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## ► To cite this version:

S. Duros, Y. Joueidi, K. Nyangoh Timoh, L. Boyer, P. Lemeut, et al.. A prospective study of the frequency of severe pain and predictive factors in women undergoing first-trimester surgical abortion under local anaesthesia. *European Journal of Obstetrics and Gynecology and Reproductive Biology*, Elsevier, 2018, 221, pp.123-128. 10.1016/j.ejogrb.2017.12.024 . hal-01685804

**HAL Id: hal-01685804**

**<https://hal-univ-rennes1.archives-ouvertes.fr/hal-01685804>**

Submitted on 25 Apr 2018

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**A prospective study of the frequency of severe pain and predictive factors in women undergoing first-trimester surgical abortion under local anaesthesia.**

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**Abstract**

**OBJECTIVE:** To determine the frequency of severe pain among women and to identify the associated predictive factors during first-trimester surgical abortion under local anaesthesia (LA).

**STUDY DESIGN:** A prospective cohort study from November 2013 to January 2014 at the Department of Gynecology and Obstetrics, Rennes, France. The study population was composed of one hundred and ninety-four patients who underwent an elective first-trimester

surgical abortion under LA. In an anonymized questionnaire, the participants were asked to self-record their perceived pain level 30 minutes after the completion of the procedure using a 10 cm visual analogue scale (VAS). The main outcome measure was the frequency of severe pain among women, defined as  $VAS \geq 7$ . Secondary outcome measure was the risk factor(s) for severe pain.

**RESULTS:** Severe pain (i.e.  $VAS \geq 7$ ) was experienced by 46% (95% CI: 39%-53%) of the population. Multivariate analysis confirmed that  $> 10$  weeks of gestation (OR: 2.530 [95% CI: 1.1-5.81],  $p=0.0287$ ) and having 0 or 1 child (OR: 5.206 [95% CI: 1.87-14.49],  $p=0.0016$ ) were significant independent factors of severe pain.

**CONCLUSION:** Nearly half of the women experienced severe pain. More than 10 weeks of gestation and parity were predictive factors of severe pain. These findings should be useful in counselling women undergoing surgical abortion under LA.

**Key word:** predictive factor, surgical abortion, severe pain, local anaesthesia

## **Introduction**

Induced abortion is one of the most common surgical procedures worldwide. In 2012, approximately 196,000 procedures were performed in England and Wales [1], 699,202 in the

United States [2], and 225,000 in France [3]. Many first-trimester surgical procedures are performed under local anaesthesia (LA) all over the world to avoid the use of general anaesthesia or because general anaesthesia is not available. Surgical abortion below 7 weeks is rare in France, because the French Ministry of Health suggests performing abortions medically up to 7 weeks' gestational age, which can be performed without any hospitalization [4]. Despite LA, women requesting surgical abortion still experience some pain [5-10]. A survey based on almost 2,300 women seeking surgical abortion with LA showed that 78% of patients reported "moderate" or "severe" pain [11]. Even with conscious sedation (25 to 100µg fentanyl), the mean pain scores ranged from 3.4 to 4.9 out of 10 cm on a visual analogue scale (VAS) with dilation and from 3.8 to 7.1 cm with curettage [6, 12-15]. Studies that have investigated psychological, social and medical predictive factors of pain experienced during first-trimester surgical abortion are rare [11, 16-18]. Because LA is used in a significant number of all first-trimester surgical abortions, it is important to identify predictive factors of severe pain in order to suggest more effective analgesia for these women, such as general anaesthesia or more efficient premedication with an oral analgesic prior to LA.

The aim of this study was to determine the frequency of severe pain among women after first-trimester surgical abortion under LA and to identify the associated predictive factors in order to seek out those patients for whom more analgesia may be necessary.

## Materials and Methods

We conducted a prospective cohort study on patients who underwent an elective first-trimester surgical abortion under LA from November 2013 to January 2014 in the pregnancy termination clinic at Rennes Teaching Hospital, France. At this clinic, we routinely perform surgical abortions up to 14 weeks' gestational age. Surgical abortions were performed under LA (paracervical or intracervical block) or under short general anaesthesia with induction using propofol (bolus of 2 mcg/kg) and morphomimetics (sufentanyl, remifentanyl) as desired by the patient. Eight experienced practitioners performed all procedures. All participants were informed of the study and gave their written consent to be included. The study was approved by the Institutional Review Board of the French college of obstetricians and gynecologists (Comité d'Ethique de la Recherche en Obstétrique et Gynécologie) (CEROG-2011-GYN-08-03).

