
From: 袁中玉 <yuanzhy@sysucc.org.cn>
Sent: Friday, January 29, 2021 3:49 AM
To: Carlson, Robert
Subject: evidence recommendation for NCCN guidelines

Dear Dr. Carlson

Wish you safe and health.

The NCCN guidelines that are continuously revised under your leadership have provided an irreplaceable guide for oncologists worldwide to treat breast cancer. In order to provide more comprehensive information in the section of treatment of TNBC, I would like to recommend our findings recently published in *JAMA* (*doi:10.1001/jama.2020.23370*), entitled “Effect of Capecitabine Maintenance Therapy Using Lower Dosage and Higher Frequency vs Observation on Disease-Free Survival Among Patients With Early-Stage Triple-Negative Breast Cancer Who Had Received Standard Treatment: The SYSUCC-001 Randomized Clinical Trial”.

We conducted this multicenter, phase III, randomized controlled study to evaluate the efficacy and safety of metronomic capecitabine maintenance for one year compared with observation after standard treatment in patients with early TNBC. The primary endpoint of the study was 5-year disease-free survival (DFS). In the study, 434 patients with early TNBC were randomly assigned to receive either metronomic capecitabine maintenance for one year (intervention) or observation (control) after standard treatment. With a median follow-up of 61 months, the addition of metronomic capecitabine maintenance to standard treatment for early TNBC provided an absolute improvement in 5-year DFS of 10% (82.8% vs. 73.0%, HR, 0.64; 95% CI, 0.42 to 0.96; P = 0.029), which is of major clinical benefits.

Our encouraging and breaking-through findings provide not only high-level clinical evidence, but also fill in the gaps where there is no effective maintenance therapy for patients with TNBC. We sincerely hope that the results of SYSUCC-001 study can be considered by you and the expert panel as a candidate for treatment recommendations in the NCCN guidelines.

Sincerely,

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