Sustained-release chemotherapy gives new option for frail patients with invasive bladder cancer

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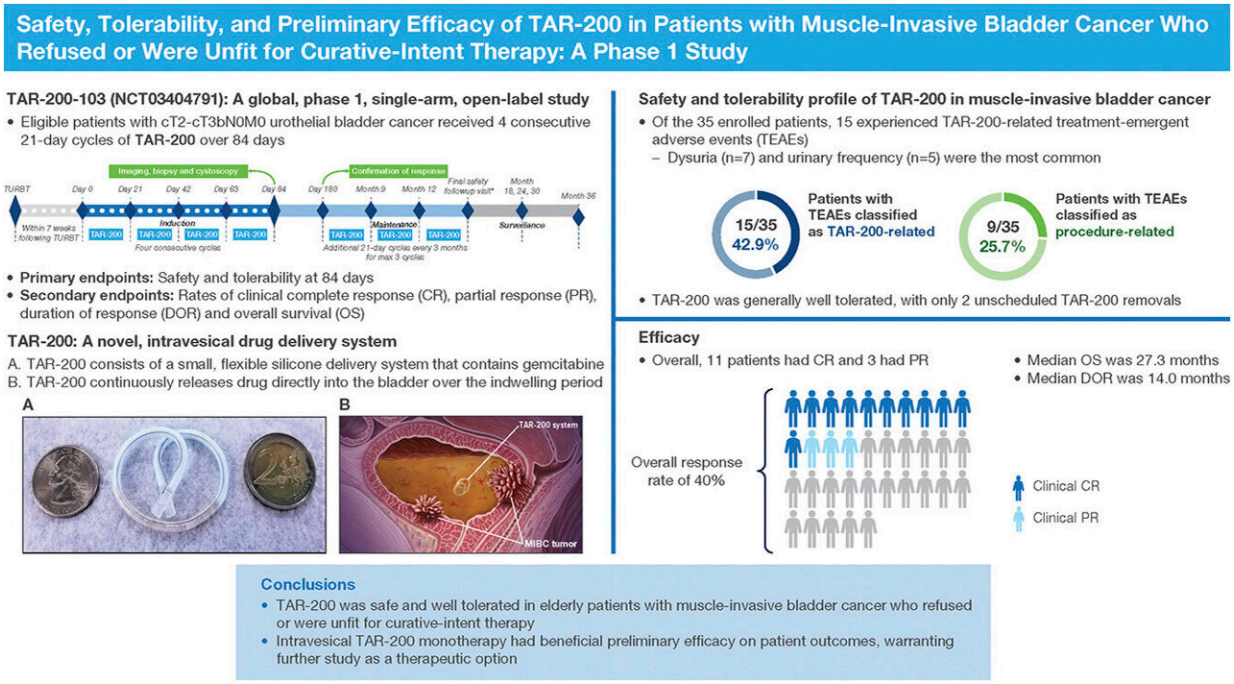

Graphical abstract. Credit: *Journal of Urology* (2023). DOI: 10.1097/JU.0000000000003195

For patients with advanced bladder cancer who are medically unfit for standard treatment, a new intravesical (inside the bladder) chemotherapy delivery system called TAR-200 is safe and shows initial evidence of effectiveness, reports a study in *The Journal of Urology*.

TAR-200 is a drug-device combination product that is inserted into the bladder and provides continuous, low-dose, local delivery of chemotherapy. "Our preliminary clinical trial found that TAR-200 was generally safe, well tolerated, and had beneficial effects on bladder cancer outcomes, in a group of patients with limited treatment options," comments lead author Mark Tyson, MD, MPH, of Mayo Clinic Arizona, Phoenix.

'Critical need' for new treatment options for MIBC

Bladder cancer is a common disease in older adults. By the time of diagnosis, about one-fourth of bladder cancers have spread into the muscle layer of the bladder wall. For these muscle-invasive bladder cancers (MIBCs), chemotherapy followed by surgery is the standard treatment.

However, some patients are considered medically unfit or decline to pursue this treatment, which carries substantial rates of complications and adverse effects. Based on previous studies, 25% to 57% of patients worldwide may not receive any "curative-intent" therapy for MIBC. "This suggests a critical need for alternative therapies that are tolerable and effective in an elderly population," the researchers write.

The TAR-200 is a small device implanted into the bladder, where it releases a continuous, low dose of gemcitabine, a standard chemotherapy agent. The goal of treatment is to limit cancer growth or progression while limiting the toxic effects of chemotherapy.

In the new phase one study, TAR-200 was used in 35 patients with MIBC: 24 men and 11 women, median age 84 years. The patients were deemed medically ineligible for standard surgery (radical cystectomy) and chemotherapy, or opted not to receive this treatment. All patients underwent minimally invasive surgery (transurethral resection of bladder

tumor, or TURBT) to remove visible tumor.

The patients then underwent a simple procedure to place the TAR-200 device, which released gemcitabine over 21 days. At that time, another procedure was performed to remove and replace the device, for a total of four treatments over 84 days.

Few adverse events, evidence of efficacy with TAR-200

TAR-200 treatment was safe and well-tolerated, assessments suggested. About one-fourth of patients had problems related to device placement or treatment procedures. About 40% had some kind of treatment-related adverse event, most commonly related to problems with urination. These relatively minor problems were "as expected" in a group of frail elderly patients with MIBC, according to the authors. Just two patients were considered "not tolerant" of TAR-200, requiring device removal.

Overall, 11 of 35 patients had a complete tumor response to TAR-200, with no evidence of bladder cancer at follow-up. Three more patients had a partial response, for an overall response rate of 40%. Median overall survival was about 27 months. That compared to a 12 overall survival rate in previous studies of MIBC patients not receiving curative-intent treatment.

Among 14 patients with lasting responses to TAR-200 treatment, 70.5% remained free from progressive bladder cancer at 12 months after treatment. "Overall, the observed clinical response to TAR-200 was robust and durable in a cohort with very limited curative-intent treatment options," Dr. Tyson and co-authors conclude.

The researchers note the small size of their study, the lack of a

comparison group, and incomplete assessment of response rates. Dr. Tyson comments, "Despite these limitations, the safety, patient tolerance, and promising preliminary effects of TAR-200 warrant further study as an alternative treatment for MIBC."

More information: Mark D. Tyson et al, Safety, Tolerability, and Preliminary Efficacy of TAR-200 in Patients With Muscle-invasive Bladder Cancer Who Refused or Were Unfit for Curative-intent Therapy: A Phase 1 Study, *Journal of Urology* (2023). DOI: 10.1097/JU.0000000000003195

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