

# THE WALL STREET JOURNAL.

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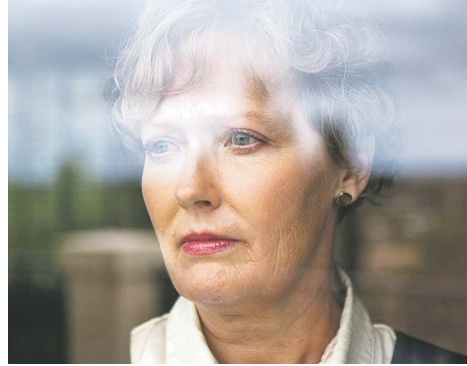


## DEADLY MEDICINE

An investigation of a troubled surgical device changes medicine and saves lives.



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## DEADLY MEDICINE

# Medical Device Sidelined Too Late to Save Some

BY JENNIFER LEVITZ AND JON KAMP

SATURDAY, NOVEMBER 22, 2014



Linda Interlichia found out she had cancer after she had a hysterectomy with a morcellator.

Mike Bradley for the Wall Street Journal

Linda Interlichia arrived alone at her family's Cape Cod vacation home a half-mile from the beach last fall. Her routine there had been unchanged for years: She opened the doors to let the breeze flow in from the marsh and sat on the deck in the afternoon, sipping a glass of Chardonnay.

The second night, ease gave way to dread. Heavy pelvic bleeding left her faint, and the next morning, she drove herself to the emergency room.

It was, she confided to her husband, Frank, among the most frightening episodes in her life. The hemorrhaging under control, she returned home to Rochester, N.Y., and saw her doctor the same week.

To Mrs. Interlichia's relief, her gynecologist, Wendy Dwyer, linked the bleeding to benign uterine growths, she

said, and offered an enticing solution, a brochure extolling a robot-assisted hysterectomy through tiny incisions.

“She slapped it on the table between us as we sat in her office like she was giving me a Christmas present,” Mrs. Interlichia said.

“She said I’d be up and running — she knew I liked to jog — in three weeks with minimal scarring and pain,” she said. “I left thinking I didn’t have a care in the world.”

But her problem wasn’t benign. It was an aggressive cancer, leiomyosarcoma, identified only after her surgery. And Dr. Dwyer had used a laparoscopic power morcellator, a tool inserted through an incision to cut up and remove the uterus.

A morcellator can leave behind bits of malignant tissue that seed multiple new tumors, scientists say. No one told Mrs. Interlichia her October 2013 surgery would use a morcellator, she said. Eight weeks later, another doctor found a softball-size mass and other tumors in her pelvis that he said weren’t there before her hysterectomy.

“It is terrible,” Dr. Dwyer said this month, her voice catching with emotion. “It’s never what I wanted for her.” Little was known about the cancer in the past, she said, and it was good it was now being looked at. She declined to comment further for this story.

Dozens of cases have come to light this year of women whose cancers rapidly worsened after morcellation. The U.S. Food and Drug Administration warned in April that the tools can worsen cancer. The top U.S. morcellator maker, Johnson & Johnson, halted sales in April, and many hospitals have curtailed their use.

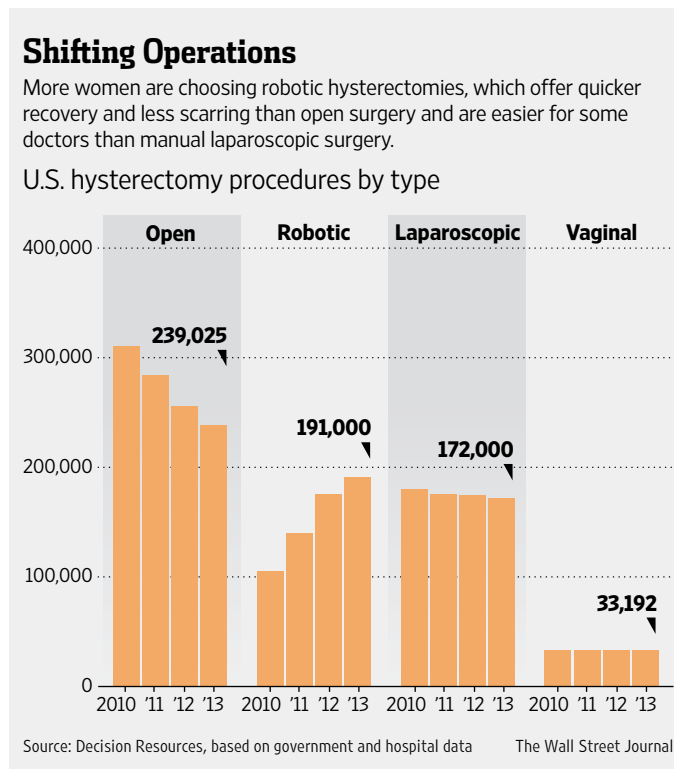
While the newfound scrutiny of the morcellator may save lives, women like Mrs. Interlichia and their families are still paying a grim price for decisions they and their doctors made not long before the alarms rang.

