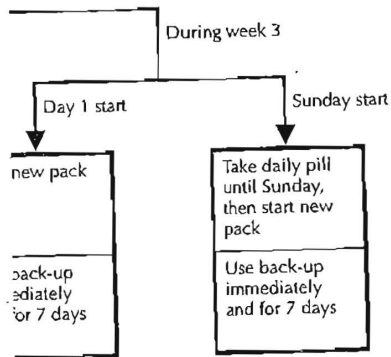
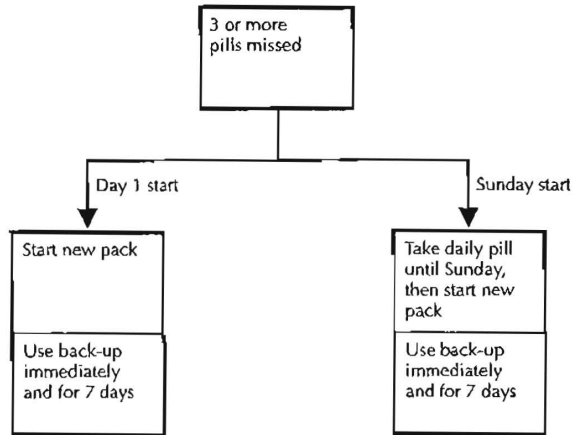


Studies have questioned whether... One study demonstrated varying times in the cycle did not women deliberately lengthened the to show signs of ovulation.^{303,344} So lower doses has had an impact on follicular activity with the lowest-d effectively prevented.³⁴⁵ The stud women and given the large individu women might be at risk with a s However, the progestational effects serve to ensure good contraceptive current recommendations are too c of getting pregnant with missing, conservative advice is the safest me

The most prevalent problems that c ent oral contraceptive failures are v have been missed, patients should b at least 7 days after an episode of, tated vaginal for oral administrati



Studies have questioned whether missing pills has an impact on contraception. One study demonstrated that skipping 4 consecutive pills at varying times in the cycle did not result in ovulation.³⁴¹ Studies in which women deliberately lengthened their pill-free interval up to 11 days failed to show signs of ovulation.^{343,344} So far there is no evidence that moving to lower doses has had an impact on the margin of error. Despite greater follicular activity with the lowest-dose oral contraceptives, ovulation is still effectively prevented.³⁴⁵ The studies have involved small numbers of women and given the large individual variation, it still is possible that some women might be at risk with a small increase in the pill-free interval. However, the progestational effects on endometrium and cervical mucus serve to ensure good contraceptive efficacy.¹⁸ We may well prove that current recommendations are too conservative, and that a woman's chance of getting pregnant with missing pills is nearly zero. Nevertheless, this conservative advice is the safest message to convey.

The most prevalent problems that can be identified associated with apparent oral contraceptive failures are vomiting and diarrhea.^{19,20} *Even if no pills have been missed, patients should be instructed to use a backup method for at least 7 days after an episode of gastroenteritis, unless they have substituted vaginal for oral administration without missing a day.*

Clinical Problems

Breakthrough Bleeding

A major continuation problem is breakthrough bleeding. Breakthrough bleeding gives rise to fears and concerns; it is aggravating, and even embarrassing. Therefore, on starting oral contraception, patients need to be fully informed about breakthrough bleeding.

There are two characteristic breakthrough bleeding problems: irregular bleeding in the first few months after starting oral contraception, and unexpected bleeding after many months of use. Effort should be made to manage the bleeding problem in a way that allows the patient to remain on low-dose oral contraception. *There is no evidence that the onset of bleeding is associated with decreased efficacy, no matter what oral contraceptive formulation is used, even the lowest dose products.* Indeed, in a careful study, breakthrough bleeding did not correlate with changes in the blood levels of the contraceptive steroids.³⁴⁶

The most frequently encountered breakthrough bleeding occurs in the first few months of use. The incidence is greatest in the first 3 months, ranging from 10–30% in the first month to less than 10% in the third. Breakthrough bleeding rates are higher with the lowest dose oral contraceptives, but not dramatically.³⁴⁷ Breakthrough bleeding is further increased in women who smoke and in smokers who use formulations with 20 µg ethinyl estradiol.³⁴⁸ However, the differences among the various formulations currently available are of minimal clinical significance. The basic pattern is the same, highest in the first month and a greater prevalence in smokers, especially in later cycles.

Early breakthrough bleeding is best managed by encouragement and reassurance. This bleeding usually disappears by the third cycle in the majority of women. If necessary, even this early pattern of breakthrough bleeding can be treated as outlined below. It is helpful to explain to the patient that this bleeding represents tissue breakdown as the endometrium adjusts from its usual thick state to the relatively thin state allowed by the hormones in oral contraceptives.

Breakthrough bleeding that occurs after many months of oral contraceptive use is a consequence of the progestin-induced decidualization. This endometrium and blood vessels within the endometrium tend to be fragile and prone to breakdown and asynchronous bleeding.

There are two recognized factors (both preventable) that are associated with a greater incidence of breakthrough bleeding. Consistency of use and smoking increase spotting and bleeding, but inconsistency of pill taking is

more important and has a greater effect. Consistent pill taking can help. Infection can be another cause of breakthrough bleeding. Cervical chlamydial infections in women who report breakthrough bleeding

If bleeding occurs just before the start of the next pill, it can be managed by having the patient stop the pill for a few days. If breakthrough bleeding is prolonged, it can be managed regardless of the point in the cycle. If breakthrough bleeding is achieved with a short course of 1.25 mg, or estradiol, 2 mg, if breakthrough bleeding is present, no matter how long the patient continues to adhere to the course of estrogen solves the problem. If breakthrough bleeding is unusual (but if it does recur, an

Investigation of irregular bleeding is not effective. The progestin component of the pill, hence, doubling the number of pills, has little impact and its decidualizing, a destabilizing effect on endometrial growth, while keeping the progestin component of the pill. This allows the patient to continue with its advantage of greater safety. There is no sufficient reason to expose patients to higher dose oral contraceptives if irregular bleeding in the first few months of use requires investigation if

There is no evidence that any oral contraceptive is approximately equivalent in effectiveness to another. It is different in the rates of breakthrough bleeding. It is more responsible factor, and bleeding is more frequent and regardless of product.

Amenorrhea

With low-dose pills, the estrogen component of the pill to stimulate endometrial growth to such a degree that a shallow endometrium is sufficient tissue to yield withdrawal bleeding. Permanent atrophy of the endometrium

is breakthrough bleeding. Breakthrough concerns; it is aggravating, and even embarrassing. For oral contraception, patients need to be fully informed.

