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RESEARCH ARTICLE

CLINICAL EVALUATION OF EFFICACY AND SAFETY OF TRANSVERSUS ABDOMINIS PLANE BLOCK INJ. LEVOBUPIVACAINE AND INJ. ROPIVACAINE FOR POST OPERATIVE ANALGESIA FOLLOWING LOWER SEGMENT CESAREAN SECTION : A PROSPECTIVE, RANDOMIZED, DOUBLE BLIND STUDY

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Transversus Abdominal Plane Block, Ropivacaine, Levobupivacaine, Post-Operative Analgesia, Lower Segment Cesarean Section

Abstract

Backgrounds and Aims : Levobupivacaine is a pure S-enantiomer of bupivacaine with similar anesthetic profile and with reduced toxic potential than racemic bupivacaine.This study aims to compare efficacy and safety of Transverse Abdominal Plane block inj. Levobupivacaine Vs. Inj. Ropivacaine for post operative analgesia following lower segment cesarean section.

Methods and Material:A prospective, randomized, controlled, double blind clinical study. 60 patients divided in 2 groups by computer generated randomization.60 healthy women undergoing cesarean delivery under spinal anesthesia were randomized into two groups (Group I, Group II). Group I received TAP block with 15 ml of 0.25% ropivacaine while Group II received TAP block with 15 ml of 0.25% levobupivacaine on each side. Postoperatively, time for first request for rescue analgesia and number of women requesting analgesia in 6 h,8 h, 10 h, 12 h and 24 h were noted. Pain score was measured with the Visual Analogue Scale (VAS) at rest and on first 24 h. Patient comfort and satisfaction with analgesia was evaluated at the end of 24 h.

Statistical analysis used: The data were analyzed with Student's t-test.

Results: The duration of analgesia was significantly prolonged in Group I than group II. The VAS score in patients who received Inj. Ropivacaine was significantly lower than who received inj. Levobupivacaine. Patient and surgeon satisfaction score were significantly higher in Ropicavaine than levobupivacaine.

Conclusions:0.25% Ropivacaine provided longer duration of analgesia compared to 0.25% Levobupivacaine in TAP Block for postoperative analgesia after lower segment cesarean section.

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Introduction:-

Cesarean deliveries are increased in numbers now a day's worldwide.The abdominal wall is a significant source of pain after any abdominal surgeries.Pain after caesarean section is usually described as moderate to severe by most patients[1]. The provision of effective postoperative analgesia is of key importance to reduce postoperative stress response and associated morbidity and accelerates recovery from surgery[2]. It facilitates early ambulation and infant care which includes breast feeding, care of baby and mother-baby bonding. Risk of thrombo-embolism is increased

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during pregnancy which is aggravated by immobility due to pain to the patients. The analgesic regimen needs to meet the goals of providing safe, effective analgesia, with minimal side effects to the mother and her child[2].

Pain of cesarean section essentially has two components: somatic (from abdominal wall incision) and visceral (from the uterus). A significant component of pain experienced by the patients is derived from abdominal wall incision.Multimodal analgesic regimen is most likely to achieve these goals[1,3].

The usual tendency is to prescribe an opioid analgesics or a NSAID for postoperative analgesia. The opioids have number of side effects such as respiratory depression, emesis, and reduction in gut movement, sedation, etc. NSAIDs relieves visceral component of pain through their action via Prostaglandin (PG) synthesis inhibition, but it is insufficient for relieving somatosensory pain of abdominal wall incision but also have certain side effects like haemostasis alteration, renal dysfunction, gastrointestinal haemorrhage, etc[1,2,3]. However in regional analgesic technique, there are minimum systemic side effects because of drugs have peripheral site of action. Hence regional analgesic technique has gained widespread popularity as an important component of postoperative analgesia regimen.

Transversus abdominis plane (TAP) block is a newly defined peripheral nerve block technique which can be used for any surgical procedure that comprises the lower abdominal wall[1, 2,3].

TAP block can be performed by injecting Local Anesthetics (LA) into the Neuro fascial plane between the transversus abdominis and the internal oblique muscles via a blind technique based on surface anatomy landmarks[1, 2, 3] and, most recently an ultrasound (US) -guided technique under direct vision[4, 5]. The TAP block is now established as an effective and important technique for providing analgesia without the need of the opioids as the part of multimodal analgesic regimen following caesarean section delivery[6].

