



# Italian Journal of Gynæcology & Obstetrics

December 2023 - Vol. 35 - N. 4 - Quarterly - ISSN 2385 – 0868

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

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### ARTICLE INFO

#### History

Received: 31 October 2022

Received in revised form: 06 January 2023

Accepted: 12 January 2023

Available online: 12 December 2023

DOI: 10.36129/jog.2023.95

#### Key words

Epidural analgesia; ropivacaine; obstetric labour.

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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 labour on the motor block, haemodynamic 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 10 ml of ropivacaine at 0.2% + 5 gamma of sufentanil, and group 2 receiving an initial bolus of 20 ml 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.

### 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, foetal wellbeing and the neuro-psychological maternal state in postpartum period [1]. The management of labour 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 anaesthetic agents can be manipulated to provide affective analgesia with limited motor block and with less haemodynamic variations related to the sympathectomy. The control of the undesirable effects allows the parturient to walk during the labour.

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, haemodynamic modifications, analgesia, and parturient satisfaction [5-7].

The aim of this study is to compare the effect of the initial bolus of epidural analgesia: 20 ml of ropivacaine 0.1% (high volume, low concentration) and 10 ml of ropivacaine 0.2% (small volume, high concentration) during obstetrical labour on the motor block, haemodynamic 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 anaesthesia 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, monofoetal pregnancy, cephalic presentation,  $\geq 37$  week of amenorrhoea 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  $\leq 150$  cm, and scarred uterus. The exclusion criteria were: failure of the epidural, disclosure of the study protocol, complications (*e.g.*, dural breach), extensive block (sensory level greater than T5), delivery through caesarean section.

The main judgment criteria in this study is the evaluation of motor block. The secondary judgment criteria were: 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 pa-

tients) 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 labour room after the pre-anaesthetic evaluation and the consent of the parturient. The choice of the envelope was done by an anaesthesiologist 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 anaesthetic 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 foetal heart rate monitoring. On the delivery table, a gynaecological examination was done by an obstetrician; an 18 G peripheral venous line was placed and filled with 500 ml of saline was started.

The placement of the epidural was determined by the obstetrician at cervical dilation  $\geq 3$  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 (4 cm 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 gynaecological examination were made by an anaesthesiologist 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 5 ml 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 were 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 labour 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 anaesthetic 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 caesarean 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 ( $93.87 \pm 61.56$  minutes in group 1 *vs*  $123.11 \pm 71.51$  minutes in group 2;  $p = 0.13$ ).

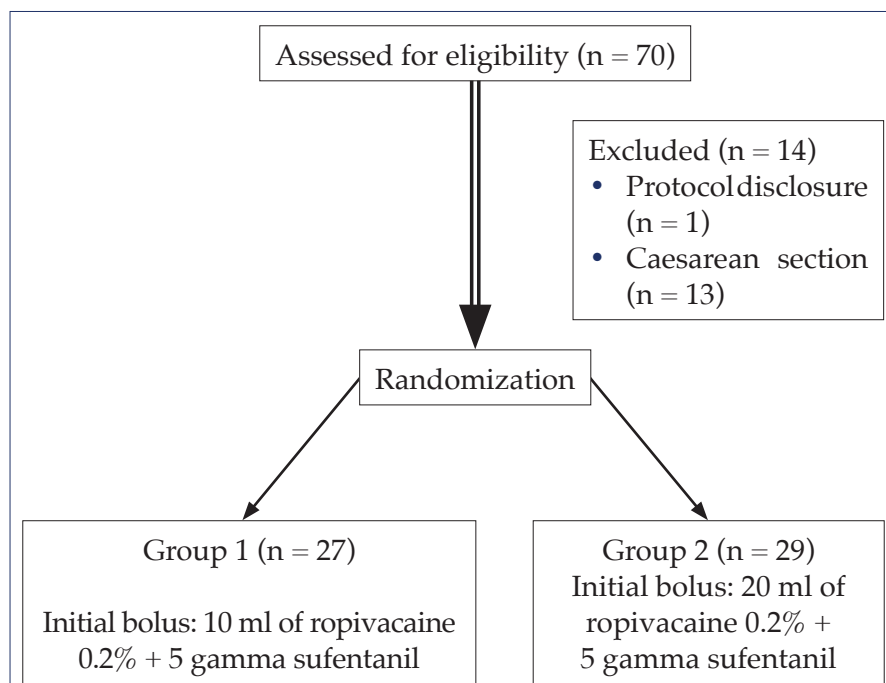


Figure 1. Distribution of parturients.

**Table 1.** Demographic characteristics of parturients.

	Group 1	Group 2	P-value
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/m <sup>2</sup> )	27.81 ± 2.96	27.38 ± 3.51	0.56

**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)).

**Haemodynamic variations**

From an analytical point of view and concerning the haemodynamic variations, the means of HR, SBP and DBP during labour were comparable in the two groups (p > 0.05) (Tables 2-4).

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 labour were comparable in the two groups (p > 0.05) (Table 5).

