A COMPARISON OF INTRAVENOUS AND ORAL FORMULATIONS OF FLUDARABINE IN THE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA

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OBJECTIVES: Fludarabine (Flu) has been proven to be highly effective in the treatment of chronic lymphocytic leukemia (CLL). Both oral and IV Flu are used internationally. Recently, the oral formulation of fludarabine was approved in the US for treating CLL, which may offer advantages for providers, payers and patients. This study is a systematic review of clinical trial and retrospective data for oral and IV fludarabine, focusing on differences in efficacy, complications, resource utilisation and patient preference. METHODS: PubMed and manual bibliographic searches were conducted to identify relevant publications for oral and IV Flu. Studies were included if they were: 1) published before January 1, 2000, 2) derived from human subjects, 3) written or translated in English 4) focused on oral and iv Flu and evaluated efficacy, resource utilisation, costs and patient preference. RESULTS: There were 17 articles that met inclusion criteria. Results indicated that the pharmacokinetic profile of oral and IV Flu were similar, with 25 mg/m² of IV being equivalent to 40 mg/m² of oral Flu. Oral Flu has similar efficacy and safety to IV Flu, and eliminates infusion related adverse events and administration costs. Studies indicated that providing oral Flu was more convenient for patients and nurses due to the absence of IV administration. No cost or pharmacoeconomic data were found. CONCLUSIONS: Oral and IV Flu were found to have similar clinical efficacy and safety. The oral formulation may potentially lead to substantial economic benefits which may result in possible reductions in infusion related administration and adverse events. Future studies need to compare real-world clinical outcomes and economic impact of oral vs IV Flu, taking into account decision-making in clinical practice of both health care providers and patients.

IMPACT OF 5-HT3-RECEPTOR ANTAGONIST STEP THERAPY ON CHEMOTHERAPY INDUCED NAUSEA AND VOMITING ASSOCIATED HOSPITAL AND EMERGENCY ROOM EVENTS

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OBJECTIVES: To explore the impact of step therapy policies requiring the use of a 1st-generation 5-hydroxytryptamine-3 receptor antagonist (5-HT3-RA) treatment before palonosetron (a 2nd generation 5-HT3-RA) on the incremental risk of chemotherapy induced nausea and vomiting (CINV) associated with a hospital or emergency room (ER) event. METHODS: Cohort of patients with cancer who received chemotherapy on day 1/cycle 1 of CT treatment. 4505 patients initiated and maintained on palonosetron throughout CT. Patients were stratified into those initiated and maintained on palonosetron throughout CT (Group 1) versus those treated on day 1cycle 1 with any other 5-HT3-RA regimen (Group 2). Results and frequency for CINV-associated hospital or ER events identified through ICD-9-CM codes for nausea, vomiting, and/or dehydration during a 6-month follow-up period were estimated using Poisson and Poisson regression models, controlling for age, gender (LC only), comorbidity, and CT days. RESULTS: Of 3606 BC and 4497 LC identified patients, 1864 BC (52%) and 1806 LC (40%) initiated palonosetron. Groups 1 and 2 had comparable morbidity and CT treatment days. Compared to 2 patients, group 1 patients had a significantly lower probability of CINV-associated hospital or ER events (3.5% vs. 5.5% in BC and 9.3% vs. 12.8% in LC), had 47.4% (BC) and 29.1% (LC) fewer hospital or ER days with CINV, and fewer 5-HT3-RA claims (mean ± SD: 6.2 ± 3.3 vs. 7.9 ± 4.1 in BC and 7.7 ± 4.9 vs. 10.3 ± 6.4 in LC), all at p < 0.05. Risk for CINV was 48% (BC) and 29% (LC) lower for group 1 patients (Odds Ratio = 0.62 in BC and 0.71 in LC, p < 0.05). CONCLUSIONS: LC or BC patients initiated and maintained on palonosetron throughout CT were at significantly lower risk for costly CINV versus those on any other 5-HT3-RA on day 1 cycle 1 of CT treatment.

USING PROPENSITY SCORES TO REDUCE SELECTION BIAS IN AN OBSERVATIONAL STUDY COMPARING RASBURICASE TO ALLOPURINOL IN THE US

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BACKGROUND Randomized clinical trials remain the gold standard in evaluating different drug therapies on outcomes but are resource intensive. Retrospective studies using observational data are inexpensive but prone to selection bias due to non-random differences between the intervention and comparator groups. The Propensity Score (PS) method is a novel, multivariate adjustment procedure that reduces confounding and selection bias. METHODS: This case-control study used the Health Core database (Centere Database, Kaiser City, MO), which integrates patient information from hospitals throughout the United States. Cancer patients receiving rasburicase or allopurinol were eligible for study inclusion. Both drugs reduce uric acid (UA) elevation otherwise resulting from tumor lysis syndrome. The PS is the...