RESEARCH LETTER

Trends in Use and Outcomes of Women Undergoing Hysterectomy With Electric Power Morcellation

Concern about the safety of electric power morcellation for gynecologic surgery led the US Food and Drug Administration (FDA) to issue a safety communication in April 2014 discouraging use of the devices and, in November 2014, to recommend against use of morcellation in perimenopausal and postmenopausal women. Concern has been raised that these actions may result in performance of a greater number of hysterectomies via laparotomy, with an increased risk of complications. We examined trends in the route of hysterectomy, use of electric power morcellators, and prevalence of abnormal pathology before and after the FDA’s guidance.

Methods | The Columbia University institutional review board deemed the study exempt. Women aged 18 to 95 years who underwent hysterectomy from 2013 to the first quarter of 2015 recorded in the Perspective database were identified. Data undergo extensive quality control. International Classification of Diseases, Ninth Edition, codes were used for diagnoses, procedures, and complications. Patients were stratified based on route of hysterectomy (abdominal, minimally invasive, or vaginal). Among women who underwent minimally invasive hysterectomy, electric power morcellation use was determined from device billing codes. Intraoperative, surgical site, and medical complications during hospitalization were analyzed. Adverse pathologic outcomes in women undergoing morcellation included uterine cancer, other gynecologic malignancies, uterine tumors of indeterminate potential and endometrial hyperplasia.

Outcomes were compared before and after the FDA’s alert in April 2014. Trends in use of power morcellation and changes in complications were compared using Cochran-Armitage trend tests. Trends in route of hysterectomy were compared using linear regression, whereas the prevalence of pathologic outcomes before and after the FDA advisory were compared using Fisher exact tests. Analyses were conducted with SAS (SAS Institute), version 9.4. All statistical tests were 2-sided. A P value of less than .05 was considered statistically significant.

Results | We identified 203,520 women, including 117,653 women (57.8%) who underwent minimally invasive hysterectomy. Although the number of hospitals decreased over time (512 in Q1 2013 to 395 in Q1 2015), hospital and patient characteristics were similar. The mean age was 48 years (SD, 12) and 66.8% of the population were white.

Minimally invasive hysterectomy accounted for 59.7% (95% CI, 59.0%-60.4%) of hysterectomies in Q4 2013, then declined to 56.2% (95% CI, 55.3%-57.2%) by Q1 2015 (P < .001, Figure, A). Abdominal hysterectomy use increased from 27.1% (95% CI, 26.4%-27.7%) in Q1 2013 to 31.8% (95% CI, 30.9%-32.7%) in Q1 2015 (P = .004). Among women who underwent minimally invasive hysterectomy, power morcellation was used in 13.5% (95% CI, 13.0%-14.1%) in Q1 2013, peaked at 13.7% (95% CI, 13.2%-14.2%) by Q4 2013, and declined to 2.8% (95% CI, 2.4%-3.1%) by Q1 2015 (P < .001) (Figure, B).

The overall complication rate was unchanged over time (8.3% for Q1 2013 vs 8.4% for Q1 2015; difference, 0.1% [95% CI, −0.5% to 0.7%]; P = .53 for trend). Complications...
declined for abdominal hysterectomy (18.4% for Q1 2013 to 17.6% for Q1 2015; difference, −0.9% [95% CI, −2.4% to 0.7%], P < .001 for trend), attributable to a decline in intraoperative complications (7.0% for Q1 2013 to 6.1% for Q1 2015; difference, −0.8% [95% CI, −1.8% to 0.1%], P = .001 for trend), but were stable for minimally invasive hysterectomy (4.4% for 2013 to 4.1% for 2015; difference, −0.4% [95% CI, −0.9% to 0.2%], P = .71 for trend) and vaginal hysterectomy (4.7% for Q1 2013 to 4.2% for Q1 2015; difference, −0.6% [95% CI, −1.7% to 0.6%], P = .45 for trend).

The prevalence of uterine cancer, endometrial hyperplasia, other gynecologic cancers, and uterine tumors of indeterminate behavior in women who underwent morcellation were unchanged (Table).

Discussion | Electric power morcellation declined after the FDA warning, whereas use of abdominal hysterectomy increased. Use of minimally invasive hysterectomy in Michigan and Florida decreased 4% to 6% following the FDA advisory.3,6 Paradoxically, although the rate of abdominal hysterectomy increased, no change in the rate of major perioperative complications was found.

The FDA warnings might result in a lower prevalence of cancer among women who underwent morcellation due to greater scrutiny on patient selection. However, the high rate of abnormal pathology after the warnings highlights the difficulty in the preoperative detection of uterine pathology. Continued caution is needed to limit the inadvertent morcellation of uterine pathology.

Limitations include potential misclassification of pathology, undercapture of morcellation, the ecologic nature of the design, and lack of generalizability.5

Table. Prevalence of Abnormal Pathology in Women Who Underwent Minimally Invasive Hysterectomy With Electric Power Morcellation Before and After the April 2014 FDA Advisory

<table>
<thead>
<tr>
<th>Abnormal Pathology</th>
<th>Rate, % (95% CI)</th>
<th>Difference, % (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to FDA Advisory (Q1 2013-Q3 2014)*</td>
<td>After FDA Advisory (Q2 2014-Q1 2015)*</td>
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<tr>
<td>Uterine cancerb</td>
<td>0.28 (0.18 to 0.39)</td>
<td>0.53 (0.23 to 0.83)</td>
<td>0.24 (~2.04 to 2.53)</td>
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<tr>
<td>Other gynecologic cancerc</td>
<td>0.10 (0.04 to 0.17)</td>
<td>0.04 (0.00 to 0.24)</td>
<td>−0.06 (~2.35 to 2.23)</td>
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<tr>
<td>Endometrial hyperplasia</td>
<td>1.13 (0.92 to 1.34)</td>
<td>0.97 (0.56 to 1.37)</td>
<td>−0.16 (~2.45 to 2.12)</td>
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<tr>
<td>Uterine tumors of indeterminate behavior</td>
<td>0.22 (0.13 to 0.31)</td>
<td>0.04 (0.00 to 0.24)</td>
<td>−0.18 (~2.46 to 2.11)</td>
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Abbreviations: FDA, US Food and Drug Administration.

* The database contained patients who underwent hysterectomy from 512 hospitals with a mean age of 48 years (SD, 12) in Q1 2013. In Q1 2015, patients who underwent hysterectomy had a mean age of 48 years (SD, 12) and were drawn from 395 hospitals. Hospital characteristics and the racial composition of the patients were similar over time.

b Including all histologic subtypes of uterine cancer.


