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Low-dose fentanyl and midazolam in outpatient surgical abortion up to 18 weeks of gestation

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Abstract

Background: We investigated the safety of a conscious sedation protocol using intravenous fentanyl and midazolam by direct venous injection in women who underwent outpatient surgical abortion up to 18 weeks of gestation.
Study Design: This retrospective cohort study evaluated 1433 abortion procedures performed on women who received intravenous conscious sedation between April 1, 2001, and December 31, 2006. Women were allowed oral intake before the procedure. De-identified data were abstracted from charts using a standardized extraction form. Primary outcomes evaluated were need for reversal agents, need to obtain emergency intravenous access, pulmonary aspiration, need for oxygen supplementation and hospitalization for any reason.
Results: Of the 1433 procedures, 410 women received sedation with continuous intravenous access, and 1023 women received sedation by direct venous injection. More than 95% of women received fentanyl 100 mcg combined with 1–2 mg of midazolam. We identified four (0.3%) instances of adverse events, none of which occurred as a result of oversedation. No women experienced oral content aspiration.
Conclusions: Intravenous conscious sedation with fentanyl and midazolam is safe for outpatient surgical abortion in women without cardiovascular compromise up to 18 weeks of gestation. The risk of aspiration or oversedation requiring reversal agents is rare and does not warrant universal direct venous access or restriction of oral intake.

Keywords: Abortion; Sedation; Fentanyl; Midazolam; Aspiration

1. Introduction

Conscious sedation is commonly used by medical personnel to achieve pain relief and relaxation for painful outpatient procedures. Use of conscious sedation reduces hospitalization time, speeds recovery, and improves overall patient comfort [1]. Commonly, a moderate level of sedation is achieved by administering narcotics with or without benzodiazepines with the goals of relaxation, raising the pain threshold, and partial amnesia. The American Society of Anesthesiologists defines conscious sedation as "a drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation" while retaining cardiovascular function and maintenance of the airway without the need for provider intervention [2].

Despite the widespread use of conscious sedation in a variety of fields including gastrointestinal endoscopy [1], dentistry [3], emergency medicine [4], and gynecology [5–7], many questions concerning the safety of conscious sedation remain unanswered. In combination, opioids and benzodiazepines have the potential for serious complications including respiratory depression and aspiration of gastrointestinal contents [8,9]. However, these risks must be considered within the context of the great comfort and pain relief these medications provide to patients [10,11]. Although the efficacy of conscious sedation for pain management as compared to local and general anesthesia in an outpatient surgical setting has been investigated

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[1,6,7,10,11], detailed information exploring its relative safety is lacking. Information about the relative importance of a patient having nothing by mouth is unknown. In addition, recommendations regarding postoperative monitoring are vague, and the frequency with which reversal agents are required is not known.

Traditionally, preoperative fasting is recommended for all levels of sedation to avoid complications of anesthesia, particularly pulmonary aspiration of abdominal contents. In its extreme, this recommendation has been translated to define recent oral intake as a contraindication for receiving sedation [6]. Consequently, patient care may be delayed, or the patient may decide to undergo a painful procedure without sedation because she has eaten. Whether there is actually an increased risk of complications among patients who undergo conscious sedation after eating has been difficult to evaluate because pulmonary aspiration is a relatively rare event [9]. The American Society of Anesthesiologists' practice guidelines acknowledge that "the literature does not provide sufficient evidence to test the hypothesis that pre-procedure fasting results in a decreased incidence of adverse outcomes in patients undergoing either moderate or deep sedation" [2]; yet, the panel goes on to recommend fasting for all patients undergoing elective procedures who wish to receive conscious sedation. Emergency physicians have taken a special interest in the question of preoperative fasting and the risks it may or may not present for adequate sedation [4]. A recent consensus-based practice guideline for emergency physicians deemed a "light snack" to be acceptable for "nonextended moderate sedation" [4]. Clearly, more investigation into the relative risks of eating prior to being sedated is needed.

