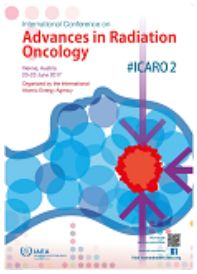

Contribution ID: **276** Type: **Poster**

Electro-hyperthermia as a radiosensitiser for locally advanced HIV positive and negative cervical cancer patients in South Africa

Wednesday, 21 June 2017 15:30 (5 minutes)

INTRODUCTION: 5-year survival rates for cervical cancer can be as much as 50% lower in developing countries than in developed countries. The treatment of cervical cancer patients in State facilities in South Africa is complicated by the advanced stage of disease at presentation, limited resources in the facilities and high HIV incidence amongst patients. These challenges contribute to the poorer prognosis of State patients in South Africa. The high morbidity and mortality rates associated with cervical cancer increases the socio-economic burden of the disease on the community and the healthcare system. The investigation of a feasible radiosensitiser which can be used in conjunction with cisplatin to improve clinical outcomes for locally advanced cervical cancer is therefore warranted. The aim of this study is to determine the clinical and economic benefit of the addition modulated electro-hyperthermia to standard treatment protocols for locally advanced HIV positive and negative cervical cancer patients in State healthcare in South Africa.
METHODS: This is an ongoing phase III randomised clinical trial with a target sample size of 236 participants. The trial is being conducted at the Charlotte Maxeke Johannesburg Academic Hospital in South Africa. Eligibility criteria include female participants between 18 and 70 years of age with FIGO stage IIB (initial distal parametrium involvement) to IIIB cervical cancer. HIV positive participants with a CD4 count above 200/µL and who have been on ARVs for at least 6 months are included. Participants with bilateral hydronephrosis or a creatinine clearance below 60 mL/min are excluded. Participants are being randomised into a "Hyperthermia"group and a "Control"group. Randomisation stratum: HIV status, age and stage of disease. Participants in both groups are treated with 50Gy of external beam radiation administered in 25 fractions, 3 doses of 8Gy HDR and up to 3 doses of cisplatin (80mg/m2). Participants in the Hyperthermia group are treated two local electro-hyperthermia (EHT) sessions per week, each lasting 55 minutes at 130W. EHT sessions are administered directly before external beam radiation using the EHY 2000 Plus capacitive coupling technique (device is supplied by Onotherm Gmbh). The measured outcomes are local disease control, quality of life, early and late toxicity and 2 year survival. Local disease control is assessed by Positron Emission Tomography (PET) scans and toxicity is graded according to the CTCAE version 4. EORTC and EuroQoL forms are used for the assessment of quality of life.
RESULTS: Our preliminary results show a benefit in local disease control in the hyperthermia group without the addition of any unexpected early toxicities or adverse events and without a large increase in treatment costs.
CONCLUSION: mEHT appears to be a safe an effective radiosensitiser which may be used in low resource settings to improve clinical outcomes.

Country

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Session Classification: Wednesday afternoon - Poster Presentations - Screen1

Track Classification: New Technologies in Radiation Oncology/Radiotherapy