

Anestesia Espinhal com 10 mg de Bupivacaína Hiperbárica Associada a 5 µg de Sufentanil para Cesariana. Estudo de Diferentes Volumes *

Spinal Block with 10 mg of Hyperbaric Bupivacaine Associated with 5 µg of Sufentanil For Cesarean Section. Study of Different Volumes

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RESUMO

Braga AFA, Frias JAF, Braga FSS, Pinto DRS – Anestesia Espinhal com 10 mg de Bupivacaína Hiperbárica Associada a 5 µg de Sufentanil para Cesariana. Estudo de Diferentes Volumes.

JUSTIFICATIVA E OBJETIVOS: Diversos fatores influenciam na dispersão cefálica da solução anestésica no espaço subaracnóideo, entre os quais destacam-se as alterações fisiológicas inerentes à gravidez, baricidade, dose e volume do anestésico local. O objetivo deste estudo foi avaliar em cesarianas a efetividade e os efeitos colaterais de diferentes volumes da associação de bupivacaína hiperbárica e sufentanil por via subaracnóidea.

MÉTODO: Quarenta pacientes, ASA I e II, submetidas à cesariana eletiva sob raqui-anestesia distribuídas em dois grupos, de acordo com o volume da solução anestésica empregada: Grupo I (4 mL) e Grupo II (3 mL). Nos dois grupos o anestésico local empregado foi a bupivacaína hiperbárica (10 mg-2 mL) associada ao sufentanil (5 µg-1 mL). No Grupo I, para obtenção do volume de 4 mL, foi adicionado 1 mL de solução fisiológica a 0,9%. Foram avaliados: latência do bloqueio; nível máximo do bloqueio sensitivo; grau do bloqueio motor; tempo para regressão do bloqueio motor; duração total da analgesia; efeitos adversos maternos e repercussões neonatais.

RESULTADOS: A latência, o nível máximo do bloqueio sensitivo, o grau e o tempo para regressão do bloqueio motor foram semelhantes nos dois grupos; a duração da analgesia foi maior no Grupo I, com diferença significativa em relação ao Grupo II. Os efeitos adversos ocorreram com frequência semelhante em ambos os grupos. Ausência de alterações cardiocirculatórias maternas e repercussões neonatais.

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CONCLUSÕES: A bupivacaína hiperbárica na dose de 10 mg associada ao sufentanil na dose de 5 µg, com volume de 4 mL, foi mais eficaz que a mesma associação em menor volume (3 mL), proporcionando melhor analgesia intra e pós-operatória, sem repercussões materno-fetais.

Unitermos: ANESTÉSICO, Local: bupivacaína hiperbárica; CIRURGIA, Obstétrica: cesariana; TÉCNICAS ANESTÉSICAS, Regional: subaracnóidea.

SUMMARY

Braga AFA, Frias JAF, Braga FSS, Pinto DRS – Spinal Block with 10 mg of Hyperbaric Bupivacaine Associated with 5 µg of Sufentanil for Cesarean Section. Study of Different Volumes.

BACKGROUND AND OBJECTIVES: Several factors affect the cephalad dispersion of the anesthetic solution in the subarachnoid space; among them, physiological changes of pregnancy and the dose and volume of the local anesthetics should be mentioned. The objective of this study was to assess the effectivity and side effects of different volumes of the subarachnoid administration of the association of hyperbaric bupivacaine and sufentanil in cesarean sections.

METHODS: Forty patients, ASA I and II, undergoing elective cesarean section under spinal block were divided in two groups, according to the volume of the anesthetic solution: Group I (4 mL) and Group II (3 mL). The association of hyperbaric bupivacaine (10 mg-2 mL) and sufentanil (5 µg-1 mL) was used in both groups. In Group I, 1 mL of NS was added to the solution to achieve the volume of 4 mL. The following parameters were evaluated: latency of the blockade; upper limit of the sensorial blockade; degree of motor blockade; time for regression of the motor blockade; total duration of analgesia; maternal side effects; and neonatal repercussions.

RESULTS: Latency, the upper limit of the sensorial blockade, and the degree and time for regression of the motor blockade were similar in both groups; duration of analgesia was greater in Group I than in Group II, which was statistically significant. The incidence of side effects was similar in both groups. Maternal cardiocirculatory changes and neonatal repercussions were not observed.