The literature is also lacking in data to support guidelines for maintenance of intravenous access in patients receiving conscious sedation. The American Society of Anesthesiologists recommend that intravenous access be maintained until patients are no longer at risk for cardiovascular or respiratory compromise to "decrease the likelihood of adverse outcomes" [2]. Presumably, this is to facilitate titration of sedatives as well as enable quick delivery of reversal agents should oversedation occur. Whether intravenous access is necessary to provide reversal agents in a timely manner has not been studied. Many existing protocols for delivering sedation do not explicitly address this issue including that published by the American Society for Gastrointestinal Endoscopy [1]. Furthermore, the frequency with which reversal agents are necessary has not been adequately investigated.

We performed this retrospective chart review with the goal of examining the safety of conscious sedation delivered under a well-defined protocol. Specifically, we wanted to address the safety of allowing patients to eat before the procedure and the frequency of adverse events related to oversedation in order to understand whether continuous intravenous access is necessary. Our study was carried out in a population of young women undergoing surgical abortion up to 18 weeks gestation in the outpatient setting. Under this protocol, preoperative oral intake was not restricted, and continuous intravenous access was not mandated. Because surgical abortion is one of the most common outpatient procedures performed in the United States [12,13] and because many abortion providers use conscious sedation in this setting [5], it is important that we have a clear understanding of the safest way to provide analgesia for this procedure.

2. Materials and methods

This retrospective cohort study included 1,501 consecutive abortion procedures performed on women who received intravenous conscious sedation under the clinic's standard protocol for outpatient surgical abortions at 18 weeks or less of gestation between April 1, 2001, and December 31, 2006, at Planned Parenthood of Western Pennsylvania. The start date was based on when this clinic started providing abortion services. Patients were identified using the clinic's medication tracking log. Women were included if they received fentanyl or midazolam, in any combination, regardless of whether the abortion was completed. The records for all 1501 procedures were fully available for review. For women who had more than one abortion during this time period, we only included the first one, leaving 1433 procedures for our data set. The University of Pittsburgh institutional review board approved the study.

Per the clinic protocol, women were ineligible for intravenous sedation only if intravenous access could not be achieved or they had active cardiac or respiratory disease that compromised cardiovascular function. Women who were obese or were determined to have difficult airways for intubation were not restricted from receiving sedation. The standard protocol for intravenous conscious sedation included evaluation of the cardiorespiratory system to ensure that the lungs were clear to auscultation, no arrhythmias were present, and baseline oxygen saturation was 97% or greater. Oral intake was permitted before and after the procedure without restriction. Clinic staff generally encouraged women to eat before the procedure in hopes of minimizing nausea and vomiting related to preoperative antibiotic use, although this practice is not supported by published literature. Medications were either administered as a single direct injection into a vein or via continuous intravenous access with a heparin lock port which was left in place for the duration of the procedure. Medications included fentanyl 50–100 mcg with or without midazolam 1–2 mg; dosages were based on the provider's clinical judgment with a goal of providing comfort while maximizing the likelihood of maintaining consciousness. The surgeon administered the drugs before performing the procedure. Surgical procedures routinely included cervical anesthesia using bupivacaine 0.25% 20 cc delivered intracervically or paracervically at the discretion of the surgeon. This differentiation was not

recorded in the operative note. Except when contraindicated, vasopressin (2 U) was added to the cervical anesthetic for gestations up to 12 weeks, and 4 U for gestations greater than 12 weeks of gestational age. Clinic assistants who routinely assisted in abortion procedures served as patient advocates and were trained to recognize signs of oversedation (low oxygen saturation, unresponsiveness, poor inspiratory effort). Persons in the room during the procedure included the patient, the physician, a trained clinical assistant, and, if desired, a support person (i.e., parent or partner). A licensed clinician other than the physician either acted as the clinical assistant or was available in an adjacent room. Monitoring during the procedure included continuous oxygen saturation monitoring with blood pressure and pulse every 10 min. Vital signs and oxygen saturation were recorded before and immediately following the procedure. Monitoring was discontinued immediately after the procedure unless the surgeon felt it was clinically indicated. The decision to administer supplemental oxygen or reversal agents or to establish emergency intravenous access was made at the discretion of the surgeon. Following the procedure, patients were moved to the recovery room for observation for a minimum of 1 h. Pulse and blood pressure were assessed upon arrival to the recovery room, 15 and 30 min later, then every 30 min until the patients were determined to be stable and ready to leave the clinic.

