# What has been published on QoL & Gyne oncol

The Fall 2018 update

# GCIG studies

- QoL in the AGO-OVAR 16 study (M Friedlander et al.)
- QoL in the ENGOT-OV16/NOVA study (A Oza et al)
- QoL in the SOLO2/ENGOT- Ov 21 (M Friedlander et al)
- QoL in the MITO-8 study (M Piccirillo et al)

# AGO-OVAR 16

- Maintenance therapy w/pazopanib vs placebo
- EOC, after first line chemotherapy
- Health-related quality of life (HRQoL) was a secondary end point in AGO-OVAR 16
- HRQoL was measured with EORTC-QLQ-C30, QLQ-OV28, EQ-5D-3L and QAPFS

Friedlander et al. Ann Oncol 2018

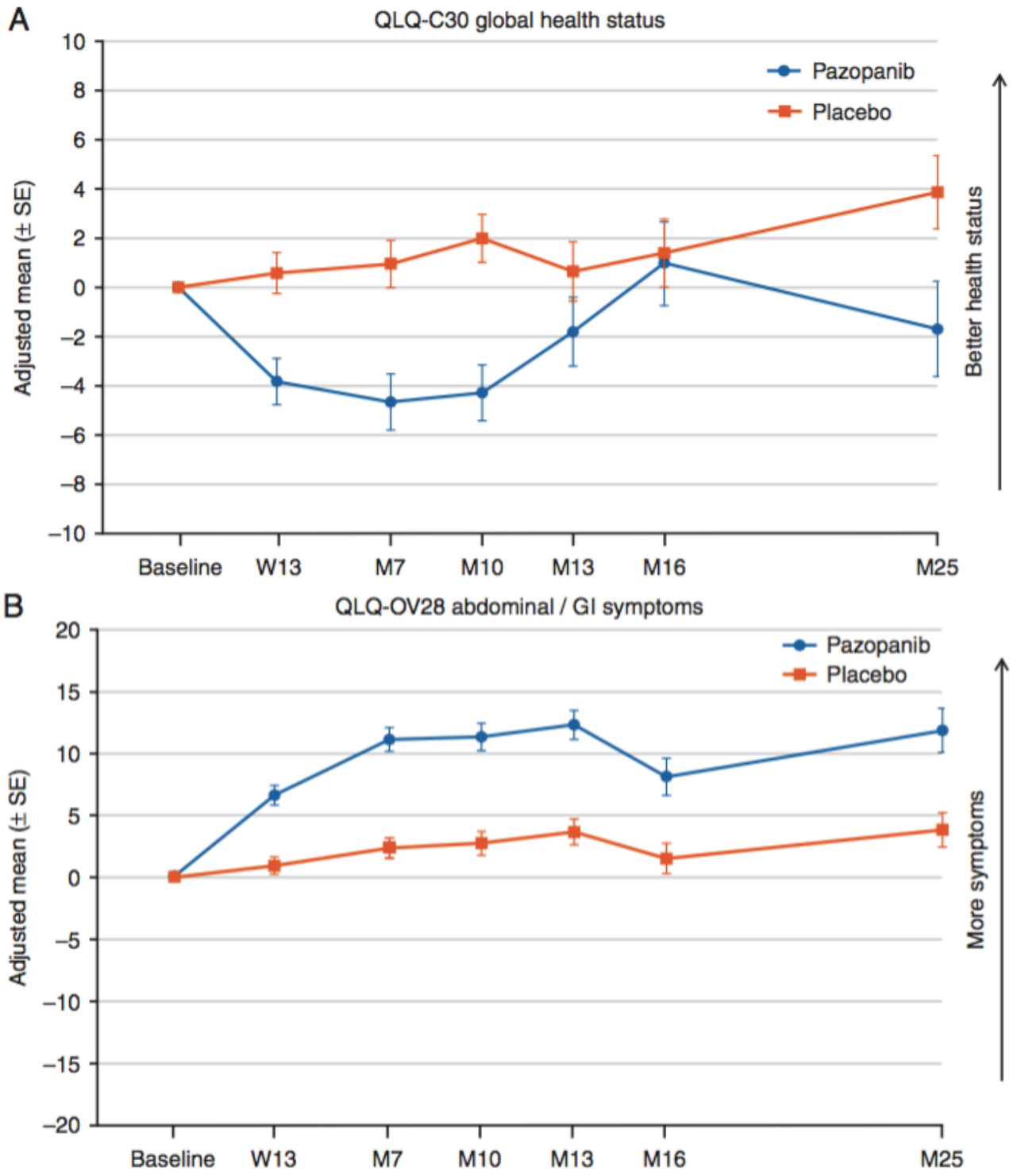
# AGO-OVAR 16

**Table 1. Restricted mean progression-free survival time (PFS) and quality-adjusted progression free survival time (QAPFS) (days)**

