e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(3); 305-311

Original Research Article

Clinical Evaluation of Comparison of Ropivacaine (0.375%) & Bupivacaine (0.25%) in Bilateral Transversus Abdominis Plane Block for Post-Operative Analgesia in Patient Undergoing Elective Abdominal Hysterectomy under Subarachnoid Block: A Prospective, Randomized, Controlled, Double Blind Study

Kaushikkumar Lakhabhai Vaniya[1], Shilpa Mitul Doshi[2], Nisarg Ramanbhai Dindor[3], Jugal Pankaj Shukla[4]

[1,3,4]Senior Resident, Department of Anaesthesiology, Government Medical College, Bhavnagar, Gujarat, India

[2]Associate Professor, Department of Anaesthesiology, Government Medical College, Bhavnagar, Gujarat, India

Received: 25-12-2023 / Revised: 23-01-2024 / Accepted: 26-02-2024

Corresponding Author: Dr. Jugal Pankaj Shukla

Conflict of interest: Nil

Abstract:

Background: Total abdominal hysterectomy is one of the most commonly performed surgical procedures. Transversus abdominis plane (TAP) block is a recently introduced regional technique that blocks abdominal wall neural afferents between T6 and L1 and thus can relieve pain associated with an abdominal incision.

Objective: This study was conducted in 64 female patients to assess total duration of analgesia as per Visual analogue scale (VAS) score, requirements of rescue analgesics, hemodynamic parameters, Side effects & Complications if any.

Material and Methods: Patients were randomly allocated to one of the two groups of 32 patients each. In Group R (TAP block with 15 ml of 0.375 % Ropivacaine bilateral) given and in Group B (TAP block with 15 ml of 0.25 % Bupivacaine bilateral) given. The assessment of pain was done for 24hours. At any point of time if VAS is ≥4, intravenously Diclofenac sodium 25 mg was given to the patient as a 1st & 2nd rescue analgesic and for 3rd rescue analgesic intravenously Tramadol 75mg was given.

Results: The mean total duration of analgesia was longer in ropivacaine group compared to bupivacaine group. The VAS pain score was significantly lower in ropivacaine group compared to bupivacaine. Total requirement of rescue analgesia was reduced in patients of group R as compared to patients of group B. Hemodynamics remained stable in both the groups. No complications were noted in any of group.

Conclusion: TAP block as a part of multimodal analgesic regimen in patient with total abdominal hysterectomy provided reliable and effective analgesia in this study. 0.375% Ropivacaine provided longer duration of analgesia and resulted in lesser analgesic requirement than 0.25% Bupivacaine when used in TAP block and no complications due to the TAP block were detected.

Keywords: Transversus abdominis plane (TAP), Visual analogue scale (VAS), Diclofenac sodium, Tramadol, Postoperative pain, Analgesia.

Introduction

Total abdominal hysterectomy is one of the most commonly performed surgical procedures. After total abdominal hysterectomy substantial postoperative discomfort and pain is usually described as moderate to severe by most patients. [1]

Poorly controlled acute postoperative pain is associated with increased morbidity, functional and quality of life impairment, delayed recovery time, prolonged duration of opioid use and higher healthcare costs. In addition, the presence and intensity of acute pain during or after surgery is predictive of the development of chronic pain. [2]

Postoperative pain control can be achieved by multimodal analgesia system, including the use of pharmacological agents (NSAIDS, opioids) and interventional techniques (Nerve blocks). Opioids have some side effects including sedation, constipation, itching, postoperative nausea and vomiting (PONV) and respiratory depression etc.

NSAIDs also have certain side effects like haemostasis alteration, renal dysfunction, gastrointestinal haemorrhage etc. [3]

The provision of effective postoperative analgesia is of key importance to reduce postoperative stress response and associated morbidity, facilitates early ambulation and accelerates recovery from surgery. It also reduces risk of thrombo- embolism which is aggravated by immobility due to pain to the patients. The analgesic regimen needs to meet the goals of providing safe, effective analgesia with minimal side effects. [4-6]

Pain associated with total abdominal hysterectomy is somatic (from abdominal wall incision). Systemic or neuraxial opioids are the mainstay for treating postoperative pain. However, they are associated with a number of undesirable side effects such as nausea, vomiting, pruritus, constipation and respiratory depression. [8-10]

Non-steroidal anti-inflammatory drugs (NSAIDS) like Diclofenac Sodium relieves visceral component of pain through their action via inhibition of Prostaglandin synthesis, but it is insufficient for relieving somatosensory pain of abdominal wall incision.

