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ORIGINAL INVESTIGATION

Effectiveness and safety of ultra-low-dose spinal anesthesia versus perineal blocks in hemorroidectomy and anal fistula surgery: a randomized controlled trial

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Abstract

Background: Ultra-low-dose Spinal Anesthesia (SA) is the practice of employing minimal doses of intrathecal agents so that only the roots that supply a specific area are anesthetized. The aim of this study was to compare the effectiveness and safety of ultra-low-dose spinal anesthesia with that of Perineal Blocks (PB).

Methods: A two-arm, parallel, double-blind randomized controlled trial comparing two anesthetic techniques (SA and PB) for hemorrhoidectomy and anal fistula surgery was performed. The primary outcomes were postoperative pain, complementation and/or conversion of anesthesia, and hemodynamic changes.

Results: Fifty-nine patients were included in the final analysis. The mean pain values were similar in the first 48 h in both groups ($p > 0.05$). The individuals allocated to the SA group did not need anesthetic complementation; however, those in the PB group required it considerably (SA group, 0% vs. PB group, 25%; $p = 0.005$). Hemodynamic changes were more pronounced after PB: during all surgical times, the PB group showed lower MAP values and higher HR values ($p < 0.05$). Postoperative urinary retention rates were similar between both groups (SA group 0% vs. PB group 3.1%, $p = 0.354$).

Conclusion: SA and PB are similarly effective in pain control during the first 48 h after hemorrhoidectomy and anal fistula surgery. Although surgical time was shorter among patients in the PB group, the SA technique may be preferable as it avoids the need for additional anesthesia. Furthermore, the group that received perineal blocks was under sedation with a considerable dose of propofol.

Abbreviations: BMI, Body Mass Index; CONSORT, Consolidated Standards of Reporting Trials; HR, Heart Rate; LA, Local Anesthesia; LL, Lower Limbs; MAP, Mean Arterial Pressure; NIMAP, Noninvasive Mean Arterial Pressure; PB, Perineal Blocks; PONV, Postoperative Nausea and Vomiting; POUR, Postoperative Urinary Retention; RCT, Randomized Controlled Trial; SA, Ultra-low-dose Spinal Anesthesia; SD, Standard Deviation; SpO_2, Peripheral Oxygen Saturation; SPSS, Statistical Package For Social Sciences; VAS, Visual Analog Scale.

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Introduction

Ambulatory surgery is a safe and economic approach to manage anorectal conditions.[1] Hospital admissions occur in up to 17% of cases,[2] and in up to 61% of cases undergoing hemorrhoidectomies.[3] Major causes of morbidity for ambulatory anorectal procedures include pain, bleeding, urinary retention, and Postoperative Nausea and Vomiting (PONV).[2]

Neuraxial blocks are available in addition to other effective anorectal surgery methods. However, they have been traditionally associated with high postoperative urinary retention rates,[1] although there is still conflicting evidence on this issue.[1,2,4]

General anesthesia, spinal anesthesia, and sedation are commonly associated with perineal block or infiltration during ambulatory hemorrhoidectomy. There is disagreement in the literature regarding the best technique for postoperative analgesia.[3] Recently, local infiltration has shown lower analgesic efficacy than spinal anesthesia in hemorrhoidectomy.[5]

Spinal anesthesia causes longer hospitalization and recovery times in addition to urinary retention in anorectal surgeries[1,4,6] and hemorrhoidectomy.[3] However, local anesthesia (LA) decreases costs, anesthesia time, nausea, and increases patient satisfaction in anorectal surgeries.[6]

The incidence of general postoperative urinary retention is 2—3.8%, after anorectal surgery it is 2048%,[4] and it also occurs more frequently after hemorrhoidectomy.[1] Risk factors that vary according to the populations studied are as follows: age above 50—60 years, neuraxial anesthesia, operative time longer than 120 min, intravenous fluids higher than 750—2000 ml, laparoscopic surgery, anorectal and lower limb arthroplasty, neurological comorbidities, and specific pharmacological agents.[4]

The proposed mechanisms of anorectal surgery leading to postoperative urinary retention (POUR) are well established and include alpha-adrenergic activation, change in bladder position after surgery, and injury of autonomic nerves, despite the surgical approach.[4]

Spinal anesthesia results in blockage of the urination reflex, which lasts until the spinal anesthetic regresses to level S3, in that longer acting anesthetics result in greater urinary retention.[4] Lower values of local anesthetic have been proposed, aiming at less pronounced motor and sensory block, and facilitating early discharge of the patient. Ultra-low-dose spinal anesthesia was defined as levobupivacaine or bupivacaine $\leq$5 mg administered as a single injection of spinal anesthesia.[7]

Studies that address side effects of spinal anesthesia in hemorrhoidectomy in the outpatient setting have used different LA, with varying doses of LA and opioids.[3]

This study was based on the hypothesis that ultra-low-dose spinal anesthesia is effective in some specific types of ambulatory benign anorectal surgeries. The main objective of this study was to compare the effectiveness and safety of ultra-low-dose spinal anesthesia with that of perineal blocks.

Methods

Study design

A two-arm, parallel, double-blind (surgeons and patients) randomized controlled trial comparing two anesthetic techniques, ultra-low-dose spinal anesthesia and perineal blocks, for hemorrhoidectomy and anal fistula surgery was performed.

Participants

Patients scheduled for hemorrhoidectomy, anal fistula surgery, or internal lateral sphincterotomy were included in this study. Each surgical intervention followed a technique with a higher level of evidence and/or was standardized[10-12] so that there was no variation in the surgical technique among patients with the same clinical condition.

