International Journal of Research in Medical Sciences
Mir TA et al. Int J Res Med Sci. 2017 Oct;5(10):4588-4594
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20174602

Original Research Article

Evaluation of efficacy of bupivacaine and bupivacaine plus clonidine in transversus abdominis plane (TAP) block for postoperative analgesia: a prospective, randomized, double blind, comparative study

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Received: 12 August 2017
Accepted: 07 September 2017

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ABSTRACT

Background: Pain is the commonest symptom encountered postoperatively and hence multimodal analgesia is tried to overcome it. In this study, we have compared bupivacaine and bupivacaine plus clonidine in transversus abdominis plane (TAP) block for postoperative analgesia in patients undergoing lower abdominal surgeries under spinal anaesthesia.

Methods: Sixty ASA I and II patients in the age range of 18-60 years undergoing various lower abdominal surgeries were randomly divided into two groups, who were operated after giving spinal block using 2.5 ml of 0.5% hyperbaric bupivacine and 25ug of fentanyl. At the end of surgical procedure tranversus abdominis plane (TAP) block was given by giving 25 ml of injection bupivacaine 0.25% in group I and 25 ml of 0.25% of bupivacaine with 1 ug.kg-1 of clonidine in group II. Quality of analgesia was assessed by visual analogue scale (VAS), categorical pain scoring system and frequency of rescue analgesia given and duration was assessed with the time at which first rescue analgesia was given. Side effects of clonidine such as sedation, bradycardia and hypotension were also noted. The hemodynamic parameters like heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP) were noted for both the groups.

Results: Demographic characteristics like age, weight, sex, ASA class and type of surgeries were comparable in both groups. SBP, DBP and HR were less in group II than in group I and was statistically significant (p-value<0.05). The overall mean VAS score in group I was 3.03 ± 1.57 and group II was 1.72 ± 1.02 with p-value of 0.0005 and hence better quality of analgesia in group II. Categorical pain scoring system also showed statistically better scores in group II than group I. The duration of analgesia which was calculated by mean time for first rescue analgesia in group I was 6.38 ± 2.56 hours and group II was 14.23 ± 4.63 hours with a p-value of <0.0001 and the difference was statistically significant. The mean number of doses of rescue analgesia in group I for the first 24 hours was 1.37 ± 0.89 and in group II was 0.60 ± 0.62 with a p-value of 0.0003 and the difference was statistically significant. Group II patients showed more sedation scores than group I patients (p-value <0.05). None of the patients had any episode of bradycardia or hypotension.

Conclusions: Addition of clonidine 1 ug.kg-1 to 25 ml of 0.25% bupivacaine compared to 25 ml of 0.25% bupivacaine alone in tranverse abdominis plane (TAP) block improves quality of analgesia, increases duration of postoperative analgesia and decreases postoperative analgesic requirements with minimal side effects.

Keywords: Bupivacine, Clonidine, Lower abdominal surgeries, Transverse abdominis plane block

INTRODUCTION

Pain is one of the most common symptoms experienced postoperatively and poorly controlled pain is associated with patient distress, suffering, respiratory complications, increased blood pressure and chances of myocardial infarction, prolonged hospital stay and increased likelihood of chronic pain. In abdominal surgeries, major reason for the pain is the abdominal wall incision and remainder is from internal visceral trauma. Various modalities have been used for the postoperative analgesia such as systemic administration of non-steroidal anti-inflammatory drugs, opioids, ketamine, wound infiltration by local anesthetics, epidural analgesia, transdermal analgesia, intravenous patient controlled analgesia (PCA), peripheral nerve blocks. The goal of postoperative pain management is to relieve pain while keeping side effects to a minimum. This is often best accomplished with a multimodal approach.[1]