Transversus abdominis plane (TAP) block is a recently introduced regional technique that blocks abdominal wall neural afferents between T6 to L1 and thus can relieve pain associated with an abdominal incision. [11,12] TAP is a neurovascular plane located between the internal oblique and transverse abdominis muscles and nerves supplying abdominal wall pass through this plane before supplying anterior abdominal wall.13Therefore, if the local anaesthetic is deposited in this space, myocutaneous sensory blockade results.

The benefits of TAP block include the avoidance of neuraxial analgesic techniques and their associated risk as well as a reduction in opioid consumption. As the side-effects of opioids are dose-dependent, reducing postoperative opioid requirements could significantly reduce the incidence of opioid-related problems such as sedation, nausea, vomiting, urinary retention, respiratory depression, delayed recovery of colonic mobility and prolonged postoperative ileus. [14,15]

Transversus abdominis plane (TAP) block is a safe regional anaesthetic technique which is now increasingly being used for postoperative analgesia for caesarean section, hysterectomy and various other surgeries involving the lower abdomen. Ropivacaine and Bupivacaine are the most commonly used local anaesthetic (LA) agents used for administering TAP block. Ropivacaine is a new, long-acting local anaesthetic. Numerous comparative studies between ropivacaine and bupivacaine suggested that ropivacaine produces less cardiac as well as central nervous system toxic effects, less motor block and a similar duration of action of sensory analgesia as bupivacaine. [16,17]

There have been many studies comparing 0.5% bupivacaine and 0.75% of ropivacaine when used for various peripheral nerve blocks and most of them have shown a similar efficacy when used in above-mentioned concentrations. [18-20] We undertook this prospective randomized study to compare 0.25% bupivacaine and 0.375% ropivacaine for postoperative analgesia using TAP block in patient undergoing total abdominal hysterectomy.

Material and Methods

A prospective, randomized, controlled, double blind clinical study was conducted in 64 patients in the department of Anaesthesiology, Government Medical College and Sir T. hospital, Bhavnagar for the duration of 12 months. After thorough pre-anaesthetic evaluation patients were included or excluded according to following criteria.

Inclusion Criteria

1. In formed written consent for participation in study
2. Patient undergoing total abdominal hysterec-tomy
3. Age:35-65years
4. ASA physical status I and II.

Exclusion Criteria

1. Patients refusing consent.
2. Contra indications to Spinal Anaesthesia
3. Allergy to local anaesthetic drugs and NSAIDS.
4. Patient on any form of analgesics therapy.
5. BMI≥ 25 kg/m

Patients were randomly allocated to one of the two groups of 32 patients each by computer generated randomization software

Group R (n=32) – 15ml of 0.375% Ropivacaine on each side of abdomen. Group B (n=32) – 15ml of 0.25% Bupivacaine on each side of abdomen.

In preanesthetic preparation room, Standard monitoring for Heart Rate (HR), Non Invasive Blood Pressure (NIBP), Peripheral oxygen saturation (SpO2) was established and baseline vital parameters was recorded then peripheral intra venous line was secured with 18G venous cannula.

All patients were pre-loaded with Ringer Lactate (10 ml/ kg body weight) before starting the surgery and were received subarachnoid block with3 ml of 0.5% heavy hyperbaric bupivacaine in L3-L4 Interspinous space with 25 G spinal needle in lateral position. Surgery was started after adequate sensory and motor block was achieved. In both

groups, TAP block was given at the end of surgery. End of the injection was taken as Time '0' & the time required for 1st rescue analgesic (VAS ≥4) was defined as total duration of analgesia. The assessment of pain was done immediately after transfer to Post Anaesthetic Care Unit (PACU) and at 0, 1, 3, 6, 9, 12, 16, 20 and 24 hours after completion of surgery. Pain severity was measured by Visual Analog Scale (VAS 0=No pain, 10=Worst pain). At any point of time if VAS was ≥ 4, intravenously diclofenac 25 mg was given to the patient as a 1st& 2nd rescue analgesic. For 3rd rescue analgesic intravenously tramadol 75mg was given.

