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Research Article

Cost Benefit Ratio of Different Methods for Controlling Postoperative Pain in Women Delivered by Cesarean Section: Prospective Randomized Clinical Study

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Abstract

Background: One of the most frequent surgical procedures is the caesarean section (CS). It has been documented that using local anesthetic techniques considered an essential component of perioperative multimodal analgesia, effectively decrease pain &the need for opioids. **Aim:** to evaluate the use of different methods of Postoperative analgesia in controlling cesarean section pain. **Methods:** 150 pregnant women who were going to have a caesarean section from those admitted to Minia Maternity University Hospital. Patients have been categorized randomly into three parallel equal groups. Control group taken patient-controlled analgesia (PCA) only, local infiltration group received skin infiltration with local anesthesia and PCA, and transversus abdominis block (TAPB) group received ultrasound guided TAP block and PCA**.** The 1ry result was the patient pain score, and the 2ry were total analgesic consumption, patients' satisfaction, time till release from bed & any adverse impacts have been documented. **Results:** a significant decrease in VAPS (visual analogue pain score) was observed in TAPB group comparing with local infiltration and control group at two, four, six, eight, and twenty four-hour postoperative. Nevertheless, insignificant variance was observed among local infiltration and control groups. TAPB & local infiltration groups exhibited significant decrease in nalufin consumption compared to control group. Additionally, TAPB and local infiltration group demonstrated faster release from bed than control group. **Conclusion:** the use of ultrasound guided transversus abdominis block & local infiltration of the skin incision demonstrated more efficient in curing pain following surgery, decrease opioid consumption, & allow faster ambulation compared to PCA.

Keywords: TAPB, local infiltration, Controlling postoperative pain, Cesarean Section.

Introduction

CS is a surgical technique used to deliver a baby through an abdominal and uterine incision in the mother, often performed when a vaginal delivery is not possible or vaginal delivery would put the baby or mother at risk. Emergency CS may be done with spinal or under general anesthesia. (1) However, CS is being a lifesaving intervention surgery; Due to potential complications, CS are linked to a three-times greater risk of maternal death than vaginal births. (2)

One of the most preventable negative effects of CS is pain following surgery, which is a physiological response to tissue damage at the surgical site. With an 11.8 percent incidence of chronic pain, inadequate therapy may result in persistent pain. There are numerous ways to control postoperative pain, involving using pharmacological agents and interventional procedures. Traditionally, for acute post-operative pain following CS, acetaminophen, also referred to as paracetamol, and non-steroidal anti-inflammatory drug therapy are

the most frequently prescribed medications. [3]
A common method for managing acute postoperative pain is PCA. PCA was clinically introduced to adults in 1971. [4] This technique is depended on the utilize of a controlled infusion pump that delivers a preprogrammed dose of opioid usually via intravenous doses, which allows the patient to self-administer analgesics, maximize pain relief & minimize risk of overdose.[5]
*Local infiltration analgesia (LIA) is an analgesic method that was first introduced by Kerr & Kohan in 2008 (Kerr & Kohan, 2008), it includes the infiltration of a low volume dilute solution of a local anesthetic agent into the tissues in the area that requires anesthesia to anesthetize nerve endings. The technique works by reversibly blocking the sodium channels of nerve fibers, thus impeding the conduction of nerve impulses (McCarthy and Iohom, 2012), which is focused on the injection site. [6]

A regional technique for analgesia of the anterolateral abdominal wall is the transversus abdominis plane (TAP) block. Rafi initially introduced it in 2001. [7] It includes the injection of a local anesthetic solution into a plane that is situated among the internal oblique muscle &the transversus abdominis muscle. The local anesthetic spread in this plane may block the neural afferents &provide analgesia to the anterolateral abdominal wall, as the thoracolumbar nerves originating from the T6 to L1 spinal roots run into this plane and supply sensory nerves. The wall of the abdomen. TAP blocks have become technically simpler & safer to perform for analgesia following abdominal surgeries as a result of the development of ultrasound technology. [8]
This research aimed to assess and evaluate the different methods of Postoperative analgesia in controlling postoperative pain among women delivered by cesarean section.

