

Clinical trial tests COXEN model to predict best treatment for bladder cancer

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Imagine being able to match a cancer's genes to the best treatment. That's the promise of COXEN (CO eXpression Extrapolation) – a computer program that looks at a panel of cancer genes in a patient's tumor to predict whether it will respond to chemotherapy. Now a clinical trial recently approved by the National Cancer Institute will open at the University of Colorado Cancer Center and nationally via the Southwest Oncology Group (SWOG) to test the COXEN model in bladder cancer – can it predict which cancers will and which cancers will not respond to two common chemotherapies?

"It's an important question. Chemotherapy before surgery or radiation has been shown to have benefit overall, but picking which specific patients benefit and which have no benefit is currently not possible. If we treat a bladder cancer with chemotherapy and the tumor doesn't respond, we've lost valuable months in which we could have done surgery or radiation and have exposed the patient to toxicity," says Dan Theodorescu, MD, PhD, professor of Urology and Pharmacology, director of CU Cancer Center and a developer of COXEN.

The COXEN program is powered by data known for what is called the NCI-60. Basically, extensive genetic and drug testing has been done against a panel of 60 cell lines curated by the National Cancer Institute, representing a range of human cancers. Because we know the genetics of cancers that respond to certain drugs, we can extrapolate this knowledge to predict new cancers that will respond to these drugs – based on genetic similarity between cancers, we can make accurate inferences

about what will work and what will not work even for cancers not represented among the NCI-60, such as bladder cancer. In fact, because COXEN depends on genes and not on tumor types like "lung" or "bladder" or "breast" to make its predictions, it could be applied across various cancers, based only on genetic similarity.

"Bladder cancer isn't rare, but there hasn't been a major medical breakthrough in treating bladder cancer 20 years," says Thomas Flaig, MD, medical director of the CU Cancer Center Clinical Investigations Shared Resource, associate professor of medicine at the University of Colorado School of Medicine, and national chair of the current SWOG clinical trial. "We have new, targeted treatments for lung cancer, breast cancer, and others, but so far there hasn't been a good way to select patients with the best chance of responding to traditional chemotherapies. COXEN could allow us to better target these therapies, predicting what will work and what will not based on a cancer's genetic structure for individual patients."

The phase 2 randomized trial now underway will use tissue from a biopsy before surgery. Researchers will then examine the cancer's [genetic structure](#). In this case, patients will have been randomized to one of two currently accepted chemotherapeutic regimens, namely Gemcitabine plus Cisplatin or MVAC, a 4 drug combination. Researchers will watch patient outcomes to discover if the COXEN algorithm predicted the most useful drug more often than current methods. If successful, future trials will allow COXEN to choose bladder cancer treatment proactively, and could be expanded to many additional cancer types.

"This is a big deal for three reasons," Flaig says. "First, it could help us correctly assign patients to chemotherapy versus immediate local therapy with surgery or radiation in bladder cancer. Second, it could help us direct chemotherapy in many other human cancers if proven here. And

third, it could represent the first advance in a disease that has lagged far behind many others in the modern era of molecularly-driven cancer care."

The COXEN trial will enroll 184 [bladder cancer](#) patients at the CU Cancer Center and at other NCI [clinical trials](#) sites around the country. More information is available at ClinicalTrials.gov.

Provided by University of Colorado Denver

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