

Provisionally accepted for publication

## ORIGINAL ARTICLE

### **Pudendal nerve block vs usual lidocaine infiltration for pain relief in episiotomy repair: a comparative prospective study**

**Short title:** Pudendal nerve block vs lidocaine infiltration for episiotomy repair

Yasmine **Ellouze**<sup>1,\*</sup>, Melek **Jallouli**<sup>1</sup>, Ali **Chaabouni**<sup>1</sup>, Marwa **Abdelmoula**<sup>1</sup>, Mohamed **Derbel**<sup>2</sup>, Kais **Chaabene**<sup>2</sup>, Anouar **Jarraya**<sup>1</sup>, Kamel **Kolsi**<sup>1</sup>

<sup>1</sup> Department of Anesthesiology and Critical Care, Faculty of Medicine of Sfax, Hedi Chaker University Hospital, University of Sfax, Sfax, Tunisia.

<sup>2</sup> Department of Gynecology, Faculty of Medicine of Sfax, Hedi Chaker University Hospital, University of Sfax, Sfax Tunisia.

**Doi:** 10.36129/jog.2023.122

**\*Corresponding author:** Ellouze **Yasmine**, Anesthesiology department/Hedi Chaker Hospital, University of Sfax, N 84 Merkez Chaker 3072, Sfax, Tunisia.

Email: ellouzeyasmine@yahoo.fr

**ORCID:** 0000-0003-0804-0026

## ABSTRACT

**Objective.** we aimed to compare the anesthetic and analgesic effect of the pudendal nerve block (PNB) and of the local lidocaine infiltration during episiotomy repair and in the following 24 hours.

**Patients and Methods.** 70 parturients undergoing natural birth requiring episiotomy and presenting contraindication or refusal of epidural analgesia were randomized to receive pudendal nerve block with ropivacaine or local lidocaine infiltration. The main endpoint was: evaluation of obstetric analgesia by visual analogical scale . The secondary judgment criteria were: hemodynamic parameters, suture duration, onset time of sensory block, time to first analgesic request, rehabilitation parameters, parturient and obstetrician satisfaction and pain intensifying factors.

**Results.** Mean VAS pain score was significantly lower in pudendal group versus infiltration group at T10min(10 minutes after local anesthetic injection) ( $7.20 \pm 8.56$  vs.  $20.43 \pm 18.25$ ,  $p < 0.01$ ), T15min ( $5.43 \pm 8.17$  vs.  $17.71 \pm 16.42$ ,  $p < 0.01$ ), T20min (repair starting) ( $29.63 \pm 23.59$  vs.  $44.06 \pm 28.16$ ,  $p = 0.023$ ), T1h ( $13.14 \pm 19.18$  vs.  $32.20 \pm 21.25$ ,  $p < 0.01$ ), T1h30min ( $10.57 \pm 14.74$  vs.  $27.34 \pm 16.74$ ,  $p < 0.01$ ) and T2h ( $9.57 \pm 15.69$  vs.  $25.34 \pm 16.32$ ,  $p < 0.01$ ), T6h ( $13.57 \pm 14.07$  vs.  $41.43 \pm 23.24$ ,  $p < 0.01$ ), T12h ( $22.60 \pm 20.41$  vs.  $36.49 \pm 23.35$ ,  $p = 0.010$ ) and T18h ( $12.23 \pm 11.84$  vs.  $27.94 \pm 23.40$ ,  $p < 0.01$ ). Significantly shorter average suture time and better obstetrician's satisfaction were observed in pudendal group. Nevertheless, parturient satisfaction did not reveal significant difference in our study, as well as time to first analgesic request.

**Conclusions.** Nerve stimulator guided PNB proved to be more effective for pain management in episiotomy repair than the classical lidocaine infiltration.

### Key words

Episiotomy; analgesia; pudendal block; infiltration.

## Introduction

Episiotomy is a surgical incision of the vagina and the perineum made during childbirth [1] used since the 19th century[2]. It is associated with a higher risk of acute and chronic pain and threatens the mother's quality of life and the bonding with her baby[3–5].

