Published in final edited form as:

Contraception. 2017 August ; 96(2): 118–123. doi:10.1016/j.contraception.2017.06.003.

Nitrous Oxide Versus Oral Sedation for Pain Management of First Trimester Surgical Abortion – A Randomized Study

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Abstract

Objectives—To compare nitrous oxide with oxygen (N₂O/O₂) to oral hydrocodone/acetaminophen and lorazepam (oral) for analgesia during first-trimester surgical abortion.

Study Design—This double-blind randomized trial assigned women undergoing first-trimester surgical abortion at < 11 weeks' gestation to inhaled N₂O/O₂ vs. oral sedation for pain management. The N₂O/O₂ group received up to 70:30 ratio during the procedure and placebo pills pre-procedure; the oral group received inhaled oxygen during the procedure and oral hydrocodone/acetaminophen 5 mg/325 mg and lorazepam 1 mg pre-procedure. The primary outcome was maximum procedural pain, assessed on a 100-mm Visual Analog Scale (VAS; anchors 0 = no pain and 100 = worst pain) at two-minutes post procedure. A difference of 13 mm on the VAS was considered clinically significant. Satisfaction with pain management was measured on a 100-mm VAS (anchors 0 = very unsatisfied, 100 = very satisfied).

Results—We randomized 140 women, 70 per study arm. Mean age of participants was 26 ± 6.6 years; mean gestational age was 7.3 ± 1.5 weeks. Mean maximum procedure pain scores were 52.5 ± 26.7 and 60.8 ± 24.4 for N₂O/O₂ and oral groups, respectively (p=0.09). Satisfaction with

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Clinical Trial Registration: ClinicalTrials.gov, www.clinicaltrials.gov, NCT02096575

Conflicts of interest: none

Presentation information:

This study was presented as an oral presentation at the National Abortion Federation Annual Meeting, April 15–19, 2016, Austin, TX.

pain management was 69.3 ± 28.4 and 61.5 ± 30.4 for N₂O/O₂ and oral groups respectively ($p=0.15$).

Conclusion—We found no difference in mean procedural pain scores between women assigned to N₂O/O₂ vs. those assigned to oral sedation for first trimester surgical abortion. Satisfaction with both options was high.

Keywords

Nitrous Oxide; Surgical Abortion; Pain; Oral Analgesia; First Trimester

Introduction

Approximately 700,000 abortions occurred in the United States in 2012; 91.4% were 13 weeks gestational age [1]. Many first trimester surgical abortions take place in outpatient clinics under a paracervical block (PCB) with or without oral medication or under PCB with or without intravenous sedation. Surgical abortion is painful; up to 97% of patients report at least moderate procedural pain [2]. Outpatient pain management measures—preoperative non-steroidal anti-inflammatory drugs (NSAID), oral and intravenous narcotics, and anxiolytics—show varying efficacy in reducing the pain of surgical abortion. Use of narcotics and anxiolytics requires a ride home, can prolong post-operative recovery and has side effects [3]. Offering intravenous sedation requires compliance with local and state facility guidelines; clinical staff must receive and maintain competency in specialized training/skills including advanced cardiac life support, and certification for moderate sedation.

Nitrous oxide is an inhaled gas delivered with oxygen (N₂O/O₂) in a fixed ratio which can be titrated for anesthesia and sedation. Onset of action is rapid and the gas has analgesic, sedative and anxiolytic effects. It is ultra-short-acting; effects dissipate rapidly after use is stopped. N₂O/O₂ is safely used in a variety of settings including reduction of fractures or joint dislocations, suturing of pediatric lacerations, dental procedures and labor analgesia [4–6].

Three prior publications have examined N₂O/O₂ use for first trimester abortion, two of which did not find reduced pain compared to either intravenous sedation [7] or local anesthesia plus intravenous paracetamol [8]. Additionally, these studies used a relatively low concentration (50:50) of nitrous oxide. A small feasibility study found that higher concentrations of N₂O/O₂ (70:30) resulted in higher satisfaction with pain management compared to oral sedation [9]. We conducted this study to compare pain management with N₂O/O₂ and oral sedation during first trimester surgical abortion.

2. Materials and Methods

This randomized double-blind trial comparing N₂O/O₂ and placebo pills to oral sedation and oxygen (O₂) during first trimester surgical abortion, was conducted at the University of New Mexico Center for Reproductive Health between September 2013 and March 2015. Our primary outcome measure was recall of maximum procedure pain two minutes' post-

procedure. Secondary outcome measures were satisfaction with pain management, pre-and post procedure anxiety levels and provider and patient assessment of their treatment assignment.

