Are Routine, Minimally Invasive Surgeries for Fibroids Safe?

An ESUN Article

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Fibroids are benign smooth muscle growths of the uterus that are also known as leiomyomas. They are estimated to affect 50-80% of women at some point in their lives. Most fibroids are asymptomatic, but a significant fraction may cause symptoms, including heavy bleeding, pelvic pain or discomfort.

In the United States, it is estimated that 650,000 women will undergo a surgical myomectomy or hysterectomy for the management of symptomatic uterine fibroids.[1] In the last decade, open exposure surgical hysterectomies ("C-sections") have been increasingly replaced with routine, minimally invasive hysterectomies that necessitate the use of an electric morcellator surgical device. Commonly used by gynecological surgeons, the morcellator is a rotary blade device that shreds a large mass (a presumed fibroid within the uterus) through small port incisions on the woman's abdomen, either laparoscopically or with use of a da Vinci robot. The morcellator, by virtue of its mechanics, is essentially a grinder with a vacuum. The morcellator's fast spinning blade not only shreds masses for removal, but through centrifugal force may also disperse cellular particles from masses throughout the abdomen.

For many women, minimally invasive surgeries are safe; however, when a "presumed fibroid" is broken up inside the abdomen by a morcellator device, the end result can be a significant clinical problem if the mass turns out to be an unsuspected uterine cancer, such as a uterine leiomyosarcoma. When morcellation is used on a malignant mass, there is a risk that it will spread cancer cells inside the woman's abdominal and pelvic cavity.

Recently, the routine use of the morcellator device has been under critical scrutiny for concerns about its safety in the setting of removing uterine masses. Seidman et al, in their study of 1091 uterine morcellations, state: "While additional study is warranted, these data suggest uterine morcellation carries a risk of disseminating unexpected malignancy with apparent associated increase in mortality much higher than appreciated currently.[2]" Serrano, et al, conclude in their recent study that "tumor morcellation of uterine LMS was associated with increased risk of recurrence, shortened time to recurrence and a marked increased risk of peritoneal recurrence when compared to ULMS removed by TAH [Total Abdominal Hysterectomy] as first surgery.[3]"

It has been proposed that morcellation be performed within a protective bag.[4-6] Menge et al recommend that, "General abandonment of these techniques [morcellation] is a must as soon as there is any hint for malignancy to avoid spillage of tumor cells to the peritoneal cavity. A specimen extraction bag could be the easiest aid to avoid devastating tumor progression.[7]" However, Pasic et al caution that "because of the risk of dissemination, **tissue suspicious for malignancy should never be morcellated**, but removed intact using an impermeable retrieval bag.[8]" [emphasis added]

Most of these procedures are not, in fact, done within a protective bag. This can allow an occult deadly cancer to seed to the nurturing surfaces inside the woman's abdomen and pelvis. When the diagnosis is an aggressive cancer such as uterine leiomyosarcoma (ULMS), current data

support the fact that this procedure worsens the clinical prognosis for the patient as noted above. Most women are not properly informed about this risk so that they might consider it versus the risk of the alternative open surgical procedure or even a vaginal hysterectomy.

It should be obvious that morcellation devices should not be used to remove malignancies or potential malignancies. The medical consequences of morcellating ULMS are of grave concern. In the last five years, articles in medical journals have compiled data of ULMS morcellation that indicates a 2-4 fold increase of recurrence, with a potential increase in cancer-related mortality, compared with hysterectomies performed without the use of a morcellator.[9-11] The 5-year survival rate of a patient diagnosed with Stage 1 ULMS is 60%; whereas it is reduced to 15% with a Stage IV diagnosis.[12]

So why has the medical community been complacent with continuing use of morcellation devices to remove uterine masses? There is a bias by gynecologists, including specialty trained gynecologic oncologists, and their supporting societies that uterine sarcomas such as ULMS are so rare as to make the use of morcellators a "reasonable risk." As a result, and regrettably so, women undergoing minimally invasive hysterectomies are not adequately informed pre-operatively that morcellation can spread a hidden deadly cancer. Sadly, women may be falsely assured that uterine masses are not cancerous, despite the fact that there is no definitive way to diagnose a benign or malignant uterine mass prior to surgical removal.

ULMS is a rare diagnosis, affecting approximately 5 out of 100,000 women.[13] However, based on demographic research, about **one woman will be diagnosed with ULMS out of every 500-1000 who undergo hysterectomy or myomectomy for a uterine mass.**[14] Affected women are often in the prime of their lives, between the ages of 40-60 years old, and are healthy, active, contributing members of their families and communities.

