

ORIGINAL ARTICLE

A comparison of pain-reducing effectiveness using laparoscopic-guided transverse abdominal plane block and port site infiltration in laparoscopic cholecystectomy: A randomized controlled trial.Kamran Ali¹, Tayyab Nasim², Zahid Sattar³, Farooq Ahmad⁴, Shamaila Hassnain⁵, Farwa Zohaib⁶

ABSTRACT... **Objective:** To compare the effectiveness, in terms of pain score and additional analgesia requirement, using laparoscopic-guided transverse abdominal plane block in comparison to port site infiltration in laparoscopic cholecystectomy. **Study Design:** Randomized Control Trial. **Setting:** Surgical Unit 2, Jinnah Hospital, Lahore. **Period:** Jan 2022 to Dec 2022 **Methods:** Included 92 patients (46 in each group) undergoing elective laparoscopic cholecystectomy. Group A patients received a laparoscopic TA plane block with 40 ml 0.25% bupivacaine, 20 ml in each subcostal region, while group B received 40 ml 0.25% bupivacaine, 10 ml in each port site. The outcomes were assessed at 1st, 4th, 12th, and 24 hours post-operatively. **Results:** In Group A versus B patients, the mean age was 43.30+10.875 versus 44.22+8.894 years, the mean score at 1 hour was 3.26+0.953 vs 4.09+0.725, at 4 hours was 4.17+0.877 vs 4.87+1.046, at 12 hours was 4.52+0.983 vs 5.35+ 0.822 and at 24 hours 4.52+1.110 vs 5.52+ 1.516, respectively. In Group A vs B, rescue analgesia at 1st, 4th, 12th, and 24 hours was required in 8.7%, 26.1%, 43.5% & 52.1% versus 30.4%, 65.2%, 82.6% & 82.6%, respectively (p<0.05 at all intervals). **Conclusion:** The laparoscopic-guided transverse abdominal plane block is considerably superior to port site infiltration in terms of pain score and additional analgesia requirement.

Key words: Laparoscopic-guided TAP Block, Laparoscopic Cholecystectomy, Postoperative Pain.

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INTRODUCTION

Gallstones were discovered in Egyptian mummies and have been known since antiquity.¹ Gallstone disease (GD) impacts 10–15% of Western adults, with females and the elderly being the most affected.² Each year, between one and four percent of individuals with gallstones become symptomatic and may require surgical intervention. Acute cholecystitis, cholangitis, obstructive jaundice, and acute pancreatitis can all be life-threatening if left untreated.³

In comparison to standard open cholecystectomy, laparoscopic cholecystectomy is associated with less post-operative discomfort, less painkiller usage, a quicker recovery period, and a reduction in hospital stay. Despite this, the intensity of postoperative abdominal and shoulder pain remains high, preventing cholecystectomy via laparoscopy from being performed on the same day in a significant proportion of patients.⁴ Various therapy

approaches and tactics have been developed and deployed throughout the years to address the problem of untreated post-operative pain.⁵ One of these treatments is wound infiltration, which is used in conjunction with another regimen of analgesia. The effects of a peripherally administered local anesthetic, such as bupivacaine, might differ depending on the application site, such as instilling intraperitoneally, infiltration at the port and trocar site, and infiltration in the viscera.⁵ A blind 'double pop' technique was used in 2001 to provide local anesthetics into the fascial plane.⁶ TAP block with ultrasound guidance was first introduced in 2007, and while it is a better alternative to blind infiltration, it is still dependent on the operator.⁷ Later, long-acting local anesthetics such as bupivacaine were used with laparoscopy-guided fascial infiltration.⁸ GI surgeons have used the laparoscopically inserted TA plane (LTAP) block with comparable results to the ultrasound-guided TA plane (UTAP) block technique⁹, especially in colorectal surgery and

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laparoscopic cholecystectomies.¹⁰ A recent meta-analysis claims that in patients who underwent a surgical intervention that was invasive minimally (such as laparoscopic abdominal procedures), LTAP was found to be a safe and superior intervention than local wound analgesia in terms of early control of pain, consumption of opioids, and satisfaction of patients.¹¹ Because laparoscopic techniques have advanced significantly, several doctors have recently started using TAP block and comparing it to port site infiltration to determine whether the block is better; nonetheless, the results are still unclear.¹²

OBJECTIVE

The objective of the research was to assess the effectiveness of port site infiltration against the laparoscopic-guided transverse abdominis plane block in laparoscopic cholecystectomy.

