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Comparison of medical abortion follow-up with serum human chorionic gonadotropin testing and in-office assessment^{☆,☆☆,★,★★}

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Abstract

Background: The study was conducted to compare lost to follow-up (LTFU) rates in women having a medical abortion who chose follow-up by in-office ultrasound assessment or serum beta human chorionic gonadotropin (β-hCG) testing.
Methods: This retrospective chart review included 865 women who underwent medical abortion in a free-standing outpatient clinic from September 1, 2007, through September 30, 2010. Patients had a 1-week follow-up evaluation after receiving the medications consisting of in-office ultrasound assessment or serial serum β-hCG testing. Ultrasound assessment was offered throughout the study period, and serum β-hCG testing was offered as of September 1, 2008. Demographic and medical data were reviewed to evaluate LTFU rates based on patient's chosen method of follow-up. Multivariable logistic regression analysis was performed to evaluate factors that were independently associated with lack of follow-up.
Results: LTFU rates increased from 18% to 27% in the first and third years of the study period, respectively (p=.009). LTFU rates with ultrasound and β-hCG testing were 22.9% and 33.7%, respectively (p=.024). In multivariable analysis, follow-up method was not associated with increased LTFU. Increased parity, any previous induced abortion, increased distance from home to clinic site and unemployment were independently associated with increased LTFU.
Conclusions: Although LTFU rates are higher with serum β-hCG testing than in-office ultrasound follow-up in our patient population, the women who choose this method are inherently more likely not to follow-up because of other characteristics that predict a high likelihood of being LTFU. Offering serum β-hCG testing does not decrease the LTFU rate in women having a medical abortion.
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Keywords: Medical abortion; Follow-up; Ultrasound; β-Human chorionic gonadotropin

1. Introduction

Medical abortion accounts for approximately one quarter of all abortions before 9 weeks' gestation and 17% of all abortions performed in the United States based on 2008 data [1]. Whereas follow-up after surgical abortion is unnecessary to assess for treatment success, medical abortion requires follow-up to evaluate for expulsion and diagnose and treat

any complications [2]. In the United States, follow-up commonly consists of in-clinic transvaginal ultrasound examination 1 week after treatment [3]. Investigators have attempted to find more convenient and less expensive means of follow-up than an in-office visit, including urine pregnancy testing [4] and telephone follow-up [5]. A single study found that a decline in serum beta human chorionic gonadotropin (β-hCG) concentrations of at least 80% over 6 to 7 days after initiating treatment with mifepristone and misoprostol was indicative of a successful abortion [6]. Based on this data, Planned Parenthood Federation of America (PPFA), the largest provider of sexual and reproductive health services in the United States, instituted a protocol change for its clinics in 2008 [7]. The change allowed women having a medical abortion to choose to have a serum β-hCG level drawn at the time of mifepristone administration with follow-up via remote-site serum β-hCG testing approximately 1 week later.

This policy change had the potential to make medical abortion follow-up more accessible and improve lost to follow-up (LTFU) rates which have been reported to be as high as 45% in clinical settings [8]. Although studies have documented patient preference of medical abortion method [9,10], none have evaluated compliance with different follow-up options. The aim of this retrospective chart review was to describe the LTFU rate after medical abortion at Planned Parenthood of Western Pennsylvania (PPWP) and to compare rates between patients that chose in-office ultrasound or serum β-hCG evaluation.

2. Materials and methods

This retrospective chart review included 865 women who had a medical abortion at PPWP from September 1, 2007, through September 30, 2010. PPWP maintains a medication distribution record which was used to identify women who received mifepristone and misoprostol for medical abortion during the study period. The University of Pittsburgh Institutional Review Board and the PPFA research department both approved the study.