Breakthrough bleeding problems: irregular bleeding within the first 3 months after starting oral contraception, and within 6 months of use. Effort should be made to find a way that allows the patient to remain on the pill. *There is no evidence that the onset of breakthrough bleeding is related to the efficacy, no matter what oral contraceptive lowest dose products.* Indeed, in a careful study, breakthrough bleeding did not correlate with changes in the blood levels of estradiol.³⁴⁶

Breakthrough bleeding occurs in the first 3 months of use. The incidence is greatest in the first 3 months, ranging from 10% in the first month to less than 10% in the third month. The incidence is higher with the lowest dose oral contraceptives.³⁴⁷ Breakthrough bleeding is further increased in smokers who use formulations with low-dose estrogen. However, the differences among the various formulations are of minimal clinical significance. The incidence is highest in the first month and a greater prevalence in later cycles.

Breakthrough bleeding is best managed by encouragement and reassurance. It disappears by the third cycle in the majority of patients. This early pattern of breakthrough bleeding is due to the breakdown of the endometrium as it adjusts from a thick state to the thin state allowed by the hormones in the pill.

Breakthrough bleeding occurs after many months of oral contraception. This is due to the progestin-induced decidualization. This is due to the endometrium tend to be fragile and asynchronous bleeding.

Factors (both preventable) that are associated with breakthrough bleeding. Consistency of use and correct pill taking is important.

more important and has a greater effect in later cycles, whereas smoking exerts a general effect from beginning to later cycles.³⁴⁹ Reinforcement of consistent pill taking can help minimize breakthrough bleeding. Cervical infection can be another cause of breakthrough bleeding; the prevalence of cervical chlamydial infections is higher among oral contraceptive users who report breakthrough bleeding.³⁵⁰

If bleeding occurs just before the end of the pill cycle, it can be managed by having the patient stop the pills, wait 7 days and start a new cycle. If breakthrough bleeding is prolonged or if it is aggravating for the patient, regardless of the point in the pill cycle, control of the bleeding can be achieved with a short course of exogenous estrogen. Conjugated estrogen, 1.25 mg, or estradiol, 2 mg, is administered daily for 7 days when the bleeding is present, no matter where the patient is in her pill cycle. The patient continues to adhere to the schedule of pill taking. Usually, one course of estrogen solves the problem, and recurrence of bleeding is unusual (but if it does recur, another 7-day course of estrogen is effective).

Responding to irregular bleeding by having the patient take 2 or 3 pills is not effective. The progestin component of the pill will always dominate; hence, doubling the number of pills will also double the progestational impact and its decidualizing, atrophic effect on the endometrium and its destabilizing effect on endometrial blood vessels. The addition of extra estrogen while keeping the progestin dose unchanged is logical and effective. This allows the patient to remain on the low-dose formulation with its advantage of greater safety. Breakthrough bleeding, in our view, is not sufficient reason to expose patients to the increased risks associated with higher dose oral contraceptives. Any bleeding that is not handled by this routine requires investigation for the presence of pathology.

There is no evidence that any oral contraceptive formulations that are approximately equivalent in estrogen and progestin dosage are significantly different in the rates of breakthrough bleeding. Clinicians often become impressed that switching to another product effectively stops the breakthrough bleeding. It is more likely that the passage of time is the responsible factor, and bleeding would have stopped regardless of switching and regardless of product.

Amenorrhea

With low-dose pills, the estrogen content is not sufficient in some women to stimulate endometrial growth. The progestational effect dominates to such a degree that a shallow atrophic endometrium is produced, lacking sufficient tissue to yield withdrawal bleeding. It should be emphasized that permanent atrophy of the endometrium does not occur, and resumption

of normal ovarian function will restore endometrial growth and development. Indeed, there is no harmful, permanent consequence of amenorrhea while on oral contraception.

The major problem with amenorrhea while on oral contraception is the anxiety produced in both patient and clinician because the lack of bleeding may be a sign of pregnancy. The patient is anxious because of the uncertainty regarding pregnancy, and the clinician is anxious because of the medicolegal concerns stemming from the old studies which indicated an increased risk of congenital abnormalities among the offspring of women who inadvertently used oral contraception in early pregnancy. We reviewed this problem earlier, and emphatically stated that there is no association between oral contraception and an increased risk of congenital malformation, and there is no increased risk of having abnormal children.

The incidence of amenorrhea in the first year of use with low-dose oral contraception is less than 2%. This incidence increases with duration, reaching perhaps 5% after several years of use. It is important to alert patients upon starting oral contraception that diminished bleeding and possibly no bleeding may ensue.

Amenorrhea is a difficult management problem. A pregnancy test will allow reliable assessment for the presence of pregnancy even at this early stage. However, routine, repeated use of such testing is expensive and annoying, and may lead to discontinuation of oral contraception. *A simple test for pregnancy is to assess the basal body temperature during the END of the pill-free week; a basal body temperature less than 98 degrees (36.6°C) is not consistent with pregnancy, and oral contraception can be continued.*

Many women are reassured with an understanding of why there is no bleeding and are able to continue on the pill despite the amenorrhea. Some women cannot reconcile themselves to a lack of bleeding, and this is an indication for trying other formulations (a practice unsupported by any clinical trials, and, therefore, the expectations are uncertain). But again, this problem does not warrant exposing patients to the greater risks of major side effects associated with higher dose products.

Some clinicians have observed that the addition of extra estrogen for 1 month (1.25 mg conjugated estrogens or 2 mg estradiol daily throughout the 21 days while taking the oral contraceptive) will rejuvenate the endometrium, and withdrawal bleeding will resume, persisting for many months.

Weight Gain

The complaint of weight gain is frequent, but often due to poor compliance. Yet, studies of the low-dose oral contraceptives show no significant weight gain with oral contraception among the various products.¹⁶⁶⁻¹⁷⁰ In fact, a conclusion supported by a study comparing low-dose oral contraceptives and placebo, weight gain and headaches was identical in both groups.¹⁷¹ The clinician has to caution patients between low-dose oral contraceptives and moderate amount of weight as the diet or not.

Acne

Low-dose oral contraceptives (progestin only and combined) currently used are insufficient to suppress acne.

Ovarian Cysts

Anecdotal reports suggested that oral contraceptives suppress acne more frequently and suppress lesions. This observation failed to withstand scrutiny; cysts occurred less frequently in patients on oral contraceptives.³⁵⁷ This protection is reduced at the point where little effect can be seen; cysts is not eliminated; and, there are reports of cysts in patients taking any of the oral contraceptives.

Drugs That Affect Efficacy

There are many anecdotal reports of decreased contraceptive efficacy while taking antibiotics such as ampicillin, tetracycline, which reduce the bacterial flora, and, therefore, the excretion of contraceptive steroid. There is no evidence of ovulation in patients derived from dermatology who were on oral contraceptives and antibiotics (tetracyclines, penicillins).

