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AN EVALUATION OF POSTOPERATIVE ANALGESIC EFFECT OF TRANSVERSUS ABDOMINIS PLANE BLOCK IN COMPARISON TO INTRAVENOUS DICLOFENAC SODIUM IN TOTAL ABDOMINAL HYSTERECTOMY SURGERIES: A PROSPECTIVE RANDOMIZED STUDY

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ABSTRACT

Background: Effective postoperative pain management is essential in enhancing recovery and reducing morbidity after lower abdominal surgeries such as Total Abdominal Hysterectomy (TAH). The Transversus Abdominis Plane (TAP) block is a technique of regional anesthesia that is increasingly used to control postoperative pain. This study aimed to compare the efficacy of ultrasound-guided TAP block with intravenous Diclofenac sodium for postoperative analgesia in TAH.

Methods: Thirty ASA Grade I–II female patients aged 30–60 years undergoing elective TAH under spinal anesthesia were randomized into two equal groups. Group T received bilateral ultrasound-guided TAP block with 15 ml of 0.25% Bupivacaine on each side, while Group D received intravenous Diclofenac sodium (1 mg/kg) on demand. Pain was assessed using the Visual Analog Scale (VAS) at 0, 2, 4, 6, 12, and 24 hours. Secondary parameters included time to first rescue analgesia, total analgesic requirement, hemodynamic changes, and adverse events.

Results: VAS scores were significantly lower in Group T at all time points from 2 hours onward ($p < 0.05$). Group T showed longer time to first rescue analgesia (11.40 ± 0.74 vs. 2.93 ± 1.03 hours; $p < 0.01$) and reduced total analgesic consumption (105.00 ± 38.03 vs. 205.00 ± 34.33 mg; $p < 0.01$). Hemodynamic parameters were more stable in the TAP group. No major complications were observed.

Conclusion: TAP block provides superior and prolonged postoperative analgesia compared to intravenous Diclofenac in TAH and is a safe and effective analgesic technique.

KEYWORDS: Postoperative Pain; Total Abdominal Hysterectomy; Transversus Abdominis; Ultrasound-guided; Analgesia; Visual Analog Scale.

INTRODUCTION

Pain, as defined by the International Association for the Study of Pain (IASP), is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in

terms of such damage" [1]. Effective postoperative pain management is a crucial component of surgical care, directly influencing patient comfort, early ambulation, reduced morbidity, and faster recovery. Inadequate control of postoperative pain not only impairs patient outcomes but also increases hospital stay and overall healthcare costs. The American Pain Society advocates for multimodal analgesia, which combines different classes of analgesics and techniques, including non-pharmacological interventions, to optimize pain relief and minimize opioid-related adverse effects[2]. Among common surgical procedures, lower abdominal surgeries such as Total Abdominal Hysterectomy (TAH) are associated with significant postoperative pain, which has nociceptive, inflammatory, neurogenic, and visceral components [3]. Tissue injury during surgery induces peripheral sensitization through the release of inflammatory mediators that activate nociceptors, while central sensitization involves heightened excitability of spinal neurons, prolonging pain perception even after the initial stimulus is removed.

Traditionally, intravenous nonsteroidal anti-inflammatory drugs (NSAIDs) have been used widely to manage postoperative pain. Aqueous diclofenac sodium, an NSAID drug, exhibits anti-inflammatory, antipyretic, anti-edema, and analgesic properties. It is widely used for managing postoperative pain by inhibiting the synthesis of prostaglandins in peripheral tissues, a process triggered by tissue injury. Diclofenac achieves this effect by blocking both cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2) enzymes with relative equipotency, interrupting the activation of nociceptors responsible for pain and inflammation [4]. It is favored globally due to its efficacy and the absence of opioid-related side effects. However, despite its advantages, diclofenac is not free from systemic side effects, prompting continued research into safer and equally effective alternatives for postoperative analgesia.

