

Original article

Patterns of Oral Contraceptive Pill-taking and Condom Use among Adolescent Contraceptive Pill Users

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Abstract:

Purpose: Imperfect oral contraceptive pill (OCP) regimen adherence may impair contraceptive effectiveness. The purpose of this study was to describe daily adherence patterns of OCP use, to analyze OCP protection on an event level basis, and to examine pill-taking and condom use during method transitions.

Methods: Women (n = 123, ages 14–17 years) completed quarterly interviews to classify OCP method choice into four categories: stable, initiated, stopped, and discordant use. Within each OCP category, daily diaries were used to assess occurrence of coitus, condom use, and patterns of day-to-day OCP use (i.e., consecutive days of OCP use reported with no more than two consecutive days of nonuse). A coital event was OCP protected if pills were used on both the day of the coitus and the day preceding.

Results: There were 123 participants who reported at least some OCP use in 210 diary periods (average diary length = 75.5 days). Fifty-three participants categorized as stable users reported 87 diary periods: the average interval of consecutive OCP use in this group was 32.5 days. Among stable users, only 45% of coital events were associated with both OCP and condom use. Over one-fifth of coital events in all groups were protected by no method of contraception.

Conclusion: Dual use of OCP and barrier contraception remains an elusive goal. The time during OCP adoption or discontinuation is often unprotected by condoms. However, concurrent missed pills and condom nonuse increase pregnancy and infection risk even among stable OCP users. Understanding motivation for method usage may improve education and prevention techniques. © 2006 Society for Adolescent Medicine. All rights reserved.

Keywords:

Adolescent; OCP; Condom; Coital event

Oral contraceptive pills (OCP) have failure rates of less than 1% under perfect-use conditions. However, imperfect use contributes to failure rates as high as 30% [1]. Effective OCP use requires method commitment (i.e., considering one's birth control method to be OCP) as well as OCP use consistent with the method's pharmacology and mechanism of action (i.e., method adherence). Moreover, OCPs provide

no protection against sexually transmitted infections (STIs). This means that the choice of OCP as a contraceptive method creates a need for a second prevention method, usually coitus-dependent use of male condoms. However, fewer than 25% of adolescents use dual contraceptive methods such as OCP and condoms [2–5].

OCP method choice is not a fixed characteristic of young women's contraceptive behavior. Over 60% of contraception users switch methods at some time point, and many discontinue a method within the first three months of use [6–9]. Variable patterns of OCP pill-taking during periods

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of transition into and out of OCP use may make these especially vulnerable times in terms of method adherence [10]. Condom use during transition periods is especially important for contraceptive as well as STI prevention purposes.

Even among women who continue OCP use, daily OCP pill-taking can be difficult. Up to 60% of adult users report missed pill doses and up to 50% miss enough doses to place them at risk for pregnancy [11,12]. Therefore, clinicians must be aware that actual OCP usage differs from the ideal with associated perfect pill usage.

Understanding the dynamics of OCP pill-taking and condom use is limited by several conceptual and methodological issues. From a conceptual perspective, earlier studies have not distinguished real-world patterns of pill-taking and condom use according to varying levels of ongoing commitment to the method [3,13,14]. Women just beginning OCP may have different patterns of pill-taking adherence and different levels of condom use than those on the verge of method discontinuation. Failure to distinguish these periods likely leads to misrepresentation of pill-taking adherence and condom use among adolescent women. Thus, interventions to simultaneously support both pregnancy and STI prevention may be misdirected because of insufficiently detailed data.

From a methodological perspective, previous studies often focus on pill-taking at defined time points separated by several months [15–17]. Along with retrospective patient reports, compliance has been monitored among adults with the use of electronic monitoring devices [11,12]. Therefore, there is a gap in the literature as we are unaware of the daily pattern, or patterns, of pill usage among adolescents.