There is reason to believe that drug interactions, can affect oral contraceptive efficacy. A large database failed to disc-

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Weight Gain

The complaint of weight gain is frequently cited as a major problem with compliance. Yet, studies of the low-dose preparations fail to demonstrate a significant weight gain with oral contraception, with no major differences among the various products.¹⁶⁶⁻¹⁷⁰ This is obviously a problem of perception, a conclusion supported by a placebo-controlled randomized trial of low-dose oral contraceptives and acne, in which the incidence of weight gain and headaches was identical in both the treated and the placebo groups.¹⁷¹ The clinician has to carefully reinforce the lack of association between low-dose oral contraceptives and weight gain and focus the patient on the real culprit: diet and level of exercise. Most women gain a moderate amount of weight as they age, whether they take oral contraceptives or not.

Acne

Low-dose oral contraceptives improve acne regardless of which product is used.^{146,351-355} The low progestin doses (including levonorgestrel formulations) currently used are insufficient to stimulate an androgenic response.

Ovarian Cysts

Anecdotal reports suggested that functional ovarian cysts are encountered more frequently and suppress less easily with multiphasic formulations. This observation failed to withstand careful scrutiny.³⁵⁶ Functional ovarian cysts occurred less frequently in women on higher dose oral contraception.³⁵⁷ This protection is reduced with the current lower dose products to the point where little effect can be measured.³⁵⁸⁻³⁶¹ Thus, the risk of such cysts is not eliminated; and, therefore, clinicians can encounter such cysts in patients taking any of the oral contraceptive formulations.

Drugs That Affect Efficacy

There are many anecdotal reports of patients who conceived on oral contraceptives while taking antibiotics. There is little evidence, however, that antibiotics such as ampicillin, metronidazole, quinolone, and tetracycline, which reduce the bacterial flora of the gastrointestinal tract, affect oral contraceptive efficacy. Studies indicate that while antibiotics can alter the excretion of contraceptive steroids, plasma levels are unchanged, and there is no evidence of ovulation.³⁶²⁻³⁶⁵ A review of a large number of patients derived from dermatology practices failed to find an increased rate of pregnancy in women on oral contraceptives and being treated with antibiotics (tetracyclines; penicillins; cephalosporins).³⁶⁶

There is reason to believe that drugs, which stimulate the liver's metabolic capacity, can affect oral contraceptive efficacy. On the other hand, a search of a large database failed to discover any evidence that lower dose oral

contraceptives are more likely to fail or to have more drug interaction problems when other drugs are used.³⁶⁷ Indeed, a careful pharmacokinetic study in 12 women indicated that rifampin and rifabutin increased oral contraceptive estrogen and progestin clearance, but ovulation was not detected.³⁶⁸ Troglitazone decreases the circulating levels of ethinyl estradiol and norethindrone by approximately 30%.³⁶⁹ This drug effect may not be sufficient to allow escape ovulations. Because studies have been limited by relatively small numbers and only a small number of women might be susceptible to escape ovulation, it is better to be cautious; patients on medications that affect liver metabolism should choose an alternative contraceptive. These drugs are as follows:

Carbamazepine (Tegretol)
 Felbamate
 Oxcarbazepine
 Phenobarbital
 Phenytoin (Dilantin)
 Primidone (Mysoline)
 Rifabutin,
 Rifampicin (Rifampin)
 Topiramate
 Vigabatrin
Possibly ethosuximide, griseofulvin, and troglitazone.

Other Drug Interactions

Although not extensively documented, there is reason to believe that oral contraceptives potentiate the action of diazepam (Valium), chlorthalidopexide (Librium), tricyclic antidepressants, and theophylline.³⁷⁰ Thus, lower doses of these agents may be effective in oral contraceptive users. Because of an influence on clearance rates, oral contraceptive users may require larger doses of acetaminophen and aspirin.³⁷¹

Migraine Headaches

True migraine headaches are more common in women, while tension headaches occur equally in men and women. There have been no well done studies to determine the impact of oral contraception on migraine headaches. Patients may report that their headaches are worse or better.

Studies with high-dose pills indicated that migraine headaches were linked to a risk of stroke. More recent studies reflecting the use of low-dose formulations yield mixed results. One failed to find a further increase in stroke in patients with migraine who use oral contraception, another concluded that the use of oral contraception by migraineurs was associated with a 4-fold increase of the already increased risk of ischemic stroke.^{372,373}

A third case-control study concluded increased the risk of ischemic stroke with migraine headaches, and an ischemic and hemorrhagic stroke history of migraine headaches.^{110,374} If a woman with a history of migraine headaches, one would expect recent studies of thrombosis to be limited to migraineurs. An adverse effect of oral risk in migraineurs should have an increased risk of stroke in these

Because of the seriousness of this visual symptoms or severe headache at a higher dose, a move to a low-dose headache. Switching to a different placebo response. Oral contraceptives have migraine with aura, or if add age, smoking, hypertension).³³²

Clues To Severe Vascular Headache

- Headaches that last a long time
- Dizziness, nausea, or vomiting
- Scotomata or blurred vision
- Episodes of blindness.
- Unilateral, unremitting headache
- Headaches that continue during

In some women, a relationship exists between headache levels during a menstrual cycle and headache characteristically coinciding with the menstrual cycle. Success (anecdotal to be sure) all menstrual cycle, either with the use of administration of a progestational hormone (terone acetate) or the use of depot women with migraine headaches. Women who experience an exact relationship to oral contraception should consider one

Summary: Oral Contraceptive Use

Gestational Diabetes. There is no contraindication to oral contraceptive use following gestational diabetes with breastfeeding women using oral (Chapter 3).

to fail or to have more drug interaction used.³⁶⁷ Indeed, a careful pharmacokinetic that rifampin and rifabutin increased oral gestin clearance, but ovulation was not as the circulating levels of ethinyl estradiol rarely 30%.³⁶⁹ This drug effect may not be ions. Because studies have been limited by only a small number of women might be, it is better to be cautious; patients on metabolism should choose an alternative as follows:

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A third case-control study concluded that the use of oral contraceptives increased the risk of ischemic stroke but not hemorrhagic stroke in women with migraine headaches, and another indicated that the risk for both ischemic and hemorrhagic strokes is increased among women with a history of migraine headaches.^{110,374} Because 20–30% of women experience migraine headaches, one would expect the study populations in the most recent studies of thrombosis to have included substantial numbers of migraineurs. An adverse effect of low-dose oral contraceptives on stroke risk in migraineurs should have manifested itself in the data. The lack of an increased risk of stroke in these studies is reassuring.

Because of the seriousness of this potential complication, the onset of visual symptoms or severe headaches requires a response. If the patient is at a higher dose, a move to a low-dose formulation may relieve the headaches. Switching to a different brand is worthwhile, if only to evoke a placebo response. Oral contraceptives should be avoided in women who have migraine with aura, or if additional stroke factors are present (older age, smoking, hypertension).³⁵²

Clues To Severe Vascular Headaches:

- Headaches that last a long time.
- Dizziness, nausea, or vomiting with headaches.
- Scotomata or blurred vision.
- Episodes of blindness.
- Unilateral, unremitting headaches.
- Headaches that continue despite medication.

