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RESEARCH ARTICLE
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A CLINICAL COMPARATIVE STUDY OF ANALGESIC EFFECT OF INJECTION 0.125% BUPIVACAINE, INJECTION TRAMADOL, INJECTION DEXAMETHASONE, GIVEN EPIDURALLY IN CASES OF INFRA UMBILICAL SURGERIES

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Abstract:
Introduction: Epidural anaesthesia for post-operative pain relief offers advantages for patients who has undergone infraumbilical surgeries. This study aims to compare three drugs- Dexamethasone, 0.125% Bupivacaine and tramadol for post-op epidural analgesia.
Methodology: The study was done on 90 patients. After getting informed written consent, patients were explained about Verbal numerical/Analog scale for assessment of pain. Patients were given Subarachnoid block and Epidural catheter was fixed under local anaesthesia under strict aseptic conditions. During post-operative period, patients were assigned randomly to three groups B, D and T for Inj. 0.125% Bupivacaine, Inj Dexamethasone, and Inj Tramadol respectively. Patients were monitored for effective post operative analgesia (VAS score), duration of post operative analgesia, hemodynamic changes and postoperative side effects like hypotension, respiratory depression, nausea, vomiting and urinary retention.
Result: Our study has showed that the onset of pain relief for Dexamethasone was 24.8(±6.48), Bupivacaine was 21.4(±6.63) and for Tramadol 29.16(±6.63). The duration of analgesia is observed to be higher for Dexamethasone which was 5.64(±1.34) hours, followed by Tramadol 5.44(±1.7) hours and Bupivacaine was 4.55(±1.22). So, our study has concluded that Dexamethasone has provided adequate analgesia via epidural administration for infra-umbilical surgeries than 0.125% Bupivacaine and Tramadol.
Conclusion: Dexamethasone can be preferred as a better alternative for epidural analgesic agent for post operative pain relief with stable haemodynamic.

Keywords: VAS score, post-operative pain, Epidural analgesia, infraumbilical surgeries.

Introduction:

Pain is a complex subjective experience which is difficult to measure in reproducible way [1]. It is found that operative pain is severe after surgery which diminishes gradually over next 24 hours. Providing effective analgesia for patients undergoing major surgery is a challenge for anaesthetists

[2]. Epidural Anaesthesia is the most preferred anaesthetic technique for infraumbilical surgeries and it provides effective surgical anaesthesia and can meet the extended duration of surgical needs, provides prolonged post operative analgesia, offers haemodynamic stability due to sympathetic blockade. The incidence of PDPH is less as dura is not pierced. [3] Epidural analgesia with local anaesthetics is one of the most effective techniques used for post-operative pain relief and may improve patient outcome [17]. Finding the balance between motor block and analgesia is the major challenge in epidural analgesia.

Bupivacaine is a potent local anaesthetic with unique characteristics from the amide group of local anaesthetics, first discovered in 1957. Local anaesthetics are used in regional, epidural, spinal anaesthesia and local infiltration. Local anaesthetics block the generation of an action potential in nerve cells by increasing the threshold for electrical excitation. The progression of anaesthesia is dependent on factors such as the diameter, degree of myelination, and conduction velocity of nerve fibres [18]. The adverse effects of Bupivacaine include nausea, vomiting, headache, dizziness, tinnitus, blurry vision, tremors which may precede more severe adverse effects such as convulsion and cardiovascular collapse. The cardiotoxic effect of bupivacaine can lead to asystole, and most of the time it is refractory to resuscitative measures [19]. A 20% lipid emulsion has emerged as a potential treatment for such types of prolonged or refractory cardiac arrest. If available, cardiopulmonary bypass or extracorporeal membrane oxygenation (ECMO) should be considered that allows the patient to clear the drug from the circulatory system and regain normal cardiac function [20].

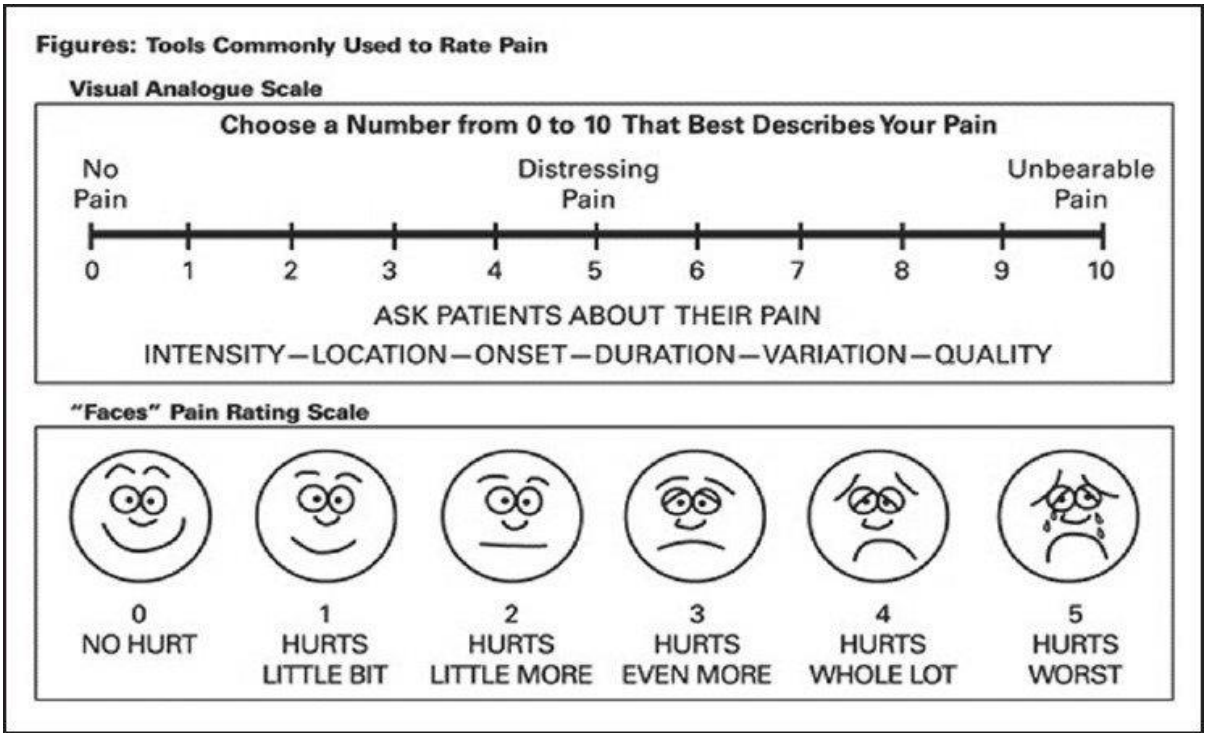
Dexamethasone is a high-potent, long-acting glucocorticoid with little mineralocorticoid effect that has been used for prophylaxis of post-operative nausea. Single doses of dexamethasone and other glucocorticoids have also been reported to improve analgesia after various operations, whether by oral or intravenous (I.V.) routes. Epidural dexamethasone may suppress prostaglandin formation in the spinal cord [21]. Adverse effects with a single dose of dexamethasone are extremely rare and slight in nature, and prior studies have demonstrated that short-term (<24 hour) use of dexamethasone is safe [23].

