MAYO CLINIC

What is new on gynecological malignancies in 2020

Cervical cancers, Endometrial cancers and Ovarian cancers

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15th Annual New Orleans Cancer Conference
New Orleans, Louisiana

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- **Gynecologic Tumors**

  Cervical
  Uterine
  Ovarian

CA: A Cancer Journal 2020

ated New Cases

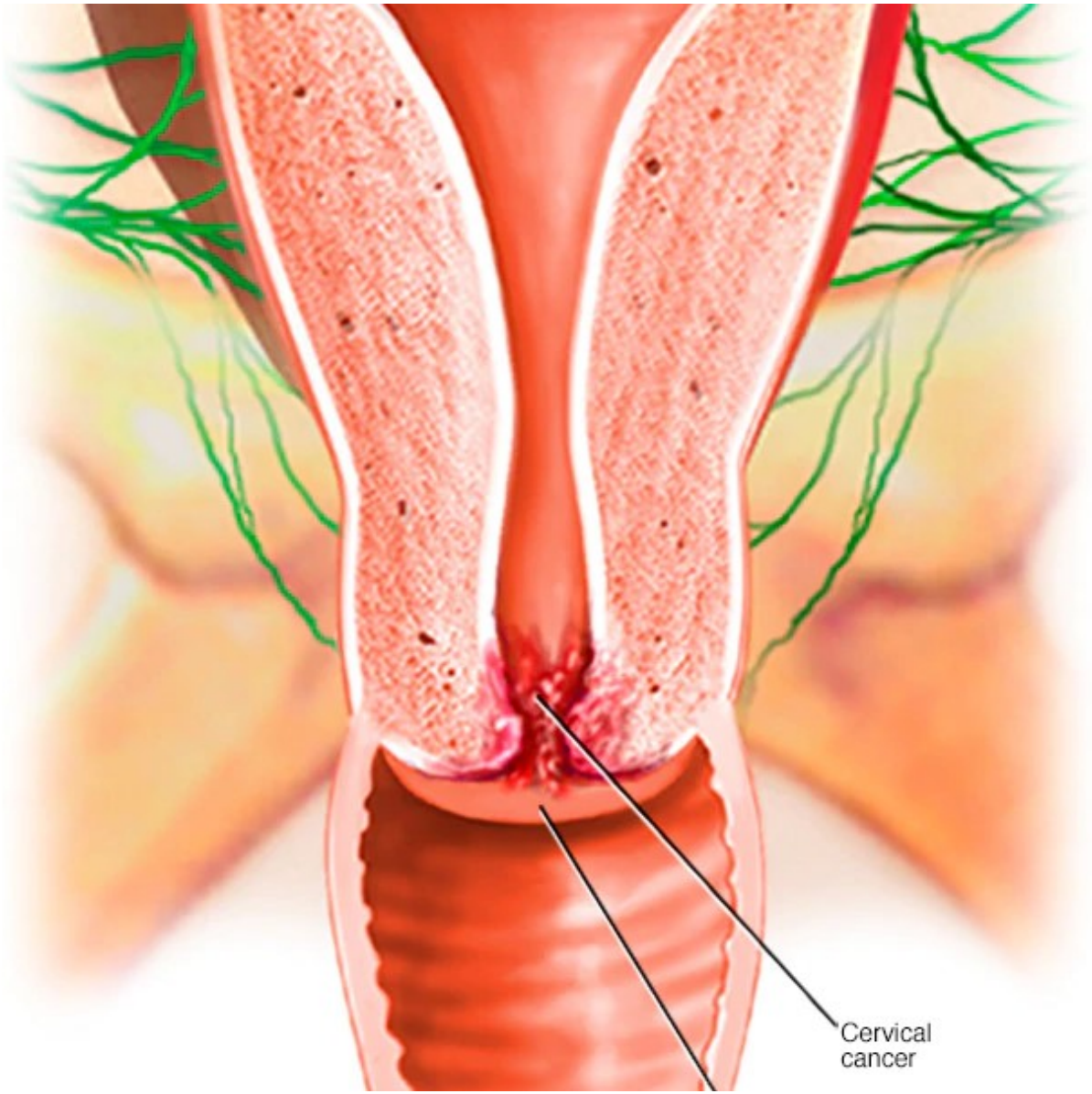
			Males	Females		
Prostate	191,930	21%			Breast	276,480
Lung & bronchus	116,300	13%			Lung & bronchus	112,520
Colon & rectum	78,300	9%			Colon & rectum	69,650
Urinary bladder	62,100	7%			Uterine corpus	65,620
Melanoma of the skin	60,190	7%			Thyroid	40,170
Kidney & renal pelvis	45,520	5%			Melanoma of the skin	40,160
Non-Hodgkin lymphoma	42,380	5%			Non-Hodgkin lymphoma	34,860
Oral cavity & pharynx	38,380	4%			Kidney & renal pelvis	28,230
Leukemia	35,470	4%			Pancreas	27,200
Pancreas	30,400	3%			Leukemia	25,060
All Sites	**893,660**	**100%**			**All Sites**	**912,930**

