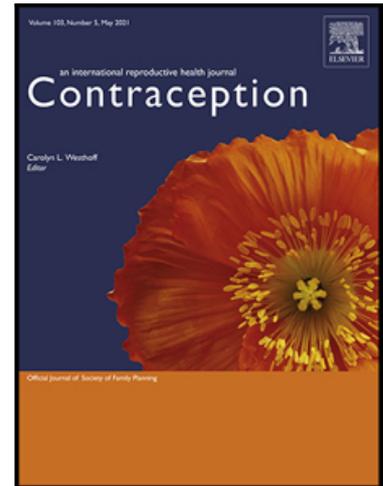


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Society of Family Planning clinical recommendations: Pain control in surgical abortion part 2 – moderate sedation, deep sedation, and general anesthesia

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Abstract

Analgesic options for surgical abortion (also called procedural abortion) beyond local anesthesia and minimal sedation include moderate sedation, deep sedation and general anesthesia. These clinical recommendations review the effectiveness of various moderate sedation, deep sedation, and general anesthesia regimens for pain control during abortion; medication regimens used to induce analgesia and

anesthesia; patient factors affecting anesthesia safety; pre-operative and intra-operative protocols to reduce anesthesia risks; personnel qualifications for administration; recommended patient monitoring protocols; and general risks of anesthesia in the context of abortion care. The scope of these recommendations is based on limited available evidence and considerably relies on existing professional society guidelines and recommendations developed by content experts and reviewers. Further research to compare the efficacy and safety of different regimens is needed.

Keywords: Moderate sedation; Deep sedation; General anesthesia; Pain relief for surgical abortion

1. Background

Both surgical (also called procedural) and medication abortions are associated with some pain, and the intensity of pain varies. With use of verbal support and minimal sedation, discussed in a separate clinical guideline [1], Duros et al. [2] report that 46% of women undergoing surgical abortion experience pain reported as “severe pain” defined as level 7 and above on a visual analogue scale. An increasing number of options for moderate sedation, deep sedation, and general anesthesia to address pain related to surgical abortion are available [3,4]. In separate national surveys of first- and second-trimester abortion providers, 79% of first-trimester surgical abortion providers preferred using either a combination of local anesthesia and intravenous moderate sedation, deep sedation, or general anesthesia, and most clinics that offered these options employed these analgesic options for >80% of their patients [3,4].

Table 1 provides a general overview of the different levels of sedation; however, individual patients can experience varying analgesic effects throughout their treatment course (intra-operative and post-operative), and these effects may differ from the intended results [5]. Providing safe anesthetic regimens requires attention to patient selection, whether it is the identification of which patients may receive sedation or which regimen is appropriate for a given patient, and ensuring that providers and staff are adequately trained to provide and manage complications of specific anesthetic regimens. Staff training, adequate monitoring, and preparation for emergencies are essential to ensure that staff and practice settings are prepared to respond to over-sedation or other anesthesia-related complications.

In these recommendations, we address several questions about moderate and deep sedation and general anesthesia for surgical abortion provided in both out-of-hospital and in-hospital settings. In developing these recommendations, a search of the medical literature was performed using the

PubMed program of the National Library of Medicine and the Cochrane Library of Clinical Trials from the beginning of the databases through April 5, 2021. Search terms include but were not limited to analgesia, anesthesia, and sedation, in combination with abortion, gynecology, obstetrics, pregnancy, and termination. Publications and relevant statements of the American College of Obstetricians and Gynecologists (ACOG), the American Society of Anesthesiologists (ASA), the European Society of Anaesthesiology (ESA), the National Abortion Federation (NAF), Planned Parenthood Federation of America (PPFA), the Royal College of Obstetricians and Gynaecologists (RCOG), and regulatory guidance from The Joint Commission were reviewed. These organizations' publications were primarily referenced when applicable since their guidelines are highly relevant to abortion practice and peer reviewed. Many clinical settings for abortion services also follow guidelines issued by these professional organizations.

While some questions have been addressed by well-designed studies, there are important gaps in the literature; for some questions, the only available answers come from the standards and policies of professional organizations or there is limited clear guidance. We have specified these evidence gaps throughout the document when applicable.

2. Clinical questions

1. What medication regimens are used for moderate sedation, deep sedation, or general anesthesia?

Different medication regimens may be used to induce sedation (depression of awareness), analgesia (insensibility to pain) and/or anesthesia (loss of sensation, with or without loss of consciousness). On the ASA continuum of depth of sedation, moderate sedation is not defined by the exact medication used, but rather by the level of responsiveness and cardiopulmonary function of each individual patient resulting from a particular regimen (specific medication and dose) (Table 1) [5,6]. Typical medications used for moderate sedation include analgesics which may be given in combination with sedatives to induce varying degrees of analgesia, sedation, anxiolysis, and amnesia. Doses are titrated as needed to achieve the desired level of sedation and anesthesia [5,6]. This desired effect is defined based on agreement between the provider and patient that incorporates both parties' expectations with regard to immobility and analgesia, ultimately leading to a safe and complete procedure. There is no clear guidance that prescribes specific regimens for patient-related factors such as body mass index (BMI),

medical comorbidities, sedation goals, anticipated procedure-related pain, and planned procedure length to determine which regimen to use.

