Effectiveness of Tramadol with Bupivacaine Versus Bupivacaine Alone on Postoperative Analgesia at Wolaita Sodo, Southern Ethiopia: Observational Cohort Study

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Research Article

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Abstract

Background: Postoperative pain can cause immediate and extended consequences of poor outcome and result in extended hospitalization. It also progresses to chronic pain, if not intervening early. Wound site infiltration with a mixture of tramadol and bupivacaine is inexpensive, easy, and useful means of providing desirable analgesia for postoperative pain relief. The purpose of the study was to compare the analgesic effectiveness of bupivacaine with the tramadol combination and bupivacaine alone as part of postoperative pain management.

Method: A prospective cohort study was employed on 120 patients who underwent elective lower abdominal surgery under general or spinal anesthesia with a systematic random sampling technique. Pain severity was measured by using a numerical rating scale, and the employment of additional analgesics was recorded for 24 hours between the two groups. The Mann-Whitney test and chi-square test were used to compare the median pain score and total analgesia consumption. Kaplan-Meier survival analysis was used to compare the time to first analgesic request between the two groups. Statistical significance was stated at a p value < 0.05 with a power of 95%.

Result: Postoperatively, the median (interquartile range) of pain severity score was 1.0 (0-5) in the BT group compared with 5 (3-6) in the BA group. And, time to first analgesic request with the BT group, was 18 hours, 95% CI: (14.53- 21.47), had longer time compared to patients in the BA group was 6 hours, 95% CI:(4.48 - 7.71).

Conclusion and Recommendation: Local wound infiltration with a mixture of Bupivacaine and Tramadol decreases the postoperative pain score, total analgesia consumption and has prolonged time to first analgesia request. Therefore, we recommend using a mixture of 0.25% bupivacaine with tramadol is effective for postoperative analgesia.

Background

According to the International Association for Study of Pain, “Pain is outlined as unpleasant emotional and sensory experience because of actual tissue damage”(1). A significant part of the pain experienced by patients who underwent lower abdominal surgeries was mainly related to somatic pain signals derived from the abdominal wall structure (2). Procedural pain is the acute type and has a probability of progressing to chronic pain unless intervened properly(3).

Every day, numerous patients undergo surgical procedures, and a large portion of them endure moderate to extreme pain postoperatively(4, 5). That is, over 80% of patients who undergo surgical procedures experience intense postoperative agony(6).

Inadequately managed pain after surgery can negatively affect patient wellbeing on multiple levels, such as hypertension, myocardial ischemia, arrhythmia respiratory impairments, ileus, poor wound healings

and DVT(7, 8). And, results prolonged hospitalization, which causes huge extra healthcare costs and patient financial expenses(9).

After abdominal surgery, even if strong narcotics are an alternative to manage postoperative pain, they have been clearly recognized as reasons for the delay of postoperative recovery due to their side effects such as prolongation of gastric ileus, chest wall rigidity, postoperative nausea and vomiting, urinary retention, respiratory depression, sedation, and dizziness occurred (10, 11). Their cost also not affordable for all patients.

Neuraxial strategies are likewise powerful and safe but should be performed by an accomplished individual and require close monitoring. Again, the practice and use of patient-controlled analgesia are impracticable and unsafe due to lack of equipment and the need for careful ward monitoring in growing countries(12, 13).

The target in postoperative pain management is the use of approaches that involve fewer side effects and quicker recuperation (14). As a significant part of surgical pain originates from the surgical site, it is logical to use local anesthetics at the site of wound to manage postoperative pain It includes Perineural catheter techniques, that can be efficient and provide good analgesia for several days, but this technique is limited by difficulties in placement and removal of the catheter or rarely with infection(15–17). In addition to decreasing the cost and side effects of opioids, the use of local wound site infiltration with a mixture of tramadol and bupivacaine also supports the principle of multimodal analgesia(18, 19). And, it can also be a straightforward, cheap, and effective technique and is employed habitually in several hospitals without any major side effects(20).

Bupivacaine is a well-known amide-type of local anesthetic. The mechanism of action of bupivacaine is by binding with a selected region of the subunit and inhibiting voltage-gated sodium channels, preventing channel activation and inhibiting the sodium influx related to membrane depolarization(21). wound site infiltration with bupivacaine has a bacteriostatic and bactericidal effect that limits the risk of infection at the wound site(22). And, also it has immediate postoperative analgesia, even though it is limited to 5–8 hours (23, 24).