Analgesia administered before the painful stimulus occurs may prevent or substantially reduce subsequent pain or analgesic requirements. Pre-emptive analgesia can be administered via local wound infiltration, peripheral nerve blocks, epidural or systemic administration prior to surgical incision. The transversus abdominis plane (TAP) block is a peripheral nerve block that results in anesthesia of the abdominal wall.[2] The block, first described by Rafi in 2001, is a simple and safe technique for analgesia whether guided by anatomical landmarks, laproscopically or by ultrasound. McDonnell et al in 2004 described TAP block for pain control of procedures involving the anterior abdominal wall.[3,4] This technique was improved with a blind landmark technique, via the 'lumbar triangle of Petit'.[5] The skin, muscles, and parietal peritoneum in this region are innervated by the T7 through L1 nerve roots. The authors described deposition of local anesthetic in the plane between the internal oblique and the transversus abdominis muscle where the terminal branches of the T7 through L1 nerves lie. Since then, the TAP block has been shown to effectively provide analgesia for a variety of abdominal procedures. In 2007 an ultrasound guided approach was described by Hebbard et al.[6] The main indications of TAP block are lower abdominal surgeries viz-appendectomy, hernia repair, cesarean section, abdominal hysterectomy and prostatectomy. There are reports of using TAP block in laparoscopic surgery. TAP block is capable of giving good analgesic effect in the region between T10 and L1 following a single posterior injection and to achieve higher block up to T7, it needs to be augmented with a subcostal injection.[7]

Charlton et al published a Cochrane systematic review assessing the effect of TAP block for pain relief after abdominal surgery. They included 8 prospective randomised studies. A clear opioid-sparing effect was found as compared to placebo or "no block". Compared with no TAP block or saline placebo, TAP block resulted in significantly less postoperative requirement for morphine at 24 hours (mean difference -21.95 mg) and 48 hours (cumulative difference -28.50 mg). No effect was found on nausea and vomiting. The authors requested further studies comparing TAP block with alternative local anaesthesia techniques, for example, local infiltration and single-shot intrathecal anaesthesia.[2] Siddiqui et al published a second meta-analysis around the efficacy of the TAP block. Four studies were included; laparoscopic cholecystectomy, caesarean section with Pfannenstiel incisions, total abdominal hysterectomy, and large bowel resection midline incision. It was found that patients that were randomized to active TAP block had a significantly lower cumulative morphine need during the first 24 hours post-surgery ($P<0.001$), a significantly longer time until they needed rescue morphine ($P<0.001$), as well as less pain up to 24 hours post- surgery. No significant effects from the TAP block were noticed in postoperative nausea and vomiting. The most profound TAP block effects were noticed for the caesarean section and colon surgery.[8] In an enhanced recovery protocol, TAP plus IV paracetamol in laparoscopic colorectal surgery resulted in earlier resumption of diet and discharge from hospital compared with morphine PCA.[9] One study from 2012 compared TAP plus patient controlled analgesia (PCA) versus subcutaneous local infiltration plus PCA in open right hemicolectomies.[10] This study showed reduced PCA morphine use at 24 hours and decreased sedation in the TAP group. Similarly, Conaghan et al reported decreased IV opioid use in laparoscopic colorectal resections with TAP plus PCA versus PCA alone.[11] Although there is limited evidence to suggest improvement in pain scores and opioid consumption after abdominal surgery, further studies are needed to evaluate the role of TAP blocks compared with other modalities of pain management such as epidural anesthesia.

Transverse abdominis plane block has been traditionally given with local anaesthetics like bupivacaine and ropivacaine.[12] Additives to local anaesthetics like opioids, ketamine and α_2 agonists like clonidine and dexmeditomidine have been successfully used in peripheral nerve blocks to increase the duration of postoperative analgesia. Various studies have been conducted for the post-operative analgesia in abdominal surgeries by comparing the transverses abdominis plane (TAP) block with placebo or local wound infilitration. In this study, we compared postoperative analgesia in two groups by giving TAP block bupivacaine and bupivacaine-clonidine combination.

METHODS

This randomized, prospective and double blinded study was carried out from December 2014 to May 2016, in a tertiary care hospital and the study population included patients of either sex, ASA grade I and II in the age range of 18-60 years. After obtaining approval from hospital ethics committee and written informed consent, patients planned for lower abdominal surgeries like inguinal

hernia repair, appendicectomy, post caesarian section wound repair, wound dehiscence were enrolled into study and divided into two groups of 30 patients each by computer generated randomized list. Patients who refused, ASA class III and IV, patients with cardiac, respiratory, renal ailments, patients with allergy to drugs used and pregnant patients were excluded from the study.

