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Influence of Sitting Puncture Position Compared to Lateral Decubitus on 0.5% Isobaric Levobupivacaine in 50% Enantiomeric Excess (S75:R25) Solution for Orthopedic Surgery. Retrospective Study

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Abstract

Background: The commercially used bupivacaine is presented as a racemic mixture of RS (±) bupivacaine, the levorotatory enantiomer S (-), levobupivacaine, which is less toxic to the central nervous system and cardiovascular system than R (+) bupivacaine. In Brazil, there is 0.5% isobaric levobupivacaine in 50% enantiomeric excess (S75:R25), which has been used since the last century. The aim of this retrospective study was to evaluate a fixed dose of this substance injected into the lumbar subarachnoid space in two different positions: sitting and lateral decubitus, in orthopedic patients.

Methods: The study included 603 patients aged 18 to 60 years, ASA physical status I and II, scheduled for lower limb orthopedic surgeries under spinal anesthesia. The patients received a fixed dose of 15 mg of 0.5% isobaric S75:R25 and were randomly divided into two groups according to the puncture position of the subarachnoid space: SIT group and LLD group. The following parameters were evaluated and compared: analgesia latency, motor blockade, duration of effects, cephalad dispersion of analgesia, cardiovascular changes and neurological complications.

Results: The latency of analgesia was the same regardless of the puncture position. The isobaric solution of S75:R25 showed hypobaric behavior. Cephalic dispersion was significantly higher with puncture in the SIT group compared with the LLD position. The quality of motor blockade was the same in both groups. There was no significant difference in cardiocirculatory parameters. There were no reports of neurological complications.

Conclusion: The enantiomeric mixture of 75% levobupivacaine with 25% dextrobupivacaine, 0.5% isobaric, injected into the subarachnoid space in the SIT and LLD positions, produces sensory and motor blockade like that for orthopedic surgeries.

Keywords: Local Anesthetic; S75:R25; Regional Anesthesia; Spinal Anesthesia

Abbreviations: LA: Local Anesthetics; LLD: Left Lateral Decubitus; SIT: Sitting Position; CSF: Cerebrospinal Fluid; TNS: Transient Neurologic Symptoms

Introduction

Following reports of cardiac arrest during etidocaine and bupivacaine anesthesia, attention has been drawn to the need for safer anesthetics, particularly for epidural and peripheral blocks [1]. Most marketed substances are presented as racemic mixtures, despite knowledge of the significant pharmacological, pharmacodynamic and pharmacokinetic differences of the

individual isomers [2]. Study of the two isomers of bupivacaine showed that R-bupivacaine was shown to be 3 times more potent than S-bupivacaine [3]. The electrophysiological studies in the guinea pig papillary muscle were performed with bupivacaine separated into its enantiomers and demonstrated lower depressive activity with S (-) bupivacaine compared with R (+) bupivacaine [4]. With the help of Brazilian technology, the dextroenantiomer R (+) was separated from the levoenantiomer S (-), showing the inferior cardiodepressant potency of levobupivacaine compared to racemic bupivacaine in atrial pacemaker (chronotropism) and in the contraction force of the electrically stimulated left atom (inotropism) of rats, confirming the results in the literature [5-7].

The levobupivacaine in 50% enantiomeric excess (S75:R25) mixture needs a larger dose than racemic bupivacaine to sacrifice rats [5]. The effects of bupivacaine isomers showed to be stereospecific and demonstrated that the combination of isomers provides an important efficacy in the activity of the local anesthetic, in terms of onset and duration of neuronal blockade. Local anesthetics (LA) are used in clinical practice to block the transmission of impulses in nerve fibers, reducing or eliminating the sensation of pain. In this way, LA are used to provide analgesia and anesthesia in the neural axis, peripheral nerve blocks, subcutaneous and peritoneal infiltration in different tissues and local anesthesia. The aim of this study was to compare the blockade produced by 0.5% isobaric enantiomeric mixture containing 75% levobupivacaine and 25% dextrobupivacaine (S75:R25) in two puncture positions (lateral decubitus and sitting position) evaluating the characteristics of the blockade in spinal anesthesia for orthopedic surgeries.

