

A Study of the Efficacy of Ultrasound Guided Tap Block Using 0.375% Ropivacaine for Postoperative Analgesia in Patients Undergoing Total Abdominal Hysterectomy

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Abstract: As important component of the pain experienced by patients after abdominal surgery derives from the abdominal wall incision so the TAP block, as part of a multimodal analgesic regimen, may result in improved analgesia and reduce the requirements of opioids in the first 24 hours after TAH compared with a placebo block. The purpose of this study was to test this hypothesis, observe the side effects and evaluate the satisfaction level in patients. This study was conducted in 60 patients at YASHODA HOSPITAL in Secunderabad over a period of 1st July 2014 – 30th June 2015. USG guided TAP block using 20ml of 0.375% ropivacaine is a promising technique in alleviating postoperative pain in patients undergoing total abdominal hysterectomy through a lower abdominal skin incision when used as part of multimodal analgesia regimen.

Keywords: Total abdominal hysterectomy, post-operative pain, and ultrasound guided tap block, ropivacaine.

INTRODUCTION

Poorly controlled acute pain after abdominal surgery is associated with a variety of unwanted post-operative consequences, including patient suffering, distress, respiratory complications, delirium, prolonged hospital stay and an increased likelihood of chronic pain [1-3]. The open abdominal hysterectomy is considered a major surgery and is associated with a medium to high pain level [4]. A major contributor to the pain experienced after abdominal surgery is pain from the incision made in the abdominal wall [5], with the remainder resulting from internal visceral trauma.

Traditional methods for postoperative pain management include opioids administered systemically using patient-controlled i.v. analgesia (PCA), or neuro axially via epidural or spinal injections. However, pain relief, specifically on movement, is not always adequately controlled when using PCA, despite moderate-large doses of morphine. This is associated with side-effects such as postoperative nausea and vomiting (PONV), tiredness, pruritus, headache, and constipation [6]. Therefore, epidural or intrathecal analgesia may be considered by some to be the gold standard for pain management after abdominal surgery, and leads to enhanced and prolonged postoperative analgesia [7]. Although concerns remain regarding complications after central blocks, specifically in older patients [8], recent evidence suggests that these are extremely rare [9].

There has been recent interest in alternative methods for analgesia with minimal side-effects and a trend towards movement from central blocks towards other peripheral and less invasive methods for pain relief [10] which works by anaesthetizing the sensory nerves conveying pain impulses from the incision site to the spinal cord and brain. The TAP block is a new regional anesthesia technique that provides analgesia to the parietal peritoneum as well as the skin and muscles of the anterior abdominal wall [11]. Nerves located within the TAP are the intercostal, subcostal and ilioinguinal/iliohypogastric nerves (T6-L1). First described a decade ago TAP block has undergone several modifications, which have highlighted its potential utility for an increasing array of surgical procedures [12]. It has been shown in prospective randomized placebo-controlled trials to be effective in

reducing morphine consumption and improving postoperative pain relief in several clinical settings, such as caesarean delivery, hysterectomy, and prostatectomy [13-16]. Despite a relatively low risk of complications and a high success rate using modern techniques, TAP blocks remain overwhelmingly underutilized [17]. In part, this may be related to limited sources for anesthesiologists to develop a comprehensive understanding of the transversus abdominis plane. The proponents of TAP block suggest that analgesia provided by TAP block is equal to or superior to that provided by systemic opioids like morphine. It is also claimed that postoperative opioid consumption and opioid derived side effects will be reduced [18]. Furthermore, the TAP block may have a lower risk of complications and greater acceptability to patients than epidural analgesia. However, there is limited information about block level and block duration.

The present study is designed to assess the analgesic efficacy of TAP blockade in women undergoing total abdominal hysterectomy via a transverse lower abdominal wall incision.

AIMS & OBJECTIVES

Aim

To compare the postoperative pain relief among the patients undergoing elective TAH through transverse lower abdominal incision by assessing the requirements of injection tramadol for 24hrs postoperatively in Group C (n=30) receiving bilateral TAB block with 20ml saline & Group T (n=30) Bilateral TAB block with 20ml of 0.375% ropivacaine.