In some women, a relationship exists between their fluctuating hormone levels during a menstrual cycle and migraine headaches, with the onset of headaches characteristically coinciding with menses. We have had personal success (anecdotal to be sure) alleviating headaches by eliminating the menstrual cycle, either with the use of *daily* oral contraceptives or the daily administration of a progestational agent (such as 10 mg medroxyprogesterone acetate) or the use of depot-medroxyprogesterone acetate. Some women with migraine headaches have extremely gratifying responses. Women who experience an exacerbation of their headaches with oral contraception should consider one of the progestin-only methods.

Summary: Oral Contraceptive Use and Medical Problems

Gestational Diabetes. There is no contraindication to combined oral contraceptive use following gestational diabetes.^{153,154} There is a concern with breastfeeding women using the progestin-only minipill (discussed in Chapter 3).

Diabetes Mellitus. Oral contraception can be used by diabetic women less than 35 years old who do not smoke and are otherwise healthy (especially an absence of diabetic vascular complications). A case-control study could find no evidence that oral contraceptive use by young women with insulin-dependent diabetes mellitus increased the development of retinopathy or nephropathy.¹⁵⁶ In a one-year study of women with insulin-dependent diabetes mellitus who were using a low-dose oral contraceptive, no deterioration could be documented in lipoprotein or hemostatic biochemical markers for cardiovascular risk.¹⁵⁷ And finally, no effect of oral contraceptives on cardiovascular mortality could be detected in a group of women with diabetes mellitus.¹⁵⁸

Hypertension. Low-dose oral contraception can be used in women less than age 35 years old with hypertension well controlled by medication, and who are otherwise healthy and do not smoke. We recommend the lowest estrogen dose formulations.

Pregnancy-Induced Hypertension. Women with pregnancy-induced hypertension can use oral contraception as soon as the blood pressure is normal in the postpartum period.

Hemorrhagic Disorders. Women with hemorrhagic disorders and women taking anticoagulants can use oral contraception. Inhibition of ovulation can avoid the real problem of a hemorrhagic corpus luteum in these patients. A reduction in menstrual blood loss is another benefit of importance.

Gallbladder Disease. Oral contraception use may precipitate a symptomatic attack in women known to have stones or a positive history for gallbladder disease and, therefore, should either be used very cautiously or not at all.

Obesity. An obese woman who is otherwise healthy can use low-dose oral contraception.

Hepatic Disease. Oral contraception can be utilized when liver function tests return to normal. Follow-up liver function tests should be obtained after 2-3 months of use.

Seizure Disorders. There is no impact of oral contraceptives on pattern or frequency of seizures. The concern is that anticonvulsant-induced hepatic enzyme activity can increase the risk of contraceptive failure. Some clinicians advocate the use of higher dose (50 µg estrogen) products; however, no studies have been performed to demonstrate that this higher dose is necessary.

Mitral Valve Prolapse. Oral contraception can be used in asymptomatic patients who are asymptomatic (I). There is a small subset of patients with increased risk of thromboembolism, migraine headaches, or clotting on progestin-only methods or the IUD insertion if mitral regurgitation is present.

Systemic Lupus Erythematosus. Systemic lupus erythematosus, an autoimmune disease, when present, represents a contraindication to oral contraceptives.³⁷⁵ The progestin component of oral contraceptives. However, in patients with stable disease and high antiphospholipid antibodies, oral contraception can be considered.³⁷⁷ SELENA (Safety and National Assessment) is an on-going study of oral contraceptive therapy in patients with systemic lupus erythematosus (as well as patients with other autoimmune diseases).

Migraine Headaches. Low-dose oral contraception (low-dose formulation) can be tried in women with common migraine headaches. Daily use of oral contraceptives for migraine headaches. Oral contraceptives for classic migraine headaches associated with hypertension. Factors that increase the risk of hypertension).

Sickle Cell Disease. Patients with sickle cell disease. The risk of thrombosis in sickle cell disease is theoretical (and medication is not recommended against pregnancy in these patients). Oral contraception. In the only long-term study with sickle cell disease and using oral contraceptives, effects were observed (at a time when the study was in progress).³⁷⁸ A study of erythrocyte sedimentation rate and anemia could detect no adverse effects. Keep in mind that depot-medroxyprogesterone acetate is associated with inhibition of sickle cell disease.³⁸⁰

Benign Breast Disease. Benign breast disease is not a contraindication for oral contraception; with 2 years of use, the risk of breast cancer is increased.

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Mitral Valve Prolapse. Oral contraception use is limited to nonsmoking patients who are asymptomatic (no clinical evidence of regurgitation). There is a small subset of patients with mitral valve prolapse who are at increased risk of thromboembolism. Patients with atrial fibrillation, migraine headaches, or clotting factor abnormalities should consider progestin-only methods or the IUD (prophylactic antibiotics should cover IUD insertion if mitral regurgitation is present).

Systemic Lupus Erythematosus. Oral contraceptive use can exacerbate systemic lupus erythematosus, and the vascular disease associated with lupus, when present, represents a contraindication to estrogen-containing oral contraceptives.³⁷⁵ The progestin-only methods are a good choice.³⁷⁶ However, in patients with stable or inactive disease, without renal involvement and high antiphospholipid antibodies, low-dose oral contraception can be considered.³⁷⁷ SELENA (Safety of Estrogen in Lupus Erythematosus National Assessment) is an on-going randomized, controlled clinical trial of oral contraceptive therapy in premenopausal women with systemic lupus erythematosus (as well as postmenopausal hormone therapy).

Migraine Headaches. Low-dose oral contraception (the lowest estrogen dose formulation) can be tried with careful surveillance in women with common migraine headaches. Daily administration can prevent menstrual migraine headaches. Oral contraception is best avoided in women with classic migraine headaches associated with neurologic symptoms, or if factors that increase the risk of stroke are present (older age, smoking, hypertension).

Sickle Cell Disease. Patients with sickle cell trait can use oral contraception. The risk of thrombosis in women with sickle cell disease or sickle C diseases is theoretical (and medicolegal). We believe effective protection against pregnancy in these patients warrants the use of low-dose oral contraception. In the only long-term (10 years) follow-up report of women with sickle cell disease and using oral contraceptives, no apparent adverse effects were observed (at a time when higher dose products were prevalent).³⁷⁸ A study of erythrocyte deformability in women with sickle cell anemia could detect no adverse effects of contraceptive steroids.³⁷⁹ Keep in mind that depot-medroxyprogesterone acetate used for contraception is associated with inhibition of sickling and improvement in anemia in patients with sickle cell disease.³⁸⁰

Benign Breast Disease. Benign breast disease is not a contraindication for oral contraception; with 2 years of use, the condition may improve.

