

Continuous wound infusion as a valid alternative to tap block for postoperative analgesia after abdominal hysterectomy: A randomized controlled trial

ABSTRACT

Background: Total abdominal hysterectomy is a procedure associated with moderate to severe postoperative pain. Regional anesthesia techniques, such as fascial plane blocks, have shown promise in improving postoperative pain control. While continuous wound infusion is recommended for cesarean section, it is not recommended for open abdominal hysterectomy. Our aim is to compare surgically placed catheter for wound infusion with the transverse abdominis plane block.

Methods: A single-center prospective randomized controlled trial was conducted in Italy from January to July 2023. Patients undergoing elective hysterectomy were randomly assigned to receive either bilateral transverse abdominis plane block or continuous wound infusion. The primary outcome measure was the assessment of static pain in the recovery room and at 6, 12, 24, and 48 hours postoperatively using the numeric rating scale (NRS) for pain. Of the 34 patients assessed for eligibility, 32 were randomized and equally distributed between the continuous wound infusion and transverse abdominis plane block groups.

Result: Patients receiving continuous wound infusion consistently reported lower static NRS pain scores compared to those receiving transverse abdominis plane block across all postoperative time points. The median NRS scores were significantly lower in the wound infusion group at 6, 12, 24, and 48 hours post surgery ($P < 0.05$). Importantly, similar significant differences were also observed between the groups for dynamic NRS scores. However, no significant differences were observed between the groups for secondary outcomes, including nausea and vomiting, and recovery of functional capacity.

Conclusion: Continuous wound infusion with a properly positioned catheter is noninferior to transverse abdominis plane block for postoperative pain management following total abdominal hysterectomy and may even provide superior pain control.

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These findings suggest continuous wound infusion as a viable alternative for effective pain management in total abdominal hysterectomy procedures.

Key words: Acute pain, hysterectomy, postoperative analgesia, regional anesthesia

Introduction

Total abdominal hysterectomy (TAH) is the second most practiced gynecological surgery after cesarean section (CS).^[1]

It is associated with a moderate-high pain in the postoperative period;^[2] therefore, effective pain management is crucial both to ensure patient satisfaction and to avoid chronic pain syndromes, improving the quality of life and contributing to a reduction in length of hospital stay.

Regional anesthesia techniques are useful in improving postoperative pain management. Epidural analgesia is considered the most effective technique for managing postoperative pain in abdominal surgeries; however, it is associated with risk of hypotension, headache, inaccurate catheter placement, or dislocation.^[3] Recently, fascial plane blocks (FPBs) showed to be useful for postoperative pain in many procedures. Among them, erector spinae plane (ESP) block, quadratus lumborum blocks (QLB), and transversus abdominis plane (TAP) block have proven to be effective in reducing pain and opioid consumption after abdominal surgeries. ESP block and the anterior QLB are innovative techniques that provide both somatic and visceral analgesia at the abdominal level. In contrast, the TAP block only involves somatic nerve fibers of the abdominal wall. TAP block is performed through an ultrasound guided injection of local anesthetics inside the fascial plane between the internal oblique and the transversus abdominis muscle. It provides anterior and lateral abdominal wall numbness below the umbilicus, reducing somatic pain for abdominal wall incisions involving the T10-L1 metamer, like the Pfannenstiel incision commonly used for hysterectomy procedures.

FPBs require good anatomy knowledge and expertise in the use of ultrasound and need to be performed by experienced anesthesiologists. On the contrary, continuous wound infusion (CWI) is a technique that consists in a postoperative continuous infusion of local anesthetics directly into the surgical wound through a multiholed catheter placed directly by the surgeon intraoperatively. It showed effectiveness for several abdominal surgeries.