ated Deaths

			Males	Females		
Lung & bronchus	72,500	23%			Lung & bronchus	63,220
Prostate	33,330	10%			Breast	42,170
Colon & rectum	28,630	9%			Colon & rectum	24,570
Pancreas	24,640	8%			Pancreas	22,410
iver & intrahepatic bile duct	20,020	6%			Ovary	13,940
Leukemia	13,420	4%			Uterine corpus	12,590
Esophagus	13,100	4%			Liver & intrahepatic bile duct	10,140
Urinary bladder	13,050	4%			Leukemia	9,680
Non-Hodgkin lymphoma	11,460	4%			Non-Hodgkin lymphoma	8,480
rain & other nervous system	10,190	3%			Brain & other nervous system	7,830
All Sites	**321,160**	**100%**			**All Sites**	**285,360**

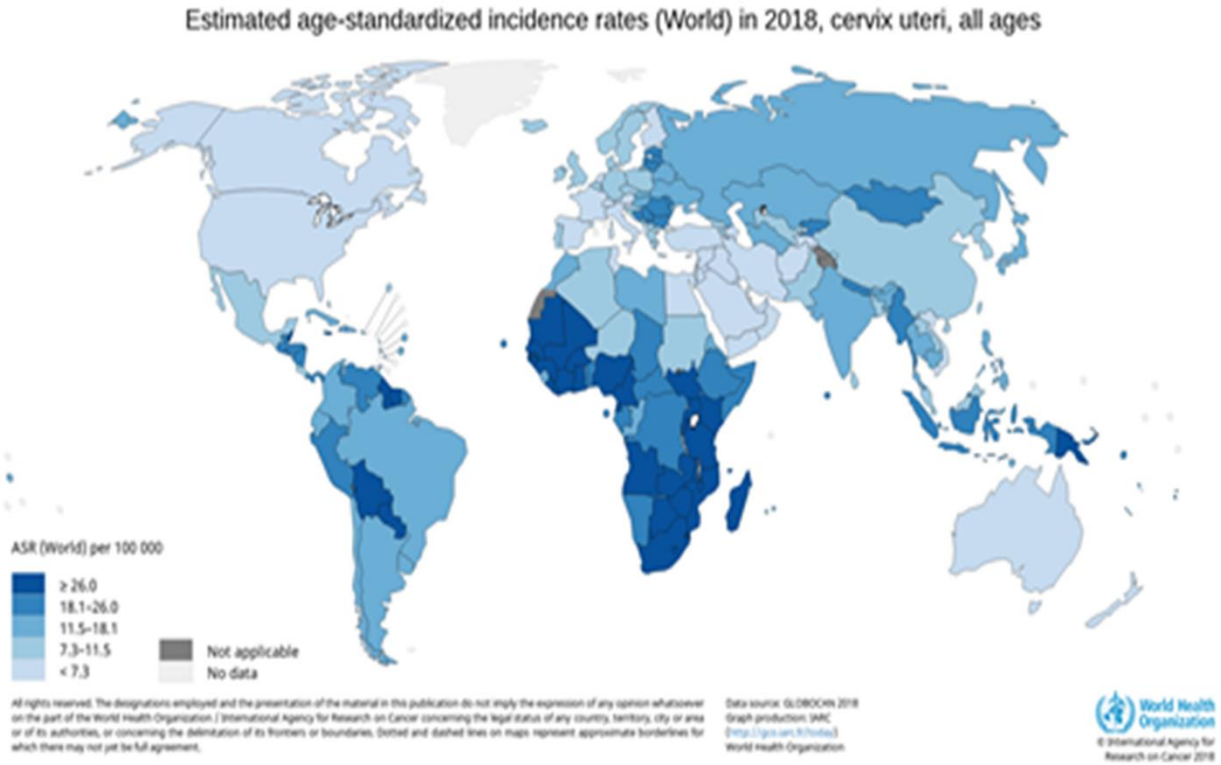
1

Cervical Cancer



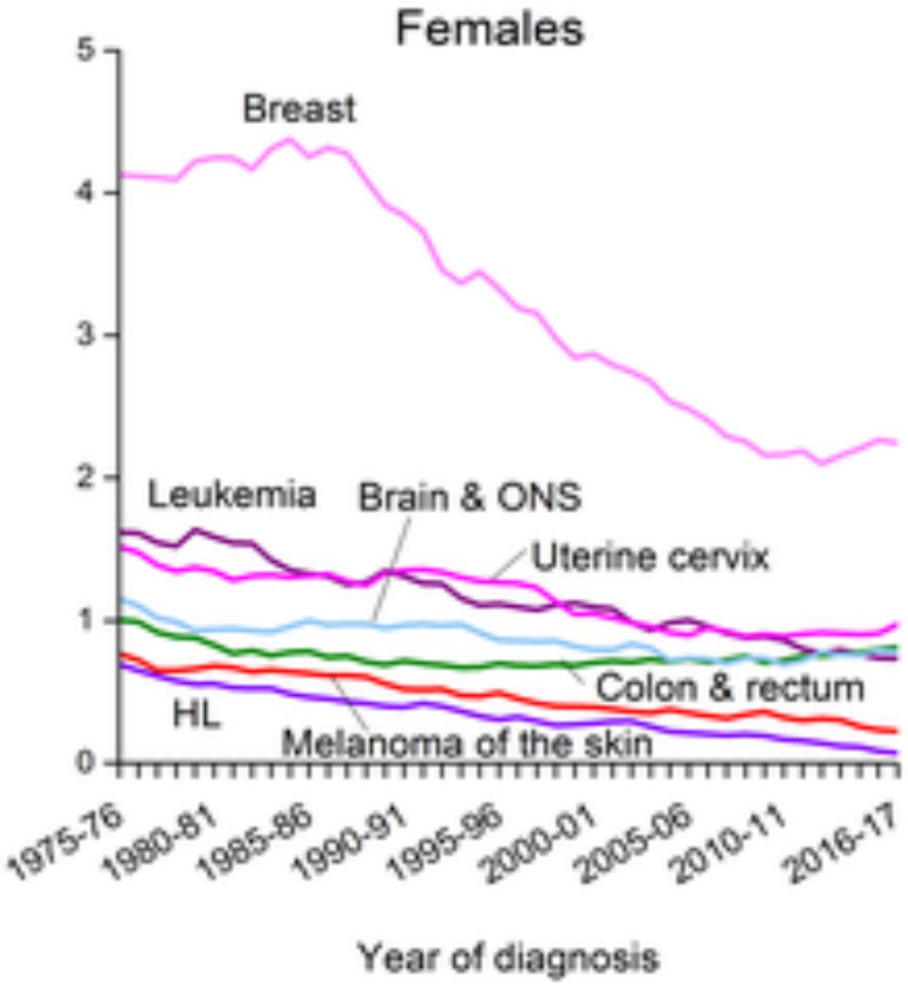
Cervical Cancer

- Number one cause of cancer deaths among women in Africa



Cervical Cancer

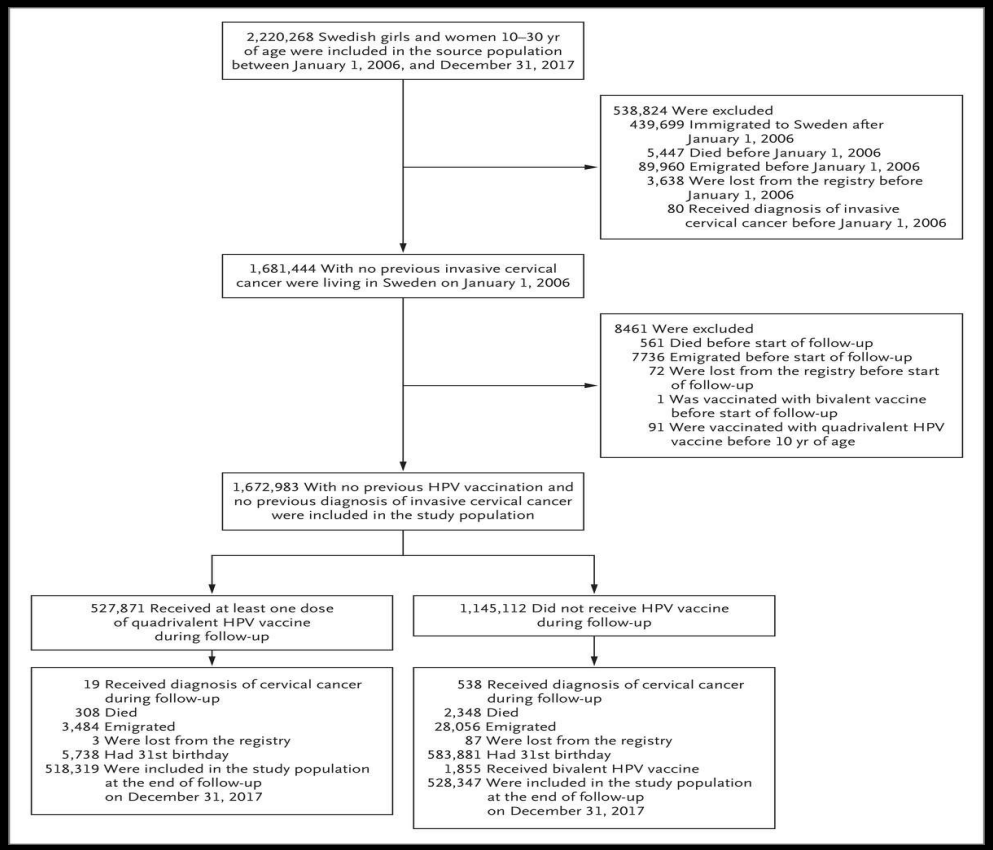
- Number 2 cause of cancer deaths among women age 30-40 in USA



Ref: Miller KD et al: CA: A Cancer Journal for Clinicians: Sept 2020; CA: A Cancer Journal for Clinicians

https://doi.org/10.3322/caac.21637

Study Population.

