

A COMPARATIVE STUDY OF 0.125% BUPIVACAINE WITH DEXAMETHSONE AND CLONIDINE THROUGH SINGLE SPACE PARAVERTEBRAL BLOCK FOR POST OPERATIVE ANALGESIA IN THORACIC AND UPPER ABDOMINAL SURGERIES

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INTRODUCTION: Regional anesthesia using paravertebral block has been suggested as an ideal adjunct to general anesthesia for thoracic^[1,2] and abdominal surgeries. Than multiple injections, one-time technique has several advantages and there are minimal technical problems with infusions or catheters. For a select group of patients with serious co-morbidities, paravertebral block may be used as a sole anesthesia technique, obviating general anesthesia.^[3]

Thoracic paravertebral block appears promising due to reduction in postoperative pain, postoperative nausea and vomiting,^[4] decreased opioid consumption, drowsiness, risk of respiratory depression and cost saving.^[5,6] Additional advantages reported include decrease in incidence of chronic postsurgical pain and improvement in subcutaneous oxygenation in the wound site with a possible reducing infection risk and improved wound healing.^[7]

With the addition of clonidine to the local anesthetic, a longer sensory nerve block has been observed.^[8] Various additives has been used by chronic pain specialists to prolong pain-relieving blocks.^[9,10]

The main objective of the study is to compare the duration and efficacy of postoperative analgesia and hemodynamic stability of equal doses of Bupivacaine with Dexamethasone and Bupivacaine with Clonidine through single space paravertebral block in the thoracic and abdominal surgeries.

METHODS: After obtaining approval from the hospital research and ethics committee and written informed consent, 80 patients of ASA grade 1 and 2 scheduled for total mastectomy and open cholecystectomy were enrolled from November 2012 to August 2014. The exclusion criteria were local infection, anatomic deformities of the spine, coagulation disorders, morbid obesity (BMI>35kg/m²), allergy to local anesthetics, pre-existing neurological deficits, liver or renal insufficiency, pregnancy and failure to attain block.

During the preanesthetic assessment informed consent was obtained and patients were educated about reporting pain on the 10 point visual analog rating scale(VAS), where 0= no pain and 10=worst imaginable pain. Oral diazepam 0.1mg/kg was administered the night before and on the morning of surgery. After initiation of general anesthesia, all patients received paravertebral block on the side of surgery and were assigned to one of the two groups at random.

Group ' C ' [n=40] – 0.3ml/kg of 0.125% Bupivacaine + 1µg/kg Clonidine.

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Group 'D' [n=40] – 0.3ml/kg of 0.125% Bupivacaine + 4 mg of Dexamethasone.

On arrival to the operating room, monitoring lines were established for non-invasive blood pressure measurements, continuous electrocardiography, pulse oximetry and end tidal CO₂. General anesthesia was induced with fentanyl 1µg/kg IV and propofol 2-3mg/kg followed by vecuronium 0.1mg/kg to facilitate endotracheal intubation. Anesthesia was maintained with Sevoflurane 0.8-1%. Patients were placed in the lateral position with the side to be blocked and operated uppermost. The paravertebral block was performed with an 18G tuohy needle using the loss of resistance technique, seeking contact with the lateral process of T-4 for mastectomy and T-7 for open cholecystectomy surgeries and 3-4cm of 20G epidural catheter was introduced into the paravertebral space and fixed. Test dose of 3ml of 1.5% of xylocaine with adrenaline was given to rule out intravascular placement. Patient was turned supine and surgery was performed.

At the end of surgery neuromuscular blockade was reversed with neostigmine 0.05mg/kg and glycopyrolate 0.01mg/kg and extubation was done on return of consciousness and adequate motor power. Intraoperative monitoring included continuous electrocardiogram, pulse oximetry and non-invasive blood pressure measurement every 5 minutes.

