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Original article

A Randomized Comparative Study of Transversus Abdominis Plane Block with or without Intravenous Diclofenac Sodium as A Component of Multimodal Regimen for Post-Operative Analgesia Following Caesarean Section

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Abstract:

Background: The caesarean birth rate has risen dramatically globally, the same as in Egypt. The Cesarean section is one of the commonly performed surgical procedures in the field of obstetrics. This study aimed to compare the analgesic efficacy of intraoperative intravenous aqueous diclofenac sodium with transversus abdominis plane block in caesarean section under spinal anaesthesia as part of multimodal analgesia regimen. **Methods:** This randomized comparative study was conducted on sixty women who underwent cesarean section. The patients were divided into two groups: First group (A): underwent TAP block only and second group (B): underwent TAP block and intravenous diclofenac sodium. **Results:** Group B had a statistically significantly longer time to first rescue analgesic compared to Group A ($p<0.001$). Mean dose of total analgesic consumption in the first 24 h post-surgery was found lesser in Group B compared to that in Group A, which was statistically significant ($P < 0.001$). Group B had a significantly higher satisfaction score compared to Group A ($p<0.001$). **Conclusion:** The results demonstrated a statistically significant improvement in pain management for patients in the group receiving both TAP block and intravenous diclofenac sodium compared to those receiving only the TAP block. These findings suggest that the addition of intravenous diclofenac sodium to the TAP block enhances the analgesic efficacy and patient satisfaction, making it a superior option for post-cesarean section pain management within a multimodal analgesia regimen.

Keywords: Transversus Abdominis Plane Block; Intravenous Diclofenac Sodium; Multimodal Regimen; Post-Operative Analgesia; Caesarean Section.

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Introduction

Surgery and anesthesia are important healthcare procedures that strive to reduce the risk of death and disability. Furthermore, anesthetic treatments aid in reducing the occurrence and severity of acute discomfort during and soon after surgery [(1)].

According to recent research, the caesarean birth rate has risen dramatically globally, as in Egypt [(2)]. The Cesarean section is one of the commonly performed surgical procedures in the field of obstetrics. It accounts for more than one-fourth of all births worldwide [(3)].

Postoperative pain typically contains nociceptive qualities, meaning it is caused by tissue or organ lesions that produce painful nociceptive impulses.

Neuropathic pain may occur because of direct nerve damage, as well as tension or compression. In this scenario, very common surgeries like caesarean sections require extra attention, as they occur during a period of significant hormonal and emotional changes related to pregnancy and the birth of the baby, which can have a negative impact on postoperative pain, given the multifaceted nature of this experience [(4)].

Several modalities are available to combat the pain after cesarean section which includes parenteral or neuraxial opioids, parenteral non-steroidal anti-inflammatory drugs (NSAIDs), and regional anesthesia techniques such as epidural analgesia [(5)].

No single modality is utterly effective in relieving postoperative pain and has their own limitations. Opioids, even though effective against both somatic and visceral components of pain, are associated with side effects such as nausea, vomiting, pruritus, constipation, and respiratory depression [(6)]. NSAIDs have fewer side effects compared to opioids but alone may be insufficient to treat pain [(7)]. Epidural analgesia provides quality pain relief without any sedation, but it may cause complications such as hypotension, urinary retention, and muscle paralysis [(8)].

Considering the complications associated with the above methods, there has been a recent trend toward a less invasive but effective method for pain relief. Transverse abdominis plane (TAP) block is one such method which acts by blocking afferent impulse from T6 to L1 [(9)].

Aqueous diclofenac sodium, being an NSAID, has anti-inflammatory, antipyretic, anti-oedema, and analgesic properties. It is efficacious in post-caesarean 3 section pain as it acts via inhibiting peripheral tissue prostaglandin synthesis in response to tissue injury and uterine contraction [(10)].

The purpose of this study was to compare the analgesic efficacy of intraoperative intravenous aqueous diclofenac sodium with transversus abdominis plane block in the caesarean section under spinal anaesthesia as part of multimodal analgesia regimen.

Patients and methods

This randomized comparative study was done at Benha University Hospitals. Sixty women who underwent cesarean section were enrolled in this study From February 2023 to February 2024.

Written informed consent from every patient included in this study. The study was approved by the Ethics Committee of the Faculty of Medicine at Benha University Hospital, specifically in the Anesthesia and ICU Department.

Inclusion criteria were female aged 18-40 years and elective and emergency caesarean section under spinal anesthesia.

