Could transvaginal, ultrasound-guided ovarian interstitial laser treatment replace laparoscopic ovarian drilling in women with polycystic ovary syndrome resistant to clomiphene citrate?

A number of novel surgical modalities that destroy or remove some ovarian tissue to restore ovarian function in patients with polycystic ovary syndrome have been described in the most recent literature. Although these modalities were reported to have easy applicability and low cost with shorter hospital stay, the efficacy and safety concerns need to be discussed extensively. (Fertil Steril® 2009;92:2039–40. ©2009 by American Society for Reproductive Medicine.)

Since 2006, three reports on the effectiveness of transvaginal, ultrasound-guided ovarian interstitial laser treatment have been published by Zhu et al. in prestigious journals with high impact factors (1–3). In all of their articles, the authors reported the outcomes of 19, 23, and 80 anovulatory women, respectively, with clomiphene citrate (CC)–resistant polycystic ovary syndrome (PCOS) who underwent transvaginal, ultrasound-guided ovarian interstitial laser treatment. It is assumed that all of the three trials were designed and initiated in 2005.

In their last report (3), the sample size was calculated, and 15 to 20 subjects per group were found to be required to reach 90% power at α = 0.05 level by giving 10% to 20% ovulation rates in one to two points per ovary and 60% to 80% for three to five points. Although the authors have not given full details of the sample size calculation, one can calculate the sample size by using the most optimistic figures, which are as follows: 80% ovulation rates can be expected, and at least 20% difference in ovulation rates between groups might be the reasonable effect size to reveal any clinically meaningful difference among the groups. This makes a 16% difference on the 80% ovulation rates. However, at least 97 subjects would be needed in each group at the α = 0.05 level and β = 0.1 (as the authors did). From the more pessimistic (more realistic) point of view, if 20% ovulation were expected and 20% difference (which makes 4% of the expected rate) were taken as the figures of the sample size calculation, 2,303 patients per group would be needed to reach the same level of significance. If the sample size were recalculated on the basis of the pregnancy rates rather than the ovulation rates the results would be inflated further in each group.

Another issue of debate is the method of randomization used in the last trial (3). The method described in the article is neither clear enough nor appropriate. Besides, clinicians should be blinded to patients’ allocations while they collect the follow-up parameters of the trial.

Although the authors suggested that intraovarian coagulation be created at a spot 10 mm in diameter away from the ovarian surface, the coagulation was kept to at least a 5-mm distance from the surface so that there was minimal damage to the ovarian surface (3). However, it is well known that the intraovarian vessels and main blood supply enter the ovary from the hilum and the blood supply is distributed from the medulla toward the cortex. Thus, there seems to be a potential risk of damaging the cortical blood supply by intraovarian coagulation. On the other hand, with the use of this new technique, the destruction takes place mainly in the medulla rather than the cortex, where most of the antral follicles are located.

Because transvaginal, ultrasound-guided ovarian interstitial laser treatment seems to prevent ovarian surface damage, it might have a theoretical advantage of preventing postoperative adhesion formation over laparoscopic ovarian drilling. However, this has not yet been proved. On the other hand, there may be a risk of unrecognized inadvertent hemorrhage from the ovary and adjacent pelvic organ damage because the technique is not applied under direct visualization.

Additionally, the fiber-optic cable 400 μm in diameter is not easy to be visualized even by using the most advanced ultrasound technology with high resolution. Therefore, another risk associated with the procedure may be an unrecognized ovarian surface perforation if the cable is inserted more than the intended distance. Because the transvaginal, ultrasound-guided ovarian interstitial laser treatment is not performed with the patient under general anesthesia, any unintentional movement of the patient during the procedure potentially may cause inadvertent needle movements inside the ovary. Consequently, this potential risk may have catastrophic consequences in cases where the fiber-optic cable tip reaches beyond the ovarian surface when the laser energy is activated.
Besides, fiber-optic cable transmits the laser beam in one direction along the cable; therefore there is no need to bare the insulated tip of the 10-mm cable and to insert it beyond the tip of the needle. In either case, the laser beam has the potential to damage the surrounding tissues located beyond the tip of the cable.

Although transvaginal, ultrasound-guided ovarian interstitial laser treatment is reported to be cheaper and easier to apply, it necessitates the use of laser equipment, which is expensive and not available everywhere, as well as skilled and experienced personnel. Furthermore, the operation time for the transvaginal, ultrasound-guided ovarian interstitial laser treatment procedure is almost as long as the time for laparoscopic ovarian drilling. On the other hand, transvaginal, ultrasound-guided ovarian interstitial laser treatment seems to be devoid of some of the advantages possessed by laparoscopic ovarian drilling, which are laparoscopic direct visualization of pelvic organs such as the tubo-ovarian relationship, tubal patency, adhesions, and endometriosis.

The second-line intervention recommended by the European Society of Human Reproduction and Embryology/American Society for Reproductive Medicine–sponsored PCOS Consensus Workshop Group, should CC fail to result in pregnancy, is either exogenous gonadotropins or laparoscopic ovarian surgery (4). In a recent randomized controlled trial, Badawy et al. (5) reported the results of ultrasound-guided transvaginal ovarian needle aspiration of visible small follicles without any additional destruction to the ovaries for treatment of PCOS. With the patient under propofol general anesthesia, continuous manual vacuum pressure was used on each ovary with use of a 16-gauge, 35-cm long sharp needle. Three to six punctures were applied from different angles. They recommended that for ease of scheduling, reduced costs, and rapid recovery, this should be a first-line treatment for PCOS cases resistant to CC (5).

According to my previously proposed hypothesis of the effect of surgical therapy on polycystic ovaries, some part of the ovarian tissue has to be removed or destroyed to be effective in any surgical modality in patients with PCOS (6–8). As a conclusion, although this new technique described by Zhu et al. (1–3) seems to be a promising novel treatment method, it has not yet been investigated thoroughly, and further studies for its efficacy and safety should be undertaken.

REFERENCES