Episiotomy pain is underestimated [4]. Despite being the gold standard for pain relief in natural childbirth, epidural analgesia is used only on 4% of the parturients in the world [6–8].

Local anesthetic infiltration is commonly used for episiotomy repair[9], an easy and effective technique which can be performed by the obstetrician. The pudendal nerve block (PNB) has demonstrated its efficiency in pain management for perineal procedures, particularly for episiotomy[10,11].

The aim of this study is to compare the anesthetic and analgesic effect, during suture and the following 24 hours, of the PNB to that of the local lidocaine infiltration in the episiotomy repair.

## Materials and Methods

This is a prospective, randomized study performed by the team of the anesthesia department and the gynecology-obstetrics department of a tunisian university hospital. The study period was from February to May 2022.

The study was approved by CPP SUD (Le Comité de Protection des Personnes SUD) under the reference = CPP SUD N°0390/2022, and informed consent was taken prior to patient enrolment. Parturients undergoing natural birth requiring episiotomy were included if they had 20 years old or more, an ASA (American Society of Anesthesiologists) physical status I or II, BMI < 30 and presenting contraindication or refusal of epidural analgesia.

Parturient women who presented any contre-indication to standard epidural analgesia could succeed to be included in our study if they responded to our inclusion criteria.

Non included parturient women weren't eligible for the trial from the beginning. Non-inclusion criteria were chronic pain, long-term use of analgesics, inability to use a visual analog scale (VAS), forceps delivery, allergy to local anesthetics, tissue infection of the perineum, sepsis, diabetes, hemostasis disorders and neurological disorders. Excluded parturient women went through the trial procedure and were excluded if they presented one or more exclusion criteria which were block failure, eclampsia and the use of another type of anesthesia.

### Randomization

For each group(R or X), we accorded the same number of sealed envelopes.

After delivery and the consent of the parturient, and before episiotomy repair, an operator took aleatory an envelope and prepared the syringe according to it. 70 participants were randomized into two groups.

-Group R (n=35): unilateral PNB was performed on the episiotomy side with a nerve stimulator, 15ml of ropivacaine 0.75% (FRESENIUS, KABI) were injected.

-Group X (n= 35): the wound line was infiltrated with 10 ml of lidocaine 2% (LIDOCAINE, AGUETTANT).

The practitioner in charge of performing the technique and the assisting nurse were the only unblinded persons. A second anesthetist, responsible for the documentation of outcomes, had access to the labour room after the injection. The parturient wasn't able to distinguish between the two techniques.

## Pudendal Nerve Block

Ten minutes after episiotomy, the women still in lithotomy position, transperineal PNB was performed in a sterile fashion, guided by nerve stimulator (Stimuplex® HNS12), using a 100 mm short bevel insulated needle (Locoplex®, VYGON, France). The puncture site is located at the intersection of a vertical line passing inside the ischial tuberosity and a perpendicular line passing through the upper edge of the anus .

The contraction of the constrictor vulvae muscle or the bulbospongiosus muscle or the clitoral hood under 0.5 milliampere of stimulation imposes local anesthetic (LA) injection after repeated aspiration tests (with doses commonly used [12])

## Local Lidocaine Infiltration

Under the same conditions of timing, position and sterile preparation, and after negative aspirations, both edges of the wound were infiltrated while slowly withdrawing and redirecting the needle in order to infiltrate the maximum possible structures and layers (the dose used should be inferior than 200mg [13]).

For both techniques, episiotomy repair started 20 minutes after the injection, all parturients were admitted for 2 hours after delivery in the labor room and for a minimum of 24 hours in the post-partum unit. Additional analgesia was ensured with paracetamol 1g (4x a day), and ketoprofen 50 mg (a maximum of 3x a day).