| | PFS | | | QAPFS | | |
|---|---|---|---|---|---|---|
| | Pazopanib | Placebo | Difference | Pazopanib (PZ) | Placebo (PL) | Difference |
| (A) Overall population | | | | | | |
| Available *N* | *N* = 455 | *N* = 464 | | *N* = 455 | *N* = 464 | |
| Restricted mean (day 731) (95% CI) | 494 (472–517) | 446 (421–469) | 48 (17–82) | 386 (366–404) | 359 (338–379) | 27 (–1 to 54) |
| *P* value | 0.006 | | | 0.052 | | |
| (B) Subpopulations (Asian versus non-Asian) | | | | | | |
| Asia (available *N*) | *N* = 104 | *N* = 101 | | *N* = 104 | *N* = 101 | |
| Restricted mean (day 731) (95% CI) | 512 (466–560) | 528 (476–579) | –16 (–83 to 55) | 418 (377–459) | 446 (400–490) | –28 (–91 to 30) |
| *P* value | 0.626 | | | 0.372 | | |
| Non-Asia (available *N*) | *N* = 351 | *N* = 363 | | *N* = 351 | *N* = 363 | |
| Restricted mean (day 731) (95% CI) | 488 (461–517) | 424 (395–451) | 65 (27–103) | 375 (353–398) | 336 (314–361) | 39 (6–72) |
| *P* value | <0.001 | | | 0.018 | | |

CI, confidence interval; PL, placebo; PZ, pazopanib.

# AGO-OVAR 16




« Although the analysis showed a trend in favor of PZ, it failed to reach statistical significance in the overall population which is a clear demonstration of how the AE's of PZ negate the PFS gain »

