

PRE-INCISION VERSUS LAPAROSCOPIC-ASSISTED TRANSVERSUS ABDOMINIS PLANE (TAP) AND RECTUS SHEATH BLOCK FOR POST-CHOLECYSTECTOMY PAIN MANAGEMENT: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Laparoscopic cholecystectomy is the gold standard treatment for the management of cholelithiasis. The Transversus Abdominis Plane (TAP) block with rectus sheath block is a loco-regional anesthesia technique reducing the need of parenteral analgesics and yields quick recovery after Laparoscopic cholecystectomy. **Objective:** To compare the mean post-operative pain score at (3, 6, 12 and 24 hours) after Transversus abdominis plane (TAP) and Rectus sheath block given pre-incision versus laparoscopic-assisted in patients undergoing elective Laparoscopic cholecystectomy at a tertiary care hospital.

Methods: This is a single-center, parallel-group, randomized controlled trial conducted in the General Surgery Department at a tertiary care institute from January 2022 to December 2023. The intervention group received laparoscopic-assisted blocks (TAP and rectus sheath blocks) (LATAP) administered by the surgical team, and the control group received pre-incision blocks (TAP and rectus sheath blocks) (PITAP) administered by an anesthesiologist. The primary outcome was postoperative pain, measured using the visual analog scale at 3, 6, 12, and 24th hours at rest. Secondary outcomes included rescue analgesia, visceral injury, peritoneal entry, and blocks timing.

Results: A total of 224 were included in the study, 112 patients were randomized to each group. Demographics of the patients (i.e. Age, gender, American society of anesthesiologists score, functional class, co-morbidities and BMI) were comparable between the groups. Pain score at third hour post operatively in LATAP and PITAP was 3.38 ± 1.56 vs 3.8 ± 1.7 respectively (P -value= 0.053). Difference in post-operative pain score at 6, 12 and 24 hours was also statistically insignificant. Total rescue analgesia and peritoneal entry between both groups were also statistically insignificant as well. No visceral injury was recorded or observed in both groups. However, mean duration of block between two groups was statistically significant (P -value <0.001) with higher block timings in PITAP group (400.65 ± 108.517 seconds) as compared to LATAP group (142.58 ± 43.464 seconds).

Conclusion: Laparoscopic-assisted TAP block is not inferior to pre-incision TAP block in managing post-operative pain for patients undergoing laparoscopic cholecystectomy, however, the procedure time in LATAP group was shorter than

PITAP group. Therefore, we recommend Laparoscopic assisted block to save overall anesthesia and operating room time

INTRODUCTION

Each year Worldwide, more than 13 million Laparoscopic surgeries are carried out (1). Laparoscopic technique is used for 90% of cholecystectomies in the United States (2). Since laparoscopic cholecystectomy is less invasive than open cholecystectomy, it is now the gold standard in most health facilities (3).

In addition to preventing complications after surgery, effective pain management is crucial for early ambulation and a return to daily activities. In addition to relieving pain, it's critical to minimize adverse effects. Therefore, pre-emptive analgesia has gained popularity. Pre-emptive analgesia, such as transversus abdominis plane block (TAP), is an anti-nociceptive treatment that is given prior to surgery to lessen the sensitization of the peripheral and central pain pathways, which happens as a result of pain signals evoked by tissue damage. The effectiveness of preemptive analgesia has been the subject of conflicting analyses, with some studies finding no beneficial effect (4, 5).

For post-laparoscopic pain management, a multimodal approach with non-steroidal anti-inflammatory drugs, opioids and loco-regional techniques have been recommended (4). The Transversus Abdominis Plane (TAP) block is an analgesia technique that is loco-regional, consists of infiltrating a local anesthetic solution between the plane of the Transversus abdominis muscle and the internal oblique muscle (4).