## Outcome measures

Demographic characteristics such as age, weight, height, medical and surgical history (including perineal injuries), gestational age, parity, and previous types of deliveries were collected. The pudendal nerve depth (for group R) was collected. Onset time of sensory block was measured using the cold test. The inability to proceed suturing without switching to another type of anesthesia defined the block failure. The intensity of pain was evaluated according to the visual analogue scale (VAS). Non-invasive blood pressure, heart and respiratory rates and VAS were monitored every 5 minutes for 40 minutes starting from the incision, then every 30 minutes for 2 hours and then every 6 hours. T-10min = episiotomy, T0min = LA injection, T20min = first knot for the suture.

The main judgment criteria in this study is the quality of analgesia based on VAS pain score during repair and the following 24 hours. In the post-partum unit, static VAS (when resting) and dynamic VAS (when moving) were noted. Secondary outcomes included variations in blood pressure, heart and respiratory rates, time of the first request for rescue analgesics, suture duration, onset time of sensory block, rehabilitation after episiotomy (time of the first ambulation, first micturition and first defecation), parturient and obstetrician satisfaction and potential complications related to LA toxicity. Pain intensifying factors were studied too.

## Statistical methods

Ten parturients (five in each group) were studied to determine the required sample size. Assuming a margin error of 0.05, a power of 0.80 and a possible drop out of about 10% of the participants, the results of this pre-study are reported in Table 1.

Statistical analysis was performed using IBM SPSS (Statistical Package for Social Sciences) 28.0 for Windows. Continuous variables were expressed as means  $\pm$  standard deviations and categorical variables were expressed as percentages. Normal distribution of data was assessed using Kolmogorov-Smirnov test. To compare two continuous variables, Student's T-test was used after normality verification, otherwise, Mann-Whitney U test was used. To compare multiple continuous variables ( $>2$ ), one-way ANOVA was used. Pearson's Chi-square Test was used to

compare categorical variables if expected frequencies > 5, Fisher's exact test was used otherwise. A p value < 0.05 was considered significant for all statistical tests.

## Results

The study included 70 randomized parturients (35 in pudendal group: R and 35 in infiltration group: X). All eligible patients accepted to participate and were enrolled in the study.

As shown on table 2, no difference was detected between groups at baseline.

In the labor room, VAS scores in each group were summarized in Figure 1. Significant difference was observed at T10min ( $7.20 \pm 8.56$  vs.  $20.43 \pm 18.25$ ,  $p < 0.01$ ), T15min ( $5.43 \pm 8.17$  vs.  $17.71 \pm 16.42$ ,  $p < 0.01$ ), T20min ( $29.63 \pm 23.59$  vs.  $44.06 \pm 28.16$ ,  $p = 0.023$ ), T1h ( $13.14 \pm 19.18$  vs.  $32.20 \pm 21.25$ ,  $p < 0.01$ ), T1h30min ( $10.57 \pm 14.74$  vs.  $27.34 \pm 16.74$ ,  $p < 0.01$ ) and T2h ( $9.57 \pm 15.69$  vs.  $25.34 \pm 16.32$ ,  $p < 0.01$ ) in the pudendal and infiltration groups respectively.

Static and dynamic VAS scores in the post-partum unit are summarized respectively in figure 2 and 3. The mean VAS was higher in the infiltration group with a significant difference at T6h (static:  $13.57 \pm 14.07$  vs.  $41.43 \pm 23.24$ ,  $p < 0.01$ ; dynamic:  $30.29 \pm 22.57$  vs.  $59.46 \pm 26.65$ ,  $p < 0.01$ ), T12h (static:  $22.60 \pm 20.41$  vs.  $36.49 \pm 23.35$ ,  $p = 0.010$ ; dynamic:  $43.34 \pm 20.53$  vs.  $55.69 \pm 23.65$ ,  $p = 0.023$ ) and T18h (static:  $12.23 \pm 11.84$  vs.  $27.94 \pm 23.40$ ,  $p < 0.01$ ) in the pudendal and infiltration groups respectively (table 3).