Methods

1	S75:R25 ISOBARIC SIT POSITION												
2						Min	NS	BM	Alt Card				
3	Sx	Age	Wei	Hei	ASA	Lat	15'	15'	Hipo	Brad	Du BS	Du BM	C.Neur
4	M	60	96	179	1	01:12	T12	3	Não	Não	03:05	03:45	Não
5	M	55	64	165	2	01:36	T11	3	Não	Não	03:50	04:05	Não
6	F	59	50	154	1	01:19	T8	3	Não	Não	02:35	02:55	Não
7	F	33	65	178	1	02:05	T7	3	Não	Não	02:55	03:15	Não
8	M	25	65	167	2	02:04	T8	3	Não	Não	02:35	02:55	Não
9	M	20	56	170	2	02:01	T12	3	Não	Não	02:25	02:55	Não
10	M	46	70	157	1	02:02	T11	3	Não	Não	02:50	03:25	Não
298													
299													
300	M	39	99	178	1	01:39	T9	3	Não	Não	02:35	02:45	Não
301	F	41	60	160	2	01:28	T6	3	Sim	Não	02:50	02:55	Não
302	F	23	74	160	2	01:47	T9	3	Não	Não	02:55	03:05	Não
303	M	19	65	163	1	01:37	T9	3	Não	Não	02:45	02:55	Não
304	S75:R25 ISOBARIC LLD POSITION												
305						Min	NS	BM	Alt Card				
306	Sx	Age	Wei	Hei	ASA	Lat	15'	15'	Hipo	Brad	Du BS	Du BM	C.Neur
307	M	46	96	179	1	01:12	T10	3	Não	Não	03:05	03:45	Não
308	M	60	64	165	2	03:36	T11	3	Não	Não	03:50	04:05	Não
309	F	46	50	154	1	02:19	T10	3	Não	Não	02:35	02:55	Não
310	F	33	65	178	1	03:07	T9	3	Não	Não	02:55	03:15	Não
311	M	25	65	167	2	02:05	T11	3	Não	Não	02:35	02:55	Não
312	M	20	56	170	2	02:01	T8	3	Não	Não	02:25	02:55	Não
313	M	26	70	157	1	02:03	T10	3	Não	Não	02:50	03:25	Não
314	M	47	84	174	2	02:05	T12	3	Não	Não	02:45	02:55	Não
315	F	60	62	151	1	01:58	T11	3	Não	Não	03:10	03:15	Não
316	M	47	60	162	2	01:41	T11	3	Não	Não	02:45	03:10	Não
603													
604													
605	M	58	74	180	2	01:46	T11	3	Não	Não	02:50	02:55	Não
606	M	48	74	181	2	01:55	T11	3	Não	Não	02:55	03:05	Não
607	M	38	91	176	1	01:33	T6	3	Sim	Não	02:45	02:55	Não
608	F	25	62	158	2	01:54	T8	3	Não	Não	03:10	03:15	Não
609	F	35	51	168	2	01:47	T10	3	Não	Não	03:05	03:20	Não
610	F	37	63	167	2	01:59	T10	3	Não	Não	03:10	03:20	Não

Figure 1: Excel spreadsheet to record spinal procedure.

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The study was registered in the Brazil Platform (CAAE: 09061312.1.0000.5179). The Ethics Research Committee approved the study protocol (Number: 171,924) and was a retrospective study. All spinal anesthesia with 0.5% isobaric S75:R25 for orthopedic surgery were recorded in an Excel spreadsheet for further study (Figure 1). From 2005 to 2021 carried out in several hospitals, from three different Brazilian states, 603 spinal anesthesia's were recorded according to the consort flowchart (Figure 2). The Free and Informed Consent Form (FICF) was signed and saved with the Excel spreadsheet, and all patients signed the authorization form for future publication. However, as it is a retrospective study, the FICF is not mandatory to be shown. The density (g/ml) of 0.5% isobaric levobupivacaine solutions at 37oC was measured using a DMA 4500 densimeter. All patients of both sexes, between 18 and 60 years of age, physical status ASA I and II, eligible for orthopedic surgery were offered the first option to spinal anesthesia with isobaric 0.5% S75:R25 solution comparing puncture in the left lateral decubitus (LLD) position with puncture in the sitting position (SIT), at a fixed dose of 15 mg.

