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Comparison of a Fixed Dose of 2% Hyperbaric and Isobaric Lidocaine for Short-Term Lower Limb Orthopedic Surgeries Retrospective Study

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Spinal anesthesia; Lidocaine, Density;
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1. Abstract

1.1. Background and Objectives: Lidocaine is a fast-acting, short-acting local anesthetic that has been used safely since the 1940s as an anesthetic for spinal anesthesia. Over a 20-year period, 2090 spinal anesthesia procedures were performed with various lidocaine solutions. Recently, I wrote an article showing that lidocaine for spinal anesthesia, can and should be used. The aim of the study was to compare 60 mg of 2% plain lidocaine with 2% lidocaine with 8% glucose, injected in the lateral decubitus position for spinal anesthesia in short-term orthopedic surgeries.

1.2. Methods: Six hundred patients, physical status ASA I and II, aged 20 to 60 years, of both sexes participated in the study. Patients were randomly divided in two groups receiving the same dose of 60 mg of 2% lidocaine isobaric and 2% lidocaine hyperbaric. Density, of both solutions were determined by densimeter DMA 450. Patients were placed in the lateral position and lumbar puncture was performed with a 27G or 29G Quincke needle.

The following parameters were observed: onset of analgesia, motor block, effect duration, level of cephalic spread of analgesia, cardiovascular changes and transient radicular symptoms.

1.3. Results: The density values at 37ºC obtained were 0.99900±0.00010 g/ml for 2% plain lidocaine and 1.02600±0.00000 g/ml for 2% hyperbaric lidocaine with 8% glucose. The onset of anesthesia (latency) was significantly shorter with the hyperbaric solution. Spread of analgesia was significantly higher with 2% hyperbaric lidocaine. With the hyperbaric solution, the sensory block was significantly longer lasting than the motor block. With the isobaric solution, the sensory block was significantly shorter lasting than the motor block. The incidence of bradycardia and hypotension was significantly lower with the isobaric solution. Transient radicular irritation occurred in 14 (2.3%) patients with both solutions without significant difference and all related to knee arthroscopic surgery.

1.4. Conclusions: For short-term orthopedic surgeries, 2% isobaric and hyperbaric lidocaine injected in the lateral decubitus position were considered safe for spinal anesthesia, with the hyperbaric solution having the highest incidence of bradycardia and hypotension.

KEY POINTS

Question

What is the reason for not using lidocaine in spinal anesthesia in its various solutions such as 2% isobaric, 1.5% and 2% hyperbaric, and 0.6% hypobaric, for short-term and outpatient surgeries?

- Four cases of cauda equina syndrome occurring after continuous spinal anesthesia, 3 with 28G microcatheter and 1 with 20G epidural catheter.
- Similarly, there were four cases of cauda equina syndrome, 3 cases with 5% hyperbaric lidocaine and 1 case with 1% tetracaine.
- Paracelsus, a physician and physicist in the 16th century, said that the difference between medicine and poison is the dose.
- Transient neurological symptoms occur with all types of anesthetics and are transitory.
- Most of the anesthesiologists' preference for the sitting position and hyperbaric solution.
- Few schools of anesthesiology apply the lateral decubitus position for neuraxial anesthesia.

Findings

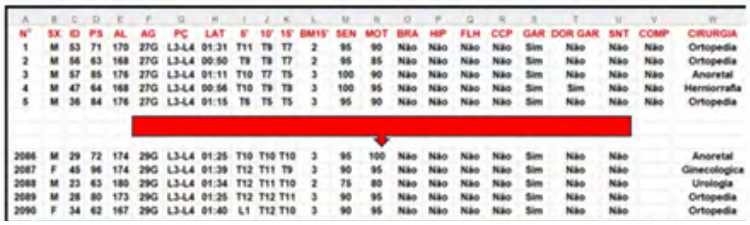
- From 1998 to 2018, 2,090 spinal anesthesia with 0.6% hypobaric, 1.5% and 2% hyperbaric, and 2% isobaric lidocaine with several published articles.
- No case of cauda equine syndrome was observed.
- After several studies we use the fixed dose of 60 mg for orthopedic surgery always with lateral position.
- Transient neurological symptoms occurred in 14 (2.3%) patients, all related to video arthroscopy of the knee.

