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ORIGINAL ARTICLE

Bolus of ropivacaine 0.1% versus 0.2% in obstetric epidural analgesia: a comparative prospective study

Short title: Bolus of ropivacaine 0.1% versus 0.2% in obstetric epidural analgesia

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ABSTRACT

Objective. Aim of this study is to compare the effect of the initial bolus: 10 ml of ropivacaine 0.2% (small volume, high concentration) and 20 ml of ropivacaine 0.1% (high volume, low concentration) during obstetric labor on the motor block, hemodynamic consequences, analgesia and parturient satisfaction.

Patients and Methods. 56 parturients were included in this prospective, randomized, double-blind study. The parturients were randomized into two groups: group 1 receiving an initial bolus of 10ml of ropivacaine at 0.2% + 5 gamma of sufentanil and group 2 receiving an initial bolus of 20ml of ropivacaine at 0.2% + 5 gamma of sufentanil. The main endpoint was the evaluation of motor block.

The secondary judgment criteria were: haemodynamic consequences, evaluation of obstetric analgesia by visual analogical scale, evaluation of the sensory level and satisfaction of the parturient.

Results. The haemodynamic consequences were comparable for the 2 groups ($p>0.05$). The means of the VAS were similar ($p>0.05$). Motor block was similar in the 2 groups (14.81% for group 1 versus 6.89% for group 2 with $p=0.57$). A statistically significant difference was noted according to the sensory level which was higher in group 2 ($p<0.05$). The mean satisfaction was without significant difference ($p=0.64$). The adverse effects were similar in the two groups ($p>0.05$).

Conclusions. Our study does not show a benefit of the use of a high volume low concentration compared to the use of small volume high concentration during the induction of the epidural.

Keywords: epidural analgesia; ropivacaine ; obstetric labor .

Introduction

Labor-related pain is classified as severe. It is felt as the worst pain ever felt. Moreover, this pain can affect the course of labour, fetal well being and the neuropsychological maternal state in post partum period[1] .

The management of labor pain is therefore a major issue during childbirth. Epidural analgesia is currently the reference technique of obstetric analgesia. Many studies have demonstrated its superiority over any other form of analgesia (pharmacological or otherwise)[2–4] .

The concentration and the dose of local anesthetic agents can be manipulated to provide affective analgesia with limited motor block and with less hemodynamic variations related to the sympathectomy. The control of the undesirable effects allows the parturient to walk during the labor.

Protocols in epidural analgesia are very heterogeneous: Many studies have discussed the consequences of differences in the volume and the concentration of the initial bolus on the motor block, hemodynamic modifications, analgesia, and parturient satisfaction[5–7].

The aim of this study, is to compare the effect of the initial bolus of epidural analgesia: 20ml of ropivacaine 0.1% (high volume, low concentration) and 10ml of ropivacaine 0.2% (small volume, high concentration) during obstetrical labor on the motor block, hemodynamic variables, analgesia assessed by the visual analogical scale (VAS), and parturient satisfaction.

Materials and Methods

This is a prospective, randomized, double-blind study, performed by the team of the anesthesia department of a tunisian university hospital in collaboration of the gynecology-obstetrics department. The study period was from September 2021 until December 2021.

The study was approved by the local and hospital ethics committee. After obtaining a written informed consent, parturients aged more than 20 years who are going to give birth were included in this study if they had an ASA (American society of anesthesiology) score of I or II, height > 160 cm, body mass index (BMI) < 35, monofetal pregnancy, cephalic presentation, ≥ 37 week of amenorrhea and with cervical dilatation more than 3 cm.

The non-inclusion criteria were: the refusal of the parturient, contraindication to epidural, neurological, muscular, psychiatric pathology or other medical history, BMI > 35, height ≤ 150cm, and scarred uterus. The exclusion criteria were : failure of the epidural, disclosure of the study protocol, complications (dural breach..), extensive block (sensory level greater than T5), delivery through cesarean section.

The main judgment criteria in this study is the evaluation of motor block . The secondary judgment criteria are: the haemodynamic consequences, the evaluation of obstetric analgesia by visual analogical scale (VAS), the evaluation of the sensory level and the satisfaction of the parturient.

