

Quick Start: a novel oral contraceptive initiation method[☆]

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Abstract

Conventional oral contraceptive (OC) starting instructions require waiting until menses to begin the OC. The conventional approach requires detailed patient education about when to begin and also may require the use of less effective or less acceptable interim contraceptive protection until menses. At our urban family planning clinic, we routinely offer patients starting the OC the option of taking the first tablet sooner. We prospectively evaluated predictors of short-term OC continuation among 250 OC requestors who were offered several approaches to OC initiation. Telephone follow-up of 91% of participants showed that women who swallowed the first OC in the clinic were more likely to continue the OC until the second package than women who planned to start the OC later (adjusted OR 2.8, 95% C.I. 1.1–7.3). Other factors associated with short-term continuation were: partner's knowledge of planned OC use, older age, and participant's agreement that she would be very unhappy about becoming pregnant in the next 6 months. © 2002 Elsevier Science Inc. All rights reserved.

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1. Introduction

Conventional approaches to the initiation of oral contraceptives (OC) require waiting for the next menstrual period to take the first pill. Specific instructions may vary by pill and by clinic, and include Sunday-start, first-day start, and even fifth-day start. An early motivation for this approach to OC initiation was to avoid giving contraceptive hormones to a woman who might have already conceived. We now know that inadvertent exposure to OC early in pregnancy is not harmful [1]. Another motivation for the conventional starting instructions was to cause the first withdrawal bleed while using the pill to appear about 4 weeks after spontaneous menses, thus creating or maintaining the appearance of a regular cycle [2].

Practical problems may result from the conventional approach to initiation of OC. First, it delays the onset of contraceptive protection, especially for those women who

do not have a regular menstrual cycle. Thus, we have cared for many women who became pregnant while waiting to begin the pill because alternative contraceptives were either less effective or completely unacceptable to them. Second, women may not start the pill at the correct time because of temporary waning of motivation or because of confusion about the starting instructions. Failure to begin any medication after receiving a prescription is widespread [3], and the OC is no different [4]. Prospective studies of oral OC use often focus on high discontinuation rates, but there has been little attention to data showing that up to 25% of OC study participants never even begin their assigned treatment [5,6].

To increase successful OC use in our clinic, we have encouraged initiation of OC as soon as possible, regardless of the patient's menstrual cycle day. In particular, we developed an initiation protocol that we call 'Quick Start.' In this approach, the woman swallows her first pill in the clinic immediately after prescription, and continues pill taking daily; no counseling about when to begin is needed. All patients who receive the first pill during the clinic visit first undergo a sensitive urine pregnancy test. All patients, regardless of starting instructions, receive emergency contraceptives if needed. All receive at least one pack of OC so that no patient has to go to a pharmacy to fill a prescription

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Table 1
Distribution of OC initiation approaches at study enrollment, follow-up and analysis, among 250 OC requestors at an urban family planning clinic

Type of OC initiation	Total enrolled n (%)	Total followed-up n (%)	Total analyzed n (%)
Total	250	227*	213†
Quick Start	62 (24.8)	58 (25.6)	57 (26.8)
Other Start	188 (75.2)	169 (74.4)	156 (73.2)
Today, tonight, tomorrow, or this Sunday	149 (59.6)	134 (59)	126 (59.2)
After abortion, day after abortion, or Sunday after abortion	39 (15.6)	35 (15.4)	30 (14.1)

* 23 participants lost to follow-up.

† 14 participants excluded from analysis because they did not start or they did not continue the OC for an appropriate reason.

before she can begin. The Quick Start approach has been accepted by the providers and patients in our clinic for several years, and is offered to the patients at the discretion of the provider. This article describes short-term OC use according to the method of OC initiation in our clinic. Specifically, we compare continuation of OC following directly observed ingestion of the first pill in the clinic (Quick Start) to continuation after other approaches to initiation (other start).

