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# COMPARISON OF FENTANYL AND DEXMEDETOMIDINE AS ADJUVANT TO ROPIVACAINE IN TRANSVERSUS ABDOMINIS PLANE BLOCK FOR POSTOPERATIVE PAIN IN INFRA UMBILICAL SURGERIES UNDER SPINAL ANAESTHESIA: A RANDOMISED COMPARATIVE STUDY

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## ABSTRACT

**Introduction:** Transversus abdominis plane (TAP) block is effective as part of multimodal pain management following Infra umbilical surgeries in absence of advance modern technical tools, as it is a simple clinical anatomical landmark procedure.

**Aim:** TAP was used to compare the duration of analgesia produced by two drugs fentanyl and dexmedetomidine as adjuvants to ropivacaine. It also looked at the advantage of this block in reducing the consumption of rescue analgesia postoperatively.

**Methods:** This is a randomized comparative study done from January 2021- August 2022 in which 60 patients were enrolled. The patients were randomly assigned to one of two groups of 30 patients each. Group A- Combination of Inj. Fentanyl (25 mcg) + Ropivacaine (0.375%)-. Total volume = 20 ml (each side). Group B- Combination of Inj. Dexmedetomidine (25 mcg) + Ropivacaine (0.375%) – Total volume = 20 ml (each side). The study parameters were: comparison of time duration of analgesia measured via ten point numerical pain score measured at 3, 6, 9, 12, and 24 hrs postoperatively, consumption of rescue analgesia, demand for rescue analgesia and any side effects (hypotension, bradycardia and fall in oxygen saturation)

**Results:** The demographical data showed comparable findings. The mean duration of analgesia in group A (496.15± 44.70) is lower than group B (865.87± 244.63). Statistically, a significant difference was observed (P=

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<0.001) between the groups. The mean VAS score was higher at every follow-up in Group-A as compared to in Group-B. The number of times analgesia needed by group A [76.7%] is higher than group B [13.3%].

**Conclusion:** The use of dexmedetomidine (25mcg) as an adjuvant with Ropivacaine (0.375%) for TAP blocks was proven to be a more effective adjuvant in providing postoperative analgesia, improve the quality of recovery and reduce the total consumption of analgesia without increasing related complications when compare to fentanyl (25mcg).

Key Words: TAP Block, postoperative analgesia and sedation, VAS score

## INTRODUCTION:

Most Infra-Umbilical surgeries are major surgical procedure after which substantial postoperative discomfort and pain can be anticipated.[1] The provision of effective postoperative analgesia is an important aspect in patient care which facilitates early ambulation, and prevention of postoperative morbidity.The analgesic regimen needs to meet the goals of providing safe and effective analgesia with minimal side effects.

A multimodal approach to postoperative analgesia after infra-umbilical surgery is an unmet medical need.

Postoperative pain management involves oral or intravenous (IV) epidural analgesia, and peripheral nerve blocks, they however, produce effective analgesia, but are associated with side effects, like nausea, vomiting, and pruritus, sometimes respiratory depression which reduces overall patient satisfaction.[1,2] TAP Block as a part of multimodal analgesic regimen would result in decreased opioid consumption and improved analgesia.[3-6]It's regional anesthesia technique that provides analgesia to the parietal peritoneum as well as the skin and muscles of the anterior abdominal wall.[7] Blind anatomical landmark technique approach is used in areas devoid of modern technological tools n remote places.

Ropivacaine[8] is a long-acting amide regional anesthetic that is structurally related to Bupivacaine. It is less lipophilic thus less likely to penetrate large myelinated motor fibers and selectively acts on the nociceptive A, B, and C fibers. It is a pure S(-)enantiomer, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles. However, its period of action is quite brief, ranging between 3.7 hours to 8.7 hours.

However, many different combinations of local anesthetics and adjuvants have been used via TAP Block in infra-umbilical surgeries such as fentanyl, Dexmedetomidine, bupivacaine, levobupivacaine, dexamethasone, morphine, Tramadol, and buprenorphine, etc have been used to prolong the effect of ropivacaine and, therefore, extend analgesia's duration into the postoperative period as well.. Each drug, however, has inherent quality, acceptance, limitations, complications and the need for alternate techniques or drugs will always remain. Alpha2 agonists are adjuvants used in anesthesia and analgesia. They can be administered orally, trans dermally, intravenously, perineurally, or neuraxial.

