



# Ultrasound-guided transverse abdominis plane and ilioinguinal-iliohypogastric nerve block versus ilioinguinal- iliohypogastric nerve block for inguinal hernia repair in patients with liver cirrhosis

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## ABSTRACT

**Background:** Patients with chronic liver disease and liver cirrhosis have many anesthetic considerations with general anesthesia and limitation of ability to receive regional anesthesia due to coagulopathy and low platelets count.

Our study aims to compare the combination of the Ilioinguinal-iliohypogastric (ILIH) nerve block with the Transverse Abdominis Plane block (TAB) versus the Ilioinguinal-iliohypogastric (ILIH) nerve block alone as a sole anesthetic technique in hepatic patients with liver cirrhosis for surgical repair of inguinal hernia.

**Methods:** Sixty patients known to have chronic liver disease and liver cirrhosis undergoing unilateral repair of inguinal hernia were randomly assigned to two equal groups:

**Group (T)** received ipsilateral transverse abdominis plane block (TAB) ultrasound-guided (US) in combination with Ilioinguinal-iliohypogastric (ILIH) nerve block intraoperatively.

**Group (I)** received US-guided ipsilateral Ilioinguinal-iliohypogastric nerve block only intraoperatively.

The degree of pain was evaluated using the VAS score for pain hourly for the first 6 h and at 12, 18, and 24 h postoperatively. Need for LA infiltration into surgical field or the conversion to GA was assessed. Onset of sensory block, duration of analgesia, the use of rescue analgesia and its total dose in 24 hours, the patient's and surgeon's satisfaction and any adverse events were recorded. Liver functions were measured 24 h postoperatively.

**Results:** The duration of analgesia was significantly longer in group (T) ( $14.27 \pm 2.5$  hours) than in group (I) ( $11.81 \pm 2.9$  hours;  $p = 0.039$ ). The total required dose of acetaminophen in first 24 hours was higher in group (I) ( $1.1 \pm 0.81$  gm) than in group (T) ( $0.6 \pm 0.94$  gm;  $p = 0.021$ ). There was no significant difference between groups in onset of sensory block, need for LA infiltration, need for GA, or incidence of postoperative side effects. Patients' satisfaction was statistically better in group T compared to group I whereas there was no statistical significant difference between both groups regarding surgeon's satisfaction.

**Conclusion:** Combined Transverse Abdominis plane block (TAB) with Ilioinguinal-iliohypogastric (ILIH) nerve block has longer duration of analgesia and less dose of rescue analgesia with more patient satisfaction than the use of Ilioinguinal-iliohypogastric (ILIH) nerve block in surgical repair of inguinal hernia in chronic hepatic patients with liver cirrhosis.

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## 1. Introduction

Liver cirrhosis is considered a significant marker for adverse postoperative outcome which makes surgeons reluctant to perform inguinal hernia repair surgeries for fear of putting the patients at additional risk. Cirrhotic patients have limited hepatic reserve and are vulnerable to physiological stress and hepatic decompensation [1].

The interest in performing nerve blocks and local anesthetic infiltration has been lately expanding especially in high-risk patients with poor systemic status. Although the ilioinguinal-iliohypogastric (ILIH) block is safer and easier to perform and was used almost routinely to provide analgesia for inguinal surgical procedures, but it has a relatively short duration and a relatively high failure rate of 10–25%, even in

experienced hands [2]. Thus the combined use of ILIH and transverse abdominis plane blocks using the ultrasound technique were thought to increase the success and the duration of both the intraoperative and the postoperative analgesia especially in such patients where general or regional anesthesia is considered too risky.

The purpose of this study is to compare the efficacy of using TAB and ILIH nerve blocks versus ILIH nerve block only for inguinal hernia repair in patients with liver cirrhosis.

## 2. Patients and methods

The study was done after obtaining approval of the Research Ethics Committee in the Faculty of Medicine,

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Ain Shams University (number FMASU R48/2019), registration in ClinicalTrials.gov (NCT 04553328) and obtaining a written informed consent from all patients enrolled. Sixty patients between the age of 40 and 70 years, belonging to American Society of Anesthesiologists (ASA) physical status II and III, undergoing unilateral inguinal hernia repair were enrolled in this prospective randomized single observant study. All patients had liver cirrhosis, having a Child-Pugh [3] class B with a score  $< 8/15$ , Moemen modified classification of liver disease [4] class B, and an international normalized ratio (INR)  $< 1.5$ . Need for LA infiltration into surgical field or the conversion to GA was assessed as the primary outcome. The secondary outcomes were the onset of the block, duration of analgesia, total dose of the rescue analgesic duration of surgery, ambulation time, patients' and surgeon's satisfaction.

