

AGO-OVAR OP.2

(AGO DESKTOP OVAR II)

**Validation of a score of predictive factors
for complete resection in platinum-sensitive
recurrent ovarian cancer**

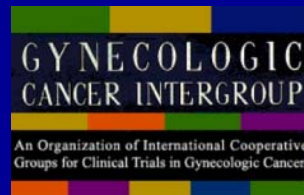
**A project of the
AGO Kommission OVAR**

AGO Study Group Ovarian Cancer (AGO-OVAR)

Nordostdeutsche Gesellschaft f. Gyn. Onkologie (NOGGO)

Arbeitsgemeinschaft Gyn. Onkologie Austria (AGO-Austria)

Multicenter Italian Trials in Ovarian Cancer (MITO)



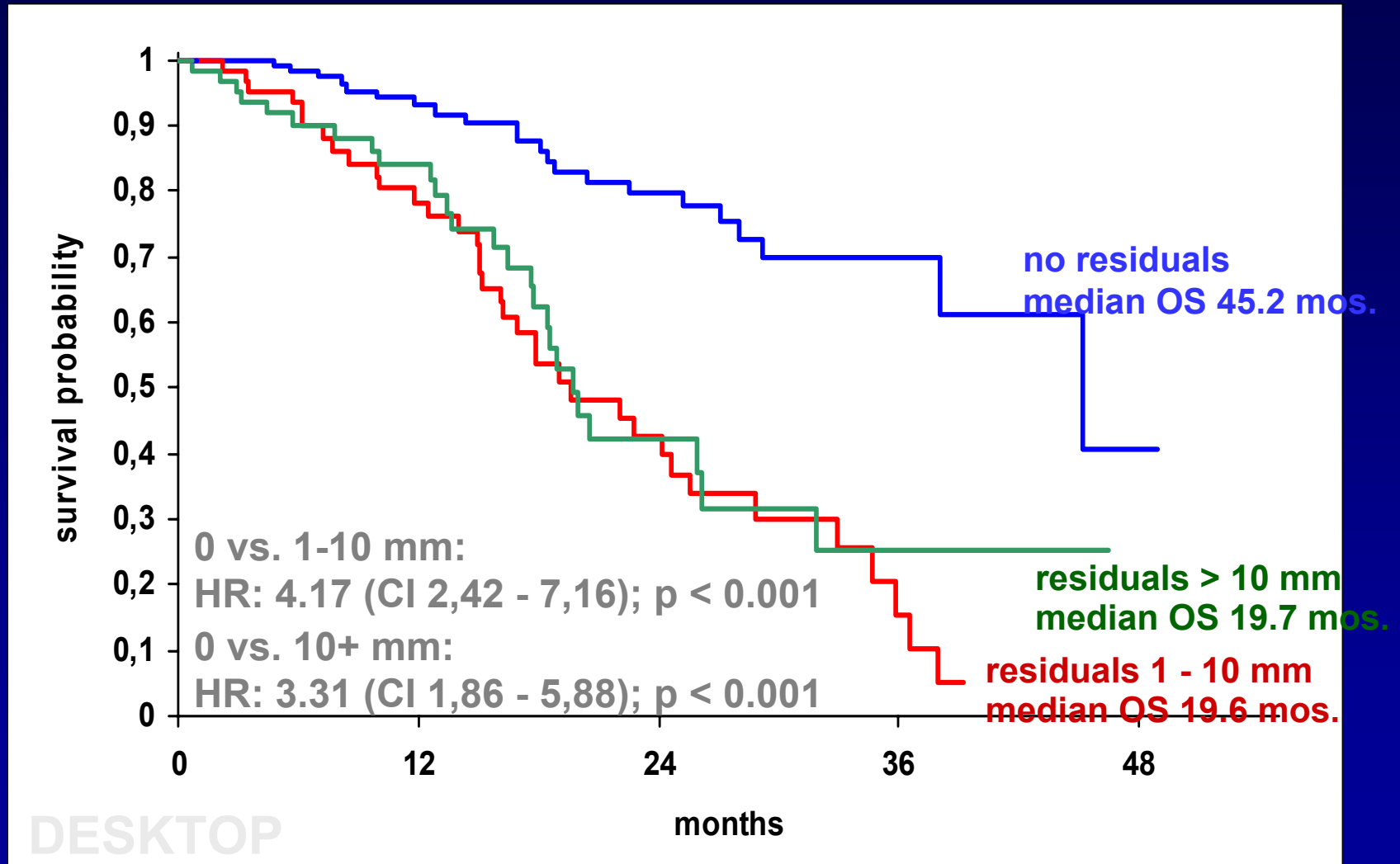
An open-label prospective multicenter-trial

