

Comparison of Bilateral Ilioinguinal-Iliohipogastric Nerve Block Versus Transverses Abdominis Nerve Block for Post-Operative Pain Management for Parturient Undergoing Elective Cesarean Section in Dilla University Referral Hospital, Ethiopia, A Randomized Controlled Trial

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Research article

Keywords: Ilioinguinal, iliohypogastric, TAP, Ethiopia

Posted Date: June 3rd, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-31017/v1>

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Abstract

Background: Pain is one of the most common complaint and cause of distress in the perioperative period. The postoperative pain after cesarean section is believed to be of mild to moderate intensity lasting for up to 72 hours. Apart from patient preferences, number of factors affect choices of analgesia in a resource limited setting like Ethiopia. Availability of resources, a trained man power and inter-individual variation in pain threshold were among a factor affecting analgesia choices. Thus, this study aims to compare TAP block versus II/IH block for post cesarean delivery analgesia in resource limited areas where ultrasound guided block is not practiced.

Method: A randomized controlled trial study were conducted in Dilla University teaching and referral Hospital found in southern Ethiopia. A pregnant women scheduled for elective cesarean section was randomized to either TAP block (n = 36) or II/IH block (n = 36) for postoperative pain management. Sample size were calculated using a G-power version 3.1.9.2 getting a total of 72 participants. Pain severity, total tramadol consumption and time to first analgesia request were asses' during the first 72 hour postoperatively. Many Whitney U-test and independent t-test were used based on distribution of data. A Kaplan Meier analysis was to asses' proportion of patients who did not require analgesia for 48hour follow up period.

Result: The cumulative median tramadol consumption over 48hour were 100 mg for TAP group and 150 mg for II/IH (p = 0.018). The median tramadol consumption at 24hr. and 36 hr. were also lower in TAP group compared to II-IH (P < 0.05). There is no statistically significant difference between groups regarding time to first analgesia request (p > 0.05). The median pain score at 36hr. and 48hr. were lower in TAP group (3 and 4) compared to II-IH group (4 and 6) respectively (p < 0.05). There is no statistically significant difference between groups regarding the postoperative side effects and complication.

Conclusion: Both II-IH and TAP block has comparable analgesic efficacy during the first 24hr. TAP block has a longer analgesic effectiveness compared to II-IH with an effect lasting for 48hr.

Background

Pain is one of the most common complaint and cause of distress in the perioperative period. It is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"[1]. Despite the recommendation by WHO, the rate of cesarean section was increasing in developing countries including Ethiopia (2–5). The postoperative pain after cesarean section is believed to be of mild to moderate intensity lasting for up to 72 hours. The development of chronic pain, prolonged hospitalization and compromised breast feeding were among the consequence of untreated acute pain [6] [7].The key to facilitate early postoperative movement, better infant care and reduction of postoperative complication were significantly relied on effective postoperative management [3]. Apart from patient preferences, number of factors affect choices of analgesia in a resource limited setting like Ethiopia. Availability of resources, a trained man power and

inter-individual variation in pain threshold were among a factor affecting analgesia choices. The use of a conventional opioid and NSAIDs have never been without side effects for post cesarean section mothers. Abdominal field block were among alternative techniques for postoperative pain management after cesarean section. Ultrasound guided Ilioinguinal-iliohypogastric nerve block (II&IH) and transverses abdominis plane block (TAP) were proven effective postoperative pain management alternative after it has proven against placebo[8–10]. The practice of ultrasound guided nerve block is limited in a resource constrained area hence a landmark technique were practiced. The choice between Ilioinguinal-iliohypogastric nerve block (II&IH) and transverses abdominis plane block (TAP) is merely based on practitioner preference hence, limited literatures comparing the two. Thus, this study aims to compare TAP block versus II/IH block for post cesarean delivery analgesia in resource limited areas where ultrasound guided block is not practiced. Specifically, time to first analgesia request, total tramadol consumption and pain score were compared between groups.

Method And Materials

Study design and patients

A parallel randomized controlled trial study were conducted from September 2017 – August 2018 in Dilla University teaching and referral Hospital found in southern Ethiopia. Ethical clearance was obtained from Dilla University institutional review board. Verbal and written informed consent was obtained from each participants. The study was prospectively registered on pan African clinical trial registry with unique identification number of PACTR201707002432259. The study was reported in line with 2010 consort guideline for clinical trial. A pregnant mother ASA II aged 18–45 were included. Pregnant mothers with hypertensive disorders, progressive neurologic disease, spinal anesthesia converted to general anesthesia, weight < 50 kg or > 100 and a mother with peptic ulcer disease were excluded from the study. Seventy five pregnant mother were assessed for eligibility and only three refused to give a consent. Seventy two pregnant mother scheduled for elective cesarean delivery were randomized to either ilioinguinal-iliohypogastric nerve block or transverses abdominis nerve block after skin closure at the end of surgery. A sealed envelope randomization technique by anesthetist who did not participate in the research or patient care.

