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A Cross-Sectional Study of the Choice of Oral Estrogen Contraceptives in Women Seeking Contraceptive Counseling: What Type of Pill Do Women Prefer After Being Counseled?

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Abstract

Objective: The availability of oral contraceptives with natural estrogen can change women's perception about the safety of combined hormonal contraceptives. This study therefore aims to investigate the reasons why women, when given the choice of hormonal contraceptives with synthetic or natural estrogen, choose one or the other.

Methods: A cross-sectional observational study of a representative sample of 14,900 Spanish women wishing to start combined oral hormonal contraception. All received uniform information about the different oral contraceptive options based on the estrogen they contained.

Results: Of the 14,900 patients included, 2,526 (17%) chose a pill with ethinyl estradiol (EE), whereas 12,374 (83%) chose a pill with natural estradiol. Mean age of the former was 28.5 ± 7.2 years and 31.7 ± 7.9 years in the latter (P<0.005). The most important reason given by women to choose a pill with EE was the price (49.4%). Women who chose a pill with estradiol did so mainly because it contained a natural hormone, similar to the produced by the ovary (70.5%).

Conclusion: Spanish women, who consult their doctors for starting or reinitiating the use of a combined oral hormonal contraceptive method, after receiving information about the estrogen content and the currently available alternatives, mostly choose contraceptives containing estradiol because it is a natural hormone similar to that produced by the ovary. Further studies are still needed to assess continuation rates and tolerability of estradiol-based pills.

Keywords: Counseling; Decision making; Estradiol; Observational study; Oral contraceptives; Spain; Women's preferences

Introduction

Over 70% of Spanish women use some contraceptive method and, of these, about 20% use combined oral contraceptives [1]. Since the introduction of the pill over 50 years ago, research has focused on the study of new formulas seeking to improve the benefit/risk ratio, that is, high efficacy with the lowest dose possible. Contraceptive research has focused on minimizing the risks, while maintaining or even improving their efficacy and ease of use. Thus, currently available preparations have permitted the dose to be reduced from 150 mcg to 15 mcg of ethinyl estradiol (EE) daily, without compromising efficacy and increasing safety and tolerability. Despite the reduction in the dose of EE and the synthesis of new gestagens, the risks of hormonal contraception persist, especially those related to thromboembolic disease [2]. The use of estradiol as an estrogenic component of combined oral contraceptives was addressed in the 1970s, but the poorer cycle control that they provided was the main reason for preventing their launch [3]. This fact may open a door to a higher rate of use of combined hormonal contraception among women from countries where its prevalence of use is low because of women's fear of synthetic steroid hormones This fact may open a door to a higher rate of use of combined hormonal contraception among women from countries where its prevalence of use is low because of women's fear of synthetic steroid hormones.

The choice of contraceptive method will depend on the information that the woman receives from the health professional about the efficacy, risks and benefits they offer, the mode of use, and factors specific to the woman, such as age, medical history, menstrual pattern, type and frequency of sexual intercourse, plans and desire for future pregnancies, failure of previous contraceptives, as well as the economic cost, characteristics of the product, route of administration, and adverse events related to treatment [4-7].

The TEAM [8] and CHOICE [9,10] studies already showed that objective information could make a women change her previous decision, generally based on preconceived ideas. The fear of possible side effects of pills containing EE, as well as the perception that steroid hormones are bad for health, determine to a larger extent the rate of use of hormonal contraception in our country, to the point that many women who do not use hormonal contraception would do so if a preparation based on natural hormones were available [11].

The availability of oral contraceptives with natural estrogen can change women's perception about the safety of combined hormonal contraceptives. To our knowledge there are not studies assessing the type of preferred pill after contraceptive advice. This study therefore aims to investigate the reasons why women, when given the choice of

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hormonal contraceptives with synthetic or natural estrogen, choose one or the other.

Materials and Methods

A cross-sectional observational study of a significant sample of Spanish women wishing to start combined oral hormonal contraception. This study was approved by the Ethics Committee of Euskadi (Spain).

Objectives

The primary objective of the study was to evaluate the degree of acceptance by women wishing to start hormonal contraception of the different combined oral hormonal contraceptive treatments based on their estrogen content. The secondary objectives were: (1) to determine the main reasons for choosing oral combined hormonal contraceptive treatments based on their estrogen content; (2) to determine the main reason for rejecting oral combined hormonal contraceptive treatments based on their estrogen content; and (3) to determine the patient profile for each of the oral combined hormonal contraceptive treatments based on the type of estrogen they contain.