Patients & Methods

This prospective randomized clinical research was performed on pregnant women who were underwent to have a caesarean section from those admitted to Minia Maternity University Hospital between October 2021 to October 2022. The research protocol was accepted by the ethical committee of Minia Maternity University Hospital.

A thorough counselling & written informed consent was taken from each case prior to contributing to the research.
The study included all pregnant women of primary CS, with Gestational age from 36 weeks to 40 weeks gestation and with Single or multiple gestation.
Exclusion criteria were all pregnant women with Presence of any scars. Contraindication to spinal anesthesia, Hypersensitivity to the drugs used, psychiatric disorders, opioid dependance, Cardiac disorder ,bronchial asthma, liver disease, renal disease.

The research parturient were randomly categorized to three equal groups (infiltration and transversus abdominis plane and control groups) utilizing a computer-generated table of random numbers
The research patients and the result evaluators didn't know the study group. A large opaque screen separated patients from the operating field & the operators. cases were categorized randomly into equal 3 groups.
Group I (control group): Consists of 50 cases who received patient-controlled analgesia (PCA) IV only, which was proved as a standard most effective methods for controlling postoperative pain; taking into consideration that this method is the highest cost method according to Wirz.[5]
Group II (study group I): Consists of 50 patients received local anesthetic infiltrative in the skin incision then PCA.
Group III (study group II): Consists of 50 patients received analgesia by ultrasound guided TAP block then PCA.
Prior to surgery, all patients were introduced to the visual analogue scale (VAS), instructed on the operation of the patient-controlled analgesia (PCA) pump, underwent standard diagnostic investigations and Continuous monitoring of the patient is essential. Vital signs, level of sedation, and pain scores are commonly assessed to ensure the patient's well-being.
PCA preparation: PCA was prepared with 40 mg nalbuphine (20 mg/2ml SERB pharmaceuticals, France) in 100 ml 0.9% saline and programmed with 2 ml/h as basal rate, 0.5 ml bolus injection and 15 min lockout interval
In group II patients received local infiltrative anesthesia in the skin incision then PCA, at the end of section, infiltrate the skin incision with 20 ml of local anesthetic (bupivacaine 0.25%).

Ensure proper distribution of the local anesthetic to minimize postoperative pain, Initiate PCA for pain management, delivering a patient-controlled dose of analgesic medication, continuously monitor the case's vital signs, pain scores, & sedation level.
In group III patients received analgesia by ultrasound guided TAP block then PCA, the transversus abdominis plane block was carried out utilizing ultrasound and injecting a local anesthetic into the TAP to block sensory nerve fibers, then PCA was Initiated for ongoing pain management.

At the end of caesarean section, Local infiltration and bilateral TAP block were carried out. The ultrasound and needle entry sites were sterilized while the case was in a supine position. The transversus abdominis plane block was administered laterally behind the midaxillary line, among the iliac crest & the most inferior extent of the ribs. The probe was positioned transverse to the abdomen, and the plane among the internal oblique & transversus abdominis muscle was situated around the midaxillary line. The needle was advanced anteriorly to align with the ultrasound beam & positioned among the transversus and internal oblique, posterior to the midaxillary line. Subsequently, 20 ml of bupivacaine 0.25% was injected, and the TAP was carried out on the opposite site using the same technique **figure (2).** All patients received postoperative care and monitoring of hemodynamics and paracetamol 1 gm/8 h and ketorolac 30 mg/ 12h was given.

Outcome measures:
The primary result was the amount of opioid used throughout the entire 24-hour period following C.S. The 2ry results included the VAS scores within the 1st twenty-four h postoperatively, patients' satisfaction, time till release from bed & the incidence of any negative impacts.