Meaning

- Lidocaine in 2% isobaric and hyperbaric solution and a dose of 60 mg with puncture in lateral decubitus can be used in outpatient lower limb orthopedic surgery effectively and safely.

2. Introduction

Lidocaine is a fast-acting, short-acting local anesthetic that has been used safely since the 1940s as an anesthetic for spinal anesthesia [**1,2**]. In 2014, a book on lidocaine was published, covering pharmacology, research, safety testing, regulation, with current concepts and use in clinical practice, where I wrote in the first chapter on its use for spinal anesthesia [**3**]. Later in 2018, I wrote an article showing that lidocaine for spinal anesthesia, can and should be used, with the following solutions, 1.5% and 2% hyperbaric, 2% isobaric (plain), and 0.6% hypobaric [**4**]. This year I am completing 50 years of practicing anesthesia, and I have never stopped using lidocaine, which was introduced for spinal anesthesia, with numerous published articles. In an excellent Editorial written in 1999, Gisvold showed that the potency ratio of lidocaine versus bupivacaine is approximately 4:1, and 5% lidocaine should be compared with 1.25% bupivacaine and not 0.5% or 0.75% bupivacaine [**5**]. Or rather, bupivacaine 0.5% should be compared to lidocaine 2% and not 5%. This was the reason why I requested the production of lidocaine in 2% (isobaric and hyperbaric) and 1.5% hyperbaric solutions, for studies in spinal anesthesia. In 1988, the Cristália Laboratory was asked to produce lidocaine for spinal anesthesia. And the following concentrations of lidocaine were produced for several studies. From this moment on, the Cristália laboratory in Brazil produced as 2% isobaric, 1.5% and 2% hyperbaric lidocaine for study by my group with several publications [**4**]. However, hypobaric solutions of any local anesthetic have never been produced by any laboratory in the world and are obtained by adding water or alcohol to the pure solution of the anesthetic to be obtained. In this way, using 2% isobaric lidocaine with the addition of water we obtained 0.6% hypobaric lidocaine. The idea for Excel was conceived in 1984 by Charles Simonyi, a Microsoft programmer who wanted to create a spreadsheet program that was more advanced than anything else available on the market at the time [**6**]. After purchasing it, I created a spreadsheet for all my anesthesia's where I could write scientific articles in the future (Figure 1). So, among these spreadsheets, all my spinal anesthesia's with lidocaine were noted. Thus, numerous articles were published with different lidocaine solutions in Brazil without any cases of cauda equina syndrome or neurological complications [**7-11**]. Likewise, we publish abroad in adults [**12,13**] and children [**14**] in english-language journals. From 1998 to 2018, 2090 spinal anesthesia were recorded in the Excel spreadsheet designed for subsequent studies, therefore retrospectively analyzing spinal anesthesia performed with 2% hyperbaric and isobaric lidocaine, for orthopedic surgeries of short surgical duration to be able to apply short-acting local anesthetic



Nº	SX	ID	PS	AL	AG	PC	LAT	5'	10'	15'	BM15'	SEN	MOT	BRA	HIP	FLH	CCP	GAR	DOR GAR	SNT	COMP	CIRURGIA
1	M	53	71	170	27G	L3-L4	01:31	T11	T9	T7	2	95	90	Não	Não	Não	Não	Sim	Não	Não	Não	Ortopedia
2	M	56	63	168	27G	L3-L4	00:50	T9	T8	T7	2	95	85	Não	Não	Não	Não	Sim	Não	Não	Não	Ortopedia
3	M	57	85	176	27G	L3-L4	01:11	T10	T7	T5	3	100	90	Não	Não	Não	Não	Sim	Não	Não	Não	Anoretal
4	M	47	64	168	27G	L3-L4	00:56	T10	T9	T8	3	100	95	Não	Não	Não	Não	Sim	Sim	Não	Não	Herniorrafia
5	M	36	84	176	27G	L3-L4	01:15	T6	T5	T5	3	95	90	Não	Não	Não	Não	Sim	Não	Não	Não	Ortopedia
2086	M	29	72	174	29G	L3-L4	01:25	T10	T10	T10	3	95	100	Não	Não	Não	Não	Sim	Não	Não		Anoretal
2087	F	45	96	174	29G	L3-L4	01:39	T12	T11	T9	3	90	95	Não	Não	Não	Não	Sim	Não	Não		Ginecologica
2088	M	23	63	180	29G	L3-L4	01:34	T12	T11	T10	2	75	80	Não	Não	Não	Não	Sim	Não	Não		Urologia
2089	M	28	80	173	29G	L3-L4	01:25	T12	T12	T11	3	90	95	Não	Não	Não	Não	Sim	Não	Não		Ortopedia
2090	F	34	62	167	29G	L3-L4	01:40	L1	T12	T10	3	90	95	Não	Não	Não	Não	Sim	Não	Não		Ortopedia