METHODS

It was a randomized control trial conducted at Surgical Unit 2, Jinnah Hospital, Lahore. A sample size of 92 patients (46 patients in each group) was taken by using a 95% confidence level, 80% power of test, and by taking mean VAS pain score after laparoscopic cholecystectomy with infiltration of local anesthesia in transverse abdominis plane and with infiltration of local anesthesia at port sites as 1.82 ± 0.42 and 2.12 ± 0.58 respectively.¹²

$$n = \frac{2\sigma^2(z_{1-\alpha/2} + z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

$$Z_{1-\alpha/2} = 95\% = 1.95$$

$$Z_{1-\beta} = 80\% = 0.80$$

$$\mu_1 = \text{Mean of population 1} = 2.12$$

$$\mu_2 = \text{Mean of population 2} = 1.82$$

$$2\sigma^2 = 2(0.50^2)$$

Following ethical committee permission (48/02/03/2021/52 ERB/11-03-21) at the hospital and patient informed consent, a randomized trial was carried out on 92 patients who had a laparoscopic cholecystectomy. Patients were admitted from the OPD. Group A had a laparoscopic-guided transverse abdominis plane block with 40 ml of 0.25% bupivacaine, 20 ml in each subcostal area, while group B received 40 ml of 0.25% bupivacaine, 10 ml in each port site. The patients were assigned

to groups A and B by using a computerized random number table.

Inclusion Criteria

Recruitment was through non-probability purposive sampling with patients of the age group 18-65 years of either gender, including patients undergoing elective laparoscopic cholecystectomy for chronic cholecystitis / symptomatic gallstones.

Exclusion Criteria

Patients with a history of bleeding disorders, emphysematous or empyema gallbladders, mucocele, acute pancreatitis, acute cholecystitis, or prior abdominal surgery; a history of allergy to local anesthesia; with abdominal wall infection on examination; patients in whom laparoscopic procedures get converted to an open procedure; and with hepatobiliary malignancy diagnosed on ultrasound were excluded.

General Anesthesia was given to all the patients on a regimen that included induction with propofol 2 mg/kg and nalbuphine 6 mg, and for intubation, 0.5 mg/kg atracurium was given. Anesthesia was maintained with volatile isoflurane 1-2 MAC in oxygen and air (FiO₂ 0.5). Standard monitoring included three leads: ECG, monitoring of blood pressure non-invasively, pulse oximetry (SpO₂), and temperature charting; the patient received intervention according to the group assignment.

A total of 40 ml of bupivacaine 0.25% was bilaterally injected. This created a bulge inferior to the Transversus Abdominus muscles, away from the Inferior Oblique muscle. While patients in group B had 40 ml of 0.25% bupivacaine and 10 ml on each site in subcutaneous tissue.

TAP block can be easily carried out laparoscopically by a surgeon. Under the guidance of a laparoscope, at the level of the midaxillary line, a Braun Stimuplex A needle is passed midway between the costal margins and the iliac crest. The needle is further advanced between the internal oblique and transversus abdominus muscle. Local anesthesia is injected, and a bulge would be appreciated laparoscopically. This procedure is performed on the opposite site as well.

Following surgery, all patients received 30 mg of intravenous ketorolac every eight hours and 1 g of paracetamol every eight hours. All individuals with visual analogue pain ratings of 4 or higher received additional analgesia with intravenous nalbuphine. This study's main objective was to assess pain score and additional analgesia requirement, which was calculated by the visual analogue score at the 1st, 4th, 12th & 24th hours post-operatively. All the data was collected through a pre-designed proforma.