A second methodological issue is the measurement of dual use. Existing studies only addressed dual use prevalence measured by recall over an arbitrary interval, and do not examine day-to-day OCP adherence and day-to-day condom use. Past studies of dual contraceptive methods have categorized adolescents as dual method contraceptive users largely from self-report measures, such as identifying oneself as an OCP user and reporting condom use with a single measure such as percent condom use or condom use at last sexual intercourse [18]. Despite such reports, even self-identified dual users do not use condoms for 100% of coital events. No studies have investigated dual contraception coverage with event level analysis that could allow for a better understanding of dual contraception and STI prevention patterns in adolescents.

The conceptual and methodological limitations of previous research suggests the need to better understand day-to-day patterns of OCP use, and to assess event-level patterns of condom use in conjunction with OCP method use and patterns of pill-taking. Specifically, the study objectives were (1) to describe daily adherence patterns of OCP use, (2) to analyze on an event-level basis protection with OCP, condoms, or both methods (dual use), and (3) to examine

pill-taking and condom use during periods with different OCP method choices (e.g., starting OCP use, stopping OCP use, or continuous method commitment during a given period).

Methods

Participants

Young women were recruited from three primary care adolescent clinics in Indianapolis, Indiana. These clinics serve urban areas characterized by high rates of poverty, early pregnancy, and sexually transmitted infections. Entry criteria included age between 14 and 17 years, English fluency, and not currently pregnant. Recruitment for subjects in the study began in 1999 (cohorts continue to be followed) with all eligible adolescents identified and invited to participate in the study. Written informed consent was obtained from each participant and written permission was obtained from a parent or legal guardian. This research was approved by the institutional review board of Indiana University Purdue University at Indianapolis – Clarian.

Study design and procedures

Data were collected as part of a longitudinal study of risk and protective factors associated with STI among girls in middle and late adolescence. Subjects were interviewed at three-month intervals and provided up to five, approximately 84-day diary collection periods over a 27-month period. Each diary collection period was initiated and terminated by a face-to-face quarterly interview, and was followed by a rest period of similar length in which no diary information was collected. The primary unit of analysis is the three-month diary period.

Characterization of daily OCP pill-taking and of condom-protected coitus

Subjects were provided diaries to establish patterns of daily OCP pill-taking, condom usage, and coital activity for three-month periods. Information on daily pill-taking allows monitoring of method adherence, stability, and change in association with overall method choice. Information on daily condom use and coital activity allow event-level analyses of dual method utilization.

The diary instrument consisted of a single bar-coded, scannable sheet containing probes and response options. Participants recorded whether coitus occurred on a given day, and if so, whether a condom was used. Participants also indicated whether or not a “birth control pill” was taken on a given day. Participants responded to this question without regard to any prior OCP use. At the beginning of each diary period, participants received detailed instructions regarding diary completion as well as a packet of blank diary sheets. Participants were asked to complete a single diary sheet at the end of each day. If an entry was forgotten, participants

were asked to complete the form as soon as it was remembered. Field personnel collected completed diaries and left blank diary forms weekly. Participants received \$2.00 for each completed diary as well as a bonus for completion of 80% of scheduled diaries.

We chose daily, preprinted diaries with weekly collection pickup because prior research with adolescent women suggested that diaries were associated with low levels of dropout, high levels of daily completion, and relatively low levels of item-level missing data, even for reports of sensitive sexual behaviors [19–21]. The diary methodology provides a useful tool to address the complex phenomenology of adolescent women's sexual activity and contraceptive behavior. This method also has the ability to accurately capture, for relatively long periods of time, consistent, erratic, or nonuse for self-administered contraceptive methods such as oral contraceptive pills [22].

Characterization of patterns of OCP method use

We characterized method choice according to self-described OCP usage utilizing quarterly (i.e., at three-month intervals) interview data. The quarterly face-to-face structured interviews assessed sexual behaviors and contraception methods used during the previous three months. Entry quarterly interviews were obtained at the beginning of each diary period. Exit quarterly interviews were conducted roughly three months later at the conclusion of a diary period. At each quarterly interview, participants were asked "Are you taking birth control pills?" This is the typical way clinicians and researchers classify contraceptive method choice.

