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Clonidine Its Role in Transversus Abdominis Plane Block: A Randomized Controlled Trial

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ABSTRACT

Background: The Transversus Abdominis Plane (TAP) block is a novel and effective approach for blocking neural afferents arising from T7 to T12, the subcostal nerve, and the lumbar nerves involved in abdominal surgeries. In this double-blind, randomized study, we evaluated the analgesic efficacy of TAP block with clonidine as an adjunct to laparoscopic cholecystectomy.

Methods: One hundred adult patients, ASA I and II, were randomly allocated into two groups, A and B (n=50 per group). All patients were premedicated with inj. Midazolam 1mg and fentanyl 2µg/kg. Induction was done with inj. propofol 2mg/kg and O2/N2O and isoflurane 1%. After completion of laparoscopic cholecystectomy, patients received TAP block using 20ml of 0.25% bupivacaine in group A and 20ml of 0.25% bupivacaine with 1µg/kg clonidine in group B. Post-operative pain was assessed using the Visual Analog Scale (VAS), and the first analgesic requirement was recorded in both groups. The average time to first analgesic requirement was 5.5 hours in Group A and 14.8 hours in Group B, with a statistically significant difference (P<0.05).

Results: Patients receiving TAP block with clonidine (Group B) had significantly lower VAS scores at 0, 4, and 8 hours postoperatively compared to those receiving bupivacaine alone (Group A). The average time to first analgesic requirement was markedly longer in Group B (14.8 hours) than in Group A (5.5 hours), with a statistically significant difference (p<0.05).

Conclusion: The addition of clonidine to bupivacaine in a TAP block significantly prolongs the duration of postoperative analgesia. It also provides lower pain scores during the first 24 hours following laparoscopic cholecystectomy.

Key-words: Bupivacaine, Clonidine, Transversus Abdominis Plane (TAP), Visual Analog Scale (VAS)

INTRODUCTION

Laparoscopic cholecystectomy has emerged as the standard surgical procedure for symptomatic gallstone disease because of its advantages of minimal tissue handling, reduced postoperative morbidity, and earlier ambulation when compared to open cholecystectomy [1,2]. Despite being minimally invasive, patients often experience postoperative pain arising from port-site tissue disruption, pneumoperitoneum-related peritoneal stretch, and diaphragmatic irritation, all of which contribute to significant discomfort in the immediate postoperative period [3,4]. Adequate analgesia is therefore essential to enhance recovery, reduce opioid consumption, and prevent postoperative pulmonary complications [5].

TAP block has become an essential component of multimodal analgesia because it provides effective somatic pain relief by blocking the thoracoabdominal nerves (T7–L1) within the fascial plane between the internal oblique and transversus abdominis muscles [6]. Since its early description and later refinement with ultrasound guidance, the TAP block has shown consistent benefit in reducing postoperative pain scores and opioid requirements in various lower abdominal and laparoscopic surgeries [7–9]. Local anesthetics such as bupivacaine are frequently used for TAP blocks.

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However, their duration is often insufficient to cover the whole postoperative pain period following laparoscopic procedures. To overcome this limitation, adjuvants such as clonidine—an α2-adrenergic agonist—have been evaluated for their ability to prolong block duration and improve analgesic depth [10]. Previous studies in abdominal and obstetric surgeries have reported that the addition of clonidine to local anesthetics enhances analgesia quality, delays the time to rescue analgesic requirement, and reduces overall analgesic consumption without causing major hemodynamic instability [11,12].

The present randomized controlled trial was therefore designed to compare the postoperative analgesic efficacy of bupivacaine alone versus bupivacaine combined with clonidine in landmark-guided TAP block for patients undergoing laparoscopic cholecystectomy.

MATERIALS AND METHODS

Study Design and Setting- The study was conducted as a double-blind, randomized trial in the Department of Anesthesiology at Dr. Baba Saheb Ambedkar Medical College and Hospital, Delhi. The research was carried out over one year, from December 2022 to December 2023, following approval from the institutional ethics committee.

Study Population- The study included 100 adult patients aged 25 to 65 years who were classified as American Society of Anesthesiologists (ASA) physical status I or II. All participants were diagnosed with cholelithiasis and scheduled to undergo elective laparoscopic cholecystectomy.

Inclusion and Exclusion Criteria

Inclusion criteria

- Adults aged between 25 and 65 years.
- Classified as American Society of Anesthesiologists (ASA) physical status I or II.
- Scheduled for elective laparoscopic cholecystectomy.

Exclusion criteria

- Patients with acute or chronic cholecystitis.
- Presence of gallbladder empyema, porcelain gallbladder, or extensive intra-abdominal adhesions.
- Coagulopathy
- Hypersensitivity to study drugs
- Obesity (BMI ≥30 kg/m²)
- Difficult abdominal anatomy or prior upper abdominal surgery

Randomization and Blinding- Patients were allocated to two groups (n=50 each) using simple random sampling based on admission sequence.

