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Instruments and techniques

Evaluation of a new surgical approach for the treatment of clomiphene citrate-resistant infertility in polycystic ovary syndrome: Laparoscopic ovarian multi-needle intervention

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KEYWORDS:
Polycystic ovary syndrome;
Laparoscopic ovarian drilling;
Clomiphene-resistant infertility;
Anovulatory cycles

Abstract. Laparoscopic ovarian drilling (LOD) is the accepted second-line treatment for clomiphene citrate-resistant anovulatory infertility in polycystic ovary syndrome (PCOS). Although multiple pregnancy rates are reduced with ovarian drilling procedures, postoperative adhesion formation is a potential complication in up to 85% of the women subjected to laparoscopic destructive ovarian procedures. Our objective was to determine the effectiveness of a new, specially designed laparoscopic device and technique that might enable treatment for patients with anovulatory PCOS with less trauma and fewer postoperative adhesions. Thirty-five infertile clomiphene citrate-resistant women with PCOS were included. Seventeen women underwent laparoscopic ovarian multi-needle intervention (LOMNI), and 18 women received step-up ovulation induction treatment with recombinant follicle-stimulating hormone followed by intrauterine insemination for three cycles. Patients were followed for a period of 6 months after either laparoscopic surgery or the initiation of ovulation induction therapy. Outcome measures were cycle regularity, pregnancy rate, safety, postoperative adhesion formation, and cost effectiveness. There were no significant differences between the two groups in terms of age, body-mass index, duration of infertility, and basal cycle-day 2 hormone levels. Significant improvement in cycle regularity ($p < .01$) was found after LOMNI. Cumulative pregnancy rates (35.3% in the LOMNI group vs 33.3% in the ovulation induction group) did not differ between the groups. No adverse events following surgery were noted. Moderate ovarian hyperstimulation syndrome and multiple pregnancies occurred in four and two patients, respectively, in the ovulation induction group. Eight nonpregnant women in the LOMNI group underwent repeat laparoscopy at the end of the follow-up period. No adhesion formation attributable to LOMNI was observed in any of those eight women. The cost of LOMNI was significantly ($p < .001$) lower than the ovulation induction treatment. In conclusion, LOMNI may be a safe, inexpensive, and effective procedure for the treatment of CC-resistant infertility in patients with PCOS. It seems to preserve the beneficial effects and probably omits unwanted effects (such as adhesion formation) of LOD.

A gold standard treatment algorithm for clomiphene citrate (CC)-resistant polycystic ovary syndrome (PCOS) has not been established. Several explanations for failure to respond to CC include precocious or impaired oocyte maturation secondary to excessive luteinizing hormone (LH) secretion in the follicular phase, premature luteinization following an untimely LH surge, increased follicle atresia, and variable implantation rates.[1] Induction of ovulation with exogenous gonadotropins has some shortcomings, such as increased risk of cycle cancellations, ovarian hyperstimulation syndrome (OHSS), and multiple pregnancies. The supplemental use of gonadotropin-releasing hormone agonists

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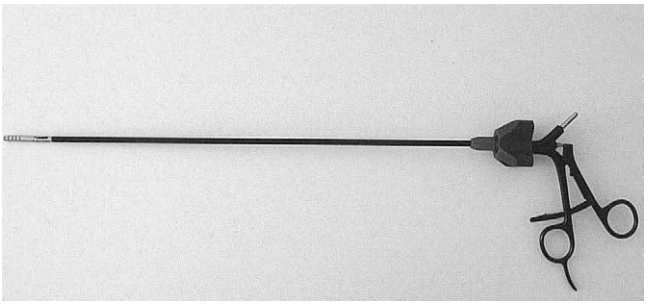

Figure 1 Panoramic view of the specially designed instrument.

or antagonists and metformin has been proposed to avoid these detrimental effects.[1–3] However, some women will not respond to such supplemental therapy, and the risk of multiple pregnancies is not thoroughly eliminated.

