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Original Research Article

Outpatient medical management of later second trimester abortion (18–23.6 weeks) with procedural evacuation backup: A large case series☆

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ABSTRACT

Objective: Document the clinical outcomes of an outpatient medical management with procedural evacuation backup procedure for abortions between 18 weeks zero days to 23 weeks six days gestation.
Study design: We conducted a retrospective medical records review of adult patients who received mifepristone and repeated misoprostol for second trimester abortion with procedural evacuation backup at an Arizona clinic between October 2017 and November 2021. We extracted patient demographics; pregnancy and medical history; and preoperative, intraoperative, and postoperative data. We assessed abortion outcomes, including procedure timing, mode of completion (medication alone or medications and procedural evacuation), and safety.
Results: All 359 patients had a complete abortion with 63.5% of patients completing with medication alone and 36.5% with procedural evacuation backup. The median time from first dose of misoprostol to fetal expulsion was six hours, among those who completed the abortion with medications alone. Of those who received procedural evacuation as backup, the median time for procedural evacuation was 10 minutes. The vast majority of patients (99.4%) did not have any adverse events. Two safety incidents (0.6%) occurred, a broad right ligament tear and a uterine rupture.
Conclusion: Patients in one outpatient setting safely and effectively received medical management of second trimester abortion with procedural evacuation backup, and two thirds completed with medications alone.
Implications: Outpatient settings may consider medical management of abortion between 18 and 24 weeks with procedural evacuation back-up as a safe, effective, and manageable second trimester abortion option. Additional research is needed on patient experience and satisfaction.

1. Introduction

Abortion provision after the first trimester is an essential part of reproductive health care. In 2020 in the United States (US), 5.8% of abortions occurred between 14–20 weeks gestation, and 0.9% occurred after 21 weeks gestation [1]. Physicians typically use dilation and evacuation (D&E) after 13 weeks, which is safe and effective in an outpatient setting [2]. D&E involves the use of pharmaceutical, osmotic, or mechanical dilators to open the cervix [2]. After adequate dilation is achieved, a physician uses instruments to remove the contents of the uterus, which takes about 10–20 minutes [3]. The use of medication abortion in procedures between 13 and 24 weeks is not common in the US, however, it is supported for use throughout pregnancy by US-based and global medical organizations, such as the American College of Obstetricians and Gynecologists [4] and the World Health Organization [5]. Data from South Africa, Europe, and the Middle East have shown medication abortion to be safe, effective, and acceptable for second-trimester patients [6–8]. In second-trimester medication abortion procedures, patients are typically given mifepristone followed by repeated doses of misoprostol 24–48 hours later, however misoprostol-alone can also be safe and effective [9,10].

In the US, the vast majority of abortions occur in free-standing clinics [11] and current evidence on the use of medication abortion in second-trimester abortion is predominately from hospital-based settings [12–14]. One US clinic, Camelback Family Planning located in Arizona, offered medical management of later second trimester (18 weeks and zero days-23 weeks and six days) abortions with procedural evacuation between 2017 and 2022. Patients came to the

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clinic to receive mifepristone and digoxin on the first day of the procedure, and then returned to the clinic the next day to receive repeated doses of misoprostol to complete their abortion. The clinic used procedural evacuation as back-up on a case-by-case basis, most commonly if patients did not expel the pregnancy during clinic hours from 8 AM to 4 PM. Given the potential benefits to new cadres of providers and to patients, this study aimed to document the clinical outcomes of medication abortion with procedural evacuation backup among patients at Camelback Family Planning between 2017 and 2021.

