

Wound infiltration or transversus abdominis plane block after laparoscopic radical prostatectomy: a randomized clinical trial

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Background: Regional anesthesia techniques are commonly used for postoperative pain management during laparoscopic surgery. Our aim was to compare the analgesic efficacy of pre-incisional subcutaneous wound infiltration (WI) with that of the transversus abdominis plane (TAP) block as part of a multimodal analgesic approach in laparoscopic radical prostatectomy.

Methods: In this prospective, double-blinded, randomized controlled clinical trial, 60 patients were assigned to either TAP or WI group. The main outcome was acute postoperative pain control assessed using the mean numeric rating scale (NRS) at the 24 hours postoperatively. The secondary outcomes were opioid requirements, procedure-related complications, overall complications, and length of stay.

Results: In this study, 60 patients were randomized: 30 to TAP group and 28 to WI (two were excluded due to conversion to open surgery). We found no significant difference in the median (1Q, 3Q) NRS scores during the 24 h postoperatively neither at rest (TAP, 0 (0, 1) vs. WI, 0 (0, 1), $P = 0.812$), nor during movement (TAP, 1 (0, 2) vs. WI, 1 (0, 2), $P = 0.708$). There were no statistical differences in the postoperative intravenous morphine requirements in the TAP vs. WI groups during the same period (1.7 ± 3.1 vs. 1.8 ± 4.1 mg; $P = 0.910$). Only one patient in the TAP group presented with postoperative nausea and vomiting.

Conclusions: Both pre-incisional subcutaneous WI and TAP blockade were associated with very low pain scores as part of a non-opioid multimodal analgesic regimen in laparoscopic radical prostatectomy. This study did not demonstrate the benefits of WI over TAP.

Keywords: Enhanced recovery after surgery; Laparoscopic prostatectomy; Multimodal analgesia; Transversus abdominis plane block; Wound infiltration.

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INTRODUCTION

Laparoscopic radical prostatectomy (LRP) is an established minimally invasive procedure for the treatment of prostate cancer. It is associated with a shorter hospital stay and less postoperative pain than the open approach [1,2].

Although laparoscopy is minimally invasive, it is associated with postoperative pain primarily at the trocar and extraction wound sites, with the highest degree of pain occurring on the first postoperative day [3].

Currently, postoperative analgesic treatment principles are directed towards facilitating early postoperative mobili-

zation and enhanced recovery. These are achieved through multimodal analgesic strategies based on the concurrent use of primarily non-opioid analgesics, which can have additive, if not synergistic, effects that produce superior analgesia, thereby decreasing opioid use and opioid-related side effects. These strategies frequently involve the use of different regional anesthesia techniques, with a preference for minimally invasive approaches over more aggressive anesthetic approaches to avoid possible complications [4,5].

Transversus abdominis plane (TAP) blockade and surgical wound infiltration (WI) are two common regional techniques used in multimodal analgesia that provide pain relief and reduce opioid consumption in a variety of surgical procedures [6-8]. TAP blocks neural afferents from the anterolateral abdominal wall (T6 to L1) by injecting a local anesthetic into the transversus abdominis fascial plane under ultrasound guidance or anatomical landmarks [6]. Although safe and effective, complications related to TAP such as nerve or vascular injuries have been reported [9-11], and the technique requires training and experience, is operator-dependent, and preferably performed under ultrasound guidance, leading to increased cost and resources. Furthermore, previous studies reported an average procedure time of 10 min [12], which might be problematic in the absence of parallel-processing space for regional anesthetic procedures [13]. In comparison, surgical WI with local anesthetics is a simple, safe, and low-cost technique for postoperative analgesia, which may provide an equally effective analgesia in the correct setting [14].

Several studies have compared the effectiveness of WI and TAP in different urologic [15], colonic [7,16], and gastrointestinal laparoscopic procedures [17], but no prospective comparative data are available for LRP.

Our hypothesis was that pre-incisional subcutaneous WI could be an alternative to TAP blockade for acute pain management in LRP as part of a multimodal analgesic approach, providing adequate analgesia and promoting enhanced recovery.

The aim of this prospective, double-blind, randomized controlled clinical trial was to compare the analgesic efficacy of WI and TAP in the first 48 h after LRP by analyzing numeric rate scale (NRS) values and opioid consumption.

