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Research Article

Hypobaric Bupivacaine 0.1% (5 mg) for Dorsal Anorectal Surgery Compared with Hyperbaric Bupivacaine 0.5% (5 mg) for Anorectal Lithotomy Surgery on an Outpatient Basis

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ABSTRACT

Background: A wide variety of anorectal surgeries can be performed on an outpatient basis. The purpose of study was to compare low dose 0.1% bupivacaine in jack-knife position with 0.5% bupivacaine lithotomy position in outpatient anorectal surgical.

Methods: Two groups of 50 patients, physical status ASA I and II, undergoing anorectal surgical procedures in a jack-knife position, received 5 mg of hypobaric 0.1% bupivacaine in the surgical position or 5 mg of hyperbaric 0.5% bupivacaine in the sitting position. Sensitive and motor blockade, proprioception at the big toe, time of first, duration of blockade and surgery, complications, fasting time, and reintroduction of oral feeding in the PACU and POUR. Patients were followed until the third postoperative day and questioned whether they experienced post-puncture headache or temporary neurological symptoms, and until the 30th day and questioned about permanent neurological complications. The p-value ≤ 0.05 was considered significant.

Results: All patient in Group 1 presented selective blockade of the posterior sacral nerve roots, while patients in Group 2 experienced blockade of the anterior and posterior nerve roots in 33 patients. The onset time of anesthesia was the same with both solutions. There was evidence that de hyperbaric bupivacaine resulted in a longer duration of the block. Proprioception in the 1st toe was observed in 47 patients at 15 minutes in group 1 versus 20 patients in group 2, with significant difference. At end of surgery all patients passed the operating table to the stretcher without help. There were no hemodynamic changes, nausea, or vomiting, POUR, or neurologic complications. Analgesia with pudendal nerve block averaged 19 hours without need for opioids.

Conclusions: Anorectal surgical procedures under spinal block with low dose hypobaric or hyperbaric bupivacaine, in jack-knife position or lithotomy position on an outpatient basis can be safety and efficacy.

Keywords: Local, Bupivacaine, Regional, Hypobaric Spinal Block, Hyperbaric Spinal Block, Pudendal Nerve Block, Surgery, Anorectal.

Introduction

Reducing unnecessary health expenditures is an important objective in good and bad economic times. Day surgery has many advantages for patients and their families, hospitals, and the healthcare system. The introduction of minimally invasive surgical procedures resulting in less tissue damage and post-operative pain has increased the potential for day surgery. Loco-regional techniques provide superior pain control but may be more time consuming and require more expertise.

A wide variety of anorectal surgeries can be performed on an outpatient basis, including condyloma, fissure, abscess, fistula, hemorrhoids, pilonidal disease, and some tumors are amenable to outpatient surgery [1]. The three primary positions used in anorectal surgery include dorsal lithotomy, left lateral decubitus, and prone position. Of note, all three described positions for anorectal surgery are well tolerated with an extremely low rate of associated complications. Positioning during surgery is essential in three aspects: ease and adequate exposure, types of anesthesia with airway maintenance and complications related to the position used [2].

Conventional spinal anesthesia may be undesirable for such procedures due to prolonged lower limb motor block with consequent change to unplanned hospital admission [1]. Modification of spinal anesthetics using short acting local anesthetic or lower concentrations of long acting ones is useful or change of the basicity is useful based on the position was successful. Isobaric solutions can be performed in both the lithotomy position and the prone position [3]. Hypobaric solutions should be used in the jack-knife position [4,5] and hyperbaric solutions in the lithotomy position [5].

A study was conducted comparing 6 mg of 0.15% hypobaric bupivacaine in a jack-knife position, with 6 mg of hyperbaric 0.5% bupivacaine in the sitting position for 5 minutes, after which they were placed in a jack-knife position [5]. Every patient in the spinal hypobaric bupivacaine in the jack-knife position had selective blockade of the posterior sacral nerve roots, while patients in the spinal hyperbaric bupivacaine in the sitting position experienced blockade of the anterior and posterior nerve roots. Sensory blockade was significantly higher and motor blockade was significantly less severe in hypobaric groups. Forty-nine patients (2%) in hypobaric bupivacaine were transferred to the stretcher unassisted while only 40 (20%) in hyperbaric bupivacaine were able to do so. There was not statistically difference in block recovery. There were no hemodynamic changes, nausea or vomiting, urine retention, or post-puncture headache.

