

Patient Communication and Counseling on Contraception and Hormone Replacement Therapy

Based on a presentation by Ronald J. Ruggiero, PharmD

Presentation Summary

Many women are unaware of the wide range of benefits resulting from hormonal therapy. Clinicians need to improve their ability to counsel patients about the benefits and risks of oral contraceptives (OCs) and hormone replacement therapy to improve patient compliance and willingness to continue therapy. For reproductive-age women, choosing the lowest effective estrogen/progestin dose will reduce the side effects and bleeding irregularities that are major reasons for patient discontinuation. Analysis has shown that compared with OCs the new transdermal contraceptive system, which is expected to be on the market in 2002, has better outcomes and lower costs at all ages.

In Dr. Ruggiero's presentation, he discussed the high rate of unintended pregnancies and abortions in the United States and the fact that more than four fifths of patients who discontinue the use of oral contraceptives (OCs) adopt either a less reliable contraceptive method or no method at all,¹ and he noted that the statistics indicate the lack of proper counseling for a broad range of patients, as unintended pregnancies occur not only in teenagers but in perimenopausal women as well.

Benefits in Addition to Contraception

Widespread misperceptions about OCs continue, as evidenced by studies that show 49% of college women believe substantial risks are associated with the use of OCs. In addition, 80% to 95% of these women are unaware of the many noncontraceptive benefits of OC use.²

A 40% reduction in the risk for ovarian cancer is one of these important noncontraceptive benefits.³ This protective effect begins within 3 to 6 months of OC use and lasts for 15 years after cessation of use,³ translating into the prevention of approximately 1700 hospitalizations and 1000 deaths annually due to ovarian cancer.⁴ OC use results in a 50% reduction in the risk of endometrial cancer when used for 12 months or longer, with the benefit also lasting for at least 15 years after cessation of use.⁵

The benefits of OC use in reducing pelvic inflammatory disease (PID) are equally impressive. The progestins in OCs cause a thickening of cervical mucus, which is largely responsible for the 50% reduction in risk of PID seen in current users who have been on OCs for at least 12 months.⁶ This decrease in PID not only prevents current hospitalizations but also leads to a subsequent reduction in future infertility. "Grasping the full impact of a reduction in PID can be difficult," Dr. Ruggiero noted, adding, "unless you treat patients every day who cannot get pregnant because they've had PID not once, but 2 or more times." By reducing the potential for ectopic pregnancies, OCs also prevent an additional 9900 hospitalizations and 10 deaths in the United States annually.⁴ In total, an estimated 1614 out of every 100,000 OC users avoid hospitalization because of the protective effects of these agents, primarily in terms of PID and ectopic pregnancies.¹

"Two thirds of the women who are seen by obstetrician/gynecologists in general

are anemic," Dr. Ruggiero noted, adding, "OC users have one third the amount of endometrium of nonusers, resulting in a decrease in menstrual blood flow and a subsequent decrease in anemia.⁴ In addition, with two thirds less endometrium, lower levels of prostaglandins are produced, resulting in less menstrual pain, a fact that is reflected in the 40% to 67% decrease in complaints of menstrual pain reported with the use of OCs."⁴

Other benefits of OC use include a 50% to 75% reduction in benign breast disease, with increased protection related to duration of use; a decreased risk of developing ovarian cysts, more rapid resolution of pre-existing cysts, and reduced surgery rates for ovarian masses; and a 29% reduction in premenstrual tension and other symptoms of premenstrual syndrome (PMS), which could lead to a subsequent reduction in prescriptions for medications such as fluoxetine and sertraline.^{4,7}

This raises the question of why, given the benefits of OCs, women discontinue using them. The primary reason given by patients is bleeding irregularities, followed by nausea, weight gain, mood changes, breast tenderness, and headaches.⁴

Improving Patient Counseling

"We clearly need to improve our ability to counsel patients about contraception," Dr. Ruggiero commented. One of the areas most in need of improvement concerns the type of language used. Dr. Ruggiero suggested that physicians are too technical, that they need to translate epidemiologic information and jargon into something that is meaningful to patients, such as absolute numbers rather than relative risk.

Making the point that many obstetrics and gynecology and pharmacy residents have never actually seen OCs and therefore are not equipped to give the detailed instructions that patients need, Dr. Ruggiero advised that clinicians learn what the package looks like and how to use the OCs, as well as exactly what day and what time of day patients are supposed to begin taking the pills. "Variance in taking OCs leads to spotting and break-

through bleeding," he pointed out, "and subsequent discontinuation and pregnancy." He also noted the importance of the providers knowing which preparation the patient's health plan supports.

Other critical steps in educating patients include counseling them about the benefits and side effects of treatment before they start taking OCs, advising them as to what to do if they miss pills, and making sure they know the importance of using condoms for protection against sexually transmitted diseases.⁸ Another important point to stress is that correct, consistent OC use will reduce side effects. Finally, providers need to help patients develop clues for remembering when to take their pills.

