

Two studies involved moderately emetogenic regimens. Palonosetron 0.25mg was associated with a significantly higher complete response (CR) rate in the delayed phase compared to ondansetron (74.1% vs. 55.1%,  $p=0.001$ ) and dolasetron (54.0% vs. 38.7%,  $p=0.004$ ). The CR rate with palonosetron 0.25mg in the acute phase was significantly higher than ondansetron (81.0% vs. 68.6%,  $p=0.009$ ), but only numerically better than dolasetron (63.0% vs. 52.9%,  $p=0.049$ ). In the trial with highly emetogenic agents, CR rates were comparable between palonosetron 0.25 mg and ondansetron in both the acute (59.2% vs. 57.0%,  $p=0.701$ ) and delayed (45.3% vs. 38.9%,  $p=0.180$ ) phases. The FDA considered the CINV claims relative to placebo due to lack of approval of comparators for delayed CINV. Because of its long half-life, NCCN guidelines indicated that single-dose palonosetron could be considered at the start of a multi-day chemotherapy regimen instead of multiple daily doses of other 5-HT<sub>3</sub>-RAs; however, none of the guidelines designated a preferred 5-HT<sub>3</sub>-RA. **CONCLUSION:** 5-HT<sub>3</sub>-RAs can be considered clinically interchangeable. While palonosetron may provide convenience by avoiding the need for repeat daily dosing, this needs to be balanced against its additional cost given the advent of generic 5-HT<sub>3</sub>-RAs.

**PCN3****EFFECTIVENESS OF BORTEZOMIB IN MULTIPLE MYELOMA: PRELIMINARY RESULTS FROM AN INTERNATIONAL ELECTRONIC OBSERVATIONAL STUDY**

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**OBJECTIVE:** Multiple myeloma (MM) is a plasma-cell malignancy with approximately three years median survival. Patients usually relapse or become refractory to existing treatments. Bortezomib (VELCADE) is indicated for the treatment of MM in patients who have received at least one prior therapy. The electronic VELCADE Observational Study (eVOBS) is a multicenter naturalistic study designed to evaluate the clinical and outcomes benefits of bortezomib in actual clinical practice. **METHODS:** This is a multi-center study with sites in Belgium, France, Greece, Russia, Spain, Sweden, and Turkey. The study enrollment period is between October 2006 and December 2008 with a 3-year follow-up. Adults are eligible for study if they are scheduled to initiate bortezomib within the approved indication. All bortezomib dosages and concomitant treatments are permitted, except investigational therapies. Data treatment response, and safety are collected prospectively. **RESULTS:** The current analysis reports data collected on patients initiated with bortezomib between October 2006 and July 2007. A total of 86 pts with at least four months of data are included in this analysis. Demographic and clinical characteristics of the initial participants were similar to those of the participants in the prospective controlled phase 3 APEX trial. Adverse events (AEs) were reported in 61 (71%) pts, including Grade  $\geq 3$  AEs in 38% and Grade  $\geq 4$  AEs in 9%. AEs were treatment-related in 45% of patients and treatment-limiting in 9%. Presently, 72 of 86 pts have been evaluated for response, of whom 5 (7%) achieved complete response, 9 (13%) achieved near complete response, and 30 (42%) achieved partial response. Updated data will be presented at the meeting. **CONCLUSION:** In this preliminary analysis of data from a prospective, observational study, response rates and

safety data demonstrate that bortezomib-containing regimens are effective and well-tolerated in the treatment of MM in actual clinical practice and the results are in line with previously published studies.

