PCN7

AN ANALYSIS OF BIOMARKER TESTING AND APPROPRIATE TREATMENT AMONG WOMEN WITH BREAST CANCER USING ONCOLOGY EMR DATA

Foley K[1], Bizier R[1], Hansen LG[2]

[1]*Truven Health Analytics, Cambridge, MA, USA,* [2]*Truven Health Analytics, Northwood, NH, USA*

OBJECTIVES: Personalized treatment for biomarker-specific breast cancer is a reality. However, outcomes research has lagged behind due to lack of data sources capturing testing, results, and drug treatment. This study uses a new oncology electronic medical record (EMR) database to examine testing, documentation of results, and appropriate treatment among a cohort of women with breast cancer treated in community oncology practices. **METHODS:** The Truven Health MarketScan® Oncology EMR Database was used to select patients diagnosed with breast cancer between July 1, 2011 and September 30, 2013 who had at least 2 visits and known disease stage. Biomarker tests and results for estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) were observed along with patients' drug treatment. **RESULTS:** 57,660 women met inclusion criteria. Documented biomarker testing varied by disease stage and test. ER testing was >90% for women with stage I or II; 77% for stage IV patients. More than 86% of women with stage 0-III and 71% with stage IV had a PR test. HER2 testing was documented in 66% with stage 0, 77% with stage I-III, and 63% with stage IV. Overall, 74%, 55%, and 2% of women who were ER positive, HER2 positive, and HER2 negative respectively received biomarker specific treatment. Treatment rates varied by disease stage, with >80% of stage IV women receiving appropriate treatment for ER positive or HER2 positive cancer. Among HER2 negative stage IV women, appropriate treatment was 16%. 6%, 12%, and 14% of patients respectively had a biomarker result that was not consistent with ER positive, HER2 positive, and HER2 negative treatment received. **CONCLUSIONS:** Documentation of appropriate testing varied both by the type of test and disease stage. Quality improvement programs aimed at documentation as well as appropriate treatment may benefit patients treated in community oncology practice.

PCN8

IS DEPRESSION RELATED TO UNDERUSE OF BREAST CANCER SCREENING?

Park C, Ma X, Lawson KA

The University of Texas at Austin, Austin, TX, USA

OBJECTIVES: Many studies have demonstrated that depression is associated with poor adherence to treatment of various diseases. Previous research has shown inconsistent results regarding the impact of depression on mammography use behaviors. The objective of this study was to assess the relationship between women's depression and mammography use. To **METHODS:** This cross-sectional study used data from the 2012 Behavioral Risk Factor Surveillance System (BRFSS) and employed the Health Belief Model (HBM). The independent variable was the presence of depression. The dependent variable was mammogram use, which was defined based on the U.S. Preventive Services Task Force's mammogram guidelines, categorized at three levels: 1) had never been screened, 2) had been screened, but not within two years, and 3) had been screened within two years. Multivariate ordinal logistic regressions were used for analyses. **RESULTS:** An estimated population size of 45,578,030 women was included. Among this population, 23.02% of women reported the presence of a depressive disorder. A chi-square test showed a significant relationship between mammogram use and depression ($p<0.001$). The unadjusted proportional odds ratio [95% CI] when comparing women with depression to women without depression on mammogram use was 0.81 [0.76, 0.86], which means that both the odds of 'screened within two years' versus the combined 'screened, but not within two years' and 'never screened' and the odds of combined 'screened within two years' and 'screened, but not within two years' versus 'never screened' were 0.81 times lower for women with depression when compared to women without depression ($p<0.001$). However, when demographic and HBM characteristics were held constant in the regression model, the adjusted proportional odds ratio [95% CI] (1.05 [0.97, 1.14]) was not significant ($p=0.197$). **CONCLUSIONS:** Depression itself was related to the underuse of mammography. However, after controlling for demographic and HBM characteristics, depression was not associated with the underuse of mammography.