Population

The study population was formed by patients meeting the following selection criteria:

Inclusion criteria: women aged 18-49 years seeking contraceptive counseling and starting or reinitiating combined hormonal contraception who have given their written informed consent to participate in the study.

Exclusion criteria: users choosing a different combined hormonal contraception method; users of combined hormonal contraception in the last three months and/or women unable to comply with the study requirements or any condition preventing them from following the study instructions (e.g. women taking contraceptive pills, or those using contraceptive patches or vaginal rings at the beginning of the study could not be enrolled).

Sample size calculation

Other studies similar to ours have been previously published that evaluated the acceptability of different routes of administration of hormonal contraceptive methods [8-10]. The Spanish study by Lete et al. [8] included 10,513 users; nearly 8% of whom were excluded for different reasons. This study proposed to analyze the distribution and percentages of acceptance of three routes of administration of combined hormonal contraceptive methods: patch, pill, and ring. Assuming there are more differences in the choice of the route of administration than in selection of the contraceptive method based on its estrogen component, and that there are no data on the acceptability of the different oral contraceptive methods, we estimated that an additional 30% of patients could cover these smaller differences expected in the distributions based on the pill components. Thus, 12,610 women would need to be recruited which would increase to 13,871 if we consider a 10% rate of post-recruitment losses. Based on these data, we estimated that for this study to be representative, it would have to include 15,0000 women.

Study conduct

A single visit was performed during the study. Users who came to the contraceptive counseling clinic seeking an oral method were invited to participate in this study. Users were consecutively recruited for three months. After obtained informed consent and confirming that the patient met the selection criteria, a single visit was performed for the study.

At this visit, specific contraceptive counseling was provided to all women of childbearing age wishing to start hormonal contraception. To ensure counseling was done uniformly, all investigators had identical material to explain the combined hormonal contraceptive methods and their characteristics (Table 1).

The data were collected using a case report form specifically designed for this study (Table 2), which included closed answers based on data evidenced by the Creacion study [11]. The database included internal consistency rules and ranges to guarantee quality control of the data.

Data analysis

Quantitative variables were described with measures of central tendency and dispersion (mean ± standard deviation), and qualitative variables with absolute (N) and relative (%) frequencies. To compare patient subgroups, parametric (Student's t or ANOVA) or nonparametric (Mann-Whitney or Kruskal-Wallis) tests were used for quantitative variables, depending on the specific characteristics of the study variables. The chi-squared test was used for qualitative variables.

All analyses were performed from a single sample of evaluable patients that included all users eligible to use contraceptive methods who met the selection criteria and also had data on the primary study variable.

The data were analyzed using the SAS version 9.1 statistical package.

Results

We recruited 14,900 women, whose mean age was 31.2 ± 7.8 years. With regard to their educational level, 1,328 women (8.9%) had primary studies, 5,652 (37.9%) secondary studies, 7,657 (51.5%)

Method	Action	Efficacy	Regimen	Route	Characteristics	You should know
Pill (EE + P)	Inhibits ovulation	>99%	1 tablet daily 21/22/24 days + 6/7/4 days subsequent to rest 1 tablet daily 28 days without week of rest	Oral	Daily administration One of the most studied medicines 53 years of experience Pill with levonorgestrel recommended by some health authorities due to the lower risk of venous thromboembolism EE combined with different gestagens Confirmed beneficial effects	Method most studied and with greatest experience Daily dependence Confirmed beneficial effects
Pill (E2 + NOMAC or DNG)	Inhibits ovulation	> 99%	1 tablet daily 24/26 days + 4/2 days subsequent to rest	Oral	Contains natural estrogen Laboratory studies demonstrate lower impact on metabolism and hemostasis than with levonorgestrel contraceptives No data from epidemiological studies are available Longer half-life of NOMAC minimized impact of poor compliance Decreased menstrual bleeding with amenorrhea in 5% of women	

Table 1: Information sheet used in the study.

Case report form to be completed by the woman (self-administered)	
Women choosing pill with EE	
Reasons for choosing EE	☐ Most used estrogen ☐ It is combined with different gestagens ☐ Price
Reasons for NOT choosing E2	☐ It is new ☐ Price ☐ Control of cycle
Women choosing pill with E2	
Reasons for choosing E2	☐ Natural estrogen ☐ Less impact on clotting parameters ☐ More effective
Reasons for rejecting EE	☐ Synthetic estrogen ☐ More impact on clotting parameters ☐ Less effective

Table 2: Questionnaire used.

university studies, and 245 (1.7%) reported another educational level. Regarding their occupation, 9,414 women (63.2%) worked outside home, 1,785 (12.0%) worked at home, 3,242 (21.8%) were students, and 459 (3.1%) had another occupation.