Congenital Heart Disease or Valvular Heart Disease. Oral contraception is contraindicated only if there is marginal cardiac reserve or a condition that predisposes to thrombosis.

Hyperlipidemia. Because low-dose oral contraceptives have negligible impact on the lipoprotein profile, hyperlipidemia is not an absolute contraindication, with the exception of very high levels of triglycerides (which can be made worse by estrogen). In women with triglyceride levels greater than 250 mg/dL, estrogen should be provided with great caution. If vascular disease is already present, oral contraception should be avoided. If other risk factors are present, especially smoking, oral contraception is not recommended. Dyslipidemic patients who begin oral contraception should have their lipoprotein profiles monitored monthly for a few visits to ensure no adverse impact. If the lipid abnormality cannot be held in control, an alternative method of contraception should be used.³⁴¹ Oral contraceptives containing desogestrel, noregestimate, or gestodene can increase HDL levels, but it is not known if this change is clinically significant. If hypertriglyceridemia is the only concern, keep in mind that the triglyceride response to estrogen is rapid. A repeat level should be obtained in 2–4 weeks. A level greater than 750 mg/dL represents an absolute contraindication to estrogen treatment because of the risk of pancreatitis.

Depression. Low-dose oral contraceptives have minimal, if any, impact on mood.

Smoking. Oral contraception is absolutely contraindicated in smokers (any amount) over the age of 35. In patients 35 years old and younger, heavy smoking (15 or more cigarettes per day) is a relative contraindication. The relative risk of cardiovascular events is increased for women of all ages who smoke and use oral contraceptives; however, because the actual incidence of cardiovascular events is so low at a young age, the real risk is very low for young women, although it increases with age. An ex-smoker (for at least one year) should be regarded as a nonsmoker. Risk is only linked to active smoking. Is there room for judgment? Given the right circumstances, low-dose oral contraceptives might be appropriate for a light smoker or the user of a nicotine patch. A 20 µg estrogen formulation may be a better choice for smoking women, regardless of age (because this dose of estrogen has no impact on clotting factors and platelet activation).^{40,41}

Polycystic Ovaries and Insulin Resistance. Because older, high-dose oral contraceptives increased insulin resistance, it has been suggested that this treatment should be avoided in anovulatory, overweight women. However, low-dose oral contraceptives have minimal effects on carbohydrate metabolism, and the majority of hyperinsulinemic, hyperandrogenic

women can be expected to respond to low-dose oral contraceptives.³⁴² Insulin and glucose (200 µg ethinyl estradiol) oral contraceptives are believed that they are of no clinical significance. Large clinical studies have failed to detect any increase in insulin resistance or impaired glucose tolerance (high-dose pills).^{149,151} Furthermore, the increased risk of cardiovascular disease among women with recent gestational diabetes with insulin-dependent diabetes has not produced deterioration of cardiovascular disease or increased nephropathy.^{155,156,157} The administration of oral contraceptives to women with extreme obesity and insulin resistance results in only a mild deterioration of glucose tolerance in a follow-up study (about 10 years) of women with hyperinsulinism, comparing oral contraceptives to metabolic parameters not only did not worsen, but actually improved, including body weight, insulin resistance, HDL-cholesterol levels, which was worsened or not observed in the non-users of oral contraceptive treatment for hyperinsulinemic women.

Eating Disorders. In patients with eating disorders, oral contraceptives may be used as long as an abnormal weight is not maintained. Estrogen treatment with an increased risk of adverse bone effects of the hyperandrogenism. Furthermore, because the risk is significant, individuals who fail to continue to have a deficit in bone density. Reduced menstrual function (for adolescents) may leave a residual deficit in bone density, which is not totally retrieved with resumption of menses.^{346,347}

Pituitary Prolactin-Secreting Adenoma. Oral contraceptives can be used in the presence of microadenomas.

Infectious Mononucleosis. Oral contraceptives can be used if liver function tests are normal.

or Valvular Heart Disease. Oral contraception is contraindicated if there is marginal cardiac reserve or a thrombosis.

Low-dose oral contraceptives have negligible effect on lipid profile, hyperlipidemia is not an absolute contraindication (even with high levels of triglycerides and estrogen). In women with triglyceride levels above 300 mg/dL, oral contraception should be avoided. In women with hypertension, especially smoking, oral contraception is contraindicated. In diabetic patients who begin oral contraception, lipid profiles should be monitored monthly for a few visits. If the lipid abnormality cannot be held in check with diet and exercise, oral contraception should be used.³⁶¹ Oral contraceptives containing norgestrel, noregestimate, or gestodene can cause a decrease in HDL cholesterol. It is not known if this change is clinically significant. If it is the only concern, keep in mind that the change is rapid. A repeat level should be obtained in 2-3 months. A level less than 750 mg/dL represents an absolute contraindication because of the risk of pancreatitis.

Oral contraceptives have minimal, if any, impact on bone density.

Oral contraception is absolutely contraindicated in smokers 35 years of age and older. In patients 35 years old and younger, smoking (10 cigarettes per day) is a relative contraindication. The risk of cardiovascular events is increased for women of all ages using oral contraceptives; however, because the actual risk is so low at a young age, the real risk is not clear. An ex-smoker should be regarded as a nonsmoker. Risk is only increased in older women. Is there room for judgment? Given the right circumstances, oral contraceptives might be appropriate for a young woman using a nicotine patch. A 20 µg estrogen formulation is appropriate for young women, regardless of age (because this is not a concern on clotting factors and platelet activation).

Insulin Resistance. Because older, high-dose oral contraceptives increase insulin resistance, it has been suggested that they should be avoided in anovulatory, overweight women. Low-dose oral contraceptives have minimal effects on carbohydrate metabolism. In hyperinsulinemic, hyperandrogenic women, oral contraceptives can be used as long as liver function tests are normal.

women can be expected to respond favorably to treatment with oral contraceptives.³⁶² Insulin and glucose changes with low-dose (less than 50 µg ethinyl estradiol) oral contraceptives are so minimal, that it is now believed that they are of no clinical significance.¹⁴⁸ Long-term follow-up studies have failed to detect any increase in the incidence of diabetes mellitus or impaired glucose tolerance (even in past and current users of high-dose pills).^{149,151} Furthermore, there is no evidence of an increase in risk of cardiovascular disease among past users of oral contraceptives.^{65,66} In addition, low-dose oral contraceptives have been administered to women with recent gestational diabetes without an adverse impact, and in women with insulin-dependent diabetes mellitus, low-dose oral contraceptives have not produced deterioration of lipid and biochemical markers for cardiovascular disease or increased the development of retinopathy or nephropathy.^{153,154,156,157} The administration of a low-dose oral contraceptive to women with extreme obesity and very severe insulin resistance resulted in only a mild deterioration of glucose tolerance.³⁶³ Impressively, in a follow-up study (about 10 years) of women with polycystic ovaries and hyperinsulinism, comparing oral contraceptive users with non-users, the metabolic parameters not only did not worsen in the users, but they actually improved, including body weight, glucose tolerance, insulin levels, and HDL-cholesterol levels, which was in striking contrast to the metabolic worsening observed in the non-users.³⁶⁴ This experience supports the safety of oral contraceptive treatment for anovulatory, hyperandrogenic, hyperinsulinemic women.

