Does my patient need more therapy after prostate cancer surgery?

Contact the GenomeDx Patient Care Team at: 1.888.792.1601 (toll-free) or e-mail: client.service@genomedx.com
Decipher® Prostate Cancer Classifier Predicts Metastasis after Surgery

Decipher classifies post-surgery patients* into genomic risk categories for metastasis with 98.5% Negative Predictive Value (NPV).

Post radical prostatectomy (RP) indications for Decipher test

- Pre-operative PSA ≥ 20ng/mL
- High Gleason Score ≥ 7
- Tertiary Gleason 5
- Perineural or Lymphovascular Invasion
- Positive Surgical Margins (SM+)
- Extraprostatic Extension (pT3a disease)
- Seminal Vesicle Invasion (pT3b disease)
- Bladder Neck Invasion (pT4 disease)
- Lymph Node Involvement (LNI)
- Rising PSA or Biochemical Recurrence

Decipher Classification

| Genomic Low Risk | Observation with PSA monitoring until detectable PSA rise, if any/ever.² | 98.5% 5 year metastasis-free survival³ |
| Genomic High Risk | 80% reduction in metastasis risk in Decipher high-risk patients who receive adjuvant or early radiation¹,² | Radiation alone is insufficient. Intensification of treatment may be needed.³ |

Treatment recommended post-surgery¹,⁷,⁸

- Observation with PSA monitoring until detectable PSA rise, if any/ever.²
- 98.5% 5 year metastasis-free survival³
- 95% 10 year prostate cancer-specific survival³

Treatment recommended post-surgery after PSA rise or biochemical recurrence

- Radiation alone is sufficient. Concurrent hormone therapy may be avoided.³

References


*Clinically high risk patients with one or more of the “Post radical prostatectomy (RP) indications for Decipher test” listed above.
Decipher®
Know what treatment. And when to treat.

Decipher for patients after prostate surgery

- **Decipher low-risk patients** may be managed safely with observation until PSA rise.
- **Decipher high-risk patients** may experience lower rates of metastasis when treated with adjuvant radiation post-RP.

Decipher for patients after prostate surgery with PSA rise or biochemical recurrence

- **Decipher low-risk patients** have excellent prognosis with salvage radiation and may avoid concurrent hormonal therapy, as incidence of metastasis remains low.
- **Decipher high-risk patients** may require intensification of therapy beyond radiation as incidence of metastasis remains high.

Patients treated with salvage radiotherapy

- **Decipher low-risk**
- **Decipher high-risk**

*No concurrent hormone therapy given
Suggested Patient Management Plan

References
Decipher

High Risk

Decipher

Low Risk

Observation

PSA Rise/BCR

Excellent prognosis with SRT and may avoid concurrent hormone therapy

May require intensification of therapy beyond radiation

Radiation (ART Better Results Than SRT)

Excellent prognosis with SRT and may avoid concurrent hormone therapy

Decipher

High Risk

Decipher

Low Risk
Your Decipher Result: Genomic high risk

Your Decipher genomic risk result: Independent of clinical risk factors, your five year Decipher genomic risk of metastasis after radical prostatectomy is 37.4%. Your Decipher risk is 6.2 times the average* patient with adverse pathology.

Interpretation: Clinical studies concluded that Decipher high risk men with adverse pathology have a poor prognosis overall. These men may benefit from adjuvant or early salvage radiotherapy and consideration for clinical trials.

Relevant findings from published clinical studies: Patients with Decipher high risk had 77.5% 5 year metastasis-free survival and 76.6% 10 year prostate cancer-specific survival. For these patients there was improved metastasis-free survival favoring adjuvant and early salvage postoperative radiotherapy.

In patients with PSA rise or biochemical recurrence after surgery that received salvage radiotherapy, only 66.5% remained metastasis-free after 5 years.

The Decipher risk reported here has a 95% confidence interval of 21.3% to 50.2%.

References on reverse

*Average clinical risk refers to the average cohort risk of clinically high-risk men post surgery, established in a cohort of 1,034 clinically high-risk patients that received radical prostatectomy as first line treatment at the Mayo Clinic between 2000 and 2006. The average incidence of metastasis was 6.0% at 5 years post radical prostatectomy.

Decipher Prostate Cancer Classifier.

GenomeDx Medical Director (Signature) Date

Medical Directors: Timothy J. Triche, MD PhD | Doug Dolginow, MD

Copyright © 2016 GenomeDx Biosciences Inc.
Your Decipher Result: Genomic low risk

Your Decipher genomic risk result: Independent of clinical risk factors, your five year Decipher genomic risk of metastasis after radical prostatectomy is 0.4%. Your Decipher risk is 0.1 times the average patient with adverse pathology.

Interpretation: Clinical studies concluded that Decipher low risk results in men with adverse pathology have good prognosis overall and may be optimally managed with observation after surgery. Upon PSA rise, these patients may be treated with delayed or deferred radiotherapy without concurrent hormone therapy.

Relevant findings from published clinical studies: Patients with Decipher low risk had >97.8% 5 year metastasis-free survival and >94.7% 10 year prostate cancer-specific survival. For these patients there were no significant differences in metastasis-free survival with adjuvant, early or late salvage postoperative radiotherapy treatment.

In patients with PSA rise or biochemical recurrence after surgery that received salvage radiotherapy, >97.2% 5 year metastasis-free survival was observed with or without concurrent hormone therapy.

The Decipher risk reported here has a 95% confidence interval of 0.0% to 0.8%.

References on reverse

---

GenomeDx Medical Director (Signature)

Medical Directors: Timothy J. Triche, MD PhD | Doug Dolginow, MD

Copyright © 2018 GenomeDx Biosciences Inc.
Access for All Patients

- **Medicare Coverage**
  Only post radical prostatectomy (RP) test covered by Medicare (Pre-op PSA ≥ 20ng/mL, Gleason Score ≥7, Tertiary Gleason 5, perineural or lymphovascular invasion, positive surgical margins, bladder neck invasion, pT3, lymph node involvement, or PSA rise).

- **Private Insurance Coverage**
  All plans accepted

- **Proven, and comprehensive financial assistance for patients**
  Vast majority of non-insured patients qualify

- **Proactive patient outreach by GenomeDx Client Services Team**
  Minimizing calls from patients to physician regarding billing questions and concerns

What is Decipher®?

- Predicts risk of prostate cancer metastasis post radical prostatectomy
- Based on analysis of >2,500 patients
- A genomic test that helps determine who:
  - can be safely observed after RP
  - may need adjuvant radiation
  - may be better managed with salvage radiation
  - may avoid hormone therapy with radiation
- The ONLY test covered by Medicare for post-surgery

To learn more about Decipher®, visit www.DecipherTest.com or contact the GenomeDx Patient Care Team today at 1.888.792.1601 (toll free)