OBJECTIVES: Inadequate control over emesis during cancer chemotherapy can adversely affect patient's quality of life, delay the subsequent chemotherapy cycle and may lead to poor adherence to treatment. This study was conducted to assess appropriateness of anti-emetics use in the management of chemotherapy induced nausea and vomiting. **METHODS:** A prospective observational study was conducted for a period of 6 months at private cancer hospital. Medical records of the patients on chemotherapy were reviewed and patients were interviewed to assess the prescribing pattern of anti-emetics and its appropriateness. Chemotherapy regimen and given anti-emetics for each patient were recorded and reviewed with respect to National Comprehensive Cancer Network (NCCN) guidelines for anti-emesis to ensure the appropriateness of drug use. **RESULTS:** Of 346 patients' record reviewed, majority (74%) of them were prescribed with drugs which are highly emetogenic followed by 17% of them with moderately emetogenic and 9% of them with low emetogenic potential. Unlike 30% of patients who were added with NK-1 receptor antagonist (NK1RA) either in oral or intravenous formulation, majority (n=184, 70.76%) of the patients receiving highly emetogenic regimen were placed on combination of 5-HT3 antagonist and corticosteroids without adding NK1RA for prevention of acute and delayed emesis. Majority patients (64%) receiving moderately emetogenic regimen were prescribed with combination of 5-HT3 antagonist and corticosteroids and remaining received combination of metoclopramide with corticosteroids. Most of the patients (82%) receiving low emetogenic regimen were prescribed with combination of metoclopramide and corticosteroids and remaining were prescribed with 5-HT3 antagonist and corticosteroid. Over all, selection of anti-emetic regimen was inappropriate for 32% (n=112) patients. Dosage, frequency and duration of anti-emetic use were inappropriate in 18%, 38% and 8% respectively. **CONCLUSIONS:** Most of the patients received same anti-emetic regimen for highly emetogenic and moderately emetogenic agents. Cost was the limiting factor to choose an appropriate anti-emetic regimen.

INFECTION – Clinical Outcomes Studies

PIN1

NON-INFERIORITY OF ONCE-DAILY COBICISTAT-BOOSTED DARUNAVIR VERSUS RITONAVIR-BOOSTED DARUNAVIR IN HIV-1-INFECTED ADULT PATIENTS: AN ADJUSTED COMPARATIVE ANALYSIS OF POOLED PHASE 3 DATA

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OBJECTIVES: Cobicistat, a CYP3A inhibitor, is a novel, alternative pharmacoenhancer to ritonavir. A fixed-dose combination once-daily formulation that contains darunavir and cobicistat has been developed to simplify dosing and to enhance patient convenience. This analysis compared the virological response of a cobicistat-boosted versus a ritonavir-boosted darunavir QD regimen by testing for non-inferiority. **METHODS:** Patient level data on 800mg QD darunavir treatment from 3 phase 3 trials (GS-216-0130, TMC114-C211, TMC114-C229) were combined for analysis of virological response at Week 48, using the Snapshot algorithm methodology. Patients were HIV-1-infected treatment-naïve or -experienced with no darunavir resistance-associated mutations at baseline. The non-inferiority margin was set at 0.531 on the odds-ratio (OR) scale, which corresponded to a 12% non-inferiority margin on the risk-difference scale, assuming an 80% response rate. Multiple logistic regression was used to adjust for differences in baseline patient characteristics (age, gender, race, baseline CD4+ T-cell counts, baseline HIV-1 RNA, HIV disease status, and previous antiretroviral use) and level of darunavir treatment adherence. A sensitivity analysis was performed on data from patients with viral load<50 copies/mL according to time to loss-of-virological response (TLOVR) algorithm at week 48. **RESULTS:** Treatment with darunavir/cobicistat(800/150mg QD, n=313) was non-inferior to darunavir/ritonavir (800/100mg QD, n=637). Unadjusted virological response rates were 81% and 78%, respectively. The adjusted odds ratio [95% CI] for virological response comparing darunavir/cobicistat with darunavir/ritonavir at week 48 was 0.878 [0.576, 1.339] (Snapshot). The 95% CI lower boundary was above the defined non-inferiority margin. The sensitivity analysis gave similar results: TLOVR OR=0.803 [0.534, 1.208]. **CONCLUSIONS:** This adjusted analysis of pooled phase 3 data of an 800mg once-daily darunavir dose showed that darunavir/cobicistat has non-inferior efficacy compared with darunavir/ritonavir.

PIN2

RELATIONSHIP BETWEEN MICROBIOLOGICAL ERADICATION AND CLINICAL OUTCOME WITH ANTIBIOTIC TREATMENT IN NOSOCOMIAL PNEUMONIA, COMPLICATED URINARY TRACT INFECTION, AND COMPLICATED INTRA-ABDOMINAL INFECTION