**PCN4****DATA ANALYSIS WITH GENERALIZED LINEAR MODELS ON LUNG CANCER DATA**

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**OBJECTIVES:** The Nationwide Inpatient Sample is part of the Healthcare Cost and Utilization Project, and is the only national hospital database with charge information on all patients, regardless of payer, including persons covered by Medicare, Medicaid, private insurance, and the uninsured. It is the purpose of this study to examine the relationship between patient outcomes and conditions of the patients undergoing different treatments for lung cancer. **METHODS:** There are fifteen possible patient diagnoses in the dataset. SAS Enterprise Guide was used to obtain Lung Cancer data from NIS by using the CATX and RXMATCH statements in SAS. We bring all fifteen diagnoses into one column as a string of codes, using the CATX function. Total charges are used to examine the relationship between diagnoses and procedures. The generalized linear regression model was used to fit the data. **RESULTS:** After filtering down to lung cancer using the strings of diagnoses, there were 5457 records in the data set. By the plot method, we selected variables related to Total charges. We found that the Total charges were highly related to Age in years at admission, Diagnosis Related Group, Length of stay and Died during hospitalization. By the basic criterion, deviance residuals and Pearson chi-square residuals, the specified model fits the data reasonably well. From the Type 1 and Type 3 analysis, all the estimates for the intercept, Los, Age, DRG, and Died were 10.1805, 0.1181, 0.003, -0.0008, and -1.024, respectively. All of them were statistically significant. Co-morbid diagnoses that increased total charges include coronaries, multiple significant traumas, and cardiac implant. **CONCLUSIONS:** Our analysis revealed that there was a specified relationship between these variables. With increasing of length of stay, age in years at admission, small codes of diagnosis related group and surviving during hospitalization, the total charges increase, which is reasonable.

**PCN5****META-ANALYSIS ON THE MORBIDITY AND MORTALITY OF CLODRONATE, PAMIDRONATE AND ZOLEDRONATE IN PATIENTS WITH BONE METASTASES**

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**OBJECTIVE:** Complications from skeletal-related events (SREs) constitute a challenge to the care of patients with bone metastasis originated from any type of malignancy. Our objective was to determine the reduction in morbidity (SREs) and mortality (overall) of clodronate, pamidronate, and zoledronic acid in patients diagnosed with bone metastasis. **METHODS:** Medline and Embase (from inception to October 2007) were searched in order to retrieve randomized clinical trials evaluating targeted bisphosphonates in cancer patients with bone metastasis. Patients with a definite (i.e., biopsy-proven) diagnosis of metastatic bone disease were included in the analysis. We extracted and combined data from studies describing the number of patients reporting 12-month SREs and mortality data. Two independent reviewers identified articles, then extracted data; results

were compared and settled through consensus. A random-effects meta-analytic model was applied in all calculations. Jadad's scale assessed study quality of reporting. **RESULTS:** A total of 50 potential studies were identified. Thirty-five were excluded and 15 were evaluated. Quality of reporting of included studies was on average  $59 \pm 24\%$ . All three drugs showed beneficial effects in preventing all SREs over placebo in cancer patients with bone metastasis. Zoledronate was the pharmacological strategy reporting the lowest relative risk (RR = 0.67; CI95% = 0.55, 0.81; N = 695), followed by pamidronate (RR = 0.79; CI95% = 0.71, 0.88, N = 1951), and clodronate (RR = 0.87; CI95% = 0.75, 1.00; N = 681). However, no clear advantage of one drug over the others was observed since confidence intervals overlapped substantially. All targeted bisphosphonates showed no benefits over placebo in reducing the number of deaths in a 12-month period ( $p > 0.05$ ). **CONCLUSION:** Clodronate, pamidronate, and zoledronate are able to reduce the morbidity of patients with bone metastasis in regards to SREs but not overall mortality.

