

Research Article

Efficacy of Trans-Abdominis Plane Block for Post Cesarean Delivery Analgesia in Low-Income Countries: A Phase Three Feasibility Study

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Abstract

Background: Optimal pain control in a parturient woman undergoing caesarean section is essential for preventing complications and improving maternal satisfaction, early functional recovery, mother-baby bond and breastfeeding. Intentional pain assessment and adequate management to acceptable pain severity using multimodal methods can be achieved in low-middle income countries (LMICs).

Aim: Is to assess the efficacy of transversus abdominis plane (TAP) block and satisfaction post cesarean delivery analgesia at Kilimanjaro Christian Medical Centre in Low-Income countries.

Methods: The study of 72 participants for elective and emergency caesarean section. Blindly assigned into

two groups 41 (interventional group) and 31 (Control). Interventional received 30ml 0.25% bupivacaine in each side for postoperative analgesia and Control, which was treated by the hospital pain management approach. Patients randomization and demographic were recorded before surgery, then were assessed for numeric pain score at rest and, on physical activities also patients, satisfaction at 0hrs, 6hrs, 12hrs and 24hrs.

Results: Total of 72 patients were analyzed with pain score at 0hr, 6hr and 12hr. It was significantly low by about 50% with p-value (2 tail) of < 0.001 however at 24 hrs. was 0.272. And also had improved movement 0hr, 6hrs and 12hrs with p-value <0.001 as compare to control which was limited though was not significant in coughing. Satisfaction with pain management was 95.1% with no reported adverse event.

Conclusions: Trans Abdominis Plane block when used as part of multimodal is an effective in managing postoperative pain with less physical limitation and high patients' satisfaction in post caesarean section.

Trail registration: Register in Pan African Clinical Trial Registry (PACTR) with no PACTR202011815473426 on 12 November 2020.

Keywords

Trans Abdominis Plane block; Pain and Caesarean section.

1. Background

Caesarean section has been increasing worldwide, approximately 18.5 million are done annually. On average, at KCMC there are 13 deliveries a day, 49.2% are by C/S. With a gift of a baby(s) she needs to be

alert, comfortable and have early functional recovery. However, Pain is one of the immediate outcomes post-operatively with prevalence of > 78.4% (moderate to severe) [1-3]. When pain is not treated the following will be complication delay ambulation, increased risk of thromboembolic event, delayed wound healing, hemorrhages, stress, complicated hypertension and myocardial ischemia, shallow breathing -hypoxia, hypercarbia and respiratory infections. As consequence to child will reduce mother-child bond, difficulty breastfeeding (irritability, hypoglycemia and jaundice [4-6]. Studies done in Tanzania on this area reported that pain was under treated > 80% patients reported moderate to severe pain. Mainstay Labour analgesia is by Epidural technique but this is needing a lot of monitoring and associated with more complication, However at KCMC we use a multimodal postoperative pain management protocol with paracetamol, NSAID and Opioids. There are limited data in LMICs on regional anesthesia technique in managing pain after caesarian section. There are several never blocks which have been put to practice in managing pain after caesarian section such as epidural, Paravertebral block, Transversus abdominis plane block, is a technique that block T6-L1 nerve roots suppling anterior abdominal wall. The block was first described in 1993, practiced in 2001 and 2003 publication was first made. It was performed by deposited local anaesthesia between posterior aponeurosis of the internal oblique muscle and the aponeuroses of the transversus abdominis muscle [7]. Postoperative pain is still under treated in many areas in Tanzania and still a challenge to obstetrician and anesthesiologists. We would like to explore the feasibility of add TAP block on pain management to help us rewrite our protocol to introduce as part of multimodal for post cesarean delivery analgesia in our population with scarcity of

resources.

