Original Article

Comparision of efficacy of dexamethasone with levobupivacaine, clonidine with levobupivacaine and levobupivacaine alone in ultrasound-guided transverse abdominis plane block for post-operative analgesia in lower abdominal surgeries: A randomized double blind controlled study

Rampal Singh, Ankur Garg, Ekta Singh, Malti Agarwal, Tamanna Baktier, Disha Parhi

Department of Anesthesia, Rohilkhand Medical College, Bareilly, Uttar Pradesh, India

Corresponding Author:
Dr. Ekta Singh, Department of Anesthesia, Rohilkhand Medical College, Bareilly, Uttar Pradesh, India.
E-mail: ektasin2102@gmail.com

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Introduction: Ultrasound-guided PNB is a real-time imaging of the position of aimed, targeted, or leveled nerve, needle, and surrounding vasculature. Because of effective and applicable component of multimodal analgesia for postoperative pain, transverse abdominis plane (TAP) block have been used for variety of abdominal procedures. This study was done to establish the role of clonidine and dexamethasone as an adjuvant to levobupivacaine separately in TAP block in patient undergoing lower abdominal surgery. **Materials and Methods:** Present study was carried at tertiary care Hospital. After receiving ethical approval from college ethical committee, 90 patients aged 18–60 years old with ASA Grade I and II physical status who were undergoing elective lower abdominal procedures were included in the study. Each patient was randomly allocated to one of the three groups of 30 patients each. Group A: received TAP Block with 20 ml of 0.25% levobupivacaine + 8 mg dexamethasone (2 ml). Group B: Received TAP Block with 20 ml of 0.25% Levobupivacaine + 50μg clonidine (diluted with distilled water [2 ml]). Group C: Received TAP Block with 20 ml of 0.25% Levobupivacaine and normal saline as placebo (2 ml). All patients were asked to give scores for the pain. Pain severity is evaluated using visual analog scale. Hemodynamics was monitored and any side effects was noted. **Results:** There was no significant difference in age, weight, heart rate, SBP, DBP, MAP, oxygen saturation among the groups showing comparability of the groups in terms of age ($P > 0.05$). The comparison of visual analog scale scores at different time intervals in all three Groups showed that TAP block has better analgesic effects with Levobupivacaine + clonidine as compared to levobupivacaine + dexamethasone and levobupivacaine alone in a post-operative analgesia. **Conclusion:** We conclude that the addition of clonidine as an adjuvant to levobupivacaine in TAP block for lower abdominal surgeries during anesthesia resulted into improved quality and increased duration of post-operative analgesia and decreased analgesic requirements with no side effects.

KEY WORDS: Clonidine, Dexamethasone, Transverse abdominis plane block, Ultrasound

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INTRODUCTION

Uncontrolled pain leads to profound surgical stress and stimulation. The effective pain control post-operative is a significant component of the attention of patient undergone surgery. Transverse abdominis plane (TAP) block has been given with local anesthetic (LA) such as Bupivacaine and

Ropivacaine with limited duration of action. Additives to LA such as opioids, ketamine, and alpha2 agents such as clonidine and dexmedetomidine, corticosteroids such as Dexamethasone have been successfully used in peripheral neural block to increase the duration of postoperative analgesia.[1] Ultrasound-guided PNB is a real-time-imaging of the position of the aimed or targeted or leveled nerve, the needle and the surrounding vasculature, this improves, the ease of performing the procedure and increases the ease of success rate. The TAP described firstly by Rafi in 2001.[2]

This study was done to establish the role of the clonidine and the dexamethasone as an adjuvant to levobupivacaine separately in TAP block in patient undergoing lower abdominal Surgery, to compare the duration of the Analgesia, time of first onset of pain and time of first required for analgesia, Compare post-operative rescue Analgesic requirement in first 24 h, Compare the hemodynamic and respiratory stability and any side effects or complications of study drugs and blocks.