The sample size determination was based on data from preliminary results of the 24 first patients enrolled in this study (12 patients from each group). The incidence of the motor block was 25 % (3 patients) in the first group and 0 % in the second group. So, we determined that the sample size of 26 patients in each group is required for 80% confidence level and 5% margin of error.

The parturients were randomized into two groups, after drawing lots by the method of envelopes numbered from 1 to 70. The randomization was carried out in the labor room after the pre-anaesthetic evaluation and the consent of the parturient. The choice of the envelope was done by

an anesthesiologist who is not the one who will perform the epidural nor the one who will collect the data.

Thus, parturients were randomized into two groups:

- Group 1 : Parturients receiving an initial bolus of 10 ml of ropivacaine 0.2% with 5 gamma sufentanil
- Group 2 : Parturients receiving an initial bolus of 20 ml ropivacaine 0.1% with 5 gamma sufentanil

The same anesthetic protocol is applied for all parturients : Non-invasive monitoring was performed and included: measurement of systolic blood pressure(SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR) , analysis of the electrocardiogram tracing, pulse oximetry, and fetal heart rate monitoring.

On the delivery table, a gynecological examination was done by an obstetrician; an 18 G peripheral venous line was placed and filling with 500 ml of saline was started.

The placement of the epidural was determined by the obstetrician at cervical dilation ≥ 3 cm.

The parturient was placed in a sitting position. The location of the puncture point was made respecting the rules of asepsis. We then infiltrated 2 ml of 2% xylocaine without adrenaline. Then, the Tuohy needle was inserted in the midline position, bevel up towards the epidural space. A multi-perforated catheter was introduced (4cm in the epidural space).

After fixing the catheter and positioning in the supine position, the initial bolus was given and the maintenance (containing 0.1% ropivacaine with sufentanil 0.2 gamma/ml) was prepared using an electric syringe pump at a rate of 10 ml/ h.

The monitoring of the epidural as well as the gynecological examination were made by an anesthesiologist and an obstetrician blinded to the initial bolus given.

If the analgesia was insufficient (VAS >30) we proceeded to check that there was no failure due to the equipment (electric pump) and that the length of the inserted catheter was correct. Then we reinjected a bolus of 5ml of the maintenance mixture. In case of insufficient analgesia after two consecutive boli, the parturient was excluded from the study.

In the event of hypotension, defined by SBP less than 90 mmHg or a drop of at least 20% in SBP compared to the figures prior to the institution of epidural analgesia, we proceeded as follows: placement of the parturient in left lateral decubitus position otherwise and administration of ephedrine (IV bolus of 3 to 9 mg).

We collected for each parturient: demographic characteristics: age, weight before and at the end of pregnancy, height, body mass index (BMI), medical and surgical history, parity, term of pregnancy, the quality of analgesia assessed by the VAS score, the dilation and the state of the cervix, heart rate(HR), systolic blood pressure(SBP), and diastolic blood pressure(DBP). The parturients were monitored throughout labor until expulsion: at T0 (3 min after induction) then every 10 minutes for the first 30 min and then every 30 min until expulsion.

We evaluated: the motor block (with a score of 0 = no block or 1 = presence of the motor block), the pain by the VAS, the higher sensory level, the number of boli of the mixture requested and delivered, the quantity of anesthetic room used, HR, SBP and DBP.

After delivery, we noted: The VAS during the delivery, the VAS during the suture of the episiotomy (if done), the satisfaction of the parturient (rated from 1 to 3 with 1= not satisfied, 2=moderately satisfied, 3=very satisfied), adverse effects, the total dose of ropivacaine, the number of boli of ropivacaine and the time between the placement of the epidural and delivery.

Statistical analyses were performed using SPSS 20 software. We presented values as median and range.

Results

Seventy parturients were eligible in this study and were divided into two groups: 35 parturients in group 1 and 35 parturients in group 2. Thirteen cases were excluded for converting to cesarean section. One case was excluded for protocol disclosure (Figure 1).

The parturients were comparable regards to demographic characteristics (Table 1).

