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Desogestrel: using a selective progestogen in a combined oral contraceptive

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Abstract

Desogestrel is the most selective progestogen used in oral contraceptives (OCs). The clinical characteristics of the monophasic combined OC containing 150 μg desogestrel and 30 μg EE per tablet (Marvelon) are in accordance with the strong progestogenic and minimal androgenic effects of desogestrel: a very high contraceptive efficacy is combined with minimal and, in the case of lipid metabolism, even potentially positive effects on metabolic parameters.

Through increasing the plasma levels of sex hormone binding globulin, and thereby decreasing the plasma levels of free testosterone, the desogestrel-containing OC also has substantial beneficial effects on acne.

Introduction

Since its introduction 30 years ago, the oral contraceptive pill has been subject to many modifications, aimed at improving its safety. One of the first improvements was achieved by reducing the estrogen dose. This was brought about by studies showing that women who used oral contraceptives (OCs) containing a high dosage of estrogen had a higher risk of thromboembolic disease [1]. The daily estrogen dose was consequently gradually reduced from 150 μg in the early pills to 30 μg or even lower in the present OCs. This change has drastically reduced the incidence of thromboembolic disease in OC users [2].

After focusing on the estrogen component of the pill, the attention switched to the progestogen in the 1970s. Three independent types of studies were responsible for this.

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1. Several epidemiological studies in women using oral contraceptives showed a higher incidence of ischemic heart disease [3,4]. The incidence was linked to the progestogen in a dose-related way [5].

2. A number of population studies, of which the Framingham study is the best known, showed that men and women with low serum levels of HDL-cholesterol had a higher risk of ischemic heart disease (IHD), whereas those with high levels of HDL-cholesterol were at lower risk [6].

3. Metabolic studies showed that the serum levels of HDL-cholesterol were lower in women using oral contraceptives that contained progestogens with a high intrinsic androgenicity [7].

The results of these studies led to a further investigation of the steroids used in the pill with regard to their effect on lipid metabolism. It is well known that estrogens increase the serum levels of HDL-cholesterol (HDL-C) and decrease those of LDL-C, whereas androgens have the opposite effect. The progestogens used in oral contraceptives all have some androgenic rest activity, although some more than others. The net effect of a particular OC on lipid metabolism is dependent on the dosage and the sort of progestogen used.

Changes in progestogens

To overcome the adverse effects of OCs on lipids two approaches have been followed. The first was to reduce the progestogen dose in the pill. This has led to the development of the triphasic OCs. The second approach was to improve the progestogen itself by minimizing its androgenic effects. As a result desogestrel was developed, the first of a new generation of progestogens.

In studying the hormonal characteristics of progestogens, receptor binding studies are one of the most valid tools. The binding affinity of a progestogen to the progesterone receptor is a good standard for its progestogenic activity, as is the binding affinity to the androgen receptor for its androgenic activity.

Comparing the four most used progestogens in the pill [8], both 3-keto-desogestrel (3kDSG is the active metabolite of desogestrel) and gestodene (GSD) have a stronger progestogenic activity than the older progestogens, norethisterone (NET) and levonorgestrel (LNG). On the other hand, LNG and GSD have a higher androgenic activity than 3kDSG and NET.

The most relevant information that can be obtained from receptor binding studies is the selectivity index (Figure 1). This is the ratio of the binding affinity to the progesterone receptor over that to the androgen receptor. The selectivity index has been shown to correlate well with the metabolic impact of a progestogen on lipid metabolism. The new progestogens, 3kDSG and GSD, are far more selective than the older NET and LNG. 3kDSG is the most selective progestogen available.