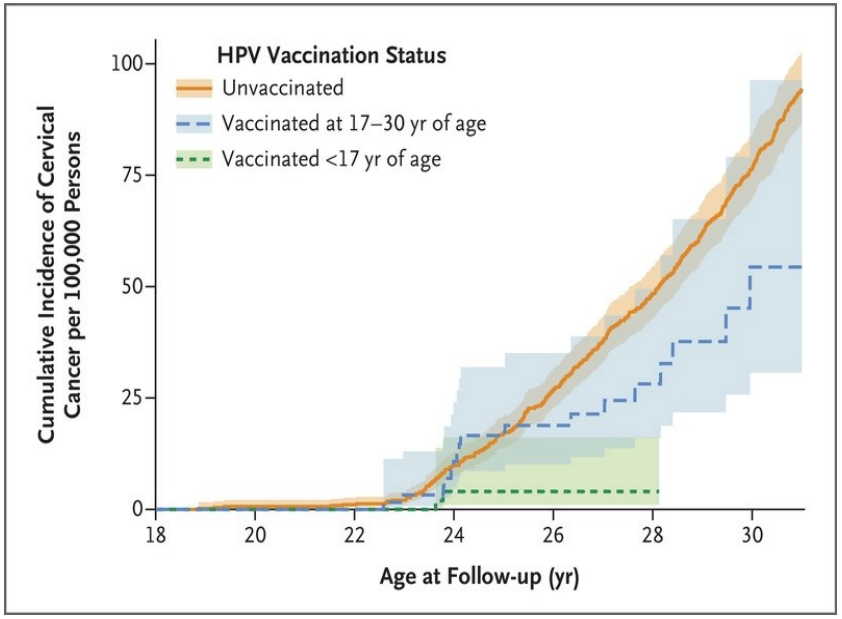


J Lei et al. N Engl J Med 2020;383:1340-1348.

Cervical Cancer

PREVENTION

- HPV vaccine can prevent 94% of cases if given in childhood and 54% of cases if given to young adults



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Cervical Cancer

Standard of care

- Surgery for early stage (Stage 1)
- Chemotherapy with weekly CDDP and RT for localized disease (Stage 1b2 or higher)
- Metastatic disease: Paclitaxel and cisplatin with bevacizumab
- Second line: PDL1 positive : pembrolizumab

Cervical Cancer

New Treatments

Cemiplimab (PD-1 inhibitor)

Gynecologic Oncology

Volume 159, Issue 2, November 2020, Pages 322-328

D Rischina et al

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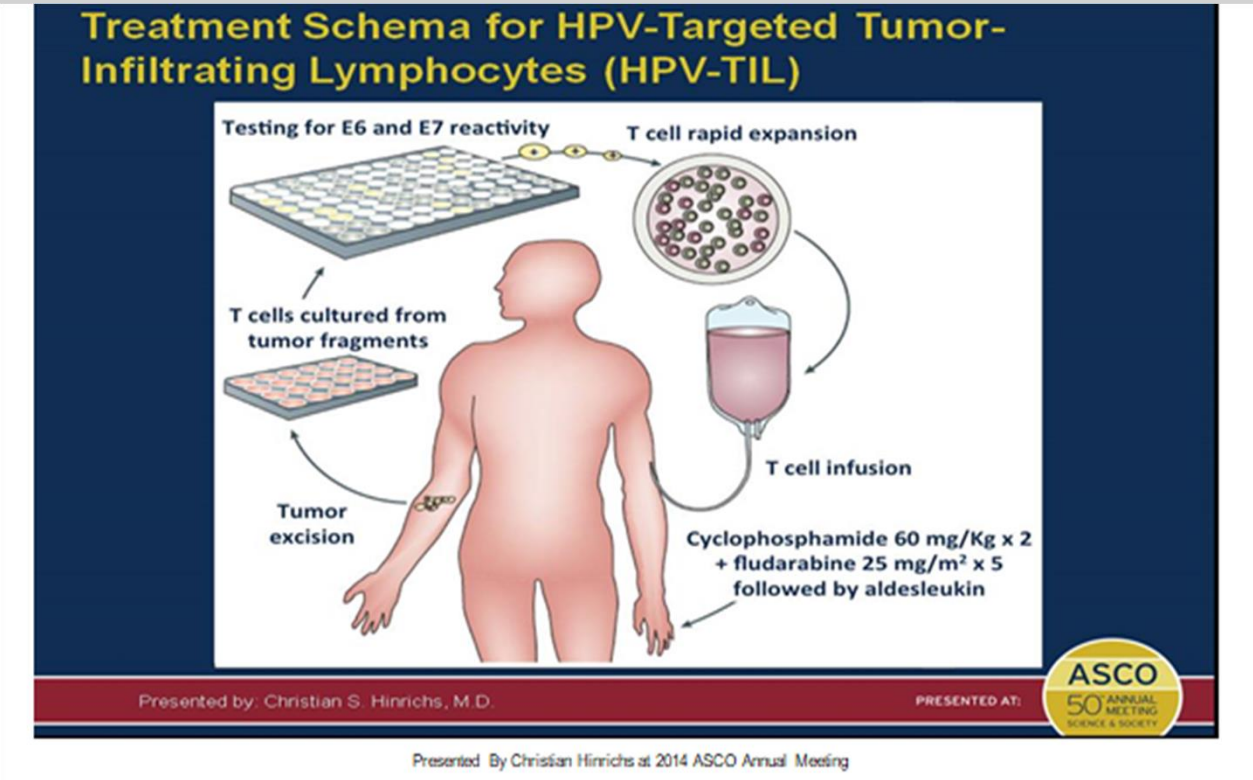
ASCO 2019