However, low spinal anesthesia doses depend on individual response and some patients may not obtain adequate anesthesia. The purpose of the present study was to compare low dose 0.1% hypobaric bupivacaine with the patient in the prone jack-knife position with low dose of 0.5% hyperbaric bupivacaine with the patient in lithotomy position for spinal anesthesia for anorectal surgery, to determine their characteristic particularly with respect to selective sensory and motor block, quality of surgical condition and subsequent recovery in outpatient anorectal surgical. Postoperative analgesia was performed with pudendal block with the aid of a neurostimulator [6].

Methods

After approval by the Ethics Committee (0869/2009) and informed consent, 100 ASA physical status I and II patients, aged 20 to 60 years, scheduled for outpatient anorectal surgery in the prone jack-knife position or lithotomy position were enrolled in this randomized double-blind study. Exclusion criteria were neurological or neuromuscular diseases, infection at the intended site of spinal needle insertion, hypersensitivity to amide local an aesthetic and refusal of the proposed method. The sample sizes estimated to detect a motor block mean time at least 5 minutes less when bupivacaine 0.15% hypobaric is used, based on a at most 9 minutes standard deviation and a 90% power at a significance level α=0.05, were of at least 100 patients, 50 in each group.

As part of Program ACERTO, all patients drank a single 200 mL liquid oral hypercaloric nutritional supplement (1.5 Kcal/ml) without residue, clarified and without addition of lipid and fiber (Fresubin Jucy®) about 2 to 4 hours before surgery and after the end of the spinal block in the PACU. The fasting times were noted before and after surgery.

The ECG and pulse oximetry were continuously monitored, and measurements of heart rate and blood pressure were recorded. Patients were not premedicated. An IV infusion of lactated Ringer's solution was begun on arrival in the operating room, but no fluid loading was used before spinal anesthesia. Patients received 1 µg/kg of fentanyl IV several minutes before positioning for lumbar puncture. Minimum fluid volume was intravenously injected in the intraoperative period, always below 500 ml.

Randomization was carried out with a computer-generated schedule, followed by preparation of coded envelopes. Bupivacaine 0.1% hypobaric (specific gravity at 37°C of 0.99726 g/ml) were prepared as from 5 mg (1 ml) 0.5% isobaric bupivacaine (specific gravity at 37°C of 0.99940 g/ml) plus 4 ml sterilized bi-distilled water [7]. Bupivacaine 0.5% hyperbaric (specific gravity at 37°C of 1.02360 g/ml) commercially prepared [8]. Patients were randomly assigned to receive 5 ml (5 mg) of hypobaric bupivacaine (Group 1) or 1 ml (5 mg) of hyperbaric bupivacaine (Group 2).

After cleansing the skin with alcoholic chlorhexidine, subarachnoid puncture was done with the patient in the prone jack-knife position with a 25 cm pillow placed under the abdomen or lithotomy position. A midline approach at L3-L4 was used after subcutaneous local anesthetic infiltration with lidocaine 1%, using a 27G Quincke without introducer. After appearance of CSF to confirm needle placement, 5 ml of hypobaric bupivacaine at 1 ml/15 or 1 ml of hyperbaric bupivacaine at the same speed were administered.

lockade onset was evaluated by loss of sensitivity in the buttocks immediately after the injection of both bupivacaine by pinprick using the stylet of the needle. Light touch was assessed with a cotton wool wet in alcohol along the mid-axillary line, outer aspects of the thigh, leg, and foot. Proprioception was tested at the big toe by asking the patient to identify movements of the toe without looking. The proprioception and sensitive block were then evaluated by another anesthetist at 15 and 60 minutes after spinal block. Assessment of the sensitive block (Figure 1) and the motor blockade was done at 15 and 60 minutes after spinal block, using the modified Bromate scale (0 to 3): 0 = free movement of the lower limbs; 1 = unable to raise extended limb; 2 = unable to bend the knee; 3 = unable to move the ankle. The duration of block was defined as the length of time it took for the patient to regain perineal sensibility. Surgery duration was defined as the time

from puncture to the end of surgery. Hemodynamic parameters were evaluated every five minutes in the first 15 minutes, and every ten minutes until the end of the surgical procedure. The incidence of postoperative urinary retention (POUR) was also assessed.

