



## TO COMPARE THE EFFICACY OF INTRATHECAL HYPERBARIC LIGNOCAINE (5%) WITH BUTORPHANOL Vs HYPERBARIC LIGNOCAINE (5%) WITH NORMAL SALINE FOR ELECTIVE LOWER SEGMENT CAESAREAN SECTION SURGERIES.

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### ABSTRACT

**Objective:** To compare the efficacy of intrathecal hyperbaric lignocaine (5%) with butorphanol vs hyperbaric lignocaine (5%) with normal saline for elective lower segment caesarean section surgeries.

**Materials and Methods:** The present study protocol was approved by Institutional Ethics Committee, IEC wherein 50 parturients of ASA grade I and II physical status scheduled for elective cesarean surgeries were selected for this study. Informed consent was obtained from all the 50 patients. During the Pre-anesthetic visit all the patients were taught to assess the intensity of pain using Ranitidine 300mg orally as premedication the night before surgery. Patients were divided into two groups GROUP A and GROUP B of 25 each randomly.

GROUP A: Hyperbaric Lignocaine 5% 1ml (53.3 mg) + Normal saline 0.9(0.2%)

GROUP B: Hyperbaric Lignocaine 5% 1ml (53.3 mg) + Butorphanol (preservative free) 0.2 ml (0.4 mg)

All the patients were preloaded with 10 ml per kg of lactated Ringer's solution. Under strict aseptic precautions, the lumbar puncture was carried out in midline through L3-L4 / L4-L5 inter space. The required volume of the drug 5% Lignocaine with normal saline 0.9% or 5% Lignocaine along Butorphanol was injected and patient turned to supine position.

Vital signs such as pulse rate, blood pressure, respiratory rate and SpO<sub>2</sub> were monitored every one minute in the first five minutes, every five minutes up to thirty minutes and every ten minutes till the end of the procedure. Onset of sensory block was assessed using pin prick and that of motor block using Bromage Scale. The time of onset of complete motor blockade was taken as time for complete paralysis according to Bromage Scale. Patients were also assessed for the onset, duration and the grade of sedation using the SEDATION SCORE. Post operatively Visual Analogue Scale score was noted every 30 minutes till 6 hours. APGAR scores were assessed for the babies at 1 minute and five minutes respectively in both the groups after delivery.

**RESULTS:** The mean duration of analgesia in Group B was 294.6 minutes and in Group A 75.8 minutes. There is no significant variation in Apgar scores.

**CONCLUSION:** It can be concluded that addition of preservative free Butorphanol 0.4mg to 1 ml of 5% Lignocaine by intrathecal route causes definite prolongation of analgesia together with mild sedation and without significant side effects and hence, can be safely used for lower segment caesarean section surgeries.

**KEYWORDS :** Lignocaine, Hyper-barric Butorphanol, Spinal Aneasthesia

### INTRODUCTION

The International Association for the study of Pain, IASP defines pain as an unpleasant sensory and emotional experience associated with actual or Potential damage.

Being a purely subjective factor, pain during surgery is often underestimated and under-treated and, its intensity varies widely among patients. While the intraoperative pain experienced by the patient has been underestimated, that of post operative pain relief has also been neglected to a large extent by anesthesiologists.

Spinal anesthesia provides profound muscular relaxation which is ideal for intra-abdominal and orthopedic procedures with decrease intra-operative blood loss, thus, reducing the need for donor blood and consequent complications. It is currently believed that spinal or epidural anesthesia techniques provide the best method of anesthesia for lower abdominal and lower limb surgeries in patients having poor ventilatory performance.

Newer trends in subarachnoid block area include use of adjuvants which reduce the nature of complications as well as improve the anesthetic effects. These solutions cause analgesia of different duration with variable latent periods and different dissemination times under clinical conditions. Choice of the solutions for various procedures to anesthetize the dermatomes depend on the depth of analgesia and duration required. Different adjuvants that can be added to local anesthetics both intrathecally and epidurally include opioids, benzodiazepines, vasoconstrictors, chlorine, neostigmine etc.

