

Research reveals prostate cancer radiation treatment can be shortened by 50% with no loss of effectiveness

Results are expected to change policy and impact the treatment of prostate cancer worldwide

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A shorter 4-week radiation regimen is non inferior to the standard 8-week regimen when it comes to prostate cancer treatment, an Ontario-led study has found.

The Prostate Fractionated Irradiation Trial, (PROFIT) was conducted by Hamilton's Ontario Clinical Oncology Group (OCOG) and according to Dr. Mark Levine, OCOG director, the study is, "A game changer." Results are expected to change policy and impact the treatment of prostate cancer world-wide.

OCOG worked with a network of investigators in three continents to carry out this research. OCOG is located in the Escarpment Cancer Research Institute, a joint initiative of Hamilton Health Sciences and McMaster University, Hamilton.

Investigators presented their findings at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. ASCO is the world's leading professional organization for health care professionals caring for people with cancer. The Annual Meeting brings together 30,000 multidisciplinary specialists from around the world.

The paper, which was selected as one of the Best of ASCO, was presented on Monday June 6, by Dr. Charles Catton the principal investigator who is a radiation oncologist at the Princess Margaret Hospital and Professor, Department of Radiation Oncology, University of Toronto. "The PROFIT trial has shown that with modern radiotherapy techniques we can treat patients with a common form of prostate cancer more safely and efficiently than in the past with fewer treatments. Specifically, the number of daily radiation treatments can be reduced from 39 to 20 with no loss of effectiveness of the radiation." said Dr. Catton.

The results of PROFIT are expected to have an impact on treatment worldwide. "The fewer number of treatments will not only reduce the physical burden and be more convenient for patients, but it will also reduce the financial burden on the health care system, while at the same time increasing capacity," said Dr. Himu Lukka, co-principal investigator who is a radiation oncologist at the Juravinski Cancer Centre and Professor in the Department of Oncology McMaster University. "By shortening the treatment by 50%, twice as many patients can be treated with the same amount of resources."

Prostate cancer commonly presents localized to the prostate gland and is classified into low, intermediate and high risk of prostate cancer recurrence. Radiation is the usual treatment for men with intermediate risk prostate cancer. The risk of recurrence is determined by the size of the cancer on rectal exam and/or ultrasound, the Gleason score (microscopic appearance of the cancer cells), and PSA (blood test).

The trial enrolled 1206 patients at 26 centres in Canada, Australia and France between 2006 and 2011. The men have been followed for an average of six years. Investigators set out to determine whether a shorter radiation treatment regimen was non inferior to the standard 8-week radiation regimen. In this case, non-inferior means “no worse in terms of preventing recurrence of the prostate cancer” and “with no increased toxicity.” Researchers hypothesized that the treatment would be as good as, without increased side effects. Explains Dr. Levine, “The hypothesis was based on experimental evidence from radiotherapy studies in the lab that suggest that an equivalent amount of tumor kill can be achieved by increasing the dose of each treatment -- called a fraction, and administering it over a shorter time period.” Specifically, the trial compared the current standard treatment of 7800 cGy administered in 39 fractions over 8 weeks to 6000 cGy in 20 fractions over 4 weeks.

Results showed that 166 subjects experienced a study outcome event in the shorter treatment group compared to 170 in the longer treatment group. About 80% of patients in each group were free of a treatment failure event at 5 years. There was no increased long term bowel or bladder toxicity with the shorter treatment. In fact, there was a trend to less toxicity with the shorter treatment.

Speaking to PROFIT’s collaborative approach, Dr. Levine says, “This was an amazing team effort. It involved 14 centres in Canada, 11 in Australia, and one in France. At each site there were study nurses who enrolled the patients, monitored them and collected the data. There were physicists who carefully planned the radiation and therapists who administered the radiation. Prior to starting each radiation regimen, the radiation plan was sent electronically to a central site in each country so that the plan could be checked for strict quality control adherence.”

Once collected, the data was sent electronically to OCOG through its web based state-of-the-art data management system where it was checked and analyzed by two study statisticians. In addition, there was an independent safety monitoring committee that monitored the accumulating data yearly to make sure there was no excess toxicity.

The potential impact of PROFIT trial results is tremendous. The strategy of increasing the dose of each radiation fraction and giving the treatment over a shorter period, called hypofractionation, is being studied in other cancer types, with different doses and durations.

The PROFIT trial is an international collaborative effort, led by Co-Principal Investigators, Charles Catton, MD, Princess Margaret Hospital, Toronto, Canada; Himu Lukka, MD, Juravinski Cancer Centre, Hamilton Health Sciences, Hamilton Canada; Chief Study Statistician, Jim Julian MMATH, Department of Oncology McMaster University and Mark Levine, MD, Director, OCOG, Chair Department of Oncology McMaster University. The trial was sponsored by the Ontario Clinical Oncology Group (OCOG) from the Escarpment Cancer Research Institute Hamilton Canada; with collaboration with the Trans-Tasman Radiation Oncology Group (TROG), Waratah Australia. Funding provided by Canadian Institutes of Health Research (CIHR), Ottawa Canada; Information provided by the Ontario Clinical Oncology Group (OCOG).