Sample size:
Epi Info STATCALC was used to detect the sample size as regard the assumptions described in the study conducted by Görkem.[9] A power of 80% and a two-sided confidence level of 95%. & A 5% error. The final maximum sample size for each group was 25 as determined by the Epi-Info output. The sample size was raised to 50 cases in every group by assuming dropout cases during follow-up and a high flow of patients through the maternity unit. The total sample size was 150 cases.

Statistical analysis
Data were gathered, revised, verified, and coded before being entered into a PC for statistical analysis &graph blotting utilizing the Statistical Package for Social Sciences (SPSS) version 25 software (SPSS, Chicago, IL, USA). The analysis of variance (ANOVA) was utilized to compare the variances among the groups, & the post hoc test was employed to conduct multiple comparisons. p-value < 0.05 was considered statistically significant for all tests.

Results
One hundred and fifty gravid women enrolled into the study. They categorized randomly into 3 parallel equal groups. 50 parturient women each group: TAPB group, local infiltration group, and control group **figure (1**).
The study group were comparable regarding gestational age (GA), age, body mass index (BMI) & laboratory data as shown in **table (1, 2).**
Total nalufin consumption throughout the 1st twenty-four h postoperative was significantly fewer in TABP group (20.89±1.30) in comparison to local infiltrative group (25.3± 1.13), and both show significantly less consumption compared to controlled group (29.6± 1.18) as shown in **table (3).**
Postoperative VAPS demonstrated in **table (4) and fig. (3)** which show significantly decreased in TABP group in comparison with local infiltration and control group from two hour postoperative till eight hour and at 20 and 24 hours postoperative. Also, at 10 hours postoperative, there was significantly less VAPS for TABP than control group. However, VAPS didn't show any significant difference between local infiltrative and control group.
Time till release from bed reported by studied patients throughout the study time was significantly fewer in TABP group than local infiltrative group & both demonstrated lower time till release from bed than controlled analgesia group as illustrated in **table (3).**
Patients who received TAPB showed a high percentage of excellent satisfaction (56%) in comparison to local infiltration (22%) and controlled analgesia group (16%). Also, very good satisfaction was reported by TABP group (44%) which was higher than local infiltration

(40%) and controlled analgesia (28%). While good satisfaction was not reported by TABP group, a higher percentage in controlled analgesia group (56%) than local infiltration group (38%), the variances were statistically significant **table (5).** Statistically insignificant variance was observed among the 3 groups as regards the side effects as demonstrated in **table (6).**

Table (1): Comparison of demographic data of the studied groups

C	Transversus abdominis plane		Controlled analgesia		Local infiltrative anesthesia		Test of sig.	
	N=50		N=50		N=50			
	Mean	SD	Mean	SD	Mean	SD	f	P-value
Age (year)	29.4	6.71	28.4	6.3	27.96	6.03	1.01	0.36
GA (weeks)	37.77	0.85	37.85	0.88	38.05	0.91	2.01	0.136
BMI	28.64	4.05	28.00	4.16	28.37	4.31	0.453	0.636

Table (2): Comparison of laboratory data of the studied groups before procedure

	Transversus abdominis plane		Controlled analgesia		Local infiltrative anesthesia		Test of sig.	
	N=50		N=50		N=50			
	Mean	SD	Mean	SD	Mean	SD	f	P-value
HB	10.44	0.96	10.57	0.94	10.53	0.88	1.875	0.157
HCT	31.01	2.85	31.81	3.44	31.60	3.30	0.354	0.702
WBCs	8.87	1.93	8.69	1.70	8.32	1.51	1.273	0.282
Plat	298.19	24.99	291.25	28.22	298.72	25.51	1.942	0.146
Urea	26.67	12.18	24.01	2.47	26.24	12.19	1.885	0.154
creat	0.71	0.11	0.71	0.10	0.70	0.10	1.52	0.221
ALT	22.84	1.32	22.77	1.27	23.01	1.27	0.416	0.66
AST	33.11	1.53	33.24	1.47	33.33	1.95	0.698	0.499
PT	23.62	2.31	23.92	2.47	23.71	2.55	0.352	0.704
PTT	33.83	2.34	34.15	2.27	34.22	2.32	0.301	0.741
INR	1.30	0.25	1.35	0.26	1.34	0.27	2.71	0.069