Objectives

To assess & compare the 24 hour cumulative tramadol consumption postoperatively

To assess and compare the postoperative pain relief using the visual analogue scores (VAS) for pain at rest and on movement i.e on coughing

To assess and compare the time of first request of tramadol

To assess and compare the incidence of complications of TAP block and side effects of opioids

To assess and compare the patients' overall satisfaction with postoperative analgesia

MATERIALS AND METHODS

Study site

The study was conducted in patients at YASHODA HOSPITAL, a multi-super specialty hospital in Secunderabad, Telangana, India.

Study population

60 ASA physical grade 1&2 patients, satisfying the inclusion criteria, undergoing elective TAH via transverse lower abdominal skin incision were included in the study after obtaining Hospital Ethical Committee approval.

Study Design

A prospective, randomized, double blind, placebo controlled study.

Sample size with justification

Basing on the review for 5% alpha error and 90% power at least 17 subjects were needed in each group. It was decided to include 30 subjects in each group in order to improve the power and efficacy of the study and this was favored by the large TAH case load in our hospital.

Time frame to address the study - 1st July 2014 – 30th June 2015

Inclusion criteria

- ASA 1 & 2
- Age 30-75yrs of female sex
- Weight 40-85kgs
- Planned electively for TAH through lower abdominal wall incision under spinal anesthesia
- Capable of completing informed consent

Exclusion criteria

- BMI > 35
- Incapable of providing informed consent
- Have impaired liver or kidney function
- H/O alcohol or drug abuse
- H/O chronic pain condition or daily intake of analgesics and steroids
- Hypersensitivity to amide local anesthetics
- Uncontrolled anxiety
- Schizophrenia or bipolar disorder
- Peripheral neuropathy

METHODOLOGY

Randomization

After obtaining written informed consent, patients satisfying the inclusion criteria were randomized into 2 groups using a computer generated random number list

Group C (placebo group)

Received USG guided bilateral TAP blocks with 20 ml of 0.9% isotonic saline each side at the end of surgery

Group T (study group)

Received USG guided bilateral TAP blocks with 20 mL of 0.375% ropivacaine each side at the end of surgery.

Allocation concealment

Group allocation was concealed in sealed, opaque envelopes.

Blinding

A pain nurse who had undergone prior education in assessment of postoperative analgesia and who was unaware of group assignment collected data on each patient. Thus both the patients and the observer were blinded.

Procedure

In the preoperative area, after obtaining institutional approval, the patients were explained about the sequence of anesthetic procedures and a good intravenous access was secured. At the end of surgery, bilateral USG guided TAP block was performed with 20ml (each side) of 0.9% isotonic saline or 0.375% ropivacaine respectively in group C or group T by the anesthesiologist.

A standard postoperative regimen consisting of intravenous acetaminophen 1gm 8th hourly & injection diclofenac 75mg every 12th hourly were commenced on admission to PACU in both the groups. Whenever the patient's VAS >3, intravenous tramadol 50-100mg boluses (upto a maximum of 400mg) along with antiemetic injection ondansetron 0.1mg/kg were given. If the patient's analgesia requirements were more than the maximum dose of tramadol, then injection pentazocine 25mg intravenously was given as rescue analgesic.

Visual Analog Scores (VAS) for pain were assessed immediately and then serially at 30 min, 60 min, 2hrs, 4 hrs, 8hrs, 12 hours, 16hrs, 20hrs and 24 hours after surgery at rest and on movement i.e, on coughing by the pain nurse blinded to group allocation. Patients' overall satisfaction scores for postoperative analgesia were also recorded.