Tables 2 and 3 list common intravenous drugs used to provide minimal to moderate sedation, respectively outlined by NAF and PPFA [7,8]. Both NAF and PPFA have policies that regulate the use and dosing schedules of specific medications used, including both the initial dose and recommended intervals for increased titration if the effect is insufficient. There is limited information comparing these agents based on the specific medications and doses. Braaten et al. [9] studied the safety and efficacy of a specific dosing algorithm of intravenous fentanyl and midazolam to standard weight-based dosing per clinic standard, noting no differences in pain scores. Their algorithm was created based on the subject's weight, BMI, airway concerns, drug and alcohol use, and anxiety scores. Several factors, including but not limited to medication cost, time of onset of desired effect, duration of effect and anticipated duration of the procedure, need for exact titration (e.g., use of an infusion pump for remifentanyl administration), provider preference, and patient-related factors, affect the chosen drug regimen for administration of moderate sedation (GRADE 1C) [7,8].

PPFA lists propofol, ketamine, and methohexital as medications used to induce deeper sedation⁸. The ASA guidelines summarize that methohexital offers satisfactory deep sedation and can be administered by non-anesthesiologists [6]. However, the guidelines do not provide detailed information regarding specific dosing regimens for methohexital use [6]. Chestnut's *Obstetric Anesthesia*, the classic textbook on this topic, indicates that propofol is used to induce sedation for monitored anesthesia care as an alternative to midazolam in surgical abortion [10]. Several cohort studies involving a total of 64,980 subjects reviewed safe use of deep sedation, often with propofol [6,11-13]. Ketamine can be used as an adjunct to parenteral opioid analgesia, and concerns for neonatal depression would not be applicable when used in surgical abortion cases [10].

There is limited evidence regarding recommended medications for general anesthesia specifically for surgical abortion. Williams' *Obstetrics* recommends a rapid sequence induction with an intravenous anesthetic; either propofol, etomidate or remifentanyl; and rapid-onset muscle relaxant such as ketamine, succinylcholine, or rocuronium [14]. Wu et al. conducted a randomized controlled study of women undergoing first-trimester surgical abortion under general anesthesia with 6 arms: propofol alone, propofol with fentanyl, propofol with fentanyl and midazolam, etomidate alone, etomidate with

fentanyl, and etomidate with fentanyl and midazolam [15]. They reported that propofol, compared to etomidate, causes a greater decrease in mean arterial pressure and pulse oxygen saturation during induction. Side effects such as myoclonus and post-operative nausea and vomiting were less likely to occur among those who received propofol compared to etomidate. Among those who received etomidate, subjects who received a decreased dose of etomidate and supplemented with fentanyl and midazolam, the side effects were less likely to occur. In separate studies, Lazenby [16] and Micks [17] note that general anesthesia in surgical abortion may include intravenous fentanyl, intravenous midazolam, inhaled nitrous oxide, intravenous propofol, and/or inhaled anesthetics. Chestnut's Obstetric Anesthesia states that general anesthesia for dilation and evacuation is commonly administered with propofol infusion and an opioid; ketamine may be preferred in patients with significant bleeding [10].

2. How effective are moderate sedation, deep sedation, and general anesthesia for pain control during abortion procedures?

Moderate sedation, deep sedation, and general anesthesia are effective in controlling pain during abortion procedures. Analgesic options for first- and second-trimester surgical abortion are similar based on patient preference and comorbidities, regardless of gestational age [3,4,18]. Most published research on the efficacy of analgesic options beyond minimal sedation has focused on moderate sedation for first-trimester abortions. Allen et al. [19] conducted a randomized controlled trial with an equivalence design noting that oral sedation with 10 mg of oxycodone and 1 mg of lorazepam is not equivalent to intravenous sedation with 100 mcg of fentanyl and 2 mg of midazolam. The National Guidance Alliance hosted by RCOG completed a comprehensive review of the literature and recommends intravenous over oral administration if "conscious" sedation is used [18]. While moderate sedation, deep sedation, and general anesthesia are more commonly used for second-trimester than for first-trimester surgical abortion [20], we could find no randomized trials of moderate sedation in second-trimester surgical abortion to assess comparative effectiveness of different anesthetic regimens or against placebo. There are limited data comparing the efficacy of deep sedation versus general anesthesia for surgical abortion at specific gestational ages.

A combination of fentanyl and midazolam is effective in reducing pain associated with first-trimester surgical abortion (GRADE 1B) [21-24]. According to a systematic review by Renner et al. [21] that only

included randomized trials, moderate sedation decreases procedure-related and post-operative pain in first-trimester surgical abortion. In 2001, Rawling and Wiebe [22] compared intravenous fentanyl 50–100 mcg to intravenous placebo (normal saline) in women undergoing first-trimester surgical abortion who also received cervical anesthesia and sublingual lorazepam and to women who received no intravenous treatment at all. Women who received fentanyl had lower pain scores than those who received placebo (mean 4.3 vs 5.3 on a 10-point scale, with a mean difference of 1.0, 95% CI 0.4, 1.6). Wong et al. [23] studied the analgesic effects of sedation using intravenous midazolam 2 mg and fentanyl 25 mcg compared with placebo among women undergoing first-trimester surgical abortion. They found no significant difference in pain between groups, but those who received IV sedation reported better satisfaction (50% IV sedation vs. 20% placebo reported satisfactory or excellent satisfaction, $p=0.003$).

