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Original Article

Anaesthesia Section

Transversus Abdominis Plane Block with or without Intravenous Diclofenac Sodium as a Component of Multimodal Postoperative Analgesia Following Laparoscopic Cholecystectomy: A Randomised Clinical Study

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ABSTRACT

Introduction: Multimodal analgesia is the recommended approach for treating post-operative pain after laparoscopic cholecystectomy. The Transversus Abdominis Plane (TAP) block is a recently introduced technique showing promising results. To control visceral and somatic pain adequately and to avoid use of opioids intra-operative diclofenac sodium, combined with TAP block as part of a multimodal approach, may be beneficial.

Aim: To evaluate the efficacy of TAP block with or without intra-operative diclofenac sodium aqueous injection for controlling post-operative pain following laparoscopic cholecystectomy.

Materials and Methods: A randomised, double-blinded study was conducted from February 2022 to October 2022 at Nil Ratan Sircar Medical College, Kolkata, West Bengal, India. Forty American Society of Anaesthesiology (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. The primary outcome was the duration of post-operative analgesia (measured by the first request for rescue analgesia after the end of the operation at a VAS score of 4). Secondary outcomes included the total post-operative analgesic requirement (diclofenac sodium), pain score (VAS) over 24 hours in the post-operative period, and the incidence of complications such as nausea, vomiting, hypotension, and bradycardia. Patient Satisfaction Score (PSS) was recorded for each patient before discharge. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 24.0 software. Continuous variables were expressed as mean and standard deviation, and categorical variables were expressed as percentages. Independent t-tests and chi-square tests were used for between-group comparisons, with a p-value ≤0.05 considered statistically significant.

Results: Amongst total 40 patients included, divided into group A (mean age: 32.95±8.74 years, 6 males and 14 females) and group B (31.90±9.16 years, 5 males and 15 females) with 20 patients each, the demographic characteristics such as age, gender, height, and weight were similar in both groups. The duration of post-operative analgesia was longer in group B (16.32±1.29 hours) than in group A (7.85±1.04 hours). The total post-operative analgesic requirement was lower in group B (32.95±20.9 mg) compared to group A (58.33±17.14 mg). Visual Analogue Scale (VAS) scores were lower in group B than in group A. PSS was significantly higher in group B patients (8.14±1.06) than in group A patients (6.16±1.38).

Conclusion: TAP block, along with intra-operative intravenous diclofenac sodium aqueous, as part of a multimodal regimen, provides superior post-operative analgesia compared to TAP block alone. It is also associated with improved patient satisfaction.

Keywords: Analgesic, Bupivacaine, Intraoperative, Patient satisfaction score, Ultrasonography

INTRODUCTION

Laparoscopic cholecystectomy is a common minimally invasive procedure typically performed under general anaesthesia with opioid analgesia. However, opioid analgesia often leads to side effects such as respiratory depression, sedation, nausea, and vomiting [1-3]. To reduce opioid use and improve post-operative analgesia, various methods including paracetamol, non-opioids, neuraxial blockade, and intraperitoneal lavage of local anesthetic have been successfully employed [4-6]. The multimodal approach, incorporating Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), opioids, and regional analgesia techniques, has been the mainstay for post-operative pain management for many years. Diclofenac, administered as a bolus injection of 75 mg, has been used as monotherapy or in combination with opioid analgesics to manage moderate to severe pain with good tolerability [7,8]. The availability of newer aqueous diclofenac allows for intravenous administration with a faster onset of action, making it suitable for intraoperative pre-emptive analgesia [9-11].

Post-operative pain following laparoscopic cholecystectomy is multifactorial [12]. It primarily arises from the incision made in the anterior abdominal wall, which is innervated by nociceptors and afferents in the fascial plane between the Transversus Abdominis (TA) and Internal Oblique (IO) muscles. In addition to somatic pain related to the incision, post-operative pain includes visceral and

referred components. Visceral pain results from surgical dissection in the gallbladder area, while referred pain is felt in the scapular region due to diaphragm irritation caused by carbon dioxide pneumoperitoneum. Effective control of post-operative pain requires a multimodal approach that addresses all components of pain [13,14]. Recently, the Transverse Abdominis Plane (TAP) block, which involves the administration of a local anesthetic into the fascial plane between the TA and IO muscles, has been shown to provide analgesia and reduce perioperative opioid use in various elective abdominal surgeries, including laparoscopic cholecystectomy, Lower Segment Uterine Section (LSCS), and open appendectomy [15,16]. Ultrasound-guided TAP block primarily targets somatic pain, while the visceral component is not adequately addressed. Additionally, the analgesic effect of a single-shot TAP block is limited, depending on the type of local anesthetic used. This limitation can be overcome by supplementing the TAP block with parenteral diclofenac sodium [17-19].