We recruited English speaking women age 18 years desiring and meeting criteria for outpatient surgical abortion at gestational age <11 weeks, and who desired local anesthesia ± oral sedation for pain management and without contraindications to the use of study medications. Participants were excluded if they had allergies to study medications or contraindications to N₂O/O₂ including active respiratory infection, inability to breathe through the nose, or use of alcohol, opiates, benzodiazepines or stimulants on the day of their procedure. Obstetrics/gynecology family planning faculty or fellows or family medicine family planning faculty performed all aspiration procedures. Participants provided written consent for study participation and received a \$25 gift card to a local retailer to compensate for their time.

An investigator not involved with recruitment generated a block randomization scheme using SAS software (version 9.4; SAS Institute, Inc., Cary, NC). Sequence generation with random blocks of four was concealed in sequentially numbered opaque sealed envelopes opened after the participant had signed the consent form and immediately before the procedure. Medications (hydrocodone/acetaminophen and lorazepam) and placebo pills (methylcellulose gel) were concealed in identical gel caps.

All participants received ibuprofen 800 mg and doxycycline 200 mg orally 30 minutes prior to the procedure. The N₂O/O₂ group received two placebo pills and the oral group received one hydrocodone/acetaminophen 5/325 mg, and lorazepam 1 mg at least 30 minutes before the procedure. The oral group received oxygen during the procedure. N₂O/O₂ or oxygen was administered via a scented nasal mask to blind participants to the intervention. N₂O/O₂ administration was started at a concentration of 20:80 and titrated up in increments of 5–10% up to a maximum of 70% N₂O and 30% O₂ based on desired anesthetic effects. Anesthetic effects of N₂O/O₂ include the patient appearing comfortable and relaxed, showing less fear and anxiety and her eyes appearing less active and glazed. A screen in the procedure room concealed the administration of gas from the participant, physician and research coordinator. A staff member trained in the administration of N₂O/O₂ and not involved in other aspects of the patient's care administered the gasses for one minute before we initiated the procedure, defined as placement of the speculum.

Participants completed a demographic questionnaire and were instructed on completion of the Visual Analog Scale (VAS) after providing informed consent for the study. Our primary outcome measure was recall of maximum procedural pain assessed on a 100 mm VAS (anchors 0 = no pain, 100 = worst pain) two minutes after procedure completion including IUD placement. Removal of the speculum defined procedure completion. Secondary outcomes, also assessed by VAS, included baseline pain, expected pain, pain at five minutes after procedure completion and pain prior to discharge from the clinic. All data was collected by a research coordinator blinded to the group assignment. VAS scores for each outcome were placed on separate sheets of paper which the research coordinator held in front of the participant allowing her to mark the VAS line with a pen. We collected baseline

anxiety levels prior to the procedure using the short-form Spielberger State-Trait Anxiety Inventory (STAI), in which women rate five statements (I feel calm, I am tense, I feel upset, I am relaxed, I am worried) on a Likert scale of one to four (not at all, somewhat, moderately, very much) [13, 14]. Post-procedure, we assessed satisfaction with pain management using a 100 mm VAS and post-procedural anxiety with the short-form STAI.

All participants received a standardized PCB of 18 ml 1% lidocaine buffered with 2 ml 8.4% sodium bicarbonate and 0.2 ml of four units of vasopressin (20.2 ml total). The PCB was injected with a 22-gauge spinal needle: two ml at the 12 o'clock tenaculum site and 18 ml over 60 seconds at the cervicovaginal junction in four equal aliquots at 2, 4, 8 and 10 o'clock [15]. The provider began dilation immediately after application of the PCB. Technique of the aspiration procedure, source of vacuum and cannula type was at provider discretion. No participants received pre-procedure misoprostol.

Sample size was based on mean procedure pain scores from current evidence. Previous studies of first trimester abortion under local anesthesia with or without ibuprofen demonstrate mean VAS between 51–62 mm with standard deviations (SD) of 22–25 mm [10–12]. Clinically important mean differences in pain are 13–20 mm on the VAS [8, 10, 11, 13]. Our sample size of 59 participants per group was based on a conservative SD of 25 mm with 80% power to detect a minimum clinically important difference in mean pain scores of 13 mm between groups with an alpha of 0.05 for a two sided test. To account for the possibility of 20% of participants dropping out, we planned to enroll 70 women in each group.

