alone: 3, other combination chemotherapy: 9 and 1 underwent reduced intensity allogeneic transplantation. Two pts were not fit to receive further treatment and had rapidly progressive disease (PD). Of the treated pts, 6 achieved CR (4 subsequently progressed), 5 PR and 7 had PD. Eleven pts remain alive (only 2 in CR) with PD accounting for all deaths. With a median follow-up of 31 months (m) post relapse for living pts, median PFS from the time of relapse post-ASCT was 5 m and OS was 34 m. No significant predictors of PFS could be identified. For OS, univariate analysis identified time to relapse (TTR; $p = 0.011$), performance status (PS; $p = 0.010$) and total IPI score ($p = 0.041$) as being statistically significant. Only TTR remained significant on the multivariate model. TTR less than 12 months portends a very poor outcome (2 year OS 0% compared to 62% form TTR >12 m; $p < 0.001$). **Conclusion:** Pts with MCL who relapse after ASCT do poorly, especially those relapsing within one year of ASCT. New therapeutic approaches incorporating maintenance therapy post-ASCT or the use of novel agents such as bortezomib or mTOR inhibitors should be explored in this group.

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FLUID RELATED COMPLICATIONS WITH FILGRASTIM (G-CSF) 10 MCG/KG ONCE DAILY VERSUS 5 MCG/KG TWICE DAILY IN AMYLOIDOSIS PATIENTS UNDERGOING PERIPHERAL BLOOD STEM CELL MOBILIZATION

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Background: High dose melphalan followed by peripheral blood stem cell (PBSC) transplantation is an established therapy for AL amyloidosis. One limitation is the frequent fluid related complications that occur during PBSC mobilization (Blood 2004:1143a). The development of fluid related complications during mobilization predicts decreased survival after PBSC transplant (Blood 2005;106:3353). At Mayo Clinic, G-CSF 10 mcg/kg once daily was the standard until 2004. In attempt to reduce fluid related complications the practice changed to G-CSF 5 mcg/kg twice daily in July 2004. It is unknown if this change impacted the incidence of fluid related complications during PBSC mobilization. **Methods:** We conducted a retrospective evaluation of patients with amyloidosis undergoing PBSC mobilization at Mayo Clinic. Following IRB approval, patients were identified by reviewing the Mayo Clinic dysproteinemia data base and data extracted from the medical record. Forty-six patients from the once daily and 22 patients from the twice daily were excluded due to use of mobilization agents in addition to G-CSF, second mobilization, syngeneic transplant or consent refusal. A fluid related complication was defined as new peripheral edema, pleural effusion or ascites, or initiation of supportive therapy (diuretics, albumin, or dopamine) to promote diuresis. **Results:** From 7/98 to 8/03, 123 patients received once daily G-CSF. From 7/04 to 8/07, 182 patients received twice daily G-CSF. Organ involvement was similar in both series; single organ (43% vs 36%; $p = 0.2$), two organs (38% vs 62%; $p = 0.5$) and 3 or more organs (22% vs 26%; $p = 0.5$). Most patients had either kidney involvement (65% vs 71%; $p = 0.2$) or heart involvement (51% vs 57%; $p = 0.3$). Baseline edema (61% vs 53% ($p = 0.06$)) and baseline diuretic use (58% vs 55% ($p = 0.7$)) was similar in both groups. Fluid related complications occurred with similar frequency regardless of administration schedule, 50% vs 51% ($p = 0.9$). Two patients in the once daily and 4 patients in the twice daily administration died prior to PBSC transplant. In patients that received a PBSC transplant, survival was similar at day 100; 88% vs 92% and one year; 83% vs 88% ($p = 0.6$). **Conclusion:** Changing from once daily to twice daily G-CSF administration in patients with amyloidosis did not impact the incidence of fluid related complications or mortality at day 100 or one year after PBSC transplant.

Comparison of Complications based on G-CSF Schedule of Administration

	Once daily Filgrastim n = 123 N (%)	Twice daily Filgrastim n = 182 N (%)	p value
Fluid Complications	**63 (50)**	**93 (51)**	**0.9**
Hospitalization	**28 (23)**	**24 (13)**	**0.03**
Hospitalization related to fluid complication	**21 (17)**	**10 (5)**	**0.001**
Diuretic adjustment needed	**42 (34)**	**89 (49)**	**0.012**
Non-pharmacological intervention*	**10 (8)**	**9 (5)**	
Death prior to PBSC Transplant	**2 (1.6)**	**4 (2.2)**	
Patient did not undergo PBSC transplant	**9 (7.3)**	**37 (20)**	

*Thoracentesis, Paracentesis, Hemodialysis, Pleurodesis, and Mechanical Ventilation.

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PHASE II TRIAL EVALUATING APREPITANT (AP) FOR PREVENTION OF NAUSEA AND VOMITING SECONDARY TO HIGH-DOSE CYCLOPHOSPHAMIDE (CY) ADMINISTERED TO PATIENTS UNDERGOING AUTOLOGOUS (A) PERIPHERAL BLOOD PROGENITOR CELL (PBPC) MOBILIZATION

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Background: Adequate PBPC mobilization in the range of 2–5 $\times$ 10^6 $CD34^+$ cells/kg body weight is a prerequisite for administration of high-dose chemotherapy and A-PBPC transplant. Cy and filgrastim combination provides a better PBPC yield as compared to filgrastim, which has a failure rate of 15–20%. In this setting, high-dose Cy is associated with significant nausea and vomiting. Ap is a new antiemetic that is a Neurokinin-1 receptor antagonist and may reduce the incidence of this side effect. We have conducted a phase II trial evaluating efficacy and safety of adding Ap to standard antiemetic combination of 5-HT3 antagonists and adjusted dose of corticosteroids. Primary objective of this study was the control of acute vomiting without the use of rescue medications at 24 hours post Cy. The data of the first interim report are presented. **Methods:** From May 2005 to May 2007, 22 pts were enrolled, four of whom are not evaluable for response. Three pts did not receive Ap; one withdrew consent after a single dose. All received Cy 4 gm/m^2 and filgrastim (10–16 mcg/kg/d) for stem cell mobilization. Granisetron 1 mg, dexamethasone 10 mg and Ap 125 mg was administered orally 1 hour before Cy followed by Ap 80 mg once daily $\times$ 2 days. This study used Simon's optimal two-stage design constrained to fewer than 40 pts with 10% type I error and 85% statistical power. Ap is considered effective if it prevents nausea and vomiting in at least 65% of patients. Ap is judged ineffective if the rate of vomiting control was 45% or less. **Results:** Ten (55%) of 18 response-evaluable pts had no vomiting episodes and received no rescue medications during the first 24 hours following Cy. Of those who did not achieve the primary endpoint, four pts reported no vomiting episodes but received rescue medications. The other four pts had at least one vomiting episode and one received rescue anti-emetic. Ten pts had no delayed vomiting (25–120 hrs). Ten pts reported no nausea in 24 hours and five pts experienced mild nausea. Only 6/18 (33%) pts experienced moderate to severe delayed nausea (25–120 hrs). No toxicities related to Ap were noted for any patients. All pts had adequate mobilization of stem cells (median $CD34^+$: 7.57 $\times$ 10^6/kg) and proceeded to A-PBPC transplant. **Conclusion:** The results of this interim analysis justify continuation to stage 2 with enrollment of 17 more patients. Ap has potential to effectively control nausea and emesis in pts receiving high-dose Cy.