Specific requirements for administering sedation varied slightly over the timeframe of the review based on administrative policy changes by Planned Parenthood Federation of America. Between April 1, 2001, and December 31, 2002, intravenous access was maintained for all procedures using midazolam, as well as procedures with a gestational age greater than 14 weeks, regardless of the agents used. Beginning in January of 2003, continuous intravenous access became mandatory, regardless of the agents used, only in women with a gestational age of 17 weeks or greater.

Chart abstraction was carried out over a 3-month period by one of the authors (L.C.W.) using a standardized data abstraction form. Information extracted from the medical records included demographics, vital signs and oxygen saturation before and after the procedure, medications prior to arrival and medications administered prior to the procedure including oral analgesics and antibiotics. Information about trough values of oxygen saturation was not recorded in the charts. Of primary interest, we collected information on the sedating medications used, noting the type, dosage, and whether medications were injected directly into the vein or by continuous intravenous access via a heparin lock port. Because standardized procedure forms were used, there were no missing data for the primary variables.

Data were de-identified and entered into a database for analysis using STATA (version 9; Stata, College Park, TX, USA). Primary outcomes (adverse events) evaluated were need for reversal agents, need to obtain emergency intravenous access, aspiration of abdominal contents, need for oxygen supplementation and hospitalization. In order to assess the necessity of continuous intravenous access for safety, we divided the groups based on mode of delivery of sedation. Of the cases evaluated, continuous intravenous access was maintained for 410 procedures, and direct venous injection was used for 1023 procedures. Student's *t* tests were used for continuous variables. chi-Square or Fisher's exact tests were used for categorical variables as appropriate. Exact binomial confidence intervals were calculated for adverse events.

3. Results

A total of 1433 women were included in the data analysis. Only the first procedure was included for the 56 women who had two procedures with sedation and the six women who had three procedures with sedation. Of the 1433 procedures, 87% were performed at 12 weeks or less of gestation. Four hundred ten women received sedation with continuous intravenous access, and 1023 women received sedation by direct venous injection. Demographics and reproductive health history are described in Table 1. There were no differences between women with continuous intravenous access and women who received direct venous injection, with the exception of gestational age ($p<.001$), as can be explained by the clinic protocol for use of intravenous access.

Medications used for conscious sedation are described in Table 2. More than 95% of women received fentanyl 100 mcg combined with 1–2 mg of midazolam. Changes in oxygenation and cardiovascular function before and after the procedure are presented in Table 3. No cases of aspiration were recorded during or after the procedure. Four (0.3%, 95% CI 0.01–0.5%) women experienced an adverse event as noted in Table 4. Of note, no adverse events were reported or occurred during the repeat procedures excluded from the data set. Upon review of the four adverse events, we considered none of these events to be a consequence of oversedation. A description of these events, based on the chart documentation, is as follows.

Case 1 (event=transfer to hospital)

A 31-year-old woman at 17 weeks of gestation was sedated using 100 mcg fentanyl and 1 mg midazolam via continuous intravenous access. The physician was unable to complete the dilation and evacuation and became concerned about possible uterine perforation. The patient was transferred to a hospital where the procedure was completed under spinal anesthesia. No complications due to sedation were identified.

Case 2 (event=emergency intravenous access, supplemental oxygen)

A 19-year-old woman at 8 weeks of gestation was sedated using 100 mcg fentanyl and 2 mg midazolam by direct

Table 1
Patient demographics (mean±standard deviation or n, %)