Objectives of the AGO-DESKTOP-series **evaluating surgery in recurrent OC**

- DESKTOP I:** - descriptive analysis in a multi-centre setting
AGO-OVAR OP.1
- identify an appropriate endpoint
 - creation of a model for a predictive score for resectability (allowing pts. selection for further studies)
- DESKTOP II:** - Validation of the predictive score
AGO-OVAR OP.2
- descriptive analysis of the selection bias for offering surgery to ROC pts.
- DESKTOP III:** - Prospectively randomized trial to evaluate the impact on OS
AGO-OVAR OP.4

DESKTOP- OVAR I: Results

- *what is the surgical endpoint ?*



Only complete resection is associated with better survival

DESKTOP- OVAR I

- *who benefits ? multivariate analysis (survival)*

Variable	OR	(95% CI)	p-value
<u>Residual after surgery (0 vs. > 0 mm)</u>	2.94	(1.68-5.17)	< 0.001
Ascites (cut-off 500 ml)	2.30	(1.31-4.04)	0.004
Pt-based chx after surgery (yes vs. no)	1.84	(1.13-3.01)	0.015

Not an independent prognostic factor for survival after surgery for recurrence are:

- Localization of recurrence (pelvic vs. others)
- PS (ECOG 0 vs. > 0)
- Residuals after 1st surgery (0 vs. > 0 mm)
- TFI (< 6 vs. > 6-12 vs. > 12 months), but small no. of pts with TFI < 6 months
- FIGO-stage at primary diagnosis (I/II vs. III/IV)

DESKTOP-OVAR I

- **Predictors of successful surgery (= complete resection)**
multivariate analysis

pre-OP variable	OR	(95%CI)	p-value
PS (ECOG 0 vs. > 0)	2.65	(1.56-4.52)	< 0.001
Residual disease 1st. Surgery (0 vs. > 0)	2.46	(1.45-4.20)	< 0.001
<u>or:</u> initial FIGO-stage (I/II vs. III/IV)	1.87	(1.04-3.37)	0.036
Ascites (cut-off 500 ml)*	5.08	(1.97-13.16)	< 0.001

