Gemtuzumab Ozogamicin Plus Standard Chemotherapy Carries a Comparable Burden of Hospitalization Compared With Standard Chemotherapy Alone in Acute Myeloid Leukemia

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Objective

- Determine whether adding fractionated-dose GO (3 x 3 mg/m^2 in induction, 2 x 3 mg/m^2 in consolidation) to SC for frontline AML treatment alters the associated burden of hospitalization (number of hospital admissions and length-of-hospital-stay [LOS]).

Background

- Gemtuzumab ozogamicin (GO) in combination with standard chemotherapy (SC) is approved for the treatment of newly diagnosed CD33-positive acute myeloid leukemia (AML).
  - GO is a CD33-targeted monoclonal antibody covalently linked to calicheamicin.
- In the phase 3 ALFA-0701 trial,[1] patients with de novo AML who received GO + SC had improved outcomes compared with patients who received SC alone.
  - Longer event-free survival: hazard ratio (HR) 0.56; *P*=0.0002.
  - Longer relapse-free survival: HR 0.53; *P*=0.0006.
  - A trend towards longer overall survival: HR 0.81; *P*=0.16.
- However, the burden of hospitalization (ie, hospital admissions and LOS) for these patients has not previously been presented.
- Determining hospitalization burden is important because:
  - Such combination therapies may be perceived to increase hospital admissions or LOS.
  - Changes in hospitalization burden may impact healthcare resource utilization and treatment costs.

Methods

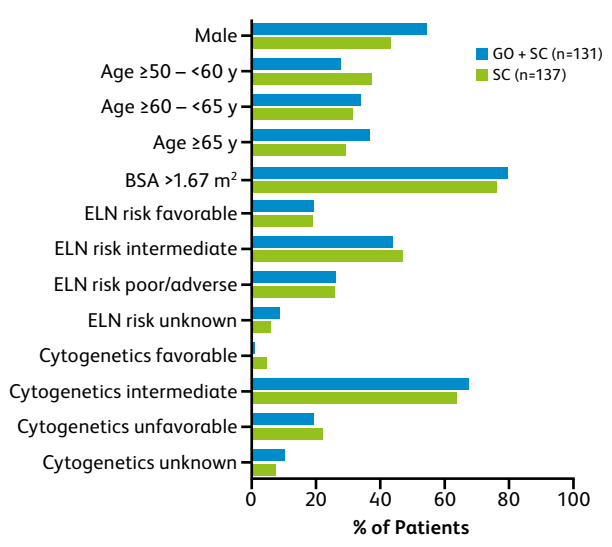
- The ALFA-0701 trial (NCT00927498) has been described previously.[2] Briefly:
  - Participants had treatment-naïve AML and were aged 50–70 years.
  - SC treatment in both treatment arms consisted of 3 + 7 daunorubicin + cytarabine.
  - In the GO + SC arm, patients received 3 mg/m^2 GO on Days 1, 4, and 7 during induction and on Day 1 of each of the 2 consolidation courses.
- All patients were hospitalized for treatment administration.
- We compared the number of hospital and intensive care unit (ICU) admissions (planned or unplanned) and LOS with GO + SC vs SC.
  - Results are presented for the as-treated population (GO + SC: n=131; SC alone: n=137, including 3 patients randomized to GO + SC but who received SC alone).
  - Data shown are for the safety reporting period (up to 28 days after the last dose of study treatment).

Results

PATIENT CHARACTERISTICS

- Baseline characteristics were similar between the GO + SC vs SC treatment arms (**Figure 1**).
  - For GO + SC vs SC, the mean age of patients was similar: mean ± standard deviation (SD), 62.2 ± 4.95 vs 60.8 ± 5.49.

Figure 1: Baseline Characteristics



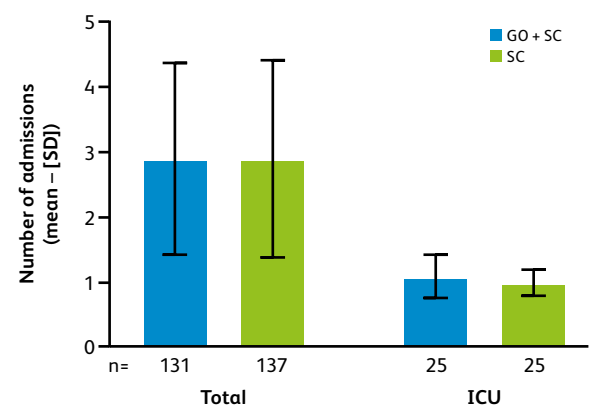
For BSA >1.67 m^2, GO was capped at 5 mg per dose. ELN risk groups were according to ELN criteria 2010. Cytogenetics were classified by the study sponsor, CHV.

