AAGL Statement to the FDA on Power Morcellation

Located in Association News (click link to see other articles).

The following statement was authored by Dr. Jubilee Brown, a member of the AAGL Board of Trustees and summarizes the presentation she made on behalf of the AAGL to the Obstetrics and Gynecology Devices Panel of the FDA Medical Devices Advisory Committee on July 11, 2014. The statement was approved by the Board of Trustees.

The AAGL is a member medical organization comprised of over 7000 physicians and health care providers. We are committed to advancing the care of women worldwide through minimally invasive surgery. The AAGL convened a 12-member panel of experts in the field to review all available data related to uterine power morcellation, and it is on the basis of these and other newly available data that we base our statement.

Approximately 600,000 hysterectomies are performed each year in the United States. The percentage of these cases performed using minimally invasive surgery (MIS) has increased from approximately 30% in 2002 to about 63% in 2012. The benefits of MIS have been widely documented in retrospective and prospective studies, and include significant improvements in morbidity and mortality compared with open surgery. When compared with hysterectomy through laparotomy, MIS results in a decrease of blood loss, transfusion, pulmonary complications, infection, thromboembolic events, hospital stay, and postoperative pain with an improvement in quality of life, body image, and return to baseline function (Level I evidence). Technology such as power morcellation has allowed hysterectomy through MIS to be performed in 50,000 – 150,000 patients annually. However, this technique has come under scrutiny because of the risk of exposing the peritoneal cavity to an undetected uterine malignancy during morcellation. The elimination of power morcellation would result in conversion to open procedures in many of these cases; the risks of power morcellation would have to exceed the benefits of MIS in order for that to be justified.

The precise risk of undetected uterine malignancy in a patient undergoing a planned hysterectomy with power morcellation is difficult to determine. Most undetected uterine malignancies are leiomyosarcomas, a rare but aggressive histologic subtype of uterine malignancy. Prevalence estimates are difficult to determine, as limited data exist, studies are small and retrospective, or of poor quality, and all data from which statistics are calculated are subject to publication bias. Estimates range from 1:360 to 1:7400[1,2]. Thus, the risk of an undetected leiomyosarcoma is not zero, but is low. The AAGL cautions against eliminating a beneficial technology based on such scant and imprecise data.

The AAGL agrees that morcellation is generally contraindicated in the presence of documented or highly suspected malignancy. Meticulous adherence to preoperative screening guidelines, including endometrial

biopsy and cervical cytology, to exclude coexisting uterine or cervical malignancy or premalignancy is imperative. Certain types of uterine cancers, such as leiomyosarcomas, are more difficult to detect preoperatively, though 38-68% of leiomyosarcomas can be detected in this manner. Magnetic resonance imaging may also be useful in determining which masses represent benign uterine fibroids and are safe for power morcellation. Appropriate triage of candidate patients may further improve the safety profile of MIS hysterectomy with power morcellation, but at this time there exists insufficient data to discontinue power morcellation in low risk, appropriately screened patients.

The data on the risk of upstaging, or worsening prognosis, of a leiomyosarcoma after power morcellation are limited. Nine reports are available that specifically document leiomyosarcoma morcellated through a variety of techniques. In total, 4/19 patients (21%) were upstaged if reoperation occurred within 30 days of original surgery, and 8/19 patients (42%) were upstaged if both early and late/unknown data were included. The delay from morcellation to upstaging, however, was up to 600 days, which confounds these data.[3] Other reports have unusually robust outcomes in the non-morcellated group compared with the morcellated group, which may lead to a falsely worsened prognosis in the morcellated group yielding questionable results. The AAGL does not believe that such limited evidence warrants removal of the option of power morcellation.

Unfortunately, leiomyosarcoma is an aggressive malignancy, and outcomes are suboptimal whether morcellation is used or not. Even when removed intact, leiomyosarcoma has an aggressive course and a poor prognosis. Therefore, determining the degree to which power morcellation contributes to worsened outcomes for patients with leiomyosarcoma is difficult, and the available data do not warrant discontinuing power morcellation.

The key question is whether the proven benefits of MIS are outweighed by the low risk of disseminating a leiomyosarcoma through power morcellation. Preliminary evidence suggests that MIS may be safer and result in fewer deaths compared with the open approach, even when using prevalence estimates that are high. Using the available literature, a decision analysis model was constructed to examine the risk of leiomyosarcoma in the population who are candidates for power morcellation, and compare morbidity and mortality of abdominal hysterectomy compared to laparoscopic hysterectomy with power morcellation4. In order to evaluate the “worst case scenario,” the median prevalence of leiomyosarcoma was conservatively estimated at 1:585. This corresponds very closely with the rate of 1:498 quoted by the FDA. Also, the risk of local spread due to power morcellation was varied from 15 to 35%. Specifically, the mortality from open hysterectomy was 0.085%, while the mortality from laparoscopic hysterectomy with power morcellation was 0.077%. This yields a difference in favor of laparoscopic hysterectomy with power morcellation even when controlling for all perioperative factors and when estimating the prevalence at 1:585. Based on these assumptions, the model suggests that the combined mortality from leiomyosarcoma and the potential dissemination through power morcellation would be less than the mortality from open hysterectomy. Converting all hysterectomies currently undergoing power morcellation to open surgery would result in an annual increase of 17 more women dying from surgery each year, and a substantial increase in morbidity from open surgery[4].

Power morcellation is an important tool in treating symptomatic uterine fibroids which allows up to 150,000 women each year to undergo minimally invasive surgery when they would otherwise require laparotomy for an abdominal hysterectomy. While research, education, and improved tissue extraction techniques can probably further enhance the safety profile of power morcellation, the elimination of power morcellation and conversion of these women to open surgery would likely increase morbidity and mortality from open surgery and cause harm to more patients. Our obligation is not only to patients with leiomyosarcoma, but to all of our patients. We must not sacrifice our patients in response to a rare event.

Thus, it is the AAGL's position that we should improve but not abandon power morcellation, and that power morcellation with appropriate informed consent should remain available to appropriately screened, low risk women.

References

1 Wright JD, et al, Uterine Pathology in Women Undergoing Minimally Invasive Hysterectomy Using Morcellation. JAMA, Epub online, July 22, 2014.
2 Pritts et al, presented at the Obstetrics and Gynecology Devices Panel of the FDA Medical Devices Advisory Committee, July 10, 2014.
3 Pritts et al, submitted to J Minim Invasive Gynecol.
4 Brown J, regarding data by Naumann RW et al (submitted), presented to the Obstetrics and Gynecology Devices Panel of the FDA Medical Devices Advisory Committee, July 11, 2014.