



- **Comparison of radiotherapy alone with radiotherapy plus hyperthermia in locally advanced pelvic tumours: a prospective randomised, multicentre trial.**

van der Zee J, Gonzalez Gonzalez D, van Rhoon GC, van Dijk JD, van Putten WL, Hart AA: *Subdivision of Hyperthermia, Academic Medical Centre, Amsterdam, The Netherlands*

Background:

Local-control rates after radiotherapy for locally advanced tumours of the bladder, cervix, and rectum are disappointing. We investigated the effect of adding hyperthermia to standard radiotherapy.

Methods:

The study was a prospective, randomised, multicentre trial. 358 patients were enrolled from 1990 to 1996, in cancer centres in the Netherlands, who had bladder cancer stages T2, T3, or T4, NO, MO, cervical cancer stages IIB, IIIB, or IV, or rectal cancer stage M0-1 were assessed. Patients were randomly assigned radiotherapy (median total dose 65 Gy) alone (n=176) or radiotherapy plus hyperthermia (n=182). Our primary endpoints were complete response and duration of local control. We did the analysis by intention to treat.

Findings:

Complete-response rates were 39% after radiotherapy and 55% after radiotherapy plus hyperthermia ($p<0.001$). The duration of local control was significantly longer with radiotherapy plus hyperthermia than with radiotherapy alone ($p=0.04$). Treatment effect did not differ significantly by tumour site, but the addition of hyperthermia seemed to be

most important for cervical cancer, for which the complete-response rate with radiotherapy plus hyperthermia was 83% compared with 57% after radiotherapy alone ($p=0.003$). 3-year overall survival was 27% in the radiotherapy group and 51% in the radiotherapy plus hyperthermia group. For bladder cancer, an initial difference in local control disappeared during follow-up.

Radiotherapy plus Hyperthermia



Interpretation:

Hyperthermia in addition to standard radiotherapy may be especially useful in locally advanced cervical tumours. Studies of larger numbers of patients are needed for other pelvic tumour sites before practical recommendations can be made.

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