

A Randomized, Multicenter Trial of Safety and Efficacy of the NovaSure System in the Treatment of Menorrhagia

Jay Cooper, M.D., Richard Gimpelson, M.D., Philippe Laberge, M.D., Donald Galen, M.D., Jose Gerardo Garza-Leal, M.D., Josef Scott, M.D., Nicholas Leyland, M.D., Paul Martyn, M.D., and James Liu, M.D

Abstract

Study Objective. To compare the safety and effectiveness of the NovaSure impedance-controlled endometrial ablation system with hysteroscopic wire loop resection plus rollerball ablation for treatment of excessive uterine bleeding in premenopausal women.

Design. Randomized, multicenter, double-arm study (Canadian Task Force classification I).

Setting. Nine academic medical centers and private offices.

Patients. Two hundred sixty-five premenopausal women with symptomatic menorrhagia.

Intervention. Ablation performed with the NovaSure system or wire loop resection and rollerball.

Measurements and Main Results. Success [pictorial blood loss-assessment chart (PBLAC) score ≤ 75] was achieved in 88.3% of NovaSure-treated and 81.7% of rollerball-treated patients. One year after treatment 90.9% and 87.8%, respectively, reported normal bleeding or less (PBLAC ≤ 100) and 41% and 35%, respectively, experienced amenorrhea (PBLAC = 0). Mean procedure time was 4.2 minutes (average 84 sec) in the NovaSure group and 24.2 minutes in the rollerball group. Local and/or intravenous sedation was administered in 73% of NovaSure patients and 18% of rollerball patients. Intraoperative adverse events occurred less frequently with NovaSure (0.6%) than with rollerball (6.7%). Postoperative adverse events occurred in 13% and 25.3% of patients, respectively.

Conclusion. The NovaSure system was safe and effective in treatment of women with menorrhagia. The procedure is both quick and effective, and eliminates the expense and side effects of endometrial pretreatment.

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From the Department of Obstetrics and Gynecology, University of Arizona School of Medicine, Phoenix, Arizona (Dr. Cooper); Department of Obstetrics and Gynecology, St. Louis School of Medicine, St. Louis, Missouri (Dr. Gimpelson); CHUQ, Pavillon CHUL, Saint-Foy, Quebec (Dr. Laberge); Department of Obstetrics and Gynecology University of California, Davis, San Ramon, California (Dr. Galen); Department of Obstetrics and Gynecology, University Hospital Dr. Jose E. Gonzalez, Monterrey, Mexico (Dr. Graza-Leal); Department Obstetrics and Gynecology, Division of Reproductive Endocrinology, University of Alberta, Edmonton (Dr. Scott); Mount Sinai Hospital and University Health Network, Toronto, Ontario (Dr. Leyland); Department of Obstetrics and Gynecology, Calgary Health Region, Calgary, Alberta (Dr. Martyn); and University Hospitals, Cleveland, Ohio (Dr. Liu).

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Address reprint requests to Jay Cooper, M.D., Ob/Gyn Consultants, 6036 North 19th Avenue, Suite 401, Phoenix, AZ 85015; fax 602 249 1377.

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