Exclusion criteria included patients with Child-Pugh  $\geq 8/15$ , INR  $\geq 1.5$ , grade 3 ascites, serum sodium  $\leq 120$  meq/l, recurrent hernia or surgery for bilateral hernia repair, body mass index (BMI)  $\geq 40$  kg/m<sup>2</sup>, known allergy to any of the medicines used, renal or cardiovascular dysfunction, bronchial asthma, hematological disorders (other than secondary to chronic liver disease), and patient refusal.

Metabolic profile was evaluated and recorded both preoperatively and postoperatively in the form of aspartate aminotransferase (AST), alanine aminotransferase (ALT), serum albumin, total bilirubin, serum creatinine, blood urea nitrogen, serum urea, and serum sodium. The degree of ascites was categorised into three groups: Grade 1: visible only on ultrasound and CT, Grade 2: detectable with flap bulging and shifting dullness, Grade 3: directly visible, confirmed by the fluid wave/thrill test [5]. All patients were instructed on the use of the visual analog scale (VAS) using a 0–10 cm VAS, the patients rated their pain intensity, where score 0 = no pain and 10 = worst pain.

Intravenous cannula was inserted and 40  $\mu$ g/kg of granisetron and 40 mg pantoprazole sodium were given 1 h before surgery intravenously. All patients were given metronidazole 500 mg and ceftriaxone 1000 mg as antibiotic prophylaxis before the skin incision. Platelet replacement was performed in patients whose platelet counts were  $\leq 50 \times 10^3/\mu$ l. Inside the operating room, an infusion of Ringer acetate was started and patients were given intravenous 0.03 mg/kg of midazolam for anxiolysis.

Patients were then randomised using a computer-generated randomization table and opaque sealed envelopes in two groups (30 patients in each group) based on the type of block they received: **Group (T)** received ultrasound-guided (US) combined ipsilateral transverse abdominis plane (TAB) and ilioinguinal-iliohypogastric (ILIH) nerve block. **Group (I)** received US-guided ipsilateral ilioinguinal-iliohypogastric nerve block only.

Monitoring during the operation included cardiac rate (HR), non-invasive mean arterial blood pressure (MAP), respiratory rate (RR) and oxygen saturation (SpO<sub>2</sub>) were recorded at baseline before the block, then at 5-minute intraoperative intervals, then at 15 and 30 minutes during the immediate postoperative phase, and at discharge from the post-anesthesia care unit (PACU).

A nasal prong was applied, and supplementary oxygen was provided at 3 l/min during the procedure. Patients were clearly explained that any pain, discomfort, or anxiety would be handled by administration of local anaesthetic (LA) infiltration with bupivacaine at 0.25% during surgery or by conversion to general anaesthesia (GA) if needed. Patients were positioned supine. Mindray M5 ultrasound (Mindray DS USA Inc., Mahwah, New Jersey, USA) with a linear high-frequency probe (7.5 MHz) was used to scan the abdominal wall in the multibeam mode. The blocks were given under complete aseptic conditions.

An anesthesiologist who is specialised in ultrasound-guided regional anaesthesia, conducted and supervised all blocks. At the end of the injection, sensory block was assessed every 3 min by thermal sensation using an alcohol swab in the skin area overlying the surgical field. The sensory block was considered successful when there was loss of cold sensation in the skin area overlying the surgical field. The period from the injection of local anaesthesia to the complete absence of thermal differentiation was identified as the onset of sensory block. The need for surgical LA infiltration or conversion to GA was evaluated. Surgical duration corresponding to the period from incision of the skin to closure of the skin was recorded. After completion of the surgical procedure, patients were transferred to the post-anesthetic care unit (PACU) and Modified Aldrete Score [6] was assessed and discharged after fulfilling an Aldrete score of  $\geq 9$ .

