

A randomised 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

Address for correspondence:
Dr. Parveen Gazala,
Lane No. 18, Rampura,
Lalgarh, Bikaner, Rajasthan,
India.
E-mail: parveengazala.720@gmail.com

Submitted: 03-Jul-2020

Revised: 23-Aug-2020

Accepted: 13-Mar-2021

Published: 15-Apr-2021

Bhati Kanta, Dhawan Sonali, Parveen Gazala, Khilji Yunus, Kuraning Kiran
Department of Anaesthesia, S.P. Medical College and A.G. of Hospitals, Bikaner, Rajasthan, India

ABSTRACT

Aims: Post-operative analgesia is a major component of perioperative care. An ideal method of pain relief after caesarean section should be cost-effective and safe for mother and baby. This study aims to evaluate the analgesic efficacy of transversus abdominis plane (TAP) block combined with intraoperative diclofenac aqueous for post-operative analgesia in caesarean section. **Methods:** A prospective randomised double-blind study was conducted on 60 patients over a period of six months. Patients were enrolled in two groups ($n = 30$). Group A and Group B both received bilateral landmark based TAP block using ropivacaine 0.75% (1.5 mg/kg), 20 ml at end of surgery. Group B received diclofenac sodium aqueous 75 mg intravenous intraoperatively. **Results:** The difference of visual analogue score (VAS) at movement was significant at 4 and 6 h in Group A versus Group B (3.00 ± 0.64 versus 2.37 ± 0.89 , 4.43 ± 0.68 versus 3.53 ± 1.2). At rest, VAS score was lower in Group B than in Group A at all time intervals ($P < 0.05$). Time to demand of first dose of rescue analgesic was prolonged in Group B (11.5 ± 4.1 h) than in Group A (7.55 ± 1.41 h). Mean dose of analgesic consumption in first 24 h was lesser in Group B (61.67 ± 34.57 mg) than in Group A (98.33 ± 37.68 mg). Patient satisfaction score was higher in Group B (8 ± 1.04) than in Group A (6.23 ± 1.04). **Conclusion:** TAP block along with intraoperative diclofenac aqueous as component of multimodal regimen provides superior post-operative analgesia and better patient satisfaction as compared to TAP block alone.

Key words: Diclofenac sodium aqueous, multimodal technique, post-operative analgesia, ropivacaine 0.75%, transversus abdominis plane block.

Access this article online
Website: www.ijaweb.org
DOI: 10.4103/ija.IJA_761_20
Quick response code


INTRODUCTION

Post-operative pain after caesarean section has many adverse physiological and psychological consequences in the parturient. It can lead to slow recovery, increased use of medications, patient dissatisfaction, and prolonged hospital stay. Poorly controlled post-operative pain may even lead to chronic pain syndrome.^[1] Therefore, adequate pain control is important to facilitate early rehabilitation and mobilisation of the mother, thereby preventing thromboembolic events and allowing early breastfeeding.^[2]

Transversus abdominis plane (TAP) block, either anatomical landmark based or ultrasound guided, represents one of the most widely used regional

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: WKHLRPMedknow_reprints@wolterskluwer.com

How to cite this article: Kanta B, Sonali D, Gazala P, Yunus K, Kiran K. A randomised 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. *Indian J Anaesth* 2021;65:316-20.

analgesia technique. It is an important component of multimodal approach for post-operative analgesia for many abdominal procedures.^[3]

In surgeries like caesarean section, there is extensive tissue dissection and organ handling. Pain after caesarean section has two components: visceral pain from uterine contractions and somatic component from surgical wounds. For management of such pain, we should approach a multimodal treatment to act on both the components of pain. TAP block provides analgesia by blocking somatic component of pain, sparing the visceral component. This limitation can be overcome by supplementing with different parenteral analgesics like opioids, non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, gabapentin, N-methyl-D-aspartate (NMDA) antagonists, etc.^[4] Opioids are known to have side effects like nausea, vomiting, somnolence, and respiratory depression, therefore limiting their use.^[5] Aqueous diclofenac sodium, being an NSAID, has anti-inflammatory, anti-pyretic, anti-oedema, and analgesic properties. It is efficacious in post-caesarean section pain as it acts via inhibiting peripheral tissue prostaglandin synthesis in response to tissue injury and uterine contraction.

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. Primary objective was to assess total analgesic consumed in first 24 h for post-operative analgesia. Secondary objectives were to assess time of rescue analgesic, pain relief at different time intervals during post-operative 24 hours, patient satisfaction scores and to observe complications if any.

