ORIGINAL ARTICLE: REPRODUCTIVE SURGERY

In-bag manual versus uncontained power morcellation for laparoscopic myomectomy: randomized controlled trial

Roberta Venturella, M.D.,[a] Morena L. Rocca, M.D.,[a] Daniela Lico, M.D.,[a] Nicolò La Ferrera, M.D.,[a] Roberto Cirillo, M.D.,[a] Salvatore Gizzo, M.D.,[b] Michele Morelli, M.D., Ph.D.,[a] Errico Zupi, M.D.,[c] and Fulvio Zullo, M.D., Ph.D.[a]

[a] Unit of Obstetrics and Gynaecology, Department of Experimental and Clinical Medicine, "Magna Graecia" University, Catanzaro; [b] Department of Woman and Child Health, University of Padua, Padua; and [c] Department of Biomedicine and Prevention, "Tor Vergata" University of Rome, Rome, Italy

Objective: To evaluate whether manualin-bag morcellation could be efficiently proposed as alternative to the uncontained power technique.
Design: Randomized controlled trial.
Setting: Academic hospital.
Patient(s): One hundred fifty-two premenopausal women eligible for myomectomy were screened, and 104 were randomized.
Intervention(s): Patients were randomized into two groups. In the experimental group, "in-bag" protected morcellation was performed. In the control group, patients were treated by uncontained power myoma removal.
Main Outcome Measure(s): The primary endpoint was the comparison of morcellation operative time (MOT). The secondary endpoints were the comparisons of total operative time (TOT), simplicity of morcellation (as defined by the surgeon using a visual analogue scale scale), intraoperative blood loss, rate of complications, and postoperative outcomes.
Result(s): A sample size of 51 per group (n = 102) was planned. Between March 2014 and January 2015, patients were randomized as follows: 53 to the experimental group and 51 to the control group. Most demographic characteristics were similar across groups. MOT was observed to be similar in both study groups (16.18 ± 8.1 vs. 14.35 ± 7.8 minutes, in the experimental and control groups, respectively). Fibroid size was identified as the principal factor influencing morcellation time (Pearson coefficient 0.484 vs. 0.581, in the experimental and control groups, respectively). No significant difference in TOT, simplicity of morcellation, delta Hb, postoperative pain, and postoperative outcomes were observed between groups.
Conclusion(s): The protected manual in-bag morcellation technique represents a time-efficient and feasible alternative, which does not interfere with surgical outcomes in women undergoing laparoscopic myomectomy.
Clinical Trial Registration: NCT02086435. (Fertil Steril® 2016;■:■–■. ©2016 by American Society for Reproductive Medicine.)
Key Words: Fibroid, in-bag morcellation, myomectomy, power morcellation, sarcoma

Discuss: You can discuss this article with its authors and with other ASRM members at http://fertstertforum.com/venturellar-in-bag-morcellation-uterine-myoma/

Use your smartphone to scan this QR code and connect to the discussion forum for this article now.*

* Download a free QR code scanner by searching for "QR scanner" in your smartphone's app store or app marketplace.

Uterine leiomyomas are frequent benign neoplasms, with an estimated incidence of 20%–80% in reproductive-age women, depending on diagnostic modality, symptomatology, or race (1, 2). When symptomatic, they adversely affect women's quality of life, causing menorrhagia, anemia, and loss of fertility (2). Thus, in symptomatic women desiring offspring, conservative surgery is mandatory to improve general well-being and achieve pregnancy.

Compared with the open approach, laparoscopic myomectomy decreases morbidity and length of hospitalization (3). While recent years have seen a wide diffusion and increasing use of laparoscopy, the long-term sequelae of such a practice are still to be investigated.

Received October 26, 2015; revised December 10, 2015; accepted December 21, 2015.
R.V. has nothing to disclose. M.L.R. has nothing to disclose. D.L. has nothing to disclose. N.L.F. has nothing to disclose. R.C. has nothing to disclose. S.G. has nothing to disclose. M.M. has nothing to disclose. E.Z. has nothing to disclose. F.Z. has nothing to disclose.
Reprint requests: Morena L. Rocca, M.D., Unit of Obstetrics and Gynaecology, Department of Experimental and Clinical Medicine, "Magna Graecia" University, Viale Europa, loc. Germaneto, 88100 Catanzaro, Italy (E-mail: morenarocca@hotmail.it).

Fertility and Sterility® Vol. ■, No. ■, ■ 2016 0015-0282/$36.00

http://dx.doi.org/10.1016/j.fertnstert.2015.12.133

A current example of possible sequelae relates to the use of the power morcellator, an instrument with a fast rotating cylindrical knife, which divides large masses of tissue, allowing extraction of smaller fragments through the abdominal cavity (4). The chief issue related to its use is the risk of dissemination of tissue fragments and the occurrence of peritoneal leiomyomatosis or, even worse, the spreading of unsuspected uterine sarcomas within the pelvis and the abdomen, significantly worsening the patient's long-term survival.