Figure 1: From 1998 to 2018, 2090 spinal anesthesia with lidocaine 0.6% hypobaric, 1.5% and 2% hyperbaric, and 2% isobaric.

3. Methods

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 carried out in several hospitals. All spinal anesthesia with lidocaine for orthopedic surgery were recorded in an Excel spreadsheet. From 1998 to 2018, 2090 spinal anesthesia's were recorded with different lidocaine solutions according to the consort flowchart (Figure 2). Because the study was retrospective, the Free and Informed Consent Term was released. The density (g/ml) of 2% isobaric and hyperbaric lidocaine solutions at 37ºC was measured using a DMA 450 densimeter. All patients eligible for short-term orthopedic surgery were offered as the first option to spinal anesthesia with isobaric 2% lidocaine solution compared with 2% lidocaine hyperbaric, at a fixed dose of 60 mg. We studied 600 patients over 20 years of age and under 60 years of age undergoing various orthopedic procedures, ASA physical status I-II, of both genders. 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, use of a pneumatic tourniquet on the thigh, puncture with a 27G and 29G Quincke needle, in lateral decubitus. Exclusion criteria were lack of data in the spreadsheet, not using a tourniquet, puncture with 25G needles, and puncture sitting or prone position. All patients received a pre-anesthetic visit by the anesthesiologist and the entire procedure was informed, but no medication was administered either orally or by muscle. A 20G catheter was inserted in the left hand 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 block position.

After asepsis and antisepsis with 70% alcohol or 0.5% alcohol chlorhexidine, the patients were placed in left lateral decubitus, we performed a puncture of the subarachnoid space through a median or paramedian with a 27G or 29G cut needle without introducer between the L3-L4 interspaces. Free flow of cerebrospinal fluid (CSF) confirmed the position of the needle into the subarachnoid space, 60 mg (3 ml) of 2% isobaric or hyperbaric lidocaine were injected and placed immediately in the supine position to evaluate the parameters proposed in the study. The latency was defined as the time to the first loss of sensitivity in the L1 metamer in both lower limbs. The segmental level of analgesia (loss of needle chuck prick sensation) was determined bilaterally at a one-minute interval at the beginning and every five minutes until 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 ankles. The duration of analgesia was considered as the return of sensitivity in the dermatome corresponding to L1 and the duration of motor blockade as the complete return of muscular activity in the lower limbs. 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 40 ml. After the lumbosacral plexus block, 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 mg/kg every 4 hours. Other postoperative events potentially related to either the 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.

4. Statistical analysis

The results were analyzed using non-parametric Fisher exact test and Kruskal-Wallis, with a p value<0.05 considered significant. The mode in statistics represents the central tendency that occurs most frequently, and the cephalic dispersion was evaluated at 5, 10 and 15 minutes.

