MONOTHERAPY OF ANDROGEN DEPRIVATION THERAPY VERSUS RADICAL PROSTATECTOMY AMONG VETERANS WITH LOCALIZED PROSTATE CANCER: A COMPARATIVE EFFECTIVENESS ANALYSIS OF RETROSPECTIVE COHORTS

Li J, Shi L, Satter O
Tulane University, New Orleans, LA, USA

OBJECTIVES: There is no consensus regarding the optimal treatment for localized prostate cancer. This study aimed to examine the comparative effectiveness of monotherapy of either primary androgen deprivation therapy (PADC) or radical prostatectomy (RP) in terms of overall survival rate. METHODS: Male patients with localized prostate cancer were identified in the Veterans Affairs Veterans Integrated Service Network 16 data warehouse (January, 2003-June, 2006), with one year baseline and at least 3-year follow-up (till 06/2009). Eligible patients (18-75 years old) had no other cancer history and used PADT or monotherapy of RP within 6 months after the first diagnosis of prostate cancer. The overall survival from initiation of index treatment was analyzed using Kaplan-Meier method and Cox proportional hazard regression, adjusted for age, race, marital status, insurance type, cancer stage, Charlson comorbidity index, alcohol and tobacco use. RESULTS: The age was 67.0(5.0) years in 249 PADT patients, 59.7(6.1) in 215 RP patients. During the follow-up of 4.2(0.95) years, the cumulative incidence of death was 29 (13.74%) among PADT patients and 6 (2.79%) among RP patients (p<0.001). The overall 3-year survival rate was 89.57% in PADT and 98.60% in RP (p<0.001). Patients who received PADT had almost 4 times as high mortality risk as those using RP (HR = 3.825, 95% CI = 1.483 to 9.845, p = 0.006). CONCLUSIONS: The overall survival rate following RP among localized prostate cancer patients was significantly higher than that after PADT, controlling for other confounders. More research among a larger population with longer follow-up are warranted to confirm this finding.

ESTIMATED EFFECTS OF THE NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM ON CERVICAL CANCER MORTALITY

Royalty J1, Li C1
University of Washington, Pharmaceutical Outcomes Research and Policy Program, Seattle, WA, USA, 2University of Washington, Seattle, WA, USA, 3University of Twente, Enschede, The Netherlands

OBJECTIVES: To assess the value of additional research for ERCC1 expression testing to guide adjuvant chemotherapy decisions in fully resected Stage I non-small cell lung cancer (NSCLC). METHODS: We refined a previously-developed decision-analytic model to estimate the expected value of perfect information (EVPI) and expected value of sample information (EVSIs) for two treatment strategies: 1) ERCC1 testing to inform adjuvant chemotherapy decisions, with ERCC1+ patients receiving no chemotherapy and ERCC1- patients receiving chemotherapy; 2) standard care, with all patients receiving no chemotherapy. Model parameters and uncertainty ranges were derived from a retrospective analysis of the International Adjuvant Lung Cancer Trial, published literature, and government sources. The affected population was derived from SEER incidence estimates, and examined over a discounted 10-year time horizon. RESULTS: At a willingness-to-pay of $150,000 per quality-adjusted life year, ERCC1 and standard care strategies resulted in average net-benefits of $630,500 and $625,200, respectively. The ERCC1 and standard care strategies produced greater net-benefit in 64% and 36% of 10,000 simulations, respectively. The average net-benefit difference was $14,000 in simulations where the standard care strategy was optimal. With an affected population of 292,855, EVPI was $1.2 billion. Preliminary estimates suggest an EVSI of approximately $20 million at plausible sample sizes. CONCLUSIONS: Considerable value could be realized through additional research to reduce uncertainty about the comparative health outcomes of ERCC1 and standard care strategies. The EVPI of $1.2 billion was driven by the large 10-year affected population, probability that ERCC1 testing is not the optimal strategy, and consequences of selecting the non-optimal strategy. Forthcoming results will enable estimation of the expected net-benefit of sampling, which compares the EVSI of various study designs and sample sizes to the cost of conducting such studies. These findings can assist stakeholders in prioritizing funding for ERCC1 research relative to alternative research investments.

