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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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APPENDIX 1:

REGIMEN	BED GY_{10}	BED GY_3
24 Gy in 12 fractions	28.8	40
20 Gy in 5 fractions	28	46.66
8 Gy single fraction	14.4	29

CALCULATIONS:

1. 24 Gy in 12 fractions:

BED Gy_3 = ND (1 + D / $\alpha\beta$)
= 24(1+ 2/3)
= 40 Gy_3

BED Gy_{10}= ND (1 + D / $\alpha\beta$)
= 24(1+2/10)
= 28.8 Gy_{10}

2. 20 Gy in 5 fractions:

BED Gy_3 = ND (1 + D / $\alpha\beta$)
= 20(1 + 4/3)
= 46.66 Gy_3

BED Gy_{10} = ND (1 + D / $\alpha\beta$)
= 20(1+4/10)
= 28 Gy_{10}

3. 8 Gy single fraction:

BED Gy_3 = ND (1 + D / $\alpha\beta$)
= 8(1+8/3)
= 29 Gy_3

BED Gy_{10} =ND (1 + D / $\alpha\beta$)
= 8(1+8/10)
= 14.4 Gy_{10}

DEFINITIONS:

BED:	Biologically equivalent dose
Gy_3:	Dose for late reacting tissue
Gy_{10};	Dose for tumour and early reacting tissue
N:	Number of fractions
D:	Dose per fraction
$\alpha\beta$:	10 for tumour and early reacting tissue 3 for late reacting tissue

APPENDIX 2:

EASTERN CO-OPERATIVE ONCOLOGY GROUP (ECOG)

PERFORMANCE SCORE DEFINITIONS:

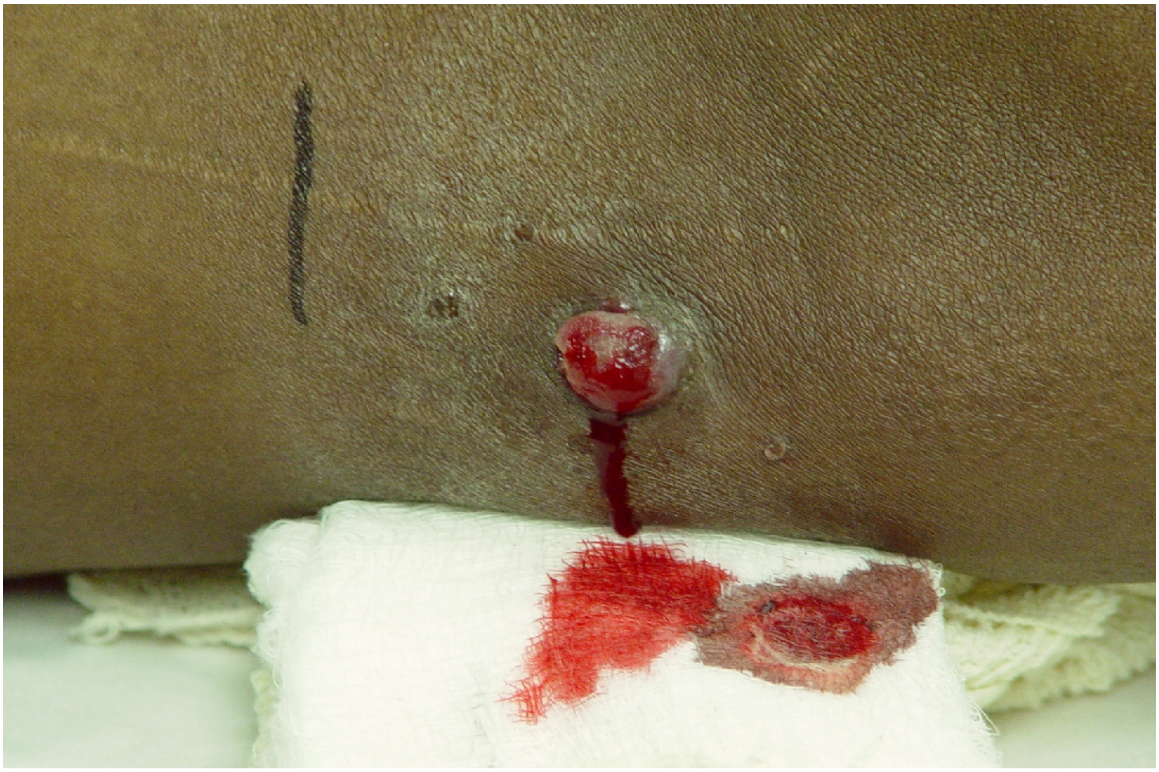
ECOG SCORE:	DEFINITION:
0	Asymptomatic; normal activity
1	Symptomatic; fully ambulatory
2	Symptomatic; in bed less than 50% of the time
3	Symptomatic; in bed more than 50% of the time
4	100% bedridden