Parturients were comparable concerning parity ($p=0.58$).

The mean time between the placement of the epidural and delivery was comparable between the 2 groups (93.87 ± 61.56 minutes in group 1 vs 123.11 ± 71.51 minutes in group 2; $p=0.13$).

The motor block

Concerning the motor block, there is no significant difference (4 parturients of group 1 or 14.81 % presented a motor block versus two parturients of group 2 or 6.89% ($p=0.57$)).

Hemodynamic variations

From an analytical point of view and concerning the hemodynamic variations, the means of HR , SBP and DBP , during labor, were comparable in the two groups ($p>0.05$) (Table 2,3,4).

Four Parturients of group 1 (14.81 %) vs 3 parturients of group 2 (10.34%) had presented hypotension. The mean number of ephedrine boli was 4 in group 1 versus 3 in group 2. No significant difference between the two groups ($p=0.63$).

Visual analogical scale

The mean VAS before induction of the epidural, at T0 (at induction of the epidural), at expulsion and at episiotomy were comparable between the 2 groups. The mean VAS scores during labor were comparable in the two groups ($p>0.05$) (Table 5).

The number of boli delivered was comparable between the 2 groups (29.62% of group 1 required emergency boli vs 24.13% for group 2; $p=0.56$).

The sensory level

We found a statistically significant difference in sensory level between the two groups. It was higher for group 2 than the sensory level for group 1 ($p=0.01$).

All parturients of group 2 had a sensory level below T8 vs 48.27% of parturients of group 1.

The mode of delivery and the use of an episiotomy

The mode of delivery was vaginal for the two groups. It was comparable concerning the use of an episiotomy ($p=0.53$) or a forceps ($p=0.53$) (Table 6).

The mean total dose of Ropivacaine

The mean dose of Ropivacaine was comparable for the 2 groups: 37.41 mg for group 1 vs 41.51 mg for group 2 with $p=0.18$.

Satisfaction

We did not note any statistically significant difference between the 2 groups regarding parturient satisfaction ($p=0.64$). In fact, 18.51% were moderately satisfied in group 1 vs 17.24% in group 2. Besides, 81.48% were very satisfied in group 1 vs 82.75% in group 2.

Adverse effects

The frequency of adverse effects was comparable for the 2 groups (33.33% for group 1 vs 17.24% for group 2, $p=0.52$). No significant difference between the 2 groups concerning nausea ($p=1.11$), vomiting ($p=0.54$), and pruritus ($p=1.12$) (Figure 2).

Discussion

As part of the improvement of epidural analgesia protocols in the obstetric settings, we focused in this comparative study on the effect of the initial bolus in the obstetric epidural (high volume small concentration versus small volume high concentration).

Patients' preferences about labour are focused on both pain relief and labour duration[8]. Admittedly, the most appropriate analgesia technique for obtaining continuous analgesia throughout the duration of labor and allowing the abolition of the visceral (T10-L1) and somatic (S2-S4) component of pain is the performance of a lumbar epidural block extending from T10 to S4. This epidural analgesia is safe and doesn't affect the onset of postpartum urinary incontinence in medium-term, regardless the mode of delivery[9].

Labor is considered less painful in multiparas. The nulliparous generally suffer from a longer labour, and consume more local anesthetics than the multiparous. However, multiparas complain of a very painful second stage of labor [10,11].

It is evident that maternal anxiety contributes to an increase in the sensation of pain [12], and it has been demonstrated that information and courses in preparation for birth, by reducing anxiety, have a favorable effect on pain.

In our study we chose ropivacaine as a local anesthetic for its satisfactory analgesic effect and its negligible side effects [13].

The evolution of practices, centered on the reduction of motor block, leads to the use of very dilute solutions (bupivacaine 0.12% to 0.06% or ropivacaine 0.1 to 0.2%) associated with a powerful morphine (fentanyl or sufentanil).

In our study we used ropivacaine 0.1% and 0.2% for the initial bolus then 0.1% for maintenance. We used sufentanil as an adjuvant at a dose of 5 μ g for induction and 0.2 μ g/ml for maintenance. It is not yet verified that intermittent epidural bolus for the maintenance is superior than continuous epidural infusion regimen[14].

