

# SARGRAMOSTIM AND LIPOSOMAL AMPHOTERICIN B FOR THE TREATMENT OF CHRONIC VISCERAL LEISHMANIASIS IN HIV CO-INFECTED PATIENT: A CASE REPORT

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## BACKGROUND AND IMPORTANCE

- In Spain, leishmaniasis is caused by *Leishmania infantum*, whose main reservoirs are dogs or small mammals, transmitted through the bite of dipterian insects of the genus *Phlebotomus*.
- *Leishmania* infection causes disease ranging from localized cutaneous to visceral leishmaniasis (VL), the most severe form, affecting frequently to profoundly immunocompromised individuals, such as late-stage HIV-infected patients, with high rates of treatment failure, relapses, and mortality.
- Liposomal amphotericin B (LAB) is the VL treatment of choice, with an induction regimen followed by maintenance (3-5mg/kg/monthly). Published data (1) suggests that sargramostim, a recombinant human granulocyte-macrophage colony-stimulating factor, has potential as co-adjuvant treatment to LAB in VL-HIV to augments immune responses and clinical control.

## AIM AND OBJECTIVES

- To report a case of **VL-HIV co-infection** successfully treated with **monthly LAB and sargramostim** for 12 weeks.

## CONCLUSION AND RELEVANCE

- **Sargramostim co-adjuvant treatment with LAB may be effective for the treatment of VL-HIV co-infected patients**, although further long-term reevaluation is needed.

## MATERIAL AND METHODS

- A 47-year-old male, diagnosed with HIV infection in 2017 (CD4 T cell count: 14/ $\mu$ L; viral load: 1380000 copies/mL. *Pneumocystis jirovecii* pneumonia and esophageal candidiasis). Despite a continuous undetectable viral load with antiretroviral treatment, CD4 count remained  $\leq 75-100/\mu$ L. In December 2020, he presented a mixed cryoglobulinemic membranoproliferative glomerulonephritis secondary to VL. Despite having received a **complete induction regimen with LAB**, febricula, systemic symptoms and positive *Leishmania* PCR persisted, therefore **monthly LAB 3mg/kg** were administered until March 2023.
- Off-label use of **sargramostim 150 mcg subcutaneously every two weeks for 3 months** was requested as **co-adjuvant treatment to LAB 3mg/kg/monthly**, was approved by the off-label Pharmacy committee and authorized by national spanish drug regulator (AEMPS). Success of the treatment was defined as the discontinuation of LAB without clinical relapse.

## RESULTS

- After having completed 3 months of sargramostim plus LAB, the patient was asymptomatic, HIV viral load was undetectable and *Leishmania* PCR in bone marrow was still positive, but microscopically negative. **LAB and sargramostim were discontinued** and the patient was monthly evaluated. Four months later, the patient remained completely asymptomatic, awaiting further evaluation.
- Regarding sargramostim safety, the patient presented fever after two doses, requiring a dose reduction by half. Treatment was afterwards well tolerated and completed with full sargramostim dose.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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