Primary Outcome Measures:

1. Total duration of analgesia as per visual analogue scale (VAS).

Secondary Outcome Measures

1. Total requirement of rescue analgesic in 24 hours.
2. Effect on hemodynamic variables like Heart Rate (HR), Mean Arterial Pressure (MAP), Oxygen saturation (SpO2).
3. Side effects & Complications if any.

Statistical analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA).

Quantitative variables were described as means and standard deviations or median and interquartile range based on their distribution. Qualitative variables were presented as count and percentages. For all tests, confidence level and level of significance were set at 95% and 5% respectively.

Results

Table 1: Mean age distribution in each group

Patient Characteristics	Group R (n=32)	Group B (n=32)	P value
Age (years) (mean±SD)	46.46±8.01	44.65±5.90	0.15

The mean age of the patients in Group R and Group B was 46.46±8.01years and 44.65±5.90 years respectively and difference was not significant statistically (p>0.05).

Table 2: Mean duration of analgesia in each group

	Group R (n=32)	Group B (n=32)	P value
Total duration of analgesia (in minutes)	888.60±234	637.2±215.4	0.00004

The mean duration of analgesia in Group R and Group B was 888.60±234 mins and 637.2±215.4 mins respectively and difference was significant statistically (p<0.05).

Table 3: Mean VAS pain score in each group

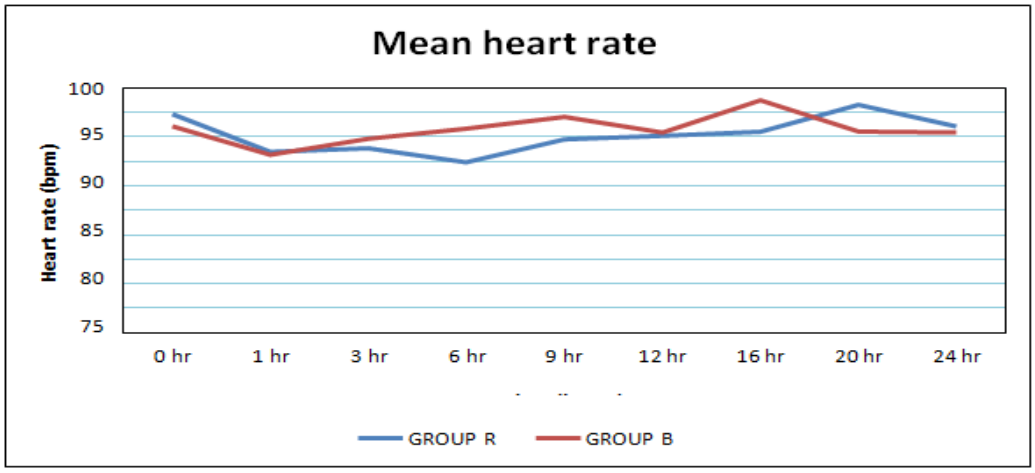
Time	Group R (n=32) (mean±SD)	Group B (n=32) (mean±SD)	P Value
0 min	00	00	00
1hr	00	0.12±0.41	0.0982
3hr	0.15±0.50	0.65±1.36	0.0597
6hr	0.81±1.07	1.46±1.25	0.0302
9hr	1.84±1.39	2.53±1.11	0.0361
12hr	2.34±1.24	3.34±0.92	0.0006
16hr	2.68±1.56	2.03±1.44	0.0919
20hr	2.15±1.58	2.78±1.34	0.0984
24hr	2.40±1.31	2.78±1.19	0.2448

The mean VAS pain Score at 0, 1, 3, 16, 20, 24 hours was comparable in both group and difference was significant statistically at 6, 9,12 hours (p<0.05).