Several studies have been carried out in order to report the differences in the results in the use of boli in the epidural at different concentrations.

Dernedde and al [5] found a significant difference in hemodynamic variations. The high volume/low concentration group had lower SBP and DBP.

Our results were different from what has been described in the literature. We found no significant difference between the 2 groups. Indeed, the hemodynamic variations were comparable.

The occurrence of motor block, evaluated by the Bromage score, is a frequent adverse effect in epidural analgesia in obstetrics that can hinder the progress of labor and the satisfaction of the parturient. The motor block is rapidly regressive when the administration is stopped.

Chhetty and al[10] compared 2 concentrations of ropivacaine 0.125% versus 0.2% and they did not find motor block for the two groups. The same goes for the study by Ginosar and al[7], the Bromage score was 0 for both groups (high volume low concentration and low volume high concentration).

In our study, there was no significant difference between the two groups. Our results are therefore consistent with those of the literature.

Concerning the evaluation of the quality of analgesia and in our study, we chose to use the VAS for the evaluation of the pain. This score is the most widely used to assess the intensity of pain[11]. Studies have assessed the impact of the use of high volume/low concentration and the use of low volume/high concentration local anesthetics on the quality of epidural analgesia. Indeed, Ginosar and al [7] compared two groups: the first received a bolus of 5 ml then 5 ml/h of bupivacaine 0.25% and the second group received a bolus of 20 ml then 20 ml/h of bupivacaine 0.0625%. They evaluated the effect of local anesthetic volume and concentration on analgesia and parturient satisfaction during labor. They found that the quality of analgesia depends on the volume of the local anesthetic injected. Therefore the use of high volume dilute local anesthetic solution provides better analgesia during labor. This was also confirmed by the study of Chhetty and al[10] which found that high concentration of ropivacaine was superior in terms of faster onset, prolonged duration, lesser breakthrough pain requiring lesser top-ups, and hence a lesser consumption of opioids.

In our study, the mean VAS scores during the second stage of labor were comparable between the two groups, as were the mean VAS scores at expulsion.

To have analgesia during obstetric labor, a sensory level of at least T10 is required. In our study, all parturients had a sensory level below T10. We found a statistically significant difference with respect to the higher sensory level. The most frequently found sensory levels were T8-T9 for group 1 and T7-T8 for group 2. So the sensory level in group 2 was higher than the sensory level in group 1.

Our results are in agreement with the results of Dervedde and al [15] who compared 2 groups with the same dose, different concentrations and different volumes of levobupivacaine. They found that the sensory level is higher for the group that has the lowest concentration and the highest volume. In our study, there was no statistically significant difference between the two groups regarding the satisfaction of parturients with the quality of analgesia. In the literature, the majority of studies have found no difference in the satisfaction of parturients [5,7].

Points of strengths in our study

Admittedly, our study has a potential contribution to improve epidural analgesia protocols in obstetrics and the results of this trial deserve to be further exploited in a large number of parturients especially when it is allowed for intrapartum pain control and even for COVID19 patients[16,17].

In addition, and despite the ease of application of our protocol (small volume/high concentration), it is important to point out the constraints of pain assessment, especially in subjects with limited intellectual abilities.

Indeed, pain is personal and subjective in nature. Self-assessment remains the reference method for assessing pain during labor. In this context, the EVA score could be applied, because of its reproducibility and objectivity.

Conclusions

Epidural analgesia is currently the "gold standard" for the management of labor pain. We hypothesized that the volume and concentration of the initial bolus could have consequences on analgesia, motor block, hemodynamics and parturient satisfaction.

The objective of this study is to compare the effect of the initial bolus: 10ml of ropivacaine 0.2% (small volume high concentration) and 20ml of ropivacaine 0.1% (high volume low concentration) during obstetric labor on motor block, haemodynamic consequences, analgesia assessed by VAS and parturient satisfaction.