MATERIALS AND METHODS

The present study was carried out after approval from the Institutional Ethics Committee {No:F:29 (Acad) SPMC/2019/302}. It was a prospective, randomised, double-blind study conducted over a period of six months (July 2019 to December 2019). All the procedures performed in this study were in accordance with the ethical standards of the Institutional Research Committee.

The study included 60 American Society of Anesthesiologists (ASA) physical status II female patients aged 18–40 years scheduled for elective and emergency caesarean section under spinal anaesthesia.

Exclusion included patients with history of drug allergy, local anaesthetic toxicity, body mass index (BMI) >30 kg/m² (to limit maximum ropivacaine dose to 3 mg/kg), contraindications to regional anaesthesia (bleeding diathesis, infection at the site of block and peripheral neuropathy), severe medical conditions such as severe pre-eclampsia and eclampsia, and patients with intraoperative complications like postpartum haemorrhage and severe foetal distress.

After obtaining informed written consent, patients were randomly allotted into two groups: Group A (TAP block) and Group B (intravenous diclofenac aqueous and TAP block) comprising 30 patients in each. Randomisation was done using computer-generated sequence of random numbers in 1:1 ratio. Allocation concealment was done using sequentially numbered opaque sealed envelopes technique. A thorough preoperative assessment was done before the surgery. All the patients were explained visual analogue score (VAS) scale preoperatively and were instructed to use it as a tool for measuring post-operative pain. After confirmation of fasting status, patients were premedicated with intravenous metoclopramide 10 mg and intravenous ranitidine 50 mg in the preoperative holding area.

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 in the subarachnoid space and patient was made supine. 15° wedge was placed under her right hip. The sensory block was assessed by pin prick method along the mid-clavicular line bilaterally. The motor block was assessed according to the modified Bromage scale. Surgical incision was allowed after achieving a sensory level of anaesthesia up to T4 and Bromage block of scale two. Mean arterial pressure and heart rate were recorded during 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 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 pain). Rescue analgesia was given to patients on demand or when VAS was more than 4 in the form of intramuscular diclofenac 1 mg/kg.

The parameters that were studied and compared were time to first request for analgesic and total diclofenac requirement in 24 h and VAS at 2, 4, 6, 12, 24 h both during movement and rest. Patient satisfaction evaluation was performed 24 h after the block. Patients were asked verbally to provide a score between 1 and 10 (0—not satisfied, 10—fully satisfied) depending on level of satisfaction achieved in pain relief and were evaluated using unpaired *t*-test.

Any complication and side effects were recorded during this period.

Sample size of 20 cases was required in each group at 80% study power and alpha error 5%. Expecting approximate 10% drop out, we designed our study with 30 cases in each group. For reference purpose, we used study by Ila B. Patel *et al.*^[6] MedCal statistical software was used for sample size calculation.

Data were collected, tabulated, and then analysed. Data were expressed as mean and standard deviation (SD). Demographic data were analysed using Student’s *t*-test. Other measurement like duration of analgesia, total requirement of diclofenac, VAS score, and vitals were analysed by unpaired Student’ *t*-test. A difference with significant level (*P* value <0.05) was considered statistically significant.

RESULTS

Sixty patients were recruited in the study; of these thirty were randomised to undergo TAP block and remaining thirty received intravenous diclofenac

Table 1: Demographic characteristics			
Characteristics	Mean±SD		P
	Group A	Group B	
Age (years)	25±3.9	26.367±3.498	NS
BMI (kg/m ²)	23.166±2.288	23.04±1.561	NS
Duration of surgery (min)	42.433±2.7877	42.7±2.667	NS

BMI=Body mass index; SD=Standard deviation

sodium aqueous with TAP block. Demographic profile, age, weight, body mass index, and duration of surgery were comparable in both groups [Table 1].

VAS was noted at 2, 4, 6, 12 and 24 h post-operatively. VAS was significantly less in Group B in first 4–12 h post-operatively both during rest and movement as compared to those in Group A [Table 2].

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) [Table 3].

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) [Figure 1].

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) [Figure 2]. The majority of patients in Group B had patient satisfaction score >7.

