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Moderate intravenous sedation for first trimester surgical abortion: A comparison of adverse outcomes between obese and normal weight women

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Abstract

Objective: To determine if obese women experience increased rates of adverse outcomes with moderate intravenous sedation during first trimester surgical abortion compared to normal weight women.

Study Design: We performed a retrospective cohort study of all first trimester surgical abortions with moderate intravenous sedation at an outpatient facility between September 2010 and June 2015. The primary outcome was supplemental oxygen administration. Secondary outcomes included reversal agent administration, anesthesia-related adverse events, and intraoperative lowest level of consciousness (LLOC). We compared three obesity groups [I (Body Mass Index, BMI=30-34.9), II (BMI=35-39.9), and III (BMI $\geq$ 40)] to normal weight women (BMI<25). We exported data from electronic medical records and reviewed adverse outcomes individually.

Results: Of 20,381 first trimester surgical abortion procedures, 31 (0.15%) utilized supplemental oxygen, 24 (0.12%) utilized a reversal agent, 40 (0.20%) had a presumed anesthesia-related adverse event and 184 of 19,725 (0.93%) had a documented low intraoperative LLOC. One patient (0.005%) required hospital transfer or hospitalization. Supplemental oxygen administration (obesity versus normal weight: obese I, aOR 0.52, 95% CI 0.12-2.27; II/III, aOR 1.51, 95% CI 0.50-4.54), low intraoperative LLOC, and anesthesia-related adverse events were not associated with obesity. The rate of reversal agent administration was lower among obese I, II and III women combined compared to normal weight women (aOR 0.13, 95% CI 0.02-0.96).

Conclusions: Adverse outcomes were rare across all BMI categories with no detectable increased risk among obese women compared to normal weight women.

68 **Keywords:** moderate sedation; intravenous sedation; obesity; BMI; surgical abortion; first
69 trimester

70

71 **Implications:** With appropriate clinical screening, obese women can safely receive moderate
72 intravenous sedation for first trimester surgical abortion in an outpatient clinical setting.

73 Restrictions on moderate intravenous sedation based on BMI alone may be unnecessary.

1. Introduction

Approximately 926,200 abortions were performed in the United States in 2014, with 89% occurring within the first 12 weeks gestation and 95% in an outpatient setting [1, 2]. By age forty-five, half of American women will have an unintended pregnancy with one in three having an abortion [3, 4]. As of 2010, 31.9% of women between the ages of 20 to 39 in the United States were obese and 55.8% were obese or overweight [5]. Thus, abortion among overweight or obese women in the United States is common.

Pain management options for surgical abortion include local anesthesia, oral, moderate, or deep sedation, and general anesthesia [6, 7]. While deep sedation and general anesthesia provide the greatest analgesia, with these options patients are not easily arousable, sometimes require airway support and require monitoring by anesthesia professionals, limiting their availability in the outpatient setting [8]. With moderate intravenous (IV) sedation patients continue to respond purposefully to verbal or tactile stimulation and have better pain control and satisfaction compared to local anesthesia alone or in combination with oral sedation. Moderate IV sedation can be administered by a wider array of health care professionals and is more commonly available in the outpatient setting, with 40%-100% of first trimester patients receiving IV sedation [6-13].

While there are limited data on the safety of moderate IV sedation for abortion in obese women, some outpatient clinics have restricted this option due to concern about increased risk of adverse events. In 2016, Planned Parenthood Federation of America issued new guidelines prohibiting IV sedation by non-anesthesia professionals in women with a body mass index (BMI) greater than or equal to 45 and recommending special consideration for women with a BMI between 40 and 45.

This study sought to determine if BMI is a predictor of adverse outcomes with moderate IV sedation during first trimester surgical abortion to elucidate if BMI-based restrictions are warranted.

2. Material and methods

We conducted a retrospective cohort study of all first trimester surgical abortion procedures performed with moderate IV sedation at Planned Parenthood League of Massachusetts (PPLM) Health Centers in Boston, Springfield, and Worcester between September 1, 2010 and June 1, 2015. We included procedures in which the patient was thirteen weeks and six days or less by ultrasound and received any IV sedation with fentanyl and/or midazolam. We excluded procedures if the patient received local anesthesia alone, was missing BMI data, or had an extreme BMI. We defined extreme BMI as BMI<15 or BMI>80 and assumed that these values were erroneous unless the patient had a similar value documented at another appointment. When women had more than one abortion procedure in our cohort, we included the first procedure and excluded all additional procedures. The Institutional Review Board of the Harvard University Faculty of Medicine exempted this research from review.