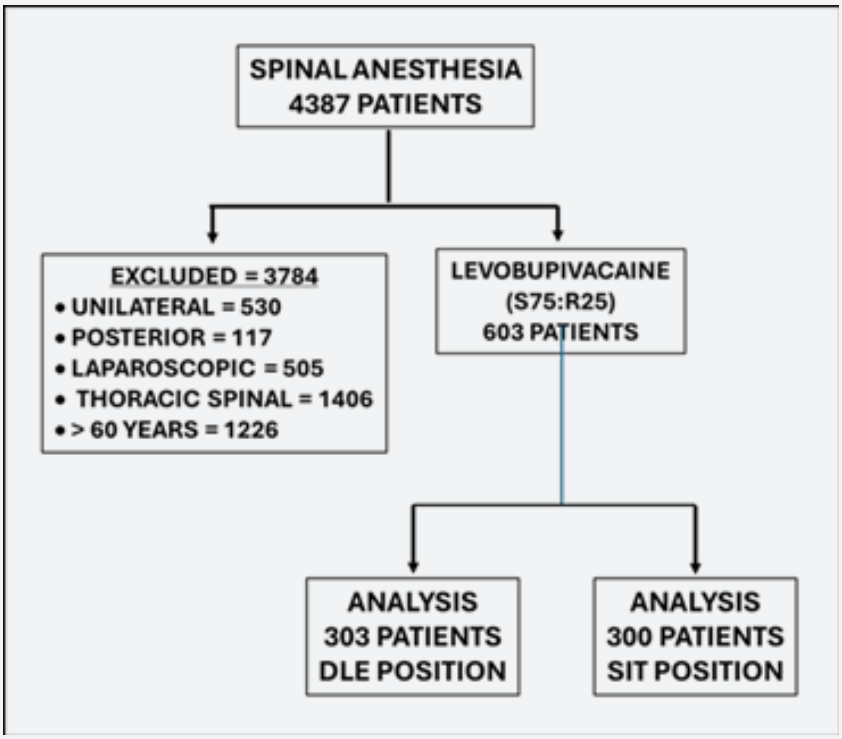

Figure 2: Consolidated Standards of Reporting Trials Flow Diagram.

Inclusion criteria were normal blood volume, no pre-existing neurological disease, no coagulation disorders, without infection at the puncture site, which did not present agitation, mental confusion and/or delirium, did not make use of bladder indwelling catheters, with hemoglobin level >10 g%, who were not in the ICU, puncture with a 27G Quincke needle, and had shortened the fast to between 2 and 4 hours, with 200 to 400 ml of maltodextrin. Exclusion criteria were lack of data in the spreadsheet, under 18 years of age or over 60 years old and injection other than the study dose or 0.5% hyperbaric bupivacaine solution, or surgery performed in lateral decubitus or prone position. All patients received a pre-anesthetic visit by anesthesiology resident and the entire procedure was informed, but no pre-anesthetic medication was administered either orally or by muscle. Upon arrival to the operating room a 20G catheter was inserted in the left or right for hydration and administration of drugs.

The monitoring used in all patients was ECG continuously in the CM5 lead, non-invasive blood pressure, oxygen saturation and expired CO2 through the capnograph placed in the nose, and all data were recorded at 5-minute intervals until the incision and afterwards every 10 minutes. After monitoring was installed, patients received 1 mg of midazolam and 50 µg of fentanyl for placement in the position for lumbar puncture, and the study covered two groups: left lateral decubitus and sitting position with a fixed dose of 0.5% isobaric S75:R25. After asepsis and antisepsis with 70% alcohol or 0.5% alcohol chlorhexidine, the patients were placed in one of the study positions. Local anesthesia was

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performed with 1 ml of 1% lidocaine using a syringe and insulin needle, followed by 2 ml of the same solution using a 27G needle to introduce the spinal anesthesia needle. We performed a puncture of the subarachnoid space through a median or paramedian with a 27G cut needle without introducing between the L3-L4 interspaces. Free flow of cerebrospinal fluid (CSF) confirmed the position of the needle into the subarachnoid space, 15 mg 0.5% S75:R25 were injected. The solutions were injected at a rate of 1 ml/15 seconds with the isobaric solution in both groups and placed immediately in a horizontal supine position to evaluate the parameters proposed in the study and perform the surgery.