Regional anesthesia techniques, particularly the Transversus Abdominis Plane (TAP) block, have gained popularity as a targeted approach to controlling somatic pain from abdominal wall incisions [5]. First introduced in 2001, the TAP block involves the deposition of local anesthetic in the neurovascular plane between the internal oblique and transversus abdominis muscles, through the anatomical landmark, the Triangle of Petit [6]. This blocks the thoracolumbar nerves (T6–L1) supplying the anterior abdominal wall,[7] providing effective analgesia for various abdominal surgeries, including laparoscopic,[8] and open procedures [9]. TAP block, either anatomical landmark-based or ultrasound-guided, represents one of the most widely used regional analgesia techniques. It is an important component of the multimodal approach for post-operative analgesia for many abdominal procedures [5].

At our institution, intravenous Diclofenac sodium is routinely used for postoperative analgesia following TAH. Considering the increasing interest in TAP blocks as an alternative modality, this study was designed to evaluate and compare the analgesic effectiveness of ultrasound-guided TAP block with that of intravenous Diclofenac sodium in patients undergoing TAH.

This prospective randomized study aimed to evaluate the postoperative analgesic efficacy of the ultrasound-guided TAP block compared to intravenous Diclofenac sodium in patients undergoing TAH. The primary objective was to compare the effectiveness of both analgesic techniques using the Visual Analog Scale (VAS) score for pain assessment. Secondary objectives included evaluating the time to first rescue analgesia, total analgesic consumption within the first 24 hours postoperatively, changes in hemodynamic parameters such as heart rate (HR) and mean arterial pressure (MAP), and the incidence of any associated complications or adverse events.

Material & Methods

This randomized comparative study was conducted after approval from the Institutional Ethical Committee (Ref: IEC-DDUH/upn78/ 2022-05-05/7/v1 dated on 10th May, 2022), and the study was registered with Clinical Trials Registry-India (CTRI Reg. No. CTRI/2023/04/051409, CTRI Ref No: REF/2023/03/06494) dated 10/04/2023. This study was conducted in the Department of Anesthesiology at Deen Dayal Upadhyay Hospital, Hari Nagar, New Delhi, between May 2023 and June 2024, following approval from the Institutional Ethical Committee. The study included a total of 30 female patients aged between 30 to 60 years, classified as American Society of

Anesthesiologists (ASA) physical status Grade I or II, who were scheduled to undergo elective TAH surgeries under spinal anesthesia. Written informed consent was obtained from all participants after a detailed explanation of the study protocol and the VAS score for pain assessment.

Patients with known allergies to study drugs, a history of coagulopathy, or contraindications to spinal anesthesia were excluded. Additionally, patients whose procedures were performed under general anesthesia or were converted to general anesthesia intraoperatively, as well as those who experienced intraoperative hemodynamic instability, were not included in the study.

Patients were randomly divided into two groups (15 in each group) using block randomization via a sealed envelope technique. Each block contained 10 envelopes with equal assignments for the two groups. Group T received a bilateral ultrasound-guided TAP block with 15 ml of 0.25% Bupivacaine on each side. Group D received intravenous Diclofenac sodium at a dose of 1 mg/kg.

The sample size was calculated based on a prior study by Jigna R. Shah et al. [10], which observed a VAS score of 0.9 ± 0.40 in the TAP group and 2.3 ± 1.02 in the control group at 2 hours postoperatively. Using these values, the minimum required sample size per group was calculated as 15, using the formula:

$n= (Z_{\alpha/2} + Z_{\beta})^{2} * 2x(SD)^2 / (\text{mean difference})^2$

Where Zα is the value of Z at a two-sided alpha error of 1% and Zβ is the value of Z at a power of 99% and the mean difference is the difference in mean values of the two groups.

Pooled standard deviation= $\sqrt{(S1^{2} + S2^{2})/2}$

Where S1 is the standard deviation of group 1 and S2 is the standard deviation of group 2. The pooled standard deviation (SD) was calculated as 0.775.