Fentanyl[9] is a synthetic opioid agonist, highly lipophilic which acts primarily at the μ-opioid receptor. It has been used an anesthetic adjuvant by anesthesiologists to improve cardiovascular and sympathoadrenal stability. Fentanyl prolongs sensory and motor block, promotes sedation, but may exacerbate hypotension.

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Dexmedetomidine[10] a short-term sedative α2-Adrenoceptor agonists have several beneficial actions during the perioperative period. They decrease sympathetic tone, with attenuation of the neuroendocrine and hemodynamic responses to anesthesia and surgery; reduce anesthetic and opioid requirements; and cause sedation and analgesia, side effects consists of mild to moderate cardiovascular depression, with slight decreases in blood pressure and heart rate.

Many studies already done in past using higher doses of bupivacaine, ropivaciane, fentanyl and dexmedetomidine and were associated with varied responses and results. Hence, the present study was conducted to evaluate the two different aadjuvants with ropivacaine through TAP block for post operative analgesia during infra umbilical surgeries

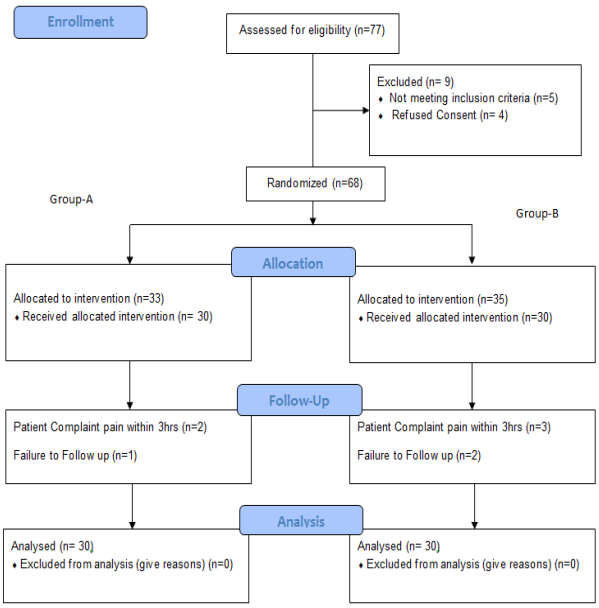
**MATERIALS AND METHODS:**

This randomized double-blinded study was conducted in the Department of Anesthesiology, Hind Institute of Medical Science, Sitapur, Uttar Pradesh, from January 2021 to August 2022. The Institutional Ethics Committee approval was obtained (IHEC-HIMSA/MD/MS(15)/RD-15/01-21). Inclusion criteria - 60 patients of 18-65 years of age, ASA-PS I –II planned for elective infra umbilical surgeries. Exclusion criteria - patients with contraindication to subarachnoid block, having renal/ hepatic dysfunction, hemodynamically unstable, bleeding disorders, allergic to study drugs, patient's refusaltoparticipate and patients who ask for rescue analgesia within 3 hrs of post-operative period.

After getting written and informed consent, patients were randomly divided into two groups, using computer-generated random number table, of 30 patients each. Group A -37.5 mg 0.375% ropivacaine (20 ml) +25 mcg fentanyl (0.5ml), Group B - 37.5 mg 0.375% ropivacaine (20 ml) +25 mcg dexmedetomidine (0.5 ml)

For ensuring the double blinding drugs were prepared by anesthesiologist who did not perform TAP block and not participating in data collection. Table 1