Inclusion criteria were as follows: 1) Grade III to IV external hemorrhoids,[8] anal fissure, and anorectal fistula indicative of surgical treatment; 2) Age 18—65 years; and 3) American Society of Anesthesiologists (ASA) physical status of I—III.[9]

The exclusion criteria were as follows: 1) Contraindication of subarachnoid anesthesia and outpatient stay (absence of telephone contact, difficulty in locomotion, and residence outside the municipality where the anesthetic-surgical intervention took place); 2) Cognitive inability; 3) Decompensated clinical pathology; 4) Neurological pathology; 5) Diabetes mellitus; 6) Urge incontinence; 7) Previous prostate, renal, or urological surgery; and 8) Drug allergy.

After identifying eligible patients, they were contacted by the research team and were guided regarding the research protocol, followed by obtaining the informed consent form, inclusion of patients, and randomization.

Sample calculation

The minimum sample size calculated per group was 28 patients assuming: α = 5% and power = 80%, for a difference of up to 30% in local anesthetic techniques versus conventional spinal anesthesia, predicting a reduction in the incidence of pain.

Randomization, blinding, and allocation concealment

After inclusion, block randomization was performed using a computer-generated number list prepared by an independent researcher. Each individual was randomly assigned to receive ultra-low-dose Spinal Anesthesia (SA group) or Perineal Blocks (PB group) with the allocation rate of 1:1.

Opaque and sealed envelopes with identification of allocation were delivered to the anesthesiologist after each participant entered the operating room. Coloproctologists, data collection teams, and statisticians were blinded to the anesthetic technique. The surgeons and individuals from the

collection group were only allowed after anesthesia was performed and patients were positioned in a lithotomy position.

Interventions

The interventions consisted of SA and PB performed by anesthesiologists. The intervention protocol for this study consisted of three phases.

The first phase, common to both groups, consisted of fasting for 8 hours before the beginning of surgery, spontaneous urinary disposal immediately before the procedure, supplemental oxygen, and restriction of intravenous fluids to 100 ml of 0.9% sodium chloride during surgery. Different anesthesiologists and surgeons performed the procedures, and all anesthesiologists were previously trained to perform these procedures.

The second phase consisted of the performance of different anesthetic techniques. The SA group received ultra-low-dose spinal anesthesia with 2.5 mg (0.5 ml) of 0.5% hyperbaric bupivacaine and 20 μg (0.4 ml) of fentanyl. The technique was performed with the patient seated between L4 and L5 or L5 and S1 using a 25G or 27G Quincke needle. After spinal anesthesia, the patient remained in the supine position with a 25° cephaloaclive for eight minutes, in order to ensure sacral dispersion of the intrathecal drugs. Patients were sedated with midazolam 0.05 to 0.1 mg.kg^{-1}.

The PB group consisted of bilateral blockades of the pudendal and anorectal nerves, with the patient in the lithotomy position. A bilateral nerve block was performed with 150 mg of ropivacaine (20 ml) diluted in 20 ml of 0.9% NaCl. Half of the solution was used on each side through a 21G 0.8 $\times$ 100 mm (B. Braun Melsungen AG) isolated needle connected to a peripheral nerve stimulator (Stimuplex®) regulated to release a square pulsatile current of 1mA, with a frequency of 2 Hz, inserted transperineal, medial, and perpendicular to the sciatic tuberosity, at a depth of approximately 4—7 cm, seeking contraction of the anal sphincter.

The anorectal block was performed with superficial and deep infiltration of 400 mg (20 ml) of lidocaine with vasoconstrictor diluted in 10 ml of 0.9% NaCl through a 25 $\times$ 0.7 mm needle anterior, posterior, and lateral to the anus, making up its entire circumference. The patients were sedated with targeted controlled infusion of propofol. The preanesthesia target and the postanesthesia targets were 2—4 μg.mL^{-1} and 1 μg.mL^{-1}, respectively.

Ephedrine 5—25 mg EV and atropine (0.5 mg) EV (could be repeated) were standardized for the treatment of hypotension and symptomatic or important bradycardia, respectively.

Both interventions received drugs with prolonged analgesic action. Patients in the SA and PB groups received intrathecal fentanyl and ropivacaine, respectively. Intrathecal fentanyl in SA for anorectal surgery is associated with a better pain score in the first 6 hours and decreased use of analgesics in the postoperative period.[13] Ropivacaine in perianal block for anorectal surgery is associated with reduced pain, opioid consumption, and faster recovery.[14]

The third phase, also common to both groups, consisted of management of complementation and/or conversion of anesthesia, analgesia, and prophylaxis of PONV.

Anesthetic complementation was implemented if there was any change after testing the incision area: complaint of pain, verbalization or movement of the sedated patient, and acute hemodynamic repercussion (tachycardia or hypertension), through a complementary anorectal block with 200 mg/10 ml of lidocaine with vasoconstrictor through a 25 $\times$ 0.7 mm needle. Conversion to general anesthesia was performed if the alterations persisted.

Postoperative analgesia before discharge was performed with morphine 0.05 mg.kg^{-1} for mild pain and 0.1 mg.kg^{-1} for moderate to maximum pain, and the dose was repeated until resolution.

Intraoperative venous prophylaxis was performed for nausea and vomiting with 6 mg of dexamethasone and 8 mg of ondansetron, and for pain with 2 g of dipyrone and 30 mg of tenoxicam. Postoperative prophylaxis for pain was recommended orally, with 1 g dipyrone at 6/6 h for 3 to 5 days, 500 mg of paracetamol and 30 mg codeine at 6/6 h for 3 to 5 days, 100 mg of nimesulide at 12/12 h for 5 days, and topical with 50 mg.g^{-1} of polycresuline and 10 mg.g^{-1} cinchocaine hydrochloride at 8/8 h for 14 days.

