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Original research article

A randomized comparison of intravenous sedation using a dosing algorithm compared to standard care during first-trimester surgical abortion☆,☆☆

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ABSTRACT

Objective: The objective was to compare the safety and efficacy of an algorithm for abortion intravenous sedation dosing (AAID) to standard dosing during first-trimester surgical abortion.
Study design: This was a randomized, single-blinded, controlled trial in which women undergoing first-trimester surgical abortion received fentanyl and midazolam dosed per either an algorithm or clinic standard. Patient-level factors including weight, airway risk, anxiety, and drug and alcohol use determined AAID doses. The primary outcome was pain with suction curettage measured immediately on a 21-point verbal numerical rating scale ranging from 0 to 100. Secondary outcomes included pain with cervical dilation and postprocedure, intraoperative pain as recalled postprocedure, need for additional doses of medication, oxygen saturation<93%, sedation level, adverse events, side effects and patient satisfaction.
Results: We enrolled 196 women and randomized 98 to the AAID and 98 to standard care. Baseline factors were similar between groups. Median intraoperative pain scores did not differ between groups when measured immediately (47.5 vs. 50, p=.81) or on recall (30 in both arms, p=.68). There were no significant differences in other secondary outcomes. Women with a body mass index (BMI) 30–35 trended toward improved pain control with the algorithm (60 vs. 27.5, p=.07).
Conclusions: Intravenous sedation determined by an algorithm did not produce differences in pain scores in a setting with highly experienced providers.
Implications: An intravenous sedation algorithm did not demonstrate significant benefit for the general population of surgical abortion patients. Providers with less experience titrating intravenous sedation might find it a helpful tool to guide sedation dosing. A possible benefit in obese patients warrants further study.

1. Introduction

Many studies have evaluated how to reduce the pain associated with first-trimester surgical abortion [1]. General anesthesia is most effective; however, the required resources and expense frequently preclude its use. A national survey from 2009 revealed that only 21% of abortion providers offer deep sedation or general anesthesia [2]. More providers offer moderate intravenous sedation, which is more effective than paracervical block alone or when combined with oral opioids and anxiolytics [3–5]. Previous studies of intravenous sedation have used variable doses of medications, making optimal dosing unclear. A 2001 survey of providers revealed that clinics offering intravenous sedation typically use fentanyl 50–100 mcg and midazolam 1–3 mg [6].

Many factors affect individuals' responses to midazolam and fentanyl. Obese patients exhibit different pharmacokinetics and periprocedural risk profiles than lean patients: they require higher drug doses yet have greater airway risk [7–9]. Alcohol and drug use, as well as anxiety, also increases dose requirements [10]. At our site, most patients receive midazolam 2 mg iv and fentanyl 100 mcg iv, though providers make ad hoc adjustments based on preference and experience [5]. With increased obesity and drug use in the general population, fewer patients now fit the "standard" on which prior research was based, and nonsystematic dose adjustments may risk inadequate pain control or oversedation [11,12]. Providers of other procedures may titrate medication doses to provide adequate pain control; however, the short procedure time of first-trimester surgical abortion may limit this ability.

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We hypothesized that a dosing algorithm would provide more individualized sedation and improve pain control without compromising safety. The goal of this study was to evaluate the efficacy and safety of this algorithm during surgical abortion as compared to standard care.

2. Materials and methods

2.1. Study procedures

This single-blind, randomized, controlled trial of 196 women compared the current standard intravenous sedation at Planned Parenthood League of Massachusetts (PPLM) in Boston to an individualized dosing algorithm [algorithm for abortion intravenous sedation dosing (AAID)]. Participants were ≥18 years seeking abortion with pregnancies <14 weeks by ultrasound. Research staff approached women who had already chosen to have their procedure with intravenous sedation. We excluded women who had medical contraindications to intravenous sedation per PPLM protocols, required cervical ripening, did not speak English or have an appropriate translator, or had an allergy or hypersensitivity to the medications being used. The Partners Healthcare Institutional Review Board approved this study.

The AAID was created by two co-investigators, a gynecologist (K.P.B.) and an anesthesiologist (R.D.U.). They reviewed data on factors that affect the metabolism of midazolam and fentanyl and, along with clinical experience and expertise, determined how the algorithm should adjust for each of these factors. The AAID calculates medication doses based on participant weight, body mass index (BMI), drug and alcohol use, and anxiety scores (Fig. 1). Investigators piloted the AAID in 10 patients prior to the study start to ensure safety, and no adjustments were made.

All participants gave written informed consent. They then completed a questionnaire that included sociodemographic data, the validated Depression Anxiety and Stress Scales (DASS), questions regarding psychiatric disease, drug and alcohol use, self-assessment of pain tolerance, and anticipated and acceptable pain during their procedure. Study staff collected additional demographic information from the electronic medical record. At PPLM, the abortion providers, who are

Starting dose:

Weight (kg)	Midazolam Dose	Fentanyl Dose
Less than or equal to 45 kg (≤99lbs)	1 mg	50 mcg
45-59 kg (100-131 lbs)	1.5 mg	75 mcg
60-79 kg (132-175 lbs)	2 mg	100 mcg
80-99 kg (176-219 lbs)	2.5 mg	125 mcg
Greater than or equal to 100 kg (≥220)	3 mg	150 mcg

Starting Dose	
Midazolam _____mg	Fentanyl _____mcg

Dose adjustments:

Airway concerns:
- ❑ BMI>35 OR
- ❑ History of OSA OR
- ❑ Class III/IV airway

} ***Decrease*** by 0.5mg/25 mcg

Alcohol use:
- ❑ None/Light (0-6 drink/week): No dose change
- ❑ Moderate >7 drinks/week: Increase by 0.5 mg/25 mcg

Opiate use:
- ❑ Opiate use in last 30 days:
- ❑ <7 days of use No change
- ❑ 7-14 days of use ***Increase*** fentanyl by 25 mcg
- ❑ 14 days of use ***Increase*** fentanyl by 50 mcg

Benzodiazepine use:
- ❑ Benzodiazepine use in last 30 days:
- ❑ <7 days of use No change
- ❑ 7-14 days of use ***Increase*** midazolam by 0.5 mg
- ❑ 14 days of use ***Increase*** midazolam by 1.0 mg

Anxiety:
- ❑ DASS anxiety score of 10 or higher OR
- ❑ Rating of 7 or higher on VAS OR
- ❑ History of anxiety diagnosis

} ***Increase*** midazolam by 0.5 mg

MAX ADJUSTED DOSE:
3 mg midazolam /150 mcg fentanyl

Final algorithm dose : _____ mg midazolam
_____mcg fentanyl

Dose Adjustments	
Midazolam	Fentanyl
Airway Concerns	
-0.5 mg	-25 mcg
Alcohol Use	
+0.5 mg	+ 25 mcg
Opiod Use	
No change	+ 25 mcg OR + 50 mcg
Benzodiazepine Use	
+ 0.5 mg OR + 1 mg	No change
Anxiety	
+0.5 mg	No change
Adjusted Dose	
Midazolam _____mg MAX 3 mg	Fentanyl _____mcg MAX 150 mcg

Fig. 1. AAID.

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