**Table/Figure 1 CONSORT Flowchart**



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A day before surgery pre- anaesthetic check-up with detailed physical and systemic examination were done. All relevant investigation was performed and reviewed. Patients were kept nil per oral for 6 h before surgery. They were premeditated with tablet alprazolam 0.25 mg and capsule pantoprazole 40 mg orally on the night before surgery. One the day of surgery, premedication was done with injection Ondansetron 0.10 to 0.15mg/kg IV, injection ranitidine 4-8 mg/kg IV and injection Ceftriaxone 25-30 mg/kg IV after performing sensitivity test The study was conducted over a period of 24 hours post operatively, numerical pain rating scale (NRS) with 0 to 10 points was explained to them before the surgery. In Operation Theatre, monitors were attached to the patient and baseline parameters including heart rate, systolic and diastolic blood pressure, SpO2, and respiratory rate were noted. All the patients were preloaded with 10ml/kg of crystalloid solution after securing 18 G intravenous line over 10 minutes. After taking all aseptic precaution spinal anaesthesia was given at level of L3-L4 or L2-L3 interspace with a total volume of 0.5% bupivacaine heavy 3 ml without adjuvant using a standard midline approach in a sitting position using 25G Quincke spinal needle. Surgery was allowed to proceed after T4 to T6 sensory blockade to pin prick sensation was been established.
Sensory block and motor block were assessed by loss of sensation to a pinprick and by modified bromage score, respectively. Sensory block onset time was defined as the time interval between the end of spinal anaesthesia administration and loss of pin prick sensation at T-4-6 level. While onset of complete motor block was defined as the time interval between completion of spinal anaesthesia and the absence of voluntary movement on feet, ankle, knee and hip (Bromage scale3).

Continuous monitoring of respiratory rate, heart rate, noninvasive systolic and diastolic blood pressure, SpO2, and electrocardiogram was done for hemodynamic response. Events like hypotension, bradycardia sedation and any other were recorded. Bradycardia (defined as heart rate <50 bpm) was treated with injection atropine sulfate intravenously according to heart rate.Hypotension (defined as systolic blood pressure <20% less than base value) was treated with intravenous ephedrine intravenously as per required and additional Ringer's lactate solution.

The operation was started when surgical anesthesia (up to the T6 sensory dermatome) has developed. In case of failed or partial neuraxial block, the patient was given general anesthesia and that patient was excluded from the study. At the end of the surgery, with complete aseptic precautions painting and draping was done. Triangle of Petit was identified using blind anatomical landmark technique on both sides (also known as the inferior lumbar triangle, is bounded by the latissimus dorsi posteriorly, the external oblique anteriorly, and the iliac crest inferiorly, which is the base of the triangle. The floor of the triangle is the internal oblique muscle.) The block was given through Petit' triangle with blunt 22 G hypodermic needle attached to a 20 ml syringe containing the drug as per the group allocation. Needle was introduced perpendicular to skin and advanced until two "POPS" or "give way" were felt. Then the drug was deposited in the fascial plane after aspiration, check aspiration was done every 5 ml to rule out intravascular injection. The patient was observed for 10 minutes and then shifted to post-anesthesia care unit (PACU). This time was considered time zero.

The TAP block will be deemed a failure if the patient requested analgesia within the first 3 h of administering the block, and the case was not included in analyses. A 10-point numerical pain score was recorded after the block at baseline, and at 3 h, 6 h, 9 h, 12 h, and 24 h intervals postoperatively. All patients were asked to give scores for

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their pain and severity was measured using visual analog scale (VAS, 0 = no pain and 10 =worst pain imaginable). The patients were made familiar to VAS scale a day before surgery during the pre-anesthetic checkup. Rescue analgesia was given if VAS score >4. Time of administration of the study drug to time of administration rescue analgesic (VAS > 4) was considered as the duration of analgesia of the study drug. Inj. Diclofenac 75mg or Inj. Paracetamol 1 gm was administered as a rescue analgesic. The changes in the cardiorespiratory parameters (heart rate, blood pressure) were monitored, number of significant events (bradycardia, hypotension, fall in Oxygen saturation) were noted and data of these significant changes are presented here (Table /Figure 5) between the two groups were compared.

