Patient Information

Royal Devon University Healthcare
NHS Foundation Trust

Laparoscopic Morcellation for Removal of Fibroids or an Enlarged Uterus

Your surgeon has identified you as suitable candidate for a laparoscopic approach to your operation (either a hysterectomy or removal of fibroid). This leaflet is to inform you about the technique used to achieve your procedure using keyhole incisions. Laparoscopic or keyhole surgery has many advantages compared to an open 'tummy cut' operation, such as a shorter stay in hospital, quicker recovery and fewer infections. When performing keyhole surgery to remove an enlarged uterus or fibroid we need to use specialised equipment to allow removal of the womb or fibroid through our keyhole incisions. This equipment is called a morcellator.

A morcellator is an electrically driven device that cuts the fibroid, or a womb containing fibroids, into small pieces so they can be removed through small surgical incisions. It is only used by trained and experienced operators.

Some years ago concerns were raised in the United States of America by the FDA (Food and Drug Administration) on the use of morcellators. These concerns have arisen from a widely publicised case where a fibroid that contained an undiagnosed cancer (sarcoma) was removed by morcellation and likely as a result of this instrument was spread more widely around the patient's body, possibly reducing a cure rate and survival.

Your surgeon does not feel you are at a high risk of an undiagnosed cancer which is why you have been recommended a keyhole approach to your operation. The likelihood of an unsuspected cancer within a fibroid is rare. Different sources quote risks between 1:350 – 1:1000, but many studies were small, relate to different population types, and were not necessarily performed in the setting of reproductive age women with a low cancer risk, i.e. this information may not be accurate for the type of women who usually will be offered an operation requiring morcellation.

All tissue that we remove is routinely looked at in the laboratory to exclude unexpected conditions such as cancer. We recognise that there is no way to accurately predict whether a fibroid has cancer within it before it has been looked at in the laboratory following an operation. However we use our experience and appropriate investigations to look at your individual case to ensure you are as low risk as possible.

Overall survival for women diagnosed with fibroid cancer (leiomyosarcoma) is often very poor with only 40% of sufferers alive at 5 years, regardless of type or route of treatment. Despite this, there is some evidence that there is a higher chance of cancer recurring, and less illness free time when a fibroid cancer is morcellated when compared with open hysterectomy. Morcellation may therefore make the outlook worse for these women, if an unsuspected cancer is present.

There are also occasional case reports of the spreading of benign (non-cancerous) tissue by morcellators, resulting in seeding of fragments in the abdomen with the chance of infection and the need for further surgery.

Overall, in Exeter, we believe that the risk from an undiagnosed cancer within a fibroid or fibroid womb is extremely low, where patients have been fully checked and where there is no suspicion of cancer. We feel these risks should be considered in balance with the advantages of a keyhole procedure which may require the morcellator in order to be achieved, i.e. lower chances of infection, blood transfusion, more rapid return home and recovery, and reduced risks from life threatening conditions such as blood clot disease (venous thromboembolism). Laparoscopic operations requiring morcellation in the correct patients, with proper testing and experienced and trained surgeons are safe and confer many advantages.

In addition to the above measures, gynaecologists in Exeter have modified the morcellation technique to enable the whole process to take place within a closed system, and avoid any spillage of material into the body. This is called 'in bag morcellation', has been largely pioneered in Exeter, and is now widely adopted across the country in hospitals providing this service. We feel this additional measure reduces the small risks even further.

We are informing you through this leaflet of the potential risks from morcellation following the warnings given by the FDA. The alternative option for you is to have an open (tummy cut) myomectomy or hysterectomy although it does still remain uncertain that if an undiagnosed cancer was found whether this different approach will guarantee a long-term cure. We are obliged to ask you to confirm that you have read this leaflet as part of your consent process and we welcome you to ask any questions that may help you to understand the situation.

We would encourage you to look at the original FDA report in order to help you understand the evidence and make an informed choice. The web address for the FDA is **https://wayback.archive-it.org/7993/20170722215731/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm** This site also has links to the other reports that relate to the situation I.E. **http://www.acog.org/Resources_And_Publications/Task_Force_and_Work_Group_Reports/Power_Morcellation_and_Occult_Malignancy_in_Gynecologic_Surgery**