Tramadol hydrochloride is an atypical centrally acting opioid with mixed opioid and non-opioid activity. The non-opioid analgesic effect of tramadol hydrochloride reflects the ability of this drug to inhibit norepinephrine and 5-Hydroxytryptamine(5HT) neuronal uptake and facilitate release in vitro, which are the neurotransmitters in descending pathways and thus enhance analgesia [24]. Tramadol hydrochloride also has been shown to provide effective, long-lasting analgesia after extradural administration. Tramadol hydrochloride is an effective analgesic when administered epidurally for postoperative pain relief without serious side effects like hemodynamic instability and respiratory depression. Increasing the dose of tramadol increased the duration of post-operative analgesia, but with increased incidence of nausea and vomiting.

Methodology

This is a clinical prospective comparative study approved by Institutional Ethical Committee 90 Patients posted for elective infra-umbilical surgeries were randomly selected for study. Inclusion criteria include patients willing to give valid consent for the study, patients' age between 18-60 years, patients of either sex, ASA grade I and II patients and patients undergoing infra umbilical surgeries. Exclusion criteria include patients being subjected to general anaesthesia for the procedure, patients contraindicated for SAB and EA surgeries lasting for more than 6 hours

Written informed consent was obtained from all these patients and were subjected to pre-anaesthetic evaluation a day before surgery. Routine investigations were done. Drugs used were explained to the patients and were advised nil oral for a period of 6 hours prior to surgery. The patients were also educated about Verbal numerical/Analog scale for assessment of pain. Grading of post-operative pain was done using Verbal Numerical Scale. The patient will be asked to quantify their pain by using VNS pain scores with 0 corresponding to no pain and 10 to worst imaginable pain. For assessing the pain, 0-taken as no pain,1-3 taken as mild pain,4-6 taken as moderate pain,7-10 taken as severe pain.



On the day of surgery, patients were shifted to operating room. They were connected to monitors and baseline heart rate, non-invasive blood pressure and Spo2 was recorded. After insertion of IV cannula, patients were preloaded with Ringer Lactate 500 ml over few minutes. The anaesthesia machine, circuits, emergency resuscitation trolley and airway equipment were kept ready. Under strict aseptic precautions, on sitting position, patients were injected with local anaesthetic solution at L2-L3 intervertebral area and epidural space was identified using 18G Tuohy's needle by loss of resistance to air technique. The epidural catheter was inserted inside epidural space and secured in place under continuous monitoring. Patient was subjected to sub-arachnoid block after epidural catheter insertion. Surgery commenced after conforming adequacy of anaesthesia depth. A test dose of 3 ml of 2% lignocaine with adrenaline 1:2,00,000 was given to rule out intravascular or intrathecal placement. Five minutes after test dose, in the absence of any adverse sequelae, appropriate amount of anaesthesia was administered on the basis of surgery. All parameters like HR, BP, SPO2, RR, urine output, blood loss were monitored closely. Post-operative period, the patients were divided into three groups - Group B received Inj. Bupivacaine 0.125% diluted in 8ml of Normal Saline in 30 patients; Group D Received Inj Dexamethasone 8mg, diluted in 8ml of Normal Saline in 30 patients and Group T Received Inj Tramadol 50 mg, diluted in 8 cc of Normal Saline in 30 patients. Total volume of Drug given was 8ml for each patient. Duration of post operative analgesia, Quality of post operative analgesia, monitoring (NIBP HR), Episodes of postoperative side effects such as hypotension, bradycardia, desaturation, and respiratory depression, pruritis, nausea and vomiting, urinary retention were monitored post-operatively and treated for the same.

Statistical analysis

The statistical analysis was done by using SPSS-20. The data was tabulated in a Microsoft Excel Spreadsheet. The analysis was done by calculating mean and standard deviation. For detail analysis, Unpaired t test, Mann-Whitney test and Fischer test were used to calculate the p value and to establish correlation between study groups. A p value < 0.001 was considered highly significant statistically, a p value < 0.05 was considered significant, whereas p value > 0.05 was considered insignificant. The analysis was further represented by various lines, Graphs, and bar diagram for comparison of various parameters between the study groups.