All data were entered into REDCap™ using dual data entry. A two-sided student's t test was used to determine differences in normally distributed continuous variables. Kruskal Wallis non-parametric test evaluated non-normal continuous data. Categorical data were compared using Pearson χ^2 test or Fisher's exact test as appropriate. Pearson correlations were performed comparing the primary outcome of maximum procedure pain with procedure characteristics including suction type, placement of IUD and cannula size. All data were analyzed with SAS software (version 9.4; SAS Institute, Inc., Cary, NC). The University of New Mexico Human Research Review Committee approved the study.

3. Results

From September 2013 to March 2015 we assessed 731 women for study eligibility; 415 (56%) did not meet inclusion criteria and 176 (24%) declined to participate. Reasons for not meeting inclusion criteria included desire for medical abortion or intravenous sedation for their procedure, higher gestational age, age less than age 18, allergy to study medication or no ride from clinic. We randomized 140 women, 70 to N₂O/O₂ and placebo pills (N₂O/O₂ group) and 70 to the oral and O₂ group. After randomization, three women in the oral group did not continue in the study; the investigators withdrew two women (one for unremitting vomiting and one for bleeding requiring intervention) and one woman opted not to have an abortion. Pain data were not collected in the former 2 patients. In the N₂O/O₂ group, one woman withdrew consent for study participation as she decided on oral medications; another withdrew because she could not swallow pills (Figure 1).

Baseline characteristics were similar between the two groups (Table 1). In the married/living with partner group, 18 (13.3%) were married and 43(31.9%) were living with a partner in a committed relationship. Fifty-seven (42%) women reported experience with nitrous oxide in a prior setting. Mean pain scores (mm) in this sub-group—those randomized to N₂O/O₂ versus oral sedation were 60.8 ± 22.7 versus 62.6 ± 24.1 (p=0.78). Among women naïve to N₂O/O₂ (n=77), mean pain scores in the N₂O/O₂ group were 46.8 ± 28.0 compared to 59.1 ± 24.8 in the oral sedation group (p=0.045). Nine (13.2%) participants received N₂O/O₂ titrated up to 50% concentration; 29 (42.6%) women received 60% and 28 (41.2%) women received 70% (missing data n=2).

Procedural characteristics were similar between participants (Table 2). There was no difference in pain scores when controlling for several variables including provider type, cannula size, source of suction or intrauterine device insertion. Average gestational age was 7.4 ± 1.5 weeks. Most women (70.4%) did not experience any complications or side effects during the procedure regardless of group assignment (Table 2). Three participants experienced procedure bleeding that required the use of uterotonics; all 3 were in the N₂O/O₂ group (N₂O/O₂ - 3 women vs. oral - 0 women; p=0.28).

Mean maximum procedural pain measured at 2 minutes after the procedure was similar between the 2 groups (N₂O/O₂; 52.5 ± 26.7 mm vs. oral; 60.8 ± 24.4 mm) (Table 3). There was no difference in baseline pain, expected pain and pain at the time of discharge from clinic. Satisfaction with pain management was similar between the groups (Table 3). The mean difference between pre-and post anxiety scores was similar between the 2 groups (p=0.69).

Oral group participants were more likely than N₂O/O₂ group participants to think they received nitrous oxide when they actually received oral sedation and O₂ (p=0.008). Physicians were also more likely to report that a participant received nitrous oxide when she actually received oral sedation (p=0.001). Without unblinding, 77.9% of participants expressed willingness to pay out of pocket for the pain medication they were assigned to. Additionally, not knowing their randomization allocation, women in the N₂O/O₂ group were more likely than those in the oral group to indicate a willingness to participate in a study that randomized women undergoing first trimester abortion to medications versus no medications (p=0.03).

4. Discussion

The main finding of our study was no difference in mean maximum procedural pain scores between women assigned to N₂O/O₂ vs. women assigned to oral sedation for first trimester surgical abortion. We detected a non-significant difference in bleeding requiring uterotonics between the two groups. N₂O/O₂ is a vasodilator of cerebral vasculature but decreases renal and splanchnic blood flow [14, 15]. Nitrous oxide would not be expected to increase bleeding as it did not affect the pulsatility index of the uterine artery in a small study of 20 term pregnant women given 30:70% N₂O/O₂ for two minutes and when used in labor at the 50:50% ratio has not been found to increase postpartum bleeding [16, 17]. Our study is not powered to detect whether increased bleeding is a risk and may need further exploration in

future studies. In addition, we used vasopressin, which may have affected bleeding, in our PCB, but both groups were equally exposed.