Tramadol hydrochloride is a synthetic opioid of the amino cyclohexanol group. Its dual mode of action (opioid and non-opioid) provides some advantages over pure opioid analgesics (25, 26). The possible reasons for the mechanisms of action supporting the rationale for using tramadol as an adjunct with local anaesthetics are; First, the presence of serotonin (5-hydroxytryptamine, 5-HT) subtype 3 (5-HT3) receptors on peripheral nerve endings and in the dorsal laminae of the spinal cord indicates possible peripheral sites of analgesic action for tramadol(27, 28). Second, tramadol has local anaesthetic properties possibly by blocking K + channels(18, 29).Finally, tramadol's monoaminergic actions include agonism at peripheral a2 receptors, suggesting a role in nerve blocks similar to that of clonidine(30, 31).

Different researchers' findings on the combination of tramadol with bupivacaine were available in different countries, but there is no studied evidence regarding the effects of adding tramadol with

bupivacaine on postoperative analgesia among adult patients undergoing lower abdominal surgery in Ethiopia. Additionally, updating health professionals with new and alternative methods of postoperative pain control is a necessary option for evidence-based clinical practice. Hence, the aim of this study was to compare the effectiveness of tramadol added to bupivacaine and bupivacaine alone for postoperative pain relief among adult patients who underwent lower abdominal surgery under general anesthesia or spinal anesthesia at Wolaita Sodo University, Teaching and Referral Hospital.

Methods And Materials

An institutional-based prospective cohort study was employed from February 28/2020 – may28, 2020 at Wolaita Sodo University, Teaching and Referral Hospital. The source of population were all adult patients who underwent abdominal surgery, and the study participants were selected elective adult patients who underwent lower abdominal surgeries during the study period. Those patients on long-term opiate users, allergy to the drug, with chronic pain diagnosis, emergency surgical patients, pregnant mothers, BMI >30 km/kg and patients with known epileptics were excluded from the study. Whereas those Men and women patients age greater than 18 years and ASA class I–II patients, who underwent lower abdominal surgery were included in the study.

The primary endpoint of this study was to assess and measure postoperative pain severity, time to first analgesic request and total analgesic consumption for 24hours. The sample size was determined based on the largest sample size and calculated by using a priori power analysis (G Power version 3.01) based on the results of a similar study performed by Roopa Sachidananda et al(32). Prior power analysis for two independent t-tests with 2 groups was conducted by taking the time for the first analgesia request from the previous study done, pain scores of the mean (SD) (μ1= 386.17±233.84 min and μ2=192.50±134.77 min).

To determine the sample size an alpha of 0.05, a power of 0.95% and effect size of 1 were substituted into the software, and the calculated sample size is 54. Sample size was doubled for the purpose of considering subgroup analysis for postoperative analgesic effectiveness effect and became 108. To ensure a minimum of 108 patients, an additional 12 patients (10 %) were added to account for potential protocol violations and missing data, so the total sample size is 120 patients with 60 in each group.

Based on monthly institutional average reports, approximately 80 patients underwent elective lower abdominal surgery. Depending upon the average number of previous records and duration of the study period, which was planned for three months, the total population size at the operating theatre expected to be 240 patients. The patients were selected every Kth unit based on log book data from the study area, and 240 patients underwent lower abdominal surgery. The sampling interval K was calculated using formula=N/n= 2. A total of 120 participants were enrolled with a chance of 50%. The first random case was chosen by a lottery method, and then every 2nd consecutive patient on the day of data collection was included. All patients who were scheduled for elective lower abdominal surgery and

who satisfied the inclusion criteria and volunteered to take part in the study were instructed, on how to self-report pain severity by using the 11-point NRS score (0 to 10), on the day of operation by trained anesthetist. Following this written, informed consent was obtained from all patients. At the end of the surgery and after the patients' vital sign stability was confirmed , based on the preference of the Anesthetist, after drug dose adjustment was performed and the infiltration site was cleaned with alcohol, the responsible anesthetist could perform infiltration at the wound site with tramadol 2 mg/kg mixed in bupivacaine 0.25% 0.7 mg/kg (diluted to 20 mL with 0.9% normal saline) or with bupivacaine 0.25% 0.7 mg/kg (diluted to 20 mL with 0.9% normal saline) for postoperative pain management. Starting from the time of wound infiltration, 24 hours postoperatively in the recovery room and ward, the presence and severity of pain (NRS for pain), time for the first analgesic request and adverse side effects were passively followed and assessed by using systematically structured questionnaires by two trained data collectors. And, also another one trained senior anesthetist was assigned to assist and supervise data collectors. The NRS score and other variables were documented at six time points: at 0 hr, 2 hr, 6 hr, 12 hr, 18 hr, and 24 hrs. Data collection was carried out by structured and pretested questionnaires consisting of general patient characteristics information. Then, the collected data were checked for completeness, accuracy, and clarity by the principal investigator and research assistant. Data clean up and crosschecking were performed before analysis, and incomplete data were not entered into the database for analysis.