Various LAs agents have been utilized for postoperative analgesia with ultrasound guided TAP block [1, 2,3]. Although ropivacaine and Levobupivacaine share a similar pKa and plasma protein binding property and are commonly used as LA agent for the TAP block. They have never been compared for their relative effectiveness and efficacy. The aim of the our study was to investigate whether ropivacaine with its inherent advantages (anaesthetic potency, long duration of action, favourable toxicity profile) is better to levobupivacaine for providing postoperative analgesia when used for TAP block in patients undergoing caesarean section.

Material And Method:-

After getting Institutional Review Board (IRB) approval, CTRI registration and informed written consent from the patient, this study had been carried out in 60 patients in tertiary care hospital. After thorough pre-anesthetic evaluation patients were included or excluded according to following criteria:

Inclusion criteria wereinformed written consent for participation in study,Age 20-35 years, Antenatal female patients scheduled for elective or non urgent lower segment caesarean section, ASA physical status I and II.

Exclusion criteria were Patients refusing written consent, Contraindications to Spinal Anesthesia like, local infection or sepsis at the site of lumbar puncture, bleeding disorders, thrombocytopenia, space occupying lesions of the brain, anatomical disorders of the spine, hypovolaemiae.g.following massive hemorrhage,Allergy to local anesthetic drugs and NSAIDS, patient on any form of analgesics therapy, BMI $\geq$ 25 kg/m^2.

Study design:-

Study Design was a prospective, randomized, controlled, double blind clinical study of 6 months duration. Patients were randomly allocated to one of the two groups of 30 patients each by computer generated random no. by third person and allocation were done by the opaque envelope method. The investigator who gave the drug and the observer were blinded to all allocation and drug related procedure.In pre-anaesthetic preparation room, Standard monitoring for Heart Rate (HR), Non Invasive Blood Pressure (NIBP), Peripheral oxygen saturation (SpO_2) will be established and baseline vital parameters will be recorded then peripheral intravenous line will be secured with 18G venous cannula.All patients will be pre-loaded with Ringer Lactate (10 ml/ kg body weight) before starting the surgery and will receive subarachnoid block with 2ml of 0.5% heavy hyperbaric bupivacaine in L3-L4 Inter spinous space with 23 G spinal needle. Surgery will be started after adequate sensory and motor block is achieved.

At the end of surgery, Patients in group L will receive TAP block. Patients in the supine position, the iliac crest will be palpated from anterior to posterior until latissimus dorsi muscle insertion could be felt. Triangle of Petit will be located (anteriorly bounded by external oblique and posteriorly by latissimus dorsi muscle and inferiorly by iliac crest). A 22 gauge 5 cm long blunt tip regional anesthesia needle will be inserted in the triangle of Petit just above the iliac crest at right angle to the coronal plane until first resistance is felt. This indicated that the needle tip pierced external oblique muscle. The needle will further advanced gently in the same direction until "pop" sensation is felt, which signaled entry into facial plane between external and internal oblique muscles. Further progression resulted in 2nd "pop"and this indicated entry into TAP. After careful negative aspiration 15 ml of 0.25% Levobupivacaine (group L) will be slowly injected in 5 ml increments. The block will be given on the other side using the same method.In the group R, 15 ml of 0.25% ropivacaine will be slowly injected in 5 ml increments. The block will be given on the other side using the same method.

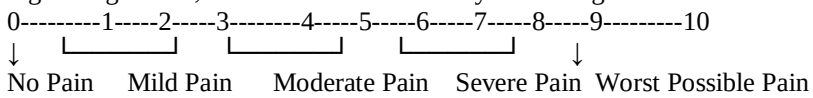
In all the patients, Incision site will be covered with a pressure dressing and will shifted to Post Anaesthetic Care Unit (PACU).

In both groups, the patients will receive standard analgesia according to obstetric department protocol consisting Diclofenac sodium 75 mg intravenous 8 hourly, first dose will be given at the end of surgery .(i.e. time 0).