Table 4: Rescue analgesics used within first 24 hours

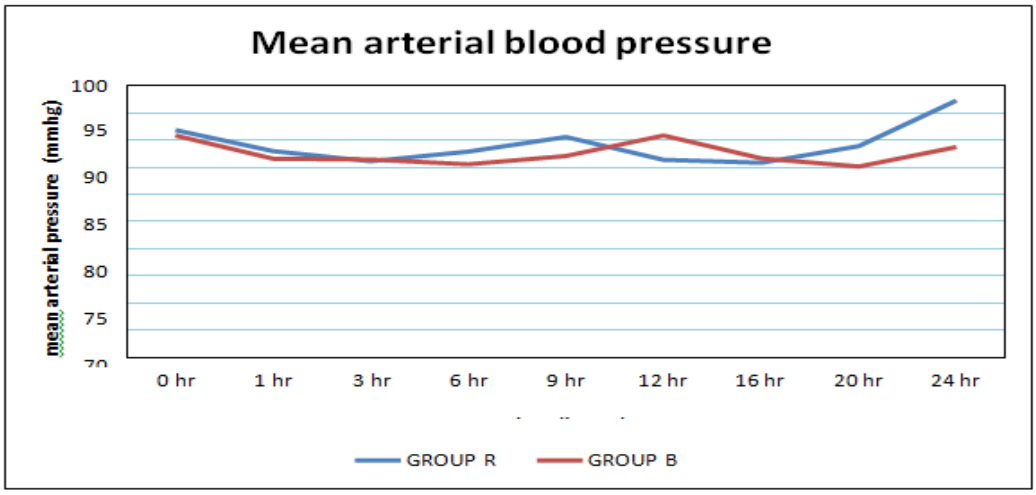
	Group R (n=32)	Group B (n=32)	P value
Total no. of analgesics used	1.56±0.60	2.03±0.52	0.0019
No. of patient required 3rd analgesic	2 (6.25%)	5 (15.62%)	

The number of analgesic doses used was higher in group B as compared to group R. (P value 0.0019). In group B 15.62% of patients required 3rd rescue analgesics while in group R only 6.25% of patients required 3rd rescue analgesic. The rescue analgesic consumption in most patients of group R was at 16 hour and of group B was at 12 hour following the performance of TAP block. The difference was found to be statistically significant.



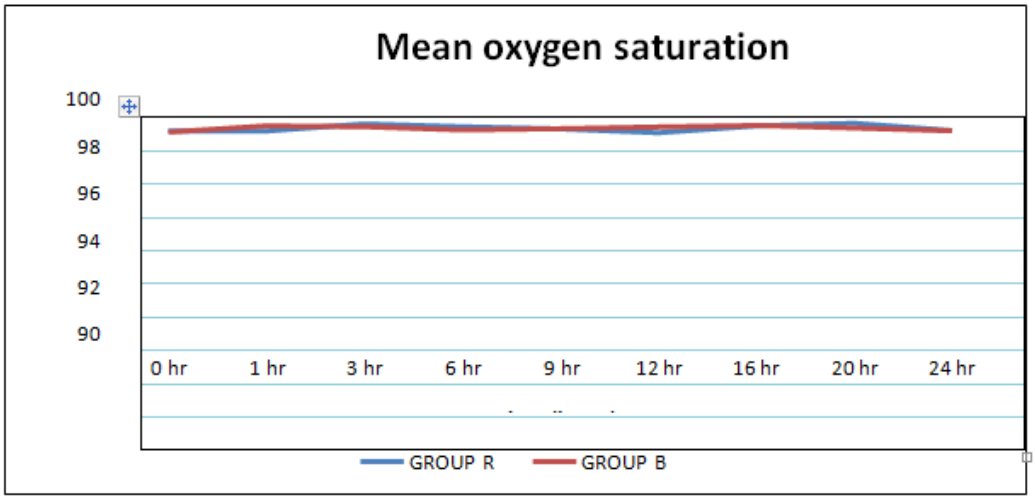
Graph 1: Comparison of mean heart rate in both group

Comparison of Patients Heart Rate at 0min, 1, 3, 6, 9, 12, 16, 20 and 24 hours was comparable in each group and difference was not significant statistically($p>0.05$)



Graph 2: Comparison of mean arterial blood pressure in both groups

Comparison of Patients Mean Arterial Blood Pressure at 0min, 1, 3, 6, 9, 12, 16, 20 and 24 hours was comparable in each group and difference was not significant statistically ($p>0.05$).