A study by Allen et al. [24] was not included in the above-mentioned systematic review because it was not randomized. In this study, 330 women undergoing first-trimester surgical abortion chose among three options for pain management: cervical anesthesia alone ($n=105$), cervical anesthesia plus sublingual lorazepam (0.5–1.0 mg orally 20 minutes before surgery) ($n=106$), or cervical anesthesia plus intravenous sedation with fentanyl (doses of 50–125 mcg) and midazolam (1–2 mg) ($n=119$). The investigators reported that subjects who received the combination of cervical anesthesia and intravenous sedation with fentanyl and midazolam had the lowest pain scores (reduction in pain score of 0.86, 95% CI 0.25–1.46). They found no significant difference in mean pain scores between those who received cervical anesthesia with sublingual lorazepam compared to those who received cervical anesthesia alone (6.78 vs. 6.22). When they divided the intravenous sedation group into low-dose (50 mcg fentanyl and 1 mg midazolam) and moderate-dose (75–125 mcg fentanyl and/or 1.5–2.0 mg midazolam) groups, mean pain scores from those who received the moderate dose were significantly lower compared to those who received the low-dose regimen (4.93 vs. 6.18, $p\leq 0.001$).

3. What pre-procedure patient evaluation or patient preparation is necessary for moderate sedation, deep sedation, or general anesthesia?

Patient evaluation and preparation for the intended level of sedation is primarily based on the patient's surgical risk and the facility's ability to manage anesthesia-related complications, including unintended

depth of sedation. Given the multifactorial interaction of medical comorbidities and anesthesia complications, recommendations for appropriate pre-procedure evaluation are primarily derived from expert opinion rather than high-quality trials. While there is no clear consensus on specific pre-procedure patient evaluation or patient preparation that is necessary prior to moderate sedation, deep sedation, or general anesthesia, professional societies do recommend that an assessment be performed, especially among patients with co-morbidities (Grade 1C) [7,8, 25-27].

There is suggestive evidence that some preexisting medical conditions may be related to adverse outcomes in patients receiving either moderate or deep sedation analgesia [27]. Consultants to the ASA Task Force, considered experts in pre-anesthesia evaluation, noted that a pre-anesthetic history and physical examination is “essential”, citing benefits that include but are not limited to the safety of perioperative care, optimal resource use, improved outcomes, and patient satisfaction. However, an ASA Task Force of anesthesiologists and methodologists from the ASA Committee on Standards and Practice Parameters concluded that there is insufficient published evidence to evaluate the relationship between sedation-analgesia outcomes and the performance of a pre-procedure evaluation.

The recommendations of the Task Force include “being familiar with the sedation-oriented aspects of the patient’s medical history, and a focused physical examination including vital signs, auscultation of the heart and lungs, and evaluation of the airway” [27]. Common comorbidities that may influence anesthesia safety include hypertension, particularly systolic blood pressure over 200 mm Hg [28]; pulmonary disease, including smoking, obstructive sleep apnea [29], and poorly controlled asthma [30]; poorly controlled diabetes [31]; renal disease [32]; and anemia [33], particularly in procedures with higher risk of blood loss and transfusion [34]. Substance use may also influence the recommended anesthesia regimen [35]. Several studies report safe use of moderate or deep sedation among obese women (combined total 5,517 subjects with BMI $\geq 40\text{kg/m}^2$, 871 of who have BMI $\geq 40\text{ kg/m}^2$) [36,37]. In addition to auscultation of the heart and lungs during the preoperative examination, the patient’s airway should be assessed for features associated with possible difficult airway management, including obstructive sleep apnea, previous head/neck radiation, surgery or trauma, small mouth opening, dysmorphic facial features, lack of teeth, or BMI $> 26\text{ kg/m}^2$ [8,27,37]. The Mallampati classification system is one standardized way of evaluating the airway of patients receiving moderate/deep sedation or general anesthesia to identify patients in whom tracheal intubation would be difficult, serving as the most accurate precautionary assessment of patients who are more likely to require rescue intubation [38,39]. However, we found no articles specifically describing its use to screen patients for safe out-of-

hospital ambulatory surgical abortions; hence, neither NAF nor PPFA make a specific recommendation on how airway assessment is conducted [7,8].

No specific standard pre-procedure laboratory tests were advised, but the Task Force recommended that pre-procedure laboratory tests be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia. ACOG guidelines similarly recommend a preoperative medical history, a physical examination, and a patient assessment using the ASA continuum of depth of sedation; no distinction between inpatient versus outpatient or ambulatory care setting was described [25]. Both NAF and PPFA clinical guidelines for moderate sedation require a pre-sedation evaluation of the patient to include relevant history and review of systems, medication review, last food intake, baseline vital signs, and targeted exam of the heart, lungs, and airway (GRADE 1C) [7,8].

4. Which patients are typically not appropriate for management in out-of-hospital ambulatory care facilities with moderate sedation, deep sedation, or general anesthesia? Which patient factors influence patient safety during anesthesia?

For individuals who want or need pain control during surgical abortion, the risks of anesthesia administration must be weighed against the analgesic benefits. Several factors may influence the decision of whether a patient is an appropriate candidate for out-of-hospital anesthesia, including provider preference (whether the surgeon or anesthesia provider), distance from nearest hospital that can accommodate post-abortion complications, and most importantly, the patient's surgical risk based on their comorbidities and the facility's ability to manage potential complications secondary to these comorbidities (GRADE 1C) [7,8]. There is no evidence-based standard regarding patient selection for abortion care in out-of-hospital ambulatory care facilities based on appropriateness for level of intended sedation. However, the NAF Clinical Policy Guidelines do stipulate that patients who have an "atypical airway assessment" or categorized as ASA Class III or greater should be offered "a reduced level of sedation, an alternate abortion procedure, or provision of care by an anesthesia professional" [7].

The ASA physical status classification system can be used as a guide to assess a patient's procedure-related risk (GRADE 2C) [40]. Classifications range from completely healthy patients (ASA Class I) to

brain-dead (ASA Class VI) (Table 4). Pregnancy of any duration is sufficient to place the patient in ASA Class II, which includes patients with mild systemic disease, due to associated physiologic changes in pregnancy such as relative hypoxia and other metabolic changes that may alter responses to medications. However, the ASA classification system by itself cannot adequately describe patient risk from surgery because it does not specify type of anesthesia and lacks a risk index for the surgery itself. Anesthesia risk and surgical risks may be additive and should be evaluated together (GRADE 2B) [41].