The results showed no significant difference between the two groups with regard to hemodynamic consequences, analgesia assessed by VAS and parturient satisfaction. On the other hand, the sensory level with a sensory block was higher in group 2 ($p=0.01$).

Thus, the use of a high volume during the induction of the epidural has no interest in epidural analgesia compared to the protocol using a small volume. However, these results should be interpreted with caution because of the limitation of this test (duration and sampling).

Certainly, our study is of a potential contribution to the improvement and standardization of epidural analgesia protocols in obstetrics and the results of this trial deserve to be exploited in a large number of parturients.

Recommendation

We recommend performing a comparative and prospective study included huge number of parturients to prove the effect of the initial bolus in the epidural analgesia.

Compliance with Ethical Standards

Authors contribution:

All the authors shared in data collection, statistical analysis of data, writing and reviewing the manuscript before publishing.

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Study registration: No.

This manuscript conform the Enhancing the QUALity and Transparency Of health Research (EQUATOR) network guidelines.

Disclosure of Interests: The authors declare that they have no conflict of interests.

Ethical Approval: The study was approved by the local ethics committee of medicine, Sfax University.

Informed consent: A signed written consent from included patients was acquired.

Data sharing: Data are available under reasonable request to the corresponding author.

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Table 1: Demographic characteristics of parturients

	Group 1	Group 2	P=
Age (years)	25,88±4,65	28,12±5,02	0,06
WEight (kg)	74,77±8,15	74,33±12,46	0,54
height(m)	1,64±0,03	1,64±0,03	0,56
BMI (kg/m2)	27,81±2,96	27,38±3,51	0,56

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Table 2: The averages of heart rate during labor in the 2 groups.

	HR Before	HR 0	HR 10	HR 20	HR 30	HR 60	HR 90
GROUP 1	95,5±12,6	96,9±13,2	95,5±19,2	96,6±18,8	91,4±15,2	93,8±18,9	87,4±19,8
GROUP 2	95,6±13,8	95,1±13,29	92,3±17,1	92,7±17,6	91,7±15,9	89,3±16,5	89,4±14,8
P=	0,77	0,49	0,45	0,32	0,89	0,31	0,62

	HR 120	HR 150	HR 180	HR 210	HR 240	HR 270
GROUP 1	88,4±18,1	96,3±17,8	90,1±31,9	100,1±24,1	93,5±22,9	101,1±28,1
GROUP 2	96,2±17,9	95,1±12,8	99,4±23,1	103,8±14,9	103,2±16,8	99,2±18,5
P=	0,22	0,81	0,71	0,82	0,67	0,91

Table 3: Mean systolic blood pressure over time in the two groups.

	SBP Before	SBP 0	SBP 10	SBP 20	SBP 30	SBP 60	SBP 90
GROU P1	125,9±13,6	125,4±15,7	121,9±16,4	119,9±13,6	122,3±18,9	121,7±14,8	115,9±12,7
GROU P2	130,1±12,9	127,3±14,2	124,5±13,9	124,7±15,3	121,4±16,4	122,3±18,2	125,9±18,1
P=	0,52	0,89	0,54	0,21	0,98	0,74	0,22

	SBP 120	SBP 150	SBP 180	SBP 210	SBP 240	SBP 270
GROUP1	124,5±18,8	116,4±20,5	137±14,4	125,4±35,1	125,1±23,2	130,4±28,7
GROUP2	132,9±20,7	122,9±16,9	123±14,1	131,3±9,9	123,9±3,4	130,4±0.6
P=	0,28	0,42	0,24	0,82	0,91	0,91

Table 4: Mean diastolic blood pressure over time in the two groups

	DBP Before	DBP 0	DBP 10	DBP 20	DBP 30	DBP 60	DBP 90
GROUP 1	75,8±9,3	76,4±13,8	72,6±12,1	100,4±16,1	73,2±15,7	70,7±9,5	68,9±10,1
GROUP 2	75,6±8,5	77,2±11,7	71,9±11,2	73,4±11,3	72,5±13,5	71,2±11,5	75,1±13,8
P=	0,92	0,71	0,72	0,32	0,82	0,87	0,19