2. Methodology

2.1 Study design

A hospital based parallel design, randomized control trial done between 1st May to 31st June 2019 at KCMC referral hospital obstetrics operating room 1 and 2 and in the postoperative obstetrics wards. KCMC is a tertiary teaching hospital with catchment area of 15.7million people. It has bed capacity of 630 beds, 55 beds in obstetrics wards and an average 4 cesarean sections are performed per day (KCMC report, 2018). Approval was obtained from Kilimanjaro Christian Medical University College (KCMUCo) Research Ethics Review Committee with no 2394 and permission from the hospital. Written informed consent was obtained from all participants after they had received a complete description of the study. Trial was Register in Pan African Clinical Trial Registry (PACTR) with no PACTR202011815473426 on 12 November 2020.

2.2 Participants

2.2.1 Inclusion criteria: All participants classified as American Society of Anesthesiologists (ASA) II and III planned for cesarean section at KCMC during the study period were enrolled in this study.

2.2.2 Exclusion criteria: Participants with communication difficulties, obese, any contraindication to spinal anesthesia, allergic to amino-amide local anesthetics such as bupivacaine, coagulopathy, and local skin infection at needle puncture sites.

2.2.3 Interventions: All patients planned for

emergency or elective caesarian section meeting all inclusion criteria, 1st interviewed for demographic data, pre-loading with Ringers solution 500ml to 1000ml and pre op antibiotic given. They were all operated with spinal anaesthesia using Heavy bupivacaine (BUPICAN 0.5% Claris 4ml ampule) 10mg (2ml) of 0.5%. By picking envelope in the box participants were randomized into two groups Group A: tap block was performed intraoperative then pain management using KCMC standard. Group B: pain management using KCMC standard. Pain was assessed by independent blinded observer at the recovery 0hr, 6 12 and 24 hrs.

2.3 Procedure

At the end of the surgery, bilateral US (ultrasound) guided TAP block was performed by one of the investigators using either 30ml of 0.25% plain bupivacaine (BUPICAN 0.5% Claris 20ml vial) each side to make a total of 60ml (obtained by mixing 15 ml of 0.5% bupivacaine with 15 ml of normal saline). The procedure was performed using aseptic by non-touch technique. After preparing the skin with an antiseptic solution, a linear high frequency ultrasound probe (6-13 MHz, Sonosite M- Turbo©) placed transversely on the anterolateral abdominal wall between the iliac crest and the costal margin. Under US guidance, the three layers of muscles i.e. external oblique, the internal oblique, and the transversus abdominis were identified. A 22-gauge, sterile 115-mm Quincke spinal needle attached with flexible tubing to a syringe filled with saline was used to perform the block. The needle was introduced through the skin anteriorly in the plane of the ultrasound beam and advanced into the fascial plane between the internal oblique and transversus abdominis muscles with its tip lying in the mid axillary line. To assist with identifying these structures, the

probe was moved anteriorly to the rectus sheath and the fascial planes followed laterally. The final position of the probe was no further anterior than the anterior axillary line. Hydro dissection with saline (2-5 ml) was used to separate the fascial layers. After aspiration to exclude inadvertent vascular puncture, a test dose of 1-2 ml of the drug was injected to confirm the needle placement. After a negative test dose, 30 ml of the study solution was injected while closely observing for signs of toxicity (tinnitus, perioral numbness, metallic taste in the mouth, slurring of speech and mental status changes). TAP block was performed in a similar fashion on the opposite side. After completion of the procedure, patients were shifted to the recovery room before transferring them to the ward. Both the groups received a usual post-operative analgesic regimen.

2.4 Outcomes

2.4.1 Primary outcomes: Primary outcome was the pain score, which was assessed by using numerical rating scale (NRS) and function assessment by using pain scores on physical activities such as turning in bed, sitting, standing, walking and coughing. Patients were asked to rate the intensity of pain out of ten using NRS. It a 10-point numerical rating scale with end points representing the extremes of the pain experience: 0 = “no pain at all” and 10 = “worst possible pain”. The score was classified as mild pain when the score is 0 to 3, moderate pain when the score is 4 to 7 and severe pain when the score is 8 to 10 [6,7]. NRS is a recommended tool in most studies due to better responsiveness and compliance, easy to use and it is applicable in most setting compared with visual analog scale/verbal rating scale (VAS/VRS) [8]. It is difficult to assess pain objectively, although it can be assessed at rest and during movement by NRS to detect changes and difference in pain scores.

