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Retrospective Evaluation of the Procedural Sedation Practices of Expert Nurses During Abortion Care

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ABSTRACT

Objective: To evaluate the provision of procedural sedation during abortion by expert nurses and to describe the factors that are associated with time to discharge for women who receive this sedation.

Design: Retrospective chart review.

Methods: Descriptive statistics were generated to describe a retrospective cohort of women presenting for abortion under procedural sedation. Analysis of variance was used to determine significant characteristics that influenced time to discharge.

Setting: A single clinical site that employs seven expert nurses.

Participants: A total of 194 medical records were available for this analysis.

Results: All women were discharged home with accompaniment, and no incidents of respiratory distress or other adverse complications occurred. Most women ($n = 136$) received at least 150 μg fentanyl and 3 mg midazolam, and 71% of women in the first trimester and 83% of women in the second trimester entered the recovery area with no pain. Variables significantly associated with time spent in the recovery area were gestational age at time of abortion ($t = -2.68, p = .008$), pain at entry to recovery area ($t = -0.254, p = .008$), and pain at 15 minutes ($t = 0.25, p = .038$).

Conclusion: Expert nurses can administer procedural sedation for pain control associated with abortion and are capable of monitoring women and helping them return to baseline status after the procedure.

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(Continued)

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AWHONN

In 2014, 926,200 million abortions were performed, and most were provided in outpatient and/or independent clinics (Jones & Jerman, 2017). Three large studies of women's experiences of their abortion care have been conducted in the United States, and researchers found that women were highly satisfied with their care; however, several factors, particularly pain management, affected how women rated their care experiences (Kaiser Family Foundation & The Picker Institute, 1999; McLemore, Desai, Freedman, James, & Taylor, 2014; Taylor et al., 2013). Personalized pain management greatly influenced women's expectations and experiences of their care (McLemore et al., 2014).

Abortion is an ideal clinical area of inquiry for research on procedural sedation for four important reasons. First, abortion is common, and it is estimated that one in three women in the United States will have an abortion in her lifetime.

Second, most (90%) abortions are performed in the first trimester before 12 weeks gestation and are short and safe procedures with low (1%–2%) complication rates (Jones & Kooistra, 2011; National Abortion Federation, 2017; Upadhyay et al., 2015). Third, women who seek abortions are generally healthy and can clearly articulate their expectations and preferences for analgesia and sedation (McLemore et al., 2014). Fourth, pain associated with abortion is an understudied area in pain literature because of social, cultural, and political restrictions to scholarly inquiry in this clinical area (Harris, 2013).

Nurses routinely provide procedural sedation (anesthesia) and pain relief (analgesia) in a wide range of settings such as emergency departments, endoscopy and colonoscopy suites, dental offices, intensive care and cardiovascular units, and plastic surgery and gynecology clinics (Couloures, Beach, Cravero, Monroe, & Hertzog,

Few researchers have evaluated pain management and analgesia in abortion care; to our knowledge, procedural sedation administered by nurses has not been evaluated.

2011; Hasen, Samartzis, Casas, & Mutoe, 2003; Holger, Satterlee, & Haugen, 2005; Lavoie, Vezina, Paul-Savoie, Cyr, & Lafrenaye, 2012; Rudner, Jalowiecki, Kawecki, Gonclarz, Mularczyk, & Petelenz, 2003; Tang et al., 2007; Thompson, Andrews, & Christ-Libertin, 2012; Ulmer et al., 2003). *Nurse-administered procedural sedation* (NAPS) is defined as anesthesia (irrespective of medications administered) provided by well-trained, expert nurses (Benner, 1982) who have achieved core nursing competencies, including pre-procedural patient assessment; appropriate patient selection; patient and family pre-, inter-, and postoperative education; and patient surveillance, assessment, and monitoring (Conway, Rolley, Page, & Fulbrook, 2014; Ketcham, Kethcam, & Bushnell, 2013).

Additional skills in basic life support, cardiopulmonary resuscitation, pharmacokinetics/pharmacology, and emergency transfer planning are also essential for safe provision of NAPS. Nurses at the registered nurse (RN) and advanced practice nurse level can provide procedural sedation. Certified RN anesthetists are master's or doctorally prepared and are certified in the provision of a wider range of medication regimens than nurses without this education. None of the RNs eligible for this study were trained as certified RN anesthetists. Expert RNs in this setting do not provide propofol as anesthesiologists do because it has no reversal agent, and advanced cardiac life support would be required for its provision.