MATERIALS AND METHODS

The present study was carried at tertiary care Hospital. After receiving ethical approval (IEC/01/2019/SEPT) from the college ethical committee and CTRI registration (CTRI/2020/01/022652), 90 patients aged 18–60 years old with ASA grade I and II physical status who were undergoing elective lower abdominal procedures were included in the study. Each patient was randomly allocated to one of the three groups of 30 patients each. Group A: Received TAP Block with 20 ml of 0.25% levobupivacaine + 8 mg dexamethasone (2 ml). Group B: Received TAP Block with 20 ml of 0.25% Levobupivacaine + 50µg clonidine (diluted with distilled water [2 ml]). Group C: Received TAP Block with 20ml of 0.25% Levobupivacaine and normal saline as placebo (2 ml).

Evaluation of patient was to be carried out through proper history taking, clinical examination, and routine laboratory investigations. All patients were informed regarding procedure (USG guided TAP Block) and were trained to use the visual analog scale (VAS). Patients were kept Nil per oral for 6 h before surgery. All patients were premeditated. The multi-channel monitor was connected to the patient to display continuous ECG monitoring for heart rate (HR), noninvasive arterial blood pressure,and peripheral oxygen saturation. Baseline monitoring data was taken.

General anesthesia (anesthesia induction) was carried out according to standard anesthesia protocol. Then ultrasound-guided TAP block was performed after the surgery finished. All patients will be positioned in the supine position. After skin disinfection the abdominal wall was scanned using the linear array transducer probe (6–13 MHz) in multibeam mode, connected to a transportable ultrasonography unit. The edge of the probe was covered by a plastic transducer sheath which is sterile and a gel that is sterile was applied over the skin. A 60–80 mm, 22G short bevel needle was than advanced from an anterolateral to a medial direction using the in-plane insertion with ultrasound real-time assessment.

The progression of the needle was visible as a bright hyperechoic line. Locate the tip correctly in the plane that is targeted and then with help of the intermittent aspiration inject the drugs, also confirm the correct placement and position of the needle by the expansion of the LAs solution which is visible as shadow dark-colored between aponeurosis of internal oblique and the transverse abdominis muscles.

The existence and severity of pain, nausea, and vomiting and any other side effect were assessed in each patients and in all three groups. These assessments were achieved in "PACU (Post Anesthetics Care Unit)" at 30 min and 2, 4, 6, 12, 24 h postoperatively. All patients were asked to give scores for the pain. Pain severity is evaluated by using visual analog scale [Figure 1].

RESULTS

The mean age of patients of Group A, Group B, and Group C was (36.20 ± 9.18), (36.30 ± 9.02) and (35.50 ± 8.78) years, respectively. There was no significant difference in age among the groups showing comparability of the groups in terms of age ($P > 0.05$). The mean weight of patients of Group A, Group B, and Group C was (60.07 ± 8.41), (60.07 ± 8.10) and (59.07 ± 7.11) years respectively. There was no significant difference in weight among the groups showing comparability of the groups in terms of weight ($P > 0.05$). Base line HR was higher as compared to different time period till 12 h. Mean ± SD value of Group A versus Group B versus Group C at base line and at different time period from 30 min to 24 h were (84.9 ± 10.74) versus (84.24 ± 11.18) versus (85.86 ± 7.82); (74.13 ± 12.07) versus (75.87 ± 9.77) versus (76.73 ± 8.96); (74.8 ± 11.21) versus (76.27 ± 9.99) versus (77.8 ± 8.93); (75.73 ± 11.12) versus (76.4 ± 10.16) versus (78.27 ± 8.63); (76.27 ± 10.88) versus (76.87 ± 10.29) versus (79.57 ± 9.29); (78.33 ± 10.97) versus (77.53 ± 10.02) versus (80.57 ± 8.9); (84.7 ± 10.26) versus (83.07 ± 11.06) versus (85.4 ± 7.66) respectively. There was no significant difference in HR among the groups at all the time periods ($P > 0.05$). HR came to base line level after 24 h of TAP block. Base line HR was higher as compared to different time period till 12 h. Mean ± SD value of Group A versus Group B at base line and at different