DISCUSSION

The result of our study shows that intraoperative diclofenac aqueous IV (intravenous), when used as part of multimodal analgesic regimen with TAP block in caesarean section, delayed time for rescue analgesia, reduced requirement of post-operative analgesic, decreased pain scores, and had better patient satisfaction. With increasing use of regional analgesic techniques in current anaesthesia practice, TAP block has made its resurgence as a part of multimodal analgesia. Various studies suggest benefit of TAP block

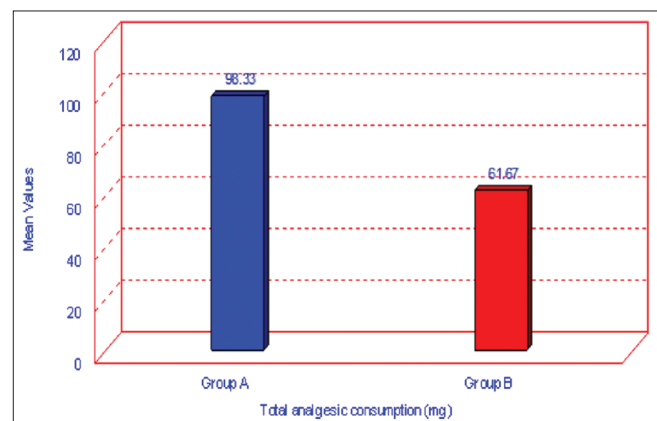


Figure 1: Total diclofenac consumption in mg in first 24 h after surgery

Table 2: Pain score (visual analogue score) at rest and on movement

Time interval (h)	VAS at rest (Mean±SD)				VAS on movement (Mean±SD)			
	Group A	Group B	t	P	Group A	Group B	t	P
2	2.27±0.91	1.67±0.80	2.714	0.009	2.27±0.91	1.76±0.87	2.701	0.009
4	3.17±0.99	2.20±0.89	3.994	0.001	3.00±0.64	2.37±0.89	2.785	0.003
6	4.50±0.73	3.17±1.05	5.696	0.001	4.43±0.68	3.53±1.22	3.521	0.001
12	5.00±0.64	4.37±0.89	3.159	0.003	4.80±0.41	4.33±1.03	2.311	0.024
24	5.29±0.61	5.17±0.75	0.671	0.505	4.89±0.32	4.83±0.54	0.512	0.610

VAS=Visual Analogue Score, SD=Standard deviation

Table 3: Interval/mean time to requirement of first dose of rescue analgesic

Time interval of requirement of first dose of rescue analgesic (hours)	Number of patients (%)		t	P
	Group A	Group B		
2–6	13.3	0		
6–8	56.7	10.0		
8–12	31	56.7		
12–24	0	33.3		
Time to first demand of rescue analgesic in hours (Mean±SD)	7.55±1.41	11.5±4.06	5.815	<0.001

SD=Standard deviation

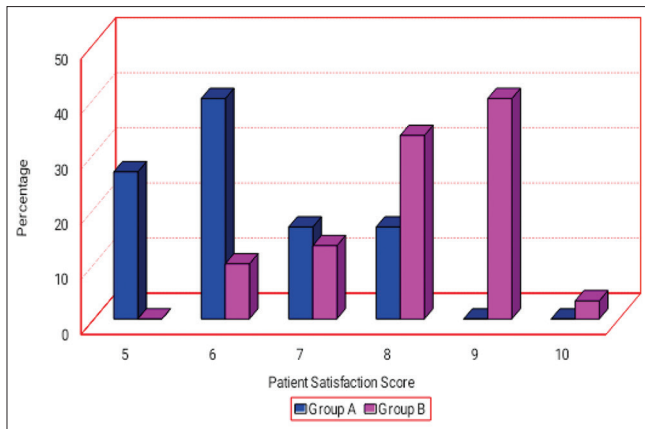


Figure 2: Percentage of patients according to post-operative patient satisfaction score

in caesarean section in terms of reduced perioperative opioid use, early ambulation, early return of bowel function, and better patient recovery.

Evidence-based guidelines hold that NSAIDs are integral to the management of acute post-operative pain. Many studies also report benefits of intravenous diclofenac infusion in caesarean surgeries.^[7] Pain after caesarean section has two components: visceral (due to uterine contraction) and somatic (from surgical wounds). Many previous studies suggested the combination of diclofenac and opioids for post-caesarean analgesia, but opioids negatively affected the neonate and mother with their well-documented side effects.

For the above-mentioned reasons, we formulated this study to find out the best suitable technique of analgesia by combining a regional analgesia technique using

TAP block with good effect on somatic component and a non-opioid parenteral analgesic diclofenac aqueous on visceral component in the form of multimodal analgesia regimen in patients undergoing caesarean section.

Our study demonstrated lower mean VAS score at movement in early post-operative period in the group of patients who received intraoperative intravenous diclofenac during surgery in addition to TAP block. The reason for this may be that during mobility, pain mainly arises from visceral component, which is not covered by TAP block alone. This was comparable with the results of Jadon *et al.*^[8] and Kabsay DT *et al.*^[9] that also reported lower post-operative median VAS pain score, both at rest and on movement. The reason for prolonged duration of analgesic effect is that TAP is relatively poorly vascularised and drug clearance may be slowed due to which drug remains in plane for longer period. Furthermore, Niraj *et al.*^[10] and Bharti *et al.*^[11] in their studies showed that TAP block group had reduced post-operative VAS at rest and on movement.

