Early Abortion in Family Medicine: Clinical Outcomes

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Conflicts of interest: none reported

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ABSTRACT

PURPOSE Clinical innovations have made it more feasible to incorporate early abortion into family medicine, yet the outcomes of early abortion procedures in this setting have not been well studied. We wished to assess the outcomes of first-trimester medication and aspiration abortion procedures by family physicians.

METHODS Prospective observational cohort study conducted from August 2001 to February 2005 of 2,550 women who sought pregnancy termination in 4 clinical practices of family medicine departments and 1 private office/training site.

RESULTS The rate of successful uncomplicated procedures for medication was 96.5% (95% confidence interval [CI], 95.5%-97.0%) and for aspiration was 99.9% (CI, 99.3%-1). Adverse events and complications of medication abortions were failed procedure (ongoing pregnancy; n = 19, 1.45%); incomplete abortion (n = 16, 1.22%); hemorrhage (n = 9, 0.69%); and patient request for aspiration (n = 1, 0.08%). One (0.08%) missed ectopic pregnancy was seen among patients receiving medication. Four types of adverse outcomes were encountered with aspiration: incomplete abortion requiring re-aspiration (n = 21, 1.83%); hemorrhage during the procedure (n = 4, 0.35%); missed ectopic pregnancy (n = 3, 0.26%); and minor endometritis (n = 1, 0.09%). Missed ectopic pregnancies were successfully treated in the inpatient setting without mortality (overall hospitalization rate of 0.16 of 100). All other complications were managed within outpatient family medicine sites. Rates of complication did not vary by experience of physician or by site of care (residency vs private practice).

CONCLUSIONS Complications of medication and aspiration procedures occurred at a low rate, and most were minor and managed without incident.

Ann Fam Med 2009;7:527-533. doi:10.1370/afm.1051.

INTRODUCTION

Although early (first-trimester) abortion is among the most common outpatient medical procedures in the United States, and it has a very low risk of complications, few patients are able to receive these procedures from their family physician.[1,2] Currently most of these procedures are provided in specialized abortion referral sites.[3] The potential benefits of providing abortion in family medicine offices include improving access to care in areas where there are few abortion providers and supporting the medical home for patients whose primary care physician can provide continuity of care.[4,5] Established relationships with family physicians may also facilitate effective follow-up care including postabortion contraception. Medication and some aspiration abortion methods are seemingly well suited to the family medicine setting and make the provision of early abortion services (less than 9 weeks' gestation for medication abortion and 12 weeks or less for manual vacuum aspiration) a realistic possibility for family physicians.[6-9] These factors have led to initiatives to bring first-trimester abortion training into family medicine settings.[10-15]

There has been little research assessing early abortion outcomes in family medicine, and studies have been of inadequate size to measure dif-

ferences in outcomes from specialized abortion sites.[12] Concern has been raised over the effectiveness and safety of providing these procedures in family medicine settings[16,17]; these sites could have unacceptably high rates of complications or have complications that go beyond the ability of that site to manage.[18,19] Abortion care settings with less-experienced physicians have in some studies had higher rates of complications than those with only fully trained physicians.[20,21] We carried out a prospective observational study in the clinical practices of 4 family medicine residency training programs and a general family medicine private office and training site to assess effectiveness and complication rates for first-trimester abortion care. Our aims were to determine success rates, to identify the nature and severity of adverse outcomes and complications encountered in family medicine practices, and to assess the ability to manage complications on site.

METHODS

Appropriate institutional review board approval was obtained for this study from all participating clinical sites.

