

A retrospective survey of over 1,000 patients on oral contraceptives in a group practice

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SUMMARY. The side-effects encountered by 1,090 patients taking the oral contraceptive pill were reviewed. The main side-effects were migraine, headaches, weight gain, depression, and irregular bleeding. Reasons for changing the Pill are discussed, and recommendations are suggested for a way of monitoring patients taking the Pill. Analysis of the results show that 50 per cent of patients are happy with their first Pill, and that the 30 microgram pill produces fewer side-effects.

Introduction

Thirty-three oral contraceptive preparations are listed in *MIMS* (October, 1975). The reported incidence of side-effects varies according to the preparation, with the latest reports about the 30 microgram pills showing the lowest side-effects.

After five years' work in one general practice, I realised that enough data had been accumulated to determine whether any one Pill was superior to another in relation to the side-effects produced, and if patients therefore continued to take a Pill which produced few side-effects for a longer time.

The results would also show how much time a general practitioner needed to devote to contraceptive care as each side-effect needed to be dealt with, and extra consulting time consequently would be needed.

Method

The practice

The practice is in a Black Country town of 60,000 inhabitants. There are eight partners, and from time to time a trainee and a medical student. We have 20,500 patients.

Special time is not set aside for contraceptive advice, but patients come as part of the normal surgery. Ten minutes is allocated for the initial consultation (history and general check) and ten minutes for a consultation if a smear is to be taken; otherwise five minutes is allocated.

All patients who attend for contraception are referred to the practice nurse by the receptionist, having been asked first if that is why they have come. The nurse checks the patient's weight and blood pressure before the patient sees the doctor. At the first visit a three-month prescription is given, six months at the second, and a year at the third, provided all is well. If the Pill prescription is changed, the patient starts again with a three-month supply. A repeat prescription for a patient well established on her oral contraceptive may not take up five minutes, but it is the rare patient who does not save up some problem for the occasion (the 'while I'm here' syndrome).

Aims

My aims were:

- (1) To record all side-effects reported from women on the Pill.
- (2) To estimate the impact of side-effects on consulting time.

Records

The data were recorded on special contraceptive record cards (red printing on white card), which were filed with the patient's records and which displayed at a glance her obstetric, gynaecological, medical, and contraceptive history. All patients in this series were seen by me, as other partners' patients were referred for contraceptive advice.

Only a small proportion of patients use the local authority family planning clinic (even when they issued free supplies.) They are mainly patients transferred from other family planning clinics and patients who do not realise that our practice offers a contraceptive service.

Results

Duration of oral contraception

Analysis of 1,090 patients records showed that 117 patients (10.7 per cent) had been taking an oral contraceptive for more than five years, although some had had breaks for pregnancy (table 1). Patients who had been on an oral contraceptive for less than six months were included as they show an initial group of side-effects.

TABLE 1
YEARS OF USE

<i>Duration</i>	<i>Number of patients</i>	<i>Percentage</i>
Six months	252	23.1
7-12 months	155	14.2
13-24 months	264	24.3
2-5 years	302	27.7
5-10 years	114	10.4
More than 10 years	3	0.3
	1090	100.0

For 252 (23.1 per cent) of patients, the oral contraceptive pill was a new experience. During the last two years, since the 50 microgram oral contraceptives were recommended, a higher number of patients are choosing oral contraception, and, of all the patients reviewed, 61.5 per cent have been using it for less than two years.

Age and social status

The largest number of patients were in the main child-bearing age group 20-29 years, but nearly a quarter were under 20 (table 2). Most patients under 20 were not married, and some were still at school. The youngest patient to start the Pill was 15 years ten months, and the oldest patient still taking it is 52.

The major employer in the practice area is a large car manufacturer, and it was not surprising to find that most of the patients (76.7 per cent) were in the social groups 3 and 4 (table 3).