Patients included in our cohort underwent dilation and vacuum aspiration. Prior to any procedure, a triage nurse medically screened all surgical abortion patients. A physician further evaluated any patients with significant medical conditions, including asthma, diabetes, hypertension, seizure disorder, or a history of cardiac or pulmonary disease, to determine eligibility to have a procedure at PPLM. Women were not eligible for surgical abortion if they had any medical condition judged to be so severe or so poorly controlled that the procedure would pose significant risk. There was no specific BMI cut-off for procedural eligibility. If ineligible, women were referred for hospital-based abortion.

The triage nurse additionally screened patients who desired IV sedation for sedation eligibility. Physicians did not provide moderate IV sedation to patients with a relevant drug allergy, no escort home, a concerning pulmonary examination, or perceived significant risk with sedation. We screened patients with asthma for disease triggers and severity and did not offer IV sedation if they had been recently hospitalized for asthma or had poorly controlled disease. Physicians did not offer sedation to any patient with wheezes on lung exam that did not clear with several puffs of an inhaler. From 2010 to 2013, PPLM required patients to be NPO. Starting in 2013, patients were still instructed to be NPO, but sedation was permitted in cases of non-adherence at physician discretion. There was no specific BMI cut-off for sedation eligibility.

A registered nurse (RN) administered sedation medications in conjunction with the operating physician. Standard initial doses were 100 mcg fentanyl and 2.0 mg midazolam and were sometimes adjusted at the outset based on clinical factors (i.e. starting dose reduced for low body weight), but could not exceed 150 mcg fentanyl and 3.0 mg midazolam. The operating physician, with input from the RN, decided on additional doses to titrate the sedation during the procedure in response to patient pain and anxiety as needed, typically not exceeding 200 mcg fentanyl and 4.0 mg midazolam, although there were no limitations placed on maximum total dosing. Doses were administered to provide a level of moderate sedation as defined by the American Society of Anesthesiologists criteria [8]. Most women remained awake and conversant throughout their procedure and maintained their oxygen saturation in normal range on room air, rarely requiring more than verbal stimulation.

An RN administered the sedation and documented all intraoperative monitoring in the electronic medical record (EMR) in real time. Heart rate and pulse oximetry were measured continuously and blood pressure and level of consciousness were recorded every five minutes.

The RN evaluated level of consciousness on a five-point scale (0-no response; 1-responds to pain only; 2-drowsy, hard to arouse, needs tactile stimuli; 3-drowsy, but opens eyes if called several times; 4-drowsy, easily aroused; 5-awake, alert, oriented). RNs did not routinely administer supplemental oxygen, which was generally the first-step intervention for patients unable to maintain oxygen saturation on room air with verbal stimulation alone. The attending physician and sometimes the nurse documented adverse events.

We exported data directly from the EMR into a research database. A single investigator (GH) individually reviewed the medical records for all procedures coded as having received supplemental oxygen or a reversal agent or resulting in an anesthesia-related adverse event. An attending physician (ABG) additionally reviewed all cases with a possible anesthesia-related adverse event, either identified directly by EMR code or upon review of cases where supplemental oxygen or reversal agents were used.

The primary outcome was the use of supplemental oxygen. Secondary outcomes included: use of reversal agents (naloxone or flumazenil), lowest intraoperative level of consciousness (LLOC) recorded, and anesthesia-related adverse events. PPLM considers a LLOC of 0-3 as “low” and considered a potential indicator of over-sedation while a LLOC of 4 or 5 is considered normal. We considered the following to be possible anesthesia-related adverse events: aspiration, intubation, asthma attack, vasovagal reaction, seizure, anxiety or psychotic reaction, or any drug reaction. We included vasovagal reactions because they represented a documented, significant change in vital signs from baseline that could have possibly been sedation related.

Demographic and clinical variables included age, race, ethnicity, gestational age, prior vaginal deliveries, prior Cesarean deliveries, initial and total fentanyl and midazolam doses, and history of drug use.