Sample size determination, sampling and randomization

Sample size was calculated using G-power statistical software v3.1.9.2 based on a previous placebo controlled study by McMorrow et al and Elizabeth A. Bell et al. (11, 12) in their RCT study, McMorrow et al found that the total 24hr morphine consumption after TAP block was 29 mg ± 11.45 mg. Similarly Elizabeth A. Bell et al. found the 24hr morphine consumption after II/IH nerve block to be 48 mg ± 29 mg. Using the two independent mean formula with 5% level of significance and power of 95%, G-power v3.1.9.2 statistics gives a minimum of 36 participants per group counting to a total of 72 participants. A systematic random sampling method was used to select study participants. Random assignment to either group T (TAP block) or group I (II-IH block) was done using computer generated random numbers

table by anesthetist who did not take part in the study. Clear explanation about the procedures was made before allocation & patients were not aware to which group they were assigned. Enrolment and allocation of study participant were shown in Fig. 1.

Anesthesia management protocol and clinical outcome measurement

All patients were fasted for 8 hours for solid food & 2 hours for clear fluid. All patients were pre-medicated with 50 mg IV of ranitidine before 30 minutes, 10 mg IV metoclopramide before 10 minutes & 0.1 mg/kg of dexamethasone before performing a spinal anesthesia. Noninvasive monitors such as an electrocardiogram, noninvasive blood pressure (BP), and pulse oximeter were connected. Before performing a spinal anesthetic 10–15 ml/kg of crystalloid was co-loaded to parturient using a standard fluid infuser. Following this under strict aseptic technique, local infiltration of the entry point using 2 ml (40 mg) of 2% plain lidocaine was performed before placing a standard spinal needle. Subarachnoid block was performed using a 25G standard spinal needle, with patient on sitting position through the midline approach using 2 ml (10 mg) plain bupivacaine & 25 mcg fentanyl. Immediately after the spinal anesthesia patient was positioned on supine position and a pillow inserted under the right hip or bed tilted 15 degrees left to prevent aortocaval compression. Level of block was checked (alcohol drips for autonomic, pin prick for sensory & Bromage scale for motor) and incision was allowed when a sensory level of T6 is reached. Only patients with successful spinal block (sensory block of T6) are included in this study.

Patients' hemodynamics (SpO₂, HR, ECG and BP) were measured every 5 minutes and recorded every 10 minutes. If mean arterial pressure of patient drops below 65 mmHg, & is not responding for fluids, a bolus of 5–10 mg ephedrine was given & with repetition as needed up to a maximum of 20 mg. Oxygen was delivered using nasal prong at flow rate 2–3 L min⁻¹ during the intraoperative and recovery periods. Following closure of the skin, using antiseptic solution was prepared in the respective areas to do either TAP or II-IH nerve blocks based on which intervention they were randomized. Patient was under the influence of spinal anesthesia and will not be aware of sensation to the area and a screen was applied above the umbilicus so as to prevent patient looking area of block.

For group T (TAP block group) a landmark technique TAP block was performed as described by McDonnell et al [13]. The block aims at the lumbar triangle of Petit which is bounded superiorly by costal margin, inferiorly by iliac crest, anteriorly by the external oblique muscle and posteriorly by the latissimus dorsi. Needle insertion point was 2 cm cephalad to the iliac crest. Using 22G blunted needle. Up on insertion of the needle there will be feeling of double pops (loss of resistance) as the needle pass through the external oblique and internal oblique muscles, which signifies the correct location of needle, following which a 20 ml of local anesthetic (0.25% bupivacaine) is deposited in the fascial plane between the internal oblique and transversus abdominis muscle. This was repeated similarly for the other side.

For group I (II-IIH) 16 ml of local anesthetic (0.25% bupivacaine) per each side was injected at a needle entry point 2 cm medial to anterior superior iliac spine (ASIS). A 22G blunted needle is used and upon insertion of the needle an initial click (pop) sound or a loss of resistance will be felt as the blunt needle passes through the external oblique muscle sheath and 8 ml of 0.25% Bupivacaine is injected in a fanwise fashion to block the ilioinguinal nerves. The needle was further advanced and another pop sound or loss of resistance is felt upon passing the internal oblique muscle sheath and additional 8 ml volume of local anesthetic is injected in a similar fashion to the previous one, to block the iliohypogastric nerves. This procedure was repeated on the other side of the lower abdomen in the same manner [14]. To avoid intravascular injection aspiration of the syringe for blood will be performed every 5 ml injection of the local anesthetic or following change in the direction of needle.