APPENDIX 3:

AIDS CLINICAL TRIALS GROUP STAGING CLASSIFICATION:

	GOOD RISK (0)	**POOR RISK (1)**
	Any of the following	Any of the following
TUMOUR	Confined to the skin and / or lymph nodes and / or minimal oral disease. [Note: Minimal oral disease is non-nodular KS confined to the palate.]	Tumour-associated oedema or ulceration Extensive oral KS Gastrointestinal KS KS in other non-nodal viscera
IMMUNE SYSTEM	CD4 cells > / = 200/microL	CD4 cells < 200 / microL
SYSTEMIC ILLNESS	No history of OI or thrush No B symptoms [i.e. unexplained fever, night sweats, greater than 10% involuntary weight loss, or persistent diarrhoea more than 2 weeks.] Performance status > / = 70 (Karnofsky)	History of OI and / or thrush B symptoms present Performance status < 70 Other HIV-related illness (e.g. Neurological disease, Lymphoma)

Appendix 4 - Bleeding and Functional Impairment





Appendix 5 - Extensive Lesion



APPENDIX 6a:

THE AIDS CLINICAL TRIALS GROUP RECOMMENDED

RESPONSE DEFINITIONS FOR KAPOSI SARCOMA:

1. COMPLETE RESPONSE:

The absence of any detectable residual disease, including tumour-associated oedema, persisting for at least four weeks. In patients in whom pigmented (brown or tan) macular skin lesions persist after apparent complete response, biopsy of at least one representative lesion is required to document the absence of malignant cells. In patients known to have had visceral disease, an attempt at restaging with appropriate endoscopic or radiographic procedures should be made. If such procedures are medically contraindicated the patient may be classified as having a clinical complete response

2. PARTIAL RESPONSE:

A 50% or greater decrease in the number and / or size of previously existing lesions (skin, oral, measurable or evaluable visceral disease) lasting for at least four weeks without the appearance of new skin or oral lesions or new visceral sites of involvement or the appearance or worsening of tumour-associated oedema or effusions, or an increase of 25% or more in the product of bidimensional diameters of any indicator lesion. A 50% decrease in the size of lesions includes a 50% decrease in the sums of the products of the largest perpendicular diameters of bidimensionally measurable marker lesions and / or complete flattening of at least 50% of the lesions (i.e., 50% of previously nodular or plaque-like lesions become macules). In those patients with predominantly nodular lesions, flattening to an indurated plaque of 75% or more of the nodules will also be considered a partial response. Whenever possible, responses based on the latter criterion should be documented with photographs. Patients with residual tumour-associated oedema or effusions who otherwise meet the criteria for a complete response will be classified as having a partial response.

3. STABLE DISEASE:

Any response not meeting the criteria for progression or partial response.

4. PROGRESSION:

An increase of 25% or more in the size of previously existing lesions and / or the appearance of new lesions or new sites of disease and / or a change in the character of 25% of more of the skin or oral lesions from macular to plaque-like or nodular. The development of new or increasing tumour-associated oedema or effusion is also considered to represent disease progression.

APPENDIX 6b:

MODIFIED TREATMENT RESPONSE CRITERIA DEFINITIONS:

RESPONSE	DEFINITION
COMPLETE RESPONSE	Absence of detectable lesion with or without persistent pigmentation
PARTIAL RESPONSE	Any decrease in number or size of lesion or any flattening of a lesion without the appearance of new lesions
STABLE DISEASE	Not meeting the criteria above
PROGRESSIVE DISEASE	Any increase in size of existing lesions and / or the development of new lesions and / or a change from macular to plaque-like or nodular appearance

APPENDIX 7:

