudent t-test
Sensory block onset (sec)	56.76(±40.52)	60.28(±55.11)	0.80

Table 9: Mean time for motor block onset

Parameters	Group		
	Group L	Group LB	p-value student-t test
Motor block onset (sec)	603.24(±196.83)	287(±98.68)	0.00

Table 10: Mean time for recovery from sensory block

Parameters	Group		
	Group L	Group LB	p-value student t-test
Recovery from sensory block(min)	85.08(±19.63)	111.4(±10.7)	0.00

Table 11: Mean time for recovery from motor block

Parameter	Group		
	Group L	Group LB	p-value student t-test
Recovery from motor block(min)	64.04(±15.49)	90.12(±13.48)	0.00

Table 12: Mean time for rescue analgesia

Parameter	Group		
	Group L	Group LB	p-value student t-test
Rescue analgesia time (min)	100.28(±22.46)	142.92(±14.55)	0.00

Table 13: Mean analgesic in 24 hours

Parameters	Group		
	Group L	Group LB	p-value student t-test
Mean rescue analgesia in 24 hrs	4.43(±0.898)	3.27(±0.868)	0.00

Table 14 the following table shows the statistically significant results obtained in present study.

Parameters	Group L	Group LB	p-value
Motor block onset (sec)	603.24(±196.83)	287(±98.68)	0.001
Recovery from sensory block (min)	85.08(±19.63)	111.4(±10.7)	0.001
Recovery from motor block (min)	64.04(±15.49)	90.12(±13.48)	0.001
Rescue analgesia time (min)	100.28(±22.46)	142.92(±14.55)	0.001
Total rescue analgesia in 24 hrs	4.43(±0.898)	3.27(±0.868)	0.001

(PF)) with 1 mg butorphanol, total volume was made as 40 mL. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 22. “p” of <0.05” was considered to be statistically significant in this study.

Age distribution: Table 2 mean age distribution of study groups . The mean age distribution in group L is 38.12 with standard deviation of 12.42 and 37.88 with standard deviation of 9.96, both the groups were compared using student t test, p>0.05 which shows there was no difference between the mean age distribution among both the groups.

Sex distribution: In group L there were 10 female and 20 male patients were included and in group LB 17 female and 13 male patients were included, there was no gender bias while allotting patients into both the groups as allotment was done by computer generated program irrespective of gender of patient.

Bmi distribution: Mean BMI distribution of both the groups were compared by using student t test and obtained p-value was >0.05 showing that there was no difference with respect to BMI in both the groups.

Vitals: Pulse rate the above table shows p value for pulse rate during intra and post-operative period. Rise in pulse rate was seen at intervals 60 min and 90 min which can be attributed to early regression of block in the group L having p-value of 0.01 and 0.009 respectively which is statistically significant.

Mean arterial pressure: The above table shows p-value for mean arterial pressure during intra and post-operative period. Rise in mean arterial pressure was seen at intervals 60 min and 90 min which can be attributed to early regression of block in the group L having p-value of 0.04 and 0.04 respectively which is statistically significant.

Respiratory rate: p-value of both the groups.

Oxygen saturation: Rise in pulse rate and mean arterial pressure was observed at 60 min and 90 min in patients with group L which was found to be statistically significant. No significant changes in other

parameters like respiratory rate and oxygen saturation in both the groups.

Onset of sensory block: Mean onset of sensory block in both the groups was compared by using student t test and results were comparable with no statistical difference between both the groups.

Onset of motor block: Mean onset of motor block in Group L was 603.24 with standard deviation of 196.83 and in group LB it was 287 with standard deviation of 98.68, both the results were compared by using student t-test and the difference was found to be statistically significant.

Recovery from sensory block:
Mean recovery time from sensory block in both the group was compared by using student t-test, in Group L. In group L mean value was 85.08 and 111.4 in group LB. p-value is found to be statistically significant.

Recovery from motor block:
Mean time for recovery from motor block is 64.04 with standard deviation of 15.49 in group L and 90.12 mins with standard deviation of 13.48 in group LB, p value was < 0.01 signifying statistically significant difference in both the groups.

Time for rescue analgesia: Rescue analgesia in Group L was found to be 100.28 and in group LB 142.92, for both the p-values student test was applied and the obtained p-value was <0.01 showing the difference significant in both the groups.

Mean rescue analgesia in 24 hrs:
The average number of analgesic injections in 24 hours required by patients in group L was 4.43 and 3.27 was in group LB with p value of 0.00 signifying statistically significant difference. The total number of analgesics received in both the groups were compared, in group L mean rescue analgesia received by patients was 4.43 and in group LB it was 3.27, with p-value of <0.01 indicationg that its statistically significant.

