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What do these results mean for individuals with bladder cancer, for whom previous treatment with BCG did not work?

This study found that for individuals with high-risk nonmuscle invasive bladder cancer (HR NMIBC) with carcinoma in situ (CIS) where previous treatment with Bacillus Calmette-Guérin (BCG) was not effective:

- Most (71%) received chemotherapy directly to the bladder as their next treatment
- 21% of patients had their whole bladder surgically removed (radical cystectomy)
- For 84% of patients who received subsequent chemotherapy, the cancer had returned or got worse within 24 months
- Despite the standard recommendation being major surgery (radical cystectomy), many patients had less invasive treatments, which often do not prevent the cancer returning, highlighting the need for new bladder-sparing treatments

What was the purpose of this study?

The purpose of this study was to understand how patients with a specific type of bladder cancer, high-risk non-muscle invasive (HR NMIBC) with carcinoma in situ (CIS), where standard treatment with Bacillus Calmette-Guérin (BCG) did not work, are treated and how well these treatments work

How was the study carried out?

- Patients with HR NMIBC were identified using the American Urological Association's Quality (AQUA) Registry (2015–2022) and the Komodo's Healthcare Map (a healthcare claims database)
- Researchers studied what treatments the patients received and how well these treatments worked
- Statistical methods were used to understand the time until the cancer came back or got worse

What were the limitations of the study? \bigcirc

- The healthcare database lacked detailed clinical information such as test results and reasoning for procedures, which may have impacted interpretation of when the cancer returned
- The registry may have missed non-urological medical care details and mortality data was not available, which may have impacted analyses. Participation in the registry was voluntary, which may have impacted demographic representation 5

Treatment patterns and clinical outcomes in patients with high-risk BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ

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What were the results?

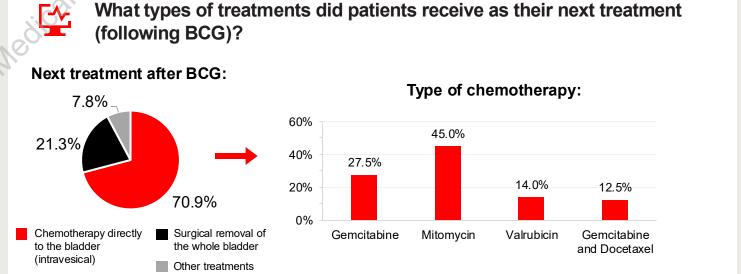
- Among all patients with HR NMIBC with CIS, 71% received chemotherapy directly to the bladder within one year as their next treatment (after previous treatment with BCG that was not effective), while 21% of patients had their whole bladder surgically removed
- Of the 200 patients who received subsequent chemotherapy, 84% had their cancer come back or get worse within 24 months following treatment and the median time for the cancer to return was 6.9 months



Who was in the study?

There were **282** participants with HR NMIBC with CIS for whom previous treatment with BCG did not work (known as BCG-unresponsive), who:

- Previously had at least 7 BCG treatments in 6 months that were not effective
- Started a different treatment within 1 year after the 6-month BCG treatment period
- Median age of patients was 72 years
- 84% were male and 16% were female
- 93% were White and 5% were Black or African American







Of those who received chemotherapy as the next treatment 84% had their cancer come back or get worse within 24 months

ossary of Terms		

Glossary of Terms					
Bacillus Calmette- Guérin (BCG)	An immune therapy administered within the bladder for the treatment of bladder cancer. BCG is the standard treatment for HR NMBIC patients	Carcinoma in situ (CIS)	An aggressive, non-invasive cancer that is confined to the surface layer of the bladder and has a high likelihood of getting worse	Gemcitabine, Mitomycin, Valrubicin, Gemcitabine + Docetaxel	Chemotherapy drugs used to treat various cancers including bladder cancer
High-risk non-muscle invasive bladder cancer (HR NMIBC)	A type of bladder cancer that has not spread into the muscle layer of the bladder, but is at risk of doing so	Intravesical chemotherapy	Treatment involving the direct introduction of chemotherapy into the bladder	Radical cystectomy	A surgical procedure to remove the whole bladder



The median time for the cancer to return (recurrence) was 6.9 months