Study C-145-04
NCT03108495

Iovance Biotherapeutics

27 patients
ORR 44%

Jazaeri AA et al:
J Clin Oncol 37, 2019 (suppl; abstr 2538)



Presented By Christian Hinrichs at 2014 ASCO Annual Meeting

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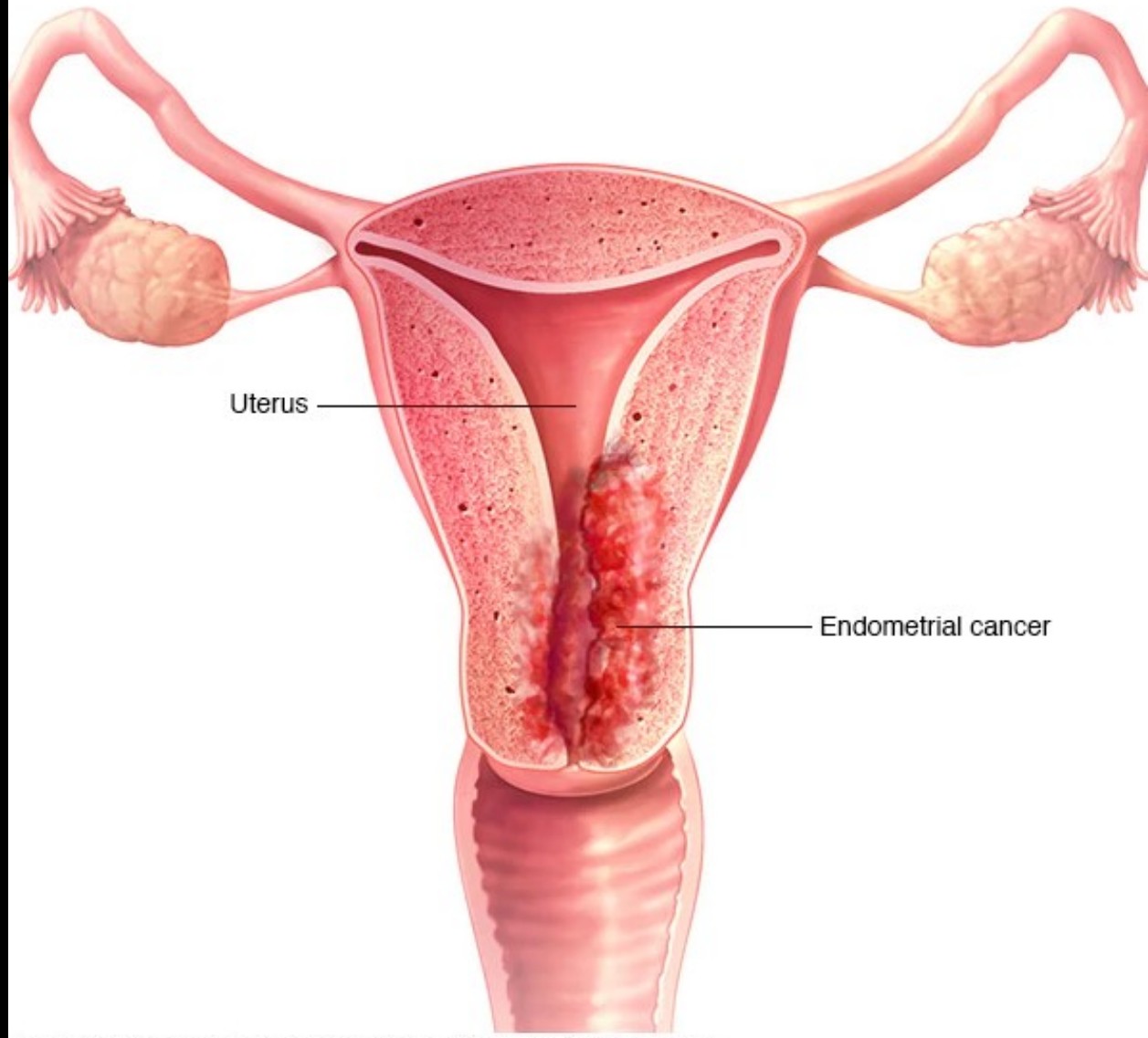
Endometrial Cancer