MATERIALS AND METHODS

This was a single-center, prospective, controlled, double-blinded randomized trial with two parallel arms per-

formed between September 7, 2020 and June 19, 2022. The study protocol was registered at EudraCT.gov (Identifier number: 2019-004089-16) on October 14, 2019 and approved by the Institutional Review Board committee (approval number 15/19) on April 30, 2020. This study was conducted in accordance with the principles of the Declaration of Helsinki. The results are reported according to the current consolidated standards of reporting trials guidelines.

Recruitment, randomization, and blinding

All the patients scheduled to undergo LRP between September 2020 and June 2022 were screened for participation in the trial.

Exclusion criteria were: 1) age < 18 years, 2) American Society of Anesthesiologists score \geq IV, 3) body mass index \geq 35 kg/m², 4) history of allergy to local anesthetics, opioids, paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), or metamizole, 4) chronic opioid use, 5) conversion to open surgery, or 6) patient's refusal. Patients who did not meet the exclusion criteria and agreed to participate signed an informed consent form during their visit for pre-operative anesthesia.

On the day of surgery, consenting patients were randomly assigned to either a TAP block or WI (1:1) using a random allocation sequence concealed in 60 consecutively numbered sealed opaque envelopes. The patients were blinded to study allocation.

At the end of the surgery, surgical dressings were applied in the same fashion (at the incision and TAP infiltration sites), regardless of group allocation.

The anesthesiologists and nurses who performed the NRS pain assessments in the post-anesthesia care unit (PACU) and hospitalization ward were blinded to the allocation group.

Anesthesia and perioperative management

All surgical procedures were performed by the same group of specialized surgeons and anesthesiologists. The same standardized procedures for orotracheal general anesthesia were used in both groups: midazolam (1-2 mg) intravenous (IV) prior to induction, followed by fentanyl (1.5 µg/kg), propofol (1.5-2 mg/kg), and rocuronium (0.6 mg/kg). Subsequently, regional anesthesia was administered according to the assigned group.

WI group: Prior to skin incision, two syringes containing

40 ml of 0.375% ropivacaine were prepared and handed-over to the surgeon, who infiltrated the subcutaneous tissues of the incision sites (15 ml at the mini-laparotomy site and 25 ml distributed at the trocar sites).

TAP group: Prior to skin incision, an ultrasound-guided mid-axillary TAP block was performed. A high-frequency linear probe (Sonosite MicroMAXX™, Sonosite Inc.) was placed midway between the costal margin and iliac crest, and the transversus abdominis muscle was located behind the rectus abdominis and below the internal oblique muscle. Twenty milliliters of 0.375% ropivacaine was administered via a 22 G Quincke spinal needle inserted in-plane on each side of the abdomen. An ultrasound-evident interfacial local anesthetic spread was considered a successful block.

Extraperitoneal LRP was performed using five trocars (a 12 mm infraumbilical trocar, two 5 mm trocars, and two 10 mm trocars in the lower right and left quadrants).

Anesthesia was maintained using target-controlled propofol infusion to achieve a patient state index between 25 and 50, and remifentanyl infusion at 0.1 µg/kg/min for hemodynamic management. Rocuronium (0.6 mg/kg/h) was administered to ensure muscle relaxation. No additional analgesics were administered during surgery. All patients received postoperative nausea and vomiting (PONV) prevention drugs i.e., IV dexamethasone (4 mg) after induction of anesthesia and IV ondansetron (4 mg) 30 min before the end of surgery. At the end of surgery, patients were awoken from general anesthesia and transferred to the PACU for observation for 4 h.

All patients were prescribed a standardized multimodal non-opioid analgesic regimen in the postoperative period, which included IV paracetamol (1 g/8 h), IV NSAIDs (dexketoprofen 50 mg/8 h; not administered in case of renal failure), and IV metamizole (2 g/8 h). IV Morphine (2 mg/20 min as needed for an NRS value > 3) was prescribed as rescue medication in cases of inadequate pain control. After 4 h of observation in the PACU, if the clinical parameters permitted, oral intake was initiated, and patients were transferred to the hospital ward, where our hospital's acute-pain team conducted the protocol-driven follow-up.

