

Epoetin Alfa vs Best Standard Care in NSCLC Patients

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**for the INT - 49 Study
Group**



VIIENNA

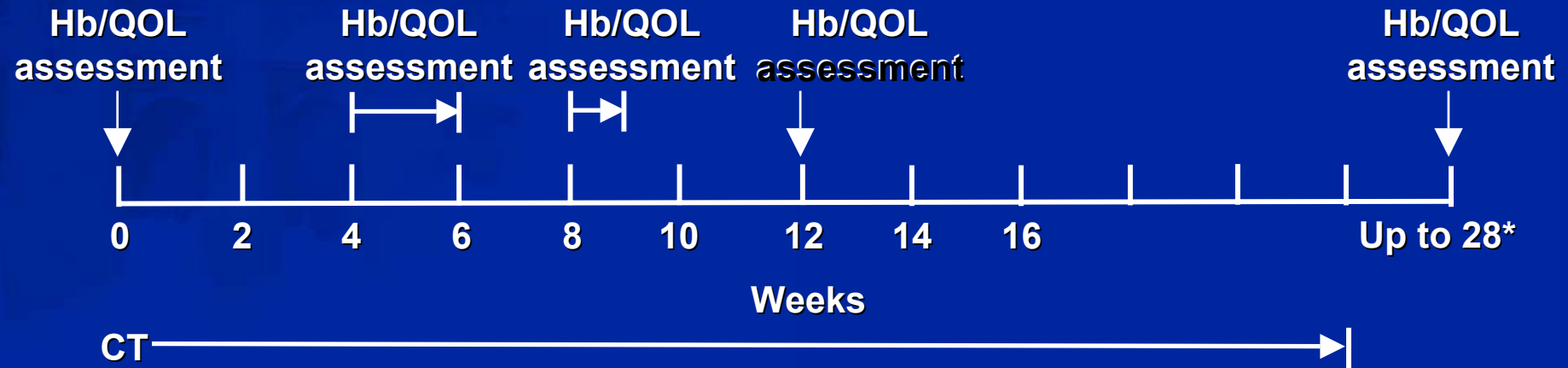
Early Intervention With Epoetin Alfa in NSCLC Patients

- Multicenter, international, randomized trial in 425 chemotherapy (CT)-naive non-small cell lung cancer (NSCLC) patients
 - Stage IIIB/IV
 - Scheduled to receive platinum-based CT
 - Hemoglobin (Hb) ≤ 15 g/dL for males and ≤ 14 g/dL for females
- Patients randomized 1:1 to receive
 - Epoetin alfa 10,000 IU subcutaneously (sc) three times weekly (tiw) when Hb ≤ 13 g/dL for males and ≤ 12 g/dL for females
 - OR best standard care (BSC)

Study Endpoints

- Hb change from baseline
- Number of patients transfused
- Quality of life (QOL): change from baseline
- Survival at 6 and 12 months post chemotherapy

Treatment Schema



Immediate treatment ■	Delayed treatment ■
Male: baseline Hb \leq 13 g/dL	Male: baseline Hb: >13-15 g/dL; trigger Hb: \leq 13 g/dL
Female: baseline Hb \leq 12 g/dL	Female: baseline Hb: >12-14 g/dL; trigger Hb: \leq 12 g/dL

