cell (pCD34) count of < 10/μL after 4 days of F alone. In this study we present the results of efficacy and an estimate of cost of such a risk adaptive strategy for autologous peripheral blood HPC collection. 42 patients with history of NHL or MM undergoing peripheral blood HPC mobilization from February to December 2009 were included in the analysis. All patients received daily filgrastim for 4 days. Our risk adaptive approach was to add P for those 'at-risk' patients, who on day 4 had a pCD34 count of < 10/μL, with apheresis commencing the following morning. Morning administration of F and evening dosing of P was continued daily in this group of 'at-risk' patients for up to a maximum of 4 days or until > 5×10^6 $CD34^+$ cells/kg were collected. Results of consecutive patients who had peripheral blood HPC mobilization were prospectively collected. A decision analytic model was created to estimate the mean cost and effectiveness rates in patients who underwent mobilization with F versus F + P. 18 patients were mobilized with F alone and 24 patients required F + P. Administration of P was safe and no severe adverse events were recorded. Addition of P increased the pCD34 count by 6.8 fold with an average total yield of 4.9×10^6 $CD34^+$ cells/kg. The frequency of poor mobilization among F only and F + P patients was 25% and 7% respectively. The pooled average cost benefit for mobilization with F + P may be up to $ 16,900 per patient and could potentially increase the annual number of transplants by more than 18%. Following autologous stem cell infusion, days to neutrophil and platelet engraftments were similar between the patients who mobilized HPC with F versus F + P (p = 0.12). These results suggest that addition of P to F based on a risk adaptive strategy significantly reduces the frequency of mobilization failures and is also cost effective. Addition of P to F for HPC mobilization has no significant impact on the neutrophil and platelet engraftment.

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NEUTROPENIC ENTEROCOLITIS (NE) IN ADULT PATIENTS (PTS) UNDERGOING HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT): IMPACT OF BOWEL WALL THICKNESS ON CLINICAL OUTCOMES

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Background: NE is an acute, life-threatening condition characterized by transmural inflammation of the intestinal wall in severely myelosuppressed patients. Although initially described in pediatric leukemia pts it has increasingly been reported in adults with a variety of malignant conditions and in the setting of immunosuppression with HSCT. The aim of this retrospective study was to evaluate the prognostic value of clinical and radiographic findings in HSCT recipients diagnosed with NE.

Patients and Methods: Data from 264 HSCT recipients over a 5 year period was reviewed. 24 pts with a clinical diagnosis of NE supported by the triad of fever, abdominal pain and neutropenia with radiographic evidence of bowel wall thickening (BWT) were identified. Degree of BWT by CT scan [mild (m): 3-6 mm, moderate (M): 6-12 mm and severe (S) > 12 mm] along with clinical characteristics (age, sex, diagnosis, co-morbidities, type of transplant, conditioning regimen and neutropenia length) were evaluated and correlated with clinical outcomes [complicated (CNE) vs. non-complicated (cNE)] and mortality. CNE was defined as those who became bacteremic with enteric flora, required ICU admission or died.

Results: 264 pts underwent a HSCT from 2004 to 2010. A total of 24 (9.1%) pts (average age 52.67 yrs, range 23 – 70yrs) were diagnosed with NE. 14 (58.3%) pts underwent an autologous HSCT and 10 (41.7%) an allogeneic HSCT. Median BWT was 6 mm (range 2 -15 mm). 11 (45.8%) pts had mBWT, 9 (37.5%) pts MBWT and 3 (12.5%) pts SBWT. 13(54.2%) pts had cNE and 11 (45.2%) pts had CNE. 7(29.2%) pts required ICU admission and 3 (12.5%) pts died. Clinical characteristics had no impact on morbidity or mortality in our pt population. Degree of BWT failed to impact mortality on univariate analysis (dead vs. alive: ≥ 3mm p = 0.25, ≥ 6 mm p = 0.48, ≥ 12 mm p = 1.00), but the presence of MBWT and SBWT (≥ 6 mm) was associated with a higher rate of CNE (CNE vs. cNE: ≥ 6 mm p = 0.003 OR:30.0, 95 % CI 2.6-342.7). BWT ≥ 6 mm highly correlated with CNE on multivariate analysis (p = 0.009 OR:31.5 [2.35-422.3]).

Conclusion: Clinical characteristics had no prognostic impact in adult patients who developed neutropenic enterocolitis following HSCT. Patients with moderate and severe bowel thickening have a worse clinical outcome however this failed to predict mortality; likely the result of a small sample size. Larger studies and development of standardized criteria for bowel thickness measurement are warranted.

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LONG-TERM FOLLOW-UP OF METASTATIC BREAST CANCER PATIENTS RECEIVING HIGHLY PURIFIED AUTOLOGOUS CD34+THY-1+ HEMATOPOIETIC STEM CELLS AFTER HIGH-DOSE CHEMOTHERAPY

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In the 1990's high-dose chemotherapy (HDCT) with autologous hematopoietic cell transplantation (auto-HCT) was considered a promising, potentially curative treatment approach for patients (pts) with advanced or metastatic breast cancer (MBC). When randomized trials did not confirm a significant benefit of HDCT over standard chemotherapy (CTx) enthusiasm for this therapy fell and transplantation studies ended abruptly. Despite improvements in overall survival (OS) due to better CTx, endocrine, and immunologic agents, MBC remains an incurable disease. One potential reason for the failure of HDCT with auto-HCT is the high rate of occult tumor cell contamination (OTC) in bone marrow, and accordingly in mobilized blood grafts. Here we report the long-term follow-up of 15 pts that underwent HDCT (cisplatin, cyclophosphamide, BCNU) at our institution between 12/96 and 4/98. FACS-purified CD34+Thy1+ hematopoietic stem cells (HSC) with no detectable tumor contamination (detection level 1/106 cells) were used as grafts. Of note, 4/15 leukapheresis products contained OTC prior to sorting. Pts were a median age of 43 years (y), were treated for primary stage IV BC (n = 5), or relapsed BC (n = 10). Status of remission at HCT was CR in 47%, and PR and SD in each 26.5% of pts. More than 12 years after the end of the study 33% pts are alive, 27% in CR. Median progression-free survival (PFS) is 16 months (m), the PFS rate at 3y is 47%, at 10y 27%, each. Median OS for the entire group and for survivors is 120m and 160m, respectively. 5y and 10y OS rates are 60% and 47%, respectively. In comparison, of 78 pts given the same HDCT regimen but unmanipulated grafts, 9% are alive, and 6% without disease, 71% died of their BC, 22% died of other reasons, and 4% were lost to follow-up. Median PFS is 9m, and the PFS rates at 3, 5, and 10y are 18%, 11%, and 8%, respectively. Median OS for the entire group was 26m, and 154m for the 7 survivors. OS rates at 3y, 5y and 10y were 39%, 25%, and 13%, respectively. Even though pts numbers in the HSC group are small, and may include a highly selected population, our data suggest that infusion of a hematopoietic graft, devoid of OTC, may be critical to prolong time to relapse, and increase the proportion of CR. We believe HDCT could regain relevance within multimodal treatment approaches, as a good remission and avoidance of relapse due to OTC in the graft could serve as a foundation for treatment with novel biological and small molecule agents.

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ADAPTIVE RANDOMIZATION FOR BMT CLINICAL TRIALS WITH BOTH EFFICACY AND FUTILITY OUTCOMES

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Bone marrow transplant (BMT) clinical trials generally feature fixed randomization schedules determined before patient accruement. Bayesian adaptive designs based on in-trial treatment