Standard clinic protocols were followed for medical abortion with mifepristone and misoprostol, with the day of mifepristone treatment considered day 1. Patients were to have follow-up approximately 1 week after starting the treatment. Prior to September 1, 2008, follow-up consisted of an appointment at the clinic during which a transvaginal ultrasound examination was performed to evaluate for pregnancy expulsion. Beginning on September 1, 2008, patients could choose to return for the ultrasound examination or have a serum β-hCG level drawn at the clinic that day and repeated in approximately 1 week. Because PPWP uses Quest Diagnostics laboratories, the patient was instructed to obtain her second β-hCG level at the clinic or at any Quest Diagnostics site close to her. The clinic staff helped her locate that lab at the time she received the medications. The clinic procedure for women who did not follow up was

to call the patient 1 day after a missed ultrasound appointment or on day 9 if the patient was to have serum β-hCG drawn and no results were available. Letters were mailed to the patient if there was no follow-up by days 15 and 22. For this study, LTFU was defined as failure to return to the clinic for an ultrasound examination or to have serum β-hCG levels drawn at a remote site and the results received by PPWP. Patients for whom PPWP had a record of emergency department visit with ultrasound were considered to have followed up.

Charts were reviewed, and pertinent information was abstracted to a standardized data extraction form. Information abstracted included choice of follow-up, time to follow-up, number of clinic phone calls and letters follow-up with patients, number of problem calls to PPWP emergency hotline and reason for calls, and demographic information including age, gestational age determined by ultrasound, gravidity, parity, number of previous therapeutic abortions and spontaneous abortions, intended method of contraception after abortion, history of smoking or alcohol use, self-reported emotional problems, body mass index, marital status, race, income, household size, ethnicity, employment and/or student status and payment method. The clinic had philanthropic funds available to supplement, depending on income level, up to 30% of an individual's cash payment for women without insurance. Data were deidentified and entered into a database by a single investigator (E.L.H.).

All statistical analyses were performed with Stata statistical software (release 11.2; Stata Corp., College Station, TX, USA), and statistical tests were evaluated at the two-sided .05 significance level. The proportion of women that were LTFU was the primary outcome. Fisher's Exact Test and Student's t tests were used, where appropriate, to assess differences in patient characteristics by LTFU status, date of treatment (September 1, 2007, through August 31, 2008, and September 1, 2008, through September 30, 2010) and follow-up method (ultrasound or serum β-hCG evaluation). The data were divided into three time periods; September 1, 2007, to August 31, 2008; September 1, 2008, to August 31, 2009; and September 1, 2009, to September 30, 2010. The χ^2 test for linear trend was used to determine whether LTFU increased over time. Multivariable logistic regression was performed to determine which patient characteristics were independently associated with being LTFU. For the regression model, variables with an unadjusted p value of .20 or less were considered for inclusion. Follow-up method was included in the final regression model regardless of statistical significance. Models were developed using forward regression, and variables were retained in the model if the p value from the Wald χ^2 test statistic was .05 or less.

3. Results

Of the 856 women in the analysis, 157 (18%) received medical abortions in the year prior to the option of serum

Table 1
Characteristics of patients by date of treatment and follow-up method [n (%) unless otherwise specified]