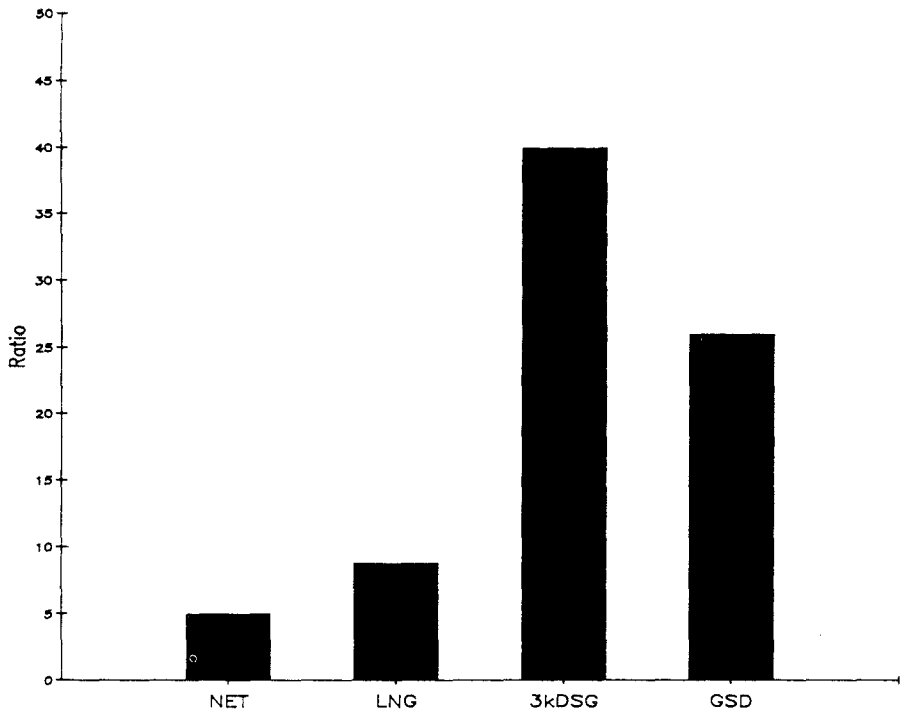

Figure 1 Selectivity index of progestogens: ratio of binding affinity to the progesterone receptor/binding affinity to the androgen receptor [8]. NET = norethisterone, LNG = levonorgestrel, 3kDSG = 3-keto-desogestrel, GSD = gestodene

A good oral contraceptive has to fulfil three basic requirements:

1. It should have a high contraceptive reliability
2. It should be acceptable for the woman who uses it
3. It should not have adverse effects on safety parameters.

Contraceptive reliability

With desogestrel, an amount of 60 μg per day is sufficient to achieve 100% ovulation inhibition [9]. In Marvelon, each tablet contains 150 μg, resulting in a broad margin of reliability. For levonorgestrel, 100 μg per day is needed to achieve 100% ovulation inhibition [10]. In the first 11 tablets of the triphasic pill, the dose of levonorgestrel is below the level needed for complete ovulation inhibition, which can lead to escape ovulation.

Evidence that the triphasic pill is less reliable than others was obtained in a Dutch study of women requesting artificial abortion (Table 1) [11]. All women had become pregnant in spite of taking their pills correctly. The share that a particular OC had of

the total number of pregnancies was compared with the market share of the same OC. If all OCs were equally effective, the ratio of pregnancy share/market share would be 1. The triphasic OC containing levonorgestrel had a ratio significantly higher than 1; there were more pregnancies with this OC than expected. Marvelon (30 μg EE/150 μg DSG) had a significantly lower ratio than 1; there were fewer pregnancies than expected.

Also, in large-scale clinical studies, the contraceptive reliability of the DSG-containing combination (Pearl index 0.05) compares favorably with that of other low-dose pills [12–17].

Table 1 Failure of low-dose OCs to prevent pregnancy in relation to their relative market shares in The Netherlands, 1982 [11]

Type of OC	*Failures (%)*	*Market share (%)*	*Ratio (failures:market share)*
Monophasics			
EE/DSG	5.3	13.0	0.4 ($p<0.05$)
EE/LNG	37.7	46.6	0.8 (ns)
EE/NET	7.0	4.3	1.6 (ns)
EE/LYN	15.8	21.6	0.7 (ns)
Triphasic			
EE/LNG	34.2	14.5	2.4 ($p<0.05$)
Total	100.0	100.0	1.0

LYN = lynestrenol; ns = not significant

Acceptability

The presence or absence of irregular bleeding is an important issue affecting the acceptability of an OC. In this regard it is difficult to compare OCs based on the results of single studies, because different designs and different definitions of irregular bleeding are used in the various studies. A better comparison can be obtained from the grouped results of a number of studies [8]. Comparing the incidence of irregular bleeding from the 5 largest studies with the combined DSG-containing pill and with the triphasic levonorgestrel-containing OC in this way, it can be concluded that there are no statistically significant differences between these two OCs in this respect [8].