TAP block has gradually become an alternative postoperative analgesia technology and it was described in 2001 by Rafi (6). Several techniques are currently used to deliver TAP blocks, including blinded double pop technique (8), ultrasound-guided (7) and laparoscopic-assisted approaches (10). Chetwood et al. introduced laparoscopic approach in 2011 while performing laparoscopic nephrectomies (9). The advantages of this technique include ease of performance, less dependency on specialized skill set or equipment, time efficient, less risk of visceral injury and avoidance of intraperitoneal local anesthetic infiltration.

Many studies have demonstrated the therapeutic benefit of laparoscopic-assisted TAP block in initial post-operative pain management in comparison with periportal local anesthetic infiltration for patients undergoing elective laparoscopic procedures (e.g. for laparoscopic hernia repair) (10,11). To the best of our knowledge, there is a paucity of data since laparoscopic-assisted TAP block has not been utilized or evaluated prospectively to see if the effectiveness of TAP block varies according to whether it is performed pre-incisional (pre-emptive) or intraoperatively under Laparoscopic vision for laparoscopic procedures. Furthermore, the potential benefit of combining TAP block with rectus sheath block for enhanced postoperative analgesia has not been adequately explored in this context.

This study aims to compare the mean post-operative pain score at (3, 6, 12 and 24 hours) with pre-incision versus laparoscopic-assisted transversus abdominis plane (TAP) block in conjunction with Rectus sheath block in patients undergoing Laparoscopic cholecystectomy at a tertiary care hospital.

We hypothesize that laparoscopic-assisted TAP block will provide non-inferior pain control after cholecystectomy compared to pre-incisional TAP block.

Materials and methods

This was a single centered, parallel group, randomized controlled trial, conducted in General Surgery Department at a tertiary care institute in Karachi, Pakistan from January 2022 to December 2023. The trial was conducted in accordance with the CONSORT checklist.

Patients included were of age between 18 to 65 years, both genders and undergoing elective Laparoscopic cholecystectomy (LC) with American society of anesthesiologists (ASA) physical status I & II. Patients were excluded who had coagulopathy, history of allergy, hypersensitivity or contraindication to ropivacaine, nalbuphine, paracetamol, local skin allergy, who had laparoscopic converted to open cholecystectomy, previous open upper abdominal or midline surgeries, diagnosis of chronic pain syndrome

(migraine, rheumatoid arthritis, cystic fibrosis, myalgia), known alcohol or substance abuse within the last 6 months, anti-psychotic, antidepressants, steroids use, multiple procedures planned under same anesthesia, pregnant patients and patients who were unable to understand (i.e. deaf, language barrier, mentally incapacitated).

Study was started after approval by the institutional ethical committee (PH/IRB/2022/006) and registered with Trials.Gov (NCT05856682). Once patient was admitted for LC after detailed history, examination and relevant investigations; patient was evaluated on a separate recruitment form consisting of all the inclusion & exclusion criteria. Informed and written consent was taken before randomization. Intervention group was Laparoscopic-assisted TAP/rectus sheath block (LATAP) and control group was Pre-incision TAP/rectus sheath (PITAP) block by Anesthetist. Primary outcome of this study was post-operative pain at 3,6,12 and 24 hours and secondary outcomes were Rescue analgesia need, visceral Injury, peritoneal entry and block timings.

TAP Block is a regional analgesia technique which involves the injection of a local anesthetic solution into a plane between the internal oblique muscle and transversus abdominis muscle. Since the thoracolumbar nerves originating from the T6 to L1 spinal roots run into this plane and supply sensory nerves to the antero-lateral abdominal wall, the local anesthetic spread in this plane can block the neural afferents and provide analgesia to the antero-lateral abdominal wall (11). Site of TAP block in this study was immediate right subcostal region, 3 cm medial to mid axillary line.