TABLE 2
AGE OF PATIENTS

	<i>Number of patients</i>	<i>Percentage</i>
Up to 20 years	266	24.4
20-29 years	475	43.6
30-39 years	288	26.4
40 years and over	61	5.6

TABLE 3
SOCIAL CLASS OF PATIENTS

<i>Social class</i>	<i>Number of patients</i>	<i>Percentage</i>
1	48	4.4
2	139	12.8
3	380	34.9
4	456	41.8
5	67	6.1

Gravidity

More than a quarter (29.6 per cent) of the patients had not experienced pregnancy (table 4), and about half (51.2 per cent) of the women had experienced two or less. One patient had had nine pregnancies. The youngest patient who became pregnant was 11 years and 11 months.

TABLE 4
PREVIOUS PREGNANCIES

<i>Number of previous pregnancies</i>	<i>Number of patients</i>	<i>Percentage</i>
0	323	29.6
1	277	25.4
2	281	25.8
3	181	16.6
4	24	2.2
5+	4	0.4

Oral contraceptives and their side-effects

Table 5 shows the oral contraceptive preparations that are used regularly in the practice, and the number of patients taking them. In each case the preparation shown is one which the patient took initially.

TABLE 5
ORAL CONTRACEPTIVES AND THEIR SIDE-EFFECTS

<i>Preparation</i>	<i>Patients using</i>		<i>Side-effects</i>									
			<i>Migraine</i>		<i>Headache</i>		<i>Weight gain</i>		<i>Fluid retention</i>		<i>Hypertension</i>	
	<i>Per Number</i>	<i>cent</i>	<i>Per Number</i>	<i>cent</i>	<i>Per Number</i>	<i>cent</i>	<i>Per Number</i>	<i>cent</i>	<i>Per Number</i>	<i>cent</i>	<i>Per Number</i>	<i>cent</i>
1 'Anovlar'	37	3.4	5	13.5	6	16.2	1	2.7	1	2.7	1	2.7
2 'Gynovlar'	172	15.8	4	2.3	24	13.9	15	8.7	6	3.5	—	—
3 'Norlestrin'	4	0.5	—	—	1	25.0	1	25.0	—	—	—	—
4 'Volidan'	18	1.6	1	5.6	1	5.6	1	5.5	—	—	—	—
5 'Ovran'	10	0.9	—	—	—	—	—	—	2	20.0	—	—
6 'Norinyl-1'	67	6.2	3	3.9	7	9.1	5	7.5	1	1.5	2	2.9
7 'Minilyn'	91	8.4	—	—	19	20.1	8	8.8	2	2.2	1	1.1
8 'Ovulen-50'	173	15.8	3	1.7	25	14.4	9	5.2	4	2.3	—	—
9 'Minovlar'	221	20.3	4	1.8	35	15.8	12	5.4	3	1.4	1	0.5
10 'Demulen-50'	57	5.2	—	—	9	15.7	3	5.3	—	—	—	—
11 'Ortho-Novin 1/50'	17	1.5	1	5.8	1	5.8	1	5.8	—	—	—	—
12 'Eugynon-30'	69	6.3	—	—	14	20.3	5	7.3	1	1.5	—	—
13 'Microgynon-30'	82	7.4	—	—	1	1.2	—	—	—	—	—	—
14 'Ovranette'	35	3.2	—	—	2	5.7	—	—	—	—	—	—
15 'Femulen'	38	3.5	1	2.6	2	5.2	2	5.3	—	—	—	—
	1090	100.0	21	1.9	147	13.4	63	5.8	20	1.8	5	0.5

Migraine and headaches

Twenty-one patients (1.9 per cent) experienced symptoms of migraine whilst taking the Pill (table 5), but of these only three developed migraine for the first time. Of these three patients, one developed transient anopia, and two experienced numbness and tingling of the left arm and leg during the attack. These three patients were advised to stop taking the Pill.

The other 18 patients reported either an increase in the frequency or severity of the migraine, or both, and were changed to another preparation, with relief of symptoms. The prevalence of

migraine was not related to any particular preparation, though a higher proportion of patients taking 'Anovlar' were affected. The onset of migraine while on oral contraception is an indication for stopping it.