Data Processing and Analysis

After the data obtained from the data collector and manually checked and cleaned for errors and coded, it was entered into Epi-data software. After data entry was completed, the data were exported into SPSS version 23 statistical package software, and statistical analyses were performed. The Shapiro-Wilk test and histogram were used to test for normal distributions. Frequency and percentage were used to describe the categorical variables. Comparison of asymmetric variables between study groups to compare median pain score and total analgesia consumption between groups and significant differences between groups were described by using the Mann-Whitney test and chi-square test. Kaplan-Meier survival analysis was used to compare the time to first analgesic request using the log-rank test and curve graph to compare the proportion of patients not requesting analgesia over 24 hours between the two groups. Box and whisker plots were used to show median pain score differences between groups. Statistical data were reported as the mean ± SD for normally distributed data, median ± IQR for non-normally distributed data and categorical data were reported as numbers and frequencies (percentages), and statistical significance was stated at a p-value < 0.05 with a power of 95%.

Operational Definitions

Local wound infiltration: is the technique of administering local anesthetic directly into the surgical incision site at the end of the procedure.

Acute postoperative pain: is the pain experienced immediately after an operation, usually lasting for days or sometimes weeks.

Chronic pain: is normally considered to be pain that persists or keeps coming back for more than three months or for longer than the expected healing time.

Chronic post-surgical pain; pain that develops after a surgical operation that lasts for at least three months.

Postoperative pain: the presence of pain in the postoperative period as a patient complaining of pain and any pain score other than zero within 24 hrs.

Numerical Rating Scale: is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0-10 (11-point scale) with the understanding that 0 is equal to no pain and 10 equals the worst possible pain(9).

Total analgesic consumption: is the total amount of analgesic drugs in milligrams used in the first 24 hrs.

Lower abdominal surgery: any operation that involves opening the abdominal cavity below the umbilicus

Time to first analgesic request: is the time in minutes measured from the end of the procedure to time when the patient requests analgesics.

Duration of surgery: time in minutes from skin incision to skin closure.

Duration of anesthesia: a time in minutes it takes from loss of consciousness to awake fully from anesthesia

Postoperative analgesic Effectiveness: Postoperatively after analgesic agent was used and, if the pain intensity score was NRS $\leq$ 3 during rest and on coughing for over 24 hours.

Censored (0): A patient did not request analgesia until the end of the study period.

Die censored (1): A patient requesting analgesia until the end of the study period.

ASA status: is a surgical risk stratification validated by the American Society of Anesthesiologist.

ASA I: a healthy patient with no organic/physiological/psychotic problems.

ASA II: controlled medical conditions with mild systemic effects and no limitation of functional ability.

Results

Sociodemographic and perioperative characteristics

During the study period, a total of 120 patients were included for the final analysis based on whether they received local wound infiltration with a combination of Bupivacaine and Tramadol or local wound infiltration with Bupivacaine Alone for postoperative analgesia, and those patients who took Bupivacaine Alone considered as non-exposed groups. Among the 120 patients, 72 (60.9%) were males, while 48 (39.1%) were females. The mean (standard deviation) age of patients was 47.32 ± 16.13 and 49.33 ± 17.94 years for LWI with BT and LWI with BA, respectively. The educational status of the study participants was 80 (66.7%) literate and 40 (33.3%) illiterates. Approximately 98 (81.7%) of the ASA status of respondents was ASA II (Table 1).

Table 1
Sociodemographic characteristics of patients who underwent lower abdominal surgery at Wolaita Sodo University, Teaching and Referral Hospital from February 28 – may28, 2020.

