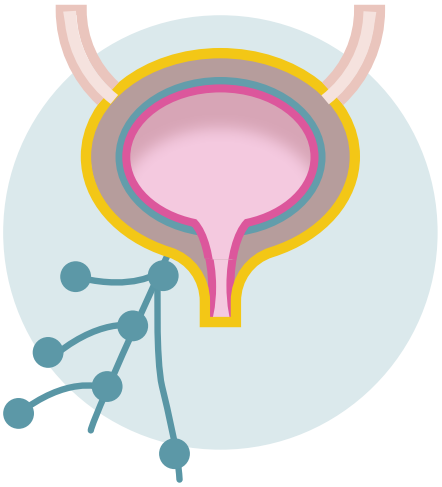
Clinical Trial Results Summary

S1011: Comparing Standard and Extended Lymph Node Removal in People Having Bladder Removal Surgery

Overview



S1011 compared 2 types of surgery to remove lymph nodes (called a lymphadenectomy) in people having their bladders removed to treat muscle-invasive bladder cancer (cancer that has grown into the muscle layer of the bladder):

- Standard lymph node removal, which removes lymph nodes from a small area around the bladder
- Extended lymph node removal, which removes lymph nodes from a larger area around the bladder

The study asked if people who had extended lymph node removal were less likely to die or to have the cancer come back than people who had standard lymph node removal.

What we learned

- 5 years after joining the study, about the same percent of people in the extended and standard lymph node removal groups were alive with no signs of cancer
- But serious side effects — and death (though not common) — within 3 months after surgery were more common in people who had extended lymph node removal

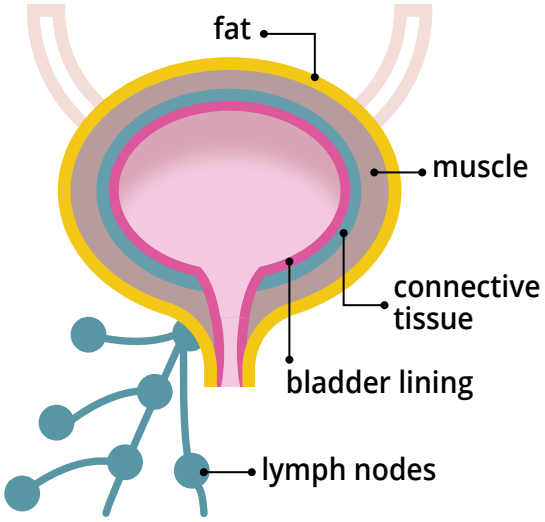
Why this study matters

Many people who have their bladders removed to treat bladder cancer have extended lymph node removal. But there hasn't been clear evidence showing if extended lymph node removal is better than standard lymph node removal at preventing death and keeping the cancer from coming back.

S1011 showed that extended lymph node removal doesn't work better and is more likely to cause serious side effects.

Detailed Trial Results

What was the trial about?



S1011 compared 2 types of **lymph node removal** in people having their bladders removed to treat muscle-invasive bladder cancer. Muscle-invasive bladder cancer has grown into the muscle layer of the bladder or farther into the fat layer around the bladder or nearby organs. Lymph nodes are found throughout the body and help fight infection and disease.

Cancer often spreads to lymph nodes, which makes it more likely to spread to other parts of the body. Getting rid of all the cancer can require removing enough lymph nodes.

The study compared standard lymph node removal with extended lymph node removal:

Standard Lymph Node Removal	vs.	Extended Lymph Node Removal
Lymph nodes are removed from a small area around the bladder.		Lymph nodes are removed from a larger area around the bladder.

Why was the study important?

For people having their bladders removed to treat bladder cancer, it's common to have an extended lymph node removal — but there hasn't been much high-level evidence supporting this. S1011 was designed as a **randomized trial** to compare extended lymph node removal with standard lymph node removal in people with bladder cancer. In randomized trials, people are randomly assigned to treatment groups, which helps make sure the results are fair and reliable.

What were the goals of the study?