Postoperative complications were considered if they occurred during the hospital stay after the surgery. PONV was treated with on-demand IV ondansetron (4 mg/8 h, as needed) during the entire postoperative period. On the second postoperative day, if oral intake was tolerated, multimodal analgesia was changed to oral medications—paracetamol (1 g/8 h) and metamizole (575 mg/8 h) or dexketoprofen (25

mg/8 h) in all patients (depending on renal function). Despite this, if the patient reported a NRS value > 3 at rest, oral tramadol (50 mg) was administered as needed in both groups. Tramadol consumption was calculated and reported as milligrams of morphine equivalents (MMEs).

Oral paracetamol (1 g/8 h) was prescribed to all patients at discharge.

Outcomes

The study was conducted during the first 48 h after surgery. The primary endpoint was the NRS values at rest (NRSr) and during movement (NRSm, coughing in the PACU) at the 24 h post-operatively. As a secondary endpoint, pain assessment were also done at 1, 2, 3, 4, 6, 12, 18, 36, and 48 h post-operatively. Patients rated their pain from 0 (no pain) to 10 (worse pain imaginable) according to a previously validated NRS [18]. The exploratory secondary endpoint to determine analgesic efficacy was MMEs administered during the first 48 h.

Secondary outcomes were procedure-related complications and adverse effects, intraoperative hemodynamic events (hypotensive or hypertensive), length of surgery, PONV, time to first flatus, time to sitting and ambulation, in-hospital postoperative complications, and length of stay.

All recorded parameters were registered prospectively and stored in an IRB-approved database.

Statistics

According to a previous study, a two-point difference in NRS values can be considered as a clinically significant difference [8,19] with a standard deviation of 2.5 [19]; 25 patients will be required in each group at a significance level of 5% and a power level of 80% to detect a difference between groups. Smaller differences may still be considered significant by some authors; however, our study was not designed to detect such differences. We increased the sample size by 20% (30 patients) to account for possible exclusions or losses to follow-up.

Results are reported as means and standard deviations for quantitative data and percentages or ranks for qualitative data. The Kolmogorov-Smirnov test was used to evaluate data distribution. The independent samples *t*-test or U-Mann Whitney test were used to compare differences in the means and the Pearson chi-square test for categorical data. Fisher's exact test was applied in place of the chi-

