BINOCRIT®
epoetină alfa

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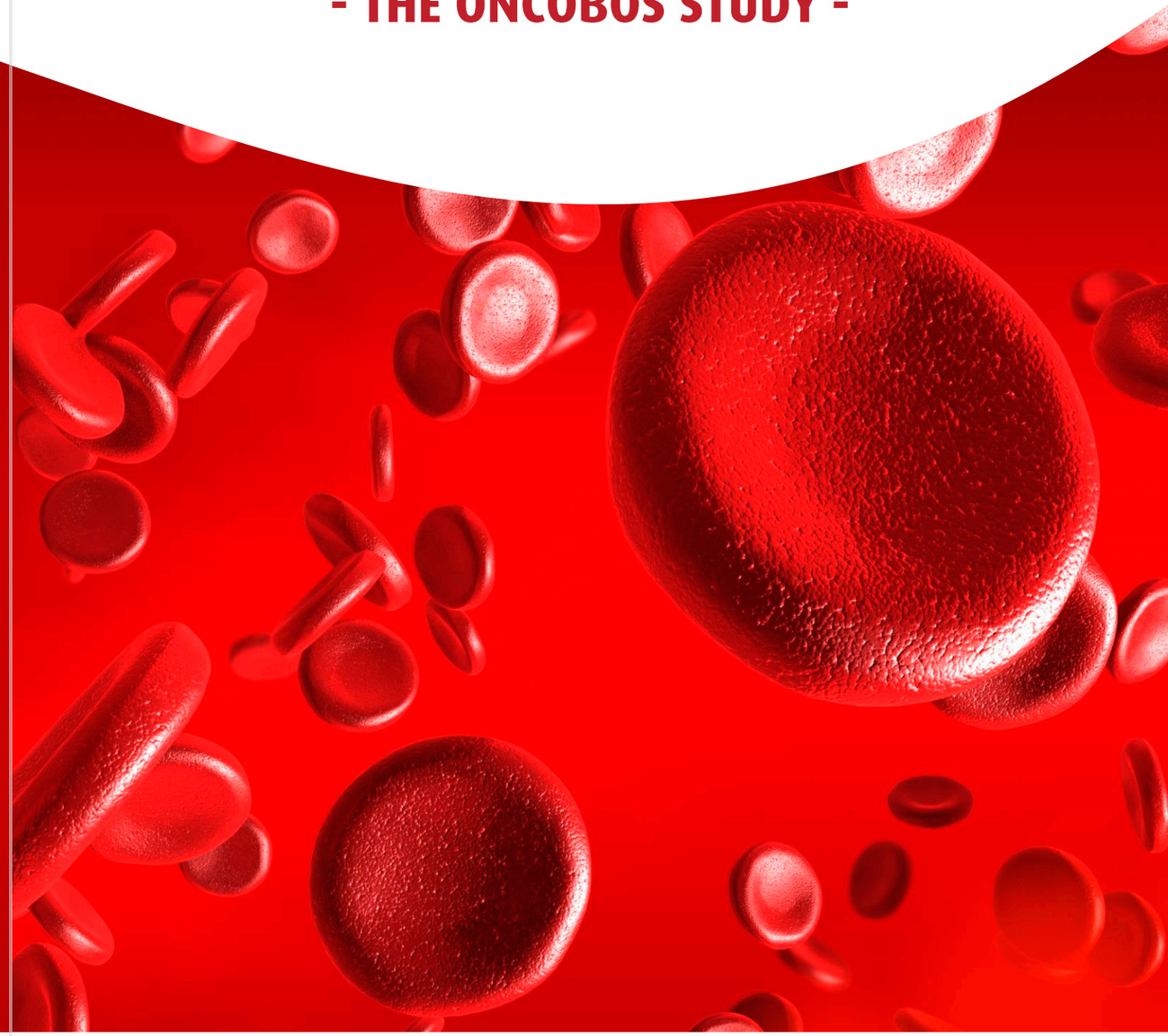
OVERVIEW

OF ROMANIAN ROUTINE CLINICAL PRACTICE FOR THE MANAGEMENT OF CHEMOTHERAPY-INDUCED ANEMIA (CIA) IN ONCO-HEMATOLOGICAL PATIENTS TREATED WITH BINOCRIT®

- THE ONCOBOS STUDY -



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OVERVIEW OF ROMANIAN ROUTINE CLINICAL PRACTICE FOR THE MANAGEMENT OF CHEMOTHERAPY-INDUCED ANEMIA (CIA) IN ONCO-HEMATOLOGICAL PATIENTS TREATED WITH BINOCRIT® - THE ONCOBOS STUDY -

