

Post-Market Evaluation for the Safety of Laparoscopic Power Morcellator

Study Category:

- Post-market evaluation study
- Risk analysis study

BACKGROUND

Laparoscopic power morcellator (LPM) are surgical instruments used in minimally invasive abdominal procedures such as, laparoscopic hysterectomies and fibroid removal [4]. LPMs were first introduced in 1991, which were designed in the shape of a drill with sharp blades at the end, and classified as class II medical devices. The device provides quicker recovery, less post-operative pain and fewer wound complications [5]

Laparoscopic power morcellators work through minimally invasive incisions to remove the uterine fibroids by shredding them into small pieces, which leaves behind tissue debris for the vacuum system to extract out of the body [4]. Recently, and due to a believe that cancer cells may still remain in the body following certain uterine surgical procedures in patients with fibroids, a containment system was introduced to isolate the morcellated tissue from the body, and thus, prevent the spread of morcellated tissue through the abdominal cavity [4]

This study was designed to fulfill two main objectives, which are:

- Evaluate the current practice of using LPM in Saudi healthcare facilities, and
- Test the awareness of the device users of the LPM risk of spreading cancer cells following uterine surgical procedures, and whether or not the manufacturer recommendation of using a containment system is followed.

CLINICAL BURDEN

LPMs are devices that are used during minimally invasive surgeries to shred tissue into small pieces that can be removed through a very small incision site. The device can be used for the removal of the abdominal organs, i.e. gallbladder, kidney, liver, and spleen. Furthermore, it is commonly used in the uterus removal surgical procedures, which include hysterectomy, the surgical procedure of the uterus removal, and myomectomy, the surgical procedure of the uterine fibroids removal [4].

Uterine *fibroids* refer to non-cancerous growths in uterus, while uterine *sarcomas*, on the other hand, are cancerous cells, and these two conditions are difficult to distinguished with available tests. According to the US FDA, uterine sarcomas are more frequent than previously estimated. Thus, when using an LPM for myomectomy or hysterectomy in women with assumed uterine

fibroids that are essentially uterine sarcomas, the procedure would pose a risk of spreading cancer cells beyond the uterus. These findings are assumed to lower the patient chance of long-term survival without cancer [4], which add to the myomectomy or hysterectomy post-operation complications, and require certain actions, i.e. utilizing a containment system, to protect the patient safety.

RISKS AND COMPLICATIONS

In reference to a review published by the US FDA by 2014, 1 in 350 women who undergo morcellation for hysterectomy or myomectomy could essentially have uterine sarcomas, the rate that is much higher than previously estimated rate of 1 in 10,000 [1].

In 2017, another white paper was published to tackle the issue of spreading cancer cells by LPMs, which included more studies and estimated rates of 1 in 225 to 1 in 580 women who undergo fibroid removal may have uterine sarcomas [4]. The process of morcellation could shred some cancerous cells causing them to disperse faster, resulting in an upstage of the hidden uterine cancer from stage one up to stage four, and thus, reduce the chances of survival and the possibility of treatment [4].

On the other hand, and with respect to the medical device reports, the same study indicated that, and as of April 2017, a total of 262 reports were submitted to the FDA database. These reports described the spreading of cancer cells in association with LPMs, with 18 reports that claimed upstaging the cancer after the morcellator surgery [4].

EVALUATION OUTCOMES

Part I: Methodology

In order to meet the objectives of this study the following steps were accomplished:

- A screening over the SFDA database was conducted to figure out the manufacturers that are authorized to distribute laparoscopic power morcellators in the Saudi market [6].

- The authorized representative of each manufacturer was then contacted to report the Saudi sites that have the device in question.
- The SFDA officer of each Saudi healthcare facility was then requested to fulfill a survey that was designed to meet the study objectives. The developed survey contained 8 specific questions regarding the device in question, which are illustrated in figure 1.

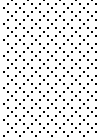
Laparoscopic Power Morcellation	
<p>This survey is built to evaluate the current situation of using Laparoscopic Power Morcellation (LPM) during gynecologic surgery in women in Saudi healthcare facilities. According to recent studies, approximately 1 in 225 to 1 in 580 women undergoing surgery to remove uterine fibroid (non-cancerous) might have hidden uterine sarcoma (cancerous tissue). With that in mind, the removal surgery could upstage the sarcoma by spreading some leftover cancerous debris throughout the abdominal cavity, hence, lowering the patient's long-term survival. The postmarket evaluation team from Saudi Food and Drug Authority would like you to participate in a research study to evaluate the safety of LPM by answering the survey below.</p>	
<p>1. Prior to any intervention using an LPM, do you follow any method or technique to distinguish between uterine sarcoma and fibroids? If yes, please specify.</p> <p style="text-align: center;">Yes, specify: No</p>	<p>4. Do you usually use tissue containment system during the surgery?</p> <p style="text-align: center;">Yes No</p>
<p>2. Which brand of LPM do you currently use?</p> <p style="text-align: center;">  </p>	<p>5. Do you usually guarantee the compatibility of the containment system with the LPM in usage, as per the manufacturer recommendations?</p> <p style="text-align: center;">Yes No</p> <hr style="width: 20%; margin: 0 auto;"/> <p>6. Do you usually follow-up with the patients after the surgery? If yes, please specify for how long.</p> <p style="text-align: center;">Yes, specify (How long): No</p>
<p>3. Do you inform the patient of the potential risks associated with the surgery in regards to the spread of cancerous tissue beyond the uterus?</p> <p style="text-align: center;">Yes No</p>	<p>7. Have you ever been notified with any sarcoma cases developed after any intervention using LPM? If yes, please specify how many.</p> <p style="text-align: center;">Yes, specify: No</p> <p>8. Do you check the history of patients diagnosed with sarcoma if they have undergone myomectomy or hysterectomy using an LPM?</p> <p style="text-align: center;">Yes No</p>