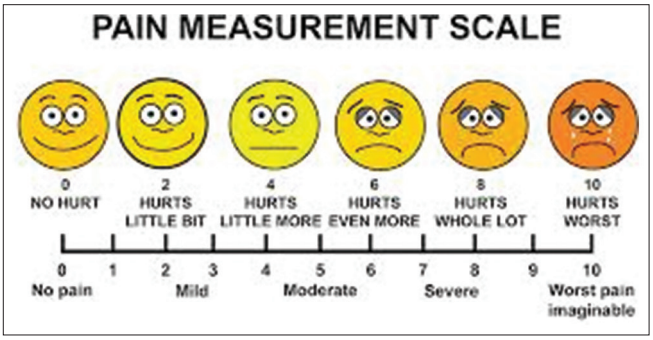

Figure 1: Visual analogue scale. 1–2 = No pain, 3–4 = Mild pain, 5–6 = Moderate pain, 7–8 = Severe pain, 9–10 = Intolerable pain

time period from 30 min to 24 h were (84.9 ± 10.74) versus (84.24 ± 11.18) versus (84.24 ± 11.18); (74.13 ± 12.07) versus (75.87 ± 9.77); (74.8 ± 11.21) versus (76.27 ± 9.99); (75.73 ± 11.12) versus (76.4 ± 10.16); (76.27 ± 10.88) versus (76.87 ± 10.29); (78.33 ± 10.97) versus (77.53 ± 10.02); (84.7 ± 10.26) versus (83.07 ± 11.06) respectively. There was no significant difference in HR between the groups at all the time periods ($P > 0.05$). HR came to base line level after 24 h of TAP block. Base line HR was higher as compared to different time period till 12 h. Mean ± SD value of Group A versus Group C at base line and at different time period from 30 min to 24 h were (84.9 ± 10.74) versus (84.24 ± 11.18) versus (85.86 ± 7.82): ($P > 0.05$); (74.13 ± 12.07) versus (76.73 ± 8.96): ($P < 0.05$); (74.8 ± 11.21) versus (77.8 ± 8.93): ($P < 0.05$); (75.73 ± 11.12) versus (78.27 ± 8.63): ($P < 0.05$); (76.27 ± 10.88) versus (79.57 ± 9.29): ($P < 0.05$); (78.33 ± 10.97) versus (80.57 ± 8.9): ($P < 0.05$); (84.7 ± 10.26) versus (85.4 ± 7.66): ($P > 0.05$) respectively. There was no significant ($P > 0.05$) difference in HR between the groups at base line and at 24 h while there was significant difference from 30 min to 12 h of time periods ($P > 0.05$). HR came to base line level after 24 h of TAP block. Base line MAP was higher as compared to different time period till 12 h. Mean ± SD value of Group A versus Group C at base line and at different time period from 30 min to 24 h were (93.46 ± 6.52) versus (92.96 ± 7.26): ($P > 0.05$); (83.29 ± 5.81) versus (80.29 ± 4.62): ($P < 0.05$); (83.29 ± 5.81) versus (80.42 ± 4.34): ($P < 0.05$); (83.87 ± 5.57) versus (82.22 ± 5.25): ($P < 0.05$); (85.13 ± 6.72) versus (87.03 ± 6.07): ($P < 0.05$); (89.98 ± 5.94) versus (91.44 ± 7.85): ($P < 0.05$); (94.22 ± 6.74) versus (92.82 ± 7.54): ($P > 0.05$), respectively. There was no significant ($P > 0.05$) difference in MAP between the Group A and Group C at base line and at 24 h while there was significant ($P < 0.05$) difference at 30 min, at 2 h, at 4 h, at 6 h, and at 12 h of time periods. MAP came to base line level after 24 h of TAP block. Base line VAS scores was higher as compared to different time period. Mean ± SD value of the Group A versus Group B versus Group C at base line and at different time period from 30 min to 24 h were (5.36 ± 0.76) versus (5.84 ± 0.72) versus (5.88 ± 0.68): $P > 0.05$; (0 ± 0) versus (0 ± 0) versus (0.03 ± 0.18); (0 ± 0) versus (0 ± 0) versus (0.13 ± 0.51); (0 ± 0) versus (0.13 ± 0.43) versus (0.57 ± 1.07); (0.63 ± 1.45) versus (0.17 ± 0.46) versus (3.67 ± 0.76): $P < 0.05$; (3.97 ± 1.03) versus (0.27 ± 0.64) versus (4.6 ± 0.5): $P < 0.05$; (4.63 ± 0.89) versus (5.63 ± 0.76) versus (5.7 ± 0.7): $P < 0.05$. There was no significant ($P > 0.05$) difference in VAS scores among the groups at the base line while there is significant ($P < 0.05$) difference at 6 h, at 12 h and at 24 h [Table 1 and Figure 2].

