



ORIGINAL INVESTIGATION

Comparison between epidural technique and mid-axillary ultrasound-guided TAP block for postoperative analgesia of laparoscopic radical prostatectomy: a quasi-randomized clinical trial[☆]

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Abstract

Background: Our goal was to evaluate whether TAP block offers the same analgesic pain control compared to epidural technique in laparoscopic radical prostatectomy surgery through the morphine consumption in the first 48 hours.

Methods: In this study, 45 patients were recruited and assigned to either TAP or epidural. The main study outcome was morphine consumption during the first 48 hours after surgery. Other data recorded were pain at rest and upon movement, technique-related complications and adverse effects, surgical and postoperative complications, length of surgery, need for rescue analgesia, postoperative nausea and vomiting, start of intake, sitting and perambulation, first flatus, and length of in-hospital stay.

Results: From a total of 45 patients, two were excluded due to reconversion to open surgery (TAP group = 20; epidural group = 23). There were no differences in morphine consumption (0.96 vs. 0.8 mg; $p = 0.78$); mean postoperative VAS pain scores at rest (0.7 vs. 0.5; $p = 0.72$); or upon movement (1.6 vs. 1.6; $p = 0.32$); in the TAP vs. epidural group, respectively. Sitting and perambulation began sooner in TAP group (19 vs. 22 hours, $p = 0.03$; 23 vs. 32 hours, $p = 0.01$; respectively). The epidural group had more technique-related adverse effects.

Conclusion: TAP blocks provide the same analgesic quality with optimal pain control than epidural technique, with less adverse effects.

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Introduction

The purpose of enhanced recovery programs pathways combined with laparoscopic techniques is to reduce postoperative stress and complication rates, shorten the length of hospital stay, and provide an optimal anesthesia avoiding high opioid doses.¹ Good results were obtained in colorectal surgery,² and they have become extensive to various surgical procedures,³⁻⁵ with the aim of improving postoperative recovery.⁶⁻⁸ However, bibliography is scarce regarding urological surgery.^{5,9-11}

Multimodal pain management is essential to enhanced recovery programs.⁷ Epidural analgesia has been established as the most adequate analgesic technique for this type of surgery,¹² as it allows for proper pain management⁸ without the adverse effects of other analgesics such as morphine, and a decrease in complications.^{13,14} However, it is not free of side effects or complications.^{15,16} All of these can affect early patient mobilization, satisfaction, and increase hospital stay.^{7,8} These aspects go against the enhanced recovery programs, hence various studies have been published recommending other analgesic techniques such as the transversus abdominis plane (TAP) block in abdominal surgeries.^{17,18} The TAP block is an interfascial plane block based on the injection of local anesthetic in the neurofascial space between the internal oblique muscle and the transversus abdominis muscle. Within this space run the nervous fibers that gather abdominal wall sensitivity. The clinical effectiveness of TAP block versus epidural technique or other analgesic techniques have been studied.¹⁹ However, there are no direct comparisons between both techniques regarding the degree of analgesia provided in laparoscopic radical prostatectomy. Specific bibliography considering the analgesic effect of the TAP blockade in laparoscopic radical prostatectomy is scarce, and mostly refers to robot-assisted surgeries.^{11,20,21} To our knowledge, no study has been published evaluating TAP vs. epidural in laparoscopic radical prostatectomy in the enhanced recovery programs context, evaluating both analgesia and enhanced recovery programs-related outcomes.

Our main objective was to compare morphine consumption and analgesic efficacy between epidural technique and TAP block in the first 48 hours after laparoscopic radical prostatectomy.

Methods

Patient selection

The study was a controlled, quasi-randomized, non-blinded, single center trial with two parallel arms. The study protocol was reviewed and approved by our local ethics committee (approval number 16/42) and was conducted in accordance with the Declaration of Helsinki. The results are reported according to current TREND guidelines. The allocation procedure was performed using a 1:1 sequential assignment, to either TAP or epidural group, by the anesthesiologist at the preoperative visit, where the patients were recruited. Informed consent was obtained from all those patients who underwent laparoscopic radical prostatectomy between October 2016 and May 2018 before entering the study. The

study was registered in Clinicaltrial.gov with the number 03884335.