Endometrial Cancer

Standard of care

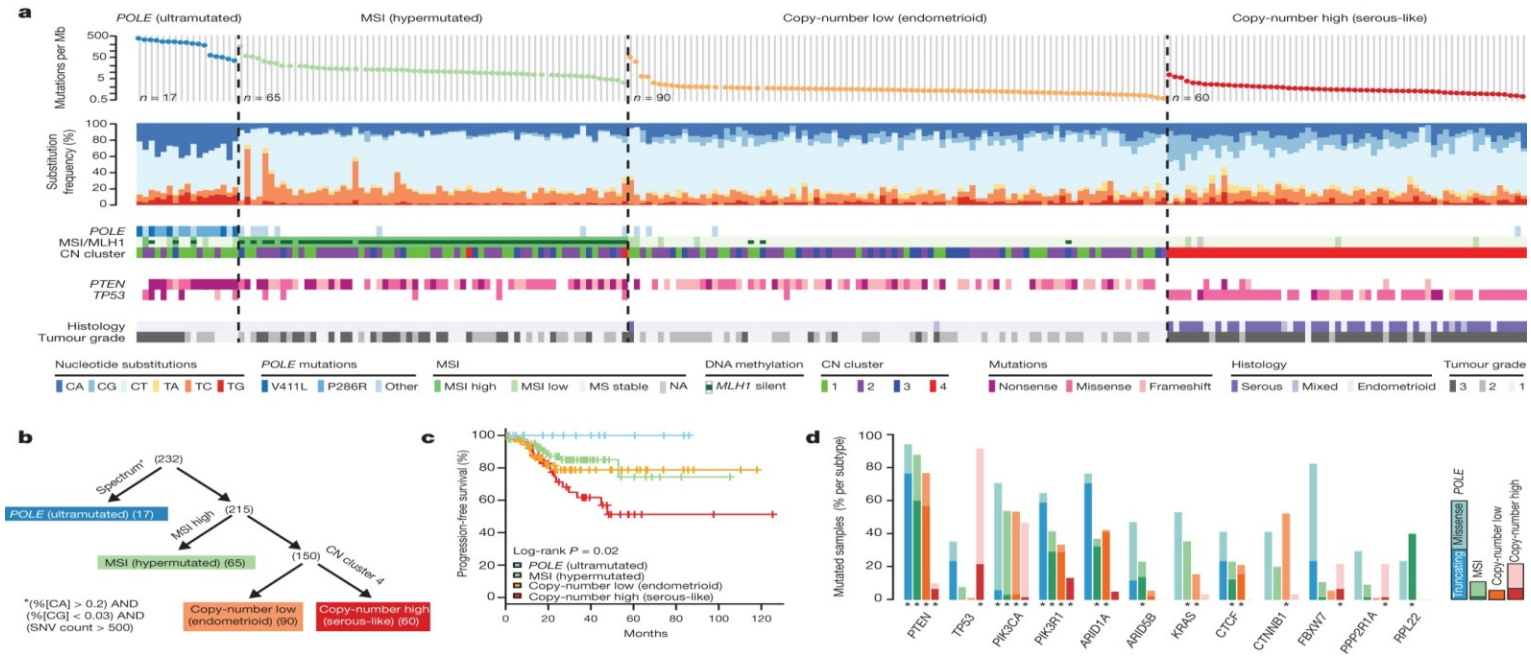
- Surgery for early stage (Stage 1-3)
- Adjuvant radiation and chemotherapy for Stage 3 disease and for serous, clear cell and MMT
- Metastatic disease: Paclitaxel and carboplatin
- Second line: MMR deficient: pembrolizumab
- MMR sufficient: pembrolizumab and lenvatinib

Endometrial Cancer

What is new

- PORTEC 3 data- Molecular biology
- HER2 positive disease
- ER positive low grade endometrioid

Mutation spectra across endometrial carcinomas.