Major strengths of this study include its double-blind design and its adequate power to detect a clinical difference in the experience of procedure related pain. We had several limitations in this study including a control group of women who received oral sedation instead of PCB and NSAID alone. We sampled subjects from a population who all had a ride home and were therefore flexible to the study intervention they received. Women who don't have a ride home may perceive procedural pain differently, enhancing the importance of N₂O/O₂ as a pain management option. We identified that assessment of maximum procedural pain in the N₂O/O₂ group occurred after complete reversal of the gas while pain in the oral group was assessed while still under the effect of sedation; the timing of pain assessment may have led to higher reported pain scores in the N₂O/O₂ group. This difference in duration of effect of the medications may have made a difference in women's assessment of their maximum procedural pain. In this study, we began the procedure once N₂O/O₂ had been administered for only one minute. We have learned from other studies that N₂O/O₂ must be administered for a few minutes to achieve optimal effectiveness [18]. The total duration of exposure may also play a role since we found that N₂O/O₂ worked better in a hysteroscopic sterilization study, in which average procedure duration was longer than we report in our current study [18].

Additionally, the altitude of Albuquerque, New Mexico where the study was conducted, is 5350 feet above sea level; the analgesic effect of N₂O/O₂ is incrementally reduced at higher altitudes, potentially reducing the analgesic effect of N₂O/O₂ [19]. Women who had never before experienced nitrous sedation were more susceptible to its effects, and more than half the women in this study received less than 70:30% concentration sedation. Use of lower concentration may be attributed to training and experience with administering N₂O/O₂ for pain management. Women recruited in the latter half of the study were more likely to be titrated up to 70:30%. We chose to assess pain for the entire procedure instead of assessing it at individual time points during the procedure such as immediately after the PCB, dilation and aspiration to not interrupt the experience of sedation with nitrous oxide. We used a nasal mask to administer N₂O/O₂; during verbal communication inhalation stops and the effects of N₂O/O₂ may dissipate quickly.

Based on our experience with N₂O/O₂ in this study, we incorporated these observations into the design of a study of N₂O/O₂ for in-office hysteroscopic sterilization. In this subsequent study, N₂O/O₂ was administered for three minutes before starting the procedure. We found that women in the N₂O/O₂ group had significantly less pain than the group receiving oral sedation. Additionally, in this study, pain was assessed while the patient was still under the effect of N₂O/O₂ and the total procedure was longer which may also impact the positive effects of N₂O/O₂ [18].

Even without improved pain control and satisfaction, the advantages of fewer side effects and no need for a ride home make nitrous oxide an attractive alternative to oral sedation. The currently available N₂O/O₂ machines have built-in scavenging systems allowing their use in facilities without preexisting ventilation mechanisms. It may be beneficial to repeat this

study but allow for N₂O/O₂ to take effect for a few minutes before performing the procedure and to assess pain while women are still under the effect of N₂O/O₂. Additionally, a study comparing outcomes for women using N₂O/O₂ with PCB/ibuprofen compared to women only receiving O₂ with PCB/Ibuprofen would assess the true effects of N₂O/O₂.

Acknowledgments

none

Funding source

This project was also supported in part by the National Center for Research Resources and the National Center for Advancing Translational Sciences of the National Institutes of Health through Grant Number UL1 TR000041 and by 1R01HD049819-01A2. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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Implications

Women undergoing early surgical abortion experienced no differences in pain and satisfaction between those who used inhaled nitrous oxide and oral sedation. Nitrous oxide, with side effects limited to the duration of inhalation and no need for a ride home, is a viable alternative to oral sedation for first trimester abortion pain management.