After proper pre-anaesthetic assessment and baseline investigations patients were shifted to operating room where the monitors like electrocardiogram, non-invasive blood pressure (NIBP), pulse oximetry, temperature probe were attached. A 20 G intravenous cannula was secured and intravenous fluid connected. Regional anaesthesia was given by spinal block using 2.5 ml of 0.5% hyperbaric bupivacine and 25ug of fentanyl in sitting position. Patient was positioned spine and spinal neuraxial blockade confirmed. Then the surgical procedure was started and patient kept on oxygen inhalation via facemask. Heart rate, blood pressure, oxygen saturation and temperature were monitored throughout the procedure. Any incidence of bradycardia was treated with injection atropine 0.6 mg and hypotension was treated with intravenous fluids and injection ephedrine 6 mg intravenous bolus. At the end of surgical procedure tranversus abdominis plane (TAP) block was given by giving 25 ml of injection bupivacaine 0.25% in group I and 25 ml of 0.25% of bupivacaine with 1 ug.kg-1 of clonidine in group II. The drugs were prepared by anaesthesiologist not involved in study and coded, which were decoded at the end of study. The puncture site was just above the iliac crest and just posterior to the mid axillary line within the triangle of petit. A 24G blunt tipped 50mm needle was inserted perpendicular to the skin, and a give or 'pop' was felt when the needle passed through the fascial extensions of the internal oblique muscle. The needle tip was therefore between the fascial layers of the external and internal oblique. Further advancement with a second 'pop' indicated that the needle has advanced into the fascial plane above transversus abdominis and, after aspiration, 25 ml of local anesthetic was injected. The aim of a TAP block was to deposit local anesthetic in the plane between the internal oblique and transversus abdominis muscles and targeted the spinal nerves in this plane. The goal was to interrupt the innervation to abdominal skin, muscles and parietal peritoneum.

The endpoint was to assess duration and quality of post-operative analgesia in both groups. Quality was assessed by visual analogue scale (VAS), categorical pain scoring system and frequency of rescue analgesia given and duration was assessed with the time at which first rescue analgesia was given.[13-15] Patients were made familiar with visual analogue scale (VAS) preoperatively with score of 0 as no pain and 10 as worst imaginable pain. Categorical pain scoring system was assessed with score of 0 as no pain, 1- mild pain, 2-moderate pain and 3-severe pain. Side effects of clonidine such as sedation, bradycardia and hypotension were also noted. Sedation scores were measured using sedation scale with awake and alert- 0, quietly awake- 1, asleep but easily roused – 2 and deep sleep- 3. Rescue analgesia was given when VAS score was ≥ 3 in form of injection diclofenac 1 mg.kg-1 slowly in a 100 ml of normal saline in post postoperative period to a maximum of 3 mg.kg-1day-1. All the observations were made by the anaesthesiologist not involved in the study.

Statistical analysis

All the collected data was entered in Microsoft Excel sheet and then transferred to SPSS software version 17 for analysis. Qualitative data was presented as frequency and percentages and analyzed using chi-square test of fisher's exact test (in case of 2x2 contingency tables). Quantitative data was presented as mean and SD and compared by unpaired t-test or Man Whitney U test (in case of non-normal distribution). P-value < 0.05 was taken as level of significance.

RESULTS

The demographic characteristics (age, weight, male-female ratio and ASA-PS) were comparable between two groups (Table 1).

Table 1: Comparison of patient characteristics in two groups.

Patient characteristics	Group I (n=30)	Group II (n=30)	P-value
Age (years)	46.03±11.242	45.50±11.89	0.855
Sex (Male/Female)	17/13	16/14	0.79
Body weight (Kgs)	66.36±7.74	66.43±8.16	0.83
ASA-PS(I/II)	18/12	19/11	0.79

Value expressed as mean ± SD, ASA-PS: American society of anesthesiologists' physical status, SD: standard deviation.