The contraceptive methods previously used by patients included in the study are shown in (Table 3).

Of the 14,900 patients included, 2,526 (16.9%) chose a pill with EE, whereas 12,374 (83.0%) chose a pill with natural estradiol. Mean age of the former was 28.5 ± 7.2 years and 31.7 ± 7.9 years in the latter (P<0.005). Among the women who chose EE, 30.3% were students versus 20.0% of those who chose estradiol (P<0.001). Regarding occupation, 54.0% of the former worked outside home, whereas the percentage rose to 65.1% in the group that chose a pill with estradiol (P<0.001).

The most important reason given by women to choose a pill with EE was the price (49.4%). The reasons given by women who chose a pill with EE for their decision are shown in (Table 4). These 2,526 women responded that the reasons for not choosing a pill with natural estradiol were: the price (48.8%) and that it was a pill with less experience on the market (31.7%).

Women who chose a pill with estradiol did so mainly because it contained a natural hormone, similar to the produced by the ovary (70.5%) and because it reduced the amount of menstrual bleeding (45.2%). The main reason for rejecting pills with EE was the fear of synthetic hormones (60.8%).

Discussion

To our knowledge, this is the first study evaluating the impact of information on the decision regarding the type of oral contraceptive chosen by women after counseling.

In our study, 83% of women who requested an oral combined hormonal contraceptive and received information about the different options chose a pill based on estradiol. The main reason for this decision was to be able to use a natural hormone (70.5% of women) followed by the decreased bleeding associated with contraceptives with estradiol (45.2%). Women who chose a pill with EE did so mainly because it costs less money (48.8%). It seems likely that in a context of a deep and sustained economic crisis, women valued economic costs more than other issues related to safety or the side effect profile [12]. However, the majority of women chose pills with natural estradiol, which confirms the findings of a previous study in which 84% of 1,988 oral contraceptive users stated they would change to a preparation with natural estradiol if it were available [11]. Our data confirm the hypothesis that the low use of hormonal contraception in Spain is due to women's fear about steroid hormones [1].

Younger women, students, and those without remunerated work chose pills with EE more than those containing estradiol. Some of the pills containing EE are financed by the National Health System, but none of those containing estradiol. In the current situation of economic crisis affecting Spain, it is not surprising that the more economically disadvantages sectors choose cheaper and financed methods.

Another important aspect revealed by our study is the impact of information on the final choice of contraceptive method, and specifically the type of pill. According to the results, it seems that the possibility of using a pill containing estradiol is well accepted by women. It all seems to indicate that, given the hormonophobia among Spanish women, an option that involves the use of a hormone structurally identical to the estradiol produced by the ovary is welcomed and accepted.

Probably the greatest strength of our study is based on the large sample of women included, nearly 15,000, which makes it significant for the Spanish reality. In addition, the fact that women using a combined hormonal method were excluded allowed us to know women's preferences in a purer, less contaminated way.

The most important limitation of our study was that the sample of women included was not preselected but obtained from those women who over a given period consulted their doctors for starting or reinitiating combined hormonal contraception. This could bias the sample because the women were recruited at gynecology clinics and therefore already showed a certain interest in hormonal contraception. Another of the limitations is that it was not a prospective follow-up study in which the continuation rate of the type of oral contraceptive chosen was assessed. In other words, we do not know how many women who chose a contraceptive with natural estradiol continued using it later.

Several previous studies have already shown that the information provided during contraceptive counseling can modify women's choice of the type of contraceptive they want to use [8,9,13]. The first two, the TEAM study [8] and the European CHOICE study [9], showed that information influenced the choice of administration regimen (daily, weekly, or monthly) of the contraceptive method, whereas the

Contraceptive method	N	%
Condom	8,999	60.4
None	3,586	24.1
Coitus interruptus	1,158	7.8
Intrauterine device	824	5.5
Gestagen-only pill	500	3.4
Implant	138	0.9
Other	81	0.5
Combined contraceptive	0	0.0
Total	14,900	100.0

Table 3: Contraceptive method used before participating in the study.