Sample size estimation: For sample size calculation, the study by Bincy Joseph et al.[11] was considered.
[10]The sample size formulae :
Sample size (n) $(z \propto + z\beta)2\ (SD)2/d2$

$n \geq (1.96 + 0.84)2\ (0.2)2/(0.11)2$

$= (2.80)2\ (.04)2/.0121 \quad \geq 25.91$

Where n = required sample size

value of Z at α =5% level of significance=1.93

value of Z at α =80% power of test=0.84

Mean standard deviation= 0.2

The calculated sample size 30 each group.

Where the confidence interval and power of study were 95% and 80%, respectively. Calculated sample size was 52 but considering drop out total sample size of 60 (30 in each group) was taken for study. A total of 77 patients were included to allow for drop outs from the study.

**Statistical analysis:**
The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical Analysis Software. The continuous data were summarized as Mean ± SD while discrete (categorical) in %. To test the significance of two means the student 't' test was used. $P < 0.05$ was considered statistically significant with 95% confidence interval.

**RESULTS:**
Sixty individuals were included and randomly allocated into two study groups (group A and group B). Patients were comparable to each other in terms of demographic characteristics.(Table-2) There were 28 males and 32 females. There was no statistically significant difference in duration of infra-umbilical surgical procedures between the two groups. (Table /figure 3) Among the both groups, the majority of the patients operated observed were TAH+ BSO, Elective LSCS, followed by L-Hernioplasty. However, Statistically, a non-significant difference was observed between both groups. (Table / Figure 3)

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The mean level of dermatome for the sensory and motor block in both groups was more or less same. ( Table / Figure 4). The mean duration of analgesia of group A was significantly less than group B. The mean VAS score were higher at every follow-up in Group-A as compared to in Group-B. The VAS score showed significant difference at every follow-up except at 9 hrs and 12 hrs of enrolled patients. [Table/figure-5]. Bradycardia and Hypotension were most common side effect in both groups (Table / Figure 6)

**DISCUSSION:**

Fentanyl and Dexmedetomidine used as an adjuvant with local anaesthetics produces analgesia of varying potency and duration and augments post operative analgesia. There was no significant difference regarding the age, gender, body weight, height, type of surgeries and also mean duration of surgeries among the two groups.

The primary outcomes were the first request time duration of analgesia and quality of postoperative recovery assessed using the universal pain score for the next 24 hrs after surgery. The secondary outcomes were the visual analog scale (VAS) scores at rest across the different time intervals,3,6,9,12, 24 hrs and the total number of time rescue analgesia was required in 24 hrs postoperatively, and associated complications.

In present study, the mean dermatomal level of sensory block for both groups were more or less same. This study is comparable with the study done by **Qi Chen et al.**[12] The first request time for PCIA was significantly longer in the TAP-DEX than in the TAP, TAP-FEN, and control groups (9.86±0.77, 7.86±0.56, 8.79±0.55, and 1.56±0.65 hours, respectively; P<0.01)

In this study **Anita et al**,[13] 90 patients were randomised into 3 groups and 30 patients were included in each group randomly. Group A, B & C received 0.375% ropivacaine, 0.375% ropivacaine + 1 μg/kg dexmedetomidine, 0.375% ropivacaine + 1 μg/kg fentanyl ( total volume 20 ml each side) respectively. It was observed that the group receiving combination of ropivacaine with dexmedetomidine (Group B) & Ropivacaine with Fentanyl (Group C) has significantly lower pain scores postoperatively compared to group receiving only ropivacaine (Group A). In this study, there was significant difference in the terms of VAS over time (p = <0.001) & total Analgesic Consumption (mg) ( p = <0.001) between the three groups in twenty four hours.

The results obtained by two studies **Hesham et al**.[14] and **Bincy Joseph et al**. were comparable. However, different local anesthetic drug used, (0.5% hyperbaric bupivacaine, 0.5% ropivacaine, 0.5%) with different adjuvants, fentanyl and dexmed

In comparison to **Hesham et al**. the duration of analgesia in the present study was shorter in both groups, owing to the use of a higher percent dose of bupivacaine (0.5%) in both groups in comparison to ropivacaine. Similarly, the present study observed significantly longer duration of analgesia in group B different local anesthetic drug used, however, with same percentage, 0.5% with same set of adjuvants used,i.e dexmed and fentanyl.