The assessment of presence and severity of pain (both on rest and on passive Flexion of hip and knee)will be done immediately after transfer to Post Anaesthetic Care Unit (PACU) and at 30 minutes, 2, 4, 6, 12, 16, 20 and 24 hours after completion of surgery. Pain severity will be measured by Visual Analog Scale (VAS 0=No pain, 10=Worst pain). At any point of time if VAS is ≥ 4, intravenously Paracetamol 1gm is given to the patient as a rescue analgesic.

Visual analogue scale (vas) for pain:
VAS is a continuous scale comprised of a horizontal (HVAS) or vertical (VVAS) line, usually10 centimeters in length. It is self completed by the respondent, is asked to place a lineperpendicular to the VAS line at the point that represents their pain intensity.

Scoring: Using a ruler, the score is determined by measuring the distanceon the10 cm line.



Outcome measures:
Primary outcome wasVisual analogue scale (VAS) for pain score and Total dose and frequency of rescue analgesics required in 24 hours.Secondary outcome wasEffect on hemodynamic variables like Heart Rate (HR), Mean Arterial Pressure (MAP), Oxygen saturation (spo_2), Side effects & Complications if any.

Statistical analysis:
Primary outcome measure was time for first request of analgesia. Secondary outcome measured are number of patients requested for analgesia in a particular time interval and the side effects like sedation, nausea and vomiting. We considered difference of 180 minutes between levobupivacaine group and ropivacaine group for first call for rescue analgesia as clinically significant. Based on pilot study with nine patients, sample size was calculated with α error of 5% and power of the study 80%, we required 28 patients in each group. Considering possible dropouts we included 30 patients in each group. The data were entered into the Graph Pad SOFTWARE version 3.06. Statistics were represented in terms of mean ± standard Error of Mena (SEM) for normal distribution. Data were analyzed with unpaired Student's t-test ($P < 0.05$ was considered as statistical significant).

Results:-

All 60 patients enrolled successfully completed the study and no patient had a primary block failure. Patient characteristics in term of age and weight were comparable between the groups. (Table 1).VAS score was significantly decrease in ropivacaine group as compare to Levobupivacaine after the LSCS ($P<0.0001$) (Table 2 Fig. 1).The two groups were comparable with regard to cardiovascular and respiratory status.Patient satisfaction score with pain relief was significantly higher in the ropivacaine group. Mean satisfaction scores were 2.06 and 2.5 in the

levobupivacaine and ropivacaine group respectively (P<0.0084) (Fig. 2).Surgeon satisfaction score were 2.23 and 2.46 in the Levobupivacaine and ropivacaine group respectively (P<0.0235) (Fig.3).Rescue analgesia was needed early in the Levobupivacaine group as compare to ropivacaine group.Patients in both the group not reported nausea and vomiting. There was no local complication attributed to TAP block in either group.

Discussion:-

Managing pain after cesarean section is quite complex. The analgesic approach should be effective, safe and lacking of side effects. Over recent years, there has been growing interest in regional nerve block techniques with promising results on efficacy, as they diminish the requirement of supplemental analgesia[6]. In the variety of regional block, TAP block is a quite new abdominal nerve block technique with excellent efficacy after a variety of abdominal surgeries including cesarean section[14, 15]. Moreover, since less blood vessels are located in the TAP, the risk of systemic toxicity from the local anaesthetics, which may be caused by blood vessel puncture, the complication that commonly occurs during other peripheral nerve block procedures, can be reduced. The simplicity of the procedure can also offer an advantage for clinical use.

Racemic bupivacaine is widely used local anesthetic agent for block[7]. However, high dosage or any inadvertent intravascular injection may cause fatalities through cardiovascular[10] and central nervous system toxicity[8,9]. These toxic effects attributed mainly from dextroenantiomer of R(+) bupivacaine[8, 10.] So, the another enantiomer of levorotatory form of S(+) bupivacaine has fewer toxic effects. Hence, it emerged as safer alternative with similar clinical profile as racemic bupivacaine. Levobupivacaine has less tendency to cause cardiac toxicity due to dextro enantiomer R(+) bupivacaine has 2.4 times higher affinity for cardiac sodium channels and dissociates it from slowly than levorotatory enantiomer[11]. Plasma protein binding of Levobupivacaine is >97%, whereas bupivacaine is 95% which means availability of free drug is less in Levobupivacaine (<3%) to cause undesired toxic effects[9, 12]. Levobupivacaine has inherent vasoconstrictor activity which gives prolonged duration of action and less systemic toxicity. Numerous studies have been done to evaluate the efficiency of Levobupivacaine as localanaesthetic agent in respect to onset time, duration, andanalgesic qualities[13].