Rectus sheath block is a regional anesthesia technique that provides pain relief for midline abdominal surgeries at or above the umbilicus. Local anesthetic is injected at the lateral edge of the rectus sheath where branches of the intercostal nerves enter (12). Instillation of local anesthetic bilaterally between the rectus muscle and the posterior sheath provides midline analgesia for several dermatomes around the injection site (12). Site of rectus block in this study was bilaterally 3 cm lateral to Umbilicus and bilaterally 3cm lateral to midpoint between xiphisternum and umbilicus, total four block points (Figure 1).

Anesthesia was standardized in all patients. All patients received paracetamol 1000 mg and

nalbuphine 0.15mg/kg after induction of anesthesia. Both the procedures were performed by either Senior Resident (year 4)/Registrar (having experience of procedure) or a consultant. Syringes were prepared by one of the research team members for each patient in a designated sterile area on the day of surgery. One ampule of Ropivacaine (10 ml) consists of 50mg and a total of 50ml solution was prepared by mixing three ampoules of Ropivacaine i.e. 30 ml with 20mls of distilled water. The solution was then divided between the four rectus block sites (5ml each point) and one TAP block site (30ml). Needle used for the blocks was of 25 gauge and tip of the needle was blunted by gentle tapping on metallic surface.

In PITAP group, block was performed after induction & intubation under sterile conditions by blind double pop technique. In LATAP group, block was performed after insertion of laparoscopic optical port by one designated consultant or the same senior registrar across all cases. When a LATAP was performed, peritoneal bulging was seen (Figure 2). Timing of block was noted in seconds by putting the timer on at the start of the procedures when anesthesia/surgery team called the procedure on and by putting the timer off, when they called the procedure off. Peritoneal entry was seen under laparoscopic vision. For LATAP, entry was labelled when tip of needle was seen piercing peritoneum and for PITAP any erythema or bleed at the site of entry seen under laparoscopic vision. Visceral injury was observed under laparoscopic vision for both LATAP and PITAP.

Diet was Regular and started after 6 hours of the surgery. Ambulation was started as soon as patient was awake. Antibiotics (cefazolin 1gm) was given at the time of induction in all cases and then repeated two post operative doses eight hours apart post-operatively in contaminated cases. Patient-controlled analgesia (PCA) pump was given in the post-operative period for all patients for rescue analgesia and explained to them pre-operatively. On having pain, as per need, Patient used to press the button on a pump that was connected to IV catheter. Patient received a preset dose of Nalbuphine 2mg.

Pain was assessed using a visual analogue scale (0-10). The Visual Analogue Scale (VAS) is the standard tool for rating of pain - either patient's own rating or rated by the health care worker. The visual analog scale is a

straight line from 1 to 10 with one end meaning no pain and the other end meaning the worst pain. (Figure 3). Patient marked a point on the line that matched the intensity of pain he or she felt (13). Pain was assessed at rest, at 3,6,12, and 24 hours after surgery by an observer blinded to both intervention and control group.

Sample size was 112 patients in each arm, Sample size was Calculated using WHO software. Keeping Power set as 90% and Level of significance was 5% based on a two-sided hypothesis. Sampling technique was Purposive, non-probability. Randomization was done by Computer generated randomization table with blocks of four. Allocation was disclosed to the research team in OR just before the procedure by the Co-Ordinator of Hospital Research Forum who had the table. Patient and Person assessing post-operative pain were blinded to the both groups (Double blinding).

The data were entered and analyzed in SPSS V.23. Numerical data such as VAS pain score at 3, 6, 12, and 24 hours, rescue analgesia (PCA) at 3, 6, 12, 24 and total in 24 hours and TAP block time were reported as mean \pm standard deviation (SD) and compared between LATAP and PITAP by using Students t-test. Categorical variables as gender, comorbid, functional class, ASA status, person performing TAP block, peritoneal entry and visceral injury during procedure were reported as frequencies and percentages and compared between LATAP and PITAP by using chi square test. A P-value less than 0.05 was taken as significant.