“Looking back now,” Mrs. Interlichia said this June, “I wish I had asked more questions.”

When Mrs. Interlichia, a Rochester copy editor, came to Dr. Dwyer in 2013, most gynecologists still rarely told patients that a morcellator might spread cancer. The risk was considered too small.

Dr. Dwyer didn’t suggest options other than robotic surgery, Mrs. Interlichia said, and “I figured she would tell me what was best.”

She went in for surgery Oct. 21, 2013, expecting a quick recovery. Her husband found her chatting with the nurse in good spirits in the recovery room. “The patient toler-



ated the procedure well,” Dr. Dwyer wrote in postoperative notes that day.

The shock came 10 days later. As the Interlichias sat in Dr. Dwyer’s office, they said, the gynecologist seemed near tears as she told them what she had thought was a fibroid, a common benign growth, was actually leiomyosarcoma.

“I felt bad for her,” said Mrs. Interlichia. “She was devastated it happened.” Soon after, she dropped off a gift — holiday-themed socks — for Dr. Dwyer.

The couple still hadn’t heard the word “morcellator.”

That came eight weeks later. In late December, she visited Dr. Christopher Awtrey, gynecologic oncology director at Boston’s Beth Israel Deaconess Medical Center, for exploratory surgery to see if her cancer had spread.

Leiomyosarcoma experts like Dr. Awtrey say there is far greater probability of recovery if surgeons remove the uterus intact. Once spread, the malignancy usually isn’t curable, cancer experts say.

Mrs. Interlichia lay in her hospital bed, gripping her husband’s hand as she listened to Dr. Awtrey explain the morcellator and describe her tumors. Fragments left behind had embedded in her abdomen and grown wildly, he concluded. “That tumor, once morcellated, appeared to be like a small fire with gasoline on it,” he told the Journal.

Mrs. Interlichia told him she wished she had sought a second opinion. “He said I could have gotten a second, third, fourth and fifth opinion, and they would all say the same thing. This has been gynecologists’ common practice,” she said. Dr. Awtrey corroborated the conversation.

In early January, she became aware of surging publicity around the morcellator's risk.

Dr. Amy Reed, a Boston anesthesiologist, had gone public in December with her story: After a hysterectomy for fibroids, she learned a hidden cancer had been morcellated.

Mrs. Interlichia started following news on the issue closely as she began chemotherapy. She lost her long hair, which she had dyed blond. Photos after that point show her with short gray hair.

In April, as she was trying a second type of chemotherapy — the first failed to stop tumor growth — she was shocked to read a Wall Street Journal page-one article showing there had been years of scattered but accumulating evidence of the morcellator's risk.

Days later, the FDA issued its advisory. That was some comfort, but Mrs. Interlichia was troubled to read of a divide in gynecology: Some doctors were still using the device, insisting the FDA had overreached.

"I think this is mostly public relations and not science,"

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*After a visit to the doctor, Mrs. Interlichia said, 'I left thinking I didn't have a care in the world.'*

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one doctor told the Journal in a May 21 article Mrs. Interlichia read. Incensed, she would later write to the FDA: "As I lay in my hospital bed after a second surgery to address the damage done by my hysterectomy ... I was anything but fodder for a public relations scheme."

That month, in one of her first public outings after losing her hair, she saw her youngest daughter, Grace, graduate from college. Her other daughter, Katie, was in graduate school in Boston.

Mrs. Interlichia insisted that her illness not throw her two daughters' lives off track. "Look, if you think you're going to come back to Rochester and stare at us and cry, that is not what we want," she told them. The daughters were heartbroken about their mother's diagnosis, her husband said.

As summer approached, Mrs. Interlichia began frequenting websites for women and families who had morcellation experiences, learning of other women like her in Rochester.

One was Brenda Leuzzi. In 2012, doctors at a University of Rochester Medical Center hospital diagnosed her with bleeding from fibroids. The Zumba instructor had a hysterectomy with morcellation in September 2012, records provided by her lawyer show.

She screamed when she got the call with a postsurgery

diagnosis: leiomyosarcoma.

She and her husband, Rochester firefighter George Leuzzi, in May filed suit against J&J's Ethicon unit, the morcellator's maker, in New York federal court, alleging it sold an unsafe product and failed to adequately warn of dangers. An Ethicon spokesman said it "acted appropriately and responsibly in the development, testing, marketing, and voluntary withdrawal of our devices."

When Mrs. Interlichia connected online with Mrs. Leuzzi's family, Mrs. Leuzzi was already in the late stages of cancer. Mrs. Leuzzi's uncle, Gene Manley, who planned to testify at FDA hearings on the device, asked Mrs. Interlichia if he could mention her name. She agreed, also writing her letter to the FDA.