The latency was defined as the time to the first loss of sensitivity in L2 through the 27G needle pin prick in the quadriceps muscle. The segmental level of analgesia (loss of needle prick sensation) was determined in the bilateral limb only after 15 minutes. Motor block was assessed 15 minutes before the start of surgery by modified Bromage scale: 0 = free movement of the lower limbs, 1 = inability to raise the extended limbs, 2 = inability to flex knees, 3 = inability to move the ankle in the operated limb and in the contralateral limb. The duration of analgesia was considered as the return of sensitivity and motor block in the dermatome corresponding to L1. Hypotension was defined as a decrease of more than 30% from the baseline systolic arterial blood pressure and treated with IV boluses of 2 mg ethilephryne. Bradycardia was defined as heart rate <50 bpm (beat per minute) and treated with atropine 0.50 mg. The numbers of hypotensive and bradycardic episodes were recorded. Anxiety was treated with midazolam 1 mg.

Postoperative analgesia was performed using lumbosacral plexus, depending on the innervation of interest to the surgical procedure. All blocks were performed with an HNS12 neurostimulator with A50, A100 or A150 needles depending on the depth of the plexus. After desired contraction to plexus stimulation, all blocks were injected with 0.25% enantiomeric excess levobupivacaine (S75:R25) at a dose of 30 to 40 ml, and the duration of analgesia was evaluated. During the study the hospital did not have an ultrasound device for performing peripheral nerve blocks. Analgesia was performed via the veins with ketoprofen 100 mg every 8 hours and dipyrone 40 m/kg every 4 hours. Other postoperative events potentially related to either surgical or anesthetic procedure, i.e., discomfort, nausea and vomiting, urinary retention, pruritus, headache, or other neurologic sequelae, were also recorded. All patients were followed before hospital discharge and on the 2nd and 3rd postoperatively up by telephone to check for neurological complications, and special attention to transient neurologic symptoms (TNS), and if any, it was correlated with the type of surgery.

Statistical Analysis

We used the Mann-Whitney and Kruskal-Wallis tests for unpaired samples and the Wilcoxon test for paired samples. To assess the association between categorical data, we used the Chi-Square test of independence, $P<0.05$ was considered significant.

Results

There is no difference in the demographic data assessed between the two groups (Table 1). The retrospective study included 603 patients, 329 males and 274 females. The physical status in all patients was ASA I in 330 patients and ASA II in 273 patients (Table 1). The 15 mg dose of 0.5% isobaric S75:R25 injected into the LLD and SIT position did not cause any failures in the 603 patients studied and for the type of surgery. Therefore, there was no need for supplementation with general anesthesia in any patient in the study. The average onset of analgesia in 603 patients was rapid (01:39 minutes) with no difference between the two puncture positions. There was no significant difference in the duration of sensory and motor blocks with the two puncture positions. The onset of motor block was rapid and complete motor block (grade 3) occurred in all patients regardless of puncture position. However, the duration of the motor block was greater (Wilcoxon $p\approx0.00$) than the sensory block in both puncture positions (Table 2).

Table 1: Patient data from both groups (m ± SD).

Data	S75:R25 - SIT	S75:R25 - LLD	P Value
Number	300 Patients	303 Patients	-
Age (years) Limits	42.01±11.80 (18 - 60)	41.19±11.69 (18 – 60)	0.3985*
Weight (kg) Limits	69.05±12.76 (42 - 102)	70.83±13.20 (42 - 102)	0.08445*
Height (cm) Limits	165.75±9.02 (147 - 196)	168.18±8.87 (149 - 196)	0.001149*
Gender: M / F	155 / 145	174 / 129	0.1556**

*Mann-Whitney Test

**Chi-Square Test

Table 2: Characteristics of sensory and motor blockade.

Parameters	S75:R25-SIT	S75:R25-LLD	P Value
Number	300 Patients	303 Patients	-
Latency (min)	01:37±00:18	01:42±00:21	0.03326*
Duration Sensitive Block (h)	02:47±00:16	02:47±00:16	0.6751*
Duration Motor Blok (h)	03:00±00:16	03:01±00:16	0.6371*
Dispersion 15 minutes-Mode	T8	T10	0***

*Mann-Whitney Test

***Kruskal-Wallis Test

The cephalic spread of anesthesia was assessed only after 15 minutes, showing that there is a significant difference, being higher with the seated puncture (Figure 3). The mode was 2 segments higher than the SIT puncture (T8) compared with the LLD puncture (T10), with a significant difference (Table 2). The vertical axis represents the cephalad dispersion values, which in