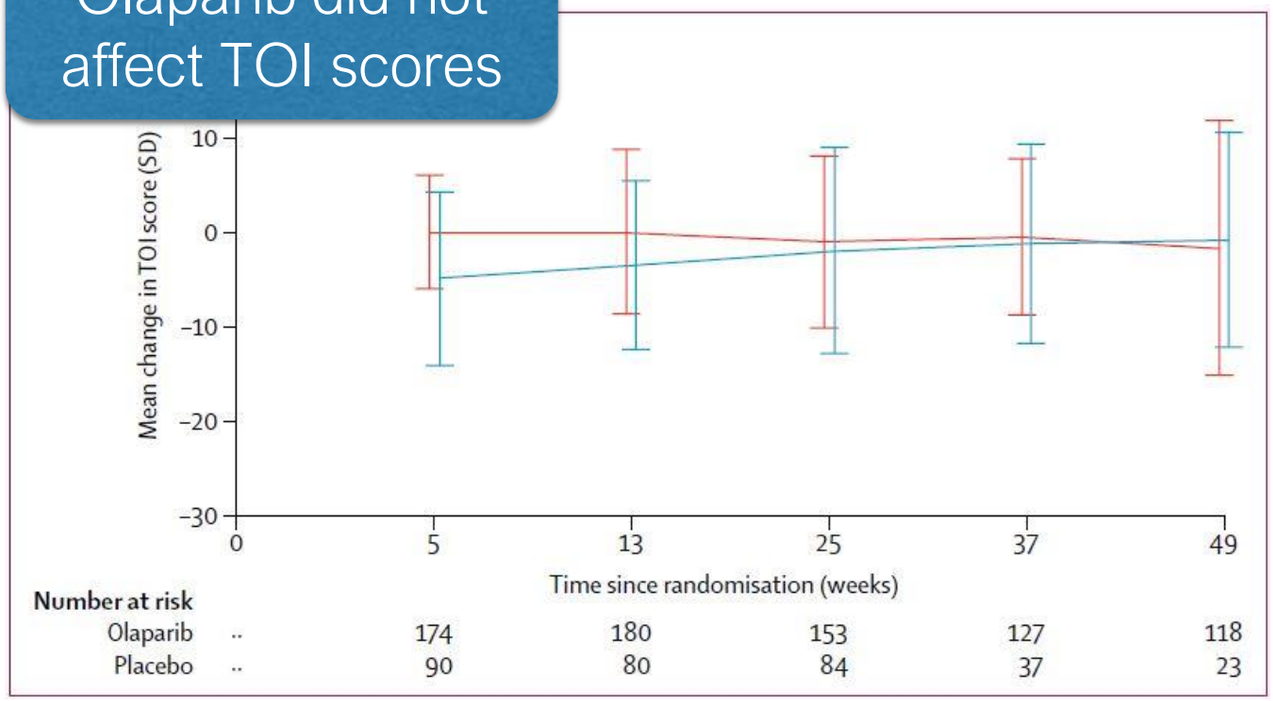
# SOLO2/ENGOT Ov21

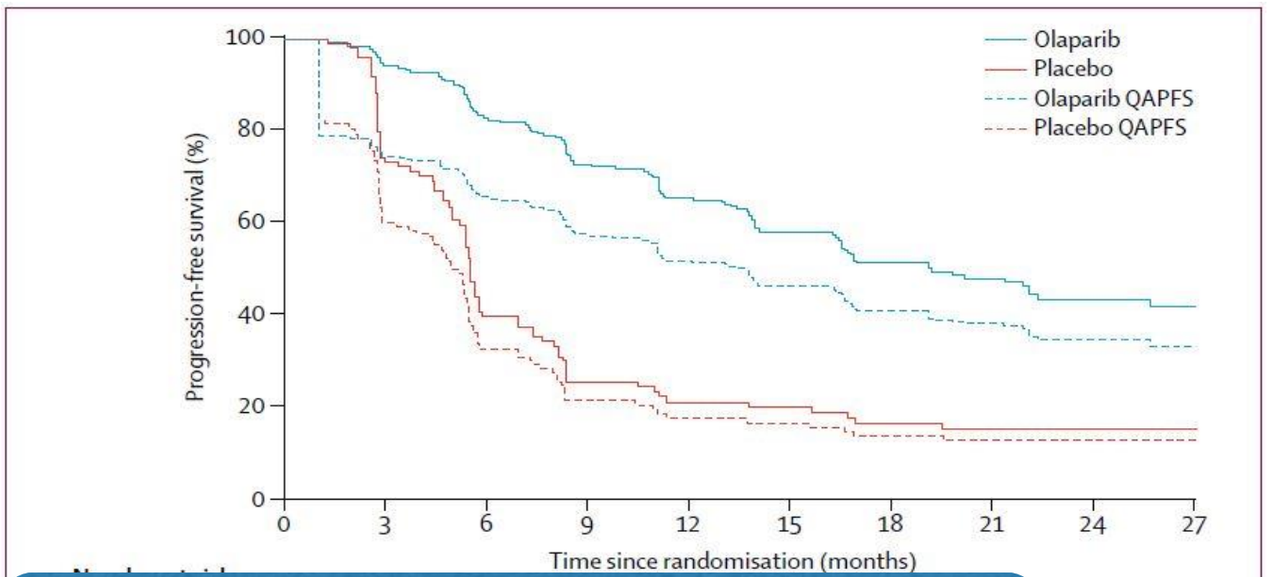
- Maintenance therapy w/olaparib tablets vs placebo
- HGSOC or HGEOC, BRCA1/2m, 2nd+line
- HRQoL as the change from baseline FACT-O TOI (Trial Outcome Index) during the first year on treatment, QAPFS and QTWIST(Time w/o symptoms of toxicity)