Total postoperative nalbuphine requirement was noted in the first 24 hours. Nalbuphine was provided by the nursing staff, who were blinded by the study. When the VAS score was above 4, 10 mg of nalbuphine every 8 hours was used. A maximum of 3 doses was given in the first 24 hours.

Data were analyzed using SPSS v25.0. Quantitative variables such as age and pain scores were expressed as mean \pm SD, while qualitative variables such as gender were expressed as frequencies and percentages. An independent sample t-test was used to compare pain scores between groups, and a chi-square test for categorical outcomes. To adjust for potential confounding factors (age, gender), multivariable linear regression (for pain scores) and logistic regression (for additional analgesia requirement) were applied. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

Among 46 patients of Group A, 17.4% were males and 82.6% were females. Similarly among 46 patients of Group B, 21.7% were males and 78.3% were females.

Among 46 Group A (TAP Block) patients, 43.5% were up to 40 years old and 56.5% were above 40 years old. The mean age of the patients was 43.30 \pm 10.875 years.

Among 46 patients of Group B (Port Site Infiltration), 34.8% were up to 40 years old and 65.2% were above 40 years old. The mean age of the patients in this group was 44.22 \pm 8.894 years. (Table-I)

In Group A, 91.3%, 73.9%, 43.5%, and 47.8% patients had 1-4 pain score (analgesia not required)

and 8.7%, 26.1%, 43.5% and 52.1% patients had >4 pain score (analgesia required) while the mean score of patients was 3.26 \pm 0.953, 4.17 \pm 0.877, 4.52 \pm 0.983 and 4.52 \pm 1.110 at one, four, twelve, and twenty-four hours, respectively.

Likewise in Group B, 69.6%, 34.8%, 17.4%, and 17.4% patients had 1-4 pain score (analgesia not required) and 30.4%, 65.2%, 82.6% and 82.6% patients had >4 pain score (analgesia required) while the mean score of patients was 4.09 \pm 0.725, 4.87 \pm 1.046, 5.35 \pm 0.822 and 5.52 \pm 1.516 at one, four, twelve, and twenty-four hours, respectively. (Table-II)

TABLE-I

Comparison of age between both groups

Age	Group A		Group B	
	TAP Block	Port Site Infiltration	TAP Block	Port Site Infiltration
	Frequency	Percentage	Frequency	Percentage
<40 years	20	43.5	16	34.8
>40 years	26	56.5	30	65.2
Total	46	100.0	46	100.0
Mean \pm SD	43.30 \pm 10.875		44.22 \pm 8.894	

In Group A, 8.7%, 26.1%, 43.5% & 52.1% of patients required analgesia, while 91.3%, 73.9%, 43.5% & 47.8% did not require analgesia at one, four, twelve, and twenty-four hours, respectively.

Whereas in Group B, 30.4%, 65.2%, 82.6% & 82.6% of patients required analgesia, while 69.6%, 34.8%, 17.4% & 17.4% did not require analgesia at one, four, twelve, and twenty-four hours, respectively. (Figure-1)

