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A randomised study to compare radical concurrent chemoradiation against radical radiotherapy, as a treatment of cancer of the cervix in HIV infected patients

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ABSTRACT

Title

A RANDOMISED STUDY TO COMPARE RADICAL CONCURRENT CHEMORADIATION AGAINST RADICAL RADIOTHERAPY, AS TREATMENT OF CANCER OF THE CERVIX IN HIV INFECTED PATIENTS

Objectives

Cancer of the cervix is one of the commonest cancers in South African females. Up to 30% of patients are HIV positive. The addition of chemotherapy to radiotherapy has been shown to significantly improve local control and survival and concurrent chemoradiation is the standard treatment for locally advanced cancer of the cervix. There is very limited literature available concerning the tolerance and efficacy of this treatment in HIV positive patients. This study aims to assess the acute toxicity of combined modality treatment in these patients. This study is part of a multicenter International Atomic Energy Agency sponsored study.

Materials and methods

Patients with FIGO stage IB2 to IIIB (without hydronephrosis) cervical cancer and who are HIV positive, were randomized to receive radiotherapy alone or chemo-radiation. All patients received 46 Gy in 23 fractions external beam radiation and high-dose-rate-

brachytherapy 8 Gy x 3 fractions. Chemotherapy consisted of bolus Cisplatin 30mg/m^2 weekly given concurrently with the radiotherapy. Acute treatment toxicity was documented weekly during treatment.

Results

64 patients were recruited to the study. 31 patients were randomized to the chemoradiation arm and 33 patients to the radiation alone arm. Of the 64 patients recruited to the study, 6 in the chemoradiation arm and 5 in the radiation only arm did not receive any treatment and were therefore not evaluated. Stage IIB was the most common stage. The mean CD4 count was 410 in the chemoradiation arm vs. 358.4 in the radiation only arm at randomization. Only 6 patients were on antiretroviral therapy at start of treatment, 3 in each arm. The number of chemotherapy cycles received by patients in the chemoradiation arm ranged between 0 and 5 cycles. A total of 96 chemotherapy cycles were administered, with a median of 4 cycles per patient. Overall, at least 76% of patients received at least 4 cycles of chemotherapy. The full five intended courses of cisplatin were administered in 10 (40%) patients. Chemotherapy was not administered most commonly due to toxicity (renal, leucopaenia), other reasons being logistical and non compliance. The principle major adverse effects observed were leucopaenia and cutaneous reactions.

The incidences of Grades 3 and 4 leucopaenia were significantly higher in the chemoradiation arm. 41 of the 51 evaluable patients at 3 months had complete responses to treatment, 20 (80%) in the chemoradiation arm and 21 (80.7%) in the radiation alone arm.

Conclusion

The treatment was well tolerated. This study has shown that radical chemoradiation in conventional doses can be given safely in HIV positive patients with invasive cervical cancer. Many patients did not receive the planned cisplatin dose due to various factors not related to toxicity. Chemoradiotherapy is a resource intensive treatment, involving considerable input from doctors, nurses, radiographers and pharmacists and a high degree of coordination is necessary for treatment to be delivered effectively. In general the same principles that guide the oncologic management of immunocompetent patients should be applied to HIV patients. Further follow up is required to assess survival functions. Larger studies assessing toxicity and efficacy of concurrent chemoradiation in cervical cancer patients who are also HIV positive need to be done.