In comparison to **Bincy Joseph et al.** the duration of analgesia in the present study was shorter in both groups, owing to the use of a higher percentage of dose of ropivacaine (0.5 %) in both groups. Similarly, the present study observed significantly longer duration of analgesia in group B with dexmed. In this study, the mean VAS score was higher at every follow-up in

Group A. Most of the patient were given rescue analgesia at or equal to 4 VAS score. In this study, mean duration of rescue analgesia were higher with TAP-D in comparison to TAP-F or with simple bupivacaine or ropivacaine.

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**Summaira Jan** et al.[15], Difference in incidence of complications (like hypotension and bradycardia, vomiting) between the two groups was statistically insignificant. None of the patients from either group experienced any hypotensive episode

**CONCLUSION**

The authors conclude that Dexmedetomidine (25µg) added to local anesthetic in a TAP block has proven to be a more effective adjuvant in prolonging the post operative analgesia and the number of recue analgesia demanded when compared to Fentanyl 25µg, with no significant adverse consequences.

Based on our findings, we suggest that TAP block is a preferable choice of multimodal analgesia for Infra-Umbilical surgeries.

**LIMITATIONS :**

This study had some limitations, we were unable to assess the plasma levels of the local anesthetics in the area, also the quantity of the spread and absorption of the local anesthetics. The Analgesia Nociception Index (ANI) and numeric rating scale (NRS) and controls are needed to account for confounding variables and boost study reliability

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**Availability of data and materials**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Authors' contributions**

PM and BB designed the study, PM performed the transversus abdominis plane blocks and wrote the first draft of the manuscript. PM collected the clinical data. BB and SR analyzed the data and interpreted the results. BB designed the study and revised the manuscript. All authors read and approved the final manuscript.

**Ethics approval and consent to participate**

The current study was approved by the Ethics Committee of the Hind Institute of Medical Sciences-HIMS, Informed written consent was obtained from all patients.

**Patient consent for publication**

Not applicable.

**Competing interests**

The authors declare that they have no competing interests.

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TABLES AND FIGURERS

**Table -2 Patients demography and duration of surgery**

| | Group A **[n = 30 ]** | Group B **[n = 30 ]** | p-value |
|---|---|---|---|
| Age in years (Mean±SD) | 39.13±12.29 | 40.00±12.05 | 0.784 |
| Weight in kilograms (Mean±SD) | 62.37=8.60 | 63.87=7.70 | 0.479 |
| Height in centimeters (Mean±SD) | 160.70=6.39 | 161.40=6.55 | 0.677 |
| Gender<br>Male<br>Female | <br>46.7% (14)<br>53.3% (16) | <br>46.7% (14)<br>53.3% (16) | 1.000 |
| Mean duration of surgery in minutes | 66.73± 14.24 | 67.43± 14.31 | 0.850 |

Table -3 Tabular distribution of the type of surgery of the enrolled patients.

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| TYPE OF SURGERY | GROUP | | | | | |
|---|---|---|---|---|---|---|
| | Group A | | Group B | | Total | |
| | N | % | N | % | N | % |
| ELECTIVE LSCS | 3 | 10.0% | 3 | 10.0% | 6 | 10.0% |
| L-HERNIOPLASTY | 3 | 10.0% | 4 | 13.3% | 7 | 11.7% |
| OPEN APPENDECTOMY | 3 | 10.0% | 3 | 10.0% | 6 | 10.0% |
| R-HERNIOPLASTY | 9 | 30.0% | 8 | 26.7% | 17 | 28.3% |
| TAH +BSO | 12 | 40.0% | 12 | 40.0% | 24 | 40.0% |

