REVIEW ARTICLE

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Compliance and Oral Contraceptives: A Review

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Compliance difficulties are more common among oral contraceptive (OC) users than generally appreciated by clinicians, in part because unintended pregnancy is a relatively infrequent consequence and in part because more common manifestations such as spotting and bleeding may not be recognized as resulting from poor compliance.

While improving compliance is a shared responsibility of patients, clinicians, and manufacturers, the clinician is the focal point for these efforts. Counseling must be individualized, which requires knowledge of factors that predict compliance and an understanding of the patient's decision-making process as it relates to medications. Most OC compliance research has focused on adolescents, where predictors of poor compliance include multiple sex partners, low evaluation of personal health, degree of concern about pregnancy, and previous abortion. Good compliance has been linked with patient satisfaction with the clinician, the absence of certain side effects, establishing a regular daily routine to take OCs, and reading information distributed with OC packaging. CONTRACEPTION 1995;52:137–141

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Introduction

The term compliance is widely used to indicate the degree to which patients adhere to a prescribed regimen.[1] The issue of compliance with oral contraceptives (OCs) is in many ways similar to that faced by clinicians attempting to treat chronic disorders, since the medication must be taken on a long-term basis. Treatment regimens may be complicated, inconvenient, and expensive, and it is not difficult to imagine why compliance problems occur. After decades of compliance research and more than 4,000 articles on the subject,[2] we know basically that, "it seems a third of patients always comply, a third never comply, and a third sometimes comply."[3] We still do not know enough about what motivates and separates these three groups.

To a much greater extent than we might like to admit, physicians find it difficult to identify patients who are poor compliers.[4] In one study, primary care physicians were asked to estimate compliance only for patients they knew well. They were able to identify only 10% of patients who complied poorly.[4] This emphasizes medical education's focus on the diagnosis and treatment of disease, with little attention paid to what happens after the prescription is made.

In the US, approximately 30%, or 18 million, women of reproductive age currently use OCs,[5] and 80% of all US women will use OCs at some time during their reproductive years.[6] OCs provide a high degree of contraceptive efficacy, similar to the IUD, implants, and long-acting injectables, but the method is unique in providing a range of non-contraceptive benefits, including protection against endometrial and ovarian cancers. The method also has an excellent safety profile that reflects steady decline in the constituent components, estrogen and progestin, over the thirty years they have been marketed.

OC efficacy, however, requires proper use. Many users find it difficult to take their pills consistently,[7] and as many as half of new users will stop using OCs within the first year.[8] Poor OC compliance includes missing pills, taking pills out of order, and starting a package early or late. Additional problems related to poor compliance are sporadic use (frequent starting and stopping), not using a backup contraceptive method when indicated, and discontinuing the method but failing to substitute another while still at risk for unintended pregnancy. The potential consequences of improper use range from none to minimal side effects such as spotting or breakthrough bleeding,

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to the profound such as unintended pregnancy.[9] In the US, it has been estimated that over one million unintended pregnancies are the result of OC method failure, misuse (missed pills), or discontinuation; more than half of these pregnancies are due to discontinuation.[10]

Because poor compliance may have no immediate or uniform consequence, the idea that proper, consistent use is not important is reinforced for some women. Even when problems such as side effects do occur, women may not associate them with improper use of OCs. Likewise, physicians may not associate side effects such as spotting and bleeding with improper use, despite these problems being a leading reason for physician calls and unscheduled visits.[11] While one study found that women who missed one or more pills per cycle were three times as likely to have an unintended pregnancy,[12] the extent to which missing pills directly increases the probability of ovulation and pregnancy is not well defined.[13,14] This may create additional ambivalence among physicians about the need to stress proper compliance.

Unfortunately, few large studies of OC compliance have been conducted in the general population. The existing literature on contraceptive use focuses on adolescents, and the large majority of these studies involve small numbers of subjects that are not able to differentiate between a number of risk factors. Here we discuss the scope of the problem of OC noncompliance, review factors associated with incorrect use of OCs, and evaluate approaches and make suggestions for improving OC compliance.

How Common Are Compliance Problems?

Information on the extent of OC compliance problems focuses primarily on adolescents. This attention to adolescents is understandable, given that one in eight adolescents age 15–19 years will become pregnant, and that 47% of sexually active teenage females rely on OCs as their primary method of birth control.[15]

As might be inferred from high pregnancy rates, adolescents commonly miss pills and frequently discontinue OCs. In one study, adolescents missed an average of three pills in each cycle.[16] Another study reports that compliance among 13–19 year olds, defined as returning for the scheduled visit and either having taken the pill as directed or having stopped taking the pill because contraception was no longer needed, varied from 48% to 84%.[17] Compliance was related to socioeconomic factors, with the lower rate of compliance for inner-city teenagers enrolled through a hospital-based adolescent clinic and the higher rate for upper-middle class teenagers enrolled through a suburban private practice. Another study reports similar OC discontinuation rates of 50% in the first three months of use.[16]

A particular problem for young women is sporadic use of OCs. Many cease using OCs when they are not in a sexual relationship, only to restart them when another relationship starts. This intermittent use may leave women unprepared. No method or a method less effective than OCs is used, often resulting in unintended pregnancy.[6,10] Finally, compliance and continuation may be affected by ambivalence about becoming pregnant,[18] and the degree of this ambivalence may vary between adolescents and older women.