Hypotension was defined as a reduction in systolic blood pressure greater than 30% of baseline values. Bradycardia was defined as a reduction in heart rate below 50 bpm. Every patient received oxygen (3 l/min) through a Hudson mask. Sedation during the procedure was maintained with small doses of midazolam (0.5 to 1 mg). Fentanyl (50 μg) would be administered if the patient complained of discomfort.

At the end of the surgery, bilateral pudendal nerve block was performed with the patient in jack-knife or lithotomy position under spinal anesthesia, by the transperineally approach in each side. The bilateral pudendal nerve was located with the aid of a nerve stimulator, using the short bevel isolated needle (100 mm). The direction was perpendicular to the skin in a horizontal and sagittal plan, and the proximity of the nerve was demonstrated by anal sphincter contraction; 20 ml of 0.25 percent levobupivacaine (S75:R25) was injected in each side, with analgesia time being recorded. After bilateral pudendal block, the patient's ability to move from the operating table to the transport stretcher without assistance from the operating room staff was assessed.

After the operation, patients were transferred to the post-anesthetic care unit (PACU) for continuous monitoring of vital signs and regression of block. Before being discharged from the hospital, an Anaesthesiology resident recorded the patient's satisfaction with the technique that was classified as good, satisfactory, or bad. Patients were discharged when they were awake, able to walk unaided, and had stable signs for at least 1 h. Follow-up of the patients at home was done using a questionnaire asking about post-Dural puncture headache (PDPH) or any transitory neurological symptom (TNS), and up to the 30th day regarding any permanent neurological complication.

Statistics

Results are presented as mean (sd) or median (iqr: interquartile range) for quantities variables, and as count (%) for categorical ones, as recommended. Quantitative variables were compared by Wilcoxon-Mann-Whitney test, Kolmogorov-Smirnov test, and Two-Way ANOVA. To verify the use of Two-Way ANOVA, we tested the normality of the data using the Shapiro-Wilk test and we tested the equality of variances between the groups using the Levene's test. Qualitative variables era tested using Fisher's Exact Test. Differences were taken as significant when p-value ≤ 0.05.

Results

One hundred and seventeen patients participated in the study and after using the exclusion criteria 100 patients were included in the final study. Patient recruitment and flow are summarized in (Figure 2).

The demographics data are shown in (Table 1). None complained of perineal discomfort. No patient needed a rescue dose of fentanyl.

(Table 2) shows the onset time, duration of surgery and duration of block, time of intake of CHO drink before surgery in the ward and after surgery in the PACU. There was evidence that the onset time of Anesthesia was practically the same with both solutions and

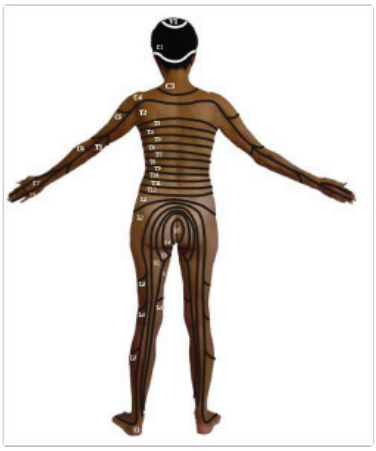

Figure 1: Dermatome Distribution of the Various Nerve Roots.