We recruited women seeking elective surgical abortion of an ultrasound-confirmed intrauterine pregnancy with an estimated gestational age not exceeding 98 days (14 weeks) from the first day of the preceding menstrual cycle. Participants had to be verbally fluent in French and undergoing elective surgical abortion under LA. The information concerning the difference between local or general anaesthesia was provided to the patients by the nurse and they underwent a full informed consent process as to risks, benefits, and alternatives to anaesthesia. The termination clinic nurse approached all women seeking surgical abortion under LA after they had completed the preprocedural medical evaluation and invited them to participate in the study. Monetary incentives were not offered. Exclusion criteria included 1) surgical abortion under general anaesthesia, 2) miscarriage, 3) untreated acute cervicitis or pelvic inflammatory disease, 4) contraindications to lidocaine, 5) allergic reaction or sensitivity to midazolam or nonsteroidal anti-inflammatory drugs (NSAIDs), 6) long-term NSAID use (daily use for more

than 3 months) , 7) history of gastritis or gastric ulcer, 8) acute renal failure or chronic renal disease, 9) chronic liver disease, 10) women who did not speak French.

All patients received oral analgesics consisting of ibuprofen 4x200 mcg, 7.5 mg of oral midazolam one hour before the procedure. The choice of paracervical (PCB) or intracervical (ICB) bloc was at the physician's discretion. All women had a healthcare assistant at the bedside providing verbal and physical support (e.g., hand holding, instructions in deep breathing). As per the clinic's protocol, all women underwent cervical priming with 400 µg of sublingual misoprostol two hours prior to the procedure, except women with pregnancies  $\geq 12.0$  weeks' gestational age and nulliparous women with pregnancies  $\geq 10$  weeks' gestational age who underwent cervical priming with 200 mg of oral mifepristone 36 hours prior to the procedure. The surgical procedure was standard. The PCB consisted of administration of 20 mL of lidocaine at four and eight o'clock at the cervicovaginal reflection. The ICB was performed by injecting 20 mL of lidocaine at the 3, 6, 9 and 12 o'clock positions, two minutes later, cervical dilation was performed with mechanical dilators. Cervical dilation was not systematic. Vacuum aspiration was performed with an electric vacuum aspirator using a flexible Karman® cannula. The practitioners sought to use a cannula that was consistent with the participant's gestational age of pregnancy, i.e. 6 mm at 8 weeks' gestational age up to 12 mm at 14 weeks' gestational age. An ultrasound (endovaginal probe) was performed on completion to confirm that the empty uterine cavity was free of conceptus.

Sociodemographic and medical information were collected before the procedure, including age, parity, length of gestation at termination, and number of previous pregnancy terminations. In an anonymous questionnaire prior to the procedure, participants were asked to self-report the relationship of the accompanying person in the procedure room on the day of the abortion procedure, the type of first health worker approached for the abortion, the quality of the information provided by the first health worker and pregnancy termination clinic nurse

before the surgical abortion (rated on a four-point Likert scale: 1, very satisfied, 2, relatively satisfied, 3, relatively dissatisfied, 4, very dissatisfied), the initial desired type of analgesia (local, general or undecided) before receiving information from the pregnancy termination clinic nurse, the perceived waiting time until surgical abortion (rated on a four-point Likert scale), and the level of fear before surgical abortion (rated on a 10 cm Visual Analogue Scale (VAS): 0-cm end indicated “no fear” and 10-cm end indicated “the worst fear ever”). In an anonymous questionnaire, the participants were asked to self-record their perceived pain level during surgical procedure, as well as to evaluate their pain alone 30 min. after completion of the surgical procedure in order to avoid intraoperative room stress and medical team influence, using a 10 cm VAS: 0-cm end indicated “no pain” and 10-cm end indicated “the worst pain ever”. After the surgical procedure, the practitioner reported: the type of cervical block, the degree of mechanical cervical dilation and the size of the Karman® suction cannula.

The main outcome measure was the rate of severe pain, defined as, described by Jensen *et al*,  $VAS \geq 7$  as [19], among women during surgical abortion under LA. The secondary outcome measure was the risk factor(s) for severe pain among women seeking surgical abortion under LA.