Figure 1. The study survey that was developed to evaluate the safety of LPM.

Part II: Results

- The market analysis revealed a total of 16 Saudi healthcare facilities that have LPM in use.
- 50% of the surveyed Saudi healthcare facilities are not following any method or technique to ensure and validate the absence of malignancy prior to the surgical procedures of hysterectomy or myomectomy procedure using an LPM.
- 50% of the surveyed Saudi healthcare facilities, are unaware of the importance of using containment system to reduce the risk of spreading cancer tissue in the abdominal cavity.
- 25% of the population do not even follow up with patients after the surgery, which may jeopardize the welfare of patients by being unaware of the patients' status.

- So far Saudi healthcare facilities reported zero cases of developed sarcoma following a hysterectomy or myomectomy surgeries using power morcellators. However, 25% of the surveyed healthcare facilities usually do not check the history of patients diagnosed with sarcoma to establish a relationship between the two cases.

Part III: Conclusion

The overall findings indicated no reported cases of sarcoma subsequent to hysterectomy or myomectomy surgeries using LPM. However, the survey responses highlighted some incorrect practices that need to be avoided during gynecologic surgeries, to ensure the patients safety. More importantly, despite the recent warning of the risk of spreading cancer cells when using LPMs with cases that have potential uterine sarcomas, some Saudi healthcare facilities are still not using containment system during hysterectomy or myomectomy surgeries, which may put patients at risk.

SFDA ACTIONS

Due to the laparoscopic power morcellation potential risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus, following hysterectomy or myomectomy surgery procedures, SFDA would like to bring the attention of healthcare providers to the following recommendations.

Recommendations for healthcare providers:

- Make sure to use laparoscopic power morcellation with an authorized laparoscopic power morcellation containment system, whenever you decide that morcellation is appropriate.
- Make sure that the laparoscopic power morcellation containment system is compatible with the utilized laparoscopic power morcellator.
- Make sure to discuss the risks and benefits of all relevant treatment options with your patients, informing them about the potential risk associated with the morcellation

surgeries, and that the use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease their long-term survival.

- Make sure to conduct a thorough preoperative screening, and not to use laparoscopic power morcellators in cases when the intended morcellated tissue is known or suspected to be malignant.
- In reference to current recommendations revealed by international regulatory agencies, it is recommended that the use of laparoscopic power morcellation is limited to certain appropriately selected women undergoing myomectomy or hysterectomy. Recent reports also highlighted that the risk of spreading cancer cells is increased when using laparoscopic power morcellators for removal of uterine tissue containing suspected fibroids in patients who are post-menopausal, or over 50 years of age, or candidates for removal of tissue (en bloc) through the vagina or via a mini-laparotomy incision. Furthermore, uncontained power morcellation is expected to be associated with the spread of benign uterine tissue, i.e. parasitic myomas and disseminated peritoneal leiomyomatosis, which would possibly require additional surgeries.
- Make sure to report any adverse event you notice with laparoscopic power morcellators through the National Center for Medical Devices Reporting (NCMDR) system: <https://ncmdr.sfda.gov.sa>, the Saudi Vigilance System <https://ade.sfda.gov.sa>, or the SFDA call center: [19999](tel:19999)

Recommendations for SFDA Actions:

- Issuing a safety communication with the above mentioned recommendations to raise the awareness of device users in the Saudi market.
- Following-up with the manufacturers to ensure that each LPM manufacturer is in-compliance with the previous SFDA recommendations in regards to include a warning box on the device label to highlight the need to utilize a containment system, which was previously directed to LPM manufacturers.
- Prior to the authorization of new laparoscopic power morcellators in the Saudi market, it is recommended to check that the device labeling highlights specific gynecologic indications. Such indication are to include a boxed warning, contraindications, and warnings regarding

the risk of use related to age, spreading malignant and benign uterine tissue, and the use of laparoscopic power morcellators containment systems, as provided in the guidance: "Product Labeling for Laparoscopic Power Morcellators" [3].

- Laparoscopic power morcellator manufacturers SHALL develop a plan to raise the awareness of the device users and healthcare practitioners to follow the recommended practices in gynecologic surgeries, as specified in the device Indications for Use.

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For further information or inquiries related to this study, you may contact us at: cia.md@sfd.gov.sa

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