

Six months hormone therapy in addition to radiotherapy improves prostate cancer survival

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Vienna, Austria: Men with prostate cancer that is small and confined to the prostate gland but that is at risk of growing and spreading, do better if they are treated with radiotherapy combined with androgen deprivation therapy, which lowers their levels of the male hormone, testosterone, according to new research.

The findings, which will be presented at the 33rd conference of the European Society for Radiotherapy and Oncology (ESTRO33) in Vienna today (Monday), are expected to change [clinical practice](#).

Professor Michel Bolla, a professor of radiation oncology at Grenoble University Hospital (Grenoble, France), will tell the conference: "Although we need longer follow-up to assess the impact on these men's overall survival, these findings need to be taken into account in daily clinical practice. They show that three-dimensional conformal radiotherapy, whether intensity modulated or not, and regardless of the dose level, has to be combined with short-term [androgen deprivation therapy](#) in order to obtain a significant decrease in the risk of relapse. Therefore, during multidisciplinary team meetings to discuss a patient's treatment, this combined treatment approach should be one of the options proposed for men with localised [prostate cancer](#) that has an intermediate or [high risk](#) of growing and spreading."

Prof Bolla and colleagues from 37 centres in 14 countries recruited 819

men to a clinical trial. The patients had early stage prostate tumours (as confirmed by analyses of biopsy samples and levels of [prostate specific antigen](#) (PSA)) that were at intermediate or high risk of growing and spreading to other parts of the body. They were randomised to receive either radiotherapy alone or radiotherapy and two injections under the skin of hormone drugs called luteinizing hormone-releasing hormone analogues (LH-RH analogues), which lower levels of testosterone to cause reversible chemical castration. Each drug injection lasted three months; the first was given on the first day of irradiation and the second three months later. When LH-RH analogues are first given, testosterone levels go up briefly before falling to very low levels. This effect is called flare and, in order to prevent it, the patients took an oral anti-androgen (bicalutamide, 50 mg per day) for 15 days before the first injection.

Doctors could chose between one of three irradiation doses, 70, 74 or 78 Grays (Gy). They followed up the men for an average of 7.2 years and found that, regardless of the radiotherapy dose and whether it was intensity modulated or not, the 403 men who had been treated with radiotherapy combined with hormone treatment were significantly less likely to have suffered a relapse and progression of their cancer than the 407 men who had been treated with radiotherapy alone. (Nine men did not receive the planned treatment).

Men receiving the combined treatment had nearly half the risk (47%) of biochemical progression of their disease compared to men treated with radiotherapy only. In the combined treatment group, 118 men had a biochemical progression of their disease compared with 201 men in the radiotherapy only group. (Biochemical progression was assessed according to whether or not PSA values had risen above the lowest level plus two nanograms per millilitre; if it had risen, then this required confirmation in subsequent checks).

Five years after their treatment, the men in the combined treatment

group were doing significantly better. "They had better survival without biochemical progression," Prof Bolla will say. "Among those receiving the combined treatment, 17.5% had progressed compared to 30.7% receiving radiotherapy alone."

When the researchers looked at clinical progression of the disease – whether the cancer had recurred, spread to other parts of the body (proven by biopsies and imaging) or the patients had died – they found that five years after their treatment 88.7% of the men in the combined treatment group had not progressed, compared with 80.8% of men receiving radiotherapy only.

So far, 152 patients have died, of which 25 died from prostate cancer. Side-effects, relating mainly to problems with urination, were seen in 5.9% of patients receiving the combined treatment versus 3.6% of patients on radiotherapy alone. Problems with sexual function were higher in the combined treatment group: 27% versus 19.4%.

Prof Bolla will conclude: "These results show that, in men with localised prostate cancer that is at risk of recurring and spreading, the addition of six months of hormonal treatment to radiotherapy improves the time these men survive without their disease progressing. It is important to ensure that the radiation treatment is of the best quality; further clinical research is required to optimise radiation techniques and to find new hormonal treatments."

Professor Vincenzo Valentini, president of ESTRO and a radiation oncologist at the Policlinico Universitario A. Gemelli, Rome, Italy, commented: "The results from this trial are important and practice-changing. It is clear that an additional six months of hormonal treatment in addition to [radiotherapy](#) improves the outcome for men with localised prostate cancer. This option should now be considered for all these men with prostate cancer that is at risk of growing and spreading."

More information: Abstract: O-0522, "Selected randomised trials" session at 11.45-12.30 hrs (CEST) on Monday, 7 April, Auditorium.

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