NON-INVASIVE PHYSICAL PLASMA FOR PREVENTING RADIATION DERMATITIS IN BREAST CANCER: AN INTRAPATIENT-RANDOMISED DOUBLE-BLIND PLACEBO-CONTROLLED TRIAL

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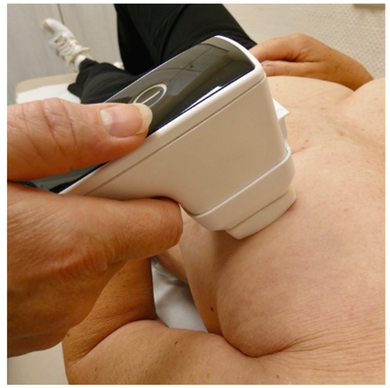
Introduction

In this first phase 2 trial, we investigate the effect of topical non-invasive physical plasma (NIPP), a volatile mix characterised by free electrons generated out of ambient air, on prevention of acute radiation dermatitis (RD) during whole-breast irradiation (WBI).

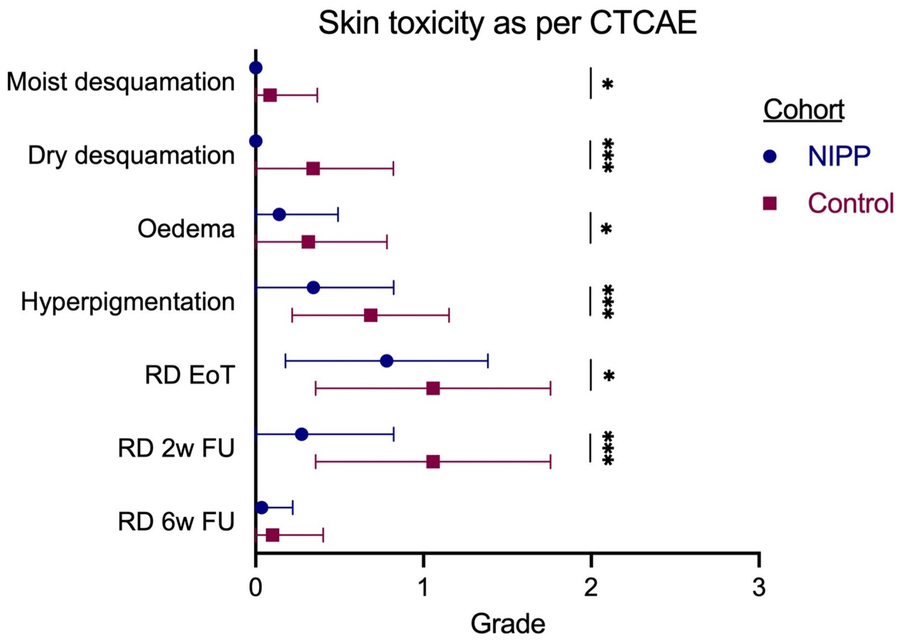
Methods

Lateral and medial breast halves were randomised within each patient to receive either 120 seconds of NIPP or sham treatment daily during WBI. Standard skin care with urea lotion was applied twice daily to the whole breast. Blinded acute skin toxicity was assessed weekly for each breast half separately and included clinician- (CTCAE), patient-reported (modified RISRAS), and objective (spectrophotometry) assessments. As an additional external control, a comparable standard of care (SoC) patient collective (70 patients) from a previously published prospective trial was used, identical in terms of inclusion criteria.



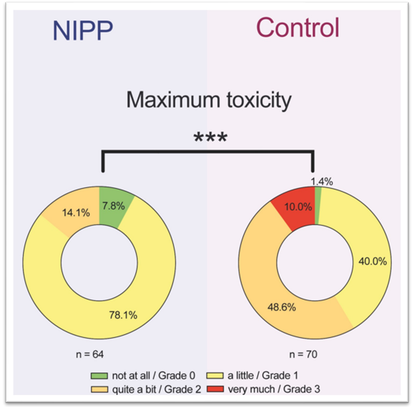
Results

Sixty-four patients were included. There were no significant differences between breast halves. Comparison with the independent SoC control collective revealed **OR = 0.28** (95% CI 0.11–0.76; p = 0.014) for grade ≥ 2 RD upon WBI completion, confirmed by the objective assessment, along with less hyperpigmentation ($p < 0.001$), oedema (p = 0.020), dry ($p < 0.001$) and moist desquamation (p = 0.017), pain, itching, and burning ($p < 0.001$ for each). Tolerability of NIPP was excellent, patient acceptance high, and side effects were not observed. **Diffusion** of the volatile NIPP towards the placebo half is the most likely explanation for the observed discrepancy.



Conclusion

Even though there were no differences between intrapatient-randomised breast halves, the overall incidence and severity of acute radiation-induced skin toxicity were considerably lower when compared to an almost identical prospectively collected SoC cohort. Our data suggest a benefit of NIPP in RD prevention. A randomised **phase 3 trial** with a physical control group, ruling out diffusion, has been initiated to confirm these promising results.



References

[1] Dejonckheere et al. *Pharmaceutics* 2022 10.3390/pharmaceutics14091767.

[2] Dejonckheere et al. *Clin Transl Radiat Oncol* 2023 10.1016/j.ctro.2023.100699.