TITLE:
A Randomized Control Trial of Combined Vaginal Misoprostol and Perivascular Vasopressin during Robotic Myomectomy

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A randomized control trial of combined Vaginal Misoprostol and perivascular Vasopressin during robotic Myomectomy.

The study will be a prospective, randomized placebo-controlled study to assess the differences in operative outcomes when using vaginal misoprostol with perivascular myometrial vasopressin injection versus perivascular myometrial vasopressin injection alone at the time of robotic assisted laparoscopic myomectomy. Differences in operative blood loss between the two study groups is the primary outcome of interest; differences in procedure time and changes in three hour postoperative hematocrit levels will also be analyzed.

The study population will be derived from reproductive aged women scheduled for robotic assisted laparoscopic myomectomy at Maimonides Medical Center, under the care of surgeons in the Minimally Invasive Gynecologic Surgery department. Patients will be excluded from the study if they have a significant history of cardiac or pulmonary disease, history of adverse reaction or allergy to any of the studied drugs, or history of prior myomectomy. Informed consent for participation in the study will be obtained in private at their preoperative appointment. Sociodemographic and clinical data including age, race, parity, body mass index, uterine size, number of uterine fibroids, and size of uterine fibroids will be collected.

All patients between 18 to 55 years in age scheduled for a robotic assisted laparoscopic myomectomy will be approached in the surgical holding area the day of their procedure and asked to participate in the study. Those that agree to participate will sign an informed consent, and will be given a copy for their records. Study subjects will then be randomized based on their subject number; those assigned to an odd number will be randomized to receive a Misoprostol suppository, and those assigned to an even number will not receive the suppository.

All patients will have a uterine manipulator placed as part of the normal protocol for the surgical procedure after induction of general anesthesia, but only those randomized to receive vaginal Misoprostol will receive a 400 mcg suppository at that time. The primary surgeon will not be present as this time, and therefore blinded to which patients receive the suppository. All study subjects will have a diluted solution of Vasopressin 20 mU/100 mL injected into the uterine muscle surrounding the uterine fibroids. The time from uterine manipulator placement to uterine incision will be recorded, as well as time from uterine manipulator placement to removal of trocars.

Additionally, preoperative complete blood counts, as well as three hour post operative complete blood counts will be obtained. The primary surgeons estimate of surgical blood loss will be recorded. The amount of blood in the suction canisters will also be recorded, with care to subtract any fluid used for irrigation for a more accurate assessment.