Data collection

Sociodemographic and clinical data were collected preoperatively. Surgical and anesthetic data were collected both intraoperatively and postoperatively. Standard intraoperative monitoring included noninvasive mean arterial pressure (NIMAP), peripheral oxygen saturation (SpO_2), and heart rate (HR) recorded every 5 min. Follow-up started during the intraoperative period at the end of surgery (T0), and continued in the postoperative periods 1 h (T1), 3 h (T3), 5 h (T5) in the anesthetic recovery room and 10 h (T10), 24 h (T24), 48 h (T48) through telephone contact at the exact time indicated after surgery.

Outcome measures

Primary outcome measures

The primary outcome was the effectiveness and safety of SA compared to that of PB.

Effectiveness was evaluated through postoperative pain analysis and complementation and/or conversion of anesthesia.

Pain was assessed using the visual analog scale (VAS) and was quantified as follows: 0 = No pain, 1 to 3 = Mild pain, 4 to 6 = Moderate pain, 7 to 9 = Severe pain, and 10 = Maximum pain. It was grouped into the following categories: absence of pain, minor pain in case of mild pain and major pain in case of moderate to maximum pain, for statistical analysis in order to understand the profile of analgesia techniques.

The safety of the techniques was evaluated through hemodynamic changes measured through MAP and HR variation analyses.

Secondary outcome measures

The secondary outcomes were the incidence of side effects, interference of anesthesia in outpatient discharge, and user satisfaction.

The evaluated side effects were incidence of constipation, pain at first evacuation, average pain when first evacuating, strength limitation in the lower limbs, difficulty in walking, and incidence of POUR/PONV. POUR was diagnosed

using the following clinical criteria: presence of voiding desire and inability to empty the bladder spontaneously and adequately at any time during the first 24 h after the intervention. Constipation was defined as a delay in bowel movement for 48 h.

The interferences of anesthesia analyzed during outpatient discharge were the incidence of ambulatory discharge delay and unplanned hospital admission. Delay of outpatient discharge was defined as discharge from the medical service beyond 5 h after the end of the procedure.

User satisfaction was assessed using a form adapted from the Iowa Satisfaction with Anesthesia Scale. Patients received a form containing five sentences: "I'd like to have the same anesthesia again", "I felt pain", "I felt safe", "I felt pain during surgery", and "I was satisfied with my anesthetic care". In each sentence, they had to mark only one of two options: agree or disagree.[15]

Statistical analysis

The data were entered with double entry and verified with the "validate", Epi-info Program module, version 6.04 (WHO/CDC; Atlanta, GE, USA), to identify any inconsistencies. The Statistical Package for Social Sciences (SPSS) for Windows software, version 17.0 (SPSS Inc.; Chicago, IL, USA) was used for analyses.

Statistical analyses consisted of descriptive analyses using measures of central tendency and frequency, the Shapiro-Wilk test to verify the normality pattern of continuous variables, Pearson chi-square test or Fischer's exact test, and *t*-test for independent samples; *p*-value below 0.05 was considered statistically significant.

Ethics criteria

This Randomized Controlled Trial (RCT) was approved by the university ethics committee of Universidade Federal de Alagoas (Study number: 2,508,805). RCT Registration: https://ensaiosclinicos.gov.br/rg/RBR-5fn873. This study was conducted between March 2018 and January 2019 at Hospital*** and is in compliance with the Declaration of Helsinki. This trial was performed according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Financial statement

The research was carried out with the resources of the researchers themselves.

Results

Seventy patients scheduled for ambulatory anorectal surgery were eligible for the study and were randomly allocated to the SA or PB groups. Only 59 patients were included in the final analysis, as demonstrated in Fig. 1.

Characteristics of groups

Socio-demographic and clinical profiles did not vary between the groups. However, the surgical time was shorter in the PB group ($p = 0.000$) (Table 1).

Primary outcomes

The mean pain values were similar in the first 48 h in both groups, even when analyzed by type of surgery, regardless of the hemorrhoid grade. The highest mean pain was after 24 h (4.00 ± 2.70) and 1 h (3.20 ± 1.78) in the SA and PB groups, respectively (Table 2).

There was no difference in the incidence of pain in the first 24 h when the groups were subdivided into the following categories: absence of pain, major pain, and minor pain. However, there was a difference after 48 h (SA group: 85.2% without pain, 7.4% with minor pain, and 7.4% with major pain vs. PB group: 71.9% without pain, 28.1% with minor pain, $p = 0.048$). It is noteworthy that major pain was found earlier in the PB group (after 1 h and 5 h) compared to the SA group (after 10 h, 24 h, 48 h). When the incidence of pain was analyzed according to the type of surgery, there was only major pain in hemorrhoidectomy, which was similar between the groups (Fig. 2).

The individuals allocated to the SA group did not need anesthetic complementation; however, those in the PB group required it considerably (SA group, 0% vs. PB group, 25%; $p = 0.005$). Nevertheless, the need for anesthetic conversion did not differ between the groups (SA group, 0% vs. PB group, 9.4%; $p = 0.102$).

During all surgical times, the PB group showed lower MAP values (statistically significant after 5, 10, 15, and 20 min) and higher HR values (statistically significant after 5, 45, 50, and 55 min). Even when these hemodynamic changes were analyzed by the type of surgery, we found the same pattern for NIMAP changes in both hemorrhoidectomy (statistically significant after 5, 10, 15, and 20 min) and anal fistula surgery (statistically significant after 5, 10, and 15 min) (Fig. 3).

