RELAPSED OVARIAN CANCER

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ENGAGE
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Who needs sugery in relapsed ovarian cancer?

What are the goals?

Improving **QoL**	Increasing **PFS**	Increasing OAS
		

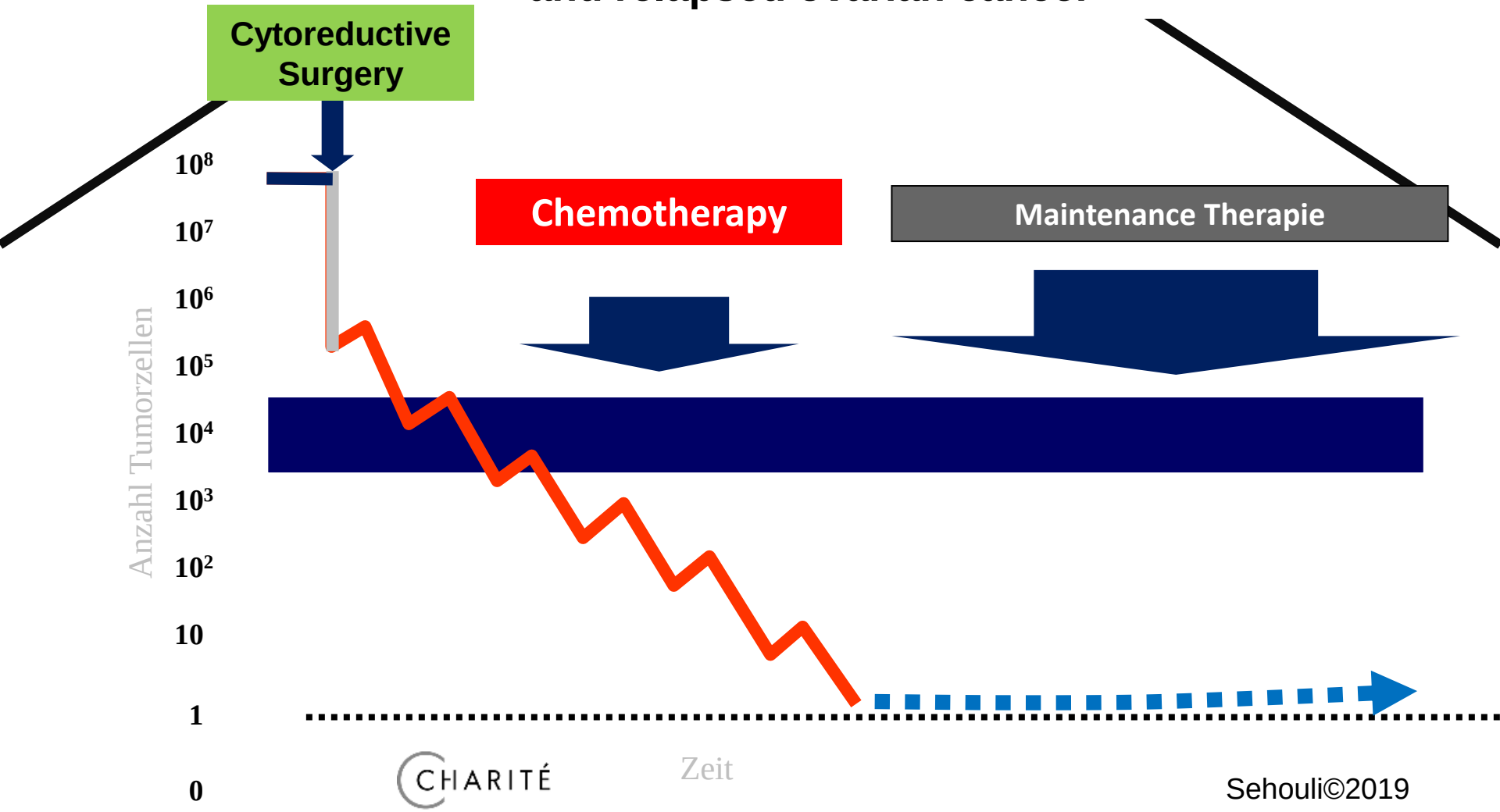
What factors influence the treatment decision making process („the Charité-algorhytm“)

