

Users' awareness of factors associated with complications during pill use

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Abstract

This study compared the frequency of factors and diseases that contribute to the risks of oral contraceptive use among current users and non-users of oral contraception in order to evaluate the users' awareness of factors associated with complications during oral contraceptive use. Data from 5317 current users and 8863 non-users in the state of São Paulo, Brazil, were collected using questionnaires requesting information on the following variables: use of oral contraceptives, age, weight, smoking status, and the presence or history of hypertension, diabetes, cardiopathies, painful varicose veins, and epilepsy. Half of the users had some risk factors, and 17.4% were at high risk of complications from oral contraceptive use. Risk factors and diseases which appeared to be poorly known by the population as increasing the risk of oral contraceptive use were smoking, hypertension and painful varicose veins. Only a small percentage of the population appeared to know that these diseases and factors could increase the risk of health problems during oral contraceptive use. The results suggest a lack of information among users and providers on factors which are associated with an increased risk of health problems during use of oral contraceptives.

Introduction

More than three decades have passed since the introduction of oral contraceptives (OCs), and the OCs (also known as 'the pill') have now become the symbol of modern contraception. During the first few years after its introduction, the pill won increasing popularity. Later on, the first reports of severe complications among OC users were published, and finally the association of OC use with an increased risk of some diseases was better established by the report of the Royal College of General

Practitioners released in 1967 [1], which showed an increased incidence of thromboembolism among British users of the pill.

Soon after, several risk factors were identified as increasing the incidence of complications when associated with pill use, including hypertension, diabetes mellitus, epilepsy, cardiopathies, smoking, obesity and advanced age [2–5]. Many deaths caused by stroke, myocardial infarction, heart attacks, and thromboembolism were observed when women with some of these risk factors used OCs.

In an attempt to reduce this problem, the pharmaceutical industry has gradually decreased the dosage of contraceptive steroids contained in OCs and synthesized progestogens with a better metabolic profile. Today, these new low-dose pills represent 85% of sales in developed countries but only 65% in developing countries [6].

The new formulations, correct prescription and a well-informed population have made health disorders due to the use of OCs a minor problem in developed countries.

However, the trends in Brazil are different. Older-formulation pills with higher steroid doses are still available at pharmacies, and although a prescription is 'legally' required, most users buy them over the counter without a medical evaluation or appropriate counseling. The higher cost of low-dose OCs detracts from their acceptability and is a primary reason for the continued use of high-dose pills. According to the official sales report from pharmaceutical companies, over 20% of the OCs sold in Brazil during the first semester of 1992 contained an estrogen dosage higher than 35 μg .

Furthermore, other methods such as IUDs, injectables and diaphragm are less known and frequently not available. Consequently, OCs represent 40% of contraceptive methods currently used by the female population, with an additional 40% using surgical sterilization [7].

In these circumstances, it was not surprising that two studies, one restricted to one hospital and another evaluating a larger population-based study in the state of São Paulo, found that a large proportion of OC users had risk factors for cardiovascular disease [8,9].

In order to evaluate the extent of the misuse of the pill and other contraceptive methods, the State Secretariat of Health of São Paulo took advantage of the yearly poliomyelitis vaccination campaign to administer a questionnaire on contraception and general health to thousands of women bringing their children to the primary health units.

This paper compares the prevalence of those conditions associated with higher risk of complications among women using the pill and those either using other methods or no contraception. This information is used as a surrogate measure of the level of awareness the population has on who is, and who is not, a good candidate for pill use.

Materials and methods

Poliomyelitis vaccination campaigns have been carried out throughout Brazil with great success for more than a decade. Between 1988 and 1991, the State Secretariat of

Health of São Paulo took advantage of the large number of women who took their children to be immunized to carry out other health-enhancing interventions. In 1991, three women's health care activities were included: measurement of blood pressure, measurement of serum glucose concentration, and the administration of a questionnaire to identify the prevalence and appropriateness of contraceptive methods used. For the first 1991 campaign, 18 600 simple self-administered questionnaires were sent to 62 primary health care units in the state of São Paulo, and the women were asked to fill them out during the immunization campaign.

A total of 14 180 completed questionnaires were analyzed. Two-thirds of the respondents were younger than 30 years of age and 35% were younger than 25 years of age.

The questionnaires were designed to collect information on the following variables: use of OCs, age, weight, smoking status and presence or history of certain illnesses, including hypertension, diabetes, cardiopathies, painful varicose veins, and epilepsy.