Socio-demographic characteristics		LWI with BT	LWI with BA	Total
Sex	Female n (%)	26(43.3%)	22(36.7%)	48(39.1%)
	Male n (%)	34(56.7%)	38(63.3%)	72(60.9%)
ASA status	ASA I n (%)	10(16.7%)	12(20%)	22(18.3%)
	ASA II n (%)	50(83.3%)	48(80%)	98(81.7%)
Educational status	literate n (%)	40(66.7)	40(66.7%)	80(66.7%)
	Illiterate n (%)	20(33.3%)	20(33.3%)	40(33.3%)
Age (mean ± SD)		47.32 ± 16.13	49.33 ± 17.94	
Weight (mean ± SD)		62.93 ± 5.21	61.70 ± 7.13	

Hint: n (%) = Number and percentage, mean (standard deviation) = mean ± SD. The value is given as the mean ± SD for age, weight and number of patients or frequency for the rest.

Intraoperative characteristics of the study participant's

Most of the study respondents, took spinal anaesthesia (80%), and some of the patients were induced with ketamine (20%). Tramadol (20.8%) and diclofenac (18.33%) were the most commonly used analgesic agents during the intraoperative period. Most operation duration that took 1 hour was 76.7%, whereas the duration of anaesthesia for 2 hours and 60 minutes was 53.33% and 10%, respectively. Most of the respondents' operations were performed by senior surgeons (47.5%) with transverse skin incision type (78.3%), and the majority of local wound infiltration for postoperative pain relief was performed by B.Sc. Anaesthetist (78.3%) (Table 2).

Table 2
Intraoperative characteristics of patients who underwent lower abdominal surgery at Wolaita Sodo University, Teaching & Referral Hospital from February 28 – may28, 2020.

Variables		LWI with BT	LWI with BA	Total	P-value
Induction agents	Ketamine	12(20%)	12(20%)	24(20%)	1.00
Spinal Anaesthesia	Yes	48(80%)	48(80%)	96(80%)	1.00
Intraoperative analgesia given	pethidine	2(3.3%)	2(3.3%)	4(3.3%)	0.663
	Tramadol	12(20%)	13(21.6%)	25(20.8%)	
	Diclofenac	11(18.3)	11(18.3%)	22(18.3%)	
Experience of surgeon who did operation	R2(resident)	4(6.6%)	4(6.6%)	8(6.6%)	0.841
	R3(resident)	14(23.3)	16(26.7%)	30(25%)	
	R4 (resident)	20(33.3)	14(23.3%)	34(28.33%)	
	Senior surgeon	28(46.7)	29(48.3)	57(47.6%)	
Type of skin incision	Midline incision	14(23.3%)	12(20%)	26(21.7%)	0.659
	Transverse incision	46(76.7%)	48(80%)	94(78.33%)	
Experience of the Anaesthetist who did block	B.Sc. anaesthetist	46(76.7%)	48(80%)	94(78.3%)	0.659
	M.Sc. Anaesthetist	14(23.3%)	12(20%)	26(21.7%)	
Duration of the operation	45 minutes	12(20%)	6(10%)	18(15%)	0.112
	1hours	44(73.5)	48(80%)	92(76.7%)	
	1hr & 30minutes	4(6.7)	2(3.3%)	6(5%)	
	2hours	-	4(6.7%)		
Duration of Anaesthesia	60 minutes	8(13.3%)	4(6.7%)	12(10%)	0.070
	70 minutes	18(30%)	16(26.7%)	34(28.3%)	
	90minutes	4(6.7%)	2(3.3%)	6(5%)	
	2 hours	30(50%)	34(56.7%)	64(53.33%)	

Hint: n (%) = Number and percentage: The value is given as number of patients and frequency.

Variables		LWI with BT	LWI with BA	Total	P-value
	1 hours & 50min	-	4(6.7%)		
Hint: n (%) = Number and percentage: The value is given as number of patients and frequency.					

Comparison of Postoperative Pain Severity Score Between the two groups

The median (IQR) of pain severity (NRS) score was 0.0 (0–0) until 12 hours and 1 (0–5) and 3 (1–5) at 18 and 24 hrs in the LWI with BT groups compared to LWI with BA in the recovery room and ward (Table 3). Man-Whitney tests revealed significant differences at the 12th, 18th, and 24th hours between the exposed and non-exposed groups ($p < 0.001$).