Results

Table 1: Results – Average age of patients taken for study

PARAMETER	GROUP B	Group D	Group T
Age (in years) (Mean SD)	42.3(±11.28)	41.3(±11.96)	39.83(±7.46)

Abbreviations: SD-standard deviation**.**

Figure 1: Onset of pain relief in minutes. Dexamethasone has rapid onset of action (p=0.01)

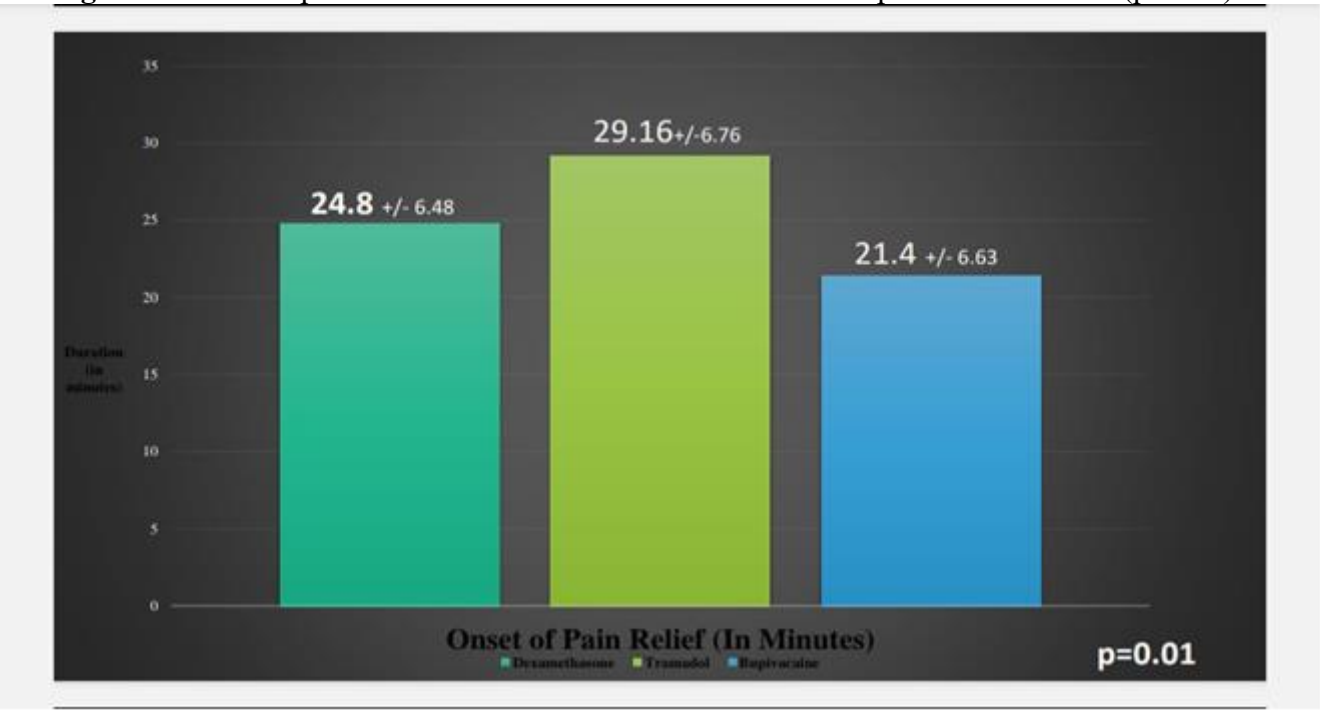


Figure 2: Hemodynamic parameters after drug administration - Dexamethasone

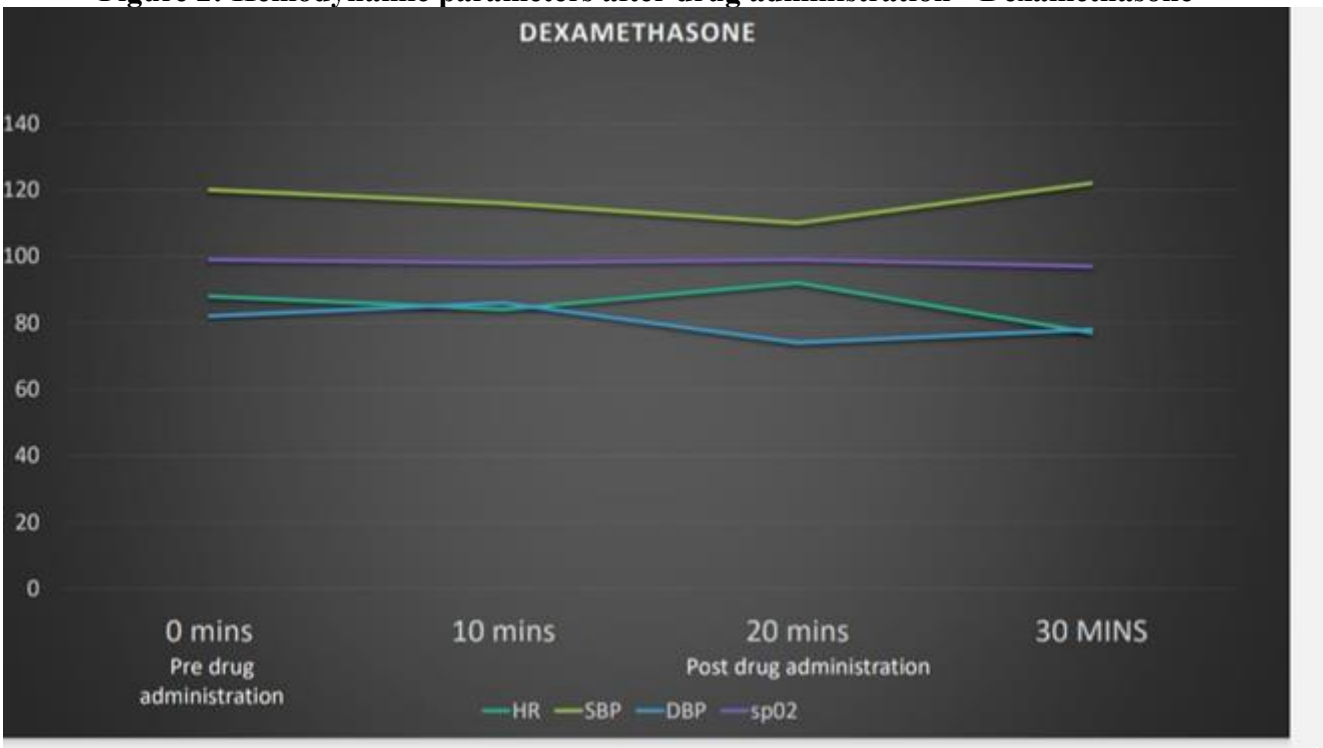


Figure 3: Hemodynamic parameters after drug administration – 0.125% Bupivacaine

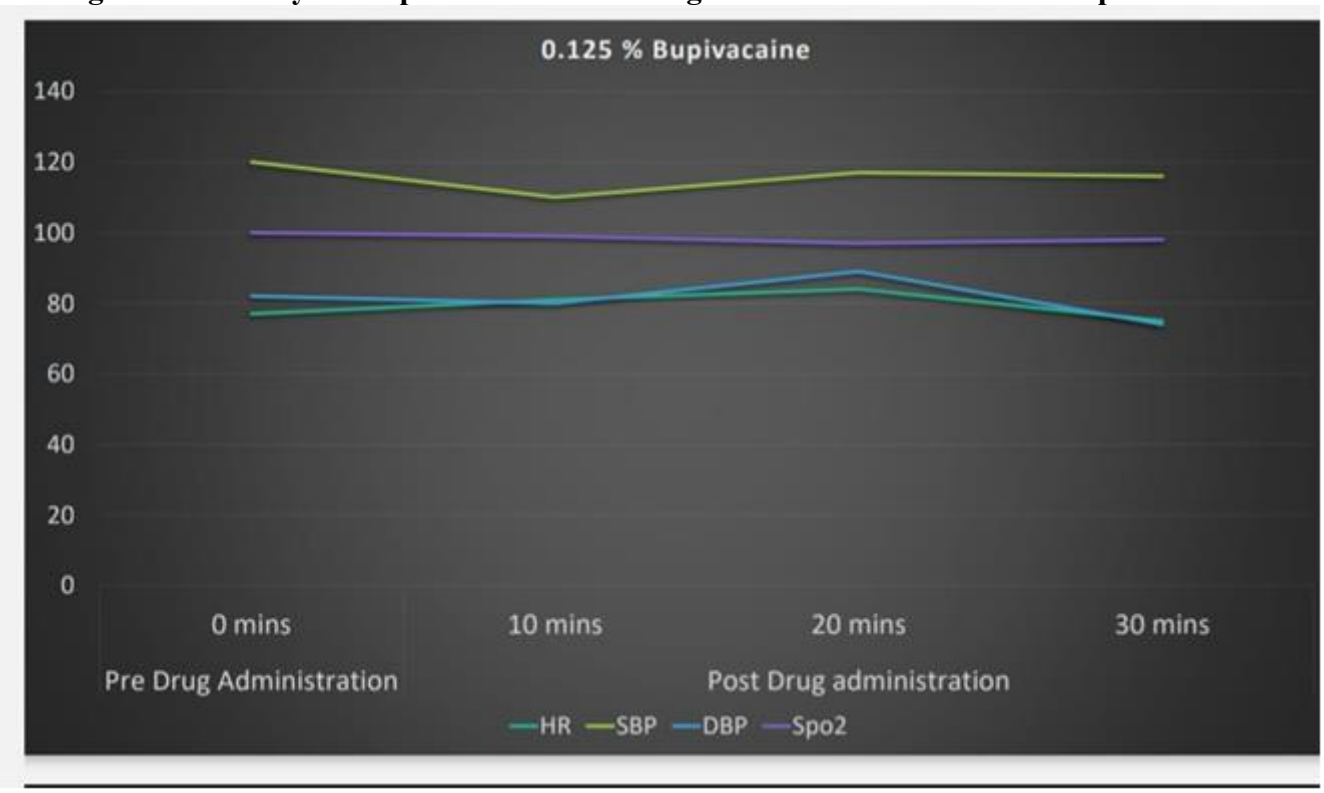


Figure 4: Hemodynamic parameters after drug administration - Tramadol

