Are Further Studies of Breast Cancer Tumor Markers Justified? A Value of Research Analysis

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INTRODUCTION

In a recent trial a CA 27.29 radioimmunoassay was able to identify patients with breast cancer recurrence 5.3 months before recurrence is clinically established. However, American Society of Clinical Oncology (ASCO) guidelines recommend against the use of these tumor markers to detect recurrence following breast cancer therapy. However, usage estimates for biomarker testing exceed 20% of all cases of early breast cancer. The ASCO recommendation is based on the absence of data showing a survival or other outcome benefits such quality of life, drug toxicity etc. Two prospective trials conducted in the 80s following breast cancer patients with intensive vs. standard follow-up regime showed no significant differences in overall survival. Given newer therapies with improved efficacies and toxicity profiles, earlier detection and treatment of breast cancer recurrence may yield substantial improvements in healthcare outcomes. However, a trial would represent an efficient use of resources. Value of research methods can be used to evaluate if such trials focusing on reducing uncertainty in specific parameters, may provide substantial value.

OBJECTIVE

To assess the value of additional research for testing carcinomembronc antigen (CEA), cancer antigen (CA)15-3 and CA 27.29 biomarkers for earlier detection and treatment of recurrent breast cancer.

EVSI - CONFIDENCE IN EXPERT OPINION AND TRIAL SIZE

An analysis was also conducted to determine the impact of different trial sizes. We also explored the impact of different levels of confidence in expert opinion i.e. being equivalent to an existing trial with n=1 to n=50. Note that the sharp edges below are due to convergence errors.

Breast Cancer Tumor Markers: Value of Research (EVSI), Trial Size and Expert Confidence

RESULTS

Our results indicate that substantial value to society can be obtained by evaluating the clinical utility of serial tumor marker assessment for early detection of breast cancer recurrence. This value is driven by the current paucity and conflicting information in this area, severity of outcomes, and large population that could be affected. Even small trials focusing on reducing uncertainty in specific parameters, may provide substantial value.

CONCLUSIONS

Expected Value of Sample Information (EVSI)

An emerging field in health economics—value of information (VOI) analysis—quantifies the value of future research, and may be helpful in resource allocation decisions. Based on Bayesian decision theory, these methods provide an analytical framework to assess the societal value obtained by the reduction of uncertainty around a treatment or testing decision. The value of information is a function of 1) the probability of selecting the optimal monitoring strategy based on current vs. future information, 2) the clinical and economic impacts of each strategy, and 3) the size of the population affected.

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