HOSPITAL BASED OBSERVATIONAL STUDY ON THE TOLERABILITY, AND EFFICACY OF TWO GEMCITABINE OXALIPLATIN REGIMENS

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Background: GemOx, has regained attention after recent pooled- and meta-analysis suggested a survival benefit of Gemcitabine-platinum doublets over Gemcitabine in various malignancies like pancreatic, hepatobiliary, Lymphoma etc. This regimen, however, is associated with variable toxicity like cumulative dose dependent neuropathy and thrombocytopenia. In addition, fixed dose rate of Gemcitabine showed no benefit > 30 min infusion schedule in the ECOG6201 study and the day 1 and day 8 is still debated. Pharmacokinetic and Pharmacodynamic and disease biology [most of these have high proliferation indices], suggest an advantage with dose dense regimens. Hence this study was carried out to look at the tolerability, and efficacy of two different regimens of GEMOX.

Methods: This study was carried out at the Apollo hospital, BIBI hospital and at ClinSync Hyderabad. The case records Between September 2011 and September 2012, were reviewed who received either of the regimens. Different regimens include Gemcitabine (1 000 mg/m(2)) at Day 1 and Day 8, and intravenous injection of Oxaliplatin (85-130 mg/m(2)) at Day 1; repeated every 21 days [Ai Zheng. 2007 Dec;26 (12):1381-4.], Gemcitabine 1000 mg/m(2) > 100 min on day 1 and Oxaliplatin 100 mg/ m(2) on day 2 every 2 weeks [Expert Opin Drug Saf. 2010 Mar;9(2):207-13.] CTC version 3.0 was used to assess toxicity and RECIST 1.1 to assess the response rates and Intention to treat analysis for the Survival.

Results: A total of 32 patients with various indications were included, with distribution of pancreatic, hepatobiliary vs lymphomas are 14,9, 2 cases vs 4,3 and 0 in GEMOX 14 vs 21 respectively. The Gemox 14 is having better response rates than GEMOX 21 with PR + SD, CR and PD of 68%, 8% and 24% with GEMOX 14 vs. 43%, 0 and 57% with GEMOX 21 respectively. Similarly the Grade III/IV toxicity for haematological parameters was 32% vs 43%, for nausea 48% vs 57%, and neuropathy 4% vs 29% favouring GEMOX 14. Similarly QOL improvement was observed in 76% of the patients on GEMOX 14 vs 43% in GEMOX 21 respectively. The median progression free survival was 9.6 months vs 7.2 months favouring GEMOX 14.

Conclusion: Though the sample size is small to draw conclusions regarding the apparent advantages of GEMOX 14 in terms of better toxicity, better QOL improvement as well as Progression free survival, it can be concluded that in ethnic Indian patients, GEMOX 14 is feasible and might be better than GEMOX 2. Prospective study is planned in Pancreatico- biliary malignancies to have the first hand Indian data.