Among older women, most studies report lower missed pill and discontinuation rates. In a recent telephone survey of 2,003 women 18 to 30 years old, 30% of women report missing one or more pills per month [Rosenberg MJ, Waugh MS (unpublished data)]. Similarly, 25% of women in a large retrospective study (n = 1,311) did not take their pill within the recommended "window of hormonal safety," by either taking a pill every day or always remembering to take a missed pill by the end of the next day.[7] Discontinuation rates over a year's time are in the range of 25% to 50%, somewhat lower than those for adolescents.[8]

While young age has been commonly perceived to be a marker for poor compliance, recent work suggests that this may be an oversimplification that holds true only for the youngest teenagers. When pill-taking "microbehaviors" (take the pill daily, take only one's own pill, take all pills in the pack, take all pills in the prescribed order within two hours of the same time, and use of a backup method when needed) were measured, most adolescents performed about as well as older women.[19] These data show that only the youngest adolescents (age 14 and younger) do very poorly, with only 26% taking a pill every day, whereas roughly 40% of all other age groups report taking a pill every day. Similarly, older adolescents, age 18–19, were found not to be at greater risk for missing pills than women aged 20–24 or 25–29 through an analysis of recent survey data using logistic regression to identify the independent effect of numerous risk markers.[12] Thus, other factors may prove to be better predictors of OC compliance than "adolescence" alone.

Identifying Factors and Markers That Predict Poor Compliance

Three approaches have been used to identify factors predicting noncompliance.[20] The first is a nonspecific model in which a broad range of characteristics, behaviors, and other factors are measured in an attempt

to identify those associated with poor compliance (*individualistic model*). By use of statistical techniques such as logistic regression, characteristics are identified in an attempt to identify patients at risk for poor compliance. The second model postulates that health behavior generally and contraceptive behavior specifically depends on patient perceptions of susceptibility to the particular illness (in this case, pregnancy), severity of consequences resulting from pregnancy, and costs (physical, psychological, financial) vs. benefits (preventing/reducing susceptibility) if the health action (proper use of OCs) is taken (*health belief model*).[21] The third approach hypothesizes that the interaction between patient and provider is one of the primary determinants of compliance (*patient-provider model*).[22] The degree to which a patient participates in discussion when visiting the physician, the attitude of the physician (friendly or antagonistic), the quality of communication and information provided by the physician are all components of this interaction and are potential determinants of patient compliance.[22,23] These three approaches are not necessarily exclusive of one another.

Empiric Findings

The majority of these studies employ individualistic models. Of these, factors most commonly associated with incorrect daily use of OCs are side effects such as breakthrough bleeding, spotting, nausea, heavy periods, and amenorrhea. Women with these side effects are significantly more likely to miss one or more pills each monthly cycle than women who do not [Rosenberg MJ, Waugh MS (unpublished data)].[12,13] However, one small study (of adolescents) reported no relationship between the occurrence of side effects and compliance.[24] In large retrospective surveys of contraceptive compliance and discontinuation conducted in the United States and Europe, the strongest single factor related to compliance was whether women had a regular routine for taking their pills: women who did not were over three times more likely to miss one or more pills each monthly cycle than women who always took their pill at the same time [Rosenberg MJ, Waugh MS (unpublished data)].[12] Morning routines were the most reliable, with evening routines slightly less so. Women who reported reading and understanding little or none of their pill package information were roughly two times more likely to miss one or more pills each monthly cycle than women who read and understood all the information.

Among adolescents, better OC compliance has been linked with a parent having made the clinic appointment and accompanied their child to the clinic.[25] However, another study reported that teens who made their own clinic appointment were significantly more compliant with their contraceptive regimen over a three-month period than those who did not.[26] Psychosocial characteristics associated with poor OC compliance among 14–19 year olds include multiple sexual partners, low evaluation of personal health, feelings of hopelessness, worry about becoming pregnant, and previous abortion.[27] Teens were also significantly more compliant if they expressed satisfaction with the pill, experienced no side effects, and expressed a desire to go to college.

Little is known about the importance of the relationship between physician and patient as a determinant of OC compliance. One study reported that adolescents were significantly more compliant if they considered the physician "helpful."[27] However, no insights were provided as to the specific criteria that make one physician more helpful than another.

Despite imperfect compliance and frequent unplanned pregnancies, few evaluations of strategies to improve compliance have been conducted. Among adolescents, using peer counselors improved contraceptive compliance.[28] Fifty-seven adolescents counseled by a peer had significantly better compliance at one- and two-month follow-up visits than another group of teens who received counseling from nurses. No studies that evaluated methods of improving compliance among older women are available.