Exclusion criteria were age below 18 years old; anesthesia ASA (American Society of Anesthesiologists) score \geq IV; body mass index (BMI) \geq 30 kg.m⁻²; history of local anesthetic allergies; chronic opioid use, coagulopathy; peripheral neuropathy; reconversion to open surgery; or patient's refusal.

Secondary outcomes registered were technique-related complications and adverse effects, surgical and postoperative complications, length of surgery, need for rescue analgesia, postoperative nausea and vomiting, start of intake, sitting and perambulation, first flatus; and length of in-hospital stay.

Data was recorded at different time points (Figure 1): *Pre-operative visit*: age, anesthesia ASA score and BMI; *Intraoperative period*: complications related to analgesic technique (vascular puncture, peritoneal or intestinal puncture in the TAP block, number of attempts, impossibility to perform technique), surgery-related complications (bleeding, intestinal, bladder or diaphragmatic perforation), and length of surgery; *Postanesthesia care unit*: milligrams of administered morphine, pain as evaluated by the visual analogue scale (VAS) upon rest (VASr) and movement – cough – (VASm) at 1, 2, 3, 4, and 6 hours; failure of analgesic technique (need of morphine PCA), surgical complications, analgesic technique adverse effects (motor blockade, paresthesia, accidental catheter disconnection) and complications (spinal hematoma, infection, postdural-puncture headache, nerve lesions), hydric tolerance, postoperative nausea or vomiting, and time to bowel movement (first flatus after surgery); *Hospitalization ward*: milligrams of administered morphine; VASr and VASm at 12, 18, 24, 36, and 48 hours; time to sitting position and perambulation; postoperative nausea or vomiting; complications of surgical and analgesic technique (including infection at this point) and adverse effects related to analgesic technique; failure of analgesic technique (need of morphine PCA); and length of in-hospital stay.

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

Intraoperative management

All patients underwent combined anesthesia: either general anesthesia + epidural (epidural group); or general anesthesia + TAP block (TAP group). Patients were premedicated with intravenous midazolam 0.05 mg.kg⁻¹. In the epidural group, the catheter was inserted 4–5 cm into the epidural space at L1–L2 level. Three milliliters (mL) lidocaine 2% were injected as a testing dose to exclude intrathecal placement prior to induction. Induction was performed intravenously with fentanyl (1.5 mcg.kg⁻¹), propofol (1.5–2 mg.kg⁻¹), and rocuronium (0.6 mg.kg⁻¹). Orotracheal intubation was performed. Prior to skin incision 8 mL of 0.25% levobupivacaine were administered epidurally, and a continuous perfusion of 0.125% levobupivacaine at 5 mL.h⁻¹ was started. In the TAP group, a bilateral, ultrasound-guided mid-axillary TAP block was performed immediately after induction (which was the same as described in the epidural group) but prior to surgery. The high-frequency lineal

