

## Laparoscopic hysterectomy: weigh harms, but do not dismiss benefits

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One year ago, in an editorial contemplating the firestorm surrounding power morcellation during minimally invasive hysterectomy, I noted that physicians and patients perceive risks differently and encouraged patient-centered valuing of surgical risks and benefits and developing shared decision-making tools and processes.<sup>1</sup>

In this month's Journal, Siedhoff et al<sup>2</sup> provide a valuable analysis to help in this endeavor. Using decision modelling, they compared outcomes over a 5 year time horizon for premenopausal women undergoing laparoscopic hysterectomy with morcellation vs abdominal hysterectomy for presumed fibroids. There were more deaths from leiomyosarcoma following laparoscopic hysterectomy with morcellation (86 vs 71 of 100,000) but more deaths overall following abdominal hysterectomy (32 vs 12 of 100,000). The laparoscopic group had lower rates of transfusion, wound infection, venous thromboembolism, and incisional hernia but higher rate of vaginal cuff dehiscence. And the laparoscopic group had more quality-adjusted life-years after surgery than the abdominal group.

The recent public discourse on the spread of occult leiomyosarcoma after morcellation has focused nearly entirely on the risks of morcellation. Siedhoff et al<sup>2</sup> bring us back to the big picture by assessing the risk-benefit balance of the 2 examined procedures. Given the rarity of leiomyosarcoma, a randomized trial comparing mortality after different types of hysterectomy is not feasible. In this instance, a decision analysis is particularly helpful. Obviously a decision analysis is only as good as the data entered into it. The authors gave preference to higher-quality studies and more recent publications, reflecting advances in surgical practice. They assigned all laparoscopic patients a worse prognosis than abdominal patients by assuming that morcellation would lend the same poorer prognosis as spontaneous cancer spread. And they conducted sensitivity analyses, varying the expected incidence of occult leiomyosarcoma. Using the lowest estimate, the additional number of deaths per 100,000 ranged from 11 to 19 more with abdominal hysterectomy and using the highest estimate, from 36 to 44 more with laparoscopic hysterectomy

with morcellation. The quality-adjusted life-years were greater for laparoscopic than abdominal hysterectomies in all scenarios.

The literature to help us understand trade-offs between different surgical treatments is rapidly emerging. In this month's issue, Tan-Kim et al<sup>3</sup> provide additional incidence rates for leiomyosarcoma in women undergoing minimally invasive hysterectomy with morcellation. In a large managed care organization over an 11 year period, 941 of 3523 premenopausal women undergoing laparoscopic hysterectomy had morcellation of presumed benign fibroids. The incidence of leiomyosarcoma diagnosed postoperatively was 0.3%, within the higher range of estimates used by Siedhoff et al.<sup>2</sup>

A newly published study using a statewide database reported an incidence of uterine sarcoma of 0.22% but also highlighted that other cancers may also be diagnosed in women undergoing hysterectomy for benign indications: ovarian, peritoneal, and fallopian tube, 1.08%, endometrial 1.02%, metastatic 0.2%, and cervical 0.17%.<sup>4</sup> Tan-Kim et al<sup>3</sup> demonstrates how following up women in a captured care organization for longer than 5 years (the time projected in the decision analysis) could have an impact on estimates. Three additional sarcomas were diagnosed a median of 6 years after the morcellation. Accounting for these increased the incidence of leiomyosarcoma to 0.6%. This longer-term follow-up also identified 4 women (incidence 0.4%) who developed parasitic benign myomas at a median time of 5 years.

With the recent emphasis on quality improvement databases, we are becoming better equipped to begin to understand the true risks associated with our surgeries. Also in this month's issue, Barber et al<sup>5</sup> used the American College of Surgeons National Surgical Quality Improvement Project database to determine the incidence of venous thromboembolism (VTE) after hysterectomy for benign conditions. From 2010 through 2012, 44,167 women underwent hysterectomy: 28.8% were open, 51.1% laparoscopic, and 20.1% vaginal hysterectomy. The incidence of clinically diagnosed VTE was 0.35%; the majority of women had a pulmonary embolus. The odds of VTE were 2.5 times higher after open than the 2 minimally invasive approaches.