CS and TAH have similar surgical characteristics (same “Pfannenstiel” incision at L1 dermatome; same viscera

involved in surgical manipulations). Wound infiltration and TAP block are both recommended for CS by the PROSPECT guidelines,^[4] but the same working group, for TAH, surprisingly consider CWI as not recommended. From the literature, we understood that the most effective anatomical plane which the catheter should be placed into is the preperitoneal plane. However, the majority of trials that contributed to PROSPECT guidelines about TAH and CWI utilized a subfascial or subcutaneous catheter.^[5] The hypothesis was whether a preperitoneal position (below the rectus muscles and above the parietal peritoneum), which can act on the peripheral nociceptors directly affected, potentially resulting in a reduced inflammatory and immunologic response, could lead to more encouraging results and possibly a modification of the guidelines. Moreover, continuous preperitoneal wound infusion had not yet been compared with TAP block for TAH.

We conducted this prospective randomized controlled open label trial on patients undergoing TAH to test the hypothesis that CWI is noninferior to TAP block for postoperative pain management which represents the standard of practice as the regional anesthesia technique in our hospital. The primary outcome measure was the assessment of static pain in the recovery room and at 6, 12, 24, and 48 hours postoperatively using the numeric rating scale (NRS) for pain.

Material and Methods

We performed a single-center prospective randomized noninferiority trial in a teaching hospital in Italy from January to July 2023. The trial was approved by local Ethics Committee (Prot. PAR 71.22) and prospectively registered on ClinicalTrials.gov (NCT05686382). Informed consent was obtained from all study participants before randomization. Participants were screened for eligibility during the preoperative anesthesiology consultation and were asked to participate and sign informed consent forms on the day of surgery. This report follows the Consolidated Standards of Reporting Trials guidelines [Figure 1]. The procedures were conducted in accordance with the Helsinki Declaration 2013.

Inclusion criteria

To participate in the study, patients had to meet all inclusion criteria:

CONSORT 2010 Flow Diagram

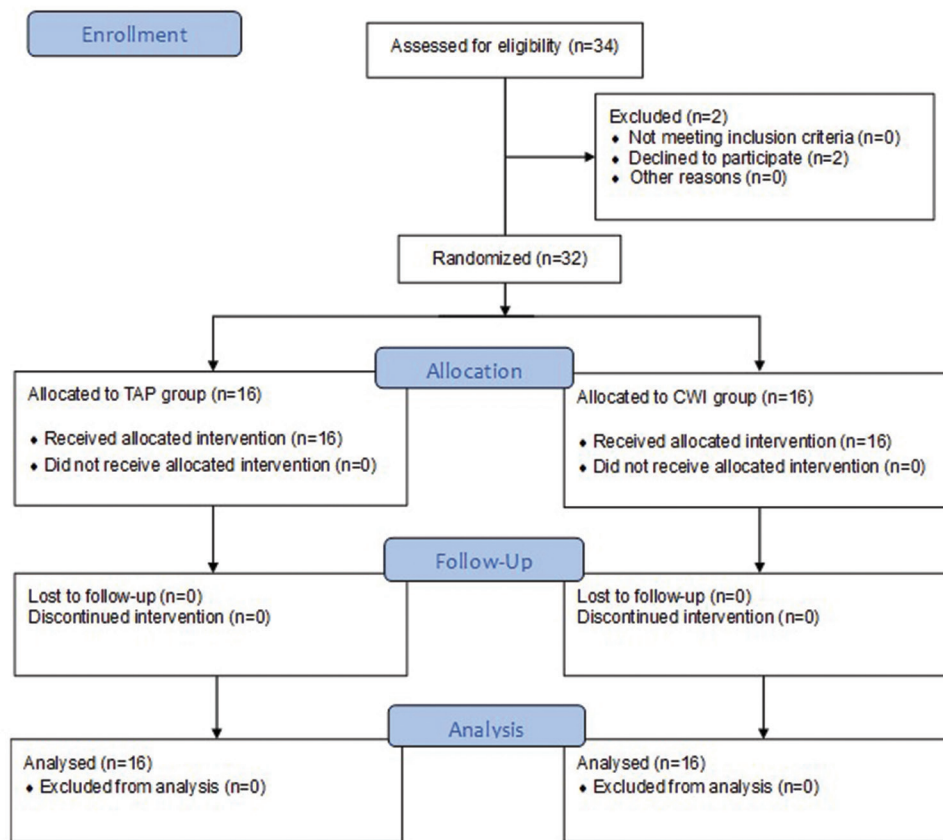


Figure 1: Consort flow diagram

- (1) American Society of Anesthesiologists status 1 to 3
- (2) Aged 18 and older
- (3) Scheduled for elective TAH
- (4) Signed written informed consent.