The main objective in using spinal opioid is to obtain a reduction in dose compared to that of systemic administration resulting in effective analgesia with fewer side effects. By passing through the blood and the blood-brain barrier, small doses of opioids administered spinally provide profound and prolonged segmental analgesia. Analgesia with spinal opioids in contrast to regional analgesia with local anesthetics is

not associated with any sympathetic denervation or motor blockade, and, is more specific to visceral than somatic pain. Addition of opioids through epidural and intrathecal routes provides better analgesia and sedation than local anesthetics alone without producing major side effects.

### PATIENTS AND METHODS

The present study protocol was approved by IEC. 50 parturients of ASA grade I and II undergoing elective cesarean surgeries in Government General Hospital, Rangaraya Medical College, Kakinada were selected for this study. A written informed consent was taken before enrolment in English and in Telugu.

During the Pre-anesthetic visit, all the patients were taught to assess the intensity of pain using visual analogue scale.

### METHODOLOGY

A total of 50 patients were enrolled in the study as per the selection criteria. They were randomly allocated to two groups with 25 patients each.

GROUP A: Hyperbaric Lignocaine 5% 1 ml (53.3 mg) + Normal saline 0.9(0.2%)

GROUP B: Hyperbaric Lignocaine 5% 1ml (53.3 mg) + Butorphanol (preservative free) 0.2 ml (0.4 mg)

Vital signs such as pulse rate, blood pressure, respiratory rate and SpO<sub>2</sub> were monitored every one minute in the first five minutes, every five minutes up to thirty minutes and every ten minutes till the end of the procedure respectively.

Onset of sensory block was assessed using pin prick and that of motor block using Bromage scale. Patients were also assessed for the onset, duration and the grade of sedation using the Sedation Score. Post

operatively Visual Analogue Scale score was noted every 30 minutes till 6 hours. APGAR scores were assessed for the babies at 1 minute and five minutes in both the groups after delivery.

**RESULTS**  
**SEDATION**

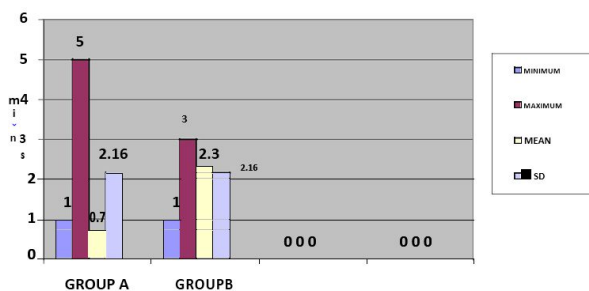
No sedation was noted in Group A, where as all patients in group B were under sedation. Sedation score in Group B patients varied between Grade II to Grade IV according to Wilson's scoring.

SEDATION SCORE	GROUP A	GROUP B
GRADE I	—	3
GRADE II	—	09
GRADE III	—	11
GRADE IV	—	02
GRADE V	—	—
TOTAL	—	25

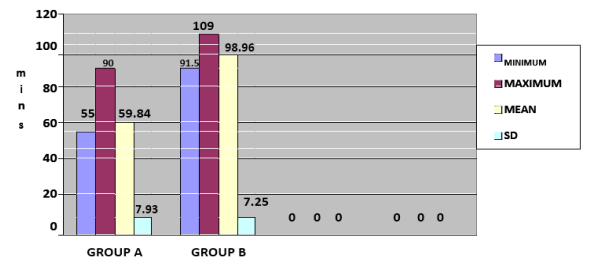
The duration of sedation in Group B had a range of 50 to 75 minutes.

**ONSET OF ACTION – SENSORY**

It was determined with pinprick at every 30 seconds intervals after completion of injection. Onset of sensory block was a little faster in Group B than in Group A. Onset of sensory action was in the range of 1 to 5 minutes in Group A and 1 to 3 minutes in Group B respectively.