Eating Disorders. In patients with eating disorders, bone density correlates with body weight. The response to hormone therapy will be impaired as long as an abnormal weight is maintained.³⁶⁵ The failure to respond to estrogen treatment with an increase in bone density may be due to the adverse bone effects of the hypercortisolism associated with stress disorders. Furthermore, because the pubertal gain in bone density is so significant, individuals who fail to experience this adolescent increase may continue to have a deficit in bone mass despite hormone treatment. Reduced menstrual function for any reason early in life (even beyond adolescence) may leave a residual deficit in bone density that cannot be totally retrieved with resumption of menses or with hormone treatment.^{366,367}

Pituitary Prolactin-Secreting Adenomas. Low-dose oral contraception can be used in the presence of microadenomas.

Infectious Mononucleosis. Oral contraception can be used as long as liver function tests are normal.

Ulcerative Colitis. There is no association between oral contraception and ulcerative colitis. Women with this problem can use oral contraceptives.¹⁷³ Oral contraceptives are absorbed mainly in the small bowel.

Regional Enteritis (Crohn's Disease). In a prospective cohort of women with Crohn's disease, no adverse impact of oral contraceptives could be detected on the clinical course, specifically on flare-ups.³⁸⁸

An Alternative Route of Administration

Occasionally, a situation may be encountered when an alternative to oral administration of contraceptive pills is required. For example, patients receiving chemotherapy can either have significant nausea and vomiting, or mucositis, both of which would prevent oral drug administration. The low-dose oral contraceptives can be administered vaginally. Initially, it was claimed that two pills must be placed high in the vagina daily in order to produce contraceptive steroid blood levels comparable with the oral administration of one pill.³⁸⁹ However, a large clinical trial has demonstrated typical contraceptive efficacy with one pill administered vaginally per day.³⁹⁰

Athletes and Oral Contraception

Because athletes are often amenorrheic and hypoestrogenic, oral contraceptives provide not only confidence against the risk of an unwanted pregnancy, but also estrogen support against bone loss. This is a situation where bone density measurements are worthwhile. A low bone density can help motivate an athlete to take hormone therapy, and a subsequent bone density measurement that reveals a failure of response to estrogen can indicate the presence of a hidden eating disorder.

Competing athletes are often concerned that oral contraceptives could reduce exercise performance. A rationale for the concern can be traced to the physiologic increase in ventilation during pregnancy, mediated by progesterone. Thus, progestin enhancement of ventilatory response could consume energy otherwise available for athletic performance. Indeed, reports have generated conflicting data as measured by laboratory testing. However, experimental studies that simulate athletic events can find no adverse effects on oxygen uptake or respiratory rate.^{391,392} One study documented decreased soreness, both perceived and with palpation, after exercise in women using oral contraceptives.³⁹³ Oral contraceptive use has no effect on prevalence or severity of low back pain, a common problem among female athletes.³⁹⁴

Oral contraceptives have a lot to offer athletes. In athletes who wish to avoid pregnancy, oral contraceptives can be administered on a cyclic basis to avoid withdrawal bleeding.

The Noncontraceptive Benefits of Oral Contraception

The noncontraceptive benefits of oral contraception are grouped into two main categories: the contraceptive benefits that result from the use of oral contraception and the noncontraceptive benefits that result from the use of oral contraception and disorders.

Noncontraceptive Incidental Benefits

- Effective Contraception.
 - less need for induced abortion
 - less need for surgical abortion
- Less Endometrial Cancer.
- Less Ovarian Cancer.
- Fewer Ectopic Pregnancies.
- More Regular Menses.
 - less flow.
 - less dysmenorrhea.
 - less anemia.
- Less Salpingitis.
- Increased Bone Density.
- Probably Less Endometriosis.
- Possibly Less Benign Breast Disease.
- Possibly Less Rheumatoid Arthritis.
- Possibly Protection against Osteoporosis.
- Possibly Fewer Fibroids.
- Possibly Fewer Ovarian Cysts.

Many of these benefits have been documented. Pelvic inflammatory disease is a major cause of infertility. Oral contraception has been shown to contribute to not only preservation of fertility but also to the prevention of pelvic inflammatory disease. Also important is the prevention of osteoporosis, which has increased in incidence in women. Oral contraceptives represent a major cost for our society for individual patients.

Of course, prevention of benign breast disease is a major feature of oral contraception. Oral contraceptives have decreased the incidence of benign breast disease.

no association between oral contraception and this problem can use oral contraceptives absorbed mainly in the small bowel.

(Disease). In a prospective cohort of 100, no adverse impact of oral contraceptives on the clinical course, specifically on flare-ups.³⁸⁸

Administration

may be encountered when an alternative to oral contraceptive pills is required. For example, patients who either have significant nausea and vomiting, or who would prevent oral drug administration. The pill can be administered vaginally. Initially, it was placed high in the vagina daily in order to maintain blood levels comparable with the oral route. However, a large clinical trial has demonstrated efficacy with one pill administered vaginally.

Contraindications

Menorrhagic and hypoestrogenic, oral contraceptive use confers confidence against the risk of an unwanted pregnancy and support against bone loss. This is a situation where oral contraceptives are worthwhile. A low bone density can be corrected by hormone therapy, and a subsequent bone density increase is a failure of response to estrogen can indicate a disease.

Concerned that oral contraceptives could affect ventilation during pregnancy, mediated by the enhancement of ventilatory response could be available for athletic performance. Indeed, laboratory data as measured by laboratory testing, and field data that simulate athletic events can find no effect on respiratory rate.^{391,392} One study documented both perceived and with palpation, after oral contraceptives.³⁹² Oral contraceptive use has been associated with a prevalence of low back pain, a common problem

Oral contraceptives have a lot to offer with no serious drawbacks for athletes. In athletes who wish to avoid menstrual bleeding, oral contraceptives can be administered on a daily basis, with no breaks, preventing withdrawal bleeding.

The Noncontraceptive Benefits of Oral Contraception

The noncontraceptive benefits of low-dose oral contraception can be grouped into two main categories: benefits that incidentally accrue when oral contraception is specifically utilized for contraceptive purposes and benefits that result from the use of oral contraceptives to treat problems and disorders.

Noncontraceptive Incidental Benefits

- Effective Contraception.
 - less need for induced abortion.
 - less need for surgical sterilization.
- Less Endometrial Cancer.
- Less Ovarian Cancer.
- Fewer Ectopic Pregnancies.
- More Regular Menses.
 - less flow.
 - less dysmenorrhea.
 - less anemia.
- Less Salpingitis.
- Increased Bone Density.
- Probably Less Endometriosis.
- Possibly Less Benign Breast Disease.
- Possibly Less Rheumatoid Arthritis.
- Possibly Protection against Atherosclerosis.
- Possibly Fewer Fibroids.
- Possibly Fewer Ovarian Cysts.

