

Bendamustine in Combination with Gemcitabine and Vinorelbine (BEGEV) is an Effective Regimen for Heavily Pretreated Relapsed or Refractory Hodgkin Lymphoma Patients: A Retrospective Study

A. Russo^{1,7}, A. Pulsoni², S. Viviani³, F. Ricci¹, R. Mazza¹, M. Magagnoli¹, L. Morello¹, F. Landi³, A. Guidetti³, M. Merli⁴, M. Rodari⁵, A. Serrao², G. Annechini², B. A. Nervini², L. Giordano⁶, L. Castagna¹, F. Passamonti⁴, A. Chiti^{5,7}, P. Corradini³, A. Santoro^{1,7}, C. Carlo-Stella^{1,7}

¹ Oncology and Hematology, Humanitas Cancer Center, Humanitas Research Hospital, Milano, Italy ² Department of Cellular Biotechnology and Hematology, La Sapienza University, Rome, Italy ³ Division of Hematology and BMT Unit, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano, Italy ⁴ Department of Hematology, University of Insubria, Varese, Italy ⁵ Nuclear Medicine, Humanitas Research Hospital, Milano, Italy ⁶ Biostatistics Unit, Humanitas Research Hospital, Milano, Italy ⁷ Department of Biomedical Sciences, Humanitas University, Milano, Italy



Introduction

- With many new therapies available, there is no consensus on how Hodgkin Lymphoma should be treated beyond second line
- BEGEV regimen has been proved a highly effective second line treatment for patients with relapsing/remitting Hodgkin Lymphoma as reported in a previous phase 2 study¹
- We wanted to investigate if BEGEV could also be used on highly-treated patients far beyond second line treatment or patients on which immunotherapy or autologous stem cell transplantation (auto-SCT) had proved ineffective.
- We report a retrospective analysis of efficacy of the BEGEV regimen administered as second- or subsequent-line therapy to relapsed and refractory classical Hodgkin Lymphoma patients

Patients & Methods

- HL patients analyzed underwent BEGEV regimen (4 cycles every 3 weeks) from January 2013 to March 2018 in 4 different Italian hospitals. Patients characteristics are summarized in **Table 1**.
- Patients that underwent BEGEV beyond second line had previously received a median of 3 (range, 2-8) lines of therapy prior to BEGEV, including Brentuximab Vedotin (83%) and auto-SCT (43%).

Table 1. Patients characteristics

| | All Patients | 2nd line | beyond 2nd line |
|------------------------------|--------------|----------|-----------------|
| Patients number | 73 | 50 | 23 |
| Sex | | | |
| Male | 37 | 24 | 13 |
| Female | 36 | 26 | 10 |
| Age, years | | | |
| Median | 34 | 33 | 34 |
| Range | 19 - 71 | 19 - 70 | 23 - 71 |
| Response to 1st line therapy | | | |
| Chemorefractory | 46 | 28 | 18 |
| Chemosensitive | 27 | 22 | 5 |