Tramadol consumption was recorded every 12 hour interval. Total cumulative 48hr. tramadol consumption was the primary end-point. Secondary outcomes include; post-operative pain score both at purposeful movement and rest, first analgesic request time and side effects. 48hr. Pain score was recorded using a worldwide validated tool called the numerical pain rating scale (NRS) score both at rest and on movement (light compression of wound dressing and purposeful flexion of the thigh at the hip). Pain score was recorded at 0, 4, 8, 12, 24, 36 and 48 hours. During each visit patients were asked for any kind of pruritus, nausea vomiting, and sedation. Patients were told to record their pain intensity at any time and request analgesics. Pain score was labeled as 0 if there was no pain and 10 is considered as the worst pain ever experienced. Any form of sedation was scored using a sedation score of 0 to 3 (0 = awake and alert, 1 = quietly awake, 2 = asleep but easily arousal, 3 = deep sleep & only responding to painful stimulus). Pruritus was graded as mild, moderate or severe correlating with scores of 1, 2, and 3 respectively. The patients received standard analgesia according to obstetric department protocol consisting IM diclofenac 75 mg 8 hourly, first dose was given on arrival to PACU. IV tramadol 50 mg was used as a rescue analgesia on patient demand. Despite our protocol depicts the use of 1 mg/kg IM Pethidine for further inadequacy in administered analgesia within 30 minutes or breakthrough pain there were no such requirements for further pain killer in our cohort. Patients were considered as sedated if a sedation score is more than 2 and oxygen by nasal prongs was protocolled. Intra-operative antiemetic were not used routinely, but if needed 0.1 mg/kg ondansetron was the protocol.

Data analysis and interpretation

SPSS version 20 were used for analysis. Normality of data was checked using the Shapiro-Wilk normality test, Q-Q plots and histograms. Quantitative categorical variables were analyzed using chi-square or Fisher's exact test. Continuous variables were analyzed using independent t-test for normally distributed data or Mann Whitney U-test for irregular distribution. A Kaplan Meier analysis was done to see if there were differences based on the time of survival until an initial request of analgesia and to determine the proportion of patients who did not require analgesia for 48hour follow up period. Normally distributed data are presented as mean \pm SD, and non-normal equivalent are presented as median (interquartile range), and categorical data are presented as raw data and frequencies.

Result

A total of 72 parturient were enrolled in the current study. Mean age was 27.33 ± 3.74 for group T and 27.27 ± 4.69 for group I. According to the 2018 modified ASA physical status classification all patients fall in the ASA II category. With regard to the number of previous C-sections majority of the participants were having their first C-section while 13.9% were having their second operative delivery and a single parturient was having third operative delivery in group T. Table 1

Table 1
Comparison of demographic and clinical data of cases between 2 groups

Demographic data	Group T	Group I	p-value
Age (years)	27.33 ± 3.74	27.27 ± 4.69	0.956
BMI (kg/m ²)	27.78 ± 3.08	27.18 ± 2.17	0.348
Previous C-section (%)	14 (38.9)	15 (41.7)	
0	16 (44.4)	16 (44.4)	
1	5 (13.9)	5 (13.9)	
2	1 (2.8)	0	
3			
Baseline HR (beats/min)	88.36 ± 9.98	85.61 ± 7.80	0.197
Baseline MAP (mmHg)	87.57 ± 7.70	87.45 ± 5.03	0.938
Duration of surgery (min.)	30 (25–40)	30.5 (27.75–35)	0.338
• Results are expressed either with mean \pm SD or median (IQR)			

Total analgesic consumption

A Mann-Whitney U test was run to determine if there were differences in tramadol consumption at 12, 24, 36, 48 hour intervals and cumulative 48 hour. Distributions of tramadol consumption for both TAP and II/IH were similar as assessed by visual inspection of the population pyramids.

Interval tramadol consumption was not statistically significant at 12 & 48 hours with $U = 654.5$, $Z = 0.086$, $P = 0.931$ & $U = 700.5$, $Z = 0.838$ & $P = 0.402$ respectively. However, median tramadol consumption at 24 hour were 0.0 mg for TAP & 50.0 mg for II/IH. This was found to be statistically significant with $U = 832.0$, $Z = 2.310$, & $P = 0.021$. Similarly at 36 hour median tramadol consumption was 25 & 50 mg for TAP & II/IH groups respectively. This was statistically significant with $U = 855.0$, $Z = 2.791$ & $P = 0.005$.

Overall the cumulative median tramadol consumption over 48hour were 100 mg for TAP group and 150 mg for II/IH group. This was statistically significant between TAP & II/IH groups, with $U = 853.5$, $Z = 2.367$, $P = 0.018$. (Table 1)

Table 2
Interval and overall cumulative tramadol consumption

Time interval	Group T	Group I	p-value
12 hour	0 (0–50)	0 (0–50)	0.931
24 hour	0 (0–50)	50 (50–50)	0.021 *
36 hour	25 (0–50)	50 (50–50)	0.005 *
48 hour	50 (50–50)	50 (50–50)	0.402
Cumulative 48 hour	100 (50–150)	150 (100–200)	0.018 *
• Results expressed as median (IQR), * statistically significant ($P < 0.05$)			

Time to first analgesic request time

Kaplan-Meier survival analysis (Kaplan & Meier, 1958) was conducted to compare the different interventions for their effectiveness in preventing analgesia requirement. The percentage of censored cases present in the TAP 7(19.4%) and II/IH 3(8.3%) intervention groups was not similar. Participants who underwent TAP block had a median analgesic request time of 1200.0 (95% CI, 861.9 to 1538.1) minutes. This was slightly shorter than the groups receiving II/IH nerve block, which had a median time to first analgesic request of 1285.0 (95% CI, 1245.31 to 1324.69) minutes. A log rank test conducted to determine if there were differences in the survival distributions for the two types of interventions & was not statistically significantly different, $\chi^2 (1) = 0.467$, $p = .494$.