Motor block- Modified Bromage Scale

Score Criteria

- Complete block (unable to move feet or knees)
- Almost complete block (able to move feet only)
- Partial block (just able to move knees)
- Detectable weakness of hip flexion while supine
- No detectable weakness of hip flexion while supine
- Able to perform partial knee bend

ASSESSMENT OF SEDATION - Ramsay sedation score

- Patient is anxious and agitated or both
- Patient is cooperative, oriented and tranquil
- Patient responds to commands only
- Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
- Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
- Patient exhibits no response to light glabellar tap or loud auditory stimulus

ASSESSMENT OF NAUSEA- Categorical scoring system

0- None ; 1- Mild ; 2- Moderate ; 3- Severe

ASSESSMENT OF PATIENTS' SATISFACTION- Likert- type satisfaction scale

1- very satisfied ; 2- satisfied ; 3- not very satisfied ; 4- unsatisfied ;5- very unsatisfied

OUTCOME MEASURES- Postoperatively,

- VAS pain scores at rest and movement
- time of first request for tramadol after completion of surgery
- 3)total dose of tramadol received in the first 24hrs postoperatively
- requirement of pentazocine (if any)
- any adverse effect of TAP block or any side effects of opioids
- overall satisfaction scores of the patients for analgesia

STATISTICAL ANALYSIS

Statistical Methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean \pm SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Significance levels (ascending order): * = p<0.05; ** = p<0.01; *** = p<0.001

The following assumptions on data are made: 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random, and cases of the samples should be independent.

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact test and ANOVA (analysis of variance test) has been used to find the significance of study parameters on categorical scale between two or more groups.

Statistical software

The Statistical software namely Windostat version 9.2 was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

OBSERVATIONS AND RESULTS

A total of 60 patients completed the trial, 30 in the placebo group (group C) and 30 in the ropivacaine group (Group T).

Demographic data, level of block, duration of surgery, time to first request of tramadol

postoperatively, VAS scores at rest and on coughing and total tramadol requirements in 24hrs, additional pentazocine requirement (if any), side effects of opioids, complications of TAP block and patients' satisfaction scores were compared between the Group C and Group T.

Demographic Data

There were no statistically significant differences between the two groups in the patients' demographic characteristics including age, height and weight.

Age distribution in two groups

Table-1: study parameter distribution in two groups

Study Parameter	Group C (n=30)		Group T (n=30)		t test	'p' Value	Mann Whitney test	'p' Value
	Mean	Std.Dev.	Mean	Std.Dev.				
Age (Yr)	45.10	4.25	44.90	4.26	0.18	0.856	439.00	0.439
Height(cm)	154.93	3.51	154.33	2.84	0.727	0.47	362	0.099
Weight(kg)	64.238	8.23	63.63	6.3	0.315	0.754	428	0.376
ASA grade	1.60	0.498	1.567	0.50	0.258	0.798	395	0.212
Level of block	4.53	0.90	4.53	0.9	0.00	1.00	271	0.004**
Duration of Surgery	77	12.21	76	12.89	0.308	0.759	4.45	0.47
TTFR	196.66	27.71	363.66	98.13	8.97	0.00	7.00	0.00
24 hr tramadol (mg)	310.0	66.17	185	72.09	6.99	0.00***	84.00	0.00***
ASO	0.267	0.45	0.10	0.305	1.68	0.09	326	0.034
Sedation score	0.90	1.39	0.23	0.72	2.31	0.024	373	0.13
PONV	0.80	1.34	0.30	0.91	1.68	0.09	329	0.037
Satisfaction score	2.93	0.64	1.90	0.54	6.72	0.00	110	0.00

The average age in Group C was 45.10±4.25 yrs and average age in Group T was 44.90±4.26 yrs(Table 1).There is no statistically significant difference in age between the two groups and the groups are age matched with P=0.856.