Figure 1.
Flow Diagram of Participants

Table 1**Baseline Characteristics by Study Allocation Group**

Characteristics	N ₂ O/O ₂ (N = 68)	PO (N = 67)	P value
Age (years)	26.7 ± 6.9	26.0 ± 6.3	0.55
Gestational age (weeks)	7.4 ± 1.5	7.3 ± 1.4	0.50
Parity			0.08
0	34 (50.8)	37 (54.4)	
1	13 (19.4)	16 (23.5)	
2	19 (28.4)	8 (11.8)	
3	1 (1.5)	7 (10.4)	
Prior Abortions	62 (91.2)	61 (91.0)	0.98
Prior Miscarriages	18 (26.5)	13 (19.4)	0.33
Ethnicity			
- Hispanic or Latina	32 (47.1)	34 (50.8)	0.67
Race			0.18 *
- White	37 (54.4)	45 (67.2)	
- Native American/Alaska Native	13 (19.1)	6 (8.9)	
- Other	18 (26.5)	16 (23.9)	
Marital status			0.16 *
- Single living alone	36 (52.9)	30 (44.8)	
- Married/Living with partner ^I	26 (38.2)	35 (52.2)	
- Divorced/Separated	6 (8.8)	2 (3.0)	
Education completed			0.24
- High school	17 (25.0)	23 (34.3)	
- > High school	51 (75.0)	44 (65.7)	
Household income			0.25 *
- < \$20,000	20 (30.3)	23 (34.3)	
- \$20,001 – \$40,000	27 (40.9)	25 (37.3)	
- \$40,001 – \$60,000	12 (18.2)	6 (9.0)	
- > \$60,001	7 (10.6)	13 (19.4)	
Previous nitrous use	26 (38.2)	31 (46.3)	0.42
Perception of periods			0.34 *
- Requiring no medication	38 (54.3)	32 (45.7)	
- Cramping requiring OTC medication	24 (47.8)	32 (57.2)	
- Cramping requiring prescription medication	5 (7.5)	3 (4.5)	

Data are mean ± standard deviation or n (%);

* Fisher's Exact test used.

OTC = over the counter.

N₂O/O₂ – Nitrous Oxide and Oxygen group; PO – Oral sedation and Oxygen group.

^I Living with partner in a committed relationship.

Table 2

Procedure Characteristics by Study Group Allocation

Characteristics	N ₂ O/O ₂ (N = 68)	PO (N = 67)	P value
Procedure provider			0.59
- Obstetrics-Gynecology	49 (72.1)	51 (76.1)	
- Family Medicine	19 (27.9)	16 (23.9)	
Total procedure time (min)	9.7 ± 3.1	9.6 ± 3.1	0.91
Source of suction			0.81
- MVA	44 (64.7)	42 (62.7)	
- EVA	24 (35.3)	25 (37.3)	
Intrauterine Device insertion	31 (45.6)	30 (44.8)	0.97
Complications/Side effects ²			0.51
- None	45 (66.2)	50 (74.6)	
- Lethargy	4 (5.9)	5 (7.5)	
- Nausea	11 (8.1)	11 (16.4)	
- Dizziness	9 (13.2)	4 (6.1)	
- Vomiting	5 (7.4)	7 (10.4)	
- Bleeding requiring medications	3 (4.4)	0	

Data are n (%); MVA = manual vacuum aspiration; EVA = electric vacuum aspiration; N₂O/O₂ – Nitrous Oxide and Oxygen group; PO – Oral sedation and Oxygen group;

²Patients reported more than one complication.

P value was generated by comparing the no complication group to those with complications.

Table 3

Pain, Satisfaction and Anxiety Scores by Study Group Allocation

Outcomes	N ₂ O/O ₂ ² N = 68	PO ² N = 67	P value
Baseline pain ¹	4.74 ± 12.9	4.44 ± 11.8	0.83
Expected pain ¹	56.2 ± 24.5	50.3 ± 21.7	0.18
Worst Procedural Pain within 2 minutes ¹	52.5 ± 26.7	60.8 ± 24.4	0.09
Worst Procedural Pain within 5 minutes ¹	54.4 ± 28.1	60.5 ± 22.0	0.28
Pain at clinic discharge ¹	26.7 ± 22.3	26.0 ± 24.3	0.63
Satisfaction with pain management ¹	69.3 ± 28.4	61.5 ± 30.4	0.15
STAI Anxiety Score [*]			
- Pre-procedure	11.4 ± 3.0	10.5 ± 2.8	0.06
- Post-procedure	10.4 ± 3.3	9.7 ± 3.0	0.18

Data are mean ± standard deviation;

¹ Measurements were obtained using a 100-mm visual analog scale to assess pain (0=no pain, 100=worst imaginable pain) and satisfaction (0=very unsatisfied, 100=very satisfied); p values are Kruskal Wallis non-parametric tests;

^{*} STAI, State-Trait Anxiety Inventory, score on a scale of 0–20 (0=low anxiety, 20=high anxiety); P values from t-test.

² N₂O/O₂ – Nitrous Oxide and Oxygen group; PO – Oral sedation and Oxygen group.