	Continuous IV	Direct injection	Total	p
	n=410	*n*=1023	*n*=1433	
Age (years)	23.4±6.5	23.5±6.0	23.5±6.2	.71
Tobacco use	210 (51.2%)	502 (49.1%)	712 (49.7%)	.46
Body mass index (kg/m^2)	24.6±5.0	25.0±5.1	24.9±5.1	.15
Gravidity				.37
1	175 (42.7%)	470 (45.9%)	645 (45.0%)	
2	91 (22.2%)	201 (19.7%)	292 (20.4%)	
3	54 (13.2%)	153 (15.0%)	207 (14.5%)	
4 or more	90 (22.0%)	199 (19.5%)	289 (20.2%)	
Parity				.79
0	242 (59.0%)	593 (58.0%)	835 (58.3%)	
1	91 (22.2%)	214 (20.9%)	305 (21.3%)	
2	54 (13.2%)	151 (14.8%)	205 (14.3%)	
3 or more	23 (5.6%)	65 (6.4%)	88 (6.1%)	
Prior abortion				.42
0	278 (67.8%)	729 (71.3%)	1007 (70.3%)	
1	92 (22.4%)	201 (19.7%)	293 (20.5%)	
2 or more	40 (9.8%)	193 (9.1%)	133 (9.3%)	
Gestational age	10.2±3.5	8.5±2.2	9.0±2.8	<.001
12 weeks or less	299 (72.9%)	950 (92.9%)	1249 (87.2%)	
More than 12 weeks	111 (27.1%)	67 (6.6%)	178 (12.4%)	
Not available	0	6 (0.6%)	6 (0.4%)	

venous injection. Within 30 s of local anesthetic administration, the patient experienced "seizure-like activity." She was administered supplemental oxygen and became responsive within minutes. An emergency intravenous line was started after the seizure but was not utilized. No post-ictal findings were recorded. The procedure was completed without difficulty.

Case 3 (event=use of reversal agent, supplemental oxygen)

A 28-year-old woman at 9 weeks of gestation was sedated using 100 mcg fentanyl and 1 mg midazolam by direct venous injection. Following administration of the local anesthetic, the patient experienced seizure-like activity. The physician administered intramuscular naloxone 0.2 mg. She was reported to "quickly" become responsive and the procedure was performed without complications. No post-ictal findings were recorded.

Case 4 (event=reversal agent)

A 36-year-old woman at 7 weeks gestation was sedated using 100 mcg fentanyl and 2 mg midazolam via continuous intravenous access. Her oxygen saturation dropped to 94% before starting the procedure. Although the physician documentation states she was fully responsive, the physician administered naloxone 0.1 mg intravenously and repeated the dose two more times in a brief interval. Her oxygen

Table 2
Procedure type and medications used for conscious sedation

	Continuous IV	Direct injection	Total	p
	n=410	*n*=1023	*N*=1433	
Procedure				<.001
D&C	352 (85.9%)	1014 (99.1%)	1365 (95.3%)	
D&E	56 (13.7%)	8 (0.8%)	65 (4.5%)	
None[a]	2 (0.5%)	1 (0.1%)	3 (0.2%)	
Sedation				
Fentanyl 50 mcg/midazolam 1 mg	6 (1.5%)	24 (2.4%)	30 (2.1%)	
Fentanyl 50 mcg/midazolam 2 mg	1 (0.2%)	2 (0.2%)	3 (0.2%)	
Fentanyl 75 mcg/midazolam 1.5 mg	2 (0.5%)	0	2 (0.1%)	
Fentanyl 100 mcg	1 (0.2%)	11 (1.1%)	12 (0.8%)	
Fentanyl 100 mcg/midazolam 1 mg	181 (44.2%)	447 (43.7%)	627 (43.8%)	
Fentanyl 100 mcg/midazolam 1.5 mg	49 (12.0%)	0	48 (3.4%)	
Fentanyl 100 mcg/midazolam 2 mg	163 (39.8%)	533 (52.1%)	698 (48.7%)	
Other	7 (1.7%)	6 (0.6%)	13 (0.9%)	

D&C, dilation and curettage (suction aspiration); D&E, dilation and evacuation.
[a] Three patients did not have a procedure following administration of the sedation.