PCN9

COMPLEX SCREENING TEST FOR EARLY CANCER DIAGNOSTICS

Blavatska O

Danylo Halytskyj Lviv National Medical University, Lviv, Ukraine

OBJECTIVES: Screening of colon, stomach, bladder, prostate cancers is very relevant to reduce mortality. The applicable diagnosis scheme doesn't allow detecting tumor processes in the early stages, later diagnosis increases cost of the next treatment, reducing its effectiveness and declines the length and quality of life. **METHODS:** We proposed to improve diagnostics of colorectal and stomach cancer using one test; to apply the test for occult blood for urological field. Application of a combined test for determining hidden "high" and "low" bleeding in both fields displays this type of screening in a very interesting and economically appropriate rank. Rapid test for occult blood specific for human hemoglobin and transferrin is more sensitive, freely available in the pharmacy network, economically priced, easy to use and gives results on "cito". **RESULTS:** The first year results of the test use data are analyzed. Patients used tests purchased at their own expense. We've tested 88 patients for diagnosing possible colorectal and stomach cancer and 182 urological patients for diagnosing possible cancer of bladder and prostate. All 88 digestive patients test results for diagnosing possible colorectal and stomach cancer were negative; among 182 tests of the urological patients we received 17 positive results, future diagnostics proved 7 Cr-cases and 1 with precancerous (is under control). Such data does not allow yet statistic analysis. **CONCLUSIONS:** The project is under implementation. For 7 Cr-diagnosed patients the treatment allows almost twice increase of expected life time and the 8-th patient may become our first preventive Cr-case. Proved efficiency of the screening algorithm would become a basis for changing the national standard of medical care in Lviv region and Ukraine in general.

PCN10

RELATIONSHIP BETWEEN PROGRESSION-FREE SURVIVAL (PFS) AND OVERALL SURVIVAL (OS) IN HORMONE RECEPTOR-NEGATIVE METASTATIC BREAST CANCER (MBC): A COMPARATIVE EFFECTIVENESS ANALYSIS USING LINKED CLAIMS, EMR, AND MORTALITY RECORDS

Schabert VF[1], Chen YJ[1], Sun K[2], Wang Y[2]

[1]*IMS Health, Alexandria, VA, USA,* [2]*IMS Health, Plymouth Meeting, PA, USA*

OBJECTIVES: FDA accelerated approvals for some chemotherapies used PFS as an OS surrogate. However, one mBC approval was revoked after OS gains were not observed post-approval. We compared PFS with OS by first-line (1L) chemotherapy using real world evidence from US mBC patients. **METHODS:** IMS Health Comprehensive Disease Records for Breast Cancer link IMS PharMetrics Plus, oncology EMRs, and Social Security Death Index. Female breast cancer patients (ICD-9-CM 174.x, 233.0) were selected with index metastasis (ICD-9-CM 196.x-198.x or EMR Stage IV) 7/1/2006-3/31/2012, age ≥18, no HR overexpression, 1L chemotherapy (anthracyclines or txanes [AT] or new cytotoxic agents [NCA]), enrollment 180 days pre-index and ≥30 days post-index, and no other malignancies. PFS proxy was 1L duration; OS was measured until death or censoring (end of enrollment). Log-rank analysis compared PFS by 1L treatment. A Cox proportional hazards model assessed post-1L OS by 1L chemotherapy and duration, propensity for NCA vs. AT, HER2 status, and patient characteristics. **RESULTS:** Of 845 mBC patients, 334 met study criteria (mean [SD] age=51.7 [8.7] years, 20.4% HER2+). Propensity for NCA (n=70) vs. AT (n=264) increased with diabetes history (OR=2.79, 95% CI 1.12-6.90) and higher pre-index health care expenditures (OR=1.27, 95% CI 1.05-1.54). 1L NCAs were administered a mean (median) 195.2 (73.0) days (anthracyclines 53.5 [44.0], taxanes 122.2 [47.5], -2Log LR 54.3, 2 df, p<.0001). Cox regression estimated that 30 additional days of 1L chemotherapy predicted slightly shorter post-1L OS (HR=1.03, 95% CI 1.00-1.06); NCA (vs. AT) predicted stronger decreases in post-1L OS (HR=2.32, 95% CI 1.11-4.86) despite propensity adjustment. **CONCLUSIONS:** Duration of 1L chemotherapy, as a proxy for PFS, predicted slightly shorter post-1L OS. Choice of 1L chemotherapy was a stronger predictor of post-1L OS, adjusted for selection bias. Real world data suggests that PFS is a poor OS surrogate in mBC.

