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A Randomized Controlled Trial to Know Effectiveness of Transversus Abdominis Plane (TAP) Block in Patients Undergoing Cesarean Section for Postoperative Pain Management

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Abstract:

Aim: To assess the adequacy of TAP block in managing pain caused by performing a cesarean section.

Study Design: A Randomized controlled trial

Place and Duration: This study was conducted at Ghulam Muhammad Mahar Medical College Sukkur Pakistan from July 2020 to June 2021

Methodology: A total of 100 study participants were to go through a cesarean section and were divided into two groups; one group was prepped for TAP. TAP group patients received a bilateral, landmark orientated TAP block in the triangle of Petit. For both groups, post-surgery care was kept similar. Pain experienced by the patients in both groups was measured post-operatively via the visual analog scale (VAS). Simultaneously painkillers that were being administered were also being measured and mutually compared.

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Results: TAP block assessment showed no adverse reactions. Patients of the TAP block group complained less of pain and were relatively at ease when it came to resting, breathing, coughing, or moving. The other group (the control group) showed more morphine and diclofenac consumption.

Conclusion: Tranversus abdominis plane block helped reduce pain in both rest and mobile conditions. Consequently, patients relied less on painkillers. As this method of pain management postoperatively is cheaper and easily available even in economically challenged third world nations, incorporating this technique could significantly improve cesarean section's multimodal analgesia regimen.

Keywords: Tranversus abdominis plane block, morphine, pain, management

Introduction

Pain relief, if the possibility of acquiring it is there, is considered every human being's basic right (1). Recent research into the pathophysiology of pain has shown it to be an extremely difficult matter to tackle adequately. Especially when it comes to low-income third world countries, where there are only a handful of techniques available for pain management in the first place, there is also a lack of properly trained staff. In such cases, it is indeed effective to resort to inexpensive drug use but unfortunately, due to problems in the management systems, this solution also becomes, in certain situations and conditions almost inconceivable (1,2). Thus, the fact remains that in such nations, the majority of the citizens do not have any access to even basic pain therapy plans (2).

In sub-Saharan Africa, C-sections are among the most common abdominal surgeries to be performed (3). Sadly, despite being so common, the condition of its post-operative care is still disappointing. There are many methods of treating pain in such cases but due to the low economic situation in third world countries, there is no possibility for adopting such advanced techniques. Firstly there are no facilities available in the hospitals. In addition to that, the employed staff number is also not proper. Some anesthetic options such as low anesthetic blocks can be administered via a single injection. These are effective but even these are underutilized. TAP (landmark approach) block is an alternative technique. This technique has promise as it is cheap, accessible, difficult to obtain, or too technical to understand (4).

The method of placing a TAP block includes the placement of an anesthetic (local) bolus into the TAP, which is the area between the transversus abdominis muscles and the internal oblique muscles. This technique is known as the one pop technique and was developed in the year 2001 by Rafi (5, 6). Mcdonnel et al. modified this technique and called it 'two-pop' as their method involved a blind insertion of a regional anesthetic into the area which is behind the mid-axillary line and is superior to the iliac crest. This insertion is made keeping the injection perpendicular to the skin (7). The study being attempted by the authors of this paper was also attempted by Mcdonnel et al. They concluded the use of TAP block to be very beneficial to the patients for

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pain relief post-surgery. In cases that were done by experienced practitioners, TAP treatment was found to be quite successful with a rate as high as 85%.

The research quoted in this study was conducted in countries that were adequately equipped for advanced pain management therapy. These countries also had experienced physicians who were well-trained in case any complications arose. This study, however, aimed to focus on communities that were devoid of such facilities. The study was strategized to test whether administering TAP blocks alongside multimodal low-dose systemic analgesics was enough to manage pain effectively.