"There is no justification in the world for a doctor making my condition worse when it was absolutely avoidable," she wrote. "I had hopes, dreams, plans and a life I loved. In short, I am a human being, not a data point."

The Interlichias watched the July FDA hearing on a laptop while she was receiving chemotherapy. One panel member, Craig Shriver, a surgical oncologist at Walter Reed National Military Medical Center, said: "There is at present no safe way to offer laparoscopic power morcellation as part of any minimally invasive surgery."

But some who testified defended morcellators, Mr. Interlichia said, and "we stopped watching because it was too upsetting to hear such vigorous defense of the process that put her in that infusion chair."

At the hearing, Mrs. Leuzzi's uncle found another Rochester-area cancer victim's husband, Jim Leary, a police officer from Greece, N.Y. Mr. Leary told of how his wife, a church-preschool teacher, had died.

Barb Leary, a mother of two, had come in with bleeding to her gynecologist in 2009. The doctor diagnosed fibroids, and she had morcellation at Rochester General Hospital, according to records provided by her family.

Days later, the pathology report revealed Mrs. Leary had leiomyosarcoma. "It was like getting hit with a baseball bat upside the head," Mr. Leary said.

Barb Leary died of the cancer in September 2013 at age 52.

The gynecologist who performed her surgery was Dr. Dwyer. A month after Mrs. Leary's death, Dr. Dwyer, who is affiliated with Rochester General, would morcellate Mrs. Interlichia.

Mrs. Interlichia knew of Mrs. Leary through an online





Mrs. Interlichia with her family in 2012.

Mike Bradley for the Wall Street Journal Interlichia family

community. “When I learned she had done this before, unfortunately to Barbara, I was stunned,” Mrs. Interlichia said of Dr. Dwyer after a Journal reporter told her of the connection. “It’s a depth of anger and shock that’s hard to quantify or express.”

Dr. Eugene Toy, Rochester General’s chief of obstetrics and gynecology, declined to discuss patients. Rochester General, where Mrs. Interlichia and Mrs. Leary had their surgeries, suspended power morcellation after the FDA advisory, and he said the new policy showed the hospital was doing all it could to reduce risks.

Mrs. Interlichia wrote Mr. Leary an email suggesting they meet, but she became too ill. Her MRI showed two tumors were growing and several new ones had appeared.

Instead, in August, her husband met Mr. Leary at a Rochester Italian restaurant. Mr. Interlichia had a beer. Mr. Leary nursed a Jack Daniel’s. Each ordered another.

“For the first time, I was able to really talk to someone who understands what I went through with Barb,” Mr. Leary said. He shared the little things he had done as she weakened, like how he learned the smell of coffee made her feel nauseated and stopped making it around her.

“We drank a bit and talked about our sad, common bond,” Mr. Interlichia, who oversees fundraising at the University of Rochester Medical Center, said a few days afterward.



“We certainly share anger.”

Soon their group included Mr. Leuzzi, who knew of Mrs. Interlichia’s case from support websites. “There’s a unique bond between the three of us,” Mr. Leuzzi said. “I can’t describe how terrible this ordeal has been,” he said. “There’s only a few people out there who understand that.”

Late this summer, Mr. Leuzzi was busy caring for his wife, who was often doubled over in pain.

Her cancer was “unexpected and tragic,” said Dr. Marit Sheffield, who evaluated Mrs. Leuzzi before surgery. Her surgeon, Uma Penmetsa, said of Mrs. Leuzzi that “she is helping physicians to rethink if, when, and how to use power morcellation, which until recently, has been standard practice.”

The two doctors declined to say whether they told Mrs. Leuzzi about the morcellator and its risks. University of Rochester said its hospitals stopped using power morcellators in May.

Dr. Joseph Skitzki, a sarcoma specialist at Roswell Park Cancer Institute in Buffalo, N.Y., evaluated Mrs. Leuzzi this year and said he believes morcellation worsened her cancer.

In an interview this summer, Mrs. Leuzzi said she was heartbroken she wouldn’t see her 3-year-old daughter, Peyton, grow up. She blamed morcellation for robbing her of a fair fight against her cancer.

With another procedure, Mrs. Leuzzi said, “I would have had more time.”

Mrs. Interlichia, too, had other minimally invasive options that would have given her a fighting chance, Dr. Awtrey said. Preoperative tests, he believed, showed she could have had a vaginal hysterectomy.

“My most fervent wish,” Mrs. Interlichia said this summer, “is to make sure this never happens to anyone else.”

By September, Mrs. Leuzzi was too weak to talk. Mrs. Interlichia had tried three types of chemotherapy, but her tumors kept growing. Midmonth, she traveled with her husband to their Cape Cod house but could only manage walks to the end of the street.

By October, Mrs. Leuzzi was bedridden. Mrs. Interlichia, who needed help standing up, eventually stopped treatment. “I am not afraid,” she told her husband.

Brenda Leuzzi died Oct. 24, 2014, at age 44.

Linda Interlichia died one week later, on Halloween. She was 55.