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# POSTOPERATIVE PAIN MANAGEMENT BY FENTANYL VS DEXMEDETOMIDINE AS AN ADJUVANT WITH ROPIVACAINE BY TRANSVERSUS ABDOMINIS PLANE (TAP) BLOCK IN INFRA UMBILICAL SURGERIES UNDER SPINAL ANAESTHESIS: A COMPARATIVE STUDY

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**Keywords:**

Adjuvant, Infra Umbilical surgeries, Pain, TAP block

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**ABSTRACT: Introduction:** The analgesia effect of anesthetic drugs namely Ropivacaine, can further be enhanced with adjuvants. For postoperative pain management in infra-umbilical surgeries, Ropivacaine with an adjuvant can be used through a Transversus Abdominis Plane (TAP) block, which is a simple and clinical anatomical landmark procedure, suitable in remote areas without advanced modern technical tools. **Aims:** Fentanyl and Dexmedetomidine (Dexmed) were used as adjuvant to Ropivacaine, injected in TAP, postoperatively, and were compared in terms of pain relief. **Material & Methods:** In this randomized comparative study, undertaken from January 2021 to August 2022, 60 patients were randomly divided into two groups of 30 each, Group A- Injection Fentanyl (25 mcg) + Ropivacaine (0.375%) in 20ml dilution and Group B- Injection Dexmed (25 mcg) + Ropivacaine (0.375%) in 20 ml dilution were injected in TAP block on either side. The outcome was studied at 3, 6, 9, 12, and 24 hours, postoperatively. **Results:** The mean duration of analgesia in patient's of group B was higher and statistically significant ("p-value"<0.001) than group-A. Similarly, pain on Visual Analog Scale (VAS)) in patient's Group B was less at each stage of follow-up; postoperatively. The drug demand for the desired analgesia in Group B was six times less and without any marked side effects, as compared to Group A. **Conclusion:** Dexmed was found to be more effective in providing postoperative analgesia with low drug demand and without any significant side effect, as compared to Fentanyl, as an adjuvant with Ropivacaine, given through TAP blocks.

**INTRODUCTION:** Most Infra-Umbilical surgeries are major procedures, wherein substantial postoperative discomfort and pain can be anticipated [1].

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An effective postoperative analgesia is an important aspect of patient care that facilitates early ambulation and reduces 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, pruritus, and sometimes respiratory depression which reduces overall patient satisfaction [1, 2]. Transversus abdominis plane (TAP) block as a part of a multimodal analgesic regimen results in decreased opioid consumption and improved analgesia [3-6]. It's a regional anaesthesia 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 in remote places.

Ropivacaine [8] is a long-acting regional anesthetic that is structurally related to Bupivacaine. It is less lipophilic and thus less likely to penetrate large myelinated motor fibers and selectively acts on the nociceptive A, B, and C fibber's. However, its period of action is quite brief, ranging between 3.7 to 8.7 hours. However, many different combinations of local anaesthetics and adjuvants have been used via TAP block in infra-umbilical surgeries such as Fentanyl, Dexmedetomidine (Dexmed), Bupivacaine, Levobupivacaine, Dexamethasone, Morphine, Tramadol, and Buprenorphine, *etc*. to prolong the effect of Ropivacaine. Each drug, however, has inherent quality, acceptance, limitations, and complications. Alpha2 agonists are adjuvants used in anaesthesia and analgesia. They can be administered orally, trans-dermally, intravenously, perineurally or neuraxial. Fentanyl is a synthetic opioid agonist, highly lipophilic which acts primarily at the μ-opioid receptor [9]. It has been used as an anaesthetic adjuvant. Fentanyl prolongs sensory and motor block but promotes sedation and exacerbates hypotension. Dexmedetomidine is a short-term sedative α2-Adrenoceptor agonist has several beneficial actions during the perioperative period [10]. It decreases sympathetic tone, with attenuation of the neuro-endocrine and hemodynamic responses to anaesthesia and surgery; reduces anesthetic and opioid requirements; and causes sedation and analgesia. The studies undertaken in the past, using higher doses of bupivacaine, ropivacaine, fentanyl, and dexmed were associated with varied responses and results. Hence, the present study was conducted to evaluate the two different adjuvants with ropivacaine through TAP block for postoperative analgesia in infra-umbilical surgeries.