DISCUSSION

August bier introduced IVRA in 1908. It is also known as Bier's block. IVRA is a simple technique which is easy to perform and provides adequate analgesia intraoperatively and decreases analgesic requirements in post operative period, while the circulation is occluded. It can be performed in upper and lower extremity surgeries where general anaesthesia may be contraindicated either due to their comorbidities or inadequate nil per oral status. It is cost effective and time saving anaesthetic technique because of which it is a day care procedure. Patients have advantage of early discharge and can resume normal activities at the earliest. Multiple local anaesthetics agents like Prilocaine, Mepivacaine, Procaine, Bupivacaine and Ropivacaine have been used, but Lignocaine has been used most commonly when compared with other agents. IVRA has disadvantages of developing local anaesthetic toxicity, tourniquet pain and inadequate post operative analgesia. These factors have been overcome by modifying the technique and by adding additives to local anaesthetics.

In our study, we investigated whether the addition of Butorphanol to IVRA solution enhanced the sensory and motor block duration along with post operative duration by increasing the quality of IVRA. Several group of drugs e.g. Muscle relaxants, alpha 2 agonists, opioids and NSAIDS have been used as adjuncts to IVRA in order to prolong the duration, improved the quality of block and for prolongation of post operative analgesia in patients undergoing IVRA. Lignocaine is widely available drug and has been used widely. It is used in dose of 1-2 mg kg^{-1} of concentration 2% for attenuation of cardiovascular pressor response during endotracheal intubation.

In our study we used fixed dose of lignocaine i.e. 0.5% lignocaine of volume 40 mL for all patients which was similar to studies done by Simon *et al*[1], Gorgias[2] *et al.* and Ko[3] *et al.* where they used 0.5 % lignocaine of volume 40 mL and produced adequate analgesia and anaesthesia without any side effects. In our study as well analgesia and anaesthesia was adequate with this concentration. In study conducted by Galloway *et al* the analgesic properties of different doses of intravenous butorphanol (0.5 mg 1 mg and 2 mg) and meperidine (20 mg and 40 mg) and their side effects were studied. The dose of 1 mg butorphanol was found to produced analgesia for 2-4 hrs duration with minimal postoperative sedation or other side effects.

In studies done by Bansal *et al.* and Kataria *et al.* where 1 mg dose of butorphanol was used in accordance to which in our study we used butorphanol as additive to 0.5% lignocaine as there are less studies done with this drug and it has been used as potent analgesic. As shown in results there was no significant difference in demographic variable between both the groups. Vitals were monitored in both the groups during the intra operative and post-operative period. All the patients were hemodynamically stable, without any adverse reactions to study drug and any other technique related complications. In our study there was rise in pulse rate and mean arterial pressure at 60 min and 90 min in group L which could be due to pain because of early regression of sensory block with p-value of 0.01 and 0.009 respectively for pulse rate and 0.04 and 0.04 respectively for mean arterial

pressure. Patients were given rescue analgesia injection paracetamol 1 gram IV when patient complained of pain having VAS score >4.

Subsequently also rescue analgesia was given with 1 gram paracetamol when patient complained of pain within first 24 hrs having VAS score >4. In study conducted by Bansal *et al.* similar result was observed, where sensory block onset was 5.05 min with lignocaine alone and 3.88 min with addition of butorphanol but finding was statistically insignificant. In the studies done by Kataria *et al.* comparing Butorphanol and Ketorolac as additive to IVRA, onset of sensory blockade was found to be 3.08 mins in group with Butorphanol and 3.5 mins in the group receiving Ketorolac which was found to be statistically insignificant.

In our study mean onset of sensory block was 56.76 sec and 60.28 sec in group L (lignocaine) and group LB (lignocaine and butorphanol) respectively and was comparable with p-value of 0.23, which was statistically insignificant. In other study conducted by Nilekani *et al.* the motor onset of block with lignocaine was found to be 12.06 mins with lignocaine which is prolonged when compared with the group containing dexmedetomidine as additive. In study done by Siddiqui *et al*. who used tramadol as adjuvant to IVRA and compared with 0.5 % lignocaine as control group, onset of motor blockade with lignocaine was found to be 14.3 mins in group where lignocaine was administered alone and 13.6 mins and 13.1 mins in group where tramadol was used at two different doses, but result was statistically insignificant.

In study done by Kataria *et al*. onset of motor block in group with butorphanol as additive was 7.6 mins and in the group receiving ketorolac was 8.01 mins the difference between both the groups was statistically insignificant. In our study mean onset of motor blockade was found to be 603.24 secs in group L receiving lignocaine alone and 287 secs in group LB receiving lignocaine with butorphanol.

Derived p-value was <0.01 which was statistically significant. In study done by Bansal *et al*. results were comparable in the aspect of recovery time from sensory block the study, in group 1 (lignocaine only) it was 13.60 mins after tourniquet deflation and was 17.20 mins in group receiving butorphanol after tourniquet deflation with p-value of >0.05 and was satistically insignificant. In study conducted by katarаia *et al.* recovery from sensory block was 4.59 mins from the release of tourniquet in the group which received butorphanol and 4.18 mins in the group receiving ketorolac, results obtained was statistically insignificant. Recovery from sensory block of study done by Nilekani *et al.* was 6.02 min after deflation of tourniquet in the group receiving 0.5 % lignocaine only and 8.63 mins in the group which received 0.5 microgram kg^{-1} and the difference was statistically significance with p-value of 0.007.

