Hysteroscopic Sterilization Device Nears Market

BY PATRICE WENDLING
Chicago Bureau

The Adiana transcervical sterilization system appears to be easy to use, safe, and effective, according to phase III data, Alan Johns, M.D., reported at the annual meeting of the AAGL.

The Adiana Complete system is available only for experimental use, but U.S. Food and Drug Administration submission is anticipated in mid-2006, said Dr. Johns, one of the clinical investigators in the trial.

The FDA approved Essure, currently the only nonincisional approach to female sterilization, in November 2002. The Adiana system "is the next step in the evolution of hysteroscopic devices," Dr. Johns said in an interview. It may be better than the Essure simply because it doesn't require as much manipulation and the whole device is altogether shorter and easier to put in and cannulate, he said. "More importantly, in contrast to the Essure system, after the Adiana matrix has been deployed, nothing remains in the endometrial cavity."

This may be important in women who later choose to undergo in vitro fertilization or endometrial ablation, because these options can be limited by the presence of a portion of a device in the endometrial cavity, he said.

The Adiana system also differs from Essure in that it uses radio frequency energy before placement of the polymer matrix in the fallopian tubes. This process is designed to stimulate vascularized tissue ingrowth into the matrix material, said Dr. Johns of Fort Worth, Tex. He accepted payment to enroll and treat patients in the trial but said he has no financial interest in Adiana Inc.

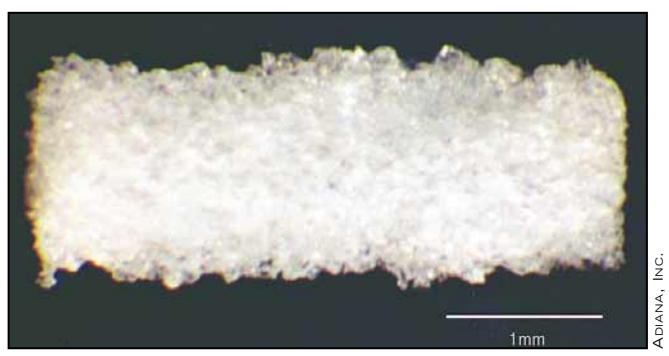
As of Sept. 30, 2005, the Evaluation of the Adiana System for Transcervical Sterilization Using Electrothermal Energy in Women (EASE) study had enrolled 770 women at 16 sites. Almost half (47%) were aged 28-33 years. A total of 655 patients were taken for hysteroscopy, and 10 were excluded for hysteroscopic findings. The remaining 115 patients either withdrew from the study or were excluded from the study protocol.

Treatment was attempted in 645 patients and bilateral placement was achieved in 614 (95%).

This placement rate is comparable with that attained by Essure in its clinical trials, he said. Lateral location of the ostia is the most common reason for failure of placement of hysteroscopic sterilization devices.

The average procedure time from insertion to removal of the hysteroscope was 12 minutes. Local and oral anesthesia was used in 35% of patients, local anesthesia plus intravenous sedation in 48%, and local plus intravenous analgesia in 17%. Nine patients were lost to follow-up or are awaiting 3-month hysterosalpingogram (HSG).

Failure of tubal occlusion occurred in 26 (4.29%) women, and there were two pregnancies. One occurred after proper placement of the device and HSG confirmation of occlusion. The second occurred when a physician misinterpreted the HSG and retreated the patient but placed the device in the occluded tube instead of the patent tube. There were no device-related significant adverse events. One procedure-related incident of hyponatremia was reported. All other events were minor and included spotting, cramping, and headache. ■



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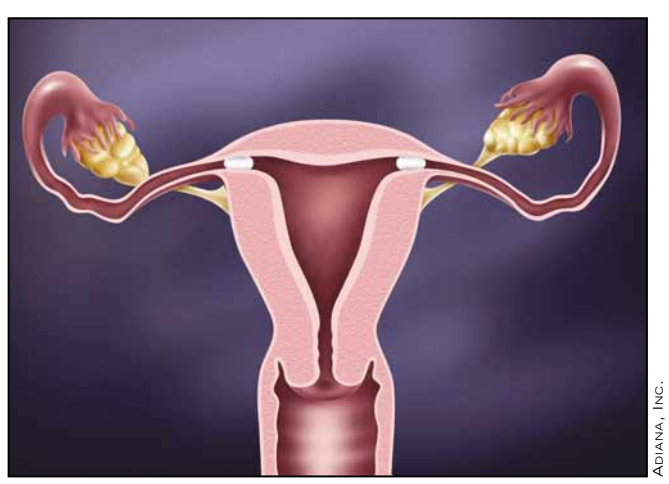
Radiofrequency energy is used before the Adiana implantable matrix is placed in the fallopian tubes.