Most of the patients (56%) in Group A demanded first dose of rescue analgesic during first 6–8 post-operative hours, whereas in Group B, maximum rescue analgesic requirement was during first 10–12 h (36%) and 12–18 h (23%) [Figure 1]. This finding is consistent with studies done by various authors.^[12–14]

Local anaesthetic infiltration is commonly used as a traditional method for post-operative analgesia, but TAP block has been found to have better and

long-lasting effect. Hence, 73% of the patients in the TAP block with diclofenac group were highly satisfied with pain relief. Belavy *et al.* also showed increased patient satisfaction with TAP block.^[12]

This study has certain limitations—We could not maintain uniformity in terms of incision length and tissue handling, which may have led to variability in severity of pain. Also, the subjects were not followed up long term for incidence of chronic pain.

Sample size of our trial was insufficient to assess the safety of block. Even though systemic toxicity is not reported in the literature as a complication of TAP block, it remains a possibility. However, no complications were found in our study.

CONCLUSION

We conclude that intravenous diclofenac along with TAP block when used as a component of multimodal analgesic regimen provides superior post-operative analgesia as it prolongs the time to first analgesic request. It also decreases total analgesic requirement and leads to better patient satisfaction.

Financial Support and Sponsorship

Nil.

Conflicts of Interest

There are no conflicts of interest.

REFERENCES

- Brennan F, Carr DB, Cousins M. Pain management: A fundamental human right. *Anesth Analg* 2007;105:205-21.
- Patel SA, Gotkin J, Huang R, Darling C, Pates JA, Dolinsky B. Transversus abdominis plane block for postoperative analgesia after caesarean delivery. *J Matern Fetal Neonatal Med* 2012;25:2270-3.
- American Society of Anesthesiologists Task Force on Acute Pain Management. Practice guidelines for acute pain management in the perioperative setting: An updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management. *Anesthesiology* 2012;116:248-73.
- Young MJ, Gorlin AW, Modest VE, Quraishi SA. Clinical implication of the transversus abdominis plane block in adults. *Anaesthesiol Res Pract* 2012;2012:731645.
- Adeel S, Narayan P, Chandrashekar MM, Abuhassan KA, Elsemeen RM, Skowronski S. Ultrasound-guided transversus abdominis plane block: An evaluation of its efficacy in reducing post-operative opioid requirements in caesarean section. *J Obstet Anaesth Crit Care* 2017;7:81-4.
- Patel IB, Shah AP, Bhiwal AK. Observational study to evaluate transversus abdominis plane (TAP) block in abdominal surgery by total requirement of diclofenac as a post operative analgesia drug. *Intern J of Biomed Research* 2015;6:841-6.
- Sujata N, Hanjoo VM. Pain control after caesarean birth. *J Gen Pract* 2014;2:1000164.
- Jadon A, Jain P, Chakraborty S, Motakal M. Role of ultrasound guided transversus abdominis plane block as a component of multimodal analgesic regimen for lower segment caesarean section: A randomized double blind clinical study. *BMC Anesthesiol* 2018;18:53.
- Kahsay DT, Elsholz W, Bahta HZ. Transversus abdominis plane block after Caesarean section in an area with limited resources. *S Afr J Anaesth Analg* 2017;23:90-5.
- Niraj G, Searle A, Mathews M, Misra V, Baban M, Kiani S, *et al.* Analgesic efficacy of ultrasound-guided transversus abdominis plane block in patients undergoing open appendectomy. *Br J Anaesth* 2009;103:601-5.
- Bharti N, Kumar P, Bala I, Gupta V. The efficacy of a novel approach to transversus abdominis plane block for postoperative analgesia after colorectal surgery. *Anesth Analg* 2011;112:1504-8.
- Belavy D, Cowlshaw PJ, Howes M, Phillips F. Ultrasound-guided transversus abdominis plane block for analgesia after Caesarean delivery. *Br J Anaesth* 2009;103:726-30.
- Dwivedi D, Bhatanagar V, Goje HK, Ray A, Kumar P. Transversus abdominis plane block: A multimodal analgesia technique-our experience. *J Mar Med Soc* 2017;19:38-42.
- Das N, Shukla V, Singh D, Yadav U. Comparison of analgesic efficacy between TAP block and local site infiltration postoperatively in caesarean section. *Int J Res Med Sci* 2018;6:1407-13.