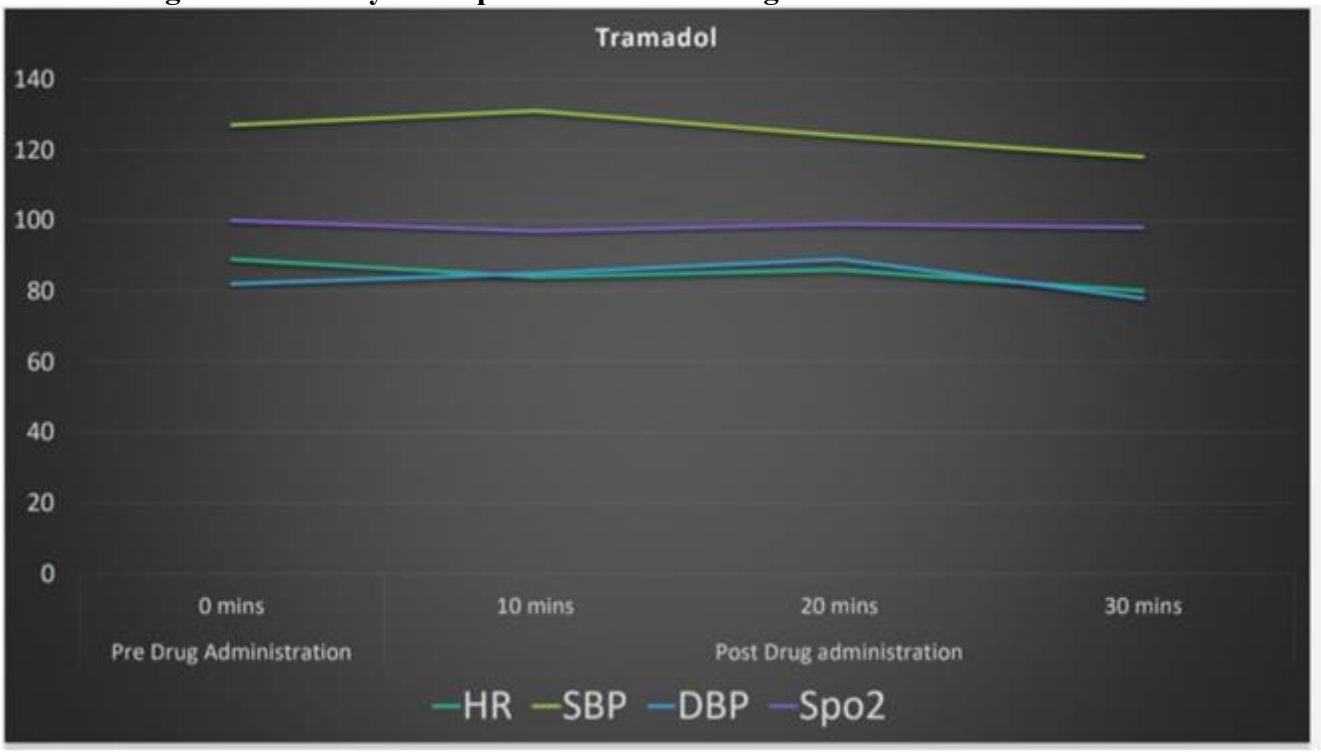


Figure 5: Duration of analgesia during post-operative period. Dexamethasone has offered longer post-operative analgesia (p=0.016)

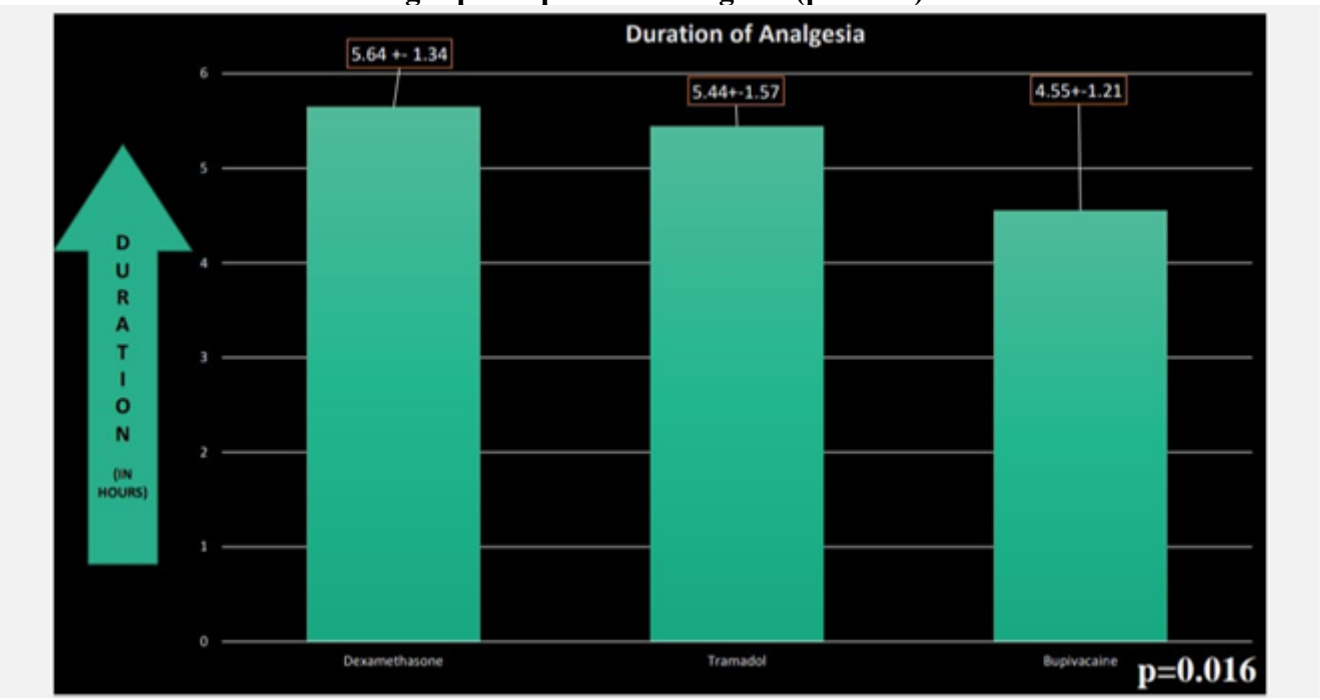


Figure 6: Dexamethasone – duration of post operative analgesia by VAS score.