The degree of pain was assessed using VAS for hourly pain during the first 6 h and at 12, 18 and 24 h postoperatively. Duration of analgesia was described as the period from leaving the operation theatre to the first pain complaint (Pain Score  $\geq 4$ ) requiring rescue analgesia. Rescue analgesic was given in the form of 1 g of intravenous acetaminophen (Perfalgan 10 mg/ml solution; Bristol-Myers Squibb Pharmaceuticals Ltd, Middlesex, UK) with a maximum daily dose of not more than 3 gm. The total of 24 h analgesic consumption was calculated.

Any adverse events including bradypnea (Respiratory Rate (RR)  $< 10$  bpm), SpO<sub>2</sub> reaching  $\leq 92\%$ , hypotension (MAP  $< 55$  mmHg), nausea, and vomiting were recorded. Ambulatory time for the patient (out of bed time) was measured hourly, from surgery completion to the time of first out of bed ambulation. Patients were asked by means of a 7-point Likert-like verbal rating scale to rate

satisfaction of their anaesthesia and analgesia [7] where 1 = extremely unhappy, 2 = unhappy, 3 = slightly unhappy, 4 = unsure, 5 = somewhat content, 6 = satisfied, and 7 = quite satisfied. = quite satisfied. This patient satisfaction assessment was carried out 6 hours after leaving the PACU. An overall surgeon satisfaction was recorded, where a score of 1 = excellent, 2 = good, 3 = poor, and 4 = bad.

### 2.1. Sample size justification

For sample size, statistical calculation was based on a power of 80% and 95% confidence interval, the MedCalc® version 123.0.0 software was used with  $\alpha$ -error 5%, according to a previous study done by Bondok and Ali in 2014 showed that no patients necessitated the conversion to GA and only three patients (10%) needed LA infiltration [8]. Sample size was calculated according to these values showed that a minimum of 57 cases were enough to find such a difference. Assuming a drop-out ratio of 5%, the sample size was 30 cases in each group.

### 2.2. Statistical analysis

The collected data were statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 20.0

Descriptive statistics were done for numerical parametric data as mean  $\pm$  SD (standard deviation) and for numerical nonparametric data as median and interquartile range, while they were done for categorical data as number and percentage.

Inferential analyses were performed in two independent groups with parametric data for quantitative variables using an independent t-test and Mann Whitney U in two independent groups with non-parametric data.

Qualitative data were analyzed with Chi square test or Fisher's exact test as appropriate. The degree of statistical significance was considered when the P-value was less than 0.05.

## 3. Results

No significant differences were found between the two groups regarding the demographic data and patients' characteristics (Table 1).

No statistical significant difference between two groups regarding HR (Table 2).

No statistical significant difference between two groups regarding MAP (Table 3).

No statistical significant difference between both groups regarding  $SO_2$  (Table 4).

No statistically significant difference between both groups regarding RR (Table 5).

**Table 1.** Demographic data and patients' characteristics.

	Group T (n = 30)	Group I (n = 30)	P-value*
Age(years)	57.3 $\pm$ 6.34	59.4 $\pm$ 5.11	0.163
Height(cm)	171.78 $\pm$ 9.12	173.65 $\pm$ 8.31	0.409
Weight(kg)	85.71 $\pm$ 7.15	83.64 $\pm$ 6.95	0.260
BMI(kg/m <sup>2</sup> )	28.13 $\pm$ 4.18	29.11 $\pm$ 5.12	0.420
ASA status (II/III)	18/12	20/10	0.789#
Ascites grade (1/2)	23/7	22/8	0.770#
Child-Pugh score	7 (7,8)	7(7,8)	0.874
Moemen modified classification of liver disease score	10.35 $\pm$ 0.51	10.44 $\pm$ 0.57	0.522
Duration of surgery (min)	25.31 $\pm$ 9.15	27.28 $\pm$ 8.13	0.382

Data are presented as mean  $\pm$  SD, median and range, or number  
BMI (body mass index), ASA (American Society of Anesthesiologists).