Graph 3: Comparison of mean oxygen saturation in both groups

In our study, none of the patients in either group had any complications associated with the technique as well as local anaesthetics.

Discussion

Effective postoperative pain control is an essential component of the care of the surgical patient. Inadequate pain control may result in increased morbidity or mortality. [21,22]

Evidence suggests that surgery suppresses the immune system and this suppression is proportionate to the invasiveness of the surgery. [23] Good analgesia can reduce this deleterious effect. The advantages of effective post-operative pain management include patient comfort and therefore satisfaction, early mobilization, fewer pulmonary and cardiac complications, a reduced risk of deep vein thrombosis, faster recovery with less development of neuropathic pain, and reduced cost of care.

Postoperative pain should be cured to alleviate nociception induced responses, such as the endocrine, metabolic and inflammatory responses to surgery which activates autonomic reflexes with adverse effects on organ function and reflexes leading to muscle spasm. [24]

Untreated or poorly treated post-operative pain increases incidence of nausea and vomiting. Increased sympathetic activity can lead to increase urinary sphincter tone and subsequent urinary retention. So, it is a primary duty of an anaesthesiologist to provide postoperative analgesia to make patient more comfortable and relax after surgery.

A multimodal analgesic regimen is most likely to achieve these goals. single shot neuraxial analgesic techniques using long-acting opioids, or patient-controlled epidural opioid administration produce effective analgesia but they are associated with a frequent incidence of side effects like nausea, vomiting and pruritus which reduce overall patient satisfaction. So in this study we have studied regional analgesia technique thus avoiding side effects of opioids and neuraxial analgesia.

The present study was conducted to compare efficacy of Ropivacaine (0.375%) & Bupivacaine (0.25%) in TAP block following total abdominal hysterectomy to assess post-operative analgesia. We also compared 24 hr rescue analgesics consumption, side effects and complications. In the present study, Total 64 adult female patients undergoing total abdominal hysterectomy were randomized in a double-blind manner.

There is no statistically significant difference between the groups with regard to age and weight ($p>0.05$). The Mean total duration of analgesia was significantly longer in Group R with 888.60±234 mins compared to Group B with 637.2±215.4 mins and the difference was statistically significant. The result was comparable with the previous study done by Damodar puchakala et al [25] (2021). Study performed by Nidhi Sharma et al concluded that ultrasound-guided TAP block with 0.5% Ropivacaine provides effective analgesia for longer duration and decreases the total analgesic consumption as compared to 0.25% Bupivacaine in lower abdominal surgeries. The result of this study was comparable with our study. [26]

Mean total duration of analgesia was significantly longer in Group R with 888.60±234 mins compared to Group B with 637.2±215.4 mins and the difference was statistically significant In the study by Fuladi N et al [27] 20 mL of local anaesthetic was used and the surgeries were only on one side of the abdomen. In the study by Sharma N et al. [26] also a lot of patients underwent surgery only on one side of the abdomen and this could have contributed to the difference in duration of analgesia achieved in their studies vis-à-vis our study. [26,27] Ropivacaine has some intrinsic vasoconstrictor properties and this to could have led to the difference in the duration of analgesia achieved by both the local anaesthetics. [28]

Pain severity was measured by Visual Analog Scale pain score. The mean VAS pain Score at 0, 1, 3, 16, 20, 24 hours was comparable in both group but significantly lower at 6,9,12 hours in group R compared to group B ($p<0.05$). Fuladi N et al. [27] reported lower VAS scores with Ropivacaine at 2, 4, 6 and 12 h whereas Sharma N et al.26 reported significantly lower VAS scores at 8 and 12 h after cessation of surgery. However in the study by Sinha S et al [29] VAS scores with Ropivacaine were lower only at 10,30 and 60 min after surgery and the authors did not find any significant difference in VAS scores at 4,8,12 and 24 h.

