

## Can you keep your bladder after bladder cancer strikes?

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After being diagnosed with bladder cancer, some patients face an almost



impossible decision—have their bladder removed or take a risk knowing that the cancer may be more likely to spread if the bladder is left intact.

But what if there was another way?

For David Cabelis, 68, the decision was more straightforward than most, as he had a unique opportunity to take part in a clinical trial testing a combination of chemotherapy and immunotherapy as a potential replacement for <u>bladder</u> removal.

More than two years after the trial began, Cabelis is part of a small group of <u>patients</u> for whom the experimental treatment was successful. Cabelis is now living cancer-free, with his bladder still in place.

While the trial is ongoing, the results thus far appear promising, suggesting that some people with his stage of bladder cancer may have a chance to avoid bladder removal in the future with good outcomes.

Surgical removal of the bladder, or cystectomy, is part of the standard treatment regimen for people with muscle-invasive bladder cancer, when cancer cells have grown into the deeper layers of the bladder wall and can quickly spread beyond the bladder. Around 1 in 4 people are diagnosed at this stage.

However, after removing the bladder, the cure rate is far from perfect.

"We know that even when patients undergo surgical removal of the bladder for muscle-invasive bladder cancer, the risk of metastatic recurrence is about 50%," said Dr. Matthew Galsky, an investigator in the trial. He is the co-director of the Center of Excellence for Bladder Cancer at The Tisch Cancer Institute at Mount Sinai Health System in New York City.



Of course, the prospect of losing one's bladder is daunting. Without the bladder, urine still needs to exit the body somehow. One option is an ileal conduit, which lets urine flow through a tube made of intestinal tissue. The tube connects to a small opening in the abdomen, and urine is stored in an external bag.

Other patients can get a "neobladder," which replicates the function of the original bladder. In the best-case scenario, a neobladder can mimic a reasonably normal urine function, but sometimes they don't work properly or come with complications, according to Dr. Jonathan Rosenberg, chief of bladder cancer service at Memorial Sloan Kettering Cancer Center in New York City.

## Avoiding the trauma of losing one's bladder

"A respected urologist I know once said, "The best bladder is the one you're born with, and if you can keep it, that would be great," Rosenberg said.

Cabelis, originally from Greece, has been living in the United States and driving a taxi in New York City for more than three decades.

In May 2017, after spotting blood in his urine and visiting the emergency room, he was referred to a doctor at Mount Sinai. There, he learned he had muscle-invasive bladder cancer and was given two options: to have his bladder removed or to enroll in the clinical trial.

"They asked me if I want to remove my bladder or go through a cycle of treatments with a clinical trial," Cabelis recalled. "I said, "I don't want to have half a life. I would love to have a full life, so I'd be happy to join the trial and not have my bladder removed."

The clinical trial began in 2018 and is the first to give patients with



muscle-invasive bladder cancer a combination of chemotherapy and immunotherapy as their initial treatment. These cancers are typically treated with chemotherapy alone, followed by surgery to take out the bladder.

The addition of immunotherapy and the idea of not necessarily needing to remove the bladder is novel.

The trial included 76 participants who were given four cycles of chemotherapy with a dose of the immunotherapy drug, nivolumab, on the first day of each cycle. After three months of treatment, patients underwent rigorous testing to assess how their cancer responded to treatment.

Of the 64 patients for which data is currently available, 31 patients appeared to be cancer-free at the end of the three months. They were able to proceed with treatment, receiving four more months of immunotherapy alone.

The other 33 patients, who did not seem to benefit from the <u>experimental treatment</u> based on various tests, were recommended to have their bladders removed immediately.

Thus far, the results appear promising. To date, none of the 31 patients who responded well to the therapy have died of causes related to cancer, and only one patient's cancer has spread. "Of the 18 patients that we have greater than one year of follow-up, 12 of the 18 have had no recurrence and have their bladder intact," Galsky said.

The trial's results were presented online at the American Society of Clinical Oncology's annual meeting June 4-6. Research presented at meetings should be considered preliminary until published in a peer-reviewed journal.



## Longer-term results needed before changing practice

However, more research is needed for this approach to become an accepted practice in the future.

"It's the long-term outcomes that are going to be most important," Galsky said. "Are patients really cured without having to have their bladders removed? The test of time will tell us that definitively. This is not ready for prime-time until we have longer follow-up."

Rosenberg, who was not involved in the trial, agreed. "I think the oneyear survival data looks quite good, but it's only one year," he said.

According to Rosenberg, there is also the question of whether chemotherapy alone, which is already part of the standard treatment for this cancer, would result in the same positive outcomes.

"It's very difficult to pull out the effect of immunotherapy from the chemotherapy," he said. "Immunotherapy may be the key player here, but I don't think the data supports that conclusively yet."

Another problem is that this approach only seems to work for a specific subset of patients.

According to Galsky, after chemotherapy, when patients have their bladders removed, around 30% of the bladders are entirely free of cancer.

"Now, the problem with that approach is obvious," Galsky said. "We have patients' bladders removed after chemotherapy, and we tell them, "Oh, great news, there's no cancer in your bladder—your prognosis is very good," and they look at you like you're crazy. They just had their bladder removed, and there's no cancer in their bladder."



In the future, the hope is that Galsky and other doctors in this field will know how to identify which patients may not need to have their bladders removed.

"If we knew which patients had <u>cancer</u> eliminated from the bladder ahead of time, we could potentially change the treatment paradigm and improve both the longevity and the quality of life in patients with muscle-invasive <u>bladder cancer</u>," Galsky said.

"The underlying hypothesis of this trial and others is that there are patients who benefit tremendously from the systemic therapy, and then there are people who don't," Rosenberg added. "The idea would be to find those patients who've benefited tremendously from chemotherapy or immunotherapy, and for those who don't, rather than spend three or four months getting chemotherapy, the hope is you can take them to surgery sooner or try other ways of treating them that would get them to those high cure rates."

**More information:** The U.S. National Cancer Institute has more about bladder cancer.

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