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Effect of "observed start" vs. traditional "Sunday start" on hormonal contraceptive continuation rates after medical abortion

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Abstract

Objective: This study was conducted to determine whether early initiation of combined hormonal contraception under direct clinical observation following successful medical abortion increases continuation rates with the method compared to traditional "Sunday start."
Study Design: Women enrolled in a multicenter medical abortion trial with mifepristone and misoprostol who requested combined hormonal contraception (pill, ring or patch) following medical abortion were recruited. Women were randomized to initiate the method under supervision either at the 1-week medical abortion follow-up visit ("observed start") or at the first Sunday following this visit ("Sunday start"). Primary outcome was continuation of the chosen method at 6 weeks.
Results: Of the 1128 women in the primary trial, 261 subjects enrolled in this substudy and 36/261 (13.8%) were lost to follow-up. There was no significant difference in method continuation at 6 weeks [observed start 108/114 (94.7%), Sunday start 101/111 (91.0%, p=.27].
Conclusion: Short-term continuation rates among those choosing hormonal contraception following medical abortion are high and are not significantly improved by initiating the method at the time of the first follow-up visit.

Keywords: Medical abortion; Combined hormonal contraception; Contraceptive initiation; Contraceptive continuation

1. Introduction

Failure of patients to begin any medication after receiving a prescription is widespread, and hormonal contraception is subject to similar adherence issues [1,2]. Moreover, instructions for when and how to start hormonal contraception are more complicated than for many other medications. Many patients seeking oral contraceptives (OCs) are unable to recall pill-taking instructions at the end of the same clinic visit [3]. Twenty-five percent of women with a prescription for OCs will not even begin taking them [4,5].

Traditional approaches to the initiation of hormonal contraception require waiting for the next menstrual period to begin the method. One approach to increase successful use of combined hormonal contraception is to encourage initiation of the method as soon as possible. Westhoff et al. [6] first described the "Quick Start" concept with OCs. The patient swallows her first pill in the office and continues taking the pill daily from that day forward. No complicated counseling about when to start is needed. In the original study, women who swallowed their first pill in the office were more likely to continue the method into the second month than women who planned to start the OC later (adjusted OR, 2.8; 95% CI, 1.1–7.3). Similar studies have been performed for Quick Start initiation with the contraceptive injection [7], contraceptive ring [8], and contraceptive patch [9] — these studies showed mixed effectiveness of this initiation technique to increase continuation rates.

Women who have recently undergone termination of an undesired pregnancy are in special need of effective contraception. Medical abortion does not always have a

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day of completion that is as clearly defined as with surgical abortion. To be sure that the medical abortion is complete, women are asked to return for an evaluation 1 to 2 weeks after initiating treatment. Given this extended process, women may be instructed to initiate contraceptive use at varying time points. Extrapolating from the Quick Start data that were collected in nonabortion patients, various recommendations for initiating hormonal contraceptives have been suggested. These include starting on the day the mifepristone is taken, the day the misoprostol is taken, the Sunday following the misoprostol or the day that the medical abortion is confirmed to be complete (at the follow-up visit 1–2 weeks after the first medication). However, some clinicians still recommend the more traditional approach — waiting until the next Sunday or even the next period before beginning hormonal contraception.

Since no objective data exist supporting any of these recommendations, we designed a study to test the hypothesis that initiation of a combined hormonal contraceptive method after medical abortion under early and direct clinical observation will result in superior method continuation rates compared to delayed "Sunday start." We also collected data to determine whether factors previously reported to be associated with method continuation — unscheduled bleeding [10,11] and sexual partner knowledge of planned contraception use [6] — might also influence continuation following medical abortion.

2. Materials and methods

This study was a planned substudy as part of an open-label, prospective, randomized multicenter medical abortion trial utilizing mifepristone and misoprostol administered simultaneously or 24 h apart [12]. It was conducted between April 2004 and May 2006 at four medical centers in the United States: University of Pittsburgh, Oregon Health and Science University, Northwestern University and University of Southern California. The institutional review boards of the respective institutions approved the protocol, and all participants provided written consent prior to enrollment.

Patients were offered participation in this substudy if they attended the first follow-up visit 6–8 days after their medical abortion, chose to start a combined hormonal method of contraception (pill, patch or ring) and had no contraindications to their use [13]. Subjects had an ultrasound examination at this visit and were invited to participate in this substudy only if the evaluation demonstrated expulsion of the gestational sac.