The comparison of VAS scores at different time intervals in all three Groups showed that TAP block has better analgesic effects with Levobupivacaine + clonidine as compared to Levobupivacaine + Dexamethasone and Levobupivacaine alone in post-operative analgesia.

DISCUSSION

Controlling pain effectively not only facilitates recovery from surgery but also accelerates rehabilitation from surgery. In TAP block LA agent is used, which is the simple and effective analgesic technique, adequate enough for any surgical procedures to provide a relief from a significant and important component of a parietal post-operative pain. The excellent analgesia (pain relief) to the skin and the musculature of the anterior wall of abdominal is provided by the use of LA agents in TAP block, in patient undergoing colonic resection surgery in whom midline abdominal wall incision is done, also in patient undergoing cesarean delivery [Tables 2 and 3; Figures 3 and 4].

The procedure known as transversus abdominis plane (TAP) block is commonly used as a new safe regional anesthetic technique alternative to neuroaxial blockade for abdominal surgeries without the use of opioids (El Fawy and El Gendy).[3] Better operative conditions and a short duration or interval of post-operative analgesia are provided by the use of LA agent throughout the regional blocks. Therefore, lots of clinical trials used adjuvant to prolong the duration and increase the action of LAs for post-operative analgesia.[4]

Clonidine acts centrally as an alpha2 agonist and has attracted interest as an adjunct to anesthesia. Previous studies have suggested that clonidine reduces or minimizes the need for volatile anesthetics when approached by hemodynamic responses (Thomson *et al*.).[5] Fehr *et al*.[6] found that intravenous clonidine allows a lower propofol dose to be used when a same type of anesthesia is provided in spite of any intraoperative awareness or prolonged recovery times.

Owen D J *et al*.[7] compared the efficacy of dexamethasone as an adjunct used in TAP block along with bupivacaine. It is concluded that with addition of dexamethasone as an adjuvant in TAP block prolongs the duration of analgesia as compared to addition of saline (placebo). Increase in the time interval of the block effect is because of the anti-inflammatory effect of dexamethasone. Another school of thought suggests that there is the direct effect of the drugs on the nerve membrane in place of its effect as an anti-inflammatory action were able as dexamethasone, which is a corticosteroid drug, were to inhibit ectopic neural discharge originating in the neuromas (Devor *et al*.).[8]

The action of various LAs is potentiated by steroid via the intonation or we can say inflection of the function of the potassium channels in the excitable cells. Further, pain signal modulation within the spinal cord is a suggested mechanism because as betamethasone used intrathecally produces quick and fast analgesia for pelvic and perineal cancer pain that existed for 5 days.[9]

Our study revealed that there was no statistically significant difference ($P > 0.05$) in HR among three groups at all the time periods. Baseline HR was higher as compared to different time period till 12 h and at 24 h HR becomes equivalent to baseline, this occurs because patient's pain was relieved due to TAP block effect but as time passes the effect of TAP block starts decreasing after certain time periods.