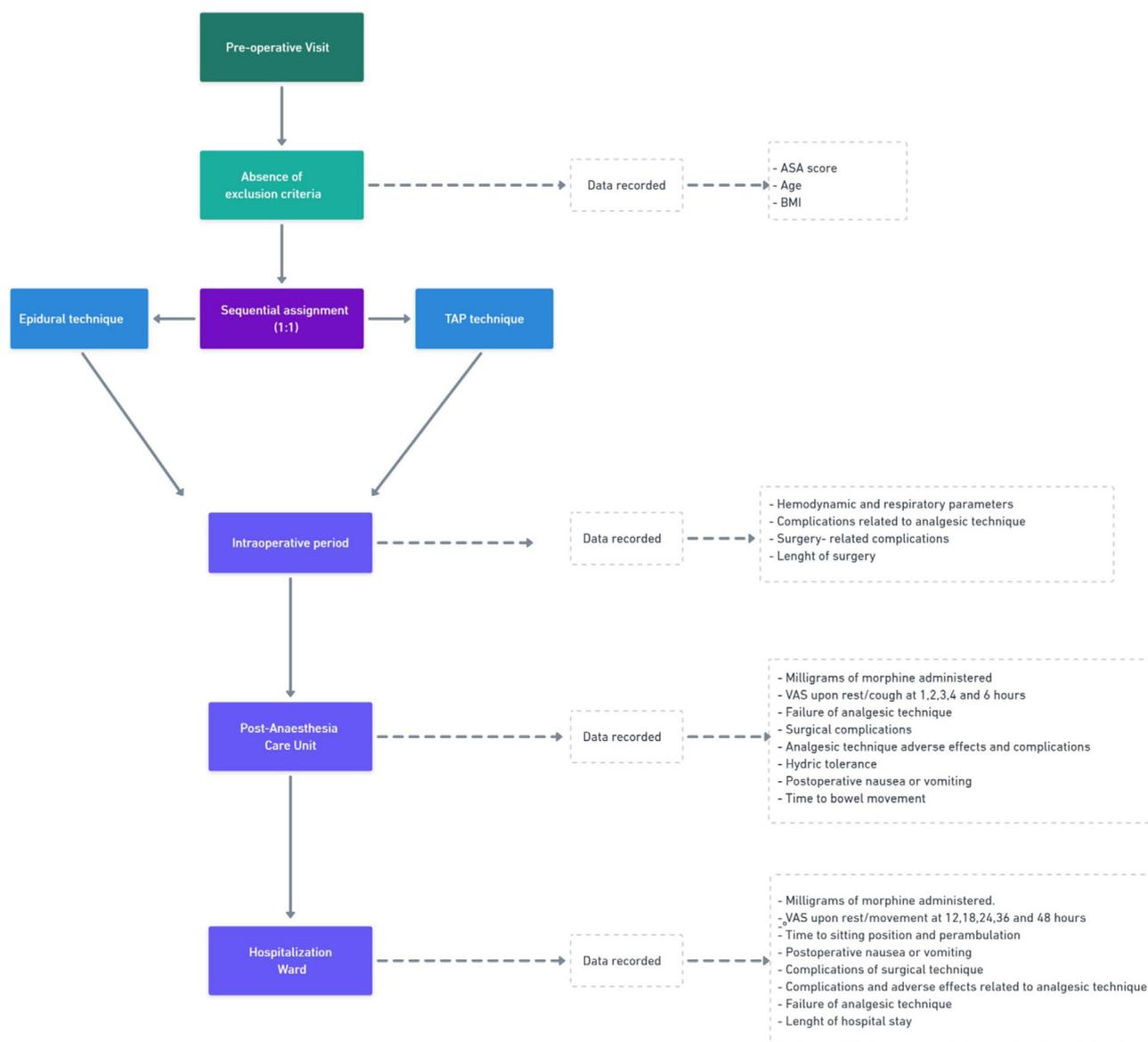


Fig. 1 Flowchart of this study.

probe (Sonosite MicroMAXX_{TM}) was placed midway between the costal margin and iliac crest, and transversus abdominis muscle located behind the rectus abdominis and below the internal oblique muscle. Twenty mL of local anesthetic (bupivacaine 0.375%) was administered via a 22G Quincke spinal needle inserted in-plane on each side of the abdomen. We considered a successful block if ultrasound vision evidenced interfacial local anesthetic spread.

A laparoscopic radical prostatectomy was performed. Intraoperative anesthetic maintenance was performed with propofol target-controlled infusion for BIS between 40 and 60. Net zero fluid therapy was maintained, as well as normothermia and normotension following enhanced recovery programs criteria.¹ After surgery, patients were awoken from general anesthesia and transferred to the postanesthesia care unit for a 6-hour follow-up prior to transfer to conventional ward and optimal postoperative analgesia.