All patients underwent standard preoperative assessment, including detailed history, physical examination, and relevant investigations (CBC, blood sugar, renal function tests, ECG, and coagulation profile as indicated). In the operating room, standard monitoring (ECG, non-invasive blood pressure, and pulse oximetry) was applied. Intravenous access was secured using an 18G cannula. Spinal anesthesia was given in the sitting position with a 25G Quincke spinal needle with 3 to 3.5 ml of 0.5% hyperbaric Bupivacaine hydrochloride.

In Group T, the TAP block was performed at the end of surgery under real-time ultrasound guidance using a high-frequency linear transducer (8–13 MHz) placed in the Triangle of Petit. A needle was inserted using the in-plane technique, and after confirming placement in the transversus abdominis plane with 2 ml of saline hydrodissection, 15 ml of 0.25% Bupivacaine was injected on each side with continuous visualization of drug spread. Group D patients received intravenous Diclofenac sodium (1 mg/kg) on demand when the VAS score reached ≥ 3. In both groups, intravenous Diclofenac was used as the rescue analgesic.

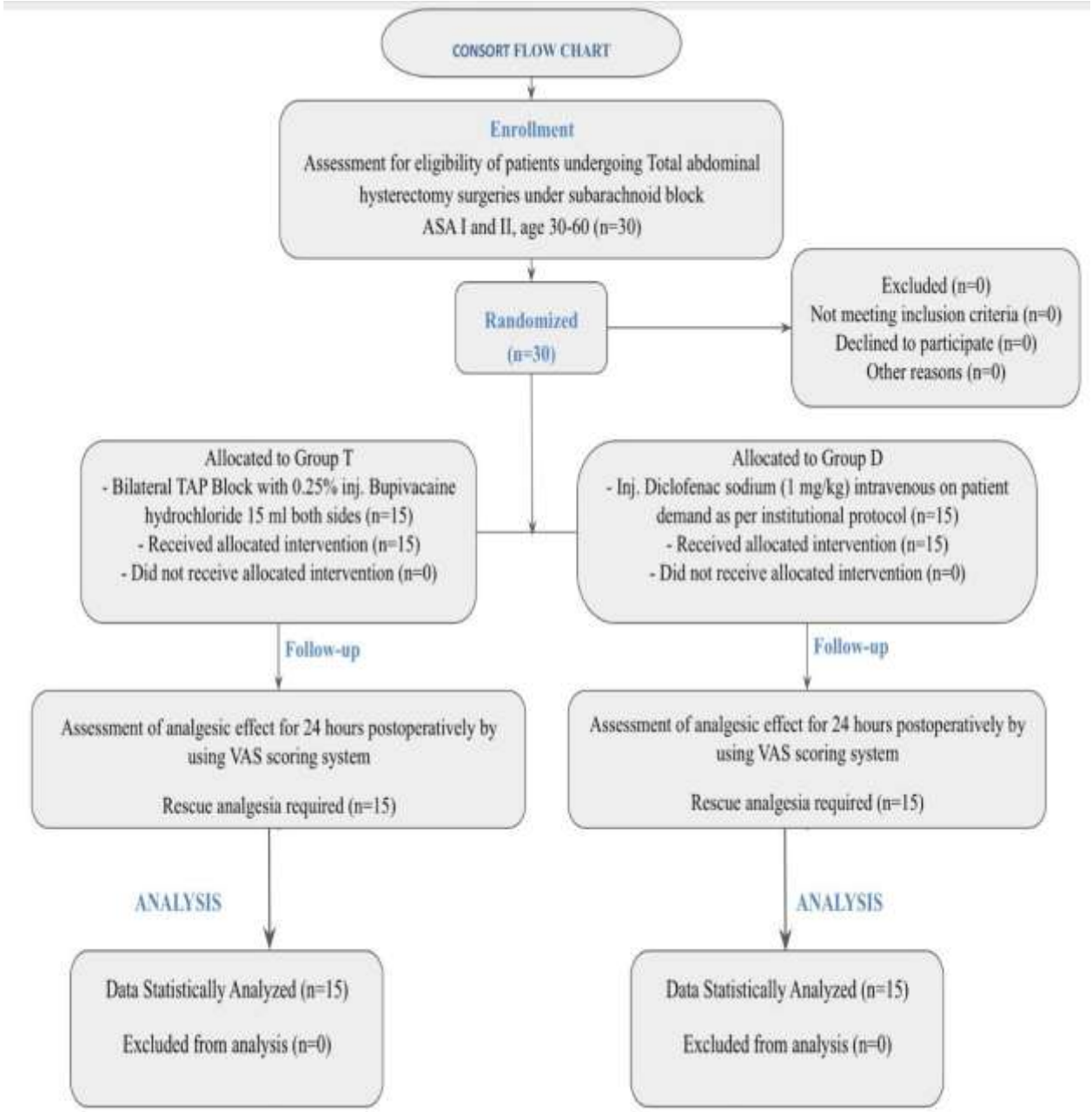
The postoperative period started at the patient transfer from the operating table. VAS scores were documented at 0, 2, 4, 6, 12, and 24 hours. Time to first rescue analgesia (VAS ≥ 3) and total 24-hour analgesic use were noted. Hemodynamic parameters (HR and MAP) were monitored, and any adverse events (e.g., hypotension, bradycardia, nausea, vomiting, dizziness) were documented.