Group A: Bupivacaine alone

Group B: Bupivacaine + clonidine

Patients, the anesthesiologist performing postoperative assessment, and nursing staff were blinded to group assignment.

Pre-Anesthetic Preparation and Anesthesia Technique- Standard monitors (ECG, pulse oximeter, non-invasive blood pressure) were applied. All patients received:

- Midazolam 1 mg IV
- Fentanyl 2 µg/kg IV

Induction was achieved with propofol 1.5–2 mg/kg, and intubation was facilitated with succinylcholine. Anesthesia was maintained with O_2/N_2O and isoflurane.

TAP Block Technique- After surgery and before extubation, a bilateral landmark-guided TAP block was administered.

- The triangle of Petit was identified.
- A 22-gauge blunt needle was inserted perpendicular to the skin.
- The characteristic “pop” sensation confirmed entry into the correct fascial plane.
- After negative aspiration, the drug solution was injected.

Group A: 20 mL of 0.25% bupivacaine on each side

Group B: 20 mL of 0.25% bupivacaine + clonidine 1 µg/kg on each side

Postoperative Monitoring and Assessment- After extubation, patients were transferred to the postoperative care unit. Monitoring included:

- Heart rate, blood pressure, respiratory rate
- Sedation
- Adverse events (bradycardia, hypotension, dry mouth, nausea/vomiting)

Pain assessment was performed at 0, 4, 8, 12, and 24 hours postoperatively using VAS.

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Rescue analgesia- Intramuscular diclofenac 75 mg was administered whenever the VAS score was ≥4. Total diclofenac usage and the time to the first analgesic requirement were documented.

Outcome Measures

Primary outcome- The duration of postoperative analgesia, measured as the time interval until the first rescue analgesic was required.

Secondary outcomes

- VAS scores at predefined intervals
- Total rescue analgesic consumption
- Incidence of sedation and other adverse effects
- Block-related complications

Statistical Analysis- Data were analyzed using SPSS software. Continuous variables were assessed using the Student's t-test or analysis of variance (ANOVA), whereas categorical variables were evaluated with the chi-square test. A p-value of less than 0.05 was considered indicative of statistical significance.

RESULTS

A total of 100 patients were analyzed, with 50 in Group A (bupivacaine) and 50 in Group B (bupivacaine + clonidine). Both groups were comparable with respect to demographic variables, including age, sex distribution, weight, ASA status, and duration of surgery, and no statistically significant differences were observed (Table 1).

Table 1: Demographic Characteristics of the Study Population

Parameter	Group A (Bupivacaine) (n=50)	Group B (Bupivacaine + Clonidine) (n=50)	p-value
Age (years), mean±SD	44.2±9.1	45.6±8.7	0.52
Sex (M/F)	22 / 28	24 / 26	0.68
Weight (kg), mean±SD	63.8±8.5	64.5±7.9	0.71
ASA I / ASA II	32 / 18	30 / 20	0.68
Duration of surgery (min), mean±SD	54.6±6.8	55.3±7.2	0.63

Postoperative pain scores showed a clear advantage in the clonidine group. VAS scores at 0, 4, and 8 hours were significantly lower in Group B than in Group A ($p<0.001$), indicating superior early analgesia. Pain reduction was more modest at 12 hours ($p=0.04$), whereas VAS scores at 24 hours were comparable between both groups (Table 2). The duration of analgesia differed markedly between the two groups. The mean time to first rescue analgesic was 5.5±1.2 hours in Group A, whereas Group B demonstrated significantly prolonged analgesia with a mean duration of 14.8±2.1 hours ($p<0.001$). Correspondingly, the need for rescue analgesia was substantially higher in Group A (36 patients) than in Group B (8 patients). Total diclofenac consumption was also significantly reduced in the clonidine group (65.4±18 mg vs. 150±32 mg, $p<0.001$).

Table 2: Postoperative Pain Scores and Analgesic Requirements

Outcome Variable	Group A (n=50)	Group B (n=50)	p-value
VAS at 0 hr	5.8±1.1	3.2±0.9	<0.001
VAS at 4 hr	6.4±1.2	3.6±1.0	<0.001
VAS at 8 hr	5.9±1.3	3.9±1.1	<0.001
VAS at 12 hr	4.8±1.0	4.2±1.1	0.04
VAS at 24 hr	3.4±0.9	3.0±0.8	0.07
Time to first analgesic (hrs)	5.5±1.2	14.8±2.1	<0.001
Patients requiring rescue analgesia (n)	36	8	<0.001
Total diclofenac consumption (mg)	150±32	65.4±18	<0.001

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Sedation and dry mouth were significantly more frequent in Group B compared to Group A (p=0.01 and p<0.001, respectively). The incidence of nausea and vomiting was comparable between the groups, and no cases of hypotension, bradycardia, hematoma, or block-site infection were observed in either group (Table 3).

