

First series of 18 pregnancies after ulipristal acetate treatment for uterine fibroids

Mathieu Luyckx, M.D.,^a Jean-Luc Squifflet, M.D., Ph.D.,^a Pascale Jadoul, M.D.,^a Raffaella Votino, M.D.,^a Marie-Madeleine Dolmans, M.D., Ph.D.,^{a,b} and Jacques Donnez, M.D., Ph.D.^c

^a Gynecology Department, Cliniques Universitaires Saint-Luc; ^b Pôle de Recherche en Gynécologie, Institut de Recherche Expérimentale et Clinique, Université Catholique de Louvain, Cliniques Universitaires Saint-Luc; and ^c Société de Recherche pour l'Infertilité, Brussels, Belgium

Objective: To study the pregnancy rate after ulipristal acetate (UPA) therapy for fibroids.

Design: Retrospective analysis of a series of 52 patients prospectively included in the PGL4001 (ulipristal acetate) Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata (PEARL) II and III trials.

Setting: Academic hospital.

Patient(s): Among the 52 patients, 21 wished to conceive upon treatment completion.

Intervention(s): None.

Main Outcome Measure(s): Pregnancy rate and live birth rate.

Result(s): Twenty-one patients attempted to get pregnant, among whom 15 (71%) succeeded, totaling 18 pregnancies. Among these 18 pregnancies, 12 resulted in the birth of 13 healthy babies and 6 ended in early miscarriage. No regrowth of fibroids was observed during pregnancy.

Conclusion(s): We report the first series of pregnancies achieved after UPA treatment. Our data confirm a sustained long-term effect after UPA therapy. (Fertil Steril® 2014;102:1404–9. ©2014 by American Society for Reproductive Medicine.)

Key Words: Fibroids, selective progesterone receptor modulators (SPRMs), ulipristal acetate, pregnancy

Discuss: You can discuss this article with its authors and with other ASRM members at <http://fertstertforum.com/luyckxm-pregnancies-ulipristal-acetate-fibroids/>



Use your smartphone to scan this QR code and connect to the discussion forum for this article now.*

* Download a free QR code scanner by searching for "QR scanner" in your smartphone's app store or app marketplace.

Ulipristal acetate (UPA), a selective P receptor modulator (SPRM) with pharmacokinetic properties allowing a single daily dose, potently modulates P activity and exerts proapoptotic antiproliferative effects on fibroid cells without suppressing E₂ to nonphysiologic levels. Two randomized clinical trials have shown that UPA is efficient for control of excessive bleeding in patients with symptomatic uterine fibroids (1, 2). It also reduces myoma size and uterine volume, found to be maintained for at least 6 months in patients not undergoing surgery (1,

2). Rapid control of bleeding serves to normalize hemoglobin levels, which is important before a surgical procedure, because we know that anemia, even to a mild degree, increases the risk of postoperative morbidity and mortality in both cardiac and noncardiac surgery (3).

Administration of SPRMs induces endometrial changes (P receptor modulator-associated endometrial changes, PAECs), which spontaneously reverse over a period of several weeks to months after cessation of UPA therapy (4). Very recently a strategy involving intermittent

courses of 12-week UPA treatment with off-treatment intervals was demonstrated to be a potential option for long-term medical management of fibroids (5). New algorithms were proposed to evaluate the remaining place of myoma surgery in current practice (6).

To date, no data on fertility or pregnancy after UPA are available from the literature.

Here we report the first series of 18 pregnancies obtained in 15 infertile patients who underwent UPA therapy.

MATERIALS AND METHODS

The PGL4001 (ulipristal acetate) Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata (PEARL) II and III trials were approved by our local ethics committee and were conducted in accordance with the International Conference on Harmonization–Good Clinical Practice guidelines.

Received May 21, 2014; revised and accepted July 30, 2014; published online September 17, 2014. M.-M.D. reports grants from Fonds National de la Recherche Scientifique, the Foundation Against Cancer, and Fondation Saint-Luc. J.D. is a board member of PreGlem and received payment for lectures from Serono, MSD, Organon, and Ferring. M.L. has nothing to disclose. J.-L.S. has nothing to disclose. P.J. has nothing to disclose. R.V. has nothing to disclose. Reprint requests: Mathieu Luyckx, M.D., Gynecology Department, Cliniques Universitaires Saint-Luc, Avenue Hippocrate 10, B-1200 Brussels, Belgium (E-mail: mathieu.luyckx@uclouvain.be).

Fertility and Sterility® Vol. 102, No. 5, November 2014 0015-0282/\$36.00
Copyright ©2014 American Society for Reproductive Medicine, Published by Elsevier Inc.
<http://dx.doi.org/10.1016/j.fertnstert.2014.07.1253>