Table (3): Comparison of VAPS score of the studied groups over 24 hours

	Transversus abdominis plane group		controlled analgesia group		local infiltrative anesthesia group		P-value
	N=50		N=50		N=50		
	Mean	SD	Mean	SD	Mean	SD	
VAS at 1 h	1	0	1	0	1	0	0.568
VAS at 2 h	1.93	0.68	3	0.69	3.09	0.65	<0.0001
VAS at 4 h	2.42	0.49	3.3	0.59	3.02	0.72	<0.0001
VAS at 6 h	2.49	0.50	3.24	0.54	3.14	0.35	<0.0001
VAS at 8 h	2.57	0.49	3.36	0.58	3.26	0.59	<0.0001
VAS at 10 h	2.8	0.6	3.25	0.57	3.09	0.54	<0.0001
VAS at 12 h	2.82	0.62	2.68	0.73	2.65	0.75	0.28
VAS at 16 h	2.85	0.67	2.94	0.76	2.93	0.73	0.7
VAS at 20 h	2.42	0.49	2.61	0.49	2.72	0.478	0.0008
VAS at 24 h	2.09	0.618	2.53	0.528	2.59	0.52	<0.0001
Post hoc LSD analysis							
	Group (TABP V controlled analgesia)		Group (TABP V local infiltrative)		Group (controlled analgesia V local infiltrative)		
VAS at 1 h	0.994		**0.62**		**0.626**		
VAS at 2 h	<0.0001		<0.0001		0.69		
VAS at 4 h	<0.0001		<0.0001		0.014		
VAS at 6 h	<0.0001		<0.0001		0.39		
VAS at 8 h	<0.0001		<0.0001		0.51		
VAS at 10 h	<0.0001		0.005		0.20		
VAS at 12 h	0.44		0.30		0.96		
VAS at 16 h	0.725		0.775		0.99		
VAS at 20 h	0.05		0.06		0.350		
VAS at 24 h	<0.0001		<0.0001		0.78		

Table (4): Comparison of analgesic use of the studied groups

	Transversus abdominis plane		controlled analgesia		Local infiltrative anesthesia		P-value
	N=50		N=50		N=50		
	Mean	SD	Mean	SD	Mean	SD	
Time till release from bed (hs)	8.07	0.55	11.15	0.59	9.95	1.40	<0.0001
nalufin consumption at 1st 24 hs	20.89	1.30	29.6	1.18	25.3	1.13	<0.0001
Post hoc LSD analysis							
	Group (TABP V controlled analgesia)		Group (TABP V local infiltrative)		Group (controlled analgesia V local infiltrative)		
Time till release from bed (hs)	<0.0001		<0.0001		<0.0001		
nalufin consumption at 1st 24 hs	<0.0001		<0.0001		<0.0001		

Table (5): Comparison of Patient Satisfaction of the studied groups

	TABP Group		Control Group		Local infiltrative Group		P-value
	N=75		N=75		N=75		
	N	%	N	%	N	%	
Excellent	28	56	8	16	11	22	0.0001
Very Good	22	44	14	28	20	40	
Good	0	0	28	56	19	38	
Bad	0	0	0	0	0	0	