**Table 2.** Heart rate changes in beat/min.

	Group T (n = 30)	Group I (n = 30)	P-value
Baseline	82 $\pm$ 3.34	81 $\pm$ 4.35	0.731
5 min	79 $\pm$ 3.27	78 $\pm$ 3.81	0.714
10 min	75 $\pm$ 2.86	74 $\pm$ 3.18	0.625
15 min	74 $\pm$ 3.29	74 $\pm$ 3.10	0.720
20 min	76 $\pm$ 3.22	73 $\pm$ 2.72	0.581
25 min	75 $\pm$ 3.16	72 $\pm$ 3.13	0.571
30 min	75 $\pm$ 3.64	72 $\pm$ 3.06	0.657
35 min	74 $\pm$ 3.56	71 $\pm$ 3.00	0.642
40 min	79 $\pm$ 3.11	76 $\pm$ 3.46	0.562
55 min	81 $\pm$ 4.03	80 $\pm$ 3.38	0.727
70 min	82 $\pm$ 3.34	81 $\pm$ 2.96	0.710
Discharge from PACU	84 $\pm$ 3.97	83 $\pm$ 3.74	0.716

Data are presented as mean  $\pm$  SD.

**Table 3.** MAP changes in mmHg.

	Group T (n = 30)	Group I (n = 30)	P-value
Baseline	75 $\pm$ 2.93	76 $\pm$ 3.80	0.639
5 min	73 $\pm$ 2.86	74 $\pm$ 3.33	0.625
10 min	65 $\pm$ 2.50	64 $\pm$ 2.78	0.547
15 min	67 $\pm$ 2.88	64 $\pm$ 2.72	0.630
20 min	66 $\pm$ 2.82	65 $\pm$ 2.38	0.508
25 min	65 $\pm$ 2.77	65 $\pm$ 2.74	0.499
30 min	65 $\pm$ 3.19	66 $\pm$ 2.67	0.575
35 min	66 $\pm$ 3.11	66 $\pm$ 2.63	0.562
40 min	66 $\pm$ 2.72	67 $\pm$ 3.03	0.492
55 min	76 $\pm$ 3.52	77 $\pm$ 2.96	0.636
70 min	77 $\pm$ 3.44	77 $\pm$ 2.59	0.621
Discharge from PACU	78 $\pm$ 3.47	80 $\pm$ 3.27	0.626

Data are presented as mean  $\pm$  SD.

No statistically significant difference between both groups regarding characteristics of the block and side effects. Need for local anesthetic infiltration was significantly higher in group I compared to group T. Duration of analgesia was statistically longer in the group T than group I. Need for conversion to general anesthesia was only one patient in group T (due to patient irritability not block failure) and two patients in group I (one due to patient irritability and other patients for being uncomfortable in the supine position) (Table 6).

Analgesic requirement in the post-operative period was statistically lower in group T compared to group I (Table 7).

There was no statistical significance between both groups regarding pre and post-operative laboratory results (Table 8).

The VAS score was statistically lower in group T compared to group I at 12 hours and no significant

**Table 4.** SpO<sub>2</sub> changes in %.

	Group T (n = 30)	Group I (n = 30)	P-value
Baseline	97 ± 2	97 ± 2	0.913
5 min	98 ± 1	97 ± 2	0.892
10 min	98 ± 1	98 ± 1	0.781
15 min	98 ± 1	98 ± 1	0.900
20 min	98 ± 1	98 ± 1	0.726
25 min	98 ± 1	98 ± 1	0.713
30 min	98 ± 1	98 ± 1	0.822
35 min	98 ± 1	98 ± 1	0.803
40 min	98 ± 1	98 ± 1	0.703
55 min	98 ± 1	98 ± 1	0.908
70 min	98 ± 1	98 ± 1	0.887
Discharge from PACU	98 ± 1	98 ± 1	0.895

Data are presented as mean ± SD.

**Table 5.** Respiratory rate changes.

	Group T (n = 30)	Group I (n = 30)	P-value
Baseline	15 ± 1	16 ± 1	0.365
5 min	14 ± 2	15 ± 1	0.357
10 min	10 ± 4	11 ± 4	0.312
15 min	10 ± 5	11 ± 3	0.360
20 min	11 ± 3	11 ± 4	0.290
25 min	11 ± 4	11 ± 2	0.285
30 min	11 ± 4	11 ± 3	0.329
35 min	11 ± 4	11 ± 4	0.321
40 min	11 ± 3	11 ± 3	0.281
55 min	13 ± 2	11 ± 2	0.363
70 min	14 ± 1	12 ± 3	0.355
Discharge from PACU	15 ± 1	15 ± 1	0.358

Data are presented as mean ± SD.