Weight &Height distribution in the two groups studied

The average weight in Group C was 64.238±8.23 Kg and in Group T was 63.63±6.3 Kg. There was no statistically significant difference in weight between the two study groups. (p=0.754) (Table 1)The average height in Group C was 154.93±3.51 cm and in Group T was 154.33±2.84 cm. There was no statistically significant difference in height between the two study groups. (p=0.47) (Table 1)

American Society of Anesthesiology (ASA) Physical Status Grade Distribution

The two study groups were comparable with regard to ASA physical status grade distribution. (p=0.798) (Table 1)

Comparison of level of block in the two groups studied

The two study groups were comparable with respect to level of subarachnoid block with p value 1.00 (Table 1)

Comparison of duration of surgery between the two study groups:

The average duration of surgery in group C was 77±12.21 mins and in group T was 76±12.89 mins. There was no statistically significant difference in duration of surgery between the two study groups. (p= 0.759) (Table1)

Comparison of time of first request for tramadol in the two groups studied:

The time of first request of tramadol in the control group was 196.66 ±27.71 min and that in the block group was 363.66 ±98.13 min. There was statistically significant difference between the two groups (p value= 0.00).(Table 1)

Comparison of postoperative static VAS scores in the two groups studied

Table-2: Postoperative static VAS scores in the two groups studied

Study Parameter	Group C (n=30)		Group T (n=30)		t test	'p' Value	Mann Whitney test	'p' Value
	Mea	Std.Dev.	Mean	Std.Dev.				
Rest pain								
2 hr	1.90	1.70	0.00	0.00	6.089	0.00***		
4 hr	4.50	1.04	1.26	1.25	10.84	0.00***		0.00***
8 hr	5.46	0.62	3.50	0.68	11.60	0.00***	13	0.00***
12 hr	4.66	0.75	3.36	0.66	7.04	0.00***	83	0.00***
16 hr	3.63	0.89	3.33	0.71	1.44	0.15	421	0.33
20 hr	3.56	1.006	3.20	0.66	1.66	0.10	425	0.36
24 hr	2.53	0.68	1.63	1.18	3.59	0.001***	320	0.028*

The mean static pain score on VAS in group C and group T was 1.90 ± 1.70 and 0.00 ± 0.00 respectively 2 hrs after surgery (table 2). The difference in the two groups was statistically significant (p value =0.00).

The mean static pain score on VAS in group C and group T was 4.50 ± 1.04 and 1.26 ± 1.25 respectively 4 hours after surgery (table 2). The difference in the two groups was statistically significant (p value = 0.00).

The mean static pain score on VAS in group C and group T was 5.46 ± 0.62 and 3.50 ± 0.68 respectively, 8 hours after surgery (table 2). The difference in the two groups was statistically significant (p value = 0.00).

The mean static pain score on VAS in group C and group T was 4.66 ± 0.75 and 3.36 ± 0.66 respectively, 12 hours after surgery (table 2). The

difference in the two groups was statistically significant (p value = 0.00).

The mean static pain score on VAS in group C and group T was 3.63 ± 0.89 and 3.33 ± 0.71 respectively 16 hours after surgery (table 2). The difference in the two groups was statistically insignificant (p value = 0.15).

The mean static pain score on VAS in group C and group T was 3.56 ± 1.006 and 3.20 ± 0.66 respectively, 20 hours after surgery (table 2). The difference in the two groups was statistically insignificant (p value = 0.10).

The mean static pain score on VAS in group C and group T was 2.53 ± 0.68 and 1.63 ± 1.18 respectively, 24 hours after surgery (table 2). The difference in the two groups was statistically significant (p value = 0.001).

Comparison of postoperative dynamic VAS scores in the two groups studied

Table-3: Postoperative dynamic VAS scores in the two groups studied

Study Parameter Dynamic VAS	Group C (n=30)		Group T (n=30)		t test	'p' Value	Mann Whitney test	'p' Value
	Mean	Std.Dev.	Mean	Std.Dev.				
2 hr	3.63	2.17	0.93	1.36	5.76	0.00***	169	0.00***
4 hr	6.80	0.80	3.36	0.96	14.96	0.00***		0.00***
8 hr	6.90	0.96	3.20	0.84	15.83	0.00***	3.00	0.00***
12 hr	6.63	0.71	3.46	0.90	15.06	0.00***	3.00	0.00***
16 hr	3.73	0.74	3.46	0.73	1.40	0.165	403.00	0.24
20 hr	5.06	0.98	3.33	0.71	7.83	0.00***	59.00	0.00***
24 hr	3.96	0.85	2.66	0.66	6.61	0.00***	110.00	0.00***

The mean dynamic pain score on VAS in group C and group T was 3.63 ± 2.17 and 0.93 ± 1.36 respectively 2 hrs after surgery (table 3). The difference in the two groups was statistically significant (p value =0.00).