To assess risk in relation to care setting, Guiahi and colleagues [42] evaluated whether women with one or more chronic medical conditions [asthma (45%); hypertension (19%); hypothyroidism (7%); epilepsy (6%); diabetes, HIV, hematologic disorders (<5% combined); BMI >40 (<1%)] who were seeking first-trimester surgical abortion were at greater risk for complications in the office setting compared to their healthy peers. These patients were classified as ASA class II, with the addition of 16 patients classified as ASA Class III only for BMI > 40 kg/m². No difference in anesthetic-related complications was noted in the two groups (0 complications in either group, with a total of 176 who received moderate sedation).

Thirty-nine patients in the study were managed in the inpatient setting for classification as ASA class III or IV or for whom the abortion provider was concerned about increased risk for complications based on pregnancy characteristics or reproductive histories. Four of these 39 patients who had inpatient abortions had a complication, none of these complications were anesthesia-related, and the authors found that patients who underwent inpatient procedures with comorbidities that met classification criteria for ASA Class III or IV were not more likely to experience a complication than those without comorbidities. Results from Guiahi's study imply that most women classified as ASA II for comorbidities in addition to pregnancy can safely undergo first-trimester abortion in an ambulatory care setting. The authors also concluded that providers in the study were able to appropriately identify patients who should be managed in an inpatient setting based either on medical history or pregnancy-related factors.

5. What qualifications must providers have to safely administer moderate sedation, deep sedation, and general anesthesia? What policies and standards are available?

Employing qualified personnel and ensuring continued competency to administer the planned anesthetic regimen is imperative for providing safe care. There are several types of healthcare providers who may be involved in providing anesthesia care (Table 5). The ASA recommends that health care organizations require non-anesthesiologist sedation practitioners to meet specific standards before

granting privileges to administer moderate sedation through education, training, and licensure (GRADE 1C) [43]. These requirements include: (1) satisfactory completion of formal education and training on administration of moderate sedation and rescue from over-sedation referring to a state beyond the intended effect, (2) current active medical licensure, (3) evaluation of the practitioner's practice pattern, and (4) active participation in a program for performance improvement. The ASA does not further specify any particular evaluation process or program for performance improvement.

Supervised sedation professionals can administer and monitor moderate sedation when under the supervision of an anesthesia professional or non-anesthesiologist sedation practitioner. These supervised sedation professionals must meet similar licensing and competency-training requirements. Methods to assess competency can be individualized for each organization, ensuring satisfactory completion of a program that teaches the safe administration of medications used to establish a level of moderate sedation and the rescue of patients who exhibit a level of sedation that is deeper than intended.

Certified registered nurse anesthetists are independently licensed anesthesia professionals who plan and deliver anesthesia, including moderate sedation, deep sedation, and general anesthesia [44,45]. The medical and nursing practice of CRNAs is further governed by institutional, state, and federal restrictions with regard to the required level of supervision needed, if any [45]. Given the continuum of depth of sedation, non-anesthesiologist physicians who administer deep sedation must be qualified and trained specifically in providing this level of sedation. In addition, they should be similarly qualified to recognize the need for rescue and be adept at rescuing a patient from unintended general anesthesia. They can neither delegate the administration or monitoring of deep sedation to individuals who are not similarly qualified, nor supervise such individuals in performing the administration or monitoring of deep sedation. Furthermore, they must be dedicated solely to administering and monitoring deep sedation; they cannot participate in or perform the diagnostic or therapeutic procedure for which the sedation is being administered (GRADE 1C) [46,47].

Among individuals whose deep sedation progresses to unintended general anesthesia, such care should be provided, medically directed, or supervised by an anesthesiologist, the operating practitioner, or another licensed physician with specific training in sedation, anesthesia, and rescue techniques related to general anesthesia (GRADE 1C) [46]. Otherwise, routine general anesthesia should only be

administered by anesthesia professionals (i.e., anesthesiologists, nurse anesthetists, and certified anesthesiologist assistants) (GRADE 1C).

Most institutional policies follow ASA personnel standards [7,8]. Abortion care practices must adopt pertinent policies that are consistent with the care setting, whether they are hospital-based or free-standing sites. These policies frequently align with those set by NAF or PPFA [7,8]. In addition, state laws may regulate whether or not authorization from an accrediting body such as The Joint Commission must be obtained to secure permission for health care organizations to provide such sedation and analgesia procedures.

6. What monitoring is required for moderate sedation, deep sedation, or general anesthesia?

The ASA recommends monitoring the patient's level of consciousness for both moderate and deep sedation. While there is no clear evidence on whether monitoring improves patient outcomes or decreases risk, Task Force consultants who authored ASA guidelines "strongly agree that monitoring level of consciousness reduces risks for both moderate and deep sedation" (GRADE 1C) [6].

The ASA requires that all patients undergoing sedation or analgesia be monitored by pulse oximetry with appropriate alarms in order to detect "oxygen desaturation and hypoxemia in patients who are administered sedatives/analgesics" (GRADE 1C) [6]. In addition, ventilatory function should be continually monitored by observation or auscultation. Pulse oximetry detects hypoxia, but not hypercarbia; hypercarbia is an earlier sign of inadequate ventilation compared to hypoxia (GRADE 1C) [6]. The ASA also recommends that monitoring of exhaled carbon dioxide should be considered for all patients receiving deep sedation and for patients receiving moderate sedation whose ventilation cannot be directly observed (GRADE 1C).