Calling patients 2 weeks after they have started a new hormone, either OCs or hormone replacement therapy (HRT), is imperative, followed by another call 6 weeks later to assess how they are doing and to answer questions. Dr. Ruggiero emphasized the importance of patients having an on-going dialogue with their providers to prevent having them discontinue treatment as soon as they have problems or concerns.

Other concrete steps can be taken by providers to improve patient compliance and willingness to continue OC use.⁸ Choosing the lowest effective estrogen/progestin dose will reduce the side effects and bleeding irregularities that are major

Table 1. Five-Year Cost Savings with the Transdermal Contraceptive System Versus OCs

Age	Savings		
	1 Year	2 Year	5 Year
17	\$128.67	\$234.32	\$514.71
25	\$ 47.14	\$ 88.41	\$164.08
35	\$ 24.82	\$ 40.43	\$ 81.33
40	\$ 28.38	\$ 35.27	\$122.33

OCs = oral contraceptives.

Source: Sonnenberg FA. Unpublished data, 2001.

reasons for patient discontinuance of therapy. The selection of user-friendly packaging and 28-pill packs facilitates consistent use.⁸

There will be an additional contraceptive option in the near future, with the new transdermal contraceptive system expected to be on the market in 2002. Analysis has shown that compared with OCs the transdermal system has better outcomes and lower costs at all ages, as shown in **Table 1** (Sonnenberg FA, written communication, August 2001). The cost savings and improvement in outcomes are greatest in the youngest age groups, where the discrepancy in compliance is greatest between the 2 methods.

Concerns of Perimenopausal Women

Perimenopausal women have particular concerns and beliefs that result in their underutilization of OCs. Many believe that they do not need contraception. Others fear serious health risks, such as cancer,⁹ myocardial infarction, stroke, and venous thromboembolism, that they believe to be associated with oral contraception. Further, many think that long-term use increases health risks.¹⁰ Fifty-three percent of women between 35 and 45 years of age believe that OCs cause weight gain, and this concern deters many from therapy.¹¹ "Perimenopausal women frequently bounce back and forth on OCs, first taking, then discontinuing them," Dr. Ruggiero said. "They try OCs to deal with symptoms, then quit because of their fears and misconcep-

tions. When symptoms return, they go back on OCs, then discontinue again because their fears have not been addressed."

Dr. Ruggiero suggested specific messages that should be conveyed when counseling the perimenopausal patient group. In addressing the belief that women of this age do not need OCs, providers need to make the point that perimenopausal women are second only to teenagers in unplanned pregnancies,¹² and that OCs are one of the most reliable forms of reversible contraception. Moreover, providers should emphasize that many noncontraceptive benefits are seen with OCs that are important to all women, including those without an intact uterus (**Table 2**). Providers must also help perimenopausal women understand that OCs are safe for women who are older than 35 years who do not smoke and do not have cardiovascular disease. Finally, women should be informed that placebo-controlled trials have demonstrated no difference in weight gain between women receiving placebo and those receiving OCs.¹³

Hormone Replacement Therapy

As illustrated in a survey by the North American Menopause Society, menopausal women take HRT for a variety of reasons, including relief of hot flashes (33%), prevention of osteoporosis (18%), hysterectomy (11.5%), to improve mood or memory (9.6%), and because a physician recommended it (9.4%), although this advice is more likely to be followed if offered by a female, rather than a male gynecologist.¹⁴ Although most studies do not mention it, at least 5% of patients present with a loss of libido, either secondary to vaginal dryness or lack of sexual desire.

Unfortunately, despite the benefits of treatment, 62% of eligible menopausal women are not receiving HRT.¹⁵ Twenty-one percent of women who are 50 to 55 years of age stop HRT within 12 months, most (64%) citing unacceptable side effects as the primary reason.¹⁶ Other reasons include the fear of cancer or thrombosis; bleeding, which is a significant problem for many; the desire to deal with symptoms naturally; the wish to find out if

Table 2. Noncontraceptive Benefits of Oral Contraceptives

- Treatment of irregular periods/DUB, menorrhagia, and/or dysmenorrhea
- Reduction in vasomotor symptoms
- Higher bone density and fewer fractures
- Prevention of ovarian and endometrial cancers
- Diminished androgen-related side effects (eg, acne)
- Improved quality of life

DUB = dysfunctional uterine bleeding.

menopausal symptoms have disappeared, often combined with the plan to determine if continuing to take this drug, which they perceive as somewhat dangerous, is necessary; and other concerns, such as nausea and weight gain.¹⁷ Dr. Ruggiero pointed out that many women change clinicians, resulting in their new physicians not being aware that the patients have discontinued therapy.

