Laparoscopic Enclosed Morcellation; Electromechanic Morcellation vs Vaginal Removal

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Objective

To compare the laparoscopic enclosed electromechanical morcellation and tissue removal thorough vagina with posterior colpotomy in laparoscopic myomectomy procedures.

Background

Laparoscopic tissue removal is one of the most challenging steps for the laparoscopic surgery. Therefore, electromechanical morcellation has long been used to facilitate the tissue removal especially for myomectomy and hysterectomy. However, electromechanical morcellation has undergone increased scrutiny because of important concerns related to tissue dissemination during intracorporeal power morcellation according to the US Food and Drug Administration (FDA) warnings in November 2014.

Design

Prospective randomized interventional clinical study.

Methods

We enrolled 118 patients to the study between 18 to 40 years old with an indication of myomectomy. These indications were infertility, pelvic pain, dysmenorrhea, dyspareunia, and menometrorrhagia. Seventeen patients with prior abdominal surgery and 4 participants without previous vaginal intercourse were excluded from the study. After exclusions, 97 participants randomized into two groups according to sequential randomization; Group 1 (n:49): Enclosed

Electromechanical Morcellation (EEM) and Group 2 (n:48): Vaginal Morcellation (VM).

Statistical Analysis Plan (SAP)

Categorical variables will be analyzed with frequency tables, and descriptive statistics will be calculated for continuous variables. The Shapiro-Wilk normality test will be used to analyze whether continuous data were normally distributed. As the data not normally distributed, Mann-Whitney U test will be used for comparison of two independent groups; Wilcoxon signed rank test will be used to compare two dependent groups. The significance level is taken as 0.05 in all hypothesis tests. All statistical analyses will be performed using the IBM SPSS Version 25.0 statistical package program.