We created four categories to characterize OCP method usage during a given diary period, based on OCP method use at the flanking entry and exit interviews. Because this analysis focuses on OCP method choice, the sample was limited to diary periods of sexually active adolescent women where OCP use was reported on at least one diary day.

Stable use describes diary periods with reported OCP use as the method choice at two consecutive quarterly interviews flanking a diary period. In other words, subjects who contributed diary periods to the stable use group reported pill use at the beginning and at the end of a three-month diary period. From an ideal use perspective, diaries for these periods would record OCP use on each day. Subjects who *stopped* OCP reported OCP as their method choice at an entry quarterly interview but not at the exit interview for that diary period. Subjects who initiated OCP reported OCP as their method choice at an exit but not entry quarterly interview. The diary periods collected with this information constituted the stopped use and initiated use groups. Finally, subjects that provided diary periods for the *discordant use* group did not report OCP as their method choice at either flanking interview, but did report OCP use on at least one

diary day. We included the discordant use category as it reflects access to OCP that young women may have outside of interactions with their primary provider (i.e., previous prescription, friend or family member's prescription). Each participant contributed up to five diary periods during the course of follow-up, and each of the contributed diary periods could be classified into a different OCP use category.

It is possible that periods of nonuse of oral contraceptive pills were under contraceptive protection by another method such as injected depot medroxyprogesterone acetate (DMPA). At each interview, subjects were asked about receipt of DMPA in the previous three months. This circumstance could occur, for example, during the transition from OCP to DMPA, or vice-versa. Among those subjects indicating DMPA use, medical records were reviewed to ascertain dates of injections. DMPA contraceptive coverage was considered to have lapsed for intervals of greater than 14 weeks beyond the most recent documented injection.

For 26 diary periods, one of the flanking interviews was missing. Diary periods with missing entry interview data ($n = 1$) were excluded from the analysis. For the remaining 25 diary periods with missing information about OCP use, we used the nearest three diary days to impute OCP use. After imputation, the diary periods were then assigned to one of the four previously defined OCP groups.

Other measures

Demographic and behavioral characteristics included age (in years), race, years since first coitus, number of sex partners (past three months), lifetime sex partners, and the number of coital events in the past three months.

Data analysis

The primary unit of analysis was the three-month diary period. Within a given diary period, outcomes of interest included the number of diary days, daily OCP pill-taking, the number of coital events, and condom use associated with coital events.

For our first objective, to describe daily pill-taking adherence patterns of OCP use by method choice, we describe consecutive days of pill-taking and interruptions (three or more consecutive missed pills) of OCP use for each method choice category. We assessed the number of consecutive days of pill usage, the number of intervals of pill usage that were interrupted by three or more consecutive days of missed pills, and the number of days on which pills were not taken. As subjects were recruited from clinics where 28-day OCP packs are uniformly prescribed, perfect pill use would be described by a single unbroken sequence of consecutive pill-use days. Patients are routinely instructed to take the seven inert pills in the pack.

Our definition of an interruption of pill use as three or more consecutive days of missed pills is based on theoretical concerns and typical clinical practice. First, pituitary-

Table 1

Patterns of oral contraceptive pill (OCP) use over three months, by OCP method choice category^a

OCP use category	Diary periods	Mean number diary days ^b (SD)	Mean days of consecutive OCP (SD)	Mean days of sequential missed OCP (SD)	Episodes of 3 or more missed OCP
Stable (n = 53)	87	72.6 (22.3)	32.5 (29.2)	17.4 (16.2)	1.9 (1.0)
Initiated (n = 24)	25	77.6 (13.9)	20.4 (22.7)	26.3 (24.8)	1.9 (1.0)
Stopped (n = 45)	48	75.4 (20.9)	20.5 (26.5)	26.4 (22.7)	1.9 (1.1)
Discordant (n = 45)	50	79.6 (13.2)	7.2 (10)	31.2 (24.1)	2.2 (0.8)
All groups ^c	210	75.5 (19.3)	23.4 (26.8)	25.9 (22.7)	2.0 (1.0)

^a Stable use = OCP use reported at diary period entry/exit interviews; Initiated use = OCP use at diary period exit interview only; Stopped use = OCP use at diary period entry interview only; Discordant use = no OCP use reported at diary period entry/exit, with at least one day of use recorded in the diary.