Table 3
Changes in cardio-respiratory function with use of conscious sedation

	Continuous IV	Direct injection	Total	p
	n=410	*n*=1023	*N*=1433	
Oxygen saturation				
Baseline SO_2 (mean±S.D.)	98.2±0.8	98.2±0.8	98.2±0.8	.75
Baseline ≤97% [*n* (%)]	60 (19.5%)	128 (15.7%)	189 (16.8%)	.13
Post proc. SO_2 (mean±S.D.)	97.7±1.6	97.8±1.1	97.7±1.2	.14
Post ≤97% [*n* (%)]	138 (35.3%)	298 (32.0%)	436 (33.0%)	.25
Pre and post ≤97% [*n* (%)]	34 (8.3%)	69 (6.7%)	103 (7.2%)	.14
Received O_2 [*n* (%)]	0 (0%, 95% CI 0, 0.7%)	2 (0.2%, 95% CI 0, 0.7%)	2 (0.1%, 95% CI 0, 0.5%)	1.0
HR				
Baseline HR (mean±S.D.)	78.5±12.0	76.4±9.0	77.0±10.2	<.001
Baseline HR <60 [*n* (%)]	5 (1.2%)	12 (1.2%)	17 (1.2%)	1.0
Post HR (mean±S.D.)	84.1±13.4	83.5±12.9	83.7±13.1	.45
Post HR <60 [*n* (%)]	12 (3.1%)	18 (1.9%)	30 (2.2%)	.20
Pre and post HR <60 [*n* (%)]	0 (0%)	1 (0.1%)	1 (0.1%)	1.0
Discharge HR (mean±S.D.)	77.4±8.2	77.9±8.5	77.8±8.4	.32
Discharge HR <60 [*n* (%)]	3 (0.7%)	9 (0.9%)	12 (0.8%)	.79
Hypotension [*n* (%)]	0	0	0	

SO_2, oxygen saturation; HR, heart rate.
No statistically significant differences were noted between groups except baseline HR (p=.0002).

saturation improved to 98% with stimulation, and her procedure was completed without difficulty.

4. Discussion

The aim of our study was to specifically address the safety of conscious sedation under a defined protocol in women who received an abortion up to 18 weeks of gestation in an outpatient setting. We found an extremely low incidence of adverse events (four of 1433 procedures, 0.3%) associated with this sedation protocol in which women were allowed to eat before the procedure, and an indwelling catheter was not mandated. Our study is unique in that it addresses many of the questions practitioners face when considering safety issues related to the administration of sedation including need for nothing-by-mouth status, the necessity of continuous intravenous access, dosage levels and appropriate monitoring. The extremely low incidence of adverse events under this protocol indicates that direct venous injection of low dose fentanyl and midazolam in women who have been allowed oral intake rarely causes adverse events and also speaks to the overall safety of surgical abortion in the outpatient setting.

The absence of oral-content aspiration while under conscious sedation implies that patients are capable of maintaining patency of the airways in the event of vomiting. If this is true, oral intake of food prior to the procedure should not be used as a contraindication for conscious sedation. Unfortunately, because vomiting was recorded in a passive manner (i.e., no check box on the forms) and the charts did not document the time and nature of last oral intake, it is difficult to draw definitive conclusions about the risk of eating before conscious sedation. Although oral intake was not limited, it is possible that some chose not eat prior to the procedure. However, given that clinic policies were to encourage women to eat and snacks were available in the waiting room, we expect that most women did eat. Accordingly, our data does not support nothing-by-mouth status as a requisite for receiving conscious sedation.

Table 4
Untoward events with use of conscious sedation [*n* (%, 95% CI)]

	Continuous IV	Direct injection	Total
	n=410	*n*=1023	*N*=1433
Reversal for oversedation	0 (0%, 95% CI 0–0.7%)	0 (0%, 95% CI 0–0.3%)	0 (0%, 95% CI 0–0.2%)
Reversal agents (any reason)	1 (0.2%, 95% CI 0–1.4%)	1 (0.1%, 95% CI 0–0.5%)	2 (0.1%, 95% CI 0–0.5%)
Emergent IV access for oversedation	–	0 (0%, 95% CI 0–0.3%)	–
Emergent IV access (any reason)	–	1 (0.1%, 95% CI 0–0.5%)	1 (0.07%, 95% CI 0–0.4%)
Aspiration	0 (0%, 95% CI 0–0.7%)	0 (0%, 95% CI 0–0.3%)	0 (0%, 95% CI 0–0.2%)
Hospitalization related to sedation	0 (0%, 95% CI 0–0.7%)	0 (0%, 95% CI 0–0.3%)	0 (0%, 95% CI 0–0.2%)
Hospitalization (any reason)	1 (0.2%, 95% CI 0–1.4%)	0 (0%, 95% CI 0–0.3%)	1 (0.07%, 95% CI 0–0.4%)

No statistically significant differences were noted between groups.