Expert RNs have full decision-making autonomy with women to determine before the procedure what a woman's goals are for procedural sedation. Upon entry to a clinic, women receive decisional assessment and comprehensive counseling from the support staff, and RNs prepare them for their abortion experience. If at any point the counseling, RN, and/or provider staff in partnership with a woman determine that she is not a suitable candidate for NAPS, arrangements can be made for the woman to receive procedural sedation from an anesthesia provider. Expert RNs trained in basic life support in this setting work under standardized procedures using written clinician orders and

provide oral and intravenous sedation using benzodiazepine and narcotic agents. Standardized procedural sedation modules are required for all RNs in a hospital who provide sedation; these modules must be successfully completed shortly after hire and updated annually. This annual assessment and update of procedural sedation training includes airway management, cardiopulmonary resuscitation, and medication administration. Nurses are routinely proctored and supervised by clinical nurse specialists and other RN preceptors until agreement is reached that confidence and competence to provide sedation has been achieved.

Despite regulatory standards for treating procedural pain, little evidence exists regarding the medication regimen that provides safe sedation and optimal pain management for abortion procedures (National Abortion Federation, 2017; The Joint Commission, 2012). Fourteen studies were conducted to evaluate pain control for abortion care, but none of the researchers focused on nurses or their roles in the provision of sedation (Allen, Fortin, Barz, Goldberg, & Clark, 2012; Braaten, Hurwitz, Fortin, & Goldberg, 2014; Dean, Jacobs, Goldstein, Gevirtz, & Paul, 2011; Meckstroth & Mishra, 2009; Micks et al., 2012; Rawling & Wiebe, 1998, 2001; Renner, Jensen, Nichols, & Edelman, 2009, 2010; Renner, Nichols, Jensen, Li, & Edelman, 2012; Roche, Li, James, Fechner, & Tilak, 2012; Suliman, Erickson, Labuschgne, de Wit, Stein, & Seedat, 2007; Wiebe, Byczko, Kaczorowski, & McLane, 2013; Wilson, Chen, & Creinen, 2008). Six studies were randomized controlled trials; however, the authors assessed the effect of different medication regimens, specifically, intramuscular ketorolac versus oral ibuprofen (Braaten et al., 2014), oral hydrocodone-acetaminophen in addition to oral ibuprofen (Micks et al., 2012), paracervical block only (Renner et al., 2009, 2010; Renner et al., 2012), and intravenous (IV) fentanyl (Rawling & Wiebe, 2001). In one study, researchers reported qualitative findings of women's preferences (Allen et al., 2012), and in another, researchers conducted a survey of pain management practices in abortion clinics (Rawling & Wiebe, 1998). In the final five studies, researchers evaluated the safety of deep sedation without intubation (Dean et al., 2011; Wiebe et al., 2013), pain and stress biomarker changes during abortion based on local versus IV sedation (Suliman et al., 2007), effectiveness of low-dose fentanyl to 18 weeks gestation (Wilson et al., 2008), and the effect of preoperative ketorolac on postprocedure abortion pain (Roche et al., 2012).

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Additionally, three systematic reviews were conducted to assess pain control in first trimester abortion (Renner et al., 2009, 2010; Renner et al., 2012), but the reviewers focused on the effect of the paracervical block and the use of oral agents for analgesia. In one review, Renner et al. (2010) included 40 studies that had seven distinct groupings of procedural sedation (local anesthesia, paracervical block with premedication, analgesia per cervical os only, conscious sedation, general anesthesia with or without premedication, nonpharmacologic interventions); conscious sedation was discussed in only three studies, and the authors did not mention nurses or NAPS. None of the authors of these reviews directly evaluated the practice of NAPS, nor did they mention the use or role of RNs in medication provision, despite the fact that pain management is one of the primary roles of the expert RN during abortion (McLemore, Kools, & Levi, 2015).