In addition, the Task Force recommends that vital signs are monitored at 5-minute intervals "once a stable level of sedation is established" during moderate and deep sedation⁶. However, Wilson et al. [48] reported no anesthesia-related complications when monitoring patients at 10-minute intervals, suggesting that a longer interval between measurements may be sufficient among low-risk surgical patients. Electrocardiographic monitoring should be used for all undergoing deep sedation and select patients undergoing moderate sedation, such as those with significant cardiovascular disease or a history of dysrhythmia [6]. ASA recommends that the frequency of recording the patient's functional

status (level of consciousness, ventilator and oxygenation status, and hemodynamic parameters) depends on the type and amount of medication administered, procedure length, and the general condition of the patient. Minimum time points of assessment include: (1) before the procedure, (2) after administration of sedatives/analgesics, (3) regular intervals during the procedure, (4) during initial recovery, (5) prior to discharge from the facility (GRADE 1C).

7. What are the anesthesia-related side effects and risks associated with moderate/deep sedation and general anesthesia? What equipment is necessary to manage these risks?

Side effects associated with anesthesia regimens range from mild to life-threatening. Nausea and vomiting are common side effects from several anesthesia medications; pruritus is commonly associated with opioid use; and paradoxical agitation can occur with benzodiazepine use, even with recommended doses.

More serious adverse events are also possible with specific anesthesia agents. When opioids and benzodiazepines are used in combination, their sedative effects may be additive [6]. Older halogenated agents, such as halothane or isoflurane, are associated with increased blood loss due to uterine relaxation and a higher risk of blood transfusion when used for general anesthesia during cesarean delivery [49-52]. However, these inhaled agents are now rarely used. Micks et al. [17] studied the effects of sevoflurane, a newer halogenated agent, among women undergoing surgical abortion with general anesthesia and did not find an increased risk of interventions to address bleeding; however, the study was underpowered to detect clinically important differences and no clear recommendation can be made regarding the safety profile of newer halogenated agents. RCOG recommends use of a short-acting opioid in addition to propofol for general anesthesia rather than inhalational agents [18]. It does not distinguish sevoflurane from other inhalational agents since all of these agents cause uterine relaxation which is the likely cause of increased blood loss.

In addition to increased bleeding and the inadvertent administration of a greater depth of anesthesia than intended, other significant anesthesia-related complications associated with the administration of moderate/deep sedation and general anesthesia include cardiovascular decompensation, cerebral hypoxia and death⁶. The Centers for Disease Control and Prevention reported anesthesia-related abortion mortality in the United States for 1998–2010, though no information on clinical setting was provided [53]. With approximately 16.1 million abortion procedures, 108 deaths occurred (mortality rate of 0.7 per 100,000 procedures), with 22 deaths (20% of the total) attributed to anesthesia

complications. Among 28 deaths after surgical abortion at 13 weeks' gestation or less, anesthesia complications were the most common cause (n=13). Rates of death with different types of anesthesia were not reported, so it is not possible to estimate whether death was more likely with sedation or general anesthesia than with local anesthesia only. In the systematic review of first-trimester surgical abortion by White et al, the authors noted 0.02% anesthesia-related complications among procedures that occurred in office-based settings and <0.5% of procedures that occurred in surgical centers and hospitals; no deaths were reported [54].

The ASA Task Force and consultants agree that ready availability of appropriately sized emergency equipment reduces the risks of both moderate and deep sedation (Table 6) [6]. The ASA does not specify any distinction in medications or equipment necessary for moderate sedation, and deep sedation, or general anesthesia. It does advise that for moderate sedation, a defibrillator should be immediately available for patients with mild (e.g., hypertension) or severe cardiovascular disease (e.g., ischemia, congestive failure). A defibrillator should be available for all patients receiving deep sedation (Grade 1C).

The ASA states that the literature supports the use of supplemental oxygen during moderate sedation and suggests that it should be used during deep sedation to reduce the frequency of hypoxia (GRADE 1C) [6]. If hypoxemia is anticipated or develops during sedation or analgesia, supplemental oxygen should be administered. The ASA concludes that "supplemental oxygen should be considered for moderate sedation and should be administered during deep sedation unless specifically contraindicated for a particular patient or procedure."

NAF requires functioning equipment and current medications to be available on-site for medical emergencies, including an oxygen delivery system, oral airways, epinephrine, antihistamines, appropriate antagonists for benzodiazepines and opioids (if used), bronchodilators, and bag-valve masks capable of delivering supplemental oxygen [7]. An automatic external defibrillator should be available at sites where deep sedation and general anesthesia are used. NAF guidelines require the use of supplemental oxygen with deep sedation and general anesthesia.

8. What post-sedation care is needed for moderate sedation, deep sedation, or general anesthesia?

Anesthesia-related complications and deaths may result from inadequate post-anesthesia monitoring, emphasizing the importance of vigilant post-anesthesia care [55,56]. The ASA recommends that "all

patients should be observed in an appropriately staffed and equipped area (Table 6) until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression” (GRADE 1C) [6]. Clinical question #5 and Table 6 respectively review suggested and required staffing and equipment. Post-sedation goals and monitoring are similar for patients receiving moderate sedation, deep sedation, and general anesthesia (GRADE 1C). Until subjects return to their baseline level of consciousness, oxygenation should be monitored periodically during this period when they continue to be at risk for hypoxemia. Ventilation and circulation should be monitored at regular intervals until patients are suitable for discharge.” There are no further details available regarding recommended expertise among recovery room staff, staffing ratios, or equipment, and the Task Force concluded that there was insufficient literature to examine the impact of post-procedure monitoring on patient outcomes.

