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Original Research Paper

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EFFECT OF DEXMEDETOMEDINE, DEXAMETHASONE AND TRAMADOL ON DURATION OF POSTOPERATIVE ANALGESIA OF TRANSVERSE ABDOMINIS PLANE BLOCK WITH BUPIVACAINE IN LOWER ABDOMINAL SURGERIES: A PROSPECTIVE RANDOMIZED DOUBLE BLIND ACTIVE CONTROL STUDY

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ABSTRACT

Introduction: Safe and effective postoperative analgesia is important for enhancing recovery abdominal surgery. TAP block provides adequate post-operative pain relieve following abdominal surgeries. Various adjuvants are added to LA for effective pain relief & extended duration of analgesia. **Objectives:** To compare duration of postoperative analgesia, analgesic requirement & complications with dexmedetomidine, dexamethasone and tramadol when added to bupivacaine in TAP block in lower abdominal surgeries. **Methods:** A Prospective Randomized Double Blind Active Control Study was conducted on 51 patients undergoing lower abdominal surgeries at tertiary care hospital. Patients were randomly allocated into 3 groups. All patients received TAP block with 20ml bupivacaine 0.25% mixed with one of the 3 additives- Dexmedetomidine 0.5mcg/kg in Group 1, Dexamethasone 8mg in Group 2 & Tramadol 100mg in Group 3 dissolved in 2ml normal saline. **Results:** The mean duration of postoperative analgesia with TAP block in group 1 was 368.23±24.29 minutes, 365.29±21.82 minutes in group 2, 245.88±34.65 minutes in group 3 ($p<0.0001$). The mean VAS score in all three groups was insignificant at 1 hour ($p=0.617$) and it statistically significant from 2-24 hours ($p<0.0001$). Difference between Group 1 and 2 was insignificant whereas VAS score in Group 1 and 3, group 2 and 3 were found to be significant. **Conclusion:** Dexmedetomidine and dexamethasone has longer duration of post operative analgesia compared to tramadol when added to TAP block in lower abdominal surgeries.

KEYWORDS : Transversus abdominis plane block, dexmedetomedine, dexamethasone, tramadol, post operative analgesia, lower abdominal surgeries.

INTRODUCTION:

Safe and effective postoperative analgesia is important for enhancing recovery after surgery; however, severe pain after abdominal surgery remains a significant problem. Inadequate control of post-operative pain leads to several unwanted adverse events ranging from patient discomfort, prolonged immobilization to thromboembolic phenomenon and pulmonary complications[1] Analgesic multimodalities were recommended to relieve the postoperative pain.[2] Opioids although provide satisfactory analgesia, they are associated with unwanted side-effects.[3] As part of a multimodal analgesic regimen, a peripheral nerve block can decrease opioid consumption, providing more effective analgesia with fewer adverse effects.

TAP block is a novel peripheral nerve block that involves innervations of the anterolateral abdominal wall derived from T6-L1.[4] It provides adequate post-operative pain relieve following abdominal surgeries.[5-8] Various adjuvants are added to LA to prolong the effect of TAP block.[9] Dexmedetomidine is a selective alpha 2 (2) adrenergic agonist with both analgesic and sedative properties.[10] Dexamethasone microspheres have increased the block duration in both human and animal studies.[11,12] Tramadol is centrally acting synthetic codeine analogue drug that has monoaminergic and mu-receptor agonistic activity together with some peripheral local anaesthetic properties with low incidence of side effects.

In this prospective randomized double blind active controlled study, we compared the analgesic efficacy of dexmedetomidine, dexamethasone and tramadol as adjuvant to local anaesthetic 0.25% bupivacaine for TAP block.

MATERIALS AND METHODS:

This randomized double blind active control prospective study conducted at tertiary care hospital with objectives to compare duration of postoperative analgesia, analgesic requirement, postoperative complications with dexmedetomidine, dexamethasone and tramadol when added to 0.25% bupivacaine in TAP block in lower abdominal surgeries.