CONCLUSIONS: Four milliliter of anesthetic solution composed of hyperbaric bupivacaine, 10 mg, associated with 5 µg of sufentanil was more effective than 3 ml of the same solution, providing better intra- and postoperative analgesia without maternal-fetal repercussions.

Keywords: ANESTHETIC, Local: hyperbaric bupivacaine; ANESTHETIC TECHNIQUE, Regional: subarachnoid; SURGERY, Obstetric: cesarean section.

Spinal Block with 10 mg of Hyperbaric Bupivacaine Associated with 5 μ g of Sufentanil For Cesarean Section. Study of Different Volumes

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INTRODUCTION

Spinal blocks with disposable, low caliber spinal needles and the use of 0.5% hyperbaric bupivacaine associated with adjuvant became the technique of choice for elective cesarean sections and in urgent and emergency situations¹. In parturients at term, the different mechanisms that influence dispersion of the local anesthetic (LA) in the subarachnoid space are exacerbated by the physiological changes of pregnancy, which, consequently, contribute for the higher incidence of maternal-fetal complications, especially maternal hypotension. The dose of the LA, an important factor in the determination of the level and duration of the sensorial blockade, as well as the intensity and duration of the motor blockade, can be reduced as a consequence of the changes seen during pregnancy and the association of adjuvant, especially liposoluble opioids. On the other hand, the volume and concentration of the hyperbaric anesthetic solutions can also affect those parameters, but they are secondary to those related to the dose of the LA²⁻⁹. Addition of opioids to hyperbaric bupivacaine in spinal blocks reduces the latency, prolongs significantly the duration, and improves the efficacy of analgesia when compared to isolate bupivacaine^{7,9}. The objective of the present study was to assess the effectivity of different volumes of the association of hyperbaric bupivacaine and sufentanil in the quality of the blockade and maternal-fetal repercussions in parturients undergoing elective cesarean sections.

METHODS

This study was undertaken after approval by the Medical and Research Ethics Committee of the institution and signing of the

informed consent. This is a clinical, randomized, double-blind assay, in which consecutive gravidas at term, physical status ASA I and II, undergoing elective cesarean sections under spinal block, were enrolled. Exclusion criteria were as follows: pre-eclampsia, physical status ASA III and IV, prematurity, multiple gestation, and contraindications to the spinal block.

The size of the sample was based on the results of Chung et al.⁶, considering the difference of 34 ± 26.8 minutes among the means of the sensorial blockade in L₅ (GI x GIII), in which Group I – 0.25 bupivacaine (3.2 to 3.6 mL), and Group III – 0.25% bupivacaine (4.0 to 4.4 mL). Assuming this difference for the Student *t* test, considering a significance of 5% ($\alpha = 0.05$) and a test power of 80% ($\beta = 20\%$), the calculated size of the sample population was of 11 individuals in each group, but we included 20 individuals in each group to compensate for possible losses. Therefore, 40 patients were randomly divided, using the SAS 9.1 software and a uniform distribution with $p = 0.50$ – probability of 50% to be included in Group I (volume = 4 mL) and 50% to be included in Group II (volume = 3 mL).

One of the authors prepared the anesthetic solution and performed the blockade, which were unknown to the anesthesiologist who evaluated the parameters investigated.

In both groups, a fixed dose of 10 mg (2 mL) of 0.5% hyperbaric bupivacaine associated with sufentanil (5 μg – 1 mL) was used. One milliliter of NS was added to the solution used in Group I to obtain a volume of 4 mL. The drugs used were commercial products provided by the same manufacturer, without the lot number. The density of the solutions was analyzed in the laboratory of the manufacturer using a digital densitometer Anton Paar model DMA 4500 calibrated with milli-Q water at 37° C. Table I shows the characteristics of the resulting solutions.

Besides the subarachnoid block, the epidural space was punctured in both groups, and a catheter was introduced for intraoperative complaints of pain and maintenance of adequate analgesia during the surgery. The criterion for anesthetic supplementation with LA through the catheter was: patient complaining of pain (NVS ≥ 3), in which case the use of 0.25% bupivacaine with vasoconstrictor (12.5 mg) was recommended.