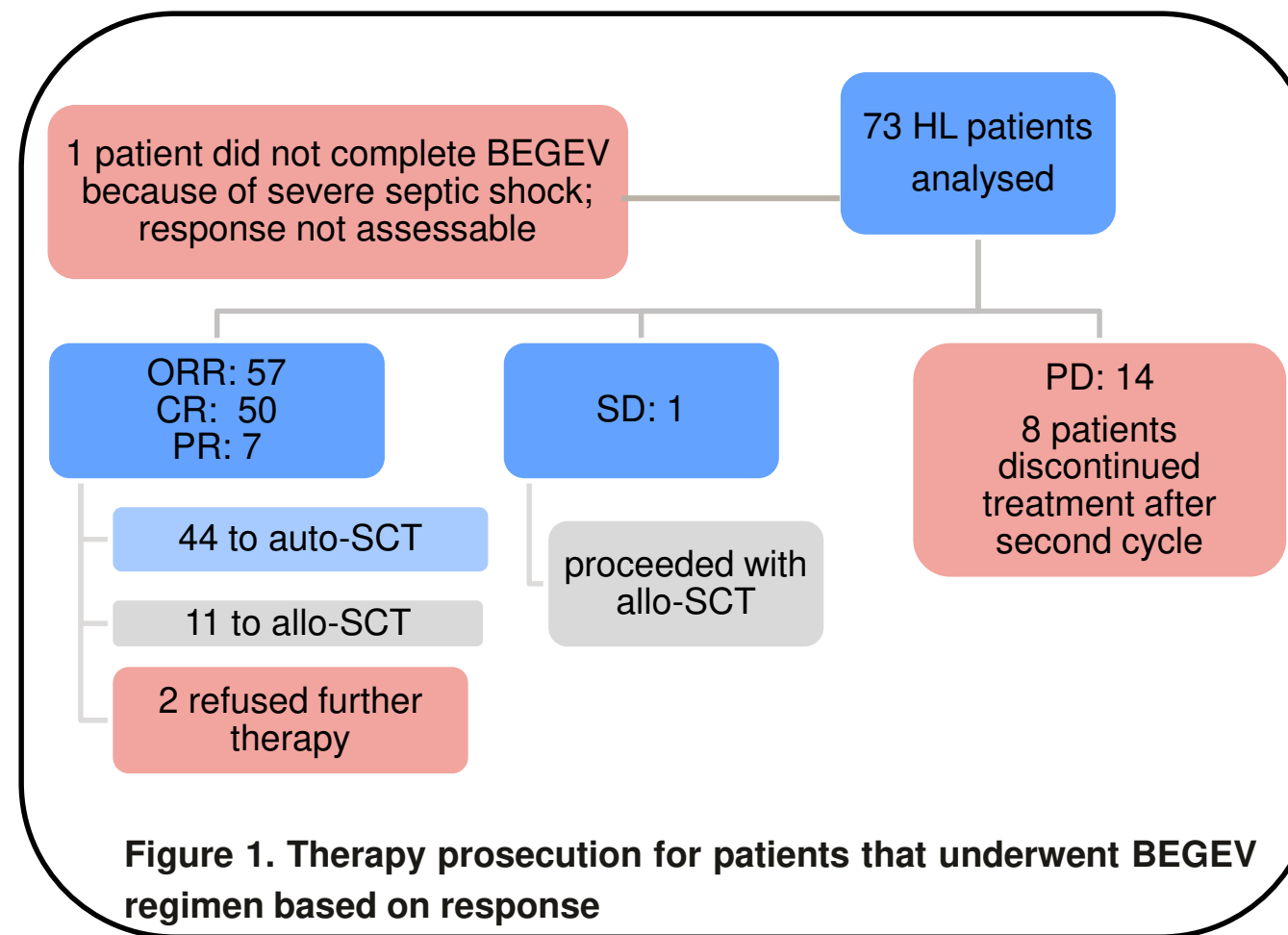


Figure 1. Therapy prosecution for patients that underwent BEGEV regimen based on response

Table 2. BEGEV response rate

| | All Patients | 2nd line | beyond 2nd line |
|-----------------------------|--------------|----------|-----------------|
| Patients evaluable | 72 | 49 | 23 |
| Response to Treatment | | | |
| Overall Response Rate (ORR) | 57 (79%) | 41 (84%) | 16 (69%) |
| Complete Remission (CR) | 50 (69%) | 35 (71%) | 15 (65%) |
| Partial Remission (PR) | 7 (10%) | 6 (12%) | 1 (4%) |
| Stable Disease (SD) | 1 (1.4%) | 0 | 1 (4%) |
| Progressive Disease (PD) | 14 (19%) | 8 (16%) | 6 (26%) |