The study was set up to find out:

Which type of lymph node removal does a better job of keeping the cancer from coming back

Which type of lymph node removal helps people live longer

What side effects the surgeries can cause

Who took part in the study?

People joined the study at 27 hospitals in the United States and Canada. **592** people met all study requirements and were included in the analysis of study findings. Everyone in the study had bladder cancer between stage T2 (it had only spread into the bladder's muscle layer) and stage T4a (it had spread to nearby organs). They all had their bladders removed to treat the cancer.



Age

People in the study were between **37** and **92** years old.



Sex

Bladder cancer is much more common in men than women, so the study included more men.

79% of people in the study were male **21%** were female



Race and Ethnicity

The chart to the right shows what's known about the races of the people in the study.

Note: Bladder cancer is much more common in white people.

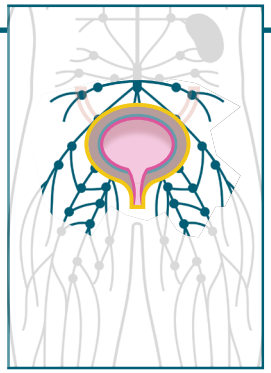
27 people reported their ethnicity as Hispanic.

Asian	12
Black	22
White	536
other, multiracial, or unknown	22

What happened during the study?

People were randomly assigned to one of 2 treatment groups:

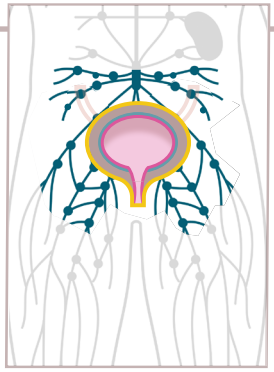
Standard lymph node removal
Surgery to remove lymph nodes from a small area around the bladder



300 people



Extended lymph node removal
Surgery to remove lymph nodes from a larger area around the bladder



292 people

In both groups, surgery was performed by highly experienced surgeons.

57 percent of people in the study received chemotherapy before having surgery. (This was not part of the study.) The study team recommended that the rest of the study participants have chemotherapy after surgery, but this wasn't required.

The study team monitored people's health for up to 6 years.

Study results

The study team found that people who had extended lymph node removal were *not* less likely to die or have the cancer come back within 5 years than people who had standard lymph node removal.

5 years after joining the study, about **6 out of 10** people in each group were alive with no signs of cancer.



But more people in the extended lymph node removal group had serious side effects or died soon after their surgery (within 3 months).

Standard lymph node removal



About **4 out of 10** people had serious side effects.

Extended lymph node removal



About **5 out of 10** people had serious side effects.

The most common serious side effects were:

- Anemia (a lower-than-normal number of red blood cells) that led to blood transfusion (getting blood through an IV)
- Urinary tract infection (UTI)
- Sepsis (a reaction to an infection that causes the immune system to harm healthy tissues and organs in the body)
- Wound complications

Standard lymph node removal	Extended lymph node removal
2% of people (7 out of 300) died within 3 months of surgery.	**7%** of people (19 out of 292) died within 3 months of surgery.

Most of the deaths were caused by complications related to surgery. Other deaths happened because the cancer grew or spread.

How has this study helped patients and researchers?

The S1011 trial showed that extended lymph node removal doesn't work better than standard lymph node removal — but is more likely to cause serious side effects. These study results can help people with muscle-invasive bladder cancer and their doctors decide between the lymph node removal options.



How to learn more

- Visit clinicaltrials.gov/study/NCT01224665
- Read the report in the *New England Journal of Medicine* at https://nejm.org/doi/full/10.1056/NEJMoa2401497
- Talk to your doctor if you have questions

Thank you!

We're grateful to everyone who joined this trial and made it possible. Trials like this one help answer important questions that will make cancer care better for future patients.

The S1011 clinical trial was sponsored by SWOG Cancer Research Network and funded by the National Cancer Institute (NCI), part of the National Institutes of Health. The trial was conducted through the NCI's National Clinical Trials Network.

This results summary was published on August 13, 2026. Newer information may have become available since that time.