

INDIRECT TREATMENT COMPARISONS OF IBRUTINIB-OBINOTUZUMAB VERSUS VENETOCLAX-OBINOTUZUMAB IN NAIVE CHRONIC LYMPHOCYTIC LEUKAEMIA

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Backround

Venetoclax and Ibrutinib are drugs of recent appearance and are currently election treatments according to the guidelines in patients diagnosed with high risk chronic lymphocytic leukaemia (CLL).

Aim and objectives

To conduct an indirect comparison of the efficacy of Venetoclax (12-cycles)+Obinotuzumab(6-cycles) compared with Ibrutinib(until progression)+Obinotuzumab(6-cycles) and its costs.

Material y methods

The clinical trials CLL14 and ILUMINATE were reviewed, the main outcome and the similarity of the population (median age, percentage of high-risk patients according to Binet or Rai classification and percentage of patients with high risk cytogenetics) were evaluated.

An indirect comparison of the median of progression free survival (PFS), PFS at 24-months, minimal residual disease (MRD) in peripheral blood, overall survival (OS) and complete response was conducted.

Results

trials CLL14 The clinical ILUMINATE were reviewed, the main outcome and the similarity of the population (median percentage of high-risk patients to according Binet Rai or classification and percentage of risk high patients with cytogenetics) were evaluated.

An indirect comparison of the median of progression free survival (PFS), PFS at 24-months, minimal residual disease (MRD) in peripheral blood, overall survival (OS) and complete response was conducted.

Lastly, the cost of both 12 and 24 months of treatment were compared.

	CLL14	ILUMINAIE
Nº patients	432 (1:1)	229 (1:1)
Age (median)	72	70
High risk (Binet/Rai)	43%	52%
% patientwith del p17	8%	14%
% patient tp53	9,5%	15,5%
Unmutaded IGHV	60%	75,7%
INDIRECT COMPARISION		
PFS	HR 0,66 (95%CI 0,36 a 1,22 p=0,18) favor to Ibrutinib	
PFS at 24 months	RR 0,64 (95%CI 0,32 a 1,08 p=0,09) favor to Ibrutinib	
MRD peripheal blood	RR 1,41 (95%CI 0,85 a 2,32 p=0,18) favor to Venetoclax	
CR	RR 0,85 (95%CI 0,39 a 1,86 p=0,69) favor to Venetoclax	
COST		
	Venetoclax+Obinotuzumab	Ibrutinib+Obinotuzumab
12 months	76.374€	76.786€
24 months	76.374€	127.891€

Conclusion

- 1. Although in advance, populations could be comparable, limitations like time of treatment with clorambucil exist (6months vs. 12months).
- 2. No statistically significant differences were found between:
- Median PFS and 24-months PFS
 - ☐ Beauchemin et al conclude that **correlation between PFS and OS exist** in patients previously treated, **but not in naïve patients.** Beauchemin et al DOI: 10.1182/blood-2018-03-839688
- MDR and CR
 - □ Langerat et al conclude "MRD status is associated with PFS and OS in CLL patients, and has the potential to act as a surrogate marker" Langerat et al DOI: 10.3747/co.22.2119.
- 3. Ibrutinib cost is superior after the first year of treatment.
- 4. To conclude, it is necessary to obtain OS data to conduct and indirect comparison of greater quality.