From the Kaplan Meier analysis survival curve, we can see that for almost half of the follow-up period (first 24 hour), the II/IH group has a better profile to tolerate pain and had high threshold to request for additional analgesia. However, after this point the TAP group showed a better profile, yet the overall survival function shows that there was no significant difference between groups who survived (censored) the whole 48hours without the request of additional analgesia.

Post-operative NRS score at rest and on purposeful movement

A Mann-Whitney U test was run to determine if there were differences in pain score (NRS) between TAP and II/IH groups both at rest and on purposeful movement.

At rest distributions of the pain scores (NRS) for TAP and II/IH groups were similar, as assessed by visual inspection. Median pain score was not statistically significantly different between TAP and II/IH groups at

4, 8, 12 and 24 hours ($P > 0.05$). However, median pain score for TAP (median = 3.0) and II/IH (median = 4.0) was statistically significantly different at 36 hour interval with $U = 1,084.5$, $z = 5.035$, $p = < 0.0005$. Similarly the Median pain score for TAP (median = 4.0) and II/IH (median = 6.0) was statistically significantly different at 48 hour with $U = 1,137.0$, $z = 5.673$, $p = < 0.0005$.

Distributions of the pain scores (NRS) on purposeful movement for TAP and II/IH groups were similar, as assessed by visual inspection. At rest median pain score was not statistically significantly different between TAP and II/IH groups at 4, 8 and 12 hours ($p > 0.05$). However, it was statistically different between groups both at 24, 36 and 48 hour. Median pain score for TAP (median = 4.0) and II/IH (median = 4.0) was statistically significantly different at 24 hour with $U = 819.0$, $z = 2.066$, $p = 0.039$. At 36 hours median pain score for TAP (4.0) and II/IH (6.0) was statistically significantly different with $U = 1,050.0$, $z = 4.655$, $p = < 0.0005$. In a similar fashion pain score was statistically different at 48 hour between TAP (median = 6.0) and II/IH (median = 7.5) groups with $U = 1,121.0$, $z = 5.517$, $p = < 0.0005$.

Side effects/complications

Two patients complained only nausea from each group. More patients had had mild itching in the TAP group compared to II/IH group (15 Vs 9), yet there was no statistical significance difference between the groups. 1 patient was quietly sedated in the TAP group, but no patient had sedation in the II/IH group. No complications related to blind technique block was reported in our study. No patient in our study requested rescue anti-emetic treatment.

Table 3
Side effects

Side effect	TAP n (%)	II/IH n (%)	P – value
Nausea vomiting	34 (94.4)	34 (94.4)	1
• No symptoms	2 (5.6)	2 (5.6)	
• Only nausea			
Pruritus	21 (58.3)	27 (75)	0.211
• No itching	15 (41.7)	9 (25)	
• Mild itching			
Sedation	35 (97.2)	36 (100)	1
• Awake & alert	1 (2.8)	0	
• Quietly awake			

Discussion

The result of our randomized controlled trial showed that cumulative tramadol consumption was lower in TAP compared to II/IH group during the total 48 hours follow up period. Pain scores were similar between TAP & II/IH groups until 24 hours both at rest and on purposeful movement. However, at 36 & 48 hour intervals pain score was lower in TAP group with a statistically significant result. A differences in time to first analgesic request, proportion of pruritus, nausea vomiting and sedation score were not statistical significant.

Post-operative tramadol consumption was found to be comparable at 12 ($p = 0.931$) & 48 ($p = 0.402$) hour intervals. However, at 24 & 36 hour intervals median tramadol consumption was lower in TAP group compared to II/IH groups with $p = 0.021$ & $p = 0.005$ respectively. On top of this cumulative 48 hour median tramadol consumption was lower in TAP group with $p = 0.018$. Though there are limited research on a landmark techniques, our finding is in line with L. Vamsee Kiran, et al, where interval and cumulative 24 hour tramadol consumption were lower in TAP group compared to II/IH group after an ultrasound guided block in patients who underwent cesarean section under spinal anesthesia ($p = 0.00$) [15]. Similarly, C. Aveline et al, in their ultra-sounded guided block comparison between TAP & II/IH nerve block for inguinal day case surgery found that postoperative morphine requirements were lower during the first 24 h in the TAP block group ($p = 0.03$) [16]. A nearly similar result was found by Bessmertnyj AE et al from Russia in their prospective randomized study where they concluded that both TAP & II/IH were comparable in terms of postoperative opioid consumption after caesarean delivery for the first 24 hours [17].

In contrast to our finding, retrospective analysis of TAP Vs. II/IH block for post cesarean delivery pain after spinal – epidural by Yulu Jin et al, found that cumulative morphine consumption were comparable between groups until 12 hour (all $p > 0.05$). Yet, at 24 & 48 hour II/IH group consumed less morphine than their counter parts with $p < 0.05$ and $P < 0.001$ respectively. Study design (non-randomized, retrospective), the use of intrathecal morphine & blocks done with ultrasound guided technique could have contributed for the difference seen to our finding [18]. Similarly a cohort by Seid et al, in a study done in Gondar, Ethiopia found that 24 hour total tramadol consumption was lower in II/IH group compared to TAP group ($P = 0.009$) [19]. Difference in study design and different people performing the blocks in their cohort could explain this discrepancy. In addition the use of diclofenac as part of multimodal analgesia in our case for control of visceral pain could have contributed for this difference.