Figure 2. OS and PFS of the whole patient cohort

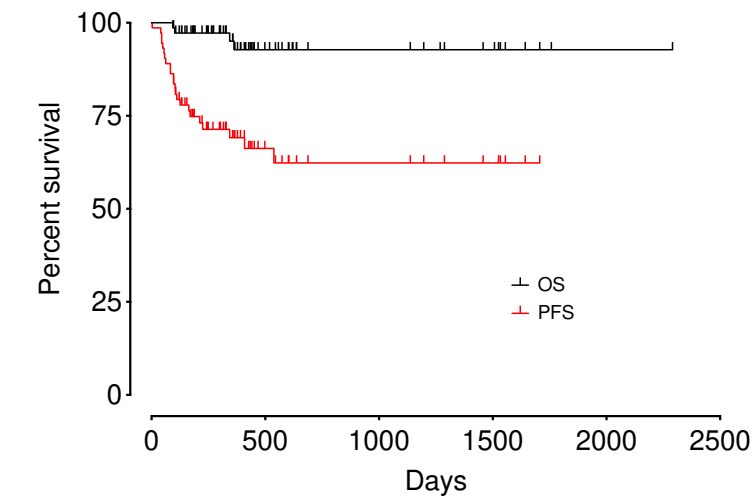


Figure 3. Comparison between OS of chemosensitive vs chemorefractory patients

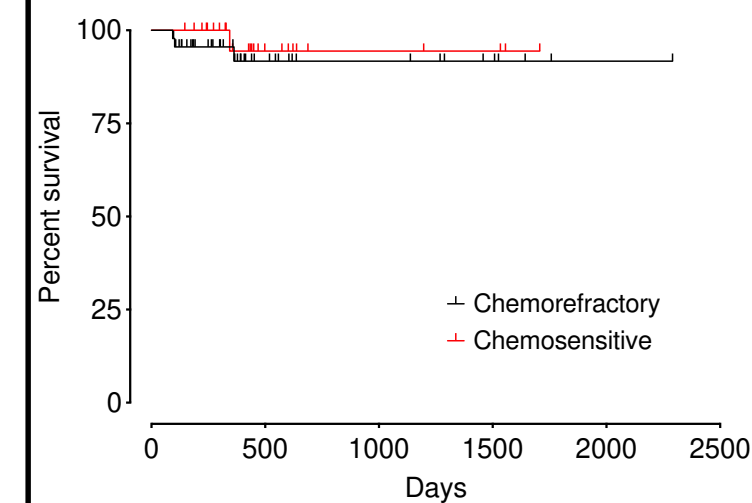
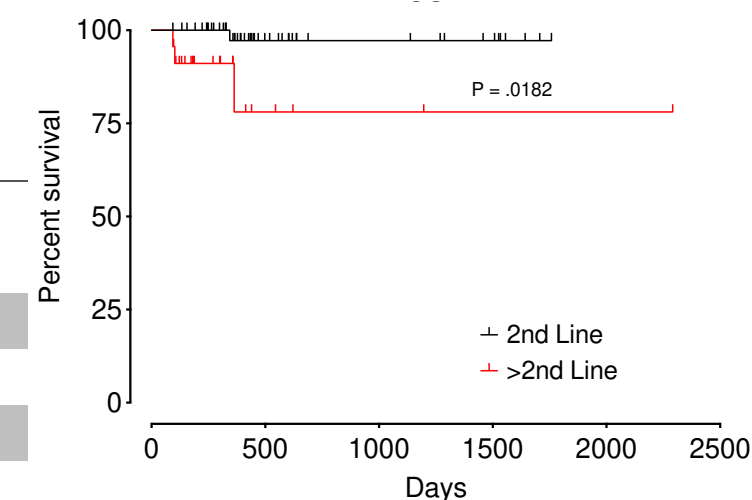


Figure 4. Comparison between OS of second line vs beyond second line patients



Results

- Probability of achieving response to BEGEV was significantly higher in primary chemosensitive vs chemorefractory patients (**96% vs 70%, P=0.007**)
- There was no statistical difference in probability of achieving response between patients receiving BEGEV as 2nd-line vs beyond 2nd-line (**83.7% vs 69.5%, P=0.217**)
- Therapy prosecution for the BEGEV-responders is summarized in **Figure 1**
- With a median follow-up of 14 months, 1-yr OS and PFS are 93% and 69% (**Figure 2**)
- Disease status (primary chemosensitive vs chemorefractory) had no impact on survival (1-yr OS: 94% vs 92%, P=0.57) likely due post-BEGEV consolidation therapy (**Figure 3**)
- Instead, timing of BEGEV administration (2nd line vs subsequent lines) significantly affected survival (1-yr OS: 97% vs 78%, P=0.018) (**Figure 4**)

Conclusion

Data from this real-world analysis show that BEGEV is an effective salvage regimen even when administered to heavily pre-treated Hodgkin Lymphoma patients, thus representing an optimal therapeutic platform prior to consolidation with SCT or immunotherapy

References

1. Santoro et al., *J Clin Oncol*, 2016

Contact

carmelo.carlostella@hunimed.eu