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A Comparison of Oral Contraceptive and Non-Hormonal Contraceptive Use in Women Over 40

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ABSTRACT

Objective To compare the continuation rate, cycle control and clinical change of combined oral contraceptives (COCs) and non-hormonal contraceptive methods in women over 40 years of age.

Design Comparative study.

Setting Family Planning Unit of King Chulalongkorn Memorial Hospital.

Subjects 29 women aged over 40 years using low-dose COCs and 30 women using non-hormonal contraceptive methods. (IUD)

Methods Subjects in COC group and non-hormonal group were supplied with diary cards to record pills taking, bleeding characteristics and side effects. Each subject was scheduled to come to follow-up visit after the first, third and sixth menstrual cycles.

Main outcome measures Continuation rate, cycle control and clinical change of the methods

Results The two groups were comparable in terms of baseline characteristics at the beginning. Continuation rate was 92.6 % in COC group and 93.3 % in non-hormonal group. Compliance of COC group was 77.6 %. None of the women became pregnant during the study. Significantly better cycle control was exhibited in COC group, as evidenced by more women with regular cycle than in non-hormonal group (100 % VS 63.3 %). There were no changes in body weight and blood pressure in both groups. No significant difference in side effects was also found.

Conclusion COCs had good acceptability, high efficacy and could be used safely in women over 40 years old.

Key words : combined oral contraceptives, women over 40 years old

Women over 40 years of age have decreasing ovarian function that causes irregular menstruation, change of duration and amount of menstruation[1] and decrease in fertility.[2] However, they can become pregnant.[3] Pregnancy at this age is considered high-risk that can cause unfavorable effects to both a mother and her infant. Pregnancy during this period, occasionally unwanted,[4] increases both maternal and perinatal morbidity and mortality.[5-7] Hence, contraception remains necessary in this age group.[5,8] Each contraceptive method has variable effects on women's health. Choosing the suitable types of

contraception for women during this age should be individualized for each woman.

Combined oral contraceptives (COCs), the most common form of contraceptive used worldwide, used to be considered contraindicative for older women. High-dose formulation used in the past was shown associated with some serious adverse effects which included cardiovascular and cerebrovascular diseases. However, low-dose formulation, commonly used nowadays, has been found in many studies to be both safe and effective. Serious adverse effects rarely occurred with the present low-dose COCs. Currently, it is recommended that women who over 35 years of age who neither smoke nor have any cardiovascular risk can use COCs until menopause.[1,9] Among various contraceptive methods available, COC is an option that older women can choose to control their fertility. Apart from contraceptive advantages, COCs can reduce climacteric symptoms[5] due to reduction of estrogen level during this period of life. COCs can also control regularity of menstrual cycle.

This study is aimed to evaluate continuation rate, cycle control and clinical change in women over 40 years old, who used COCs, compared to those who used non-hormonal methods of contraception.

Material and Methods

An observational study was performed in women over 40 years old who attended Family Planning Clinic of King Chulalongkorn Memorial Hospital, who wanted to use COCs or other non-hormonal contraceptive methods. The continuation rate, cycle control and clinical change of the two groups were compared for six cycles of their menstrual periods.

Women were subjected to strict inclusion criteria before being recruited into the study. Healthy nonsmoking women who were older than 40 years of age to menopause could be included in this study if they were willing to use contraceptive for at least 6 cycles. Women were eligible if they had never used hormonal contraception within 12 weeks prior to the entering of the study and that they could come for follow-up visits and to keep a record on their assigned diary card. They would not be allowed to participate in the study if they had any conditions specified in the exclusion criteria, i.e., pregnancy, having history of allergy to estrogen or progesterone and their derivatives or having a contraindication to contraceptive.[10,11]

Subjects in the COC group received COCs preparations containing 30 µg ethinyl estradiol and 150 µg levonorgestrel (30 µg EE / 150 µg LNG). The medication started within the first five days of their menstrual cycle – for 21 days followed by a 7-day period of a pill-free interval. Subjects in the non-hormonal group, who served as controls, had used non-hormonal intrauterine devices (IUD).

During their initial visits, data including age, height, body weight, medical, gynecological and contraceptive history were taken. The subjects underwent physical and gynecological examinations. The patients were supplied with diary cards with instruction on how to use it to record the pills taking, their bleeding days, which included their duration, amount of bleeding and concomitant symptoms. Each subject had to bring the diary cards on follow-up visits at regular interval which were scheduled after the first, third and sixth menstrual cycles.