Regarding the type of surgery, the procedures were statistically comparable in two groups with p-value > 0.05 (Table 2).

Table 2: Comparison of different type of surgeries in two groups.

Diagnosis	Group I n (%)	Group II n (%)	Total n (%)
Inguinal Hernia	25 (83.3)	20 (66.7)	45(75)
Appendicitis	3 (10)	4 (13.3)	7(11.7)
Post Caesarian wound infection	2 (6.7)	3 (10)	5(8.3)
Wound dehiscence	0 (0)	3 (10)	3(5)
Total	30 (100)	30 (100)	60(100)

The hemodynamics such as heart rate, blood pressure and oxygen saturation were closely monitored in both the groups for first 24 hours postoperatively (Table 3).

Table 3: Comparison of mean heart rate (HR), mean Systolic blood pressure (SBP), mean diastolic blood pressure (DBP), mean Visual analogue scale (VAS) score between two groups at different intervals of time.

Time	HR (I)	HR II)	SBP (I)	SBP (II)	DBP(I)	DBP(II)	VAS(I)	VAS(II)
Baseline	94	90.03	125	132	77.6	76.7	0	0
5 mins	77	71.1	124	113	73.3	64.3	-	-
10 mins	78	67.43	123	111	70.86	61.6	-	-
15 mins	78.2	64.93	123	110	69.63	60	-	-
30 mins	79	62.5	123	107	69	59.4	0	0
1 hour	76	62.26	123	106	67.9	59.2	0	0
2 hours	77.7	62.63	123	107	68.83	59.3	0	0
3 hours	77	65.3	122	109	71.73	61.8	0.37	0
4 hours	79	69.63	124	116	79	65.5	1.7	0.1
5 hours	79.9	70	123	114	77	64.7	2.4	0.9
6 hours	79.2	69.46	124	113	78	64.5	4	2
7 hours	78.7	68.46	125	112	78	64.1	3.3	2
8 hours	78.2	68.5	125	111	76.4	64.3	3.87	2
9 hours	75	67.8	124	111	75	64.5	3.5	2.1
10 hours	76	68.3	125	111	76	64.5	3.13	2.9
11 hours	77.8	68.7	125	111	76.6	63.1	3.07	2
12 hours	77	70.83	123	114	76	63.5	3.1	2.9
13 hours	76.2	71.53	123	114	78.13	64.9	3.93	2.3
14 hours	75	71.06	125	116	77	65.9	3.37	3
15 hours	77	71.66	125	116	77.63	67.7	3.47	2.4
16 hours	75	72.56	127	118	77.6	69.1	3.83	2.3
17 hours	74	72.63	124	119	77.33	70.1	3.97	2.5
18 hours	77	72.7	124	119	75	71	4.33	2.6
19 hours	77	74.43	126	121	77	71.4	4.2	2.7
20 hours	76	74.93	125	122	75	71.6	4.8	1.3
21 hours	76	76.36	126	123	74	71.9	4.43	1.9
22 hours	76	77	127	123	76.13	73.1	4.5	1.8
23 hours	74	77.33	125	123	76	73.8	4.8	1.9
24 hours	77.14	73.14	127	124	79	73.7	4.83	1.9
Total Mean ± SE	77.42 ± 0.612	70.94± 0.9646	124.46 ± 0.25	115.11 ± 1.15	75.19 ± 0.59	66.38 ± 0.90	3.038 ± 0.298	1.728 ± 0.193

(I)= Group I (Bupivacaine group), (II)= Group II (Bupivacaine+clonidine group). Values are expressed as mean of all patients at that interval of time, SE= Standard error of mean

The overall mean systolic blood pressure (mean ± SE) of group I was 124 ± 0.25 and group II was 115.11 ± 1.15 with p-value of <0.0001, mean diastolic blood pressure of group I was 75.19 ± 0.59 and group II was 66.38 ± 0.90 with p-value of < 0.0001 and overall mean heart rate of group I was 77.45 ± 0.61 and group II was 70.94 ± 0.96 with p-value of <0.0001 and the difference was statistically significant which means the average hemodynamic parameter values of group I were greater than group II. Overall mean VAS score (mean ± SD) for group I (bupivacaine) was 3.03 ± 1.57 and group II (bupivacaine + fentanyl) was 1.72 ± 1.02 with a p-value of 0.0005. The VAS score indicated better quality of analgesia in group II (Table 3).

