months showed a complete disappearance of the laryngeal mass that was observed. **Keywords:** multiple myeloma, MM, bortezomib, thalidomide, plasmacytoma, rhabdomyosarcoma, case

MM-053

Nursing Considerations for the Use of Isatuximab in the Treatment of Multiple Myeloma

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Context: Isatuximab (Isa) is a monoclonal antibody that binds to a specific epitope on CD38 and triggers death of multiple myeloma (MM) cells. Isatuximab-irfc is FDA-approved in combination with pomalidomide and dexamethasone (Pd) to treat adults with relapsed/refractory MM (RRMM) who have received ≥2 prior therapies, including lenalidomide and a proteasome inhibitor. **Objective:** ICARIA-MM (NCT02990338) compared efficacy and safety of Isa plus Pd (Isa-Pd) to Pd in RRMM. **Design:** Eligible patients had RRMM and ≥2 prior lines of therapy, including lenalidomide and a proteasome inhibitor. **Setting:** Prospective, randomized, open-label, active-controlled, multicenter Phase 3 study. **Patients or other participants:** 307 patients were randomized to receive either Isa-Pd (n=154) or Pd (n=153). **Interventions:** Isa was administered intravenously at 10 mg/kg weekly for 4 weeks, and every other week thereafter. **Main outcome measures:** Progression Free Survival (PFS). Safety assessed according to National Cancer Institute Common Toxicity Criteria for Adverse Events (NCI-CTCAE; v4.03). **Results:** Median PFS, 11.5 months Isa-Pd, 6.5 months Pd; HR 0.596 (95% CI 0.44–0.81); P=0.001. ORR 60.4% Isa-Pd, 35.3% Pd (P<0.0001). 86.8% Isa-Pd patients and 70.5% Pd experienced Grade ≥ 3 AEs; 7.2% Isa-Pd and 12.8% Pd patients discontinued due to AEs. Common AEs (any grade) were infusion reactions ([IRs] 38.2% Isa-Pd, 0.0% Pd), and upper respiratory infections (28.3% Isa-Pd, 17.4% Pd). The most common laboratory abnormality was neutropenia (any grade; 96.1% Isa-Pd, 93.2% Pd). Most IRs occurred at first infusion and were reversible; 2.6% were Grade ≥ 3. No delayed IRs were reported. To manage IRs, patients were premedicated with acetaminophen, ranitidine, diphenhydramine, and dexamethasone. No post-infusion prophylaxis was required. Only 2.1% of isatuximab infusions were interrupted and median time to interruption was 55 minutes. Neutropenia and infections were reversible and manageable with colony-stimulating factors and antibiotics. **Conclusions:** The dosing regimen, clinical activity, and manageable safety profile distinguish Isa as a new treatment option for patients with RRMM. Oncology nurses will be key in the infusion process, administration of pre-medications, management of IRs, and education of patients receiving Isa treatment. **Study Sponsor:** Sanofi
Keywords: CD38, isatuximab, monoclonal antibody, relapsed/refractory, multiple myeloma, MM

MM-069

Autologous Hematopoietic Stem Cell Transplant in Multiple Myeloma: Plerixafor Mobilization and Progression-Free Survival

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Context: Plerixafor is a CXCR4 receptor antagonist developed for improving the mobilization of CD34+ cells prior to collection for autologous hematopoietic stem cell transplantation (Auto-HSCT) in hematologic malignancies, used when a high rate of insufficient collection by apheresis is expected. In multiple myeloma (MM), apart from an increase in the number of CD34+ cells, it has been shown a rise in the amount of plasma cells collected. **Objective:** Our hypothesis is that Plerixafor-mobilized patients and their potentially contaminated product could have an impact on their relapse-free survival. The primary outcome of this study was to evaluate if the addition of Plerixafor to filgrastim (G-CSF+P) for mobilization phase was related to a lower progression-free survival (PFS) compared to patients who received only filgrastim (G-CSF). **Design:** Observational, retrospective, longitudinal trial that included adults with MM who received Auto-HSCT between January 2012 to May 2019. Mean follow-up for surviving patients was 37 months. **Setting:** Hospital care, high-complexity center. **Patients or other participants:** 88 MM patients received Auto-HSCT in the studied period. 28 were excluded due to insufficient follow-up, second transplant, or missing relevant data. Median age was 57 years (range 31-73). A mean of 4.67 (± 2.42) and 6.65 (± 3.17) × 10^6 CD34+ cells/kg were infused in the G-CSF and G-CSF+P groups, respectively. **Interventions:** Follow-up after Auto-HSCT. **Main outcome measures:** Kaplan-Meier analysis to determine PFS and overall survival (OS). **Results:** Median PFS (n=60) was 24 months. In the subgroup analysis, PFS was 36.3 months for the filgrastim group (n=25) and 21.5 months for patients who received G-CSF+P (n=35; p=0.24). Median OS was 70 months (70 months vs not reached for G-CSF and G-CSF+P groups, respectively, p=0.6). **Conclusions:** Adding Plerixafor prior to autologous collection in MM showed a tendency towards a lower PFS, and a controlled trial with a larger sample size and longer follow-up is needed to define if this trend becomes statistically significant. Biological studies, such as the quantification of plasma cells and their apoptotic rate could add to the evaluation of the impact of the mobilized product in the relapse rate of MM patients. **Keywords:** MM, multiple myeloma, plerixafor, progression-free survival