Secondary outcomes

The frequency of constipation (SA group, 59.3% vs. PB group, 40.6%; $p = 0.154$) and the incidence of pain at first evacuation (SA group, 54.5% [6/11] vs. PB group, 57.9% [11/19]; $p = 0.858$) evaluated after ambulatory discharge were similar between the groups. Mean pain at the first evacuation was also similar (SA group, 5.33 ± 2.33 vs. PB group, 4.27 ± 2.83; $p = 0.447$). Pain was more frequent among those who evacuated later regardless of the allocated group.

Only the PB group showed force limitation in the lower limbs, which occurred after 1 h (SA group, 0% vs. PB group, 3.1%; $p = 0.354$). Patients with strength limitations were only able to move their knees (partial motor block). After 3 h and 5 h, no difference (SA group, 0% vs. PB group, 0%) was observed. Difficulty in walking was only found in the PB group (9.4 %, $p = 0.102$) because they were drowsy.

The incidence of POUR after 3 h of the procedure was similar between the groups (SA group, 0% vs. PB group, 3.1% [1/32]; $p = 0.354$). In the PB group, one patient (female, 64 years old) underwent hemorrhoidectomy (surgical time of 25 min), and partially emptied the bladder without needing catheterization. Besides this case, none of the patients presented with POUR.

The incidence of nausea (SA group 0% $\times$ PB group 6.3%, $p = 0.186$) and vomiting (SA group, 0% vs. PB group, 3.1%; $p = 0.354$) was similar between the groups throughout the

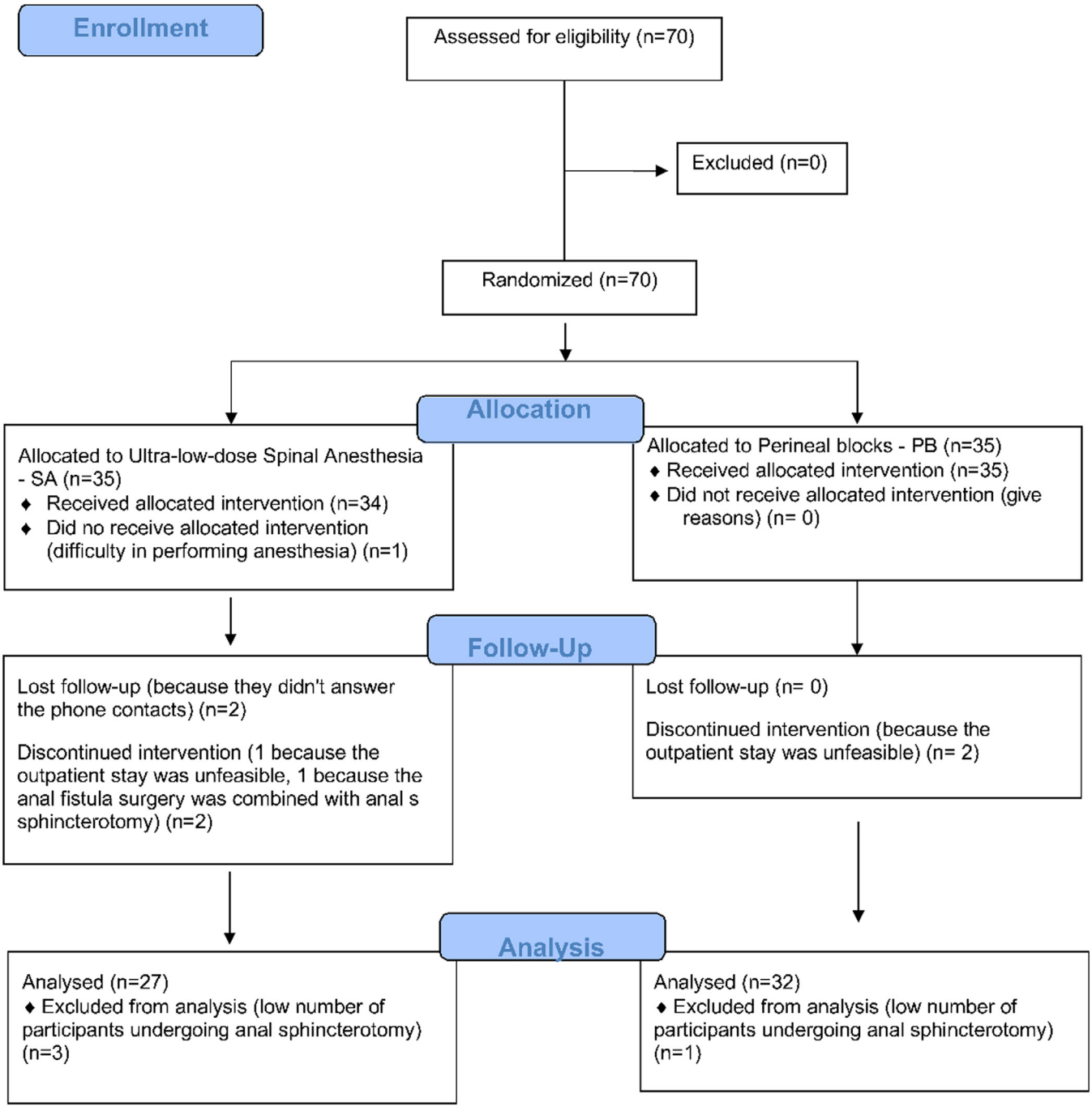


Figure 1 Flow diagram based on the Consolidated Standards of Reporting Trial (CONSORT) statement.

study, occurring only after 5h. One patient who experienced nausea vomited.