The mean dynamic pain score on VAS in group C and group T was 6.80 ± 0.80 and 3.36 ± 0.96 respectively 4 hours after surgery (table 3). The difference in the two groups was statistically significant (p value = 0.00).

The mean dynamic pain score on VAS in group C and group T was 6.90 ± 0.96 and 3.20 ± 0.84 respectively, 8 hours after surgery (table 3). The difference in the two groups was statistically significant (p value = 0.00).

The mean dynamic pain score on VAS in group C and group T was 6.63 ± 0.71 and 3.46 ± 0.90 respectively, 12 hours after surgery (table 3). The difference in the two groups was statistically significant (p value = 0.00).

The mean dynamic pain score on VAS in group C and group T was 3.73 ± 0.74 and 3.46 ± 0.73 respectively 16 hours after surgery (table 3). The difference in the two groups was not statistically significant (p value = 0.165).

The mean dynamic pain score on VAS in group C and group T was 5.06 ± 0.98 and 3.33 ± 0.71 respectively, 20 hours after surgery (table 3). The difference in the two groups was statistically significant (p value = 0.00).

The mean dynamic pain score on VAS in group C and group T was 3.96 ± 0.85 and 2.66 ± 0.66 respectively, 24 hours after surgery (table 3). The difference in the two groups was statistically significant (p value = 0.00).

Comparison of postoperative tramadol usage in the two study groups

The postoperative 24hr tramadol consumption in group C and group T were 310 ± 66.17 mg and 185 ± 72.09 mg respectively (Table 1). There was statistically

significant differences between the two groups ($p=0.00$)

Comparison of additional strong opioid (ASO) in the two study groups

The amounts of pentazocine used in 24hrs in group C and group T were $0.26 \pm 0.45\text{mg}$ and 0.10 ± 0.30 .(Table 1). There was no statistically significant difference between the two groups ($p=0.09$).

Comparison of sedation scores & PONV in the two study groups

The sedation scores in group C and group T were 0.9 ± 1.39 and 0.23 ± 0.72 which were statistically significant as p value was 0.024. (Table1)

The incidence of PONV in group C and group T were 0.8 ± 1.34 and 0.3 ± 0.91 and p value was 0.09; hence the two groups were comparable in this aspect. (Table1)

Patients' satisfaction scores in the two study groups

The patients' satisfaction scores in group C and group T were 2.93 ± 0.64 and 1.9 ± 0.54 respectively and difference was statistically significant (p value 0.00) (Table 1)

DISCUSSION

We randomised 60 ASA physical status I & II patients scheduled for TAH via a Pfannenstiel incision, in a double blind, placebo controlled clinical trial to undergo bilateral TAP block with 20ml saline ($n=30$) (GROUP C) or 20ml of 0.375% ropivacaine ($n=30$) (GROUP T) in addition to standard postoperative analgesia comprising regular diclofenac and paracetamol. All patients received a standard spinal anaesthetic and at the end of the surgery USG guided TAP block was performed by the same investigator. Rescue analgesics in the form of tramadol (maximum 400mg) or pentazocine (if tramadol requirement exceeded 400mg) were offered to the patients who complained VAS score >3 .

In our study the two groups were comparable in age, weight, and height, and ASA physical grade, level of block and duration of surgery. The postoperative 24hr tramadol consumption in the block group decreased by almost 40%. This opioid sparing effect is comparable to the first study performed on the analgesic efficacy of TAP block in TAH patients in the postoperative period by Carney *et al.* wherein the PCA morphine dose in the postoperative period in the block group decreased by 50% [14] and was also demonstrated in many other studies like those done by Ayedi *et al.* [19], Charlton *et al.* [20], Hyun jun Shin *et al.* [21], etc.