**MATERIAL AND METHODS:** This randomized double-blinded study was conducted in the Department of Anesthesiology, Hind Institute of Medical Science, Sitapur, India from January 2021 to August 2022 after getting clearance from the Institutional Ethics Committee vide letter no. IHEC-HIMSA/MD/MS (15)/RD dated 15.01-21. Out of 77 patients aged 18 to 65 years screened for elective infra umbilical surgeries under spinal anesthesia, only sixty patients fulfilled the pre-decided inclusion criteria and were included in the study. The outcome results of these cases were analyzed. The dropouts are shown on a consort flow chart as given in **Fig. 1.**

Patients having subarachnoid block, renal/hepatic dysfunction, hemodynamically unstable, bleeding disorders, allergic to study drugs, refused to participate, and who ask for rescue analgesia within 3 hrs of the postoperative period were excluded. For sample size calculation, the study by Bincy Joseph *et al.*[11] was considered. The calculated sample size was 30 for each group. Where the confidence interval and power of study were 95.0% and 80.0%, respectively.

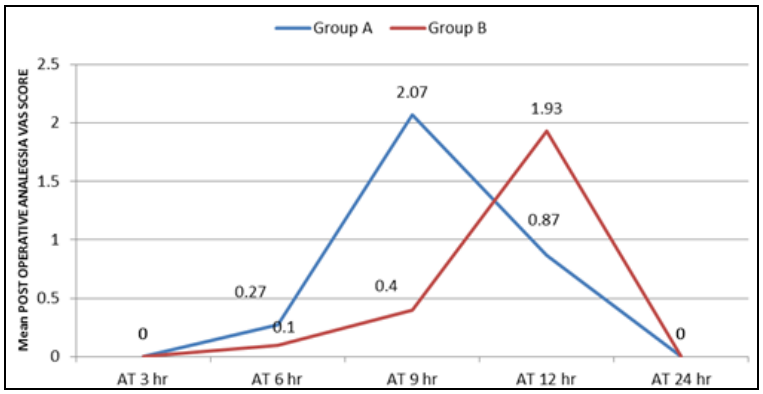
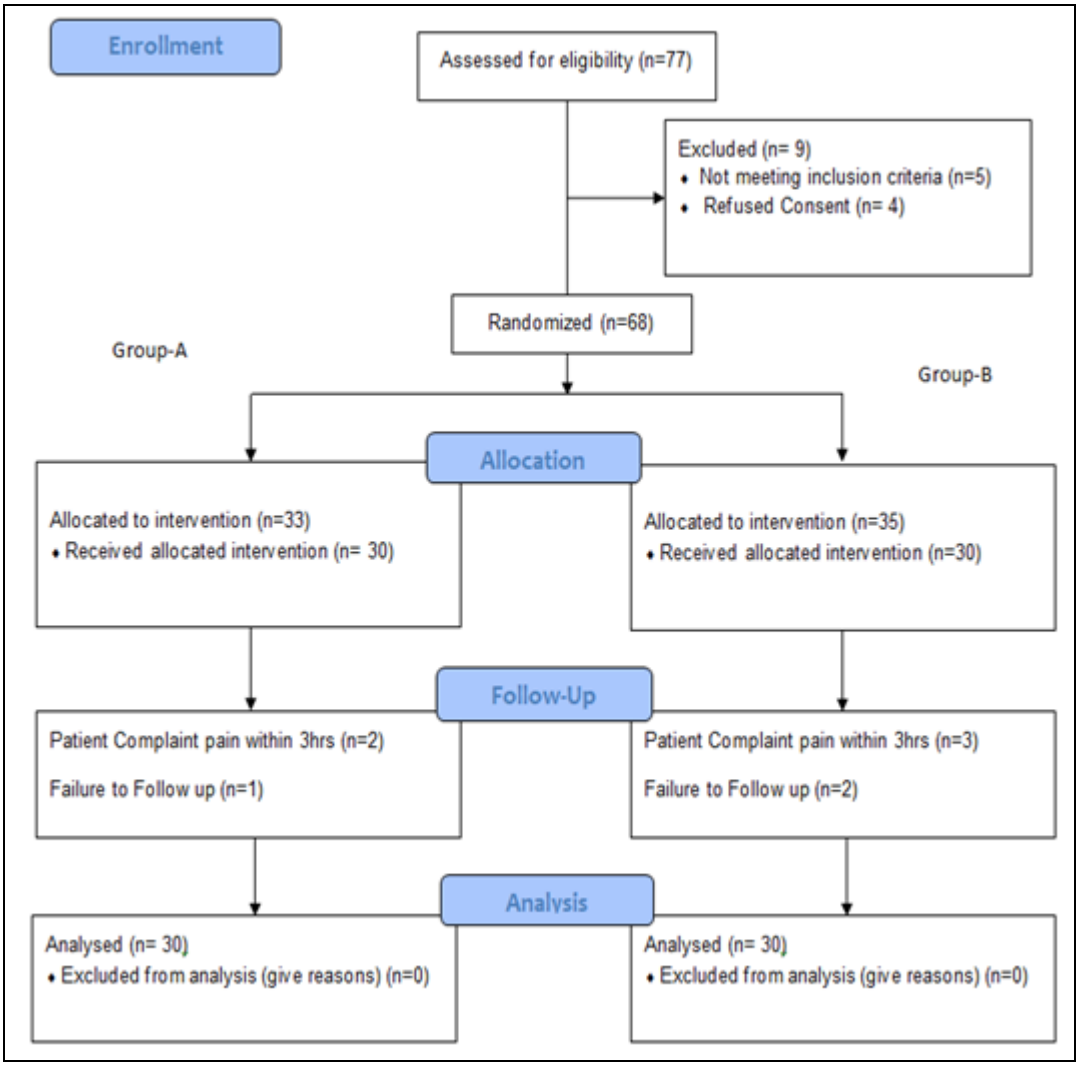