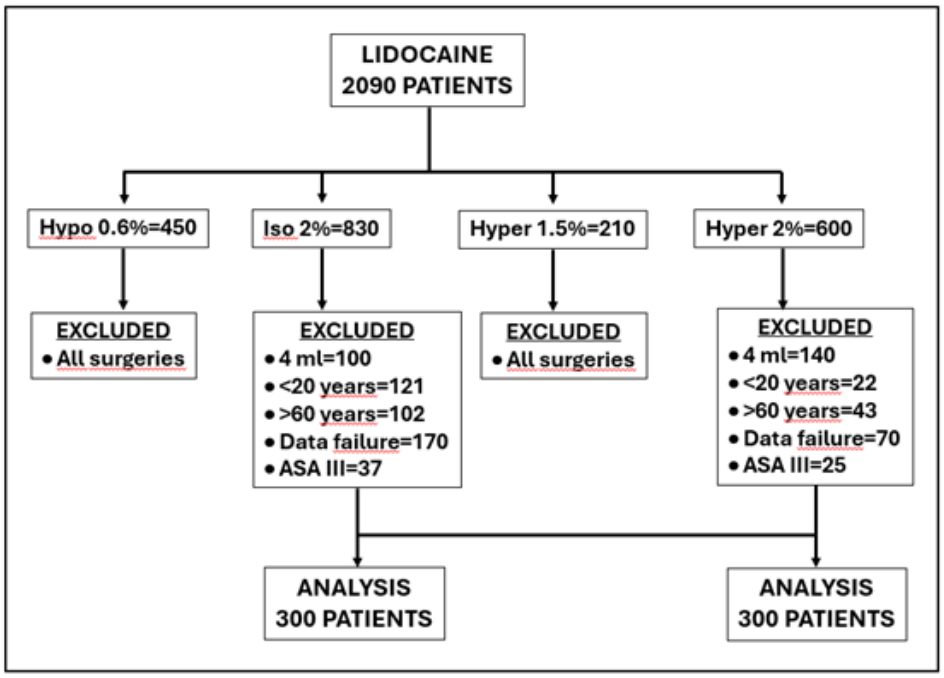


Figure 2: Consort flowchart 2090 spinal anesthesia with lidocaine, performed between 1998 to 2018.

5. Results

There was no significant difference between the average age, weight, height and gender of the patients (Table 1).

In all patients there was a sufficient level for the proposed orthopedic surgery regardless of the type of 2% lidocaine solution. The density values at 37ºC obtained were 0.99900±0.00010 g/ml for 2% isobaric lidocaine and 1.02600±0.00000 g/ml for 2% hyperbaric lidocaine with 8% glucose. The mean latency time of 1:01 minutes with lidocaine containing glucose was significantly shorter than the mean of 1:32 minutes with the pure (isobaric) solution (Table 2). Cephalic spread of analgesia was significantly higher at 5, 10 and 15 minutes in patients anesthetized with 2% hyperbaric lidocaine solution (Figure 3). The maximum level of analgesia was significantly higher with the glucose-containing solution. The mode of cephalic dispersion of analgesia at 5, 10 and 15 minutes was significantly higher with the hyperbaric solution (T8 - T7 - T5) than with the isobaric solution (T12 - T11 - T10). There was no anesthesia failure in any patient in both groups. After recovery from blockades with both doses, it was shown that the duration of sensory blockade was significantly longer than with the hyperbaric solution, and the duration of motor blockade was significantly longer with the isobaric solution (Table 2). Evaluating the duration of sensory and motor blocks with the two solutions, it was shown that the duration of the sensory block was significantly greater than the duration of the motor block with the hyperbaric solution, while the duration of the motor block was significantly greater than the duration of the sensory block with the isobaric solution (Table 2). Grade zero and 1 motor block of the lower limbs was not observed in any patient with both 2% lidocaine solutions, up to 15 minutes. Grade 2 motor block was observed in 15.4% of patients with the hyperbaric solution and 7% of patients with the isobaric solution, with a significant difference. Grade 3 motor block was observed in 83.6% with the hyperbaric solution and 93% with the isobaric solution, with a significant difference. The motor block grades 2 and 3 were significantly more present with the isobaric solution compared to the hyperbaric one (Table 2).