Patients were fasting and pre-anesthetic medication was not administered. In the operating room, all patients were monitored with cardiograph on the D_{II} derivation, non-invasive blood pressure, and pulse oximeter. After establishing an intravenous access with an 18G catheter before the blockade, 500 to 750 mL of Ringer's lactate were administered. With patients in the sitting position, the epidural puncture was carried out with a 16G Tuohy needle in the L₂-L₃ space and an epidural catheter was inserted in the cephalad direction. A 25G Quincke needle, introduced in the L₃-L₄ space, was used for the subarachnoid block, and the anesthetic solution was injected at a rate of 1 mL.25 secs⁻¹ without barbotage. After the blockade, patients were placed in horizontal dorsal decubitus, using a Crawford wedge to dislocate the uterus to the left until delivery. Oxygen (2 to 5 L.min⁻¹) was administered through a nasal catheter. Hydration was maintained with the administration of Ringer's lactate (10 mL.kg⁻¹.h⁻¹). The following parameters were evaluated: 1) latency of the sensorial blockade – time from the end of the injection of anesthetic solution in the arachnoid space (assessed every minute) to the loss of pin prick sensation in T₁₀; 2) upper limit of the

sensorial blockade – evaluate 20 minutes after the administration of the anesthetic solution; 3) maximal motor blockade – evaluated every 20 minutes after the administration of the anesthetic solution, according to the methodology proposed by Bromage¹⁰: 1 = incapable of moving feet or knees (complete); 2 = capable of moving only the feet (almost complete); 3 = capable of moving feet or knees (partial); 4 = complete extension of the knees and feet (absent); 4) time until total regression of the motor blockade – time between the blockade and free movement of the lower limbs (4 – absent); 5) total duration of analgesia – time from the blockade until the first spontaneous complaint of pain (NVS ≥ 3) in the immediate postoperative period, determined by the numeric verbal scale (NVS); 6) maternal cardiocirculatory and respiratory parameters: systolic blood pressure (SBP – mmHg), heart rate (HR – bpm), respiratory rate (bpm), and oxygen saturation (SpO₂ – %) were evaluated at the following moments: before the blockade (M0); immediately after the blocked (M1); every five minutes during the surgery (M2); at the end of the surgery (M3); and at the time of discharge from the post anesthetic recovery room (M4); 7) intraoperative maternal side effects: nausea, vomiting, pruritus, somnolence, respiratory depression (SpO₂ $\leq 90\%$ and respiratory rate lower than 10 bpm); and 8) neonatal repercussions: Apgar on the first and fifth minutes.

Hypotension was defined as the reduction in systolic blood pressure greater than 20% of baseline levels or below 100 mmHg in the first 30 minutes after the blockade, which would be treated with rapid crystalloid infusion followed by the administration of ephedrine (5 mg – intravenous bolus) if the patient did not respond to the crystalloid infusion; bradycardia was defined as a heart rate below 50 bpm, treated with atropine (0.01-0.02 mg.kg⁻¹).

Duration of the surgery (minutes) – it was defined as the time between the incision of the skin and the end of the surgery; fetal extraction time (minutes) – time between the beginning of the surgery and removal of the fetus.

The Student *t* test was used to evaluate the latency of the blockade, duration of analgesia, and time for regression of the motor blockade; Fisher exact test was used for the degree of the motor blockade and level of the sensorial blockade. In the analysis of the cardiocirculatory and respiratory parameters, moment M2 was considered the mean of the levels obtained during the surgery at five-minute intervals, which was analyzed by MANOVA. A level of significance of 5% was established.

RESULTS

Significant differences in the physical characteristics of the patients were not observed between both groups (Table II). Mean surgery and extraction times and standard deviations were, respectively, 83.40 ± 26.21 and 18.0 ± 5.62 minutes, in Group I (4 mL), and 75.70 ± 16.89 and 17.55 ± 5.88 minutes, in Group II (3 mL), without statistically significant differences between both groups.

Latency of the sensorial blockade was similar in both groups; maximal upper limit of the blockade ranged from T₂ to T₆, with a predominance of T₄, without statistically significant differences; grade 1 (complete) motor blockade predominated, and

time for reversal of the motor blockade did not show statistically significant differences; total duration of analgesia was significantly higher in Group 1 (Table III). Three patients (patients 05, 09, and 12) in Group II (3.0 mL) required intraoperative supplementation of LA through the epidural catheter, at 80, 92, and 71 minutes, respectively (Figure 1).

