Adding chemotherapy to standard prostate cancer treatment may extend life expectancy

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New research led by the University of Warwick shows newly diagnosed advanced prostate cancer patients who received the chemotherapy drug docetaxel with standard hormone therapy lived ten months longer on average, compared to those who received standard therapy alone.

In contrast, adding zoledronic acid to standard therapy did not affect survival, and adding the combination of zoledronic acid and docetaxel was not more effective than adding just docetaxel.

The STAMPEDE trial was led by Professor Nicholas James, Director of the Cancer Research Unit at the University of Warwick in Coventry, United Kingdom and Consultant in Clinical Oncology at Queen Elizabeth Hospital Birmingham. It was run from the MRC Clinical Trials Unit at UCL and supported by Cancer Research UK.

STAMPEDE is the largest randomized clinical trial of treatment for men with prostate cancer ever conducted, with more than 6,500 patients enrolled since 2005. The research team will be talking about the trial at the American Society of Clinical Oncology's Annual Meeting on 31 May in the US.

Professor James said: "We hope our findings will encourage doctors to offer docetaxel to men newly diagnosed with metastatic prostate cancer, if they are healthy enough for chemotherapy. Men with non-metastatic advanced prostate cancer may also consider docetaxel as part of upfront therapy, as it clearly delays relapse.

"It's also clear that zoledronic acid does not benefit these patients and should not be offered as an upfront treatment for advanced prostate cancer."

The standard of care (SOC) treatment was at least three years of androgen deprivation therapy, with local radiation for suitable patients.

The researchers will be reporting results on 2,962 hormone-naïve men who started long-term hormone therapy for the first time. The men were assigned to four different treatment arms: standard of care (SOC), SOC with docetaxel for 6 cycles, SOC with zoledronic acid for 2 years, and SOC with both docetaxel and zoledronic acid. About 60% of the patients had metastatic disease when joining the trial and the rest had high-risk, non-metastatic prostate cancer.

After a median follow-up of 42 months, 948 men had died. Overall survival was on average ten months longer in the docetaxel arm compared to the SOC arm (67 vs. 77 months) with a relative improvement of 24% (hazard ratio 0.76). For the subset of patients with metastatic disease, the average improvement in overall survival was even higher, 22 months (from 43 vs. 65months). Importantly, docetaxel also extended the time to relapse by 38% in all patients (hazard ratio 0.62).

Two previous, smaller trials have reported results on using docetaxel in the hormone naïve metastatic setting. These trials showed conflicting results. CHAARTED in the USA reported in the plenary session of ASCO 2014 showed a survival advantage; GETUG-15 in France did not. STAMPEDE goes a long way in clarifying the role of docetaxel in men with newly diagnosed high risk prostate cancer. The trial also included a larger and broader patient population than those trials, comprising men with both metastatic and advanced non-metastatic prostate cancer. This includes nearly 600 men with non-metastatic node-negative disease similar to RTOG 0521 which is being reported in the same session of

ASCO 2015.

According to the authors, the overall findings of this study suggest that men with newly diagnosed metastatic prostate cancer should be offered docetaxel as part of their initial therapy. Doctors may also discuss the option of adding docetaxel with patients who have advanced, non-metastatic prostate cancer, given the reduction in risk of relapse seen in this study. However, longer follow up is needed to determine if there is any survival advantage in men with non-metastatic disease.

While docetaxel was associated with some additional toxicity compared to SOC alone, the side effects were manageable and very few patients discontinued docetaxel due to side effects. Results of a quality of life analysis will be reported at a later time.

The difference in survival was not statistically significant between the SOC and SOC plus zoledronic acid arm. Addition of zoledronic acid to the combination of SOC and docetaxel yielded similar outcomes as SOC with only docetaxel.

More information: Docetaxel and/or zoledronic acid for hormone-naïve prostate cancer: First overall survival results from STAMPEDE (NCT00268476). abstracts.asco.org/156/AbstView_156_147721.html

Provided by University of Warwick