Functional assessment was assessed by functional activity including turning in bed, sitting, standing and walking was marked on a numeric rating scale ranging from zero = “no pain” to 10 = “maximum pain” [9]. Thus, all these two were assessed at 0hrs, 6hrs, 12hrs and 24hrs.

2.4.2 Secondary outcome: Patients satisfaction, question was adopted from the 5-point Likert scale ranging from 1= very dissatisfied to 5=Very satisfied. Participant were asked two questions on were they satisfied with information of TAP block and 24 pain management. It improves learners’ perceptions of readiness, knowledge and prioritization skills by 30% to 45% [10,11]. A pilot study was conducted with 20 patients to validate the data collecting tool and further categorized into 3-point Likert scale for easy analysis. And complications of TAP block were assessed such as LAST which was lighted headedness, blurred vision, Tinnitus, metallic test on the tongue, confusion and loss of consciousness. Patients satisfaction was assessed at 24hrs and complications were assessed all the time up to 24hrs.

2.4.3 Criterial for stop intervention: Criteria for stop intervention were refusal by the participant at any point in time, sign of LAST which was Lighted headedness, blurred vision, Tinnitus, metallic test on the tongue, confusion and loss of consciousness and those transferred to intensive care unit (ICU). No medication or other procedures were discontinued, denied or prevented as a result of stop intervention of this study.

2.4.4 Sampling: For study with 80 % power to detect 30% difference VAS pain score between two groups P-value 0.05 for clinically significant. And standard

deviation of 10 with 10% fall out a sample size of 68 participants (34 to each groups) [12].

2.4.5 Randomization: Randomization with parallel design through number from 1 to 86 all even numbers were group A TAP group and odd numbers were assigned group to be control group. Each number was placed in an envelope closed and placed in a box mixed up and participant pick one. Investigator only who will do TAP block was told number by participant to determine intervention.

2.4.6 Blinding: Blinding was done complete research assistant who was going to assess the participant. Although full blinding of participants to condition in this study was not possible, several strategies were employed to reduce the risk of bias. First, partial information of the study hypothesis. Second participants were clearly instructed only to contact the

investigator personally and to avoid contact with the research assistant for any scheduling concerns, questions regarding intervention.

2.4.7 Data analysis: Data were collecting by coding, cleaned and analyzed used SPSS V24. Summarized in form proportions, frequency tables and bar charts for categorical variables and Mean and standard deviation used to for continuous.

3. Results

A total of 72 participants met the criteria were recruited. 12 participants were removed as 3 did not wish to continue. 3 were sent to ICU after surgery of obesity, 4 with hemodynamic instability and 2 participants didn't visualize layer to identify transversus abdominis plane to deposit local anesthetics. Thus 41 were in TAP group and 31 in non-intervened.