Reasons for choosing ethinyl estradiol	N	%
Price	1,246	49.4
Good control of cycle	1,046	41.4
It is the classic contraceptive	886	35.1
Other	495	19.6
It is combined with different gestagens	206	8.2
Total	2,524	100.0

Table 4: Reasons for choosing pills with ethinyl estradiol.

US CHOICE study [13] investigated the effect of free dispensation at no cost of the different contraceptive methods. All three showed a change in the initial choice after receiving adequate information. It seems appropriate to state that information can change the choice of method, but not so much so to conclude that it can change the continuation rates of the method. Although our study did not include follow-up of the patients to determine the continuation rate, a recent randomized study conducted in users of a long-acting reversible contraceptive method concluded that intensive information did not change the discontinuation rates if side effects appeared [14]. Similarly, a Cochrane review concluded that there are no valid strategies to improve adherence to the contraceptive method [15].

The results of clinical trials have shown that the options with estradiol are generally well tolerated by women and have high satisfaction rates [16-18]. The two clinical trials [17,18] included 1,375 patients treated with an oral contraceptive containing 1.5 mg estradiol and 2.5 mg nomegestrol acetate (NOMAC) per pill and 463 patients treated with a pill containing 30 mcg EE and 3 mg drospirenone , followed during 13 cycles. In both groups intermenstrual bleeding rates were low and similar (16.2% versus 15%, $P \geq 0.05$). In the investigational group, the most frequently reported adverse events were acne (16.4%), weight gain (9.5%), and irregular withdrawal bleeding (9.1%). In an open noncomparative study evaluating the efficacy and acceptability of an oral contraceptive with estradiol valerate/dienogest administered in a quadriphasic regimen in 1,377 women, 79.5% of the patients included reported being satisfied or very satisfied with the treatment after 7 cycles of use [16].

In addition, a recent review on the impact of use of a contraceptive with natural estradiol on premenstrual symptoms and premenstrual syndrome concluded the oral contraceptive with NOMAC/17beta-estradiol was the more effective for control of this type of symptoms than an oral contraceptive with drospirenone in a 21+7 regimen [19]. Although it seems reasonable to conclude that adequate, complete and accurate information can result in variations in the final choice of contraceptive method, there are studies with contradictory information about the effect of contraceptive counseling on women's decision. A randomized clinical trial in which 96 women received structured contraceptive counseling and 90 received counseling according to usual care concluded that structured counseling has little impact on the choice, initiation or continuation of the contraceptive method [20]. Another more recent randomized clinical trial [14] that evaluated the impact of intensive counseling on continuation rates of three long-acting reversible contraception methods (implant, copper intrauterine device and levonorgestrel intrauterine system) also concluded that intensive counseling on the different characteristics and different side effect profile of these long-acting reversible contraceptive methods did not change continuation rates of the methods. On the other hand, a study conducted in 1,032 Swiss adolescent women who received comprehensive information on the three combined hormonal methods available in their country, concluded that the information provided was a definite factor in the choice of method [21].

In our study, the information was provided in all cases by physicians who usually perform contraceptive counseling and prescription. Other studies have shown that nurses [22] and pharmacists [23] can play a more important role than physicians in providing contraceptive information. Moreover, a subanalysis performed in university students within the US CHOICE project showed that effective contraceptive information can be provided by health care providers without prior experience who use an appropriate information questionnaire [24].

Regardless of the need to receive information of women wishing to use a contraceptive method, the participation of health care providers in the decision-making process is valued and requested by women [25]. This does not means that health care providers should be the ones who make the final decision about the method an individual women should use, but rather that we should take part in the decision-making process in an ethical and aseptic manner while sharing with the patient our qualified point of view.

Our study shows that having information determines the choice of contraceptive method that will be used by women and confirms the results of other European studies where the information provided during contraceptive counseling changed the women's final choice of method [9,10]. Moreover, in our experience, woman viewed very positively the possibility of using oral contraceptives containing estradiol. This fact may open a door to a higher rate of use of combined hormonal contraception among women from countries where its prevalence of use is low because of women's fear of synthetic steroid hormones.

In conclusion, Spanish women who consult their doctors for starting or reinitiating the use of a combined oral hormonal contraceptive method, after receiving information about the estrogen content and the currently available alternatives, mostly choose contraceptives containing estradiol.

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Disclosure

IL, RSB and EV are members of the advisory board of TEVA. and have received honoraria for lectures at symposia from TEVA. NB and LU have no conflict of interest.

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