Impact of Ibrutinib in Quality of Life (QoL) in Patients with Chronic Lymphocytic Leukemia (CLL): Preliminary Results of Real World Experience

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Abstract

Context: Controlled trials report improvements in QoL in CLL patients treated with ibrutinib monotherapy. Confirmatory real-life evidence is necessary. **Objective:** evaluate impact of ibrutinib treatment in QoL. **Interventions:** FACIT-fatigue and EQ5D visual-analogue-scale (VAS) performed at baseline and every 3 months for 1 year. This abstract shows data after 3 months. **Results:** a change in FACIT score ≥ 3 points was reached in 13 patients (62%) as compared to baseline ($p=0.024$). The improvement in EQ5D VAS and hemoglobin levels was not meaningful at 3 months. **Conclusion:** We suggest an early improvement of fatigue within the first 3 months of treatment with ibrutinib.

Background

The impact of fatigue on the QoL of oncology patients is substantial and under-recognized. Fatigue in these patients may begin with a simple decrease in physical activity, but can progress to include a wide range of negative effects that often culminate in patients feeling out of control, lonely and isolated¹.

Context: Clinical data from controlled trials report an improvement in QoL in patients with CLL with ibrutinib monotherapy². Real-life evidence is necessary to confirm this data.

Design: This is a prospective, longitudinal, single arm study enrolling consecutive CLL patients under ibrutinib monotherapy either as first or further line of treatment. Median follow-up was 7 months (range 1-28). The last QOL evaluation is planned to be after 12 months of treatment for all the cohort. Here, we are showing the results after the first 3 months.

Setting: Patients are recruited in an academic referral center in Buenos Aires.

Objective

The disease control when treatment is initiated could lead to decreased fatigue. It is likely that treatment with ibrutinib could result in an improvement in QoL in our real-world population.

Primary Objective: to evaluate impact of ibrutinib treatment in QoL.

Primary endpoint: detect a clinically meaningful improvement defined as rise of ≥ 3 points in FACIT-fatigue score compared to baseline.

Secondary Endpoints:

Detect a 10% improvement by EQ5D VAS. Correlate baseline and follow-up hemoglobin levels (meaningful improvement ≥ 1 g/dl).

Materials & Methods

Interventions: QoL was explored with FACIT-fatigue and EQ5D-VAS questionnaires (with copyright permission). Assessment by results reported by patient questionnaires were completed on months 0, 1, 3, 6 and 12 since the beginning of treatment.

Patients reported their QoL outcomes for fatigue, mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

Main outcomes measures: We are reporting preliminary results after 3 months of treatment compared to baseline.

Statistical analysis: data was analyzed with the Sign Test (Binomial Test).

Study Follow-Up Chart

	Baseline	Mo 1	Mo 3	Mo 6	Mo 12
Basal characteristics	X				
Ibrutinib Dose	X				
Blood count	X	X	X	X	X
Response Evaluation			X	X	X
QOL	X	X	X	X	X
Survival Status			X	X	X

Results

A total of 21 CLL patients who started ibrutinib between 2016 and 2018 were included. Median age was 75 years (range 57-84); 12 patients (57%) were males. Ibrutinib was first-line therapy in 7 patients (33%), second-line in 7 patients (33%) and 7 patients (33%) received ≥ 3 previous lines.

After 3 months of treatment, the median change in FACIT-fatigue score ≥ 3 points was reached in 13 patients (62%) as compared to baseline ($p=0.024$). After 3 months of treatment there was no evidence of a median change $>10\%$ on the EQ5D VAS ($p=0.593$) nor a significant improvement on hemoglobin level ($p=0.105$).

Summary

Discussion

These results suggest an early improvement of fatigue within the first 3 months of treatment with ibrutinib. Longer follow-up and larger number of patients are necessary to confirm this data and determine the further improvements of QoL with continuous treatment and correlation with hemoglobin changes.

References

1. Fatigue and quality of life: lessons from the real world. *Oncologist*. 2003
2. Sustained Efficacy And Detailed Clinical Follow-Up Of First-Line Ibrutinib Treatment In Older Patients With Chronic Lymphocytic Leukemia: Extended Phase 3 Results From RESONATE-2. *Haematologica* 2018

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