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PALIFERMIN USE IN ADOLESCENT STEM CELL TRANSPLANT PATIENTS: CASE REPORTS

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Purpose: This is a case series report of two adolescent stem cell transplant patients who received palifermin therapy to decrease the duration and severity of oral mucositis.

Background: Oral mucositis, an injury of the oral mucosa found most commonly in patients receiving chemotherapy and/or radiation, is one of the most debilitating toxicities associated with stem cell transplantation. Oral mucositis has been associated with the need for total parenteral nutrition, longer hospital admissions with an increase in hospital charges, and an increased risk of mortality within the first 100 days post-transplant.

Several risk factors have been identified for increased risk of severe oral mucositis. Risk factors that may predispose patients to more severe oral mucositis include allograft agent chemotherapy stem cell preparative regimens, radiation containing preparative regimens, and herpes simplex virus. Palifermin (Kepivance®), a human keratinocyte growth factor, has been used to decrease the incidence and severity of oral mucositis. Palifermin is not FDA-approved for pediatric patients and reports on its use in the pediatric hematopoietic stem cell transplant patient population are limited.

This is a report of two cases of palifermin use in adolescent stem cell transplant patients. The observed patients include a 14-year-old who received a double cord blood allogeneic transplant following a fludarabine, cyclophosphamide total body irradiation and focal radiation prep, and a 14-year-old who received an autologous transplant following a BEAM (Carmustine, Etoposide, Cytarabine, Melphalan) and focal radiation prep. In both cases, the use of palifermin prevented progression to severe, grade three or four mucositis.

Results: Conclusion: Palifermin is an effective alternative to decrease severity of oral mucositis in adolescent stem cell transplant patients.

Table. Palifermin Results

<table>
<thead>
<tr>
<th>Patient</th>
<th>Duration of Mucositis (Days)</th>
<th>Most Severe WHO Grade Oral Mucositis</th>
<th>Able to Take Oral Solids During Mucositis (Days)</th>
<th>BMT Prep Regimen</th>
<th>Transplant Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>2</td>
<td>4/4</td>
<td>BEAM, Radiation</td>
<td>Autologous</td>
</tr>
<tr>
<td>2</td>
<td>11</td>
<td>1</td>
<td>8/11</td>
<td>Fludarabine, Cyclophosphamide, Total Body Irradiation, Focal Mandible Radiation</td>
<td>Cord Blood</td>
</tr>
</tbody>
</table>

*Throat Pain, Abdominal Pain, No Oral Ulceration.

44World Health Organization.

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PHARMACISTS’ ROLE IN IMPLEMENTATION OF AN ALLOGENEIC HPC TRANPLANT PROGRAM

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The autologous hematopoietic progenitor cell (HPC) transplant program at USC Norris Comprehensive Cancer Center has been in practice since 1987. In 2011, the planning and implementation of allogeneic HPC transplant program began with efforts of a multi-disciplinary team of experts providing collaborative clinical practice. Pharmacists played a key role especially in the creation of policies, preprinted orders, drug therapy management, and education.

Pharmacists reviewed medications for the conditioning regimen, graft-versus-host disease (GVHD) prophylaxis, and various supportive care by evaluating literature and bench-marking with other HPC transplant centers. The goal was to ensure evidence-based practices as well as to meet current regulatory standards. The pharmacists’ diligence in procuring and ensuring adequate supply of medications as well as their timely delivery to patients was crucial in light of recent drug shortage challenges. Instituting standing orders for electrolyte transfusion, STAT antibiotic, and busulfan pharmacokinetics were compiled to provide a quick reference and educational tool for pharmacists.

By participating in daily patient rounds, pharmacists monitored patients’ clinical status closely, managed complications of high-dose chemotherapy and adjusted levels of anti-GVHD medications in a timely manner. To ensure optimal therapeutic dosing with minimal toxicity, busulfan pharmacokinetics was implemented under joint leadership of pharmacists and nurses. In addition, pharmacists played a major role in educating nurses on high-dose chemotherapy, immunosuppressive agents and the supportive care for infection, mucositis, nausea and vomiting in allogeneic HPC transplant patients.

In conclusion, pharmacists played a critical role by providing their expertise in the management of complex drug therapy, monitoring busulfan pharmacokinetics, educating their peers and thus, contributing to the success of the program.

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AN EFFECTIVE HEMATOPOIETIC STEM CELL MOBILIZATION ALGORITHM FOR ADDING PLERIXAFOR TO G-CSF FOR MULTIPLE MYELOMA PATIENTS UNDERGOING AUTOLOGOUS TRANSPLANTATION

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Purpose: To add plerixafor to G-CSF for mobilizing CD34+ cells in multiple myeloma (MM) patients. In addition, it is standard practice to collect sufficient stem cells for more than one transplant. Therefore, it is critical to have an effective mobilization strategy in order to efficiently collect enough CD34+ cells. Administering granulocyte-colony stimulating factor (G-CSF) alone to MM patients can produce sufficient CD34+ yields in the majority of patients. However, some patients may require > 4 apheresis days to achieve those yields or fail to collect enough CD34+ cells for ASCT. Plerixafor (P) can increase the average daily CD34+ yields by 3-fold. Since the majority of patients can collect with G-CSF alone, an algorithm was developed in 2009 to judiciously administer P only to those patients at higher perceived risk for mobilization failure.

Methods: G-CSF 10mcg/kg/day was administered SC from day 1 to 4. On day 4, a peripheral absolute CD34+ cell count was drawn. If the absolute CD34+ count was ≥ 12 cells/mm³ then apheresis started on day 5. If the absolute CD34+ count on day 4 was < 12 cells/mm³ P 240mcg/kg was administered SC the evening prior to apheresis beginning on day 5. During apheresis, if the CD34+ yield was < 1.0x10^6 CD34+ cells/kg or < 50% of the previous collection, P was initiated. The minimum collection yield for all patients was ≥ 4x10^6 CD34+/kg. The maximum number of apheresis days was 5.

Results: From 10/09 – 5/11, 68 MM patients were mobilized with G-CSF +/- P. 93% (63/68) of patients achieved minimum collection yield of ≥ 4.0x10^6 CD34+ cells/kg. 98% of patients achieved a yield of at least 2.0x10^6 CD34+ cells/kg. 44% (30/68) of the patients required at least 1 dose of P with the majority requiring it prior to the first apheresis (83%). The median days of apheresis was 2 (1-5). The overall average yield on the first apheresis day and total yield was 4.3x10^6 CD34+ cells/kg (95% CI: 0.6-0.64) and 8.71x10^6 CD34+ cells/kg (95% CI: 0.95-0.93), respectively. 60% (41/68) and 76% (52/68) of patients collected ≥ 6.0x10^6 CD34+ cells/kg in ≤ 2 days and ≤ 4 days of apheresis, respectively.

Conclusion: Adding P to G-CSF based upon a day 4 CD34+ count and collection yields is an effective strategy to mobilize CD34+ cells.