Participants were assigned a study number. Statistical analysis was performed using SAS statistical software, version V9.4 (SAS Institute, Cary, NC, USA). The overall rate of severe pain was estimated with its associated 95% Confidence Interval (CI) from women experiencing severe pain as a proportion of all women seeking surgical abortion under LA. The age-specific rates for severe pain were calculated and demographic and behavioural variations in rate were also investigated.

Univariate analysis was performed using a Chi2 test or Fisher’s exact test as appropriate. A *P* value of  $\leq 0.05$  was considered statistically significant. Stepwise multiple logistic

regression was performed to obtain some adjusted odds ratio (OR) for each sociodemographic factor with  $p < 0.01$  in univariate analysis. The unadjusted ORs (95% CI) associated with these risk factors were also calculated.



## Results

During the period of investigation, of the 315 women presenting at the clinic for induced abortion, 217 women underwent a surgical abortion, of which 199 under LA. Finally, 194 women who underwent a surgical abortion under LA were enrolled. The population characteristics are presented in Table 1. Mean age was  $27.2 \pm 7.5$  years old (range 15-45). Mean gestational age was  $9.1 \pm 1.8$  weeks (range 6-14). Thirty-one percent of the enrolled women had one or more children, and 22% of them had had previous induced abortions. Thirty-two percent of the enrolled patients had already desired general anaesthesia before receiving information from the clinic nurse. The information delivered by nurses allowed changing misconceptions about general anesthesia. Seventy-one percent of them were accompanied on the day of the surgical abortion.

Mean pain during surgical abortion under LA was 5.8 ( $\pm 2.6$ ) cm. The rate of severe pain (i.e. VAS  $\geq 7$ ) was 46% (95% CI: 39%-53%). Univariate analysis (Table 2) found that severe pain was significantly associated with age  $< 28$  years (OR: 2.65 [95% CI: 1.47-4.77]), having 0 or 1 child (OR: 5.80 [95% CI: 2.29-14.67]), gestation of more than 10 weeks (OR: 2.56 [95% CI: 1.17-5.63]), having an accompanying person on the day of the surgical abortion (OR: 2.95 [95% CI: 1.49-5.96]), PCB (OR: 1.96 [95% CI: 1.01-3.49]), and cannula size  $> 8$  mm (OR: 2.18 [95% CI: 1.13-3.40]). The choice of general anaesthesia before information given by pregnancy termination clinic nurse was not a predictive factor of severe pain (OR: 1.97 [1.03-3.80],  $p=0.94$ ). Multivariate analysis confirmed that  $> 10$  weeks of gestation (OR: 2.530 [95% CI: 1.1-5.81],  $p=0.0287$ ) and having 0 or 1 child (OR: 5.206 [95% CI: 1.87-14.49],  $p=0.0016$ ) were significant independent factors of severe pain (Table 3).

## Discussion

### Main Findings

The rate of severe pain among women seeking first-trimester surgical abortion under local anesthesia was 46%. The multivariable analyses identified two independent predictive and objective factors of severe pain: gestation of more than 10 weeks and having 0 or 1 child.

### Strengths and Limitations

Our study is the first study showing that pain decreased only from 2 children. Having one child is not correlated with less pain during surgical abortion. The lack of information on previous caesarean (because of not recorded data) is a limitation of our study. Although we analyze available data about previous cesarean and no correlation was found with severe pain (data not shown). Of note, the rate of cesarean in France is around 20%, similar in present study. The perception of pain is highly subjective. A universal limitation of studies of pain perception is the inherent variability of the scales used to measure pain. While there are no data evaluating VAS differences during surgical abortion, the scale has already been validated for accurately measuring pain experienced during surgical procedures [20]. As previously described, confounding factors using pain scale were: anchor descriptors, methods of administration, time frames, information related to the use of scales [21]. The strength of our study is that VAS pain was evaluated by the patient alone after the surgical abortion procedure without any influence from the medical team. Singh *et al.* [18] analyzed pain and predictors of pain in 144 women undergoing surgical abortion, and the pain VAS was reported by the physicians and the patients, but it is well known that physicians tend to report much lower scores than the women themselves.