One hundred and forty seven patients (13.4 per cent) developed headache other than migraine. It was noticed that the headaches fell into two categories: those that occurred when the patient first began to take the Pill, and those that occurred after two years or more. The first type usually disappeared spontaneously after about three months, but occasionally persisted. The second type occurred mainly in the week off the Pill, but in other patients occurred during other points in the cycle. The usual remedy was to change to a Pill of lower or different oestrogen content. Some patients, who had experienced headache before starting the Pill, noticed an exacerbation.

Weight gain, fluid retention, and hypertension

The criteria adopted to define weight gain was either an increase in weight of at least 3.2 kg (seven pounds) in the first three months, or steady gain over a longer period despite dieting. Sixty-three patients (5.8 per cent) with weight gain were found (table 5). None of the 81 patients taking 'Microgynon-30' experienced abnormal weight gain. The mechanism of weight gain is uncertain, but many patients report an increase in appetite which leads to overeating and weight gain.

The presence of fluid retention was determined by weighing the patient before and after a period, a post-menstrual loss of 2.25 kg (five pounds) or more being regarded as significant. Twenty patients (1.8 per cent) had fluid retention and were treated either by a change of Pill or with a diuretic—this being determined by ascertaining how generally satisfied with her Pill the patient was.

Hypertension was defined as a persistently raised blood pressure above 140/90. Only five patients developed hypertension. One, aged 47, had been taking an oral contraceptive for 12 years. Despite advice she refused to change her preparation or permit any investigation of her raised blood pressure, and keeps well with a pressure of 160/100 mm Hg. The second patient, aged 24, developed hypertension after being on an oral contraceptive for four years. She had not had her blood pressure measured regularly before coming to this practice, despite her strong family history (mother and father affected). She was investigated and found to have essential hypertension, and is well on treatment. She was subsequently fitted with an intra-uterine device, a 'Gravigard.' The other three patients continued to have raised blood pressure after stopping their Pill, and were referred for investigation. They have all accepted alternative methods of contraception, and have treatment for their hypertension. All five patients had essential hypertension.

Since they were symptom-free, their hypertension would have gone unrecognised if they had not had their blood pressures checked regularly.

When a patient develops raised blood pressure whilst taking the Pill I change her to a progesterone-only product. Usually the blood pressure falls to normal levels, but if not, full investigation is arranged.

Depression, loss of libido, and tiredness

These symptoms often occur together in the same patient, although the overall incidence of tiredness (10.6 per cent) is almost twice that of depression (5.8 per cent). Loss of libido is often the presenting complaint, and enquiry may reveal that depression is the underlying cause of both loss of libido and tiredness.

Sixty patients (5.8 per cent) complained of depression (table 6), all of whom began to notice it as soon as they started on a new pack each month. It then worsened during the course of the month, and improved in the week off. Only patients who improved with a change of Pill have been included in these figures.

I think that patients are more willing nowadays to complain of having "gone off sex" and to discuss the subject in a more open way.

Eight of the depressed patients were given pyridoxine 50 mg tablets daily for one month. None of them then reported an improvement. However, they did respond to a change of oral

contraceptive. Forty-seven patients (4.3 per cent) complained of loss of libido and they were treated with a change of Pill and counselling.

One hundred and sixteen patients (10.6 per cent) complained of excessive tiredness. The symptoms did not show a pattern, in that some patients reported it occurring whilst taking the Pill, and some only in the week off.

TABLE 6
OTHER SIDE-EFFECTS

Preparation	Patients using		Depression		Loss of libido		Tiredness	
	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent
1 'Anovlar'	37	3.4	—	—	—	—	1	2.7
2 'Gynovlar'	172	15.8	10	5.8	8	4.7	19	11.1
3 'Norlestrin'	4	0.5	1	25.0	—	—	—	—
4 'Volidan'	18	1.6	—	—	—	—	1	5.6
5 'Ovran'	10	0.9	—	—	2	20.8	3	30.0
6 'Norinyl-1'	67	6.2	4	5.9	3	4.5	13	19.4
7 'Minilyn'	91	8.4	7	7.7	9	9.9	11	12.1
8 'Ovulen-50'	173	15.8	12	6.9	5	2.9	22	12.7
9 'Minovlar'	221	20.3	13	5.9	12	5.4	22	9.9
10 'Demulen-50'	57	5.2	2	3.5	3	5.3	5	8.8
11 'Ortho-Novin 1/50'	17	1.5	2	11.8	1	5.9	3	17.7
12 'Eugynon-30'	69	6.3	7	10.1	3	4.4	12	17.4
13 'Microgynon-30'	81	7.4	—	—	—	—	—	—
14 'Ovranette'	35	3.2	—	—	—	—	1	1.2
15 'Femulen'	38	3.5	2	5.3	1	2.6	3	7.9
			—	—	—	—	—	—
			60	5.8	47	4.3	116	10.6