**FIG. 1:**




**FLOWCHART**

The calculated sample size was 52 but considering the drop out a total sample size of 60 (30 in each group) was taken for study. A total of 77 patients were initially screened but 17 were dropped at different stages of the study. After getting written and informed consent, patients were randomly divided (using a computer-generated random number table) into two groups, of 30 each and were given.

Group A: Ropivacaine (37.5mg, 0.4%) + Fentanyl (25 mcg in 0.5ml) diluted in 20 ml NS,

Group B: Ropivacaine (37.5 mg, 0.4%) +Dexmed (25mcg in 0.5ml) diluted in 20 ml NS.

To ensure double-blinding, drugs were prepared by a third person, not involved in the procedure or study. A day before surgery pre-anaesthetic check-up was done. All relevant investigations were performed, and reviewed as per a standard preoperative protocol. The study was conducted over a period of 24 hours postoperatively. A Numerical Pain Rating Scale (NRS) with 0 to 10 points were explained to the patient preoperatively. In the operation theatre, baseline parameters including heart rate, blood pressure, SpO2, respiratory rate, *etc*. were noted. After taking all aseptic precautions, spinal anaesthesia was given and surgery was allowed to proceed after ensuring T4 to T6 sensory blockade to pinprick sensation. Sensory and motor block were assessed by loss of sensation to a pinprick and by modified Bromage Score. The time interval between the end of spinal anaesthesia administration and loss of pinprick sensation at the T4 to T6 level was taken as sensory block onset time. The continuous monitoring of blood pressure, SpO2 level, respiratory and heart rate, and electrocardiogram was done to assess a hemodynamic response. Events like hypertension, bradycardia and sedation, etc. were also recorded

and were maintained as per a standard anaesthesia protocol. The 'Triangle of Petit' was identified using the blind anatomical landmark technique on both sides. The TAP block was given through Petit's triangle with a blunt 22 G hypodermic needle attached to a 20 ml syringe containing the drug as per the group allocation. The needle was introduced perpendicular to the skin and advanced until two "POPS" or "give way" were felt. Then the drug was deposited in the fascial plane after check aspiration every 5 ml to rule out the intravascular injection. The patient was observed for 10 minutes and then shifted to the post-anaesthesia care unit (PACU). This was considered time zero. The TAP block was taken as a failure if the patient requested analgesia within the first 3 hrs of administering the block, and the case was dropped from the study. A 10-point numerical pain score (NPS) was recorded after the block at baseline, and at 3, 6, 9, 12, and 24 hrs, postoperatively. All patients were asked to give scores for their pain and severity was measured using a visual analogue scale (VAS). Rescue analgesia was given if the VAS score was more than 4. The time of administration of the study drug to the time of administration of rescue analgesia (VAS >4) was considered as the duration of analgesia. Inj. Diclofenac 75mg or Inj. Paracetamol 1 gm was administered as a rescue analgesic. The changes in the cardio-respiratory parameters were monitored, and a number of significant events (bradycardia, hypotension, fall in SpO2 saturation) were noted. The statistical analysis was done using SPSS Version 21.0 software. The continuous data were summarized as mean ± S.D while discrete (categorical) in percentage (%). To test the significance of the two means the student's test was used. The "p-value" of< 0.05 was considered statistically significant with a 95.0% confidence interval.