**DURATION OF ACTION – SENSORY**



**DURATION OF ACTION (MOTOR)**

The duration of motor blockade was also higher in Group B. The range of motor blockade in Group A was 50 to 65 minutes with a mean value of 54.2 minutes, while that in Group B was in the range of 85 to 103.5 minutes with a mean value 93.34 minutes.

GROUP	RANGE		MEAN
	[MINUTES]	S.D.	
A	50- 65	3.35	54.52
B	85 –103.5	6.68	93.34

**DURATION OF ANALGESIA:**

The duration of analgesia was significantly increased in Group B. It was in the range of 195 to 375 minutes in Group B with a mean value of 294.6 minutes and in Group A it was in range of 55-90 minutes with a mean value of 75.8 minutes.

GROUP	RANGE		Mean
	(MINUTES)	S.D.	
A	55-90	10.27	75.8
B	195-375	53.01	294.6

**APGAR SCORES**

APGAR scores were assessed for the babies at 1 minute and five minutes in both the groups respectively after delivery.

GROUP	1 min	5min
A	8-10	8-10
B	8-10	8-10

**ADVERSE EFFECTS**

INTRAOPERATIVE COMPLICATIONS	GROUP A		GROUP B	
	PATIENTS	%	PATIENTS	%
HYPOTENSION	6	24%	5	20%

ADVERSE EFFECTS	GROUP A		GROUP B	
	PATIENTS	%	PATIENTS	%
BARDYCARDIA	2	8%	2	8%
SEDATION	-	-	25	100%
NAUSEA AND VOMITING	1	4	1	4
URINARY RETENTION	-	-	-	-
PRURITIS	-	-	-	-
RESPIRATION DEPRESSION	-	-	-	-

**DISCUSSION**

Provision of effective post operative analgesia is important not only for humanitarian reasons but also because of deleterious effects of postoperative pain.

Effective postoperative analgesia decreases morbidity allowing early ambulation and discharge. Pain relief may involve administration of local anesthetic drugs by various routes or through non-pharmacological techniques. Of all these measures, spinal and epidural administration of Local Anesthetics, either combined with Opioids or with Benzodiazepines and other adjuvants have proved to be very effective in providing good post operative analgesia with minimal side effects.

With the discovery of spinal cord receptors, intrathecal opioids have evolved as a new pharmacological means of providing intraoperative and postoperative analgesia. All opioids in clinical use produce analgesia and decrease neuronal excitability via the same molecular mechanism, i.e. by binding to G-protein coupled opioid receptor with subsequent inhibition of adenylate cyclase, activation of inwardly rectifier K<sup>+</sup> channels and by inhibition of voltage gated Ca<sup>2+</sup> channels. Although the use of intra-spinal opioid is not a new concept, it has gained popularity in the last decade or so, after obtaining a clear of knowledge of opioid receptors present in the substantia gelatinosa of the dorsal horn of the spinal cord.

Addition of a local anesthetic to opioids is generally recommended for all acute perioperative pain conditions due to the synergistic effect following their intrathecal administration. There is an improved analgesia, enhanced recovery of gastrointestinal motility and decreased severity of side effects. Solitary/Sole use of local anesthetic had been associated with significant failure rate resulting from regression of sensory block and an unacceptable high incidence of motor block as well as hypotension.

Opioids alone have an advantage of motor and autonomic sparing effect with very little or no impact on stress response and organ dysfunction compared with local anesthetic based regimens. The combination of opioids and local anesthetics can limit the regression of sensory block which is seen when local anesthetics are used alone and, also decrease the dose required as local anesthetic and improve the dynamic pain relief.

Recent studies have shown that a combination of agonist and antagonist group of opioids have decreased incidence of side effects such as respiratory depression, pruritus, nausea and vomiting etc. when compared to pure agonist. So these drugs when given via intrathecal routes can provide effective control of intra-and postoperative pain without significant side-effects.

Butorphanol is a new non-narcotic opioid analgesic, a mixed agonist-antagonist ( $\mu_1$ ,  $\kappa$  agonist producing profound analgesia and a  $\mu_2$  antagonism producing less or no Respiratory depression). It provides rapid onset of analgesia and meets the criteria of an ideal opioid for clinical use.