Variations in heart rate, systolic and diastolic blood pressure and respiratory rate were similar between the two groups. The average suture time was significantly shorter in pudendal group ( $17.5 \pm 6.2$  minutes vs.  $24 \pm 7.5$  minutes,  $p < 0.01$ ).

Onset time of sensory block was longer in the pudendal group as shown in Figure 4 but the difference did not reach statistical significance ( $p = 0.712$ ).

60% of parturients in group X and 54.3% in group R required additional analgesia ( $p = 0.629$ ), time of the first request for rescue analgesics was  $9.68 \pm 5.7$  hours in group R against  $8 \pm 5.54$  hours in group X ( $p = 0.35$ ).

The rehabilitation data after episiotomy are summarized in table 4.

As shown in table 5, the evaluation of obstetrician's comfort during suturing revealed statistically significant results in favor of pudendal group, maternal satisfaction was better too but the difference did not reach statistical significance.

During the study period, no adverse events related to LA toxicity were recorded in both groups.

In the study of pain intensifying factors, parturients under 30 years old and parturients with a BMI below  $25 \text{ kg/m}^2$  experienced significantly more pain only at T24h (at rest and during exercise) with  $p = 0.045$ . The intensity of pain was inversely proportional to parity with a significant difference at T30min (ANOVA=0.007), T6h during exercise (ANOVA=0.032), T12h during exercise (ANOVA=0.015), T18h at rest (ANOVA<0.001) and T18h during exercise (ANOVA=0.029). More pain was experienced by parturients with a history of perineal injury with a significant difference at T12h during exercise ( $p = 0.033$ ), T18h at rest ( $p = 0.014$ ) and T18h during exercise ( $p = 0.07$ ).

The mean depth of the pudendal nerve with the approach used in our study is  $71.37 \pm 7.58$  mm with a median of 70 mm and a range of 55-85 mm.

## Discussion

Episiotomy is practiced in 60% to 70% of natural births in the general population. It is a protective practice in eutocic deliveries[14]. In fact, episiotomy can significantly reduce the number of genital lacerations and delivery-related perineal trauma[15,16]. It limits in some cases the duration of the second stage of labour and avoid extended perineal tears such like the disengagement of the deeply impacted fetal head[17]. But if the patient has extensive adenomyosis and a high risk of uterine rupture, she may require close follow up and eventual delivery assistance[18]. Besides, pre-labor uterine rupture risk can be evaluated by a simple ultrasound examination[19].

LA perineal infiltration is the most commonly used technique for pain management during episiotomy repair[9,20] due to its effectiveness, safety and ease of use, however intra wound multiple injections remains a painful and unaccepted procedure suggesting to think about alternative techniques. PNB is performed with a single puncture of intact skin [12]ensuring anesthesia of an entire nerve territory. Despite being used only on 4% of parturients worldwide, epidural analgesia is the gold standard for labor pain management[21–23]. Yet the PNB still has a place even in the presence of epidural catheter, thanks to its ability to reduce LA doses and minimize side effects. In this study, PNB was done after delivery to avoid LA fetal toxicity as reported in literature[24].

For a long time, PNB has been used with the aid of a nerve stimulator to ensure optimal nerve location. During the 21st century, the use of ultrasonography to guide invasive procedures in medicine including regional anesthesia has decreased side effects such as vascular punctures and nerve injury. Ultrasound guided PNB is performed in the lateral position with a puncture in the gluteal region, which can make obtaining informed consent from women in labor difficult in our country.

Lidocaine is the only LA that can be intravenously administered, plenty of studies have proven its fast onset, short duration, low cost and safety[25–27]. Lidocaine perineal infiltration in the presence or not of epidural catheter is the most widely adopted protocol for pain management in episiotomy repair[26]. We tried to compare it like it is to a current technique with a recommended LA and used by the majority of authors, ropivacaine. It is characterized by a longer duration of action and a lower cardiotoxicity than other long-acting local anesthetics[28] and point to a potential superiority in the context of multimodal analgesia.