The incidence of subjective side-effects is usually higher during the first month of treatment with an OC than before treatment, especially in pill-starters. After 3 cycles the percentage of women suffering from such side-effects as nausea, headache and breast tenderness is back at the pretreatment level or even lower. Low-dose OCs do not differ between each other in this respect.

After one year of Marvelon use, the average body weight in 1603 users was increased by 0.2 kg. Analyzing the effect on body weight in different age groups, it seems that the weight increase is only present in the group of women younger than 20 years (Table 2) [12]. The same rise in body weight is also seen in the same age group without any form of hormonal contraception and thus must be seen as a consequence of natural growth rather than an effect of the pill.

Table 2 Effects of the EE/DSG combination on body weight in age groups [12]

Cycle	*<20 years*	*20–29 years*
1	+ 0.3 kg	0.0 kg
3	+ 0.5	0.0
6	+ 0.7	0.0
12	+ 1.2	0.0

Safety parameters

Four parameters are of relevance for oral contraceptives concerning a possible effect on the risk for cardiovascular disease: their effects on blood pressure, on lipid and carbohydrate metabolism and on hemostasis.

In a study in which more than 11,000 women took the EE/DSG-containing OC for at least 6 months, no effect on blood pressure was seen in the majority of women. In 44 women, a pretreatment diastolic blood pressure (BP) > 90 mmHg decreased to < 90 mmHg. An increase to a diastolic BP > 90 mmHg occurred in only 8 women in the study [13].

With regard to the effects of OCs on lipid and carbohydrate metabolism, the Cavendish Clinic study is the largest ever performed [18]. This cross-sectional study was sponsored by the National Institute of Child Health and Human Development of the USA and the results have recently been published in the New England Journal of Medicine [18]. 1128 women took part in the carbohydrate metabolism assessments and 1478 in the lipid assessments (OC users and controls). All women were Caucasian and aged between 18 and 45. Women who had used an OC for at least 3 months were compared with controls who had not taken any form of hormonal contraception for 3 months or more. The following combined OCs were investigated:

Monophasic OCs	*Triphasic OCs*
EE/LNG 30/150	Triphasic LNG
EE/LNG 30/250	Triphasic NET
EE/NET 35/500	
EE/NET 35/1000	
EE/DSG 30/150	

The glucose plasma levels during an oral glucose tolerance test (OGTT) were elevated in all OC groups compared with the control group.

The least effect was seen with the monophasic DSG and the monophasic low-dose NET-containing OC; the LNG combinations all had a much larger impact. Also the DSG- and NET-containing OCs had the least effect on the insulin levels during the OGTT. Increased plasma glucose and insulin levels are indicative of impairment of glucose tolerance and may be associated with a higher risk for cardiovascular disease [19]. The OCs with the least effect should therefore be favored.

Concerning the relevance of the lipid parameters investigated in the Cavendish Clinic study: HDL2-cholesterol (a subfraction of HDL-C) and LDL-cholesterol have been shown to be the strongest predictors of cardiovascular disease risk [20,21]. Most of the combined OCs had a negative effect on HDL2-C serum levels with the exception again of the monophasic DSG and low-dose NET-containing OCs (Table 3). The LNG containing OCs all strongly decreased HDL2-C, an effect which is generally seen as adverse. LDL-C serum levels were not affected by most of the OCs in the study. The monophasic DSG and low-dose NET-containing OCs caused a decrease in LDL-C levels, an effect which can be regarded as positive.

Concerning HDL-C, the monophasic LNG-containing OCs decreased the serum level, whereas the two triphasic pills and the high-dose monophasic NET-containing OC did not have an effect. The monophasic DSG and low-dose NET-containing pills raised the HDL-C levels significantly.