^b Total number of diary days = 15,859.

^c Individual participants n = 123. Some participants contribute to multiple OCP method choice categories.

ovarian suppression may decline as the number of missed pills increases, especially for formulations containing less than 30 μg of estrogen [23]. Although ovulatory “escape” is rare even with early or late cycle pill omission, three or more missed pills constitutes an OCP adherence pattern associated with increased risk of ovulation and pregnancy [24,25]. Second, women who miss three or more active pills are often instructed to begin a new pill pack, to abstain from sex, or to use alternative contraceptive methods [26].

For our second and third objectives we examined coital events on an event-level basis among stable OCP diary periods as well as among transition diary periods. The coital events were protected by OCP alone, condoms alone, OCP with condoms, or were unprotected. We defined coital events as OCP-protected if the participant reported OCP use on both the diary day preceding and the diary day of a given coital event. Participants reported directly on daily diaries whether coital events were condom protected. This event level analysis allowed us to examine whether sexual activity itself serves as a cue to pill-taking and if condom use is more likely if pills have been missed. Specifically, we reported the number of coital events in each type of OCP use period and tabulated the numbers and percentages of coital events protected by various methods, including OCP, condom, DMPA, and certain combinations of the three methods. Finally, we compared the percentages of coital events protected by each contraceptive method (or combination methods) between different OCP use categories.

To accommodate the interdependency among the diary periods contributed by the same subject, we used bootstrap techniques to construct 95% confidence intervals for the difference of percentages of coital events protected by each of the contraceptive methods between two OCP use categories. Bootstrapping is a widely used statistical re-sampling technique used to empirically estimate standard errors. Specifically, in each bootstrap iteration, subjects were randomly selected (with replacement) from the original sample. In each iteration, rates of OCP pill-taking were then estimated. After 10,000 iterations, empirical estimates of distributions OCP pill-taking were obtained. From such empirical distributions, 95% confidence intervals were cal-

culated using the t-percentile method [27]. This resampling strategy accommodates the contribution of multiple non-independent diary periods contributed by single subjects. Due to the large number of comparisons involved, the resulting confidence intervals were also adjusted for multiple comparisons using the Bonferroni method, with statistical significance accepted at $p < .016$.

Results

Demographic data

The sample consisted of 123 pill users (82.9% African-American) with a mean age of 16 years (SD 1.0 year) at enrollment. The mean time elapsed since sexual debut was 2.3 (SD 1.3) years, the mean number of sex partners in the previous three months was one, number of lifetime sex partners was 3.2 (SD 3.0), and the mean number of sexual events in the past three months was 8.0 (SD 16.5) at the time of enrollment.

These 123 individual participants contributed 210 diary periods containing 15,859 diary days (mean diary length = 75.5 days, SD 19.3). There was no significant difference in the average number of diary days contained in the four OCP use groups (see Table 1).

OCP method usage and adherence

Fifty-three subjects contributed 87 diary periods defined as “stable OCP use.” Twenty-four subjects contributed 25 diary periods defined as “initiated OCP use” (i.e., started OCP during the three-month interval). Forty-five subjects contributed 48 diary periods defined as “stopped OCP use.” Forty-five subjects contributed 50 diary periods defined as “discordant OCP use.” Because many individual subjects contributed multiple diary periods, they were counted in more than one OCP method use group.

