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Comparative Baseline Health-Related Quality of Life in Real-Life Patients with Monoclonal Gammopathies

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Introduction

Monoclonal gammopathies (MG) are a heterogeneous group of diseases ranging from asymptomatic patients to those with severe clinical deterioration.

Health-related quality of life (HRQoL) is increasingly used as a secondary end-point in clinical trials, in particular, in multiple myeloma (MM)-related studies. However, several issues preclude a generalized use. First, the evidence available is still scarce; furthermore, some weaknesses and inconsistencies in analysis and presentation are observed [1]. Second, standardization for data collection, analysis and reporting is lacking. Third, an internationally validated questionnaire should be used.

The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQC30) [2] is a 30-item self-administrated questionnaire, with one-week recall period, including five functional scales (physical, role, emotional, social, and cognitive functioning), three symptom scales (fatigue, nausea/vomiting and pain) and a global health status/ quality of life scale. This is one of the most widely used patient-reported outcome measures in oncology clinical trials and practice. In recent years, the QLQ-C30 has demonstrated reliability and validity in MM patients. Its internal reliability has been recently pointed out [3] for most domains with the exception of cognitive functioning. The QLQ-C30 is considered a reliable instrument and may therefore be used to aid decision-making processes in clinical trials and in clinical practice.

To the present, most HRQoL studies in MG have been developed in the context of MM clinical trials. Therefore, little is known about HRQoL in MM real-life patients outside clinical trials or in the setting of other MG. The aim of this study is to report on the baseline value of the QLQ-C30 in a series of MG real-life patients, including the full range of MG, allowing for comparison between groups.

Patients and Methods

All unselected consecutive patients diagnosed with MG in our Monoclonal Gammopathies Unit and included in the Granada population-based registry from January 2013 to October 2015 were the basis of the study. Patients were diagnosed according with the International Myeloma Working Group (IMWG) criteria [4,5]. A copy of the QLQ-C30 was given to each patient, at the moment of diagnosis, usually after a bone marrow aspiration or biopsy was performed. The questionnaire was self-administrated at home and the results were presented at the next visit. A complementary database was created to record prospectively these results. Common baseline prognostic factors and comorbidities were recorded as previously reported [6]. This preliminary study focus on the global health status/ quality of life scale, ranging from 0 (the worst) to 7 (the best) (items Q29 and Q30 of the questionnaire, respectively).

Comparisons for categorical variables among different groups were made with the $\chi 2$-test, whereas comparisons of means of quantitative continuous variables between two groups were made with the t-test. All p-values were two-sided. Data were analyzed with SPSS v20 software.

Results

155 patients were recruited in the period of study: 69 symptomatic MM, 67 monoclonal gammopathy of undetermined significance (MGUS), 5 symptomatic Waldenström macroglobulinemia (WM), 5 patients without MG but with other diseases: control (CTL) group, 4 MM smoldering (MMS), 3 WM smoldering (WMS), and 2 amyloidosis, one light chain (AL) amyloidosis (AAL) and one reactive amyloidosis (AAA).

Median age was 66 years (42-88) for MM, 80.5 (56-86) for MMS, 66 (55-81) for WM, 75 (52-84) for WMS, 71 (39-86) for MGUS, and 69 (53-90) for CTL (Figure 1). There were 35 men (50.7%) in MM, 2 (50%) in MMS, 4 (80%) in WM, 2 (66.7%) in WMS, 38 (56.7%) in MGUS, and 2 (40%) in CTL.

Mean global health status (Q29) for CTL group was 3.6; 95% confidence interval, 2.18-5.02. Mean quality of life scale (Q30) for the CTL group was exactly the same. Q29 was 3.64 versus (vs) 3.07 for MGUS and MM (including MMS), respectively (p=0.029). Q30 was 3.72 vs 3.12 (p=0.030) for MGUS and MM. We did not find statistically significant differences between MM and MMS for Q29 and Q30: 3.06 vs 3.25 (p=0.801) and 3.12 vs 3.25 (p=0.863), respectively, and the same happens for WM and WMS: 4.40 vs 4.67 (p=0.785) and 3.80 vs 5.33 (p=0.288), respectively. The results for the other groups of patients are shown in Figures 2 and 3.