*Study drug continued until 4 weeks after the last CT cycle

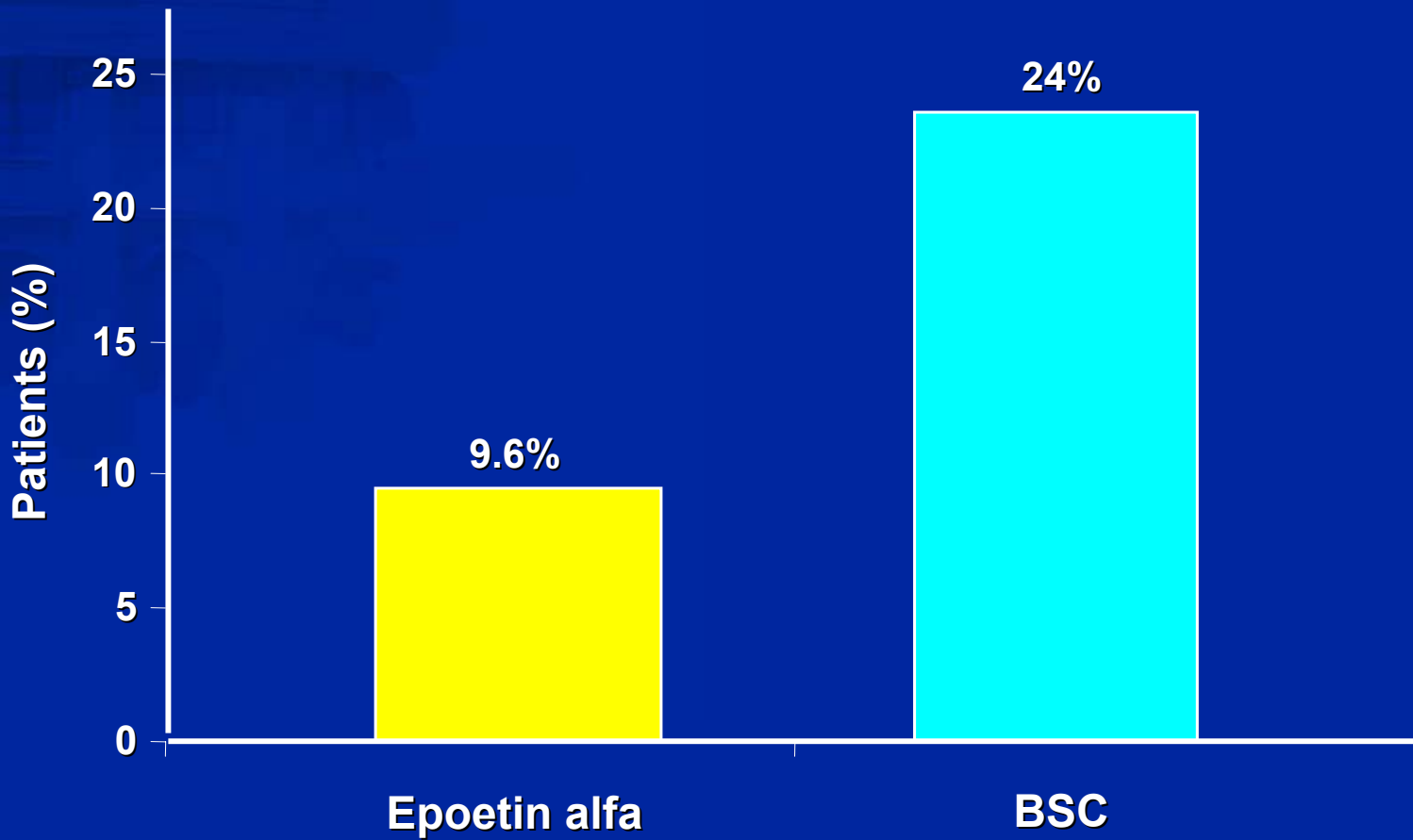
Baseline Demographic and Clinical Characteristics ($n = 380$)

- Characteristics comparable between epoetin alfa and BSC groups
- Stage
 - 41% stage IIIb
 - 59% stage IV
- Mean baseline Hb: 12.7 g/dL

Summary: Hematologic Effects of Epoetin Alfa vs. BSC in NSCLC Patients

- Immediate epoetin alfa treatment maintains Hb levels during chemotherapy
- Delayed epoetin alfa treatment with patients with higher Hb baseline values results in falling Hb values for two or three chemotherapy cycles, followed by increase and stabilization
- Epoetin alfa treatment is able to maintain Hb between 12.5 g/dL and 12.8 g/dL for up to 28 weeks
- During chemotherapy, BSC patients experience an Hb decrease of
 - 2.6 g/dL (delayed group)
 - 0.7 g/dL (immediate group)

Patients Receiving at Least One Blood Transfusion



$p < .0001$

Discussion: QOL Effects of Epoetin Alfa Treatment in NSCLC Patients

- Immediate treatment with epoetin alfa reduces decline in QOL for patients during chemotherapy and at study end
- Delayed treatment with epoetin alfa fails to improve QOL (relative to BSC) for patients with higher initial Hb
 - Epoetin alfa treatment not initiated until after 1–3 cycles of platinum-based chemotherapy
 - Substantial decrease in Hb (over 1.0 g/dL)
 - Delayed intervention with epoetin alfa cannot protect against immediate myelosuppressive effects of platinum-based chemotherapy
- A 1 g/dL Hb decrease is clinically significant¹

Survival Results

- No significant difference between treatment groups (epoetin alfa vs. BSC) in overall survival throughout the study period or at 12-month follow-up
- A 20% improvement in overall survival was seen for patients with baseline Hb ≥ 13 g/dL (male) and ≥ 12 g/dL (female), compared with patients with lower baseline Hb
- Dominant influence of baseline Hb on survival may have confounded any influence of epoetin alfa treatment on survival

Conclusions

- **Epoetin alfa maintains Hb >12.5 g/dL (to 28 wks)**
 - 1.0–1.8 g/dL higher than with BSC
 - Consistent for immediate and delayed treatment
- **Epoetin alfa treatment reduces transfusion use by over 50%**
- **Immediate treatment with epoetin alfa can protect patients against decreased QOL**
 - During chemotherapy
 - After chemotherapy
- **Strong correlation between baseline Hb and overall survival**
- **Epoetin alfa was well tolerated**