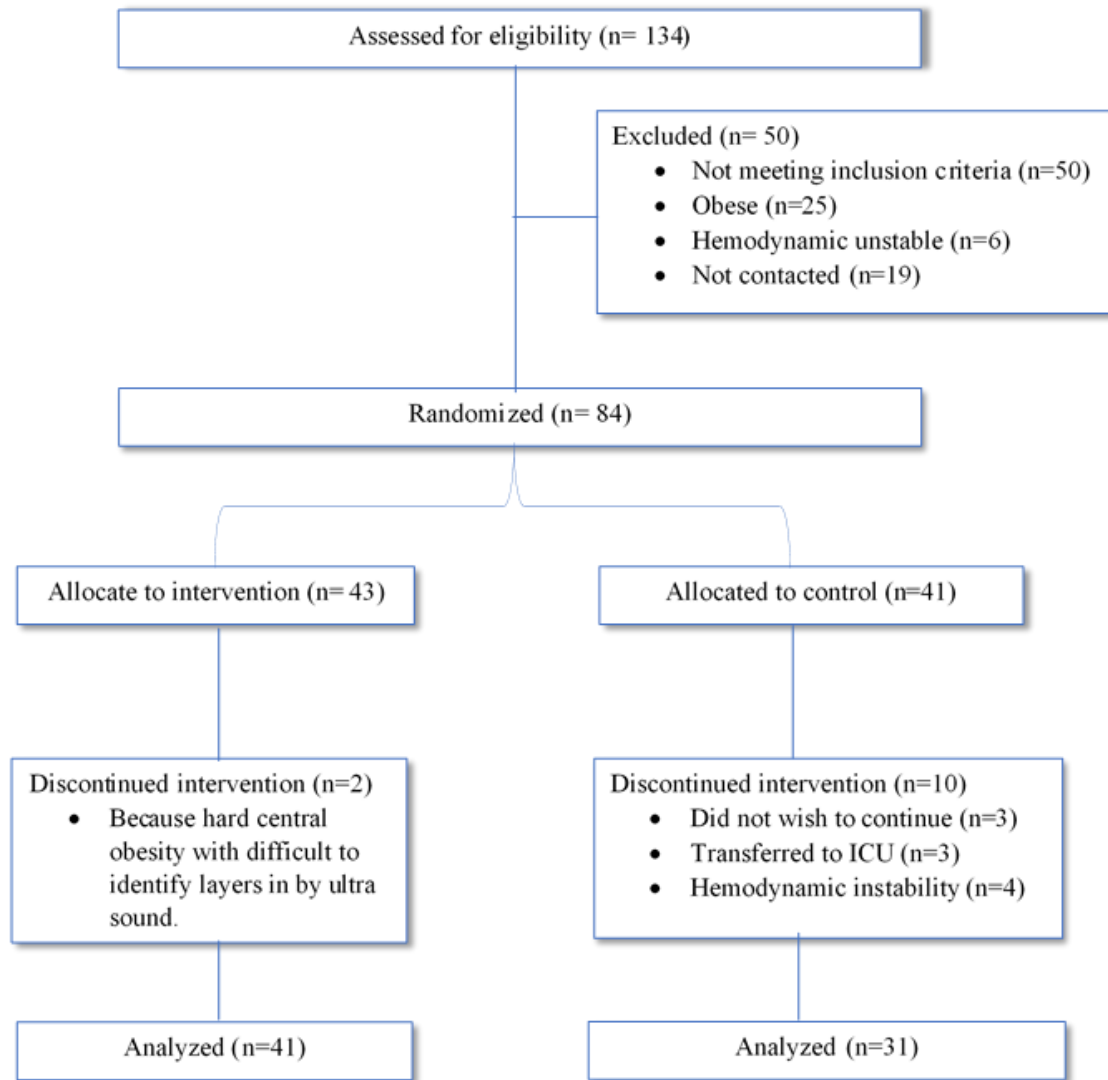


Figure 1: Flow diagram

From table 1 presents the demographic characteristics of participants, seventy eight percent (n= 32/41) of participants aged 20-34 years old were in the intervention group compared with 83.9% (n=26/31) in control groups. The mean ± standard deviation of the age was (29 ± 5.4). Chagga were 43.9%(n=18/41) in TAP group and 71%(n=22/31) in the control group, 36.6%(n=15) were had reached to college level in TAP group while 38.7% (n=12) had secondary education in

Control group.92.7% (n=38) participants were ASA II in the TAP group and 90.3%(n=28) in control group, 44% (n=28) participants were overweight among TAP group and 51.6%(n=16) from the control group. 53.7%(n=22) in TAP group came in Labor while 51.6%(n=16) were in the control group. Tribe only was statistically significant between TAP group and control with P-value of 0.05.

