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**Study Objective:** Report baseline Uterine Fibroid Symptoms Quality of Life Questionnaire (UFS-QoL) data from Elaris UF-1 and UF-2 to characterize disease burden from heavy menstrual bleeding (HMB) associated with uterine fibroids (UF).

**Design:** Elaris UF-1 (NCT02654054) and UF-2 (NCT02691494) were identical, phase 3, double-blind, randomized, placebo-controlled studies investigating safety and efficacy of elagolix alone or combined with hormonal add-back therapy for HMB associated with UF.

**Setting:** Outpatient in clinic/office.

**Patients or Participants:** Premenopausal women (n=790) aged 18–51 years with diagnosed UF and HMB (menstrual blood loss [MBL] >80 mL/cycle for ≥2 menses).

**Interventions:** N/A

**Measurements and Main Results:** A modified UFS-QoL (4-week recall) was conducted before study drug administration. UFS-QoL is a self-administered, 37-item, disease-specific questionnaire that measures symptom severity and health-related QoL (HRQoL; calculated from 6 subscales and scored 0–100). Lower HRQoL scores indicate worse QoL. At baseline, mean (standard deviation [SD]) age was 42.4 (5.4) years, and MBL was 239.7 (158.7) mL. Baseline total HRQoL score was low, reflecting low QoL (mean [SD], 42.9 [23.2]). Mean (SD) scores were generally low across HRQoL domains (concern, 28.1 [24.6]; activities, 40.9 [27.0]; energy/mood, 47.4 [25.3]; control, 54.2 [28.3]; self-consciousness, 39.9 [30.7]; sexual function, 47.5 [35.4]). In each HRQoL domain, the questions most frequently answered ‘most’ or ‘all’ of the time were how often symptoms made patients: feel concerned about soiling underclothes (80%; concern), decrease the amount of time on exercise or other physical activities (59%; activities), feel tired or worn out (68%; energy/mood), feel less productive (50%; control), feel conscious about the size and appearance of their stomach (57%; self-consciousness), and avoid sexual relations (46%; sexual function).

**Conclusion:** There was considerable baseline disease burden. Patients reported the greatest impacts to concern and self-consciousness. Common issues included concerns about soiling underclothes and feeling tired or worn out.

### Transcervical Fibroid Ablation (TFA) in an Ambulatory Surgical Center Setting: Utility during the COVID-19 Pandemic

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**Study Objective:** To describe the experience of TFA with the Sonata<sup>®</sup> system in the ambulatory surgicenter (ASC) setting, relative to current recommendations by medical societies for elective procedures during the COVID-19 pandemic.

**Design:** Prospective, longitudinal, multicenter controlled trial.

**Setting:** 22 clinical sites in the US and Mexico.

**Patients or Participants:** 147 premenopausal women between the ages of 25 and 50 with heavy menstrual bleeding secondary to nonpedunculated fibroids.

**Interventions:** Transcervical, intrauterine ultrasound-guided radiofrequency ablation with the Sonata system. Pain scores were recorded after each procedure using a scale from 0–10. Length of stay (LOS) was measured from procedure start through discharge.

**Measurements and Main Results:** Of 147 treated patients, 49 were treated in an ASC setting and 98 were treated in other outpatient settings. Fifty-five percent of patients treated in an ASC had general anesthesia and 45% had conscious sedation vs 48% and 52%, respectively for non-ASC population. Average number of fibroids treated per patient was 3.2±2.0 and 2.9±2.1 in ASC and non-ASC, respectively. Mean LOS was 2.1±0.9 hours vs. 2.8±1.3 hours for ASC and non-ASC patients, respectively. Mean procedure pain

scores were 0±0% for the ASC patients (0.4±1.1 for non-ASC patients). Mean return to normal activity for patients treated in ASC was 1.7±1.4 days (2.4±2.5 for non-ASC patients). Mean 12-month improvements in SSS and HRQL scores were -34.8±23.9 and 48.6±26.2 points, respectively, in ASC patients (-30.4±19.3 and 41.0±23.0, respectively, in non-ASC patients).

**Conclusion:** Current surgical guidance during the COVID-19 pandemic encourages avoidance of endotracheal intubation when appropriate and minimizing exposure time for patients and staff. Transcervical Fibroid Ablation with the Sonata system is performed without pneumoperitoneum or a requirement for intubation, providing short LOS, minimal pain scores and improved outcomes while potentially reducing risk to healthcare personnel and patients alike.