The incidence of discharge delay (SA group, 0% vs. PB group, 3.1%; p = 0.354) and unplanned hospital admission (SA group, 0% vs. PB group, 3.1%, p = 0.354) were similar between the groups. Both ambulatory discharge delay and unplanned hospital admission occurred because of bleeding related to patients' surgical condition. The results are summarized in Table 3.

Overall satisfaction with anesthesia was appropriate in both groups (>80%) and no significant differences were found between them.

Discussion

Ultra-low-dose spinal anesthesia and perineal blocks for anorectal surgeries can be performed in many ways using several drugs and in different amounts. The comparison presented in this RCT aimed for intense anesthetic reduction in the SA group and the association of blockades in the PB group to make the comparative analysis more equitable.

The intense reduction in the amount of local spinal anesthesia was motivated by the high rates of POUR associated with this technique, which were published without anesthetic methodological descriptions.[3]

Table 1 Sociodemographic and clinical profiles.

	SA Group (27)	PB Group (32)	*p*-value
Age – mean ± SD	46.4 ± 10.5	44.3 ± 12.5	0.489[b]
Sex, n (%)			0.197[a]
Male	66.7% (18)	50% (16)	
Female	33.3% (9)	50% (16)	
Schooling – % (n)			0.530[a]
Illiterate	11.1% (3)	12.5% (4)	
Incomplete elementary	22.2% (6)	21.9% (7)	
Complete elementary	14.8% (4)	9.4% (3)	
Incomplete high school	22.2% (6)	6.3% (2)	
Complete high school	25.9% (7)	40.6% (13)	
Incomplete superior	0%	3.1% (1)	
Complete superior	3.7% (1)	6.3% (2)	
Types of Surgery – % (n)			0.832[a]
Hemorrhoidectomy	63% (17)	65.6% (21)	
Anal fistula surgery	37% (10)	34.4% (11)	
ASA – % (n)			0.534[a]
I	66.7% (18)	71.9% (23)	
II	33.3% (9)	25% (8)	
III	0%	3.1% (1)	
BMI - mean ± SD	26.11 ± 5.41	26.69 ± 4.79	0.668[b]
Surgical Time – Méd. ± DP	43.2 ± 14.1	28.3 ± 14.3	0.000[b]

[a] (Pearson's qui-square).
[b] (*t*-test for independent samples).
AS, Ultra-low-dose Spinal Anesthesia; PB, Perineal Blocks; ASA, American Society of Anesthesiologists; SD, Standard Deviation; BMI, Body Mass Index.

Although the techniques are equivalent in terms of analgesia, SA was more effective than PB for hemorrhoidectomy and anal fistula surgery because of the lower incidence of anesthetic complementation and hemodynamic changes (hypotension and tachycardia). The incidence of side effects (limitation of strength in the lower limbs, difficulty in walking, POUR, PONV, and constipation), interference of anesthesia in ambulatory discharge, and user satisfaction in both techniques were similar.

There are conflicting reports regarding the best technique (perineal block or traditional spinal anesthesia) for controlling immediate postoperative pain.[3] In a previous study, local infiltration showed lower efficacy postoperative analgesia when compared to spinal anesthesia in hemorrhoidectomy surgery.[5] Unlike this study, in our research, local anesthesia was performed with double blockade, and SA was performed with a dose of LA which was four times lower, consequently, analgesia was similar in both groups.

Even when potentiating LA in the PB group and reducing the anesthetic dose in the SA group, resulting in ultra-low-dose spinal anesthesia, the incidence of general pain and pain at the first evacuation was low and similar between the groups.

Anesthetic complementation occurred only in the PB group and was significant, indicating that anesthesia is not always efficient. The tendency for more pain to appear earlier in the PB group strengthens these findings. The absence of anesthetic complementation in the SA group demonstrated effective anesthesia and the tendency for major pain to appear late strengthens the need for optimization of postoperative analgesia.

Postoperative analgesics may cause pain interpretation bias. For ethical reasons, the same pain protocol was applied to both groups. The multimodal preventive association of analgesics at the end of surgery was used[5] aiming to improve recovery after surgery (enhanced recovery after surgery).[6]

The absence of hemodynamic changes in the SA group resulted from the low dose of the local intrathecal anesthetic. The hemodynamic changes observed in the PB group can be due to the propofol infusion necessary to perform the blockade in an extremely innervated region. An additional contribution to this situation could arguably have been the absorption of local anesthetics. Although propofol does not have analgesic properties, those receiving high doses of this drug may experience a decrease in response to painful stimuli. Dose-dependent hypotension is the most common complication and occurs due to vasodilation (sympathetic activity decreases by direct effect on intracellular influx of calcium and sodium from smooth muscle and mediated by increased release of nitric oxide by the vascular endothelium). Propofol inhibits the baroreceptor reflex and, consequently, reduces the physiologic elevation of heart rate in response to hypotension.[16] This may justify a statistically significant hypotension initially, when the vasodilator effect was maximum, and statistically significant tachycardia later, when the effect on baroreceptors may not have been strong.

Ultra-low-dose spinal anesthesia has been used in other studies of anorectal surgery. Intrathecal 2.5 mg hyperbaric levobupivacaine plus 12.5 μg or 25 μg fentanyl was used, which resulted in good quality anesthesia without motor block and the need for supplementary analgesia during

Table 2 Average postoperative pain.

