Laparoscopic radiofrequency volumetric thermal ablation (Acessa System; Halt Medical Inc.) for treatment of uterine fibroids

HAYES, Inc

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' objectives
Uterine fibroids (also called leiomyomata or myomas) are common benign tumors of the myometrium, the smooth muscle layer of the uterus. They can produce pain, pressure, frequent and heavy bleeding, infertility, urinary frequency, dyspareunia, and miscarriage. Complications associated with common treatments include hemorrhage, abdominal adhesions, and interruption of uterine integrity. Medical management often only provides short-term relief. Description of Technology: The Acessa System (Halt Medical Inc.) is a minimally invasive, ultrasound-guided system for performing laparoscopic radiofrequency volumetric thermal ablation (RFVTA) of fibroids in the outpatient setting. The system includes a dual-function generator and a disposable handpiece equipped with a 7-electrode array. Standard laparoscopic ports are used and the Acessa handpiece is inserted through a small skin incision under laparoscopic guidance. After laparoscopic ultrasound confirms the location of the fibroids, the handpiece is inserted 1 centimeter into the tumor and the electrode array is deployed. Real-time feedback on the anatomical location of the probe and the temperature of the tissue aid in targeting the area of tissue and avoiding damage to surrounding normal structures. Multiple fibroids may be treated through a single uterine puncture. In addition to radiofrequency energy for ablation, the generator also performs traditional electrocautery for control of bleeding. Patient Population: The Acessa System is indicated for use in percutaneous laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. Clinical Alternatives: Treatments for uterine fibroids include medical management, hysterectomy, myomectomy (open, laparoscopic, robotic, or hysteroscopic), radiofrequency ablation, uterine artery embolization, laser ablation, cryoablation, and magnetic resonance–guided or ultrasound-guided HIFU. Other RFVTA devices are available, including those that are employed via a transvaginal route.

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