

# 早期のビスフォスフォネート投与は遅延した 投与に勝る(Abstract # S1-3)

ZO-FAST:内分泌療法直後のゾレドロン酸投与により閉経後早期乳がん 患者の再発が減少し生存率が上昇した

ZO-FAST: Immediate zoledronic acid use with endocrine therapy reduced recurrence, increased survival in postmenopausal early breast cancer

アジュバント内分泌療法にゾレドロン酸を追加することにより、ホルモン受容体陽性早期乳がんを有する閉経後女性の骨塩密度が上昇し乳がん再発リスクが低下した、と2011年CTRC-AACRサンアントニオ乳がんシンポジウムで発表された。研究者らは、アロマターゼ阻害薬レトロゾール開始直前の患者1,065人を、直後にゾレドロン酸を6ヵ月ごとに投与する群と、患者が骨折や明らかな骨密度低下を認めた場合のみゾレドロン酸を後に開始する群とに無作為に割り付けた。60ヵ月後にトライアルの一次エンドポイント達成に成功した―直後のゾレドロン酸投与により腰椎および骨盤骨密度喪失が有意に減少した。ゾレドロン酸を直接に投与された患者においては再発が34%少なく、二次エンドポイントである無病生存期間もまた改善した。診断時に真に閉経後であった女性においては、直後のゾレドロン酸により乳がん再発リスクが29%低下し、全生存期間が35%改善した。

# Full Text

The addition of zoledronic acid to adjuvant endocrine therapy increased bone mineral density and reduced the risk for disease recurrence among postmenopausal women with early hormone receptor-positive breast cancer, according to new data from the ZO-FAST trial.

Richard de Boer, M.D., of the Royal Melbourne Hospital in Victoria, Australia, presented long-term data from the Zometa-Femara Adjuvant Synergy Trial (ZO-FAST) at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium.

De Boer and colleagues explored adding zoledronic acid, an intravenous bisphosphonate, to adjuvant endocrine therapy to reduce bone mineral density loss seen with aromatase inhibitors and to improve survival outcomes.

When he presented initial data from ZO-FAST at the 2010 CTRC-AACR San Antonio Breast Cancer Symposium, de Boer indicated that early zoledronic acid resulted in a significantly improved bone mineral density and an improved disease-free survival. At this year's symposium, he reported long-term data and data on the effect of menopausal status at breast cancer diagnosis on disease-free survival.

Researchers randomly assigned 1,065 patients who were about to commence letrozole, an aromatase inhibitor, to receive immediate zoledronic acid every six months or to a delayed group where zoledronic acid was started at a later time only if the patient experienced a fracture or a documented fall in bone mineral density.

After 60 months of follow-up, "the primary endpoint of the trial was successfully achieved - up-front zoledronic acid significantly decreased bone mineral density loss in both the lumbar spine and the hip," de Boer said. "The secondary endpoint of an improvement in disease-free survival was also met with a 34 percent decrease in disease recurrence in the patients receiving the up-front zoledronic acid."

Researchers conducted an exploratory subgroup analysis based on menopausal status at the time of breast cancer diagnosis. Data indicated that in women who were truly menopausal at diagnosis, immediate treatment with zoledronic acid reduced the risk for disease recurrence by 29 percent and improved overall survival by 35 percent.

"In addition, patients in the delayed group, who did not start with zoledronic acid but who switched to start at a later time, also appeared to benefit from the zoledronic acid with an improvement in disease outcomes compared with those women who never started the bisphosphonate," de Boer said.

Additional studies are needed to fully define the patient populations most likely to benefit from adjuvant zoledronic acid in this setting.

Until then, "patients with hormone receptor-positive breast cancer who are postmenopausal and about to commence letrozole have the option of considering the addition of zoledronic acid - primarily to maintain bone mineral density but also with the aim of reducing the risk for disease recurrence," de Boer said.

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