TREATMENT PATTERNS STUDIES

TP2

TREATMENT PATTERNS AMONG ELDERLY STAGE IV BREAST CANCER PATIENTS TREATED WITH HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2-TARGETED THERAPY: AN ANALYSIS OF 2006-2010 UNITED STATES NATIONAL REGISTRY DATA

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OBJECTIVES: There are few studies of treatment patterns among elderly, newly diagnosed Stage IV breast cancer (BC) patients receiving human epidermal growth factor receptor 2- (HER2-) targeted therapy. **METHODS:** Women aged 65+ with an incident diagnosis of Stage IV BC (index) and no history of other cancer were identified from 2006-2010 linked Surveillance, Epidemiology, and End Results (SEER) and Medicare data. Continuous enrollment from 1 year pre-index (baseline) through disenrollment, death, or the end of the data (follow-up) was required. Patients were required to receive HER2-targeted therapy (trastuzumab or lapatinib) during follow-up. Treatment therapies during follow-up were evaluated, as was the distribution of treatment combinations. Initial treatment regimens were evaluated based on the treatment(s) received after index. A 42-day gap in therapy or the addition of a biologic therapy was used as a marker for a subsequent regimen. **RESULTS:** 173 patients were identified (mean [SD] age: 73.9 [6.7]). The majority received trastuzumab (98.8%) during follow-up (mean [SD] duration: 24.3 [11.3] months), with 9.8% receiving lapatinib. Most received chemotherapy (83.2%), approximately half received surgery (55.5%), over 40% received hormonal therapy, and one-third received radiation (35.3%). Trastuzumab + chemotherapy was the most common initial treatment regimen (43.9%); less common therapies include trastuzumab alone (17.3%), and trastuzumab + chemotherapy + hormonal (13.3%). Among those with subsequent treatment lines, approximately one-fifth of patients received chemotherapy alone and another fifth received trastuzumab plus chemotherapy. Among patients receiving chemotherapy, the majority received a taxane-based chemotherapy with fewer patients receiving antimetabolites, vinca alkaloid and platinum-based chemotherapy. Treatment pattern and sequencing were similar using 30-day or 90-day gap in therapy. The average treatment duration for any treatment regimen was just less than a year (44.9-52.5 weeks). **CONCLUSIONS:** Among Medicare patients with Stage IV BC receiving a HER2-targeted agent, the majority received taxane-based combination chemotherapy, consistent with NCCN guidelines.

TP3

LONGITUDINAL RESOURCE USE FOR LOW BACK PAIN IN COMMERCIALLY-INSURED PATIENTS IN THE UNITED STATES

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OBJECTIVES: To assess medical-resource use for commercially-insured patients with low back pain (LBP) in the United States. **METHODS:** We identified patients with new LBP episodes using inclusion/exclusion criteria consistent with the Back Pain Outcomes using Longitudinal Data (BOLD) registry, using the Marketscan® Research Databases (2007-2011). We required four years of continuous enrollment, one year prior to index with no evidence of spinal surgery, and six-months prior without lumbar spine-related care. We used clustering algorithms to identify LBP-related health care resource use groups over three years, assessing LBP-related use of imaging, provider visits, medications, injections, and surgeries. **RESULTS:** 513,980 patients (54% female, mean age: 45.2 years) met criteria. Clustering approaches grouped patients as very low (30%, one quarter in first year only), low (40%), medium (23%), or high (7%) users. Care patterns among groups were consistent for imaging, provider visits, injections, and medications, with higher-use groups having greater intensity of and variability in use among nearly all resource use types. Lumbar x-ray use was approximately 30% for all groups (year 1). Lumbar MRI rates ranged from 14%-19% (year 1), and 2%-15% (years 2-3), increasing by group. Chiropractic and physical therapy visits were prevalent (30%-50%, year 1), and remained high in higher-use groups. Highly-prescribed medications included long-acting opioids, non-steroidal anti-inflammatory drugs, muscle relaxants, and anti-depressants, with consistent three-year patterns among use groups. Opioid use was high (25%-41% year 1, 15%-51% years 2-3). Trends in average number of opioid days supplied by low-, medium-, and high-use groups increased each year (ranges (# days): 32-102 year 1, 49-165 year 2, 51-176 year 3). **CONCLUSIONS:** New LBP episodes were associated with substantial rates of imaging, provider visits, and medication use in commercially-insured patients, with the highest use in the first year following diagnosis, and persisting high use for select patients during two additional years.