Friedlander et al. Lancet Oncol 2018

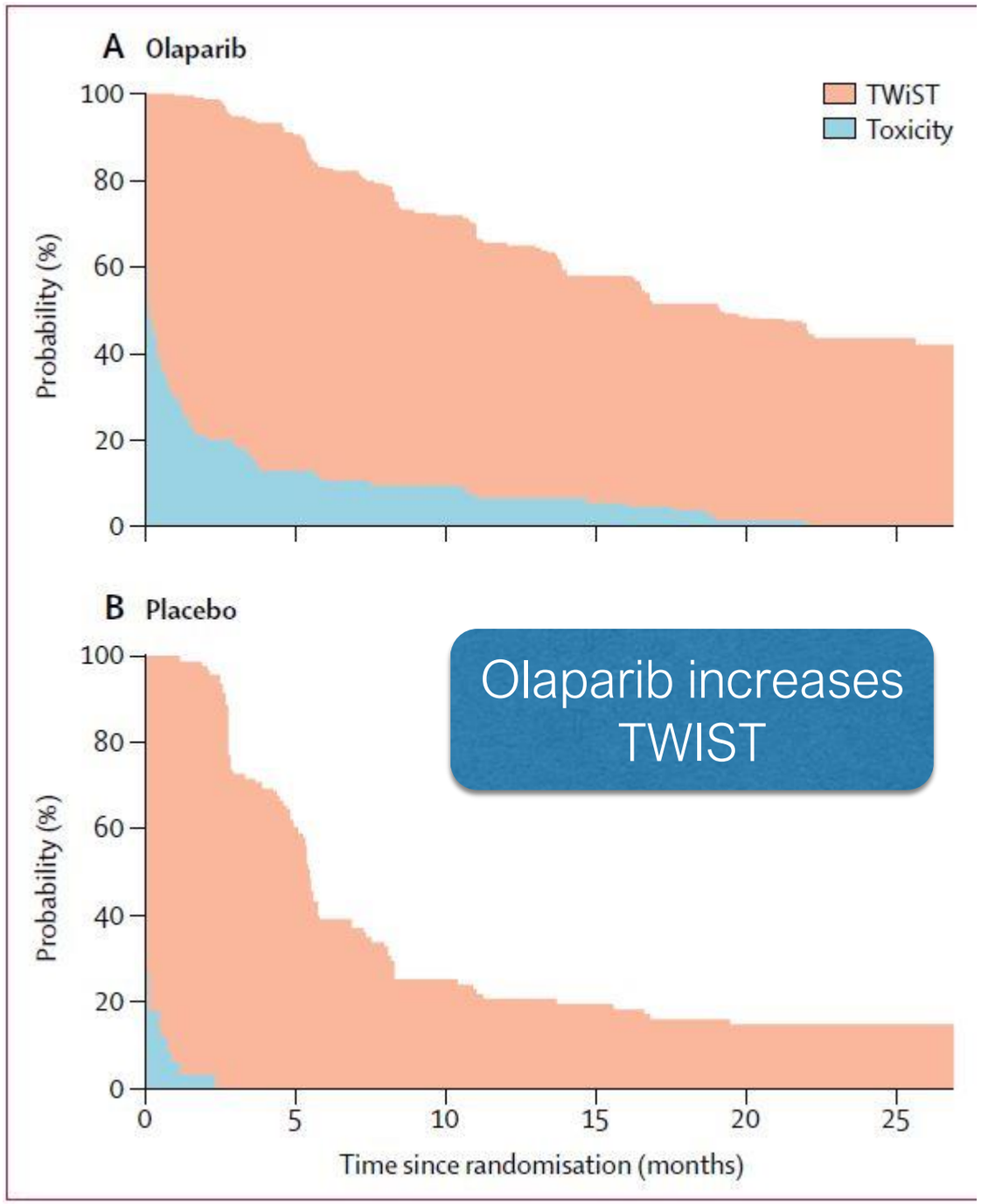
# SOLO2/ENGOT Ov21

Olaparib did not affect TOI scores




Olaparib associated w/significant improvement in QAPFS



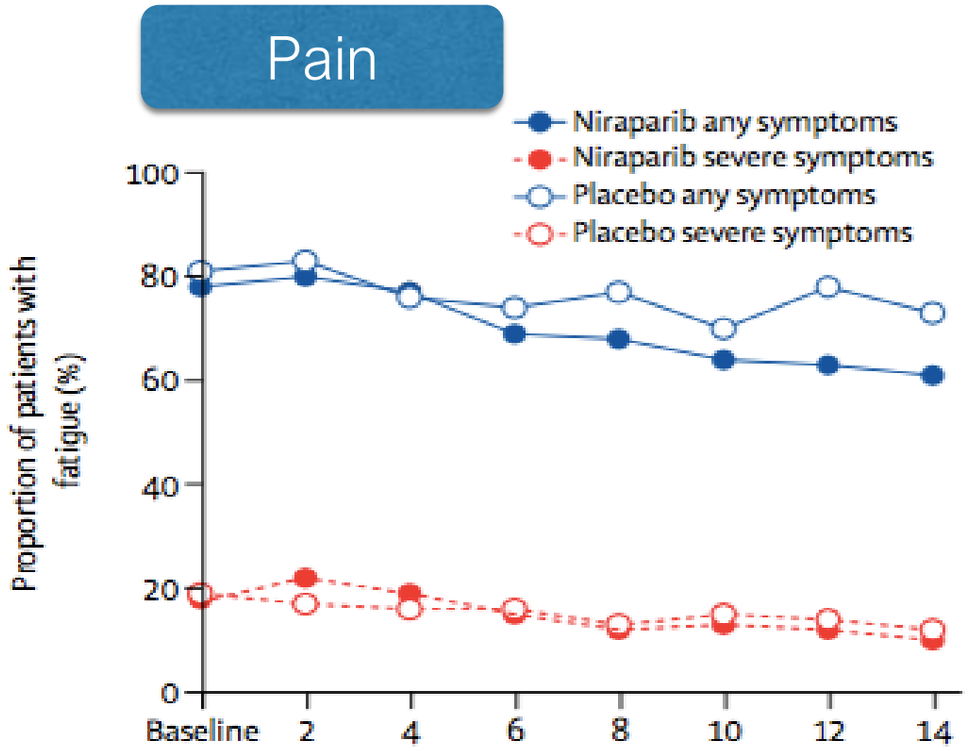

Olaparib increases TWIST

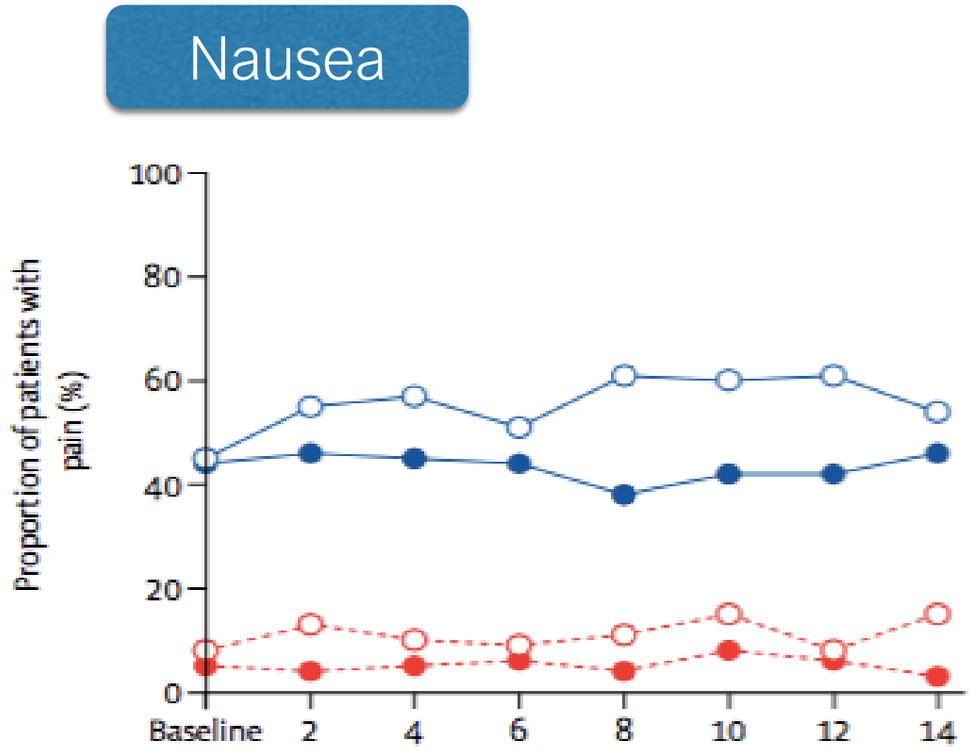
