Evaluating an alternative clinical genetics care delivery model for patients with prostate cancer

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Background: About 12% of men with advanced prostate cancer harbor a germline DNA damage response (DDR) gene mutation. Identifying patients with mutations is increasingly clinically relevant—germline DDR gene mutations can predict improved responses to poly-ADP ribose polymerase (PARP) inhibitors, and possibly to platinum-based chemotherapy. To date, there are no reliable clinical criteria to guide which patients are at greater risk of germline mutations and who should be tested. Given the large population of patients at risk, and the need to receive timely results for therapy selection, novel methods of delivering clinical genetics testing and results are needed.

Methods: We have designed a prospective, single-arm study to examine how an alternative clinical genetics care delivery model affects patients' psychological and behavioral outcomes. The aims of this study are to assess whether this approach is safe and acceptable to patients with prostate cancer, and to assess the clinical utility of broad germline testing in this population. Patients are eligible if they have advanced prostate cancer. During routine medical visits, the patients' oncologists offer genetic testing on the protocol after a brief standardized pre-test education, which includes a written brochure and narrated video specific for prostate cancer. Genetic testing is performed the same day using a clinically approved and validated multigene panel assay that includes the following: *BRCA1, BRCA2, CHEK2, HOXB13, PALB2, RAD51D, MLH1, MSH2, MSH6, PMS2, EPCAM, TP53* and *ATM*. Within 2 weeks of consent, patients are asked to complete an email questionnaire using a secure, REDCap system. Genetic counselors contact the patient over the telephone for an initial personal and family history assessment, and then again to disclose the results of genetic testing and perform post-test counseling. Patients then complete two additional email questionnaires 1 week and 2 months after receiving results. Optional in-person counseling for patients and their families is also offered to all patients. We will define clinical utility if one of three scenarios are met: actual treatment change that would not have occurred without treatment results, future therapy implications, or immediate genetic counseling implications. We will assess psychological and behavioral outcomes by patients' self-report in the email questionnaires. The questionnaires will assess several constructs including ambiguity aversion, emotional distress, genetics and cancer knowledge, satisfaction with genetic testing, educational material and counseling.

Results: To date, 10 patients have consented to germline testing during routine medical oncology visits. Updated results will be presented at the conference.

Conclusions: There is clinical need to evaluate alternative clinical genetics care delivery models for patients with advanced prostate cancer. Testing a model delivered by oncologists using standardized pre-test educational material and telephone genetic counseling is feasible.

Conflict of Interest: There are no conflicts of interest to report.

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