The main complication observed was arterial hypotension, 8% with the hyperbaric solution and 3.3% with the isobaric solution, with a significant difference (Table 3). Bradycardia was observed in 4.3% with the hyperbaric solution versus 0.6% with the isobaric solution, with a significant difference (Table 3). Transient neurological symptoms occurred in 8 patients with the hyperbaric 2% lidocaine solution and 6 patients with the isobaric lidocaine solution, without significant difference. When reviewing the records, it was found that all cases of TNS were related to video arthroscopy of the knee. No post-dural puncture headache was observed with the 27G and 29G Quincke needles. The use of plexuses involving the surgical area with neurostimulation and a solution of 0.25% enantiomeric excess levobupivacaine (S75:R25) provided an average analgesia of 22 hours.

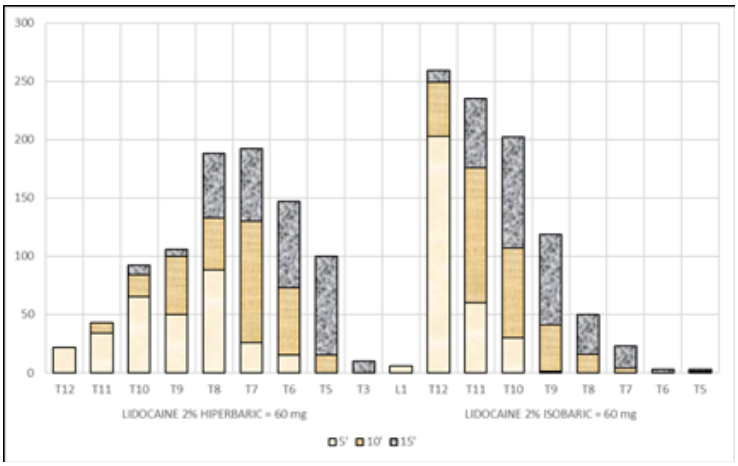


Figure 3: Cephalic spread of analgesia to the 5, 10 and 15 minutes.

Table 1: Patient demographics data

Data	Lidocaine 2% Hyperbaric = 300	Lidocaine 2% Isobaric = 300	Value P
Age (yr)	40.20±10.99	34.85±10.56	3.44e-11 *
Weight (kg)	72.12±12.39	67.22±11.82	0.000000541 *
Height (cm)	169.55±7.66	166.41±8.34	0.000003538 *
Gender: M / F	180 / 120	161 / 139	0.1378 **

*Krukal-Wallis **Fisher

Table 2: Assessment of blocks in both groups

Data	Lidocaine 2% Hyperbaric = 300	Lidocaine 2% Isobaric = 300	Value P
Latency (min)	01:01±00.11	01:32±00:06	2.2e-16 *
Sensory block duration (min)	88±7	84±5	9.074e-13 *
Motor block duration (min)	81±7	91±5	2.2e-16 *
Degrees of motor block:			0.0005203 **
MB O	0	0	
MB 1	0	0	
MB 2	49 (15.4%)	21 (7%)	
MB 3	251 (83.6%)	279 (93%)	

*Krukal-Wallis **Fisher

Table 3: Cardiocirculatory changes in both groups

Data	Lidocaine 2% Hyperbaric = 300	Lidocaine 2% Isobaric = 300	Value P
Bradycardia	13 (4.3%)	2 (0.6%)	0.006707 **
Hypotension	24 (8%)	10 (3.3%)	0.02046 **