Setting

Consecutive patients seeking abortion care at 4 family medicine residency training programs and 1 private family medicine office were prospectively enrolled over a 42-month period (August 2001 to February 2005). The sites participating in this study were part of the Early Options (EO) network, a collaborative practice-based research network whose goal was to develop abortion-training programs in family medicine residency programs, described in detail previously.[10,22] Sites were located in New York City and Philadelphia. Abortion care at the residency sites was provided by 1 to 2 faculty physicians who had completed training (described below) and a fully supervised resident physician-in-training. Care at the private practice was provided by faculty-in-training under the supervision of family physicians with extensive abortion experience. Communication among members of the network regarding specific cases (which included formal case review) was carried out through monthly meetings at the private office or faculty training site, as well as by telephone and e-mail. To assess clinical outcomes prospectively, we established a standardized case-monitoring procedure. Logs were completed by physicians for each step of the clinical process. Complications were recorded on standardized forms using predefined categories. All forms and data entry were reviewed and checked for miscoding. De-identified data were entered into a common electronic database by research assistants.

A 1-week follow-up visit was scheduled for patients receiving medication procedures. Women who did not attend the follow-up visit were contacted by telephone to reschedule. When the patient could not be contacted, a registered letter was sent to encourage follow-up. The follow-up rate was 91%. Follow-up for aspiration procedures was required only when a definitive intrauterine pregnancy was not identified (see clinical protocols below).

Physician Training

Physicians in the EO network had a range of clinical abortion experience. Before beginning at an EO site, all physicians completed 50 supervised aspiration abortion procedures at specialized abortion centers and completed an 8-hour ultrasonography-training workshop for first-trimester pregnancy dating at the University of Medicine and Dentistry of New Jersey. The subsequent EO training program included didactic and hands-on experiences. Training in ultrasonography included 8 additional hours of didactic lectures by a certified ultrasound trainer, the satisfactory completion of a written and oral examination, and supervised sonography for dating of 50 early pregnancies (less than 13 weeks' gestation). Together this training exceeds that used for staff carrying out sonograms at national organizations providing abortion care.[23] Abortion procedure training included a minimum of 10 hours of didactic lecture and a subsequent supervised satisfactory completion of 50 medication and 150 aspiration abortions. Abortion training for residents was delivered by faculty who had completed the EO faculty-training program.

Clinical Protocols

Patients were offered both medication or aspiration procedures through 63 days of estimated gestational age (EGA) and aspiration only from 64 to 84 days' EGA. Patients were counseled on the risks and benefits of each procedure and gave informed consent. The price of both abortion procedures was $350, which was comparable to the cost at specialty abortion sites in the region.

The medication protocol used in this study was that used for most medication abortion procedures in the United States.[24] Gestational age was determined for all patients by in-office transvaginal sonography. For medication abortions mifepristone (200 mg orally) was administered in the medical office; 24 to 72 hours later at home the patient applied misoprostol (800 µg vaginally).[25] The success of the procedure was determined at the required 1-week follow-up visit by history and repeat sonography.

Aspiration abortion using the manual vacuum aspiration technique followed standard practices: an Ipas

syringe and flexible cannula (Ipas, Chapel Hill, North Carolina) through 84 days' EGA. Rigid dilators were used after local anesthesia was provided through a paracervical block. Antibiotic prophylaxis (doxycycline, 200 mg orally, twice a day for 3 days) was provided to all patients. Uterine aspirates were examined for the presence of products of conception to verify successful removal of an intrauterine pregnancy.

If a definitive intrauterine pregnancy could not be determined by sonography (no yolk sac identified) and if no products of conception could be found on examination after the aspiration procedure, human chorionic gonadotropin (hCG) serum levels were assessed and monitored. An initial quantitative hCG level was measured at the time of the procedure and then repeated in 1 week. If the initial serum level was consistent with an early pregnancy (< 1,500-2,000 U/mL) and decreased by more than 50% during the course of the intervening week, then the abortion was determined to be complete. Any patient whose initial serum level was more than 2,000 U/mL or decreased less than 50% was referred for evaluation of possible ectopic pregnancy.

Statistical Analysis

Differences in continuous and categorical variables were assessed using the Student *t* test and χ^2 statistics as appropriate. Statistical significance of association was $P < .05$ for all analyses. Poisson regression methods were also used to estimate complication rates by the level of prior experience, adjusting for differences in numbers of procedures (experience) performed by each physician. In addition, time-to-event Kaplan-Meier analysis was used to assess whether less experience (fewer than 50 prior procedures) with either medication or aspiration procedures was associated with a shortened time to first complication. Statistical analysis was carried out using SPSS, version 11 and SAS version 9 (SAS Institute, Cary North Carolina), software.