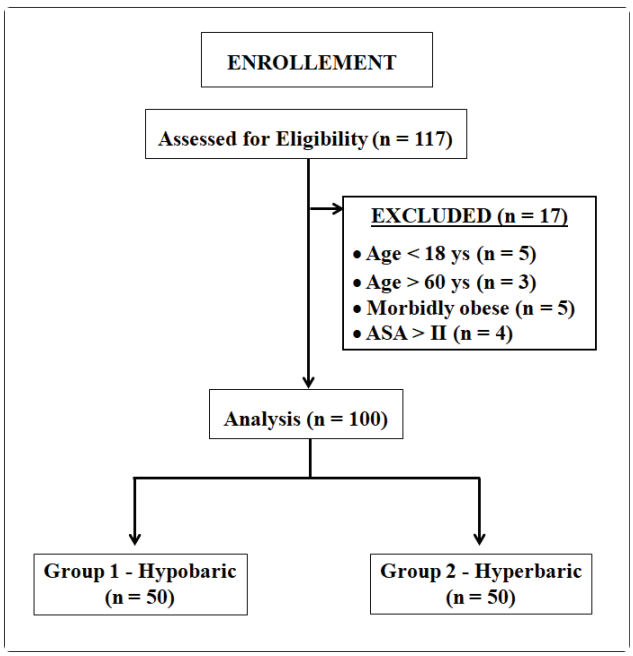

Figure 2: Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

the same dose (5 mg) and different volumes. Using the Wilcoxon-Mann-Whitney test, it shows that the average duration of surgery is significantly different for both groups (p = 0.005483).

The (Figure 3) shows that the duration of the surgery was longer with the hypobaric solution. There was evidence that de hyperbaric bupivacaine resulted in a longer duration of the block (p = 0.0000). The average fasting time before surgery was 2:49±0:29 hours and the introduction of the CHO drink in the PACU was 1:07±0:17 h with no difference between groups.

(Table 3, 4) show the evaluation of the sensory blockade in times of 5, 15 and 60 minutes after injection of the local anesthetic. There is a significant association between time and cephalad dispersion within groups. The Cochran-Mantel-Haenszel test suggests a significant association (p = 0.0000), with a degree of association through the

McFadden-Puig-Kerschnfer performance measure, with a value of 0.50 (Figure 4).

In the group that received 0.1% hypobaric bupivacaine, the absence of motor blockade (grade 0) was observed in all patients at 5, 15 and 60 minutes, against 39 patients at 5 minutes, 17 patients at 15 minutes and 30 patients at 60 minutes with 0.5% hyperbaric bupivacaine solution. There is a significant difference in the degree of motor block in the three periods evaluated being more intense in group 2 (hyperbaric solution) (p=0.0000367).

Proprioception in the 1st toe was observed in 47 patients at 15 minutes in group 1 versus 20 patients in group 2, with significant difference (p=0.0000 Fisher Exact test). At 60 minutes, all patients with the hypobaric solution reported proprioception in the 1st toe against 37 patients with the hyperbaric solution, with significant difference (p=0.0000 Fisher Exact test).

Regardless of whether the solution was hypobaric or hyperbaric, the dose of 5 mg of bupivacaine showed in this study that all patients passed the operating table to the stretcher without help at the end of the surgery.

There was no case of hypotension or bradycardia in any patients at a dose of 5 mg with both bupivacaine solutions. None of the patients developed post-spinal headache, nor nausea and vomiting in the PACU and in the residence. There was no report of urinary retention from the day-surgery unit. In the post-operative interviews, no complaints of TNS after discharge were offered. There was no significant difference in the satisfaction item among the groups. Postoperative analgesia with bilateral pudendal nerve block under spinal Anesthesia has resulted in mean 19±4 hour's analgesia without need for opioids in all patients.

Table 1: Patients Data.

Variables	Group 1 Hypobaric	Group 2 Hyperbaric	P-Value
Age (years)	43.16±9.79	38.92±11.56	0.09424*
Weight (kg).	69.92±13.09	69.04±17.53	0.5324*
Height (cm)	167.06±9.20	163.46±6.49	0.0218*
Gender (M/F)	27 / 23	16 / 34	0.04282**

* Wilcoxon-Mann-Whitney test
** Fisher's Exact test

Table 2: Parameters Evaluated.

Variables	Group 1 Hypobaric	Group 2 Hyperbaric	P-Value
Onset time (min)	2:00±0:27	1:53±0:24	0.07899*
Surgery duration (min)	34.1±6.6	30.7±4.3	0.005483*
Block duration (min)	62.7±7.1	96.7±8.3	0.0000*
CHO before surgery (h)	2:54±0:28	1:08±0:16	0.03582*
CHO in PACU (h)	2:43±0:30	1:07±0:19	0.8006*

* Wilcoxon-Mann-Whitney test

Table 3: Cephalic Dispersion of Analgesia.