McDonnell et al[16]. reported that the total dose of morphine injected by the IV-PCA to the patients who underwent Cesarean section for 48 hours after the operation was reduced by the TAP block that conducted with 0.75% ropivacaine 1.5 mg/kg (Max. 150 mg), as compared to the total dose of morphine used in the controls. In our study 0.5% ropivacaine was used for postoperative analgesia and also for monitoring haemodynamics. Analgesia was maintained for 24 hrs without any discomfort and haemodynamics were stable till the above mentioned period.

Bhavna et al, [17] conducted study in 2012 on fifty women to undergo bilateral TAP block with ropivacaine 0.5%(N=25) versus placebo (N=25). In our study, duration of analgesia was 24 hrs with 0.5%ropivacaine,which is comparable to Bhavna et al study, which is for 24 hrs.

Priya sharmaet al.,[18] in 2013 conducted on Sixty patients (mean age 36.2 ± 9.6 years) of either sex of ASA grade 1 and 2 who underwent major gynecological or surgical operation were randomized either to receive standard care, including patient-controlled tramadol analgesia (n = 30), or to undergo TAP block (n = 30) with 20 ml of 0.375% Levobupivacaine. The TAP block reduced VAS pain scores at most (2, 4, 6, 12, 24 h), but not at all time (36, 48 h) points observed. Patients undergoing TAP block had reduced tramadol requirement in 24 h (P < 0.01) and 48 h (P < 0.01), and a longer time to the first PCA tramadol request (in minutes), compared to the control group (P < 0.001). This study demonstrates that TAP is superior in providing analgesia when compared to opioids or other intravenous medications. In our study, 0.25% Levobupivacaine was used for TAP block which provided analgesia for 12 hrs post operatively and also lesser requirements for iv analgesic medication.

Sooyoung Cho, Youn-Jin Kim, Dong-Yeon Kim, and Soon-Sup Chung [19] in 2013 conducted study on forty-four patients undergoing appendectomy were assigned either to undergo a right sided-TAP block (group I, n = 22), or to obtain standard care (group II, n = 22). All patients received standard anesthetics care, and the TAP block group given ultrasound-guided right side TAP block using 20 mL of 0.5% levobupivacaine after induction of anesthesia. The TAP block group with levobupivacaine compared to the control group reduced VAS Score significantly up to 12 hours postoperatively which is compatible with our results.

Niraj et al[20] used 0.5% bupivacaine with a TAP block in an open appendectomy, and the morphine requirements and pain scores decreased in the first 24 hours.

P. Raghunath etal[21] in 2017 conducted study on Transversus abdominus plane block with ropivacaine vs levobupivacaine for post-operative analgesia in patients undergoing lower abdominal surgeries and they found the average duration was 419.6 ± 49.95 minutes in group Levobupivacaine and 2140± 511.12 minutes in group Ropivacaine. This difference between two groups was statistically significant ($p<0.05$) and they are compatible with our study.

While comparing analgesic efficacy, in the present study VAS score was comparable in both the groups and difference was significant statistically significant at 6, 8, 10, 12 hours ($P<0.05$). The result was comparable with the previous study done by **Uma Srivastava et al.,**who concluded the scores were significantly lower at all time points up to 24 hours in study group both at rest and on movement ($P< 0.0001$) compared to control group [22.]

Maitreyi Gajanan Mankikaret al., showed VAS score was reduced after TAP block with 0.5% ropivacaine for the first 8–10 hour postoperatively as compared to patients receiving placebo block[23].

To compare rescue analgesic requirement in the present study, the number of patients requiring rescue analgesics at time interval is less in ropivacaine group as compare to levobupivacaine group which was statistically significant. Study done by **Uma Srivastava et al.,**showed requirement of rescue analgesia was reduced in study group as compared to control group and difference was statisticallysignificantt ($P<0.0001$) [22]. While comparing patient's and surgeon's mean satisfaction score, in the present study patient's mean satisfaction score were statistically significant for ropivacaine as compare to levobupivacaine.