Changes in menstrual pattern

Cycle control does not appear to depend only on the amount of hormones in the Pill, as all changes occurred with all types of Pill. Dysmenorrhoea is secondary i.e. developing whilst on the Pill. Ten patients (0.9 per cent) developed it severely enough to warrant a change of Pill. Heavy periods were experienced by 32 patients (2.9 per cent), even when taking strongly progestogenic oral contraceptives. The highest incidence occurred in patients on a progesterone-only pill. Patients on 30 microgram pills had good control of their periods. The same applies to irregular periods. Patients on all types of oral contraceptives experienced them, but more so on the oestrogen-free pill.

Intermenstrual bleeding occurred in quite a high percentage of patients (10.5 per cent). It did not occur only in the first three months, but may develop after some time. It often follows missed tablets, but may be due to any of the other causes of intermenstrual bleeding, and may demand investigation in its own right. In this survey the intermenstrual bleeding occurred during more than one cycle, so in these patients missed tablets were not to blame. However, intermenstrual bleeding as an isolated occurrence is probably due to missed Pills. 'Ovulen 50' and 'Demulen 50' both show a higher prevalence of intermenstrual bleeding, but I do not know why.

Scanty periods were complained of by 30 patients (2.8 per cent). Many patients experience it on direct questioning, but do not complain. The small proportion of patients who complained of scanty periods felt unhappy unless they had a reasonable blood loss, and were not amenable to explanation and reassurance.

Forty-nine patients (4.5 per cent) developed amenorrhoea for longer than three months. These patients were all either nulliparous, in which case they were advised either to change their oral contraceptive, or stop it (depending on how soon they wanted to start a pregnancy), or multiparous wanting to become pregnant or to start their periods again.

TABLE 7
ALTERATIONS IN BLEEDING PATTERNS

	Patients using		Dysmenorrhoea		Heavy periods		Irregular periods		Inter-menstrual bleeding		Scanty periods		Amenorrhoea	
	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent
1 'Anovlar'	37	3.4	2	5.4	2	5.4	3	8.1	2	5.4	1	2.7	1	2.7
2 'Gynovlar'	172	15.8	3	1.7	7	4.0	1	0.6	11	6.4	8	4.6	8	4.6
3 'Norlestrin'	4	0.5	—	—	—	—	—	—	—	—	—	—	1	25.0
4 'Volidan'	18	1.6	—	—	1	5.5	1	5.5	1	5.5	4	22.2	2	11.1
5 'Ovran'	10	0.9	—	—	—	—	—	—	—	—	—	—	—	—
6 'Norinyl-1'	67	6.2	—	—	1	1.5	3	4.5	8	11.9	3	4.5	5	7.5
7 'Minilyn'	91	8.4	1	1.1	1	1.1	—	—	7	7.7	—	—	3	3.3
8 'Ovulen-50'	173	15.8	1	0.6	3	1.7	2	1.5	36	20.8	6	3.5	9	5.2
9 'Minovlar'	221	10.3	1	0.5	4	1.8	5	2.3	25	11.3	4	1.8	9	4.1
10 'Demulen-50'	57	5.2	1	1.8	4	7.0	2	3.5	12	21.0	1	1.8	2	3.5
11 'Ortho-Novin 1/50'	17	1.5	—	—	—	—	—	—	1	5.9	1	5.8	2	11.7
12 'Eugynon'	69	6.3	1	1.5	1	1.5	—	—	4	5.8	—	—	3	4.4
13 'Microgynon-30'	81	7.4	—	—	—	—	1	1.2	1	1.2	—	—	—	—
14 'Ovranette'	35	3.2	—	—	—	—	1	2.9	1	2.9	—	—	—	—
15 'Femulen'	38	3.5	—	—	8	21.0	9	23.7	5	13.1	2	5.7	4	10.5
			10	0.9	32	2.9	28	2.6	114	10.5	30	2.8	49	4.5