Although much attention has been given to the role of nurses in pain management for women in labor (AWHONN, 2015; Collins, 2015; Lee, 2013; Poole, 2003; Woods, 2012), researchers who reported findings on pain management for women seeking abortion have not described the role of expert nurses who provide this care. Given the differences between abortion procedures and birth, including the trajectory of pain over time, the lack of fetal monitoring, and the short length of abortion procedures, care for women who have abortions is different and requires translation of extant skills, such as pre-procedure counseling and consent; assessment and management of postabortion bleeding; comfort measures; psychosocial support; and patient education before, during, and after analgesia and anesthesia.

To better understand the role of the expert RN during abortion, we designed a retrospective chart review study to evaluate NAPS for abortion using standardized patient selection criteria. The specific aims of the study were to evaluate the provision of procedural sedation during abortion by expert nurses and to describe the factors that are associated with time to discharge for women who receive this sedation.

Methods

Sample and Setting

Data for this study come from a retrospective chart review of seven expert RNs in abortion care provision (McLemore, Levi, & James, 2015) who were employed at the Women's Options Center at

San Francisco General Hospital between January 2009 and December 2012. RNs in this clinic received mentored, on-the-job training including observing patient counseling and education and then observation in the recovery area. A customized training plan was developed among the RNs, preceptors, and managers. Although the total amount of training time varied and most RNs came to the clinic with experience, on average RNs in this clinic are trained for a year before they are considered to have gained competence. The nurses in this clinic had a range of 7 to 35 years of experience in nursing.

The selection of the time period for medical record inclusion from January 2009 through December 2012 was based on two factors: (a) permanent positions were filled in 2008, which allowed the research team to control variability in RN staff, and (b) the clinic modified its standard patient selection criteria (see Table 1), which are used to help the staff make decisions about whether sedation with an RN or an anesthesiologist is appropriate for a woman. Only IV fentanyl and midazolam were included as procedural sedation regimens for this study. Several factors were considered in the development of the standardized criteria, including overall health of women; the pharmacokinetics of fentanyl and midazolam, including the wide variation of population responses to fentanyl and the synergy and half-life of both medications (Mawhinney, Mabourakh, & Lewis, 2013); anticipated procedure time; clinician skill; women's expectations of sedation; and setting.

The setting of the Women's Options Center, a hospital-based clinic, is described in detail elsewhere (Lederle, Steinauer, Montgomery, Aksel, Drey, & Kerns, 2015). Briefly, women are seen for abortions between 5 and 24 weeks gestation via aspiration or dilation and evacuation. A licensed obstetrician-gynecologist is present for each procedure, and anesthesia care is available during routine business hours and 24 hours per day based on emergency need and patient acuity and/or hospital census. The clinic is licensed by the state and allows for the provision of NAPS.

The sampling goals for this study were to obtain at least 30 medical records for review for each nurse of women who met the study inclusion criteria ($N = 210$); however, 16 records were not available for inclusion. Therefore, each nurse had a minimum of 23 patient records, except for

Table 1: Standard Patient Selection Criteria for Procedural Sedation by Expert Registered Nurses

Characteristics	Range or Parameter
Clinical characteristics	All women eligible to receive local anesthesia (i.e., paracervical block) ASA score I or II Normal physical examination results with BMI ≤ 35 kg/m ^{2a} Gestational age between 5 and 22 weeks
Demographic characteristics	Verifiable accompaniment Manageable preoperative pain/anxiety with oral analgesics as defined by pain scores ≤ 30 out of 100 on a VAS No food or drink by mouth 8 hours before procedure

Note. ASA = American Society of Anesthesiology; BMI = Body Mass Index; NAPS = nurse-administered procedural sedation; VAS = visual analog scale.
^aWomen with BMI > 35 kg/m² with no other risk factors for poor outcomes evaluated by anesthesiologist and cleared for NAPS on a case-by-case basis.

one nurse who had 21. Ethics approval was provided by the institutional review board of the University of California, San Francisco.

Women 18 years of age or older who presented to the clinic for a first or second trimester abortion (5–22 weeks), were eligible for participation in this study. Exclusion criteria included any woman who was medically unstable or was considered extremely high risk, defined as having uncontrolled hypertension, uncontrolled diabetes, current medical treatment for clotting disorders or current blood clots requiring anticoagulant therapy, severe asthma, or other respiratory conditions that for which women are considered ineligible for procedural sedation in an outpatient setting. Additionally, those women not meeting the standard criteria for NAPS (Table 1) were excluded.