Characteristics	TAP Group n=41(%)	Control Group n=31(%)	p-value
Age			
<20yrs old	2(4.9)	2(4.9)	0.25
20-34 yrs old	32(78)	26(83.9)	
>35 yrs old	7(17.1)	3(9.7)	
Tribe			
Masai	4(9.8)	1(3.2)	0.05
Chagga	18(43.9)	22(71)	
Sambaa	3(7.3)	1(3.2)	
Others	16(39)	7(22.6)	
Education Level			
No Education	1(2.4)	0(0)	0.78
Primary	12(29.3)	8(25.8)	
Secondary	13(31.7)	12(38.7)	
College	15(36.6)	11(35.5)	
ASA Classification			
ASA II	38(92.7)	28(90.3)	0.72
ASA III	3(7.3)	3(9.7)	
BMI			
Normal Weight	12(30)	15(48.4)	0.65
Over weight	28(44)	16(51.6)	
Labour pain			
Yes	22(53.7)	16(51.6)	0.86
No	19(46.4)	15(48.4)	

Table 1: Demographic characteristics of participants

3.1 Pain score at rest

Table 2 presents the NRS of pain at rest, the scores were different in post anaesthesia care unity (PACU) at 0 hour both groups but were significantly lower at all-time up to 24 h in TAP group compared to control group. By using ANOVA, pain score at 0hr, 6hr and

12hr was significantly low by about 50% in TAP group with compared with the control group with (p-value (2 tail) of < 0.001). However, at 24 hrs. there was a small difference between the two groups with (p-value (2 tail) = 0.272).

Time	TAP (Mean ± SD)	Control (Mean ± SD)	p-value
Pain score at			
0	1.6 ± 1.83	4.5 ± 2.18	<0.001
6	2.8 ± 1.39	4.9 ± 1.74	<0.001
12	2.5 ± 1.72	4.3 ± 1.43	<0.001
24	2.4 ± 1.22	2.7 ± 1.26	0.272

Table 2: Pain score at 0hr, 6hrs, 12hrs and 24 at rest

3.2 Pain score on physical activities

Table 3 showing pain score on physical activities using

NRS of pain. Since about 94.4% were given spinal anaesthesia and we didn't interfere post op KCMC

hospital protocol, which says the patient will not walk until 12hrs, hence was not accessed at 0hr and 6hrs. Participants in TAP group had more movements 0hr, 6hrs and 12hrs with p-value <0.001 as compared to

control, which was reduced (such as could not turn on bed or sit). However, the was no significant difference between the groups at 24hrs (p-value = 0.283).