Results

A total of 230 patients were assessed; Six patients were excluded from the study. Finally, a total of 224 were included in the study, 112 patients were randomized to each Laparoscopic assisted TAP/rectus block (LATAP) and Pre-incision TAP/rectus block (PITAP) group, as shown in consort flow diagram (Figure 4). The mean \pm SD age was 43.014 ± 13.07 years in LATAP and 46.38 ± 14.24 years in PITAP. There was female pre-dominance in each group with 79 (70.5%) in LATAP and 77 (68.8%) in PITAP group and males were 33 (29.5%) in LATAP and 35 (31.3%) in PITAP. The Demographics of the patients such as age, Body mass index (BMI), gender, co-morbidities (like Diabetes, Hypertension, obesity, and others),

functional class (FC), American Society of Anesthesiology (ASA) status, total duration of surgery (from incision to dressing of wounds), person who performed TAP and rectus sheath block were comparable in both control and intervention group with no significant difference in the P-value as shown in Table 1.

Primary outcome

Pain score at third hour postoperatively in LATAP and PTAP was 3.38 ± 1.56 vs 3.8 ± 1.7 (P-value= 0.053). Difference in post-operative pain score at 6,12 and 24 hours, were statistically insignificant as well, as shown in Table 2.

Secondary outcomes

Rescue analgesia at third hour in PITAP group was consumed more than the LATAP group. However, Total Rescue analgesia need was statistically insignificant between two groups. Peritoneal entry was encountered in four patients in LATAP group and only one patient in PITAP group but difference was statistically insignificant (P-value= 0.18).

Mean duration of TAP and rectus sheath block between two groups was statistically significant (P-value <0.001) with higher block timings in PITAP group (400.65 ± 108.517 seconds) as compared to LATAP group (142.58 ± 43.464 seconds). No visceral injury was encountered with the administration of TAP and rectus sheath block in both groups as shown in Table 2.

DISCUSSION:

This double-blinded randomized controlled trial demonstrated that laparoscopic-assisted TAP and rectus sheath blocks (LATAP) are not inferior to pre-incisional (pre-emptive) blocks (PITAP) in terms of post-operative pain control after laparoscopic cholecystectomy. Pain scores at rest measured via VAS at 3, 6, 12, and 24 hours post-operatively were comparable between the two groups. Although the third-hour pain score was slightly lower in the LATAP group (3.38 vs 3.80), the difference narrowly missed statistical significance (P = 0.053), but may still hold clinical relevance in early post-operative recovery.

Laparoscopic cholecystectomy is the most common laparoscopic procedure performed worldwide. Good and adequate post-operative pain control, not only

prevents post-operative complications but is also essential for early ambulation and return to daily routine and shortens the recovery period. For post-laparoscopic pain management, a multimodal approach with non-steroidal anti-inflammatory drugs, opioids and loco-regional techniques have been recommended. (4). Furthermore, most studies have demonstrated that reducing post-operative opioid requirements diminishes opioid-induced side effects such as sedation and nausea (14). Transversus abdominis plane (TAP) block technique seems to offer one of the most efficient methods for a local pain control (14). There is now sufficient published evidence to routinely recommend laparoscopic-assisted TAP blocks in elective inguinal hernia repairs, cholecystectomies, and laparoscopic colon resections (10).

One of the earliest prospective randomized controlled trials about the efficacy of TAP block published in late 2000's. McDonnell et al. declared that TAP block was found "highly" effective in post-operative wound pain relief. According to the study results, in TAP block group Visual analogue scale (VAS) scores has been reduced at all post-operative time points and at the 24th hour after surgery mean VAS scores were lower (15). However, there is limited evidence comparing the effectiveness of TAP blocks based on the timing of administration—i.e., pre-incision (pre-emptive) vs. intraoperative laparoscopic-guided—particularly in conjunction with rectus sheath blocks. Our study aimed to fill this gap by evaluating both approaches in terms of pain scores, rescue analgesia requirements, procedural time, and safety.

