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Laparoscopic uterine power morcellation (tissue comminution) – Statement by Swissmedic in conjunction with the Study Group for Endoscopic Gynaecology of the SGGG (Swiss Society of Gynaecology and Obstetrics)

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Following safety communications published by the US Food and Drug Administration (FDA) on 17 April and 24 November 2014 regarding the procedure of laparoscopic uterine power morcellation (tissue comminution), Swissmedic, in conjunction with the Study Group for Endoscopic Gynaecology of the Swiss Society of Gynaecology and Obstetrics (SGGG), has decided to issue a statement.

In April 2014, the FDA published a recommendation on its website discouraging the use of laparoscopic uterine morcellation with electrically operated morcellators (= power morcellation) for hysterectomy and myomectomy in women with uterine fibroids[1]. Based on its latest research, the FDA stated incidences of 1 in 498 for leiomyosarcoma and 1 in 352 for unsuspected uterine sarcoma in patients undergoing a hysterectomy or myomectomy for uterine fibroids. Since leiomyosarcoma is difficult to diagnose preoperatively, identifying it before the surgical procedure is unreliable. The FDA mentions the existence of a correlation between uterine morcellation and an increased risk of tumour cell spread and a worsening of the chances of survival.

In an update to the FDA recommendations issued on 24 November 2014,[2] the FDA described new contraindications to the use of morcellators for myomectomy or hysterectomy where the uterus is known or suspected to contain malignant cells and in certain populations with suspicious fibroids. Manufacturers of morcellators have been asked to include these contraindications, as well as warnings that uterine tissue may contain undiscovered malignant cells that can be spread during morcellation, in their instructions for use.

On the basis of the available literature and statements published by various professional associations (AAGL[3], BSGE[4], ESGE[5]) and European authorities (BfArM[6], ANSM[7]), Swissmedic and SGGG issue the following declaration:

[1] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm393689.htm
[2] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm
[3] https://www.aagl.org/aaglnews/aagl-statement-to-the-fda-on-power-morcellation/
[4] http://bsge.org.uk/newsFull.php?id=75&start=0
[5] http://www.esge.org/article/218-statement-on-morcellation
[6] http://www.bfarm.de/SharedDocs/Risikoinformationen/Medizinprodukte/DE/laparoskopische_Morcellatoren.html
[7] http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Morcellement-par-caelioscopie-pour-une-ablation-chirurgicale-de-fibromes-uterins-Recommandations-de-l-ANSM-Point-d-Information

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Intra-abdominal morcellation of an unsuspected leiomyosarcoma correlates with an increased rate of recurrence and possibly with a poorer prognosis. However, in view of the limited number of studies, the actual effect of morcellation on the survival rate of patients cannot be ascertained[8]. The minimally invasive surgical procedure for hysterectomy and myomectomy offers certain advantages over traditional methods; it is less likely to be accompanied by the serious postoperative complications observed with other techniques (for example major blood loss, blood transfusion, pulmonary complications, infections, thromboses) and has a lower morbidity rate[9]. Consequently, Swissmedic and the SGGG Study Group for Endoscopic Gynaecology believe that a ban on laparoscopic uterine morcellation during hysterectomy and myomectomy for uterine fibroids is not justified and therefore recommend the following:

1. The need for laparoscopic uterine power morcellation should, insofar as possible, be established on a case-by-case basis by risk stratification (comprehensive history; clinical examination; transvaginal ultrasound, if appropriate Doppler with evaluation of vascularisation; cytology to rule out cervical pathology; investigation of the endometrium if symptoms or abnormal imaging findings are present; an MRI/PET/CT scan may be helpful in individual cases)
2. A critical approach is required when deciding whether morcellation is indicated in post-menopausal women. Morcellation is contraindicated if tissue is known or suspected to contain malignancy. It is also contraindicated in patients with a corresponding risk situation in their personal or family history.
3. Patients should be informed before the operation about the risks associated with the use of uterine morcellation (particularly the possibility of tumour cell spread, carryover on the histopathological findings).
4. The safety of vaginal uterine morcellation can be increased during total laparoscopic hysterectomy by the use of a plastic bag[10]
5. Further studies are needed before definitive conclusions can be drawn about the risk-benefit ratio of laparoscopic uterine morcellation.

We would advise patients who have questions on this subject to contact the doctor treating them, while users with questions on medical assessment and procedure should contact the Swiss Society of Gynaecology and Obstetrics (SGGG).

[8] Bogani, Giorgio, William A. Cliby, and Giovanni D. Aletti. 'Impact Of Morcellation On Survival Outcomes Of Patients With Unexpected Uterine Leiomyosarcoma: A Systematic Review And Meta-Analysis'. *Gynecologic Oncology* 137.1 (2015): 167-172. Web.
[9] https://www.aagl.org/aaglnews/aagl-statement-to-the-fda-on-power-morcellation/
[10] Günthert, Andreas R. et al. 'Safe Vaginal Uterine Morcellation Following Total Laparoscopic Hysterectomy'. *American Journal of Obstetrics and Gynecology* 212.4 (2015): 546.e1-546.e4. Web.

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