The time of first request of tramadol in the placebo group was 196.66 ± 27.71 mins and for the block group was 363.66 ± 98.13 mins which was statistically

significant. Priya Sharma *et al.* [22] in their RCT on patients undergoing major gynaecological or surgical operation through midline abdominal wall incision also demonstrated longer time to first PCA tramadol request and a more than 70% decrease in mean PCA tramadol consumption during the first 24 postoperative hours in the levobupivacaine TAP block group compared to the control group.

The VAS scores of pain at rest were significantly lower in the ropivacaine group at 2hr, 4hr, 8hr, 12hr and 24hr. The VAS scores on coughing were significantly lower in the ropivacaine group at 2hr, 4hr, 8hr, 12hr, 20hr and 24hr. Peterson *et al.* [23] in their meta-analysis of 7 clinical trials of both landmark-based and USG guided TAP blocks for managing postoperative pain after abdominal surgery with incisions below the umbilicus also demonstrated reduced early postoperative VAS both at rest and during mobilization in 4 of the 7 studies (1 study did not record VAS scores). Bharti *et al.* [24] also demonstrated a significant reduction in early postoperative pain scores both at rest and with coughing in the bupivacaine TAP block group.

In our study, at the 16th postoperative hours, the dynamic VAS pain scores were same in both groups. This can be attributed to the period of sleep of the subjects as all the surgeries were performed in morning hours. Again at 20th & 24th postoperative hours, the dynamic pain scores were significantly less in the block group as compared to the placebo group.

The amount of pentazocine requirement was less in the block group than placebo group, however the difference was not statistically significant. The sedation scores were significantly less in the block group which is attributed to the less tramadol consumption in this group. The decreased tramadol consumption in the block group also probably resulted in decreased incidence of PONV however it didn't reach a statistical significance. This can be explained by the fact that gynaecological surgeries already have a higher risk of PONV [25]. The satisfaction scores were significantly higher in the ropivacaine group than the placebo group.

These results are on par with the study conducted by Bharti *et al.* [24] on patients undergoing colorectal surgery who received intraoperative TAP blocks with either 0.25% bupivacaine or saline. In the bupivacaine group; early postoperative sedation scores were significantly lower, patient satisfaction was higher and there was no difference between the groups in the incidence of PONV; it reduced postoperative pain scores both at rest and on movement also the sedation scores. Charlton *et al.* [20] also did not appreciate any significant difference in PONV between TAP block and non-TAP block group in their meta-analysis.

Carney *et al.*[14] also demonstrated a decrease in postoperative VAS pain scores at rest and on movement and in sedation scores in the TAP block group using ropivacaine (maximum dose 150mg) compared to placebo group and there was no significant difference in incidence or severity of nausea at any time point between the groups. Also, no complications attributing to TAP block were noted though ultrasound was not used while giving the block. These surgeries were however performed under general anesthesia and blocks were given prior to surgical incision.

Our findings are also consistent with randomized double blind clinical trial performed by Atim *et al.*^[26] who concluded that patients who received bilateral USG guided TAP blocks has significantly less pain at rest and on movement and reduced tramadol requirements in first 24 hrs postoperatively compared with either sham TAP blocks or superficial wound infiltration. They also concluded that TAP block proved to be a more effective method of postoperative pain relief following TAH then wound infiltration.

Drawbacks

However there are few areas of uncertainty like optimal dosing schemes (i.e., single shot versus catheter, intermittent versus continuous catheter infusions, type of local anesthetic, use of adjuvants), coagulation status which require further research.

CONCLUSION

USG guided TAP block using 20ml of 0.375% ropivacaine is a promising technique in alleviating postoperative pain in patients undergoing total abdominal hysterectomy through a lower abdominal skin incision when used as part of multi-modal analgesia regimen. The procedural simplicity and safety of this block, along with reliable level of longer duration of analgesia and the opioid sparing effect makes the TAP block a good option for postoperative pain relief in lower abdominal gynecological surgeries.

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