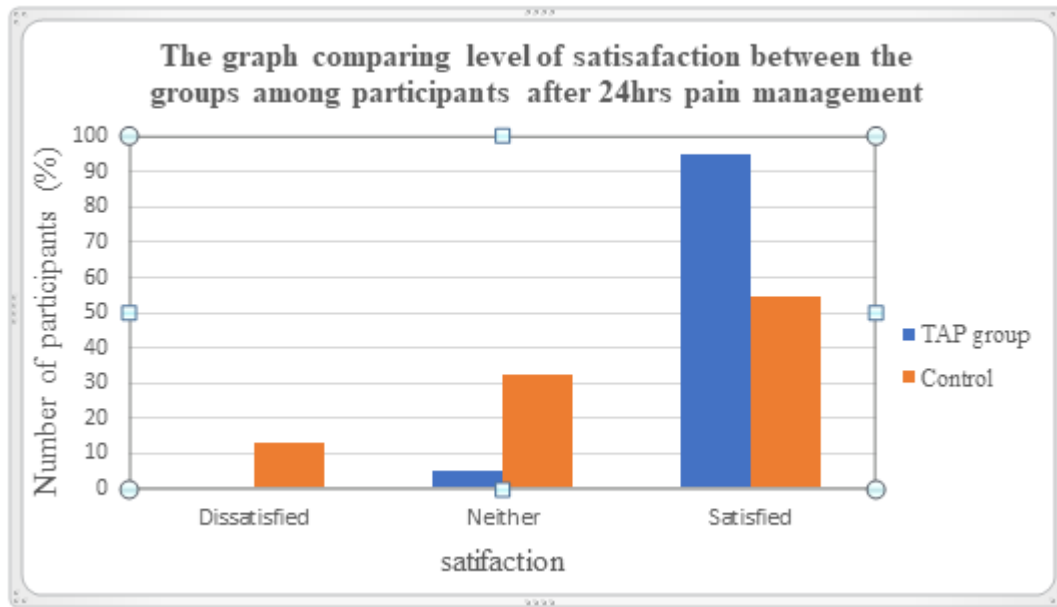
Characteristics	TAP (Mean ± SD)	Control (Mean ± SD)	p-value
Pain score on movement			
0	0.6 ± 1.83	2.1 ± 2.88	0.009
6	2.5 ± 1.89	4.4 ± 2.46	0.018
12	2.3 ± 1.72	3.9 ± 1.99	0.002
24	2.2 ± 1.22	2.3 ± 1.50	0.68
NRS on sleeping			
0	0.7 ± 1.88	2.0 ± 2.66	0.002
6	2.0 ± 1.62	3.4 ± 1.99	<0.001
12	1.6 ± 1.56	2.5 ± 1.61	<0.001
24	1.4 ± 1.31	1.4 ± 1.50	0.95
NRS on deep breath			
0	1.3 ± 2.21	3.3 ± 2.83	0.001
6	2.5 ± 1.31	4.3 ± 2.25	0.024
12	1.8 ± 1.41	3.0 ± 1.88	0.004
24	1.4 ± 1.18	1.7 ± 1.74	0.023
NRS on coughing			
0	1.4 ± 2.19	3.7 ± 2.67	0.001
6	2.7 ± 1.56	4.5 ± 2.43	0.02
12	2.7 ± 1.91	3.4 ± 1.89	0.023
24	1.9 ± 1.41	2.3 ± 1.70	0.237

Table 3: Pain score at 0hr, 6hrs, 12hrs and 24 on physical movement

3.3 Patients’ satisfaction

Patients’ satisfaction was categorized into 3-point Likert scale satisfied, neither and dissatisfied. All participants were given information about TAP block and pain management from which 97.6% and 96.8% were satisfied about the information given to them in TAP and control group (p-value=0.81). There was no statistical difference between them as graph 2.

However, after block 95.1% of a participant in the TAP group were satisfied with their pain management as compared to 54.8% in the control group as in graph 3 treated by systemic oral analgesia. Of these complications of TAP block; LAST, nausea vomiting and dizziness explored in the study There was no complication related to TAP block was reported in this study.



Graph 3: Comparing level of satisfaction between the groups among participants after 24hrs pain management

4. Discussion

Caesarean section is increasing significantly more recently, pain post-operative being among immediate consequence. Pain management after CS is aiming at conferring maternal comfort, no side effect to mother and a born child and early recuperate to normal function to help a new born baby. However, there is a challenge in achieving this due to fact that is associated with lots of poor pain control, nausea and vomiting. Local regional technique such as TAP have been studied and compared to other techniques to incorporate as component in multimodal pain management approach proved efficacious.

4.1 Pain score at rest

The results in this study have demonstrated that when TAP block is added as a component in normal standard oral and parenteral pain management pain severity is further reduced up to 12 hours after a single shot. About 50% in TAP group as compared to control

group with p-value (2 tail) of < 0.001. Our results are comparable with the RCT’s conducted in America in 2017 concluded that TAP block was effective at different concentration in reducing post caesarean section pain even at 24hrs with p-Value 0.0281. Similar to study done in India, both pain and additional analgesic requirements were reduced with (p-value < 0.0001) at rest. They had similar groups and used pain scores not opioids consumption to show the difference. In this study hospital post-operative pain management was not altered.