Dr. Ruggiero attributed the underutilization and discontinuation of HRT to deficits in counseling, pointing out that less than 40% of women of very low socioeconomic status receive any HRT counseling at all. In addition, he stated that discontinuation associated with side effects reflects the fact that counseling is not effectively directed toward managing these effects. Choosing the wrong product may also be a factor in patient discontinuation.

Counseling Menopausal Women

The reasons cited for taking HRT in the North American Menopause Society survey mentioned above suggest that, like women of reproductive age, many menopausal women are unaware of the wide range of benefits resulting from hormonal therapy. Thus, patients need to be educated about the benefits of HRT after menopause and how these benefits can enhance their quality of life (Table 3).

Primary among the benefits is the reduction in hip fractures experienced by patients receiving therapy.¹⁸ HRT use also is associated with less cognitive decline,¹⁹ a serious concern for older individuals of both sexes. Other benefits cited by Dr. Ruggiero include prevention of vaginal atrophy and descended uterus,²⁰ as well as the prevention of tooth loss.²¹ Additionally, HRT not only reduces the chances of weight gain, it decreases the risk for central obesity, a major risk factor for cardiovascular disease.²² In one study, patients receiving HRT weighed less than those receiving placebo.²³ Finally, more recently developed HRT regimens have beneficial effects on lipids, with new products that avoid medroxyprogesterone acetate (MPA) resulting in better

Table 3. Benefits of Hormone Replacement Therapy

- Fewer fractures
- Less Alzheimer's disease
- Prevents vaginal atrophy and descended uterus
- Prevents tooth loss
- Prevents central obesity
- Reduces gain in body weight

lipid profiles. In the Postmenopausal Estrogen/Progestin Interventions (PEPI) trial conjugated estrogen (CEE) alone resulted in an increase in high-density lipoprotein (HDL) of 5.6 mg/dL.²³ CEE/MPA resulted in an increase of only 1.6 mg/dL with cyclical regimens and 1.2 mg/dL with continuous regimens. In contrast, CEE/micronized progesterone resulted in an increase of 4.1 mg/dL. In another study,²⁴ 17 β -estradiol/norgestimate HRT resulted in a significant increase (4.8%) in HDL.

An important first step in effectively counseling patients is to solicit their expectations of treatment. This includes determining the patient's knowledge and expectations in terms of the short-term relief of menopausal symptoms achieved with

Table 4. Anticipatory Guidance About Possible HRT Side Effects

- Prepare patients for side effects that may occur
 - Bleeding/spotting
 - Fluid retention
 - Breast tenderness
 - Change in hair growth
 - Bloating
 - Mood changes
 - Headache
 - Abdominal pain
- Emphasize that most resolve within 3 months
- Dispel fear of weight gain: HRT lower than placebo after 36 months with more appropriate

HRT = hormone replacement therapy.

Source: Reference 23.

Subsequent to the Spring 2001 conference described in this journal supplement, The North American Menopause Society (NAMS) issued a press release on July 26, 2001 addressing the recent science advisory statement from the American Heart Association (AHA) (Mosca L, Collins P, Herrington DM, Mendelsohn ME, Pasternak RC, Robertson RM. Hormone replacement therapy and cardiovascular disease: a statement for health care professionals from the American Heart Association. *Circulation* 2001;104:499-503) on the relationship between hormone replacement therapy (HRT) use in postmenopausal women and cardiovascular disease (CVD). The AHA statement recommends against the use of HRT by women with existing CVD. Wulf H. Utian, MD, PhD, and NAMS Executive Director, responded to the advisory by suggesting, as stated in the NAMS study guide, that until more evidence is available, emphasizing cardiovascular risk reduction with established evidence-based treatments is most prudent for women with CVD rather than initiating HRT. Dr. Utian noted that women who have been using HRT for several years without problems should be advised not to discontinue therapy until more definitive data are available. The NAMS study guide mentions that for women who do not have a history of CVD, initiating HRT for other indications may eventually be shown to demonstrate CVD benefits.

HRT; the long-term prevention of diseases such as osteoporosis, Alzheimer's disease, cardiovascular disease, and tooth loss; and the improvement in quality of life associated with HRT. Physicians should ask the patient about her reasons for using or not using HRT. The question should be repeated each year, emphasizing that a decision either way is not irrevocable.

Anticipatory guidance in preparing patients for possible HRT side effects (such as bleeding/spotting, fluid retention, breast tenderness, change in hair growth, bloating, mood changes, headache, and abdominal pain) and in managing these events effectively is extremely important in encouraging patients to remain on treatment (Table 4). Reassuring patients that most side effects resolve within 3 months is also helpful. Dr. Ruggiero concluded by emphasizing the importance of a yearly physical examination in providing a good opportunity to re-evaluate, counsel, and provide support.

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