- Current syptoms?, tumor pattern?
- Therapie free and progression free interval? (platinum resistance *yes/no*, relative or platinumsensitive?)
- General and functional status
- Relevant comorbidities? comedication?
- Side effects and complications of previous therapies?
- Ressources to overcome complications?
- Quality and results of the surgical and medical therapies?
- Previous therapy with bevacizumab?
- Tumorbiology (BRCA-Test?)
- Surgery vs. Surgery + medical therapy vs medical therapy vs best supportive care
- <u>Motivation of the patients (preference, attitude)</u>
- Treatment options?
- <u>Study participation?</u>

Treatment decision

CHARITÉ

The „Three Cornerstone Model“ in the management of primary and relapsed ovarian cancer

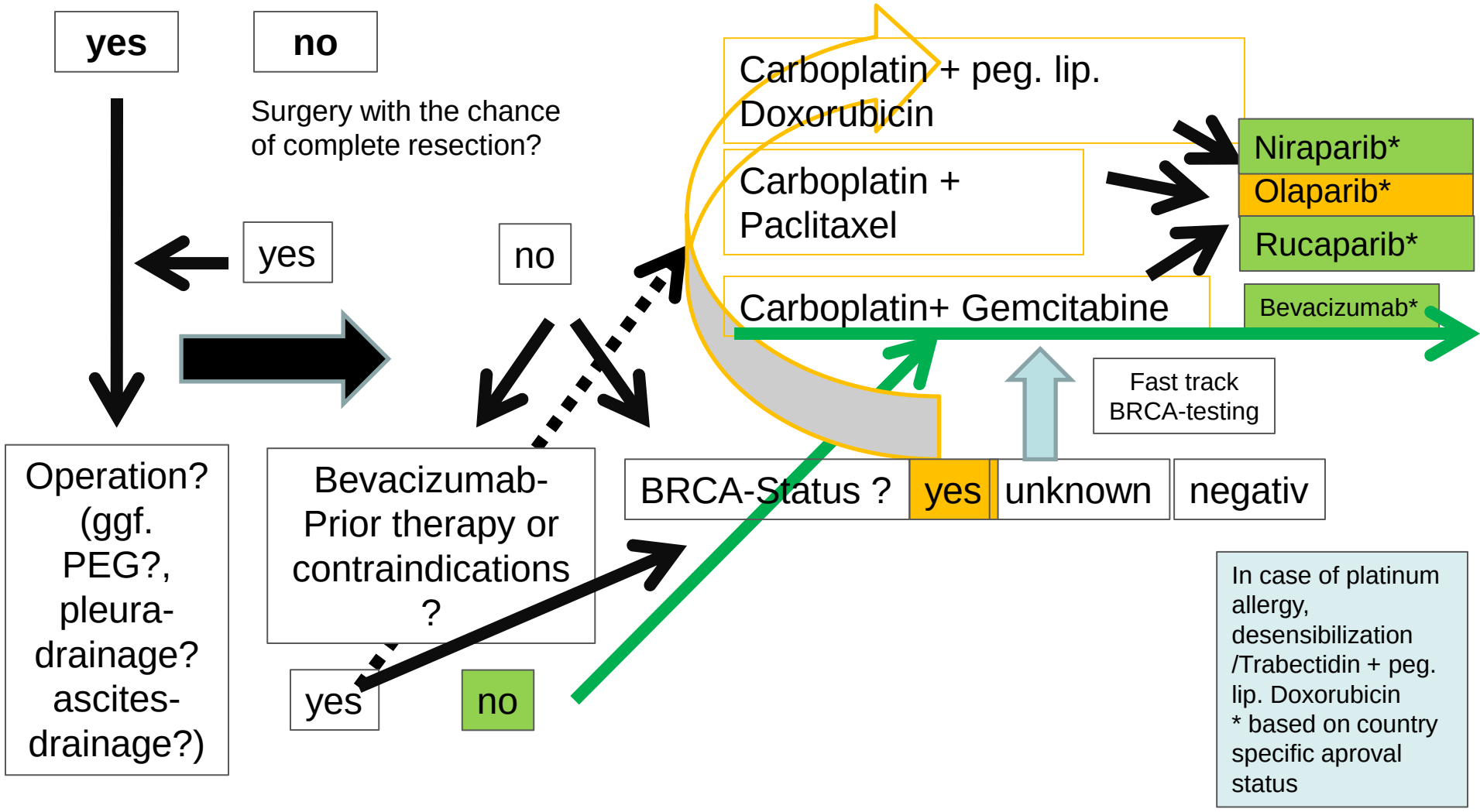


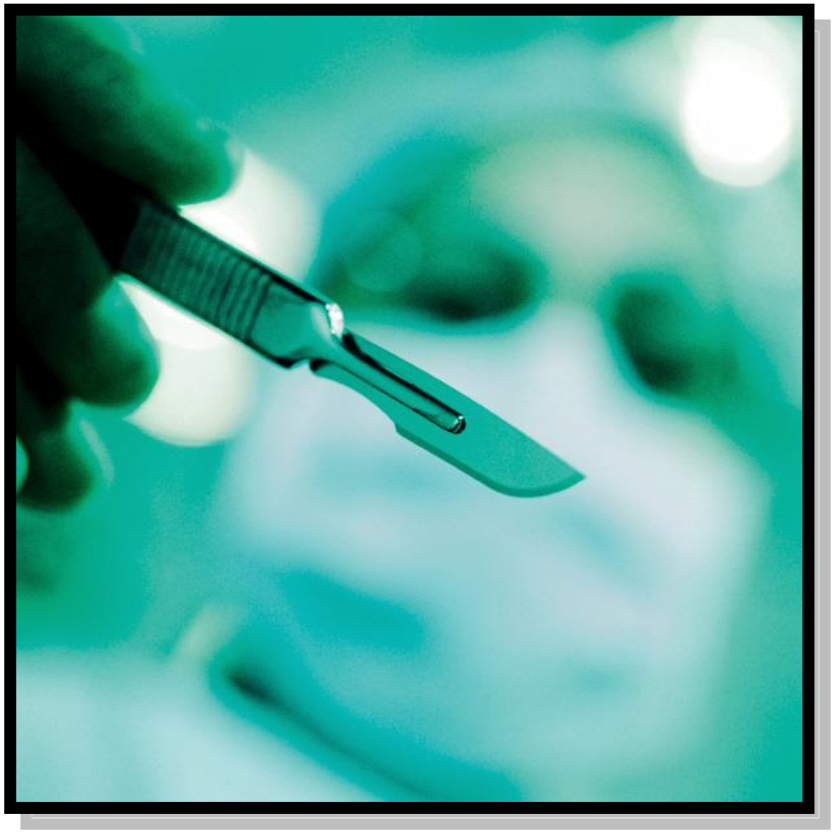
CHARITÉ

CHARITÉ

Personalized Strategies in Relapsed Ovarian Cancer

Symptoms?
Bowel obtruction? (Subileus/Ileus), Pleural effusion?/Ascites?





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Design: AGO DESKTOP III

(ENGOT-ov20; NCT01166737)

Pts. with:

- 1st relapse
- PSROC
- AGO Score +ve

R
n = 408

Cytoreductive Surgery with max. effort for complete resection → **Platinum-based Combination therapy** *strongly recommended*

No OP → **Immediate Platinum-based Combination therapy** *strongly recommended* → OP Allowed *3rd line*

- 80 centres in 12 countries
- Recruitment 9/2010 - 3/2015
- 407 pts evaluable

AGO DESKTOP III: translation into daily routine

(AGO–OVAR OP.4; ENGOT-ov20; NCT01166737)

- **Patients with recurrent ovarian cancer and a platinum-free interval > 6 months should be evaluated regarding their eligibility for cytoreductive surgery:**
  - **AGO Score, imaging, patient & tumor characteristics**
- **and should be counseled for the options of secondary surgery (in specialized and experienced centres):**
  - **50% AGO Score positive in pts with platinum-free interval > 6 mos**
  - **75% complete resection in AGO Score positive pts**
  - **median survival gain > 12 mos *if complete resection* is achieved**

Final overall survival results from SOLO2/ENGOT-ov21: a Phase III trial assessing maintenance olaparib in patients with platinum-sensitive, relapsed ovarian cancer and a BRCA mutation