INTRODUCTION

- The European Cancer Anaemia Survey (ECAS) highlighted the high incidence of anemia among patients with cancer in Europe [1]: anemia was present in about 63 % of the patients under chemotherapy treatment (CT), due to the cytotoxic effect of chemotherapy on erythroid precursors in bone marrow [1].
- Whatever its severity, CIA has a major impact on the quality of life (QoL) of the patients, especially on physical and social activities. CIA is largely responsible for fatigue, felt by a great majority of the patients, and can require red blood cell transfusions [1,2].
- Use of erythropoiesis-stimulating agents in congruence with European Organisation for Research and Treatment of Cancer (EORTC) guidelines leads to improved results in terms of Hemoglobin (Hb) outcomes[3]. Epoetins have been shown to be effective in correcting anemia, in improving QoL, and in reducing the need for red blood cell transfusions.
- BINOCRIT® (biosimilar epoetin alfa, Sandoz), was the 1st biosimilar recombinant human erythropoietin to be granted marketing authorization in Europe (4). It has been approved for the treatment of CIA since 2007 and is currently licensed in 30 countries worldwide (excluding the USA).
- In accordance with the European label (4), BINOCRIT® treatment should be administered subcutaneously to patients with anemia (Hb ≤ 10 g/dL). Hb variability should be addressed through dose management, with consideration for the Hb target range of 10–12 g/dL, and a sustained Hb level of greater than 12 g/dL should be a voided.

METHODS

- The OnCoBOS study is a national, prospective, non-interventional, multicentre, observational study conducted in Romania to describe modalities of treatment with BINOCRIT® in routine clinical practice setting, for the correction of Hb levels in 770 patients with CIA receiving CT for solid tumors (ST), lymphoma or myeloma.
- The OnCoBOS study describes the patient characteristics and the outcomes in the 770 Romanian patients treated with BINOCRIT®, between November 2011 and June 2014.
- Patients aged ≥ 18 years with tumors (ST), lymphoma or myeloma,CIA secondary to ST, lymphoma or myeloma and eligible for treatment with BINOCRIT® (and whose clinicians had freely decided to prescribe biosimilar epoetin alfa for the treatment of CIA prior to the study) were included in study.
- This analysis reports patients characteristics along with anemia-related data such as Hb outcomes, biosimilar epoetin alfa treatment characteristics and concomitant treatments received, at initiation of treatment (W0), 3–4 weeks (W3-4), 12 (± 1) weeks (W12) and a follow-up visit (W16).
- Assessed Hb outcomes included the proportion of patients achieving Hb increases of ≥ 1.0 g/dL and ≥ 2.0 g/dL, and mean Hb change from baseline.

RESULTS

- Patient demographics and baseline characteristics are shown in Table 1. Type of malignant tumors and chemotherapy treatment characteristics are reported in Table 2.
- The mean ± SD age was 60.6 ± 10.9 years, and 47.5% of patients were male.
- 85.2% of patients had ST and 14.8% of patients had malignant hemopathy.

Table 1. Patient demographics and baseline characteristics

		n=770
Gender	**Male**, n (%)	366 (46.5)
	Female, n (%)	404 (52.1)
	n	Mean ± SD
Age (years)	770	60.6 ± 10.9
Karnofsky index (%)	757	83.0 ± 10.4

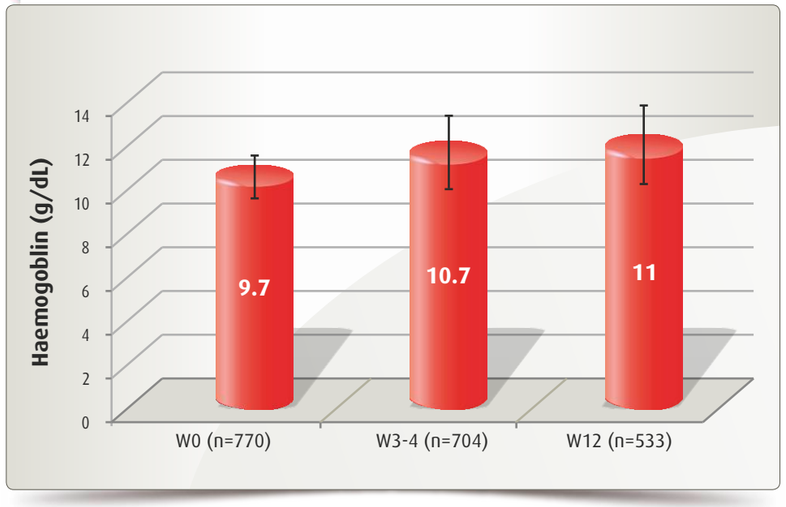
Table 2. Type of malignant tumors and chemotherapy treatment characteristics