	All surgeries			Hemorrhoidectomy			Anal fistula surgery		
	SA Group (27) Mean ± SD (n)	PB Group (32) Mean ± SD (n)	*p*-value	SA Group (17) Mean ± SD (n)	PB Group (21) Mean ± SD (n)	*p*-value	SA Group (10) Mean ± SD (n)	BP Group (11) Mean ± SD (n)	*p*-value
T0	–	–	–	–	–	–	–	–	–
T1	–	3.20 ± 1.78 (5)	–	–	3.75 ± 1.50 (4)	–	–	1.00 (1)	–
T3	2.50 ± 0.70 (2)	1.83 ± 0.98 (6)	0.420	3.00 (1)	1.60 ± 0.89 (5)	0.226	2.00 (1)	3.00 (1)	–
T5	1.83 ± 0.75 (6)	2.00 ± 1.54 (6)	0.817	1.83 ± 0.75 (6)	2.00 ± 1.54 (6)	0.817	–	–	–
T10	3.25 ± 1.66 (8)	1.66 ± 0.81 (6)	0.055	3.42 ± 1.71 (7)	1.75 ± 0.95 (4)	0.109	2.00 (1)	1.50 ± 0.70 (2)	0.667
T24	4.00 ± 2.70 (4)	1.75 ± 0.95 (4)	0.168	4.00 ± 2.70 (4)	1.33 ± 0.57 (3)	0.162	–	3.00 (1)	–
T48	3.25 ± 2.87 (4)	1.88 ± 0.92 (9)	0.209	3.25 ± 2.87 (4)	1.85 ± 0.89 (7)	0.252	–	2.00 ± 1.41 (2)	–

p-value (*t* test for independent samples).
SA, Ultra-low-dose Spinal Anesthesia; PB, Perineal Blocks; SD, Standard Deviation; (n), Number of participants. T1, T3, T5, T10, T24, T48 correspond to the times 1h, 3h, 5h, 10h, 24h and 48h postoperatively.

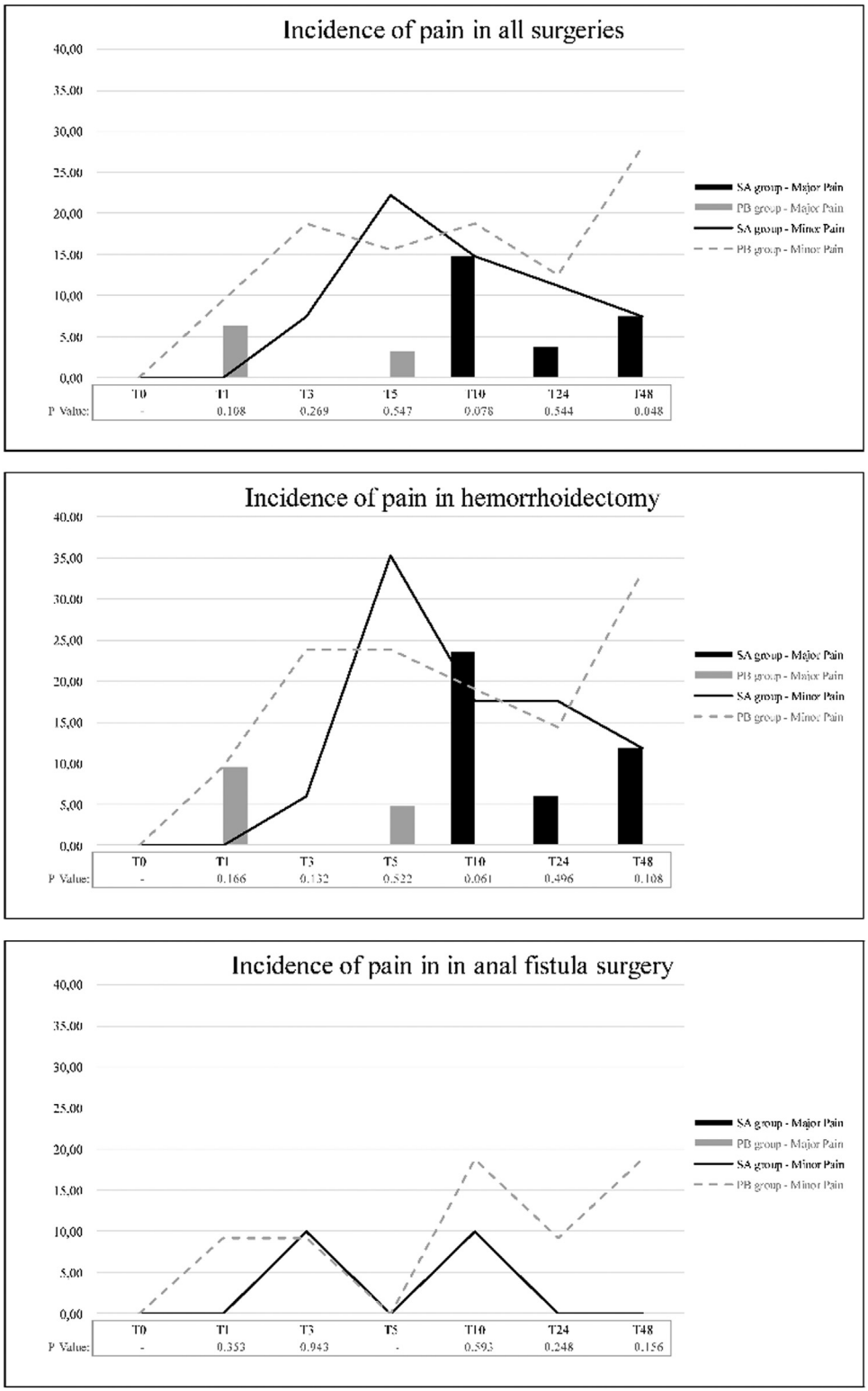
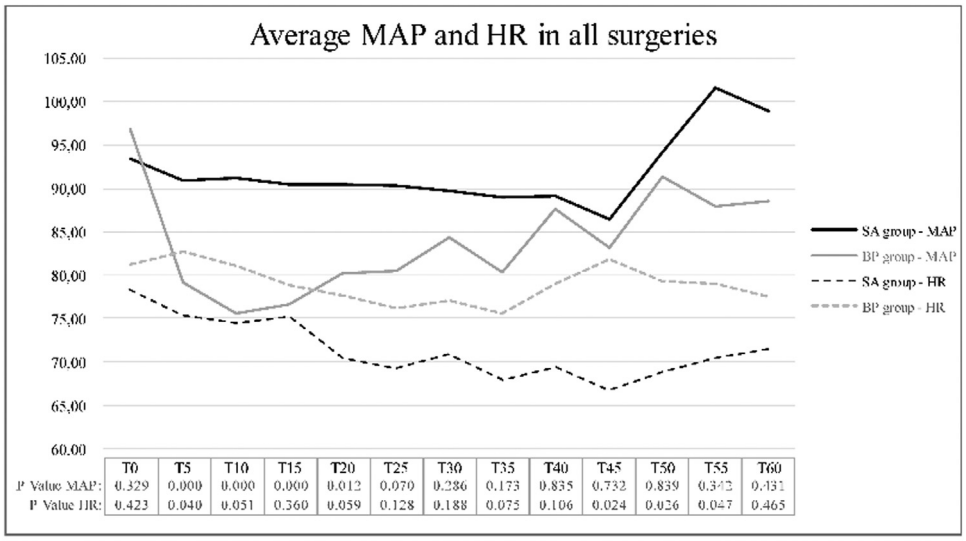
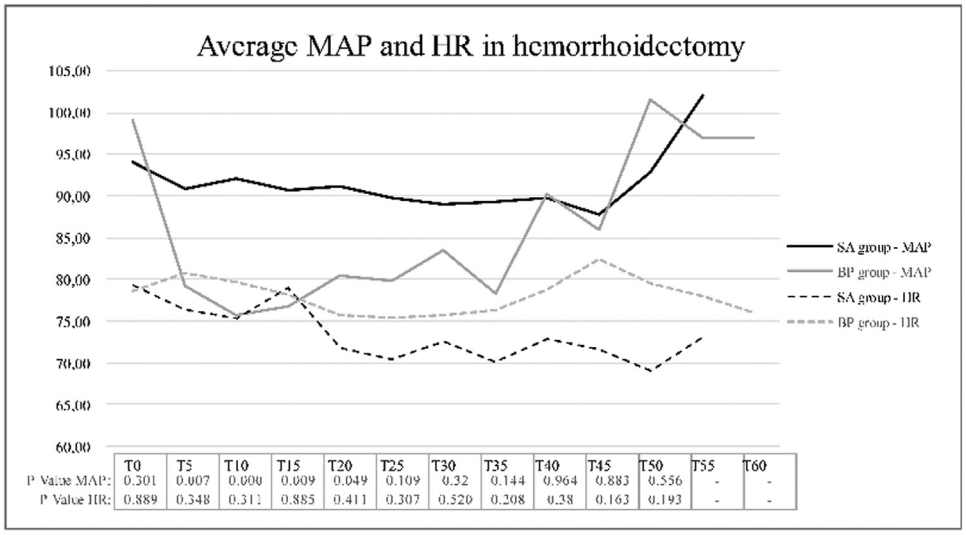