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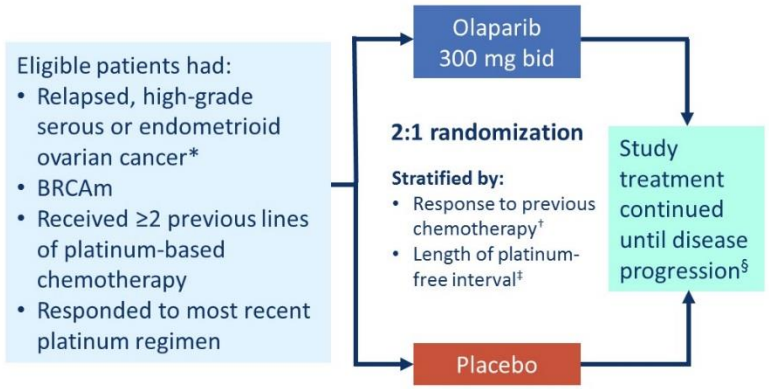
ClinicalTrials.gov identifier: NCT01874353. This study was sponsored by AstraZeneca and is part of an alliance between AstraZeneca and Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA

Presented By Andres Poveda at TBD

SOLO2: study design



Primary endpoint

- Investigator-assessed PFS

Time-dependent secondary endpoints

- **Overall survival**
- PFS2
- TFST
- TSST
- TDT
- HRQoL¶

Final analysis

DCO: Feb 3, 2020

- Planned for **60% data maturity** (~177 events)
- **Prespecified adjusted OS analysis (RPSFT model, re-censored):** to adjust for subsequent PARP inhibitor therapy in placebo group
- ***Post hoc* OS sensitivity analysis (eCRF)**: to correct for patients mis-stratified at randomization
- **Prespecified OS sensitivity analysis**: Myriad gBRCAm subgroup

*Includes primary peritoneal of fallopian tube cancer; †Complete or partial response; ‡>6–12 or >12 months; §Or until discontinuation criteria were met, and treatment could continue beyond progression if the investigator deemed the patient be experiencing benefit; ¶Assessed by the TOI of the FACT-O
eCRF, electronic case report form; gBRCAm, germline BRCA mutation; FACT-O, Functional Assessment of Cancer Therapy – Ovarian; HRQoL, health-related quality of life; PFS2, time to second progression; RPSFT, rank preserving structural failure time model; TDT, time to study treatment discontinuation or death; TFST, time to first subsequent therapy or death; TOI, trial outcome index; TSST, time to second subsequent therapy or death

Presented By Andres Poveda at TBD

SOLO2: patient characteristics

	Olaparib (N=196)	Placebo (N=99)
Primary tumor location, n (%)		
Ovary	162 (83)	86 (87)
Fallopian tube or primary peritoneal	31 (16)	13 (13)
Other	2 (1)	0
Missing	1 (1)	0
Histology, n (%)		
Serous	183 (93)	86 (87)
Endometrioid	9 (5)	8 (8)
Mixed	3 (2)	5 (5)
Missing	1 (1)	0
gBRCAm by Myriad testing, n (%)		
BRCA1	132 (67)	61 (62)
BRCA2	58 (30)	35 (35)
Missing*	6 (3)	3 (3)
ECOG performance status, n (%)		
0	162 (83)	77 (78)
1	32 (16)	22 (22)
Missing	2 (1)	0

Percentages may not total 100% because of rounding

*Patients with a confirmed gBRCAm by local testing, but without confirmed gBRCAm status as part of this trial. ECOG, Eastern Cooperative Oncology Group