**Table 2.** The averages of heart rate during labour in the 2 groups.

	HR before	HR 0	HR 10	HR 20	HR 30	HR 60	HR 90	HR 120	HR 150	HR 180	HR 210	HR 240	HR 270
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	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	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	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-value	0.77	0.49	0.45	0.32	0.89	0.31	0.62	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	SBP 120	SBP 150	SBP 180	SBP 210	SBP 240	SBP 270
Group 1	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	124.5 ± 18.8	116.4 ± 20.5	137 ± 14.4	125.4 ± 35.1	125.1 ± 23.2	130.4 ± 28.7
Group 2	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	132.9 ± 20.7	122.9 ± 16.9	123 ± 14.1	131.3 ± 9.9	123.9 ± 3.4	130.4 ± 0.6
P-value	0.52	0.89	0.54	0.21	0.98	0.74	0.22	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	DBP 120	DBP 150	DBP 180	DBP 210	DBP 240	DBP 270
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	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	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	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-value	0.92	0.71	0.72	0.32	0.82	0.87	0.19	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-value
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

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  $p = 0.18$ .

**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 %

**Satisfaction**

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

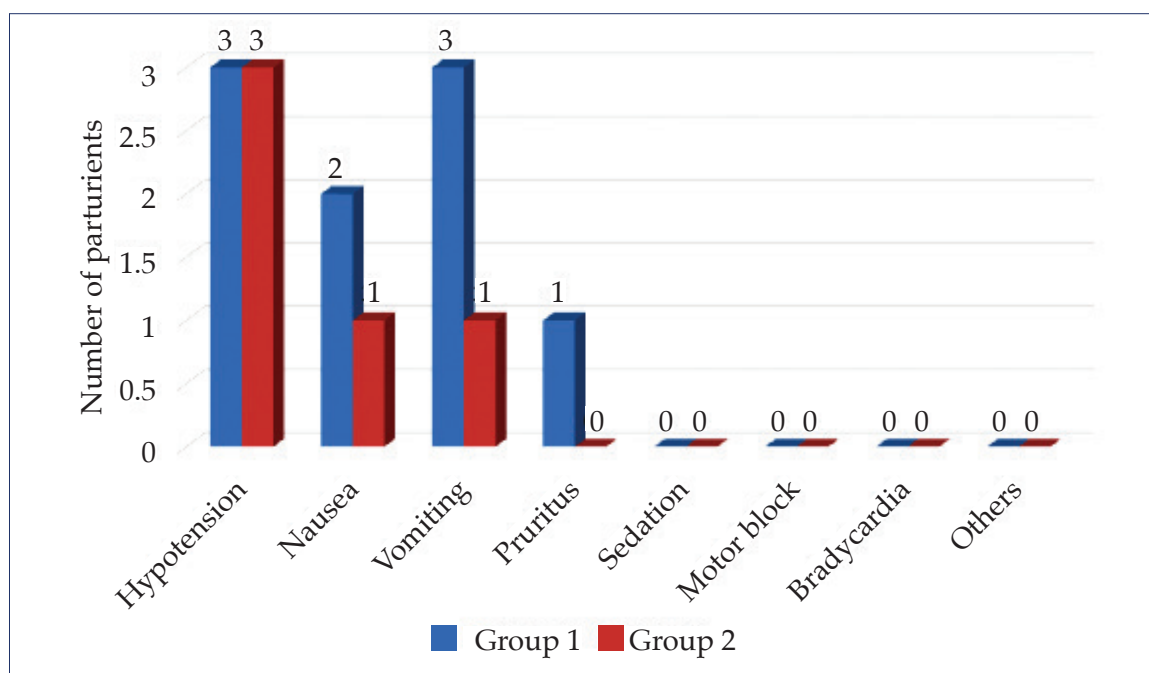
**Adverse effects**

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 du-



**Figure 2.** Adverse effects in the two groups.



ration of labour 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 anaesthetics than the multiparous. However, multiparas complain of a very painful second stage of labour [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 favourable effect on pain.

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

The evolution of practices, centred 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 µg for induction and 0.2 µg/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 *et al.* [5] found a significant difference in haemodynamic 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 haemodynamic 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 labour and the satisfaction of the parturient. The motor block is rapidly regressive when the administration is stopped.

Chhetty *et 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 *et 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 anaesthetics on the quality of epidural analgesia. Indeed, Ginosar *et 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 anaesthetic volume and concentration on analgesia and parturient satisfaction during labour. They found that the quality of analgesia depends on the volume of the local anaesthetic injected. Therefore, the use of high volume dilute local anaesthetic solution provides better analgesia during labour. This was also confirmed by the study of Chhetty *et 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 labour were comparable between the two groups, as were the mean VAS scores at expulsion.

To have analgesia during obstetric labour, 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 Dernedde *et 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

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 COVID-19 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 labour. 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 labour pain. We hypothesized that the volume and concentration of the initial bolus could have consequences on analgesia, motor block, haemodynamics and parturient satisfaction.

The objective 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 labour 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 haemodynamic 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 authors contributed equally to this work.

#### Funding

None.

#### Study registration

N/A.

#### 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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