TABLE 8
OTHER SIDE-EFFECTS

	Patients using		Nausea		Constipation		Aching legs		Leg cramps		Varicose veins worse		Mastitis	
	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent	Number	Per cent
1 'Anovlar'	37	3.4	—	—	1	2.7	3	8.1	—	—	—	—	2	5.4
2 'Gynovlar'	172	15.8	4	2.3	2	1.2	7	4.1	2	1.2	—	—	9	5.2
3 'Norlestrin'	4	0.5	—	—	—	—	—	—	—	—	—	—	—	—
4 'Volidan'	18	1.6	1	5.6	—	—	—	—	1	1.1	—	—	—	—
5 'Ovran'	10	0.9	—	—	—	—	1	10.0	—	—	—	—	—	—
6 'Norinyl-1'	67	6.2	2	3.0	—	—	4	—	—	—	—	—	6	8.9
7 'Mimilyn'	91	8.4	3	3.3	—	—	4	—	1	1.1	—	—	3	3.3
8 'Ovulen-50'	173	15.8	10	5.8	—	—	9	—	—	—	—	—	4	2.3
9 'Minovlar'	221	10.3	14	6.3	—	—	9	—	2	0.9	3	1.4	10	4.5
10 'Demulen-50'	57	5.2	7	12.3	—	—	5	—	—	—	1	1.8	3	5.3
11 'Ortho-Novin 1/50'	17	1.5	1	5.9	—	—	—	—	—	—	1	5.9	—	—
12 'Eugynon-30'	69	6.3	3	4.4	1	1.5	2	—	1	1.5	1	1.5	3	4.4
13 'Microgynon-30'	81	7.4	—	—	—	—	—	—	—	—	—	—	1	1.2
14 'Ovranette'	35	3.2	—	—	—	—	—	—	—	—	—	—	—	—
15 'Femulen'	38	3.5	1	2.6	1	2.6	2	—	—	—	1	2.6	—	—
	46	4.2	46	4.2	5	0.5	46	4.2	7	0.6	8	0.7	41	3.8

Other side-effects

Constipation, aching legs, leg cramps, and exacerbation of varicose veins occurred, in each case in fewer than ten patients. Constipation was cyclical i.e. worse towards the end of the packet and better in the week off (one patient complained of diarrhoea, which always woke her at 0500 hours after taking her Pill at bedtime). Patients with aching legs, cramps, and exacerbation of varicose veins found that their symptoms improved in the week off the Pill. A small number of patients (eight=0.7 per cent) complained that more veins became varicosed and/or caused more symptoms as soon as they started their oral contraceptive. When a patient with varicose veins has been on the Pill for a while, and an exacerbation of symptoms occurs, it is more likely to be due to natural causes and not to the oral contraceptive.

Forty-six patients (4.2 per cent) experienced nausea mainly during the first three months, and severely enough to warrant a change of Pill. Forty-one patients (3.8 per cent) developed mastitis. As a control, mastitis also occurred in eight patients out of 73 (10.9 per cent) with intra-uterine contraceptive devices *in situ*. This supports a clinical impression that this condition is commoner and more severe in patients *not* on oral contraceptives.

Other conditions found included chloasma (four), benign breast cysts (three), superficial phlebitis (three), otosclerosis (two), hepatitis (two), pulmonary embolism (two, site of thrombosis in one patient was legs, and in the other patient unknown), and one each of uterine fibroids, Bell's palsy, erythema nodosum (patient on mestranol-containing oral contraceptive), suicide, cholelithiasis, and hypoglycaemia. Both patients with hepatitis immediately became pregnant on stopping their oral contraceptives, and whilst still clinically ill. There were six positive smears (0.55 per cent). Four patients had cone biopsies, which cleared three, but one needed hysterectomy. Two smears became negative on follow-up. Apart from one patient, all were under 25 years of age.