RESULTS

As displayed in Table 1, 2,550 patients sought care during the course of the study period. Approximately 96% of patients received either medication or aspiration procedures (split nearly evenly between the 2), whereas less than 4% did not receive care because of contraindications. The demographic characteristics of the population were typical of women receiving abortion care: young, economically diverse, the majority with a history of previous pregnancy but without a history of previous induced abortion. The gestational age among patients receiving medication abortion was significantly less than those receiving aspiration abortion, reflecting the difference in upper limit of gestational age for the procedures (9 weeks vs 12 weeks).

Outcomes are illustrated in Table 2. There were 3 ectopic pregnancies (3 of 2,550 = 0.12%) and 1 molar pregnancy (1 of 2,550 = 0.04%) identified during assessment that were referred outside the family medi-

Table 1. Patient Characteristics

Characteristic	Medication (n = 1,309) No. (%)	Aspiration (n = 1,149[a]) No. (%)	Ineligible[b] (n = 92) No. (%)
Age, y[c]			
15-20	123 (43.6)	138 (48.9)	21 (7.5)
20-24	383 (54.5)	292 (41.5)	28 (4.0)
25-29	379 (53.8)	308 (43.8)	17 (2.4)
≥30	410 (50.0)	384 (46.9)	25 (3.1)
Payment[c]			
Cash	427 (47.7)	457 (51.1)	11 (1.2)
Private insurance	417 (52.9)	357 (45.2)	15 (1.9)
Medicaid	448 (57.0)	320 (40.7)	18 (2.3)
Other	3 (7.5)	5 (12.5)	32 (80)
Gravidity[d]			
1	326 (46.6)	321 (45.9)	53 (7.5)
2	274 (53.7)	231 (45.3)	5 (1.0)
≥3	707 (53.6)	593 (45.0)	18 (1.4)
Prior medication abortion[c]			
0	1,075 (49.1)	1,027 (46.9)	89 (4.0)
1	172 (62.6)	101 (36.7)	2 (0.7)
2	42 (76.4)	12 (21.8)	1 (1.8)
≥3	19 (67.9)	9 (32.1)	0 (0.0)
Prior aspiration abortion			
0	705 (50.5)	615 (44.0)	77 (5.5)
1	348 (51.8)	315 (46.9)	9 (1.3)
2	162 (54.7)	131 (44.3)	3 (1.0)
≥3	94 (51.1)	87 (47.3)	3 (1.6)
Estimated gestational age, wk			
<6	256 (61.8)	156 (37.7)	2 (0.5)
6-9	941 (53.7)	801 (45.7)	10 (0.6)
10-12	2 (2.9)	65 (92.8)	3 (4.3)
>12	0	10 (30.3)	23 (69.7)
Practice type			
Residency	348 (75.1)	97 (21.0)	18 (3.9)
Private office	961 (46.4)	1,052 (50.8)	58 (2.8)

[a] The number of procedures may not add to 1,149 because of missing data.
[b] Ineligible because of advanced gestational age, miscarriage, not pregnant, referred out, sonogram only, chose not to have an abortion.
[c] Significant difference between choice of aspiration or medication abortion ($P < .05$).
[d] Total pregnancies.

Table 2. Early Abortion Outcomes (Encountered vs Published Rates)