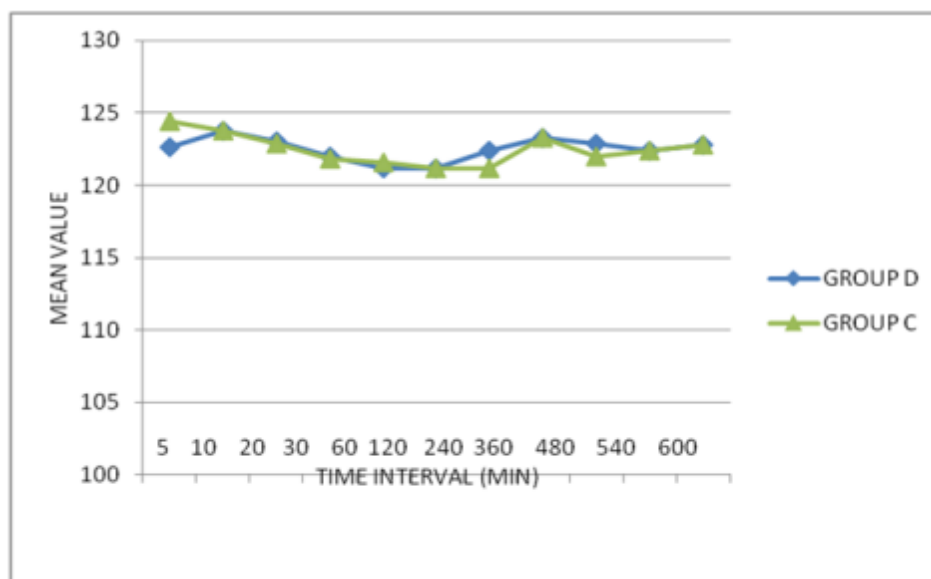
Then 0.3ml/kg of assigned drug was given through paravertebral catheter. Patient was shifted to postoperative recovery room and pain levels were assessed using VAS scale. Onset of sensory blockade was assessed every 1 minute up to 10 minutes. VAS score was assessed every hourly till patient complained of pain or VAS>4, then rescue analgesia was given with intravenous Fentanyl 2µg/kg and 5 ml/hr of 0.125% Bupivacaine infusion through syringe pump started and continued up to 48hours post operatively.

The level of postoperative nausea & vomiting was assessed with 3 point Numerical Rating Scale (NRS). Starting from 0-no nausea, 1-nausea, 2- retching, 3-vomiting. Ondansetron 0.1mg/kg was given for anti-emesis to patients with NRS score of two or more in both the groups.

STATISTICAL ANALYSIS: The apparent differences in mean values of both groups were compared using standard error of difference between means and standard error of difference between proportions. If the two means in the two groups were found to be separated by more than twice of standard error (>2SE) then the two means were considered as highly significant apart (p<0.05). If the two means were found to be separated by more than thrice of standard error (>3SE), then the two means were considered as very highly significant (p<0.001). We used Ranksum test when data was not normally distributed. Student's paired 't' test was used when data was normally distributed. The software used for calculation of p value was Stata (Version 10).

RESULTS: All the 80 enrolled patients completed the study protocol. The patient characteristics and Intra-operative hemodynamic parameters were similar in the two groups (Table 1 & Graph 1).

| Table 1: Patient Characteristics | | | |
|---|------------------|------------------|------------|
| Parameter | Group 'C' (n=40) | Group 'D' (n=40) | ' P' value |
| Age (years) | 52.30(5.78) | 50.33(9.76) | 0.9232 |
| Weight (Kg) | 59.97(8.59) | 60.0(11.58) | 0.4950 |
| Duration of Surgery(min) | 88.7(22.6) | 86.2(17.8) | 0.98 |
| All variables expressed as mean (SD). Group 'C' stands for group that received 0.125%bupivacaine+clonidine1µg/kg.Group'D' stands for group that received 0.125%bupivacaine+dexamethasone 4mg. | | | |



Graph-1: Systolic Blood Pressure Variation

In this study we found that the onset of sensory blockade was slightly earlier in the study group of dexamethasone having a mean onset time of 6.60 ± 2.38 minutes in comparison with the clonidine group having a mean onset time of 8.20 ± 2.84 . The statistical analysis by student's unpaired 't' test was found to be statistically significant as the p value was 0.036 ($p < 0.05$).