Exclusion criteria were Body mass index (BMI) >30kg/m2, history of drug allergy or local anesthetic toxicity, contraindications to regional anesthesia (bleeding diathesis, infection at the site of block and peripheral neuropathy), severe medical conditions such as severe pre-eclampsia and eclampsia, intraoperative complications like postpartum haemorrhage and severe fetal distress, and significant neurological or respiratory disease.

Grouping: Patients were divided into two equal groups: **First group (A):** underwent TAP block only**. Second group (B):** underwent TAP block and intravenous diclofenac sodium.

All studied cases were subjected to the following: Detailed history taking, including **[**parity, previous sections or abdominal surgery.]. **Full clinical examination: General examination including [**Vital signs: pulse, blood pressure, capillary filling time, respiratory rate and temperature], **Systemic examination including** [Cardiovascular, respiratory, GIT and neurological assessment]. **Routine laboratory investigations [**Complete blood count, pre- and post-operative, PT, PTT, INR, random blood sugar, kidney function tests, liver function tests, urine analysis.].

After confirmation of fasting status, patients were premedicated with intravenous metoclopramide 10 mg and intravenous ranitidine 50 mg in the preoperative holding area.

Group A and Group B both received bilateral landmark-based TAP block using ropivacaine 0.75% (1.5 mg/kg), 20 ml at the end of surgery. Group B received diclofenac sodium aqueous 75 mg intravenous intraoperatively.

Patients were received in operation theatre, identified and multichannel monitors which included electrocardiography, heart rate, non-invasive blood pressure, and pulse oximeter were attached and baseline values obtained. After taking full aseptic precautions, lumbar puncture was performed at L3–L4 interspace through midline approach in sitting position using a disposable 25 Gauge Quincke's spinal needle. 2.5 ml of hyperbaric bupivacaine (0.5%) was then injected into the subarachnoid space and the patient was made supine. A 15° wedge was placed under the right hip.

Mean arterial pressure and heart rate were recorded during the whole procedure. Any complications (nausea, vomiting, hypotension and bradycardia, bleeding) were recorded during intraoperative and post-operative periods. At the end of surgery, regression of sensory block was assessed. After this, under all aseptic precautions TAP block was performed in both the groups; ropivacaine 0.75% (1.5 mg/kg diluted in 0.9% normal saline) 20 ml volume was injected on each side. Patients in Group B were also given intravenous diclofenac sodium aqueous 75 mg after delivery of the baby. Patients were observed for 30 min and then shifted to post-anaesthesia care unit.

Pain Assessment

Pain severity was assessed by an investigator blinded to the allotment every 2, 4, 6, 12 and 24 h at rest and movement. It was measured using VAS (0 = no pain and 10 = the worst possible. Rescue analgesia was given to patients on demand or when VAS was more than 4 in the form of intramuscular diclofenac 1 mg/kg.

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Statistical analysis

Statistical analysis was done by SPSS v25 (Armonk, NY: IBM Corp.). Quantitative variables were presented as mean and standard deviation (SD) and compared between the two groups utilizing unpaired Student's t- test and ANOVA (F) test. Qualitative variables were presented as frequency and percentage (%) and were analyzed utilizing the Chi-square test or Fisher's exact test when appropriate. A two tailed P value < 0.05 was considered statistically significant.

Results

There was no significant difference between the studied groups according to age, BMI and distribution of previous operations. **Table 1**

There was no significant difference between the two groups according to VAS at 24 hours during rest. VAS was significantly less in Group B in first 2–12 hours post-operation during movement as compared to those in Group A ($p<0.001$). No significant difference between the two groups according to VAS at 24 hour during movement. **Table 2**

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Table 1: Demographic data and Previous operations in the studied groups.

Variable		Group A (n=30)	Group B (n=30)	p
Age (years)		29.1±6.6	31.3±5.7	0.173
BMI (kg/m^2)		26.1±2	26.3±1.9	0.699
Previous operations	Cesarian section	18(60%)	23(76.7%)	0.461
	Dilatation and curettage	6(20%)	3(10%)	
	Exploration	0(0%)	1(3.3%)	
	Myomectomy	2(6.7%)	1(3.3%)	
	No previous operations	4(13.3%)	2(6.7%)	

*: Significant ≤0.05; BMI: Body mass index; Data represented as Mean and Standard deviation

Table 2: Pain score at rest and at movement in the studied groups.