Outcome	No.	Rate	95% CI	Published Rates Per 100 Cases
Initial evaluation	2,550			
Diagnosed molar pregnancy	1	0.04	0.00-0.13	0.01-0.012[26,27]
Diagnosed ectopic pregnancy	3	0.12	0.00-0.13	0.03-0.33[28-30]
Medication abortion	1,309			
Successful, uncomplicated	1,263	96.49	95.49-96.99	92.0-98.0[31-34]
Adverse events and complications				
Continuing pregnancy[a,b]	19	1.45	0.80-1.78	0.39-4.5[16,17]
Incomplete abortion[a]	16	1.22	0.63-1.53	2.4-4.5[16,17]
Patient request for aspiration[a]	1	0.08	0.00-0.15	0.12-0.3[33,35]
Hemorrhage[a,c]	9	0.69	0.24-0.92	0.0-2.0[36]
Infection	0	0.00	–	0.09-0.5[36]
Missed ectopic pregnancy[d]	1	0.08	0.00-0.15	0.0-0.26[27,32,37]
Aspiration abortion	1,149			
Successful, uncomplicated	1,109	96.52	95.46-97.06	95.9-99.095[1,6,26,38-40]
Adverse events and complications (immediate)				
Unable to dilate cervix	10	0.87	0.27-1.04	NA
Hemorrhage[a]	4	0.35	0.01-0.52	0.007-0.8[1,26,38,40-42]
Perforation	0	0.00	–	0.0009-0.195[1,26]
Cervical injury	0	0.00	–	0.13-3.9[26,38,43,44]
Delayed complication (3 h to 21 d)				
Continuing pregnancy[a,b]	1	0.09	0.00-0.17	0.036-2.3[26,38,39]
Incomplete evacuation[*]	21	1.83	1.05-2.22	0.85-4.7[1,38,45]
Hematometra (postabortal syndrome)[a]	2	0.17	0.00-0.30	0.1-1.4[26,39,41,46]
Endometritis (received antibiotic treatment)	1	0.09	0.00-0.17	0.1-0.6[26,39]
Hemorrhage[a,c]	0	0.00	–	0.007-0.28[1,26]
Missed ectopic pregnancy[d]	3	0.26	0.00-0.41	0.00-0.3[26,28-30,38,39]

NA = Information not available.

[a] After aspiration (initial medication) or re-aspiration (initial aspiration), these patients had successful terminations without need for outside referral or hospitalization.

[b] Sonographic-documented progression of pregnancy.

[c] More than 250-cc blood loss (none required transfusion).

[d] Required hospitalization: published rates of hospitalization for medication abortion = 0.02-0.26,[25,31,47] and aspiration abortion = 0.0071-0.3.[1,29]

cine setting for management. Four ectopic pregnancies were missed in the initial assessments (0.16%). These patients' conditions were determined after completing abortion care. All were hospitalized and successfully treated without mortality.

Medication procedures had a 96.5% success rate. Of the procedures that failed (required subsequent aspiration), 19 patients (1.5%) had continuing pregnancies with interval growth; 16 patients (1.2%) were determined (after initiation of the procedure) to require aspiration because of incomplete abortion (products of conception or blood clots); 9 patients (0.84%) were determined to have uterine hemorrhage; and 1 (0.08%) aspiration was done at the patient's request. Aspiration procedures had a 99.1% success rate with 96.2% having no complications. The most common immediate complication was hemorrhage (4 cases, 0.35%), though no patients required emergency transfer for care and no transfusions were required. Ten patients (0.12%) could not be dilated and were then offered a medication abortion: 8 patients accepted this offer and were successful, and 2 patients chose not to continue with the procedure. Among complications occurring after the initial treatment in the office (delayed complications), the most common was incomplete aspiration (intrauterine products of conception or blood clots), with 21 cases comprising 1.83% of all aspiration abortion cases. There were no cases of late hemorrhage, and 1 patient had endometritis (0.08%) treated with re-aspiration of the uterus and outpatient oral antibiotics. One continuing pregnancy was identified (0.08%).

Of the 66 complications in this series, 8 patients were referred or went on their own to an emergency department for assessment: 4 for abdominal pain later identified as missed ectopic pregnancies; 3 for difficulties with medication abortions; and 1 who had received an aspiration abortion. One patient with complications from a medication abortion was referred to another family medicine practice within the EO network for care. No patients within this series required referral to a specialty obstetrics-gynecology outpatient practice. As shown in the last column of Table 2 the rates of occurrences of the outcomes identified fell within the range published from specialty abortion and obstetrics-gynecology sites.

