

Alternative bladder cancer treatment emerges amid worldwide shortage of standard of care BCG

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An on-going, worldwide shortage of bacillus Calmette-Guérin (BCG) means that many patients with a common and serious type of bladder cancer have limited access to this effective standard of care treatment.

But for the first time in almost 50 years, there appears to be a viable treatment alternative.

A new study from the University of Iowa finds that a safe, inexpensive combo-chemotherapy is better tolerated than BCG and is better at preventing high-grade cancer recurrence in patients with non-muscle invasive [bladder cancer](#) (NMIBC).

Bladder cancer is the sixth most common cancer in the U.S., and NMIBC accounts for about 75% of bladder cancer cases. High-risk NMIBC has a significant risk of both recurrence and progression. Typical treatment for high-risk NMIBC involves surgical removal of the tumor followed by treatment with BCG.

The new approach, which was developed by Michael O'Donnell, MD, at the University of Iowa over 10 years ago, replaces BCG with a combination of two inexpensive, readily available chemotherapy drugs—gemcitabine and docetaxel (gem/doce). Based on this pioneering research from the UI, other major cancer centers have increasingly adopted this regimen, as well. Most recently, a UI study published in 2022 showed that 82% of patients with high-risk NMIBC who were treated with gem/doce instead of BCG remained cancer-free two years after treatment.

"With that earlier study we showed that patients with untreated non-muscle invasive bladder cancer who received gem/doce had excellent safety and efficacy outcomes that were on par with historical outcomes of BCG," says Vignesh Packiam, MD, clinical assistant professor of urology with UI Health Care.

"This was novel and impactful as it provides the first highly effective and accessible alternative to BCG, for which none previously existed. However, one limitation in that study was there was no direct

comparison to the standard of care treatment—BCG."

With the new study, published Feb. 28 in *JAMA Network Open*, Packiam, O'Donnell and their UI colleagues address that limitation by retrospectively comparing outcomes of 312 patients who received either gem/doce or BCG over a 10-year period at UI Hospitals & Clinics.

The study found that gem/doce provided better recurrence-free survival in patients with high-risk NMIBC compared to BCG, and fewer patients who received gem/doce therapy discontinued their treatment compared to patients who received BCG.

"The results were very promising," says Packiam, who also is a member of UI Holden Comprehensive Cancer Center. "We believe this new study will have an immediate impact as it shows stronger evidence for using gem/doce for [patients](#) with newly diagnosed non-muscle invasive bladder [cancer](#), for whom there is no alternative option due to the BCG shortage."

In addition to Packiam and O'Donnell, the UI team included first author Ian McElree, a medical student at the UI Carver College of Medicine, as well as Ryan L. Steinberg, MD, and Sarah Mott.

More information: Ian M. McElree et al, Comparison of Sequential Intravesical Gemcitabine and Docetaxel vs Bacillus Calmette-Guérin for the Treatment of Patients With High-Risk Non–Muscle-Invasive Bladder Cancer, *JAMA Network Open* (2023). [DOI: 10.1001/jamanetworkopen.2023.0849](https://doi.org/10.1001/jamanetworkopen.2023.0849)

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