Modulated Electro-Hyperthermia: Role in Developing Countries

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Modulated Electro-Hyperthermia: Role in Developing Countries

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DISCLOSURES:
The study has been funded by the National Research Foundation (South Africa) and the device used has been supplied by Oncotherm

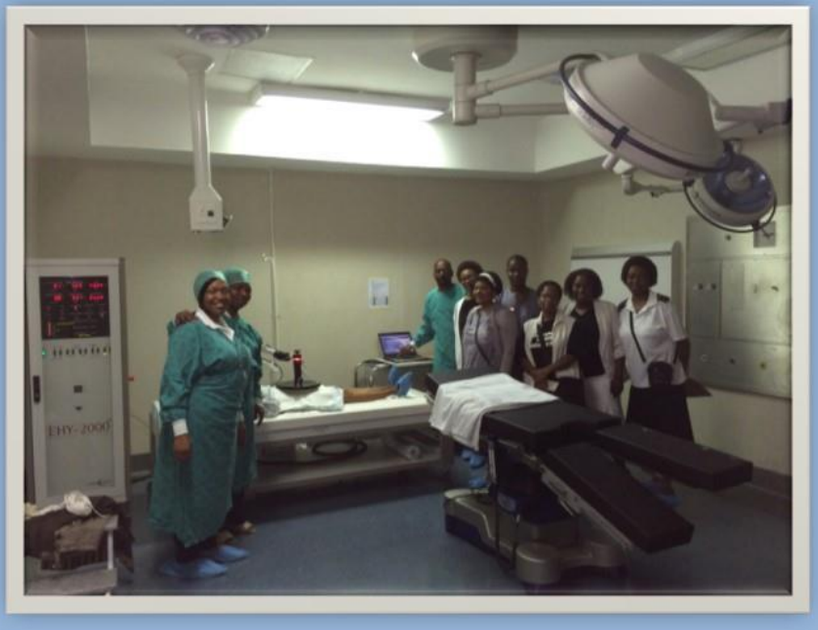
AIM

Preliminary results: Ongoing Phase III clinical study

Addition of mEHT to chemoradiotherapy protocols for locally advanced cervical cancer in a low resource setting.

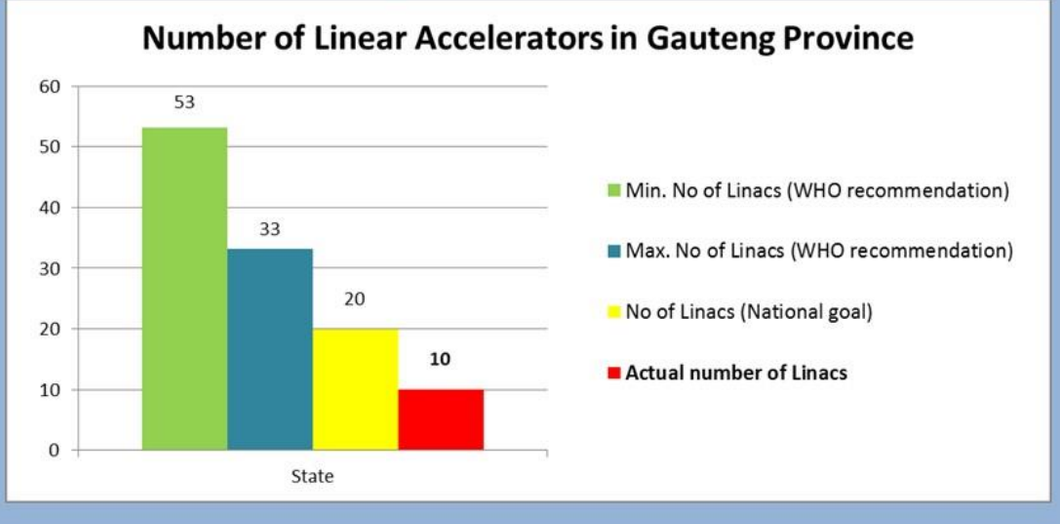
- 555 000 new cervical cancer cases per year
- 80% in developing countries
- Up to 20% HIV incidence in South Africa
- Survival rates for cervical cancer up to 50% lower in developing countries

