

Instituting Medical Abortion Services: Changes in Outcome and Acceptability Related to Provider Experience

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A prospective case series carried out at 34 Planned Parenthood sites studied the safety, efficacy, and acceptability of medical abortion with methotrexate and misoprostol in 1973 women. Women with pregnancies of 26 to 49 gestational days were given methotrexate followed by vaginal misoprostol. Eighty-one percent of women had documented complete medical abortions; abortion was not confirmed by examination in 6%, and 13% had documented suction curettage. The rate of suction curettage decreased with site experience, from 17% during the first 20 procedures to 10% at sites that had performed more than 50. Sites that had previous experience with either methotrexate or mifepristone medical abortion had a rate of 9% after they had performed at least 50 procedures. Exit interviews with 755 of the 902 women having abortions in the first year inquired about the level of comfort with the abortion and its overall acceptability. Women's satisfaction with the side effects did not directly correlate with site experience. Overall satisfaction with the abortion experience was related to whether the women had complete medical abortions or suction curettage. (JAMWA. 2000;55:173-176)

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Medical abortion may be more acceptable than surgical abortion to many women; in some studies as many as 70% of women indicated that they would prefer a medical abortion if it were available.^{1,2} Twenty-six percent of eligible women in a North American study actually chose medical abortion with methotrexate and misoprostol when it was offered.³

The combination of methotrexate and misoprostol has been shown to be safe and effective in several case series performed in academic research settings and well-established private practices.⁴⁻⁷ We designed a case series of early medical abortion using methotrexate and misoprostol to evaluate the feasibility of medical abortion services in a heterogeneous group of sites with a heterogeneous clientele. We were also interested in evaluating the acceptability of medical abortion to patients and staff and in assessing the changes in practice as sites gained experience.

Methods

Planned Parenthood affiliates providing abortion services were asked to participate in a study of medical abortion using methotrexate and misoprostol. Planned Parenthood provides approximately 12% of abortion services in the United States, and its clientele and clinician background, training, and prior research experience are varied. Sites were required to have vaginal ultrasound capability and at least two physicians as investigator or sub-investigator to provide 24-hour backup. The study imposed no additional restrictions on the role of advanced practice clinicians beyond those required by law. The study was approved by Independent Review Consultants, Inc, an independent institutional review board.

Women with pregnancies of no more than 49 days' gestation were eligible to enroll. Vaginal ultrasound was required. The fetal embryonic pole, if present, was

used to determine gestational age;⁸ otherwise the gestational sac diameter was used.⁹ Women with embryonic poles longer than 10 mm could not enroll. A gestational sac was not required for enrollment, but if a sac was not present, a serum β -HCG was done. If the β -HCG was less than 2000 mIU/ml, and the woman did not have symptoms suggestive of ectopic pregnancy, she could enroll.

Women with hematocrits of less than 30% were excluded. Rh-negative women received mini-dose Rh immune globulin on the day of methotrexate administration.

Women under 18 years old needed parental consent to enroll, even in states where abortion itself did not require parental consent.

Women were generally charged the same fee they would pay for an equivalent surgical abortion, and sites were not permitted to charge more than that. No financial incentives or compensation was offered to women or to sites.

Women received 50 mg/m² methotrexate IM. Eight 200 μ g misoprostol tablets were dispensed, four of which were inserted four to six days later at home. If the woman felt that the abortion was not complete after 24 to 48 hours, she inserted the second dose of misoprostol. Some affiliates routinely called women after the first scheduled dose, and others encouraged a visit after the first dose. Affiliates were not discouraged from adding extra visits or telephone calls.

A return visit by day 14 to 16 was required. If a complete abortion was confirmed by ultrasound, another visit was not required. Women with viable pregnancies at day 14 to 16 were advised to have surgical abortions. If the ultrasound showed a nonviable pregnancy, the woman was instructed to return by day 27 to 29. If a gestational sac was still present at day 27 to 29, the woman was advised to have a surgical abortion.