Figure 2 Incidence of pain (%) subdivided into categories in all surgeries, in hemorrhoidectomy and in anal fistula surgery; *p*-value (Pearson Chi-Square). Minor pain: VAS = 1 to 3. Major pain: VAS = 4 to 10. VAS, visual analog scale.

surgery.[17] In our study, we used equivalent doses of bupivacaine, which resulted in the absence of anesthetic complementation and residual motor block, and low incidence of POUR, which is the main side effect of benign anorectal surgeries (20—48% in anorectal surgeries).[4]

The intense reduction in intrathecal bupivacaine associated with the described management of the technique (urinary disposal before the procedure, restriction of intravenous fluids, and supine position with 25° cephaloaclive for eight minutes after spinal anesthesia) provided low





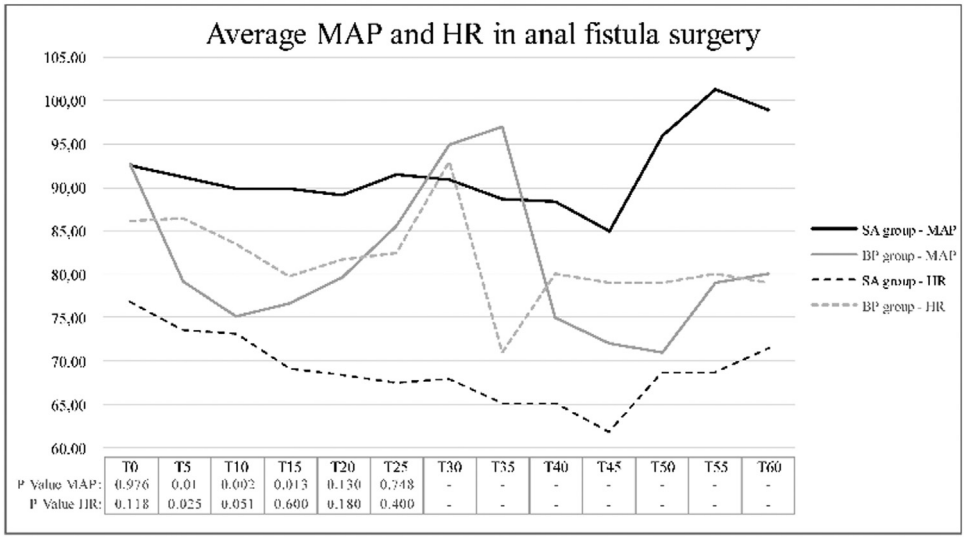


Figure 3 Average Mean Arterial Pressure — MAP (mmHg) and Heart Rate — HR (bpm) in all surgeries, hemorrhoidectomy, and anal fistula surgery.

