Uterine sarcoma and power morcellation to treat fibroids

Earlier this year, the United States Food and Drug Administration (FDA) expressed concern about women undergoing laparoscopic power morcellation for the treatment of uterine fibroids and the risk of inadvertent spread of unsuspected cancer (sarcoma) to the abdominal and pelvic cavities, and issued guidance on its use.

Power morcellators are medical devices used when removing the uterus (hysterectomy) or removing uterine fibroids (myomectomy).

Morcellation refers to the division of tissue into smaller pieces or fragments and is often used during laparoscopic surgeries to allow the easy removal of tissue through small incision sites.

When used for hysterectomy or myomectomy in women with uterine fibroids, laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus.

The FDA guidance, based on current available information and data (from the US), states that:

- It is estimated that 1 in 350 women (in the US) undergoing hysterectomy or myomectomy for the treatment of fibroids will have an unsuspected uterine sarcoma, most often a sub-type of uterine cancer called leiomyosarcoma.

- If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient’s likelihood of long-term survival. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

- In July, one of the largest manufacturers of power morcellators in the US, Johnson & Johnson, issued a voluntary return of the device. The company determined the procedure to be too risky, and decided to permanently remove all existing devices from the market.
Implications for the UK:

- In April 2014, NICE published guidance on hysteroscopic morcellation of uterine fibroids. This was challenged by Sarcoma UK on the grounds of patient safety and the guidance was withdrawn on 10 September 2014.

- NICE is developing new guidance on hysteroscopic morcellation of uterine fibroids, expected to be published in February 2015.

- The British Society for Gynaecological Endoscopy has set up a working group in response to the FDA guidance and currently recommends that patients are made aware of the facts during counselling and consent processes for women considering power morcellation of fibroids through myomectomy or hysterectomy.

- This NICE guidance only relates to hysteroscopic morcellation for uterine fibroids. This is when a power morcellator is passed into the uterus via the endocervical canal (a narrow passage that goes from the vagina to the inside of the womb). It does not cover laparoscopic morcellation (via minimally invasive or keyhole surgery) or the use of morcellation in general. Sarcoma UK will continue to lobby for official guidance from NICE on these techniques.

Sarcoma UK’s response:

- Sarcoma UK has been working collaboratively with sarcoma specialist healthcare professionals in the UK to raise awareness of this issue and bring about a change in practice.

- Sarcoma UK lobbied NICE extensively during the last six months to bring to their attention the inaccuracies in their original guidance (April 2014) on hysteroscopic morcellation of uterine fibroids. The charity submitted an official complaint to NICE in June. We are delighted that NICE has recognised the concerns and evidence presented by Sarcoma UK on behalf of patients and professionals, and we welcome NICE’s decision to withdraw the original guidance and develop new guidance.

- Sarcoma UK will continue to work with NICE to provide input to new guidance due to be published in February 2015. We will also continue to lobby for specific guidance on laparoscopic procedures relating to the risk of spreading sarcoma, and morcellation generally as a technique.

- Sarcoma UK is committed to improving treatment and care for women diagnosed with gynaecological sarcoma. The charity is playing an important role in expert discussions, providing the patient experience to enhance clinical evidence. A Sarcoma UK survey of women who have been diagnosed with gynaecological sarcomas has recently closed and is currently being analysed, with a report due in late October 2014.
• Sarcoma UK is launching new patient information for women diagnosed with gynaecological sarcomas in October 2014.

Sarcoma UK’s guidance for patients
We are aware that this latest information about power morcellation will be of huge concern to women who have already been treated for fibroids using these techniques, as well as women about to undergo treatment. We recommend:

Women who have already been treated for fibroids using this technique:
• If you have already undergone a hysterectomy or myomectomy for fibroids, the tissue removed during the procedure is typically tested for the presence of cancer. If you are at all concerned about the result of this test, contact your gynaecologist.

• If you are experiencing persistent or recurrent symptoms of any kind, contact your gynaecologist as soon as possible, and take this information with you.

Women who are considering treatment for fibroids using this technique
• If laparoscopic or hysteroscopic hysterectomy or myomectomy is recommended, ask your doctor if power morcellation will be performed during your procedure, and to explain why he or she believes it is the best treatment option for you. It is very important that the risks associated with this procedure are fully explained to you.

• You should be able to ask your doctor any questions you may have and be satisfied with the answers you get. This can include asking about alternatives if they have not already been explained to you. Your decision to proceed should be based on your judgement about risks and benefits of this treatment. You should be able to take an informed decision about your treatment, alongside your doctor.

Sarcoma UK recommends that every woman diagnosed with a gynaecological sarcoma should have her treatment and care reviewed by a specialist sarcoma multidisciplinary team.

Further information:
Sarcoma UK: www.sarcoma.org.uk, or contact us for more information by phone: 020 7250 8271 or by email: info@sarcoma.org.uk.

Federal Drugs Agency statement:
http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm393576.htm

British Society for Gynaecological Endoscopy:
http://www.bsge.org.uk/newsFull.php?id=68&start=0

Sarcoma UK supports an online group for women who have been diagnosed with gynaecological sarcoma: http://www.sarcoma.org.uk/Sarcoma-UK-Online-Support-Groups