# ENGOT OV 16 NOVA

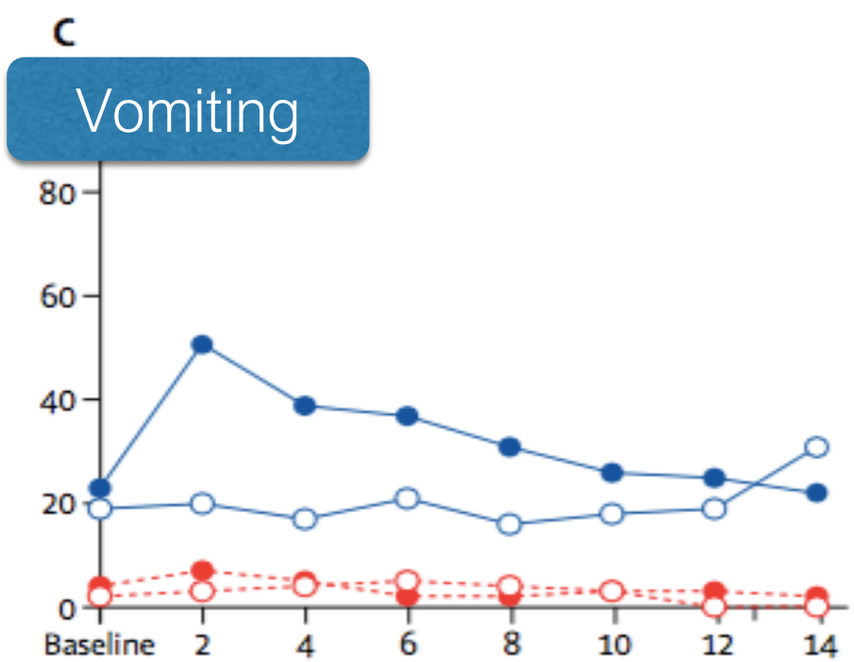
- Maintenance therapy w/niraparib vs placebo
- EOC, platinum-sensitive relapse, PR/CR, 2 cohorts (gBRCAmut/non gBRCAmut)
- Health-related quality of life (HRQoL) was a secondary end point in NOVA
- HRQoL was measured with PROs (FOSI, EQ 5D 5L, EQ VAS)