Our study also demonstrated that TAP block had a superior analgesic benefit beyond 24 hour as evidenced by interval and cumulative tramadol consumption was lower. TAP is accustomed to provide prolonged (48 hour) analgesia in other placebo controlled studies too [20–22]. The reasons for the prolonged duration of analgesic effect after TAP blockade may relate to the fact that the TAP is relatively poorly vascularized area, and therefore drug clearance may be slowed [31]. A study by Abdellah et al, found that posterior TAP block, have prolonged effect than a lateral TAP in terms of lower post-operative morphine consumption and pain score until 48 hours post-operative ($p < 0.05$) [23].

Regarding time to first analgesic request there is no statistically significant difference between TAP and II/IH groups with median time of 1200.0 (95% CI, 861.9 to 1538.1) & 1285.0 (95% CI, 1245.31 to 1324.69) minutes respectively ($\chi^2(1) = 0.467, p = .494$). Similarly Yulu Jin et al [18] didn't find statistically different result in terms of time to first analgesic request between groups. In contrast to our finding Seid et al and Bessmertnyj AE et al, found that time to first analgesic request were longer in II/IH group compared to TAP group for post cesarean delivery patients with $P < 0.05$. [17, 19]. The difference in study design in the former & technique of block (Ultrasound guided) in the later could have contributed for this difference. Compared to the above mentioned researches our RCT showed that the time to first analgesic request time was longer for both groups. The use of diclofenac on TID basis as part of multimodal analgesia for visceral pain control might have contributed for this.

In our study median pain score (NRS) at rest & on purposeful movement were similar between groups at 0, 4, 8, 12 and 24 hours post operatively. However, at 36 & 48 hour intervals was pain scores were lower in TAP compared to II/IH group both at rest & on purposeful movement ($p < 0.0005$). Seid et al, Anatoli Stav, et al & Sofiene Ben Marzouk et al found no difference in NRS score between groups both at rest and on movement during their 24 hour follow up for post cesarean section pain ($P > 0.05$) [19, 24, 25]. Our result is also supported by a study comparing TAP with IINB + wound infiltration for post-operative analgesia after inguinal surgery in adults, did not found significant difference in pain score between groups ($P > 0.05$) [26]. In contrary to our finding two studies comparing intrathecal morphine to TAP and II/IH for post cesarean section, did not find differences in pain score at 36 & 48 hour interval [27, 28]. Similarly our result is in contradiction with a study done by Faiz SHR et al, on patients undergoing open inguinal surgery where patients who received IINB block who expressed less pain at rest (4, 8, and 12 hours) & on movement 48 hours after the nerve block [29]. Different population and method of block (blind Vs ultrasound) may have contributed for the discrepancy.

The proportion of patients who had either nausea vomiting, pruritus or sedation were similar between groups in our study ($P > 0.05$). On top of this there were no request of anti-emetic medication in any case. In the same way C. Avelin et al also did not find any differences in terms of PONV and ondansetron consumption (5.9% vs 9.3%, $p = 0.69$) between TAP and II/IH after day case open inguinal surgery [30]. In contrast to our result, Ghassan E et al, found that Nausea scores were higher in patients who too intrathecal morphine group than were those in the TAP group ($P = 0.02$) [24]. The use of a short acting opioid (fentanyl) for intrathecal use in our patients might not have the aforementioned side effects as compared to morphine which is more potent and long acting. Additionally, our strict protocol of dexamethasone administration might have contributed to the fact that less patients are experiencing in both groups and had not requested anti-emetic during the 48 hour follow up. Our action was supported by Anatoli Stav et al, who concluded that the use of prophylaxis for PONV was effective in their RCT [28].

In summary both ilioinguinal-iliohypogastric and transverses abdominis nerve block were equally effective in decreasing post-operative pain after cesarean section, total tramadol consumption within 24 hr. TAP block has achieved longer analgesic duration compared to Ilioinguinal-iliohypogastric nerve block.

Lack of adequate literatures and the use of landmark techniques for the abdominal nerve block is among the limitation of the study

Abbreviations

ASA - American Society of Anesthesiologists, BMI - Body Mass Index, CI - Confidence Interval, C-section - Cesarean section, IASP - International Association of Study of Pain, II-IH - Ilioinguinal-Iliohipogastric, IINB Ilioinguinal Nerve Block, IV–Intravenous, NRS - Numeric Rating Scale, NSAID - Non Steroidal Anti-Inflammatory Disease, PACU - Post Anesthesia Care Unit, SPSS - Statistical Package for Social Science, TAP - Transverses Abdominis Plane

Declarations

Ethical approval and consent to participate: Ethical approval was secured from Dilla University College of Health Sciences and Medicine institutional review board. Participation in the study was on the voluntary and ability to give informed consent.

