FAQs About Radiation Therapy for Localized Prostate Cancer

Both radiation and surgery are highly effective treatments for localized prostate cancer. A large, long-term study found that, after 15 years, survival rates were nearly identical (~97%) regardless of which treatment was chosen.[1] Since both radiation and surgery offer similar survival outcomes, treatment decisions are often influenced by which option is most likely to preserve long-term quality of life and minimize the risk of side effects.

What is external beam radiation therapy (EBRT)?

EBRT is a common treatment where radiation "beams" are targeted on a tissue with cancer from outside of the body. The treatment is designed to focus on the tissue with cancer while sparing healthy tissue. Treatment is delivered over multiple sessions (fractions) and common schedules used to treat localized prostate cancer are called:

- **Stereotactic Body Radiation Therapy (SBRT):** 5–7 higher-dose sessions over approximately 10 days
- **Moderately Hypofractionated Radiation Therapy (MHFRT) or Conventionally Fractionated Radiation Therapy (CFRT):** 20–28 sessions over 4–5 weeks or 37–45 sessions over 7–9 weeks

What are side effects from radiation therapy?

Side effects, also known as toxicity or adverse events, can occur with radiation therapy. Modern radiation therapy techniques minimize exposure of normal healthy tissues to radiation, but some prostate cancer patients are more sensitive to radiation, leading to side effects that develop from radiating the prostate gland itself. In prostate cancer, the most common side effects involve the genitourinary (GU) system. The most bothersome GU side effects are "late" GU side effects, which occur six or more months after EBRT in 20% or more of men.[2] These side effects can include:

- Pain or burning during urination
- Frequent or urgent urination
- Blood in the urine (hematuria)
- Urine leakage

Is there a way to identify who is at risk for late GU side effects?

Because every patient can respond differently to treatment, factors like age, overall health, and existing symptoms are not sufficient to reliably identify which men are at a higher risk of developing late GU side effects. Recent advances in genetics have allowed the ability to predict individual risk of developing late GU side effects. By analyzing inherited DNA biomarkers, it is now possible to predict if a patient is at low-average or high risk for developing these side effects after SBRT or MHFRT/CFRT. Because each radiation therapy regimen has its own unique genetic risk profile, a patient may be at high risk for side effects with one treatment and low-average risk with another, and it is rare for a patient to be at high risk for SBRT and MHFRT/CFRT. This personalized information can provide more information to support safer, more individualized care.

Why is understanding individual risk before choosing treatment important?

Choosing a treatment involves balancing potential benefits with possible side effects. A clear understanding of personal risk for late GU side effects for the common types of EBRT for localized prostate cancer helps patients and their care team make decisions with greater clarity. For example, knowing there is a low-average risk for late GU side effects for SBRT may provide greater confidence in that option. A high risk may support considering alternatives such as MHFRT/CFRT. Having this information before treatment begins can help select the approach most likely to preserve long-term quality of life while minimizing side effects.

What is PROSTOX®?

PROSTOX tests are genetic tests that can predict a risk of late GU side effects from specific radiation therapy treatment approaches. They look at inherited DNA differences that help identify patients at high versus low-average risk of late GU side effects. These results can help support discussions between a patient and their healthcare provider as they consider treatment options for localized prostate cancer.

There are two PROSTOX tests available to cover the most common radiation regimens. A patient can take one test or both, depending on the treatment option(s) being considered.

- ***PROSTOX Ultra*:** For those considering SBRT
- ***PROSTOX Standard*:** For those considering CFRT or MHFRT

What will PROSTOX results mean?

Results are reported as "LOW-AVERAGE RISK" or "HIGH RISK" for developing late GU side effects. A high-risk result means that the patient is significantly more likely to develop late GU side effects compared to a patient with a low-average risk result:[3]

PROSTOX Ultra (for SBRT) high risk: Late GU side effects are ~7x more likely

PROSTOX Standard (for CFRT or MHFRT) high risk: Late GU side effects are ~11x more likely

- A patient can have a high-risk result for one test, but not the other, since each test's biomarkers are unique.
- Very few people (1–2%) receive a high-risk result for both tests. If that is the case, the patient and their health care provider can explore alternative treatment options.

Frequency of low-average and high-risk results when tested with both PROSTOX Ultra and PROSTOX Standard

What is the process for getting a PROSTOX test?

PROSTOX is ordered by a health care provider

A home collection kit is mailed to the patient

Sample collection is a simple gumline swab

Results are available within 5 to 7 business days

Is PROSTOX covered by insurance?

PROSTOX tests are new and innovative, so insurance coverage may vary. MiraDx has a generous Financial Assistance Program, which offers reduced pricing based on need.

Learn more about genetics, prostate cancer, and PROSTOX at mirakind.org/prostox-testing

References

1. Hamdy FC, Donovan JL, Lane JA, et al. Fifteen-year outcomes after monitoring, surgery, or radiotherapy for prostate cancer. *N Engl J Med.* 2023;388(17):1547-1558. doi:https://doi.org/10.1056/NEJMoa2214122.
2. Tree AC, Ostler P, van der Voet H, et al. Intensity-modulated radiotherapy versus stereotactic body radiotherapy for prostate cancer (PACE-B): 2-year toxicity results from an open-label, randomised, phase 3, non-inferiority trial. *Lancet Oncol.* 2022;23(10):1308-1320. doi:https://doi.org/10.1016/S1470-2045(22)00517-4.
3. Based on internal data from patients in clinical trials and real-world clinical settings.