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MEETING ABSTRACTS Open Access

The KAART Trial: a randomized controlled trial of HAART compared to the combination of HAART and \chemotherapy in treatment-naïve patients with HIV-associated Kaposi sarcoma (HIV-KS) in KwaZulu-Natal (KZN), South Africa

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Background

KS is the most common cancer in people with HIV/AIDS, affecting both men and women in sub-Saharan Africa. Without HAART, mortality is high. Given poor access to HAART and prevalent HIV and KS-associated herpesvirus co-infection, advanced HIV-KS is an increasing problem in KZN. This is the first prospective study evaluating the impact of HAART and the role of early chemotherapy in HIV-KS in Africa.

Methods

We performed a randomized, controlled, open-label trial comparing HAART to the combination of HAART and chemotherapy (CXT) in treatment-naive patients with biopsy-confirmed HIV-KS, recruited from the dermatology clinic at King Edward VIII Hospital, KZN, South Africa. Patients were stratified by ACTG risk group. HAART was stavudine, lamivudine, and nevirapine. CXT consisted of HAART plus bleomycin (10 U/m^2), doxorubicin (20 mg/m^3), and vincristine (1.4 mg/m^2). Responses were evaluated by ACTG criteria. We performed an intention-to-treat comparison between arms of KS clinical responses at month 12 (Fisher exact test), rate of response (Mantel-Haenszel rate ratio), and overall survival (log-rank test). ACTG prognostic criteria were evaluated (Cox proportional hazard regression). Toxicity was monitored using DAIDS criteria. Adherence was assessed by a 7-day recall questionnaire. Toxicities, adherence, and changes in CD4 and HIV-1 viral load were compared between arms (Fisher exact test).

Results

Baseline characteristic: 310 patients were screened, with 112 (62 women, 50 men) randomized; 59 to HAART and 53 to CXT arm. Mean age 34 (20-63 yrs). 89% had advanced disease (T1 disease), 93% poor risk by ACTG criteria, 58% with CD4 <200, 42% had a history of co-morbid infection; commonly tuberculosis (34%). Responses: The overall response rate (complete responses plus partial responses) at month 12 was 39% in the HAART arm and 66% in the CXT arm (p=0.005). The CXT arm had a 2.7 times faster response rate (p<0.001). Overall survival at 12 months was 76%, with no significant differences between arms (p=0.49). ACTG TIS staging was validated (p=0.03), with systemic illness the most significant prognosticator of overall survival. There were no significant differences in CD4 improvement, HIV viral load decay, adverse events, or adherence between arms.

Conclusion

HAART dramatically improves overall survival in African patients with HIV-KS compared to historic controls. Addition of chemotherapy improves response rates in patients with advanced (T1) HIV-KS.

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