

cost was 16 USD in group A and 11.43 USD in group B. **Conclusions:** In this series of 39 patients the efficacy of the single daily dose of levofloxacin was equivalent to the combination of ciprofloxacin plus amoxicillin as bacterial prophylaxis. A daily dose of levofloxacin is more convenient and cheaper than the combination therapy.

#### 416

##### **G-CSF(FILGRASTIM) ON DAY -1 (DAY BEFORE STEM CELL INFUSION) PROVIDES STABLE ENGRAFTMENT AND GOOD PROGRESSION FREE AND OVERALL SURVIVAL (PFS AND OS) IN HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT)-TATA MEMORIAL CENTRE EXPERIENCE**

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**Background:** Recombinant human G-CSF hastens neutrophil recovery following hematopoietic stem cell transplantation (HSCT), thus accelerating engraftment. The optimal timing for use of G-CSF in conjunction to HSCT needs to be established. We present our data on effects of adding an extra dose of G-CSF (filgrastim 5 micro gm/kg) on day -1 of HSCT. **Patients and Methods:** Forty three consecutive patients who underwent HSCT in one year period were given G-CSF on day +1 (day before stem cell infusion) in addition to the regular doses from day +1 till engraftment. **Results:** Among the 43 patients (median age 36 years), males were 34 and females 9 with 19 allograft and 24 autografts. The type of harvest was PBSC in 39, BM alone in 1 and both in 3 cases. Disease wise distribution was AML-13, MM-8, ALL-1, NHL-6, HL-5, CML-5, MDS-2, Aplastic Anemia, ALL, and Ca nasopharynx 1 each. The median MNC and CD 34 doses infused were  $5.3 \times 10^8/\text{Kg}$  and  $2.26 \times 10^6/\text{Kg}$ , respectively. Median days of Grade IV neutropenia was 11 (range 5-19) and that of ANC <100 was 6 (range 2-19). Neutropenic fever was present for a median of 10 days (range 4-19). Neutrophil engraftment and platelet engraftment occurred at day +11 (range 8-21) and day +21 (range 11-73), respectively. Median number of packed cells and platelets (SDP) transfused were 4 and 5, respectively. Mucositis was present for a median of 9 days with Grade III in 51% (n = 22) and Grade IV in 20% (n = 9) patients. TPN was used in 76% (n = 33) patients with a median of 5 days. Median number of days of antibiotics use was 10%, and 58% (n = 25) needed 3 lines of antibiotics. Antifungals were used in 60% (n = 26), and 96% of its use was empirical. Infections were documented in 40% (n = 17). Median days of hospitalization was 23 (range 13-38). Transplant related mortality was 11.6% (2 auto and 3 allo). At 7 months the overall survival is 78% with median follow up of 3.5 months. **Conclusions:** Addition of G-CSF on day -1 of HSCT is safe and provides stable engraftment and acceptable results in terms of neutropenic fever, requirement of blood products, antibiotics, TPN, and duration of hospital stay. Further randomized trials comparing conventional scheduling of G-CSF (post infusion day +1 onwards) with the present schedule are warranted.

#### 417

##### **PEGFILGRASTIM FOR HEMATOPOIETIC RECOVERY AFTER AUTOLOGOUS PERIPHERAL BLOOD STEM CELL TRANSPLANTATION**

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Filgrastim (FIL), granulocyte-colony stimulating factor, reduces time to neutrophil engraftment, hospital stay, and antibiotic therapy. FIL requires uncomfortable and inconvenient daily subcutaneous (SC) injections. Pegfilgrastim (PFIL), while more expensive, requires

a single SC injection. **Method/Results:** An ongoing Phase II trial compares PFIL 6 mg SC starting day +1 to FIL 480 mcg SC daily starting day +7 historical controls. Nine patients have been accrued to date (10/10/05) (multiple myeloma = 1; NHL = 4; HD = 4). Thirty consecutive patients (MM = 4; NHL = 14; HD = 12) were analyzed as historical controls. ANC  $\geq 500/\text{mm}^3$  was reached on the mean day +10 (range 9-12) for PFIL and day+ 12 (range 9-19) for FIL. Platelets  $\geq 50 \text{ K}/\text{mm}^3$  were attained on a mean of day +13 (range 9-21) for PFIL versus day +27 (range 11-63) for FIL. No PFIL patients required additional G-CSF. One patient had prolonged fever, probably PFIL-related. Average cost of PFIL was \$2681/patient; average FIL cost was \$2736/patient. **Conclusions:** Preliminary analysis indicates the equivalency of PFIL and FIL related to hematopoietic recovery. Collection of engraftment, economic, and length-of-stay data continues.

#### 418

##### **THE DEVELOPMENT OF A SUCCESSFUL SATELLITE BONE MARROW TRANSPLANT (BMT) UNIT AS A MODEL FOR HEALTH CARE OUTREACH**

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Recent innovations have expanded and evolved the field of stem cell transplantation. These changes and the increased complexity of the field have largely limited transplantation to traditional academic centers. Despite being the fifth largest metropolitan city in the United States, in 1997 patients who lived in Phoenix, Arizona, who required transplantation were required to travel approximately 120 miles to the nearest transplant center. At that time, prompted by local physicians, the Banner Health System (the largest oncology provider in the city) partnered with the City of Hope National Medical Center (COH), a nationally recognized transplant center located in Duarte, California, to form the City of Hope Samaritan BMT unit (COHS), a joint venture between the 2 parties designed to build on each other's strengths. The COH provides the local physicians medical leadership, clinical trials, and expertise with biomedical statistics. Banner Health provides the physical structure, local administrative support, nursing, and all ancillary care services. The programs are clinically fully integrated. Patients are discussed at new patient conference via teleconference, pathology is reviewed at the COH, donor choices are made in cooperation with the COH team, and patients are enrolled on joint clinical trials. In addition, the Phoenix COH physicians actively participate in disease committees and in weekly research rounds via teleconference. COHS initially performed only autologous transplants but now offers all forms of transplant services. To date 470 patients (auto n = 334, sibling allogeneic n = 80, MUD n = 55, cord blood n = 1) have been transplanted. In the past 2 years approximately 40% of patients underwent allogeneic transplantation. Patient demographics are similar between the 2 institutions. The 100 day transplant related mortality for the COHS compares favorably to the COH (auto 1 vs 2%, allo 4 vs 8%, and MUD 24 vs 29%). COHS is part of the CTN trials network through its association with COH and is a member of the SWOG. The program achieved full FACT accreditation in 2003 prior to the parent organization at COH. The success of this model has been achieved because of similar corporate cultures, close clinical integration, and oversight from a board composed of members from each of the parent organization. We believe this model can successfully be replicated if the parent organizations share similar cultures and are committed to integrating the programs clinically.