In relation to the number of comorbidities, 30.3% of patients with MM had ≥3 comorbidities vs 100% of patients with MMS (p=0.034), while WM and WMS had 70% and 75% respectively (p=0.852).

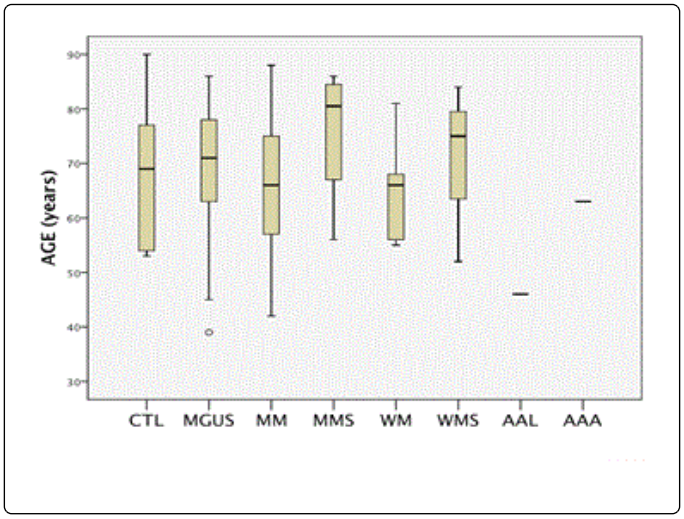

Figure 1: Comparative median age among group.

Abbreviations: CTL: Control Group; MGUS: Monoclonal Gammopathy of Undetermined Significance; MM: Multiple Myeloma; MMS: MM Smoldering; WM: Waldenström Macroglobulinemia; WMS: WM Smoldering; AAL: Light Chain Amyloidosis; AAA: Reactive Amyloidosis.

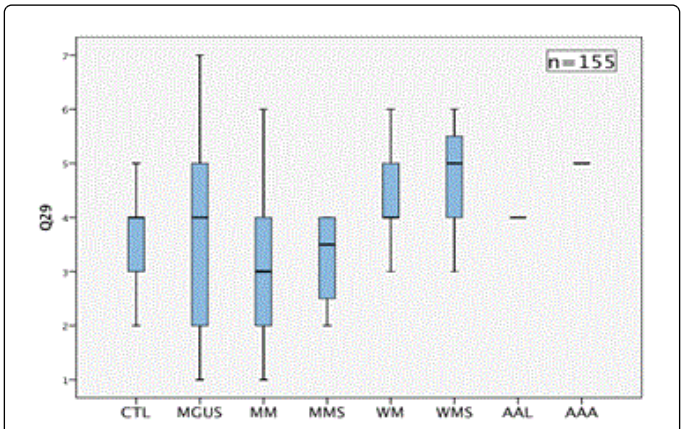

Figure 2: Comparative global health status.

In MM, when we manage Q29 and Q30 as categorical variables (Q29c and Q30c), the results are as follow. For Q29c, 42 patients (60.9%) had Q29 low values (1-3) vs 27 patients with high values (4-7). 18 of these 42 patients were younger than 65 years and 24 (57.1%) were 65 or older (p=0.222). 23 (85.2%) out of 27 patients with high values (4-7) had less than three comorbidities (p=0.010), and 26 (96.3%) out of 27 patients had less than four comorbidities (p=0.001).

For Q30c, 43 patients (62,3%) had Q30 low values (1-3) vs 26 patients with high values (4-7). 19 of these 43 patients were younger than 65 years and 24 (55.8%) were 65 or older (p=0.277). However, taking into consideration the number of comorbidities, 24 (92.3%) out of 26 patients with Q30 high values (4-7) had less than four comorbidities vs only 2 patients with ≥4 (p=0.019).

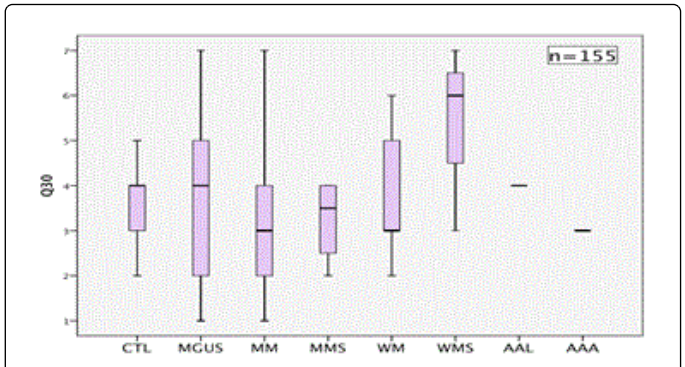

Figure 3: Comparative quality of life scale.