BSA=body surface area; CHV=Centre Hospitalier de Versailles; ELN=European LeukemiaNet; GO=gemtuzumab ozogamicin; SC=standard chemotherapy

HOSPITALIZATIONS DURING THE STUDY

- The mean number of admissions to hospital and the intensive care unit (ICU) showed no significant differences between treatment arms (**Figure 2**). With GO + SC vs SC:
  - Median number of hospitalizations was identical: median (range) 3 (1–8) vs 3 (1–7).
  - Median number of ICU admissions was identical: median (range) 1 (1–2) vs 1 (1–2).

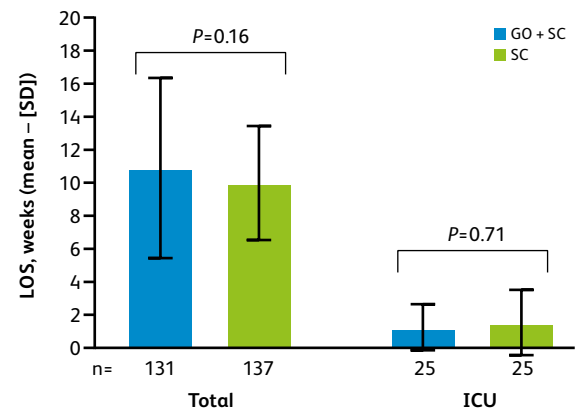
Figure 2: Hospitalizations During Study Treatment



GO=gemtuzumab ozogamicin; ICU=intensive care unit; SC=standard chemotherapy; SD=standard deviation

- There were no significant differences between treatment arms in the mean LOS in the hospital or the ICU (**Figure 3**). With GO + SC vs SC:
  - Median (range) LOS in hospital was 10.7 (1.4–59.1) vs 10.1 (0.4–21.9) weeks.
  - Median (range) LOS in the ICU was 0.7 (0.3–6.0) vs 0.6 (0.1–7.6) weeks.
- All patients were hospitalized for administration of treatment.
  - Other reasons for hospitalization are not available, as hospital admission data were not linked to cause during data collection.

Figure 3: Time in Hospital

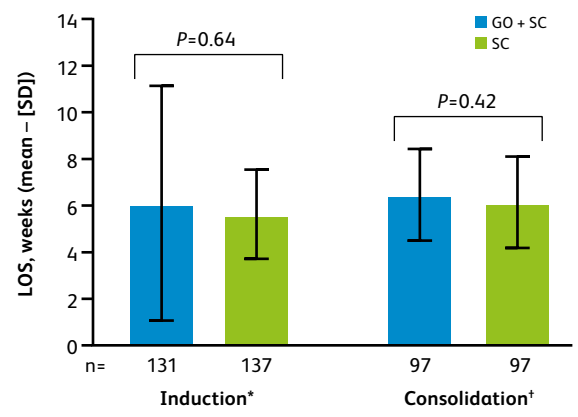


GO=gemtuzumab ozogamicin; ICU=intensive care unit; LOS=length of hospital stay; SC=standard chemotherapy; SD=standard deviation

HOSPITALIZATIONS BY TREATMENT PHASE

- Only patients who responded to induction therapy received consolidation therapy.
- For consolidation therapy, the sample size was identical between GO + SC vs SC (**Figure 4**).
- Whether patients received induction or consolidation therapy, there were no significant differences in mean LOS between GO + SC vs SC (**Figure 4**). With GO + SC vs SC:
  - Median (range) LOS was 5.1 (1.4–59.1) vs 5.0 (0.4–16.7) weeks for induction.
  - Median (range) LOS was 6.3 (2.7–12.4) vs 6.4 (1.4–14.7) weeks for consolidation.

Figure 4: Time in Hospital, by Treatment Phase



* Induction includes first and second induction/salvage therapy (if applicable).

† Consolidation includes both consolidation 1 and 2.

GO=gemtuzumab ozogamicin; LOS=length of hospital stay; SC=standard chemotherapy; SD=standard deviation

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1. Lambert J, et al. Haematologica 2019;104:113-9.
2. Castaigne S, et al. Lancet 2012;379:1508-16.

Disclosures: SS, TARS, VLW, PD, and RJB are employees of and own stock in Pfizer.

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