The difference in analgesic effectiveness may be due to the injection technique, to the local anesthetic or both. Arslan and al. reported significantly lower pain during the suture in pudendal group (mean VAS = 2.70 +/-2.50) than in infiltration group (mean VAS = 4.76 +/-1.97) using the same dose of prilocaine in each group[9]. In 2021, a meta-analysis showed similar analgesic effects of lidocaine and ropivacaine during episiotomy repair after performing a local anesthetic infiltration[26]. Those trials concluded to the superiority of the PNB compared to local wound infiltration in term of analgesic efficacy at suturing regardless of the used LA which was comparable to the findings of our study.

In the study of Arslan and al, PNB provided more effective analgesia than local infiltration 30 minutes after suturing[9]. Gutton et al. described a significantly greater analgesic effect of ropivacaine than lidocaine 2, 24, and 48 hours after repair under the same technique of local anesthesia[13]. Deshpande and Saundattikar found similar results 2 and 4 hours after repair[29]. Schinkel et al. performed a local infiltration and did not find significant difference between both local anesthetics during the first 24 hours[30].

51.4% of the included parturients in our study are primiparous. It is known that episiotomy concerns preferentially primiparous women[31,32]. As was the case for our findings, Olayemi and al. [33] and Green[34] concluded that primiparous experienced more pain than multiparous women, Eshkevari et al. [20] affirms that postpartum pain which is caused by the uterus' return to its original size is felt more intensely by multiparous women. Those studies did not separate

episiotomy-related pain to postpartum pain. Parturients younger than 30 years of age and those with a BMI less than 25 felt significantly more pain only 24 hours after LA injection. The correlation between young age, lower weight and primiparity may explain this difference keeping in mind that the study of pain as a function of parity gave more conclusive results during different times. Perineal trauma and hemorrhoids are associated with an increased pain intensity after childbirth[20,35], which concur with our results. Also, chronic pelvic pain due to some diseases such as endometriosis can cause more elevated level of pain [36,37]. Other factors that may influence the severity of pain were not investigated in our study, such as information quality, psychological status[20], instrumental delivery[38], repair technique, suture type[39], ethnicity and education level[33].

Maternal and obstetrician satisfaction indicate the good management of the pre, per, and post-interventional periods. In our study, obstetricians were significantly more satisfied during repair in the pudendal group, coinciding with a shorter suture time in the same group and proving a higher anesthetic efficacy of PNB. A higher rate of strongly satisfied mothers was found in group R. This difference did not reach statistical significance, which can be explained by the sample size, the inclusion of parturients who did not receive epidural analgesia, and the injection of LA after episiotomy. A new study by Xu et al. revealed a significantly higher rate of maternal satisfaction in the pudendal group versus placebo in the presence of epidural analgesia[40]. Gil-Wey et al. have identified other factors that may affect maternal satisfaction such as high-risk pregnancy, difficult delivery, overall negative experience, delay, poor care coordination and the presence of potential complications[41].

That's why, our study offers an interesting alternative for parturients women who unfortunately can't have epidural analgesia( in case of contraindication or refusal). The use of neurostimulation in PNB offers more precision in the treatment of episiotomy's repair. This pain is known to be very intensive and causes a major discomfort even in the long term.

Several other modalities are used for episiotomy pain relief in addition to oral analgesics(paracetamol, nonsteroidal anti-inflammatory drug) such as epidural analgesia, prenatal perineal massage during the last 4 weeks of pregnancy[42], topical anesthetics[43] and paracervical block[37]. Even Vocal Distraction proves to be a powerful weapon against fear and pain in women[38].

Points of strengths in our study

Admittedly, our study has a potential contribution to improve analgesia protocols in obstetrics. Our results showed a statistically significant reduction of the pain during episiotomy repair .These results deserve to be further exploited in a large number of parturients. This study had some other limitations. There is a possibility that patients were not completely blinded. Besides, there was no long term follow- up to detect eventual side-effects and complications of PND.