TAP block combined with post-operative parenteral diclofenac is a commonly used technique and has been shown to effectively control pain in various abdominal operations. This combination has been successfully used for pain control after cesarean section [20]. However, no study has evaluated the efficacy of this multimodal technique in laparoscopic cholecystectomy.

The present study aimed to evaluate the analgesic efficacy of TAP block combined with intraoperative intravenous diclofenac sodium in reducing post-operative pain, opioid consumption, and recovery time following elective laparoscopic cholecystectomy. The primary objective was to compare the duration of post-operative analgesia between the groups. Secondary objectives include assessing total analgesic consumption in the first 24 hours, patient pain scores (VAS), and the observation of any complications.

MATERIALS AND METHODS

This randomised, double-blinded study was conducted over a period from February 2022 to October 2022, at Nil Ratan Sircar Medical College, Kolkata, West Bengal, India. The study received approval from the institutional ethical committee (No. NRSMC/IEC/71/2021 dated 08.10.2021).

Inclusion criteria: The study included 40 ASA physical status I/II patients aged 20-50 years with a body weight <80 kg scheduled for elective laparoscopic cholecystectomy under general anaesthesia. after obtaining informed consent.

Exclusion criteria: Patients beyond the specified age range, weight above 80 kg with acute cholecystitis, anticipated difficult airway, history of drug allergy, local anesthetic toxicity, recent myocardial infarction, pregnancy, and patients with cardiovascular, hepatic, or renal diseases were excluded from the study.

Sample size: The sample size was calculated to be 40 with 80% study power and an alpha error of 5%. The study was designed with 20 cases in each group.

The sample size calculation was performed using the following formula:

$$N=\frac{2\,(Z_{\alpha/2}+Z_{\beta})\sigma}{d^2}$$

Where,

N=Sample size in each group

$Z_{\alpha/2}$=1.96 at the type 1 error of 0.05,

Z_{β}=0.84 at the desired power of 80%, σ=Standard deviation=2.15

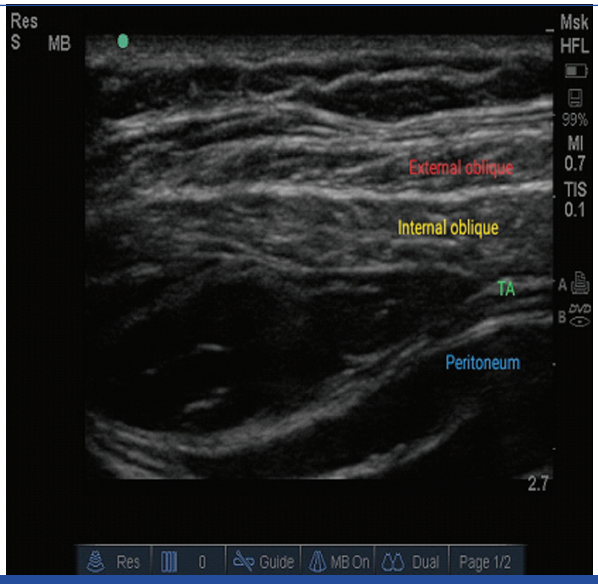
d=Mean difference of clinical significance=1.90. Putting the values the sample size in each group was determined to be 20, resulting in a total sample size of 40.

Procedure

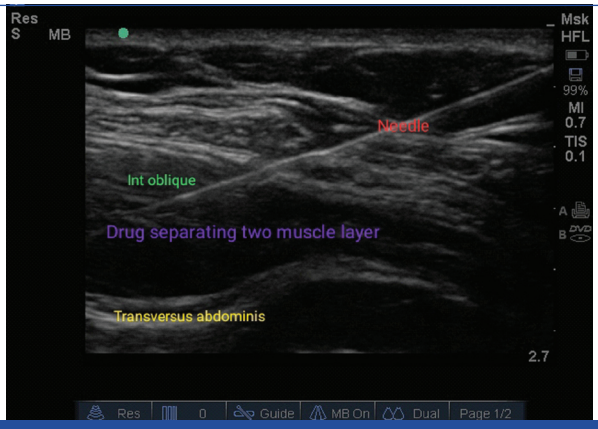
All patients were randomly assigned to two groups: Group A (n=20) received TAP block only, and group B (n=20) received TAP block along with intraoperative intravenous diclofenac aqueous. Randomisation was performed using a computer-generated sequence of random numbers in a 1:1 ratio. Allocation concealment was achieved by using sequentially numbered opaque sealed envelopes.