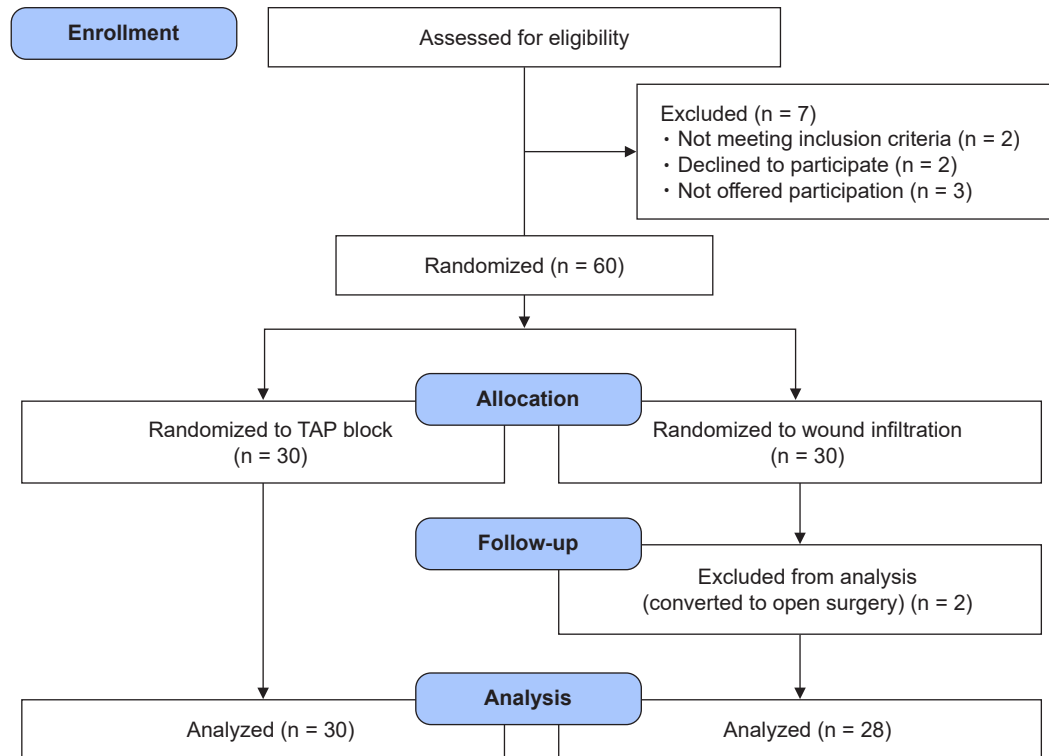


Fig. 1. CONSORT diagram. CONSORT: consolidated standards of reporting trials, TAP: transversus abdominis plane.

square test when cell count is less than 5. A multivariate analysis using linear regression for continuous data was performed to identify factors associated with NRS values at the first 48 hours postoperatively. The effect size measures were reported as 95% confidence interval (CI). All P values were two-sided. Statistical significance was set at $P < 0.050$. Statistical analyses were performed using the Statistical Package of Social Sciences (version 22.0, SPSS Inc.)

RESULTS

From September 2020 to June 2022, 67 patients were assessed for eligibility, of which seven were not enrolled on the basis of exclusion criteria or refusal. Sixty patients were enrolled in the trial and were randomized. Two patients were excluded after being allocated to the WI group because of conversion to open surgery. The remaining 58 patients were analyzed (Fig. 1).

Baseline characteristics were similar in both groups except for diabetes, which was more common in the WI group ($P = 0.038$), and age, which was lower in TAP patients ($P = 0.031$). The patient characteristics are summarized in Table 1.

The details of intraoperative hemodynamic management,

Table 1. Demographic Data and Clinical Characteristics of 58 Patients Undergoing Laparoscopic Radical Prostatectomy Managed according to the TAP or WI Group

Variable	TAP (n = 30)	WI (n = 28)	P value
body mass index (kg/m ²)	26.9 ± 6.4	26.3 ± 5.8	0.762
Age (yr)	63 ± 6	65 ± 4	0.031*
ASA			0.330
I	0 (0.0)	1 (3.6)	
II	30 (100.0)	26 (92.9)	
III	0 (0.0)	1 (3.6)	
Smoking status	3 (10.0)	7 (25.0)	0.173
HTA	11 (36.7)	16 (57.1)	0.118
DM	3 (10.0)	9 (31.2)	0.038*
CKD	4 (13.3)	3 (10.7)	1.000
Stroke	1 (3.3)	1 (3.6)	1.000
COPD	6 (20.0)	4 (14.3)	0.732
Heart diseases	1 (3.3)	3 (10.7)	0.344

Values are presented as mean ± SD or number (%). TAP: transversus abdominis plane, WI: wound infiltration, ASA: American Society of Anesthesiologists, HTA: hypertension, DM: diabetes mellitus, CKD: chronic kidney disease, COPD: chronic obstructive pulmonary disease. * $P < 0.05$ was considered significant, chi-square test or independent t-test.

surgical features, and lengths of surgery are presented in [Table 2](#). No hypotensive events were observed during the surgery. No patient experienced complications related to regional analgesia, and there were no intraoperative events attributable to the systemic effects of local anesthetics in either group.

Median NRS values registered at rest and during cough/movement during the immediate postoperative period in PACU (0–4 h period; at rest: at 1 h $P = 0.844$; at 2 h $P = 0.736$, at 3 h $P = 0.700$; at 4 h $P = 0.971$; during cough: 1 h $P = 0.698$; at 2 h $P = 0.834$, at 3 h $P = 0.922$; at 4 h $P = 0.618$) and on the hospitalization ward (6–48 h period; at rest: 6 h $P = 0.816$; at 12 h $P = 0.395$, at 18 h $P = 0.472$; at 24 h $P = 0.812$, at 36 h $P = 0.358$, at 48 h $P = 0.397$; during cough: 6 h $P = 0.974$; at 12 h $P = 0.712$, at 18 h $P = 0.691$; at 24 h $P = 0.708$, at 36 h $P = 0.572$, at 48 h $P = 0.929$) did not show statistically significant differences and are shown in [Figs. 2](#) and [3](#) respectively.