Postanesthesia care unit management

In the postanesthesia care unit, the patient was kept under observation for 6 hours for pain and bleeding control, as well as hemodynamic and respiratory management. Besides epidural or TAP blockade, standard analgesia was maintained with paracetamol 1 g/8 h IV (intravenous) alternate with metamizole 2 g/8 h IV, as well as 2 mg bolus of morphine, if required. If pain was unmanageable, in the epidural group the first option was administration of 8 mL of 0.125% levobupivacaine; next catheter was repositioned, and if these options failed catheter was removed, and a morphine infusion was begun. In the TAP group, if rescue morphine bolus (of up to 10 mg) was not enough, TAP-block was repeated. If after 20 minutes, the patient showed no improvement, morphine infusion was begun. In these cases (both epidural and TAP groups), data was recorded as analgesic technique failure.

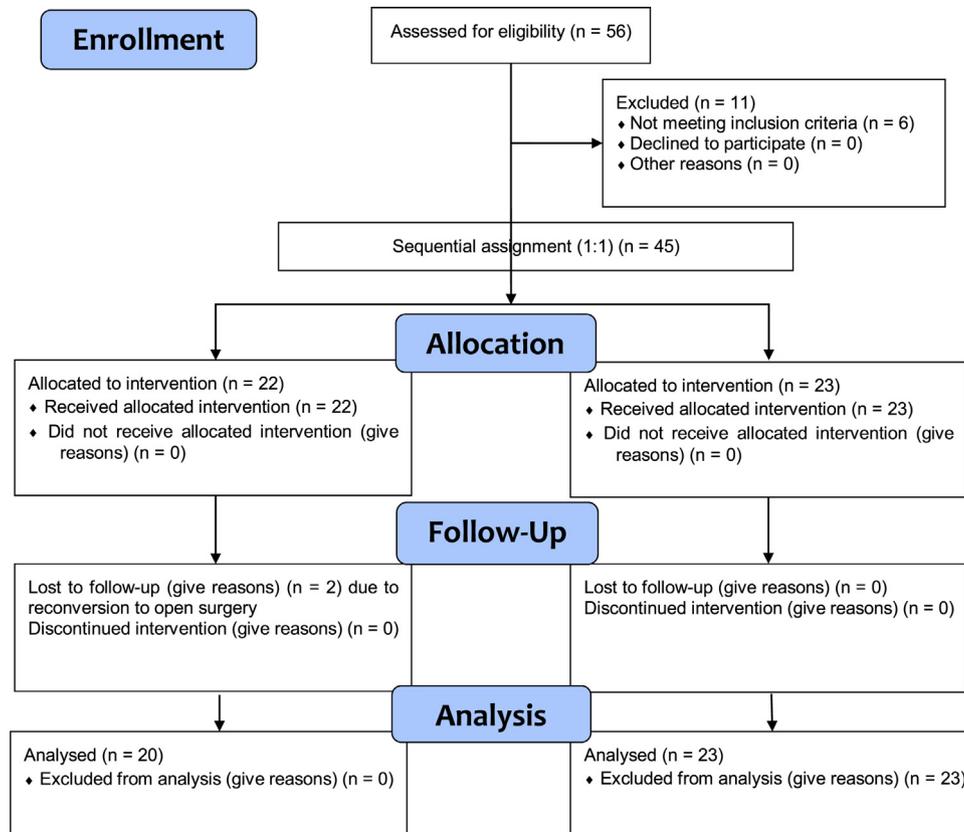


Fig. 2 Flow Diagram of this study.