Exclusion criteria

Exclusion criteria included:

- (1) Allergy to local anesthetics or other components of multimodal analgesia
- (2) Inability to walk or eat or cognitive impairment.

Randomization and masking

Thirty-two patients were randomly allocated in a 1:1 ratio to receive either a bilateral TAP block (16) or a CWI (16) using a predetermined computer-generated randomized schedule. The random.org website (<https://www.random.org/>) was used to generate online the randomization schedule.

Blinding and concealment

The study was not blinded for patients or the study team as the differences between CWI and TAP block would be apparent due to the presence of the ropivacaine pump during the study period. The allocation sequence was concealed

from patients, healthcare providers, data collectors, and the treatment team. Allocation concealment was ensured because the randomization code was not revealed until the patient was enrolled in the study. The sequence was further safeguarded by a university office responsible for holding the allocation sequence, which was consulted before each procedure when a patient was enrolled.

Perioperative management

Eligible patients were premedicated with intravenous midazolam 2 mg and fentanyl 50 mcg and received a multimodal pre-emptive intravenous (IV) analgesia with ketorolac 30 mg, paracetamol 1 g, dexamethasone 0.1 mg/kg, and granisetron 3 mg. In the operating room, all patients had an intravenous line and standard vital sign monitors were applied, (noninvasive blood pressure, electrocardiogram, and oxygen saturation). General anesthesia was induced with IV propofol 3 mg/kg, fentanyl 5 mcg/kg, and rocuronium 0.6 mg/kg to facilitate tracheal intubation. Volume-controlled mechanical ventilation with 40% oxygen in medical air was maintained to keep the end-tidal carbon dioxide concentration from 30 to 35 mmHg. Desflurane was administered to keep bispectral index (BIS) values within 40–

60. Target controlled infusion of remifentanyl (0.5–1 mcg/ml) and fentanyl 50–100 mcg boluses were administered upon judgement of the anesthesiologist on the basis of the clinical needs. Rocuronium 10–20 mg boluses were administered to maintain Train of Four (TOF) count ≤ 1 on neuromuscular monitoring. All patients had a urinary catheter inserted.

At the end of surgery, residual neuromuscular block was antagonized by the administration of sugammadex in order to obtain a TOF ratio $\geq 90\%$, and after recovery of adequate spontaneous ventilation and consciousness, the tracheal tube was removed. Patients were transferred to the postanesthesia care unit (PACU) and then (after obtaining a White and Song PACU discharge score of 12 or more) to the ward. A standard postoperative multimodal pain management regimen was started in the ward consisting of: IV Ketorolac 90 mg/24 h; IV Paracetamol 1 g x 3; IV Granisetron 3 mg on demand, in case of postoperative nausea and vomiting (PONV).

Intervention group: CWI

At the end of the surgery, before the closure of the muscle layer, the surgeon inserted a multiorifice 15 cm catheter below the rectus abdominis muscles, superficial to the parietal peritoneum. The catheter was inserted percutaneously by a peel apart introducer, 3 cm from the left lateral edge of the wound [Figure 2]. After closure of the skin, a starting bolus of 10 ml of 0.5% ropivacaine was injected through the catheter; then it was taped to the skin and connected to a prefilled pump (Readyfusor – BioQ Pharma – San Francisco - USA) delivering 0.2% ropivacaine at a rate of 5 ml/h for 48 h (total dose 240 mg/24 h).