Poupak et al. compared the effect of pre-emptive versus postoperative (at the end of the surgery) use of ultrasound-guided transversus abdominis plane (USG-TAP) block on pain relief after laparoscopic cholecystectomy and concluded that the postoperative TAP block could offer better postoperative analgesia than pre-emptive TAP block (16). Kalu et al. investigated whether administering a Transversus Abdominis Plane (TAP) block before or after surgery had a different impact on postoperative opioid use. Although both pre- and post-operative TAP blocks effectively reduced pain following surgery, opioid consumption was similar in both groups (20). Our results align with these findings, demonstrating no statistically significant difference in postoperative pain

scores at 3, 6, 12, and 24 hours. Although the third-hour VAS score was slightly lower in the LATAP group (3.38 ± 1.56 vs. 3.80 ± 1.73), the difference narrowly missed statistical significance ($P = 0.053$), suggesting a trend that may have clinical relevance in early postoperative recovery.

Importantly, our study found that LATAP was significantly faster to perform than PITAP (142.58 ± 43.46 seconds vs. 272.69 ± 96.62 seconds; $P < 0.001$). This is consistent with findings from Ravichandran et al. and Civitella et al., who reported shorter times for laparoscopy-assisted blocks compared to ultrasound-guided techniques (17,18). This efficiency may be due to the avoidance of ultrasound setup and the ability to directly visualize anatomical structures during laparoscopy. Such time savings are clinically meaningful, particularly in high-volume settings where operating room efficiency impacts resource utilization and cost.

Regarding safety, no visceral injuries were encountered in either group, consistent with the known safety profile of TAP blocks (16,17). While peritoneal entry was observed in four patients in the LATAP group versus one in the PITAP group, this difference was not statistically significant ($P = 0.175$) and was not associated with adverse outcomes. LATAP may offer an additional safety advantage by enabling real-time visualization of the needle tip, potentially reducing the risk of visceral trauma compared to blinded techniques. The double-pop technique used for PITAP, as described by Rafi et al., is designed to minimize such risks, though direct visualization remains preferable where feasible (6).

Mughal et al. compared total rescue analgesic requirements between periportal anesthesia and TAP block in patients undergoing total extraperitoneal inguinal hernia repair and found that total rescue analgesic requirements were significantly reduced in the TAP block group $P < 0.001$ (10). Poupak et al., as mentioned earlier also studied on rescue analgesia need between pre-emptive versus postoperative (at the end of the surgery) use of ultrasound-guided transversus abdominis plane (USG-TAP) block after laparoscopic cholecystectomy and concluded that the time to first analgesic request was significantly shorter in the post-operative group, which was statistically significant P -value = 0.089 (16). Our findings on rescue analgesia requirements also support the non-

inferiority of LATAP. While total nalbuphine consumption over 24 hours was similar between groups, analgesic use was significantly higher in the PITAP group during the third hour postoperatively (0.63 ± 1.27 mg vs. 0.39 ± 0.92 mg; $P = 0.02$). This may suggest that LATAP provides faster onset of effective analgesia, though the overall impact on total analgesic use was minimal.

Finally, performing blinded TAP blocks in obese patients can be challenging due to excess subcutaneous fat and increased tissue depth, which can make accurate needle placement difficult (19). In such cases, laparoscopic visualization may provide a safer and more reliable alternative.

Despite these strengths, our study has several limitations. It was conducted at a single center, which may affect the generalizability of the findings. Pain scores were recorded only at rest, not during movement or coughing, which are more representative of functional recovery. Furthermore, long-term outcomes such as time to full recovery, hospital discharge, or patient satisfaction were not assessed. Finally, subgroup analyses (e.g., stratification by BMI or ASA status) were not performed but may be valuable in future investigations.

Conclusions:

In summary, Laparoscopic-assisted TAP and Rectus sheath blocks are a safe, efficient, and non-inferior alternative to Pre-incisional administration for post-operative analgesia in laparoscopic cholecystectomy. LATAP offers significant procedural time savings without compromising pain control or safety, supporting its use as a practical alternative, especially in high-volume settings where anesthesia time is critical. Further multicenter trials including pain scores on movement and broader laparoscopic procedures may strengthen these findings.

