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A prospective randomized trial of two fractionation regimens of radiation therapy in the management of AIDS- associated Kaposi Sarcoma

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ABSTRACT:

A PROSPECTIVE RANDOMIZED TRIAL OF TWO FRACTIONATION REGIMENS OF RADIATION THERAPY IN THE MANAGEMENT OF AIDS-ASSOCIATED KAPOSI SARCOMA

OBJECTIVE:
To compare a standard fractionation scheme with a hypofractionated scheme in the treatment of AIDS-associated Kaposi sarcoma with the aim of showing non-inferiority of the shorter schedule.

PATIENTS AND METHODS:
HIV positive patients with histologically proven Kaposi sarcoma presenting consecutively to Radiation Oncology at Johannesburg Hospital were randomized between January 2003 and May 2004 to receive a standard regimen of 24 Gy in 12 fractions (ARM A) or the study regimen of 20 Gy in 5 fractions (ARM B). The radiation technique used was individualized for each site in accordance with departmental practice. Follow-up assessment was done at monthly intervals. Treatment response and toxicity were recorded at each follow-up visit.

RESULTS:
A total of 60 patients were recruited, of which 41 were male and 19 were female. The median age was 36 years (range: 23 – 55 years). Thirteen patients died prior to receiving treatment. The remaining 47 patients were treated to 65 sites, of which 35 sites received 24 Gy in 12 fractions (ARM A) and 30 sites received 20 Gy in 5 fractions (ARM B). The main indications for treatment were pain (n=71), oedema (n=44), functional impairment (n=35), cosmesis (n=14) and bleeding (n=4). At the time of reporting 28 patients were alive and 32 patients have died. The overall survival of the whole group was 37% at 1 year. A complete response was recorded at 28 sites, a partial response at 19 sites and stable disease at 3 sites. The mean time to maximum objective response was 3 months (range: 1 – 14 months). The response rates were equal in the 2 treatment arms (p=0.73). Local control was equal in the 2 treatment arms with a median local recurrence free survival of 150 days for ARM A and 455 days for ARM B (p=0.11, log rank test). Acute skin toxicity occurred at 27 sites. Moist desquamation developed at 7 sites while necrosis developed at 2 sites. Acute skin toxicity was equal in the 2 treatment arms (p=0.77). Acute mucosal toxicity occurred at 2 sites. Late skin reactions developed at 21 sites, of which necrosis or ulceration occurred at 5 sites. Chronic skin reactions were equivalent in the 2 treatment arms (p=0.24). Post radiation oedema developed at 5 sites.

CONCLUSION:
In our experience, 20 Gy in 5 fractions gave similar results to 24 Gy in 12 fractions in terms of treatment response, local recurrence free survival and toxicity in this small group of patients.