Methodology

After obtaining the official permission from the committee in charge of the ethical conduct of the institute, mothers that were designated to undergo a C-section procedure with Pfannenstiel incision under spinal anesthesia were selected for the study. Patients having the following conditions/diseases were not considered for this study: Allergy to certain drugs, obesity (BMI ≥ 30 kg/sqm), infection at the site where TAP was to be administered, cardiovascular disease, pulmonary disease, neurological disease, the requirement of general anesthesia by the patient (any medical reason), the requirement of an upper segment cesarean section, severe maternal distress and severe fetal distress

The sample size for this experiment was determined by sample size calculation which was done for randomized controlled trials. No study prior to this one has made use of VAS pain scores in this area. Hence for this study, the sample size of the group was determined on the basis of the visual analog scores that were used in a study which was done in Denmark (8). In order to be clinically relevant, the pain scores were kept 30% less. With a type I error of 0.05 and a type II error of 0.20, sample size calculation determined that 100 participants would appropriately meet the requirement of this study. In order to make up for the people that would drop out during the course of the experiment, an additional number of 6 patients had to be included in the study. Once the patients were selected, their detailed clinical history was taken in order to make sure which out of the selected number were to be excluded. The remaining were asked to fill out an informed consent form that dictated their voluntary participation. After this, the method of dividing these patients into two groups was completely random. Each individual was handed a sealed envelope. On this basis, half the patients were selected to undergo TAP block treatment (n=53) and the other half was selected for conventional care (n=53).

The patients of both groups were monitored using the following equipment: Blood pressure monitor (non-invasive + arterial), pulse oximeter, and electrocardiogram

The surgery was initiated by administering IV metoclopramide 10 mg to the patient, after which a conventional spinal anesthetic (0.5% hyperbaric bupivacaine, 10–12 mg) was injected in a sitting position. When the patient's condition proceeded from having T6 to T4 sensory blockades to experiencing cold sensations, surgery was stopped. As it is usual for blood pressure to drop post-surgery, ephedrine and IV crystalloids (ringer lactate/normal saline) were given to treat this

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post-operative hypotension. All patients were also given an IV infusion (oxytocin 30 IU) and rectal paracetamol 1000 mg after the surgery.

Each patient in the TAP group received a bilateral TAP block of landmark orientation in the triangle of Petit which had a bodyweight of 0.3ml/kg and 0.25% isobaric bupivacaine. The injection sites were cleaned with gauze (sterile). In order to avoid even the chance of administering an accidental injection of bupivacaine to the blood vessels, continuous syringe aspiration after every 5 ml dose of bupivacaine was maintained. All women of the TAP block group were checked by their surgeons one hour after surgery to check whether any symptom of local anesthetic systemic toxicity (LAST) had appeared. The TAP bolus was placed soon after the last suture. This chronology of administration prevented the patients from feeling any pain from the injection. On the other hand, the control group only received non-invasive sterile covers on their injection sites. The post-operative assessment was done by three tiers of professionals: Nurses, anesthesiologists, and physicians

The assessments made by these professionals allowed for in-depth pain and postoperative complications evaluation. The trick here was to allow those professionals to evaluate the patient situation who had neither performed nor had any inkling of the type of procedure that had been performed on the patients. This method was named by the authors as the double-blinded method. It was also agreed mutually by the researchers that no placebo treatment will be given to the patients.

For both groups, the protocol for post-surgery pain management was kept the same.

Level of Pain	VAS (Visual Analogue Scale) (cm)	Administered painkillers
Mild	0<4	- Oral paracetamol (dose of 15 mg/kg): With 6 hour gaps for the first 24 h postoperatively after finishing rectal paracetamol
Moderate	4<7	- Paracetamol - Diclofenac (dose of 1 mg/kg intramuscularly (IM): With 8 hour gaps if required starting 2 h postoperatively for the duration of 24 hours

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Severe	7-10	- Paracetamol - Diclofenac (dose of 1 mg/kg IM): With 8 hour gaps - Morphine (dose of 0.1 mg/kg intravenously (IV)): With 4 hour gaps as required starting at 2 h postoperatively for the duration of 24 hours

The above Table shows that the painkiller administered to the patient corresponded with the level of pain being experienced by the patient. A 24 hour based report was made every day by the researcher which detailed the usage of morphine and diclofenac. This helped calculate the sum amounts of the two painkillers consumed by each patient of the two groups.
At hours 2, 4,6,8,12,18, and 24, VAS pain scores were calculated for each patient; first at rest and when under stress. The stress condition consisted of deep breathing, moving, and intentionally coughing.