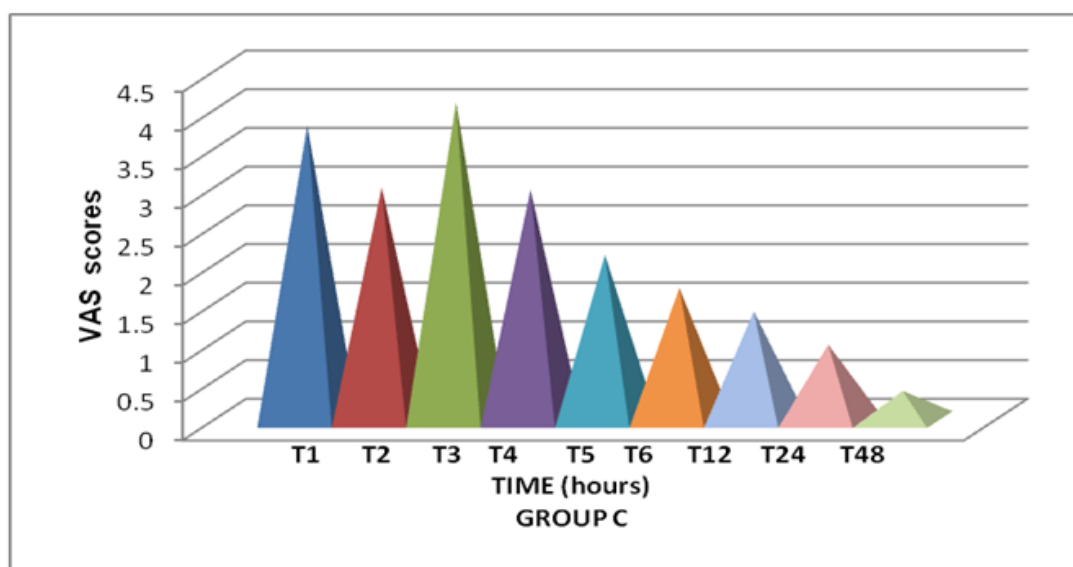
Patients of both groups were observed and VAS scores were assessed at intervals. Time of request for first rescue analgesia (or VAS score > 4) was noted. The mean duration of analgesia in group C was 353.60 ± 52.03 minutes and in group D was 594.40 ± 71.78 minutes. The statistical analysis by students unpaired 't' test showed that the duration of analgesia in group D was very highly significantly longer when compared to group C ($p < .001$) [Table 2].

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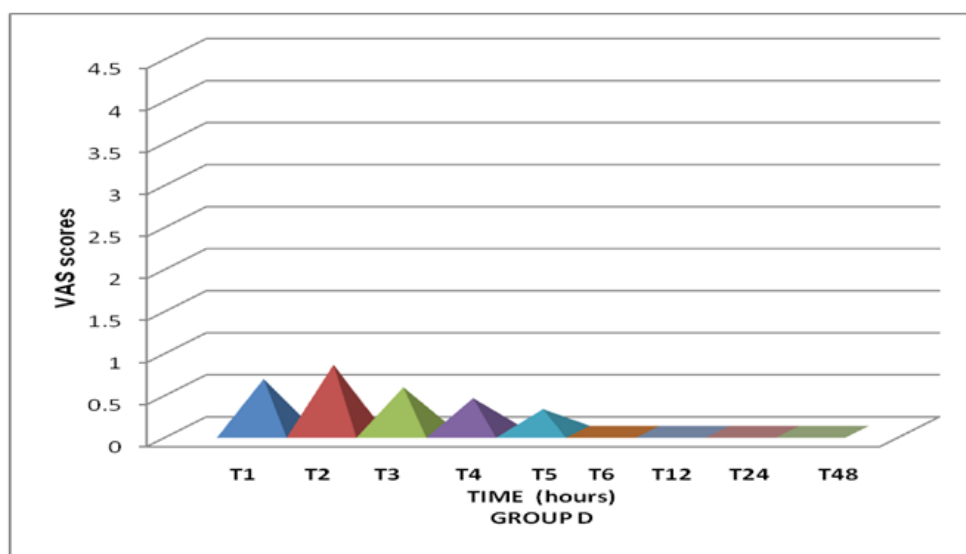
Table 2: Onset and Duration of sensory block

| Parameter | Group 'C' (n=40) | Group 'D' (n=40) | 'P' value |
|---|------------------|------------------|-----------|
| Onset of sensory block (in minutes) | 8.20±2.84 | 6.60±2.38 | <0.001 |
| Duration of analgesia (in minutes) | 353.60±52.03 | 594.40±71.78 | <0.001 |
| All variables expressed as mean (SD). Group 'C' stands for group that received 0.125%bupivacaine+clonidine1µg/kg.Group'D' stands for group that received 0.125%bupivacaine+dexamethasone 4mg. | | | |