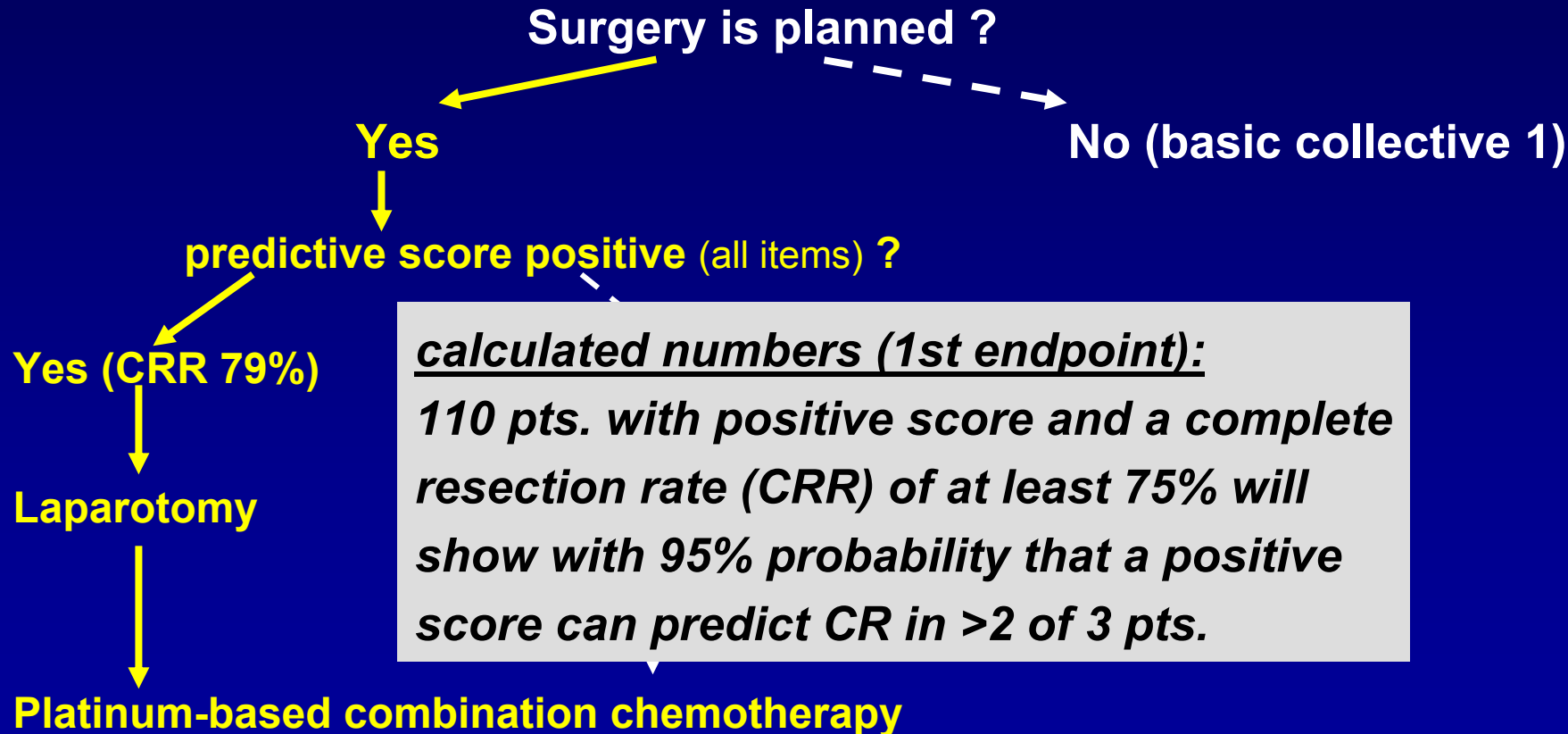
* *exclusively CA 125 (Correlation with ascites)*

***Not significant for complete resection in multivariate model
(multivariate Model with all significant pre-OP variables)***

- **Localization of Recurrent disease (Pelvic vs. others)**
- **Treatment-free-interval**

AGO-DESKTOP II: Prospective Validation of a Predictive Score for Resectability in Platinum-Sensitive ROC (PFS > 6 mos)

- PS ECOG = 0
- no residuals after primary surgery (or, if unknown: initially FIGO I/II)
- absence of ascites > 500 ml



AGO-OVAR OP.2 (DESKTOP II)

Primary objective:

Frequency of complete resection in patients with positive AGO-score?

(frequency = positive predictive factor; PPF)

Secondary objectives:

1. Assessment of selection quotient by applying the score (documentation of all platinum-sensitive relapsed patients within study period).
2. Description of the collective which underwent surgery despite negative AGO-score.
3. Feasibility and complications in surgery in relapsed ovarian cancer in a multicenter setting