In April 2014 the Food and Drug Administration (FDA) published a press release discouraging the use of power morcellation owing to potential upstaging of uterine sarcoma, despite the rarity of this circumstance, which is reported to range from 0 to 0.49% in patients with presumed fibroids (4, 5).

To date, no diagnostic modalities are available to preoperatively differentiate benign from malignant uterine tumors (6–8), and this is the main concern about the current management of sarcoma. The validation of alternative surgical techniques for the safe removal of surgical specimens (myomas or the entire uterus) is vital.

The aim of this prospective randomized controlled trial (RCT) was to verify whether a "protected extracorporeal in-bag" morcellation by flat knife or scissors coring could be efficiently proposed in alternative to the standard intracorporeal uncontained power technique.

MATERIALS AND METHODS

An unblinded RCT was conducted at the Department of Obstetrics and Gynecology, University "Magna Graecia" of Catanzaro.

The methodology was in accordance with the guidelines of the Declaration of Helsinki on Human Experimentation and of Good Clinical Practice. The study protocol was approved by the Ethical Committee of the Department of Gynecology and Obstetrics (University 'Magna Graecia' of Catanzaro) and submitted to the website for clinical trials (www.clinicaltrials.gov, identifier number NCT02086435). The purpose of the protocol, in light of U.S. FDA recommendations, was carefully explained, and written informed consent was obtained from each patient.

Between March 2014 and January 2015, premenopausal women with heavy menstrual bleeding or patients already diagnosed with fibroids from referral sources and undergoing a myomectomy were enrolled in the study. Inclusion criteria were the following: age between 18 and 40 years, body mass index (BMI) 18–40 kg/m^2, heavy menstrual bleeding, and the presence of at least one myoma measuring 4 cm or more in diameter (but no myoma measuring >10 cm, according to our clinical practice on eligibility for laparoscopy).

The exclusion criteria were age over 40 years, presence of uterine neoformation suspicious for malignancy, acute or chronic psychiatric disorders, use of drugs during the 6-month period before enrollment date that affect cognitive ability or state of consciousness and alertness, presence of calcified fibroids at ultrasound examination (for which the effort to morcellate them mechanically may outweigh the amount of time saved), presence of ovarian cysts or adnexal lesions, previous endometrial hyperplasia, abnormal PAP test, positive pregnancy test, previous laparotomic pelvic surgery, major medical conditions, or hepatic, renal, and cardiovascular disorders or other concurrent medical illnesses.

On admission for each enrolled patient, clinical and biochemical assessments were performed. Anamnestic information regarding menstrual cycle characteristics (age at menarche; regularity, quantity, and duration of menstruation; presence of dysmenorrhea; parity; and previous abortion status) were noted. Anthropometric measurements (age, height, weight, BMI) were also recorded.

All subjects underwent venous blood sampling for hematochemical (including ferritin) and coagulation evaluation. Blood samples were obtained in the morning between 08:00 and 09:00 a.m. following an overnight fast and bed rest. In all women, a gynecological inspection and an instrumental evaluation were performed. Transvaginal ultrasound was performed by the same experienced operator (D.L.) who assessed uterine size and morphology and ovarian characteristics. Presence, location (intramural, submucosal, or subserosal myoma), and size of fibroids were described; additionally, vascularization by echo-color Doppler was also assessed. Fibroids were measured in three perpendicular planes, and size was determined, while volume was calculated using the ellipsoid formula.

Standard preoperative workup included a serum dosage of CA125 and LDH isoenzymes 3-4-5 to exclude cases at increased risk for malignant uterine disease. If there was a suspicion of neoplastic fibroid degeneration, magnetic resonance imaging, hysteroscopy, and endometrial biopsy were also performed, according to our standard clinical practice.

All eligible patients were randomized 1:1 by computer software to one of two independent treatment arms (experimental and control) by a blinded nurse. The experimental group included patients treated with manual "protected" removal by in-bag extracorporeal morcellation by knife or scissors coring; the control group included patients treated with standard uncontained power morcellation, using a reusable electronic device.

Immediately before surgery, each patient received 2 g IV of antibiotic prophylaxis (Ceftriaxone). No treatment for thrombosis prophylaxis was administered on the day of surgery.

All laparoscopic myomectomies were performed by two experienced surgeons (F.Z., M.M.), who were informed about the patient's group only at the time of morcellation. Surgeons followed the same standardized procedures for each intervention. After induction of anesthesia, in both groups, a uterine manipulator was positioned and pneumoperitoneum, through the introduction of the Veress needle, was obtained. Laparoscopic myomectomy was carried out according to our described standard technique (9), but using Monocryl suture CT 0 (Ethicon) instead of Vicryl CT 2-0 (Fig. 1A). During each surgical intervention, a careful and systematic inspection of the uterus, ovaries, and entire pelvis was performed (Fig. 1B).

In the experimental group, each enucleated myoma was placed within a rip-stop nylon specimen bag (Endo Catch