

Use of combined oral contraceptives: retrospective study in Isfahan, Islamic Republic of Iran

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استخدام حبوب منع الحمل الفموية المشتركة: دراسة استيعادية في أصفهان، جمهورية إيران الإسلامية
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الخلاصة: قام الباحثون بإجراء دراسة استيعادية، شملت 500 سيدة من مختلف القطاعات في أصفهان، ممن تناولن حبوب منع الحمل الفموية المشتركة خلال المدة من 21 آذار/مارس 1995 حتى 20 آذار/مارس 1997. وقد انخفض معدل المواظبة التراكمي من 77% إلى 12% على مدى 60 شهراً. وكان السبب الرئيسي في عدم المواظبة هو الآثار الجانبية. فهناك ترابط يُعتدُّ به إحصائياً بين الآثار الجانبية وبين معدل المواظبة التراكمي ($P < 0.05$). وكانت أدنى معدلات المواظبة بين السيدات اللاتي أبلغن عن حالات قيء وغثيان. ومن ثمَّ فلا بد من حصول الراغبات في تناول حبوب منع الحمل الفموية المشتركة على استشارات مكثفة حول الآثار الضائرة المحتملة، كما يجب مساعدتهن على إيجاد وسيلة لتنظيم الأسرة تتلاءم مع حالتهن الفيزيولوجية والمزاجية.

ABSTRACT We carried out a retrospective cross-sectional study on 500 women in Isfahan who started taking combined oral contraceptives (COCs) during the period 21 March 1995–20 March 1997. The cumulative continuation rate fell from 77% to 12% over 60 months. The most common reason for discontinuation was side-effects. There was a significant correlation between side-effects and cumulative COC continuation rate ($P < 0.05$). The lowest rate was seen in women reporting nausea or vomiting. Women who are interested in COCs should receive extensive counselling about the possible side-effects and should be helped to find a method of birth control suited to their temperament and physiology.

Utilisation des contraceptifs oraux associés : étude rétrospective à Ispahan (République islamique d'Iran)

RÉSUMÉ Une étude transversale rétrospective portant sur 500 femmes qui ont commencé à prendre des contraceptifs oraux associés durant la période du 21 mars 1995 au 20 mars 1997 a été réalisée à Ispahan. Le taux cumulatif de poursuite de la contraception est passé de 77 % à 12 % sur 60 mois. La raison la plus courante pour l'abandon de la contraception était les effets secondaires. Il y avait une corrélation significative entre les effets secondaires et le taux cumulatif de poursuite de l'utilisation des contraceptifs oraux associés ($p < 0,05$). Le taux le plus faible a été observé chez les femmes signalant des nausées ou des vomissements. Les femmes qui souhaitent prendre des contraceptifs oraux associés devraient être bien conseillées au sujet des effets secondaires possibles et devraient être aidées pour trouver une méthode de régulation des naissances correspondant à leur tempérament et à leur physiologie.

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Introduction

Despite advances in family planning, population growth remains a worldwide concern. In 1999, the world population reached 6 billion (6 000 000 000), an increase of 4.4 billion since 1900 [1].

Contraceptive technology has been a medical success. For the majority of users, contraception enhances the quality of life, allowing couples to choose whether and when they have children [2]. Oral contraceptive pills have been studied since 1960; they are used every day by more than 50 million women around the world for prevention of unwanted pregnancy. The effects are reversible and there are many non-contraceptive health benefits, some of which last for years [3].

To ensure effective practice of family planning it is not necessary that the client makes the optimal choice of method but it is important that she continues to use the method properly [4]. Continuation rates are reliable indicators of the overall use of a contraceptive method. High rates of discontinuation are generally recognized as the major problem facing family planning programmes and there is a need to look for associated factors [5].

Women who discontinue oral contraception often substitute a less reliable method or no method at all, often leading to unintended pregnancy. Side-effects of oral contraceptives were the most frequent reasons given by women for discontinuation of use [6]. Some studies indicate that 3%–25% of the women who use this method have reported at least 1 side-effect, and over half of those who discontinue the use report the occurrence of side-effects as the reason for discontinuation. Studies sponsored by the World Health Organization have shown substantial levels of discontinuation associated with menstrual problems, gastrointes-

tinal complaints and central nervous system disturbances. Less has been written about the occurrence of side-effects and their association with discontinuation in populations from developing countries [7].