There was no significant difference in the rates of complication by number of cases completed (experience) for the 96 unique physicians providing abortions represented in the sample or between the 2 types of practices (Table 3). The estimated rate of complications ratio, from a Poisson regression model of the number of complications, adjusting for each physician's total number of procedures performed (eg, an offset term) was 0.71 (95% CI, 0.43-1.15) indicating no statistical evidence of differential rates of complications for physicians with more experience relative to those

Table 3. Complication Rates of Abortion for Physicians by Previous Procedures Completed and Practice Type

Characteristic	Uncomplicated Procedures No. (%)	Complications No. (%)	χ^2 (df)	*P* Value
Physician experience				
Aspiration (n = 1,149)				
<50	420 (96.8)	14 (3.2)	0.946 (3)	.814
50-99	235 (95.9)	10 (4.2)		
100-999	266 (96.7)	9 (3.3)		
≥1,000	188 (96.4)	7 (3.6)		
Medication (n = 1,309)				
<50	704 (96.3)	27 (3.7)	2.337 (3)	.505
50-99	246 (98.0)	5 (2.0)		
100-999	290 (95.7)	13 (4.3)		
≥1,000	23 (95.8)	1 (4.2)		
Practice type				
Aspiration (n = 1,149)				
Residency	93 (95.9)	4 (4.1)	0.072 (1)	.782
Private office	1,012 (96.2)	40 (3.8)		
Medication (n = 1,309)				
Residency	336 (96.6)	12 (3.4)	0.006 (1)	.940
Private office	927 (96.5)	34 (3.5)		

df = degrees of freedom.

Note: Attribution of physician was determined based on the initial physician assignment and not to a supervising/training physician even if a supervisor intervened in the course of a procedure.

with less experience. In an additional Kaplan-Meier (survival) analysis included as Supplemental Figure 1, available online at http://www.annfammed.org/cgi/content/full/7/6/527/DC1, less-experienced physicians did not have shorter time to first complication than those with more experience (fewer than 50 procedures vs 50 or more procedures) for either medication or aspiration abortion. Among the 3 physician types the number of procedures completed varied as follows: private practitioner-trainer, mean = 265, SD 154 (n = 3); resident faculty, mean = 100, SD 52 (n = 12); resident, mean = 8, SD 15 (n = 81).

DISCUSSION

We assessed the outcomes of medication and aspiration abortion procedures among family physicians in 4 residency training programs and 1 private practice. The effectiveness of these procedures was high with 95.7% of medication abortions successful (not resulting in aspiration for any reason) and 99.05% of the aspiration abortions successful (no interval fetal growth). All but 2 of the medication and aspiration procedures on patients with normal pregnancies were successful within the family medicine setting. Less than 4% of either the medication or aspiration abortions had any related complications. Most complications for both procedures in the first trimester were minor and managed within these family medicine sites. The effectiveness and complication rates we observed were within those reported by specialty obstetrics-gynecology practices and research settings. The most serious adverse event observed was missed ectopic pregnancy for 1 patient who received a medication procedure and for 3 patients receiving aspiration procedures. We also found no evidence that the risk of complications was associated with abortion experience or practice setting.

The rates of undiagnosed ectopic pregnancy in patients treated with medication and aspiration in this study were within the range of rates reported a meta-analysis of medication abortion studies.[18,26,28-30,37-39] Given the severity of the potential outcomes of missed ectopic pregnancy, however, it is critical to identify factors that contributed to these missed cases and work to reduce the risk of this event. Of the 4 missed ectopic pregnancies, 1 was related to ultrasound findings mistakenly indicating an intrauterine pregnancy. Although it is theoretically possible that the original ultrasound interpretation was correct, and there was a simultaneous ectopic pregnancy (heterotopic pregnancy), this possibility is generally discounted because of its rarity.[48] Such an outcome reinforces the importance of high-quality training in ultrasound diagnosis of pregnancy and the need for care in the interpretation of ultrasound findings in early abortion care.