Preoperative assessment: A thorough preoperative assessment was conducted before surgery. Patients were informed about the Visual Analog Scale (VAS) to express their pain levels in the post-operative period.

Surgical procedure and anaesthesia: Patients were received in the operating theater and identified. Multichannel monitors were attached to measure Electrocardiogram (ECG), Heart Rate (HR), Non-invasive Blood Pressure (NIBP), and pulse oximetry, and baseline values were recorded. Preoxygenation was performed for 3-5 minutes, followed by induction of anaesthesia with Propofol at a dose of 2 mg/kg body weight. Endotracheal intubation was facilitated using succinylcholine at a dose of 2 mg/kg body weight. Anaesthesia was maintained with a combination of O_2, N_2O, intermittent inhalational agent (Isoflurane), and muscle relaxants (Atracurium). Group B patients received intravenous diclofenac sodium 75 mg after 30 minutes of the start of the operation, while group A patients received the same volume of normal saline as a placebo. Baseline and intraoperative hemodynamics {pulse, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP)} were recorded for each patient. After closure of the laparoscopic ports, under aseptic precautions, an ultrasound-guided TAP block was performed in both groups [Table/Fig-1]. TAP block was performed by using a Sonosite M Turbo USG machine and injecting Bupivacaine 0.125% 20 mL in the plane between the TA and IO muscles by placing the probe at mid-axillary line between the costal margin and iliac crest [Table/Fig-2]. Consort flow chart is shown in

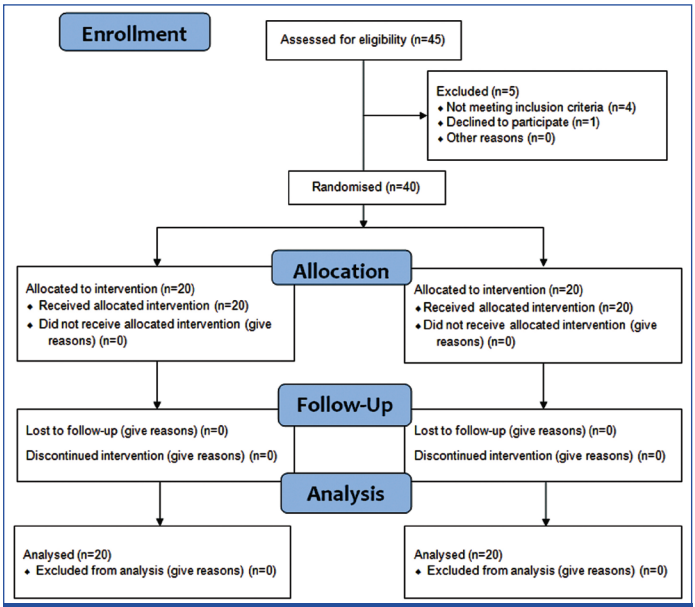


[Table/Fig-1]: USG-guided TAP block showing structures.



[Table/Fig-2]: Drug (Local anaesthetic) separating two muscle layer, i.e., Internal Oblique (IO) and Transversus Abdominis (TA).

[Table/Fig-3]. At the end of operation all patients were reversed by Injecting Neostigmine and Glycopyrrolate. VAS score was assessed for each patient at 2, 4, 6, 12, and 24 hours post-operatively. The duration of post-operative analgesia (from the end of the operation to the first request for rescue analgesia at a VAS score of 4) and the total analgesic (diclofenac sodium) requirement in 24 hours were recorded for each patient. Any intraoperative and post-operative complications (nausea, vomiting, hypotension, bradycardia) were also documented. Patients' convenience and satisfaction regarding analgesia were assessed using a verbal score ranging from 0 to 10 (0=not satisfied, 10=fully satisfied) before discharge. All patients were blinded to the treatment group allocation, as well as the anaesthesiologist who assessed the patients in the post-anaesthesia care unit and collected data.



