Protocol Eases Switch to Office-Based Ablation

Guidelines from the ACS, ASA, and liability insurance providers are included in the protocol.

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CHICAGO — Global endometrial ablation can be performed easily and safely in the office as long as physicians are adequately prepared and strictly adhere to protocols, Dr. Ted Anderson said at the annual meeting of the AAGL (formerly the American Association of Gynecologic Laparoscopists).

Dr. Anderson and his associates developed a protocol incorporating guidelines for office-based procedures from the American College of Surgeons, American Society of Anesthesiologists (ASA), personal or published accounts, and professional liability insurance providers.

Some of its primary considerations are:

► Strict adherence to the indications and contraindications for each technique.

► Thorough diagnostic evaluation. Imaging and sampling should be done in advance to avoid surprises and to determine the thickness of the myometrium, a frequently overlooked aspect.

"Doing these procedures in the office is not the place for an atypical patient or an atypical uterus," he said. "You want a straightforward procedure, don't take risks, and keep in mind that doing this procedure in your office is not just simply changing the place that you're doing it. It's a mentality that you're changing as well. You need to be absolutely comfortable before you move to the office."

► Careful patient selection. Consider American Society of Anesthesiologists class I or II patients only. Avoid patients with comorbid conditions such as asthma, anxiety, obesity, or heart disease which might decompensate in the office.

► Consider psychosocial issues. Look for clues during the biopsy for how well the patient might tolerate an in-office procedure. Make sure she has realistic expectations of the procedure and its outcomes.

► Anesthesia considerations. Start with full sedation in the operating room (OR) and slowly lessen the anesthesia over time as you become confident in your technique. Operate at this reduced level of anesthesia in the OR before moving the procedure to your office.

"Ultimately, how you may modify the exact nature of the anesthesia will be dictated by your comfort level and the technology you use," said Dr. Anderson of Vanderbilt University Medical Center, Nashville.

► Ergonomic considerations. Reduce the instrumentation in the OR to exactly what you will have available in your office. Ultimately, you want to be performing the procedure in the operating room exactly the way you plan to do it in the office.

► Use oral NSAIDs and intravenous ketorolac (Toradol) 30 mg up to an hour before the procedure, and paracervical blocks in all patients.

► Patient monitoring. If you're going to use conscious sedation, have someone present with advanced cardiac life support certification or someone who is a certified registered nurse anesthetist. Resuscitation and stabilization equipment should be readily available in the event that the patient decompensates and needs to be stabilized or moved to another facility.

► Physician preparation. Have absolute comfort with the technology and technique, and your ability to perform that technique. Written protocols should be in place that detail how and what you are going to do. Regulatory agencies and professional liability carriers will demand them.

The protocol, "Office-based Endometrial Ablation: paradigm for the future," is available free of charge from CME Outfitters of Rockville, Md., 240-243-1300, www.cmeoutfitters.com. ■

Adherence to Protocols Would Cut Injury Risk in Endometrial Ablation

CHICAGO — The risk of injury occurring during global endometrial ablation could be greatly reduced if physicians simply followed protocols, Dr. Howard T. Sharp said at the annual meeting of the AAGL (formerly the American Association of Gynecologic Laparoscopists).

An analysis of 387 reports with 186 injuries in women who underwent global endometrial ablation showed that 24.2% (45/186) of overall complications and 36.5% (42/115) of all major injuries potentially could have been avoided by strict adherence to intraoperative protocols and technique.

A history of cesarean delivery, even via low transverse hysterotomy, also was identified as a potential risk factor.

Data were culled from the Food and Drug Administration's Manufacturer and User Facility Device Experiences (MAUDE) database from patients undergoing global endometrial ablation surgery via a wide range of techniques between January 1998 and April 2005.

A checklist could be used to make sure procedures are being performed in the appropriate patients and to stay within manufacturers' recommendations.

Primary injuries found in these patients included genital tract burns (43), bowel burns (39), uterine perforation (33), infection (30), and uterine/cervical scarring (19).