**Table 6.** Characteristics of the block and side effects.

	Group T (n = 30)	Group I (n = 30)	P-value*
(1) Onset of sensory block (min)	15.33 ± 4.1	18.41 ± 5.2	0.083
(1) Need for LA infiltration	4 (13.3%)	12 (40%)	0.041*
(1) Need for conversion to GA	1 (3.33%)	2 (6.7%)	0.719
(1) Duration of analgesia (hr)	14.27 ± 2.5	11.81 ± 2.9	0.039*
(1) Ambulation time (min)	83.61 ± 53.41	78.54 ± 51.33	0.416
Side effects			
• Nausea	2 (6.7%)	1 (3.33%)	0.719
• Vomiting	1 (3.33%)	0 (0%)	0.652
• SpO <sub>2</sub> < 92%	2 (6.7%)	0 (0%)	0.317
• Bradypnea	0 (0%)	0 (0%)	1.000
• Hypotension	0 (0%)	0 (0%)	1.000

Data are presented as mean ± SD, or number (percentage).

(LA) local anesthetic, (GA) general anesthesia.

\*P-value < 0.05 is significant

**Table 7.** Analgesic requirements in the post-operative period.

	Group T (n = 30)	Group I (n = 30)	p-value
Total required dose of IV acetaminophen in 1 <sup>st</sup> 24 hrs(g)	0.6 ± 0.94	1.1 ± 0.81	0.021*

Data are presented as mean ± SD.

\*p-value < 0.05 is significant

statistical difference between both groups at other times (Table 9). There was some discomfort before beginning of surgery in most of the patients (at baseline).

Patients' satisfaction was statistically better in group T compared to group I where as there was no statistically significant difference between both groups regarding surgeon's satisfaction (Table 10).

## 4. Discussion

This study showed that the use of the combined TAB with ILIH nerve blocks has longer duration of analgesia, lesser need for local anesthetic infiltration, lower VAS score at 12 hour and lower total analgesic requirements postoperative than the ILIH nerve block alone. Patients' satisfaction was better in the combined TAB with ILIH nerve block compared to the ILIH block alone.

Inguinal hernia repairs are considered one of the most commonly performed day case surgeries. There is an increased incidence rate of inguinal hernias in patients with a cirrhotic liver accompanied by ascites when comparing them to the general population. Patients with liver cirrhosis posted for abdominal surgeries are unquestionably at a high risk of developing perioperative complications [9]. Although all cases of inguinal hernias must be treated surgically by hernia repair due to the possibility of strangulation or incarceration, there is a controversy regarding patients with liver cirrhosis due to the poor physical status, low hepatic reserve and increased risk with using general anesthesia. **Horn et al.** [10] stated that high-risk patients with advanced portal hypertension and ascites must be treated conservatively whenever possible to decrease the risk of significant perioperative complications, such as recurrence, and leakage of ascitic fluid. While others as **Hurst et al.** [11] reported that life-threatening complications from inguinal hernia repair in such patients are not very common, and should not prevent hernia repair. Others stated that elective hernia repair for patients with cirrhosis should be done after medical optimization [12,13].

Cirrhotic patients have increased systemic vascular resistance, high cardiac index and deficient neuro-hormonal mechanisms. General anesthesia in these patients blunts the compensatory mechanisms in response to hypotension further decreasing the hepatic blood flow which would compromise the already borderline hepatic reserve [14]. Coagulation abnormalities are common in cirrhotic patients prohibiting in some patients the use of neuroaxial blocks [15]. Local infiltrative anesthesia or nerve blocks became the most appropriate techniques in these types of patients with ASA III–IV status who could not tolerate any hemodynamic variations occurring during general or regional anesthesia. The direct use of the ultrasound facilitated the direct visualization of the nerves decreasing the failure rates of nerve blocks especially in patients with anatomical variations [16].

