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Instruments and techniques

Ultrasound-directed transvaginal myolysis: Preclinical studies

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Abstract. The ultimate goal is to develop a safe vaginal ultrasound-directed myolysis needle to treat uterine myomas. The specific preclinical study objective was to determine the optimal power to coagulate myomas in hysterectomy specimens with a prototype needle in a prospective preclinical study with an echogenic insulated needle electrode. In phase I of the study, myolysis was performed with ultrasound guidance at various powers and times. In phase II, a 20-W coagulating current was applied at defined distances from the serosa and surface temperatures measured. Myolysis with 10 to 20 W applied 5 to 10 seconds was optimal, because tissue popping occurred at 30 W or more when the needle was 5 mm or less from the serosa. The serosal temperature was never elevated above physiological ranges at any distance at this setting. Ultrasound-directed transvaginal myolysis may provide another option for women with uterine myomas if it is proven safe and effective in future clinical studies. On the basis of the observations in these preclinical studies, myolysis with 20 W for 10 seconds should be a safe parameter for clinical research, because there is no increased serosal temperature at these settings.
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The ultimate goal of our group is to develop a safe, simple, and effective vaginal ultrasound–directed myolysis needle as a treatment option for women with uterine myomas. Before studying the vaginal ultrasound–directed myolysis needle in a clinical setting, pilot studies are needed to determine: (1) the optimal power setting (wattage) to coagulate a myoma; (2) the optimal time to coagulate a myoma; and (3) the serosal surface temperature increase with coagulation at different distances from the serosa to determine how close to the serosal surface the myoma needle can be used. These parameters can be assessed in hysterectomy specimens immediately after removal for uterine myomas without exposing patients to surgical risk.

Material and methods

The first preclinical study (phase 1) was a controlled experimental trial to determine the optimal power and time needed to coagulate myomas. For this, we used a prototype vaginal ultrasound-directed myolysis needle (U.S. patent number 6,936,048) and treated 8 fresh hysterectomy specimens. The "optimal" power was considered the highest energy and least time to provide coagulation without raising surface temperature or causing tissue popping. Popping occurs when rapid heating produces pockets of vapor under pressure, leading to a sudden bursting of tissue and a characteristic popping sound. Tissue popping is considered un-

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Figure 1 Prototype needle was manufactured from a Cook 16-gauge Echotip in vitro fertilization aspiration needle, insulated with polyolefin, and attached to a standard Bovie (Bovie Medical Corporation, St. Petersburg, FL) hand-held electrosurgical pencil.

acceptable because of potential damage that could occur to adjacent organs in a clinical setting from tissue boiling and gas production.

The prototype needle was manufactured from a Cook 16-gauge Echotip in vitro fertilization aspiration needle (Cook Ob/Gyn, Inc., Spencer, IN), insulated with polyolefin, and attached to a standard handheld electrosurgical pencil (Figure 1) and connected to a standard Valley Lab Force II (Boulder, CO) generator. The Carolinas HealthCare System Institutional Review Board (IRB) consent was obtained for the 8 women undergoing hysterectomy for multiple symptomatic uterine myomas. Eight hysterectomy specimens with at least 4 uterine myomas were used for this phase of the study, and 4 or 5 ultrasound-accessible myomas from each specimen were treated as noted below.

Immediately after hysterectomy, the uterus was placed on a return electrode pad, and testing was started. Myomas were identified with a G.E. Voluson 730 (Waukesha, WI) transvaginal ultrasound probe placed on the uterine serosal surface. The myolysis needle was advanced to the myoma/myometrium interface using ultrasound guidance. Of the 8 hysterectomy specimens used in the first study, the median diameter of myomas treated was 18 mm (range 35 mm; max-minimum diameter 9-35 mm). Coagulation currents of 10-, 20-, 30-, and 40 W were each studied at 5-, 10-, 15-, and 20 seconds. Controls included 3 noncoagulated myomas. Three tests were done at each power and time setting, determined by computer randomization.

A surface digital Omegaette HH306 Thermometer (Stamford, CT) was used to record the uterine serosal surface temperature during coagulation, with placement of the temperature probe on the serosal surface nearest to the myolysis needle tip. Up to 5 sites were treated per uterus.

Tissue popping was assessed by noting the characteristic sudden loud sound. Ultrasound visualization and the ease of needle placement were assessed as "easy," "intermediate," or "difficult." It was important to ensure that the needle did not damage the ultrasound equipment, because this would have resulted in failure of the study.

The second preclinical study was a prospective trial to ensure that excessive serosal heating (temperature >40° C) did not occur with the time and power setting established in phase 1. The same prototype needle was used for phases 1 and 2. IRB consent was obtained. Immediately after hysterectomy, the uterus was placed on a return electrode. The needle was positioned at defined distances from the serosa (10 mm, 15 mm, 20 mm, 25 mm, and 30 mm), and a coagulating current 20 W was applied for 10 seconds. A digital thermometer recorded serosal temperatures. This entire series was repeated in 5 hysterectomy specimens.

Results

During the initial study, tissue popping occurred twice: once at 40 W for 15 seconds, when the needle tip was 4 mm from the serosa, and once at 30 W for 10 seconds, again when the needle tip was near the serosa. These observations were used to determine the wattage and time for the second phase of the study.

Figure 2 shows the change in mean surface temperature at each wattage and coagulation time used for this study. Of note, the surface temperature was never elevated above physiological ranges at any temperature setting. The surface temperature was unaffected at 10 and 20 W, regardless of the coagulation times used. In addition, there was no change in surface temperature when coagulation was performed for 5 seconds, regardless of the wattage used. However, the temperatures tended to be slightly elevated with 30 W or more and time 10 seconds and longer. From these observations, the optimal power appears to be 20 W, although 30 and 40 W for 5 seconds may also be acceptable.

Ultrasound visualization was excellent. Ultrasound images were lost only during activation of the electrical generator, and the vaginal probe was not damaged. The surface thermometer recorded peak temperatures within a few seconds after myolysis was completed. Histologic samples

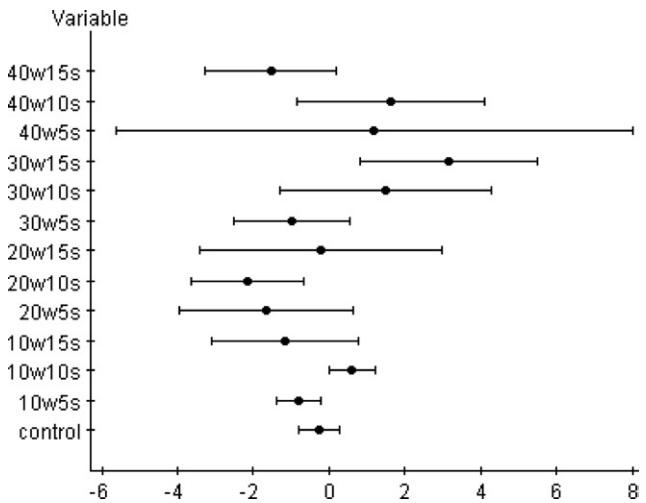

Figure 2 Change in mean surface temperature ± SD in °C for all settings of time and wattage used during phase 1. The distances to the uterine serosa were not controlled in study phase 1.

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