South Africa



South Africa

Limited resources



METHODOLOGY

We report on 129 participants with 6 month post treatment data

Randomisation Stratum: HIV, FIGO stage and Age group

Exclude: Bilateral hydronephrosis, renal / immune impairment

Treatment:

- 50Gy External Beam Radiation
- 3 x 8Gy HDR doses
- Cisplatin 80mg/m2

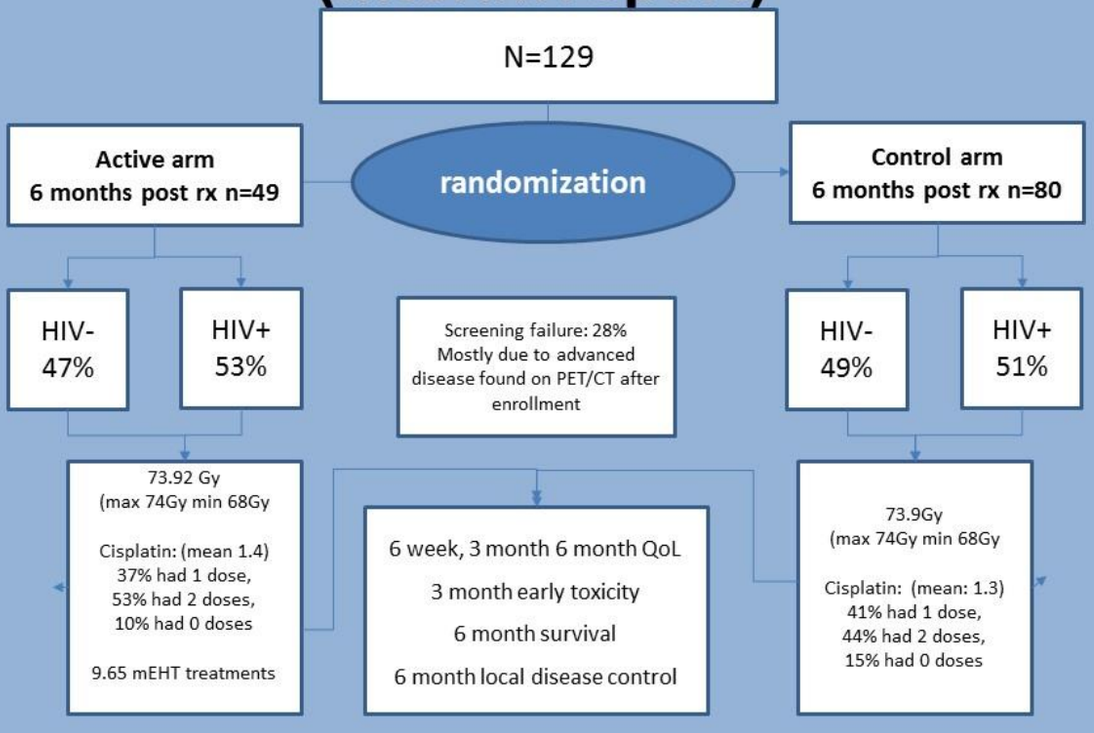
Hyperthermia: 2 x 55 minutes mEHT /week directly before EBR