The study lasted 21 months. The

Table 1. Characteristics of Women Receiving Medical Abortion at Planned Parenthood Sites, 1996-1998, n (%)

Age	
<18	17 (1)
18-19	115 (6)
20-24	535 (27)
25-29	583 (29)
30-34	408 (21)
35-39	230 (12)
≥ 40	83 (4)
Not stated	2
Parity	
Never pregnant	529 (27)
Prior abortion (induced or spontaneous)	501 (25)
Prior birth	943 (48)
Ethnic group	
White	1433 (73)
Hispanic	151 (8)
African American	241 (12)
Native American	12 (0.6)
Asian	104 (5)
Other or not stated	32 (2)
Education	
< 8 th grade	6 (0.3)
Some high school	92 (5)
Completed high school	409 (21)
Some college	739 (38)
Completed college	662 (34)
Not stated	65 (3)
Public assistance	
Yes	214 (11)
No	1755 (88)
Not stated	4 (0.2)
Gestational age (days)	
<30	24 (1)
30-34	139 (7)
35-39	517 (26)
40-44	712 (36)
45-49	564 (29)
>49	12 (0.6)
Not stated	5 (0.3)

Percents may not total 100 due to rounding.

study staff administered exit interviews by telephone or in person during the first ten months, after which they were discontinued for financial reasons.

The exit interview asked women to rate their degree of physical and emotional comfort with various aspects of the procedure on a 5-point Likert

Table 2. Rates of Suction Curettage According to Site Enrollment and Experience, n (%)

	Early Experience (1-20)*	Intermediate Experience (21-50)*	Experienced (>50)*	P Values
Affiliates that enrolled ≤50 women; no prior experience with methotrexate	189 (15)	102 (16)	...	ns
Affiliates that enrolled >50 women; no prior experience with methotrexate	206 (17)	266 (13)	247 (14)	0.005
Affiliates that had prior experience with mifepristone, but not methotrexate	138 (20)	175 (12)	275 (9)	0.002
Staff had experience with methotrexate	20 (10)	30 (7)	326 (9)	ns
Overall	553 (17)	572 (13) [†]	848 (10) [†]	0.001

*Number of procedures performed.

[†]Significant decrease in rate of SC by prior site experience ($p < 0.003$, χ^2 , corrected for multiple comparisons).

scale from strongly disagree (1) to strongly agree (5).

Possible outcomes included documented complete medical abortion, loss to follow-up, and suction curettage; these will be described in detail elsewhere.

The distribution of responses to the exit interview was examined with ANOVA and chi-square tests (SAS, Cary, NC) where appropriate.

Results

Thirty-one Planned Parenthood affiliates at 34 sites participated in the study from October 1996 to July 1998, during which time 1973 women had 2005 abortions. The general analysis was limited to the first methotrexate abortion for each of the 1973 women. Characteristics of study women are shown in Table 1.

All but two of the women without documented outcomes who were contacted by telephone (n=63) said they were fine. The two exceptions were one woman who had had a curettage for postabortion bleeding and another who withdrew from the study. Several other women were seen after the study ended and reported uneventful medical abortions. It is unlikely that many women would seek curettage elsewhere, because

they could have it performed at Planned Parenthood without additional charge.

The outcomes were thus combined into two categories: known or probable complete medical abortion (CMA, n=1715) and suction curettage (SC, n=257). One woman had an ectopic pregnancy. Overall rates were 87% for CMA and 13% for SC. Most curettage (9%) was done because of patient request, but 3% had SC because of protocol requirements, and 1% were advised to have SC by their physicians.

Most principal investigators were obstetrician/gynecologists, but some were certified in family practice, pediatrics, or preventive medicine. Principal investigator specialty had no effect on rates of suction curettage.

The number and percentage of methotrexate abortions at individual sites ranged from 1 to 376, and from negligible to about 10% of all abortion procedures.

Seven sites had prior experience with mifepristone and misoprostol medical abortion. The principal investigator at one site had extensive previous experience with methotrexate and misoprostol abortion, and the overall SC rate at that site was 9%. Sites with prior experience with

Table 3. Acceptability of Aspects of Medical Abortion According to Level of Site Experience, Mean Score*

	Early Experience (1-20) [†]	Intermediate Experience (21-50) [†]	Experienced (>50) [†]
The cramping was acceptable	3.88	3.93	4.18
The bleeding was acceptable	4.09	4.16	3.85
The side effects were acceptable	4.17	4.25	4.09
I was afraid or worried to be at home during part of the abortion	2.18	2.17	2.14
This seemed too experimental	1.95	1.90	1.92
There were too many visits to the center	2.16	2.03	1.76
It would be an improvement if the shot (methotrexate injection) were replaced by pills	2.93	2.98	2.58
It would be an improvement if the pills that were put in the vagina (vaginal misoprostol) were replaced with pills that were swallowed	3.42	3.42	3.21

*Items were rated from 1 (strongly disagree) to 5 (strongly agree).

[†]Number of procedures performed.

ANOVA by row; p>0.05.

either methotrexate or misoprostol had significantly lower SC rates (p<0.01). Amount of site experience and SC rates were compared (Table 2). Abortion experience for each site was classified as early (the first 20 procedures), intermediate (the next 30), and experienced (more than 50). The rate of SC fell as sites gained experience (p<0.01).

