

ICON8 trial reaffirms standard dosing in ovarian cancer chemo

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European women with ovarian cancer can safely stick to the standard three-week dosing schedule for paclitaxel rather than boosting up to a weekly dose-dense regimen, according to results of the phase III ICON8 trial to be presented at the ESMO 2017 Congress in Madrid.¹

"The results clearly demonstrate that, although well-tolerated, using weekly scheduling to achieve dose-intensification of [paclitaxel](#) as part of the first-line treatment of epithelial [ovarian cancer](#) does not extend progression-free survival in this population," said study investigator Dr. Andrew Clamp, from The Christie NHS Foundation Trust and The University of Manchester, UK. "Therefore, this approach cannot be recommended as a standard-of-care treatment option for this population." But he added "it remains appropriate to continue to offer weekly dose-dense paclitaxel as a treatment option to Japanese women."

The conflicting recommendations stem from the fact that findings from ICON8 contrast with those of JGOG3016, a previously reported study of Japanese ovarian cancer patients which showed significantly increased median progression free survival (PFS) and overall survival (OS) in those treated with dose-dense weekly paclitaxel compared to the standard three-weekly schedule.²

To evaluate for a similar effect from weekly paclitaxel, ICON8 randomised 1566 predominantly European patients to receive six cycles of either the standard three-week dosing regimen (carboplatin AUC 5/6-paclitaxel 175 mg/mq; Arm 1), compared to two different regimens

that included once-weekly dose-dense paclitaxel (carboplatin AUC 5/6+paclitaxel 80 mg/mq weekly, Arm 2; and carboplatin AUC2+paclitaxel 80 mg/mq weekly, Arm 3). All patients entered ICON8 after immediate primary surgery, or received neo-adjuvant chemotherapy with planned delayed primary surgery.

The study found no benefit to either of the once-weekly regimens.

PFS was 24.4 months with standard dosing, compared to 24.9 and 25.3 months in arms 2 and 3 respectively. In terms of toxicity, there was a slight increase in grade 3-4 toxicity in arms 2 and 3 compared to arm 1 (63% vs 53% vs 42% respectively), although this increase was predominantly due to uncomplicated haematological toxicity.

Noting that the study was "robust and appropriately powered", Clamp said it is "not entirely clear" why ICON8 and JGOG3016 showed contrasting results. "Both were well-conducted trials and achieved the goal of increasing paclitaxel dose-intensity. We know the histological profile of ovarian cancer is slightly different between Japanese and Caucasian women but I think it is unlikely that this accounts for the difference. It is more likely that there are pharmacogenomic differences between these two ethnic groups that account for the different results seen."

Commenting for ESMO, Dr. Domenica Lorusso, from Fondazione IRCCS National Cancer Institute of Milan, Chair of the Gynaecological Tumours track at ESMO 2017, said: "The trial confirms that carboplatin-paclitaxel every 3 weeks is the standard first line treatment in ovarian cancer, a standard which has remained unmodified in the last 20 years, at least in the Caucasian population." She agreed that success with weekly dosing in the Japanese population "is possibly due to genetic differences.

According to the Tokyo's 5th Ovarian Consensus conference standard

options to be discussed with the patients for first-line ovarian [cancer](#) treatment include carboplatin-paclitaxel every 3 weeks, as well as the dose-dense schedule (at least in the Japanese populations)."

More information: 1 Abstract 929O_PR 'ICON8: A GCIG Phase III randomised trial evaluating weekly dose- dense chemotherapy integration in first-line Epithelial Ovarian/ Fallopian Tube/ Primary Peritoneal Carcinoma (EOC) treatment: Results of Primary Progression-Free Survival (PFS) analysis' will be presented by Dr Clamp during Proffered Papers Session 'Gynaecological cancers' on Friday, 8 September 2017, 16:00 to 17:30 (CEST), in Cordoba Auditorium.

2 Katsumata et al. *Lancet* 2009/ *Lancet Oncol* 2013.

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