METHODOLOGY

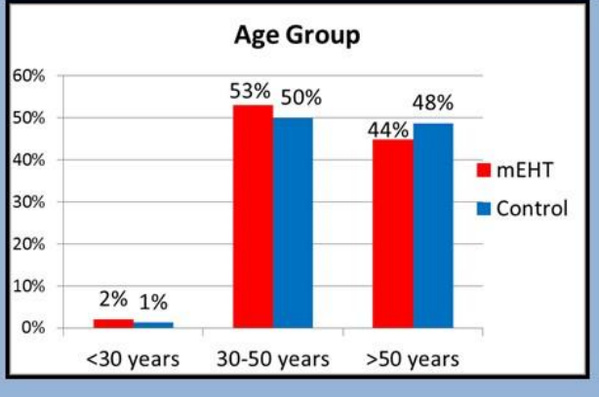
OUTCOMES

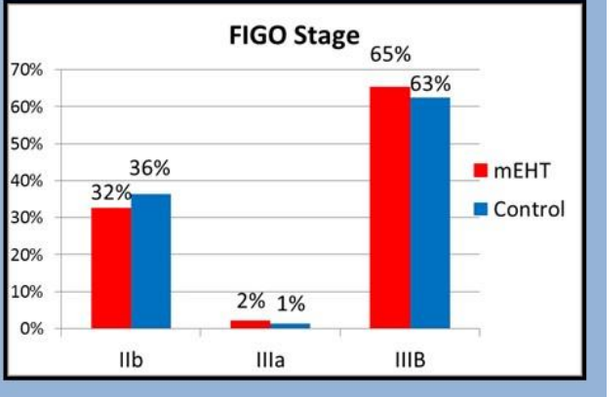
- Local disease control at 6 months (PET/CT)
- Adverse events + Early toxicity (CTCAE v4)

Randomized Phase III study (interim report)

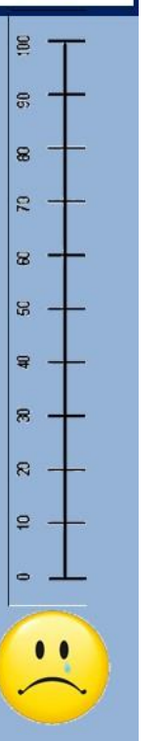


RESULTS





QUALITY OF LIFE



Some South African Optimism

30% of participants at initiation report 100% on visual analogue scale, despite pain and harsh socioeconomic conditions. When questioned, they answered:

"But I am alive, what more can I ask for?"

QUALITY OF LIFE

6 WEEKS

mEHT had significant improvement in:

- Social functioning
- Nausea and vomiting

Control had significant worsening in:

- Emotional function
- Appetite

Both showed a significant worsening in:

Fatigue, insomnia, pain, body image, symptom experience, Menopausal symptoms, financial difficulties

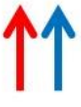
QUALITY OF LIFE

3 MONTHS

mEHT: showed significant improvement in:

- Emotional functioning
- Mobility
- Global health
- Pain
- Diarrhoea

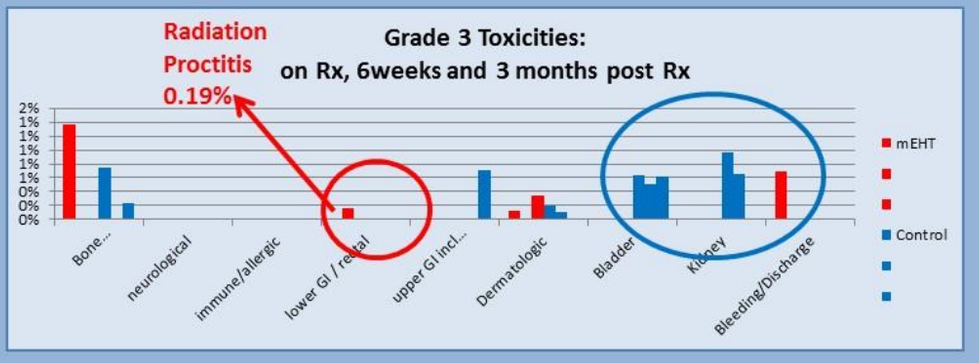
Both showed improved body image.