The following conditions were investigated simultaneously and then treated accordingly.

Condition	0 state	1 state	2 state
Respiratory depression	SPO2 > 94 on room air and/or respiratory rate (RR) 12–20 breaths per minute	SPO2 90–94 on room air and/or RR 8–11 breaths per minute	SPO2 < 90 on room air, and/or RR < 8 breaths per minute
Nausea + vomiting	No nausea + vomiting	Only nausea	Vomiting
Sedation	Awake +alert	Light sedation	Asleep but arousable
Pruritus	None	Mild	Moderate/severe

Microsoft Excel was used for data entry and storage. For data analysis, the Statistical Package for Social Science Version 20 was used. For demographic data analysis two tests were utilized:
VAS scores were recorded as mean standard deviation values and were examined using the t-test. The Student's t-test was also made use of for the analysis of post-op morphine and diclofenac consumption. Any postoperative side effects or complications that occurred were recorded in the form of percentages of numbers and Fisher's test was used to inspect them.

Results

The total number of patients to drop out of the experiment was 6; 4 dropped out from the TAP block group while 2 dropped out from the control group. A total of 3 participants dropped out

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due to postoperative bleeding, 1 due to the longitudinal incision in surgery, and 2 due to disturbance in sleep patterns

Due to a randomized distribution of patients into the two groups, both groups had a comparable patient demographic data set. In order to calculate the pain levels while walking, the staff had to wait for 8 hours postoperatively. This was done because before the lapse of the first eight hours, it was difficult for the mothers to walk around with urinary catheters. Nonetheless, the VAS findings in the TAP block group showed the pain levels to be consistently reduced, both during rest as well during stressors (deep breathing, walking, and coughing). These patients, due to their lower levels of pain also sustained on lesser doses of morphine and diclofenac.

In the TAP block, the staff on duty was asked to keep checking for any adverse side effects as a result of the morphine and/or the TAP block itself. Fortunately, the administration of the TAP block resulted in no complications/side effects. Another positive outcome for the TAP block group was that postoperatively the patients of the TAP block group's respiratory depression score 1 showed a value significantly lesser (0%) than that of the control group (17%). Score 2 for respiratory depression was shown by no one considering both groups.

Table 1: Demographic data set of patients of both groups

Variable	Control (n=51)	TAP block (n=49)	p-value
First pregnancy	16	18	0.6
Age (years)	30.0 ± 6.4	28.3 ± 5.8	0.1
Weight (kg)	64.5 ± 9.8	62.9 ± 8.4	0.3

Note: For categorical data records authors have chosen percentage representation whereas for continuous data records they have chosen mean standard deviation representation.

Table 2: Cumulative postoperative (24 h) consumption of morphine and diclofenac by the patients of the two groups

Factor	Control group	TAP block group	95% Confidence interval	p-value
Morphine consumption (mg) in 24 h	6.2 ± 5.6	0.8 ± 2.4	3.7–7.0	< 0.001
Diclofenac consumption (mg) in 24 h	144.8 ± 46.2	87.2 ± 51.2	38.8–76.3	< 0.001

Note: The data in this table is displayed in 95% CI and mean ± SD.

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Table 3: Post-surgery side effects found in the patients of the two groups as a result of systemic morphine administration

Factor	Control (n=51)	TAP block (n=49)	p-value
Respiratory depression score			
0	44	51	-
1	9	0	0.004
2	0	0	-
Sedation score			
0	33	46	-
1	18	6	0.01
2	0	0	0.5
Nausea + vomiting score			
0	46	51	-
1	3	2	0.4
2	4	0	0.06
Pruritus score			
0	51	52	-
1	0	0	0.9
2	0	0	-

Note: Data is represented as a percentage (%).