VAS scores of both the groups — Group C (bupivacaine + clonidine) and Group D (bupivacaine + dexamethasone) were compared. VAS scores were recorded in the postoperative period at 1st hour(T 1),2nd hour (T2),3rd hours(T3),4th hour (T4), 5th hour (T5),6th hour (T6), 12th hour (T 12),24th hour (T24) and 48th hour (T48). Patients reporting a VAS score of four or more were provided rescue analgesia with Inj. Fentanyl (2.0 µg/kg body weight). VAS scores of Group D was found to be significantly lower (mean VAS=2.7± 1.93) than group C(mean VAS =8.89± 1.66)

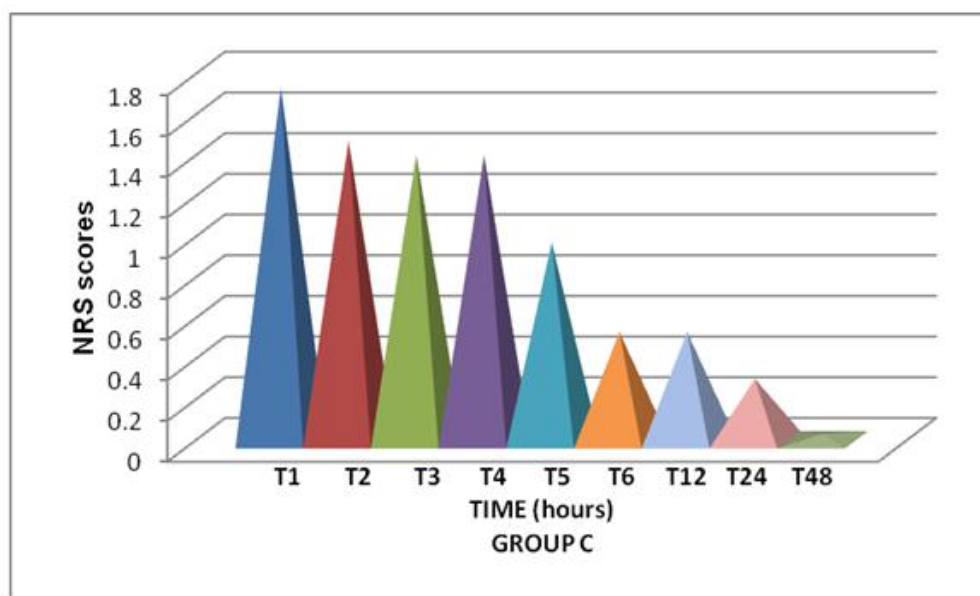


Graph-2: VAS scores for group 'C'

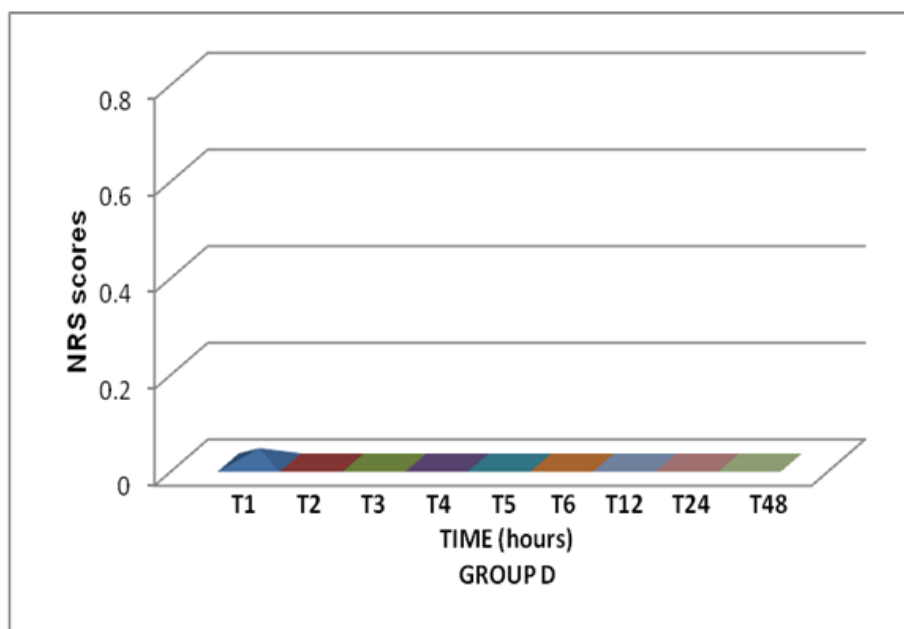


Graph-3: VAS scores for group 'D'