G Getz *et al. Nature* **497**, 67-73 (2013) doi:10.1038/nature12113

nature

Adjuvant chemoradiotherapy versus radiotherapy alone in women with high-risk endometrial cancer (PORTEC-3): patterns of recurrence and post-hoc survival analysis of a randomised phase 3 trial

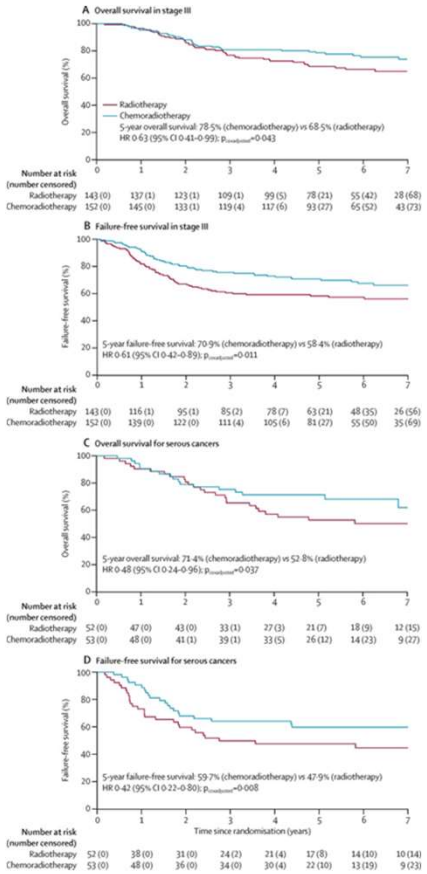
Stephanie M de Boer, MD, Melanie E Powell, MD, Linda Mileshkin, MD, Prof Dionyssios Katsaros, MD, Prof Paul Bessette, MD, Christine Haie-Meder, MD, Petronella B Ottevanger, MD, Prof Jonathan A Ledermann, MD, Pearly Khaw, MD, Romerai D'Amico, MD, Prof Anthony Fyles, MD, Marie-Helene Baron, MD, Ina M Jürgenliemk-Schulz, PhD, Prof Henry C Kitchener, MD, Prof Hans W Nijman, MD, Godfrey Wilson, MD, Susan Brooks, MD, Sergio Gribaudo, MD, Prof Diane Provencher, MD, Chantal Hanzen, MD, Prof Roy F Kruitwagen, MD, Prof Vincent T H B M Smit, PhD, Naveena Singh, MD, Viet Do, MD, Andrea Lissoni, MD, Remi A Nout, MD, Amanda Feeney, MSc, Karen W Verhoeven-Adema, PhD, Prof Hein Putter, PhD, Prof Carien L Creutzberg, MD M McCormack, K Whitmarsh, R Allerton, D Gregory, P Symonds, PJ Hoskin, M Adusumalli, A Anand, R Wade, A Stewart, W Taylor, LCHW Lutgens, H Hollema, E Pras, A Snyers, GH Westerveld, JJ Jobsen, A Slot, JM Mens, TC Stam, B Van Triest, EM Van der Steen-Banasik, KAJ De Winter, MA Quinn, I Kolodziej, J Pyman, C Johnson, A Capp, R Fossati, A Colombo, S Carinelli, A Ferrero, G Artioli, C Davidson, CM McLachlin, P Ghatage, PVC Rittenberg, L Souhami, G Thomas, P Duvillard, D Berton-Rigaud, N Tubiana-Mathieu Stephanie M de Boer, MD, Melanie E Powell, MD, Linda Mileshkin, MD, Prof Dionyssios Katsaros, MD, Prof Paul Bessette, MD, Christine Haie-Meder, MD, Petronella B Ottevanger, MD, Prof Jonathan A Ledermann, MD, Pearly Khaw, MD, Romerai D'Amico, MD, Prof Anthony Fyles, MD, Marie-Helene Baron, MD, Ina M Jürgenliemk-Schulz, PhD, Prof Henry C Kitchener, MD, Prof Hans W Nijman, MD, Godfrey Wilson, MD, Susan Brooks, MD, Sergio Gribaudo, MD, Prof Diane Provencher, MD, Chantal Hanzen, MD, Prof Roy F Kruitwagen, MD, Prof Vincent T H B M Smit, PhD, Naveena Singh, MD, Viet Do, MD, Andrea Lissoni, MD, Remi A Nout, MD, Amanda Feeney, MSc, Karen W Verhoeven-Adema, PhD, Prof Hein Putter, PhD, Prof Carien L Creutzberg, MD M McCormack, K Whitmarsh, R Allerton, D Gregory, P Symonds, PJ Hoskin, M Adusumalli, A Anand, R Wade, A Stewart, W Taylor, LCHW Lutgens, H Hollema, E Pras, A Snyers, GH Westerveld, JJ Jobsen, A Slot, JM Mens, TC Stam, B Van Triest, EM Van der Steen-Banasik, KAJ De Winter, MA Quinn, I Kolodziej, J Pyman, C Johnson, A Capp, R Fossati, A Colombo, S Carinelli, A Ferrero, G Artioli, C Davidson, CM McLachlin, P Ghatage, PVC Rittenberg, L Souhami, G Thomas, P Duvillard, D Berton-Rigaud, N Tubiana-Mathieu

The Lancet Oncology
Volume 20 Issue 9 Pages 1273-1285 (September 2019)
DOI: 10.1016/S1470-2045(19)30395-X