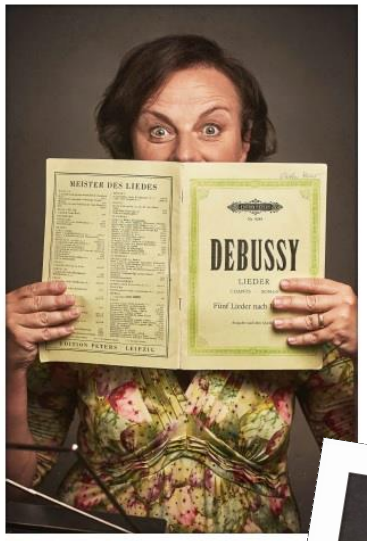
Presented By Andres Poveda at TBD

Conclusions

- **SOLO2 is the first Phase III trial of maintenance PARP inhibitor therapy to report OS data for women with PSROC and a BRCAm since the introduction of platinum-based chemotherapy**
  - Maintenance olaparib provided a clinically meaningful prolongation of median OS by 12.9 months over placebo
- **At 5 years, 42% of patients treated with olaparib were alive**
  - 22% of patients remained on maintenance olaparib for ≥5 years
  - Time to first subsequent therapy was improved with olaparib vs placebo
- **Few additional AEs, and dose modifications or discontinuations due to AEs, occurred in olaparib patients with longer-term treatment**
  - MDS/AML incidences should be interpreted in the context of their late onset and the longer OS observed with olaparib vs placebo; potential risk factors will be further explored

Presented By Andres Poveda at TBD

„Ich lebe!“



Carolin Masur

Erstdiagnose Eierstockkrebs: 2005

*„Ich habe das große Glück, meine Energie für d
und die Musik wiedergefunden zu habe
Dankbar dafür teile ich diese Leidenschaft*

„Ich lebe!“

„Ich lebe!“

Dorothea Müller

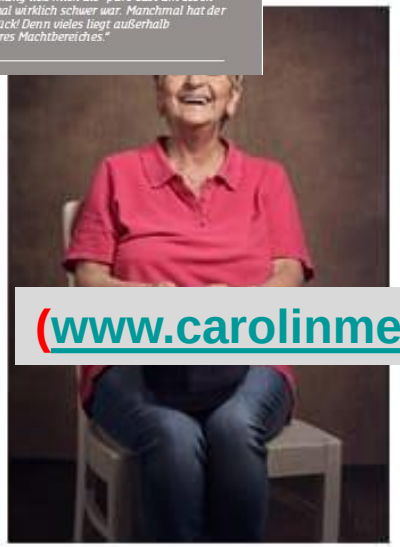
Erstdiagnose Eierstockkrebs: 2003 | Rezidiv: 2006

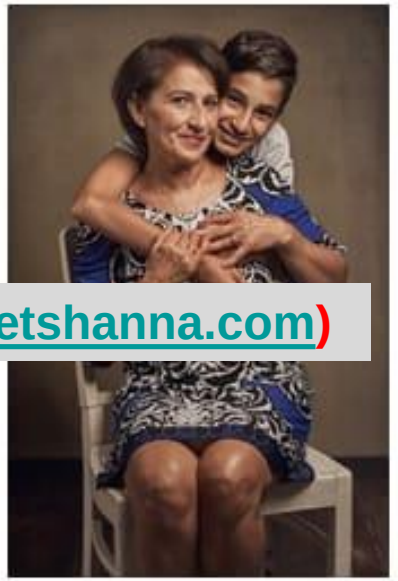
„Während meiner Erkrankung ließ mich die "pure Lust am Leben" durchhalten, was manchmal wirklich schwer war. Manchmal hat der Mensch auch Glück! Denn vieles liegt außerhalb unseres Machtbereiches."

„Ich lebe!“

Und was ist Ihr persönliches Lebenselixier?

o exhibition **I'M ALIVE!** made its debut. Sponsored by TESARO
German Ovarian Cancer Foundation, photos depicted long-term
her with the person, item or pastime that encouraged them to
r fight. Foundation co-founder, Prof. Dr. Jalid Sehouli, opened
en's stories and sharing the purpose of this traveling exhibition:
their own motivation as they bravely face cancer. Next stop will
around Germany. Thank you to TESARO DACH for living our
oices!