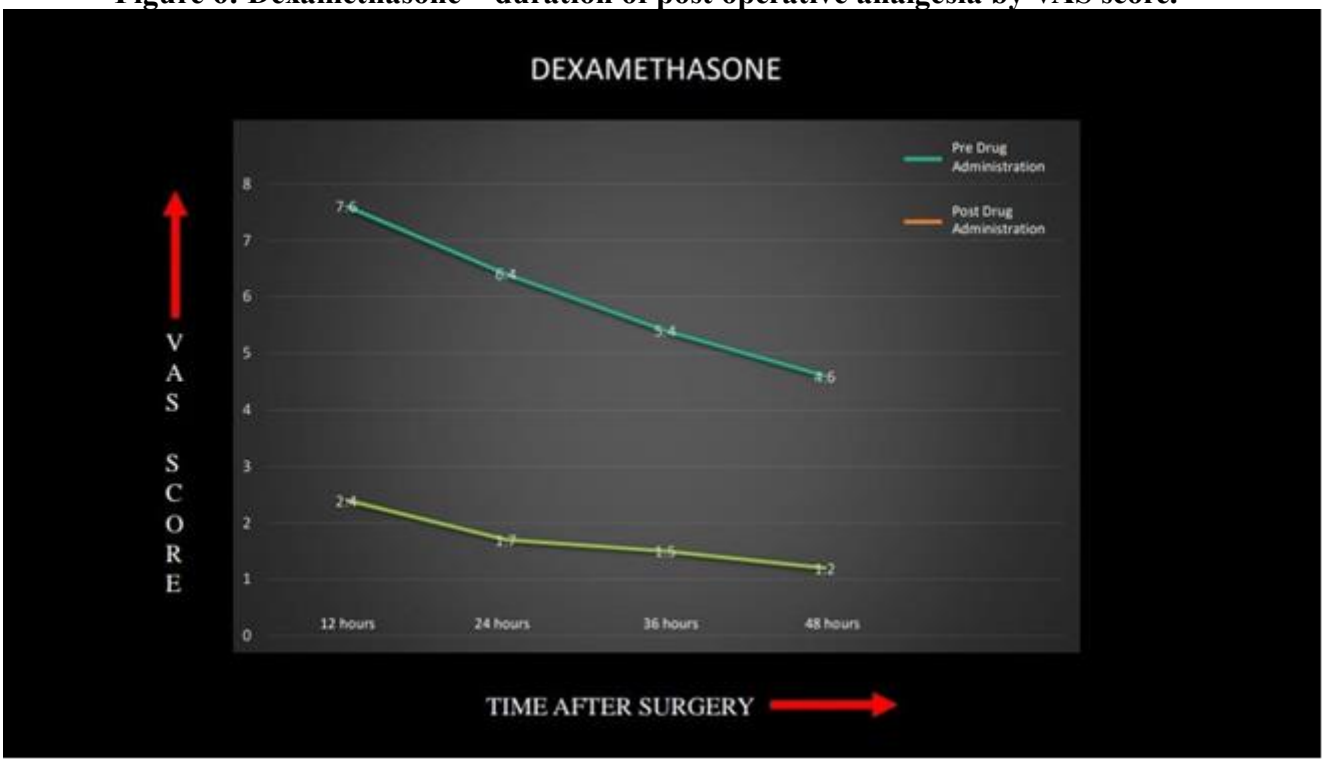


Figure 7: Bupivacaine – duration of post operative analgesia by VAS score.

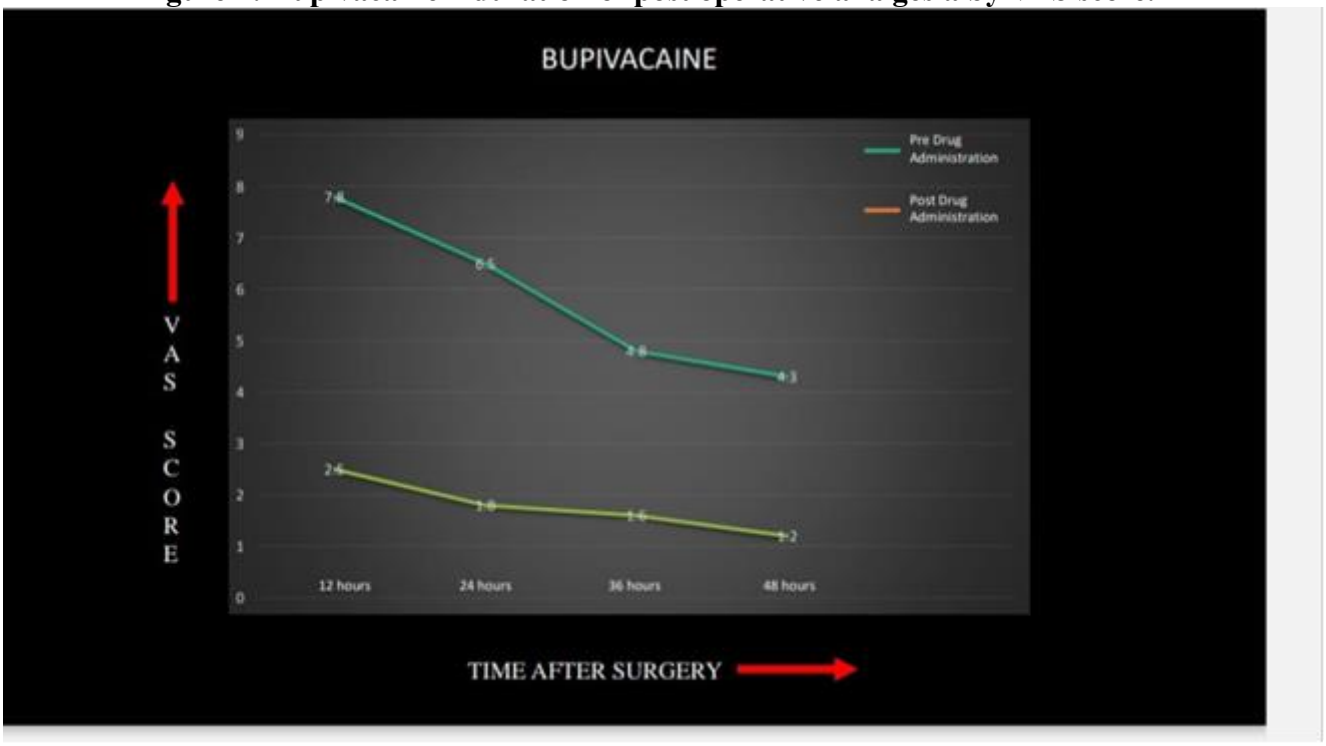


Figure 8: Tramadol – duration of post operative analgesia by VAS score.