FIGURE-1

Comparison of Need for Analgesia between Both Groups

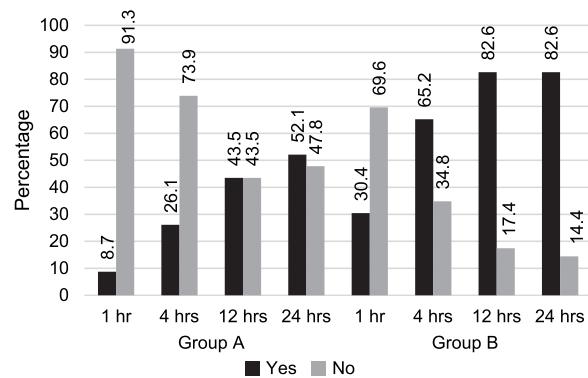


TABLE-II

Comparison of pain score between both groups

Pain Score	Group A TAP Block				Group B Port Site Infiltration			
	1 hr	4 hrs	12 hrs	24 hrs	1 hr	4 hrs	12 hrs	24 hrs
0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
1-4	42 (91.3%)	34 (73.9%)	20 (43.5%)	22 (47.8%)	32 (69.6%)	16 (34.8%)	8 (17.4%)	8 (17.4%)
>4	4 (8.7%)	12 (26.1%)	26 (43.5%)	24 (52.1%)	14 (30.4%)	30 (65.2%)	38 (82.6%)	38 (82.6%)
Total	46 (100%)	46 (100%)	46 (100%)	46 (100%)	46 (100%)	46 (100%)	46 (100%)	46 (100%)
Mean+SD	3.26+ 0.953	4.17+ 0.877	4.52+ 0.983	4.52+ 1.110	4.09+ 0.725	4.87+ 1.046	5.35+ 0.822	5.52+ 1.516

TABLE-III

Comparisons of different durations of pain score and need for analgesia

		t	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
Age	Equal variances assumed	-.441	.660	-.913	2.071	-5.028	3.202
	Equal variances not assumed	-.441	.660	-.913	2.071	-5.030	3.204
Gender	Equal variances assumed	.521	.604	.043	.084	-.122	.209
	Equal variances not assumed	.521	.604	.043	.084	-.122	.209
Pain score (1 hour)	Equal variances assumed	-4.679	.000	-.826	.177	-1.177	-.475
	Equal variances not assumed	-4.679	.000	-.826	.177	-1.177	-.475
Pain score (4 hour)	Equal variances assumed	-3.457	.001	-.696	.201	-1.095	-.296
	Equal variances not assumed	-3.457	.001	-.696	.201	-1.096	-.296
Pain score (12 hour)	Equal variances assumed	-4.372	.000	-.826	.189	-1.201	-.451
	Equal variances not assumed	-4.372	.000	-.826	.189	-1.202	-.451
Pain score (24 hour)	Equal variances assumed	-3.609	.001	-1.000	.277	-1.551	-.449
	Equal variances not assumed	-3.609	.001	-1.000	.277	-1.551	-.449
Need for analgesia (1 hour)	Equal variances assumed	2.703	.008	.217	.080	.058	.377
	Equal variances not assumed	2.703	.009	.217	.080	.057	.378
Need for analgesia (4 hour)	Equal variances assumed	4.052	.000	.391	.097	.199	.583
	Equal variances not assumed	4.052	.000	.391	.097	.199	.583
Need for analgesia (12 hour)	Equal variances assumed	2.804	.006	.261	.093	.076	.446
	Equal variances not assumed	2.804	.006	.261	.093	.076	.446
Need for analgesia (24 hour)	Equal variances assumed	3.256	.002	.304	.093	.119	.490
	Equal variances not assumed	3.256	.002	.304	.093	.118	.490

Table-III exhibits that when the t-test was applied in both groups, significant results ($P<0.05$) were found regarding pain score at 1st, 4th, 12th & 24 hours and the need for analgesia at 1st, 4th, 12th & 24 hours while age and gender showed insignificant results ($P>0.05$).

DISCUSSION

Laparoscopic cholecystectomy is mostly accepted as a standard technique to treat benign gallbladder

disease. For GD, laparoscopic cholecystectomy has become the treatment of choice and is linked with decreased post-operative pain, less analgesic consumption, reduced recovery period, and less hospital stay when compared with conventional procedures.

This study was carried out to compare the outcome of TAP block under the guidance of laparoscopy versus infiltration at the port site in individuals who

underwent laparoscopic cholecystectomy. Our study indicated that more than half of the patients in both groups were above 40 years. The mean age of the patients in the TAP block was 43.30 ± 10.875 years, while in port site infiltration, it was 44.22 ± 8.894 years. Virtually, the findings of our research are similar to a study performed by a study done in 2021, which asserted that the patient's mean age in the TAP block was 39.54 ± 3.23 years, while in port site infiltration was $38.48.2 \pm 2.55$ years.¹³

Among the general population, the major risk factor of gallstone development is gender, and it is believed that gallstones are more prevalent among females than males. The findings of our study also confirmed that 82.6% of patients in the TAP block and 78.3% of patients in port site infiltration were females.