Hospitalization ward management

After postanesthesia care unit, patients were transferred to conventional hospital ward. During this period, they were followed-up by our hospital's acute pain team, formed by an anesthesiologist and a specialized nurse. Epidural infusion and catheter removal was performed when VASm were consistently < 3 in patients with continuous perfusion of 0.125% levobupivacaine at $3 \text{ mL} \cdot \text{h}^{-1}$, if coagulation parameters and heparin regime permitted.

Statistical analysis

Previous studies reported minimal morphine consumption differences at 48 hours being of mean (standard deviation [SD]) 26.8 (19.8 mg).²² Aiming to detect a reduction in two thirds or morphine consumption as compared these previously published results, and in order to increase the study's potency, sample size was calculated with a confidence interval of 99%, a two-tailed alpha set at 0.01 and a beta of 0.1; sample size was established as 17 per group. An increase of 20% (22 patients) to be recruited for each arm was established to minimize effects secondary to patient losses.

Results are reported as mean and standard deviation (SD) in quantitative data and percentage or rank in qualitative data. Kolmogorov-Smirnov test was run to evaluate data distribution.

For normally distributed numerical data, the independent samples' Student *t*-test was used to compare the

difference in the means between the two study groups. For skewed numerical data, the Wilcoxon rank sum test was applied. The Pearson chi-square test was used for comparison of the two groups as regards differences in categorical data. Fisher's exact test was applied in place of the chi-square test when cell count is less than 5. All *p*-values are two-sided. A *p* < 0.05 is considered statistically significant. Statistical analyses were carried out using SPSS v 22.0 (SPSS, Chicago, IL, USA).

Results

A total of 45 patients were recruited, two of which (from the epidural group) were excluded due to surgical reconversion from laparoscopy to open surgery due to technical difficulties. From the 43 remaining patients, 20 were allocated in the epidural and 23 in the TAP group (Figure 2). There were no differences between groups regarding patient characteristics (Table 1).

Intraoperative results

Regarding complications related to analgesic technique, in the epidural group there were 2 cases of dural puncture (technique was repeated at a higher level); and one case of paresthesia when the catheter was being introduced. No complication was registered in the TAP group. No statistically significant differences were found between groups and appearance of complications (*p* = 0.09).

Table 1 Patient characteristics.

Variable	TAP	Epidural	<i>p</i>
Age (years)	65.6 (4.8) (54–71)	65.9 (5.4) (54–71)	0.84 ^a
ASA physical status score			0.43 ^b
I	2	3	
II	21	16	
III	0	1	
BMI (kg.m ⁻²)	27.3 (2.2)	27.7 (3.3)	0.47 ^a
Length of surgery (minutes)	241 (48)	246 (58)	0.46 ^a

Age, BMI and length of surgery were expressed as mean (standard deviation (SD)). ASA physical status score was expressed as number (n). *P*-value for significant differences between TAP group and epidural group.

Statistical test used: ^a T-test; ^b Chi-square.

As for surgical complications, there were no differences between groups in appearance of these ($p = 0.85$). Of note, there were four bladder perforations, three of which (two from the epidural and one from the TAP group) requiring simple suture as a solution, and one (epidural group) requiring suprapubic cystectomy.

Postoperative results (postanesthesia care unit and hospitalization ward)

No statistically significant differences were found between analgesic techniques in VASr (Figure 3), VASm (Figure 4) during postanesthesia care unit and conventional ward follow-up; and morphine administration during hospitalization. Morphine consumption at postanesthesia care unit, was 0.87 (1.57) mg in the TAP group vs. 0.65 (2.06) mg in the epidural group ($p = 0.66$). At hospitalization ward, morphine consumption was 0.09 (0.41) mg vs. 0.15 (0.48) mg ($p = 0.65$); and total morphine administered was 0.96 (1.58) mg vs. 0.8 (2.07) mg ($p = 0.65$), respectively. There was no case either in the epidural or in the TAP group, at any point (postanesthesia care unit or ward follow-up) that required conversion to intravenous continuous analgesia (morphine infusion).