2. Methods

We conducted a retrospective review of medical records of patients at 18 weeks and zero days to 23 weeks and six days gestation between October 2017 and November 2021. During the study period, four physicians provided care and all patients received medical management of abortion with procedural evacuation back-up with the same protocol over two days. On Day 1, typically around noon, patients received mifepristone 200 mg orally and digoxin 1 mg via vaginal injection (intra-amniotic or intra-fetal) for fetal demise. On Day 2, patients self-administered misoprostol 600 mcg vaginally at 6 AM prior to arriving at the clinic and received a cervical exam and amniotomy after presenting at the clinic. Once patients arrived at the clinic at 8 AM, they received misoprostol 400 mcg buccally or vaginally every two hours until they completed the abortion. Patients were moved to the procedure room when expulsion was imminent, where they received ketamine 25 mg for conscious sedation. Immediately after fetal expulsion, the placenta was either removed using a ring forceps or spontaneously expelled, followed by suction aspiration. After nine hours, procedural evacuation was used in cases where patients did not complete the abortion with medication alone. On a case-by-case basis, patients may have received procedural evacuation due to poor tolerance of misoprostol effects. These patients were also transferred to the procedure room and given ketamine 25 mg for conscious sedation. Procedural evacuation was then completed in standard practice under continuous ultrasound guidance. Procedural evacuation was only directed at the physician's discretion and the clinic does not offer procedural evacuation alone for patients between 18 and 24 weeks. The protocol is explained in further detail in the Appendix.

This review included patients with a live pregnancy between 18 weeks zero days to 23 weeks six days gestation. Patients presenting to the clinic with fetal demise were excluded from the study as their dilation time may be different from those without fetal demise. Data from patient records was input into an Excel template by trained clinic staff. We extracted age, pregnancy history (gravidity, parity, previous cesarean section, previous abortion), gestational age, body mass index (BMI), total misoprostol dose, time from mifepristone administration to first misoprostol, mode of abortion completion (medications alone or medications and procedural evacuation), time to expulsion, procedural evacuation procedure time, and safety incidents. One author (SC) cleaned and analyzed all data using Stata 15.1.

Our analysis aimed to evaluate safety by measuring the prevalence of incidents using the Procedural Abortion Incident Reporting and Surveillance Framework (PAIRS) [15]. PAIRS defines an incident to include patient injury (i.e., an adverse event) or risk of harm (i.e., potential adverse event), and morbidity related to pregnancy and the abortion process (hemorrhage due to uterine atony or pain and bleeding symptoms) but not related to clinical management [15]. Authors (SC, GG) defined incidents for this study as retained products of conception, failed abortion, pelvic infection, external cervical tear that required suturing, uterine perforation, anesthesia complication requiring hospital transfer, hemorrhage of greater than 500 cc, and cervical injury. We did not include potential adverse events. Authors (SC, GG) reviewed patient records with any of these incidents to classify into adverse event or morbidity and further as major or minor. We calculated times from mifepristone ingestion to first dose of misoprostol, first dose of misoprostol to fetal expulsion, and the duration of procedural evacuation (calculated from the time that the speculum was inserted to its removal). We used descriptive analyses for all reported outcomes. The Allendale Institutional Review Board provided ethical approval for this study.

Table 1
Demographic and pregnancy history characteristics extracted from a case series of patients 18 weeks and zero days to 23 weeks and 6 days gestation receiving outpatient medical management with procedural evacuation backup. Arizona, 2017 to 2021

Characteristic	Overall *N* = 359
	n (%)
Age (years)	
Mean	26.7 ± 6.3
13–17	14 (3.9)
18–25	158 (44.0)
26–35	150 (41.8)
36–43	37 (10.3)
Gravidity	
1	107 (29.8)
2	76 (21.1)
3	63 (17.5)
4+	113 (31.4)
Parity	
0	149 (41.5)
1	76 (21.2)
2	68 (18.9)
3	33 (9.2)
4+	33 (9.2)
Previous cesarean section	
Yes	39 (10.9)
No	320 (89.4)
Previous abortion	
Yes	139 (38.7)
No	220 (61.2)
Gestational age	20.2 ± 1.7
18 weeks–18 weeks, 6 days	85 (23.7)
19 weeks–19 weeks, 6 days	71 (19.8)
20 weeks–20 weeks, 6 days	49 (13.6)
21 weeks–21 weeks, 6 days	55 (15.3)
22 weeks–22 weeks, 6 days	45 (12.5)
23 weeks–23 weeks, 6 days	54 (15.0)
Body Mass Index	26.4 ± 6.2
Underweight < 18.5	9 (2.5)
Normal weight 18.5–24.9	170 (47.3)
Overweight 25–29.9	97 (27.0)
Obese 30+	83 (23.1)