2. Materials and methods

This was a prospective, observational cohort study conducted in the Family Planning Clinics of the Columbia-Presbyterian Medical Center in New York City. These clinics are funded in part by Title X, and provide family planning services to a young, predominantly Hispanic population consisting mainly of recent immigrants from the Dominican Republic and their reproductive age offspring; more than 80% of patients report incomes below 100% of the federal poverty line. There are over 25,000 clinic visits per annum; about 8000 visits per year are made by new or continuing users of OCs. All approved family planning methods are available, and most services are provided by nurse practitioners. During the study period, clinicians prescribed OCs at patient request according to clinic-specific routine protocols. Patients received Quick Start or other starting instructions based on clinician preference. All patients received at least one package of pills; those with Medicaid received prescriptions for refills; those without any insurance coverage received additional packs directly from the provider. At the end of the clinical encounter, clinicians referred patients to the study. Patient recruitment occurred over a 4-month period in 2000. The study was reviewed and approved by the Institutional Review Board of Columbia-Presbyterian Medical Center.

All patients starting or restarting combined OCs were eligible to participate, however, patients could only enroll once. After informed consent, the patients completed an in-person interview in either English or Spanish. The interview included questions regarding past contraceptive use, motivation to avoid pregnancy, relationship characteristics, and basic demographic information. The interview also de-

termined whether the patient had already taken the first pill (Quick Start), or when she intended to take the first pill. The same research assistant then contacted each subject for a follow-up telephone interview, at least 6 weeks after study enrollment. The follow-up interview was timed so that the subject would have had the opportunity to complete at least one pack of pills and begin a second pack. Up to seven attempts were made to contact participants for the follow-up interview. The follow-up interview evaluated number of pills taken, sexual activity since enrollment (i.e., need for contraception), and reassessed other questions from the first interview.

Data were analyzed using SPSS version 9.0. Baseline and follow-up variables were examined to describe the participants by OC starting regimens. OC initiation was categorized as follows: Quick Start was defined as taking the first pill in the clinic immediately before study enrollment; all other OC starting plans could be divided into two subgroups: first, subjects who had a positive pregnancy test on the day of enrollment who stated an intention to undergo abortion and start their OCs shortly after the abortion; and secondly, subjects who did not take the first pill in the clinic and stated an intention to take the first OC later the same day, the next day, or the next Sunday. There were no participants in this study who intended to wait for the next menses to take the first pill.

The primary outcome measure was short-term continuation to the second pack of pills, defined as having begun the second pack. Bivariate analyses (Student's *t*-tests for comparison of means and chi-square tests for comparison of proportions) were used to identify baseline characteristics associated with short-term OC continuation. Characteristics found to be associated with continuation were then examined in a multivariate analysis. Logistic regression was used to identify independent predictors of short-term OC continuation.

3. Results

Patients were referred to the study staff by the clinician who prescribed the OC. A total of 250 women were enrolled in the study. Table 1 shows the distribution of OC initiation approaches at enrollment, follow-up, and analysis. Sixty-two women (25%) took the first OC tablet during the en-

Table 2
Baseline characteristics of women starting OCs by OC initiation approach

Baseline characteristics	Quick start n = 58	Other start n = 169	p-value*
Mean age; yrs	22.7	22.3	0.7
Mean gravidity	2.4	2.3	0.9
% parous	70.3	63.5	0.6
Mean parity	1.1	0.95	0.4
Mean number of abortions	1.0	0.9	0.6
% ever used OCs	62.1	60.9	1.0
Median length of past OC use; mos	12.0	12.0	0.7
% who plan to use OCs for >1 yr	70.7	66.1	0.6
% very certain about wanting OCs	55.2	56.2	1.0
% unhappy if pregnant in next 6 mos.	53.4	55.6	0.9
% with current partner	94.8	95.3	1.0
Mean duration of partnership; mos	34.6	35.3	0.9
% partner knows of plan to use OCs	72.7	70.8	0.9
% employed	44.8	46.2	0.9
% Hispanic	84.5	90.5	0.3
Language at home			
English	20.7	20.1	
Spanish	43.1	43.8	0.9
Equal mix	34.5	34.9	
Language socially			
English	37.9	35.5	
Spanish	29.3	29.6	0.9
Equal mix	31.0	33.7	

* p-values for Student's *t*-tests for comparison of means and chi-square tests for comparison of proportions.

rollment clinic visit; the others reported a variety of plans for taking the first pill at a later time. Thirty-nine subjects (16%) were pregnant at enrollment and planned to take the first pill after a scheduled termination of pregnancy. One hundred forty-nine subjects (60%) were not pregnant and planned to start the OC soon after the visit. The pregnant subjects and those who planned to start the OC shortly after the clinic visit were similar to each other in their baseline characteristics, including the percentage that actually started or continued the OCs and the percentage that completed the follow-up interview (data not shown); therefore, we combined these participants into a single group for subsequent analyses. This group ('other start') includes all of the 188 women who did not take the first pill under direct observation during the clinic visit when the pill was prescribed. None of the women in this study planned to wait until the next menstrual period to start the OC.

