Trial uncovers potential dangers of chemotherapy regimen for bladder cancer patients

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Patients with muscle-invasive bladder cancer often benefit from chemotherapy before surgery to remove the tumor, but a test of one regimen by researchers at Fox Chase Cancer Center was halted when too many people experienced serious side effects such as heart attacks and blood clots in the legs and lungs.

All of the 31 patients included in the study received a combination of gemcitabine and cisplatin, two drugs normally administered for 12 weeks before surgery to remove the tumors. This became the standard of care after one study looked back, retrospectively, at a their experience with a group of patients who had already received the drugs over 12 weeks and found that more than one-quarter saw their tumors disappear before surgery. Although this is the standard of care, no one had yet followed a group of patients taking these drugs from the start—known as a "prospective" study—which is the best way to test how well the treatment works and to uncover any issues, said Dr. Plimack.

"It's important to prospectively investigate both the activity and the potential side effects of these two chemotherapy drugs in patients with bladder cancer," said Elizabeth R. Plimack, MD, MS, Attending Physician the Department of Medical Oncology at Fox Chase Cancer, who reported these findings during the 50th Annual Meeting of the American Society of Clinical Oncology. "In patients who may be cured of their cancers, chemotherapy regimens that cause blood clots and other complications may delay or prevent life-saving surgery."

In Dr. Plimack's study, she and her colleagues gave patients gemcitabine and cisplatin over 6 weeks, rather than the usual 12. "Hitting tumors with chemotherapy more frequently might be more effective, and for patients who don't respond, a shorter regimen causes less of a delay in surgery," said Dr. Plimack, "and patients spend less of their life in cancer treatment."

But Dr. Plimack and her colleagues had to stop the phase II clinical trial before it was complete after 7 patients (23%) experienced serious cardiovascular events such as stroke, heart attack, and potentially deadly blood clots in the lungs or legs.

Even though gemcitabine is known to increase the risk of cardiovascular problems, she and her colleagues were "surprised" to see so many patients were affected. It's possible that condensing the doses into 6 weeks caused problems, but that's not the only explanation, said Dr. Plimack. "Two of the most severe cardiovascular events occurred after one treatment, so the dosing schedule was not the only factor here."

Gemcitabine is a frequently administered drug, so it is critical that researchers continue to follow patients receiving it, said Dr. Plimack. "In the meantime, patients who have concerns about taking gemcitabine should consult their doctors about their individual plan."

Provided by Fox Chase Cancer Center