To determine the baseline rate of supplemental oxygen administration in our population, we performed a clinical audit of a convenience sample of all procedures performed between the introduction of the EMR on September 1, 2010 and the start of this study on June 1, 2015. This revealed a baseline rate of 0.175%. We then calculated that we would need 1,788 procedures to detect an increase in supplemental oxygen administration from 0.175% to 1%, 672 procedures to detect an increase from 0.175% to 2%, and 225 procedures to detect an increase from 0.175% to 5% (80% power, 1.7% alpha correcting for multiple comparisons). In accordance with the National Institutes of Health BMI classification system, we stratified obese women into three groups and analyzed BMI as a 5-category variable: normal (BMI<25), overweight (BMI=25-29.9), obese I (BMI=30-34.9), obese II (BMI=35-39.9), and obese III (BMI≥40) [14]. We used weight measured in the office and self-reported height to calculate BMI.

We compared primary and secondary outcomes between each obesity category and normal weight women. We performed logistic regression for all outcome analyses. We examined pre-selected potential confounders (age, race, ethnicity, gestational age, fentanyl dose, midazolam dose, and street drug use) and included any variables with p<0.10 in the univariable analysis in the multivariable model. We used the Wald test to calculate p values. All statistical analyses were performed using SAS® v 9.4 (Cary, NC).

3. Results

Between September 1, 2010 and June 1, 2015, PPLM providers performed 23,846 first trimester surgical abortion procedures with moderate IV sedation in 20,573 different patients.

We excluded 3,273 repeat procedures among 2,663 patients and 192 patients for missing BMI, leaving 20,381 patients for our study population. Fifty-four percent of women were normal weight, 26% were overweight, and 20% were obese (Table 1). Seven percent (41/550) of obese III women and 0.20% (41/20,381) of the entire study population were super obese with a BMI $\geq$ 50 [15]. At PPLM, approximately three-quarters of women undergoing first trimester surgical abortion receive moderate IV sedation. Patients received a median fentanyl dose of 100 mcg and median midazolam dose of 2.0 mg (Table 2).

The absolute rate of all primary and secondary outcomes was low (Tables 3-4). Thirty-one (0.15%) of 20,381 patients required supplemental oxygen (Table 3). In the multivariable analysis for supplemental oxygen, we controlled for fentanyl and midazolam doses and street drug use, and we combined obese II and III women into one group for analysis due to a paucity of outcomes. We found no statistically significant difference in supplemental oxygen administration when comparing obese I and obese II/III women to normal weight women (Obese I versus normal weight, aOR 0.52, 95% CI 0.12-2.27; obese II/III versus normal weight, aOR 1.51, 95% CI 0.50-4.54).

Twenty-four (0.12%) of 20,381 patients required a reversal agent, including 19 (79%) patients with a BMI<25 and 23 (96%) with a BMI<30 (Table 3). In the multivariable analysis for reversal agent administration, we controlled for ethnicity and midazolam dose, and we combined obese I, II and III women into one group for analysis due to a paucity of outcomes. We found that the rate of reversal agent administration was lower among obese I, II and III women combined compared to normal weight women (Obese I/II/III versus normal weight, aOR 0.13, 95% CI 0.02-0.96).

We documented a low LLOC in 184 (0.93%) of 19,725 patients, including 115 (63%) patients with a BMI<25 and 157 (85%) with a BMI<30 (Table 3). In the multivariable analysis for low LLOC, we controlled for ethnicity, fentanyl and midazolam doses, and street drug use. There was no significant difference in low LLOC rates between obese I, II or III women and normal weight women (Obese I versus normal weight, aOR 0.65, 95% CI 0.40-1.06; obese II versus normal weight, aOR 0.54, 95% CI 0.25-1.17; obese III versus normal weight, aOR 0.14, 95% CI 0.02-1.03).

Adverse events determined to be possibly anesthesia-related (0.20%) included (Table 4): 32 vasovagal reactions, 3 anxiety reactions, 2 seizures, 1 asthma attack, 1 psychotic reaction, and 1 other drug reaction. One of these patients (0.005% of the total sample) required hospital transfer or hospitalization (for seizure). No patients aspirated or required intubation. Overall, the risk of a non-vasovagal anesthesia-related adverse event was 1 in 2,548 and the risk of hospitalization for an anesthesia-related adverse event was 1 in 20,381.