The respiratory rate of all patients remained above 10 breaths per minute, and oxygen saturation between 95% and 100%. Hemodynamic repercussions were similar in both groups. Significant differences were not observed when mean SBP and HR at the different study moments were compared between the study groups ($p = 0.08$). In the individual analysis of the cardiocirculatory parameters, hypotension was seen in 11 (55%) patients, in GI, and 10 (50%) in GII, at M2 (intraoperative), corrected by the administration of ephedrine (10 mg). Apgar in the first and fifth minutes ranged from 8 to 9 (GI) and 8 to 10 (GII), respectively. Table IV shows the mean incidence of intraoperative maternal side effects, which was similar in both groups.

Table IV – Side Effects

	Group I (4,0 mL)	Group II (3,0 mL)
Nausea	03 (15%)	04 (20%)
Vomiting	01 (5%)	02 (10%)
Pruritus	10 (50%)	10 (50%)
Somnolence	12 (60%)	08 (40%)

Results expressed as number and percentage of patients

DISCUSSION

In obstetrics, the association of bupivacaine and liposoluble opioids in subarachnoid blocks decreased the incidence of intraoperative visceral pain and contributed for a reduction in the doses of hyperbaric bupivacaine (8.0 to 10 mg)^{8,11}. A prior study with gravidas undergoing spinal block for cesarean section showed that the use of constant concentrations of hyperbaric bupivacaine (0.25%) and increasing volumes, leading, consequently, to a progressive increase in mass, resulted in significant cephalad dispersion of the drug and better intra- and postoperative analgesia, without significant difference in motor blockade⁶. However, the effectivity of low doses, in different volumes and concentrations, of the association of local anesthetic and opioids in determining maximal upper level and quality of the sensorial blockade, as well as the degree of the motor blockade, has not been clearly defined in gravidas undergoing cesarean sections.

In the present study, artifices that could affect the cephalad dispersion of the hyperbaric anesthetic solution were avoided. Patients remained in the sitting position during the puncture, and in horizontal dorsal decubitus after the slow administration (1 mL.25 secs⁻¹) of the anesthetic solution.

The dispersion mechanism of local anesthetics in the CSF is multifactorial, involving patient characteristics: age, weight, height, gender, abdominal pressure, anatomy of the spine,

Table I – Characteristics of the Anesthetic Solutions

	Group I	Group II
Volume (mL)	4	3
Density at 37°C (g.mL ⁻¹)	1.01223 ± 0.00013	1.01632 ± 0.00027
Bupivacaine (mg)		
Total dose	10	10
Glucose (mg.mL ⁻¹)	40	53.3

Table II – Characteristics of the Patients

	Group I (4 mL) (n = 20)	Group II (3 mL) (n = 20)	p
Age (years)*	30.05 ± 5.436	28.90 ± 6.78	0.3
Weight (kg)*	83.55 ± 14.52	79.49 ± 13.24	0.6
Height (m)*	1.60 ± 0.06	1.58 ± 0.05	0.28
BMI (kg.m ⁻²)*	32.54 ± 5.3	31.96 ± 5.32	0.77

Results expressed as Mean ± SD

* Student t test

Table III – Characteristics of the Blockade

	Group I (4 mL)	Group II (3 mL)	p
Latency (min)*	4.15 ± 1.11	4.63 ± 1.91	0.1
Degree of the motor blockade**			0.3
2	1	2	
1	19	18	
T2	5 (25%)	2 (10%)	
T4	14 (70%)	16 (80%)	
T6	1 (5%)	2 (10%)	
Time for regression of the motor blockade (min)*	191.65 ± 47.23	189.55 ± 56.4	0.89
Total duration of analgesia (min.)*	298.35 ± 48.99 [#]	196.55 ± 68.68	0.0001

Results expressed as Mean ± SD; number of patients; % – percentage of patients

[#]significant difference in relation to Group II

*Student t test, **Fisher exact test

and properties of the CSF; injection technique; puncture level, caliber and bevel of the needle, turbulent flow caused by the rate of the injection, and barbotage; and anesthetic solution: density, viscosity, volume, concentration, dose of the LA, and the association with vasoconstrictors. Additionally, positioning of the patient at the moment of the puncture and afterwards also affect dispersion^{3-5,12-14}.

