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Probability of Continuation: With Triphasic and Monophasic (LD).

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Abstract:

Introduction: Despite the same complications for LD and triphasic pills, it seems as if the continuation times for the two birth control methods are different.

Aims: To compare the continuation times and side effects of triphasic and monophasic LD use, and identify factors related to continuation and discontinuation.

Methods and Materials: A historical cohort study was conducted in Isfahan, Iran to determine and compare the probability of 5 years continuation of low dose monophasic (223) and triphasic (163) use among 386 reproductive married women.

Statistical analysis used: The continuation time of triphasic pill and LD pills were compared with Kaplan Meier by SPSS11.5 software.

Results: The cumulative proportion of continuation was significantly different between triphasic and LD groups in the first year of use [0.98 (LD) VS 0.84 (triphasic)]. It was found that age, number of living children, education level and employment status didn't have any role in choosing contraceptive method ($p > 0.05$). In each group there was a significant relationship between these variables and median duration of OCP use. Despite similar complications and total discontinuation, 5 year continuation time of triphasic was lower than that observed for LD.

Conclusions: It seems as though consumption of triphasic OCP requires more attention, as it should be taken on a regular schedule, and missing a dose for more than two hours reduces its efficacy. Therefore, health care professions should consider more factors before offering clients triphasic pills in order to reduce discontinuation time.

Keywords: Triphasic, LD, OCP, continuation time

Key Messages: Individual characteristics such as age, education level, and employment status must be taken into consideration before recommending triphasic pills as a contraceptive method to increase the continuation time.

Introduction:

Despite advances in family planning, population growth remains a worldwide concern. In 1999, the world population reached 6 billion, an increase of approximately 4.4 billion since 1900.⁽¹⁾ Contraceptive technology has been a medical success, and for the majority of users, contraception enhances the quality of life, allowing couples to choose whether and when they have children.⁽²⁾ Oral contraceptives have been studied since 1960; they are used every day by more than 50 million women around the world for the prevention of unintended pregnancies. The effects are reversible and there are many non-contraceptive health benefits, some of which last for years.⁽³⁾ At present, oral contraceptives are the most effective and reversible method of contraception, and is one of the main methods used to time the spacing between children. In one study, the percentage of OCP usage was found to be 92% in Zahedan, Iran and 72% in the USA in the first six months of use.⁽⁴⁾ According to the DHS 2000 (demographic health survey), 18.4% of Iranian women who were using contraception were using OCPs.⁽⁵⁾

Three types of combined oral contraceptives are used in Iranian public health centres. These include: low dose, high dose monophasic (LD, HD) pills and triphasic pills⁽⁶⁾, though HD pills are used

primarily for emergency contraception. Many studies have compared the compliance, side effects and causes of discontinuation and continuation of birth control pills. They have found that continuation time has a close relation to the side effects produced by the pill. This is important because investigators have pointed to the discontinuation of contraception as a major problem facing family planning programs.^(8, 9, 10, 11, 12) A comparative multi central clinical trial of oral contraceptives was conducted in Malaysia, Egypt, Thailand and Mexico and revealed that the 11-month discontinuation time was 28.8%.⁽¹²⁾

In Iran, based on development goals, the government decided to take effective steps in controlling the rate of population growth. One of the most important steps was to make contraceptives available free of charge throughout the whole country.⁽¹³⁾ However, despite government efforts, the prevalence of unintended pregnancy due to the discontinuation of birth control methods is high. Although the complications for the two types of pills are not different, there are important differences in their continuation times.⁽¹⁴⁾ In this study we compared monophasic and triphasic pills for continuation time and side effects, and also determined some related factors for continuation or discontinuation of triphasic and monophasic LD.