[Table/Fig-3]: CONSORT flow chart.

STATISTICAL ANALYSIS

The data of total forty patients were tabulated in Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) version 24.0 software. Continuous variables were expressed as mean and standard deviation, while categorical variables were presented as frequency and percentage. The comparison between groups was performed using independent t-test and Chi-square test. A p-value ≤0.05 was considered statistically significant.

RESULTS

The demographic characteristics of the patients, such as age, gender, height, and weight, were similar in both groups [Table/Fig-4]. There were no significant differences observed in the mean duration of the operation between the two groups. The systolic and diastolic blood pressure (SBP and DBP) recorded at baseline, intraoperatively at different time intervals, and immediately post-operative were also comparable [Table/Fig-5].

	Group A (n=20)	Group B (n=20)	p-value
Age (years)	32.95±8.74	31.90±9.16	0.715
Sex (M/F)	6/14(33.3%/66.6%)	5/15(22.7%/7.3%)	0.347
Height (cm)	156.61±5.03	158.36±5.29	0.159
Weight (kg)	57.66±7.62	64.54±7.57	0.294
ASA (I/II)	14/6(77.8%/22.2%)	15/5 (68.2%/31.8%)	0.377
Duration of operation (min)	82.63±6.94	82.10±6.30	0.808

[Table/Fig-4]: Demographic characteristics, ASA and duration of operation.
Independent t-test and Chi-square test used

The duration of post-operative analgesia, measured as the time from the last bite of skin suture to the first request of rescue analgesia

Intervals	Group	Pulse (Mean±SD)	p-value	SBP (Mean±SD)	p-value	DBP (Mean±SD)	p-value
Baseline	Gr. A	83.98±5.299	0.519	125.89±7.89	0.883	79.79±3.99	0.870
	Gr. B	84.33±5.048		126.24±6.70		80.00±4.05	
Incision	Gr. A	81.30±4.832	0.430	130.58±6.38	0.645	81.37±2.98	0.052
	Gr. B	82.15±4.784		129.67±6.02		83.71±3.59	
15 min	Gr. A	78.43±4.601	0.577	127.42±6.70	0.870	84.00±3.46	0.056
	Gr. B	79.00±4.580		127.10±5.82		86.38±3.44	
30 min	Gr. A	76.53±4.484	0.642	130.37±6.18	0.763	86.89±3.38	0.170
	Gr. B	77.00±4.624		129.81±5.43		88.48±3.73	
45 min	Gr. A	74.95±4.242	0.777	134.11±6.44	0.680	87.58±3.93	0.058
	Gr. B	75.23±4.423		133.33±5.30		90.29±2.96	
60 min	Gr. A	73.45±4.272	0.937	137.89±6.56	0.692	88.42±3 90	0.055
	Gr. B	73.38±4.204		137.14±5.31		92.10±3.82	
After reversal	Gr. A	73.90±4.181	0.289	140.16±6.80	0.953	91.05±3.70	0.053
	Gr. B	74.90±4.199		140.05±4.73		93.95±3.35	

[Table/Fig-5]: Baseline, intraoperative and post-operative haemodynamic characteristics.
Gr: Group; SBP: Systolic blood pressure; DBP: Diastolic blood pressure

at VAS 4, was significantly prolonged in group B (16.32±1.29 hours) compared to group A (7.85±1.04 hours, p<0.001). A few patients in both groups experienced complications such as nausea/vomiting, hypotension, and bradycardia, but the differences were not statistically significant [Table/Fig-6]. VAS scores recorded at ½, 2, 4, and 6 hours were significantly higher in group A than in group B, although VAS scores at 12 and 24 hours were similar in both groups [Table/Fig-7]. Group A patients required significantly more analgesic (diclofenac) over the first 24 hours compared to group B patients (58.33±17.14 mg vs. 32.95±20.96 mg). PSS was significantly higher in group B patients (8.14±1.06) compared to group A patients (6.16±1.38) [Table/Fig-8].