Table 3
Comparison of postoperative pain severity by using the 11-point NRS score (0–10) among adult patients who underwent lower abdominal surgery at Wolaita Sodo University, Teaching & Referral Hospital, from February 28 – may28, 2020.

post-operative pain severity measurement time	LWI with BT (n = 60)	LWI with BA (n = 60)	P-value
Recovery room NRS score at 0hr	0.0(0–0)	0.0(0–0)	1.000
NRS score at 2hrs	0.0(0–0)	0.0(0–0)	0.999
NRS score at 6hrs	0.0(0–0)	0.0(0–0)	0.156
NRS score at 12hrs	0.0(0–0)	7(5–8)	< 0.001**
NRS score at 18hrs	1(1–5)	6(5–6)	< 0.001**
NRS score at 24 hrs	3 (1–5)	5(4–6)	< 0.001**
Hint: Values are presented as: =Median (IQR), Mann-Whitney test, **=statistically significant			

A Mann-Whitney test revealed a significant reduction in the postoperative pain severity score ($H = 48.9$ ($Z = 11.01$, $N = 120$), $p < 0.001$, $\eta = 0.41$) in the LWI with BT group compared with the LWI with BA group. The proportion of variability in ranked NRS score accounted by the LWI with BT group vs LWI with BA group was 0.41, indicating a moderate relationship between LWI with BT group and LWI with BA group and change in NRS score, respectively (Fig. 1).

Comparison of time to first analgesia request among the two groups

Kaplan-Meier curve shows the first analgesic request with the patient not receiving any analgesics over 24 h censored to the right (Fig. 2). Significant differences between these curves (log-rank test) were obtained between the LWI with BT group vs the LWI with BA group (p = 0.001). Particularly for the patients in the LWI with BT group, the median time:18 hours, 95% CI: (14.53–21.47) was significantly longer time to first analgesic request compared to LWI with BA group median time: 6 hours, 95% CI: (4.48–7.71) (p = 0.001). The cumulative proportion of patients not requesting analgesia at 12 h after surgery in the LWI with BA group was 45% compared to 70% in the LWI with BT group. A Cox proportional hazards model for time to first analgesic request adjusted for covariate (duration of surgery, the experience of the surgeon, the experience of the Anaesthetist who did the block, study group, sex, age, type of skin incision, and educational status of the respondents), after multivariate analysis the presence of all covariates with Cox regression had no significant association with time to first analgesic request except for the study groups. In the LWI with BT group, 64% of patients did not request analgesia, whereas in the BA group, 2.81 times more request analgesia over 24 hours than in the BT group, with an adjusted hazard ratio for LWI with BT (p < 0.001, adjusted hazard ratio (AHR) = (0.36, 95% CI ((0.22–0.58)) and LWI with BA p < 0.001, adjusted hazard ratio (AHR)= (2.81, 95% CI ((1.74–4.60)).

Comparison of cumulative analgesia consumption among the two groups

Tramadol and diclofenac were the most commonly used types of postoperative analgesics over 24 hours in the study respondents. Their cumulative median (IQR) was also higher 100 (50–100) and 75 (75–75) in the LWI with BA group compared to 0.0 (0–50) and 0.0 (0-68.75) in the BT group, respectively, with p < 0.001. The other types of postoperative analgesics were not statistically significant among the two groups (Table 4).

Table 4
Comparison of total postoperative analgesia consumption over 24 hours between the two groups among adult patients who underwent lower abdominal surgery at Wolaita Sodo University, Teaching & Referral Hospital, from February 28 – may28, 2020.

Total analgesia consumption within 24 hours in milligram	LWI with BT	LWI with BA	P-Value
Tramadol IV(Intravenous)	0.0 (0–50)	100 (50–100)	< 0.001*
Diclofenac IM(Intramuscular)	0.0 (0-68.75)	75 (75–75)	< 0.001*
Values are presented as: =median (IQR), Mann-Whitney test, *=statistically significant			

Incidence of postoperative complications between the two groups

The common incidence of postoperative complications in the recovery room and ward over 24 hours between the two groups was nausea and vomiting, which was 1.7%. The proportions of patients with

nausea and vomiting were lower (0%) in the LWI with BT group compared to (1.7%) in the BA group with p = 0.174. The incidence of hypotension and desaturation did not differ between groups (Table 5**).**

Table 5
Postoperative complications over 24 hours in two groups among adult patients who underwent lower abdominal surgery at Wolaita Sodo University, Teaching & Referral Hospital, from February 28 – may28, 2020.