Categorical pain scoring system showed 1 patient in group I and 18 patients in group II with no pain, 8 patients in group I and 10 patients in group II with mild pain and 21 patients in group I and 2 patients in group II with moderate pain. None of the patients in two groups had severe pain. The comparison between two groups was statistically significant with more favorable results in group II with a p-value of <0.05 (Table 4).

Table 4: Categorical pain scoring system (CPSS) amongst different study population.

Pain Score	Group I n (%)	Group II n (%)	Total n (%)
None	1 (3.3)	18 (60)	19 (31.7)
Mild	8 (26.7)	10 (33.3)	18 (30)
Moderate	21 (70)	2 (6.7)	23 (38.3)
Severe	0(0)	0(0)	0(0)
Total	30 (100)	30 (100)	60(100)

n=number of patients, %= percentage of patients.

The duration of analgesia which was calculated by mean time for first rescue analgesia in group I was 6.38 ± 2.56 hours and group II was 14.23 ± 4.73 hours with a p-value of <0.0001 and the difference was statistically significant.

The mean number of doses of rescue analgesia in group I for the first 24 hours was 1.37 ± 0.89 and in group II was 0.60 ± 0.62 with a p-value of 0.0003 and the difference was statistically significant. This shows that group II (bupivacaine + fentanyl) patients had increased duration of analgesia and also needed less rescue analgesics. Group II patients showed more sedation scores than group I patients (Table 5).

Table 5: Sedation score comparison between two groups.

Sedation Score	Group I n (%)	Group II n (%)	Total n (%)
Awake and Alert	11 (36.7)	0(0)	11(18.3)
Quietly Awake(1)	8 (26.7)	10 (33.3)	18 (30)
Asleep but easily aroused (2)	21 (70)	2 (6.7)	23 (38.3)
Deep sleep (3)	0(0)	0(0)	0(0)
Total	30 (100)	30 (100)	60(100)

None of the patients had any episode of bradycardia or hypotension.

DISCUSSION

TAP block has proved beneficial in various abdominal surgeries as a part of a multimodal regimen for postoperative analgesia by virtue of its simplicity and effectiveness in providing analgesia, appropriateness for surgical procedures where parietal pain is a significant component of postoperative pain, lower pain scores, and reduction in opioid related side effects.[16] TAP block has been shown to reduce postoperative pain scores and opioid consumption, allowing for early ambulation and faster discharge, after a multitude of lower abdominal operations (colectomy, appendectomy, hysterectomy, caesarean section, abdominoplasty, renal transplantation, prostatectomy, iliac crest bone harvest).[17] Although patient controlled epidural/intravenous opioids produce effective analgesia, they are frequently associated with nausea, vomiting, and pruiritis which reduce overall patient satisfaction.[18] Use of neuraxial opiods may be limited by logistic issues and/or presence of medical contraindications.[19,20] Hence, there is a considerable potential for TAP block to be used for effective and long lasting postoperative analgesia. We in our randomized, double blind, comparative study evaluated the effects of adding adjuvant α_2 agonist clonidine plus local anaesthetic bupivacaine with bupivacaine alone in TAP block for lower abdominal surgeries under spinal anaesthesia. Local anaesthetic agents act by blocking sodium channel whereas α_2 adreno receptor agonist act by binding to pre-synaptic c fibers and post-synaptic dorsal horn neurons and shows analgesic action by depressing release of c fibers transmitter and hyperpolarising post-synaptic dorsal horn neuron.[21] The prolongation of effect may result from synergism between local anaesthetic and α_2 adreno receptor agonist.