ADIANA, INC.

After the Adiana polymer matrix has been deployed, nothing remains in the endometrial cavity.

Complications Are Rare With Laparoscopic Myomectomy

BY SHERRY BOSCHERT
San Francisco Bureau

SAN DIEGO — Complications occurred in 11% of 2,051 patients who underwent laparoscopic myomectomy, which compares favorably with a complication rate of 35% for myomectomy performed by laparotomy—a figure that has been reported in the literature, Rocco Spagnolo, M.D., said at an international congress of the Society of Laparoendoscopic Surgeons.

The new data come from the first large series of cases studied with a focus on complications from laparoscopic myomectomy. The multicenter Italian study reviewed patient records retrospectively and recorded complications prospectively, he said.

Experienced surgeons who had completed the learning curve for the procedure performed the surgeries using the same techniques.

Patients underwent single or multiple myomectomies for symptomatic myomas measuring at least 4 cm in diameter to treat abnormal bleeding in 45% of cases, pain or a pelvic mass in 28%, and infertility in 27%.

Minor complications such as fever, cystitis, and lesions due to uterine manipulation occurred in 9% of patients. Major complications were seen in 2%, according to Dr. Spagnolo of Rome.

Among the most serious complications were hemorrhages in 14 patients (0.7%), 3 of whom required transfusions (0.1%). Postoperative hematomas occurred in 0.5% of patients, one in the broad ligament and the others in the myomectomy scar. One patient suffered a bowel injury. Constant hypotension during surgery led to postoperative acute renal failure in one patient.

Surgeons found unexpected sarcomas in two patients. In one of these cases they immediately converted to laparotomy. In the other case, although the mass looked like an adenomyoma and a frozen section was negative for malignancy, the cancer was diagnosed later upon histologic examination.

Minor complications occurred in 9% of patients, and major complications were seen in 2%.

DR. SPAGNOLO

Five other cases were converted to laparotomy: three due to anesthesia problems and two because of a lack of space and limited mobility. One case was converted to laparoscopic hysterectomy due to a large intraligamentous myoma occupying most of the lateral part of the uterus.

Two patients were readmitted for surgery. One with severe hemorrhage underwent laparoscopic hysterectomy, and the other had a hematoma in the broad ligament drained.

Among the 185 pregnancies that occurred after the surgery, one patient had a uterine rupture. A majority (65%) of patients who wanted to become pregnant were able to do so. ■

Be Selective in Hysterectomy Performed for Menometrorrhagia

SAN DIEGO — Identify and treat abdominal pelvic pain or dyspareunia originating from bladder problems before performing supracervical hysterectomy for menometrorrhagia, Maurice K. Chung, M.D., advised at an international congress of the Society of Laparoendoscopic Surgeons.

By selecting only patients who are free of pain and dyspareunia and by transecting the uterus and part of the upper cervix, he said, postoperative spotting or bleeding can be avoided.

Patients who still have abdominal pelvic pain or dyspareunia after management of bladder problems should not be candidates for supracervical hysterectomy because of the risk that pain symptoms will persist after the procedure, leading to a second surgery to remove the cervix, said Dr. Chung, who has a private practice in Toledo, Ohio.

He reported on 42 laparoscopic supracervical hysterectomies he performed for menometrorrhagia from 2002 to 2004. Of the 42 women, 13 also presented with abdominal pelvic pain and dyspareunia underwent potassium sensitivity tests, which were positive in 12 patients, pointing to bladder problems as the cause of the pain. He treated all 13 medically for bladder problems until they were pain free before proceeding to laparoscopic supracervical hysterectomy.

Thirteen of the 42 patients had adenomyosis, and 6 of those had symptoms of abdominal pelvic pain or dyspareunia, in addition to menometrorrhagia. Five of the six had positive potassium-sensitivity tests, and medical treatment resolved their pain before proceeding to surgery.

Of 42 patients, none reported any postoperative bleeding or spotting, which may have been due to selection.

DR. CHUNG

The laparoscopic supracervical hysterectomies included endoscopic suturing of the bilateral ascending uterine arteries at the mid-cervix. Patients were followed for 6 months to 2 years.

In general, about 10% of women who undergo laparoscopic supracervical hysterectomy report postoperative spotting or bleeding. Twelve women in the current study underwent concomitant bilateral salpingo-oophorectomy. No bleeding or spotting would be expected after this surgery unless the patient started hormone therapy.

None of the 42 patients reported any postoperative bleeding or spotting, which Dr. Chung said was most likely due to a careful selection of patients. Selecting patients for surgery who have only menometrorrhagia will increase the rate of amenorrhea, he said.

—Sherry Boschert