3. Results

We reviewed and analyzed 359 charts of patients who underwent medical management with procedural evacuation as backup between 18 weeks and zero days and 23 weeks and six days gestation during the study period. Patients had a mean gestational age of 20 weeks and two days and were distributed across gestational age categories. More than half of patients had previously given birth (*n* = 210, 58.5%) and 10.9% (*n* = 39) previously had a cesarean section (Table 1).

All patients completed their abortion on Day 2 and no patients required mechanical dilation. The majority of patients (*n* = 228, 63.5%) completed their abortion with medication alone (Table 2). Among patients 18–20.6 weeks gestation, 57.0% (*n* = 117) completed the abortion with medication alone, and among patients 21–23.6 weeks gestation, 72.1% (*n* = 111) completed the abortion with medication alone. The median time from mifepristone to first dose of

Table 2
Procedure outcomes extracted from a case series of patients 18 weeks and zero days to 23 weeks and six days gestation receiving outpatient medical management with procedural evacuation backup. Arizona, 2017 to 2021

	Overall sample	Completed with medications alone	Completed with medications and procedural evacuation
	(*n* = 359)	(*n* = 228)	(*n* = 131)
Time from mifepristone to first self-administered dose of misoprostol at 6 AM (hours)[a]			
Median (IQR)	19 (18.2;20)	19 (18;20)	19 (18.3;20)
Total amount of misoprostol taken (mcg)			
Median (IQR)		1465 (1400;1800)	1594 (1400;1800)
Time from first dose of misoprostol to fetal expulsion (hours)			
Median (IQR)		6 (5.2;7.5)	
Fetal expulsion at home prior to taking misoprostol		3 (1.3)	
2–3 hrs		4 (1.8)	
3.1–6 hrs		108 (48.0)	
6.1–9 hrs		102 (45.3)	
9.1–11 hrs		9 (4.0)	
Length of procedural evacuation procedure (mins)			
Median (IQR)			10.0 (6;14)
2–10 mins			82 (62.6)
11–20 mins			34 (25.9)
21–30 mins			8 (6.1)
31–40 mins			4 (3.0)
41–60 mins			3 (2.3)
Safety incidents			
Major adverse events	2 (0.01)		
Minor adverse events	0 (0.0)		
Morbidity	0 (0.0)		

[a] Does not include patients that did not take any misoprostol.

misoprostol was 19 hours for all patients regardless of whether they completed the abortion with medications alone or medications and procedural evacuation. Three patients expelled the pregnancy prior to taking misoprostol at 6 AM and no patients expelled the pregnancy after taking the misoprostol at 6 AM and before coming to the clinic.

Among those who completed the abortion with medications alone, the median time from the first dose of misoprostol (6 AM on procedure Day 2) to fetal expulsion was six hours, with most patients ranging from three to nine hours. Medication alone procedures occasionally went beyond nine hours due to factors including the patient being close to delivering (and hence the staff stayed to complete the procedure); clinical reasons such as poor pain control to carry out an operative procedure or patient's anatomy not allowing for a procedural evacuation; or patient requesting an induction to view and hold the fetus.

Among those who completed the abortion with medications and procedural evacuation (*n* = 131, 36.5%), most of the procedural evacuation procedures were completed within 10 minutes (*n* = 82, 62.6%) from the time the speculum was inserted to the time it was removed. In some cases, procedural evacuation occurred before nine hours. Reasons for procedural intervention were mostly based on patient circumstances, such as fear of expulsion or pain intolerance. Although rare, clinic related factors, such as clinic flow or patient volume, also resulted in procedural evacuation before nine hours.

