



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

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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:

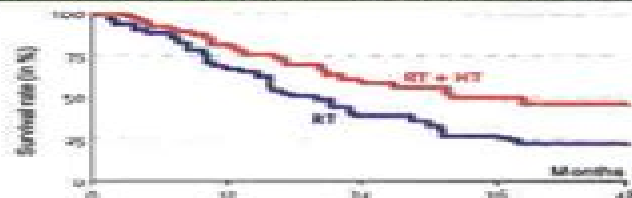
The study was a prospective, randomised, multicentre trial. 358 patients were enrolled from 1990 to 1996, in cancer centres in the Netherlands, who had bladder cancer stages T2, T3, or T4, NO, MO, cervical cancer stages IIB, IIIB, or IV, or rectal cancer stage M0-1 were assessed. Patients were randomly 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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Table of Contents Science Experiment Paper

1. Understanding the eBook Science Experiment Paper
 - The Rise of Digital Reading Science Experiment Paper
 - Advantages of eBooks Over Traditional Books
2. Identifying Science Experiment Paper
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Science Experiment Paper
 - User-Friendly Interface
4. Exploring eBook Recommendations from Science Experiment Paper
 - Personalized Recommendations
 - Science Experiment Paper User Reviews and Ratings
 - Science Experiment Paper and Bestseller Lists

5. Accessing Science Experiment Paper Free and Paid eBooks
 - Science Experiment Paper Public Domain eBooks
 - Science Experiment Paper eBook Subscription Services
 - Science Experiment Paper Budget-Friendly Options
6. Navigating Science Experiment Paper eBook Formats
 - ePub, PDF, MOBI, and More
 - Science Experiment Paper Compatibility with Devices
 - Science Experiment Paper Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Science Experiment Paper
 - Highlighting and Note-Taking Science Experiment Paper
 - Interactive Elements Science Experiment Paper
8. Staying Engaged with Science Experiment Paper
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Science Experiment Paper
9. Balancing eBooks and Physical Books Science Experiment Paper
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Science Experiment Paper
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Science Experiment Paper
 - Setting Reading Goals Science Experiment Paper
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Science Experiment Paper
 - Fact-Checking eBook Content of Science Experiment Paper
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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