After enrollment, subjects were randomized to an observed start or a Sunday start using sequentially numbered opaque envelopes containing a card with computer-generated assignment information. An individual not involved with the clinical conduct of the trial prepared the envelopes. Randomization was stratified by center with equal frequency to the two treatment arms using random block sizes.

Women assigned to observed start took their first pill, applied their first patch or placed the ring in the clinic during their first medical abortion follow-up visit that confirmed complete pregnancy expulsion. Those in the Sunday start group were instructed to begin their chosen method the first Sunday following this visit. All subjects received a sample of their chosen contraceptive method and a prescription for three more cycles. To assess the relationship between bleeding patterns and method continuation, the study utilized diaries of vaginal bleeding events recorded daily by subjects as part of the parent medical abortion study. Subjects recorded bleeding events from the first dose of medication for the medical abortion until all bleeding resolved (the time period varied for each subject, out to a maximum of 96 days). Bleeding was defined as loss of blood requiring use of a sanitary pad or tampon; spotting was defined as loss of blood requiring use of a pantyliner or no protection; and no flow was defined as neither bleeding nor spotting.

Research staff contacted subjects by phone 6 weeks after their medical abortion and recorded whether they were continuing to use their chosen method, using another method or not using contraception. Additionally, subjects were asked if their partner was aware of their contraceptive method following the abortion.

2.1. Power calculation and statistical analyses

We estimated sample size based on various possible outcomes for the number of women who would enroll in this substudy. The number of women who continued into the second cycle of combined OC using Quick Start was 88% as compared to 74% with a traditional start [6]. Using this rate of 88% as the number of subjects to continue into the second cycle, we estimated sample sizes for a control group with continuation rates of 78% (a 10% difference), 73% (a 15% difference) and 68% (a 20% difference). With 80% power and p=.05, the number of subjects required were 442, 218 and 134, respectively.

All data analyses were completed using SPSS (version 15.0; SPSS Inc, Chicago, IL). Baseline characteristics were compared according to treatment group to assess for significant differences using a Fisher's Exact Test, χ^2 test or t test where appropriate. The primary outcome of the study was short-term continuation into the second month of combined hormonal contraceptive use, and the difference in continuation rates between groups was evaluated by a χ^2 test. Secondary outcomes included partner knowledge of planned method of contraceptive use and duration of vaginal bleeding patterns as measured by bleeding diaries. Partner knowledge of planned contraceptive method resulted in small cell sizes, so the difference between groups was tested using Fisher's Exact Test. Length of bleeding and spotting during the course of the study were compared between groups using the Mann–Whitney U test since these data did not appear to be normally distributed. Univariate and multivariable logistic regression analyses were used to evaluate

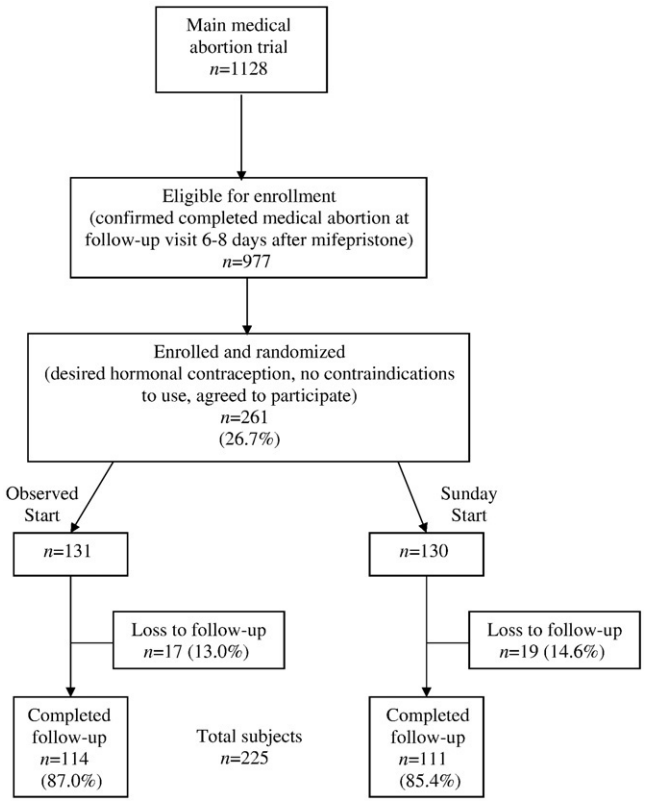

Fig. 1. Flow of study participants.

potential confounders and to determine independent predictors of contraceptive continuation.