PCN11

MAGNITUDE OF BENEFIT AND COSTS FOR RECENT SOLID TUMOR AGENTS

Binder G[1], Milentijevic D[2], Squier M[1], Whiting S[1], Brown G, Renschler MF[1]

[1]*Celgene Corporation, Summit, NJ, USA,* [2]*Market Access Solutions, Raritan, NJ, USA*

OBJECTIVES: Phase 3 oncology clinical trials have had success rates of 41% (Djulbegovic, Arch Int Med 2008). Against this backdrop, context is needed on the magnitude of benefit to expect from future successful trials, and the interplay of cost. Recognizing the limitations of comparing results across trials and therapies, we assessed recent FDA solid tumor approvals showing overall survival (OS) benefit in a randomized trial. The objective of this analysis is to define the magnitude of benefit and cost of solid tumor therapies approved by FDA from 2009-2013 having phase 3 OS benefit. **METHODS:** A systematic review of CenterWatch FDA-Approved Drugs and FDA sNDA/sBLA databases was conducted. Inclusion criteria required FDA approval or efficacy supplement, with OS data published 2009-2013. Hazard ratio (HR) and absolute and relative gain in median OS were assessed. First month drug costs were determined for 4Q2013, using methods previously described by Bach (NEJM 2009). Agents intended to be administered for £ 6 weeks were excluded from the cost analysis. Limitations include omission of many agents that represent important advances yet did not demonstrate statistically significant OS benefit relative to a control arm. **RESULTS:** 18 FDA approved agents across 25 indications for 9 tumor types were assessed. The mean HR (range) and the mean relative gain in median OS vs trial comparator was 0.702 (0.410-0.817) and 27.91% (11.9%-67.2%), respectively. Medians for each measure were 0.725 and 23.6%. Mean first month treatment costs were $12,601 ($5,881-$50,025) with median costs of $9,282. **CONCLUSIONS:** Over the last 5 years, for FDA-approved agents for treatment of solid tumors, the magnitude of survival benefit, measured either as Hazard Ratio or relative gain in median OS, was 24-30%. This benefit, and first month costs of $9 - 13,000, may represent midpoints of expected levels for future solid tumor agents.

PCN12

TREATMENT PATTERNS AND OUTCOMES IN METASTATIC COLORECTAL CANCER (MCRC) PATIENTS TREATED IN A COMMUNITY ONCOLOGY SETTING

Cartwright TH[1], PAN I[2], Wen L[3], Wadlow RC[4], Rembert D[5], Seal B[6]

[1]*Mckesson Specialty Health, Ocala, FL, USA,* [2]*Mckesson Specialty Health, Conroe, TX, USA,* [3]*Bayer HealthCare Pharmaceuticals, Inc., Pine Brook, NJ, USA,* [4]*Mckesson Specialty Health, Fairfax, VA, USA,* [5]*Mckesson Specialty Health, The Woodlands, TX, USA,* [6]*Bayer HealthCare Pharmaceuticals, Inc., White House Station, NJ, USA*

OBJECTIVES: To describe and characterize mCRC patients who received 3rd-line therapy and to investigate the association of patient outcomes and treatment patterns in a real-world community oncology network. **METHODS:** This retrospective study utilized data from the iKnowMed™ database and billing claims. Eligibility criteria included diagnosis of mCRC, initiation of 1st-line therapy between 1/1/2007 and 6/30/2011, and initiation of 3rd-line therapy (defined as index date) before 6/30/2012. The key outcome was overall survival (OS). Kaplan-Meier and Cox proportional hazard models were used to characterize the distribution and predictors of outcomes. **RESULTS:** 757 patients were eligible for the study. The most common 3rd-line therapies were anti-EGFR-based (55.4%), oxaliplatin-based (13.6%), and capecitabine-based (11.4%). OS was 8.0 (95% CI: 7.1-8.9), 8.8 (7.4-11.0), and 9.1 (6.9-11.2) months, respectively. Over half of patients were ≤65 years old (54.3%), male (55.2%), treated in the Southern region (61.8%), overweight/obese (56.6%), and the majority had an ECOG performance status ≤1 (78.7%). 51.8% of patients had prior comorbidities. The 5 most common comorbidities were hematologic, cardiovascular, gastrointestinal, neurologic, and endocrine disease. *KRAS* testing rates at index date were 35.4% (wild-type 26.3%, mutation 9.1%). Of *KRAS*wild-type patients, 80.9% were treated with anti-EGFR-based regimens which was consistent with NCCN recommendations. **CONCLUSIONS:** This comparative effectiveness study in a real-world community setting shows that