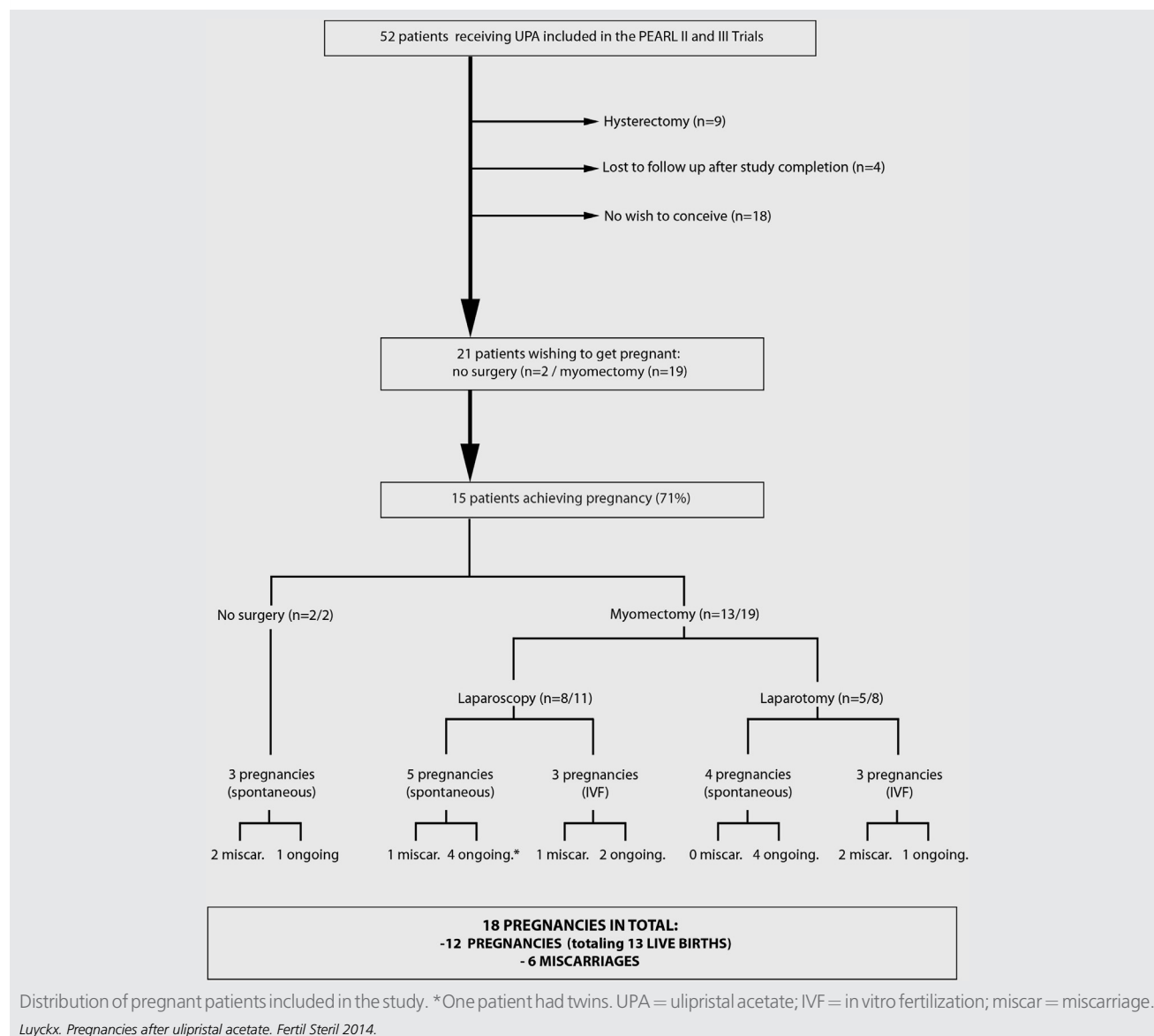
Fifty-two patients with symptomatic fibroids were prospectively included in the PEARL II and PEARL III trials at our institution, according to strict inclusion criteria (2, 5), and received UPA treatment (Fig. 1). This report is a retrospective analysis of pregnancies and births achieved in this series of 52 patients. Ten women were given 5 mg UPA for 3 months (PEARL II) (2), and 42 women received 10 mg UPA for variable periods of time (3 months [n = 27], 6 months [n = 2], 9 months [n = 7], 12 months [n = 6]) according to the PEARL III protocol (5). Among these 52 patients, 21 wished to conceive upon treatment completion and were followed accordingly. Figure 1 shows the distribution of patients.

Of these 21 patients, 19 (90.5%) underwent myomectomy at the end of therapy, according to the protocol.

Two patients did not require surgery because of an almost complete disappearance of their fibroids. The first patient presented with menorrhagia due to uterine myomatosis. She had

no wish to conceive at that time. Uterine volume was equivalent to 10 weeks of pregnancy (Fig. 2A) at the first consultation. (The uterine size was evaluated in weeks of gestation to conform to the protocol accepted by US Food and Drug Administration and European Union regulatory authorities and could not be modified to uterine volume in cm³ retrospectively.) She was given UPA therapy over four courses of 3 months, according to the PEARL III protocol (5). At the end of treatment only tiny myomas remained, and vaginal examination and magnetic resonance imaging (MRI) showed a uterus of normal volume (Fig. 2B). At her checkup 3 months after treatment completion, the fibroids were stable in size. In line with the extension protocol (bis) of the PEARL III study, it was proposed that the patient start another course of UPA treatment, because she had no clear desire for pregnancy. On the first day of menstruation she began taking 10 mg UPA (retrospectively, the bleeding that the patient interpreted as menstrual bleeding

FIGURE 1



Download English Version:

<https://daneshyari.com/en/article/6178792>

Download Persian Version:

<https://daneshyari.com/article/6178792>

[Daneshyari.com](https://daneshyari.com)