Postoperative complications within 24hours n (%)		**LWI with BT**	**LWI with BA**	**Total complication**	**p-value**
Hypotension		2(1.6%)	6(5%)	8(6.7%)	0.272
Nausea vomiting		0(0%)	2 (1.7%)	2(1.7%)	0.174
Desaturation	> 90%	60(50%)	60(50%)	120(100%)	1.000
	< 90%	0(0%)	0(0%)	0(0%)	
Hint: n (%) - number (proportion), chi-square test					

Discussion

The study demonstrates that the median (interquartile range) of postoperative pain severity (NRS) score was the same (0.0(0–0) in the exposed and non-exposed groups over 12 hours, but in the proceeding hours of the 12th, 18th and 24th hours in the exposed group, the median (IQR) of pain severity was 1.0(0–5) compared to 7(5–8), 6(5–6) and 5(4–6) in the non-exposed group with (p < 0.001) in the recovery room and ward, respectively.

The results of this study is in line with study done by Honarmand A et al.., local wound infiltration with a mixture of tramadol with bupivacaine, showed a lower postoperative pain severity score than in the control group(33). The mean (SD) of pain severity scores at the 18th and 24th hours in the exposure group were 0.11 ± .0 and 0.1 0 ± 0.4 compared to the nonexposed group (1.2 ± 1.5 and 1.5 ± 1.2) with p < 0.001, respectively. The possible explanation for the pain score difference is due to pain management practice in the study setup and the difference in medication used.

Our study also showed a comparable result with Sachidananda R et al.., study findings showed that the mean (SD) of the postoperative pain score at the 6th and 12th hours in the treatment group was 2.10 ± 0.71 compared to the control group (2.60 ± 0.97), with a statistically significant difference of p = 0.0484, but at the 18th and 24th hours, the mean (SD) of the postoperative pain score was 2.07 ± 0.64 and 2.07 ± 0.37 in the non-exposed and exposed groups, respectively(32), with P = 0.8825, which cannot meet with our study result. The possible explanation for this contradictory result due to factor such as Sociodemographic and perioperative variables can contribute to postoperative pain severity, if not correctly taken into account. In our study, confounding factors, such as experience of surgeon, type of skin incision, age, gender, duration of anaesthesia, experience of anaesthetist who did the block, intraoperative analgesia given and induction with ketamine, were all comparable between the groups, and

BMI > 30 kg/m2 was excluded from the study; thus, the difference in pain severity, time to first analgesic request and analgesic consumption between groups was likely due to BT and BA in the exposure groups.

In this study, the median time for the first analgesic request was significantly prolonged in the LWI with BT group, median time: 18 hours, 95% CI: (14.53–21.47) compared to time to first analgesic request in the LWI with BA group median time: 6 hours, 95% CI: (4.48–7.71) with p = 0.001. Similarly, another study showed that the mean time to first analgesic request after LWI with BT for lower abdominal surgery was 386.17 ± 233.84 min compared to 192.50 ± 134.7 in the LWI BA group with P = 0.0002(32). However, the small discrepancy in terms of the actual figure and duration might be explained by differences in perioperative patient management, study method and population. These findings were also supported by other studies(29, 34, 35).

In contrast to our finding, Kumar M et al .., demonstrates that the addition of tramadol to 0.25% bupivacaine in CPCB does not improve either the quality or the duration of postoperative analgesia over 24 hours (p > 0.05) (36). The possible explanation for this contradictory finding may be design differences, variability in nurses' responses to pain requests and the type of surgery performed.

Our findings also showed that the incidence of postoperative complications, such as nausea and vomiting, hypotension and other postoperative vital signs, among the two groups was not significant. Although the postoperative proportion of nausea and vomiting was higher (1.7%) in the LWI with BA group than in the BT group (0%), there was no statistically significant difference (p = 0.174).Similarly study done by Joshi V et al …, showed that the incidence of postoperative nausea and vomiting over 24 hours in the LWI with BT (exposed) group was 20% lower than that in the non-exposed group (29.9%) (p = 0.447)(32).

Conclusion

The combination of tramadol with bupivacaine has prolonged analgesia time and is effective for postoperative analgesia and reduces postoperative analgesia consumption over 24 hours compared to wound site infiltration with 0.25% bupivacaine alone for lower abdominal surgeries.

