転移性前立腺がんにおける生存の劇的な有益性（Abstract: LBA2）

初回ホルモン療法にドセタキセルを併用することで転移性ホルモン感受性前立腺がん患者の生存期間が大幅に改善する

Addition of docetaxel to initial hormone therapy substantially improves survival in men with metastatic, hormone-sensitive prostate cancer

第50回American Society of Clinical Oncology学会のLate Breaking sessionで発表された研究の結果、新たにホルモン感受性前立腺がんと診断された患者において、標準的なホルモン療法に化学療法薬ドセタキセルを併用することにより生存期間が約10か月延長することが示された。今回の第III相試験において、新たに転移性前立腺がんと診断された患者790人がアンドロゲン除去療法（ADT）単独またはADTとドセタキセルの併用を18週間投与する群にランダムに割り付けられた。約3分の2の患者において病変は広範であった。ADTとドセタキセル併用群の患者45人は疾患が悪化したため、ドセタキセルの追加投与が行われた。ADT単独群患者123人は、疾患が増悪した時点でドセタキセルの投与を受けた。追跡期間中央値29か月の時点で、ADT単独群で死亡は136人であったのに対し、ADTとドセタキセル併用群では101人であった。全生存期間中央値はADT群で44か月でありADTとドセタキセル併用群では57.6か月であった。総生存期間中央値の相対的な改善は、疾患が広範に及ぶ患者520人においてより大であった（32.2か月対49.2か月）。ECOG E3805 CHAARTEDトライアルの研究者らは、これらの結果は"日常診療を変化させる"そして"変化させる力がある"と述べている。

Full Text

Findings from a phase III study, E3805, indicate that adding the chemotherapy drug docetaxel to standard hormone therapy extends survival for men with newly diagnosed hormone-sensitive prostate cancer by roughly 10 months. The survival benefit is even greater for the subset of men with high-extent disease.

"Hormone therapy has been a standard treatment for prostate cancer since the 1950s," said lead study author Christopher Sweeney, MBBS, medical oncologist at the Lank Center of Genitourinary Oncology at the Dana-Farber Cancer Institute in Boston, MA. "This is the first study to identify a strategy that prolongs survival in newly diagnosed metastatic prostate cancer. The benefit is substantial and warrants this being a new standard treatment for men who have high-extent disease and are fit for chemotherapy."

Androgen hormones fuel prostate cancer growth. Hormonal therapy – also called androgen deprivation therapy (ADT) – alone is the standard first-line treatment for hormone-sensitive prostate cancer. Although ADT is effective, the disease eventually becomes resistant to the therapy in most patients. Chemotherapy is typically initiated only after the disease progresses despite ADT.

In this National Cancer Institute-led study, 790 men with newly diagnosed metastatic prostate cancer were randomly assigned to receive either ADT alone or ADT with docetaxel over a period of 18 weeks. Approximately two-thirds of patients had high-extent disease, meaning that the cancer had spread to major organs and/or the patient had bone metastases. When the disease worsened, 45 patients in the ADT plus docetaxel group received additional docetaxel. In the ADT only group, 123 patients received docetaxel at disease progression.

At a median follow-up of 29 months, there were 136 deaths in the ADT-alone group vs. 101 in the ADT plus docetaxel group. The median overall survival was 44 months in the ADT group and 57.6 months in the ADT plus docetaxel group. The relative improvement in median overall survival was even larger among the 520 patients with high-extent disease (32.2 months vs. 49.2 months). The median overall survival for the subset with low-extent disease takes longer to reach as these patients respond better to ADT, and the median survival has not yet been reached.

Docetaxel also delayed disease progression, assessed by either PSA rise or appearance of new metastases or symptom worsening. At one year, the proportion of patients with PSA levels less than 0.2 ng/mL was 11.7 percent in the ADT group vs. 22.7 percent in the ADT plus docetaxel group. The median time to clinical progression was 19.8 months in the ADT group vs. 32.7 months in the ADT plus docetaxel group.

This new treatment paradigm will entail earlier, multidisciplinary care involving the collaboration of both urologists and oncologists, who both commonly treat men with prostate cancer, Dr. Sweeney said. Follow-up of patients will continue to assess survival benefits for patients with low-extent disease. Quality-of-life data from this study will be analyzed and reported at a later time.

"These results demonstrate how we can use 'old tools' in new, more powerful ways to improve and extend patients' lives," said ASCO president Clifford A. Hudis, MD, FACP. "This study is also a powerful testimony to the importance of National Cancer Institute-led research, as both of these drugs are available in generic form today and this research might have otherwise not been pursued."

This research was supported by the National Cancer Institute, National Institutes of Health.

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