This is the largest study published on pain during surgical abortion to date. The few previous studies published on this topic suggest that nulliparity [16, 22-23] and increasing gestational age are predictive factors of severe pain [11]. Other predictors of increased pain were found in univariate analyses such as a young age, retroverted uterus, history of dysmenorrhea, anxiety, expected pain and lower volume of LA used, but not in multivariate analysis [11, 16, 24-25].

One other weakness of this study is that women who wanted general anesthesia were convinced to undergo the procedure under local anesthesia. But women wanting a general anesthesia is not correlated with severe pain neither women changing their mind only after nurse information. The physician who performed surgical procedure did not inform patients. Women who still wanted to have a general anesthesia after nurse information had a general anesthesia.

Another limitation is that these findings are specific to women who received misoprostol or mifepristone at certain gestational ages. Nevertheless, according international guidelines [26-27] recommend cervical priming using osmotic dilators or pharmacological agents because it may make the abortion procedure quicker and easier to perform by reducing the need for mechanical cervical dilatation. Durlot *et al* [28] has shown that mifepristone may facilitate cervical dilatation, making abortion under LA more comfortable and less dangerous. The baseline cervical dilatation was significantly greater among women who received mifepristone 48 hours before the operation ( $P = 0.02$ ) with no significant difference in patient acceptability compared to 800  $\mu\text{g}$  misoprostol vaginally 2 to 4 hours before the operation [29] suggesting lower pain with mifepristone priming cervical. Although, in our results, misoprostol is not correlated with higher pain during surgical procedure, but late first trimester termination of pregnancy is correlated with severe pain during surgical procedure, suggesting that misoprostol does not create severe pain during surgical procedure. Thus, these findings power our results that misoprostol is not a bias to generalise our results.

### Interpretation

Optimization of pain control should be a priority in surgical abortion. Many studies have investigated how pain control can be improved during surgical abortion [30-31]. In a meta-analysis, Jackson *et al.* [31] reported the results of nine studies and found that prophylactic acetaminophen, acetaminophen+codeine, ibuprofen or alverine did not reduce abortion pain. However, administration of ibuprofen after onset of cramping reduced pain and subsequent analgesia use. Intravenous (IV) sedation is also used for pain management during surgical abortion. Allen *et al.* and Rawling *et al.* evaluated the effect of IV fentanyl with LA and demonstrated that it reduced pain scores by one point on an 11-point scale [25, 32]. Conversely, another randomized controlled trial examined the use of conscious sedation with fentanyl and PCB and showed no difference in mean pain scores [33]. The use of sublingual lorazepam was associated with more dissatisfaction and no reduction in pain [25]. Some studies evaluated the efficacy of nitrous oxide (NO) with PCB for pain management in surgical abortion. Pain scores were similar between patients treated with NO *versus* intravenous sedation [34-35] and overall adverse effects were significantly higher in the NO group [34]. Use of hypnosis has also been investigated and women who underwent hypnosis required less intravenous sedation analgesia and NO [36]. PCB is a predictor of severe pain in univariate analysis, leading us to prefer ICB. Mankowsky *et al.* recommended using an ICB because it is an easier technique to teach [15].

Thus, apart from ibuprofen (used in our study), additive treatment with LA did not significantly reduce pain during surgical abortion with LA.

### **Conclusion**

We pointed out two obvious predictive factors (0 or 1 child and > 10 weeks of gestation) that independently correlated with severe pain and that proved to be useful in clinical practice. However, they are not the sole determining factors for who receives local versus general anaesthesia. The type of anaesthesia must be chosen depending on the decision taken with patient in view of level pain tolerance. Furthermore, higher power studies are required to show more criteria correlating with severe pain and determine scores to strictly screen patients to be referred to general anaesthesia.