## **Conclusions**

Episiotomy or tearing of perineal tissues during childbirth is associated with significant pain. Nerve stimulator guided PNB proved to be more effective for pain management in episiotomy repair than the classical lidocaine infiltration. Both techniques appear to be safe and unarmful but PNB provided superior analgesia with less need for supplemental analgesia even in the postpartum period. High-quality and large-sized studies must be done to verify the safety of this procedure.

## **Compliance with Ethical Standards**

### **Authors contribution:**

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

**Funding:** none

**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 CPP SUD (Le Comité de Protection des Personnes SUD) under the reference = CPP SUD N°0390/2022

**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 : Required sample size

	Group R	Group X	Required sample size
T 20min	19±19	50±29	22
T 30min	41±22	56±20	70
T 6h	34±26	52±22	62
T 18h	50±22	69±10	28

Group R: pudendal group; Group X: infiltration group;

T 20min: 20 minutes after injection; T 30min: 30 minutes after injection;

T 6h: 6 hours after injection; T18h: 18 hours after injection.

Table 2: Demographic characteristics

	Group R (n=35)	Group X (n=35)	P value
Age (years)	27.43 ±4.71	27.89 ±3.81	0.657
ASA 1	35 (100%)	35 (100%)	1
Weight (kg)	64.63 ±10.85	62.77 ±8.36	0.425
Height (cm)	162.74 ±6.25	162.43 ±5.32	0.821
BMI (kg/m <sup>2</sup> )	24.27 ±2.85	23.75 ±2.59	0.433
Parity (1/2/3/4/5)	18(51%)/7(20%)/6(17%)/2(6%) /2(6%)	18(51%)/9(26%)/8(23%) /0/0	0.338
History of perineal tears	3 (9%)	5 (14%)	0.452

Group R: pudendal group; Group X: infiltration group;

ASA: American Society of Anesthesiologists; BMI: Body mass index.

P < 0.05 shows significant difference between groups.

Table 3: VAS in the labor room and in the post-partum unit

Time	Group R	Group X	p
T10min	7.20±8.56	20.43±18.25	p<0.01 OR=2.8[1.2-2.8]
T15min	5.43±8.17	17.71±16.42	p<0.01 OR=3.2[1.4-3.4]
T20min	29.63±23.59	44.06±28.16	p=0.023 OR=2.9[1.1-2.9]
T1h	13.14±19.18	32.20±21.25	p<0.01 OR=2.2[1.3-4]
T1h30min	10.57±14.74	27.34±16.74	p<0.01 OR=2.7[1.1-3]
T2h	9.57±15.69	25.34±16.32	p<0.01 OR=2.2[1.2-1.9]
T6h static:  dynamic:	13.57±14.07	41.43±23.24	p<0.01 OR=3[1.2-2.2]
	30.29±22.57	59.46±26.65	p<0.01 OR=2.8[1.4-2.2]
T12h static:  dynamic:	22.60±20.41	36.49±23.35	p=0.010 OR=2[1.1-2.8]
	43.34±20.53	55.69±23.65	p=0.023 OR=1.8[1.6-2.1]
T18h static:  dynamic:	12.23±11.84	27.94±23.40	p<0.01 OR=2.5[1.2-1.9]
	38.1±20.3	42.3 ±21.23	p=0.02 OR=2.6[1.2-2.1]

Group R: pudendal group; Group X: infiltration group

P < 0.05 shows significant difference between groups.

Table 4: Rehabilitation after episiotomy

	Group R	Group X	P
Time to first ambulation	4.10 ±1.64	4.79 ±2.04	0.125
Time to first micturition	8.70 ±5.39	8.41 ±4.55	0.811
First defecation in the first 24h	13 (37.1%)	7 (20%)	0.112
Delayed transit recovery >24h due to pain	4 (18.2%)	9 (32.1%)	0.264
Time of first defecation if <24h	8.62 ±1.79	14 ±4.03	<0.001 OR=2.5[1.2-2.1]

Group R: pudendal group; Group X: infiltration group.

P < 0.05 shows significant difference between groups.