9. Does deep sedation or general anesthesia during abortion procedures require routine endotracheal intubation?

Given concerns about a theoretically increased risk of aspiration in pregnant patients, there have been a number of studies investigating whether endotracheal intubation is necessary for safety during surgical abortion. These descriptive studies note that low-risk patients who undergo first and second-trimester surgical abortion may safely receive moderate or deep sedation without routine endotracheal intubation (GRADE 1C) [11,12,36]. We could find no specific ASA recommendation of routine intubation of patients in the first or second trimester for deep sedation or general anesthesia.

Mancuso et al. [13] performed a retrospective chart review of deep sedation, most commonly using propofol and fentanyl, among women undergoing surgical abortion between 15 and 24 weeks’ gestation in an operating room setting. Among 332 subjects, 9 (2.7%) were routinely intubated and 5 (1.5%) were converted intra-operatively. The majority of subjects either maintained their natural airway (n=313, 94.3%) or were supported by laryngeal mask (n=5, 1.5%). There were no reported cases of pulmonary aspiration.

A retrospective study conducted by Dean et al. [12] examined the safety of deep sedation without intubation in a free-standing abortion clinic by reporting on the experience of 62,125 patients, including

11,039 having an abortion in the second trimester up to 24 0/7 weeks' gestation. Potential subjects were excluded based on the following criteria: BMI > 40 kg/m², uncontrolled hyperthyroidism, poorly controlled diabetes, hypertension suggestive of imminent stroke, acute active hepatitis, poorly controlled seizure disorders, known respiratory compromise or poorly controlled asthma, or other acute or chronic medical conditions "judged to pose significant or life-threatening risk." Subjects were also excluded if they had eaten solid food less than 8 hours before surgery or clear liquids less than 2 hours before surgery. There were no cases of pulmonary aspiration identified; only one case was converted to endotracheal intubation. Sixteen subjects were transferred to the hospital, but none were transferred for anesthesia-related problems. Based on the upper 95% confidence interval for their sample, the authors calculate the theoretical risk for aspiration at up to 1 in 21,000 abortions overall, and up to 1 in 3,700 second-trimester procedures.

While Dean et al. excluded obese women, Gokhale et al. [36] reported their experience in providing IV moderate and deep sedation without endotracheal intubation in the outpatient setting among 5,579 obese and non-obese women undergoing first- and second-trimester abortion up to 22 6/7 weeks' gestation. Subjects elected their anesthetic regimen which included IV fentanyl and midazolam or IV propofol with or without fentanyl or midazolam; methohexital or meperidine were administered in rare circumstances when other drugs were temporarily unavailable or in short supply. All women undergoing IV sedation without propofol were restricted from solid food for 8 hours prior to the procedure and from all oral intake for 4 hours prior to the procedure; those who received propofol were advised against all oral intake starting at midnight before the procedure. Intra- and post-operative monitoring were performed based on ASA guidelines. There were no patients who experienced any pulmonary complications or anesthesia-related adverse events. Based on the upper 95% CI for the sample size, the authors calculated the maximal risk of an anesthesia-related complication is 1 in 1860 procedures.

10. Is fasting necessary before moderate or deep sedation for abortion in ambulatory care settings?

Fasting is traditionally recommended for a specified interval before elective surgical procedures to reduce the risk of aspiration of gastric contents. The ASA recommends fasting for at least two hours after intake of clear liquids before elective procedures requiring general anesthesia, regional anesthesia, or procedural sedation or analgesia, as well as fasting for at least 6 hours after a light meal, and fasting for 8 hours or longer after a meal that includes fried foods, fatty foods or meat [26]. No distinction is

made between moderate sedation, deep sedation, or general anesthesia. The ESA recommends fasting for at least 2 hours from clear liquids and 6 hours from solid food [56]. Despite ASA and ESA recommendations regarding fasting guidelines for the general surgical population, observational studies on women undergoing surgical abortion suggest no risk of aspiration among non-fasting patients [48,58].

A Cochrane review found 38 randomized comparisons in 22 published trials, primarily in healthy non-pregnant adults not considered at increased risk of aspiration [59]. These studies compared the standard fasting protocol of nil per os (NPO) from midnight until surgery versus drinking water, clear liquid, or isotonic drinks until 90–180 minutes before anesthesia. The multiple studies investigated gastric volume and acidity as surrogate markers for aspiration, since more reliable measures are not available and aspiration is a rare occurrence. There was no difference in outcomes between the fasting group and those allowed to drink any of the liquids, except gastric volume was less among the group permitted to drink water. Given the mass effect of the gravid uterus and the effect of progesterone on the smooth muscle of the gastrointestinal tract, there is theoretical concern about the increased risk of aspiration in pregnant individuals given changes in gastric volume. To explore whether pregnancy is associated with increased gastric volume, Aksel and colleagues [60] used ultrasound to measure the cross-sectional area of the gastric antrum in nonpregnant women compared to those in the second trimester and third trimester of pregnancy; the fasting status of subjects were not stated. They concluded that the observed differences in residual gastric volume were unlikely to be great enough to cause aspiration.