While the mean number of rescue analgesics required was significantly lower in group R with 1.56±0.60 compared to group B with 2.03±0.52 & the difference was statistically significant ($P<0.05$). Also in group B 15.62% of patients required 3rd rescue analgesics while in group R only 6.25% of patients required 3rd rescue analgesic. Our results are different from another study where even though the total postoperative analgesic requirement in Bupivacaine group was higher than the Ropivacaine group but the difference was not statistically significant. [30]

In the study by Sinha S et al [29] 60 adults undergoing elective laparoscopic cholecystectomy were randomised to receive ultrasound guided TAP block at the end of the surgical procedure with either 0.25% bupivacaine or 0.375% ropivacaine. All patients were assessed for postoperative pain and rescue analgesic consumption at 10 min, 30 min, 1 h, 4 h, 8 h, 12 h and 24 h time points. They also did not find any difference in the 24 h cumulative analgesic requirement in between both the groups. The results of both these studies are

different from us in terms of 24 hour cumulative analgesic requirement but it will be prudent to note here that the subset of patients and type surgery in our study is entirely different from that in the above mentioned studies. In our study there was no any side effects and complication noted after TAP block given.

Our study has a few limitations. The level of sensory block was not assessed following the TAP block. Also we don't have facility of ultrasound guidance so we recommend the use of USG guided TAP block it improves the efficacy, safety and ease of administration of local anaesthetic agents.

Conclusion

Transverse abdominis block provides reliable and effective postoperative analgesia following total abdominal hysterectomy. 0.375% Ropivacaine provided longer duration of analgesia than 0.25% Bupivacaine when used in TAP block for postoperative analgesia after total abdominal hysterectomy. Also the total analgesic requirement was lower with the use of Ropivacaine. Hence, Ropivacaine (0.375%) is a better drug for postoperative analgesia than Bupivacaine (0.25%), can be routinely use for TAP block after total abdominal hysterectomy without having any side effects. It is recommended to use USG guided TAP blocks as it improves the efficacy, safety and ease of administration of local anesthetic.

References

1. Gupta, Anil, Perniola, Andrea, Axelsson, Kjell, Thörn, Sven E, Crafoord, Kristina Rawal, Narinder. Postoperative Pain After Abdominal Hysterectomy: A Double-Blind Comparison Between Placebo and Local Anesthetic Infused Intraperitoneally. Anesthesia & Analgesia: 2004; 99(4): 1173-1179.
2. Gan TJ. Poorly controlled postoperative pain: prevalence, consequences, and prevention. J Pain Res. 2017 Sep 25; 10:2287-2298.
3. Kehlet H. Multimodal approach to control postoperative pathophysiology and rehabilitation. Survey of Anesthesiology. 1998; 42(4): 233.
4. Keene DD, Rea WE, Aldington D. Acute pain management in trauma. 2011; 13(3):167-79.
5. Capdevila X, Barthelet Y, Biboulet P, et al. Effects of perioperative analgesic technique on the surgical outcome and duration of rehabilitation after major knee surgery. Anesthesiology 1999; 91:8 –15.
6. Bonnet F, Marret E. Influence of anaesthetic and analgesic techniques on outcome after surgery. Br J Anaesth 2005; 95:52– 8.
7. Gadsen J, Hart S, Santos AC. Post-caesarean delivery analgesia. Anesth Analg 2005; 101:S62-9.
8. John G. McDonnell, Gerard Curley, John Carney, Aoife Benton, Joseph Costello, Chrisen H. Maharaj, John G. Laffey. The Analgesic Efficacy of Transversus Abdominis Plane Block after Cesarean Delivery: A Randomized Controlled Trial.Anesth Analg 2008; 106:186–91.
9. Belavy D, Cowlishaw PJ, Howes M, Phillips F. Ultrasoundguided transversus abdominis plane block for analgesia after Caesarean delivery. Br J Anaesth 2009; 103:726-30.
10. Tan TT, Teoh WH, Woo DC, Ocampo CE, Shah MK, Sia AT. A randomised trial of the analgesic efficacy of ultrasoundguided transversus abdominis plane block after caesarean delivery under general anesthesia. Eur J Anaesthesiol 2012;29:88-94
11. Rafi AN. Abdominal field block: A new approach via the lumbar triangle. Anesthesia 2001; 56:1024-6.
12. McDonnell JG, O'Donnell B, Curley G, Heffernan A, Power C, Laffey JG. The analgesic efficacy of transversus abdominis plane block after abdominal surgery: A prospective randomized controlled trial. Anesth Analg 2007; 104:193-7.
13. Rozen WM, Tran TM, Ashton MW, Barrington MJ, Ivanusic JJ, Taylor GI. Refining the course of the thoracolumbar nerves: A new understanding of the innervation of the anterior abdominal wall. Clin Anat 2008; 21:325-33.
14. Kehlet H, Rung GW, Callesen T. Postoperative opioid analgesia: time for reconsideration. J Clin Anesth 1996; 8:441–5
15. Cali RL, Meade PG, Swanson MS, Freeman C. Effect of morphine and incision length on bowel function after colectomy.Dis Colon Rectum 2000;43:163–8
16. Johns N, O'neill S, Ventham NT, Barron F, Brady RR, Daniel T. Clinical effectiveness of transversus abdominis plane (TAP) block in abdominal surgery: A systematic review and meta-analysis. Colorectal Dis 2012; 14:e635-42.
17. Niraj G, Kelkar A, Jeyapalan I, Graff-Baker P, Williams O, Darbar A, et al. Comparison of analgesic efficacy of subcostal transversus abdominis plane blocks with epidural analgesia following upper abdominal surgery. Anaesthesia 2011; 66:465- 71.
18. Jankovic Z. Transversus abdominis plane block: The holy grail of anaesthesia for (lower) abdominal surgery. Period Biol 2009; 111:203-8.
19. Mukhtar K. Transversus abdominis plane (TAP) block. JNY School Reg Anesth 2009; 12: 28-33.
20. Bonnet F, Berger J, Aveline C. Transversus abdominis plane block: What is its role in postoperative analgesia? Br J Anaesth 2009; 103:601–5.