### Telemedicine for Delivery of Postoperative Care Following Minimally-Invasive Gynecologic Surgery: A Randomized Controlled Trial

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**Study Objective:** Determine if patient satisfaction is greater after delivering postoperative care via telemedicine following minimally invasive gynecologic surgery.

**Design:** Randomized controlled trial

**Setting:** University based outpatient clinic.

**Patients or Participants:** Between 18 and 60 years of age scheduled to undergo laparoscopic hysterectomy or laparoscopic excision of endometriosis.

**Interventions:** Eligible patients were randomized to receive postoperative care either through a traditional office visit or via telemedicine.

**Measurements and Main Results:** 41 patients were analyzed out of which 25 were allocated to the office group and 16 to the telemedicine group. Groups were homogenous to age (41.4 v 43.3 p=.48), BMI (31.9 v 30.6 p=.52), distance in miles from home (12.7 v 12.4 p=.92) and parity (p=.51). PSQ-18 questionnaire was scored and each category was compared between the office and telemedicine groups. When comparing medians (IQR), the general satisfaction and time spent with doctor categories were significantly higher in the telemedicine group (4.0 (4.0, 4.5) v 4.5 (4.5, 5.0) p=.05), (4.0(4.0, 4.5) v 4.5(4.0, 5.0) p=.05). The remainder of the categories analyzed were not different between groups (Technical Quality (4.0 (3.8, 4.5) v 4.5 (3.9, 5.0) p=.13), Interpersonal Manner (4.0 (4.0, 4.5) v 4.5 (4.0, 5.0) p=.34), Communication (4.5 (4.0, 4.5) v 4.5 (4.3, 5.0) p=.21) and Accessibility and Convenience (4.0 (3.5, 4.5) v 4.0 (3.6, 4.5) p=.84)). A chart review was performed, examining the first 30 days after surgery. One (4%) patient in the office group visited the ER following the postoperative visit, and 0 in the telemedicine group (p=.42). Regarding phone calls to the clinic after postoperative visit, 5(20%) patients in the office group incurred in at least one call and 4(25%) did so in the telemedicine group (p=.92).

**Conclusion:** Postoperative care via telemedicine after gynecologic surgery results in higher patient satisfaction, and does not appear to increase the risk of complications.

### Robotic Radical Trachelectomy Using the Double Bipolar Method- Aiming for a Bloodless Operative Field

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**Study Objective:** To report the application of the double bipolar technique in a patient with 1b1 cervical cancer who wished to preserve her fertility potential.

**Design:** After experiencing 105 cases of laparoscopic and robotic radical trachelectomy with a 5 year survival rate of 98% and the birth of 29 babies

from 51 of these patients who attempted pregnancy, we introduced the double bipolar method to overcome technical difficulties of the procedure due to the necessity for precise dissection and reconstruction in the deep pelvis. We will show our operative techniques, such as nerve sparing radical trachelectomy and retroperitoneal lymphadenectomy for early invasive cervical cancer in a bloodless operative field.

**Setting:** Urban general hospital.

**Patients or Participants:** Robotic radical trachelectomy using the double bipolar method was performed in three patients with 1b1 cervical cancer.

**Interventions:** After Robotic radical trachelectomy using monopolar scissors in 30 cases of stage 1b1 cervical cancer, we considered techniques for a more bloodless operative field. The double bipolar method (DBM) was originated by a robotic gastrointestinal surgeon, Prof Ichiro Uyama. Using robotic Maryland forceps as a cutting device allows for pinpoint accuracy that cannot be found in other instruments. It is important for bladder and ureteral dissection and exposure of vessels. Cuts are made at a very limited point by a lightning strike mechanism, meaning there is minimal thermal spread to adjacent organs.

**Measurements and Main Results:** Blood loss was 250ml in the cases presented. In surgeries not using the DBM (n=34), the blood loss ranged from 350ml (100-1200ml). While there is no supporting data, the dissection of the ureter was very smooth.

**Conclusion:** A bloodless operative field allows for accurate dissection and can prevent intraoperative injuries. The double bipolar method is able to provide precision cutting and limit thermal spread to adjacent tissue, reducing injury and allowing for a clear operative field.

#### An Alternate Non Umbilical Entry Port for Laparoscopic Entry in Thin Patients

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**Study Objective:** To study the feasibility of a non umbilical first blind entry port in patients with BMI less than 18.5.

**Design:** Retrospective study assessing the laparoscopic entry in patients operated during the study period from January 2011 to December 2019.

