限局性高リスク前立腺がんの有望な治療（Abstract # 4521）

術前ホルモン療法にabirateroneを追加することにより一部の高リスク前立腺がん男性の腫瘍が除去しうる

Adding abiraterone to hormonal therapy before surgery can eliminate tumor in the prostate in some men with high risk prostate cancer

第48回American Society of Clinical Oncology学会で発表された無作為化第2相スタディの結果、前立腺全摘術前の標準的なホルモン治療に6か月間の標的治療薬abirateroneを追加することにより、限局性高リスク前立腺がん男性の3分の1においてがんが消失したかまたはほぼ消失したことが示された。このスタディの対象となった男性はPSAレベルが20を超えておりGleasonスコアは8以上でステージT3がんを有していた。過去のスタディの結果、術前のleuprolideを含む標準的なホルモン単独療法の有益性は限られていることが示されている。今回のスタディでは2つのグループの男性（グループAはleuprolideホルモン療法を12週間受けた後にleuprolideとabirateroneをさらに12週間受ける男性27人、グループBはabirateroneおよびleuprolideの両者を24週間受ける男性29人）にabiraterone とleuprolideを追加した。前立腺手術は24週間の治療終了後に全員に対し施行され、組織のがんの所見の有無が調査された。グループBの男性のうち34%は手術の時点で完全消失またはほぼ完全消失していた（p=0.894）。グループAでは手術の時点で15%が完全消失またはほぼ完全消失していた。

Full Text

A randomized Phase II study presented at American Society of Clinical Oncology's 48th Annual Meeting, shows that six months of treatment with the targeted drug abiraterone, in addition to standard hormonal therapy before surgical removal of the prostate, eliminated or nearly eliminated cancer in one-third of men with localized high-risk prostate cancer. The study marks the first time that abiraterone ─ a drug used to treat more advanced prostate cancer ─ has been explored for the treatment of earlier-stages of prostate cancer, including in the neoadjuvant setting.

Localized high-risk disease is generally defined as prostate cancer in men with a PSA level above 20, high-grade disease (a Gleason score of 8 or more), and stage T3 disease. Men with this stage of disease tend to have a poor prognosis, often experiencing cancer spread to other parts of the body despite aggressive treatment with available therapies.

"For this proportion of patients with high-risk disease to have very little to no detectable cancer in the prostate after six months of therapy is dramatic," said Mary-Ellen Taplin, M.D., Associate Professor of Medicine at Harvard Medical School and the Dana-Farber Cancer Institute and the study's lead author. "Our findings suggest that this combination therapy approach could improve outcomes for a substantial number of men, but larger, long-term trials are needed to confirm this approach."

Previous studies have shown that use of standard hormonal therapy alone, including treatment with leuprolide, before surgery had limited benefits for men with localized high-risk prostate cancer. This study evaluated the effect of adding abiraterone to leuprolide in two groups of men with this form of the disease: Group A included 27 men who received leuprolide hormonal therapy for 12 weeks followed by leuprolide plus abiraterone for another 12 weeks. The second group, Group B, included 29 men who received both abiraterone and leuprolide for the entire 24-week period. Prostate surgery was performed in all men after 24 weeks of therapy, and the tissue was examined for evidence of cancer.

Among men in Group B (24 weeks of abiraterone therapy), 34 percent had either complete elimination (3/29) or nearly complete elimination (7/29) of their cancer upon surgery. In Group A (12 weeks of abiraterone therapy), 15 percent of men had either complete elimination (1/27) or nearly complete elimination (3/27) of their cancer upon surgery. Therapy was well-tolerated by both groups.

Abiraterone works by blocking production of the male hormone testosterone and related metabolites that often fuel prostate cancer growth. The addition of abiraterone to traditional hormonal therapy, which restricts testosterone production in a different way, further shuts down the body's ability to produce the hormones that prostate cancer cells need to grow. The clinical benefit of intensive androgen deprivation therapy, either before or after prostatectomy, will need to be validated in prospective, randomized clinical trials, but these data suggest a benefit for some men.

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