This is a randomized double blind controlled trial study. Variables like age, height, weight, and type of surgeries have been standardized into two groups.

1 ml of 5% Lignocaine with 0.2 ml of Normal Saline (0.9%) was

administered to patients in Group A and 1ml of 5% Lignocaine with 0.4 mg of preservative free Butorphanol (0.2ml) was administered to patients in Group B.

#### ONSET AND DURATION OF SEDATION:

It was found that sedation was induced in all patients in the study group, when compared to patients in control group, who had no sedation. Sedation score in study group ranged from grade II to grade III and only two patients had grade IV. When results were analyzed by Student 't' test, the P value was <0.01 which is statistically significant. This sedation is highly desirable, when patient is subjected to regional blockade.

#### THE ONSET AND DURATION OF SENSORY BLOCK:

In this study the mean time for sensory block in Group A was 2.30 minutes whereas in Group B was 2.16 minutes inferring that onset of block in Group B was earlier than in Group A.

The mean duration of action of sensory block in Group A was 59.84 minutes while in Group B, it was 98.96 minutes calculated by applying test of significance i.e. Students 't' test with P value <0.001 which is statistically significant.

#### THE ONSET AND THE DURATION OF MOTOR BLOCKADE:

The mean time of onset of motor block in Group A was estimated as 3.48 minutes whereas in Group B was 3.10 by applying Student 't' test with P value >0.01 which is statistically significant. So the onset of motor block even though a little faster in group B was not statistically significant.

The mean duration of motor blockade in group A was 54.52 minutes whereas in group B it was 93.34 minutes, assessed by applying the test of significance i.e. Students 't' tests with P value <0.001. So the duration of motor blockade in Group B is also prolonged which is statistically significant.

#### DURATION OF ANALGESIA:

The mean duration of pain free period in Group A was 75.8 minutes and in group B was 294.6 minutes, valued by applying student 't' test, P value <0.001 which is statistically significant. This is well documented fact and our results correlate well with the studies done by previous workers Dr. Dureja et al Professor of Anesthesia AIIMS.

#### APGAR SCORES

Apgar scores varied between 8-10 in both groups for the babies at 1 min and 10 min respectively, indicating that addition of Butorphanol to Lignocaine by intrathecal route had no adverse effect on the neonates.

When the incidence of hypotension was analyzed statistically in both the groups, P value was >0.05 which is statistically not significant. Similarly, the incidence of side effects such as nausea, vomiting, shivering and urinary retention were similar in both the groups which when analyzed statistically were in-significant, P value >0.05. None of the patients had pruritus, respiratory depression or paradoxical excitement.

For all these statistics we had considered test of significance the Student 't' test, wherein degree of freedom is  $48 (n_1 + n_2 - 2)$ . So our study corresponds well with the results of the previous studies.

The incidence of side effects like nausea, vomiting, hypotension, bradycardia, tachycardia, pruritus, shivering, paradoxical excitement was studied in both these groups. Except nausea and vomiting, no other side effects were observed. The incidence of nausea and vomiting was not much of much significance between the two groups.

Basing on the above observations, it can be concluded that Butorphanol is opioid with clinically desired effects and almost no untoward effects, thereby can be safely used for spinal anesthesia as an adjuvant to local anesthetic.

#### SUMMARY & CONCLUSION

This study was done to compare the efficacy of intrathecal hyperbaric lignocaine (5%) with butorphanol vs hyperbaric lignocaine (5%) with normal saline for elective lower segment cesarean section surgeries.

In this randomized double blind study, patients belonging to ASA I and

II undergoing elective lower segment caesarean section surgeries were divided into two groups of 25 respectively.

In the study group, patients were given 5% lignocaine with 0.4mg of Butorphanol whereas patients in control group received 5% Lignocaine with normal saline.

In the study group, the onset and duration of analgesia were significantly prolonged with good sedation and without any significant side effects.

The APGAR scoring in both the groups were compatible and there was no significant effect.

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