All data were documented in a structured format and analyzed using SPSS version 26.0. Continuous variables were expressed as mean ± SD. Intergroup comparisons of continuous variables were conducted using the unpaired t-test for normally distributed data and the Mann-Whitney U test for non-parametric data. Frequencies and percentages were used for categorical variables, with comparisons made using the Chi-square test. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 30 female patients undergoing elective TAH were randomized into two equal groups: Group T (Transversus Abdominis Plane Block) and Group D (Intravenous Diclofenac Sodium), with 15 patients in each group. All patients included in the study completed the follow-up. (Fig. 1)

Figure 1: CONSORT flowchart (n-number of patients). Group T- Transversus Abdominis Plane Block, Group D- Intravenous Diclofenac Sodium. CONSORT = Consolidated Standard of Reporting Trials



The demographic characteristics, including age, height, weight, and BMI, were comparable between the groups ($p > 0.05$). ASA physical status was similarly distributed, with 50% of patients in each group categorized as Grade I or II.

Hemodynamic parameters

HR and MAP were recorded at predefined intervals, both intraoperatively and postoperatively. Both groups exhibited comparable baseline heart rates (Group T: 76.93 ± 3.47 bpm; Group D: 75.80 ± 4.28 bpm; $p = 0.43$). Intraoperative HR values remained similar across groups ($p > 0.05$). However, a significant difference was noted postoperatively. Group D showed a progressive rise in HR, peaking

at 82.33 ± 4.07 bpm at 12 hours and 82.00 ± 3.76 bpm at 24 hours, compared to stable values in Group T ($p < 0.05$) (Table 1)

Table 1: Comparison of mean heart rate between Groups T and D

Heart Rate	Group	Mean	SD	p- value
Baseline	**T**	76.93	3.47	**0.43**
	D	75.80	4.28	
Intra-op (0 min)	**T**	81.07	3.20	**0.55**
	D	80.20	4.54	
10 min	**T**	77.07	3.73	**0.44**
	D	75.87	4.57	
30 min	**T**	73.87	3.38	**0.22**
	D	72.07	4.43	
45 min	**T**	75.27	3.11	**0.45**
	D	74.20	4.40	
End of Surgery	**T**	76.93	4.03	**0.97**
	D	76.93	4.01	
Post-op_0 h	**T**	77.07	3.81	**0.75**
	D	76.60	4.12	
2 h	**T**	77.20	2.86	**<0.01**
	D	81.53	3.68	
6 h	**T**	77.33	2.82	**<0.01**
	D	82.07	3.13	
12 h	**T**	79.13	3.83	**0.035**
	D	82.33	4.07	
24 h	**T**	78.60	3.46	**0.016**
	D	82.00	3.76	