Suggestions for Improving OC Compliance

Improving compliance is a responsibility shared by health care providers, patients, and OC manufacturers. Although a consistent understanding of factors that predict compliance is lacking, particularly in different groups of women, several strategies appear helpful (Table 1). For these, the clinician serves as the focal point, since he or she must assess each patient, decide which areas are appropriate for emphasis, and assure that the patient understands information that serves as the basis for proper OC use.

Hippocrates' warning "Keep watch also on the faults of the patients, which often make them lie about the taking of things prescribed"[29] reminds us that medication compliance has long been a problem. Compliance problems with OCs are considerably more common than recognized, for several reasons. First, many clinicians judge poor compliance by the number of unplanned pregnancies that occur while a woman is using OCs, which are generally infrequent. Second, imperfect compliance has more common manifestations, such as spotting and bleeding. In addition to being inconvenient or embarrassing for the OC user, such problems are a leading cause of unscheduled physician visits and calls. More impor-

Table 1. Means of improving OC compliance

A. Health care providers
   1. Help women think through their contraceptive choice based on their background, individual needs and concerns, taking the likelihood of method compliance into account
   2. Discuss the transient nature of most side effects for women starting OCs
   3. Dispel OC misinformation and discuss the non-contraceptive benefits of OCs
   4. Instruct in the correct use of the specific OC package prescribed
   5. Provide easy-to-understand missed pill instructions in both verbal and written form
   6. Be sure the patient knows how to get additional information about OCs and their use, should she have questions later on
   7. Use follow-up contact or phone inquiries by patients as an opportunity to evaluate consistency of use; for example, patient calls about spotting or breakthrough bleeding should be a flag for incorrect use and an opportunity to review missed-pill instructions

B. OC users
   1. Establish a regular pill-taking time
   2. Carefully read literature that accompanies pill package
   3. Know what to do if pills are missed
   4. Identify a back-up contraceptive method

C. OC manufacturers
   1. Encourage research to define predictors of and factors related to compliance
   2. Incorporate findings into pragmatic tools that help clinicians identify patients at risk for noncompliance
   3. Use OC packaging that encourages compliance
   4. Develop standardized content instructional and "reminder" written materials that are comprehensible, especially to those with reduced literacy or no English literacy

tantly, women who experience these problems are substantially more likely to discontinue OCs, often without informing their physician,[6] which frequently results in unintended pregnancy. Finally, the term "compliance" may carry negative connotations or imply an all-or-nothing phenomenon, when the issue is one of degree. A more neutral term such as "how contraceptives are used" may help.

Many of the existing compliance articles tell us things that seem to be absolutely reasonable. For example, patients don't like to take medicines that have numerous side effects,[30,31] nor do they like to follow complex therapeutic regimens.[32,33] Contrary to Hippocrates' advice, more recent compliance research has asked us to consider abandoning the assumption that the physician is the benevolent authority and that patients who do not willingly accept the doctor's orders should be seen as deviants.[34] Thus, studies would focus less on identifying variables that are strongly related to noncompliant behavior and more on the decision-making process used by patients. This strategy reminds us that people are not taking medicines in a thoughtless vacuum but that they have their own ideas and attitudes about medicine.[35]

Information about the patient-clinician relationship is also lacking. This shift in perspective emphasizes the contribution of the health care provider ("How can we best help this patient to take their OCs?") rather than considering compliance problems to rest with the patient. Little is known about what information, if any, is conveyed to patients, and how effectively. An extension would be to determine what messages are most effective for women of various socioeconomic and demographic groups, how they should be conveyed, and by which member of the health care team. These considerations are likely to be of increasing importance given growing financial pressures on health care delivery.

Given the millions of women who use OCs and the consequences of poor compliance, the dearth of studies evaluating strategies to improve OC use is surprising. The studies that have been conducted involve limited populations (often adolescents) and tend to be small, limiting both the reliability of the study and its ability to discern between factors that may be closely associated. Additionally, very little work has been done on women twenty or more years old, even though this group comprises the majority of OC users.[5] Further research is required to improve our understanding of why patients may choose not to take OCs as prescribed.

Another step toward implementing more effective means to improve compliance is to develop tools that attractively convey useful, and understandable, information about OCs. Several OC manufacturers have taken a step in this direction with "starter kits" that may contain device(s) to help patients remember to take their pills, along with information about OCs and missed pill instructions. While this is an important step, the same information is presented to all women, regardless of their background, age, or individual needs. The future promises development of tools, such as a computerized "quiz" that a patient can take during her physician visit, to assess her potential for poor compliance. Through an interactive process such tools can generate reports that make individualized suggestions to optimize the patient's compliance, based on responses to contraceptive preference and compliance-related questions. This approach might have the additional benefit of freeing staff time. This may in fact prove to be of increasing importance, as the demands of health care reform reduce the time available to clinicians for counseling

and create a "you want it, you got it" scenario of oral contraceptive prescribing with minimal physician counseling.

Clearly, developing more effective means to improve compliance demands more information than presently exists. Continued investigation into OC noncompliance and evaluations of strategies to improve compliance will ultimately prove worthwhile, since many of the causes of noncompliance are correctable and the costs of poor compliance are substantial.

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