Consent to publish: Not applicable

Availability of data and material: Data is available and can be send us a supplementary document up on request at any time.

Competing interest: None

Funding: The project was funded by Dilla University

Author's contribution: SAW, ZAF, GM and NAB contribute to study conception, collected data, and performed statistical analysis. HMK, AE, contributed for study conception and prepared manuscript. SMK and DND performed statistical analysis. All the authors read the manuscript and approved the final submission.

Acknowledgement: We the authors want to acknowledge Dilla University who funded and supported us in the development of this research paper.

Research registration number: Registered on Pan African Clinical Trial Registry with the identification number of PACTR201707002432259

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Figures

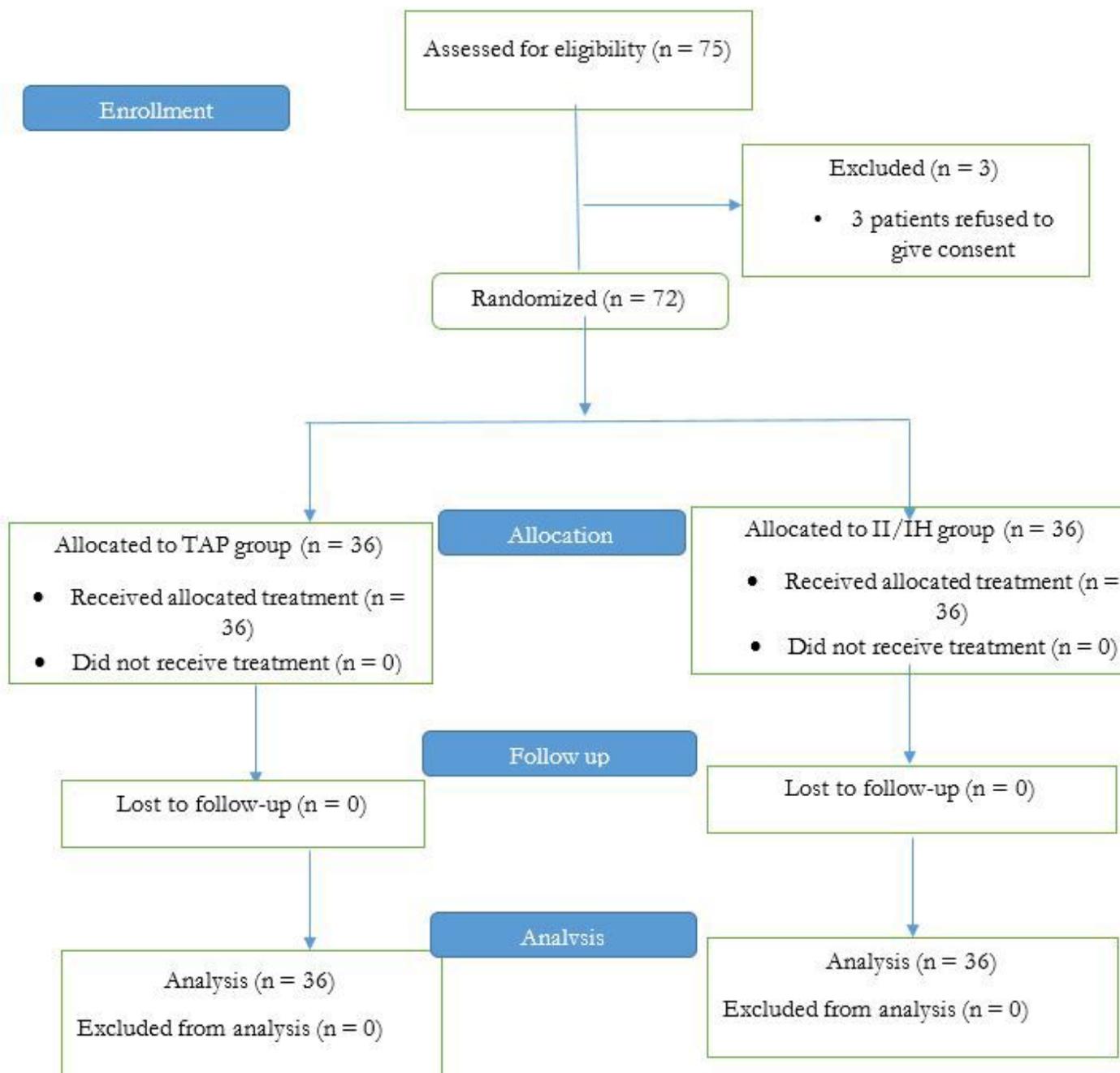


Fig 1: - CONSORT diagram of enrollment, allocation, follow-up, and data analysis.

Figure 1

CONSORT diagram of enrollment, allocation, follow-up, and data analysis.

