

Abstract:

RANDOMIZED CONTROLLED PHASE III STUDY TO EVALUATE SECONDARY CYTOREDUCTIVE SURGERY IN PLATINUM-SENSITIVE RECURRENT OVARIAN CANCER - AGO DESKTOP III/ENGOT OV20

Aims

The role of secondary cytoreductive surgery in platinum-sensitive recurrent ovarian cancer (PSROC) has not been defined by level-1 evidence.

Method

Pts with PSROC and 1st relapse if they presented with a positive AGO-score which selects approximately 50% of all PSROC pts. They were randomized to 2nd-line chemotherapy vs cytoreductive surgery followed by chemo. We report results of the predetermined interim analysis.

Results

409 pts were randomized 2010-2014. Platinum-free interval exceeded 12 mos in 75% and 76% pts in both arms. Complete resection was achieved in 72.5% of operated pts; 87% and 88% received a platinum-containing 2nd-line therapy. 60/180-d mortality rates were 0 and 0.5% in the surgery and 0.5 and 2.5% in the no-surgery arm. Re-laparotomies were performed in 7pts (3.5%). With the exception of myelosuppression no further significant differences were observed with respect to grade 3+ adverse events.

Median PFS was 14 mos without and 19.6 mos with surgery (HR: 0.66, 95%CI 0.52-0.83, p<0.001). Median time to start of first subsequent therapy (TFST) was 21 vs 13.9 mos in favor of the surgery arm (HR 0.61, 95%CI 0.48-0.77, p<0.001). Analysis of primary endpoint OS is hampered by unexpected good OS and therefore kept blinded due to immaturity.

Conclusion

Surgery in PSROC pts selected by a positive AGO-Score resulted in increase of PFS and TFST with very acceptable treatment burden. Until final OS data will definitively define the role of secondary cytoreductive surgery it should at least be considered as valuable option in pts with a positive AGO-Score.

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