MAP and Oxygen saturation (SpO_2) values remained within normal ranges and did not differ significantly between groups at any point of observation ($p > 0.05$).

Postoperative Pain (VAS Scores)

VAS scores were recorded at 0, 2, 4, 6, 12, and 24 hours postoperatively. At 0 hours, both groups had low pain scores (Group T: 0.20 ± 0.41; Group D: 0.53 ± 0.74; $p = 0.14$), indicating initial comparable analgesic effects due to spinal anesthesia.

However, after 2 hours, Group T consistently exhibited significantly lower VAS scores. At 2 hours, the mean VAS in Group T was 0.33 ± 0.49 compared to 2.20 ± 1.32 in Group D ($p < 0.01$). This trend continued through 4, 6, 12, and 24 hours, with the TAP block group maintaining lower pain scores at all time points ($p < 0.05$) (Table 2). This demonstrates the superior and sustained analgesic effect of the TAP block.

Table 2: Comparison of Mean VAS Scores between Groups T and D

VAS Score	Group	Mean	SD	p- value
0 h	**T**	0.20	0.41	**0.14**
	D	0.53	0.74	
2 h	**T**	0.33	0.49	**<0.01**
	D	2.20	1.32	
4 h	**T**	0.67	0.72	**0.022**
	D	1.80	1.66	
	T	0.80	0.86	

6 h	**D**	1.93	1.62	**0.025**
	T	1.80	1.66	
12 h	**D**	3.00	1.20	**0.031**
	T	1.13	1.25	
24 h	**D**	2.40	1.12	**<0.01**

Analgesic Requirements

The time to first rescue analgesia was significantly longer in Group T (11.40 ± 0.74 hours) compared to Group D (2.93 ± 1.03 hours) ($p < 0.01$), indicating prolonged pain relief with TAP block. Additionally, the total analgesic requirement over 24 hours was significantly reduced in the TAP group (105.00 ± 38.03 mg) versus the Diclofenac group (205.00 ± 34.33 mg) ($p < 0.01$) (Table 3), further affirming the analgesic efficacy of TAP block.

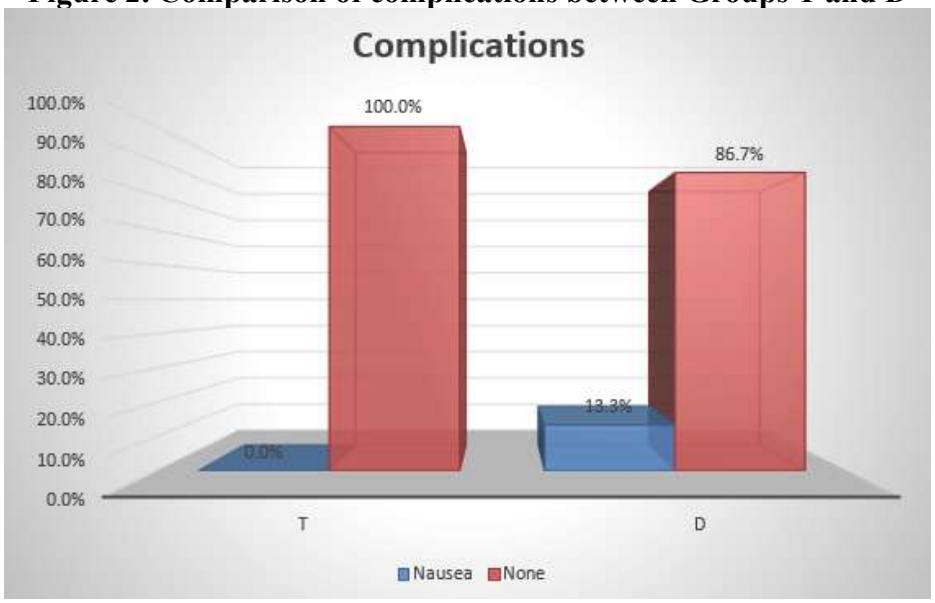
Table 3. Comparison of the mean time to first rescue analgesia and total analgesic requirement in 24 hours