Table 3: Postoperative Side Effects

Side Effect	Group A (n=50)	Group B (n=50)	p-value
Sedation (arousable)	2	15	0.01
Nausea/Vomiting	20	18	0.74
Dry mouth	0	19	<0.001
Hypotension	0	0	-
Bradycardia	0	0	-
Block site hematoma/infection	0	0	-

DISCUSSION

Effective postoperative pain control is an essential component of enhanced recovery following laparoscopic cholecystectomy. Although the procedure is minimally invasive, patients often experience significant discomfort originating from port-site trauma, pneumoperitoneum, and diaphragmatic irritation. Multimodal analgesia, particularly regional blocks, plays a vital role in reducing opioid consumption and improving postoperative recovery profiles [13].

The present study demonstrated that TAP block significantly reduces postoperative pain, and the addition of clonidine further augments its analgesic efficacy. The substantially lower VAS scores at 0, 4, and 8 hours in the clonidine group indicate superior early somatic analgesia. These findings align with previous reports where TAP block effectively reduced postoperative pain after abdominal and laparoscopic procedures [14,15]. McDonnell *et al.* and Ra *et al.* similarly reported decreased pain scores and opioid consumption in patients receiving TAP block compared with systemic analgesia alone [16,17].

In our study, the most clinically significant observation was the prolonged analgesia in the clonidine group (mean 14.8 hours) compared with the bupivacaine-only group (mean 5.5 hours). This prolonged effect is consistent with earlier findings showing that α2-agonists enhance local anesthetic action by delaying systemic absorption, increasing potassium conductance, and exerting intrinsic analgesic effects at peripheral nerves [18]. Singh *et al*. also reported an extended duration of postoperative analgesia when clonidine was added to bupivacaine for TAP block in cesarean patients [19].

Similar enhancement with clonidine has been documented across several regional anesthetic techniques [20].

The present study further showed a markedly lower requirement for rescue analgesia and reduced diclofenac consumption in the clonidine group. This opioid-sparing effect is clinically important as it helps minimize opioid-related adverse effects such as nausea, vomiting, and sedation. A previous meta-analysis also noted that the TAP block significantly decreases postoperative opioid requirements in various abdominal surgeries [21].

Side-effect analysis showed that mild sedation and dry mouth were more common among patients receiving clonidine, consistent with its known pharmacological profile as an α2-agonist. However, no patient developed significant hypotension or bradycardia, suggesting that the clonidine dose used (1 µg/kg) was safe and well tolerated. Similar safety findings have been reported in studies evaluating clonidine as an adjuvant in regional blocks [22].

Interestingly, the incidence of nausea and vomiting was comparable between the two groups in our study, whereas some authors have reported reduced postoperative nausea and vomiting after TAP block [23]. This variation may be attributed to differences in rescue analgesic protocols or anesthetic techniques among studies.

Despite strong analgesic benefits, some limitations should be acknowledged. The TAP block was performed using the landmark technique rather than ultrasound guidance. Ultrasound increases accuracy, improves drug deposition, and reduces complications [24]. Assessment of pain on movement was not performed, although early mobilization is a key component of recovery following

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laparoscopic procedures. Future studies that use ultrasound guidance and include dynamic pain assessment may further strengthen the evidence.

Overall, our study confirms that adding clonidine to bupivacaine in TAP blocks provides superior postoperative analgesia, reduces rescue analgesic requirements, and prolongs the duration of pain relief after laparoscopic cholecystectomy. These findings support the incorporation of clonidine-augmented TAP block into a multimodal analgesic strategy.

LIMITATIONS

There is limited evidence on whether TAP blocks augmented with clonidine provide superior analgesia specifically after laparoscopic cholecystectomy. With the ongoing clinical emphasis on opioid-sparing multimodal pain management, it is important to evaluate whether the addition of clonidine can meaningfully enhance postoperative pain control in these patients.

CONCLUSIONS

The present study demonstrates that adding clonidine (1 µg/kg) to bupivacaine in a landmark-guided TAP block significantly improves postoperative analgesia in patients undergoing laparoscopic cholecystectomy. Patients who received clonidine exhibited markedly lower early postoperative pain scores, significantly prolonged time to first rescue analgesia, and substantially reduced total analgesic consumption compared to bupivacaine alone. Although mild sedation and dry mouth were more common with clonidine, no serious adverse effects such as hypotension, bradycardia, or block-related complications were observed, indicating that the drug combination was safe and well-tolerated.

Overall, clonidine-augmented TAP block offers a more effective and opioid-sparing analgesic option and can be incorporated as a valuable component of multimodal analgesia in laparoscopic cholecystectomy.

CONTRIBUTION OF AUTHORS

Research concept- Sakshi Arora
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Data collection- Sakshi Arora
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