

Needs Assessment: Oral Contraceptives in Primary Care: Weighing the Options for Best Results

NEEDS OVERVIEW

Unintended pregnancy remains a major public health problem in the United States that has not declined in recent decades. Although approximately 70% of fertile, sexually active women in this country are using reversible contraceptive methods to avoid pregnancy, almost half of all pregnancies are unintended. More than 3 million (about 1 in 20) women aged 15-44 years experience an unplanned or unintended pregnancy every year. This rate was unchanged between 1994 and 2001, with about half of these pregnancies resulting in abortion.^{1,2}

Although most women use some form of contraception during their reproductive lives, many use it incorrectly, inconsistently, or discontinue its use.^{3,2} These are leading causes that contribute to the persistent problem of unintended pregnancy. In a nationally representative sample of women at risk for this problem, a telephone survey over a one year period found that only half of them practised correct, consistent contraceptive use that afforded adequate protection against pregnancy.^{2,4}

Primary care physicians are often asked to prescribe oral contraceptive pills for many of their female patients. The CDC reports that about 62% of 15-44 year old women currently use some form of contraception, with about 17% of them using oral contraceptive pills. Patient-physician discussions about contraceptive options have the largest influence on product selection, as well as adherence to, and general satisfaction with the medication regimen.⁵ Considering the high unintended pregnancy rate in this country, patients need to be appropriately educated on the oral contraceptive options available so they can select one that best suits their lifestyles and reproductive plans. Primary care physicians would therefore benefit from education to improve their knowledge of the current available contraceptive options in order to best educate and counsel patients in an unbiased manner, recommending optimal methods to individuals based on their needs, wants, and comorbid conditions.

EDUCATIONAL AND CLINICAL GAP ANALYSIS

GAP #1: Primary care physicians may not be fully aware of the trends in oral contraceptive use, the range of oral contraceptives available for prescription, or the extent of benefits and risks of available oral contraceptives.

All hormonal oral contraceptive products are effective at preventing pregnancy, and therefore decrease pregnancy-associated mortality as a result.⁶ There are two basic types of oral

contraceptive pill: the combined oral contraceptive (COC) pill, and the progestin-only “minipill”. There is also an emergency contraceptive pill, which can be taken following unprotected sex.

First introduced in 1960, the combined oral contraceptive (COC) pill has become one of the most widely and frequently used methods of contraception, and is currently estimated to be used by 28% of women of reproductive age in the United States.^{3,7,8}

COCs are the most commonly used form of oral contraceptive, and are composed of two synthetic steroid hormones, an estrogen and a progestin. Most preparations are taken daily for 21 days, followed by a seven day hormone-free interval. A withdrawal bleed subsequently occurs two to three days after taking the last pill.⁹

Early formulations of COCs comprised hormone concentrations that were much greater than current products. This was associated with significant cardiovascular risk, in particular venous thromboembolism, as well as intolerable adverse effects such as weight gain, headaches, nausea, and irregular menstrual bleeding.^{9,10} Over time, however, improvements in cardiovascular safety and tolerability have resulted from newer formulations that contain reduced hormone dosages and new progestins, while maintaining contraceptive efficacy.⁹

Despite the improved safety, however, there is a significantly increased risk of myocardial infarction (MI) in women over 35 years of age who smoke, and in those with hypertension or any other underlying cardiovascular risk factors.¹¹⁻¹⁷

Progestin type and estrogen dose have both been implicated in the risk of MI. Comparing COC users with nonusers, the aggregated odds ratio (OR) for MI with older (EE <50 mcg plus norgestrel or levonorgestrel) COCs was reported to be 2.18 (95% confidence interval [CI] 1.62–2.94), and 1.13 for newer (EE <50 mcg plus desogestrel or gestodene) COCs (95% CI 0.66–1.92).¹⁸

Early COC regimens were monophasic, with each pill containing the same dose of estrogen and progestin for daily administration during the first three weeks of the cycle. Biphasic and triphasic COCs have subsequently been developed. These reduce the total doses of steroids administered in each cycle, but must be taken in a specific sequential order. However, there is still no substantial evidence that such multiphasic regimens offer any significant clinical advantage over monophasics in terms of safety or efficacy.^{19,20} Because of this, and since women are less likely to take multiphasics correctly in the required sequential order, possibly increasing the risk of unintended pregnancy or bleeding, monophasic regimens are frequently preferred over multiphasics.⁹

Extended- and continuous-cycle COCs have also been developed as alternate regimens. The extended-cycle COC comprises 84 days of estrogen and progestin, followed by 7 days of either placebo or very-low-dose estrogen, reducing the occurrence of withdrawal bleeds to four times a year. This has been found to be as effective at pregnancy prevention as traditional regimens, and may even improve menstrual symptoms and bleeding patterns in

some women.²¹⁻²⁶ It has been associated, however, with increased bleeding initially, despite fewer total days of scheduled withdrawal bleeding.²¹

A continuous-cycle COC regimen that eliminates withdrawal bleeding throughout the year is also available. This involves 28 days of active hormones, taken continuously, without a hormone-free break, and its safety and efficacy profile is similar to that of other low-dose COC regimens. Advantages of avoidance of menses using this regimen include improved compliance, acceptability, and menstrual complaints.^{22,27,28} As with the extended-use COCs, the continuous-cycle regimen is, however, associated with the inconvenience of more unscheduled bleeding and spotting.²⁸

In addition to providing effective contraception, COC use offers other health benefits. It lowers mortality in post-reproductive years by its protective effect against endometrial²⁹⁻³² and ovarian³³⁻³⁵ cancer, and also colon cancer^{6,36,37} to a lesser degree. Their use also improves the quality of life for many women by reducing problems such as acne,³⁸ premenstrual dysphoric disorder,^{39,40} dysmenorrhea,^{41,42} and menorrhagia.⁶ A protective effect against ovarian cyst development has also been shown with higher-dose COCs, but not with lower-dose formulations.⁴³⁻⁴⁵

Although not as frequently used as COCs, progestin-only oral contraceptives are also effective at pregnancy prevention since the progestin component accounts for most of the contraceptive effect of hormonal contraceptives. Since progestin-only pills (POPs) are taken daily, with no placebo or hormone-free interval, this can be useful in helping some women adhere to a medication regimen.⁴⁶

Side effects of POPs include irregular bleeding and amenorrhea. They have been considered to be less effective than COCs since hormone levels may be undetectable 27 hours after the last pill was taken.^{47,48} Consequently it has been recommended that the pills should be taken at the same time each day. More recent data, however, suggests that their efficacy is similar to COCs.⁴⁹ Few serious risks are associated with the use of progestin-only contraceptives, and these include: stroke; deep vein thrombosis; pulmonary embolism; breast cancer; cirrhosis of the liver; liver tumors.^{50,51}

Progestin-only formulations, however, are considered safer for use in women with vascular disease, multiple cardiac risk factors, and a history of venous thrombosis, lupus, or hepatitis.^{50,52} Additional health benefits include improvement in premenstrual syndrome, dysmenorrhea, menorrhagia, and anemia.⁵³

Primary care physicians should be aware of the range of available oral contraceptives, as well as their relative risks and benefits, so that they can effectively counsel patients on appropriate birth control methods, and help to improve their lives and contraceptive method continuation.