Two cohort studies have specifically addressed whether allowing oral intake before sedation for surgical abortion conferred increased risk for aspiration. Wilson and colleagues [48] report a retrospective review of 1,433 patients who had a surgical abortion at up to 18 weeks' gestation with intravenous fentanyl with or without midazolam. Although the investigators excluded women with active cardiac or respiratory disease, they did not exclude those who were obese or were considered to have a difficult airway. Oral intake was not restricted before or after the procedure, and women were intentionally encouraged to eat to prevent nausea and vomiting with the preoperative oral antibiotic. There were no cases of aspiration. Four adverse events were recorded, none related to sedation. Wiebe and colleagues [58] completed a retrospective chart review of 47,748 women who had a surgical abortion up to 18 weeks' gestation (mean 8.8 weeks) at one of two free-standing abortion clinics between 2003 and 2010. The clinics routinely asked patients to eat a light meal, such as toast, before coming to the clinic. The

patients all received intravenous fentanyl and midazolam with cervical anesthesia. The investigators reported no immediate anesthesia-related complications.

Based on these three studies by each of the research teams of Aksel, Wilson and Wiebe, NAF recommends that “[f]or patients receiving moderate sedation who are not at increased risk of aspiration, time from last meal should not limit access to abortion care”; no specific recommendations are provided [7]. Based on the Wiebe study, PPFA recommends fasting from solid food (including pulp juices and milk products) for at least at 6 hours and clear liquids for at least at 2 hours prior to sedation [8]. RCOG guidance on anesthesia and sedation for surgical abortion specifically opted against making recommendations related to fasting requirements and simply acknowledge existence of the 2011 guidance from ESA [18]. Although research on aspiration risk in pregnancy and during abortion procedures continues to evolve, there is currently insufficient direct evidence to universally recommend or forgo fasting guidelines prior to abortion procedures.

3. Clinical recommendations

Please see Appendix 1 for a key to interpreting GRADE.

The following recommendations are based primarily on moderate- or low-quality scientific evidence:

- A combination of intravenous fentanyl and midazolam is effective in reducing pain associated with first-trimester surgical abortion (GRADE 1B).
- Patients receiving sedation and analgesia should be monitored by pulse oximetry both during and after surgery to detect oxygen desaturation and hypoxemia (GRADE 1C).
- The ventilatory function of patients receiving sedation and analgesia should be continually monitored by observation or auscultation (GRADE 1C).
- The ASA classification system can be used as a guide to assess a patient’s procedure-related risk (GRADE 2C).
- Supplemental oxygen should be used to decrease the frequency of hypoxia. Its use should be considered when administering moderate sedation and recommended when administering deep sedation unless specifically contraindicated for a particular patient (GRADE 1C).
- Low-risk patients undergoing surgical abortion in the first and second trimester may safely receive moderate or deep sedation without routine endotracheal intubation (GRADE 1C).

The following recommendations are based primarily on consensus and expert opinion.

- General anesthesia for dilation and evacuation is commonly administered with a propofol infusion and an opioid (GRADE 1C).
- Preoperative assessment should include a review of the preoperative medical history; review of systems; physical examination with measurement of vital signs, airway assessment, and cardiovascular exam; patient's analgesic and sedation goals corresponding to the anticipated procedure-related pain (GRADE 1C).
- Several factors may influence the decision of whether a patient is an appropriate candidate for out-of-hospital anesthesia, including provider preference (whether the surgeon or anesthesia provider), distance from nearest hospital that can accommodate post-abortion complications, and most importantly, the patient's surgical risk based on her comorbidities and the facility's ability to manage potential complications secondary to these comorbidities (GRADE 1C).
- Among individuals whose deep sedation progresses to unintended general anesthesia, such care should be provided, medically directed, or supervised by an anesthesiologist, the operating practitioner, or another licensed physician with specific training in sedation, anesthesia, and rescue techniques related to general anesthesia (GRADE 1C). Otherwise, routine general anesthesia should only be administered by anesthesia professionals (i.e., anesthesiologists, nurse anesthetists, and certified anesthesiologist assistants) (GRADE 1C).
- Post-sedation care requires patient monitoring until the patient resumes near baseline level of consciousness (GRADE 1C).

4. Recommendations for future research:

- Comparative efficacy of medication regimens in first- and second-trimester surgical abortion, especially in light of drug shortages.
- Comparative safety of medication regimens with regard to inducing deeper sedation than intended and adverse events such as pulmonary aspiration, unanticipated intubation, and hospital transfer.
- Bleeding parameters associated with administration of newer halogenated agents used for general anesthesia.
- Efficacy and safety of analgesic options for obese individuals and patients with other significant medical comorbidities.

5. Sources

A series of clinical questions was developed by the authors and reviewed by the Executive Board of the Society of Family Planning and Clinical Affairs Subcommittee. A search of the medical literature was performed using the PubMed program of the National Library of Medicine and the Cochrane Library of Clinical Trials from the beginning of the databases through October 16, 2019. Search terms include but were not limited to analgesia, anesthesia, and sedation, in combination with abortion, gynecology, obstetrics, pregnancy, and termination. Publications and relevant statements of the American Society of Anesthesiologists, the American College of Obstetricians and Gynecologists, the European Society of Anaesthesiology, the National Abortion Federation, Planned Parenthood Federation of America, and the

Royal College of Obstetricians and Gynaecologists, and regulatory guidance from The Joint Commission were reviewed. A comprehensive systematic review was not performed.

6. Intended audience

Providers of abortion services in ambulatory settings. This set of recommendations should guide clinicians in their medical decision-making, although it is not intended to dictate clinical care.

7. Authorship

These recommendations were prepared by Catherine Cansino, MD, MPH; Phillip Stubblefield, MD; Colleen Denny, MD; and Sue Carlisle, PhD, MD, and were reviewed and approved by the Board of the Society of Family Planning.

Conflict of Interest

The authors and board members have no conflicts of interest to report. The Society of Family Planning receives no direct support from pharmaceutical companies or other industries for the production of clinical recommendations.