**PCN6****ESTIMATION OF THE EPIDEMIOLOGICAL EFFECT OF TRASTUZUMAB OVER 10 YEARS IN 5 EUROPEAN COUNTRIES**

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**OBJECTIVE:** To assess the potential value of trastuzumab (T) to society, we initially assessed the long-term impact of T treatment in early breast cancer (EBC) on the annual number of patients developing metastatic BC (MBC) from 2005–2015 in five European countries. **METHODS:** Annual EBC incidence for 2003–2015 was projected by applying stage-specific proportions for stages I-III, according to regional registry data, to published female BC incidence rates from 1990–2002. Age-specific rates for 2002 were then applied to United Nations 2003–2015 population projections. The annual number of patients with HER2-positive MBC includes de novo MBC incidence plus patients with BC recurrence. The baseline 10-year recurrence rate for standard treatment was estimated as 37%, based on 4-year follow-up in the control arm of a combined trial analysis in patients with HER2-positive BC and the long-term timing of recurrence in all patients with BC. To model recurrence in T-treated EBC patients, the hazard ratio at median 1-year follow-up in the HERA trial (0.49; 95% confidence interval [CI]: 0.38, 0.63) was applied, resulting in an estimated 10-year recurrence rate of 18.1% (95% CI: 14.0, 23.3). **RESULTS:** In 2004, prior to T approval for EBC, the pool of de novo and relapsed MBC patients was estimated at 16,156. Between 2005 and 2015, the model predicts that T treatment will result in an annual decline of 2.5% (95% CI: 1.7, 3.2). The total number of patients prevented from developing metastases over 10 years is projected to be 27,727 (95% CI: 20,116, 33,709). **CONCLUSION:** T is expected to prevent nearly 28,000 women from developing MBC over a 10-year period in five countries alone and should considerably reduce the health resource burden of MBC treatment.

**PCN7****ANALYSIS OF MASTECTOMY IN BREAST CANCER TREATMENT**

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**OBJECTIVE:** Surgery is main treatment used in most early breast cancer cases; surgery is the primary treatment for breast cancer to remove as many as cancer cells as possible. There are two types

of surgeries: mastectomy and lumpectomy. Studies have shown that mastectomy is the most performed in comparison to lumpectomy. With our data, out of 1485 cases of breast cancer, 146 were primarily treated by mastectomy while only 26 were treated with lumpectomy. We analyzed, in detail, the information on mastectomy as a treatment option for breast cancer to compare the use of different types of mastectomy and to study the cost of the most frequent types. **METHODS:** We used the 2004 data from the National Inpatient Sample (NIS). We first filtered the data with respect to the main types of mastectomy: radical mastectomy, modified radical mastectomy, simple (total) mastectomy, and the subcutaneous mastectomy. Second, we analyzed them with summary statistics using SAS, and then finally, we looked at the cost of the most frequent by plotting the actual costs and the future trend. We used SAS Text Miner to compress patient diagnoses, and compare them to the types of treatment. **RESULTS:** The modified radical mastectomy is the most frequently used in treating breast cancer with 81.5% of the total mastectomies. Then, we have the simple (total) mastectomy with 13.7%. Finally, we have the subcutaneous mastectomy (2.7%) and the radical mastectomy (2.1%). The cost of the modified radical mastectomy has a constant trend of around \$20,000. **CONCLUSION:** The modified radical mastectomy is the most performed so far in the treatment of breast cancer by mastectomy. SAS can be used to study health care cases.

**PCN8****IMPROVED SURVIVAL OF PATIENTS WITH GLIOBLASTOMA MULTIFORME BY TEMOZOLOMIDE AS ADJUVANT THERAPY: A RETROSPECTIVE COHORT STUDY**

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**OBJECTIVE:** Glioblastoma multiforme (GBM) accounts for 35% of primary brain tumor in Taiwan. The objective of this study is to determine if patients with GBM survived longer after adjuvant therapy by temozolomide. **METHODS:** We collected all inpatients of GBM verified with pathology in Chang Gung Memorial Hospital from January 2001 to March 2006. Patients aged more than 80 at diagnosis were excluded. Outcome was followed until December 31, 2006. Survival analysis was performed by Kaplan-Meier estimation method and Cox regression model and explores the effect related to various prognostic factors including adjuvant therapy of temozolomide. **RESULTS:** There were 66 temozolomide users and 133 non-users during the study period. They were no statistical significant differences on gender, age at diagnosis and year of diagnosis between these two groups. Analysis showed 50% survival for users and non-users were 18.7 and 9.9 months, respectively (Log-rank test,  $p < 0.0001$ ). The hazard ratio was 2.58 (95% confidence interval, 1.60–4.16) for the aged 60–80 compared with patients aged 20–40, and that of temozolomide treatment was 0.47 (.34–.66). Stratified analysis showed that there was no significant difference in survival between patients with concomitant radiotherapy. **CONCLUSION:** The adjuvant therapy with temozolomide seemed to improve survival, but randomized trial is still needed to test this hypothesis.