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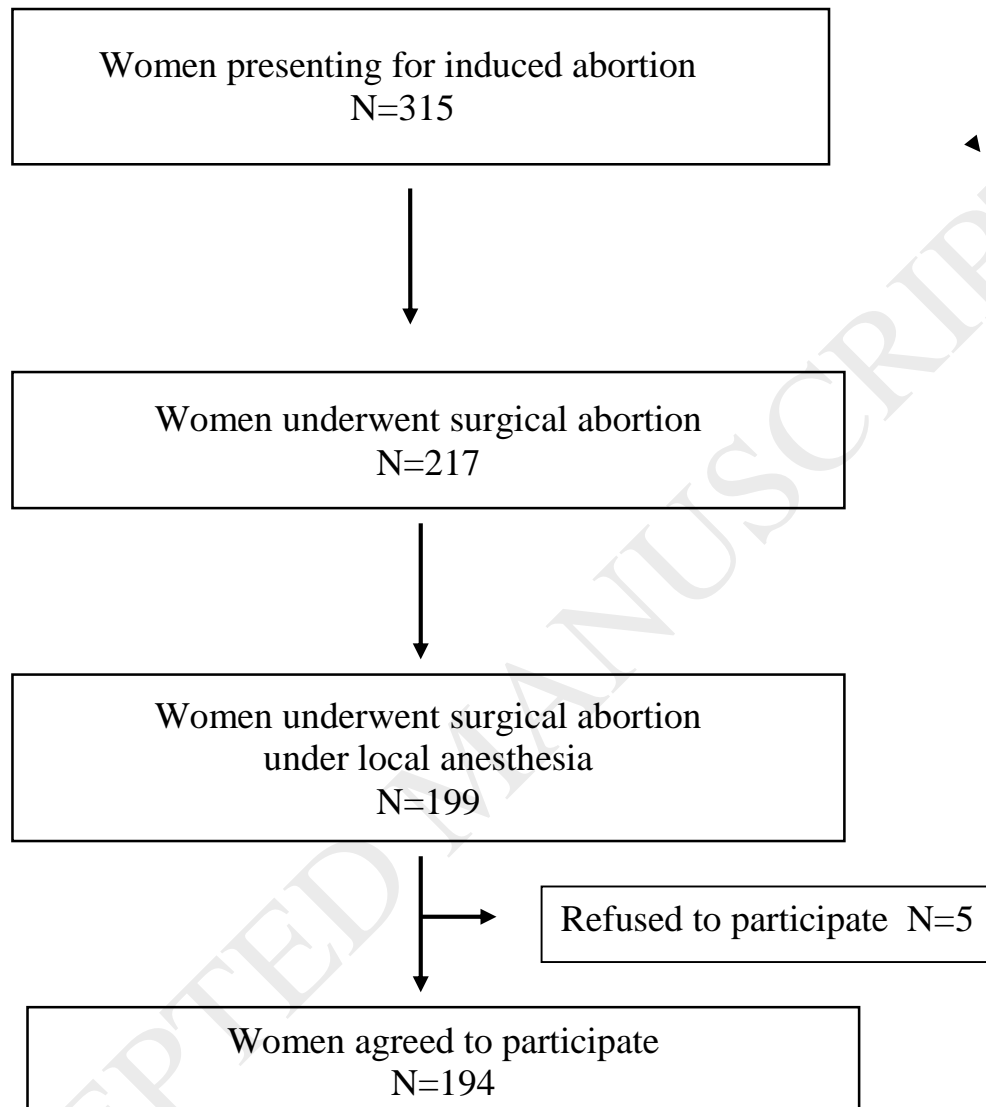
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**Figure 1:** Flowchart of participants during the study period.



**Table 1.** Characteristics of women seeking surgically induced abortion.

\*Total numbers may not equal 194 due to missing data.

Variables	Mean (standard deviation) or n (%)*
Age in years	27.2 ( $\pm$ 7.5)
Body Mass Index	22.2 ( $\pm$ 3.2)
No. children (live births)	
0	133 (68.6)
1	24 (12.4)
2	22 (11.3)
3 or more	15 (7.7)
No. miscarriages	
0	158 (81.4)
1 or more	36 (18.6)
No. previous abortions	
0	148 (76.3)
1	31 (16.0)
2 or more	12 (6.2)
Weeks of gestation for surgical abortion	9.1 ( $\pm$ 1.8)
6-8	74 (43.3)
9-10	64 (37.4)
11-12	22 (12.8)
13-14	11 (6.4)
First health worker approached for abortion	
Family doctor	98 (51.3)
Gynecologist	15 (16.5)
Family planning or termination clinic workers	78 (40.8)
Desired type of analgesia before information given by pregnancy termination clinic nurse	
Local anesthesia	92 (47.7)
General anesthesia	62 (32.1)
Undecided	39 (20.2)
Accompanying person on the day of surgical abortion	
Alone	56 (29.0)
Partner	68 (35.2)
Friend	39 (20.2)
Family member	30 (15.5)

**Table 2.** Characteristics associated with severe pain (VAS  $\geq 7$ ) among women seeking surgically induced abortion under local anesthesia