Table (6): Comparison of procedure side effects rate in the studied groups

		group I Transversus abdominis plane		group II Local infiltrative anaethesia		group III controlled analgesia		Test of sig.	
		N=50		N=50		N=50			
		N	%	N	%	N	%	X2	P-value
Side effects	NO	69	92%	70	93.3%	64	85.3%	2.721	0.257
	Yes	6	8%	5	6.7%	11	14.7%		
Hypotension		1	1.3%	0	0%	1	1.3%	1.009	0.604
Injection site infection		0	0%	0	0%	0	0%	2.027	0.363
Injection site hematoma		1	1.3%	1	1.3%	0	0%	2.027	0.363
Allergic reaction		1	1.3%	1	1.3%	0	0%	1.009	0.604
Nausea		1	1.3%	1	1.3%	2	2.6%	2.027	0.363
Vomiting		1	1.3%	0	0%	2	2.6%	2.027	0.363
Pruritus		0	0%	1	1.3%	1	1.3%	1.009	0.604
Sleepiness		0	0%	0	0%	2	2.6%	4.036	0.132
Constipation		1	1.3%	1	1.3%	2	2.6%	4.036	0.132
Urine retention		0	0%	0	0%	1	1.3%	2.009	0.366

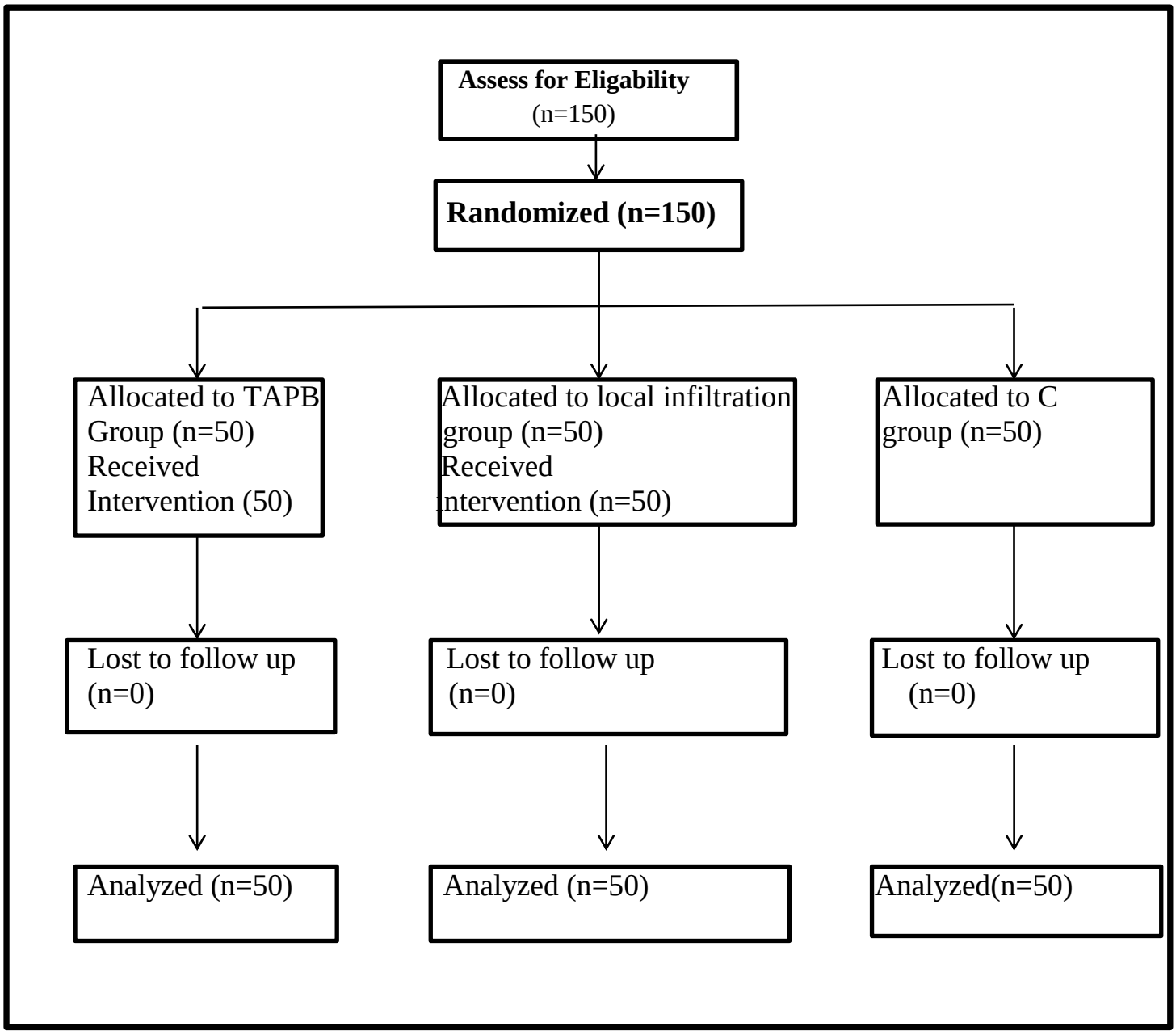

Figure (1). consort diagram of the study.

Figure (2). Ultrasound image of TAPB (Minia university hospital).

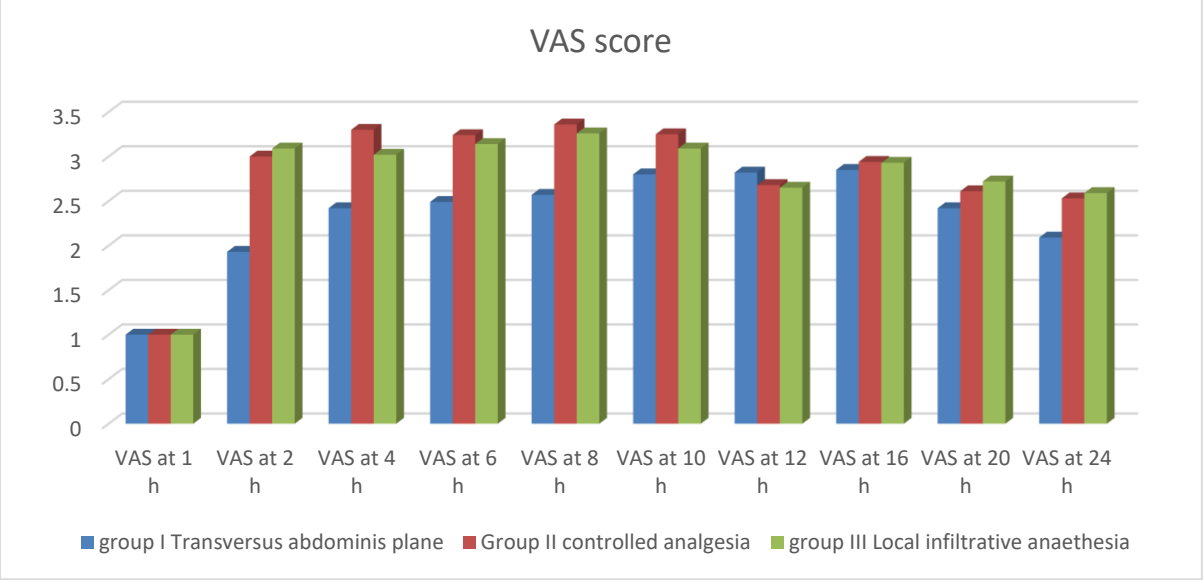

Figure (3): postoperative VAS among the study group

Discussion

The rate of Caesarean sections has increased significantly worldwide and in Egypt. [(1)] This rise is associated with a rise in females' awareness of the procedure & their preference for pain-free techniques throughout & after the surgery. This motivates obstetricians to explore new approaches & techniques in place of conventional postsurgical analgesic methods. The majority of caesarean deliveries that are uncomplicated result in moderate to severe pain for the initial forty-eight h following the procedure. Consequently, pain relief is essential, as it impacts the care of both the mother &her newborn. Additionally, extended postoperative pain may result from inadequate pain management, which may negatively influence mother-infant bonding and healing. [(10)]

In comparison to patients who received patients-controlled analgesia, this double-blind, randomized controlled trial showed a significant decline in cumulative nalufin consumption at twenty-four h in parturient who received bilateral transversus abdominis plane block or local wound infiltration following caesarean delivery carried out under spinal anesthesia. Also, patients received TAPB and local infiltration suffered less pain scores at 2, 4, 6, 8, 20 & 24 h. Patients received TAPB showed more satisfaction than local infiltration group and both more satisfied than controlled analgesia group. Insignificant variance was

observed regarding negative impacts among the study group.