21. Sharrock NE, Cazan MG, Hargett MJ, Williams-Russo P, Wilson PD Jr. Changes in mortality after total hip and knee arthroplasty over a ten-year period. Anesth Analg 1995; 80:242–248.
22. Katz J, Jackson M, Kavanagh BP, Sandler AN. Acute pain after thoracic surgery predicts long-term post-thoracotomy pain. Clin J Pain 1996; 12:50– 55.
23. Lennard TW, Shenton BK, Borzotta A, Donnelly PK, White M, Gerrie LM, Proud G, Taylor RM. The influence of surgical operations on components of the human immune system. Br J Surg 1985; 72:771–776.
24. Kehlet H and Dahl JB. The Value of "Multimodal" or "Balanced Analgesia" in Postoperative Pain Treatment. Anesth Analg 1993; 77:1048-56.
25. Puchakala D, Joshi VS, Bhardwaj A. Evaluation of 0.25% bupivacaine vs. 0.375% ropivacaine for postoperative analgesia using ultrasound guided transversus abdominis plane block for caesarean section: A comparative study. J Obstet Anaesth Crit Care 2022; 12:17-21.
26. Sharma N, Banerjee A, Jain J, Goyal PK. Comparison of ropivacaine and bupivacaine in ultrasound-guided transversus abdominis plane block for postoperative analgesia in patients undergoing elective lower abdominal surgeries - A randomized double-blind trial. Indian J Clin Anaesth 2021; 8(2):191-198.
27. Fuladi N, Deshmukh S, Bhure A. Comparative study of bupivacaine 0.25% versus ropivacaine 0.5% in transversus abdominis plane block for postoperative analgesia in lower abdominal surgeries: A randomised controlled trial. J Evol Med Dent Sci 2014; 3:4569-76.
28. McClure JH. Ropivacaine. Br J Anaesth 1996; 76:300-7.
29. Sinha S, Palta S, Saroa R, Prasad A. Comparison of ultrasound-guided transversus abdominis plane block with bupivacaine and ropivacaine as adjuncts for postoperative analgesia in laparoscopic cholecystectomies. Indian J Anaesth 2016; 60:264–9.
30. Gioia L, Prandi E, Codenotti M, Casati A, Fanelli G, Torri TM, et al. Peribulbar anesthesia with either 0.75% ropivacaine or a 2% lidocaine and 0.5% bupivacaine mixture for vitreoretinal surgery: A double-blinded study. Anesth Analg 1999; 89:739- 42.