Many of these benefits have been previously discussed. Protection against pelvic inflammatory disease is especially noteworthy and a major contribution to not only preservation of fertility but to lower health care costs. Also important is the prevention of ectopic pregnancies. Ectopic pregnancies have increased in incidence (partly due to an increase in STDs) and represent a major cost for our society and a threat to both fertility and life for individual patients.

Of course, prevention of benign and malignant neoplasia is an outstanding feature of oral contraception. High-dose oral contraceptive use has decreased the incidence of benign breast disease diagnosed clinically as well

roadenomas diagnosed by biopsy; hopefully, it is evident with current lower dose formulations that the risk of ovarian cancer and a 50% reduction in the risk of substantial protection.

Comparisons documented in long-term users of oral contraceptives and, in current users, a 78% reduction in the risk of functional ovarian cancer and a 49% reduction in the risk of functional ovarian cancer. Studies with low-dose oral contraceptives have not shown a decreasing risk with increasing duration of use after 7 or more years of use (the effect is not significant).³³⁷ Epidemiologic studies have indicated that the incidence of ovarian cysts is proportional to the duration of use.^{354,359} Current low-dose monophasic and biphasic oral contraceptives provide no protection against functional ovarian cancer. The protection afforded by the current low-dose oral contraceptives is likely that clinicians will encounter such protection.

Oral contraceptives are as effective as higher dose preparations in the management of the prevalence and severity of dysmenorrhea. Oral contraceptive use is associated with a lower incidence of the protective effect is probably limited to the extent with the belief that hormonal treatment is viewed as suppressive, not curative.³⁹⁷⁻³⁹⁹ These oral contraceptives on gynecologic problems have an important, protective effect.

It is noted that osteoporosis occurs later and is less severe in women who used long-term oral contraception.⁴⁰⁰ Most studies of oral contraception are associated with a reduction in the risk of osteoporosis and that the degree of protection is related to the duration of use. However, other studies reflecting modern use of oral contraceptives show little impact of oral contraceptive use on the risk of osteoporosis. Studies of bone density are not as important as the available evidence fails to provide a clear picture. The available evidence indicates a reduction in fractures in women who had previously used oral contraceptives.⁴¹⁰⁻⁴¹³ In the Nurses' Health Study, the overall risk of fractures in women who had previously used oral contraceptives was actually slightly increased.⁴¹⁴ This is observed in the Oxford-Family Planning Study, which suggests that the increased risk reflects lifestyle differences in active users, but there was no evidence of a protective effect. In contrast, a case-control study from

Sweden found a reduction in the risk of postmenopausal hip fractures when oral contraceptives (mostly older high dose products) were used after age 40 by women who were not overweight, with an increasing benefit with increasing duration of use.⁴¹⁶ Previous oral contraceptive users are just now becoming elderly and reaching the age of greatest fracture prevalence. Future studies of postmenopausal women should eventually reveal the accurate relationship between oral contraceptive use and osteoporotic fractures.

The literature on rheumatoid arthritis has been controversial, with studies in Europe finding evidence of protection and studies in North America failing to demonstrate such an effect. An excellent Danish case-control study was designed to answer criticisms of shortcomings in the previous literature.⁴¹⁷ Ever use of oral contraception reduced the relative risk of rheumatoid arthritis by 60%, and the strongest protection was present in women with a positive family history. One meta-analysis concluded that the evidence consistently indicated a protective effect, but that rather than preventing the development of rheumatoid arthritis, oral contraception may modify the course of disease, inhibiting the progression from mild to severe disease; whereas a later meta-analysis concluded there was no evidence of a protective effect.^{418,419}

Oral contraceptives are frequently utilized to manage the following problems and disorders:

Definitely Beneficial:

- dysfunctional uterine bleeding.
- dysmenorrhea.
- mittelschmerz.
- endometriosis prophylaxis.
- acne and hirsutism.
- hormone therapy for hypothalamic amenorrhea.
- prevention of menstrual porphyria.
- control of bleeding (dyscrasias, anovulation).

Possibly Beneficial:

- functional ovarian cysts.
- premenstrual syndrome.

Oral contraceptives have been a cornerstone for the treatment of anovulatory, dysfunctional uterine bleeding. For patients who need effective contraception, oral contraceptives are a good choice to provide hormone therapy for amenorrheic patients, as well as to treat dysmenorrhea. Oral contraceptives are also a good choice to provide prophylaxis against the recurrence of endometriosis in a woman who has already undergone more vigorous treatment with surgery or the GnRH analogues. To protect

against endometriosis, oral contraceptives should be taken daily, with no break and no withdrawal bleeding.

The low-dose oral contraceptives are effective in treating acne and hirsutism. Suppression of free testosterone levels is comparable (about a 40–50% reduction) with that achieved with higher dosage.^{352,420} The beneficial clinical effect is the same with low-dose preparations containing levonorgestrel, previously recognized to cause acne at high dosage.^{351,352} Formulations with desogestrel, gestodene, and norgestimate are associated with greater increases in sex hormone-binding globulin and significant decreases in free testosterone levels. Comparison studies with oral contraceptives containing these progestins can detect no differences in effects on various androgen measurements among the various products.⁴²¹ Theoretically, these products would be more effective in the treatment of acne and hirsutism; however, this is yet to be documented by clinical studies. It is likely that all low-dose formulations, through the combined effects of an increase in sex hormone-binding globulin and a decrease in testosterone production, produce an overall similar clinical response, especially over time (a year or more).

Oral contraceptives have long been used to speed the resolution of ovarian cysts, but the efficacy of this treatment has not been established. Randomized trials have been performed with women who develop ovarian cysts after induction of ovulation.^{422,423} No advantage for the contraceptive treatment could be demonstrated. The cysts resolved completely and equally fast in both treated and non-treated groups. Of course, these were functional cysts secondary to ovulation induction, and this experience may not apply to spontaneously appearing cysts. Two short-term (5 and 6 weeks) randomized studies could document no greater effect of oral contraceptive treatment on resolution of spontaneous ovarian cysts when compared with expectant management.^{424,425} Clinical experience (untested by studies) leads us to believe that oral contraception does provide protection in women against the recurrent formation of ovarian cysts.

Continuation: Failure or Success?