Subjects and Methods:

This was a historical cohort study, which used documents from health centres in the city of Isfahan, Iran in 2004. The city was divided into 2 areas, and 10 health centres were randomly selected from each area, with the incomplete being excluded. A total of 386 married Iranian women (15-49) with at least one year of OCP consumption (low dose monophasic or triphasic combined hormonal oral contraceptive pills) enrolled in the study (cumulative incidence). From this group, 163 participants received triphasic pills [30 mic/gr ethinyl estradiol, 50 mic/gr levonorgestrel, 5 pills, 40 mic/gr ethinyl estradiol, 75 mic/gr levonorgestrel, 11 pills: 30 mic/gr ethinyl estradiol and 25 mic/gr levonorgestrel) 6 pills] and 223 had received monophasic LD containing pills (30 mic /gr ethinyl estradiol, 150 mic/gr levonorgestrel), which were manufactured by an Iranian hormone company.⁽⁷⁾ Women with a history of medical problems like hypertension, diabetes, GI discomforts and smoking were not eligible to participate in the study. Demographic data, duration of OCP consumption, time of discontinuation, causes of OCP discontinuation and information on OCP side effects were collected by observing documents and telephone interviews. The dependent variable was defined as OCP continuation time. We

had three censored groups including: Participants who continued OCP consumption, participants who didn't have a follow up due to immigration or other reasons, and participants with unknown outcomes. Data analysis was performed with the SPSS (11.5) statistical package, using Chi-square, Kaplan Meier, log-rank and the Cox regression models.

Results:

In this study, 386 reproductive aged women who use oral contraceptives (LD or triphasic) were evaluated for continuation time and side effects. From this group, 32 were censored (loss of follow up, unknown outcome and continue using OCP), and therefore excluded from the analyses. From those in which follow-up data was available, 84 out of 223 LD users (37.7%) and 61 out of 163 TP users (37.4%) had discontinued OCP during the study ($p > 0.05$). The primary causes for discontinuation were the same in both groups, with the exception of weight gain [13.1% vs. 10.7 %] ($p < 0.05$) and freckling of the face [13.1 vs. 2.4 %] ($p < 0.05$), which was slightly higher in the TP group, and headaches which were significantly higher in the LD group [13.1% vs. 6.6 %] ($p < 0.05$).

Demographic characteristics of the subjects are shown in table 1. The mean ages of LD and triphasic users were 29.4 ± 6.4 and 28.6 ± 5.8 years, respectively ($p > 0.05$).

The continuation time of oral contraceptive pills over a 5 year period was esti-

mated by Kaplan Meier. In the first 12 months, low dose combined hormonal contraceptive pills and triphasics were continued [98% vs. %84] ($p < 0.05$), but the continuation time decreased [48% vs. 38%] ($p < 0.05$) by the end of five year period. The median duration of continuing LD and triphasics contraceptive pills was $56 \pm$ months (37-75) vs. $37 \pm$ months (21-53) with a CI of 95%. Age, number of surviving children, education level, and employment status didn't have

any role in choosing contraceptive method ($p > 0.05$) but in each group, there was a significant relation between these variables and median duration of OCP use. Females aged 35 years and older, with ≥ 3 parities and children with less than 9 years of education had a higher probability of continuing their use of oral contraceptive pills, as did housewives who used LD, and employed women who used triphasic (Table 2).

Table 1: characteristics of participants in LD and tri phasic user.

characteristics	LD		Tri phasic		Pvalue
	N(223)	%	N(163)	%	
Job status					NS*
Housewife	206	92.4	151	92.6	
employed	17	6.6	12	7.4	
Women education					NS
≤ 9 years	61	27.3	30	18.4	
10- 12 years	131	58.7	103	63.1	
> 12 year	31	13.9	30	18.4	
Children number					NS
≤2	191	85.6	139	86.8	
≥3	32	14.02	24	14.7	
Age					NS
<20	10	4.5	6	3.7	
20-35	178	79.8	132	80.9	
>35	35	15.6	25	15.3	

* NS non significant at < 0.05

Table2: comparing mean and CI 95% of OCP continuing time (months) according to age, number of alive children, education and job status in LD and Triphasic users.

variables	LD (Mean, CI 95%)	Triphasic (Mean, CI 95%)	p-value
Age			<0.05
<20	33.4 (25.3- 41.5)	21.6 (9.4-33.9)	
20-35	38.9 (35.5-42)	34.79 (30-39)	
>35	52.8(46.9-58.6)	43.5 9(34.2-52.8)	
Job			<0.01
Employee	30.8 (20.3 -41.5)	39.9(25-56.4)	
household	42.2(39-45.5)	36.8 (32.5-41)	
Education			<0.05
<9 Years	49.5 (44.7-54)	41.8 (33.5-50)	
9-12	40.5 (36-44.8)	36.5(31-42)	
>12	25.3(18.7-32)	34.7(23.9-45.5)	
Number of children			<0.05
≤2	39.6(36.2-43)	34.7 (30-39.3)	
≥3	51.9 (43.8-58.3)	52 (43.8-60.4)	