Control group TAP: TAP block is commonly performed preoperatively aiming to reduce intraoperative opioid consumption. In order to avoid a bias related to the different administration timing of the local anesthetic,



Figure 2: Example of catheter placement

we decided to carry out the TAP block at the end of the surgery, after the closure of the skin, and before to wake up the patient, similar to the experimental group. The blocks were performed by consultant anesthesiologists experienced in the technique having performed at least 50 successful blocks. The TAP block was carried out according to the technique described by Mukhtar^[6] and colleagues in 2007: Under aseptic conditions, a linear probe 13 MHz (Sonosite – Fujifilm) was positioned transversely in the mid-axillary line between the lower costal margin and iliac crest. A 100 mm 21-G echogenic needle (Stimuplex Ultra 360 – Bbraun – Melsungen – Germany) was inserted in-plane under real-time ultrasound (US) visualization from lateral to medial aiming to position the needle tip in the plane between internal oblique and transversus abdominis muscles. Normal saline was used as “seeker” inactive fluid to detect the correct fascial plane and the right needle tip position. After confirming negative aspiration, 24 ml of 0.5% ropivacaine was injected through the needle on each side (total dose 240 mg of ropivacaine).

Postoperative analgesia regimen

In the PACU, intravenous fentanyl was titrated until NRS ≤ 4 ; in the ward, both groups received the same multimodal postoperative analgesic regimen with: IV ketorolac 90 mg/24 h, IV paracetamol 1 g three times a Day.

Outcomes Assessment

Primary outcome

The primary outcome parameter was the static pain score, measured at 6, 12, 24, and 48 hours postoperatively (patients were asked to indicate perceived pain at rest) using a 0–10 NRS (0 no pain, 10 worst imaginable pain).

Secondary outcomes

Secondary outcome parameters were:

- Postoperative pain during movements – dynamic (during coughing) NRS assessed at the same time frames as the primary outcome.
- Opioid consumption – morphine equivalents requested (patients were asked to request oxycodone 5 mg (7.5 mg morphine equivalents) each time they experience pain at intensity higher than 4 in the NRS scale).
- Postoperative Nausea and Vomiting – One episode of PONV is registered if the patient experienced either nausea or vomiting in the specified time frame. The overall number of episodes in the 48 hours was also registered.

We recorded any complications or side effects. Outcome assessment was performed by the same group of clinicians (MC, EB, AR).

Sample size calculation

To calculate sample size, we considered our primary hypothesis, that postoperative analgesia is equal or improved with the CWI. Although there were no similar clinical trials, we estimated the density of pain scores as mean 2 and SD 1.5 based on published data regarding the use of TAP block for Total Abdominal Hysterectomy¹. To simulate power, we used the truncated Gaussian distribution with range 0–10, SD 1.5, and a TAP group mean of 2. Under these assumptions and 2-sided $\alpha = 5\%$, we simulated 10,000 trials with a sample size of 15 per group. With an overall sample size of 32 subjects, we estimated 90% power to detect group differences in pain as small as approximately 1.

Statistical analysis

Statistical analysis and graphic presentation were obtained using GraphPad Prism 8 software (GraphPad Software Inc., San Diego, CA, USA). The values of continuous quantitative variables are expressed as mean \pm standard deviation (SD); the values of discrete variables are expressed as the median and interquartile range (IQR). Qualitative variables are expressed as the number of observations and percentage of distribution.

The parametric distribution of numerical variables was evaluated using the Shapiro–Wilk normality test. Differences between groups were assessed by Student's *t*-test for continuous parametric variables, while the Wilcoxon–Mann–Whitney U test was used when appropriate. Categorical variables were compared with Pearson's χ^2 test. The level of statistical significance was set for a *P* value < 0.05 .

Results

Between January and July 2023, a total of 34 patients were assessed for eligibility. Two declined to participate. Thirty-two were randomized and equally allocated between groups and analyzed, and none of the patients were lost to follow-up [Figure 1 – CONSORT flowchart].

Study population

Table 1 summarizes the baseline characteristics. Among the total of 32 patients, 16 received the CWI, while 16 received a TAP block. No clinically relevant differences were noticed between group characteristics [Table 1].

Primary outcome analysis

Postoperative static NRS scores for patients who received CWI

were consistently lower from the recovery room through all other time points at which pain was assessed compared to those who received the TAP block. In the recovery room, the median (IQR) NRS score for CWI patients was 5 (3.75–7.75) compared to 7 (6–8) for TAP patients [*P* = 0.09]. At 6 hours post surgery, the median (IQR) scores were 3 (1.25–4) vs 7 (5.5–8) [*P* < 0.05] for CWI and TAP, respectively; at 12 hours, the scores were 1.5 (0–3) vs 5 (5–7) [*P* < 0.05]; at 24 hours, 1 (0–2.75) vs 4 (3.25–6) [*P* < 0.05]; and at 48 hours, 0 (0–1) vs 3 (2–4) [*P* < 0.05] [Figure 3].