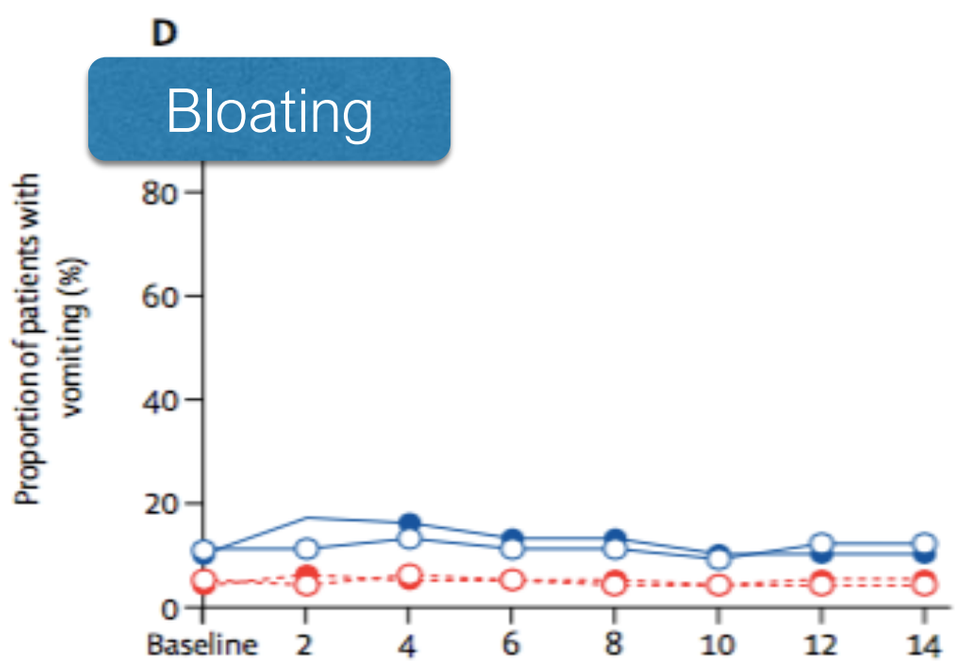
Oza et al. Lancet Oncol 2018

# ENGOT OV 16 NOVA

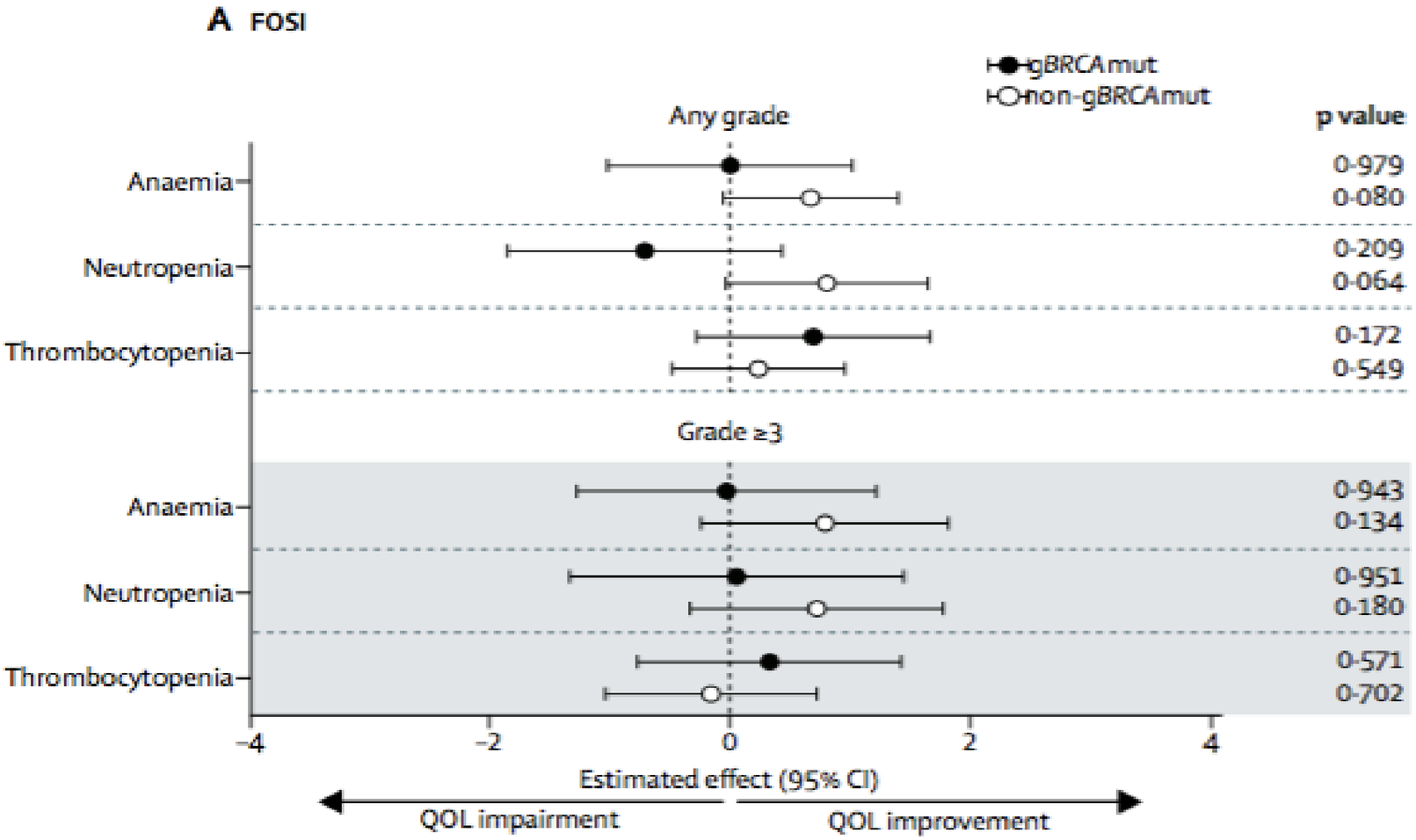


# ENGOT OV 16 NOVA




These PRO data suggest that women who receive niraparib as maintenance treatment for platinum- sensitive recurrent ovarian cancer after response to platinum treatment are able to maintain a QOL similar to placebo during their treatment.

# MITO-8

- EOC partially platin-sensitive
- PBC-NPBC or the reverse sequence (experimental)
- PFI increased in NPBC-PBC but in PFS after treatment 2 or OS better in control arm
- Analysis of QoL in the 1st treatment sequence (PBC vs NPBC
- EORTC QLQ C030, EORTC QLQ-OV28

Piccirillo et al. Ann Oncol 2018

# MITO-8

**Table 1. Best quality of life response by treatment arm**

| Scale/item | PBC | | | | | | NPBC | | | | | | *P* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Improved | | Stable | | Worse | | Improved | | Stable | | Worse | | |
| Global health status/QoL | 24 | (38.71%) | 19 | (30.65%) | 19 | (30.65%) | 11 | (22.92%) | 13 | (27.08%) | 24 | (50.00%) | 0.09 |
| Physical functioning | 12 | (18.75%) | 34 | (53.13%) | 18 | (28.13%) | 6 | (12.24%) | 23 | (46.94%) | 20 | (40.82%) | 0.32 |
| Role functioning | 21 | (32.81%) | 22 | (34.38%) | 21 | (32.81%) | 11 | (22.45%) | 15 | (30.61%) | 23 | (46.94%) | 0.27 |
| Emotional functioning | 26 | (41.27%) | 21 | (33.33%) | 16 | (25.40%) | 5 | (10.42%) | 22 | (45.83%) | 21 | (43.75%) | **0.001** |