Table 1:- Age and weight distribution.

	Ropivacaine	Levobupivacaine
Age	26 ± 0.69	24.86 ± 1.02
Weight	57.30 ± 0.42	57.23 ± 0.41

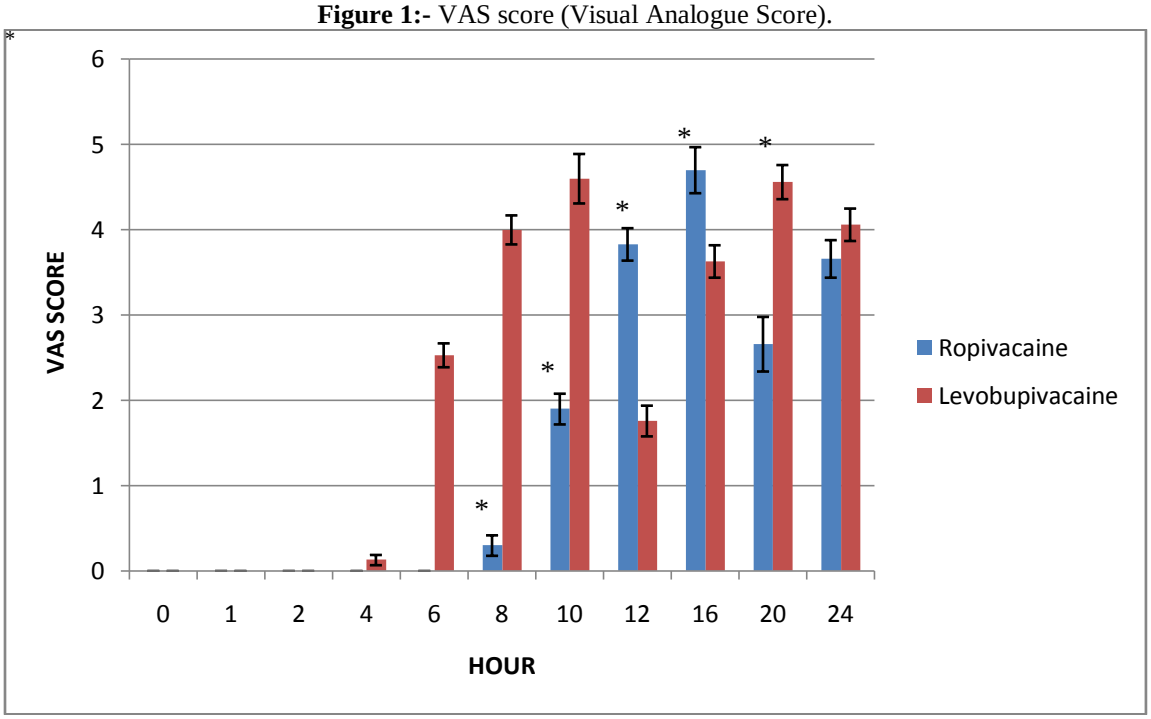
Data are expressed in Mean ± SEM.

Table 2:- VAS score.

VAS SCORE		
	ROPIVACAINE	LEVOBUPIVACAINE
0 HOUR	0	0
1 HOUR	0	0
2 HOUR	0	0
4 HOUR	0*	0.13 ± 0.06
6 HOUR	0*	2.53 ± 0.14
8 HOUR	0.3 ± 0.12*	4.0 ± 0.17
10 HOUR	1.9 ± 0.18*	4.6 ± 0.29
12 HOUR	3.83 ± 0.19*	1.76 ± 0.18
16 HOUR	4.7 ± 0.27*	3.63 ± 0.19
20 HOUR	2.66 ± 0.32*	4.56 ± 0.20
24 HOUR	3.66 ± 0.22	4.06 ± 0.19