PALOSONETRON VERSUS OTHER 5-HYDROXYTRYPTAMINE, RECEPTOR ANTAGONISTS FOR PREVENTION OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING AMONG MEDICARE PATIENTS WITH CANCER

Cavender C1, Gayle J1, Balu S2, Buchner D2
1Premier, Inc., Charlotte, NC, USA, 2Eisai, Inc., Woodcliff Lake, NJ, USA

OBJECTIVES: To assess the rate of uncontrolled chemotherapy induced nausea and vomiting (CINV) associated with palonosetron initiation versus other 5-hydroxytryptamine, receptor antagonists (5-HT3-RAs) among Medicare patients with cancer on chemotherapy (CT) treatment in a hospital outpatient setting. METHODS: Medicare patients with a cancer diagnosis initiating CT and anti-emetic prophylaxis with palonosetron (Group 1) and other 5-HT3-RAs (Group 2) for the first time (index date) between April 1, 2007 – March 31, 2009 were identified from the Premier Perspective database. Inclusion criteria were no evidence of nausea and vomiting, CT, and anti-emetic medication in the 6-month pre-index date period and 36-consecutive months of data submission. A negative binomial distribution generalized linear multivariate regression model estimating the rate of CINV events on CT emetogenicity and cycle matched groups in the follow-up period (first of eight CT cycles or six months post-index date) was developed after adjusting for several demographic and clinical variables. RESULTS: Of 4789 identified patients, 962 initiated palonosetron (Group 2, 20.1%). Group 1 patients were significantly younger [70.4 (SD: 9.3) versus 71.4 (9.0) years; p<0.0001], comprised more females [52.9% versus 48.6%; p<0.0001], less African Americans [8.7% vs. 11.3%] and more Hispanic patients [6.3% versus 2.5%]; all p<0.0001, more highly and moderately emetogenic CT [33.6% versus 20.7% and; 47.3% versus 40.3%, respectively; p<0.0001], and more long and breast [30.9% vs. 24.9% and 12.3% vs. 9.6%, respectively; p<0.0001]. In the follow-up period, the regression model predicted a 11.8% decrease in the CINV events per CT cycle for Group 1 patients versus Group 2 patients; p<0.0001. CONCLUSIONS: In this retrospective hospital outpatient study, patients switching for CT emetogenicity and cycle and adjusting for other potential confounders, Medicare patients with cancer initiated on palonosetron were more likely to experience a significantly lower rate of CINV events per CT cycle versus those initiating other 5-HT3-RAs.

THE VALUE OF RESEARCH FOR ERCC1 TESTING IN STAGE I NON-SMALL CELL LUNG CANCER

Rath J1, Carlson JF, Steuten L2, Veenstra D3
1University of Washington, Pharmaceutical Outcomes Research and Policy Program, Seattle, WA, USA, 2University of Washington, Seattle, WA, USA, 3University of Twente, Enschede, The Netherlands

OBJECTIVES: To assess the value of additional research for ERCC1 expression testing to guide adjuvant chemotherapy decisions in fully resected Stage I non-small cell lung cancer (NSCLC). METHODS: We refined a previously-developed decision-analytic model to estimate the expected value of perfect information (EVPI) and expected value of sample information (EVSIs) for two treatment strategies: 1) ERCC1 testing to inform adjuvant chemotherapy decisions, with ERCC1+ patients receiving no chemotherapy and ERCC1- patients receiving chemotherapy; 2) standard care, with all patients receiving no chemotherapy. Model parameters and uncertainty ranges were derived from a retrospective analysis of the International Adjuvant Lung Cancer Trial, published literature, and government sources. The affected population was derived from SEER incidence estimates, and examined over a discounted 10-year time horizon. RESULTS: At a willingness-to-pay of $150,000 per quality-adjusted life year, ERCC1 and standard care strategies resulted in average net-benefits of $630,500 and $625,200, respectively. The ERCC1 and standard care strategies produced greater net-benefit in 64% and 36% of 10,000 simulations, respectively. The average net-benefit difference was $14,000 in simulations where the standard care strategy was optimal. With an affected population of 292,855, EVPI was $1.2 billion. Preliminary estimates suggest an EVSI of approximately $20 million at plausible sample sizes. CONCLUSIONS: Considerable value could be realized through additional research to reduce uncertainty about the comparative health outcomes of ERCC1 and standard care strategies. The EVPI of $1.2 billion was driven by the large 10-year affected population, probability that ERCC1 testing is not the optimal strategy, and consequences of selecting the non-optimal strategy. Forthcoming results will enable estimation of the expected net-benefit of sampling, which compares the EVSI of various study designs and sample sizes to the cost of conducting such studies. These findings can assist stakeholders in prioritizing funding for ERCC1 research relative to alternative research investments.