	TAP/Rectus sheath Block		
	LATAP	PITAP	P-value
Age (yrs.); Mean ± SD	43.014±13.07	46.38±14.24	0.07 ^a
BMI (kg/m²); Mean ± SD	24.10±4.11	23.86±4.08	0.66 ^a
Gender			
Male	33(29.5%)	35(31.3%)	0.77 ^b
Female	79(70.5%)	77(68.8%)	
Co-morbidities			
Diabetes	16(14.3%)	21(18.8%)	0.431 ^c
Hypertension	34(30.4%)	24(21.4%)	
Obesity	7(6.3%)	5(4.5%)	
Others	6(5.4%)	10(8.9%)	
None	49(43.8%)	52(46.4%)	
Functional Class			
FC1	91(81.3%)	87(77.7%)	0.79 ^c
FC2	21(18.8%)	25(22.3%)	
ASA Status			
ASA1	54(48.2%)	58(51.8%)	0.59 ^b
ASA2	58(51.8%)	54(48.2%)	
Person Performing TAP Block			
Consultant	80(71.4%)	84(75.0%)	0.833 ^b
Surgical Registrar	25(22.3%)	22(19.6%)	
senior Resident (Year 4)	7(6.3%)	6(5.4%)	
Duration of surgery (in minutes)	79.12±30.32	76.49±20.55	
Mean ± SD			
BMI= Body Mass Index; ASA= American Society of Anesthesiology; SD= Standard deviation			
a=Independent t test; b=Chi square test; c= Fisher exact test			

Table-1: Baseline

Demographics

	TAP/Rectus sheath Block		
Primary outcome	LATAP	PITAP	P-value
VAS Pain Score at different time intervals; Mean ± SD			
3 Hours	3.38±1.56	3.80±1.73	0.053 ^a
6 Hours	2.78±1.33	2.95±1.47	0.368 ^a
12 Hours	2.27±1.27	2.51±1.27	0.158 ^a
24 Hours	1.91±1.11	2.04±1.09	0.398 ^a
Secondary outcomes			
PCA (nalbuphine in mg); Mean ± SD			
3 Hours	0.39±0.92	0.63±1.27	0.020^a
6 Hours	0.5±1.12	0.63±1.10	0.403 ^a
12 Hours	0.59±1.19	0.55±1.17	0.822 ^a
24 Hours	0.43±1.02	0.46±1.07	0.799 ^a
Total PCA in 24 hours	1.80±2.54	2.29±2.49	0.146 ^a
TAP Block Time (sec); Mean ± SD	142.58±43.46	272.69±96.62	<0.001 ^a
Peritoneal Entry; f (%)			
Yes	4(3.6%)	1(0.9%)	0.175 ^c
No	108(96.4%)	111(99.1%)	
Visceral Injury During Procedure; f (%)			
Yes	0	0	-
No	112(100%)	112(100%)	
VAS= Visual analogue scale; PCA= Patient-controlled analgesia; f=frequency; SD= standard deviation			
a=Independent t test; c= Fisher exact test			

