# Improved outcomes for Kaposi sarcoma using pegylated liposomal doxorubicin

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### Background

Kaposi's sarcoma (KS) is an HIV-associated malignancy associated with poor outcomes. Antiretroviral therapy (ART) is the cornerstone of KS treatment, but many patients require cytotoxic chemotherapy. Traditional regimens include conventional doxorubicin, bleomycin and vincristine, which are poorly tolerated. Pegylated liposomal doxorubicin (PLD) has been standard in high-income countries but largely unavailable in sub-Saharan Africa. In 2016, PLD was introduced at a specialized outpatient center in Maputo, Mozambique.

## **Methods**

We performed a prospective, single-arm, open-label observational study to demonstrate the feasibility, safety, and outcomes of treatment with PLD in patients with AIDS-associated KS in a low-resource setting. Chemotherapy-naïve adults were eligible; patients with Karnofsky scores <50 or contraindications to PLD were excluded. Patients received PLD on three-week cycles until meeting clinical stopping criteria. Follow-up visits monitored HIV status, KS disease, adverse events, mental health (PHQ-9) and quality of life (SF-12). Primary outcome measures included vital status and disease status at 6, 12, and 24 months after enrollment.

## **Results**

183 patients were screened and 116 participants were enrolled. At 24 months, 23 participants (20%) had died and 15 (13%) were lost to follow-up.

Baseline CD4<100 was associated with death (HR 2.7, 95%CI [1.2-6.2], p=0.016), as was T1S1 disease compared to T1S0 disease (HR 2.7, 95%CI [1.1-6.4], p=0.023).

92 participants achieved complete or partial remission at any point (overall response rate 80%), including 15 (13%) who achieved complete remission. The most common AEs were neutropenia and anemia. Quality of life improved rapidly after beginning PLD, particularly in the physical component of the SF-12.

### Conclusions

PLD was safe, well-tolerated and effective as first-line treatment of KS in Mozambique. High mortality was likely due to advanced immunosuppression at presentation, underscoring the importance of earlier screening and referral for KS. Improving supply of and access to PLD is essential for improving outcomes for KS patients.

The use of PLD as first-line chemotherapy for KS was successful. Advocacy efforts are needed to scale up access.

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