We performed an exploratory analysis of the opioid requirements. There were no statistical differences in the postoperative MME requirements in the TAP and WI groups during the entire 48-h period (1.7 ± 3.1 vs. 1.8 ± 4.1 mg; $P = 0.914$) or when analyzing the early (0–4 h) and late (4–48 h) periods separately (TAP, 1.6 ± 2.9 mg vs. WI, 1.1 ± 1.8 mg for the early period and TAP, 0.1 ± 0.5 mg vs. WI, 0.6 ± 3 mg for the late period).

There were no postoperative complications related to the TAP or WI technique or complications associated with the systemic effects of the local anesthetic in any of the patients.

The difference in the incidence of overall complications between the two groups was not statistically significant ($P = 1.000$). In the TAP group, a case of ureteral fistula required surgical reintervention, a case of bladder perforation was managed conservatively, and a case of obturator nerve injury required rehabilitation. In the WI group, cases of bladder perforation and hemorrhage did not require surgical intervention. PONV was very rare in both groups, and only one patient in the TAP group experienced PONV.

Results of the linear regression analysis showed that mean NRS values at the 48 hours postoperatively were independently associated with total opioid requirements (95% CI, 0.49 [0.03–0.09]; $P < 0.001$), while surgery duration ($P = 0.698$), age ($P = 0.383$), lymphadenectomy ($P = 0.895$), surgical postoperative complications ($P = 0.432$) and diabetes mellitus ($P = 0.844$) were not independently associated.

Neither of the secondary outcomes presented significant differences between the two groups ([Table 3](#)).

Table 2. Intraoperative Characteristics of 58 Patients Undergoing Laparoscopic Radical Prostatectomy Managed according to the TAP or WI Group

Variable	TAP (n = 30)	WI (n = 28)	P value
Time of surgery (min)	241 \pm 44	222 \pm 37	0.083
Time of anesthesia (min)	300 \pm 50	288 \pm 45	0.321
Hypertensive episode	7 (24.1)	6 (21.4)	0.807
Lymphadenectomy	5 (16.7)	7 (25.0)	0.434

Values are presented as mean \pm SD or number (%). TAP: transversus abdominis plane, WI: wound infiltration. Hypotensive events were defined by a systolic blood pressure decrease of 20% below baseline. Hypertensive events were defined by a systolic blood pressure increase of 20% above baseline. The length of surgery was recorded as the elapsed time in hours between the documented times of incision and closure.

DISCUSSION

Effective pain management is key for optimal postoperative recovery and an essential component of enhanced recovery protocols [20]. However, direct high-level evidence is often lacking to support an optimal approach, even in commonly performed procedures, such as laparoscopic prostatectomy. The current study is the first prospective randomized trial comparing two regional analgesic approaches coupled with non-opioid-based multimodal analgesia for LRP. The results of this study did not show benefits of either locoregional technique modality for acute pain management in LRP, while showing excellent pain scores when these techniques were applied as part of a standardized non-opioid-based multimodal regimen.

The choice of an ideal pain management strategy should be based not only on its safety and efficacy, but also on the ease of administration and cost. From this perspective, although WI showed no differences in terms of pain control compared with TAP, WI could be considered more advantageous because it is less time-consuming and not dependent on the availability of ultrasound equipment or specially trained personnel, and complications after WI are rare [21].

In our study, both analgesic strategies provided excellent pain control, with mean NRS values < 2 in the first 48 h, both at rest and during movement. Our results were in accordance with those of studies on other types of surgeries, such as laparoscopic colectomy [7,16], where similar levels of pain control were observed for WI and TAP. In those studies, although no differences were observed between the two techniques, similar to the results of our study, the recorded pain intensity was generally higher than our data. This could