The two study groups were equivalent in postoperative nausea or vomiting appearance at postanesthesia care unit and ward hospitalization, oral tolerance, first flatus and length of in-hospital stay. In the TAP group, 8.9% patients presented the first flatus in the postanesthesia care unit (within the first 6 hours), as compared to 2.2% of the patients in the epidural group. Also, in the TAP group, sedation and perambulation happened sooner than in the epidural group, being statistically significant (Table 2).

Concerning specific analgesic technique complications there were none in any group. However, regarding specific analgesic technique adverse effects, there were three cases of unilateral lower limb motor block (these reverted when catheter was partially withdrawn), one case of bilateral lower limb motor block (which reverted with a decrease in velocity of anesthetic infusion); and one case that required repetition of technique in the postanesthesia care unit, due to uncontrollable pain in the epidural group. There were no analgesic technique complications related to TAP block ($p = 0.01$). At postoperative 24 hours, adverse effects were also statistically significant in the epidural group ($p = 0.03$),

Table 2 Follow-up outcomes in TAP and epidural group.

	TAP	Epidural	<i>P</i>
PONV PACU/ward	0	3	0.06 ^a
PONV ward	1	3	0.25 ^a
Oral tolerance < 6 h	12	12	0.49 ^b
First flatus (hours)	18 (9)	22 (12)	0.55 ^c
Time to Sitting (hours)	19 (5)	22 (6)	0.03 ^c
Time to Perambulation (hours)	23 (8)	32 (11)	0.01 ^c
Length of stay (days)	4 (2.75)	3 (3)	0.35 ^d

Data expressed as number (n) or mean (standard deviation [SD]), except length of stay which was expressed as median (interquartile range).

TAP, transversus abdominis plane group; PONV, postoperative nausea and vomiting; PACU, postanesthesia care unit.

P-value for significant differences between TAP and epidural group.

Statistical test used: ^a Fisher test; ^b Chi-square; ^c T-test; ^d U-Mann Whitney

which presented with three cases of lower limb motor block and one case of paresthesia, all of which improved with decrease in infusion rhythm. At the 48-hour follow-up there was one case of accidental catheter extraction, but pain was correctly controlled with morphine bolus. Differences between TAP and epidural group were not statistically significant ($p = 0.46$) at 48-hour follow-up.

Finally, four surgical complications were detected. There were three cases of bladder perforation (two in the epidural and one in the TAP group), and one case of anastomosis leakage (in the epidural group). Differences between groups were not statistically significant ($p = 0.36$).

Discussion

This study was conducted in the setting of an enhanced recovery program and aimed to analyze the effect of TAP block compared to epidural technique in the management of postoperative pain.

Literature comparing TAP vs. epidural technique is available for different types of surgeries,^{5,9,10,17,18} but scarce when referring to the enhanced recovery programs