Characteristics	Dates of treatment[a]		p Value	Follow-up method		p Value
	September 2007–August 2008 (n=157)	September 2008–September 2010 (n=708)		In-office ultrasound (n=616)	Serum β-hCG (n=92)	
Age (mean, SD)	25.4 (6.1)	24.5 (5.6)	.07	24.1 (5.3)	27.5 (6.8)	<.001
Race/ethnicity			.94			.06
American Indian	0 (0)	2 (0.3)		2 (0.3)	0 (0)	
Black/African American	25 (15.9)	119 (16.8)		113 (18.3)	6 (6.5)	
White	120 (76.4)	538 (76.0)		458 (74.4)	80 (87.0)	
Asian	3 (1.9)	18 (2.5)		16 (2.6)	2 (2.2)	
Multiple	6 (3.8)	20 (2.8)		17 (2.8)	3 (3.3)	
Unknown/other	3 (1.9)	11 (1.6)		10 (1.6)	1 (1.1)	
Gestational age (mean, SD)	45.3 (5.5)	47.4 (7.0)	<.001	47.5 (7.0)	46.5 (7.1)	.18
Gravidity			.59			.001
1	67 (42.7)	331 (46.8)		304 (49.4)	27 (29.4)	
2	32 (20.4)	143 (20.2)		121 (19.6)	22 (23.9)	
3 or more	58 (36.9)	234 (33.1)		191 (31.0)	43 (46.7)	
Parity			.008			<.001
0	87 (55.4)	456 (64.4)		414 (67.2)	42 (45.7)	
1	32 (20.4)	118 (16.7)		99 (16.0)	19 (20.7)	
2	26 (16.6)	59 (8.3)		45 (7.3)	14 (15.2)	
3 or more	12 (7.6)	75 (10.6)		58 (9.4)	17 (18.5)	
Prior SAB			.27			.25
0	145 (92.4)	635 (89.7)		556 (90.3)	79 (85.9)	
1	8 (5.1)	60 (8.5)		50 (8.1)	10 (10.9)	
2	3 (1.9)	6 (0.9)		5 (0.8)	1 (1.0)	
3 or more	1 (0.6)	7 (1.0)		5 (0.8)	2 (2.1)	
Prior TAB			.26			.60
0	107 (68.2)	496 (70.1)		436 (70.8)	60 (65.2)	
1	31 (19.8)	155 (21.9)		131 (21.3)	24 (26.1)	
2	11 (7.0)	40 (5.7)		35 (5.7)	5 (5.4)	
3 or more	8 (5.1)	17 (2.4)		14 (2.3)	3 (3.3)	
BMI (mean, SD)[b]	25.6 (5.8)	25.3 (5.4)	.53	25.2 (5.4)	25.9 (5.0)	.24
Self-described medical problems	72 (45.9)	372 (52.5)	.13	318 (51.6)	54 (58.7)	.22
Smoker[b]	63 (40.1)	285 (40.7)	.93	247 (40.5)	38 (41.8)	.82
Alcohol[b]	39 (24.8)	202 (28.7)	.38	171 (27.9)	31 (34.1)	.22
Self-described emotional problems[b]	46 (29.3)	247 (34.9)	.19	224 (36.4)	23 (25.3)	.04
Planned contraception			.43			<.001
None	29 (18.5)	121 (17.1)		82 (13.3)	39 (42.4)	
Self administered	119 (75.8)	524 (74.0)		485 (78.7)	39 (42.4)	
Provider administered	9 (5.8)	63 (8.9)		49 (8.0)	14 (15.2)	
Education			<.001			.001
Full-time student	12 (7.6)	215 (30.4)		201 (32.6)	14 (15.2)	
Part-time student	5 (3.2)	46 (6.5)		42 (6.8)	4 (4.4)	
Not a student	20 (12.7)	230 (32.5)		197 (32.0)	33 (35.9)	
Data missing	120 (76.4)	217 (30.7)		176 (28.6)	41 (44.6)	
Employment			<.001			.01
Full time	13 (8.3)	186 (26.3)		152 (24.7)	34 (37.0)	
Part time	29 (18.5)	191 (27.0)		176 (28.6)	15 (16.3)	
Unemployed	115 (73.2)	331 (46.8)		288 (46.7)	43 (46.7)	
Payment method			<.001			.001
Cash	100 (63.7)	317 (44.8)		275 (44.6)	42 (45.7)	
Cash & clinic philanthropic funds[c]	41 (26.1)	299 (42.2)		272 (44.2)	27 (29.4)	
Insurance	16 (10.2)	92 (13.0)		69 (11.2)	23 (25.0)	
Distance from home to clinic (miles)			.56			<.001
0–10	66 (42.0)	331 (46.8)		306 (49.7)	25 (27.2)	

Table 1 (continued)

Characteristics	Dates of treatment[a]		p Value	Follow-up method		p Value
	September 2007–August 2008 (*n*=157)	September 2008–September 2010 (*n*=708)		In-office ultrasound (*n*=616)	Serum β-hCG (*n*=92)	
10.1–30	47 (29.9)	193 (27.3)		161 (26.1)	32 (34.8)	
30.1 or more	44 (28.0)	184 (26.0)		149 (24.2)	35 (38.0)	

BMI, body mass index; SAB, spontaneous abortion; TAB, therapeutic abortion.

[a] Patients treated before September 2008 could only have ultrasound follow-up; patients treated from September 2008 to September 2010 could choose ultrasound or serum β-hCG follow-up.