Discussion

The primary benefit provided by TAP block therapy is that its administration results in a very low incidence of complications and side effects.

Following are the few complications that have at times been reported as a result of administering TAP block in patients: Intrahepatic injection in a patient with hepatomegaly (9), intraperitoneal

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TAP catheter misplacement (no abdominal organ damage), anaphylactic reaction (post ropivacaine injection) (10,11), femoral nerve palsy (short term) and systemic toxicity

In this particular experimental research, the patients of the TAP block group showed no signs of any developing complications (above mentioned). Nonetheless, these complications should be kept in mind and appropriate remedial methods must also be made available post-operatively.

In the field of surgery, a number of controlled clinical trial studies have been conducted to discover the impact (positive as well as negative) of using the TAP block in patients undergoing both upper and lower abdominal surgeries (12). The majority of the studies dedicated to the TAP block found it to be impressively effective as a pain management treatment, as the patients undergoing it showed: Less opioid requirement, lower pain scores, and reduced opioid-related side effects

The TAP block therapy uses two techniques: the Landmark technique and ultrasound-guided technique. The researcher Jankovic studied both these techniques for a period of 10 years. He concluded in his results that using single-shot TAP blocks in randomized controlled trials showed effective pain management up to 48 h post-surgery. As a result, morphine consumption was also cut by 70-85%. Other studies focused specifically on cesarean sections and showed TAP blocks to be very effective in lowering pain, decreasing usage of opioids, and minimizing side effects (13-15).

All in all, the effectiveness of TAP block therapy as multimodal analgesia has been proved by the many numerous studies that have been conducted in the field of surgery (16, 17). What is still being debated though is the difference between the effectiveness of posterior TAP blocks and lateral TAP blocks; which of the two have a longer duration of analgesic effect. This subject matter was indeed tackled by a study that showed the posterior TAP block to be more long-lasting (up to 48 h post-op) in its effect than the lateral one in lower abdominal transverse surgery (18). When it comes to laparoscopic gynecological surgery, another study Yoshiyama et al. also showed the posterior TAP block to be more efficient but this conclusion still requires confirmation by randomized clinical trials of other surgeries (19).

Interestingly, both our study groups showed lower VAS pain scores as well as decreased painkiller use relative to previous studies. Why this is could be the result of various possibilities:

For example, in some facilities pain management is reserved only in the early stages; no labor or post-cesarean section pain medication therapy protocol exists. During labor, no analgesic treatment is offered. The same is the case for patients that are recovering from cesarean sections. They are entitled to receive no diclofenac (intramuscularly) unless the woman complains of severe discomfort post-procedure. In order to tackle such a dire status quo, during the course of this study, the researchers drafted a new pain management protocol system with the intention of providing hospitals with adequately intervene with pain relief. The majority of the volunteering women in the study had given birth before. This proved to be beneficial to the study as well as these mothers had prior experience that they could relate their present condition with. This helped them be more confident while reporting their level of pain.

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Another factor to keep in mind while analyzing this study is that prior to it the studies that had been carried out in this domain administered pain relief using the technique known as PCA, patient-controlled analgesia. Such a method of administration requires special equipment as well as well-trained staff. In this method, the total opioids requirement is determined by calculating how much morphine has the patient consumed at any given time, irrespective of their VAS scores. This method is patient-friendly but unfortunately due to its sophistication, it is not available in the majority of the low-income countries.

Conclusion

Based on the conclusions drawn from this research, the use of TAP block in pain relief is not only adequately effective but also quite feasible. It not only decreases pain but also diminishes the chance of many complications. It also reduces the use of NSAID and opioid consumption which is beneficial in its own way as these drugs also have many side effects.

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Conflict of Interest

None.

Permission

It was taken from the ethical review committee of the institute.

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