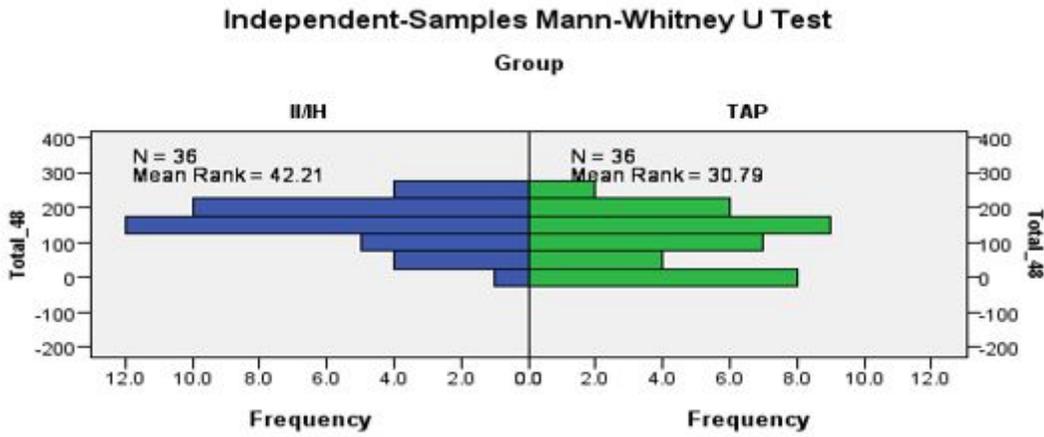


Figure 2

population pyramid for 48 hour total tramadol consumption

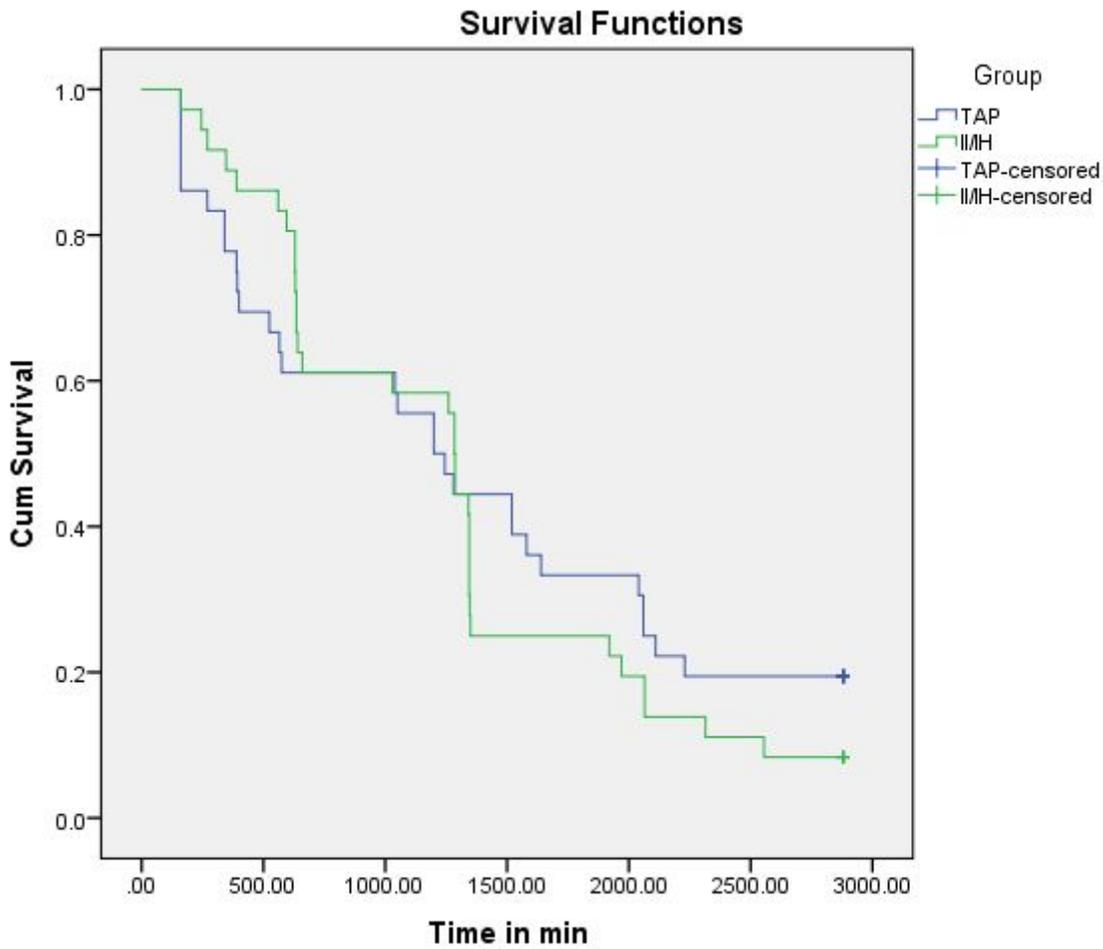


Figure 3

A Kaplan-Meier graph of the proportion of patients in each group over time who did not require supplemental tramadol (P = .494, log rank test).