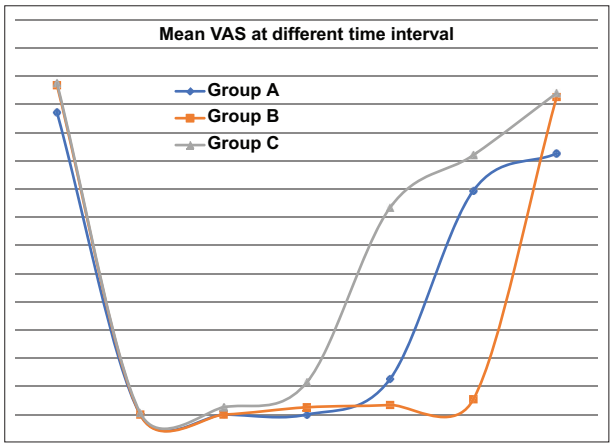

Figure 2: Comparison of visual analogue scale among the groups across the time periods

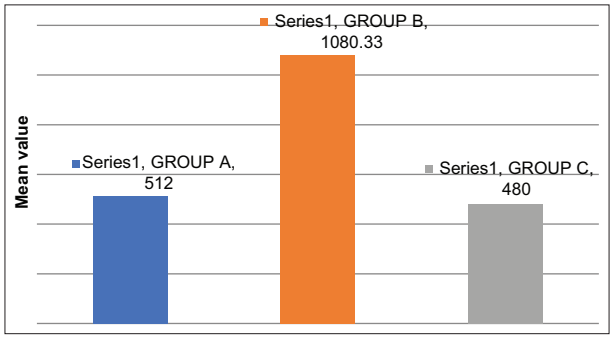

Figure 3: Comparison of time of first request of analgesia among the groups

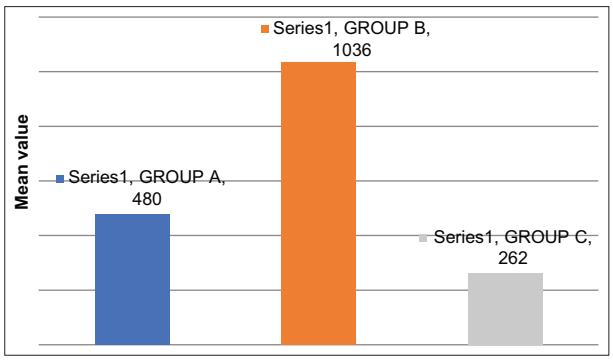

Figure 4: Comparison of duration of analgesia among the groups

However, there is still some variations in the SBP, DBP, and MAP readings among all the three groups at all the time periods. This is because the Group A patient had pain relief after TAP block for around 4–8 h but still there is hemodynamic stability because drug Dexamethasone is hemodynamic stable than drug clonidine.

In our study, there was a significant ($P < 0.001$) difference in VAS score among the groups at 6 h, 12 h and 24 h. VAS score was lower at time interval 6 h and 12 h in Group B (0.17 ± 0.46) and (0.27 ± 0.64) compared Group A (0.63 ± 1.45) and (3.97 ± 1.03) and Group C (3.67 ± 0.76) and (4.6 ± 0.5), respectively. VAS score was lower in Group A (4.63±0.89)

Table 1: Comparison of VAS among the groups across the time periods

Time interval	VAS			*P*-value
	Group A	Group B	Group C	
	Mean±SD	Mean±SD	Mean±SD	
Baseline	5.36±0.76	5.84±0.72	5.88±0.68	> 0.05#
30 min	0±0	0±0	0.03±0.18	-
2 h	0±0	0±0	0.13±0.51	-
4 h	0±0	0.13±0.43	0.57±1.07	-
6 h	0.63±1.45	0.17±0.46	3.67±0.76	< 0.001*
12 h	3.97±1.03	0.27±0.64	4.6±0.5	< 0.001*
24 h	4.63±0.89	5.63±0.76	5.7±0.7	< 0.001*

Table 2: Comparison of time of first request of Analgesia among the groups

Group (*n*=30)	Time of first request of Analgesia	*P*-value
	Mean±SD	
Group A	512.0±88.67	< 0.001* Statiscally significant
Group B	1080.33±117.49	
Group C	480.0±172.61	