	DBP 120	DBP 150	DBP 180	DBP 210	DBP 240	DBP 270
GROUP 1	68,9±11,5	79,4±17,1	76,4±4,2	75,4±13,2	77,4±10,6	79,1±1,5
GROUP 2	77,8±11,1	75,1±13,1	76,4±7,6	81,4±17,2	80,2±6,5	79,5±0,8
P=	0,02	0,65	0,94	0,65	0,77	0,72

Table 5: The mean visual analogical scale over time in the 2 groups

	GROUP 1	GROUP 2	P=
VAS before induction	64,8±12,1	64,5±13,7	0,73
VAS T0	27,5±24,1	32,3±25,2	0,10
VAS expulsion	8,56±11,4	13,2±8,66	0,93
VAS episiotomy	9,29±11,2	9,21±11,5	0,35.

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Table 6: Use of episiotomy or forceps in the two groups

	Episiotomy	Forceps
GROUP 1	74.07%	25.92%
GROUP 2	75.86%	24.13 %

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Figure 1. Distribution of parturient.

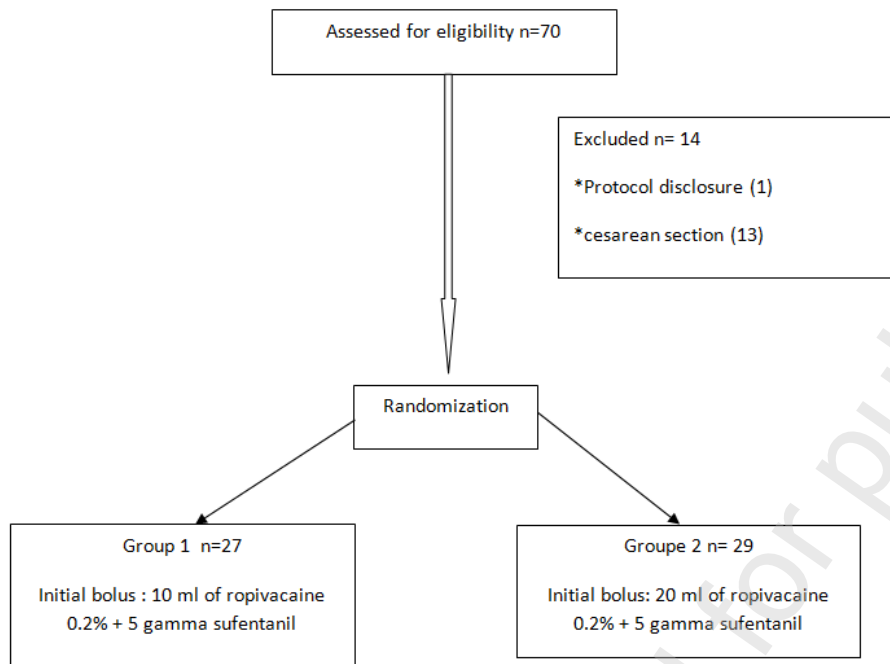
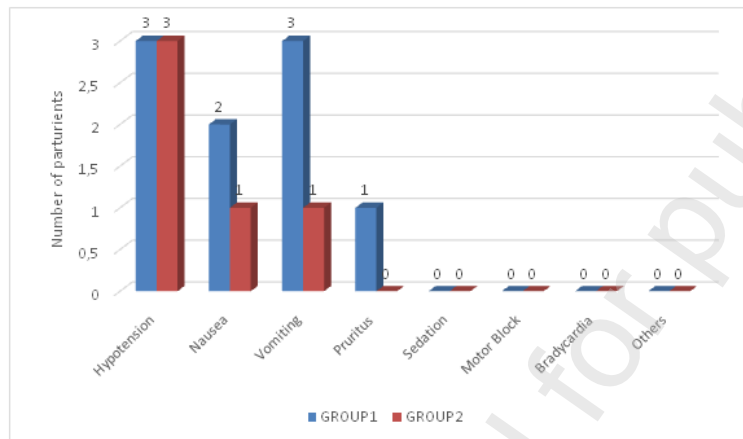


Figure 2. Adverse affects in the two groups



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