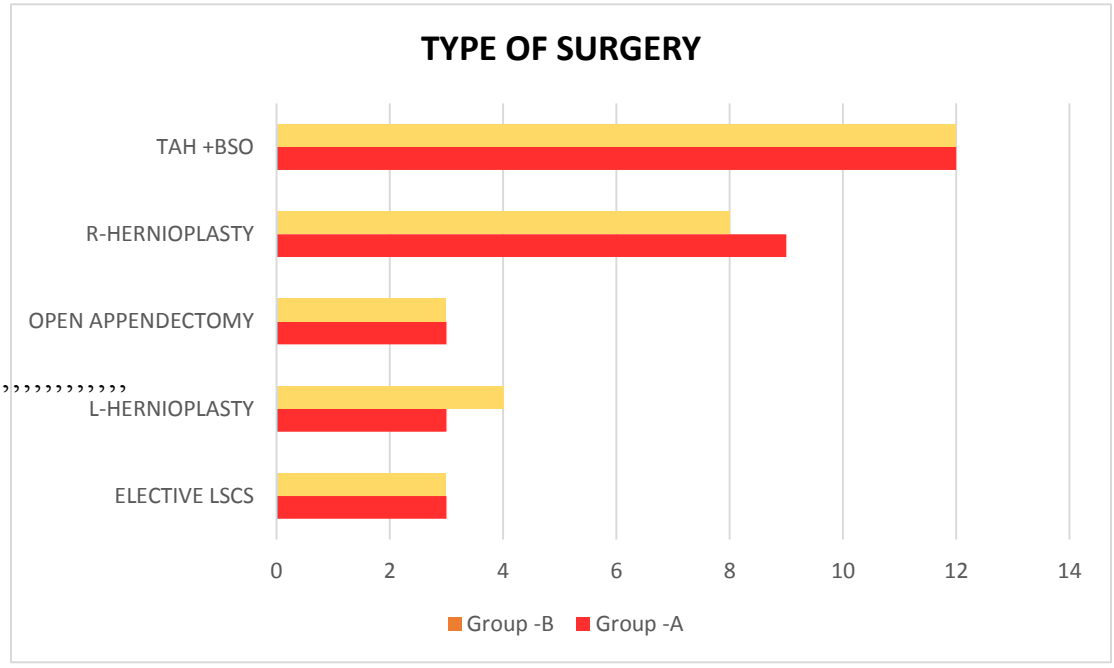

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**Table -4 Onset of sensory and motor block, and duration of analgesia**

| | Group A **[n = 30 ]** | Group B **[n = 30 ]** | p-value |
|---|---|---|---|
| Duration of analgesia in minutes (Mean±SD) | 496.15 ± 44.70 | 865.87 ± 244.63 | <0.001 |

**TABLE-10: Mean number of times rescue analgesia was demanded by the enrolled patients.**

| | | GROUP | | | | | | $\chi$2 value (df) | p-value |
|---|---|---|---|---|---|---|---|---|---|
| | | Group A | | Group B | | Total | | | |
| | | N | % | N | % | N | % | | |
| RESCUE ANALGESIA | No | 1 | 3.3% | 6 | 19.8% | 7 | 23.1% | 24.31 (1) | <0.001 |
| | Yes | 29 | 96.7% | 24 | 80.2% | 53 | 76.9% | | |

**TABLE-11: Tabular distribution of Mean VAS score of the enrolled patients.**

| POST OPERATIVE ANALEGSIA | GROUP | | | Z value | p-value |
|---|---|---|---|---|---|
| | Group A | Group B | Total | | |

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| VAS SCORE | Mean | SD | Mean | SD | Mean | SD | | |
|---|---|---|---|---|---|---|---|---|
| AT 3 hr | .00 | .00 | .00 | .00 | .00 | .00 | NA | NA |
| AT 6 hr | .27 | 1.01 | .10 | .55 | .18 | .81 | -0.626 | 0.531 |
| AT 9 hr | 2.07 | 2.12 | .40 | 1.22 | 1.23 | 1.91 | -3.387 | 0.001 |
| AT 12 hr | .87 | 1.78 | 1.93 | 2.12 | 1.40 | 2.01 | -2.001 | 0.045 |
| AT 24 hr | .00 | .00 | .00 | .00 | .00 | .00 | NA | NA |