51 consecutive male & female patients with ASA grade 1 and 2, age18– 65 years satisfying inclusion criteria undergoing elective lower abdominal surgery of surgery 1 to2 hours duration under spinal anaesthesia & giving written informed consent were included.Exclusion criteria were-patient refusal, ASA grade 3 or more, major systemic disease, known allergy to study drugs or local anaesthetics, psychiatric illness, contraindication to regional anaesthesia like coagulation abnormalities, infection at site of injection, chronic use of pain medication, patient on adrenoreceptor agonists or antagonists, BMI> 30kg/m^2,Alcohol or drug abuse etc.

After approval from Institutional ethics committee, informed written consent was taken from eligible patients for participation in the study. Patients were randomly allocated using computer generated randomization list & sealed envelope technique into 3 groups with 17 patients in each group with allocation ratio 1:1:1.

Group 1 received TAP block with Dexmedetomidine 0.5mcg/kg dissolved in 2ml normal saline mixed with 20ml bupivacaine 0.25%.

Group 2 received TAP block with Dexamethasone 8mg mixed with 20 ml of bupivacaine 0.25%.

Group 3 received TAP block with Tramadol 100mg mixed with 20 ml of bupivacaine 0.25%.

Pre-anaesthetic evaluation was done day before surgery & premedication given with tablet alprazolam 0.25mg and antacid prophylaxis orally night before surgery. Informed written consent was obtained from all patients. Study was carried according to guidelines laid down by Declaration of Helsinki. The participants were free to withdraw anytime during the conduct of study. During the preoperative visit use of 0 to10 cm visual analog pain scale (VAS) with 0 meaning no pain & 10 meaning the worst pain imaginable was explained to the patient. They were kept fasting for 6-8 hours for solid

food. On arrival in the operating room standard monitoring was established. Intravenous line started with 20G cannula & preloaded with 10ml/kg lactated ringers' solution followed by maintenance infusion 6-10ml/kg/hour. Intravenous ondansetron 4mg given as antiemetic prophylaxis. Spinal anesthesia was given under strict aseptic precautions in sitting position at lumbar 3-4 inter space using 23G disposable spinal needle & hyperbaric bupivacaine with appropriate dose as judged by the anaesthesiologist in charge of the case. Supplementary oxygen via facemask was given at 5 liter/minute throughout the surgical procedure. A dermatomal sensory level up to sixth thoracic segment (T6) considered satisfactory. Following confirmation of spinal block by loss of sensation to pin prick surgery started. Vital parameters heart rate (HR), mean arterial pressure (MAP), oxygen saturation was recorded every 5 minutes for 30 minutes, then every 10 minutes till end of surgery. No additional analgesic was given unless requested by the patient. Vomiting in absence of hypotension treated with IV metoclopramide 10mg bolus.

At the conclusion of surgical procedure, TAP block was given to operative side under strict aseptic precautions with 20G Tuhoy needle with 100cm extension tube using mid axillary landmark technique. After careful aspiration study drug was injected- Dexmedetomidine 0.5mcg/kg in Group 1, Dexamethasone 8mg Group 2 & Tramadol 100mg in Group 3 dissolved in 2ml normal saline mixed with 20ml bupivacaine 0.25%.

The study drugs were prepared by anesthesiologist not involved in outcome measurement. The patient and the anesthesiologist who performed the spinal block were blinded to group allocation.

All patients were monitored in operation theatre for 60 minutes & in PACU till complete regression of spinal anaesthesia as indicated by appearance of leg movements. Postoperative assessment was carried out at hourly interval until first analgesic dose followed by 4, 8, 12, 18, 24 hours postoperatively by anesthesiologist collecting data about study parameters and trained staff nurse both were blinded to group allocation. The patients were carefully questioned regarding duration of pain free period and severity of pain at rest and & on coughing measured using 10 cm VAS. Postoperative analgesia provided with IM diclofenac 1.5mg/kg in recovery room for VAS >3. IV metoclopramide 10mg and ondansetron 4mg to be used as rescue antiemetic. Side effects related to TAP block, bradycardia (HR<50/Min), respiratory depression (RR<12bpm or Spo2 < 90%), hypotension (Systolic BP < 90 mm Hg), sedation etc were recorded as and when they occur.