Although considerable work has been done on contraceptives in the Islamic Republic of Iran, little is known about the continuation rate of combined oral contraceptives (COCs) and problems concerning their use.

The most commonly used COCs worldwide are monophasic formulations that contain a fixed amount of estrogen and progestogen throughout the cycle [8].

The purpose of this study was to investigate the occurrence of selected side-effects and the correlation between their occurrence and continuation rate of COCs among women in Isfahan using LD or HD contraceptives (containing 0.15 mg levonorgestrel plus 0.03 mg ethinyl estradiol or 0.25 mg levonorgestrel plus 0.05 mg ethinyl estradiol).

Methods

A retrospective cross-sectional study was carried out on women in Isfahan who started taking COCs (either LD or HD) during the period 21 March 1995–20 March 1997. This time period allowed us to select a large enough sample for the study.

We obtained a list of all family planning service facilities, such as maternal and child health and family planning centres, and 16 centres were selected randomly by cluster sampling. Isfahan was divided geographically into 5 regions and 20% of the medical centres in each region were randomly selected.

In these centres, medical consultations or visits were set up on a confirmed appointment basis and a schedule of regular medical

appointments made according to the chosen contraceptive method, e.g. monthly for the women using COCs. Data collection was carried out from 15 September 2001 to 15 December 2001. Each day interviewers approached the women who were attending clinics. They were asked if they had ever used COCs. If the answer was yes, the date of starting was determined and those who had started between 21 March 1995 and 20 March 1997 were asked to participate in the study. Sample size was determined based on probability calculations. A total of 500 women were enrolled and the data from their records over a 5-year period were analysed. There were no refusals to participate.

We used a comprehensive questionnaire to collect data on characteristics such as age, level of education, employment status, number of living children and side-effects reported by the participants during the use of COCs. Collection of data was administered by 4 trained interviewers, each of whom worked in 4 of the 16 centres

Following the interviews, data were collected from medical staff and clinical records for the determination of continuation rates. We considered the duration of COC use to be from the beginning of the prescription until the date of stopping, as in O'Dell et al. [9].

Content validity was used in order to determine the validity of this questionnaire.

Results were analysed using SPSS statistical software, version 5.5.

Contraceptive continuation rates were also estimated using Kaplan–Meier analysis [5] and the association between reported side-effects and continuation rate was investigated by χ^2 test. P -value < 0.05 was considered statistically significant.

Results

Characteristics of users

Table 1 shows basic information on the characteristics of COC users. The most numerous group (43.6%) was the 15–24 year age group; 9.0% were ≥ 35 years old. Mean age was 26.24 (standard deviation 6.22) years. More than half (62.6%) were educated to secondary school level and 3.4% had a university education.

Only 22.8% of the women in the study had ≥ 3 living children. The vast majority (92.4%) were not employed outside the home.

Continuation rates

The median duration of use was 21.38 (standard deviation 15.94) months.

Table 1 Characteristics of combined oral contraceptive users in Isfahan ($n = 500$)

Characteristic	No.	%
<i>Age (years)</i>		
15–24	218	43.6
25–29	164	32.8
30–34	73	14.6
≥ 35	45	9.0
<i>Education level</i>		
None	20	4.0
Primary school	152	30.4
Secondary school	311	62.2
University	17	3.4
<i>Employment status</i>		
Employed	38	7.6
Not employed	462	92.4
<i>No. of living children</i>		
0–2	386	77.2
≥ 3	114	22.8

The cumulative proportion of continuation fell from 77% at 6 months to 12% at 60 months. The commonest reason for discontinuation was side-effects (37.0%). Other reasons included accidental pregnancy (2.8%), desire for pregnancy (16.8%), husband absent or divorce (1.2%), advice of the doctor or midwife (8.6%) and desire for a change of method (10.2%).

Analysis of the results showed that there was a significant correlation between side-effects and cumulative proportion of COC continuation ($P < 0.05$).

Kaplan–Meier analysis showed there was a significant difference in continuation rates between women reporting side-effects and those who had no side-effects. Cumulative proportion of continuation was 78% 12 months after starting COCs and 24% after 60 months for clients not reporting side-effects. These figures were 50% and 0% for the participants who had reported having side-effects.