Variable	Time interval (hr)	Group A (n=30)	Group B (n=30)	p
VAS at rest	2	2.7±0.7	1.7±0.7	<0.001*
	4	3.6±0.9	2.6±0.7	<0.001*
	6	4.6±0.6	3.5±0.7	<0.001*
	12	5.3±0.5	4.6±0.8	<0.001*
	24	5.3±0.5	5.2±0.6	0.857
VAS on movement	2	2.4±0.5	1.8±0.9	0.003*
	4	3.3±0.5	2.7±0.7	<0.001*
	6	4.5±0.6	3.7±1	<0.001*
	12	5.1±0.3	4.5±0.7	<0.001*
	24	4.8±0.4	4.8±0.5	0.718

VAS: Visual analogue scale; Test: Mann Whitney test; *: Significant ≤0.05; Data represented as Mean and Standard deviation

The heart rate was noted at 2, 4-, 6-, 12- and 24-hours post-operation. Heart rate was significantly lower in Group B in first 2–24 hours post-operation during movement as compared to those in Group A (p<0.001). SBP was significantly lower in Group B in first 2–24 hours post-operation during movement as compared to those in Group A (p<0.001). DBP was significantly lower in Group B in first 4–24 hours post-operation during movement as compared to those in Group A (p<0.001). No significant difference between the two groups in DBP at first 2 hours post-operation. **Table 3**

Group B had a statistically significantly longer time to first rescue analgesic compared to Group A (p<0.001). Mean dose of total analgesic consumption in the first 24 h post-surgery was found lesser in Group B compared to that in Group A, which was statistically significant (P < 0.001). Group B had a significantly higher satisfaction score compared to Group A (p<0.001). **Table 4**

Table 3: Heart rate post operation and Systolic blood pressure among studied groups

Variable	Time interval (hr)	Group A (n=30)	Group B (n=30)	p
Heart rate (beat/min)	2	103.7±4.1	100.5±2.9	0.001*
	4	101.7±6.8	96±3.5	<0.001*
	6	100.1±4.7	94.7±3.9	<0.001*
	12	96.9±4.8	93.1±5.7	0.017*
	24	96.9±4.9	92.6±5	0.001*
SBP (mmHg)	2	118.7±37.7	108.1±3.1	0.004*
	4	109±2.1	104.1±2.8	<0.001*
	6	107±2.8	104.3±4.1	0.001*
	12	107.6±2.3	105.6±3.3	0.002*
	24	106.8±2.2	104.2±2.3	<0.001*
DBP (mmHg)	2	70±2.9	69.2±3.2	0.173
	4	67.7±1.7	66.4±2.9	0.042*
	6	67±2.5	63.4±3.9	<0.001*
	12	64.9±1.6	63.8±3	0.049*
	24	65.3±2	64.2±3.2	0.032*

*: Significant ≤0.05; Data represented as Mean and Standard deviation

Table 4: Time of rescue analgesics, total analgesic given in the first 24 hours and Satisfaction score among studied groups.

Variable	Group A (n=30)	Group B (n=30)	p
Time to first rescue the analgesic (hr)	7.6±0.9	12.1±2.9	<0.001*
Total analgesic in first 24 hr (mg)	99±13.2	61.7±12.9	<0.001*
Satisfaction score	6.3±1.2	8.4±1	<0.001*

*: Significant ≤0.05

Discussion

In our study, according to demographic data in the studied groups, the mean age in group A was 29.1±6.6 years compared to 31.3±5.7 years in group B. The mean BMI in group A was 26.1±2 kg/m2 compared to 26.3±1.9 kg/m2 in group B. No significant difference between the studied groups according to age and BMI.

Similarly, a study by Kanta and co-workers, was performed to evaluate the analgesic efficacy of transversus abdominis plane (TAP) block combined with intraoperative diclofenac aqueous for post-operative analgesia in caesarean section and concluded that demographic profile, age, weight and body mass index were comparable in both groups [(11)].

Pain score (VAS) was noted at 2-, 4-, 6-, 12- and 24-hours post-operation. VAS was significantly less in Group B in first 2–12 hours post-operation during rest as compared to those in Group A (p<0.001). No significant difference between the two groups according to VAS at 24 hours during rest. Pain score (VAS) was noted at 2-, 4-, 6-, 12- and 24-hour post-operation. VAS was significantly less in Group B in first 2–12 hours post-operation during movement as compared to those in Group A (p<0.001). No significant difference between the two groups according to VAS at 24 hour during movement.