Of the 250 women, 227 of them (91%) completed a follow-up interview. Subjects beginning by Quick Start and other start subjects had similar baseline characteristics (Table 2). The subjects were young, Hispanic women; most had been pregnant in the past and about 60% had used the OC previously; most participants reported at baseline that they planned to use the OC for 1 year or longer.

Fourteen patients who did not start the OC ($n = 10$) or did not continue the OC ($n = 4$) for a clinically appropriate reason were excluded from analysis. Only one of the excluded patients was in the Quick Start group; 13 were members of the 'other start' group.

All of the characteristics assessed in the baseline interview were evaluated for their association with continued OC use to the second pack among the 213 subjects who were included in the final analysis. Characteristics found to be associated with continuation at least until the second pack of pills are shown in Table 3. The characteristic most strongly associated with short-term OC continuation was the patient's report that her sexual partner knew about the planned OC use. Other variables that attempted to measure the stability of the partnership and communication between the partners were also associated with OC continuation; however, all of these variables were highly correlated with partner knowledge. Because partner knowledge was the

Table 3
Baseline characteristics associated with continuation to second OC pack, among OC requestors at an urban family planning clinic*

Baseline characteristic	Odds ratio for continuation to 2 nd pack of pills	95% confidence interval for odds ratio
Quick Start	2.6	1.1; 6.1
Partner knows of plan to use OCs	3.5	1.8; 7.1
Unhappy if pregnant in next 6 mos	2.5	1.3; 4.9
Plan to use OCs for >1 yr	2.1	1.1; 4.0
Previous OC use	2.0	1.0; 3.8
Very certain about wanting to use OCs	1.98	1.0; 3.8
Employed	1.98	1.0; 3.8
>22 years of age (median age)	2.7	1.3; 5.5

* Odds ratios generated from bivariate analyses.

Table 4
Independent predictors of continuation to second OC pack, among OC requestors at an urban family planning clinic*

Baseline characteristic	Odds ratio for continuation to 2 nd pack of pills	95% confidence interval for odds ratio
Quick Start	2.8	1.1; 7.3
Partner knows of plan to use OCs	3.9	1.9; 8.3
Unhappy if pregnant in next 6 mos	2.3	1.1; 4.8
Age; continuous	1.1	1.01; 1.7

* Odds ratios generated from a logistic regression model incorporating the four variables shown in the table.

simplest and most objective of these variables, it was chosen for inclusion in further analyses.

Swallowing the first tablet in the clinic (i.e., Quick Start) was also strongly associated with continuation to the second pack of pills. Eighty-eight percent ($n = 50$) of the 57 women who took the first pill under direct observation in the clinic (Quick Start) continued to the second pack, while 12% ($n = 7$) of this group discontinued the OC prematurely. Among the 156 patients who planned to start the OC after the enrollment clinic visit, 7 (4.5%) never started, and 34 (22%) discontinued before the second pack. Thus, only 74% ($n = 115$) of participants who planned to start later began their second pack of OC. Other variables associated with continuation to the second OC pack included being employed, older age, past OC use, and several measures of commitment to OC use (intention to use the OC for more than 1 year, patient's agreement that she would be very unhappy if she became pregnant in the next 6 months, and patient's report that she was very certain about wanting to use the OC).

In multivariate analysis (Table 4), the variables that remained associated with continuation to the second OC pack were age, partner knowledge of planned OC use, the patient's agreement that she would be very unhappy if she became pregnant in the next 6 months, and directly observed ingestion of the first pill while in the clinic (Quick Start). Thus, even taking all other factors into account, women who swallowed the first OC in the clinic were almost three times more likely to continue the OC until the second pack compared with women who planned to start the OC later. Because the women who were pregnant (and planning abortion) at the time of the baseline interview could not actually begin the OC on the day of the visit, we repeated all of these analyses excluding the women who were pregnant at enrollment, and none of the associations presented in Tables 3 and 4 changed (data not shown).