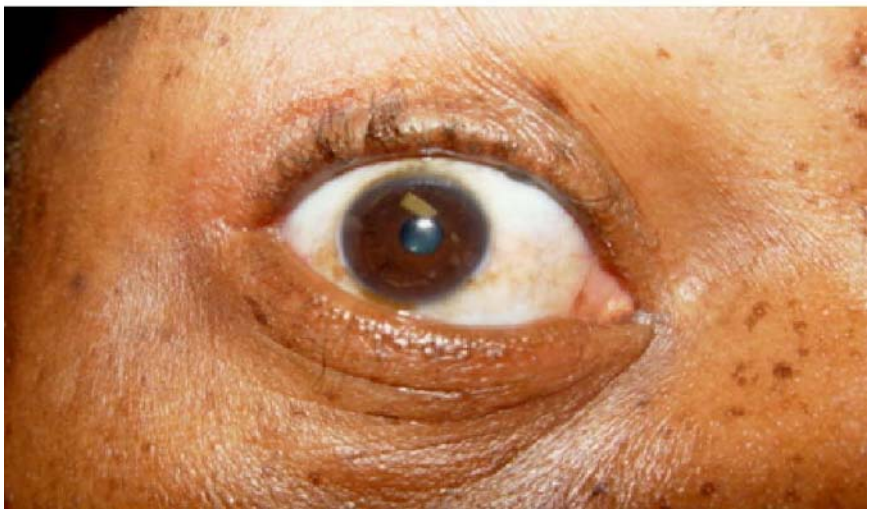
TREATMENT TOXICITY DEFINITIONS:

TOXICITY	DEFINITION
ACUTE	Skin erythema Dry desquamation Moist desquamation Necrosis / gangrene
LATE	Hyper / Hypo pigmentation Telangiectasia Ulceration Oedema

Appendix 8 - Complete Treatment Response

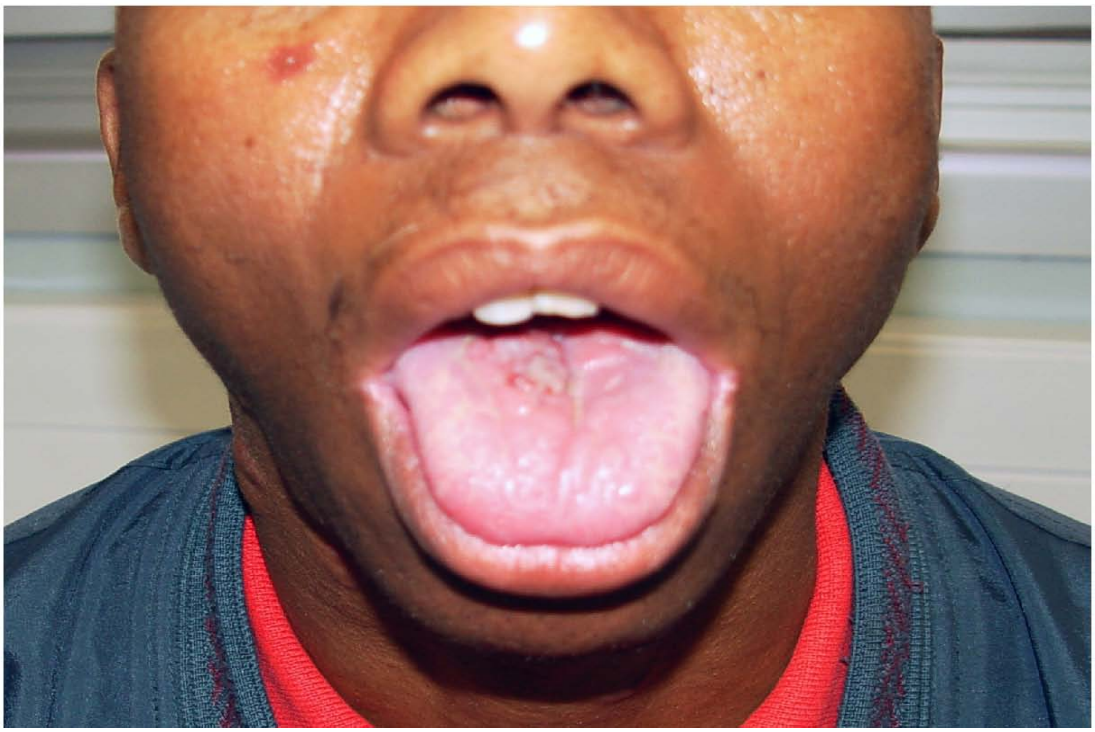






Appendix 9 - Complete Treatment Response





Appendix 10 – Partial Treatment Response





Appendix 11 - Partial Treatment Response











Appendix 12 – Necrosis