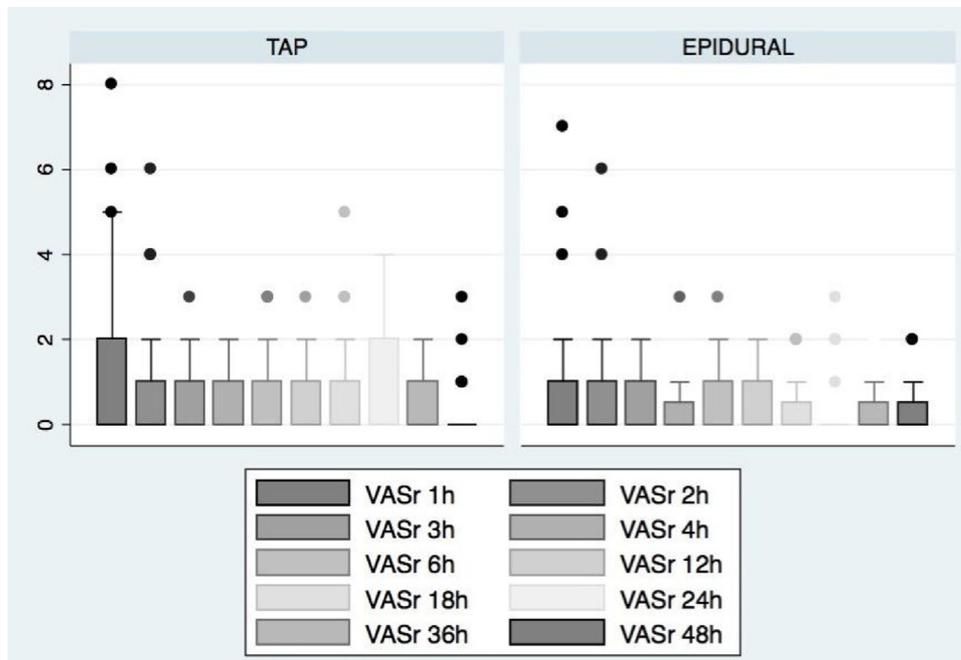


Fig. 3 VAS at rest during postanesthesia care unit stay and ward follow-up in the TAP and epidural groups. Median (line within box), interquartile range (box) and range (error bars) are shown. No statistically significant differences were found between groups and analgesic efficacy.

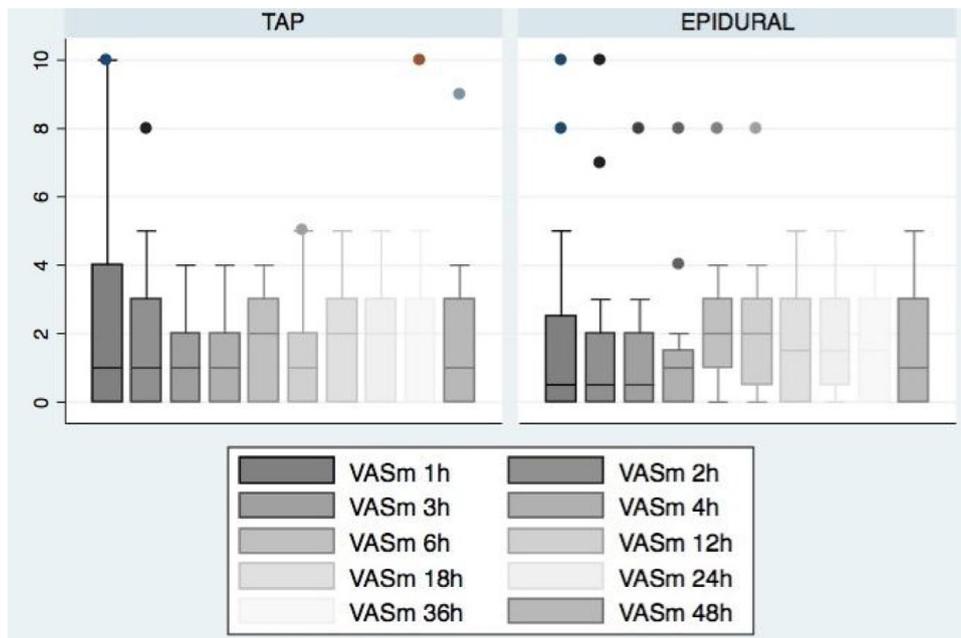


Fig. 4 VAS at movement during postanesthesia care unit stay and ward follow-up in the TAP and epidural groups. Median (line within box), interquartile range (box) and range (error bars) are shown. No statistically significant differences were found between groups and analgesic efficacy.

scenario,^{23,24} and absent when considering the specific laparoscopic radical prostatectomy situation.