In our multivariable model for all anesthesia-related adverse events, we controlled for age, fentanyl dose, and midazolam dose. There was no significant difference in the frequency of adverse events between any obesity group and normal weight women (Obese I versus normal weight, aOR 1.20, 95% CI 0.41-3.55; obese II versus normal weight, aOR 0.75, 95% CI 0.10-5.62; obese III versus normal weight, aOR 3.19, 95% CI 0.73-13.99). In this model, the risk of anesthesia-related adverse events decreased with increasing dose of both fentanyl and midazolam. This relationship was not observed in the multivariable model for anesthesia-related adverse events when excluding vasovagal reactions. Of the 8 (0.04%), non-vasovagal, anesthesia-related adverse events included in this analysis, none occurred in women with a BMI of 35 or greater (Table 4). Given the rarity of these adverse events, obese I, II and III were

combined for analysis. In our multivariable model controlling for ethnicity, there was no relationship between BMI and the occurrence of anesthesia-related adverse events excluding vasovagal reactions (obese I/II/III versus normal weight, aOR 0.59, 95% CI 0.07-5.31).

4. Discussion

We sought to determine if obese I, II and III women experienced increased adverse outcomes with moderate IV sedation during first trimester surgical abortion compared to normal weight women. Among patients undergoing a first trimester surgical abortion with moderate IV sedation, we found no difference in the rate of supplemental oxygen administration or in the rate of low intraoperative LLOC when comparing each obesity group and normal weight women. Additionally, we found that obese women required reversal agent administration at a significantly lower rate than normal weight women.

We found that the absolute rate of any anesthesia-related adverse events was exceedingly low across all BMI categories and the rate of serious adverse outcomes resulting in hospital transfer or hospitalization was even lower. Additionally, over three-quarters of anesthesia-related adverse events were self-limited vasovagal reactions, and may represent inadequate pain control given the inverse relationship with sedation dosing and/or may be related to the paracervical block, rather than over-sedation.

A strength of this study is its large sample size, which allows detection of small increases in adverse outcomes. We chose a primary outcome of oxygen administration to maximize sensitivity for detecting any possible anesthesia-related adverse events. We designated this surrogate marker as our primary outcome because in our setting oxygen is not routinely used, is reliably recorded, and is usually the first step in management of hypo-oxygenation that does not respond to verbal or tactile stimulation. This sensitive measure coupled with the large sample

size leaves us confident that we detected all adverse events in our population and that there is no clinically relevant association between supplemental oxygen use and BMI.

The retrospective nature of the data limited this study. We were limited to the data fields and procedures collected after the EMR was adopted in 2010. The template utilized for documenting abortion procedures at PPLM largely consisted of check boxes and drop-down menus, which standardizes documentation and minimizes the amount of missing data. Intraoperative pain scores were unreliably documented in EMR, so we could not assess whether sedation at the doses administered adequately controlled pain. It is possible that since most women received the same doses of fentanyl and midazolam, normal and underweight women may be receiving doses of sedation that are too high or obese women receiving doses that are too low, possibly resulting in the lower rates of complications and less effective pain control among obese women. Unfortunately we did not export data on asthma from the EMR at the time of database creation, which could have been a confounder. Different providers may also have had different thresholds for utilizing supplemental oxygen or reversal agents, so use of these interventions as a marker for over-sedation may represent varying levels of over-sedation and concern. However, we believe these outcomes consistently capture any serious anesthesia-related adverse events or cases of over-sedation and likely over-diagnose adverse events.

Only 20% of our study population was obese compared to roughly one-third of reproductive aged women in the United States. While our study population was thinner than the population of reproductive aged women in the United States, our study had a prevalence of obesity similar to that of Massachusetts [16]. Additionally, we had a limited number of women with a BMI $\geq$ 50 and physicians thoroughly screened for serious medical co-morbidities. We are fortunate in Massachusetts that most state residents can access a hospital-based abortion when

required. Thus our results may not be generalizable to the super obese population, to women with serious medical co-morbidities, and to those in settings with limited access to hospital-based care where patients may conceal medical co-morbidities in order to access abortion services [15].