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Table 1: Continuum of depth of sedation (adapted from ASA continuum of depth of sedation: definition of general anesthesia and levels of sedation/analgesia, 2014) [5]

LEVELS OF SEDATION	DEFINITION Drug induced state where:
<i>Minimal Sedation (Anxiolysis)</i>	Patients respond normally to verbal commands. Cognitive function and coordination may be impaired, but ventilator and cardiovascular (CV) functions are unaffected.
<i>Moderate Sedation/Analgesia (Conscious Sedation)</i>	Patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. CV function is usually maintained.
<i>Deep Sedation/Analgesia</i>	Patients cannot be easily aroused, but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. CV function is usually maintained.
<i>General Anesthesia</i>	Patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. CV function may be impaired.

Table 2. Recommended Dosing for Commonly Used Medications for Moderate Sedation (National Abortion Federation, 2018) [7]

Drugs	Usual initial dose	Maximum initial dose	Usual incremental dose	Maximum incremental dose
Fentanyl (opioid analgesic)	50-100 mcg	200 mcg	50-100 mcg	100 mcg
Midazolam (benzodiazepine sedative)	1-3 mg	4 mg	1-2 mg	2 mg

Table 3. Commonly Used Medications for Moderate Sedation (Planned Parenthood Federation of America, 2018) [8] *

Drugs	Maximum recommended single dose	Onset of Action	Duration	Comments
Fentanyl (opioid analgesic)	1-2 mcg/kg IV	Almost immediate	0.5-1 h	May be repeated once
Nalbuphine (opioid analgesic)	10-20 mg IV/IM	2-3 min IV <15 min IM	3-6 h	<ul style="list-style-type: none"> - May be repeated once - Allow 3-4 min between doses to assess effect of previously administered dose - Do not use following other narcotic analgesics (includes maintenance therapies such as methadone or suspected narcotic use) -- will reverse effect of nalbuphine-and can induce symptoms of opioid withdrawal
Meperidine (opioid analgesic)	50-100 mg IM/SQ	10-15 min	2-4 h	<ul style="list-style-type: none"> - May give every 3-4 h - Avoid concomitant use with benzodiazepines or other CNS depressants
Midazolam (benzodiazepine sedative)	2.5 mg	3-5 min	< 2h	<ul style="list-style-type: none"> - Initial dose 1-2.5 mg - Administer slowly with 2-3 min between doses to assess effect of previously administered dose. - May repeat in 1mg doses not to exceed a total of 5 mg to maintain desired depth of sedation

*PPFA affiliates are directed to develop their own local formulary.

Table 4: ASA Physical Status Classification Current Definitions and Examples [40]

ASA Physical Status	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient	Healthy, nonsmoking, no or minimal alcohol use
ASA II	A patient with mild systemic Disease	Mild diseases only without substantive functional limitations. Examples include (but are not limited to): current smoker, social alcohol drinker, pregnancy, obesity ($30 < \text{BMI} < 40$), well- controlled diabetes (DM)/hypertension (HTN), mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; one or more moderate to severe diseases. Examples include (but are not limited to): poorly controlled DM or HTN, chronic obstructive pulmonary disease (COPD), morbid obesity ($\text{BMI} \geq 40$), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, end-stage renal disease (ESRD) undergoing regularly scheduled dialysis, premature infant post-conceptual age < 60 weeks, history (> 3 months) of myocardial infarction (MI), cerebrovascular accident (CVA), transient ischemic attack (TIA), or coronary artery disease (CAD)/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but are not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, disseminated intravascular coagulation, acute respiratory distress or ESRD not undergoing regularly scheduled dialysis.
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but are not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction.
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

*The addition of "E" denotes emergency surgery. (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part.)

Table 5: Types of Anesthesia Providers

anesthesia professional – includes anesthesiologist, certified registered nurse anesthetist (CRNA) or anesthesiologist assistant (AA)
non-anesthesiologist sedation practitioners - licensed physicians who have not completed postgraduate training in anesthesiology but are specifically trained to administer moderate sedation
supervised sedation professionals – includes licensed registered nurses, advanced practice nurses, and physician assistants

Table 6: Recommended Emergency Equipment for Sedation and Analgesia [6] *

Intravenous equipment	Gloves
	Tourniquets
	Alcohol wipes
	Sterile gauze pads
	Intravenous catheters
	Intravenous tubing
	Intravenous fluid
	Assorted needles for drug aspiration, intramuscular injection
	Appropriately sized syringes
	Tape
Basic airway management equipment	Source of compressed oxygen (tank with regulator or pipeline supply with flowmeter)
	Source of suction
	Suction catheters
	Yankauer-type suction
	Face masks
	Self-inflating breathing bag-valve set
	Oral and nasal airways
	Lubricant
Advanced airway management equipment (for practitioners with intubation skills)	Laryngeal mask airways
	Laryngoscope handles
	Laryngoscope blades
	Endotracheal tubes (cuffed 6.0, 7.0, 8.0 mm ID)
	Stylet (appropriately sized for endotracheal tubes)
Pharmacologic antagonists	Naloxone
	Flumazenil
Emergency medications	Epinephrine
	Ephedrine
	Vasopressin
	Atropine

	Nitroglycerin (tablets or spray)
	Amiodarone
	Lidocaine
	Glucose, 50%
	Diphenhydramine
	Hydrocortisone, methylprednisolone or dexamethasone
	Diazepam or midazolam

* Appropriate medications and equipment, including a defibrillator, should be available whenever drug regimens to induce cardiorespiratory depression are administered. The list is a guide that can be tailored to individual practice needs.

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