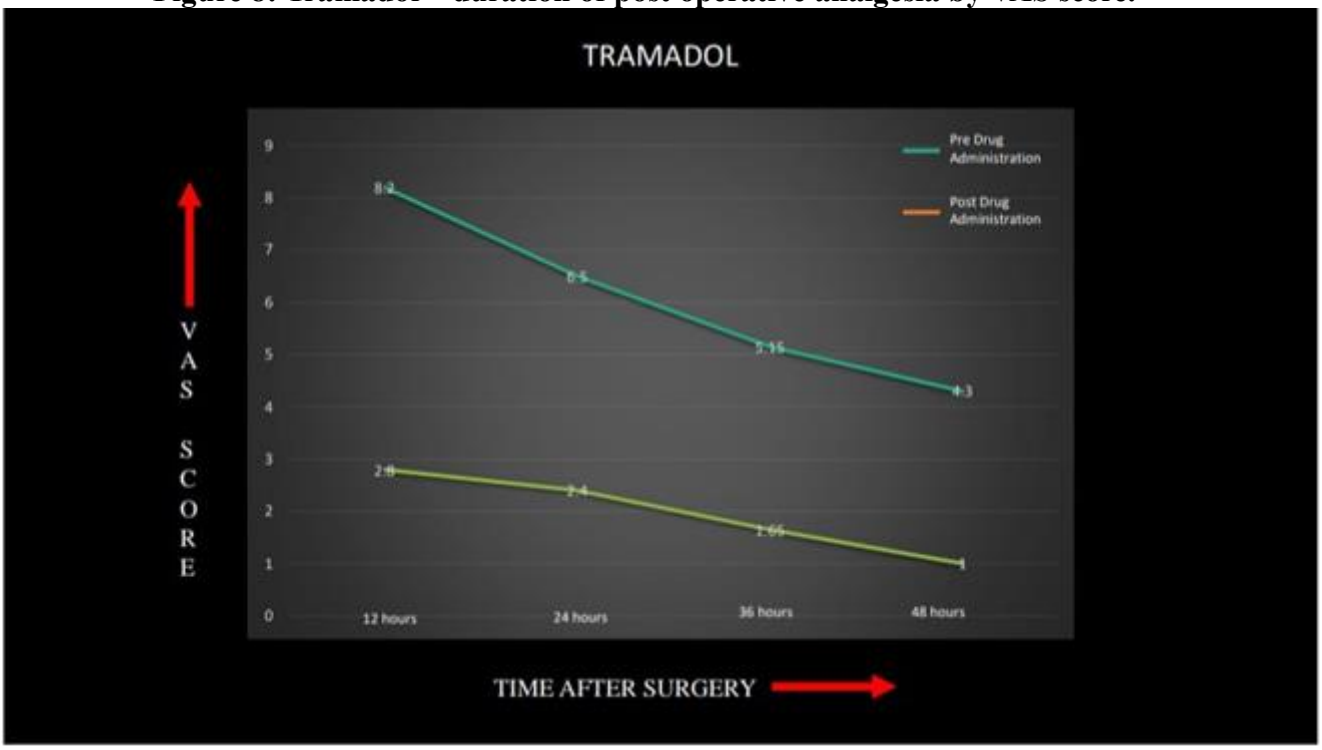
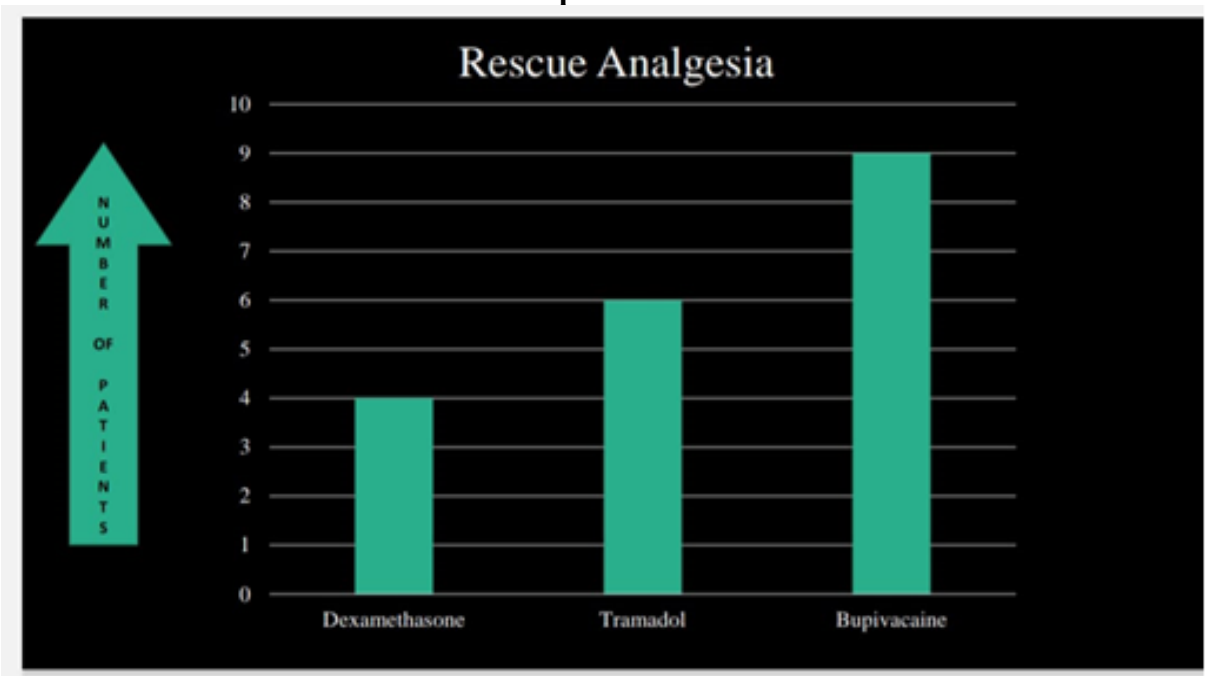