Note that, on term pregnancy, the increase in abdominal pressure and engorgement of epidural veins, with reduction in the volume of the CSF in the lumbar and lower thoracic regions, contribute for greater cephalad dispersion of anesthetic solutions. Besides, due to the lower concentration of proteins, the density of the CSF at 37° C is reduced (1.00003 ± 0.0004) on term pregnancies when compared to normal individuals (1.00007 ± 0.0003)^{2,15}.

The anesthetic solution is considered hyperbaric when its density exceeds 99% the confidence limit of the density of the CSF¹⁶. All glucose-free anesthetic solutions with bupivacaine

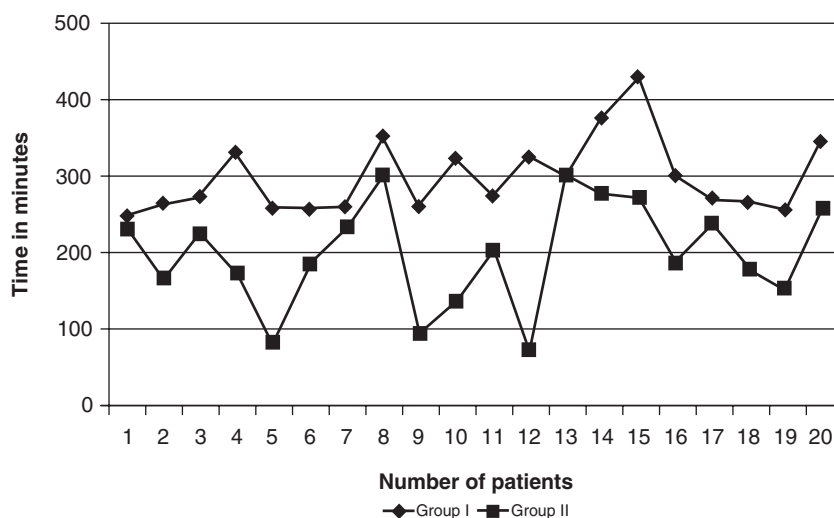


Figure 1 – Duration of Analgesia. Individual Values (minutes) in Both Groups

and opioid are considered hypobaric after subarachnoid administration unlike glucose-containing solutions, which, even in low concentrations, remain hyperbaric¹².

In a clinical study with patients undergoing cesarean sections with 0.5% bupivacaine (2.5 mL) in two solutions with different concentrations of glucose (8 mg.mL⁻¹ and 80 mg.mL⁻¹), the authors observed that, at 37° C, both solutions are mathematically hyperbaric ($1.00164 \pm 0.0.00008$ and 1.02081 ± 0.00017 , respectively), and the clinical characteristics of the blockade, as well as the quality of the surgical blockade did not show statistically significant differences between the study groups¹⁷.

Diluting hyperbaric bupivacaine with opioids and NS not only decreases its density^{18,19}, but also decreases its viscosity, facilitating cephalad dispersion^{14,17}. In the present study, we used two hyperbaric solutions with different densities. Besides, according to the clinical characteristics of the blockade observed in this study, along with the results of a recent laboratorial study, it has been confirmed that the solutions were hyperbaric, since solutions with densities below 1, equal to 1, and greater than 1 are considered hypobaric, isobaric, and hyperbaric, respectively¹⁶.

The relationship among the mass, volume, and concentration of the anesthetic solution is inseparable, i.e., mass is the result of volume x concentration; therefore, changing the volume, but not the concentration, changes the mass of the anesthetic. Studies with hyperbaric bupivacaine without opioids showed that, although the volume interferes with the dispersion of the solution in the subarachnoid space, mass is the most important element, especially in parturients at term^{5,6}.

Assessment of the total analgesia time demonstrated that, in all patients in Group I, total anesthesia time remained above 200 minutes, while in Group II this was observed only in 50% of the cases (Figure 1). Although subarachnoid block is widely used in cesarean sections, in the present study we also decided to place a catheter in the epidural space of all patients.