**RESULT:** The study population consisting of sixty patients was randomly divided into two groups (groups A and B). The demographic characteristics of patients in groups were comparable to each other. Out of 60 patients, 28 males and 32 females aged, ranging from 18 to 65 yrs. with a maximum in age group between 36 to 50 yrs. and a mean age of 39.6 yrs. The mean surgery time in patients of groups A and B was 66.7 and 67.4 minutes.

**TABLE 1: 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 kgs (Mean±SD) | 62.37=8.60 | 63.87=7.70 | 0.479 |
| Height(cms)(Mean±SD) | 160.70=6.39 | 161.40=6.55 | 0.677 |
| **Gender (mean age)** | | | |
| **Male** | 46.7% (14) | 46.7% (14) | 1.000 |
| **Female** | 53.3% (16) | 53.3% (16) | |
| The mean duration of surgery (in Minutes) | 66.73± 14.24 | 67.43± 14.31 | 0.850 |

Among both groups, out of 60 cases operated on, 35 were of general surgery, and 25 were of gynae and obstetrics. In 26 cases of general surgery, operations of hernioplasty and appendicectomy were performed. Out of 25 cases of gynae & obstetrics, in 16 cases a trans-abdominal hysterectomy and in 9 cases an elective caesarean section were performed, as shown in **Table 2.**

**TABLE 2: SURGICAL PROCEDURES UNDERTAKEN**

| Surgical procedure | Group A (N=30) | Group B (N=30) | Total (N=60) |
|---|---|---|---|
| Elective LSCS | 3 | 6 | 9 |
| L-Hernioplasty | 3 | 7 | 10 |
| Open Appendectomy | 3 | 6 | 9 |
| R-Hernioplasty | 9 | 7 | 16 |
| Transabdominal Hysterectomy with bilateral salpingo-oophorectomy | 12 | 4 | 16 |
| Total | 30 | 30 | 60 |

The mean level of dermatome for the sensory and motor block in both groups was more or less same. The mean duration of analgesia in patients of group A and B was 496.2 and 865.9 minutes, respectively. There by, it was significantly higher in Group-B ("p-value"<.001) as shown in **Table 3.**

**TABLE 3: 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 |

The number of times of a need of analgesia by group A was 23(76.7%] and was higher than need of analgesis by cases of Group B ie. 4 times (13.3%). The difference in number of times need of analgesia amongst groups was statistically significant ("p-value"<0.001). The demand for rescue analgesia was made by 24 cases of Group B against 29 in Group A, and here also the difference was found to be significant. ("p-value"<0.001) as given in **Table 4.**

**TABLE 4: MEAN NUMBER OF TIMES RESCUE ANALGESIA WAS DEMANDED BY THE ENROLLED PATIENTS**

| Rescue Analgesia demand | Group-A (n=30) | Group-B (n=30) | χ2value (df) | "p-value" |
|---|---|---|---|---|
| Yes | 29 | 24 | 24.31 (1) | <0.001 |
| No | 1 | 6 | | |
| Total | 30 | 30 | | |

At each follow-up, the mean VAS score of pain was higher in patients of Group-A as compared to Group B and the difference was significant except at 9 and 12 hrs, as shown in **Table 5.**

**TABLE 5: DISTRIBUTION OF MEAN VAS SCORE OF THE ENROLLED PATIENTS**

| Post-Operation analgesia VAS Score | GROUP | | | | | | "Z-value" | "p-value" |
|---|---|---|---|---|---|---|---|---|
| | Group-A | | Group-B | | Total | | | |
| | Mean | "S.D" | Mean | "S.D" | Mean | "S.D" | | |
| 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 |

There was no adverse effect with either of drug combinations except in two patients of Group B, who reported mild bradycardia and hypotension, which was managed without any drug intervention and therefore not significant.