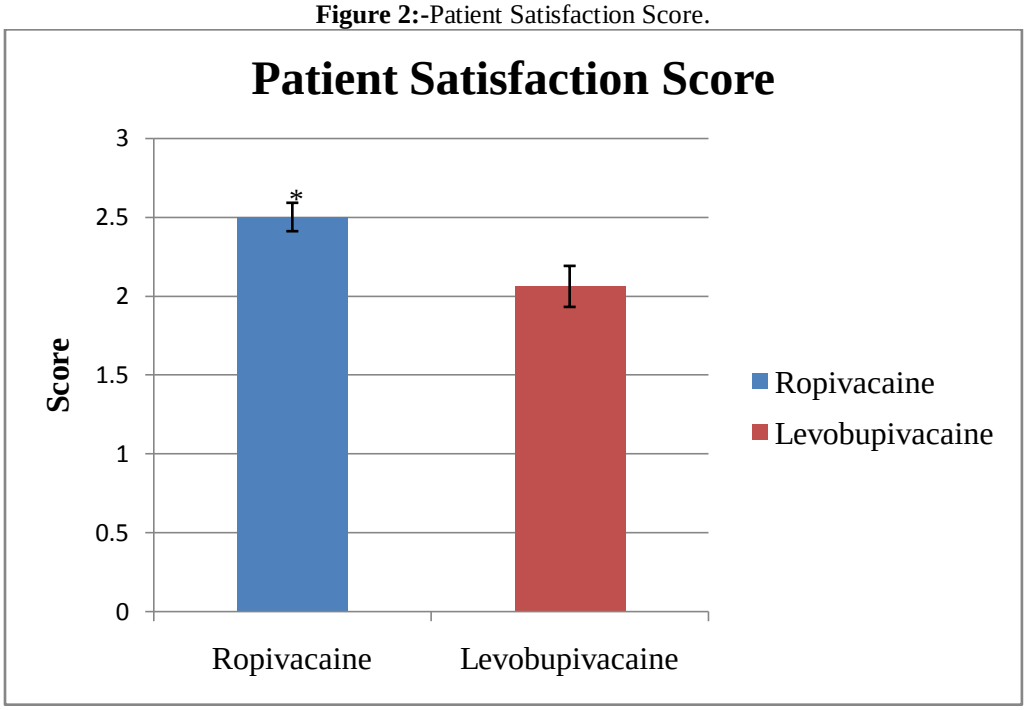
Data are expressed as Mean ± SEM. * $P<0.05$ as compared to levobupivacaine by using unpaired t test.

Figure 1:- VAS score (Visual Analogue Score).



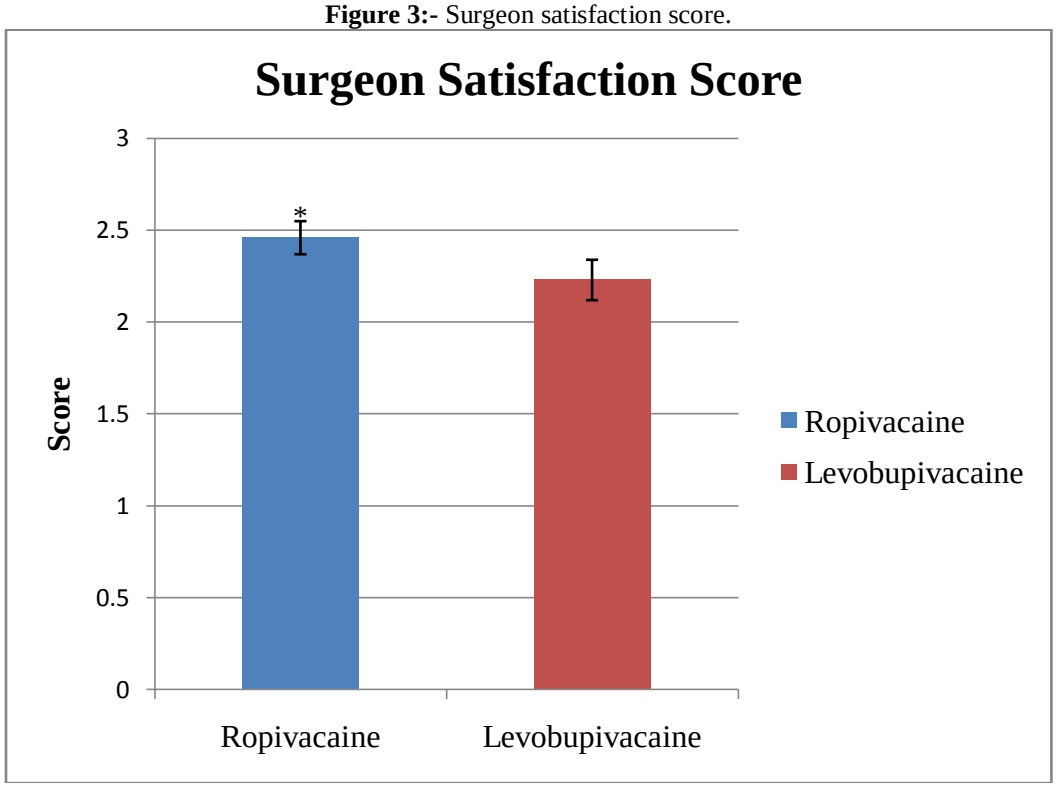
* P<0.05 as compared to levobupivacaine by using unpaired t test.