Solid tumors, n (%)	**656 (85.2)**
Site of solid tumours, n (%)	
Lung	151 (23.0)
Colorectal	93 (14.2)
Breast	74 (11.3)
Pancreas	70 (10.7)
Head and neck	56 (8.5)
Gastric	50 (7.6)
Cervical	38 (5.8)
Pancreatic	23 (3.5)
Bladder	17 (2.6)
Prostate	16 (2.4)
Other	69 (10.4)
Previous radiotherapy	**649**
Yes	167 (25.7)
Previous chemotherapy	**650**
Yes	384 (59.1)

Malignant hemopathy n (%)	**114 (14.8%)**
Type of malignant hemopathy n (%)	
Non-Hodgkin lymphoma	55 (48.2%)
Multiple myeloma	43 (37.7%)
Hodgkin disease	13 (11.4%)
Other	3 (2.6%)
Previous radiotherapy	**n = 104**
Yes	8 (7.0%)
Previous chemotherapy	**112**
Yes	68 (60.7%)

Type of Chemotherapy	**690**
Adjuvant	258 (37.4%)
Neo-Adjuvant	53 (7.7%)
Metastatic	377 (54.6%)
Number of cycles already performed before study treatment start	748
Mean ± SD	3.0 ± 2.7

Figure 1. Mean Hb levels over time



- Mean baseline Hb was 9.7 (SD 0.9) g/dL, which increased at 10.7 (SD 1.6) g/dL and 11.0 (SD 1.7) g/dL a fter 1 and 3 months, respectively (Figure 1).
- Patients received a mean biosimilar epoetin alfa dose of 37911.0 (SD 4072.2) UI onceweekly. Patients received a median dose of 40,000 UI/week.
- Oral and intravenous (IV) iron supplementation rate were low. 3.2% and 5.1% of patients concomitantly receive oral iron over the 3-4 first weeks, and over the next 2 month, respectively and 2.1% and 1.5% of patients concomitantly receives IV iron.
- Moreover, 3.7% and 5,3% of patients received red blood cells transfusion over the 3-4 first weeks, and over the next 2 months, respectively.
- Clinicians considered QoL (n=617; 80.1%), decrease of number of transfusions (n = 559, 72.6%) and fight against tiredness (n = 443, 57.5%) as predominant factors in the rationale for anemia management and treatment (Figure 3).
- Over the treatment period, 3 treatment-related adverse reactions were recorded (Table 4). Out of these, 1 was classified as a serious adverse drug reaction (0.13% of the total analyzed population).

Figure 2. Evolution of Hb levels

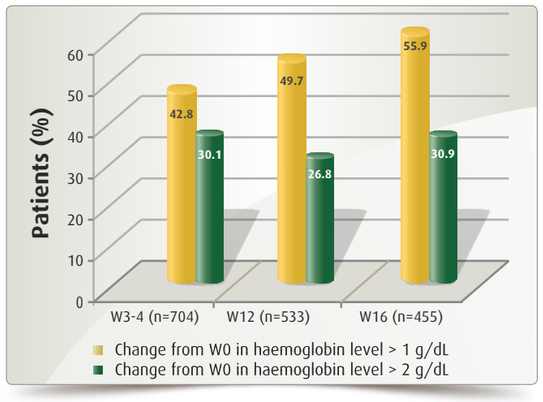


Figure 3. Major factors influencing prescription of treatment for CIA

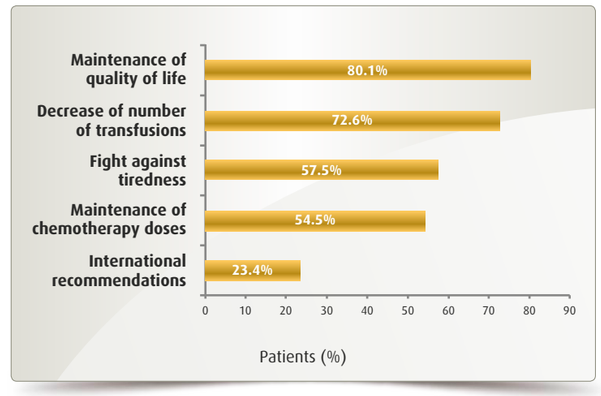


Table 4. Summary of adverse events

Type of AEs	Patients, n (%)	Events
Adverse events (AEs)	50 (6.5%)	54
Adverse drug reactions (ADRs)	3 (0.4%)	3
Serious adverse drug reactions (SADRs)	1 (0.13)	1

CONCLUSIONS

- This study indicates that in real-life clinical conditions BINOCRIT® (epoetin alpha) increases effectively hemoglobin levels, with a very low rate of adverse drugs reactions, in anemic patients with onco-hematological tumors, whatever chemotherapy treatment received.
- The effect of treatment with BINOCRIT® is rapid, with meanhemoglobin increase of 1.00 (SD ± 1.5) g/dL in 3 or 4 weeks following the start of therapy.
- Maintenance of QoL, decrease the number of transfusions and the effect against tiredness are the first thee major factors for BINOCRIT® prescription in Romania.

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