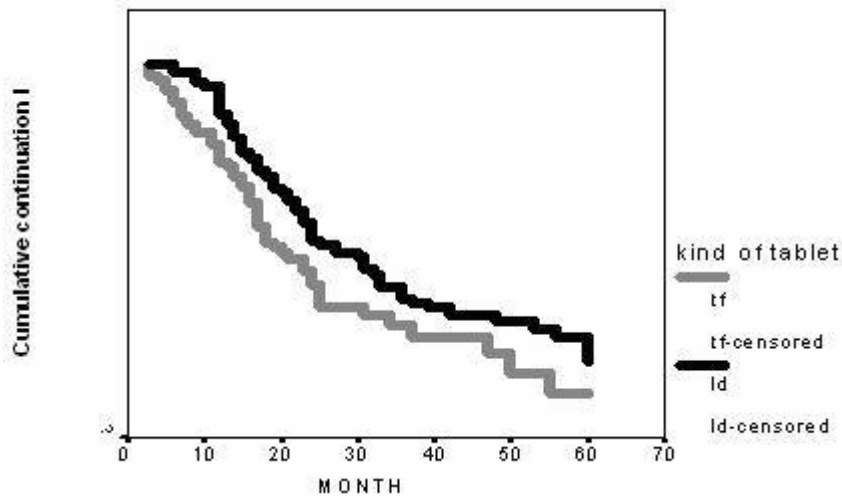


Figure 1: Comparison of continuation times of 2 oral contraceptive pills over 5 years

Discussion:

Despite the same complications and total discontinuation time in LD and triphasic users (37.7% vs. 37.4%), previous studies have shown that the 5 year continuation time among triphasic users was lower than among those who had used LD.⁽¹⁵⁾ This may be due to concerns about forgetting triphasic use and incidences of unintended pregnancy. One and two year continuation times among LD users (98% & 70%) were higher in comparison with one and two year continuation times among triphasic users (84% & 60%). One and two year continuation times among LD users in Zahedan, Iran was 83% and 73%, respectively, while one year continuation time among LD users was 52% in Egypt and 40% in Banin.^(16, 17) Three year continuation times for users of LD and triphasic were the same (57% & 56%).

The higher one and two year continuation time for LD may be attributed to cosmetic concerns, such as a lower incidence of weight gain and freckles. In addition, it is not necessary to discontinue LD consumption after forgetting 2-3 doses. The higher one year continuation time among users of LD that was observed in our study in comparison with studies performed in Zahedan, Egypt and Banin may be due to the use of a more rigorous methodology and also by understanding the importance of childbearing spacing in family planning.

Well educated women who were employed demonstrated a higher continuation time while using triphasic, while unemployed women with lower education had a higher continuation time while using LD. It can be suggested that implementing a program with a daily routine for employed educated women may be more successful in getting them to take triphasic pills at a specific time everyday. An examination of the demographic status of participants revealed that their

jobs, educational level, number of children, and age didn't have an important effect on the selection of contraceptive methods. These results were also shown in Egypt and Zahedan^(16, 17), and suggests that clients may not be given enough information about OCP, and as a result may think that both types are interchangeable.

In our study, 5 year use of LD & triphasic were found to be 48% and 38%, respectively. In Isfahan, the cumulative proportion of continuation of oral contraceptives was %12.⁽¹⁸⁾ A higher level of 5 year continuation of LD and triphasic in our study may be attributed to more effective consultation. In addition, multipartner women who had ≥ 3 children, and women wanting to preserve the size of their families used OCP for a longer period of time because contraception was more important for them.

In this study, women aged 35 years and older continued using LD longer than triphasic, which may be associated with its easy administration. In addition, we found that the predictive factor for OCP continuation was often the number of children. Women with only one child were found to have a higher rate of discontinuation, possibly because many of these women chose this method for temporary child spacing, as the possibility of conception could be easily reversed after discontinuation of the pills.

Conclusion:

Health care professions should consider the characteristics of their clients before selecting the type of contraceptives pills they should use, as the discontinuation

time is higher in triphasic users than LD users.

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