3. Results

Of the 977 eligible subjects from the main study, 261 (26.7%) desired a combined hormonal contraceptive and agreed to participate in this substudy. The number of women who chose combined hormonal contraception but declined participation, or who had medical contraindications to combined hormonal contraception, was not recorded (Fig. 1).

There were no significant differences in baseline characteristics between the observed start and Sunday start groups except for prior contraceptive use (Tables 1 and 2). The majority of women were using contraception during the 3 months prior to their medical abortion — the most common types reported were condoms and combined hormonal contraception (OCs, patch, ring). There were more condom users in the Sunday start group and more combined hormonal contraceptive users in the observed start group (Table 2). Fewer than half of the contraceptive users (45.2%) self-reported that they had used the method correctly, with no significant differences between groups (Table 2).

Overall, contraceptive method continuation at 6 weeks did not differ between groups [observed start 94% (108/114) vs. Sunday start 91% (101/111), p=.27]. Most of the subjects who were not continuing their combined hormonal contraceptive method reported switching to a less effective method such as condoms or withdrawal.

The vast majority of subjects reported that their partner was aware of their chosen contraceptive method (91.8% for the observed start and 93.6% for the Sunday start group, p=.80), and partner knowledge did not affect continuation. Marital status was the only variable statistically associated with continuation in univariate (OR, 4.82; 95% CI, 1.51–15.42) and multivariable (OR, 7.50; 95% CI, 1.51–37.12) analyses. In addition, being married was highly correlated (100%) with partner knowledge of the contraceptive plan.

The median number of bleeding and spotting days did not differ significantly between groups (Table 3). The proportion of subjects reporting bleeding or spotting events before and after 20 days (when one might expect a withdrawal bleed

Table 1
Baseline demographics of study population

	Observed start (*n*=114)	Sunday start (*n*=111)
Age (years)	26±6	25±5
Gravidity		
1	39 (29.8%)	49 (37.4%)
2	34 (26%)	24 (18.3)
3	29 (22.1%)	22 (16.8%)
4	16 (12.2%)	13 (9.9%)
≥5	13 (9.9%)	23 (17.6%)
Parity		
0	58 (50.9%)	58 (52.3%)
1	29 (25.4%)	23 (20.7%)
2	19 (16.7%)	21 (18.9%)
≥3	8 (7.0%)	9 (8.9%)
Race		
White	84 (73.7%)	77 (69.4%)
Black	27 (23.7%)	28 (25.2%)
Other/none of these	3 (2.6%)	6 (5.4%)
Hispanic ethnicity	14 (10.7%)	13 (9.9%)
Marital status		
Single	105 (80.2%)	105 (80.2%)
Married	16 (12.2%)	12 (9.2%)
Divorced/separated	10 (7.6%)	14 (10.7%)
Living with partner	47 (35.9%)	55 (42.0%)
Education status		
Some high school	8 (7.0%)	11 (9.9%)
High school graduate	26 (22.8%)	20 (18.0%)
Some college	51 (44.7%)	54 (48.6%)
College graduate	27 (23.7%)	22 (19.8%)
Graduate school	2 (1.8%)	4 (3.6%)
Annual income[a]		
<$20,000	54 (48.2%)	53 (47.7%)
$20,000–$50,000	29 (25.9%)	34 (30.6%)
$50,000–$70,000	13 (11.6%)	10 (9.0%)
>$70,000	16 (14.3%)	14 (12.6%)
Tobacco use	51 (44.7%)	40 (36%)
Parent study treatment group (misoprostol at same time)	60 (52.6%)	55 (49.5%)

Values are *n* (%) and mean (±SD). All $p > .05$ by Fisher's Exact Test, χ^2, or Student's *t* test, where appropriate.

[a] Two subjects declined to answer this question.

Table 2
Primary contraception used during the 3 months prior to medical abortion

	Observed start (*n*=114)	Sunday start (*n*=111)	p
Contraceptive method			.048 (overall)
Condoms	31 (27.2%)	50 (45.0%)	.006
Spermicide	5 (4.4%)	1 (0.9%)	.21
Condoms and spermicide	3 (2.6%)	2 (1.8%)	.99
Combined hormonal contraception [a]	45 (39.5%)	23 (20.7%)	.002
Other nonhormonal methods [b]	4 (3.5%)	3 (2.7%)	.99
None	25 (21.9%)	35 (44.3%)	.36
Reported correct usage	41 (36.0%)	35 (31.5%)	.88

Values are *n* (%).
[a] Combined hormonal contraception includes OCs, ring and patch. These were combined because of the low rate of previous ring and patch use.
[b] Include withdrawal and menstrual timing/fertility awareness.

after beginning combined hormonal contraception) was also not different between groups.