Table 5: Parturient and obstetrician satisfaction

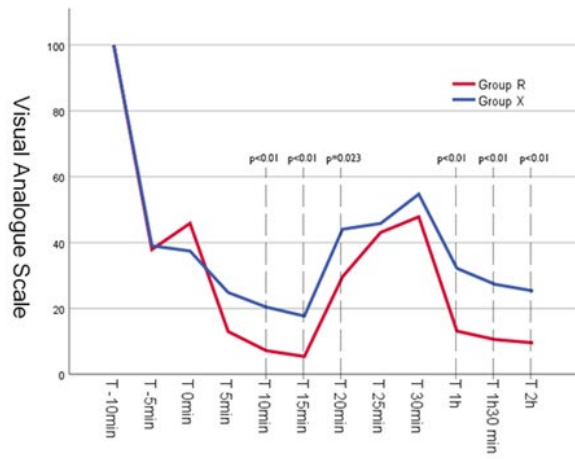
		Group R	Group X	P
Maternal satisfaction	Dissatisfied	4 (11.4%)	4 (11.4%)	0.463
	Neutral	11 (31.4%)	16 (45.7%)	
	Satisfied	13 (37.1%)	12 (34.3%)	
	Strongly satisfied	7 (20%)	3 (8.6%)	
Obstetrician's comfort during suturing	Dissatisfied	0	3 (8.6%)	<0.001
	Neutral	8 (22.9%)	26 (74.3%)	OR=3
	Satisfied	15 (42.9%)	3 (8.6%)	[1.2-
	Strongly satisfied	12 (34.3%)	3 (8.6%)	1.9]

Group R: pudendal group; Group X: infiltration group.

P < 0.05 shows significant difference between groups.

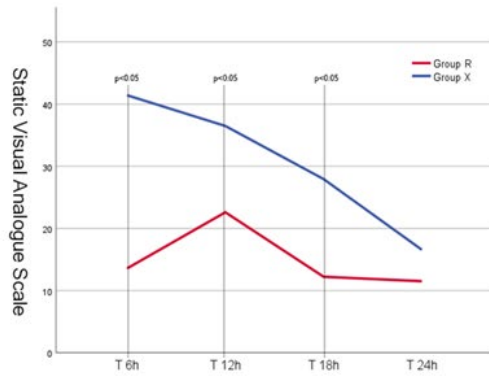


**Figure 1.** VAS in the labor room



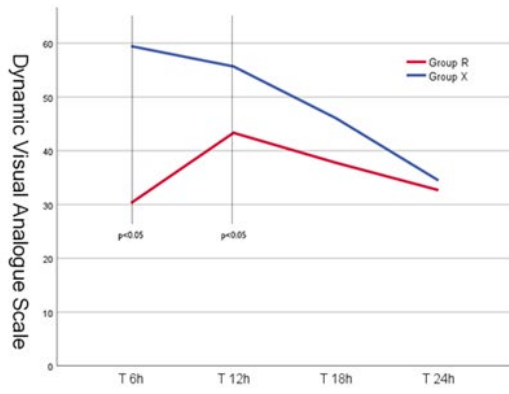
Manuscript accepted for publication

**Figure 2.** Static VAS in the post-partum unit.



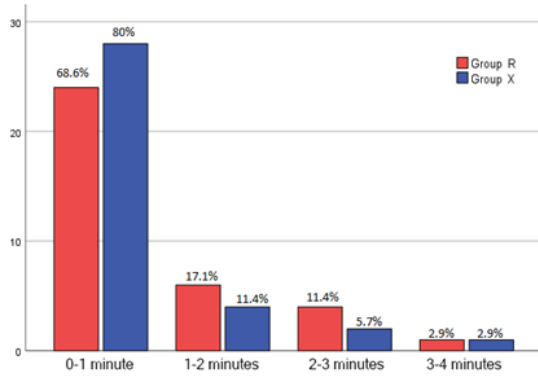
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**Figure 3.** Dynamic VAS in the post-partum unit.



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**Figure 4.** Onset time of sensory block.



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