There were no patients who developed other neoplasia, ovarian cysts, post-Pill amenorrhoea, pregnancy due to contraceptive failure, contact lens problems (out of five patients), or exacerbation of epilepsy (out of two patients), and there were no patients whose epileptic fits were initiated by an oral contraceptive.

Changes of oral contraceptive preparation

The majority of patients were satisfied with the preparation they started (table 9). Over half of the patients (54.6 per cent) took one Pill only, 319 patients (29.3 per cent) required one change and 111 patients (10.2 per cent) required two changes. Twenty patients (1.8 per cent) required more than four changes (table 9).

TABLE 9
NUMBER OF TIMES AN ORAL CONTRACEPTIVE WAS CHANGED

<i>Number of changes</i>	<i>Patients</i>	
	<i>Number</i>	<i>per cent</i>
0	596	54.7
1	319	29.3
2	111	10.2
3	44	4.0
4	15	1.4
5	5	0.5
	1090	100

Discussion

A patient starting on her first oral contraceptive has a 50 per cent chance of a side-effect occurring, which would mean a change of Pill. The main side-effects occurring are well documented, and are mainly headache, depression, and altered menstrual pattern.

Although the incidence of side-effects in this survey is small (ranging from 0·5 per cent for hypertension to 13·4 per cent for headaches) it is a significant amount, and means that to deal properly with oral contraception a general practitioner must be prepared to give time to his patients.

It does not seem to matter which oral contraceptive is chosen. Most Pills are more or less progestogenic and show the whole range of side-effects, although the 30 microgram Pills appear to offer the patient fewer side-effects with the same reliability. However, patients are motivated to take a Pill if it suits them, and will therefore, stay on it longer. It is also important for the doctor to be positively motivated towards the Pill, to ensure that patients will return to complain if they are not happy. The alternative is that the patient just stops taking her Pill, and may appear later with an unplanned pregnancy. It is also important not to advise the patient to give up her Pill lightly for the same reason. The two patients in this series who were advised to stop when they contacted infectious hepatitis both immediately became pregnant while still ill. Would it, therefore, have been more desirable to continue the Pill unless complications of the hepatitis had occurred?

It can be seen from table 9 that just over half the patients were happy with their first Pill. Another quarter were happy after one change. However, a small proportion (5·9 per cent) needed up to six different Pills. This says something for this method if patients are willing to persevere with up to five changes.

Very little serious pathology was encountered in this group of patients. They are basically healthy. Is an annual pelvic examination really necessary in the light of the results obtained? However, the number of positive smears encountered especially in girls *under* the age of 25 years is disturbing, and shows how important it is to do them in this age group.

Oral contraceptive side-effects may not in themselves be serious, but the patient does need advice about them, and therefore consulting time is taken. Often the patient may be reassured by reading the booklet accompanying her Pill, but sometimes she may be made even more worried by reading it and need reassurance. This practice has found it most helpful to have one partner who has taken a particular interest in contraception, and any problems which arise may be referred within the practice.

The outside of patients notes are tagged with various coloured pieces of paper denoting for example hypersensitivity to drugs, hypertension, or diabetes, and I have found it helpful to have a separate contraceptive card inside the notes. As they are red and white they stand out easily, and any patient on an oral contraceptive can be identified at once. In this practice the antenatal cards are filed separately, so it is often helpful to find this information on the front of the contraceptive card. It also helps to ensure that a full contraceptive history is taken and this means that the most satisfactory method for the patient can be discussed and agreed.

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REFERENCES

- Bye, P. G. T. & Elstein, M. (1973). *British Medical Journal*, **2**, 389-392.
Doll, R. & Vessey, M. P. (1970). *British Medical Bulletin*, **26**, 23-38.
F.P.A. Medical Newsletters, Nos. 49, 51.
MIMS (1975). London: Haymarket Publishing Ltd.
Royal College of General Practitioners (1974). *Oral Contraceptives and Health*. London: Pitman.
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