SURVIVAL ANALYSIS OF PAIN RELIEF PROVIDED BY DOXEPIN ORAL RINSE FOR ORAL MUCOSITIS PATIENTS

Epstein JB1, Epstein JB2, Epstein MS1, Oien HJ1, Truelove EL5

1University of Southern California, Los Angeles, CA, USA; 2Fred Hutchinson Cancer Research Center, Seattle, WA, USA; 3Private General Dental Practice, Tualatin, OR, USA; 4University of Washington, Seattle, WA, USA

OBJECTIVES: To assess covariates that affect the duration of pain relief doxepin oral rinse provided cancer patients with painful oral mucositis. METHODS: Fifty consecutive patients with oral mucositis due to head and neck radiation therapy participated in the original study. An examination of the mouth was completed and oral mucositis scored using the Oral Mucositis Assessment Scale (OMAS) which assesses erythema severity and ulceration size. Oral pain was assessed with a visual analogue scale (VAS) prior to taking the rinse and then at five, 15, 30 minutes, one-hour, while continuing every half hour up to three-hours, and at four-hours following rinsing. The time until recurrence of pretreatment pain level was defined as the time it took for VAS pain scores to reach or exceed initial pain scores. Recurrence of pain relief was right censored at four-hours for twenty patients; survival analysis was utilized to determine what factors were associated with recurrence of pain. RESULTS: Significant pain reduction was reported. Patients described, on average, a 55.6% reduction in pain after 15 minutes of doxepin rinsing. Recurrence of pain was slow and significant reduction in pain from baseline continued at four hours (p < 0.0001). The hazard ratios from the Cox proportional hazards model (p < 0.001) determined that holding all other variables constant, an increase by one unit in either the baseline pain severity, the worst documented erythema score, or the relative reduction of pain at 15 minutes, decreased the rate of pain recurrence at any time (t) by 45.3, 38.8, or 71.8% respectively. CONCLUSIONS: This research shows good results for doxepin oral rinse. Mucositis patients who reported higher baseline pain, more severe erythema, or larger relative reductions in pain after 15 minutes of rinsing, had a larger probability of extended pain relief.

ECONOMIC EVALUATION OF INTRAVENOUS (IV) Zoledronic Acid vs. Other IV Bisphosphonates in the Prevention of Bone Complications in Breast Cancer Patients with Bone Metastases: A UK Budget Impact Analysis

Bottomen M1, Aapro M2, Hay JW3, Stephens J1, Brandman J4

1PharmiVent North America, Bethesda, MD, USA; 2Clinique de Genolier; Genolier, Switzerland; 3University of Southern California, Los Angeles, CA, USA; 4Novartis Pharmaceutical Corporation, Florham Park, NJ, USA

OBJECTIVE: IV bisphosphonates are effective in reducing skeletal related events (SREs) and alleviating bone pain in breast cancer patients with bone metastasis. However, these agents are characterized by different efficacy, administration time, and costs. Formal analyses are therefore needed to understand their overall economic value and budgetary impacts. We conducted a formal economic analysis to compare the budgetary impacts of these agents, from the UK NHS perspective. METHODS: A Markov model was developed to simulate over a period of seven years the survival and incidence of SREs for a hypothetical cohort of 1000 patients receiving no treatment (NT) or monthly injections of ibandronate (IBN), generic pamidronate (PA) or zoledronic acid (ZA). Probabilities of SREs (extrapolated from skeletal morbidity rates [SMR]) were obtained from published clinical trials of each agent. Costs of drugs and their infusion and cost of SREs were estimated from published sources. Survival was identical across all groups (25 months). RESULTS: Based on relative reduction of risk of SREs (ratio of SMR of bisphosphonate therapy vs. no therapy), the cumulative number of SREs over the lifetime of the patients was lowest for ZA (3820 events), followed by PA (4430), IBN (4890), and NT (6020). Total discounted costs (which included drug costs, infusion administration costs, and cost of treating SREs) for the cohorts of 1000 patients were £2,457,000 lower for ZA than IBN, £1,160,000 lower than PA, and £556,000 lower than NT. Fifty and 75% of these savings, respectively, occurred within the first 12 and 24 months of the simulation. These findings were robust across various sensitivity analyses. ZA was less costly and more effective than all other treatment options, and is therefore the economically preferred option. CONCLUSIONS: Zoledronic acid appears to be the most cost-effective and least costly IV bisphosphonate therapy.