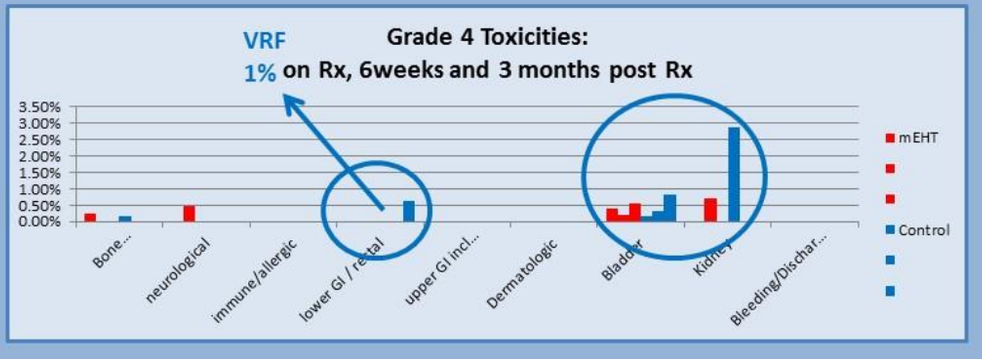


Both showed worse symptom scores and worse insomnia at 3 months.

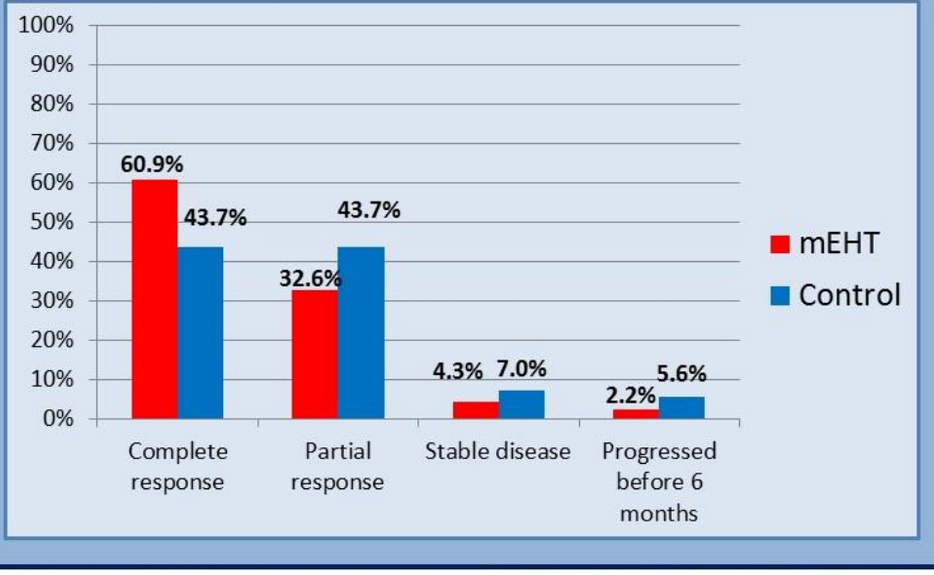
Only 5 responded to the sexual health and sexual worry questions.

EARLY TOXICITIES: Gr 3 and 4





LOCAL DISEASE CONTROL: 6 MONTHS



Demised before 6 month PET/CT:

Study group – 3 (6%)

Control group – 9 (11%)

1: unable to have PET/CT due to renal failure.

Local disease control is assessed by PET/CT at 6 months post completion of treatment.

CONCLUSION

The preliminary results continue to show a positive trend in local disease control in the group treated with mEHT combined with chemo-radiation

DISCUSSION

- The availability of mEHT in a developing country has the potential to increase the clinical outcomes in a population in which their resources, options and outcomes are limited.
- The mEHT devices are affordable, easy to use, safe and practical and are therefore suitable for the South African market.
- Further applications and benefits of mEHT in low income / low resource settings need further urgent investigations.

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