Abbreviations

CHSM: College of Health and Medicine

ERC: Ethical Review Committee

BA: Bupivacaine Alone

BT: Bupivacaine with Tramadol

ASA: American Society of Anesthesiologist

LWI: Local Wound Infiltration

CPCB: Continuous Psoas Compartment Block

BMI: Body Mass Index

IASP: International Association for the Study of Pain

NRS: Numeric Rating Scale

IQR: Interquartile Range

SD: standard deviation

AHR: Adjusted Hazard Ratio

CI: Confidence Interval

COR: Crude odds ratio

AOR: Adjusted odds ratio

Declarations

Ethics Approval and Consent to Participate

The study was conducted after obtaining ethical clearance from the ethical clearance committee of the School of Anesthesia, Wolaita Sodo University, College of Health Science and Medicine through ethical letter with protocol number CHSM/ERC/09, written on February 26, 2020. The study was also done as per the declaration of Helsinki. The Letter was provided to each hospital administrative body to get their informed consent for data collection before starting to collect data. The advantage and purpose of the study was explained to the patients, and the data collector obtained written, informed consent from each participant. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. Participants' involvement in the study was based on voluntary bases. Participants who were not willing to participate in the study and those who wished to quit their participation at any stage were informed to do so without any restriction.

Consent for Publication

This part is not applicable because the manuscript contains no any individual person's data in any form (including individual details, images or videos).

Availability of Data and Materials

All data and materials in this manuscript are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests.

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Wolaita Sodo University, but the funder has a role in publishing this research.

Author contributions

TD and MS contributed to the conception, design of the study, data acquisition, analysis and interpretation of the data, and drafted and revised the manuscript. AA, AD, and KE contributed to the conception and assisted in the initial design of the study, analyzed and interpreted the data and critically revised the manuscript. Both authors read and approved the final manuscript.

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Figures

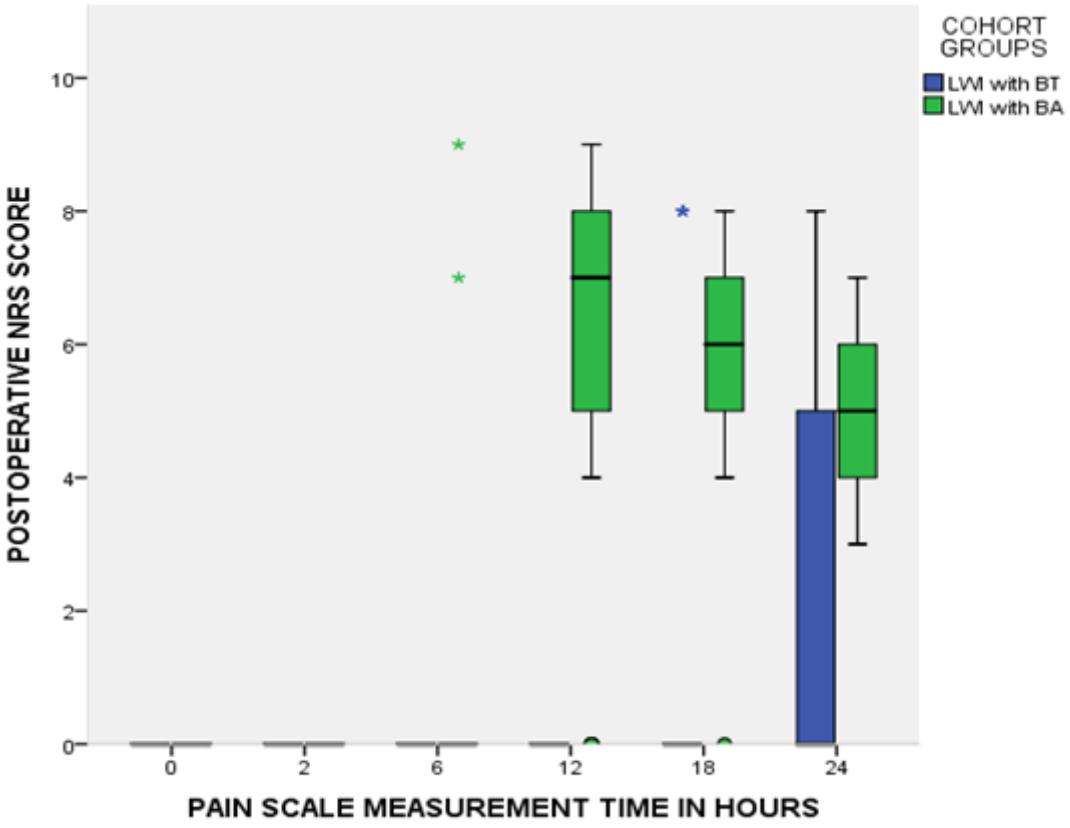

Figure 1

Comparison of postoperative pain severity between local wound infiltration of Bupivacaine with Tramadol and Bupivacaine Alone groups by using 11-point NRS Score (0-10).