Yaksh TL has shown that α_2 adrenoreceptor when given intrathecally causes dose dependent decrease in motor strength in animals.[22] α_2 adreno-receptor agonists administered intrathecally have been found to have antinocicepive action for both somatic and visceral pain.[23] The sedation effect of α_2 agonist is postulated to be in the locus ceruleus (a bilateral nucleus that contains many adrenergic receptors) in the brainstem. The locus ceruleus is also the origination site for the descending medullospinal adrenergic pathway, which is known to be a key mechanism in regulating nociceptive neurotransmission.[24]

Kanazi et al depicted the effect of low dose clonidine on the characteristics of bupivacaine spinal anaesthesia.[25] They concluded that clonidine (30 µg), when added to intrathecal bupivacaine, produced a prolongation in the duration of the motor and sensory block with preserved hemodynamic stability and lack of sedation. Giovanni Cucchiaro et al., also observed that the addition of Clonidine to Bupivacaine can extend sensory block by a few hours, and increase the incidence of motor blocks.[26] A recent meta-analysis of randomized trials has demonstrated that the addition of clonidine to local anesthetics significantly prolongs the duration of the motor block and postoperative analgesia when used for peripheral nerve and plexus blocks.[27] It is hypothesized that analgesic effects of clonidine are due to direct interaction with complex structural proteins of nerve fibres.[28-31] Systemic absorption of clonidine from the TAP block may also result into increased duration of analgesia.[32]

In the present study, we observed significantly lower VAS and CPSS scores in bupivacaine plus clonidine group as compared to bupivacaine group. Our study corresponds with the study conducted by Singh et al.[33] who concluded that addition of clonidine to bupivacaine in TAP block bilaterally for cesarean section significantly increases the duration of postoperative analgesia, decreases postoperative analgesic requirement, and increases maternal comfort compared to bupivacaine used alone. Similarly, Gunjan Jain et al. in their study entitled comparison between dexmedetomidine and clonidine as an adjuvant to spinal anesthesia in abdominal hysterectomy observed that there was decrease in VAS score in Bupivacaine plus Clonidine group.[24] Bollag et al. studied the effect of transversus abdominis plane block with and without clonidine on post-cesarean delivery wound hyperalgesia and pain. They concluded that performing a TAP block with or without clonidine does not appear to reduce analgesic consumption or any benefit in wound hyperalgesia.[34]

The duration of postoperative analgesia was assessed by the time period at which the first rescue analgesia was needed. In our study, the duration of analgesia was significantly lower in group I (bupivacaine) than group II (bupivacaine + clonidine) patients. Also, the postoperative analgesic requirements were higher in

group I than group II. Our study corresponds with the study conducted by Singh et al.[33] who concluded that addition of clonidine to bupivacaine in TAP block bilaterally for cesarean section significantly increases the duration of postoperative analgesia and decreases postoperative analgesic requirement. Duration of analgesia was significantly longer in Group BC (17.8± 3.7 h) compared to Group B (7.3 ± 1.2 h; $P < 0.01$). Mean consumption of diclofenac was 150 mg and 65.4 mg in Groups B and BC ($P < 0.01$), respectively.

We also noted higher sedation scores in bupivacaine + Clonidine group as compared to Bupivacaine group. Other side effects associated with clonidine like bradycardia, dry mouth was not seen in any patient. The limitation of the present study was that the VAS scores are recorded from the subjective response of the patient and the pain tolerability may differ between individuals and hence create bias in the scores. Also, the sample size was not large enough to assess the safety. Another limitation was the blind double pop technique used for the block as our centre still doesn't have readily available ultrasound facility in operating rooms.

CONCLUSION

Addition of clonidine as an adjuvant to bupivacaine in TAP block for lower abdominal surgeries during anesthesia resulted into improved quality and increased duration of postoperative analgesia by an average of 8 hours and decreased analgesic requirements by about half, with minimal side effects.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Mir TA, Mir AH, Gani TT, Yousuf A, Ahmad SI. Evaluation of efficacy of bupivacaine and bupivacaine plus clonidine in transversus abdominis plane (TAP) block for postoperative analgesia: a prospective, randomized, double blind, comparative study. Int J Res Med Sci 2017;5:4588-94.