[b] Missing data; *n* used for noted categories as follows: BMI (2007–2008=156; 2008–2010=706; ultrasound=614; β-hCG=92); smoker (2007–2008=157; 2008–2010=701; ultrasound=610; β-hCG=91); alcohol (2007–2008=157; 2008–2010=705; ultrasound=614; β-hCG=91); self-described emotional problems (2007–2008=157; 2008–2010=707; ultrasound=616; β-hCG=91).

[c] The clinic had philanthropic funds available to supplement, depending on income level, up to 30% of an individual's cash payment for women without insurance.

hCG follow-up, and 708 (82%) received medical abortions between September 2008 and 2010. Patient demographics and reproductive health history prior to and after September 2008 are presented in Table 1. LTFU increased from 18% between September 2007 and August 2008 to 27% between September 2009 and September 2010 (p=.009). All (100%) LTFU patients had phone and/or letter contacts attempted. Subjects required more telephone or letter contacts to encourage follow-up in the latter study period, but the number of subjects who called because of concerns or problems with the abortion was not different (Table 2).

Of the 708 women treated between September 1, 2008, and September 30, 2010, 616 (87%) chose ultrasound follow-up, and 92 (12%) patients chose serum β-hCG testing. LTFU rates with ultrasound and β-hCG testing were 22.9% and 33.7%, respectively (p=.024). In multivariable analysis (Table 3), the follow-up method was not associated with an increased likelihood of LTFU (odds ratio 1.29, 95% confidence interval 0.77–2.18). Risk factors that were independently associated with LTFU were living at least 10 miles from the clinic, prior pregnancy, unemployment and a history of induced abortion.

4. Discussion

Medical abortion follow-up using quantitative β-hCG testing was introduced to the Planned Parenthood medical abortion protocol to allow women to opt for a follow-up method that could be considered easier for patients and increase compliance. In our study, patients who chose serum β-hCG testing had lower follow-up rates than patients who chose to return to the clinic for ultrasound evaluation. Because women could choose their follow-up method, the groups are not equivalent. In multivariable analysis, type of follow-up method was not associated with likelihood of follow-up. There are two possible interpretations. First, collinearity could be present, meaning that choosing serum

Table 2

Contacts because of lack of follow-up or abortion-related issues after medical abortion (*n*, %)

	Dates of treatment[a]		p Value	Follow-up method		p Value
	September 2007–August 2008 (*n*=157)	September 2008–September 2010 (*n*=708)		In-office ultrasound (*n*=616)	Serum β-hCG (*n*=92)	
Women needing contact because of lack of follow-up			.05			<.001
One telephone call only	12 (7.6)	39 (5.5)		32 (5.2)	7 (7.6)	
More than one telephone call and/or call plus letter[b]	27 (17.2)	190 (26.8)		156 (25.3)	34 (37.0)	
Only sent letter	0 (0.0)	4 (0.5)		1 (0.2)	3 (3.3)	
No contact required	118 (75.2))	475 (67.1)		427 (69.3)	48 (52.2)	
Women calling because of concerns or problems with the abortion	40 (25.5)	148 (20.9)	.24	130 (21.1)	18 (19.6)	.79

[a] Patients treated before September 2008 could only have ultrasound follow-up; patients treated from September 2008 to September 2010 could choose ultrasound or serum β-hCG follow-up.

[b] Patients who did not follow up at approximately 1 week after initiating treatment were to receive one telephone call and up to two letters; letters were mailed if the patient did not follow up by approximately 2 and 3 weeks after treatment.

Table 3
Factors associated with LTFU

Characteristics	n	Unadjusted OR (95% CI)	Adjusted[a] OR (95% CI)
Parity			
0	456	Reference	Reference
1	118	2.03 (1.28–3.22)	1.83 (1.10–3.03)
2 or more	134	3.22 (2.12–4.90)	3.37 (1.99–5.69)
History of induced abortion	212	2.25 (1.57–3.22)	2.39 (1.60–3.56)
Smoker	285	1.71 (1.21–2.42)	1.46 (1.00–2.13)
Employment			
Unemployed	331	Reference	Reference
Full or part time	377	0.58 (0.41–0.82)	0.67 (0.46–0.98)
Follow-up method			
Ultrasound	616	Reference	Reference
Serum hCG	92	1.71 (1.07–2.74)	1.29 (0.77–2.18)
Distance from home to clinic (miles)			
0–10	331	Reference	Reference
10.1–30	193	1.67 (1.08–2.58)	1.65 (1.04–2.63)
30.1 or more	184	2.81 (1.86–4.26)	2.99 (1.91–4.69)

OR, odds ratio; CI, confidence interval.