	5 min	15 min	60 min	P-Value
Hypobaric				
L2	2	0	3	
L1	22	2	15	
T12	26	30	20	
T11	0	14	11	
T10	T0	4	2	0.0000*
Hyperbaric				
L2	13	0	27	
L1	37	24	21	
T12	0	26	2	

*** Cochran–Mantel–Haenszel Test for 3-Dimensional Tables**

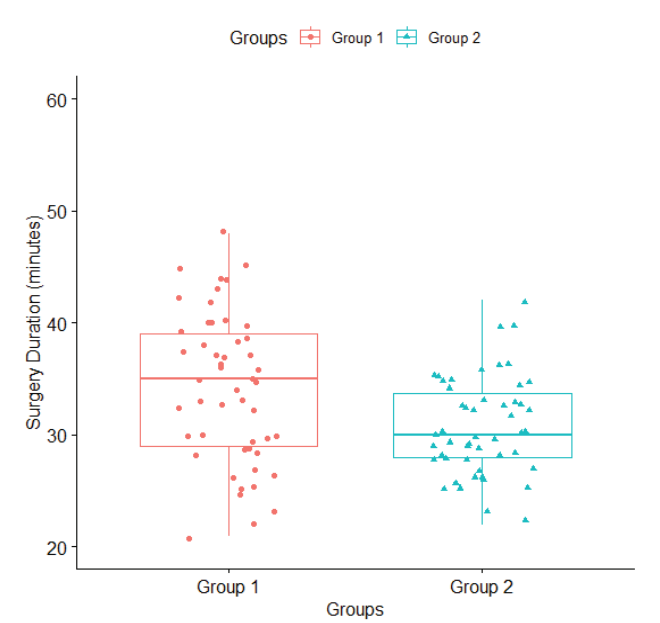

Figure 3: Surgery Duration (minutes).

Figure 4: Cephalad Dispersion of Analgesia in 5, 15 and 60 minutes.

Discussion

Low dose of 0.1% hypobaric bupivacaine (5 mg), administered in the jack-knife position, exclusively blocked the posterior (sensitive) roots in all patients at the three evaluated times. This dose provided proprioception in the 1st toe in 47 patients. The same dose of 0.5% hyperbaric bupivacaine administered in lithotomy position,

promoted posterior and anterior root block (sensitive and motor) in 33 (66%) patients at 15 minutes of evaluation, and resulting in the presence of proprioception in the 1st toe in only 20 patients. Despite the same dose (5 mg) but in different volumes (5 ml vs 1 ml) it provided the same cephalic dispersion (Mode =T12) with both solutions. This suggests that 5 mg of hypobaric (0.1% bupivacaine) or hyperbaric (0.5% bupivacaine) drug is adequate to produce a sensory level necessary for anorectal procedures.

For orifice surgeries the technique in the lithotomy position is practically used low doses of hyperbaric anesthetics with or without adjuvants [5,10]. For the same surgery in the supine position, the use of hypobaric anesthetics is a consensus. Thus, the most used hypobaric anesthetics are: 0.6% lidocaine [4], 0.15% bupivacaine [5], 0.1% bupivacaine [7] and 0.1% ropivacaine [11].

The 0.1% bupivacaine solution was chosen because it guarantees hypobaricity [7] significantly lower than the 0.15% bupivacaine solution [8]. By definition, baricity is the relationship between the density of the injected solution and the density of the CSF. The average density of the CSF is 1.00059±0.00020 g/ml [8]. The baricity of local anaesthetics can be reduced by diluting with distilled water [7]. The 0.5% bupivacaine with 8% glucose solution is hyperbaric for all patients [8]. The baricity of 0.1% bupivacaine is 0.99726±0.00232 at 37oC, being hypobaric for all patients. This fact was confirmed when all 50 patients had pure sensory block (blockade only the posterior roots) and presence of proprioception in 47 patients when blocked in prone position, against 33 patients with some degree of motor block and 20 patients with proprioception with the hyperbaric solution in the lithotomy position.