Investigation into the safety of moderate IV sedation among obese women is limited. A retrospective review of 143,000 procedures performed with fentanyl and midazolam outside of the operating room at a tertiary care medical center found that BMI, age, co-morbidities, and type of procedure (gastroenterology and cardiology) were independently associated with adverse events [17]. This patient population was markedly older, with a mean age of 59.2 years, and had more co-morbidities than patients typically seen in freestanding abortion clinics. These were also typically longer procedures with ongoing titration of medication, and it is unclear if these results are generalizable to young, generally healthy obese people who undergo short procedures.

Another study of second trimester surgical abortion up until 24 0/7 weeks gestation demonstrated that obese women required increased anesthesia and operative times, but there was no significant difference in overall complication rates compared to non-obese women [18]. However, this study evaluated procedures performed in a hospital operating room with general anesthesia and had limited power to evaluate anesthesia-specific events. A recent study evaluating anesthesia complications among 5,579 obese and non-obese women undergoing first and second trimester abortion utilizing fentanyl, midazolam, and propofol without intubation in a freestanding clinic reported no serious adverse outcomes in either group and concluded that based on the upper 95% confidence interval for their sample size, the maximal risk of a serious anesthesia-related complication was 1 in 1,860 procedures [19].

Our study suggests that with appropriate clinical screening and judgment, an RN in conjunction with an operating physician can safely administer IV sedation to obese women

301 seeking first trimester surgical abortion in an outpatient clinical setting and that restrictions based
302 on BMI alone are unnecessary. While some women denied moderate IV sedation in an outpatient
303 clinical setting might have their procedure with local anesthesia alone, others would require
304 hospital referral, which could lead to delays in care or no care at all in places with very limited
305 access and prohibitive cost [20, 21]. Increased physician comfort with the provision of moderate
306 IV sedation in obese women and elimination of restrictions on moderate IV sedation could
307 improve access to abortion for a large segment of the abortion seeking population.

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367 Table 1: Baseline characteristics of women undergoing first trimester surgical abortion with
368 moderate intravenous sedation by BMI category (N =20,381)
369

	BMI <25 n=11,029	BMI 25-29.9 n=5,303	BMI 30-34.9 n=2,436	BMI 35-39.9 n=1,063	BMI ≥40 n=550
Age (years)	24.8 ± 5.9 Range: 12-50	26.2 ± 6.1 Range: 12-52	26.6 ± 6.2 Range: 14-45	27.2 ± 6.1 Range: 15-47	27.7 ± 6.0 Range: 15-47
Race					
White	5,154 (46.7%)	2,230 (42.1%)	907 (37.2%)	361 (34.0%)	202 (36.7%)
Black/African American	1,264 (11.5%)	911 (17.2%)	508 (20.9%)	272 (25.6%)	153 (27.8%)
Asian	811 (7.3%)	155 (2.9%)	40 (1.6%)	10 (0.9%)	4 (0.7%)
Other/Declined/Unknown/Missing	3,800 (34.5%)	2,007 (37.8%)	981 (40.3%)	420 (39.5%)	191 (34.8%)
Ethnicity					
Hispanic or Latino	1,483 (13.5%)	974 (18.4%)	463 (19.0%)	178 (16.8%)	86 (15.6%)
Not Hispanic or Latino	7,092 (64.3%)	3,193 (60.2%)	1,429 (58.7%)	622 (58.5%)	352 (64.0%)
Declined/Unknown	2,454 (22.2%)	1,136 (21.4%)	544 (22.3%)	263 (24.7%)	112 (20.4%)
Parity					
Nulliparous	6,652 (60.3%)	2,412 (45.5%)	902 (37.0%)	333 (31.3%)	179 (32.5%)
Parous	4,377 (39.7%)	2,891 (54.5%)	1,534 (63.0%)	730 (68.7%)	371 (67.5%)

370 Data presented as mean ± SD or n (%).

371 Table 2: Fentanyl and midazolam dosing for moderate intravenous sedation during first trimester
372 surgical abortion by BMI category (N =20,381)