[a] Models were adjusted for age and all variables in table.

β-hCG testing for follow-up may be perceived as less cumbersome by patients and some social factors such as unemployment and distance from home to clinic may predispose patients to choose methods of follow-up perceived as more convenient. Alternatively, it is not the follow-up method chosen but the characteristics of the women that truly determined the risk of failure to follow-up. Women who chose serum β-hCG testing had more prior pregnancies, and these women were more likely to not comply with the follow-up method they chose. Either way, the conclusion is primarily the same, which is that social factors, regardless of the reason why, are more predictive of LTFU than method chosen.

Our LTFU rates with both ultrasound (22.9%) and β-hCG testing (33.7%) are higher than those most commonly reported in the medical abortion literature. The LTFU rates increased over time, although the number of subjects calling with abortion-related problems did not increase, indicating that women who did not follow-up with the clinic were likely not women experiencing problems with the abortion process. However, patients with complications could have gone to other clinics, their own doctor or an emergency room without contacting PPWP. Although we could not contact all other sites where patients might have gone with complications, it is unlikely that the number of complications increased over time along with the LTFU rates. Information on LTFU rates in medical abortion literature are derived from clinical trials and are highly variable due to differences in medication administration protocol, follow-up methods and timing, patient population and laws, as well as whether the data were collected prospectively or retrospectively. Most clinical trials report LTFU rates below 5% [6,11–19].

One report of medical abortion in a nonresearch university outpatient setting similarly found an LTFU rate of 2.3% [20]. In contrast, a retrospective chart review of 377 patients who had medical abortion in an ambulatory care unit of a university hospital in Israel showed an LTFU rate of 45% [8]. These differences are large with potentially obvious explanations. Women who receive medical abortion care in a clinic setting with a proven regimen are likely different than women who enroll in studies to test new regimens or are seen in a private-practice-type setting. Because most abortions in the United States are provided in a free-standing clinic setting [1], we feel that the 23% to 37% LTFU rates that we report more likely reflect the reality of clinical practice in the United States.

Interestingly, studies of patient's self-evaluation of outcome have demonstrated that women and providers can be highly accurate based on history alone and that in-person follow-up is likely not necessary for all women. Rossi et al. [21] examined physicians' and patients' comfort in evaluating expulsion of pregnancy without ultrasonography after medical abortion in multiple centers. The authors found that physicians and patients can predict expulsion with high sensitivity and positive predictive value. Based on these findings, a prospective feasibility study of telephone follow-up after medical abortion was performed with 139 women [5]. The investigators confirmed a working telephone before medication administration and had 100% follow-up at 1 week. Over the course of 4 weeks of extended follow-up, only four women (2.9%) were LTFU. The study found similarly high sensitivity and positive predictive values for patient and clinician prediction of pregnancy expulsion. Because ultrasound and serum β-hCG testing both require the patient to travel to the clinic or a local lab, it appears that the need to go somewhere may be the primary factor that incurs LTFU risk. Telephone follow-up presents a potential alternative that should also be explored in the same manner as we have done here.

Because the analysis was retrospective, we did not have accurate data on whether or not prior elective abortions were medical or surgical, which could also influence the primary outcome. Despite the limitations of a retrospective evaluation, this study does represent real-life experience. Our results suggest that LTFU is much higher in free-standing clinics than would be most ideal. It is important to closely follow the local LTFU rate when changing policies, such as what we have done here. Alternative follow-up methods that still require all patients to go somewhere for an evaluation do not appear to improve LTFU rates. Although we found that LTFU rates are higher with serum β-hCG testing than in-office ultrasound follow-up in our patient population, the women who choose serum testing were inherently more likely not to follow up because of other characteristics that predict a high likelihood of being LTFU. Offering serum β-hCG testing does not decrease the LTFU rate in women having a medical abortion.

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