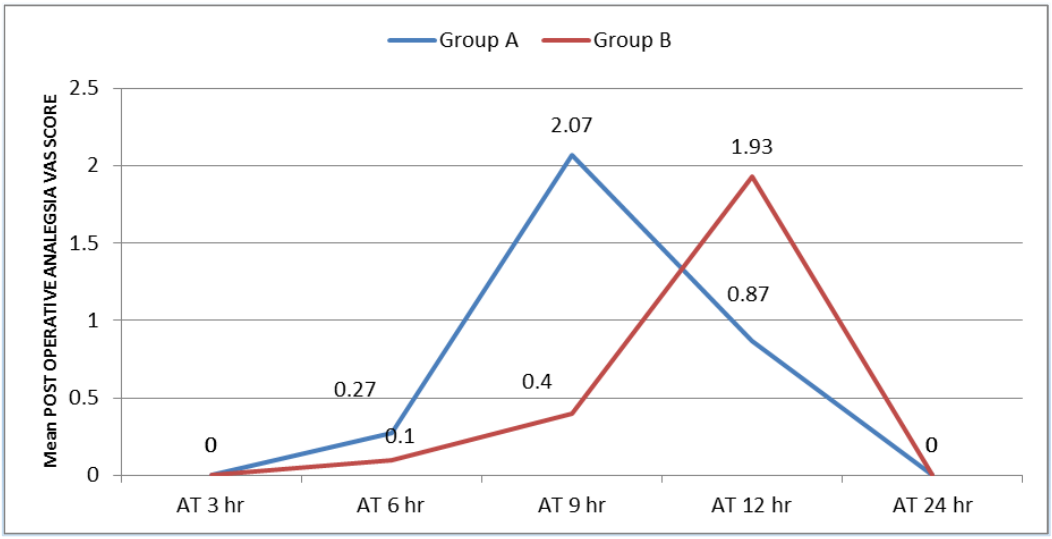


**TABLE-12: Tabular distribution of Mean VAS score at equal intervals of the enrolled patients.**

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| | | | Mean diff | SD diff | 95% Confidence Interval of the Difference | | Z value | p-value |
|---|---|---|---|---|---|---|---|---|
| | | | | | Lower | Upper | | |
| Group A | Pair 1 | VAS SCORE AT 3 hr - VAS SCORE AT 6 hr | -.27 | 1.02 | -.64561 | .11228 | -1.414 | 0.157 |
| | Pair 2 | VAS SCORE AT 3 hr - VAS SCORE AT 9 hr | -2.07 | 2.12 | -2.85686 | -1.27648 | -3.690 | <0.001 |
| | Pair 3 | VAS SCORE AT 3 hr - VAS SCORE AT 12 hr | -.87 | 1.78 | -1.52982 | -.20351 | -2.271 | 0.023 |
| Group B | Pair 1 | VAS SCORE AT 3 hr - VAS SCORE AT 6 hr | -.10 | .55 | -.30452 | .10452 | -1.00 | 0.317 |
| | Pair 2 | VAS SCORE AT 3 hr - VAS SCORE AT 9 hr | -.40 | 1.22 | -.85575 | .05575 | -1.732 | 0.083 |
| | Pair 3 | VAS SCORE AT 3 hr - VAS SCORE AT 12 hr | -1.93 | 2.12 | -2.72352 | -1.14314 | -3.557 | <0.001 |

Table -6 Tabular distribution of side effects of the enrolled patients.

| | | GROUP | | | | | | p-value |
|---|---|---|---|---|---|---|---|---|
| | | Group A | | Group B | | Total | | |
| | | N | % | N | % | N | % | |
| HYPOTENSION | Absent | 30 | 100.0% | 28 | 93.3% | 58 | 96.7% | 0.492 |
| | Present | 0 | .0% | 2 | 6.7% | 2 | 3.3% | |
| BRADYCARDIA | Absent | 30 | 100.0% | 28 | 93.3% | 58 | 96.7% | 0.492 |

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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Present | 0 | .0% | 2 | 6.7% | 2 | 3.3% | |
| $SpO_2$ | Absent | 30 | 100.0% | 30 | 100.0% | 60 | 100.0% | NA |
| | Present | 0 | .0% | 0 | .0% | 0 | .0% | |