**Setting:** Patients were operated under general anesthesia.

**Patients or Participants:** Selection criteria was patients of BMI less than 18. Out of the total 7398 patients in which laparoscopic entry was done by the left lateral port, 398 patients met the selection criteria. 70 thin patients had history of previous surgeries.

**Interventions:** In the study group veress needle and first primary port was introduced through a left lateral paraumbilical port about 10 cm lateral to the umbilicus. This point is located on a straight line drawn 2.5cm medial to the ASIS at the level of umbilicus. During veress needle and primary 5mm trocar entry the abdominal wall is not lifted up and veress needle insertion is done in one straight vertical line without changing the direction to 45 degree. Under vision of first 5mm telescope the 10mm port and then accessory ports are inserted. This port placement is aimed at avoiding the major vessel injury. 5 mm port also optimizes the 10mm telescope port entry as is needed in cases with large masses and cases with previous surgery. This port then continues as main ergonomic ipsilateral working port.

**Measurements and Main Results:** All 398 cases were entered safely without any major complication or conversion to laparotomy. First blind entry was well delineated due to good muscle tone in thin patients. No long term sequelae noted.

**Conclusion:** Left lateral paraumbilical port is a safe alternate first blind non - umbilical port in thin patients with advantage of avoiding major vascular injury and avoiding adhesions in previous surgery cases.

#### An Analysis of Medicare Reimbursement Rates in Hysterectomies Performed in Gynecologic Surgery: 2010-2019

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**Study Objective:** To investigate differences in Medicare reimbursement rates between type of hysterectomy procedure, including abdominal, vaginal, and laparoscopic/robotic to help guide reimbursement for best practices.

**Design:** Twenty-two reimbursement codes representing hysterectomy from The Physician Fee Schedule Look-Up Tool.

**Setting:** Centers for Medicare & Medicaid Services.

**Patients or Participants:** All patients who had undergone hysterectomy of any type with reimbursement by Medicare using the twenty-two codes represented in The Physician Fee Schedule Look-Up Tool from 2010-2019 in the United States.

**Interventions:** Abdominal, vaginal, or laparoscopic/robotic hysterectomy reimbursed by Medicare.

**Measurements and Main Results:** A total of twenty-two codes were identified and the average annual and total percent change in reimbursement were calculated for abdominal, vaginal, and laparoscopic/robotic hysterectomy. After adjusting for inflation, the average reimbursement for all hysterectomy procedures decreased by 14.97% from 2010 to 2019 with an average R<sup>2</sup> of 0.92. The average annual change in reimbursements was 1.75%. Reimbursement for abdominal, vaginal, and laparoscopic/robotic hysterectomies decreased by 7.85%, 10.17%, and 21.16%, with an average R<sup>2</sup> of 0.94, 0.96, 0.88, respectively. Annual decrease in reimbursements was 0.90%, 1.18%, 1.56% for abdominal, vaginal, and laparoscopic/robotic respectively. These numbers show a decrease in reimbursement for all hysterectomies, and by hysterectomy type.

**Conclusion:** Medicare reimbursement for hysterectomy declined significantly from 2010-2019. Laparoscopic/robotic hysterectomy reimbursement decreased more than other modalities. With increasing use of laparoscopic/robotic procedures for hysterectomies in gynecologic surgeries due to increased safety, it is critical to understand these reimbursement trends. A minimally invasive approach should be the standard of care for benign hysterectomy, as it has improved patient outcomes and safety. Reimbursement does not reflect this best medical practice as minimally invasive hysterectomy rates decreased more than laparotomy. Further understanding of trends is essential to provide input to policy-makers who determine these reimbursement rates.

#### The “Lapbox” Device for Contained Laparoscopic Tissue Morcellation

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**Study Objective:** Clinical evaluation of LapBox, a novel tissue containment system for power and manual morcellation in laparoscopic gynecological surgery.

**Design:** Described cases were performed as part of an ongoing First in Human prospective, open label, multi-center, non-randomized study. Primary safety endpoint was non-occurrence of device-related adverse events. Primary performance endpoint was containment integrity (leak testing) following procedure. Secondary endpoints were ease of use, intra or post-operative complications, procedure time, hospitalization duration, specimen weight.

**Setting:** The LapBox extraction device is inserted using a dedicated delivery system. The organ is then encapsulated, and double wall chamber inflated. Chamber opening is extracted offering direct access and view to the contained organ within the inflated abdomen.