These results consistent with Wang et al., who studied the effect of different techniques for postoperative pain following CS. The study involved 5039 pregnant female and founded that TAPB decrease VAPS and opioid consumption. They concluded that transversus abdominis block is the most efficient local anesthetic technique without intrathecal morphine for postoperative CS pain. [11]

Two meta-analyses Randomized trials that compared wound infiltration with TAP block were carried out by Yu et al., and Guo et al., Yu et al., performed four studies on adults who underwent a variety of lower abdominal surgeries. They discovered that transversus abdominis plane block significantly decreased pain scores at twenty-four hours. However, they did not observe significant variations in pain scores at two & four h, morphine consumption at twenty-four h, or cases of nausea & vomiting.[12] The pain scores at eight & twenty-four h and cumulative morphine consumption at twenty-four h were significantly decreased with transversus abdominis plane block in nine studies carried out on heterogeneous patient populations (children & adults, like parturient) having variable abdominal surgeries (laparoscopic and open, such as caesarean delivery) by Guo et al., however, they did not observe any significant variations in pain scores at one h, time to the 1st rescue analgesic, sedation level, or nausea & vomiting incidence.[13]

Abouhi et al., disagreed with our outcomes and conducted a cross-sectional study on 100 women scheduled for elective C-section for comparing the analgesic efficacy of TAPB and patient-controlled analgesia. They found that VAS significantly decreased in PCA group than TABP group. This could be due to the TAPB group in our study using PCA after the block. However, they are consistent with our study in terms of early mobilization, and this may be due to decreasing opioid consumption and subsequently its sedative effect. [14]

Also, Riemma et., conflicts with our study who performed a systematic review and meta-analysis of randomized controlled trials comparing wound infiltration &transversus abdominis plane block for post-CS analgesia. This research involved 5 randomized controlled trials (RCTs), which enrolled a total of 268 women. The interventions did not exhibit any significant variations in terms of cumulative opioid consumption or pain scores. [15]

In the meta-analysis performed by Pervez et al., insignificant variances were demonstrated among transversus abdominis block, continuous infusion via a catheter (WC), and wound infiltration involved single-dose infiltration (WI) groups for twenty-four h pain scores. [16]
Our outcomes demonstrated that statistically insignificant variance was observed among the 3 groups as regards the SE rate.

Our outcomes agreed with study of Tawfik et al., who studied the effect of transversus abdominis plane block Vs wound infiltration for analgesia following CS as they reported that the nausea, vomiting & pruritis incidence was few in both groups. [17] Also, these outcomes are consistent with Riemma et al., who documented insignificant variance in the adverse impact among the intervention groups. [15]
TAP block in caesarean section is preferable technique for postoperative analgesia, but obstacles in performing the block may arise from the anatomical variations after the operation. However, to perform the block, utilizing ultrasound to perform the block is preferably detected to overcome this obstacle, even following a CS. transversus abdominis plane block doesn't give visceral analgesia, that is its primary disadvantage, but we overcome this by multimodal analgesia to decline visceral pain & opioid consumption.

The limitations of the study were that Performing TAP or local infiltration while the patient is anesthetized, so the success rate of the block and the level of sensory blockade of the abdominal wall weren't evaluated. This research evaluates the impacts of single-injection block or local infiltration, instead of continuous block or infiltration.

Conclusion

PCA with nalufin alone or combined with TAPB or local infiltration of skin incision may be safely & effectively utilized for post-operative pain following CS. PCA combined

with transversus abdominis block, or local infiltration of skin incision had better analgesic effect and reduced the dose of opioids.

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