Table 2 shows the data on side-effects: 56.4% of the participants reported having ≥ 1 side-effect while using COCs. These included bleeding problems, nausea or

vomiting, mood changes, facial complexion changes, weight gain, facial complexion with mood changes, heavy discharge and headaches.

Using Kaplan–Meier analysis, we found that women who reported nausea or vomiting had the lowest cumulative proportion of continuation, 28% after 12 months; other causes included bleeding problems (50%), mood changes (52%), facial complexion changes (55%), weight gain (70%), facial complexion and mood changes (45%), heavy discharge (62%) and headaches (63%) after 12 months.

Among women who discontinued, the next contraceptive methods recommended by the midwife or preferred by the women were condoms (20.0%) and the intrauterine device (13.6%). Combined oral contraceptives were used by 5.8% of the women and withdrawal by 11.6%. Sterilization was preferred by 2.8% and 20.4% chose no contraceptive at all.

Discussion

After 18 months, the cumulative proportion of continuation of use of COCs was 52%. This is comparable to that found in the Philippines (52.3%) [10]. The cumulative proportion of continuation in our study after 12 months (62%) was better than that observed by Alihonou in West Africa (40.8%) [11].

Some couples select a contraceptive method and continue using it throughout their reproductive lives. Others will discontinue methods several times. There are many reasons why women stop using the COC method, for example, they may be dissatisfied with the side-effects, or have previously followed poor advice from clinic staff.

Only 5.8% of the women in our study who discontinued using pills for contracep-

Table 2 Side-effects reported by combined oral contraceptive users in Isfahan ($n = 500$)

Side-effect	No.	%
Bleeding problems	31	6.2
Nausea or vomiting	43	8.6
Mood changes	73	14.6
Facial complexion	16	3.2
Weight gain	28	5.6
Headaches	23	4.6
Facial complexion with mood changes	11	2.2
Heavy discharge	17	3.4
Other	40	8.0
Total	282	56.4

tion used pills again and most of the remainder started some less efficient method, e.g. withdrawal was used by 11.6% and condoms by 20.0%. Therefore, it could be concluded that side-effects associated with some modern contraceptive methods may cause women to switch to other methods, some of which may be less reliable.

On the other hand, 20.4% of the participants stopped using COCs and did not start using any other method. Clinic staff should, therefore, be prepared to facilitate switching methods so that each client can find a method of contraception suitable for her temperament and physiology [4]. In addition, if a client plans to discontinue a method and begin using another method, the provider should urge her to do so immediately. Otherwise she risks an unwanted pregnancy.

In our study, side-effects were the most common reason cited for discontinuation of COCs and women who discontinued use for this reason had a lower cumulative proportion of continuation than those who had no complaints. In a similar study, Phillips also found side-effects were a major concern of pill acceptors and an important correlate of discontinuation [10]. Kaplan–Meier analysis of 9 specific types of side-effect showed that clients with nausea and vomiting had lower cumulative proportion of continuation than others. This finding was similar to that reported in Sri Lanka by Basnayake [7].

It is essential for women who are interested in COCs to receive extensive counselling about the possible side-effects before choosing this method of contraception. Women who are unable to tolerate side-effects such as nausea or vomiting may not be good candidates [12].

On the other hand, methods such as implants and the intrauterine device require the attention of a skilled practitioner for commencing and stopping, but users of COCs can easily discontinue the method. However, it has been shown that better education and support by health workers/family planning workers are needed for clients to improve the continuation rates and use-effectiveness of oral contraception [13].

Improving compliance and preventing early discontinuation is a shared responsibility of COC users, health care providers and COC manufacturers. Providers must assure adequate initial counselling for patients about the correct use of COCs. To improve compliance, the prescriber should help women establish a regular routine for taking her COCs, ensure that she properly understands use instructions and knows where to get information in future if problems should arise.

When COC use is initiated, providers should emphasize that side-effects may be expected, though most will be transient. The health worker must have the knowledge and ability to manage side-effects and to educate women in the importance of scheduled COC use. It is also important that providers discuss with patients the immediate risk for pregnancy after discontinuation of this method.

Our evaluation also had a number of limitations. First, the data on COC continuation and side-effects were based on subject recall (which may have led to underestimations) and chart review, similar to the O'Dell et al. study [9]. Second, it is possible that higher continuation rates were more a reflection on the training and attitudes of clinic staff (some were able to manage side-effects much better than others) [14].

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