CLL – Patient registry (Bendamustine original vs. generics)

H. Linde[1], K. Blumenstengel[2], T. Göhler[3], C. Spohn[4], R. Göttel[5], MO. Zahn[6], Project team of Internal Oncology (PIO)

[1]Specialized oncology practice Potsdam, [2]Specialized oncology practice Eisenach, [3]Specialized oncology practice Dresden, [4]Specialized oncology practice Halle, [5]rgb Onkologisches Management GmbH Sarstedt, [6]Specialized oncology practice Goslar

Introduction

Since 2008, 61 hemato-oncological practices cooperating in the project team of internal oncology (PIO) have been documenting nationwide disease histories of patients with a CLL in the registry ONCOReg.

Methods

This analysis presents the results of the application of bendamustine in the first-line therapy of CLL patients in the clinical routine. Are the data of the generics comparable to those of the original?

Results

The data of 656 patients can be analysed. 97 received bendamustine, 33 BP, 337 BR, 187 BRP, 1 BD, 1 BO. The original was applied in 608 patients, a generic in 48.

Patients' characteristics (original/generics):
Gender: 62.0%/64.6% m; 38.0%/35.4% f
Age: 72/73 years
ECOG: 1/1
No symptoms before start of therapy: 63.0%/72.9%
Period from initial diagnosis to first therapy: 24.9/42.5 months

Therapy:

Both groups received 6 cycles and a median overall dose of bendamustine of 840 mg/m². The objective response is 88.3% (original) and 89.6% (generics).

Adverse events:

Grade 3/4 hem.	Original	Generics
Leukopenia	21.4%	43.7%
Neutropenia	21.4%	43.8%
Anemia	5.2%	31.3%
Thrombocytopenia	5.8%	14.6%

Grade 1-4 non-hem. >20%	Original	Generics
Nausea	38.2%	29.2%
Fatigue	29.1%	33.3%
Infection	27.5%	35.4%
Fever	23.7%	22.9%
Pain	22.5%	29.2%
Skin	19.6%	20.8%
Serum creatinine	15.0%	27.1%

Conclusion

The administered dose and the objective response are the same in both groups, but adverse events are more pronounced in patients treated with a generic. Further data will be presented.