The results of the Cavendish Clinic study are in accordance with those from a large number of prospective longitudinal studies on lipid metabolism. The majority of studies performed with the DSG-containing OC showed no effect on LDL-C serum levels. Levels of HDL-C were increased in 14 studies whereas, in 9 studies, no effect was seen (Table 4).

Table 3 Serum lipid and lipoprotein cholesterol levels in users and non-users of oral contraceptives [18]

	Serum levels (mmol/L)		
Group	*LDL*	*HDL*	*HDL2*
non-users ($n=418$)	2.40 ± 0.69	1.73 ± 0.32	0.72 ± 0.27
30EE/150LNG ($n=296$)	2.43 ± 0.72	1.65 ± 0.32**	0.51 ± 0.22*
30EE/250LNG ($n=31$)	2.41 ± 0.52	1.46 ± 0.20*	0.41 ± 0.17*
35EE/500NET ($n=116$)	2.11 ± 0.63*	1.90 ± 0.35*	0.67 ± 0.25
35EE/1000NET ($n=53$)	2.26 ± 0.66	1.66 ± 0.28	0.52 ± 0.20*
30EE/150DSG ($n=104$)	2.07 ± 0.56*	1.94 ± 0.33*	0.73 ± 0.22
tri-LNG ($n=243$)	2.32 ± 0.64	1.75 ± 0.32	0.61 ± 0.23*
tri-NET ($n=82$)	2.24 ± 0.68	1.81 ± 0.36	0.66 ± 0.26

* = $p<0.001$ compared with control values (Student's t test)
** = $p<0.01$ compared with control values (Student's t test)

Table 4 Effect on serum HDL-C and LDL-C levels of the EE/DSG combination for more than 3 treatment cycles [25–46]

	Decrease	*No change*	*Increase*
HDL-C	0	9	14
LDL-C	3	15	0

The last safety parameter of OCs, their effect on hemostasis, is the one about which we know the least. Although all low-dose OCs increase some specific factors of the coagulation system and also some of the fibrinolytic system, it is not known exactly how relevant these changes are with regard to the risk for thrombosis. It is generally accepted that the effects of low-dose OCs are minor and that the hemostatic balance is not affected by them [22].

SHBG and acne

Apart from being an extremely reliable ovulation inhibitor, the EE/DSG-containing OC has one beneficial side-effect: it cures or improves light and moderate degrees of acne. Like on lipids, estrogens and androgens also have opposing effects on the plasma levels of sex hormone binding globulin (SHBG). Estrogens increase SHBG levels whereas androgens decrease them.

The higher the plasma levels of SHBG, the more circulating testosterone can be bound to it. This will result in a decrease of the plasma levels of free testosterone and will have positive effects on androgenic skin disorders like acne. During the use of Marvelon, the SHBG plasma levels are elevated by 200% [23].

In a study involving more than 11,000 women, 8.8% of the participating women had acne before they started to use the EE/DSG-containing pill. After 3 treatment cycles, the percentage of women with acne was reduced to 4.7% and, after 6 cycles, only 2.3% of the women still had acne [13]. This implies that, in 75% of the women, the acne was cured. In another recent study more than 1700 women who suffered from acne in various grades of severity were treated with the combined OC containing DSG. After 6 months the acne was cured or improved in 42–65% of the women; the best results were obtained in the lighter grades of severity (Figure 2) [24].

Summary and conclusion

The progestogen in Marvelon, desogestrel, is the most selective of the progestogens available. It is used in a dose (150 μg/tablet) that makes the EE/DSG combination the most reliable OC of today. Regarding acceptability parameters and effect on blood pressure and hemostasis, the EE/DSG-containing pill does not differ from other low-dose OCs.