During the study, the severity of pain was evaluated by VAS, and it was found that patients in the TAP block group had a lower pain score than patients in the port site infiltration group. Patients in the TAP block had mean scores of 3.26 ± 0.953 , 4.17 ± 0.877 , 4.52 ± 0.983 , and 4.52 ± 1.110 , while patients in the post-site infiltration had mean scores of 4.09 ± 0.725 , 4.87 ± 1.046 , 5.35 ± 0.822 , and 5.52 ± 1.516 at 1, 4, 12, and 24 hours, respectively, which shows the better efficacy of the TAP block. A study in 2020 also confirmed that the TAP block is better than port site infiltration.¹⁵ They reported that patients in the TAP block had mean scores of 1.38 ± 0.23 , 2.12 ± 0.54 , 2.01 ± 0.87 , 2.65 ± 1.53 , and 1.56 ± 0.56 , while patients in post-site infiltration had mean scores of 3.83 ± 0.76 , 3.45 ± 0.30 , 3.67 ± 1.20 , 2.14 ± 1.11 , and 1.69 ± 0.79 at 3, 6, 12, 24, and 48 hours, respectively. A study done by Vindal and associates (2021) demonstrated that median VAS at 3rd, 6th, and 24th hours, at discharge, and one week after surgery were lower in the TAP block group than the port site infiltration group.¹⁶ They further elucidated that the TAP block reduced the pain severity after surgery, helped in early discharge from the hospital and quick recovery, and enhanced patient satisfaction. However, a study undertaken by Siriwardana and collaborators (2019) indicated that laparoscopic-guided TAP block does not offer extra pain relief or better outcomes.¹⁷ But a study carried out by Grape and teammates (2021) confirmed that TAP block offers better analgesia as compared to

port site infiltration among patients experiencing LC.¹⁸

It was found during the study that patients in TAP block required less analgesic than port site infiltration. In TAP block, 8.7%, 26.1%, 43.5% and 52.1% patients, but in port site infiltration, 30.4%, 65.2%, 82.6% & 82.6% of patients required analgesia at 1st, 4th, 12th & 24 hours, respectively. Similar results were reported in a study done by Majeed et al. who also asserted that patients in TAP block required less analgesia, 15.6% of patients in TAP block while 28.6% of patients in post-site infiltration required analgesia.¹⁹

A study done by Grape and teammates (2021) also indicated that patients in TAP block required less analgesia than patients in port site infiltration.¹⁸ Goel and coworkers (2021) reported in their study that TAP block notably reduced 24-hour overall analgesia consumption by 3.85 mg as compared to port site infiltration.⁶

Since this study only included a small sample size and was carried out only in one place, more research is required on a larger level to confirm the effectiveness of the laparoscopic-guided transverse abdominal plane block.

CONCLUSION

Laparoscopic-guided TAP block is better than infiltration in terms of pain score at the port site and additional analgesia requirement. This study would help us in the future for better postoperative pain management, early discharge of patients, less analgesic consumption, and fewer side effects like PONV (postoperative nausea and vomiting). This study provided local evidence that would help implement this anesthetic technique in laparoscopic cholecystectomy.

Ethical Consideration

The Institutional & Ethical Review Board of Jinnah Hospital provided the IRB. (48/02/03/2021/52 ERB/11-03-21)

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

1	Kamran Ali: Article writing.
2	Tayyab Nasim: Data collection.
3	Zahid Sattar: Manuscript writing.
4	Faroq Ahmad: Data entry.
5	Shamaila Hassnain: Data analysis.
6	Farwa Zohaib: Data Collection.