Figure 9: Number of patients who required rescue analgesia with Dexamethasone, Tramadol, Bupivacaine



Discussion

Clinical indications for epidural anaesthesia and analgesia have expanded significantly over the past several decades. Attenuation of postoperative pain may decrease perioperative morbidity and mortality [1,2]. Analgesia delivered through an indwelling epidural catheter is a safe and effective method for management of postoperative pain [3]. Hence in our study, 90 patients undergoing infraumbilical surgery has been chosen and subjected to post-operative analgesia by epidural catheter. The study population was randomly put in three groups B, D and T for Inj Bupivacaine 0.125% in 8ml normal saline [4,7], Inj Dexamethasone 8mg in 8ml normal saline [5] and Inj Tramadol 50mg in 8ml normal saline [6] respectively.

The average age of patients taken for Group B was 42 years, Group D was 41 years and Group T was 39 years and it was calculated by deriving mean Standard Deviation (SD). It was found that the average duration of surgery was 4.3(±1) hours. The onset of pain relief for Dexamethasone was 24.8(±6.48), Bupivacaine was 21.4(±6.63) and for Tramadol 29.16(±6.63). Hence Bupivacaine had faster onset of action ($p<0.01$). This was also concluded from study Conducted by *Vijayan et al* who studied the efficacy of epidurally administered tramadol hydrochloride and 0.125 % Bupivacaine for the relief of postoperative pain and fall in blood pressure was recorded in 2 patients [11]. This hemodynamic effect caused by administration of epidural Bupivacaine is further studied by *AJ Rayamajhi et al* who demonstrated fall in HR after 20-30 minutes of epidurally administrated 0.5% Bupivacaine diluted in 8ml NS in patients undergoing lower abdominal surgeries. [26]. The same study demonstrates that with addition of Dexamethasone to Bupivacaine (dilution of 8ml), VAS score was significantly lower ($p<0.001$) than plain Bupivacaine [26]

The duration of analgesia is observed to be higher for Dexamethasone which was 5.64(±1.34) hours, followed by Tramadol 5.44(±1.7) hours and Bupivacaine was 4.55(±1.22). The same was observed from the study conducted by *Hefni et al* who conducted study on Epidural dexamethasone for post-operative analgesia in patients undergoing abdominal hysterectomy [9]. The effect of analgesia caused by Dexamethasone was studied by *Ebersberger et al* which demonstrated that this effect could happen due to the peripheral tissue damage during surgery which in turn activates phospholipase A2 and upregulates the expression of cyclooxygenase-2 in the spinal cord, leading to prostaglandin synthesis and a resultant hyperalgesia state [21]. It was also observed that Dexamethasone administered patients also had less incidence of rescue analgesia requirement. Similar conclusions

were arrived in study conducted by *Hong JM et al* in which Epidural Dexamethasone was used for Postoperative Analgesia after Major Abdominal Surgery. The study states that VAS score was significantly lower with Dexamethasone ($p<0.045$), hence reducing requirement for fentanyl use which was rescue analgesia used in their study [13]. In the study conducted by *TD et al* which compared epidural Dexamethasone to Morphine which was used as adjuvants with Bupivacaine in total abdominal hysterectomies, patient who received Dexamethasone with Bupivacaine showed decreased requirement of rescue analgesia in frequent intervals [28].

Tramadol had effects of nausea in 3 patients which co-relates with study conducted by *Vijayan et al* whose study showed 5 patients with nausea [11]. The study conducted by *Suhail Sidiq et al* on patients undergoing urological procedures also demonstrates the increased incidence of PONV with higher doses of tramadol and low VAS scores were recorded 6-8 hours after administration of drug without much hemodynamic changes from baseline value ($p<0.001$). Beyond 9 hours, patients required rescue analgesia [27]. In a study conducted by *Dr. Kudary Neethi Priyanka et. al,* epidural Tramadol and epidural Dexamethasone for post-op pain relief in patients undergoing abdominal surgeries were compared. It was found that patients who received epidural Dexamethasone recorded low VAS scores post-op ($p<0.05$) and required less rescue analgesia than the patients who received epidural Tramadol and patients who received epidural Tramadol had more incidence of PONV [29].

Conclusion

Bupivacaine had a quicker onset of pain relief followed by Dexamethasone, followed by Tramadol. Duration of Analgesia was maximum with Dexamethasone, followed by Tramadol, followed by Bupivacaine. Dexamethasone has lesser adverse effect, good margin of safety with better hemodynamic stability and cost effectiveness. So, Dexamethasone can be preferred over other two drugs as better alternative for post operative epidural supplementation.

Acknowledgement:
There are no acknowledgements

Conflict Of Interest:
There are NO conflicts of interest.

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