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this case are the numeric representations of an ordinal variable. Originally, cephalad dispersion had levels ranging from T12 to T4 (with T12 being the lowest and T4 the highest in your ordering). For analysis and visualization, this ordinal variable was converted into numeric values (for example, T12 = 1, T11 = 2, ..., T4 = 9). Thus, the values on the vertical axis correspond to these numeric codes that reflect the cephalad dispersion levels, using the median of the ranks (Figure 4). There was no significant difference in the incidence of hypotension and bradycardia with either puncture position (Table 3). No case of headache or neurological complication was observed in any of the patients. The mean duration of analgesia after blockade of the plexus involved in the innervation surgery in all patients was 20 hours.

Table 3: Complications in both puncture positions.

Parameters	S75:R25-SIT	S75:R25-LLD	P Value
Number	300 Patients	303 Patients	Number
Hypotension	20 (6.6%)	16 (5.2%)	0.4964
Bradycardia	6 (2%)	9 (2.9%)	0.4443
Headache	0	0	-
Neurological	0	0	-

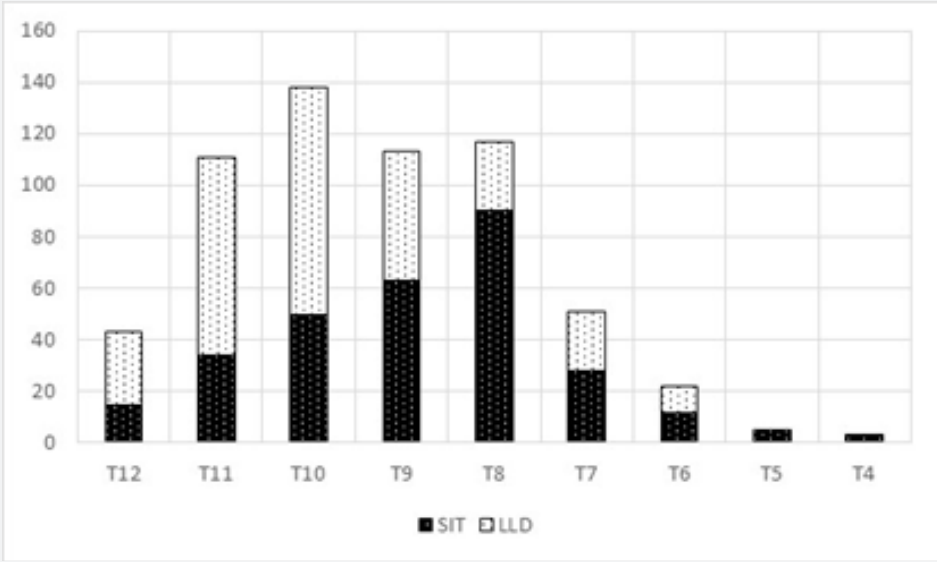

Figure 3: Cephalic spread of anesthesia with both puncture positions.

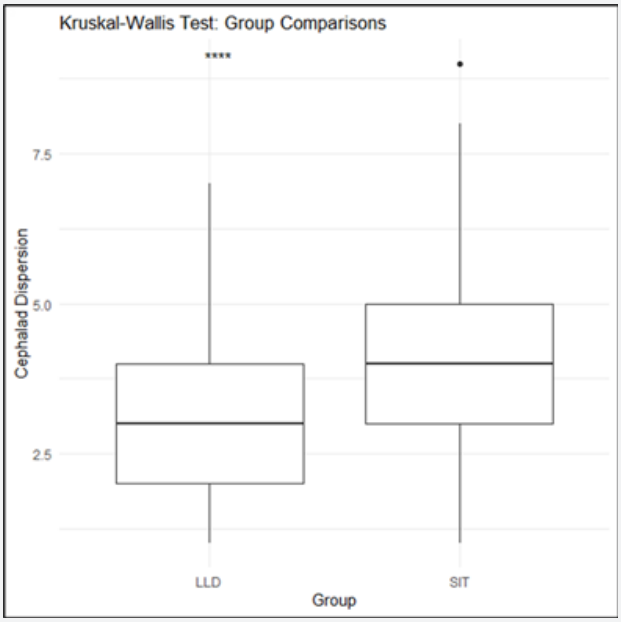

Figure 4: Cephalad dispersion using the median of ranks.