Patients were free to report any problems although no direct questions were asked. Time to first analgesic request was recorded from completion of TAP block to first analgesic dose. VAS score of 3 or less considered as satisfactory pain relief. MAP, HR, VAS, nausea & vomiting, Modified Ramsay sedation score (1- anxious, agitated, restless, 2- Cooperative, oriented, tranquil, 3- Responsive to commands only, 4- Brisk response to light glabellar tap or loud auditory stimulus, 5- sluggish response to light glabellar tap or loud auditory stimulus, 6- no response to light glabellar tap or loud auditory stimulus) was recorded.

The sample size was calculated using software OpenEpi, Version 3, to detect a difference of 120 minutes in the mean duration of analgesia, assuming a standard deviation of 127.2 minutes & 145.455 minutes based on reference study with a significance level of 5% (https://www.openepi.com/Sample Size/ SSMean.htm). The primary outcome measure used to calculate sample size is time for first analgesic request with VAS>3.

Statistical Analysis

Data was entered in Microsoft Excel and analyzed using SPSS version 24.0th. Normality of data was assessed by Shapiro-Wilk test for quantitative variable and all parameters' data was found be not normally distributed. Also for normal data Mean and SD were calculated for quantitative variables & ANOVA was applied to check significance difference between three groups and proportions were calculated for categorical variables. Chi-square test was applied to check significant association between attributes. P- Value of <0.05 was considered statistically significant.

OBSERVATION AND RESULTS:

Data from 51 patients was analyzed. The demographic profile was comparable among the three groups. All three groups were comparable in terms of their age, sex weight and ASA grading and were found to be statistically non-significant (Table 1.

Table 1: Demographic Profile Of Study Participants.

Gender	Group 1 (n =17)	Group 2 (n =17)	Group 3 (n =17)	P-value
Age	35.59±14.9	29.29±6.11	32.23±10.94	P=0.204
Weight (kg)	61.53± 8.58	60.65 ± 7.24	62.19 ± 7.04	P=0.133
Duration of surgery	54±18	63±20	63±17	P =0.087
Male	6 (35.3%)	5 (29.4%)	9 (52.9%)	P=0.347
Female	11 (64.7%)	12 (70.6%)	08 (47.1%)	
ASA Grade I	08 (47.1%)	05 (29.4%)	04 (23.5%)	P=0.317
Grade II	09 (52.9%)	12 (70.6%)	13 (76.5%)	

The mean was found to be significant among the groups(p<0.0001). The difference between group I and II not significant (p= 0.392),group I and III was (p<0.0001) was significant, between group II and III was was also significant (p<0.0001).

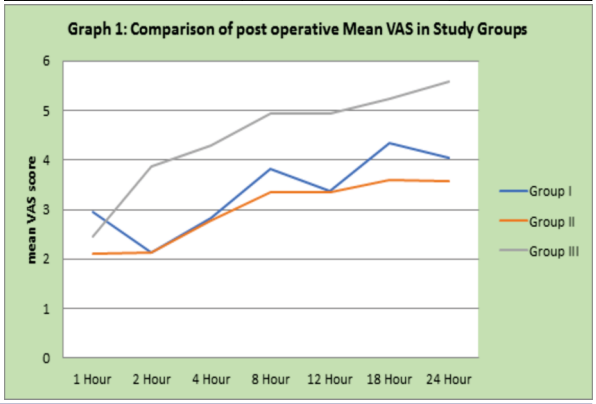
The mean VAS score in all three groups was not significant at 1 hour (p=0.617) and significant at 2,4,8,12,18,24 hrs.(p<0.0001).