Clinical variables measured during each visit included body weight, blood pressure and bleeding characteristics. Adverse effects were also recorded.

At the end of the sixth cycle, each subject underwent physical and pelvic examinations. In the analysis, the following definitions were used for regularity of cycle assessment : a normal menstrual cycle referred to a cycle that lasted from 21 to 35 days with 2 to 6 days of flow and an average blood loss of 20 - 60 ml.[12] Regular cycle referred to menstrual cycle that lasted from 21 to 35 days in length.

Variables measured used to evaluate the characteristics of the contraceptive methods were as follows:

- continuation rate at the end of the study
- regularity of cycles during the study.
- clinical changes in body weight and blood pressure as well as adverse effects during the study.

Paired T- tests were used to detect the difference between body weight and blood pressure. Unpaired T- tests were used to analyze bleeding characteristics. Additionally Chi-square test and Fisher's Exact test were used to analyze the adverse effects results.

Results

Among 59 volunteers recruited into the study, 29 were in the COC group and the other 30 women were in the non-hormonal group (IUD users).

Baseline characteristics of the two groups were summarized in Table 1. There was no statistical difference between the two groups regarding these characteristics.

Table 1. Baseline data of the subjects

Characteristics	COC (n=29)	IUD (n=30)	95 % CI
Mean age (years) ± SD	41.72 ± 2.10	42.50 ± 2.66	-2.03, 0.48
Parity : 0	6.89 %	3.33 %	
1	41.38 %	26.67 %	
≥ 2	51.73 %	70.00 %	
Mean height (cm) ± SD	155.55 ± 5.22	156.87 ± 4.42	-3.83, 1.20
Mean weight (kg) ± SD	55.52 ± 6.88	56.88 ± 7.09	-5.00, 2.29
Mean body mass index (kg/m^2) ± SD	22.96 ± 2.54	23.11 ± 2.80	-1.54, 1.25
Mean blood pressure (mmHg) ± SD			
- Systolic blood pressure	119.34 ± 11.02	116.00 ± 11.85	-2.63, 9.31
- Diastolic blood pressure	76.07 ± 7.46	73.37 ± 11.03	-2.22, 7.63
Mean cycle length (days) ± SD	30.17 ± 7.20	30.20 ± 5.35	-3.32, 3.27
Mean duration of menstruation (days) ±SD	4.17 ± 1.81	3.90 ± 1.29	-0.54, 1.09

Continuation rate was measured from the willingness of the subjects to continue using the same method after 6 cycles of the study. We found continuation rate of the COC group to be 92.59 % (27 in 29) and continuation rate of the IUD group to be 93.99% (28 in 30). There was no statistical difference in the continuation rate between these two groups (Table 2).

Compliance of the COC group was measured from the percent of cycles that the subjects did not miss any pill during the overall 174 cycles. Compliance of the COC group in this study was 77.58 % (135 in 174 cycles)

No pregnancy occurred in both groups during the 6-month period. The overall length and duration of menstruation cycles were not different between the two groups. However, subjects in the COC group had more regular cycles than those in the non-hormonal group (Table 2).

During the study no subject in the COC group had spotting, while two in the IUD group had spotting, but there was no statistical difference between the two groups (Table 2).

Table 2. Continuation rate and Cycle control

Variables	COC (n=29)	IUD (n=30)	95 % CI
Continuation	27 (92.59 %)	28 (93.33 %)	(p=1.00)#
Regularity of cycle : Regular	29 (100 %)	19 (63.33 %)	(p=0.00)#
Irregular	0 (0 %)	11 (36.67 %)	
Mean cycle length (day) ± SD	28.11 ± 0.39	29.04 ± 3.48	-2.23, 0.37
Mean duration of menstruation (day) ± SD	3.11 ± 0.74	3.76 ± 1.22	-1.18, -0.11
Spotting	0 (0 %)	2 (6.67 %)	(p=0.49)#

Fisher's Exact Test

There were only four subjects in the COC group who had dysmenorrhea, while 10 in the IUD group had it, but there was no statistical differences in the incidence of dysmenorrhea between the two groups (Table 3).

There were some differences between these two groups regarding their side effects (3 subjects in COC group had headache and 1 in COC group had melasma) but they were of no statistical significance (Table 3).