Table 3 Secondary results.

	SA Group (27)	PB Group (32)	*p*-value
Incidence of constipation	59.3% (16/27)	40.6% (13/32)	0.154
Incidence of pain at first evacuation	54.5% (6/11)	57.9% (11/190	0.858
Average pain when first evacuating	5.33±2.33 (6)	4.27±2.83 (11)	0.447
Strength limitation in LL – T1	0%	3.1% (1/32)	0.354
Difficulty walking	0%	9.4% (3/32)	0.102
Incidence of POUR	0%	3.1% (1/32)	0.354
Incidence of nausea	0%	6.3% (2/32)	0.186
Incidence of vomit	0%	3.1% (1/32)	0.354
Ambulatory discharge delay	0%	3.1% (1/32)	0.354
Unplanned hospital admission	0%	3.1% (1/32)	0.354

p-value (pearson's Qui-Square).
SA, Ultra-low-dose Spinal Anesthesia; PB, Perineal Blocks; LL, Lower Limbs; POUR, Postoperative Urinary Retention.

incidence of POUR by interfering with consecrated factors such as intrathecal amount/dispersion of local anesthetic[17] and intravenous administration of fluids, associated with this side effect.[2,4]

Residual motor block after spinal anesthesia is a factor associated with urinary retention because detrusor blocks last longer than motor blocks.[4] In our intervention, all patients presented with preserved strength in the lower limbs after 1 h and 3 h, full flexion of knees and feet, according to the Bromage classification.[18] And all patients were able to walk after 3 h. This evidences a rapid return to the condition prior to anesthesia. However, 9.4% of patients in the PB group experienced difficulty walking due to drowsiness, taking longer to return to the condition prior to anesthesia. This was due to the slow redistribution of propofol to the highly fat-soluble peripheral compartment.[19]

Spinal anesthesia is associated with POUR in anorectal surgeries[1,4,6] and hemorrhoidectomy.[3] Our study found no statistically significant difference in the incidence of POUR between the groups.

Multiquadrant hemorrhoidectomy and multiple concomitant anorectal procedures have demonstrated consistently higher rates of urinary retention.[2] Our study did not include a distinct analysis of quantitative quadrants treated with hemorrhoidectomy but identified higher levels of pain in patients with grade IV hemorrhoids at 5 h and 10 h, regardless of the allocated group ($p > 0.05$).

The adoption of a preoperative urination routine and transoperative water restriction due to the proposed intervention in SA may have led to the misdiagnosis of POUR, since there could be no time for bladder filling and consequent diuresis. In addition, ultrasound diagnosis is more accurate in estimating bladder volume.[4] However, even with the adoption of such measures, SA did not differ from PB regarding the incidence of POUR.

Although ambulatory discharge delay can be defined as a delay of more than 12 h after a medical intervention, the purpose of this study was not to justify the permanence of patients in a health service longer than this time, in addition to being followed by telephone contact.

The literature points out that local anesthesia in anorectal surgery is associated with a decrease in postoperative nausea, reduced constipation rate, and increased patient satisfaction with spinal anesthesia.[6] In our study, the incidence of constipation, PONV, and degree of satisfaction did not differ between the groups. The intense reduction of LA in the SA group avoids hypotension, often found after conventional spinal anesthesia, and the consequent PONV and poor satisfaction, which may justify these findings.[20,21]

This study had a few limitations. Firstly, the absence of analysis of intravenous opioid consumption for rescue analgesia in the postoperative period until discharge. Secondly, the clinical diagnosis of POUR is less accurate than when performed via ultrasound technique. Thirdly, the control group received a large infusion of propofol. Fourthly, the mean surgical time values were different between the groups. The shorter surgical time in the PB group can be explained by the fact that the surgeries were performed by different surgeons during this study on effectiveness and safety, which could influence pain-related outcomes as prolonged surgeries can be related to worse pain outcomes. Since the surgical time was longer in the SA group, the difficulty in controlling pain among these patients was probably higher. In the future, further RCTs addressing these issues would help in precisely establishing the magnitude of the effect of the SA technique.

Conclusion

Ultra-low-dose spinal anesthesia and perineal blocks are similarly effective in pain control during the first 48 hours after hemorrhoidectomy and anal fistula surgery. Although surgical time was shorter among patients in the PB group, the SA technique may be preferable as it avoids the need for additional anesthesia. Furthermore, it is worth noting that the group that received perineal blocks was under sedation with a considerable dose of propofol. Further research addressing this issue may help to identify additional advantages of the SA technique.

Clinical trial number

This randomized clinical trial – RCT was approved by the ethics committee of the Federal University of Alagoas and the study number was 2,508,805. After the inclusion of new election criteria, it was approved by the same committee and the study number was 2,857,891. RCT Registration: https://ensaiosclinicos.gov.br/rg/RBR-5fn873.

Declaration of Competing Interest

The authors declare no conflicts of interest.

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