A Framework for Treatment Decision Making at Prostate Cancer Recurrence.

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Abstract

BACKGROUND: Of the 50,000 men in the US who elect for radical prostatectomy for prostate cancer, 24% to 40% will have a prostate-specific antigen (PSA) recurrence (PSA-R) within 10 years. Deciding whether to administer salvage therapy (ST) at PSA-R presents challenges, as treatment reduces the risk of progression to clinical metastasis but incurs unnecessary side effects should the man die before metastasis. We have developed a new harm-benefit framework using a clinical cohort to inform shared decision making between patients and physicians at PSA-R.

METHODS: Records of 1,045 Johns Hopkins University Hospital patients diagnosed between 1984 and 2013 who had PSA-R following radical prostatectomy were analyzed using marginal structural models to estimate the baseline risk of metastasis and the effect of ST (radiation therapy with or without hormone therapy) while accounting for selection into ST on the basis of PSA growth. The estimated model predicts the harm-benefit tradeoffs of ST within patient subgroups. The benefit of ST is the absolute reduction in the risk of metastasis within 10 years; the harm is the frequency of cancers that would not have metastasized in the patient's lifetime in the absence of ST (overtreatment).

RESULTS: The adjusted hazard ratio associated with ST was 0.41 (95% CI, 0.31 to 0.55). Providing ST to all men at PSA-R reduced the risk of metastasis from 43% to 23% but led to 31% of men being overtreated (harm/benefit = 31/(43-23) = 1.6). Providing ST to men with Gleason score >7 reduced the risk of metastasis from 67% to 39%, with 13% of men being overtreated (harm/benefit = 13/(67-39) = 0.5).

CONCLUSIONS: A quantitative framework that evaluates primary harms and benefits of ST after PSA-R will facilitate informed decision making. Immediate ST may be more appropriate in patient subgroups at elevated risk of metastasis.

KEYWORDS: confounding; marginal structural model; overtreatment; prostate-specific antigen; prostatic neoplasms; recurrence; salvage treatment; shared decision making; targeted treatment

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