In a regression analysis, each 10 minute increase in operating time led to a 4% increased risk of VTE, suggesting an avenue for prevention. Using the same database from 2005 through 2009, Lake et al<sup>6</sup> found the odds of cellulitis nearly 4-fold higher after abdominal than vaginal hysterectomy but no difference between vaginal and laparoscopic approaches. Robust nationwide databases such as this one will provide estimates for rare conditions (like VTE and occult leiomyosarcoma) that are more robust and, with greater numbers of the incident condition, will allow the identification of risk

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factors that are currently elusive in smaller, single-institution studies.

In November 2014, the Food and Drug Administration (FDA) acted on the data at hand and updated its previous safety communication, concluding that a number of additional treatments are available for women with symptomatic fibroids (including uterine artery embolization, high-intensity focused ultrasound, and drug therapy), that vaginal hysterectomy has at least comparable results and fewer complications than laparoscopic hysterectomy, that the FDA discourages power morcellation during hysterectomy or myomectomy, and that “some clinicians and medical institutions now advocate using a specimen bag during morcellation in an attempt to contain the uterine tissue and to minimize the risk of spread in the abdomen and pelvis.”<sup>7</sup>

In the 3 months immediately following this safety notification, Desai et al<sup>8</sup> conducted an online survey of American Association of Gynecologic Laparoscopists Minimally Invasive Gynecology Surgery Fellowship program faculty to determine whether practices changed. The results, published in a Research Letter in this month's issue, suggest a dramatic change in practice over this short time interval. In 2013, 93% of respondents used morcellation, generally uncontained, during hysterectomy or myomectomy. Of these, 78% changed their surgical approach after the FDA warning. The majority used larger incisions or open procedures, whereas the remainder used innovative approaches, particularly various containment bags.

The latest Cochrane report on the route of hysterectomy concludes that the significantly improved outcomes for vaginal hysterectomy suggest that this route should be performed preferentially when possible and that where not possible, laparoscopic hysterectomy may avoid the need for abdominal hysterectomy.<sup>9</sup> The report found no evidence of benefits of laparoscopic vs vaginal approaches. Yet the number of vaginal hysterectomies performed in the United States continues to decrease.<sup>10</sup>

To counter arguments about concerns related to experience and quality given this decline, we can turn to the FINHYST study for some reassurance.<sup>11</sup> After a nationwide program to promulgate the recommendations of the Cochrane review, over a 10 year period, the proportion of hysterectomies done abdominally decreased from 58% to 24%, whereas that done vaginally increased from 18% to 44% and the proportion done laparoscopically increased slightly from 24% to 32%. The rate of complications associated with vaginal hysterectomy decreased from 22.2% to 11.7% and changed slightly in the other 2 groups. Consistent with other studies, with increasing experience, the overall occurrence of organ injuries in the laparoscopic group decreased from 2.8% to 1.7%.

The effects of changing surgical practices or wider adoption of nonsurgical management of fibroids will be clear only with careful evaluation of large numbers of women over time. The risks of newly adopted techniques are not known. Some modifications likely obviate the advantages of minimally invasive surgeries (for example, a large mini-laparotomy incision may no longer incur the lower risk of

wound infection and hernia associated with laparoscopic procedures). Vaginal hysterectomy is not feasible for very large fibroids, and the risks of traditionally performed morcellation during vaginal hysterectomy are not known. Data are sparse about the long-term effects of nonsurgical procedures and medications for fibroids. The risks of attempting to shrink unrecognized sarcomas using embolization, high-intensity ultrasound, or medication are recognized, but the magnitude of this risk is not known.<sup>12,13</sup>

Understanding the risk-benefit balance is crucial.<sup>14</sup> Fibroid tumors are a public health issue and, in particular for black women who have fibroids diagnosed at earlier ages, are more likely to be symptomatic and are more likely to undergo surgical intervention than other racial groups but less likely to undergo laparoscopic hysterectomies.<sup>15,16</sup> And the financial burden of fibroids is considerable, estimated to cost the United States 5.9 billion to 34.4 billion dollars annually.<sup>17</sup>

No decision analysis is ever the final word, and this one in the current Journal is no different. New data will continue to be added to the literature and the conclusions might stand as they are or change. It is incumbent upon clinicians and researchers to contribute high-quality, up-to-date data to this ongoing debate. But, most importantly, Siedhoff et al<sup>2</sup> remind us to keep the big picture in mind, to balance risks and benefits of different procedures, and to work vigilantly to decrease the impact of risks to the extent possible. ■

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