

## 症例4

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- 転移・再発乳癌に対する化学療法、特に二次治療や三次治療では、単剤順次投与が有用である可能性がある。(推奨グレードC)



本例ではどうでしょうか。

## 本例では？

- 患者さんはQOLよりも延命優先を希望
- 再発後一次治療
- Triple negativeかつ、再発までの期間2年以内

→術後FEC療法は効いていない可能性が高い。

→経過からは予後不良と予想される。

単剤 VS 併用

**Superior Survival With Capecitabine Plus Docetaxel  
Combination Therapy in Anthracycline-Pretreated Patients  
With Advanced Breast Cancer: Phase III Trial Results**

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**Purpose:** Docetaxel and capecitabine, a tumor-activated oral fluoropyrimidine, show high single-agent efficacy in metastatic breast cancer (MBC) and synergy in preclinical studies. This international phase III trial compared efficacy and tolerability of capecitabine/docetaxel therapy with single-agent docetaxel in anthracycline-pretreated patients with MBC. **Patients and Methods:** Patients were randomized to 21-day cycles of oral capecitabine 1,250 mg/m<sup>2</sup> twice daily on days 1 to 14 plus docetaxel 75 mg/m<sup>2</sup> on day 1 (n = 255) or to docetaxel 100 mg/m<sup>2</sup> on day 1 (n = 256).

**Results:** Capecitabine/docetaxel resulted in significantly superior efficacy in time to disease progression (TTP) (hazard ratio, 0.652; 95% confidence interval [CI], 0.545 to 0.780; *P* = .0001; median, 6.1 v 4.2 months), overall survival (hazard ratio, 0.775; 95% CI, 0.634 to 0.947; *P* = .0126; median, 14.5 v 11.5 months), and objective tumor response rate (42% v 30%, *P* = .006) compared with docetaxel. Gastrointestinal side effects and hand-foot syndrome were more common with combination therapy, whereas myalgia, arthralgia, and neutropenic fever/sepsis were more common with single-agent docetaxel. More grade 3 adverse events occurred with combination therapy (71% v 49%, respectively), whereas grade 4 events were slightly more common with docetaxel (31% v 25% with combination).

**Conclusion:** The significantly superior TTP and survival achieved with the addition of capecitabine to docetaxel 75 mg/m<sup>2</sup>, with the manageable toxicity profile, indicate that this combination provides clear benefits over single-agent docetaxel 100 mg/m<sup>2</sup>. Docetaxel/ capecitabine therapy is an important treatment option for women with anthracycline-pretreated MBC.

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DTX+cape > DTX

→しかし、cross-overが不十分との指摘あり

→本例でも経過が早く、後治療の機会がない可能性あり。

- ・転移・再発乳癌でのメタアナリシス解析で、併用化学療法の方が生存率の改善を認める。とくに、転移・再発の一次治療では、併用療法の方が22%のハザード比の改善を認めた。

(2005 Chocrane Library Systematic review)

- ・Triple negative 症例での再発後の生存期間は短い。

( J Clin Oncol 2008; 26:1275-1281)

- 患者さんの希望
- Triple negative症例に対しての標準的レジメンは存在しないが、通常の単剤、sequentialの治療では治療効果は望めない可能性が高い。

この状況で、ガイドライン通りに  
単剤でsequentialの治療を選択する価値  
はあまりないのでは？