(www.carolinmeetshanna.com)

ASCO 2020 - Abstract 12065

Fatigue in long-term survivors with ovarian cancer: Results of Expression VI – Carolin meets HANNA – Holistic Analysis of Long-term survival with Ovarian Cancer: the international NOGGO, ENGOT and GCIG survey

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H. Woopen[1,2], M. Keller[2], E. I. Braicu[1,2], D. Zocholl[3], P. Krabisch[2,4], T. Boxler[2,5], P. Barretina-Ginesta[6], C. Mendiola[7], J. Lafleur[8], D. Reimer[9], V. Heinzelmann[10], E. Samartzis[11], M. A. Vardar[12], C. Taskiran[13], I. Vergote[14], E. van Nieuwenhuysen[14], J. Sehouli[1,2]

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GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

European Network of Gynaecological Oncology Trials Groups
ENGOT

Figure 3:
Side effects that are still present

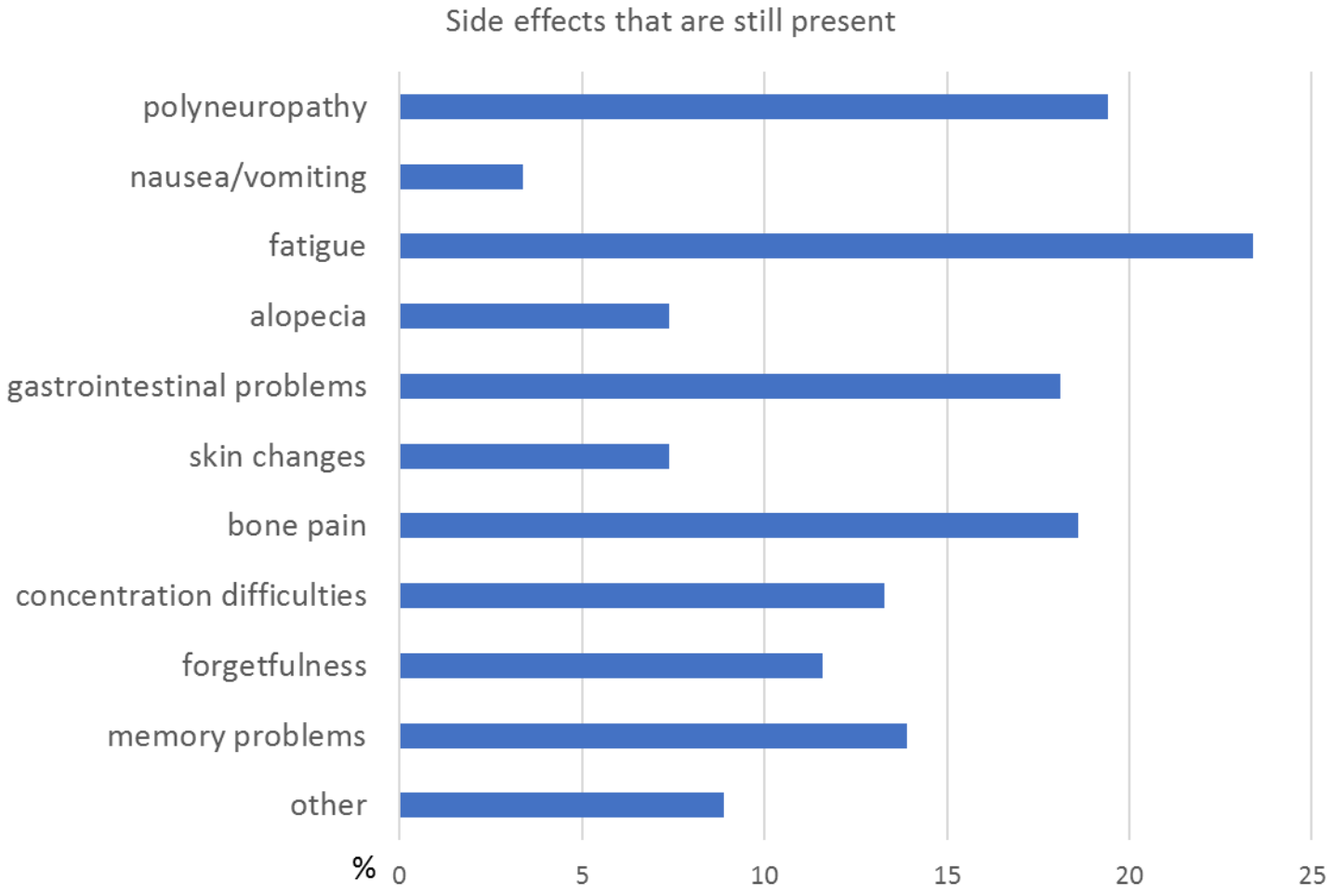

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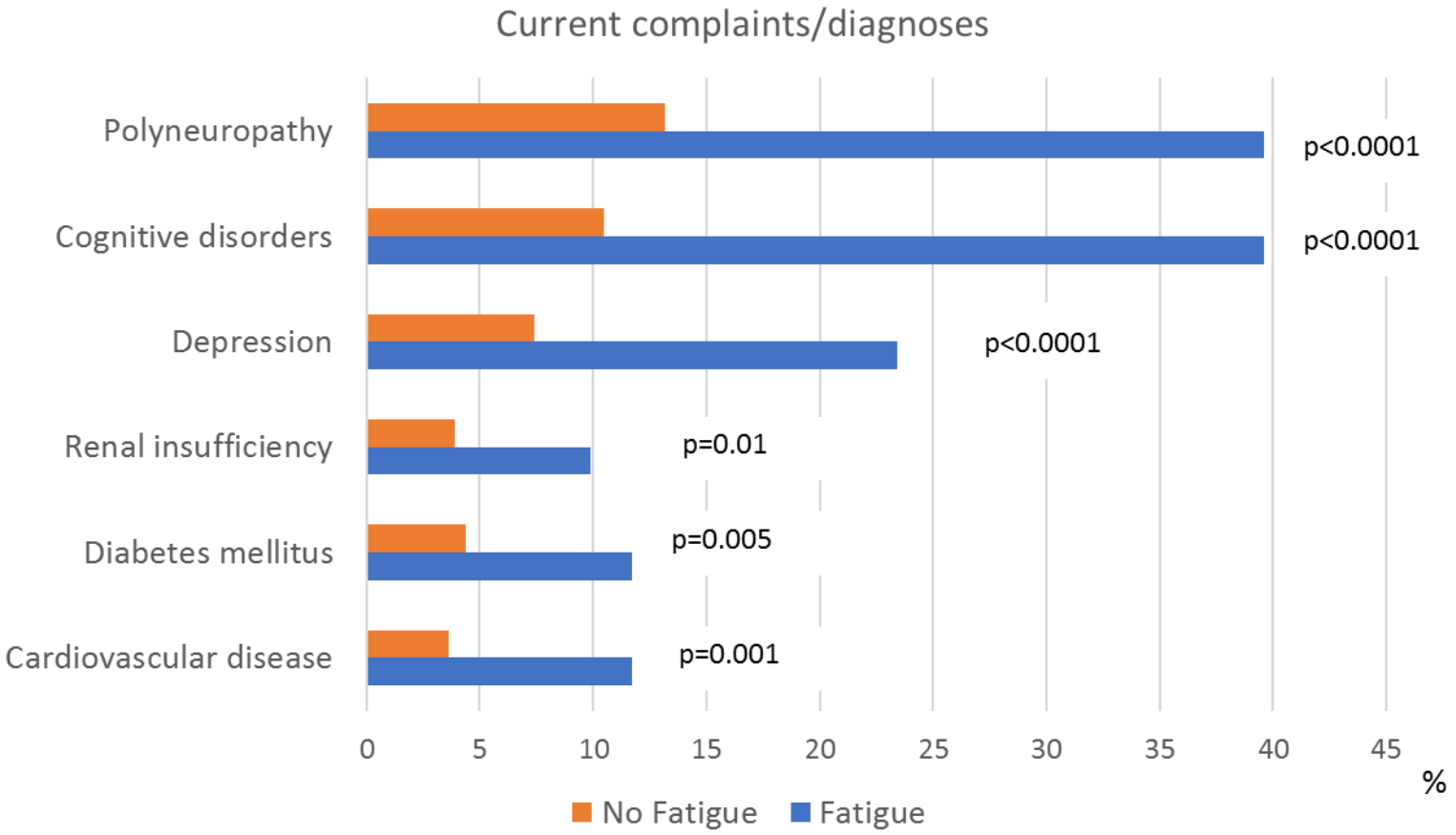
Figure 4.1: Current complaints/diagnoses in association with fatigue



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