| Cognitive functioning | 20 | (31.75%) | 24 | (38.10%) | 19 | (30.16%) | 9 | (18.37%) | 20 | (40.82%) | 20 | (40.82%) | 0.24 |
| Pain | 27 | (42.19%) | 15 | (23.44%) | 22 | (34.38%) | 9 | (18.37%) | 19 | (38.78%) | 21 | (42.86%) | **0.02** |
| Peripheral neuropathy | 14 | (22.58%) | 6 | (9.68%) | 42 | (67.74%) | 12 | (25.53%) | 13 | (27.66%) | 22 | (46.81%) | **0.03** |
| Other chemotherapy side-effects | 7 | (11.29%) | 9 | (14.52%) | 46 | (74.19%) | 9 | (19.15%) | 15 | (31.91%) | 23 | (48.94%) | **0.02** |

In conclusion, the QoL analysis of MITO-8 overall supports the primary conclusion of the study in favour of immediate retreatment with PBC

# Non-GCIG publications

- Fear of recurrence among older breast, ovarian, endometrial, and colorectal cancer survivors: findings from the WHI LILAC study

- Cancer Worry Scale (CWS), RAND-36 physical functioning subscale, MOS-Social Support Questionnaire

- Ovarian (n=83), endometrial (n=493), mean age 77

- 73 (14.8%) of 493 with endometrial, 16 (19.3%) of 83 with ovarian cancers were in the high FCR group

- Older pts, widows, and never married: less FCR

- Having received chemo: more FCR

Krok-Schoen JL and al. Psychooncology 2018

# Non-GCIG publications

- Quality of life, symptoms and care needs in patients with persistent or recurrent platinum-resistant ovarian cancer: An NRG Oncology/ Gynecologic Oncology Group study