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OBJECTIVES: Infections caused by Gram-negative bacteria, including nosocomial pneumonia (NP), complicated urinary tract infections (cUTI), and complicated intra-abdominal infections (cIAI), have been increasing. Although microbiological eradication is on the presumed causal path from antibiotic susceptibility to clinical success, other factors impact clinical success rates as well. This study assessed the relationship between microbiological eradication and clinical outcomes for NP, cUTI, and cIAI based on randomized controlled trial (RCT) evidence. **METHODS:** A systematic literature search identified RCTs (25 NP trials, 10 cUTI, 28 cIAI, and 1 cUTI & cIAI trial) that met the following criteria: Adult patients with cUTI, cIAI, or NP; Gram-negative bacteria present in at least a fraction of the population; treatment including coverage of Gram-negative bacteria; any measure of microbiological eradication and either clinical response, cure or mortality. RCTs with information on both eradication and clinical outcome were selected to estimate their relationship to treatment effects using multivariate meta-analyses. **RESULTS:** Given the variation in analysis populations and timing of outcome assessment across RCTs, a limited number of studies were considered sufficiently similar for meta-analyses. For NP, a positive relationship between microbiological eradication and cure (correlation coefficient of 0.84; 95%CI 0.07, 0.98; 5 studies) and a negative relationship between eradication and mortality (-0.86; 95%CI -0.97, -0.34; 7 studies) were observed. For cIAI, clinical outcome was used as a proxy measure for microbiological eradication, but no correlation with mortality was identified. No relationship was observed for cUTI either. **CONCLUSIONS:** Relationships between treatment effects in terms of eradication and clinical cure and between eradication and mortality were identified for NP. For cIAI and cUTI, the relationship between microbiologic eradication and treatment effects is unclear based on available study level RCT evidence. Given the great variation between studies and several uncertain findings, evaluations using patient level data are recommended.

PIN3

STUDY ON CLINICAL AND IMMUNOLOGICAL OUTCOMES OF ANTIRETROVIRAL THERAPY IN HIV POSITIVE ADULT PATIENTS IN A COMMUNITY CARE HOSPITAL

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OBJECTIVES: Human Immunodeficiency Virus (HIV) has become a chronic manageable disease after the advent of combination antiretroviral therapy (ART). Since launching of ART, the numbers of patients enrolled in to ART are increasing in developing countries like India. In this study we aim to analyze clinical and immunological outcomes of ART in a community care hospital. **METHODS:** A retrospective cohort study was conducted by including 800 ART naive HIV infected adult patients initiated on ART. All patients survived in ART centre at Mysore, India for 12 months from January 2013 to January 2014 were included. Parameters like weight, hemoglobin, WHO clinical stage and CD4 count were collected from medical records before initiation and after completion of 12 months ART. Outcomes of ART were analyzed by paired T- test using SPSS version 21. **RESULTS:** A statistically significant improvement was observed for weight [53.9 (11.9) to 58.2 (32.6) kg; $P = 0.002$] and CD4 count [206.6 (177.4) to 331.1 (220.5); $P = 0.001$] at the end of 12 months of ART treatment. Whereas, marginal improvement in hemoglobin [11.94 (4.3) to 11.98 (5.7) g%; $P = 0.91$] was observed, though it was not statistically significant. Also observed a significant increase in percentage of patients in WHO clinical stage I (64-82%) and decrease in number of patients in stages II (13-14%), III (5-2%) and IV (18-12%). **CONCLUSIONS:** The improvement in weight and CD4 count are indirect parameters of >95% medication adherence and of sustained viral suppression. The optimal outcome would have been all patients in WHO clinical stage I or II and none in III and IV, but in this study 2% and 12% of patients continued to be in stage III and IV respectively. This may be due to development of opportunistic infections such as tuberculosis which is endemic in India.

PIN4

EFFICACY AND HOSPITALIZATION LENGTH OF STAY OF SINGLE DOSE ORITAVANCIN COMPARED TO 7-10 DAYS OF VANCOMYCIN IN PATIENTS WITH ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS IN THE US AND EASTERN EUROPE

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OBJECTIVES: Oritavancin (ORI) is a lipoglycopeptide with bactericidal activity against Gram-positive bacteria including MRSA. This analysis evaluated efficacy and hospital length of stay of ORI for patients with acute bacterial skin and skin structure infections (ABSSSI) who received care in the SOLO program in the US and Eastern Europe. **METHODS:** SOLO I and II were identically-designed comparative, multicenter, double-blind, randomized studies to evaluate the efficacy and health care resource utilization (HRU) of single 1200 mg dose IV ORI versus 7-10 days of twice-daily intravenous (IV) vancomycin (VAN) for the treatment of ABSSSI. SOLO protocols were amended (Amendment 2) to allow outpatient treatment at the investigator's discretion. Efficacy and HRU of treatment were assessed in inpatient and outpatient settings. Efficacy for the European Medicines Agency (EMA) was investigator-assessed clinical cure 7-14 days after end of treatment. HRU endpoints were hospitalization rate and length of stay (LOS) in days if the patient was hospitalized. **RESULTS:** In the combined studies, 1959 patients were in the modified intent-to-treat (mITT) population; 1,172 patients (60%) received a portion of their care in as inpatients; 202 patients were treated in Eastern European countries (EUC: Russian Federation, Romania and Ukraine) and 1,165 were treated in the US. Clinical cure rates were similar for ORI and VAN in both regions (86.1% and 84.2% in EUC, 80.6% and 77.9% in the US. The average LOS (ALOS) in the EUC was longer than in the US (14.9 and 14.7 vs. 6.0 and 6.4 days). **CONCLUSIONS:** Clinical cure rates at PTE were similar between ABSSSI patients who received a single dose of ORI or 7-10 days of VAN in SOLO, but the ALOS in the US was considerably shorter than in Eastern Europe. Using oral or long-acting antibiotic treatments may reduce the numbers of inpatient IV antibiotic administrations, which has been associated with reduced LOS in other studies.

PIN5

RETROSPECTIVE PUBLIC HEALTH IMPACT OF A QUADRIVALENT INFLUENZA VACCINE IN THE UNITED STATES OVER THE PERIOD 2000-2014

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OBJECTIVES: Vaccination has proven to be an efficient preventive strategy against influenza infection. Each year, two genetically distinct influenza B lineages co-circulate. Current trivalent influenza vaccines (TIVs) contain only one influenza B and two influenza A strains, but vaccine mismatch are frequent due to the difficulty to predict which B lineage will predominate during the next epidemic.