Exit interviews were conducted with 755 of 902 women during the first half of the study. Fifty-seven women did not return for follow-up, and interviews were sometimes overlooked or refused. Because most sites did not reach “experienced” status until late in the first year or the second year, only 171 women completed exit interviews at experienced sites during the first ten months.

The responses to several items about acceptability of methotrexate abortion are shown in Table 3. There were no significant differences in ratings by level of site experience.

Although site experience did not have a significant effect on individual items, it appeared to affect overall acceptability (Table 4). The effect disappeared when data were analyzed by outcome, however. Women who had documented or pre-

sumed successful outcomes had uniformly good opinions of the process. Whether at early, intermediate, or experienced sites, only 3% disagreed with the statement, “Overall, the procedure went well.” Satisfaction was much lower for women who had SC, 32% of whom disagreed that the procedure went well. As the SC rate went down with experience, overall satisfaction increased.

Discussion

We found that rates of CMA increased and rates of SC decreased as sites gained

experience; in other words, there is a learning curve. The site with extensive staff experience with methotrexate abortion had the lowest (9%) SC rate overall. That particular site was in an urban setting with a diverse population, so it is unlikely that patient characteristics had a positive influence on outcome.

Previous experience with mifepristone abortion appeared to have a beneficial effect on outcome for all sites but one. Because of differences in regimens such as home use of misoprostol and the more prolonged course of methotrexate, we were not surprised that mifepristone experience provided a relatively modest gain. The mifepristone-experienced affiliates actually had the same or higher SC rate as inexperienced sites during the early phase, but it dropped to 12% during the intermediate phase and 9% with experience. These sites apparently learned more quickly. In the intermediate stage, sites with mifepristone experience had an SC rate of 12%, compared to 15% for sites without experience. While this was an observational study and no hypotheses were defined in advance, the difference between these rates is likely to be significant (uncorrected p<0.01).

We were concerned that women would not be able to carry out the procedures, and that medical abortion might not be suitable for Planned Parenthood patients. Patient self-selection and selection by staff probably affected the sample. Ninety-five percent of women had completed high school, and a third had completed college. There were very few women under 18, possibly because of the parental consent requirement.

Table 4. Overall Acceptability of Medical Abortion According to Site Experience and Abortion Outcome, Mean Score (n)

	Early Experience (1-20)*	Intermediate Experience (21-50)*	Experienced (>50)*
Overall, the procedure went very well	4.13 (369)	4.35 (273)	4.21 (215)
Overall acceptability complete medical abortion	4.41 (306)	4.45 (192)	4.41 (156)
Overall acceptability suction curettage	2.59 (58)	3.27 (22)	2.35 (17)

*Number of procedures performed.

We were also concerned that sites that had never participated in research studies would have difficulty with the protocol. However, the protocol was followed quite well by virtually all sites. Small errors in the timing of misoprostol administration and gestational age had no effect on outcomes. Therefore, it is unlikely that the difference in medical outcome with experience is due to medical factors or errors.

Finally, we were concerned that lack of provider familiarity with medical abortion would lead to a more anxious and, ultimately, less successful experience for the patient. Patients of inexperienced providers did not report more anxiety about the abortion process or more complaints about side effects.

Patients were very satisfied with the procedure overall, but satisfaction was clearly related to outcome. Women who did not have CMAs were much less satisfied, and the percentage of women having CMAs increased with experience.

We were surprised to find that few women objected to the methotrexate injection. We were also unprepared for the frequency of complaints about vaginal misoprostol. Women were more dissatisfied with the vaginal administration than with any other aspect of methotrexate abortion. The option of oral or buccal misoprostol may deserve further study.

Thirty of the 34 sites that participated in the study chose to continue the service. Three of the 4 sites that did not continue were unable to do so because of staff changes, and 4 more sites have since started medical abortion services. The continuation and expansion of services is an indirect indicator of acceptability to staff and patients.

Mifepristone may be approved in the United States within the year, and we anticipate that experience with methotrexate abortion will accelerate the learning process with mifepristone.

Our experience is similar to that of others who have found that methotrexate and misoprostol provide an efficient and highly acceptable method of early abortion. Methotrexate can be offered to heterogeneous groups of women with appropriate selection criteria and can be offered in a community setting. Satisfaction ratings are high even at the initia-

tion of services. Rates of SC decrease with experience, and global satisfaction increases. Therefore, we feel that providers first starting medical abortion services can expect that, although their outcomes will improve with experience, women will still be highly satisfied while this process occurs. ■

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