The risk of complications during OC use was defined by combining these variables. Women were classified into three groups, according to the risk of pill use:

- Moderate risk:** To be older than 39 years; or smoker; or obese (weight > 70 kg); younger than 35 and either smoker or obese; or have history of cardiopathies, painful varicose veins, or epilepsy
- High risk:** To be smoker or obese and older than 34 years; have history of hypertension or diabetes; or to have 2 or more factors considered moderate risk
- Low risk:** Absence of any of the above factors

The proportion of pill users and non-users who presented with each of the variables was calculated. The same analysis was repeated excluding surgically sterilized women from the group of non-users of OCs in order to eliminate the possible confounding effect of the high incidence of surgical sterilization observed in the State of São Paulo in recent years [7]. For the statistical analysis of the differences between the groups the chi-square test was used.

Results

All diseases studied were more prevalent among non-users than among OC users. The significant difference was also observed after excluding those women who were sterilized (Table 1). Many women listed more than one disease.

The percentage of smokers younger than 35 was significantly higher among OC users. The percentage of women who were obese and smoked or were obese and younger than 35 years was similar among users and non-users (Table 2); the exclusion of women with surgical sterilization did not significantly affect the results. On the

other hand, the proportion of women who were older than 39, or older than 34, and at the same time smoked or were obese, was higher among women who did not use the pill.

Table 1. Frequency of referred diseases among users and non-users of OCs

<i>Risk factor</i>	<i>User</i>	<i>Non-user</i>	<i>p</i>	<i>Non-user excluding tubal ligation</i>	<i>p</i>
Hypertension	9.7	13.6	<0.0001	14.5	<0.0001
Diabetes	0.8	1.7	<0.0001	2.1	<0.0001
Cardiopathies	1.8	4.2	<0.0001	4.1	<0.0001
Varicose veins	9.4	14.4	<0.0001	12.9	<0.0001
Epilepsy	2.6	3.6	<0.001	3.4	<0.003
<i>n</i>	(5317)	(8863)		(6114)	

The proportion of women at low and moderate risk was significantly higher among OC users than non-users. In addition, there was a significantly higher proportion of women classified as high risk among all non-users after excluding surgically sterilized women. Still, more than one out of every six pill users fell into the high-risk category (Table 3).

Table 2. Frequency of risk factors referred by users and non-users of OCs

<i>Risk factor</i>	<i>User</i>	<i>Non-user</i>	<i>p</i>	<i>Non-user excluding tub. ligation</i>	<i>p</i>
Older than 39 years	2.0	13.1	<0.0001	11.6	<0.0001
Smoker and older than 34 years	2.6	7.0	<0.0001	5.6	<0.0001
Obese and older than 34 years	0.8	3.6	<0.0001	2.9	<0.0001
Smoker and obese	1.4	1.8	N.S.	1.5	N.S.
Obese and younger than 35 years	4.3	4.7	N.S.	4.8	N.S.
Smoker and younger than 35 years	31.6	21.4	<0.0001	21.8	<0.0001
<i>n</i>	(5317)	(8863)		(6114)	

Discussion

This study showed a higher proportion of OC users at low or moderate risk of complications during pill use as compared with non-users. Comparison of Tables 2 and 3 shows that the large percentage of pill users who also smoke determined the higher proportion of 'moderate risk' among OC users. The non-user group had a

higher proportion of women at high risk of complications, although the number of OC users with high risk was elevated. These findings suggest that there was some level of awareness about factors associated with risk of complications during the use of OCs, but it was generally poor.

Table 3. Percentage of women at risk of complications during the use of OCs among users and non-users of OCs

<i>Risk level</i>	<i>User</i>	<i>All non-users</i>	<i>p</i>	<i>Non-user excluding tub. ligation</i>	<i>p</i>
Low risk	49.8	44.4	<0.0001	46.6	<0.0001
Moderate risk	32.8	28.3	<0.0001	27.7	<0.0001
High risk	17.4	27.3	<0.0001	25.7	<0.0001
Total of women	(5317)	(8863)		(6114)	

The prevalence of factors associated with risk of complications found in this study was similar to that found by other studies conducted in Brazil, which showed that almost 50% of women were at some kind of risk [8,9].

Previous studies have shown that among those women for whom the OC pill was prescribed by a health service provider or who obtained the OCs at a health center, the same percentage were at risk for cardiovascular disease as among those women purchasing OCs over the counter [9]. Based on the study by Hardy *et al.*, the only factor which had any significant effect on reducing the proportion of OC users with risk was higher level of education, which suggests that women's own awareness of the existence of risk factors for pill use is the main variable determining the appropriate use of OCs [9].

Accepting that the above hypothesis is correct, the observation of our data suggests that risk factors can be grouped into four categories, from those which apparently were not recognized, through factors which appeared to be well known as being risk factors by the population studied.

The first group included smoking among women under 35 years, which was present in a higher proportion among users than among non-users. Smoking habit at young age was the least recognized risk factor for cardiovascular disease which can be potentiated by pill intake.

The second group included obesity in women under 35 years, including those who were also smokers. The prevalence of the combination of these factors was low and there was not a difference between OC users and non-users, suggesting that obesity was not recognized as a risk factor for women's health or as producing an increase in risk if associated with OC use.