	BMI <25 n=11,029	BMI 25-29.9 n=5,303	BMI 30-34.9 n=2,436	BMI 35-39.9 n=1,063	BMI ≥40 n=550	P value
Received initial standard dose 100 mcg fentanyl and 2.0 mg midazolam	6,206 (56.3%)	3,742 (70.6%)	1,774 (72.8%)	819 (77.1%)	442 (80.4%)	<0.0001*
Total dose						
Fentanyl dose (mcg) n=20,277	100 [75, 100] 90.0 ± 23.1	100 [100, 100] 95.3 ± 20.9	100 [100, 100] 97.5 ± 20.9	100 [100, 100] 99.8 ± 21.2	100 [100, 100] 101.2 ± 21.8	<0.0001* <0.0001*
Midazolam dose (mg) n=20,320	2.0 [2.0, 2.0] 1.9 ± 0.5	2.0 [2.0, 2.0] 1.9 ± 0.5	2.0 [2.0, 2.0] 1.9 ± 0.5	2.0 [2.0, 2.0] 2.0 ± 0.5	2.0 [2.0, 2.0] 2.0 ± 0.4	<0.0001* <0.0001*
Level of total dosing						
Lower Dose <100 mcg fentanyl and/or <2.0 mg midazolam	4,150 (37.6%)	1,277 (24.1%)	521 (21.4%)	178 (16.7%)	82 (14.9%)	<0.0001*
Standard Dose 100 mcg fentanyl and 2.0 mg midazolam	6,076 (55.1%)	3,552 (67.0%)	1,689 (69.3%)	750 (70.6%)	401 (72.9%)	
Higher Dose 101-200 mcg fentanyl and/or 2.1-4.0 mg midazolam	785 (7.1%)	469 (8.8%)	222 (9.1%)	133 (12.5%)	66 (12.0%)	
Highest Dose >200 mcg fentanyl and/or >4.0 mg midazolam	18 (0.2%)	5 (0.1%)	4 (0.2%)	2 (0.2%)	1 (0.2%)	

373 Data presented as median [Q1,Q3], mean ± SD or n (%). *p <0.05 statistically significant.

374

375 Table 3: Markers of over-sedation by BMI during first trimester surgical abortion with moderate
 376 intravenous sedation

	BMI <25 Normal weight	BMI 25-29.9 Overweight	BMI 30-34.9 Obese I	BMI 35-39.9 Obese II	BMI ≥40 Obese III	P value
Received supplemental oxygen	16/11,029 (0.15%)	9/5,303 (0.17%)	2/2,436 (0.08%)	4/1,063 (0.38%)	0/550	0.61
Received reversal agent	19/11,029 (0.17%)	4/5,303 (0.08%)	1/2,436 (0.04%)	0/1,063	0/550	0.07
Documented low lowest level of consciousness	115/10,716 (1.07%)	42/5,116 (0.82%)	19/2,343 (0.81%)	7/1,027 (0.68%)	1/522 (0.19%)	0.17

377 Data are presented as n (%). p <0.05 statistically significant. Level of consciousness measured on
 378 a five-point scale (0-no response; 1-responds to pain only; 2-drowsy, hard to arouse, needs tactile
 379 stimuli; 3-drowsy, but opens eyes if called several times; 4-drowsy, easily aroused; 5-awake,
 380 alert, oriented) and score of 0-3 considered “low” and a potential indicator of over-sedation.

381 Table 4: Rate of anesthesia-related adverse events by BMI during first trimester surgical abortion
 382 with moderate intravenous sedation (N =20,381)

	BMI <25 Normal weight n=11,029	BMI 25-29.9 Overweight n=5,303	BMI 30-34.9 Obese I n=2,436	BMI 35-39.9 Obese II n=1,063	BMI ≥40 Obese III n=550	P value
Any anesthesia-related adverse event	21 (0.19%)	12 (0.23%)	4 (0.16%)	1 (0.09%)	2 (0.36%)	0.80
Anesthesia-related events excluding vasovagal reactions	4 (0.04%)	3 (0.06%)	1 (0.04%)	0	0	0.73
Anesthesia-related hospitalization	1 (0.01%)	0	0	0	0	N/A

383 Data are presented as n (%). p <0.05 statistically significant. All anesthesia-related adverse
 384 events included: vasovagal reaction, anxiety reaction, seizure, asthma attack, psychotic reaction,
 385 and drug reaction. Hospitalization for seizure.