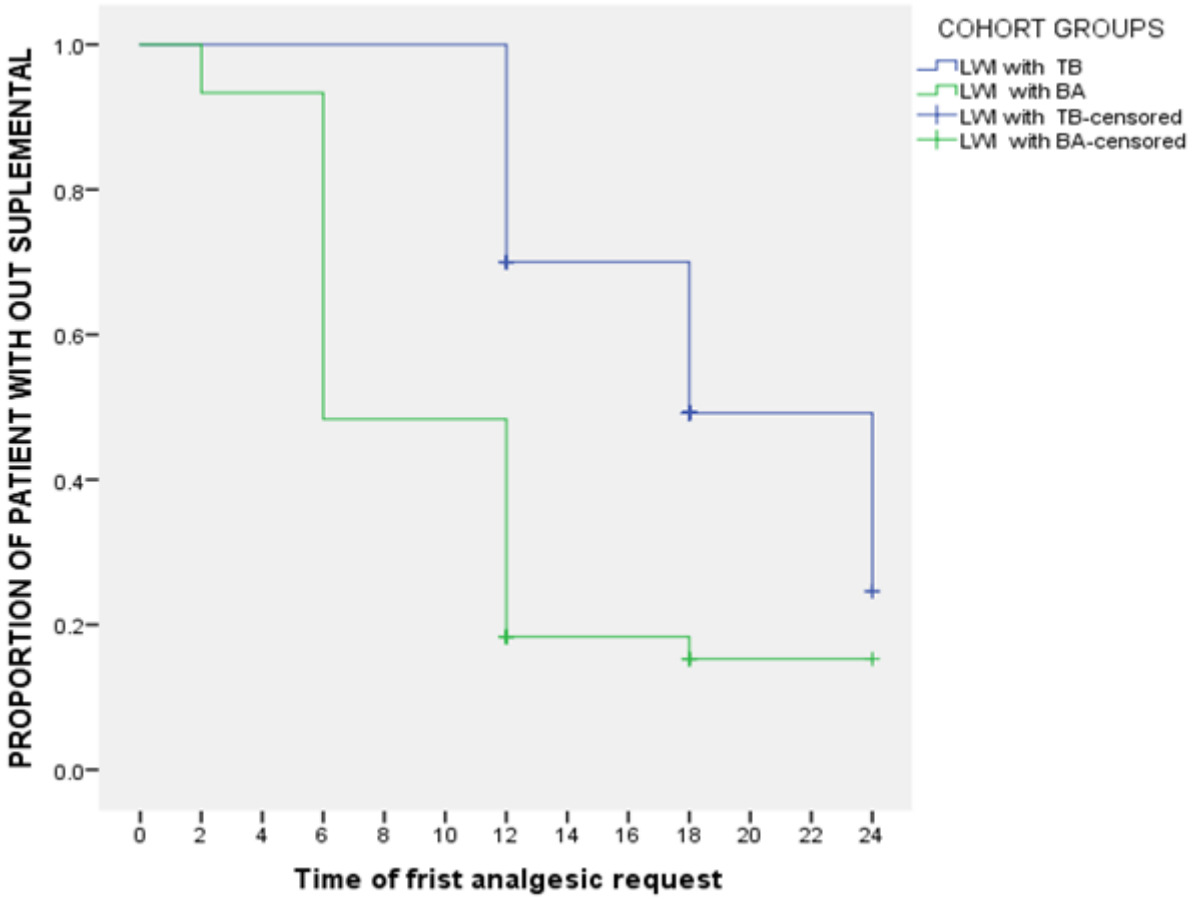

Figure 2

Kaplan Meier Survival Curve plot for Time to first analgesia request after local wound infiltration of Bupivacaine with Tramadol and Bupivacaine Alone groups.