The third group consisted of diseases or risk factors that have a higher prevalence among non-users, but still were present in a high proportion of OC users. These

factors included varicose veins, hypertension, diabetes, cardiopathies, and smoking and obesity among women over 34 years. Hypertension and cardiopathies are usually recognized by the population as serious conditions, although this fact did not prevent many women from using OCs. The lower prevalence of varicose veins among OC users may be partially explained by discontinuation of the pill resulting from leg ache, frequently observed during pill use among women with this condition.

The fourth group was formed by women older than 39 years. Apparently, older age was the risk factor best recognized by the women in this study, as judged by the much higher proportion among the non-users group and the low frequency among users.

Among women under 35, smoking and obesity were equally or more frequent among users than among non-users of OCs, while these two risk factors became less frequent among users than among non-users older than 34 years. As it is doubtful that women stopped smoking or became thinner after their 35th birthday, it should be concluded that many women were aware of the increased risk of complication with older age, among those who smoke or are obese.

Older age was the most important variable associated with a lower prevalence of OC use and with a greater difference between the two groups. The suspicion that this observation was influenced by the higher prevalence of tubal ligation with increased age was only partially confirmed, as the data only changed slightly after excluding surgically sterilized women.

We can conclude that the higher prevalence of several risk factors and diseases among non-users of OCs is probably the result of a lack of adequate information in the population. The global picture shown by our results is the logical consequence of the absence of a family planning program offering a wide range of contraceptive methods and appropriate guidelines for users and providers. We are not aware of similar studies carried out in other developing countries, where pills are sold over the counter and prevalence of use of other reversible methods is also low, but it would not be a surprise if a similar picture were observed.

To change this situation a strong effort is necessary, with a political determination to improve infrastructure and quality of care of family planning services, strengthening education/counseling activities and broadening the range of contraceptive methods available. In an environment of limited access to alternative choices, young women will continue requesting surgical sterilization, risking later regret, and many will use oral contraception even when it is the least appropriate method for them.

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Resumé

Pour évaluer dans quelle mesure les utilisatrices et non utilisatrices de contraceptifs oraux sont sensibilisées aux facteurs associés à des complications, cette étude a comparé la fréquence des facteurs et des maladies qui contribuent au risque que présente l'utilisation de ces contraceptifs. Dans l'Etat de Sao Paulo (Brésil), des données ont été recueillies auprès de 5317 utilisatrices et 8863 non utilisatrices, au moyen de questionnaires demandant des renseignements concernant les variables suivantes : utilisation de contraceptifs oraux, âge, poids, tabagisme, présence ou antécédents d'hypertension, diabète, cardiopathies, varices douloureuses et épilepsie. La moitié des utilisatrices présentaient certains facteurs de risque et 17,4% des facteurs de risque élevé de complications résultant de l'utilisation de contraceptifs oraux. Les facteurs de risque et les maladies dont la population semblait mal connaître l'effet d'augmentation des risques qu'entraîne l'ingestion de contraceptifs oraux étaient le tabagisme, l'hypertension et les varices douloureuses. Un faible pourcentage seulement de la population paraissait savoir que ces maladies et facteurs pouvaient accroître les risques de problèmes de santé durant l'utilisation des contraceptifs oraux. Les résultats suggèrent que les utilisatrices et les pourvoyeurs des services de contraception ne sont pas suffisamment informés des facteurs associés à un risque accru de problèmes de santé durant l'utilisation des contraceptifs oraux.

Resumen

Este estudio comparó la frecuencia de factores y enfermedades que contribuyen al riesgo de los anticonceptivos orales (AO) entre usuarias y no usuarias corrientes de anticonceptivos orales a fin de evaluar el grado de conocimiento entre las usuarias de los factores asociados con complicaciones durante el uso de AO. Se recopilaron datos de 5317 usuarias y 8863 no usuarias corrientes del Estado de S@o Paulo, Brasil, utilizando cuestionarios en los que se solicitaba información acerca de las siguientes variables: uso de AO, edad, peso, fumadora/no fumadora y la presencia o historia de hipertensión, diabetes, cardiopatías, várices dolorosas y epilepsia. La mitad de las usuarias tenían algunos factores de riesgo y el 17,4% de ellas corrían un alto riesgo de complicaciones por el uso de anticonceptivos orales. Los factores de riesgo y enfermedades que parecían ser poco conocidos por la población como tendientes a aumentar el riesgo del uso de anticonceptivos orales eran el fumar, la hipertensión y las várices

dolorosas. Sólo un pequeño porcentaje de la población parecía saber que estas enfermedades y factores podían aumentar el riesgo de problemas de salud durante el uso de anticonceptivos orales. Los resultados sugieren una falta de información de las usuarias y proveedores con respecto a factores que están asociados con un riesgo mayor de problemas de salud durante el uso de anticonceptivos orales.