Most patients did not experience safety incidents. Two patients who completed abortion with procedural evacuation experienced a major adverse event (0.6%), one had a right broad ligament tear, and one had a uterine rupture (Table 2). The patient who had a right broad ligament tear was transferred to the hospital, received surgical repair, and discharged the next day. The patient who experienced a uterine rupture was also transferred to the hospital where the uterus was surgically repaired. As part of routine care, the placenta was either expelled immediately or removed by the physician in the procedure room using forceps after fetal expulsion, followed by suction aspiration.

4. Discussion

Our analysis indicated that medical management with procedural evacuation as backup was safe and can be completed in an outpatient setting for abortion patients 18 weeks and zero days-23 weeks and six days gestation. All the patients in our analysis completed their abortion by the end of the second procedure day, and approximately two-thirds of patients successfully used mifepristone with repeated doses of misoprostol to complete their abortion.

The vast majority of patients who completed with medications alone completed the procedure within nine hours after their first dose of misoprostol at 6 AM, which is consistent with other studies assessing the medical management of second trimester abortion [7,9]. Our study outcomes for safety and procedural evacuation procedure time are also similar to existing literature [2,16]. Using medication to induce abortion in the second trimester can include expulsion at home, as was true for three patients in this study. Patient counseling and materials should include information on what to expect and how to respond if expulsion happens outside the clinic setting. Potential benefits of offering this procedure may include greater patient comfort on the first day of the procedure as compared to dilators used for D&E [13], patient preference for medication abortion [17], and the ability for patients to view the pregnancy after the procedure if desired [18].

Some patients and providers may prefer medication abortion, especially in cases of fetal anomalies, genetic conditions, or maternal health concerns [18,19]. One US study among women receiving medical or procedural termination for maternal and/or fetal conditions showed that offering a choice between procedural and medical termination procedures was integral to decision satisfaction, and women wanted these decisions to be driven by their personal values [18]. In settings where it is feasible, outpatient clinics may consider adding medication abortion for later abortion procedures to meet patient preferences for care. Lastly, our study showed that patients can self-administer misoprostol safely at home as well, paving the way for more efficient protocols and greater flexibility when traveling to access care.

This study has several limitations, including that these findings may not be generalizable to other settings or to trainees as they are specific to a single facility and four providers. Previous US studies show that retained placenta is a common complication in second trimester induction procedures [6,12,14], however, incidents and timing of placenta removal could not be described for this study because routine care included active management of retained placenta by removing the placenta immediately after fetal expulsion and giving suction aspiration. In addition, patient charts did not record potential adverse events, dilation at the time of procedural evacuation and fetal expulsion, side effects experienced, and pain scores. We also did not follow up with patients after they were discharged, so this assessment does not include any incidents that may have occurred after patients were discharged. Additionally, we did not include patients with fetal demise in this study. Future research studies should aim to include documenting these important indicators.

We found that this outpatient medical management of second trimester abortion with procedural evacuation as backup procedure was safe and effective. Clinics considering this procedure should have sufficient nursing staff to administer IV pain medication and adequate space for patients to labor for several hours. To better understand the acceptability of this unique procedure, more research is needed to explore patient and provider experiences. This procedure may represent an alternative technique for providers and contribute to expanding access to abortion after the first trimester.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supporting material

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.conx.2024.100104.

References

[1] Kortsmit K, Nguyen AT, Mandel MG, Clark E, Hollier LM, Rodenhizer J, et al. Abortion surveillance — United States, 2020. Morb Mortal Wkly Rep 2022;71:1–27. https://doi.org/10.15585/mmwr.ss7110a1

[2] Stubblefield P, Carr-Ellis S, Borgatta L. Methods for induced abortion. Obstet Gynecol 2004;104:174–85. https://doi.org/10.1097/01.AOG.0000130842.21897.53

[3] British Pregnancy Advisory Service. Dilation and evacuation. British Pregnancy Advisory Service 2022. ⟨https://www.bpas.org/abortion-care/abortion-treatments/surgical-abortion/dilatation-and-evacuation/⟩ (accessed October 10, 2022).

