Results: 161 evaluable pts were enrolled between Nov 2016 and Oct 2018: median age (range) 77.6 (73.9–82.6) years, 44.7% male, ECOG 0/1 57.8%, stage II (R-ISS) 41.6%, disease isotypes IgG, IgA 66.2% and 33.1%, respectively. High-risk cytogenetics were detected in 18% of the patients in chromosomes t(14;16)(q32;q23) (5%) and t(14;16)(q32;q23) (3.1%) were the most common. Renal failure was reported in 17.4% pts and cardiovascular and endocrine diseases were the most frequent comorbidities, 72.7% and 41.0%, respectively. Regarding GAH scale, the median score was 61.0 (31–84). Data for all domains were obtained from 74 pts; of these, 68.9% pts showed high probability of developing toxicity to the Tx (>42 points). A total of 156 pts received lenalidomide (32.0%) or bortezomib (68.0%) as a first-line therapy. With a median follow-up of 5.0 (3.5–11.1) months, the response rates were: CR 17.9%, PR 67.2%, SD 1.9% and PD 1.5%. 61.5% of pts remain on first line therapy. The median OS has not been reached. The analysis of changes from baseline through 5 months with EQ-SD and QLQ C30 showed that pts had an increase in HRQoL mean values for the key domains of global health status/QoL, physical, role and emotional functioning over the course of Tx, although pts experienced a significant worsening in dyspnea domain (p = 0.003). The mean QLQ-MY20 values showed a significant improvement for domains of disease symptoms (p = 0.037) and future perspective (p = 0.010) and a worsening in side effects of Tx and body image (Figure). Of the 156 pts, 56.4% experienced at least 1 adverse event. Of these, six (3.7%) pts reported at least one grade 3–4 toxicity. The most common reason for discontinuation was death in 24 pts. At the time of this analysis, 103 in-patient hospitalizations were reported with a mean time of 5 days/pt. Average costs/pt were 3,804.67 € (€2,653.98 Hematology unit + €1,150.69 other units). Mean direct costs of diagnosis per patient was €1,205.39. Figure: Changes from baseline for EQ-SD, EORTC QLQ-C30 and QLQ-MY20

PS1392 CONSOLIDATION WITH A SHORT COURSE OF DARATUMUMAB CAN SIGNIFICANTLY IMPROVE COMPLETE RESPONSE RATES IN PATIENTS WITH AL AMYLOIDOSIS OR LCDD

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Background: A deep hematologic response is associated with the highest probability of organ function and survival improvement in patients with AL amyloidosis. Bortezomib-based therapy is the primary therapy for patients with AL amyloidosis but less than 40% achieves a CR. Further improvement of hematologic response may be achieved by consolidation strategies but HDM-ASCT is associated with significant toxicity, and only a minority of AL patients are eligible for this treatment. Recent data indicate that even a short course of daratumumab (DARA) was able to induce hematologic responses in patients with relapsed or refractory AL. Thus, DARA may be a unique treatment to improve the outcomes of patients with AL amyloidosis.

Aims: To evaluate the feasibility and activity of a short course of daratumumab as a consolidation strategy, in patients with AL or LCDD which had achieved either PR or VGPR after completing their primary therapy, with bortezomib-based therapy.

Methods: The endpoint of this exploratory approach was improvement of response post completion of DARA consolidation. All patients received 4 weekly infusions of daratumumab 16 mg/kg with dexamethasone 20 mg. Pre-empreative therapy for IR was given starting two days before the first infusion of DARA. In all patients next generation flow (NGF) according to Euroflow protocol was performed before and after consolidation.

Results: 26 patients (23 AL and 3 with LCDD) received DARA consolidation. Median age was 67 and 73% were males. Kidneys and heart were involved in 80% and 73% respectively, basal albumin of 20% and 67% and 13% for stage 1,2 & 3 respectively. Baseline immunofixation in serum or urine was positive in all patients (1923 of AL patients were lambda). Median time from start of first line therapy to DARA consolidation was 18.5 months (range 1–42 months). The best response post DARA consolidation was CR in 37.5%, VGPR in 30.8% and PR in 9.2%. The response rate was 77.3% and complete response rate was 37.5%.