All participants received a 20-ml paracervical block and initial or loading doses of 100 μ g IV fentanyl and 1 mg midazolam. Subsequent doses based on standard orders included increments of 50 μ g fentanyl for pain and 1 mg midazolam for anxiety every 2 minutes. Under standard procedures and expert RN discretion, up to 400 μ g fentanyl and 6 mg midazolam could be administered.

Measures

Data were extracted from medical records using a standard form by the first author and two research assistants. Variables extracted were demographic (date of birth, gestational age at

time of procedure, height, weight, gravidity, and parity) and procedural (Aldrete scores [Aldrete & Kroulik, 1970] before and after the procedure; start and end times of procedure; all medications before, during, and after procedures; level of training of the provider completing the procedure; and pain scores at time of entry to recovery area and at 15-minute intervals until discharge). Race and ethnicity data were not extracted from the medical records.

Time to discharge or time spent in the recovery area was chosen as the primary outcome variable in this study because it serves as a proxy for complications. Given the safety of first trimester abortion (1%–2% complication rate), it is necessary to note that the addition of sedation carries its own risk. Time spent in the recovery area was calculated by subtracting the time of entry into the recovery area from the time of discharge, measured in minutes. The continuous variable of pain was used in all statistical tests. Range of procedure time was calculated by subtracting the time of the initial administration of NAPS from the time of entry into recovery area in minutes.

Analysis

Data were double-entered into an Excel spreadsheet and checked for accuracy. Once data were cleaned and resolved (i.e., data entry errors or discrepancies removed), the spreadsheet was imported into IBM SPSS version 23 for analyses. Demographic data were reported in means and frequencies where appropriate. Factors associated with time to discharge were determined by

analysis of variance of pain scores in the recovery area at entry; at 15, 30, and 45 minutes; at 1 hour; and at discharge, where the outcome variable of interest was time spent in recovery area. Predictor variables included age in years; gestational age in weeks; procedure time in minutes; dose of sedation (total amounts of fentanyl and Versed); and postprocedure contraception, specifically intrauterine device insertion. Cases performed by prelicensure learners were excluded from this analysis. Statistical significance levels were set at $p < .05$.

Results

Data from 194 records are included in this analysis. Descriptive statistics for all participants are shown in Table 2. All participants who received NAPS were discharged to home with accompaniment, and no incidents of respiratory distress or other adverse complications occurred. The range of procedure time was 4 to 44 minutes, with a mean time of 8 minutes.

Most participants ($n = 136$), regardless of gestational age, received at least 150 μg fentanyl and 3 mg midazolam, and 71% of participants in their first trimester and 83% of participants in their second trimester entered the recovery area with no pain. A total of 76 participants (39%) received 200 μg fentanyl and 4 mg midazolam, and

Expert RNs are capable of providing procedural sedation for women who have abortions using standardized protocols.

47 participants (24%) received between 250 μg and 400 μg of fentanyl and between 5 mg and 6 mg of midazolam. There were no statistically significant differences between participants with different gestational ages and total amount of NAPS received. Additionally, overall procedure time was increased on average by 1.5 minutes for the 55 participants who received a postabortion intrauterine device (IUD) insertion. This difference in time was not statistically significant, which was not surprising because abortions completed by learners were excluded from this analysis. Of the 55 participants who received IUDs, only nine reported pain levels between 4 and 10, using the visual analog scale during their time in the recovery room. However, all participants who had IUDs placed after the procedure received at least one additional dose of medication during the procedure besides the loading doses of fentanyl and Versed.

Additionally, a consistent finding across gestational ages was that pain increased as participants spent more time in the recovery area (Figure 1). Pain assessment in the recovery area is an important skill, and we hypothesize that pain increases during time in the recovery area for several reasons: grogginess at entry does not allow a clear assessment or articulation of pain; when women enter the recovery area lightly sleeping or appearing to be resting comfortably, RNs are hesitant to arouse them to assess pain; postprocedure contraception, specifically IUD placement, could serve as an additional pain stimulus; and medications administered in the procedure room could be beyond their peak of effectiveness once a woman has been transferred to the recovery area.