[4] American College of Obstetricians and Gynecologists. Induction of labor. Practice Bulletin, Number 107 2009. ⟨https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2009/08/induction-of-labor⟩ (accessed October 10, 2022).

[5] World Health Organization. Safe abortion: technical and policy guidance for health systems evidence summaries and grade tables (No. WHO/RHR/12.10). 2012.

[6] Ngoc NTN, Shochet T, Raghavan S, Blum J, Nga NTB, Minh NTH, et al. Mifepristone and misoprostol compared with misoprostol alone for second trimester abortion: a randomized controlled trial. Int J Gynecol Obstet 2011;118:601–8. https://doi.org/10.1097/AOG.0b013e318227214e

[7] Schocher T, Dragoman M, Blum J, Abbas D, Louie K, Platais I. Could second-trimester medical abortion be offered as a day service? Assessing the feasibility of a 1-day outpatient procedure using pooled data from six clinical studies. Contraception n.d.; 99:288–292. https://doi.org/10.1016/j.contraception.2018.12.004.

[8] Constant D, Harries J, Malaba T, Myer L, Patel M, Petro G, et al. Clinical outcomes and women's experiences before and after the introduction of mifepristone into second-trimester medical abortion services in South Africa. PLoS One 2016;11:e0161843.

[9] Gemzell-Danielsson K, Lalitkumar S. Second trimester medical abortion with mifepristone-misoprostol and misoprostol alone: a review of methods and management. Reprod Health Matters 2008;16:162–72. https://doi.org/10.1016/S0968-8080(08)31371-8

[10] Borgatta L, Kapp N. Labor induction abortion in the second trimester. Contraception 2011;84:4–18. https://doi.org/10.1016/j.contraception.2011.02.005

[11] Jones RK, Kirstein M, Philbin J. Abortion incidence and service availability in the United States, 2020. Perspect Sex Reprod Health 2022;54:128–41. https://doi.org/10.1363/psrh.12215

[12] Latta K, Barker E, Kendall P, Testani E, Laursen L, McClosky L, et al. Complications of second trimester induction for abortion or fetal demise for patients with and without prior cesarean delivery. Contraception 2022;117:55–60. https://doi.org/10.1016/j.contraception.2022.06.011

[13] Borgatta L, Roncari D, Sonalkar S, Mark A, Hou M, Finneseth M, et al. Mifepristone vs. osmotic dilator insertion for cervical preparation prior to surgical abortion at 14–16 weeks: a randomized trial. Contraception 2012;86:567–71. https://doi.org/10.1016/j.contraception.2012.05.002

[14] Sonalkar S, Ogden SN, Tran LK, Chen AY. Comparison of complications associated with induction by misoprostol versus dilation and evacuation for second-trimester abortion. Int J Gynecol Obstet 2017;138:272–5. https://doi.org/10.1002/ijgo.12229

[15] Taylor D, Upadhyay U, Fjerstad M, Battistelli M, Weitz T, Paul M. Standardizing the classification of abortion incidents: the Procedural Abortion Incident Reporting and Surveillance (PAIRS) framework. Contraception 2017;96:1–13. https://doi.org/10.1016/j.contraception.2017.05.00

[16] Lohr P. Surgical abortion in the second trimester. Reprod Health Matters 2008:151–61.

[17] Wingo E, Ralph L, Kaller S, Biggs M. Abortion method preference among people presenting for abortion care. Contraception 2021;103:269–75. https://doi.org/10.1016/j.contraception.2020.12.010

[18] Kerns J, Light A, Dalton V, McNamara B, Steinauer J, Kuppermann M. Decision satisfaction among women choosing a method of pregnancy termination in the setting of fetal anomalies and other pregnancy complications: a qualitative study. Patient Educ Couns 2018;101:1859–64. https://doi.org/10.1016/j.pec.2018.06.012

[19] Kerns J, Vanjani R, Freedman L, Meckstorth K, Drey E, Steinauer J. Women's decision making regarding choice of second trimester termination method for pregnancy complications. Int J Gynecol Obstet 2012;116:244–8. https://doi.org/10.1016/j.ijgo.2011.10.016