The NRS scores for PONV of both the groups studied. It was observed that the Group C had significantly higher NRS scores (mean NRS=8.33±2.47) in comparison to Group D (mean NRS=0.03±0.18)



Graph-4: NRS scores for group 'C'



Graph-5: NRS scores for group 'D'

DISCUSSION: In this prospective, randomized study, it was observed that patients who received paravertebral block with 0.125% Bupivacaine with Dexamethasone showed significantly better postoperative analgesia compared with 0.125% Bupivacaine with Clonidine.

In this study single level technique was used rather than multilevel injections because of less incidence of pneumothorax and intravascular injection with single level technique. However, it can be argued that single level injection may lead to variable spread of drug. To avoid the variable spread, we used catheter into the paravertebral space.

In this study it has been observed that the onset of sensory blockade was earlier in dexamethasone group. Patients of both groups were observed for up to 48 hours postoperatively. Duration of sensory blockade was taken as time from initiation of paravertebral block to patient request for first rescue analgesia. The duration of analgesia in group D, was significantly longer when compared to group C. Farzin Govavanchi et al.(2012)^[11] did a case series of thoracic paravertebral blocks using a combination of ropivacaine, clonidine, epinephrine and dexamethasone. Ropivacaine as a sole agent has a duration of 6hr. Addition of clonidine, epinephrine and dexamethasone prolonged the clinical duration considerably.

Both VAS and NRS scores were assessed for 48 hours postoperatively. Both scores were less in group D compared to group C. This show that satisfactory pain scores and less nausea and vomiting were observed with addition of dexamethasone showing improved quality and duration of postoperative analgesia. Dhurjoti Proad Bhattacharje et al^[12] conducted study to assess the efficacy of dexamethasone to provide postoperative analgesia after paravertebral block in patients undergoing elective thoracotomy. They concluded that dexamethasone improves the quality and duration of postoperative analgesia. But our study consisted of mastectomy and opens cholecystectomy surgeries and compared effect of dexamethasone and clonidine.

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In our study there was no statistically significant difference between PR, SBP, and DBP & SPO2 between dexamethasone group and clonidine group. This shows that addition of clonidine does not have any decrease in hemodynamic parameters, probably due to local administration.

PONV in our study population was significantly less with dexamethasone compared to clonidine group. Even though, hemodynamic parameters were similar in both groups, the nausea and vomiting prevalence decrease in dexamethasone group may be attributed to its antiemetic properties. In Dhurjoti Proad Bhattacharjee et al.^[12] Study, the incidence of PONV is less in group receiving levobupivacaine with dexamethasone than in group receiving only levobupivacaine in PVB for elective thoracotomy surgeries.

Kehlet et al. (2005)^[13] have extensively reviewed opioid sparing effects of different regimens and remarked that approximately 30% reduction in opioid requirement was clinically significant. The first rescue analgesia was supplemented with opioids (fentanyl 2µg/kg) in both groups and further analgesia was provided by continuous infusion with 0.125% bupivacaine without any addition of opioids. Hence the requirement of opioids in this study was not taken into consideration.

Various studies on PVB have quoted different rates of complications. Kairuloma et al.^[14] has reported single incidence of accidental intravascular injection of bupivacaine. Conveyeney^[15] has reported complication rate of 2.6% with two cases experiencing epidural extension while one patient developed pneumothorax. In our study no complications related to anesthetic technique were faced by the patients in both the groups. Failure of blockade was observed in two cases and was not included in the study.

CONCLUSION: Bupivacaine combined with dexamethasone provides excellent quality and duration of postoperative analgesia compared to bupivacaine combined with clonidine, when used for single level paravertebral block with catheter for thoracic and upper abdominal surgeries. The incidence of postoperative nausea and vomiting were also less in dexamethasone group.

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