Unfortunately, there is no effective testing that can distinguish between common benign fibroids and ULMS before a surgical removal of the mass. Globally, our health care systems have complacently guided patients towards minimally invasive hysterectomies because of the alleged decreased risk, efficiency and long term cost savings, all without the appropriate consideration of the deleterious impact that this procedure might have if the patient were to harbor an aggressive uterine sarcoma. In the United States, 2-5 women will be diagnosed everyday with ULMS, and 1,000 women each year have the potential to have their cancer prognosis worsened due to the “oops” implication from minimally invasive hysterectomy surgeries.

Medical institutions are contemplating the ethical question: **Should morcellation be allowed to continue, without patient consent, with the current known risks?** The FDA is currently investigating the negative consequences of using a morcellator for hysterectomy patients and is assessing whether the current language that contraindicates this procedure for malignancy is truly enforceable or sufficiently strong.

An online petition has been created to increase awareness and concern about the potential consequences of uterine morcellation. In my mind, a healthy life is invaluable. Please consider signing this petition for the health of our sisters, mothers, daughters and friends.

Responses to this Article

From Ian Judson, MD: My colleagues and I are very concerned about the increasingly common practice of minimally invasive surgery for presumed fibroids. We acknowledge the difficulty of making a pre-operative diagnosis of sarcoma in a woman with fibroids. However, there are occasions when worrying symptoms or suspicious imaging are ignored and a uterus-conserving operation is performed instead of a total abdominal hysterectomy. The risk of recurrence, which is already 50% for a woman with uterine leiomyosarcoma, is then increased to approximately 100%, resulting in a significant shortening of life expectancy and serious morbidity.

One has to ask – what level of risk is acceptable? What would it take to change practice? We would like to work with gynaecologists to see if there are ways of identifying the women most at risk before such surgery is performed and it is too late.

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Sarah's Reply: I feel honored to receive a reponse from the President of the British Sarcoma Group and the past President of CTOS. With your endorsement, I hope other MD's will band together to increase awareness of uterine leiomyosarcoma and work together with gynecologists to change how presumed fibroids are diagnosed and treated. Globally, we can actively change the practice of minimally invasive surgery that can and has diseminated sarcoma, upstaged disease, and increased mortality.

From Paul H. Sugarbaker, MD, FACS, FRCS: I read the article by Sarah Salem-Robinson with great interest. When I first heard of the "morcellation technology" for uterine fibromas, I was convinced, as a result of my clinical experience, that unsolvable problems were created as a result of this technology. I have personally taken care of patients who had morcellation of a uterine leiomyosarcoma (ULMS) that was disseminated within the abdomen and pelvis as a result of this technology. It is impossible for me to know how often this occurs but i can say from my experience that it is a reality and that is devastating.

The first and foremost requirements of cancer surgery are perfect CLEARANCE and absolute CONTAINMENT of the malignant process. In those unusual patients who have ULMS within a uterine fibroid, these principles of cancer surgery are violated and there is little, if any, recourse. We have performed pelvic peritonectomy, re-excision of the apex of the vagina, and resection of the specimen extraction site in an attempt to regain local control. It is a very big surgery. We combine the surgery with the hyperthermic intraperitoneal chemotherapy (HIPEC) in an attempt to treat microscopic disease. Although there may be some successes with this treatment strategy for ULMS, of course, it is not the way the disease should be managed.

This dissemination of a gastrointestinal and gynecologic malignancy that is contained at the beginning of a surgical procedure but then disseminated as a result of the trauma of surgery is not unique to ULMS. It occurs with laparoscopic and robotic resections of colon and rectal cancer. I have seen it as a result of the robotic resection of a uterine endometrial cancer. Personally, I would like to see thorough cytological studies of the abdominal and pelvic spaces prior to and after all laparoscopic or robotic resections of gastrointestinal and gynecologic malignancy. One aspect of cytoreductive surgery and HIPEC which is true for all peritoneal surface diseases that we treat concerns the major impact that extent of disease has on outcome.

Early diagnosis of a problem as a result of clinical features or histopathologic features of the primary tumor including peritoneal cytology can help direct patients to treatment where there is a minimal extent of disease rather than a large extent of disease diagnosed with follow-up radiologic studies or patient symptoms.

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Sarah's reply: When doctors and their societies, either out of fear or ignorance, sweep surgical errors under the table, it's refreshing to get a response like yours, Dr. Sugarbaker. Thank you for stepping up and discussing the importance of changing medical practice to prevent devastating iatrogenic disease.

It's reassuring to see wise experienced doctors whose vision has not been skewed through years of faulty practice, whose ethical code of medical practice continues to be first and foremost, "do no harm."

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