Figure 2:-Patient Satisfaction Score.



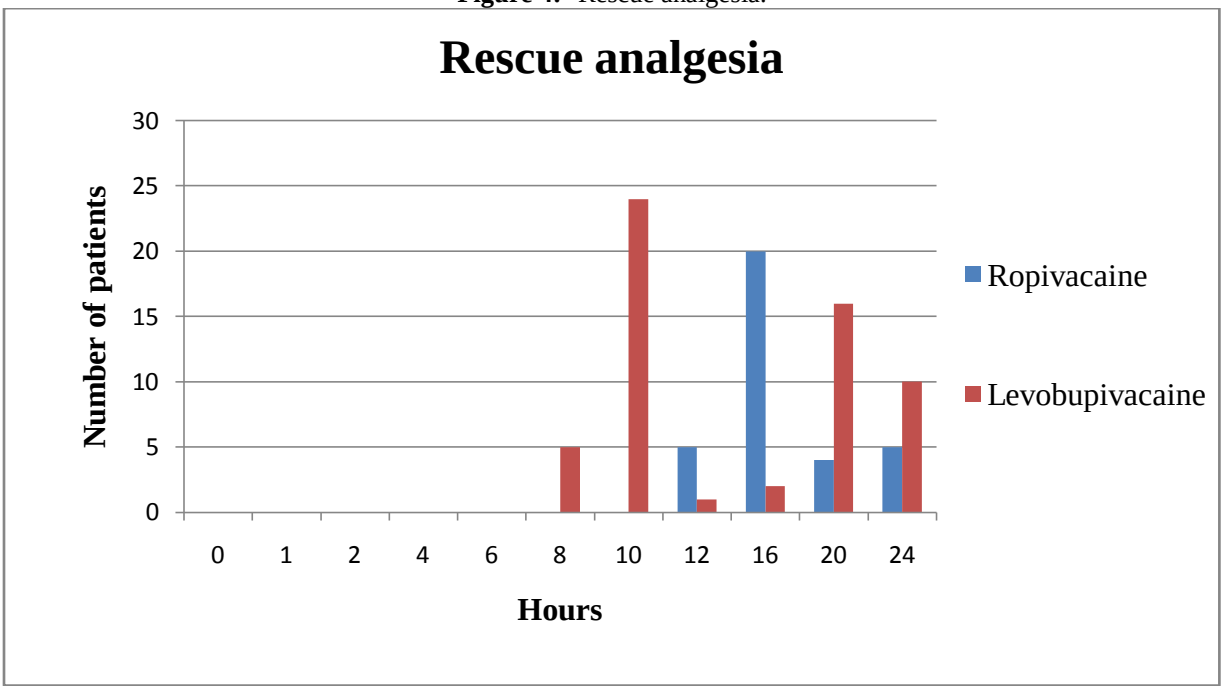
* P<0.05 as compared to levobupivacaine by using unpaired t test.

Figure 3:- Surgeon satisfaction score.



* P<0.05 as compared to levobupivacaine by using unpaired t test.

Figure 4:- Rescue analgesia.



Conclusion:-

Limitation of this study was that the sample size was too small to evaluate the safety parameter. To conclude, we observed that the analgesic effect of TAP block with ropivacaine was more effective compared to levobupivacaine. TAP block is easy technique to overcome the pain after caesarean section.

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