

Lybrel™: The New Birth Control Pill that Eliminates Menstruation

Introduction

Earlier this year, the U.S. Food and Drug Administration (FDA) approved the oral contraceptive Lybrel™, a combination of the hormones levonorgestrel and ethinyl estradiol, to prevent pregnancy. Lybrel is the first FDA-approved birth control pill that is taken 365 days a year, with no placebo phase or pill-free interval; during that time, it suppresses menstruation.

Many women have questions about the safety and benefits of a pill that causes long-term suppression of menstruation. Dr. Erin N. Marcus of the Institute for Women's Health (IWH) asked Dr. Carla Lupi, assistant professor of clinical obstetrics and gynecology and director of graduate medical education for the Department of Obstetrics and Gynecology at the University of Miami Miller School of Medicine, to discuss this new contraceptive option.

Institute for Women's Health (IWH):

Thank you, Dr. Lupi, for speaking with us. Traditionally, oral contraceptive pills are taken 21 days per month, with one week of placebo pills in between each cycle. Could you please explain how Lybrel is physiologically different from these "traditional" oral contraceptives?

Dr. Lupi:

Physiologically, it's really *not* much different. As with traditional oral contraceptives, Lybrel keeps the ovaries from ovulating and also provides protection against pregnancy by changing the cervical mucous, thinning the uterine lining, and decreasing the motility of the fallopian tubes. The only thing that's different is that it doesn't allow a monthly bleed. *All* oral contraceptives (including Lybrel and traditional 21 day birth control pills) cause a minor buildup of the uterine lining that remains stable over time.

IWH:

Why is there a need for such a medication?

Dr. Lupi:

For years, women such as surgeons, athletes, and military personnel have had problems accommodating monthly bleeding with their responsibilities – and have used oral contraceptives to stop bleeding each month. This has been done with traditional birth control pills for a long time, by simply skipping the placebo week and opening a new pack of pills every 21 days. The new FDA approval for Lybrel is really a mechanism for making this practice more mainstream. The first formal move in this direction occurred a few years ago when the FDA approved Seasonale™, which provides a pill-free week every three months instead of every month. Lybrel has taken this further by eliminating the pill-free intervals altogether.

IWH:

So, this is not a new idea?

Dr. Lupi:

It's actually the return of an *old* idea. In the 1950s, before the pill was introduced, there was open discussion about whether to use a 21 day or 28 day regimen. Ultimately, the

traditional model was settled on because there was a hope that it would be more likely to gain widespread acceptance since it mimicked a “natural state,” with a normal period. I think it’s hard now for many people to understand that many people back then feared the pill would take away female fertility permanently. So any dosing that would leave the outward manifestations of reproductive function – the period – in place was thought to bring more acceptance.

IWH:

What are the health risks of such a medication?

Dr. Lupi:

There’s no evidence from clinical research of any new risks compared with traditional oral contraceptives, but we could theorize that maybe because this regimen involves a slightly greater total hormone dose over time, there could be slightly greater chance of thromboembolic problems, i.e., clotting risk. But even a slight increase in risk, if it exists, is much much less than the increased thrombotic risk of that occurs during normal pregnancy.

Some people have expressed concern that by stopping the periods, a woman who conceives while on Lybrel – due to skipping a dosage or failure of the medication – might not realize that she’s pregnant. This is a concern with any method of contraception that stops periods.

There are many different ways of advising patients on handling the uncertainty of not having a period. I have always advised patients using methods that if they don’t have a period with their method, they can consider a pregnancy test every two to three months, at least during the first year, just to be on the safe side. Once they’ve gone through a year or so with successful method use, they can consider testing less frequently.

IWH:

Is there a risk of abnormal endometrial growth or even pre-cancerous changes if a pre-menopausal woman doesn’t experience menstrual bleeding each month?

Dr. Lupi:

This is not a risk with this particular medication, because it contains a progestin, levonorgestrel, as well as an estrogen, ethinyl estradiol. The more progestin the medication contains, the lower the risk of abnormal endometrial growth.

IWH:

Have you prescribed this medication to any patients? Whom do you think might be a good candidate for such a medication?

Dr. Lupi:

I personally have not yet prescribed it. But I do have many patients who take traditional birth control pills and skip the pill-free week whenever they don’t want to have a period. Lybrel will be most useful for women who don’t want to have their periods, as well as women who have problems associated with monthly bleeding, such as anemia. Some have theorized that continuous suppression of menstruation might benefit patients with endometriosis, also.

There are two other benefits associated with this pill. First, it may theoretically lower failure rates. If you look at the worst time to forget your pill, it's in the very first week, i.e., the week after that placebo week. That's because if you go more than seven days without the pituitary suppression of the pill, the pituitary is more likely to ramp up its FSH production and cause an ovulatory cycle. Also, insurers that do cover Lybrel usually offer a three month supply of Lybrel at one time, at one visit to the pharmacy, whereas they usually only cover a one month supply of traditional oral contraceptives at one visit. This way, a patient has less opportunity to miss going to the pharmacy and miss getting her pills on time. (It should be noted, however, that some pharmacies and insurance plans may charge a higher co-pay for Lybrel than for traditional birth control pills because it's a new drug and also because more pills will be dispensed at one time).

Thank you, Dr. Lupi, for helping explain this new development in women's health to us.