Table 3. Adverse effects of COC and IUD

Side effects	COC (n=29)	IUD (n=30)	p-value
Dysmenorrhea	4 (13.80 %)	10 (33.33 %)	0.07*
Headache	3 (10.35 %)	0 (0 %)	1.00#
Melasma	1 (3.45 %)	0 (0 %)	0.49#

* Chi-square Test

Fisher's Exact Test

There were no significantly differences in body weight and blood pressure between the two groups either before or after the 6-month period of the study. In each group, these clinical parameters were also found unchanged during the study, as shown in Fig. 1. and Fig. 2.

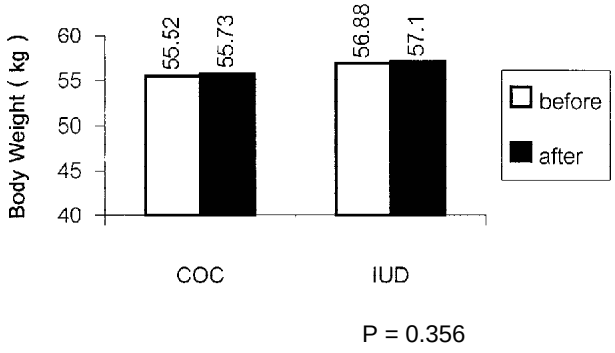

Fig. 1. Mean body weight change of COC and IUD (kg).

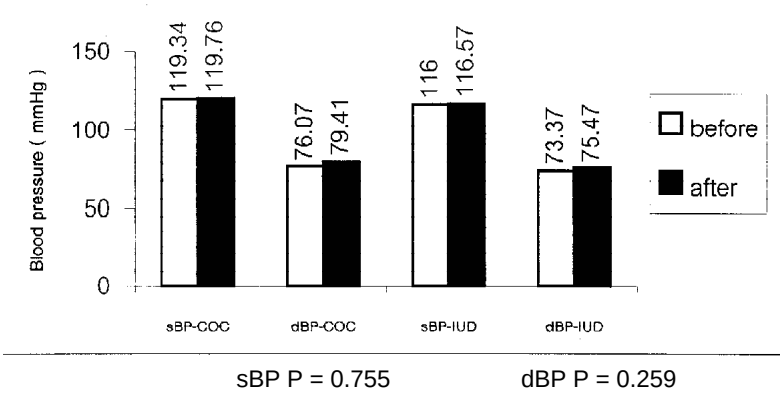

Fig. 2. Mean blood pressure change of COC and IUD (mmHg).
*sBP=systolic blood pressure, dBP=diastolic blood pressure

Discussion

COCs can be used in nonsmoking women who have no cardiovascular risk in any age group. COCs have low incidence of side effects and it is easy to be used but the most important problem of COCs is its low compliance, compared to other methods of contraception.

This study was conducted with an aim to compare continuation rate, cycle control and clinical change of COCs and non-hormonal contraception in women over 40 years of age.

The results from the study have shown that COCs were well accepted by older women. We found a high continuation rate of 92.59 % was found in the COC group, compared to higher 93.33 % in the non-hormonal group. The continuation rate found in this study was higher than that previously reported from Bangkok Health Center by Chamnijarakij who found the continuation rate of 77.58 % for COCs.[13] The compliance rate of 71.8 % for COCs found in the present study was also favorable and higher than in other study. Rosenberg reported the compliance of COCs in North Carolina, USA to be only 53 %.[14] No pregnancy occurred during the 6-month study.

There was no previous study on menstrual cycle and side effect of COC compared to other contraceptives in women older than 40 years old. In this study, however, it was found that the cycle length and duration of the COC users were similar to those of the non-hormonal users, but the cycle of the COC group seemed much regular compared to the non-hormonal group. The COC users reported less spotting and less dysmenorrhea than the non-hormonal users, but the difference was not statistically significant. In terms of safety parameters and side effects, there was no statistical difference between the COC users and the non-hormonal users. This study showed no significant change in body weight after using COCs for 6 cycles. Regarding blood pressure, there was no change in blood pressure after 6-month use of COCs which is similar to the result of a previous study which revealed that COCs caused a small, reversible increase in blood pressure which occurred at the beginning of taking the pills, but it did not increase with the duration of use.[15,16]

In conclusion, the results of this study indicate that COC can use for an alternative contraception in healthy nonsmoking perimenopausal women. An assumption from this study was that COCs had non-contraceptive benefits such as less dysmenorrhea[5,17] and more regular cycle than other non-hormonal contraceptive methods. This study was only a short-period study (6-month study), we should perform longer comparative study to evaluate more details on the next occasion.

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