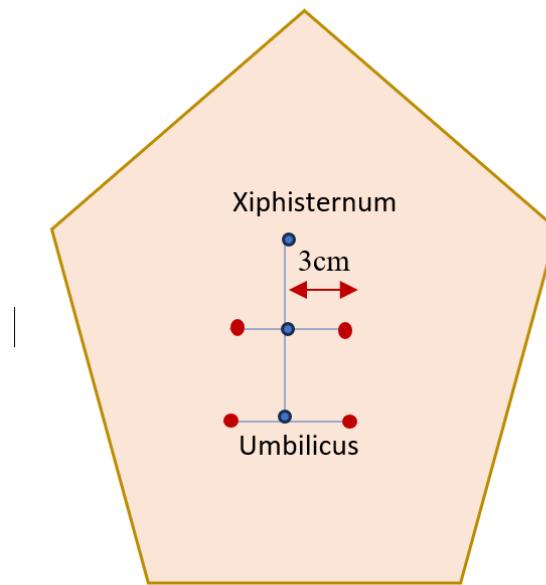
Table-2: Outcomes of the study

Figure 1: Diagrammatic Representation of the Points of Instillation for Rectus Sheath Block. The red dots represent points where rectus sheath block was instilled (bilaterally 3 cm lateral to Umbilicus and bilaterally 3cm lateral to midpoint between xiphisternum and umbilicus, total four block points).

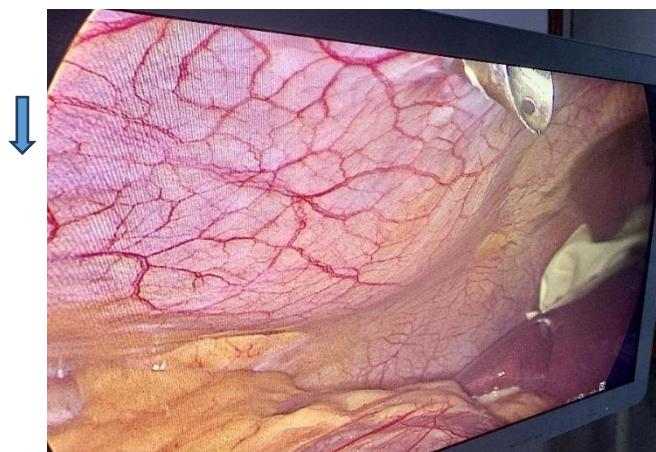


Figure 2: Laparoscopic view of a transversus abdominis plane (TAP) block. The arrow demonstrating peritoneal bulging during transversus abdominis plane block.

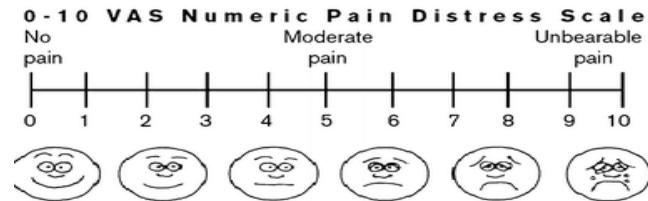


Figure 3: Visual analogue scale (

Picture courtesy: One-trocar versus multiport hybrid laparoscopic appendectomy: What's the best option for children with acute appendicitis? Results of an international multicentric study - Scientific Figure on ResearchGate. Available from:

https://www.researchgate.net/figure/0-10-VAS-Numeric-Pain-Distress-Scale_fig2_297608891 [accessed 7 Jan 2025]

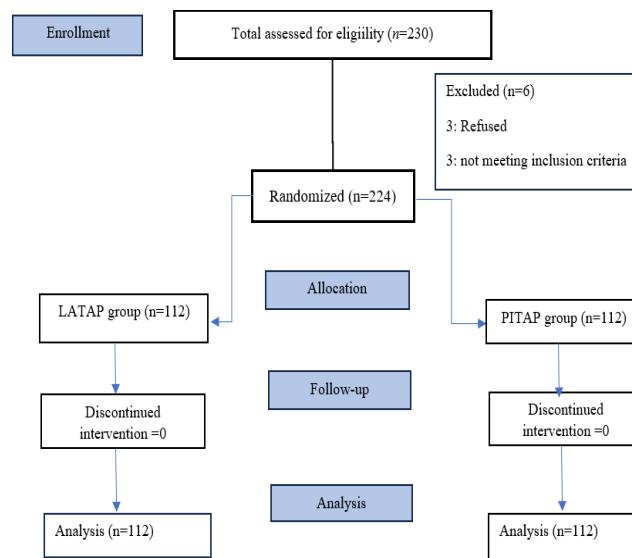


Figure 4: Study flow diagram

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