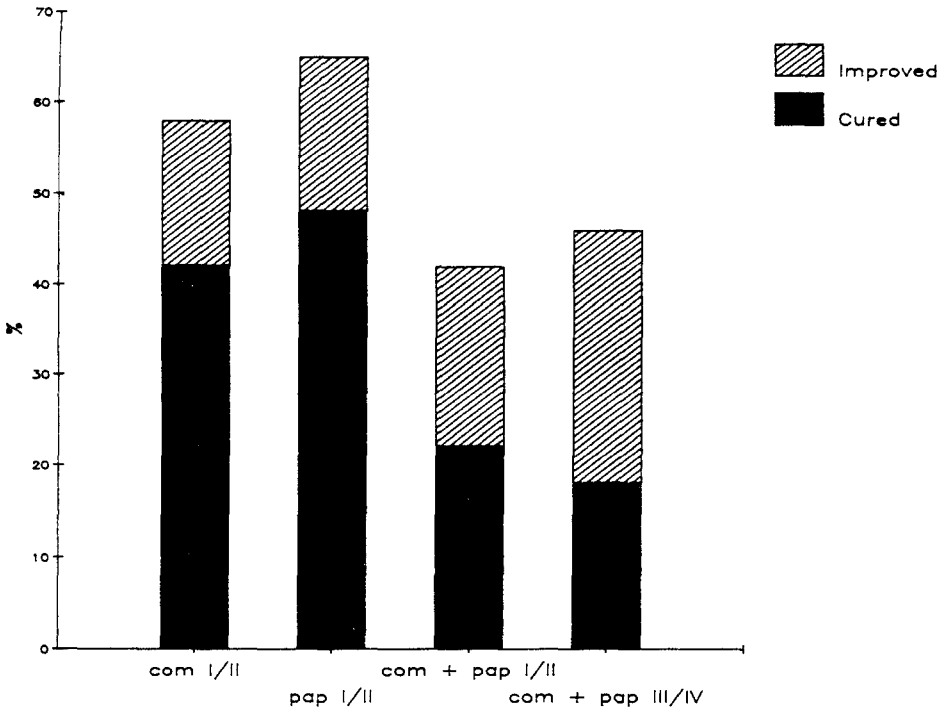

Figure 2 Effects of the EE/DSG combination on acne [24].
com I/II = acne comedonica grade I and II; pap I/II = acne papulopustulosa grade I and II;com + pap I/II = both forms of acne present in grade I and II;com + pap III/IV = both forms of acne present in grade III and IV

Because of desogestrels low intrinsic androgenicity, the EE/DSG combination has minimal adverse impact on carbohydrate metabolism and even potentially positive effects on lipid metabolism. By increasing the plasma levels of SHBG by 200%, the DSG-containing OC has a beneficial effect on acne.

In conclusion, the EE/DSG-containing OC has an overall better clinical profile than that of the OCs containing older progestogens.

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Resumé

Le désogestrel est la progestérone sélective la plus utilisée dans les contraceptifs oraux. Les caractéristiques cliniques de ce contraceptif combiné monophasique contenant 150 μg de désogestrel et 30 μg EE par comprimé (Marvelon) sont conformes aux effets progestatifs puissants et androgènes minimes du désogestrel: sa haute efficacité contraceptive se combine avec des effets sur les paramètres métaboliques qui sont minimes, et même potentiellement positifs dans le cas du métabolisme des lipides.

En augmentant les niveaux plasmatiques de la globuline liant les hormones sexuelles, et en diminuant de ce fait les niveaux plasmatiques de la testostérone libre, les contraceptifs oraux contenant du désogestrel ont un effet bénéfique considérable sur l'acné.

Resumen

El desogestrel es la progesterona más selectiva empleada en los anticonceptivos orales. Las características clínicas de este anticonceptivo combinado monofásico que contiene 150 μg de desogestrel y 30 μg EE por comprimido (Marvelon) están de acuerdo con los efectos progestágenos potentes y andrógenos mínimos del desogestrel: su alta eficacia anticonceptiva se combina con efectos minimos sobre los parámetros metabólicos, y hasta potencialmente positivos en el caso del metabolismo de los lípidos.

Al aumentar los niveles plasmáticos de la globulina que enlaza las hormonas sexuales, y disminuyendo así los niveles plasmáticos de la testosterona libre, los anticonceptivos orales que contienen desogestrel tienen un considerable efecto benéfico sobre el acné.