Several studies compared US-guided TAB block to US-guided ILIH nerve block for postoperative analgesia in hernia repair in adults [17,18] and pediatric [19] patients and stated that better pain control was provided in ILIH block group most probably due to the injection of the same volume of local anesthetics for both blocks, as TAB block is a field block requiring



**Table 8.** Pre-operative and post-operative laboratory results.

	Group T (n = 30)		Group I (n = 30)		p-value Pre	P value Post
	Pre-	Post-	Pre-	Post-		
Hemoglobin (g/dl)	11.15 ± 2.1	10.9 ± 1.9	11.25 ± 1.8	11.1 ± 1.1	0.183	0.178
INR	1.28 ± 0.21	1.1 ± 0.32	1.31 ± 0.1	1.15 ± 0.32	0.178	0.173
Platelets count(x10 <sup>3</sup> /μl)	95 ± 8.6	101 ± 6.7	93 ± 7.3	102 ± 9.7	0.156	0.167
Albumin(g/dl)	2.95 ± 1.42	2.81 ± 1.35	2.91 ± 1.39	2.89 ± 1.32	0.180	0.175
Total bilirubin(mg/dl)	1.2 ± 0.75	1.3 ± 0.71	1.3 ± 0.74	1.4 ± 0.70	0.145	0.155
Serum Na(mmol/L)	128 ± 3.3	127 ± 5.53	127 ± 5.8	126 ± 4.31	0.143	0.153
AST(U/L)	42 ± 5.02	59 ± 4.77	44 ± 4.90	58 ± 4.66	0.164	0.159
ALT(U/L)	40 ± 4.83	61 ± 4.59	39 ± 5.34	65 ± 4.67	0.161	0.172
Serum creatinine(mg/dl)	0.91 ± 0.5	0.98 ± 0.48	0.88 ± 0.49	0.89 ± 0.47	0.141	0.151

Data are presented as mean ± SD.

**Table 9.** Post-operative VAS for pain during first 24 hours.

	Group T(n = 30)	Group I(n = 30)	p-value
Baseline	1(1–2)	1(1–2)	0.548
1 hr	1(1–2)	1(1–2)	0.535
2 hr	1(1–2)	1(1–2)	0.469
3 hr	1(1–2)	2 (1–2)	0.540
4 hr	2(1–2)	2(2–3)	0.436
5 hr	2(2–3)	2(2–3)	0.428
6 hr	3 (2–3)	3 (2–3)	0.493
12 hr	3 (3–5)	5 (3–6)	0.027*
18 hr	3 (3–4)	4 (3–5)	0.422
24 hr	3(3–4)	4 (3–5)	0.545

Values are expressed as median (inter-quartile range),\*p-value <0.05 is significant.

**Table 10.** Patients' and surgeon's satisfaction scores.

	Group T (n = 30)	Group I (n = 30)	p-value
Patients' satisfaction	6	4	0.019*
Surgeon's satisfaction	21(70.0%)	20(66.7%)	0.854
	good	10(33.3%)	
	Poor	0 (0%)	
	Bad	0 (0%)	

Data are presented as median and inter-quartile range(IQR), or number (percentage).

\*p-value <0.05 is significant.

larger volume than the ILIH nerve block, also due to that the local anesthetic is injected near ILIH nerves. Other studies documented that TAB block provided adequate postoperative analgesia for lower abdominal and pelvic surgical procedures when compared to local anesthetic infiltration [20] or to placebo [21]. **Hosalli et al.** [22] in 2019 compared the efficacy of the combined TAB/ILIH nerve block to the use of ILIH nerve block alone for postoperative patients; they found that this dual block (TAB/ILIH) provided more effective postoperative analgesia and longer time.

To our knowledge, TAB or ILIH nerve blocks were used in previous studies as means for postoperative analgesia in liaison to general or regional anesthesia in ASA I, II patients. Data regarding the use of these blocks in high-risk patients as the sole anesthetic technique to offer a safe and effective alternative to general or regional anesthesia are scarce. This study showed that the use of combined US-guided TAB with ILIH nerve blocks provided better postoperative outcome and lesser need for intraoperative local

anesthetic infiltration thus more patients' satisfaction than the use of US ILIH nerve block alone, although it is still feasible to use either techniques in such patients as there were high success rates for both groups with limited comparable number of patients that needed general anesthesia; taking in consideration that US was used in both groups for better nerves visualization.

Additional informations are still required concerning the TAB block compared with other techniques of regional anesthesia in terms of efficacy and side-effects.

**In conclusion**, the use of the US-guided TAB with ILIH nerve blocks can be used in high-risk cirrhotic patients as an alternative to ILIH nerve block alone, providing more patient satisfaction and less analgesic requirements.

## Disclosure statement

No potential conflict of interest was reported by the authors.

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