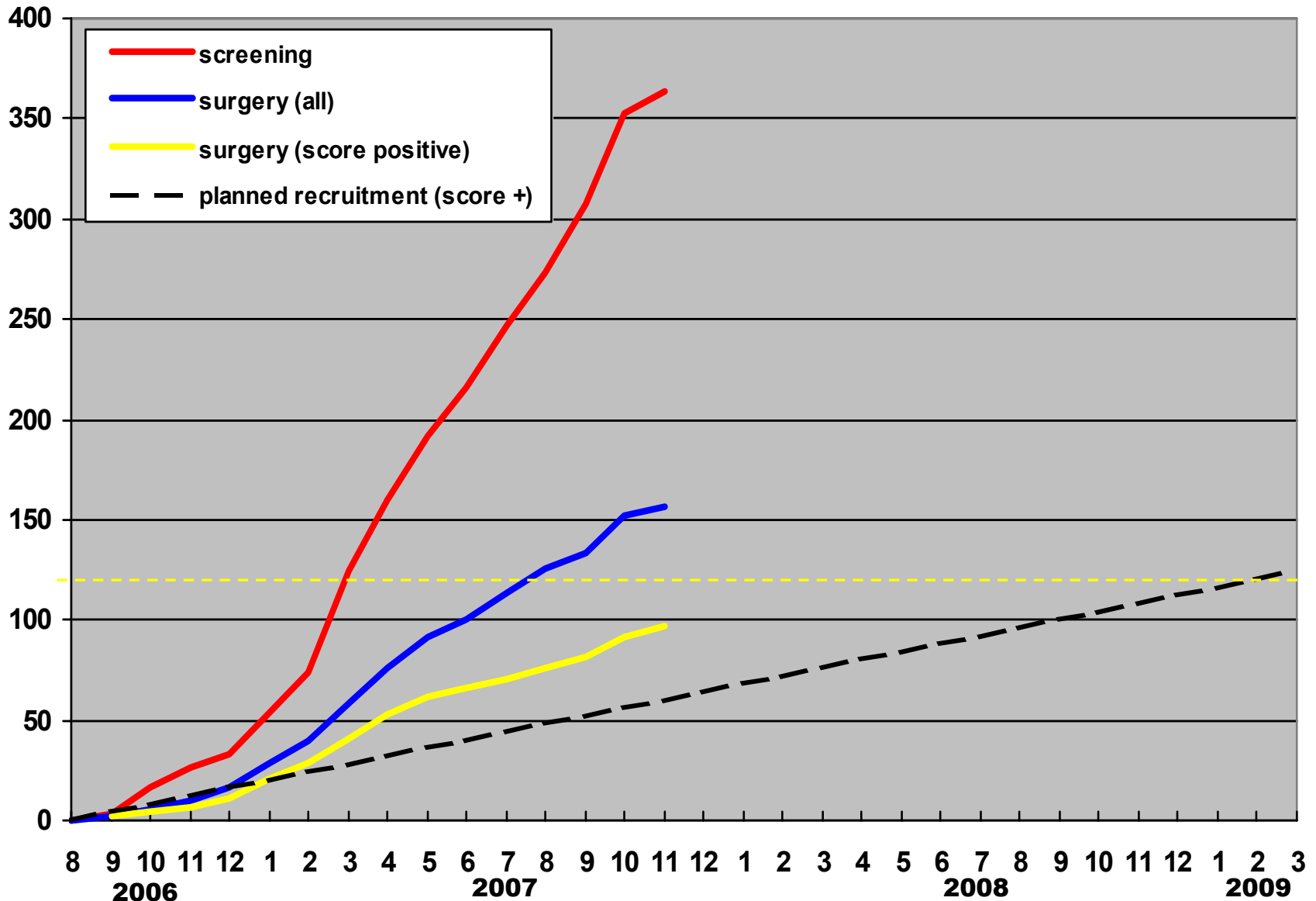
INCLUSION CRITERIA

- 1) Patients with recurrence of invasive epithelial ovarian-, fallopian tube- or primary peritoneal cancer of any initial stage who have relapsed after a tumour-free interval of at least 6 months after completion of first-line therapy. The same interval applies to patients with second relapse who are enrolled after completed platinum-containing re-induction therapy.
- 2) Women aged > 18 years
- 3) Patients who have given their signed and written informed consent to data transmission and -processing.
 - > Informed consent has to be obtained before surgery
 - > Baseline documentation has to be performed before surgery

EXCLUSION CRITERIA

- 1) Patients with non-epithelial tumours as well as borderline tumours.
- 2) Patients who undergo second-look surgery or completion surgery after end of chemotherapy or during the interval (in recurrent ovarian cancer)
- 3) Only for the study collective: patients with second malignancies who have been treated by laparotomy, as well as other neoplasias, if the treatment could interfere with the treatment of relapsed ovarian cancer.
- 4) Patients with third recurrence
- 5) Patients with so-called platinum-refractory tumour, i.e. progression during chemotherapy or recurrence within 6 months after end of former platinum-containing therapy

Recruitment AGO-OVAR OP.2 / DESKTOP II (21.11.2007)



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