We do not believe any of the four cases of adverse events identified in this review are directly related to sedation. Of note, Cases 1, 2 and 3 describe events which we believe to be related to the abortion procedure itself as opposed to the sedatives used and would have occurred regardless of whether or not sedation was utilized. Case 1 involved a hospital transfer in order to complete a "difficult procedure," and no issues in this case are related to oversedation. Cases 2 and 3 involved women who experienced seizure-like activity only after local anesthetic was administered. We believe the reactions were a response to the local anesthetic as bupivacaine toxicity has the potential to cause neurotoxicity [14]. Patient 2 recovered after receiving supplemental oxygen, and although emergency intravenous access was obtained before continuing the procedure, it was precautionary. None of the cases included in the study identified a situation in which emergency intravenous access was needed but could not be obtained in a timely fashion. Despite the absence of intravenous access, patient 3 received a reversal agent intramuscularly without difficulty, although it was likely not needed. Case 4 involved a woman whose oxygen saturation dropped prior to the procedure at which time she was administered a reversal agent as well as supplemental oxygen despite remaining responsive. Because the patient was fully responsive per the physician notes, the drop in oxygen saturation more likely represented a problem with adequate monitoring and less likely to truly represent oversedation. It is possible that having continuous intravenous access during this procedure made the clinician more likely to administer the reversal agent unnecessarily.

Our findings show that there is no difference in the frequency of adverse events between procedures utilizing continuous intravenous access and those using direct venous injection, indicating that the two modes of delivery are similarly safe. Logically, direct venous injection has the additional advantage of being quicker for practitioners as it eliminates the time needed to secure the intravenous port to the patient, restrict the patient's movement to avoid dislodgement and remove the equipment following the procedure. We would also argue that direct access is potentially more comfortable for patients given that they would not need to have their arm taped and, in the case of positional access, be maintained relatively immobile for the sake of the intravenous port. In the rare event that a reversal agent is needed, our report illustrates the ease with which it can be delivered in the absence of emergency intravenous access. One may ask what the downside is of obtaining access just in case it is needed. In fact, our study proves that such complications are rare, and in healthy women, the ability to gain such access when needed is highly probable. Accordingly, mandating any excess cost in personnel time and supplies to routinely obtain such access is unwarranted. Although one could also tape a butterfly needle in place as "continuous" access, our data shows that even this is not needed. Moreover, in a real emergency, such access is not stable enough to reliably provide medications or fluid.

Continuous oxygen saturation monitoring intraoperatively is relatively easy to deliver. More extensive monitoring in persons receiving conscious sedation does not appear to be indicated. The necessity of continuous postoperative monitoring also does not appear to be necessary considering the absence of hypoxic events in our study. For patients who are ambulatory and conversant in the recovery room, additional monitoring is likely a waste of resources.

A major limitation of our study is the use of records that were not designed specifically to extract this data. Over the 5-year period from which we selected participants, many practitioners were involved in delivering abortion care at this clinic resulting in a range of documentation quality. However, given that the clinic used standardized forms for reporting patient information, the potential for missing information is low. We are unable to draw any conclusions about effectiveness in regard to pain management as this was not a goal of our review. Such evaluations are best performed prospectively with appropriate comparators [7,10,11]. A prospective study would also allow for more precise recording of the patient's nothing-by-mouth status.

The intrinsic value of our study lies in its potential to affect policy and physician practice for delivering conscious sedation to women in need of abortion care and, potentially, other outpatient procedures. Future studies investigating safety in a prospective manner would have the ability to define their variables and elicit more standardized responses. Our study is an important first step in understanding the safety of conscious sedation in women undergoing outpatient surgical abortion.

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