4.2 Pain score on physical activities

Efficacy of block as well is measured by improving physical function which can be obtained by assessing pain on activities such as sitting, walking, moving on bed for mother to attended the baby properly. In this study, the pain was significantly reduced in TAP group as compared to control group with statistical significance at 0, 6, 12, 24 hours when assessed during

movement on bed including sitting, sleeping and deep breath. This was similar to study done in India and Islamabad-Pakistan which involved 60 participants, whereby TAP block showed less pain during movement resulted in earlier readiness for discharge, early ambulation, early resumption of bowel activity and was statistically significant with (p value=0.046). In Uganda RCT study comparing intrathecal morphine and TAP block showed the mean numerical rating score for intrathecal morphine vs. transversus abdominis plane blocks at 8 h,16hr and 24hr was significantly reduced for movement and cough in transversus abdominis plane blocks different from this study at 24hrs. In this study it was not statistically significant at all time when cough pain score was high on both groups. This could be because the pain of cesarean section essentially described into acute moderate to severe, has basically two components somatic (from abdominal wall incision) and visceral (from the uterus) which TAP act on somatic.

4.3 Patients' satisfaction

This study was able to show patients were satisfied with TAP block at 95.1% with statistical significance of (p-value < 0.001) Similarly to study done in America the mean satisfaction levels were significantly higher in each of the bupivacaine groups about 91.5% when compared to the placebo group at 24 h and 48 h. There was no difference between the two bupivacaine groups. A study done in India 2015 and 2018 satisfaction score in TAP group was higher than the control group (p value < 0.001) reasons being reduces opioid requirement, improves pain score, decreases sedation, promotes early ambulation as they could feed and attend their babies [13,14]. However, Klasen et al. showed there was patients' dissatisfaction. The main reasons could be of excessive duration of intravenous

morphine administration and their effects on them which are not related to TAP [15].

5. Conclusion

This study observed the analgesic benefit of TAP block when employed with standard postoperative analgesia after cesarean section. Somatic pain was very well controlled by TAP block and visceral pain wasn't controlled by TAP this is evident by having higher scores on coughing for both groups with no statistical difference. TAP block has the potential to become a vital component in managing postoperative pain of cesarean delivery as it is easy to perform, is safe and has definite clinical utility. Should be added in multimodal approach and not to stand alone. Despite scarcity of resource especially special needles for blocks. From this study am recommending that TAP block should be added into pain management protocol. More comparative studies with a large sample sizes to assess the safety of the block. More comparative studies with different methodology should be done to compare different dose concentration to have a standard dose in our protocol and publish the results. Because focus now is reduction of opioids consumption, future studies are required to focus on the benefit/cost balance in these new techniques in our hospital.

List of abbreviation

C/S	- Caesarean Section
LAST	- local anaesthesia systemic toxicity
NRS	- Numerical Rating Score
TAP	- Trans Abdominis Plane
PACU	- Post Anaesthesia Care Unity

Declaration

Ethical approval and consent.

Ethical clearance with Certificate no 2394 by KCMUCo Research Ethics Review board was obtained. Informed written consent was obtained from the participants, refusal didn't affect quality of treatment and file number was used for privacy and confidentiality on the information obtained.

Consent for publication

Not applicable

Availability of data and materials

The data set is with personal investigator it will be proved if necessarily needed.

Conflicts of interest

Am declaring there is no conflicts of interest

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This work was self-funded.

Authors' contributions

ES contribution: study design, collecting data analyzed and draft manuscript. RT contribution: Reviewed manuscript edited it. AS contribution: Reviewed manuscript edited it. BN contribution: Reviewed manuscript edited corrected. SS contribution: Reviewed manuscript edited corrected.

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