Table 2: Comparison Of Mean Time For Rescue Analgesia (TFRA) Of Patients In Groups

Group	Group I Mean ± SD	Group II Mean ± SD	Group III Mean ± SD	P-value
	368.23± 24.29	365.29± 1.82	245.88 ± 34.65	P<0.0001

Table 3: Comparison Of Mean Difference Duration Of Analgesia In Groups

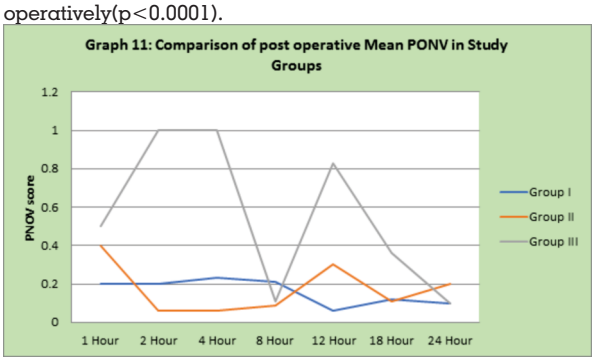
Groups	Mean Difference (Minutes)	P-value
Group I Vs Group II	2.94	P=0.392 NS
Group I Vs Group III	122.35	P<0.0001 S
Group II Vs Group III	119.41	P<0.0001 S



The baseline heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure at 1 hour, 2, 3,4,8,12,18,24 hours of post operative period was comparable in all three groups.

The mean ramsay sedation score between group 1, 2 and 3 compared at post operative 1 hr,2,4,8,12,18,24 hrs. In all three groups was found to be nonsignificant.

The mean postoperative nausea and vomiting score was significant in group III at 2,4 and 12 hours post operatively($p<0.0001$).



DISCUSSION:

This randomized double blind prospective study was carried out to evaluate the effect of dexmedetomidine, dexamethasone and tramadol in transversus abdominis plane block with bupivacaine on post operative analgesia in lower abdominal surgeries.

The main result of our study reveals that dexmedetomidine and dexamethasone are more effective than tramadol as adjuvant to bupivacaine in TAP block in terms of longer time to initial self-reporting of post operative pain and rescue analgesic administration. In our study dexmedetomidine and dexamethasone has longer duration of analgesia compared to tramadol in lower abdominal surgeries. The mean VAS score was found to be lower in dexmedetomidine and dexamethasone group compared to tramadol group. Difference between dexmedetomidine and dexamethasone group was found to be insignificant whereas difference between dexmedetomidine and tramadol & dexamethasone and tramadol was significant. Various studies demonstrate the analgesic efficacy and safety of dexamethasone and dexmedetomidine as an adjunct in neuraxial and peripheral blocks.

Dexamethasone produces analgesia through its anti-inflammatory or immunosuppressive action. It potentiates the action of local anaesthetic through modulation of function of the potassium channels. Neuroprotection and anti-hyperalgesic effects with clinically relevant dosing of perineural dexamethasone along with local anaesthetics have also been studied.[13]

Dexamethasone a high potency long-acting glucocorticoid has been shown to prolong Peripheral nerve blocked in animals, dexamethasone binds to glucocorticoids receptors and inhibits potassium conductance, which decreases nociceptive c-fiber activity. Dexamethasone may also extend the duration of analgesia via local vasoconstrictive and systemic anti-inflammatory effects. Systemic reviews and meta-analysis have confirmed the efficacy of dexamethasone for prolonging the duration of peripheral nerve block. more specifically dexamethasone provides better analgesic efficacy and decreased analgesic consumption post operatively compared with LA alone. [4, 6, 11, 14] Amany et al observed that the addition of 8 mg dexamethasone to 20 mL bupivacaine 0.25% for TAP block on both sides resulted in a significant reduction of VAS pain score over the postoperative 48h and reduction of postoperative morphine requirements.[15]

Jyoti Deshpande et al observed that the addition of 4 mg dexamethasone to 20 ml ropivacaine 0.5% for bilateral TAP block prolonged duration of analgesia, reduced opioid consumption, and decreased VAS pain score over postoperative 24 h in patients undergoing transabdominal hysterectomy.[16]