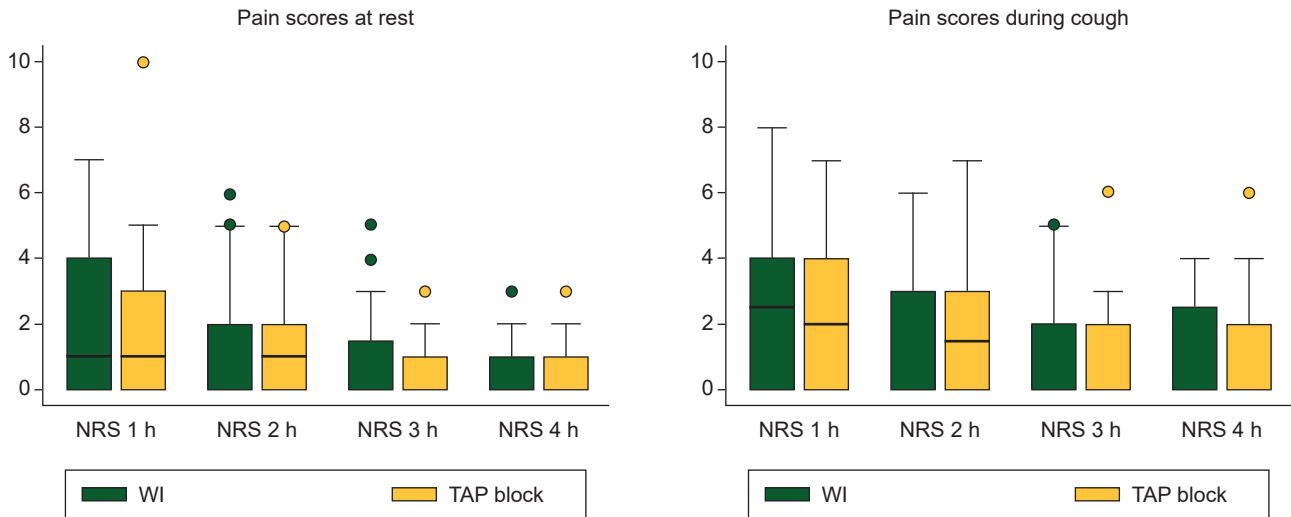


Fig. 2. Numeric rate scale (NRS) scores at rest during the first 48 postoperative hours in the TAP and WI groups. Median (line within box), interquartile range (box) and range (error bars) are shown. No statistically significant differences are observed between the analgesic efficacies of the two procedures. TAP: transversus abdominis plane, WI: wound infiltration.