Table 3: Comparison of duration of analgesia among the groups

Group (*n*=30)	Duration of Analgesia	*P*-value
	Mean±SD	
Group A	480.0±94.54	< 0.001* Statiscally significant
Group B	1036.0±119.93	
Group C	262.0±43.1	

than Group B (5.63 ± 0.76) and Group C (5.7 ± 0.7) at 24 h. In accordance to our study, Ammar and Mahmoud[7] studied 60 adult patients undergoing elective open abdominal hysterectomy were randomly allocated to receive TAP block using 20 mL of bupivacaine hydrochloride 0.25% + 2 mL saline 0.9% (control group, $n = 30$) or 20 mL of bupivacaine hydrochloride 0.25% + 2 mL dexamethasone "8 mg" (dexamethasone group, $n = 30$). It is seen that the pain VAS scoring was remarkably lower at the postoperative 2 h (4.9 vs. 28.1, $P = 0.01$), 4 h (12.2 vs. 31.1, $P = 0.01$) and 12 h (15.7 vs. 25.4, $P = 0.02$). Thakur *et al*.[10] reported in their study that VAS score was remarkably higher in group B (bupivacaine) in comparison to BDM (bupivacaine + dexmetomidine) and BDX (bupivacaine + dexamethasone), and higher in BDX in comparison to group BDM. Mir *et al*.[11] showed that the overall mean VAS score in Group I (25 ml of injection bupivacaine 0.25%) was 3.03 ± 1.57 and Group II (was 1.72 ± 1.02 with $P = 0.0005$ and hence better quality of analgesia in Group II (25 ml of 0.25% of bupivacaine with 1 ug.kg^{-1} of clonidine).

Thomson IR *et al*.[12] found that the primary outcome which was the time to first requested analgesia was prolonged in the dexamethasone group (P = 0.000) compared to bupivacaine and dexamethasone group. It was found that, no remarkable difference concerning between two groups regarding rectal diclofenac total dose with a P = 0.068.

Many studies proved that ultrasound-guided TAP block performed using LAs and dexamethasone is added, which acting as an addition or an adjuvant to it, is seen and found to be safe and effective strategies for providing analgesia in postoperative period. It was explained that by binding of dexamethasone to receptors of glucocorticoid and also it inhibits potassium conductance, thus decreasing the transmission of stimulus in unmyelinated c-fibers which is carrying nociceptive information by inhibiting the specific activity of the, K+, potassium channels on these fibers. Addition to this, dexamethasone causes vasoconstriction to the various tissues, and slower uptake by the local anesthesia is also slower absorption, thus enhancing its duration and also relief sensed by the patients. Furthermore, dexamethasone shows an effective anti-inflammatory action which is potent enough and exhibit by suppressing the secretion and synthesis of various inflammatory-mediators (IL) interleukins and cytokines which increases the period and duration of the analgesia above to 48 h.[13-15]

The maximum benefit from TAP block is among some patients includes those who are having morbidly obesity or having an OSA problem as it offers opioid-sparing effect. It may be seen and found to be safer alternative to neuraxial block for intra and post-operative analgesia in patient having coagulopathy. The use of USG for TAP is increasing these days using landmark-based anatomical approaches because with the use of USG may increases the effectiveness of the TAP block.

CONCLUSION

Overall, addition of clonidine as an additive or an adjuvant to bupivacaine in TAP block for lower abdominal surgeries is more effective and provides effective post-operative analgesia resulted into improved quality and increased duration of postoperative analgesia and decreased analgesic requirements with no side effects.

Transverses-abdominis-plane blocks are a relatively new technique used in a multimodal approach to provide post-operative analgesia followed after abdominal surgery. It is considered a technically simple block to perform, with a high margin of safety. For multimodal postoperative analgesia, the TAP block proved to be effective and safe.

It also proved that the consumption of intravenous opioids has been reduced with use of this block, resulting in fewer opioid-mediated side effects.

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