4. Discussion

This study investigated whether a technique shown to increase short-term hormonal contraception continuation rates among women attending family planning clinics would have a similar effect following medical abortion. Our results show that hormonal contraceptive continuation rates at 6 weeks following medical abortion are high in a population of women desiring hormonal contraception and receiving a 1-month sample of the method. Continuation is not significantly improved by observed initiation at the time of the first follow-up visit.

Our final sample size of 225 had 80% power to detect a difference of approximately 15% using a *t* test of proportions with an α of .05. The difference seen in continuation until the second cycle in the initial observational Quick Start study was 14% (88% with immediate initiation vs. 74% with conventional start) [6]. Although the 3% difference seen in our study was not statistically significant, a recently published large multicenter randomized controlled trial (RCT) comparing Quick Start to conventional Sunday start in nonabortion subjects showed similar high continuation rates and small positive effect size (90% Quick Start vs. 86% Sunday start) (OR, 1.5; 95% CI, 1.0–2.1) [14]. Since this study had greater power, this small effect on continuation into the second month was statistically significant. However, this positive effect is not likely to be clinically significant, especially given that this effect on continuation did not persist through 3 and 6 months of follow-up.

Of note, most of the subjects that discontinued their initial hormonal contraceptive method in our study reported switching to a less effective method such as condoms or withdrawal. Several noncontinuers also reported abstinence as their contraceptive method because they did not have a current partner. This method, too, is likely to be less effective unless they initiate another contraceptive method prior to acquiring a new sexual partner.

The rate of partner awareness of the contraceptive method was also much higher than previously reported (92.7% in our study vs. approximately 70% in prior Quick Start publication [6]). Interestingly, in the recent large RCT previously mentioned, the effect of partner knowledge on contraceptive continuation (adjusted OR, 1.6; 95% CI, 1.1–2.3) was slightly higher than the effect of initiation timing (adjusted OR, 1.5; 95% CI, 1.0–2.1) [14]. As a measure of communication in the relationship, it is encouraging to see this high rate of partner awareness among couples who have recently had an unintended pregnancy.

Of note, we provided every subject with one cycle of her chosen contraceptive method. Therefore, all subjects had the method physically in their hands and available at the time they were instructed to begin, whether it was in the office under observation or at home the following Sunday. The majority of women in this study did fill at least one prescription for the contraceptive method to be able to continue into the second cycle. Perhaps providing more cycles in advance would improve continuation for the subjects who did not continue into the second month. Other studies that have shown continuation rates around 90%, regardless of initiation timing, have provided during the entire study period worth of contraception to subjects (e.g., 3- to 4-month supply) [8,9].

The majority of subjects in our study were not using any contraception prior to their unintended pregnancy, and most of those that were using contraception felt they were not using it correctly. This highlights an important target area — not only access to contraception but also correct utilization on a long-term basis. Our data do not allow speculation as to whether continuation rate beyond 6 weeks following medical abortion is affected by start date.

Strengths of the study include that it was a randomized trial with prospective data collection. The study also had low loss to follow-up and a relatively diverse population with four separate US sites. A limitation is that the randomization process was not successful in balancing previous contraceptive use. Although this variable is an important potential

Table 3
Primary and secondary outcomes

	Observed start (*n*=114)	Sunday start (*n*=111)	p
Method continuation at 6 weeks	108 (94%)	101 (91%)	.27
Partner knowledge	107 (91.8%)	102 (93.6%)	.80
Spotting duration after abortion (median, days)	16	17	.54
Bleeding duration after abortion (median, days)	13	14	.49

Values are *n* (%), except as indicated.

confounder, continuation rates did not change in multivariable analysis when adjusted specifically for previous hormonal contraceptive or condom use. Median numbers of days of bleeding and spotting duration following medical abortion is also not affected by when hormonal contraception was initiated.

To our knowledge, this is the first study to focus on how best to provide hormonal contraception to women following medical abortion. Our data provide reassuring prospective data on how initiation timing of hormonal contraception does not impact bleeding patterns following medical abortion. Having the option to start a hormonal contraceptive method immediately when the medical abortion is confirmed to be complete provides early protection against repeat unintended pregnancy without increasing median duration of days of bleeding and spotting that could lead to discontinuation of the method.

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