4. Discussion

Flexible approaches to initiation of OCs have been acceptable to patients and providers in our clinic for several

years. This study represents our first attempt to evaluate these approaches. Here we have divided these flexible approaches into two main categories: directly observed ingestion of the first tablet during the clinic visit, regardless of menstrual cycle day (Quick Start) versus all other OC starting times that occur after the clinic visit, but before the next menstrual period. None of the participants in this study planned to start the OC with their next menstrual period, thus continuation of the OC after conventional initiation is not evaluated here.

We found that women who swallowed the first OC immediately were much more likely to continue the OC to the second pack compared to women who did not. This finding could have been, in part, a result of more motivated patients choosing to swallow the first tablet immediately. We attempted to assess motivation separately in the baseline interview and found, in the multivariate analysis, that motivation to avoid pregnancy and Quick Start had strong independent effects on OC continuation. Thus, confounding by motivation is unlikely to explain the effect of Quick Start on OC continuation.

Conversely, women who were at little risk of pregnancy because of infrequent sexual activity may have elected to delay starting the first OC. We eliminated from the analysis all patients who reported no sexual activity from enrollment until the follow-up interview, so that all women who remained in the analysis had at least some risk of pregnancy and need for contraception. Similarly, we eliminated the patients who discovered they were pregnant during follow-up because they had no need to start or continue the OC. Because this was not a randomized study, other characteristics of either the patient or the provider may have been associated with both the decision to start the OC immediately and the decision to continue to the second pack. Also, the duration of continuation that we assessed here was extremely brief. A randomized trial is needed to identify both the magnitude and duration of an independent Quick Start effect on OC continuation.

The other factors associated with short-term OC continuation in this study were older age, degree of unhappiness about becoming pregnant in the next 6 months, and partner knowledge of contraceptive plans. All of these factors have been previously identified as predictors of successful contraceptive continuation [7,8]. That our findings are consistent with other studies with regard to these other variables enhances the credibility of the Quick Start effect. Quick Start remained associated with continuation even when all of these other variables were taken into account.

Because Quick Start is a health services intervention that is aimed at OC initiation, one might expect that any effect would be immediate. Whether the apparent beneficial effect persists past the second pack needs evaluation. Not surprisingly, part of the difference in short-term continuation between Quick Start and other start was that some women who planned a later start never started at all despite continuing sexual activity (4.5%). However, when looking only at

those patients who actually began the OC, the Quick Start participants had higher continuation rates than the later starts. This finding deserves further evaluation.

Rickert and colleagues have previously shown that many clinic patients seeking OCs are unable to recall pill-taking instructions at the end of the same clinic visit [9]. Improved counseling may remedy this problem, though both clinical time and experienced counselors are likely to remain limited. The Quick Start approach to OC initiation has the great advantage of simplicity. No additional counseling time is required. In fact, Quick Start may require less counseling. Furthermore, little staff training is needed to implement the approach. OC packs must, however, be immediately available.

When considering this novel approach, we were worried about possible adverse effects. The participants in this study reported no adverse events, and the high continuation rates in the Quick Start group provided evidence of the acceptability of the approach. No patients in the Quick Start group discontinued the OC immediately after the first OC tablet, providing further reassurance of acceptability. Because of concerns that starting the OC later in the menstrual cycle may lead to adverse bleeding patterns, we carried out a separate randomized, controlled 3-month trial to compare bleeding patterns after Quick Start versus conventional OC start; we found no adverse effect of Quick Start on bleeding [10].

Directly observed OC initiation during the clinic visit, regardless of menstrual cycle day, has a great potential to increase OC continuation and to decrease unintended pregnancy without any new healthcare costs. Because current practice requires waiting for menses to start the OC, patients and clinicians alike may need reassurance that there is no medical reason for waiting until menses to initiate the OC. In the future, the Quick Start approach may also prove applicable to other highly effective methods such as the

monthly injection, the contraceptive patch, and the contraceptive vaginal ring.

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