Secondary outcome analysis

Dynamic NRS scores showed differences between the groups similar to the static pain [Figure 4]. The other secondary outcomes are summarized in Tables 2–4. Nausea and vomiting did not differ among groups. Regarding the recovery of

Table 1: Baseline characteristics of the study population

	CWI (n=16)	TAP (n=16)
AGE (years)	53.75 \pm 6.84	50.69 \pm 6.05
WEIGHT (Kg)	69.13 \pm 8.74	64.75 \pm 13.68
HEIGHT (cm)	161.8 \pm 5.65	160.8 \pm 6.41
BMI (Kg/m ²)	26.37 \pm 2.73	24.93 \pm 4.50
ASA score n (%)		
I	1 (6.25%)	2 (12.5%)
II	13 (81.25%)	14 (87.5%)
III	2 (12.5%)	/

Data are presented as n(%) or mean \pm sd. ASA: American Society of Anesthesiologist. BMI: Body Mass Index. CWI: Continuous Wound Infusion. TAP: Transversus Abdominis Plane

Table 2: Opioid consumption in the first 24 h

	CWI n=16	TAP n=16	P
OPIOID RR	0.0 (0.0–0.0)	0.0 (0.0–5.5)	0.071
OPIOID 6 H	0.0 (0.0–0.0)	0.0 (0.0–0.0)	1.000
OPIOID 12 H	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.293
OPIOID 24 H	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.333

Values are reported as median + interquartile range (IQR). CWI: Continuous Wound Infiltration, TAP: Transversus Abdominis Plane. Opioid consumption is expressed in morphine equivalent milligrams

Table 3: Incidence of PONV and Refeeding Milestones

	CWI (n=16)	TAP (n=16)	P
PONV RR	8/16 (50%)	4/16 (25%)	0.144
PONV 6 H	3/16 (18.75%)	6/16 (37.5%)	0.492
PONV 12 H	2/16 (12.5%)	2/16 (12.5%)	1
PONV 24 H	1/16 (6.25%)	2/16 (12.5%)	0.544
PONV 48 H	0/16 (0%)	1/16 (6.25%)	0.309
REFEED 3 H (Test meal)	6/16 (37.5%)	5/16 (31.25%)	0.709
REFEED 12 H (Test meal)	16/16 (100%)	14/16 (87.5%)	0.287
REFEED 6 H (Normal meal)	9/16 (56.25%)	6/16 (37.5%)	0.144
REFEED 12 H (Normal meal)	16/16 (100%)	14/16 (87.5%)	0.144

Values are reported as number (percentage) of subjects. CWI: Continuous Wound Infiltration, TAP: Transversus Abdominis Plane, PONV: Postoperative Nausea and Vomiting