**Fisher

6. Discussion

The data obtained in the comparison between 2% hyperbaric and isobaric lidocaine for short-term orthopedic surgeries with puncture in lateral decubitus, showed an onset of sensory blockade with significant difference between the two solutions, in the cephalic dispersion of analgesia, being higher with the hyperbaric solution, and a difference in the duration of sensory and motor blocks, depending on the solution used. Studying 2, 3 and 4 ml of 2% isobaric lidocaine in the sitting position for transurethral surgery of the bladder showed that the maximum level of analgesia and the duration of sensory blockade depend on the dose injected, and that 2 ml (40 mg) was insufficient to produce reliable analgesia [**15**]. Comparing 2% pure lidocaine and with glucose at a dose of 80 mg in the sitting position showed that the onset and maximum level of sensory blockade were similar with both preparations, however as hyperbaric lidocaine results in a more rapid recovery of motor blockade [**16**]. Comparing the sitting position with the lateral decubitus position with a dose of 4 ml (80 mg) of 2% pure lidocaine, showed that the spread of analgesia was significantly higher (cephalic) in the sitting position, with the same latency [**7**]. In this study with spinal puncture in lateral decubitus and a fixed dose of 60 mg 2% hyperbaric lidocaine showed a higher dispersion (5 segments) at 15 minutes than the 2% isobaric lidocaine, with significantly faster installation with the hyperbaric solution. The cephalic distribution of the anesthetic depends on numerous factors such as dose, puncture position, type of solution with or without glucose and the baricity of the solution. Because the temperature of local anesthetics quickly equilibrates with that of the CSF, densities must be measured at 37ºC. The densities obtained from lidocaine 2% with and without glucose measured at temperature 37ºC is in accordance with another study carried out with a DMA 450 densimeter [**17**]. The baricity obtained from a previously published value [**18**], confirmed that the 2% glucose solution is hyperbaric, and the pure solution is slightly hypobaric.

The mean onset time was rapid with both solutions. However, the 2% hyperbaric lidocaine solution was 1:01 minutes significantly shorter than with the 2% isobaric lidocaine solution which was 1:32 minutes. After injection of both solutions, the patients were placed in the supine position. Thus, the hyperbaric solution, by favoring the posterior roots, resulted in a significantly longer mean duration of sensory block (88 minutes) than motor block (84 minutes). Since the isobaric solution is slightly hypobaric by favoring the anterior roots, in the same position resulted in a significantly longer mean duration of motor block (91 minutes) than sensory block (81 minutes). In a previous study, 4 ml (80 mg) of 2% isobaric lidocaine produced a sensory block below T7 in 96% of patients, while with the hyperbaric solution only 8% of patients presented levels below T7 [**9**]. In this study, comparing the 60 mg dose of the isobaric solution, the sensory level was found below T7 in 92.2% of patients, while with the hyperbaric solution only 23%. This study showed that decreasing the dose from 80 mg to 60 mg with both solutions resulted in a decrease in the cephalad spread of analgesia. Motor blockade of the lower extremities is dose-dependent and complete motor blockade is obtained more frequently with pure solutions than with solutions containing glucose. No motor block or grade 1 was observed with 60 mg of lidocaine in either solution. However, grade 2 and 3 motor block were significantly greater with the isobaric solution than with the hyperbaric solution.

In a recent prospective study in 50 patients who received spinal anesthesia with 2% isobaric lidocaine in a single shot with titrated propofol sedation for outpatient hip and knee arthroplasty, it was shown to be safe and effective, all patients were discharged on the same day without TNS [**19**]. However, the article does not mention the dose or the puncture position of the lidocaine solution. In this study comparing 2% isobaric lidocaine with hyperbaric at a dose of 60 mg punctured in lateral decubitus, TNS occurred in 14 (2.3%) patients, which were all correlated with the type of surgery (knee video arthroscopy). Many anesthesiologists add epinephrine to increase lidocaine duration, but the addition of epinephrine has not been shown to increase lidocaine neurotoxicity [**20**]. In this study with a fixed dose of 60 mg lidocaine, epinephrine was not added to any patient, and no adjuvant.

7. Conclusion

In an editorial from 1999, Gisvold concludes that we should not throw out ‘‘an old champion’’ unjustified [**5**]. This study showed that 60 mg of 2% lidocaine in isobaric or hyperbaric solution for spinal anesthesia facilitates discharge of short-term orthopedic surgical outpatients within a few hours while decreasing recovery room time and nursing care. It is my opinion 2% lidocaine for spinal anesthesia has a remarkable safety record, and in this way it can and in 50 years of profession as an anesthesiologist I have never stopped using it in spinal anesthesia.

Lidocaine administered intrathecally for spinal anesthesia, on the one hand, is considered by many the prototypical drug for spinals, especially for same-day surgery and short-stay procedures while, on the other hand, the 5% solution is the source of controversy. For this reason, since 1998 I have used the 2% solution as in this study.

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