**DISCUSSION:** Fentanyl and Dexmed used as adjuvant with local anesthetics produce analgesia of varying potency and duration to augment postoperative analgesia. The difference in the distribution of patients as per age, gender, body weight, height, type of surgery, and also mean duration of surgeries among the two groups, was insignificant.

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 VAS scores at 3,6,9,12,24 hrs post-surgery, the number of time rescue analgesia was required, and associated complications. In the present study, the mean dermatomal level of sensory block for both groups were more or less the same. Our findings are comparable with the study done by Qi Chen *et al* [12], where the first request time for patient-controlled intravenous analgesia (PCIA) was significantly longer in the TAP-dexmed than in the TAP, TAP-fentanyl, and control groups.("p-value" <0.01)

Similar to our findings, Anita *et al*, [13] studied 90 patients, randomized into 3 groups of 30 each. Groups A, B & C, received 0.4% Ropivacaine, 0.4% Ropivacaine + 1 μg/kg Dexmed, 0.4% Ropivacaine + 1 μg/kg Fentanyl (diluted in 40ml)of this 20 ml was infiltrated on each side), respectively.

It was observed that the groups receiving a combination of Ropivacaine and Dexmed (Group B) & Ropivacaine with Fentanyl (Group C) had significantly lower pain scores postoperatively as compared to the group receiving only Ropivacaine (Group A). There was a significant difference in the terms of VAS over time and total analgesic consumption between the three groups in twenty-four hours. ("p-value" <0.001). The results of Bincy Joseph *et al*. and Hesham *et al.* were also comparable to us [11, 14]. However, the local

anesthetic drugs used were different ie. 0.5% hyperbaric Bupivacaine and 0.5% Ropivacaine, with adjuvant Fentanyl, and Dexmed. In comparison to Bincy Joseph *et al*., the duration of analgesia in the present study was shorter in both groups, this may be due to reasons that we have used a lesser quantity of Ropivacaine (0.4%) against the 0.5 % used by Bincy Joseph *et al*. Similarly, the present study observed a significantly longer duration of analgesia in group B (Dexmed as adjuvant). In our study, the mean VAS score was higher at every follow-up in Group A. The patients were given rescue analgesia at their VAS score of4 or above. In our study, the mean duration of rescue analgesia was higher with Dexmed in comparison to Fentanyl. This is contrary to Bincy Joseph *et al.*, who reported that Fentanyl and Dexmed as adjuvant to Ropivacaine were equally effective in both prolongation of analgesia and reducing the total consumption of analgesics in TAP block.

Similar to our findings, Bincy Joseph *et al*. reported that systolic blood pressure between the two groups was not significantly different at various time points using repeated measures of ANOVA. The difference in the incidence of complications (bradycardia and vomiting) between the two groups was statistically insignificant and without any hypotensive episode. This observation was similar to the observations of Summaira Jan *et al* [15].

**CONCLUSION:** The study concludes that Dexmed (25µg) as an adjuvant to local anesthetic (Ropivacaine 37.5mg) in a TAP block was found to be more effective as compared to Fentanyl as an adjuvant, in prolonging the post-operative analgesia and rescue analgesia demand, without any significant adverse consequences. It is therefore concluded that the Dexmed (25µg) added as an adjuvant to a local anaesthetic (Ropivacaine) in TAP block may be a preferred choice of multimodal analgesia for infra-umbilical surgeries in remote areas in particular, having limited infrastructure support.

**Limitations:** The limitations of the study were. small study population, lack of assessment of plasma levels of local anesthetics in the area, and also the quantity of the spread and absorption of the local anesthetics. Analgesia Nociception Index (ANI), numeric rating scale (NRS), and controls are needed to account for confounding variables and boost study reliability.

**Funding:** There was no funding for the study.

**Ethics Approval and Consent to Participate:** The current study was approved by the Ethics Committee of the Hind Institute of Medical Sciences, Sitapur vide letter no. IHEC-HIMSA/MD/MS (15)/RD dated 15.01-21

**CONFLICTS OF INTERESTS:** The authors declare that they have no competing interests.

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