TP4

DESCRIPTIVE ANALYSIS OF TREATMENT PATTERNS AND MORTALITY OF UNITED STATES VETERAN PATIENTS WITH COLORECTAL CANCER

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OBJECTIVES: Examine treatment combinations and mortality rate of colorectal cancer (CRC) patients in the U.S. veteran population. **METHODS:** Adult patients with at least one primary CRC diagnosis and CRC treatment (5-fluorouracil [5-FU]/LV [leucovorin, levoleucovorin]+/-biologics; Irinotecan [IRI]+/- biologics; Oxaliplatin [OX]+/-biologics; IR+OX [IROX]+/-biologics; or biologics only) were selected (01APR2006-30SEP2012) from the U.S. Veterans Health Administration database. The first observed treatment date was designated as the index date. Patients were followed until the earliest of death, or end of enrollment or study period. Patients were assigned to one of four cohorts based on treatment line (TL) number. Treatment combinations, length of therapy and incidence rate of death were calculated. **RESULTS:** A total of 11,078 patients were included for study, with the majority treated with one TL (63%), 22% with two, 8% with three and 7% with four TL. The most frequently prescribed treatment was 5FU/LV in all first TL (1 TL: 65.8%; 2 TL: 62.3%; 3 TL: 50.1%; 4 TL: 41.0%). Patients with three or four TL were prescribed significantly more OX+biologics for the first TL than patients with one or two TL. During the second TL, 5FU/LV and OX were most frequently prescribed. More variances were observed in the third and fourth TL. Length of therapy for each TL ranged from 86 to 104 days. The incidence rate of death was similar between patients with one and two TL (19.66 per 100 patient years), and higher for patients with three (26.28) and four TL (22.41). **CONCLUSIONS:** 5FU/LV was the most frequently prescribed first TL. Incidence of death was higher in patients with third or fourth TL. The greater diversity in the third and fourth TL is likely due to either the absence of proven therapies or the incidence of KRAS with tumors. However, multivariate analysis is needed to further confirm these findings.

RESEARCH PODIUM PRESENTATIONS - SESSION II

Research on Database Methods Studies

DB1

A COMPARISON OF REGRESSION AND STATISTICAL LINKAGE ESTIMATORS OF BIAS IN RETROSPECTIVE DATABASE STUDIES

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OBJECTIVES: Claims data alone are typically lacking in key clinical information capturing disease severity, specificity of diagnosis, patient reported outcomes, and many other factors. Attempts to estimate treatment effects with claims data alone, with missing key control variables, have a greater likelihood to produce biased result. This study uses claims and lab test results data from a large national health plan, in an attempt to circumvent or mitigate problem of biases in treatment effect estimators attributed to missing key clinical variables. **METHODS:** A linked dataset of claims and laboratory results is used to estimate treatment effect on resource utilization for a Hepatitis C (HCV) sample (N=2031). To empirically assess the bias from omitting the clinical information in the laboratory results (APRI scores), treatment effects are estimated using claims alone. Laboratory results are then attached to the claims through statistical linkages of records from clinical records and claims records, simulating the statistical linkage of medical datasets in situations where direct patient-level linkages are not possible. Estimation of treatment effects were calculated through the bootstrap method by running negative binomial count regressions 500 times in samples with replacement size of 500. **RESULTS:** The results from the dataset with the linked laboratory results showed bias reduction of 78.8% and 23.8% in HCV-related ambulatory visits and All-cause ambulatory visits, respectively. Statistical linkages do not appear to have any impact on the treatment effect estimators in the ER visit outcomes which are confirmed by the lack of correlations in APRI scores and outcomes. **CONCLUSIONS:** When confronted with missing key clinical variables, record linkage has the effect of reducing bias in treatment effects. The degree of this bias reduction will be a function of the strength of the correlations among the missing variable, the treatment variable, and the outcome variable.

DB2

CONDITIONS OF VALIDITY OF MEDICAL RECORDS FOR DRUG EXPOSURE ASSESSMENT IN PHARMACOEPIDEMIOLOGICAL RESEARCH

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OBJECTIVES: Patients' self-reported drug exposure (PS) is likely to be subject to recall and other biases. However, physicians' medical records (MR) are unable to capture noncompliance or over the counter drugs (OTC). This study compared PS to MR for vaccinations, musculoskeletal disorder medications (MSD) and cardiovascular drugs (CVD). **METHODS:** The international Pharmacoepidemiologic General Research Extension (PGRx) uses a network of over 300 general practitioners across France, continuously recruiting an age/gender stratified sample of patients, without reference to diagnoses or prescriptions. PS were obtained using a structured interview and an interview guide containing lists of commonly used drugs. PS and MR were compared in the three (vaccinations) or two (MSD and CVD) years drug taking history. **RESULTS:** Agreement between PS and MR were investigated using 7613 (vaccinations), 4152 (MSD) and 2072 (CVD) patient-physician pairs. For vaccinations, prevalence and bias –adjusted kappa (PABAK) values were substantial for influenza vaccines (0.74) and high for 23-valent pneumococcal vaccines (0.98) and human papillomavirus vaccines (0.92). For MSD, PABAK values ranged from low for non-aspirin non-steroidal anti-inflammatory drugs (0.26 to 0.32), to fair for non-narcotic analgesics (0.21 to 0.50), fair to substantial for muscle relaxants (0.55 to 0.71) and high for osteoarthritis drugs (0.84 to 0.94). For CVD, overall agreement was excellent (kappa =0.83, 95% CI = 0.81 -85). Disagreement was higher for OTC MSD and CVD (odds ratios=1.21 and 8.62 respectively, 95% confidence intervals=1.05-1.38 and 4.36-17.05). **CONCLUSIONS:** In the PGRx database, agreement between PS and MR tended to remain stable over long recall periods. However, less agreement was reported for OTC drugs than prescription drugs/vaccines. Electronic health care databases is a valid source of information for drugs available only by prescription, but information from patients should be obtained for drugs available OTC in order to avoid systematic errors.