The ratios of injuries to potentially avoidable injuries by method were microwave endometrial ablation 11/9 (82%), NovaSure (radiofrequency ablation) 35/12 (34%), Her Option (cryoablation) 12/1 (8%), hydrothermablation 33/10 (30%), and ThermaChoice (uterine balloon ablation) 95/18 (19%).

Reporting adverse events to the MAUDE database is mandatory for manufacturers of medical devices, but reporting these events is voluntary for providers.

The reporting requirement could result in some duplication, but it's more likely injuries are underreported, in part because of fear of potential litigation, said Dr. Sharp of the University of Utah, Salt Lake City.

"Everyone is worried about it," he said. "The key thing is to be worried about patient safety, which is why a checklist is so important."

He suggested that physicians adopt a checklist similar to ones used by pilots, to make sure procedures are being performed in the appropriate patients and to stay within manufacturers' recommendations.

Physicians also should consider using saline infusion sonography in patients with a history of cesarean section, provide adequate anesthesia, recognize that two ablations at the same setting are not better than one, avoid modifying the device or surgery, and have an exit strategy should complications arise, he said.

In a separate presentation on the same topic, Dr. Carl Della Badia and Dr. Ata Atogho of Drexel University College of Medicine, Philadelphia, concurred that the majority of serious adverse events occur when endometrial devices are used outside of the manufacturers' recommendations.

But they also concluded that the MAUDE database shouldn't be used to determine the safety of a particular ablation device because not all cases are reported, information is sketchy, and the database doesn't take into account that some devices are more widely used than others.

In addition, several device modifications are underway or have recently been made that could have an impact on outcomes, Dr. Della Badia said.

Improvements include a new tenacula for the hydrothermablation device, a new balloon for the ThermaChoice device, and a smaller probe with a new cervical stop for the microwave endometrial ablation system. ■

In-Office Placement of Essure Feasible and Fast, Study Shows

CHICAGO — Essure hysteroscopic sterilization may be performed in an office setting with minimal analgesia, Dr. Gil A. Weiss said at the annual meeting of the AAGL (formerly the American Association of Gynecologic Laparoscopists).

Physicians reported a 94% placement rate, which is comparable to the 86% rate seen in previous phase II and pivotal trials of the Essure device (Conceptus Inc., San Carlos, Calif.).

"It's reassuring that we had comparable success rates," Dr. Weiss said in an interview. "Once the learning curve is achieved, I believe that the office placement offers unique benefits that a hospital-based procedure cannot."

He presented data from a prospective study in which 155 women underwent bilateral hysteroscopic placement of the Essure device in an office setting at the Montefiore Medical Center, Bronx, N.Y.

A paracervical block and NSAIDs were provided for pain and for control and reduction of tubal spasm. The average patient age was 36 years, parity 2.7, and body mass index 30, which is classified as obese.

The rates of the confounding factors included the following: 34% of the patients had undergone cesarean section, 14% had a history of pelvic infections, and 44% had prior abdominal or pelvic surgery, which would have confounded a laparoscopic approach.

Of the 155 patients, 146 (94%) had successful bilateral placement and 9 had anatomic considerations that prevented placement, said Dr. Weiss, a fellow at the Albert Einstein College of Medicine, Bronx, N.Y., who participated in the study and presented the data on behalf of the authors, Dr. Mark D. Levie and Dr. Scott G. Chudnoff, both of Montefiore Medical Center.

To date, hysterosalpingographies performed on 106 of the 155 women revealed bilateral occlusion in 104.

Three patients had initial unilateral occlusion. One patient had another device placed with confirmed bilateral occlusion, one is awaiting a repeat hysterosalpingography, and one aborted the device into the uterus and underwent subsequent laparoscopic sterilization.

No patient required hospitalization or narcotic analgesia, and most left the physician's office within 1 hour.

Pain data that was collected on 114 women showed the average procedural pain level was 2.65 on a scale of 1 to 10, with the average menstrual pain 3.28 on a similar scale.

Follow-up on 73 women showed 95% would undergo the procedure again, 99% would recommend it to a friend, and 90% would choose the office setting again.

Dr. Weiss and Dr. Chudnoff have no financial disclosures related to Conceptus.

Dr. Levie is a consultant for Conceptus. ■