The validity of the four OCP method choice categories is supported by patterns of OCP pill-taking (Table 1). As expected, the average number of consecutive OCP use days was highest in diary periods characterized by stable OCP method use, and lowest in those characterized by discordant

Table 2
Hormonal contraceptive use and condom use in association with coital events by OCP method choice category^a

OCP use category ^b	Coital events n	OCP n (%) ^c	OCP/condom n (%) ^c	Condom n (%) ^c	DMPA n (%) ^c	DMPA/condom n (%) ^c	No protection n (%) ^c	% Protected against STI n (%) ^c	% Protected against pregnancy n (%) ^c
Stable	458	120 (26.2)	204 (44.5)	55 (12)	0	0	70 (15.3)	259 (56.5)	379 (82.8)
Initiated	115	4 (3.5)	13 (11.3)	28 (24.4)	5 (4.4)	14 (12.2)	43 (37.4)	55 (47.8)	64 (55.7)
Stopped	311	49 (15.8)	36 (11.6)	76 (24.4)	62 (19.9)	8 (2.6)	68 (21.9)	120 (38.6)	231 (74.3)
Discordant	396	23 (5.8)	24 (6.1)	89 (22.5)	90 (22.7)	69 (17.4)	82 (20.7)	182 (46)	295 (74.5)

^a OCP use defined as OCP taken either day before or day of (or both) coitus.

^b See Table 1 for definitions.

^c Total % will not equal 100 due to the fact that some events had no response to condom or pill use.

method use. The average number of sequentially missed pills was also lowest in stable OCP method use diary periods, intermediate in diary periods characterized as initiated or stopped OCP method use, and highest in those characterized by discordant OCP method use.

Diary periods characterized by stable OCP method use did not necessarily represent highly consistent day-to-day pill-taking; the median number of periods of sequential OCP (i.e., uninterrupted) pill-taking was one per diary period with a range of one to five interrupted sequences of OCP use per diary period. Mean length of consecutive days of OCP pill-taking was 32.5 (SD 29.2) days (Table 1). The average number of days of sequentially missed OCP among stable OCP method users was 17.4 (SD 16.2) days. Because missed pills were included in the definition of sequential days of pill-taking, 3.1% of pills were missed within a sequence of days of OCP pill-taking. For the initiated OCP use group, the mean consecutive OCP use was 20.4 days; the mean for days of sequential missed OCP for the initiated OCP group was 26.3 days.

OCP pill-taking and condom-protected coitus

Contraceptive use in association with specific coital events varied substantially among the four OCP choice categories (Table 2). In diary periods characterized by stable OCP use, 324/458 (70.7%) of coital events were associated with OCP use on the day before or day of coitus with or without condoms. However, for 55/458 (12%), OCP were skipped on the day before and the day of coitus: these coital events were, however, protected by condoms. Even among these apparently stable OCP users, an additional 70/458 (15.3%) coital events were neither associated with OCP use the day before and day of coitus, nor protected by a condom at the time of coitus.

Potential lack of pregnancy protection was higher in diary periods characterized by method transition (i.e., periods characterized by initiated or stopped OCP use) or those characterized by discordant use (Table 2) than those characterized by stable use. For these diary periods, more than 20% of coital events were not associated with a hormonal method or condom use. In contrast, in stable OCP use diary

periods there was no pregnancy protection from either OCP or condoms for only 15% of coital events. Similarly, STI protection by condom use was lower among transition diary periods compared to stable-use diary periods. More than 50% of all coital events in the stable-use group were condom protected, whereas in transition diary periods, less than half of all coital events were condom protected.

We next examined types of contraceptive protection for specific coital events as a function of OCP method choice (Table 3). Coital events associated with OCP protection only (without condoms) were significantly more likely to occur in diary periods characterized as stable OCP method use than by those characterized as initiation of OCP method use. More importantly, coital events associated with both OCP use and condom use were significantly more likely in diary periods characterized as stable OCP method use, compared to those characterized as initiated or stopped OCP use. No significant differences were noted between OCP choice categories and coital events associated with condoms only, or those associated with no contraceptive protection. No significant differences were noted for any type of protection when coital events occurring in diary periods characterized by initiated OCP use were compared to those characterized by stopped OCP use.