Parameters	Group	N	Mean	SD	p- value
	T	15	11.40	0.74	
Time to first rescue analgesia (h)	**D**	15	2.93	1.03	**<0.01**
Total analgesic requirement in 24 hours (mg)	**T**	15	105.00	38.03	
	D	15	205.00	34.33	**<0.01**

Complications

No major complications were observed in either group. Two patients (13.3%) in Group D experienced postoperative nausea, while no adverse effects were reported in Group T. However, the difference was not statistically significant ($p = 0.14$). (Fig. 2)

Figure 2: Comparison of complications between Groups T and D



DISCUSSION

Postoperative pain control continues to be a central focus in current anesthetic care. Particularly in lower abdominal surgeries such as TAH, optimal pain control is crucial to ensure early mobilization, reduced morbidity, and patient satisfaction. This study aimed to compare the postoperative analgesic efficacy of the TAP block with intravenous Diclofenac sodium in patients undergoing TAH.

Demographic and Baseline Parameters

In the present study, the two groups were comparable in terms of age, height, weight, BMI, and ASA grading, ensuring homogeneity in baseline characteristics. The mean age of patients was 42.97 years, consistent with studies by Jigna R. et al. [10], Sulagna et al. [11], and Prabu N. et al. [12], which evaluated similar patient populations undergoing gynecological and lower abdominal surgeries.

Hemodynamic Changes

Heart rate remained comparable between both groups during the intraoperative period ($p > 0.05$). However, during the postoperative period, Group D showed a significant rise in mean heart rate at 2, 6, 12, and 24 hours, whereas Group T maintained values closer to baseline. At 2 hours, mean HR in Group D was 81.53 ± 3.68 bpm compared to 77.20 ± 2.86 bpm in Group T ($p < 0.01$). At 24 hours, the difference persisted (82.00 ± 3.76 vs. 78.60 ± 3.46; $p = 0.016$). This may be attributed to better pain relief in the TAP group, resulting in less sympathetic stimulation. These observations are supported by Prabu N. et al. [12], who reported lower HR in the TAP group throughout 24 hours, indicating improved analgesia and hemodynamic stability. Similarly, Jigna R. et al. [10] reported a significant rise in heart rate only at the 24-hour mark in the control group ($p < 0.05$). However, Sulagna et al. [11] did not observe statistically significant HR differences, though they acknowledged better pulse rate control in the group T.

In terms of MAP, both groups remained comparable throughout the intraoperative and postoperative periods in our study ($p > 0.05$). This finding is consistent with the observations of Jigna R. et al. [10] and Sulagna et al. [11], the latter reporting a difference only at the 2-hour mark ($p < 0.05$). In contrast, Prabu N. et al. [12] noted lower MAP throughout the postoperative period in the TAP group.

Oxygen saturation (SpO_2) values were comparable in both groups at all recorded time points, with no statistically significant difference ($p > 0.05$). These results are in agreement with Sulagna et al. [11], who reported SpO_2 values ranging from 97% to 100% in both TAP and control groups.