During the recovery period, 113 participants received ketorolac, 30 received morphine, 26 received ondansetron, and two received diphenhydramine; once able to tolerate oral medications, 44 participants received acetaminophen and hydrocodone, 17 received lorazepam, and 1 received oxycodone.

In the recovery area, expert RNs have the opportunity to use their judgment in addition to eliciting women's preferences for pain

Table 2: Descriptive Statistics of Women Receiving Nurse-Administered Procedural Sedation ($N = 194$)

Characteristic	Range	Mean
5 weeks to 13.6 weeks ($n = 136$)		
Age in years	18–43	26
Gestational age at time of abortion in weeks	6–13	8
Body mass index	19–49	26
Gravidity	1–11	3
Parity	0–5	1
14 weeks to 22 weeks ($n = 58$)		
Age in years	18–43	26
Gestational age at time of abortion in weeks	14–22	17.5
Body mass index	19–42	26
Gravidity	1–11	3
Parity	0–5	1

Figure 1. Boxplots of pain scores at each time point from entry to recovery area through discharge.

management. The variation observed in types of pain medications administered in the recovery area is grounded in women's self-reported levels of pain and whether they are able to tolerate oral medications. Oral medications are withheld in the recovery area for nausea/vomiting or until two bleeding check results are within normal limits. If women have moderate or high pain levels, they are given intravenous medication.

Time to Discharge

All participants were discharged according to standard recovery area protocols and were eligible for discharge after an hour of monitoring. When participants at all gestational ages are included in time to discharge, based on time spent in the recovery area, the overall ANOVA model was significant ($F = 2.16$, $p = .013$; Table 3), indicating significant mean differences of one or more variables included in the model. The variables significantly associated with time spent in the recovery area were gestational age at time of abortion ($t = -2.68$, $p = .008$), pain at entry to recovery area ($t = -0.254$, $p = .008$), and pain at 15 minutes ($t = 0.25$, $p = .038$). In other words, participants who entered the recovery area with pain (at any level: mild, moderate, or severe) or who entered the recovery area with no pain but had increases in pain scores at the 15-minute mark spent more time in the recovery area. Additionally, participants with gestational

ages in the second trimester were more likely to spend more time in the recovery area, despite no differences in amount of NAPS received.

Table 3: Analysis of Variance of Characteristics That Influence Time Spent in Recovery Area

Variable	β	t	p
(Constant)		9.719	.000
Age in years	.069	.838	.403
Gestational age at time of abortion	-.220	-2.687	.00*
Body mass index	-.286	-1.102	.272
National Heart Lung and Blood Institute obesity categories	.284	1.088	.278
Gravidity	-.018	-.171	.864
Parity	-.062	-.568	.571
Time of the procedure	.023	.290	.772
Pain at entry to recovery	-.254	-2.700	.008*
Pain scores at 15 minutes	.250	2.094	.038*
Pain scores at 30 minutes	-.101	-.855	.394
Pain scores at 45 minutes	.173	1.570	.118
Pain scores at 1 hour	.075	.626	.532
Pain scores at discharge	-.045	-.405	.686

* $p < .05$.

Study participants were healthy, with pre- and postprocedure Aldrete scores that ranged from 12 to 14. However, 25 participants reported mild pain in the pre-procedure assessment from a variety of sources, including uterine cramping, back pain, headache, and joint pain. Some participants were taking medications such as prenatal vitamins ($n = 1$), iron sulfate ($n = 1$), antiseizure medications ($n = 6$), and asthma inhalers ($n = 8$). In total, seven participants vomited in the recovery area; five of these had gestational ages in the first trimester and two in the second.

Discussion

Expert RNs can use standard patient selection criteria and protocols to administer procedural sedation for pain control associated with first and second trimester abortion. Expert RNs already provide procedural sedation in diverse settings, including outpatient clinics, and are capable of monitoring women and helping them return to baseline status after abortion. In this study, the data specifically show that careful patient selection is crucial to the implementation of NAPS, because all participants in this study were discharged to home with accompaniment and did not require an escalation of care. It was not surprising that the participants with advanced gestations in this study spent more time in the recovery area; it is important to note that their retention was associated with additional monitoring of bleeding, rather than respiratory status or grogginess from sedation.