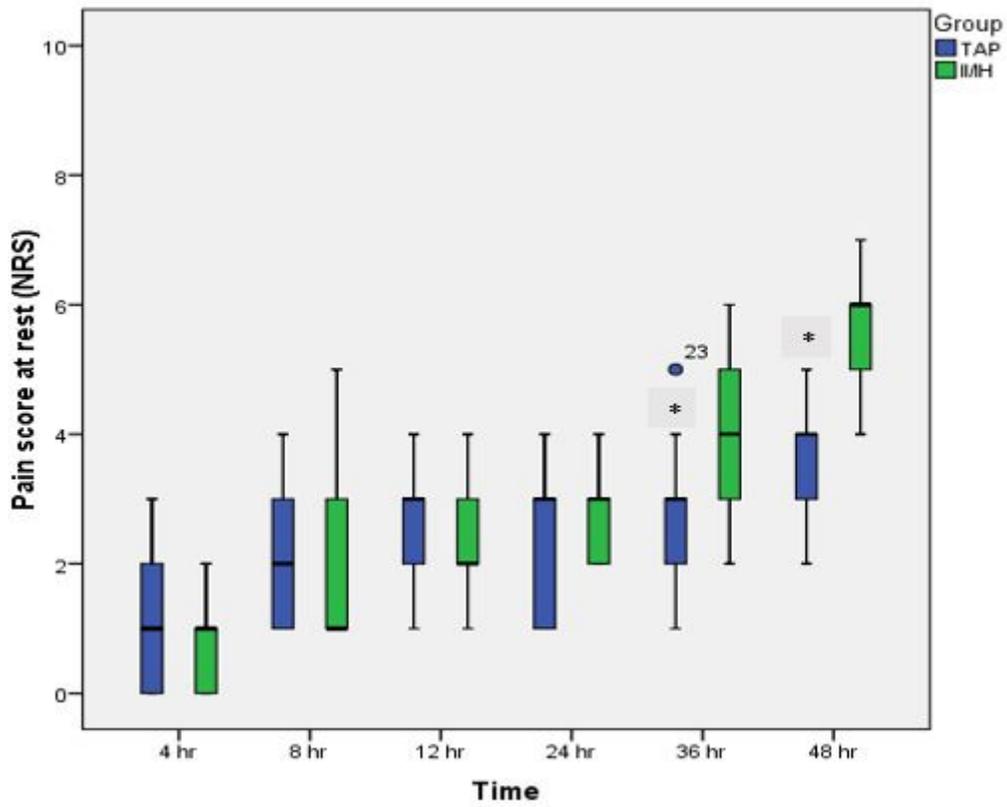


Figure 4

Numeric pain rating scores at rest

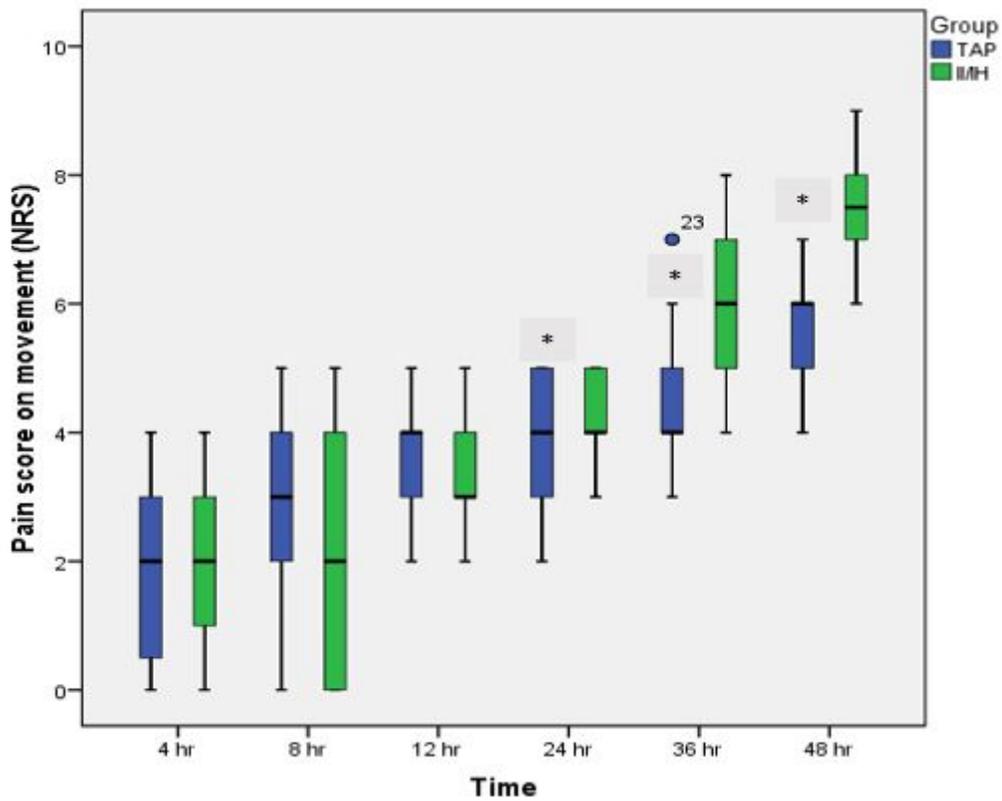


Figure 5

Numeric pain rating scores purposeful movement