Anaesthetic parameters	Group A	Group B	
Duration of post-operative analgesia (Hours)	7.85±1.04	16.32±1.29	**<0.001***
Complications			
Nausea/vomiting	2 (10.5%)	7 (33.3%)	0.084
Hypotension	2 (10.5%)	3 (14.2 %)	0.719
Bradycardia	1 (5.2%)	5 (23.8%)	0.100
Post-operative mean VAS	5.21±0.53	3.55±0.51	**<0.001***
Total analgesic (diclofenac) consumption in 24 hours (mg)	58.33±17.14	32.95±20.96	**<0.001***

[Table/Fig-6]: Additional parameters.
Independent t-test used; *Statistically significant difference exists

VAS	Group A Mean SD	Group B MeanSD	p-value
VAS 1/2 hours	1.65±1.57	1.47±0.77	**<0.001***
VAS 2 hours	2.40±0.50	1.37±0.50	**<0.001***
VAS 4 hours	3.25±0.55	2.68±0.67	**0.006***
VAS 6 hours	6.00±0.73	4.84±0.60	**<0.001***
VAS 12 hours	2.40±0.50	2.42±0.51	0.897
VAS 24 hours	3.55±0.51	3.53±0.51	0.885

[Table/Fig-7]: Visual Analogue Scale.
Independent t-test used; *Statistically significant difference exists

PSS (Patients satisfaction score)	Group A		Group B		p-value
	Mean	SD	Mean	SD	
	6.16	1.38	8.14	1.06	**<0.001***

[Table/Fig-8]: Patient Satisfaction Score (PSS).
Independent t-test used; *Statistically significant difference exists

DISCUSSION

With the increasing popularity of regional analgesia techniques and the use of ultrasound guidance in anaesthesia practice, the TAP block has become a part of multimodal analgesia for post-operative pain control. In this study, TAP block was administered with 20 mL of 0.125% bupivacaine without significant side effects.

Evidence-based guidelines recommend NSAIDs as integral to the management of acute post-operative pain [21]. Intravenous diclofenac infusion has shown benefits in laparoscopic cholecystectomy [22-25]. Intramuscular as well as Intravenous Diclofenac sodium (75 mg) are almost equally effective in relieving post-operative pain [11]. But incidence of complications associated with diclofenac sodium such as dyspepsia, gastric erosion and haemorrhage are also similar and can be easily managed with medications. Previous studies have concluded that diclofenac is a better choice as post-operative analgesic compared to opioids as far as side-effect is concerned because diclofenac spare the side effects of opioids like respiratory depression, constipation and urinary retention [26,27]. Newer aqueous intravenous diclofenac has a faster onset of action and can act as pre-emptive analgesia in laparoscopic surgeries. Various previous studies have suggested combination of diclofenac (NSAID) and opioids for post-operative analgesia compared to opioids due to its lower side-effect profile [28,29].

The efficacy of TAP block in laparoscopic surgeries has been established, with studies showing it to be superior to other analgesia methods [30-32]. The results of the present study showed that TAP block and i.v. diclofenac sodium, this combination increased the duration of post-operative analgesia, reduced the requirement for analgesics, decreased pain scores, and improved patient satisfaction. The group receiving intravenous diclofenac in addition to TAP block had lower VAS scores in the early post-operative period compared to the TAP block alone group. The duration of post-operative analgesia was prolonged in the TAP with diclofenac group, and the time to first request for rescue analgesia was delayed [33].

Total analgesic requirement in the first 24 hours after surgery was significantly lower in the TAP block with diclofenac group. Patient satisfaction scores were higher in the group receiving both TAP block and diclofenac than the patients who received TAP block only. Bhati K et al., also observed similar result in their study [20]. They studied 60 patients who underwent caesarean section. Half of them received TAB block only and other half received TAB with diclofenac for post-operative analgesia. Mean time of first administration of rescue analgesic was found to be significantly prolonged with less VAS score both at rest and movementin patients who received both TAB block and diclofenacas compared to patients who received TAB block only.

Limitation(s)

Firstly, only ASA 1 and 2 patients were included, and patients with multiple co-morbidities (ASA 3 or higher) were not studied. Additionally, pain scores during movement were not considered, even though laparoscopic surgeries aim to encourage early ambulation. The effect of administering the TAP block before the start of the operation was not evaluated, and further studies are needed in this regard. Furthermore, this study focused on assessing pain relief for the first 24 hours only, and the long-term effects of the intervention need to be evaluated.

CONCLUSION(S)

It was inferenced that the addition of intravenous diclofenac to TAP block prolongs the duration of post-operative analgesia. When used as part of a multimodal analgesic approach, this combination provides superior post-operative pain relief compared to TAP block alone. Furthermore, it reduces the total requirement for post-operative analgesics and leads to higher levels of patient satisfaction.

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