Of the 3 cases of missed ectopic pregnancy in which an hCG-monitoring protocol was indicated (no intrauterine pregnancy identified by initial ultrasound testing), 2 represented violations of the established protocol and 1 represented a failure of the protocol. Violations of protocol are indicative of the need for continuous quality improvement systems to monitor the quality of care delivery. The single case of protocol failure indicates that alternative protocols should be considered. Although some physicians choose to delay abortion care until a definitive intrauterine pregnancy can be seen, others suggest this step is unnecessary because the rate of missed ectopic pregnancies is low with current screening protocols, and delays in

care have their own negative outcomes for patients.[37] An alternative, widely used protocol that calls for a decrease of 80% from the initial hCG level by the time of the follow-up visit (rather than the 50% level used in this study) would have identified the ectopic pregnancy missed because of protocol failure.[49]

Though uncommon, the most frequent immediate complication of the aspiration procedure was the inability to dilate the cervix, which has not been described previously. The decision to desist in attempts at mechanical dilation is based on the judgment that risk of cervical injury is too great to continue.[48] Rates of injuries requiring repair of 1% or more of attempts have been documented among women in the first trimester.[39,40,43] No cervical injuries occurred in the current study, with more than 1,000 cases of aspiration procedures possibly reflecting the appropriate caution of the physicians.[18] An alternative approach to reduce the difficulty of mechanical cervical dilation is pretreatment with misoprostol.[18,43,48] This approach is an option for selected patients, including those for whom mechanical dilation failed.[18]

In contrast to previous studies, we found no evidence that either less-experienced physicians or the presence of physicians learning abortion techniques is associated with higher complication rates.[19,20,43] Our findings are important because they suggest that family physicians, following protocols and supervised by family medicine faculty who have completed training as described above, can safely learn and perform first-trimester abortions as part of family medicine outpatient care. Complications are also associated with less experience in settings that provide abortions after 12 weeks' gestation, which is beyond the limit of the present study and accounts for less than 10% of abortion care in the United States.[3,19]

There are several limitations to the current study. First, the study design was observational and subject to the biases inherent to the method. The chance of error and bias were reduced by prospective data collection using a standardized protocol. Second, even though the private practice where most abortions were carried out was a general family medicine practice, it cared for a high volume of patients receiving abortion care, and the capacity of support staff and supervising faculty may be greater than typical, limiting generalizability. There was not a significant difference in the rates of complications between the residency and the private practice, however, suggesting that any difference did not affect outcomes. Finally, the study protocol did not include a systematic follow-up of patients weeks after the clinical care was provided. It is possible that patients had late complications but did not notify the clinical sites where they received their abortion care, which would have resulted in an underestimation of negative outcomes. We believe several factors reduce the likelihood that late complications would significantly effect the outcome of the study. First, patients were provided with telephone numbers for 24-hour immediate return calls from their treating medical office, and they were strongly encouraged to call for any medical questions, concerns, or emergencies. Second, there was no cost for any follow-up care of complications. Third, health care clinicians treating major complications of abortion care would be likely to contact the physicians who conducted the abortion to get information on the clinical course.

In summary, we found that rates of complications of first-trimester abortion care in family medicine clinical sites were very low and within the range of outcomes published for obstetrics-gynecology and specialty abortion sites. With the exception of missed ectopic pregnancy, expected complications were managed by family physicians within the context of their practice without reliance on emergency services or those of specialists. Quality improvement systems and clinical protocols that reduce the risk of missed ectopic pregnancy are critical to early abortion care. This study validates the safety and efficacy of early abortion care by family physicians. Family physicians who provide abortion care promote continuity of care and the patient-centered medical home and may help to ameliorate abortion provider shortages across the United States.

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Submitted August 10, 2008; submitted, revised, March 10, 2009; accepted March 16, 2009.

Funding support: This work was funded by an anonymous foundation. The funding foundation had no role in the design and conduct of the study; in the collection, analysis, interpretation of the data; or in the preparation, review, or approval of the manuscript.

Portions of the work have been presented at the Society of Teachers of Family Medicine (STFM) meeting, Atlanta, Georgia, September 2003; and the National Abortion Federation 2003 Conference, April 2003.

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