Mean time for recovery from sensory block in present study was found to be 85.08 min in group L and 111.4 min in group LB in present study, having p<0.01 indicating that is it is statistically significant. In the study done by Nilekani *et al.* and Siddiqui *et al.* the recovery time from motor block was found to be 5.4 min and 4.9 min respectively with lignocaine 0.5% alone. In study done by Kataria *et al.* the recovery from motor blockade in the group receiving butorphanol was 8.12 min whereas 7.31 min in the group receiving ketorolac after deflation of tourniquet the difference in both the groups was statistically insignificant.

Mean time for recovery from motor block in present study was found to be 64.04 mins and 90.12 mins in group L and LB respectively in our study having p-value less than 0.01. In present study mean time for rescue analgesia was 100.28 mins and 142.92 mins in group L and group LB respectively which was in accordance with the study done by Bansal *et al.* where time to rescue analgesia was 73.63 mins in group receiving lignocaine and 169.50 mins in the group which received butorphanol. In study done by Kataria *et al.* and vijay kumar ramaiah *et al.* time for rescue analgesia was found to be 3.02 hrs with butorphanol and 129.75 mins with butorphanol respectively. In the study done by Bansal *et al.* the average number of analgesics in the group receiving lignocaine only was 2.37 and 1.65 in the group receiving 1 mg butorphanol, the difference in both the groups was statistically significant with p-value of 0.009.

In present study under group L average number of analgesic injections received by patients was 4.43 and 3.27 in group LB. The results were statistically significant (p-value 0.00). A significantly lesser number of postoperative rescue analgesic injections (paraecetamol 1 g IV) were required in group LB. There were no side effects observed during the intra operative and post operative period due to butorphanol or lignocaine in both the groups and all the patients were hemodynamically stable throughout the peri operative period.

CONCLUSION

We conclude that addition of 1 mg butorphanol as adjuvant to lignocaine in Intravenous Regional Anaesthesia prolongs the duration of blockade and time for rescue analgesia significantly.

Summary: A prospective randomised control single blinded study was conducted to assess the efficacy of Butorphanol of dose 1 mg as adjuvant to 40 mL of 0.5% lignocaine and compared to 0.5% lignocaine alone of

volume 40 ml in 60 patients. They were randomised into 2 groups, Group L patients received 0.5% of plain lignocaine of volume 40 mL , Group LB received 40 mL 0f 0.5% lignocaine with 1 mg butorphanol. Patients were shifted to operating room, standard ASA monitors were connected, heart rate, non-invasive blood monitoring (NIBP), Arterial oxygen saturation (SPO_2) and end tidal carbon dioxide($ETCO_2$) was monitored and recorded at specific interval throughout the procedure.

Two intravenous cannulas were secured according to the universal aseptic precautions-one on the dorsum of operative hand as distal as possible to field of surgery for IVRA (22 G) and another on the non operative hand for crystalloid infusion (20 G). The double pneumatic tourniquet with a proximal cuff and distal cuff, were applied. Proximal cuff was inflated after exsanguination and drug was injected after confirming absence of radial pulse and a loss of the pulse oximetry tracing. Tourniquet application time was noted. The pin prick score was analysed by using a 25G sterile needle using a three-point scale and onset of motor blockade was assessed by Modified Bromage Scale. After achieving complete sensory and motor blockade, the distal tourniquet was inflated. The proximal tourniquet was deflated after a minimum of 20 min from the time of injection of the solution. The distal tourniquet was not deflated till 30 min after the start of the procedure and was not inflated for more than 90 min. Recovery from sensory block was obtained by using the pin prick and motor block was assessed by modified Bromage scale. Rescue analgesia in the form of inj. paracetamol 1 gram IV was given to the patients when VAS was more than 4 and time to first analgesic (TTFA) was noted. The total number of rescue analgesic injections received by patients in first 24 hrs was also noted.

Vitals: Demographic data in both the groups were not statistically significant. All the patients were hemodynamically stable throughout the procedure without any adverse reactions to study drug and any other technique related complications. Rise in pulse rate and mean arterial pressure was observed at 60 min and 90 min in patients with group L which was found to be statistically significant. Rescue analgesia injection Paracetamol 1 gram IV was administered when patient complained of pain having VAS score >4. The mean onset of motor block in Group L was 603.24 sec with standard deviation of 196.83 and in group LB it was 287 sec with standard deviation of 98.68 with significant p-value.

The mean recovery time from sensory block in Group L was 85.08 min and 111.4 min in group LB, with statistically significant p-value. The mean time for recovery from motor block is 64.04 min with standard deviation of 15.49 in group L and 90.12 min with standard deviation of 13.48 in group LB, with statistically significant p-value. The mean rescue analgesia in Group L was found to be 100.28 min and in group LB 142.92 min with statistically significant p-value. The mean total number of analgesics received in 24 hrs in group L was 4.43 and in group LB it was 3.27, with $p< 0.01$.

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