This conduct allowed supplementation of the local anesthetic in three patients of Group II who complained of pain during revision of the cavity, therefore avoiding the use of high doses of opioids and sedatives, as well conversion to general anesthesia. It was also observed that, in those cases, the duration of the surgery was above the mean values obtained for this parameter.

Although significant differences in the level of the sensorial blockade were not observed, the longer time of analgesia and better quality of analgesia in Group I can be attributed to the cephalad dispersion of bupivacaine and sufentanil, involving a higher number of non-myelinated C fibers, which transmit visceral pain, therefore increasing analgesic potency^{11,20}.

Similarly to clinical studies that used 7.5 and 11 mg of hyperbaric bupivacaine, the degree and time for regression of the motor blockade were not influenced by the volume of the anesthetic solution^{6,21}.

It has been observed, in urologic procedures, that the subarachnoid administration of a fixed dose (10 mg) of hyperbaric bupivacaine in different volumes and concentrations (0.5%, 0.2%, and 0.1%) caused similar sensorial blockades, but the degree and duration of the motor blockade were significantly higher when the concentration of 0.5% was used²².

In cesarean sections, the incidence of hypotension associated with subarachnoid block ranges from 50 to 85%¹³. In studies with isolate hyperbaric bupivacaine, in concentrations of 0.25% and 0.5% isolated, in different volumes, a higher incidence of hypotension was associated with changes in volume, not in doses^{6,13,20}. In the present study, using fixed doses, but different volumes and concentrations, the incidence of hypotension was similar in both groups.

Differences were not observed in the Apgar scores of the newborns, and the results of maternal side effects were similar to those reported in the literature^{7,9,20}.

The results of the present study allow us to conclude that, in cesarean sections, the subarachnoid administration of greater volumes of the anesthetic solution containing fixed doses of

hyperbaric bupivacaine (10 mg) and sufentanil (5 µg) were more effective than lower volumes of the same solution, providing better duration and quality of analgesia without increasing maternal-fetal repercussions.

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RESUMEN

Braga AFA, Frias JAF, Braga FSS, Pinto DRS – Anestesia Espinal con 10 mg de Bupivacaína Hiperbárica Asociada a 5 µg de Sufentanil para Cesárea. Estudio de Diferentes Volúmenes.

JUSTIFICATIVA Y OBJETIVOS: *Diversos factores influyen en la dispersión cefálica de la solución anestésica en el espacio subaracnoideo, entre los cuales se destacan las alteraciones fisiológicas inherentes al embarazo, baricidad, dosis y volumen del anestésico local. El objetivo de este estudio fue evaluar la efectividad y los efectos colaterales de diferentes volúmenes de la asociación de bupivacaína hiperbárica y sufentanil por vía subaracnoidea en cesáreas.*

MÉTODO: *Cuarenta pacientes, ASA I y II, sometidos a cesárea electiva bajo raquianestesia distribuidos en dos grupos, de acuerdo con el volumen de la solución anestésica usada: Grupo I (4 mL) y Grupo II (3 mL). En los dos grupos, el anestésico local empleado fue la bupivacaína hiperbárica (10 mg-2 mL) asociada al sufentanil (5 µg-1 mL). En el Grupo I, para la obtención del volumen de 4 mL, se añadió 1 mL de solución fisiológica a 0,9%. Se evaluaron: latencia del bloqueo; nivel máximo del bloqueo sensitivo; grado del bloqueo motor; tiempo para regresión del bloqueo motor; duración total de la analgesia; efectos adversos maternos y repercusiones neonatales.*

RESULTADOS: *La latencia, el nivel máximo del bloqueo sensitivo, el grado y el tiempo para la regresión del bloqueo motor fueron similares en los dos grupos; la duración de la analgesia fue mayor en el Grupo I, con una diferencia significativa con relación al Grupo II. Los efectos adversos se dieron a menudo de forma similar en los dos grupos. Se registró la ausencia de las alteraciones cardiocirculatorias maternas y de las repercusiones neonatales.*

CONCLUSIONES: *La bupivacaína hiperbárica en dosis de 10 mg asociada al sufentanil en dosis de 5 µg, con un volumen de 4 mL, fue más eficaz que la misma asociación en un menor volumen (3 mL), proporcionando una mejor analgesia intra y postoperatoria, sin repercusiones materno-fetales.*