Dexmedetomidine, a highly selective, alpha-2-adrenergic receptor (α2-AR) agonist, has been popularly used by anesthetists in various anesthetic techniques to contribute its hemodynamic-stabilizing properties and sedative, analgesic and sympatholytic effects to local anesthetic action. There are two possible mechanisms to explain the effect of prolonging the duration of postoperative analgesia in this study. Firstly, dexmedetomidine, by the action of α2-AR, induces vasoconstriction, which might contribute to prolong the period of analgesia. Secondly, through α2-AR agonists. In our study, 0.5 μg/kg of dexmedetomidine combined with bupivacaine in TAP block resulted in a significant extension of analgesia, lower requirement of dose of analgesic, and higher satisfaction of postoperative analgesia. Similar to our study, diverse clinical trials also demonstrated that adding dexmedetomidine to different local anesthetics in neuraxial and peripheral nerve blocks can prolong the time before the first rescue analgesic in postoperative pain management [5,17] Aftab Hussain et al observed that adding adjunct dexmedetomidine to bupivacaine for TAP block provides excellent postoperative analgesia in patients who underwent hysterectomy under general anesthesia. It did not only delay the first rescue analgesia requirement but also significantly reduced the first 24 hours consumption of opioids.[18]

Waleed A et al observed that addition of dexmedetomidine to bupivacaine in TAP block provides prolonged post-operative analgesia and better pain control than LA alone. The duration of LA was longer, VAS was lower and the need for rescue morphine doses was less when dexmedetomidine was added to bupivacaine.[47]20-19

Pocket et al stated that noxious stimulation leads to release of neurotransmitters that bind to various subclasses of excitatory amino acids receptors including NMDA receptors, activation of these receptors leads to calcium entry into cell and initiates a series of central sensitization such as windup and long term potentiating setting. The mechanism by which alpha 2 adrenergic receptors agonist produces analgesia and sedation is not fully understood but likely to be multifactorial and produces analgesia by reducing release of norepinephrine and causing independent effect on nerve action potential.

Arvind et al compared dexmedetomidine & dexamethasone as additive to bupivacaine in TAP block. Pain score of patients of dexmedetomidine group was found to be significantly lower as compared to that of dexamethasone group. Requirement of rescue analgesia was higher in dexamethasone group than dexmedetomidine group and proportion of patients not requiring rescue analgesia was significantly higher in group with dexmedetomidine as compared to group with dexamethasone (50.0% vs. 16.7%). Difference in mean duration of requirement of first dose of rescue analgesia among patients of dexamethasone group was significantly earlier as compared to dexmedetomidine group.[3] In our study addition of dexmedetomidine & dexamethasone to bupivacaine in TAP block equally prolonged postoperative analgesia and better pain control.

Similar findings have been reported in study carried out by Nitika single et al, comparing efficacy of dexamethasone versus dexmedetomidine as an adjuvant to ropivacaine in ultrasound guided transversus abdominis plane block for

post operative pain relief in caesarean section in which VAS score was significantly lower in dexmedetomidine group and time for rescue analgesia was longer for dexmedetomidine group [13]

Jitender thakur et al observed that duration of analgesia was significantly higher in patients who received bupivacaine along with dexmedetomidine in comparison to the patients who received bupivacaine alone or with dexamethasone. Incidence of post-operative nausea vomiting was equivalent in all groups.[21-23]

Tramadol is centrally acting synthetic codeine analogue drug that has monoaminergic and m-receptor agonistic activity together with some peripheral local anaesthetic properties with low incidence of side effects.

Reem El- Kabariety showed that the addition of 100 mg tramadol to 20ml 0.5% levobupivacaine in a single-shot ultrasound-guided TAP block on both sides for TAH resulted in significantly less consumption of intraoperative and 48-h postoperative analgesia and a significant reduction in the VAS pain score over the postoperative 48 hours, with prolongation of time of first analgesic rescue. TAP block was associated with significantly higher rates of patient satisfaction and lower level of sedation, with no single case of TAP block-related trauma or failure[11]

CONCLUSION:

We conclude that dexmedetomedine and dexamethasone as an adjuvant to 0.25% bupivacaine in TAP block reduced VAS score, systemic analgesic consumption & prolongs the time for rescue analgesia as compared to tramadol. Dexmedetomedine and dexamethasone were superior to tramadol in case of post operative analgesia and less incidence of PONV.

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