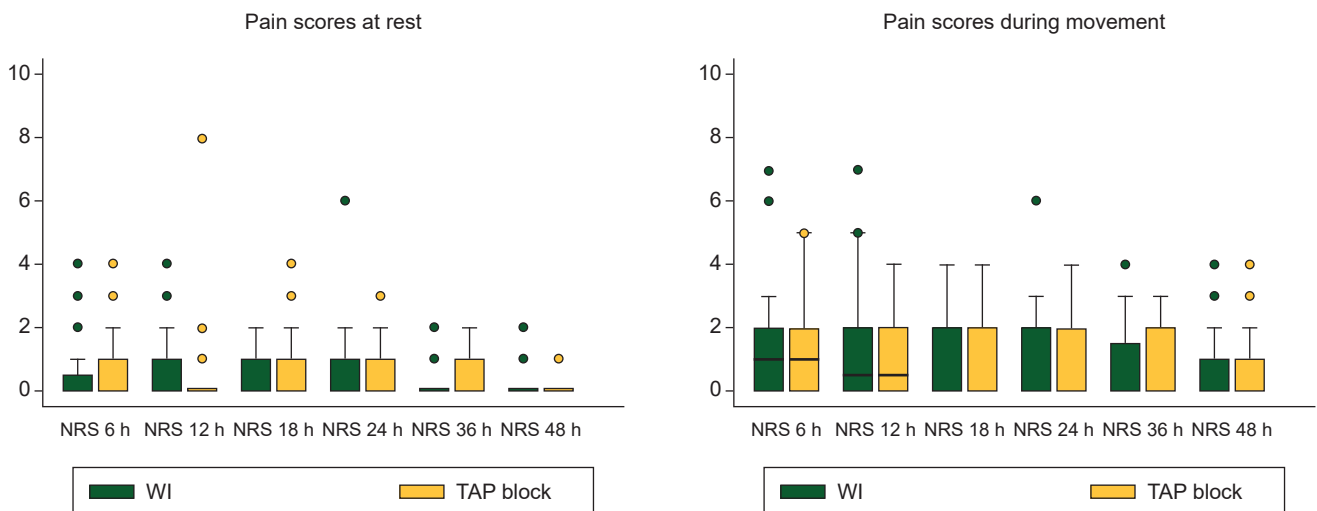


Fig. 3. Numeric rate scale (NRS) scores during movement during the first 48 postoperative hours in the TAP and WI groups. Median (line within box), interquartile range (box) and range (error bars) are shown. No statistically significant differences are observed between the analgesic efficacies of the two procedures. TAP: transversus abdominis plane, WI: wound infiltration.

Table 3. Secondary Outcomes of 58 Patients Undergoing Laparoscopic Radical Prostatectomy Managed according to TAP Group or WI Group

Variable	TAP (n = 30)	WI (n = 28)	P value
First flatus (h)	18.2 ± 12.5	20.1 ± 11.2	0.510
Time to sitting (h)	23.0 ± 14.1	23.0 ± 19.3	0.955
Time to ambulation (h)	33.1 ± 24.9	34.6 ± 29.7	0.838
Length of stay (d)	3.3 ± 2.0	3.8 ± 3.8	0.512

Values are presented as mean ± SD. TAP: transversus abdominis plane, WI: wound infiltration.

be due to the timing of the regional anesthesia administration, which was pre-incisional in our study, which could influence the effectiveness of postoperative analgesia by blocking sensory flow in the periphery before the creation of the painful stimulus [22,23], or the intrinsic differences in the type of procedure (extraperitoneal vs. intraperitoneal LRP); however, a study that compared both approaches of LRP showed that narcotic analgesic requirements were similar [24].

Another important aspect of our study was the multimod-

al analgesic regimen that accompanied both types of regional anesthesia. We used a standardized hospital protocol based on scheduled administration of paracetamol, NSAIDs, and metamizole, because several studies have demonstrated decreased opioid use with this approach [5,25]. In fact, we observed that opioid requirements were not only similar between the groups but were also extremely low. The results of other studies which compared WI and TAP in laparoscopic surgery also showed similar opioid requirements between the two groups; however, the average consumption was significantly higher in both groups [16-18]. This may be due to the fact that the multimodal analgesic regimen we used relied on non-opioid agents that may have synergistic effects and allow the administration of regularly scheduled rather than as-needed doses. Minimizing the use of postoperative opioids is a major advantage for controlling the effect of medical practices on the opioid epidemic and minimizing opioid-related side effects, such as PONV.

Our study had some limitations. Abdominal wall sensitivity tests were not performed to assess TAP blocks because they were performed after the start of general anesthesia. However, it is well known that the extent of sensory blockade may not necessarily reflect the analgesic effect of the TAP block [26], and we did not observe intraoperative hypertensive episodes, which might occur due to inadequate analgesia [27]. Another potential limitation was that an unblinded surgeon could have affected postoperative patient care. Furthermore, we did not include a control group (without a block) because both techniques had been shown to provide better analgesic effects than a placebo [28].

In conclusion, the results of our prospective trial indicate that WI is not superior to TAP in achieving pain control during the first 48 h after LRP when combined with a non-opioid-based multimodal pain management strategy. Arguably, given that the pain scores and opioid requirements were very low in both groups, it is likely that the modalities were equally efficient, although this clinical trial was not designed to assess this hypothesis directly.

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CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this published article.

AUTHOR CONTRIBUTIONS

Conceptualization: Ana Tejedor, Carme Deiros. Data curation: Ana Tejedor, Carme Deiros, Lana Bijelic, Marta García. Formal analysis: Ana Tejedor. Methodology: Ana Tejedor, Carme Deiros, Marta García. Visualization: Ana Tejedor. Writing - original draft: Ana Tejedor, Carme Deiros. Writing - review & editing: Ana Tejedor, Lana Bijelic. Investigation: Ana Tejedor, Carme Deiros, Lana Bijelic, Marta García. Supervision: Ana Tejedor. Validation: Ana Tejedor, Marta García.

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