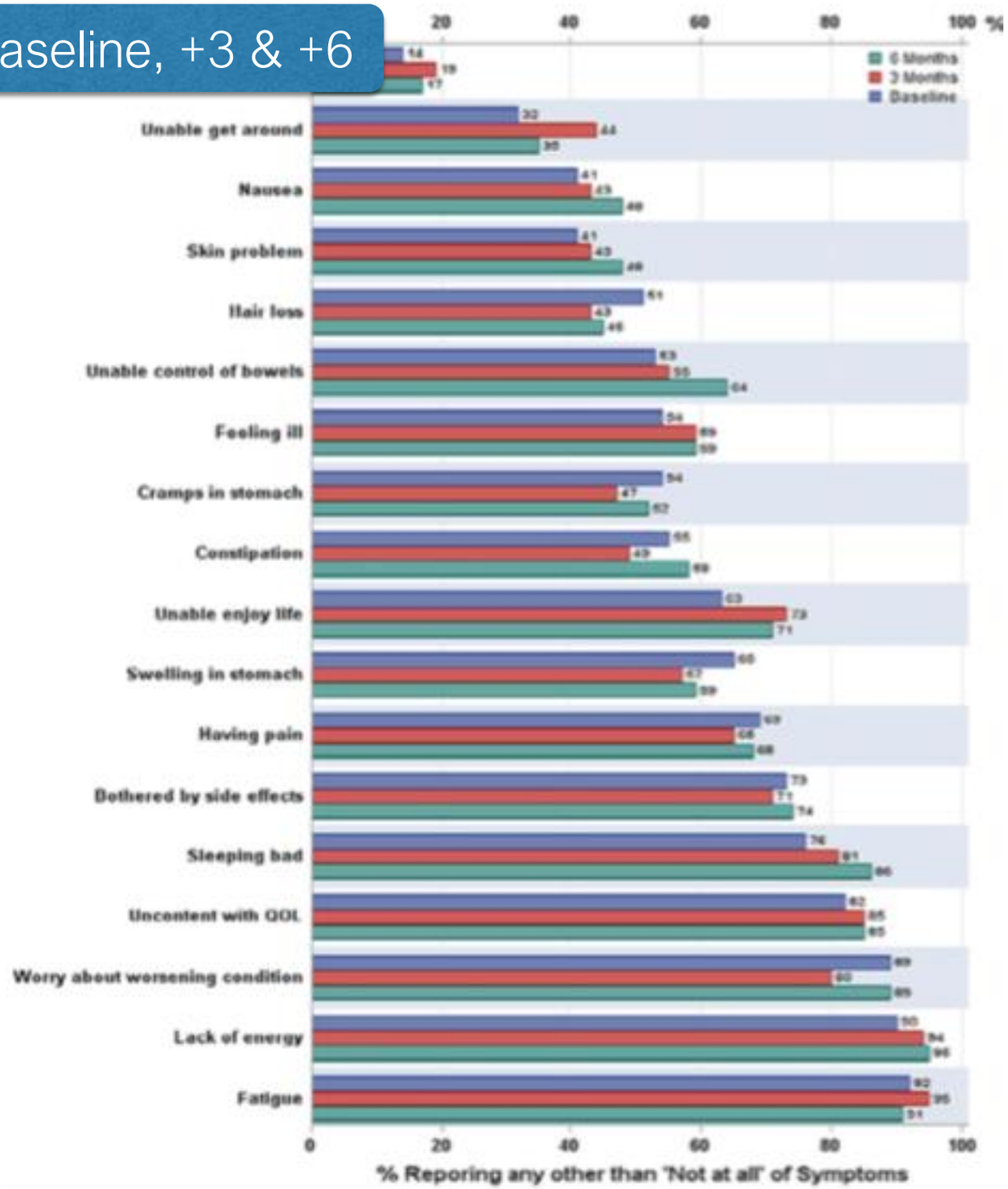
- 102 persistent or recurrent platinum-resistant ovarian cancer with an estimated life expectancy of at least 6 months.

- The Needs at the End-of-Life Screening Tool (NEST), FACIT-Fatigue (FACIT-F), NCCN-FACT Ovarian Symptom Index [NFOSI-18]; Disease Related Symptoms (DRS), Treatment Side Effects (TSE), and Function/Well Being (F/WB) were collected at study entry, 3 and 6 months

Van Gruenigen et al Gynecol Oncol 2018

# Non-GCIG publications

Baseline, +3 & +6




« The most common NEST unmet needs were in the symptom dimension »

Are these adequate PRO tools ?

Van Gruenigen et al Gynecol Oncol 2018

# Where to investigate ?

- Long survivors
- End of life
- Putting adequate PRO tools in line with the questions
- Combining QoL with outcome issues is mandatory in all GCIG trials