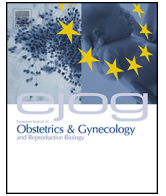




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Full length article

## 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 min 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],  $p = .0287$ ) and having 0 or 1 child (OR: 5.206 [95% CI: 1.87–14.49],  $p = .0016$ ) 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.

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### 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 2300 women seeking surgical abortion with LA showed that 78% of patients reported “moderate” or “severe” pain [11]. Even with conscious sedation (25 to 100  $\mu\text{g}$  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.

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## 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  $4 \times 200$  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 h 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<sup>®</sup> 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 (Fig. 1).

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

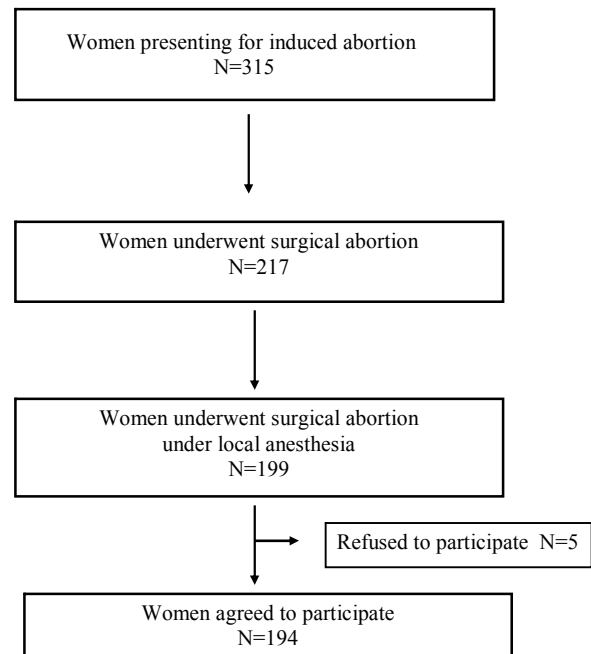


Fig. 1. Flowchart of participants during the study period.

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 intra-operative 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<sup>®</sup> 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

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