Discussion

This study identifies important challenges for clinicians committed to assisting adolescent women achieve effective contraception and STI protection. In a positive sense, the results show, through the utilization of diary periods, that many young women effectively manage the dual demands of pregnancy and STI prevention. The clinically challenging results are that many young women are at risk, especially during transitions into or out of periods of OCP use. Even among young women with stable patterns of OCP method choice, many have daily pill-taking patterns that are sufficiently inconsistent to increase pregnancy risk.

The results of this study extend observations of other research. Previous studies show that 50% of young women report imperfect pill use during a pill cycle [11,28]. Ap-

Table 3
Summary table for bootstrap mean percent of protected events and confidence intervals

Coital event-specific contraceptive method	OCP method choice group		Mean difference, 95% CI ^a
	Mean %	Mean %	
OCP only ^b	Stable 26.5	Initiator 3.6	23.0 (6.1, 41.9)*
	Stable 26.5	Stopper 15.8	10.8 (−9.1, 32.3)
	Initiator 3.6	Stopper 15.8	−12.2 (−27.6, 1.9)
OCP/condom	Stable 44.2	Initiator 11.5	32.7 (2.2, 60.5)*
	Stable 44.2	Stopper 11.7	32.6 (9.4, 56.3)*
	Initiator 11.5	Stopper 11.7	−.1 (−16, 23.9)
Condom only	Stable 12.1	Initiator 24.9	−12.8 (−39.8, 6.8)
	Stable 12.1	Stopper 24.5	−12.5 (−32.3, 5.1)
	Initiator 24.9	Stopper 24.5	.3 (−25.7, 31.5)
No contraception	Stable 14.9	Initiator 36	−21.1 (−55.8, 16.9)
	Stable 14.9	Stopper 21.9	−7 (−26.5, 19.7)
	Initiator 36	Stopper 21.9	14.1 (−19.7, 47.2)

^a Confidence intervals are adjusted for multiple comparisons.

^b OCP use day prior to coitus or day of coitus.

* Significant values.

proximately 25% of OCP users miss two or more pills during a pill cycle, placing them at increased pregnancy risk [12,29]. These figures are similar to those seen for the stable OCP method use group in our study where 27% of coital events occurred during a period of two or more missed pills. Because of other patterns of OCP method use (e.g., starting, stopping), the overall proportion of unprotected coital events was even higher. In fact, many participants who identified themselves as OCP users were in method transition, associated with less consistent pill-taking and condom use. Thus, earlier research with less-well-specified identification of OCP method use may over-estimate the degree of protection among adolescent OCP users [11,12,17,28,29]. However, it does appear that the stable OCP method use group is slightly more likely to cover coital events with condoms, although the extent to which condoms were utilized correctly was not specifically investigated. Despite such an increase, a high number of coital events were protected by no contraceptive method, which is important for both stable users and those transitioning from a contraceptive method. These numbers also suggest that OCP starters and stoppers are vulnerable to pregnancy and STI, and clinicians should closely monitor patients for periods of such susceptibility.

These data should be assessed in light of the study sample and research design. Study participants were predominantly African-American women receiving care at urban clinics. This is a relevant sample because of high rates of STI and early pregnancy. Although no data were kept on study refusals, the cohort's STI rates and race mirror the clinic population. This study also focused on participants who reported OCP use at some point during the study. Examination of the study data also explored the possibility of systematic missed pills during the placebo week; no evidence for such patterns was detected. Method use and adherence of other hormonal contraceptive methods such as

the patch were not evaluated. However, at the time of collection of these data, contraceptive patch use contributed only a small percentage of all contraceptive methods chosen. Adolescent contraceptive use is imperfect, with a significant number of coital events unprotected from pregnancy or STI risk. Given the inconsistencies of OCP use among adolescents, further insight and investigation is needed to understand factors associated with effective prevention. More detailed information may better inform clinicians about ways to encourage more stable and consistent usage of contraception.

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