

- **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, N0, M0, 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.

Published:

Lancet 2000 Apr 1;355(9210):1119-25

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1. Understanding the eBook Sample Of Scientific Paper
 - The Rise of Digital Reading Sample Of Scientific Paper
 - Advantages of eBooks Over Traditional Books
2. Identifying Sample Of Scientific 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 Sample Of Scientific Paper
 - User-Friendly Interface
4. Exploring eBook Recommendations from Sample Of Scientific Paper
 - Personalized Recommendations
 - Sample Of Scientific Paper User Reviews and Ratings
 - Sample Of Scientific Paper and Bestseller Lists
5. Accessing Sample Of Scientific Paper Free and Paid eBooks

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