In a previous article for anorectal surgery comparing 6 mg of 0.15% hypobaric bupivacaine in jack-knife position promoted exclusively blocked of the posterior (sensitive) roots in 84% of the patients, already with the same dose of 0.5% hyperbaric bupivacaine in the lithotomy position, it promoted blocked of the posterior and anterior roots (sensory and motor) in all patients for anorectal surgery [5]. In the present study, decreasing the concentration of bupivacaine to 0.1% hypobaric and the dose to 5 mg was observed blockade only the posterior roots in all patients, while with the same dose of 0.5% hyperbaric blockade of both (anterior and posterior) roots was observed in 66% of patients.

Determining a model of the ideal dose of bupivacaine for spinal Anesthesia in outpatient surgery based on data from systematic review, a dose of bupivacaine between 5 and 7.5 mg can be used in this setting without a risk of abnormal prolongation of hospital stay [12]. This was shown in this article using 5 mg of hypobaric or hyperbaric bupivacaine being discharged on the same day in all patients, to the satisfaction of all patients.

Opioids (morphine, fentanyl, sufentanil), clonidine, dexmedetomidine and ketamine, have been used as adjuvants to local anaesthetics to provide better quality in spinal Anesthesia. These adjuvants have been reported to provide superior postoperative analgesia but are associated with higher rates of opioid-induced adverse effects, including pruritus, PONV and postoperative urinary retention [13]. For ambulatory surgery, spinal anaesthesia supplemented by early oral analgesia and locoregional techniques makes the routine addition of intrathecal opioids unnecessary.

The postoperative pain after anorectal surgery is severe, requiring the use of IV opioids, which are commonly used in hospitals. Studying bilateral pudendal block with 0.25 bupivacaine with the help of a neurostimulator provided an average analgesia of 23.4 hours with low need for opioids, without local or systemic complications, and without urinary retention [14]. In the present study using the same technique with levobupivacaine (S75:R25) provided an average 19-hour analgesia without need for opioids in all patients.

In a recent review, it was demonstrated that the anesthetic technique does not influence of POUR [15]. However, the type of surgery, the volume of liquid administered during surgery, the surgical time, and the use of opioids in spinal Anesthesia can have a significant impact on POUR [15]. In the present study in anorectal surgery with a dose of only 5 mg of bupivacaine (hypobaric or hyperbaric), either in the jack-knife or lithotomy position, with abbreviation of fasting, administration of less than 500 ml of lactated Ringer, and analgesia with bilateral pudendal block, no case of POUR was observed.

Preoperative patient education is an essential component of any ERAS [16] and ACERTO program for fast track surgery [17, 18]. Preoperative patient education and preparation has positive effects on outcomes such as pain, psychological distress, and indices of recovery, including hospital stay, even if the intervention is relatively brief and not individualized. In this study, the average fasting time was 2:49 hours in all patients. The reintroduction of the drink with CHO in the PACU averaged 1:07 hours in all patients. Results similar to previously published works [17, 18]. The use of 200 mL of a single liquid oral hypercaloric nutritional supplement without residue in an average of 2:49 h before surgery allowed the reduction of volume replacement during the surgical procedure.

Conclusion

Anorectal surgery may be safely and cost-effectively performed in an ambulatory surgery center with grade de recommendation 1B [19]. And may be safely discharged home following post anesthesia care with the same degree of recommendation [19]. This prospective study demonstrated the safety and efficacy of the spinal block with low doses of hyperbaric bupivacaine for anorectal surgery in lithotomy position or hypobaric bupivacaine for anorectal surgeries in a jack-knife position on an outpatient basis. The decrease from 0.15% to 0.1% hypobaric bupivacaine in posterior spinal anesthesia allowed anesthesia of only sensitive fibers in all patients without any degree of motor block, with the presence of proprioception in 94% of patients. Different from the same dose of 0.5% hyperbaric bupivacaine in the lithotomy position (saddle spinal anesthesia) resulted in a blockage of both roots (sensitive and motor) in 66% of the patients, with proprioception in only 40% of the patients. This technique was suitable for every procedure and patient.

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