Laparoscopic treatment of patients with PCOS who fail to ovulate with CC can result in spontaneous ovulation. This therapy can be performed at the time of a planned diagnostic laparoscopy in a patient with known anovulation and polycystic ovaries.[1] The mechanism may involve reduction in ovarian androgen production through decrease in stromal mass or disruption of parenchymal blood flow.[4] Laparoscopic ovarian drilling (LOD) has been used as a second-line treatment for CC-resistant PCOS as the modern equivalent of the original ovarian wedge resection.[1] However, LOD may be associated with decreased ovarian reserve in the long term.[4] Increased periovarian adhesions that might potentially interfere with fertility are another problem.[4–7]

In the current study, we present our experience with a specially designed device and new technique for laparoscopic treatment of CC-resistant PCOS. We evaluated the outcomes of this procedure, laparoscopic ovarian multineedle intervention (LOMNI), after a 6-month-period. We also investigated pelvic adhesion formation in a subset of women in the postoperative period.

Materials and methods

Thirty-five infertile CC-resistant women with PCOS were prospectively evaluated from January 2000 through January 2004. All women had anovulatory infertility of greater than 1 year's duration. Women with a history of abdominopelvic surgery (including any laparoscopic interventions), any systemic disease, proven or suspected pelvic inflammatory disease, or ectopic pregnancy had been excluded. Resistance to CC was considered when mature follicle (≥14 mm in diameter) development on serial transvaginal ultrasonographic folliculometry was not observed following treatment with CC on cycle-day 5 to 9 at up to 200 mg/day doses. Polycystic ovary syndrome was diagnosed by hormonal (cycle-day 2 LH/follicle-stimulating hormone [FSH] ratio >2) and ultrasound (ovarian stromal hypertrophy accompanied by multiple 4- to10-mm follicles in periphery) parameters. The study was subject to approval by the institutional review board, and patient consent was obtained before all surgical interventions. Candidates were allocated into two groups using sealed opaque envelopes in a computer-generated random sequence: 17 women underwent LOMNI, and 18 women received step-up ovulation induction treatment with recombinant FSH followed by intrauterine insemination for three cycles.

Laparoscopic ovarian multi-needle intervention was performed as follows. Under general anesthesia, the patient was prepared for laparoscopic surgery in the usual manner. The patient's legs were placed in frog-leg position. A 10-cm Veres needle was placed through the anterior abdominal wall at the lower margin of the umbilicus. Pneumoperitoneum was established with approximately 4 L of CO_2. An operating laparoscope was inserted following umbilical trocar insertion, and a 5-mm single ancillary port was placed in the midline suprapubic area. After careful inspection of the pelvis, both ovaries and tubes were fully visualized and mobilized from surrounding structures using a blunt probe. A specially designed laparoscopic instrument (Kaya laparoscopic drilling device; Aygun Medical Devices Limited Company, Samsun, Turkey) was inserted through the 5-mm ancillary port. This instrument is 37 cm long with a distal grasper-like tip containing two prongs (Figure 1). Each prong is 25 × 4 mm in area and consists of 10 needle-like teeth, which are 2 mm in length and 0.4 mm in diameter (Figure 2). The maximum opening distance achieved between the two rows of teeth is 30 mm. Ovarian tissue was placed between the jaws of the instrument and squeezed by applying some force. The instrument was slipped over to the neighboring untreated ovarian tissue, its jaws closed again, and consequently the entire ovarian surface was subjected to this procedure. Any systems that yield energy such as electrocautery or laser were not used. The contralateral ovary was also similarly treated.

Step-up protocol for induction of ovulation with exogenous recombinant gonadotropins[1] and ovulation stimulation using recombinant human chorionic gonadotropin[1] (HCG) were carried out. Intrauterine insemination with the use of

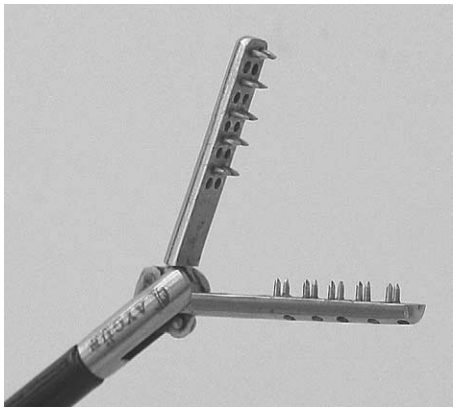

Figure 2 Close-up view of the instrument showing its prongs and needle-like millimetric teeth. Ovarian tissue is squeezed between the jaws.