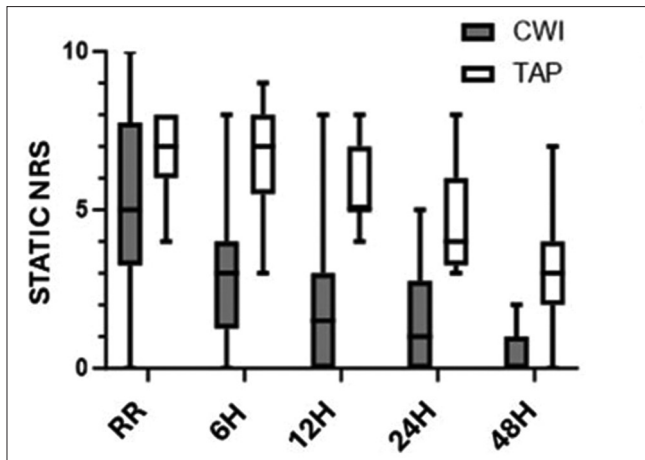


Figure 3: Box and whisker plot of static pain scores at all time points

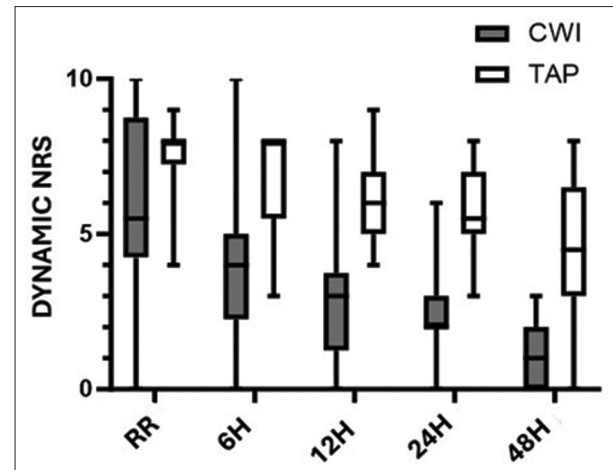


Figure 4: Box and whisker plot of dynamic pain scores at all time points

Table 4: Postoperative recovery of functional capacities

	CWI n=16	TAP n=16	P
Effort tolerance sitting 3 H	3/16 (18.75%)	2/16 (12.5%)	0.624
Effort tolerance sitting 6 H	9/16 (56.25%)	3/16 (18.75%)	0.812
Effort tolerance sitting 12 H	14/16 (87.5%)	9/16 (56.25%)	0.049*
Effort tolerance sitting 24 H	14/16 (87.5%)	15/16 (93.75%)	0.062
Effort tolerance standing 3 H	1/16 (6.25%)	0/16 (0%)	0.309
Effort tolerance standing 6 H	3/16 (18.75%)	1/16 (6.25%)	0.285
Effort tolerance standing 12 H	12/16 (75%)	8/16 (50%)	0.144
Effort tolerance standing 24 H	14/16 (87.5%)	15/16 (93.75%)	0.544
Effort tolerance 10 steps 3 H	1/16 (6.25%)	0/16 (0%)	0.309
Effort tolerance 10 steps 6 H	3/16 (18.75%)	0/16 (0%)	0.068
Effort tolerance 10 steps 12 H	11/16 (68.75%)	6/16 (37.5%)	0.076
Effort tolerance 10 steps 24 H	13/16 (81.25%)	15/16 (93.75%)	0.285

* $P < 0.05$ significant. Values are reported as number (percentage) of subjects.

CWI: Continuous Wound Infiltration, TAP: Transversus Abdominis Plane

functional capacity, no significant differences were found in ambulation outcomes except for effort tolerance sitting at 12 hours, which showed a statistically significant result, with CWI 14/16 (87.5%) and TAP 9/16 (56.25%) [$P < 0.05$]. In both groups, the recovery of full feeding was rapid; at 12 hours, 100% of the CWI group and 87.5% of the TAP group were able to consume a full meal.

Last, we did not observe any significant incidence of severe or unexpected side effects.

Discussion

Our study shows that pain scores after TAH for patients receiving multimodal systemic analgesia plus CWI are noninferior to those receiving TAP block. From the literature, we know that both CWI and TAP block are effective for postoperative pain management after laparotomy, although CWI impact on gynecological surgery has not been sufficiently investigated. Ventham *et al.*^[7] demonstrated a reduction