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Discussion

Many of the substances supplied by laboratories are said to be isobaric at room temperature, but when evaluated at 37°C or when heated upon contact with the CSF, they become hypobaric [8]. The density found for levobupivacaine in 50% enantiomeric excess (S75:R25) at 37°C was 0.99940, this value corresponds to a hypobaric solution. The results of this study with S75:R25 showed hypobaric behavior, since both the SIT and LLD groups favored the anterior fibers, resulting in a longer-lasting motor block than the posterior fibers responsible for the sensory part, regardless of the puncture position. Likewise, the cephalad spread of anesthesia was higher in two thoracic segments when punctured in the SIT position compared to the LLD position. In a study with 70 patients over 60 years of age, with the aim of comparing the puncture position (sitting versus lateral decubitus) in the different characteristics of spinal anesthesia with 12.5 mg 0.5% isobaric bupivacaine [9]. The study concluded that both sitting and lateral positions have similar effects on sensory and motor blockade and hemodynamic stability. However, patients generally found the lateral position very comfortable. Comparing 120 orthopedic patients, both 15 mg of 0.5% isobaric S75:R25 and 0.5% racemic bupivacaine presented the same density and had the same behavior in the cephalic dispersion of analgesia for up to 30 minutes, after injection in lateral decubitus [10]. In the present study with a fixed dose of 15 mg of 0.5% isobaric S75:R25 compared with the same dose of 0.5% isobaric bupivacaine, the sitting position increased the cephalad spread of anesthesia. The result showed that the puncture position did not influence the onset of anesthesia, the quality of the motor blockade, or the duration of the blockade.

The separation of racemic bupivacaine (S50:R50) allowed the obtaining of the levorotatory and dextrorotatory enantiomers. Levobupivacaine may be in pure form [6] or in proportions of 10% R (+) bupivacaine and 90% S (-) bupivacaine or 25% R (+) bupivacaine and 75% S (-) bupivacaine [11,12]. The form of levobupivacaine (S75:R25) in this study contains 75% of the levorotatory form and 25% of the dextrorotatory form and was launched some time ago in the 0.5% isobaric presentation. Several studies have shown a variation in the height of the block with isobaric bupivacaine, especially when injected in the sitting position. The same occurred with the isobaric solution of S75:R25. In this study, there was a large variation in the height of the block with S75-R25 in both the sitting SIT and LLD.

Studying the levorotatory form in comparison with the racemic form in the sciatic nerve of rats, it was observed that levobupivacaine has the same blocking efficacy as the racemic mixture, with the same intensity and duration of motor and sensory blocks, but with a markedly reduced onset time [6]. In this clinical study, no difference was observed in the onset time of the sensory block in relation to the puncture position. With the dose of 15 mg of 0.5% isobaric S75:R25, the motor block was complete in all patients regardless of the degree of arterial hypotension that occurs during spinal anesthesia has been correlated with the dispersion of the sensory block, previous hydration and patient age. In this study with the enantiomeric mixture S75:R25, both in the SIT puncture (6.6%) and LLD positions (5.2%) occurred with the same incidence of arterial hypotension in orthopedic surgeries. Likewise, no difference was observed in relation to the incidence of bradycardia in the two forms of subarachnoid puncture. Failures were not observed with the S75:R25 isobaric solution in this study when two injection positions were used in the subarachnoid space.

Conclusion

Most of the drugs used in medicine are chiral compounds and presented in racemic form. Previous preclinical studies and clinical articles suggest that S (-) enantiomer (levobupivacaine) is lower than that of either R (+) enantiomer or racemic (RS ±) bupivacaine. Levobupivacaine in 50% enantiomeric excess (S75:R25) is a local anesthetic derived from bupivacaine developed in Brazil, with two proportions (90%:10% and 75%:25%), the latter presenting the best result. The enantiomeric mixture of bupivacaine (S75:R25) represents an advance in relation to racemic bupivacaine, as it has identical efficacy for sensory block, similar or slightly lower for motor block and superior tolerability. Greater tolerability represents protection of the patient's life in cases of anesthetic accidents by inadvertent intravascular injection, a complication that is difficult to occur with spinal anesthesia.

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