Discussion

A growing body of evidence supports the use of HRQoL in all hematological malignancies [7] and in particular, in MG. This clinical tool should be used as a standard approach in both clinical trials and daily clinical practice. QLQ-C30 is a validated questionnaire to assess HRQoL in MG patients. To the best of our knowledge, this is the first study to appraise baseline HRQoL using QLQ-C30 in a series of real-life MG patients including the full range of these diseases. The use of baseline assessment avoid the effect of treatment-related adverse events as determinant of HRQoL, since even side effects of analgesia may result in a statistically and clinically significant reduction of self-reported HRQoL [8]. A recent study [9] did not found major differences in HRQoL between younger and older MM patients but interestingly, the number of comorbidities was associated with HRQoL. Our data support these findings.

As expected, MM shows the worst global health status/ quality of life scale results among all gammapathies. Patients with MMS presented slightly better results than MM, but they not reach statistical significance; this may be due to the higher median age and higher number of comorbidities in the MMS group. With respect to WM and WMS, we also found a higher median age in the WMS group without difference in the number of comorbidities. The group of MGUS is very heterogeneous, showing values in both Q29 and Q30 covering the full scale, but having median values identical to the CTL group. The number of patients in the amyloidosis group does not allow comparisons.

In short, we suggest that HRQoL can be easily evaluated with the QLQ-C30 at the moment of diagnosis in every patient with MG. MM shows the worst values for the global health status/ quality of life scale. Patients with MMS and WMS have a trend to better results than their respective symptomatic group. MGUS is a very heterogeneous group showing similar values to the CTL group. Nowadays, HRQoL is a well-established end-point in recent clinical trials [10]. Our challenge is to apply this tool in everyday clinical practice as a standardized approach.

References

1. Sonneveld P, Verelst SG, Lewis P, Gray-Schopfer V, Hutchings A, et al. (2013) Review of health-related quality of life data in multiple myeloma patients treated with novel agents. Leukemia 27: 1959-1969.

2. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, et al. (1993) The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 85: 365-376.
3. Smith AB, Cocks K, Taylor M, Parry D (2014) Most domains of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 are reliable. J Clin Epidemiol 67: 952-957.
4. International Myeloma Working Group (2003) Criteria for the classification of monoclonal gammopathies, multiple myeloma and related disorders: a report of the International Myeloma Working Group. Br J Haematol 121: 749-757.
5. Rajkumar SV, Dimopoulos MA, Palumbo A, Bladé J, Merlini G, et al. (2014). International Myeloma Working Group updated criteria for the diagnosis of multiple myeloma. Lancet Oncol 15: e538-548.
6. Ríos-Tamayo R, Sánchez MJ, Puerta JM, Sáinz J, Chang DYL, et al. (2015) Trends in survival of multiple myeloma: A thirty-year population-based study in a single institution. Cancer Epidemiol 39: 693-699.
7. Allart-Vorelli P, Porro B, baguet F, Michel A, Cousson-Gelie F (2015) Haematological cancer and quality of life: a systematic literature review. Blood Cancer J 5: e305.
8. Sloot S, Boland J, Snowden JA, Ezaydi Y, Foster A, et al. (2015) Side effects of analgesia may significantly reduce quality of life in symptomatic multiple myeloma: a cross-sectional prevalence study. Support Care Cancer 23: 671-678.
9. Van der Poel MWM, Oerlemans S, Schouten HC, van de Poll-Franse LV (2015) Elderly multiple myeloma patients experience less deterioration in health-related quality of life than younger patients compared to a normative population: a study from the population-based PROFILES registry. Ann Hematol 94: 651-661.
10. Delforge M, Minuk L, Eisenmann JC, Arnulf B, Canepa L, et al. (2015) Health-related quality of life in patients with newly diagnosed multiple myeloma in the FIRST trial: lenalidomide plus low-dose dexamethasone versus melphalan, prednisone, thalidomide. Haematologica 100: 826-833.