Time to discharge is an important variable to study in clinic-based abortion care because of cost and time. First, RNs who provide procedural sedation are an added cost, and there needs to be an adequate volume of women to justify sedation services. Next, overall wait times in clinics range in hours and are disproportionate to the actual time of the procedure, which tends to be completed in minutes. Although most women are sedated well enough to control their pain but not so sedated that they cannot leave in a timely fashion, the scheduling of RNs and women requires a high level of skill because of mandated pre-procedure counseling; patient education; and preparation through the actual procedure, recovery, and discharge.

These data are aligned with results from other studies in which researchers evaluated NAPS, particularly the use of fentanyl and Versed in

Health providers and organizations that currently do not provide procedural sedation may use these findings to determine selection criteria and to develop sedation protocols.

ambulatory settings (Couloures et al., 2011; Hasen et al., 2003; Holger et al., 2005; Lavoie et al., 2012; Rudner et al., 2003; Tang et al., 2007; Thompson et al., 2012; Ulmer et al., 2003). Two large studies (Dean et al., 2011; Wiebe et al., 2013) specific to abortion with retrospective chart methods similar to those used in this study were designed to determine the safety of sedation without intubation. Additional analyses in both of these studies included the effect of a light meal on aspiration, and results from both studies indicated minimal complications and effective pain control. In one of these studies (Wiebe et al., 2013), the authors reported exclusive use of NAPS and RNs in the recovery area for women.

In other studies not specific to abortion care, researchers evaluated the effect of NAPS on burn treatment procedures (Thompson, Andrews, & Christ-Libertin, 2012) for which intubation was not required and nurses were able to successfully monitor the women to pre-sedation baseline status. Lavoie, Vezina Paul-Savoie, Cyr, and Lafrenayo (2012) evaluated the use of NAPS with a pediatric population and had similar findings. Most studies in which researchers evaluated NAPS are specific to gastroenterology procedures (Hasen et al., 2003; Holger et al., 2005; Rudner et al., 2003; Ulmer et al., 2003) and the use of propofol by RNs. Authors of these studies also showed that nurses are capable of using standardized protocols to safely provide sedation with or without the supervision of a gastroenterologist or anesthesiologist.

There are several limitations to our study, including the retrospective chart review design that limited the analyses to description. Further, the lack of data on the race and ethnicity of the participants did not allow for assessment of differences in pain by race/ethnicity. Pain is known to be reported yet undertreated in people of color (Hoffman, Trawalter, Axt, & Oliver, 2016). The lack of cost analyses, particularly the use of expert RNs and the volume of women required to financially justify their use, is also a limitation. Many clinics that offer abortion services use oral pain medication, generally a nonsteroidal anti-

inflammatory agent and paracervical block for first trimester procedures, and many women are able to tolerate the procedure. Freestanding clinics should interpret these findings cautiously, because many institutional supports, such as access to anesthesia and advanced airway support, tend not to be readily available in those settings. The limited time period for the study is also a limitation. Expert RNs have been employed at the Women's Options Center and have provided NAPS for women who undergo abortion procedures since 1999; however, several changes in nursing practice and personnel did not allow for broader historical analyses. Despite these limitations, in this report of the effectiveness and practice of NAPS by expert RNs in the outpatient abortion context we broaden our understanding of the important services these nurses provide for women who seek this care. In future studies, researchers should prospectively assess the efficacy and safety of nurse-administered procedural sedation and include women's preferences for postabortion pain management. Finally, the relationship between sedation during procedures and need for pain management after abortion should be explored. Evaluation of these practices should ensure woman-centered pain management in abortion and skill development of expert RNs in abortion care provision.

Conclusion

Expert RNs can administer procedural sedation for pain control associated with abortion and are capable of monitoring women and helping them to return to baseline status after abortion. Institutions that do not currently use RNs or procedural sedation should be encouraged by these findings to consider the use of RNs and sedation for women based on their preferences. Efforts should be made to support RNs in the development of their sedation skills to expand the potential providers of pain management for abortion procedures.

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