Despite the fact that oral contraception is highly effective, hundreds of thousands of unintended pregnancies (close to 1 million) occur each year in the United States because of the failure of oral contraception. Worldwide, literally millions of unintended pregnancies result from poor compliance. In general, unmarried, poor, and minority women are more likely to have failures, reaching rates of 10–20%.^{426,427} Overall, the first year failure rate with actual use is as high as 8%. The difference between the theoretical efficacy and actual use reflects compliance and noncompliance. Noncompliance includes a wide variety of behavior: failure to fill the initial

prescription, failure to continue on the oral contraception. Compliance (of personal behavior, biology, and pharmaceutical continuation) reflects the Un fortunately, women who discontinue a less effective method or, worse, fail to

There are 3 major factors that affect

1. The experience of side effects and amenorrhea, and problems, such as headache and weight gain. Multiple side effects increase the likelihood. Because these complaints rement,⁴³⁰ it is reasonable to sensitive and attentive could different product.
2. Fears and concerns regarding and the impact of oral con
3. Nonmedical issues, such as taking, complicated pill packaging from the patient package in

The information in this chapter is d but the clinician must go beyond develop an effective means of co recommend the following approach one way to improve continuation wi

1. Explain how oral contracept
2. Review briefly the risks ar but be careful to put the r emphasize the safety and i dose oral contraceptives.
3. Show and demonstrate to t will use.
4. Explain how to take the p
 - When to start.
 - The importance of devel missing pills.
 - What to do if pills are m
5. Review the side effects th: orrhea, breakthrough ble nausea, etc., and what to c

Contraceptives should be taken daily, with no missing pills.

Oral contraceptives are effective in treating acne and androgen levels are comparable (about 50% of those achieved with higher dosage).^{352,420} The benefit with low-dose preparations containing ethinyl estradiol, gestodene, and norgestimate are associated with decreased hormone-binding globulin and significant effects on androgen levels. Comparison studies with oral contraceptives can detect no differences in effects on acne among the various products.⁴²¹ Oral contraceptives would be more effective in the treatment of acne than is yet to be documented by clinical studies. Oral contraceptives, through the combined effects of decreased hormone-binding globulin and a decrease in testosterone, result in an overall similar clinical response, especially

when used to speed the resolution of ovarian cysts. This treatment has not been established. It is performed with women who develop ovarian cysts. No advantage for the contraceptive is demonstrated. The cysts resolved completely and were not seen in non-treated groups. Of course, these were not randomized, and this experience may be confounded by ovulation induction, and this experience may be confounded by appearing cysts. Two short-term (5 and 6 months) studies could document no greater effect of oral contraceptives on resolution of spontaneous ovarian cysts when compared to placebo.^{424,425} Clinical experience (untested) suggests that oral contraception does provide protection against formation of ovarian cysts.

Why?

Oral contraception is highly effective, hundreds of unintended pregnancies (close to 1 million) occur each year as a result of the failure of oral contraception. Most unintended pregnancies result from poor adherence. For married, poor, and minority women are more likely to be non-compliant. Rates of 10–20%.^{426,427} Overall, the first year failure rate is high as 8%. The difference between the use of oral contraceptives reflects compliance and noncompliance. A variety of behavior: failure to fill the initial

prescription, failure to continue on the medication, and incorrectly taking oral contraception. Compliance (continuation) is an area in which personal behavior, biology, and pharmacology come together. Oral contraceptive continuation reflects the interaction of these influences. Unfortunately, women who discontinue oral contraception often utilize a less effective method or, worse, fail to substitute another method.

There are 3 major factors that affect continuation:

1. The experience of side effects, such as breakthrough bleeding and amenorrhea, and perceived experience of "minor" problems, such as headaches, nausea, breast tenderness, and weight gain. Multiple side effects dramatically and progressively increase the likelihood of discontinuation.^{428,429} Because these complaints respond well even to placebo treatment,⁴³⁰ it is reasonable to expect a favorable response to sensitive and attentive counseling, as well as changing to a different product.
2. Fears and concerns regarding cancer, cardiovascular disease, and the impact of oral contraception on future fertility.
3. Nonmedical issues, such as inadequate instructions on pill taking, complicated pill packaging, and difficulties arising from the patient package insert.

The information in this chapter is the foundation for good continuation, but the clinician must go beyond the presentation of information and develop an effective means of communicating that information. We recommend the following approach to the clinician–patient encounter as one way to improve continuation with oral contraception.

1. Explain how oral contraception works.
2. Review briefly the risks and benefits of oral contraception, but be careful to put the risks in proper perspective, and to emphasize the safety and noncontraceptive benefits of low-dose oral contraceptives.
3. Show and demonstrate to the patient the package of pills she will use.
4. Explain how to take the pills:
 - When to start.
 - The importance of developing a daily routine to avoid missing pills.
 - What to do if pills are missed (Identify a backup method).
5. Review the side effects that can affect continuation: amenorrhea, breakthrough bleeding, headaches, weight gain, nausea, etc., and what to do if one or more occurs.

6. Explain the warning signs of potential problems: abdominal or chest pain, trouble breathing, severe headaches, visual problems, leg pain or swelling.
7. Ask the patient to be sure to call if another clinician prescribes other medications.
8. Ask the patient to repeat critical information to make sure she understands what has been said. Ask if the patient has any questions.
9. Schedule a return appointment in 1–2 months to review understanding and address fears and concerns; a visit at 3 months is too late because most questions and side effects occur early.⁴²⁹ Inconsistent use of oral contraceptives is more common in women who are new starters.⁴²⁷
10. Make sure a line of communication is open to clinician or office personnel. Ask the patient to call for any problem or concern before she stops taking the oral contraceptives.
11. A good web site for information:
The JAMA Contraception Information Center
www.ama-assn.org/special/contra/contra.html

Concluding Thoughts

In the 1970s, as epidemiologic data first became available, we emphasized in our teaching and in our communication with patients the risks and dangers associated with oral contraceptives. In the 1990s, with better patient screening and epidemiologic data documenting the effects of low-dose products, we appropriately emphasized the benefits and safety of modern oral contraceptives. In the new millennium, we can with confidence promote the idea that the use of oral contraceptives yields an overall improvement in individual health, and from a public health point of view, the collection of effects associated with oral contraceptives leads to a decrease in the cost of health care.

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signs of potential problems: abdominal bloating, severe headaches, visual changes, and leg swelling.

Be sure to call if another clinician has indicated contraindications.

Obtain critical information to make sure that what has been said. Ask if the patient has

an appointment in 1–2 months to review and address fears and concerns; a visit at 3 months because most questions and side effects of consistent use of oral contraceptives is more likely to appear in new starters.¹²⁷

Communication is open to clinician or patient to call for any problem or to stop taking the oral contraceptives.

For more information:

Contraception Information Center
<http://special/contraception/contraception.html>

When the data first became available, we emphasized communication with patients the risks and benefits of oral contraceptives. In the 1990s, with better biologic data documenting the effects of low-dose oral contraceptives, we more strongly emphasized the benefits and safety of oral contraceptives in the new millennium, we can with confidence use of oral contraceptives yields an overall health benefit, and from a public health point of view, the association with oral contraceptives leads to a net health benefit.

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