Variables	Severe pain (VAS $\geq 7$ )	Unadjusted odds ratio (95% confidence interval)	P (univariate analysis)
Age group (years)			
<28	57% (60/106)	1	0.001
$\geq 28$	33% (29/88)	0.44 (0.21-0.68)	
No. children (live births)			
0-1	52% (83/157)	1	<0.001
2 or more	13% (6/37)	0.17 (0.07-0.44)	
No. miscarriages			
0	49% (77/158)	1	0.094
1 or more	33% (12/36)	0.52 (0.24-1.12)	
No. previous abortions			
0	48% (71/148)	1	0.270
1	32% (10/31)	0.51 (0.22-1.17)	
2 or more	42% (5/12)	0.77 (0.23-2.55)	
Weeks of gestation			
$\leq 10$	41% (56/138)	1	0.019
$> 10$	64% (21/33)	2.56 (1.17-5.63)	
First health worker approached for abortion			
Family doctor	44% (43/98)	1	0.363
Gynecologist	33% (5/15)	0.63 (0.20-2.01)	
Family planning or termination clinic workers	51% (40/78)	1.34 (0.74-2.44)	
Quality of information given by the first health worker approached for abortion			
very satisfied	37% (23/63)	1	0.167
relatively satisfied	49% (49/99)	1.70 (0.89-3.25)	
relatively dissatisfied	58% (15/26)	2.37 (0.93-6.02)	
very dissatisfied	0% (0/1)	NS	
Quality of information given by pregnancy termination clinic nurse			
very satisfied	41% (47/114)	1	0.202
relatively satisfied	53% (40/76)	1.58 (0.88-2.83)	
relatively dissatisfied	100% (2/2)	NS	
very dissatisfied	0	NS	
Desired type of analgesia before information given by pregnancy termination clinic nurse			
Local analgesia	38% (35/92)	1	0.094
General analgesia	55% (34/62)	1.97 (1.03-3.80)	
Undecided	51% (20/39)	1.71 (0.80-3.65)	

Perceived waiting time by women until surgical abortion				
very satisfied	38% (15/39)	1		0.130
relatively satisfied	41% (28/69)	1.09 (0.49-2.44)		
relatively dissatisfied	51% (34/67)	1.64 (0.74-3.70)		
very dissatisfied	69% (11/16)	3.52 (1.02-12.15)		
Level of fear before surgical abortion				
Mild (<4)	47% (14/30)	1		0.308
Moderate ( $\geq 4$ to <7)	38% (26/68)	0.71 (0.38-2.24)		
Severe ( $\geq 7$ to $\leq 10$ )	51% (44/87)	1.16 (0.51-2.69)		
Accompanying person on the day of surgical abortion				
Alone	30% (17/56)	1		0.047
Partner	53% (36/68)	2.58 (1.23-5.42)		
Friend	51% (20/39)	2.41 (1.03-5.64)		
Family member	53% (15/30)	2.29 (1.05-6.55)		
Analgesia				
Paracervical	53% (57/107)	1		0.021
Intracervical	37% (32/87)	0.51 (0.28-0.91)		
Preoperative cervical dilation				
No	41% (49/119)	1		0.099
Yes	55% (28/51)	1.73 (0.89-3.37)		
If cervical dilation used, degree of cervical dilation				
$\leq 8$ mm	35% (8/23)	1		0.077
$> 8 \leq 10$ mm	69% (11/16)	4.12 (1.06-16.10)		
$> 10$ mm	34% (7/11)	3.28 (0.73-14.69)		
Size of suction cannula				
$\leq 8$ mm	42% (56/134)	1		0.149
$> 8 \leq 10$ mm	58% (14/24)	1.95 (0.81-4.70)		
$> 10$ mm	37% (7/11)	2.43 (0.68-8.73)		

NS: not stated

**Table 3.** Multivariate logistic regression model

<b>Variables</b>	<b>Adjusted OR</b>	<b>95% Confidence Interval</b>	<b>P</b>
Having 0 or 1 child	5.206	[1.87;14.49]	0.002
>10 weeks of gestation	2.530	[1.1;5.81]	0.029

Variables included: years  $\geq$  28, having 0 or 1 child, number of miscarriages  $\geq$  1, weeks of gestation  $>$  10, desired type of analgesia, accompanying person on the day of surgical abortion, analgesia, preoperative cervical dilation