Parallel to our results, Soni and Pandey performed a study to evaluate the efficacy of TAP block with or without intra-operative diclofenac sodium aqueous

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injection for controlling post-operative pain following laparoscopic cholecystectomy and included 40 (ASA) physical status-I and II patients aged 20-50 years scheduled for elective laparoscopic cholecystectomy were divided into two groups of 20 patients each. Group A patients received bilateral Ultrasonography (USG) guided TAP block using 20 mL of 0.125% Bupivacaine on each side of the abdomen at the end of surgery. Group B patients received intravenous injection of diclofenac sodium aqueous 75 mg intravenous, intra-operatively, along with bilateral USG guided TAP block using 0.125% Bupivacaine and concluded that Visual Analogue Scale (VAS) scores were lower in group B than in group A [(12)].

In contrast, this was comparable with the results of Jadon *et al*. who performed a study to evaluate the analgesic efficacy of this block for post caesarean analgesia and included one hundred thirty-nine mothers undergoing caesarean delivery were randomized to receive TAP block with either 20 ml 0.375% ropivacaine or 20 ml saline. All the subjects received a standard spinal anaesthetic, and diclofenac was administered for post-operative pain. Breakthrough pain was treated with tramadol. Post-operatively, all the subjects were assessed at 0, 2, 4, 6, 8, 10, 12, 18 & 24 h. Finally, this study found that pain scores both at rest and on movement were lower in the study group ($p < 0.0001$) [(13)].

In our study, heart rate was significantly lower in Group B in first 2–24 hours post-operation during movement as compared to those in Group A ($p<0.001$). Also, SBP was significantly lower in Group B in first 2–24 hours post-operation during movement as compared to those in Group A ($p<0.001$). In contrast, no significant difference between the two groups in DBP at first 2 hours post operation was seen.

Opposite to our results, Bharti et al., performed a study to evaluate the efficacy of a novel approach to TAP block for postoperative analgesia after colorectal surgery and included 40 adult ASA physical status I to III patients undergoing colorectal surgery. The patients were randomly assigned to receive either 20 mL of 0.25% bupivacaine (TAP group) or normal saline (control group) on each side of the abdominal wall. Finally, this study revealed that postoperative heart rate, arterial blood pressure, and respiratory rate were comparable between groups [(14)].

Our results found that the mean time to first rescue analgesic was 7.6 ± 0.9 hours for Group A and 12.1 ± 2.9 hours for Group B. This suggests that Group B had a significantly longer time to first rescue analgesic compared to Group A ($p<0.001$).

Similarly, Kanta et al. found that mean time of administration of first dose of rescue analgesia was found to be prolonged in Group B (11.5 ± 4.1 h) than that in Group A (7.55 ± 1.41 h) [(11)].

In the current study, mean dose of total analgesic consumption in first 24 h post-surgery was found lesser in Group B (61.7±12.9 mg) compared to that in Group A (99±13.2 mg), which was statistically significant ($P < 0.001$).

In harmony, Kanta and colleagues found that mean dose of total analgesic consumption in first 24 h post-surgery was found lesser in Group B (61.67 ± 34.57 mg) compared to that in Group A (98.33 ± 37.68 mg), which was statistically significant ($P < 0.001$) [(11)].

Similarly, Jadon and co-workers concluded that the median number of doses of tramadol consumed in the TAP group was 0 (0,1) compared to 2 (1,2) in the control group ($p < 0.0001$)[(13)].

In our study, mean satisfaction score was 6.3 ± 1.2 for Group A and 8.4 ± 1 for Group B. This suggests that Group B had a significantly higher satisfaction score compared to Group A ($p<0.001$).

Parallel to our results, Kanta and co-workers found that patient satisfaction score was significantly higher ($P < 0.001$) in Group B (8 ± 1.04) compared to that in Group A (6.23 ± 1.04) [(11)].

In harmony, Jadon and co-workers found that median (IQR) maternal satisfaction

score was significantly higher in the TAP group compared to the control group; 2 (2,3) in the TAP group compared to 2 (2,2) in the control group (p 0.0002; 95% C.I., 0 to 1)[13].

Also, Soni and Pandey, revealed that patient satisfaction scores were higher in the group receiving both TAP block and diclofenac than the patients who received TAP block only (P value<0.001)[12].

Conclusion

The results demonstrated a statistically significant improvement in pain management for patients in the group receiving both TAP block and intravenous diclofenac sodium compared to those receiving only the TAP block. These findings suggest that the addition of intravenous diclofenac sodium to the TAP block enhances the analgesic efficacy and patient satisfaction, making it a superior option for post-cesarean section pain management within a multimodal analgesia regimen.

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Author contribution

Authors contributed equally to the study.

Conflicts of interest

No conflicts of interest

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