Pain was evaluated using the VAS score at 0, 2, 4, 6, 12, and 24 hours. At 0 hours, VAS scores were low and comparable (Group T: 0.20 ± 0.41; Group D: 0.53 ± 0.74; $p = 0.14$). However, from 2 hours onward, Group T consistently showed significantly lower pain scores. At 2 hours, VAS was 0.33 ± 0.49 in Group T and 2.20 ± 1.32 in Group D ($p < 0.01$). At 24 hours, VAS remained lower in the TAP group (1.13 ± 1.25 vs. 2.40 ± 1.12; $p < 0.01$). These findings align with those of Jigna R. et al. [10] and Prabu N. et al. [12], who both reported significantly lower VAS scores at all time points in the TAP block groups. Kumbare S. et al. [13] also found consistently higher VAS scores in the diclofenac group in patients undergoing hernia repair. Sulagna et al. [11] reported significantly lower VAS scores both at rest (3 mm vs. 27 mm) and with movement (8 mm vs. 35 mm) in TAP block recipients.

Time to First Rescue Analgesia

A significant finding of this study was the prolonged duration of analgesia in the TAP group, with mean time to first rescue analgesia being 11.4 ± 0.74 hours compared to 2.93 ± 1.03 hours in the Diclofenac group ($p < 0.01$). Sulagna et al. [11] observed a median analgesia duration of 290 minutes in the TAP group versus 16 minutes in controls ($p < 0.000$). Similarly, Kumbare S. et al [13] reported a mean analgesia duration of 669.66 ± 346 min in the TAP group and 220.33 ± 139.24 min in the control group ($p < 0.01$). Jigna R. et al. [10] observed identical values for rescue analgesia timing, reinforcing the prolonged effectiveness of the TAP block.

Total Analgesic Requirement

The TAP block significantly reduced the need for systemic analgesics. Total Diclofenac consumption in the TAP group was 105.00 ± 38.03 mg compared to 205.00 ± 34.33 mg in the control group ($p < 0.01$). This is consistent with findings by Prabu N. et al. [12] who reported reduced morphine consumption for breakthrough pain in the TAP group (5.4 mg vs. 9.4 mg; $p < 0.001$), and by Kumbare S. et al. [13], who assessed the effectiveness of unilateral TAP block versus IV Diclofenac for postoperative analgesia in hernia repair (95 mg vs. 202.5 mg). Carney et al. [14] also observed significantly lower opioid use up to 48 hours postoperatively in patients who received TAP blocks.

Complications

Both groups were well-tolerated, with no major complications reported. However, two patients (13.3%) in the Diclofenac group experienced postoperative nausea, while no such adverse effects occurred in the TAP group ($p = 0.14$). Similar safety profiles were observed in studies by Sulagna et al. [11] and Prabu N. et al. [12]. The latter noted reduced nausea and vomiting at multiple postoperative intervals in the TAP group. No TAP block-related complications were recorded in any of the referenced studies, supporting its safety and efficacy profile.

Conclusion

The present study demonstrates that ultrasound-guided TAP block is a superior modality for postoperative analgesia compared to intravenous Diclofenac sodium in patients undergoing TAH surgeries. The TAP block provided more effective and prolonged analgesia, resulting in lower postoperative pain scores, reduced total analgesic consumption, and maintained greater hemodynamic stability with minimal adverse effects. These findings highlight the TAP block as a valuable component of multimodal analgesia in lower abdominal surgeries.

Despite the promising results, this study has certain limitations. It was a single-center trial with a limited sample size of 30 patients, which may affect the generalizability of the findings. The study population was restricted to ASA I and II patients undergoing elective TAH, thereby excluding higher-risk individuals and other lower abdominal procedures. Additionally, only a single concentration and volume of Bupivacaine was used, without evaluating alternative local anesthetics or adjuvants.

Future studies should involve larger, multi-center cohorts to validate these findings. Further research is also warranted to explore the efficacy of TAP block with different local anesthetics such as Ropivacaine or Levobupivacaine, assess its use in patients with higher ASA grades, and compare outcomes across a wider range of abdominal surgeries.

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