in postoperative opiate requirements and pain scores on movement along with improvement in postop recovery using CWI techniques compared with placebo or routine analgesia in colorectal surgery. Indeed, Roofthoof *et al.*,^[4] in the PROSPECT guideline for elective cesarean section published in 2021, highlight how postcesarean pain scores and opioid consumption could benefit from some FPBs, among which TAP block is the most studied. All studies regarding TAP block, included in the guideline showed improved pain relief, increased patient satisfaction and reduction of rescue analgesia. Among them, one randomized controlled trial from Klasen and colleagues^[8] compared TAP block with continuous local anaesthetic CWI and noted no significant differences in postoperative analgesia. Thereby, CWI is listed as a feasible and effective technique after CS. The PROSPECT working group also developed in 2006 a guideline for postoperative pain management after TAH in which wound infiltration techniques were not recommended. This conclusion is in contrast with our findings; however, the guideline recommendation about wound infiltration techniques is based only over one, out-of-date article,^[9] in which catheters used were not specifically developed, the exact anatomical plane was not clearly described, and the local anesthetic was administered by boluses. Moreover, since the study was a placebo-controlled one, we could also speculate about a possible analgesic effect of the saline bolus, either as a real placebo effect or as a direct mechanical effect on nociceptor or via a dilution of local inflammation mediators inside the wound as described by Fusco *et al.*^[10] in 2024 expert opinion. However, the guideline was developed before US-guided TAP block was even described; therefore, there is no comparison between the techniques. To date, there are no other, more recent, guidelines available regarding open hysterectomy. Even though vaginal and laparoscopic procedures represent the majority of hysterectomies, the laparotomic approach is still frequently indicated and a poorly controlled

postoperative pain may have an impact on recovery. Pending for an updated guideline, we analyzed the most recent studies which underline that peritoneum plays a key role in postoperative pain generation after laparotomies.^[11] The peritoneum is a metabolically active organ, which responds to surgical insult with a local and systemic immunologic and inflammatory response. Therefore, peritoneal infiltration provides benefit as it blocks the nociceptors activated by surgical injury and intraperitoneal inflammation.^[11]

Studies also report pain relief after intraperitoneal local anesthetic injection or nebulization in patients undergoing abdominal surgery.^[12,13]

Similarly, preperitoneal local anesthetic infusion has been shown to provide excellent pain relief after colorectal surgery.^[14,15]

Gasanova and colleagues in 2015 published a trial comparing TAP block and wound infiltration with liposomal bupivacaine for TAH and obtained postoperative pain scores comparable with our results.^[11] More recently, Rocha-Romero *et al.*^[16] proposed the combination of an abdominal wall block with a preperitoneal block to achieve a more extensive and complete, somatic and peritoneal analgesia for abdominal surgery. In our study, TAP block influenced the parietal pain through blockade of the nerves between the internal oblique and the transversus abdominis muscles and does not influence the peritoneal contribution to pain perception. Also, despite TAP blocks being performed by expert clinicians, the spread of local anesthetic may not be consistent due to anatomical variations.^[17] These factors may explain the inadequate pain control in the TAP group.

On the contrary, the CWI group showed excellent pain scores. We believe that in our cases, the multiholed catheter, placed under the rectus muscles inside the wound, entering from the lateral border of the left rectus muscle and emerging from the lateral border of the right rectus muscle, allowed the local anesthetic to be delivered both lateral to the rectus muscles (where the spinal nerves pierce the transversus abdominis aponeurosis to enter the rectus sheath) and preperitoneally (deep to the rectus muscles, at this level below the arcuate line, there is no rectus sheath and the catheter lays directly above the peritoneum and the fascia trasversalis).

Moreover, the peritoneum has been opened and sutured and a quote of local anesthetic could easily penetrate through it inside the peritoneal cavity further enhancing analgesia.

These anatomical considerations may explain the significant difference we found between TAP block and CWI in our results. This study represents the first comparison between those two techniques for TAH. Future studies with greater samples will need to be conducted using this placement technique, but the results appear promising, particularly considering the importance of visceral versus somatic pain in this type of procedure.

Limitations

This study has several limitations. The total opioid consumption was not calculated due to the nursing staff's limited compliance in administering opioids and the patients' reluctance to request them. This limitation explains the high pain scores in the TAP group. For the same reason, differences in PONV and tolerance to oral feeding were not observed. In our view, this introduces a potential bias into the study; an intravenous patient-controlled analgesia (PCA) might have been a more effective alternative, mitigating heterogeneity in pain therapy compliance within the groups.

Conclusions

CWI with a properly positioned multiholed catheter is not inferior to TAP block in postoperative pain management after TAH; moreover, our results showed the technique to be superior in terms of pain control. Future studies with larger sample sizes are needed to confirm the efficacy of this technique, which could also focus on outcomes related to shorter hospital stays and to develop protocols for Enhanced Recovery After Surgery (ERAS) implementation.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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