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INFUSION REACTIONS IN PATIENTS TREATED WITH ANTI-EGFR MONOCLONAL ANTIBODY THERAPIES FOR METASTATIC COLORECTAL CANCER: RATES AND IMPACT FROM LITERATURE REVIEW

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OBJECTIVES: The objective of this study is to review the literature on the rate and impact of infusion reactions (IR) associated with anti-EGFR monoclonal antibody (MoAb) therapies for the treatment of metastatic colorectal cancer (mCRC). **METHODS:** This review searched PubMed, FDA web site, Medscape, and package inserts (PI) for studies reporting IR rates and their clinical or economic impact associated with cetuximab or panitumumab in mCRC patients. Both clinical trials and observational studies published in English by October 2009 were included. **RESULTS:** A total of 16 studies were reviewed. For patients receiving cetuximab, across all studies, rates of all-grade IRs ranged from 4% to 32%; and rates of severe IRs were 0.5%-22%. For patients receiving panitumumab, rates of all-grade IRs ranged from 0% to 4%; and rates of severe IRs were from 0%-1.0%. Among patients who received cetuximab and experienced a severe IR, 34%–50% discontinued cetuximab therapy. Only one study evaluated the resource utilization and costs associated with IRs in patients treated with cetuximab. Mean incremental costs were $9308 to treat cetuximab associated IRs that resulted in an emergency room visit or hospitalization and $1725 for those that required outpatient treatment. Several studies reported substantial burden on health care providers, patients, and caregivers when IRs occurred. Patients with IRs required 31%-80% more staff time to observe and manage these events. No study reported economic impact of severe IRs associated with panitumumab. **CONCLUSIONS:** A greater range in the rate of severe IRs associated with cetuximab treatment was reported in the literature than that for panitumumab. Severe IRs often require costly intensive medical intervention and can cause disruption or discontinuation of therapy.

PCN21

REAL-WORLD CLINICAL OUTCOMES OF PATIENTS WITH TRIPLE NEGATIVE BREAST CANCER – RESULTS FROM A US LOCAL ONCOLOGY PRACTICE

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OBJECTIVES: Triple negative breast cancer (TNBC), characterized by lack of estrogen and progesterone receptors, and HER2 not being over-expressed, does not respond to standard therapies, and exhibits more aggressive clinical behavior. The objective of this study was to assess the clinical outcomes of TNBC patients compared to other types of BC in a US local community practice. **METHODS:** A retrospective analysis was conducted using the Georgia Cancer Specialist Database (2003–2008). Patients with BC and confirmed TN/non-TN status were selected. For stage I-III patients, the outcomes were disease-free survival (DFS) and recurrence. For stage IV patients, the outcome was overall survival (OS). Kaplan-Meier curves were used to compare the event rates between TN and non-TN groups. The impact of TN status on the outcomes was examined with multivariate Cox models adjusting for demographic and clinical characteristics. **RESULTS:** There were 1572 stage I-III patients with 26.3% (n = 414) being TN and 245 stage IV with 25.7% (n = 63) TN. For stage I-III, TN group had significantly lower rate for 5-year DFS (76.8% vs. 89.0%) and higher rate for 5-year recurrence (18.8% vs. 11.2%), compared to non-TN group (all $p < 0.001$). The adjusted results demonstrated significant association between TN status and lower likelihood of DFS (HR = 0.37) and higher risk for recurrence (HR = 2.85), both $p < 0.0001$. For stage IV, TN group was found to have significantly shorter Median OS (405 vs. 847 days, P = 0.0003). The adjusted results showed TN status was associated with high risk of mortality (HR = 2.20, p = 0.0004). **CONCLUSIONS:** Based on data from a US local oncology practice, this study demonstrated inferior clinical outcomes for TNBC compared to other types of BC. The results highlight the need for better understanding and more effective treatments for TN subtype. The results could be confounded by uncontrolled factors and need to be confirmed in other oncology practices.