In our study, we observe that both techniques are equally useful for postoperative pain management. There were no statistically significant differences regarding VAS at rest and upon movement in any time point, nor in milligrams of administered morphine. In the TAP group, mobilization and

perambulation began sooner; however, length of stay was similar in both groups. Our results are similar to those published in the colorectal surgery setting, where it has been already reported that both techniques are similar as to analgesic quality.^{24,25} Published results regarding length of hospital stay are at odds.^{23,24} Pirrera and cols. found no difference in length of stay,²⁴ whereas Torgeson and col. found

a significant decrease of hospital stay, from 3.3 days in the epidural to 2.8 in the TAP group.²³

Studies specifically evaluating laparoscopic radical prostatectomy in enhanced recovery programs are scarce. Magheli and cols.⁶ reported that the patients that followed the enhanced recovery programs had peristalsis and perambulation sooner than conventional program patients. It is of note that the analgesic protocol used in these cases was COX2 for the enhanced recovery programs group (dosage unreported) and opioid PCA for the conventional group, the latter of which goes against enhanced recovery programs.

Regarding the analgesic effect of TAP block in laparoscopic prostatectomy, only results in robot-assisted, but not conventional laparoscopy surgeries have been published,^{11,20} with just one of the studies performed in an enhanced recovery program setting.¹¹ Sternlicht and colleagues evaluated analgesic quality according to different dosages of local anesthetic in the TAP group, finding no differences.²⁰ Cacciamani and col. compared TAP plus wound infiltration against wound infiltration alone in the enhanced recovery programs context; with shorter length of hospital stay and better pain control in the TAP group.¹¹

Another important parameter in enhanced recovery programs is the favoring of bowel movements. This can be evaluated by postoperative nausea or vomiting and first flatus. Our own results and those published by other authors^{24,25} found no differences between the incidence of postoperative nausea or vomiting and analgesic technique used. Similarly, the data published by Pirrera found statistically significant differences between the first flatus (which came sooner in the patients with TAP than those with epidural),²⁴ whereas other studies found none.²³ Again, our results show no statistically significant differences between start of peristalsis and analgesic technique. This could be due to the fact that laparoscopic radical prostatectomy is not an intra-abdominal technique, and thus excludes bowel manipulation, decreasing the incidence of ileus and aiding prompt intake.²⁶

Following our hospital's protocol, we used levobupivacaine at 0.125% for the epidural technique. This low concentration allows for a differential neuraxial blockade, with sensory fibers being blocked, but with preservation of motor function.²⁷ Despite this, various patients presented adverse effects associated to motor blockade. These could be solved by standard methods, although they might be the cause of a longer time to sitting and perambulation, which was significantly greater in the epidural group. Our results are similar to those found by Pirrera and cols.²⁴

The use of bupivacaine in the TAP group was chosen as it is the most potent local anesthetic,^{28,29} and toxic doses were not exceeded. Approach was always ultrasound-guided, reducing the risk of complications due to vascular injection or peritoneal puncture, as well as intoxication due to local anesthetic.³⁰

Limitations

One of the limitations of our study is that it was not designed as a double-blind study, as the personnel could know to which group the patient belonged to if the epidural catheter was in place. This study is a quasi-randomized

clinical trial – not a randomized clinical trial –, as assignment to each treatment group was sequential. This could be a risk of bias. Another limitation could be the lack of catheter placement in the TAP block group, for continuous medication administration. Our study protocol opted for single-dose local anesthetic administration based on previously published studies.¹⁹ However, compared groups were homogeneous in terms of demographic and clinical data and we used the same postoperative analgesia protocol for both groups. Another limitation is the exclusion of patients with a BMI > 30 kg.m⁻², as TAP technique might be harder to perform in these patients, as well as success of surgery itself. Our study is based on a small sample size, powered to evaluate specifically analgesic quality, secondary outcomes related to these techniques might warrant studies with a greater sample size.

Conclusions

In an enhanced recovery program, TAP block offers the same postoperative analgesia quality as compared to the continuous epidural technique in laparoscopic radical prostatectomy, with the possibility of early patient mobilization.

Conflict of interest

The authors declare no conflicts of interest.

Acknowledgements

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