PCN22

DO GAPS IN TREATMENT CONTINUATION OF DOCETAXEL AFFECT OVERALL SURVIVAL? – RESULTS FROM A US LOCAL COMMUNITY PRACTICE

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OBJECTIVES: Docetaxel (D) is well recognized as first-line chemotherapy in patients with metastatic prostate cancer (PC). To what extent gaps in treatment impact overall survival (OS) remains unknown. This study aimed to investigate the relationship between treatment gap and OS in a community practice. **METHODS:** Using the Georgia Cancer Specialist Database (2003–2008), patients with initial stage IV PC receiving D were identified and followed from the date of first D use to the earlier of death or loss to follow-up. The three-month period prior to the first D use was the baseline. A gap in treatment continuation was defined as elapsed days between any adjacent treatment cycles of >60 days during follow-up. Kaplan-Meier curve was compared between patients with and without a gap using the log-rank test. The impact of treatment gap on OS was examined with multivariate Cox model by adjusting treatment cycles, age, comorbidity, baseline PSA, baseline bisphosphonate use, hormonal therapies and other chemotherapy during the follow-up. Sensitivity analysis (SA) was conducted with gap defined as 90, 120 and 180 days. **RESULTS:** The study sample contained 47 patients, with mean age 75, average baseline PSA 296 ng/ml, 48.9% treated with bisphosphonate at baseline, 53.3% treated with hormonal therapies, and 29.8% treated with other chemotherapies during follow-up. Patients on average completed 10 cycles of docetaxel, with 7 (15%) patients experienced a treatment gap. Median survival was 387 and 333 days for groups with and without gaps, respectively (P = 0.1654). The Cox model found no increased risk of death for the group with gap (HR = 0.80, P = 0.7189). Consistent results were found in SA. **CONCLUSIONS:** This analysis implied that allowing treatment gap in docetaxel treatment did not appear to impair OS for metastatic PC. The results could be confounded by some unadjusted factors, e.g., ethnicity and patients' disease characteristics.

PCN23

OVERALL SURVIVAL AND GAP IN DOCETAXEL TREATMENT CONTINUATION IN PATIENTS WITH METASTATIC PROSTATE CANCER – RESULTS FROM A US ONCOLOGY NETWORK

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OBJECTIVES: Docetaxel (D) is the first-line chemotherapy in metastatic prostate cancer (PC). No study has assessed in a community practice, the relationship between treatment gaps and overall survival (OS). Using the International Oncology Network's Treatment and Outcomes Database (2003–2008), this study aimed to evaluate this relationship in a large community practice network in US. **METHODS:** Patients with initial stage IV PC treated with D were followed from . the first D use till the earlier of death or loss to follow-up. The three-month period prior to the first D use was the baseline. A gap in treatment continuation was defined as elapsed days between any adjacent treatment cycles >60 days. OS was compared between the groups with and without a gap using Kaplan-Meier curve. A Multivariate Cox model was used to examine the impact of treatment gap on OS with adjustment of potential confounders. Sensitivity analyses (SA) was conducted using different definitions to define the gap (90, 120, 180, and 270 days). **RESULTS:** Sixty-four patients were included in the analysis, with a mean age of 73, and a mean baseline PSA of 200 ng/ml. 32.8% were treated with bisphosphonate at baseline. A total of 23.4% were treated with hormonal therapies, and 39.1% were treated with other chemotherapies during follow-up, respectively. Twenty-three (36%) patients experienced a treatment gap. Median survival was 548 and 563 days for groups with and without a gap, respectively (P = 0.6870). The Cox model showed no increased risk of death for the group with a gap compared to the group without a gap (HR = 0.940, p = 0.8847). SA showed consistent results. **CONCLUSIONS:** This analysis implied that allowing treatment gap in docetaxel did not appear to impair OS for in metastatic PC. Results could be confounded by unadjusted factors.

PCN24

OVERALL SURVIVAL AND DOCETAXEL TREATMENT CYCLES IN PATIENTS WITH METASTATIC PROSTATE CANCER – RESULTS FROM A US ONCOLOGY NETWORK

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OBJECTIVES: Docetaxel (D) is the first-line chemotherapy in metastatic prostate cancer (PC). Not known is the relationship between the number of treatment cycles and overall survival (OS). Using the International Oncology Network's Treatment and Outcomes Database (2003–2008), this study aimed to evaluate this relationship in a large community practice network in US. **METHODS:** Patients with initial stage IV PC receiving D were followed from the first D use to the earlier of death or loss to follow-up. The three-month period prior to the first D use was the baseline. Patients were split into two cohorts based on the mean treatment cycle count. OS survival was compared with Kaplan-Meier curve. A multivariate Cox model with potential confounders adjustment was used to evaluate the impact of cycle count on OS. Correlation robustness was assessed using sensitivity analyses (SA) with cycle number controlled as a count variable and a dummy variable (different thresholds 6 or 5). **RESULTS:** Sixty-four patients, mean age of 73 (ranging 54–96), had an average baseline PSA at 200 ng/ml (0.7–1510 ng/ml). 32.8% were treated with bisphosphonate at the baseline. 23.4% and 39.1% of the sample were treated with hormonal therapies and other chemotherapies during follow-up, respectively. The average number of treatment cycles was 7.1 (1–30), with 41 (64.1%) completing <7 and 23 (35.9%) patients completing ≥7 cycles. Median survival was 366 days for <7 group, and 577 days for ≥7 group (p = 0.3505). The Cox model found a higher likelihood of survival for ≥7 group (HR = 3.62, p = 0.0035). Similar results were found in SA. **CONCLUSIONS:** This analysis suggested that higher number of treatment cycles of D was associated with prolonged OS in metastatic PC. The results could be confounded by unadjusted factors, and the sample size was small. Therefore, no cause inference can be drawn based on this analysis.