Endometrial Cancer

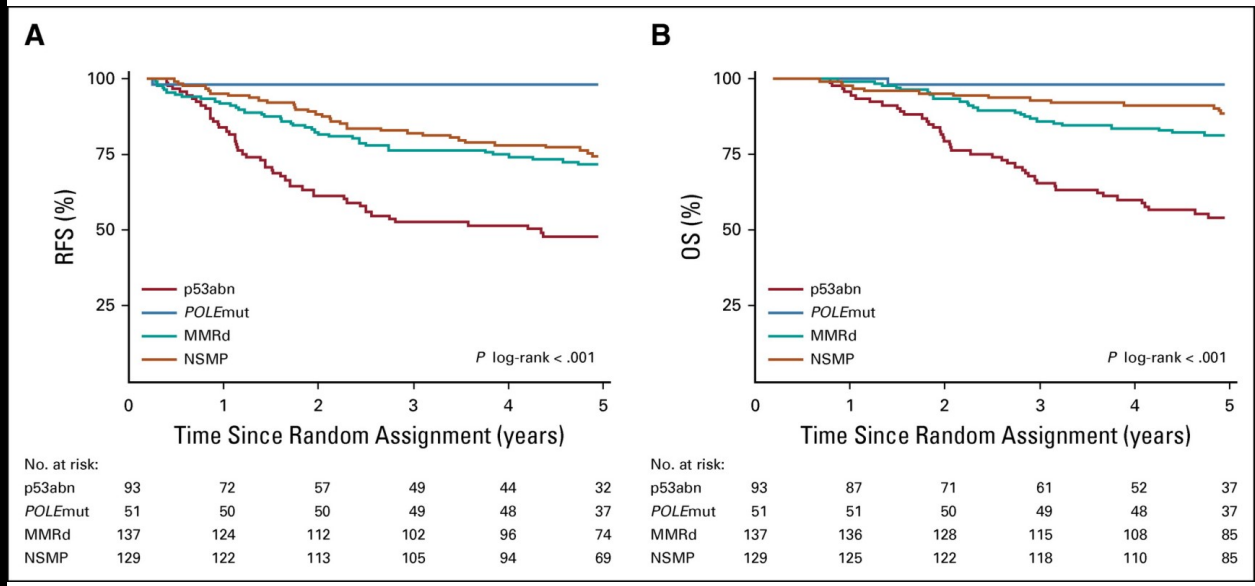
PORTEC 3

deBoer SM et al: Lancet Oncology 2019 DOI: 10.1016/S1470-2045(19)30395-X



Endometrial Cancer

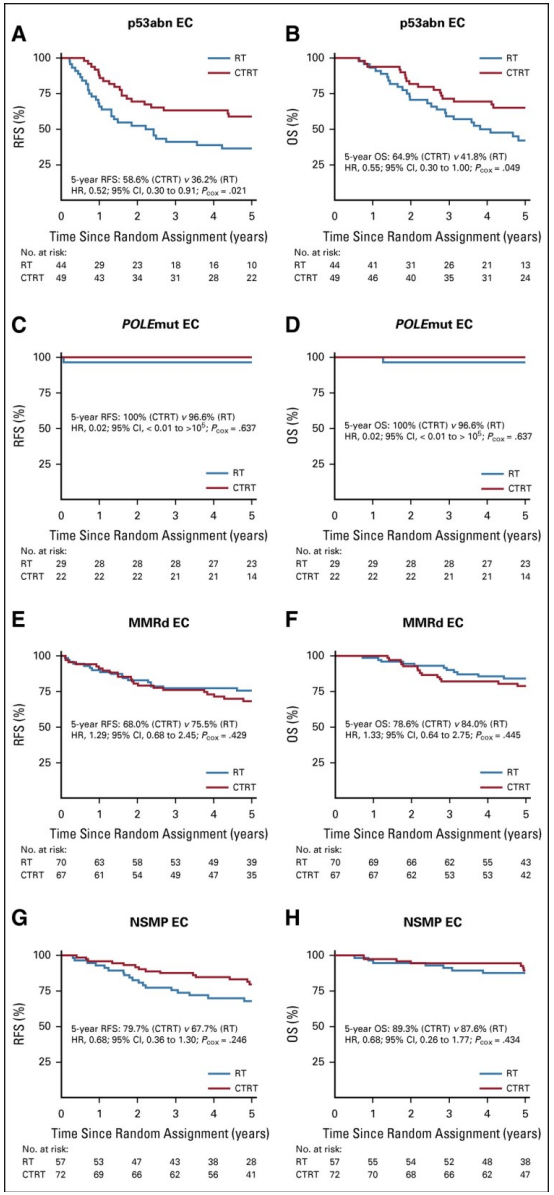
PORTEC 3
Molecular analysis



Leon-Castillo A et al: DOI: 10.1200/JCO.20.00549 Journal of Clinical Oncology 38, no. 29 (October 10, 2020) 3388-3397.

Endometrial Cancer

PORTEC 3
Molecular analysis



Leon-Castillo A et al: DOI: 10.1200/JCO.20.00549 Journal of Clinical Oncology 38, no. 29 (October 10, 2020) 3388-3397.

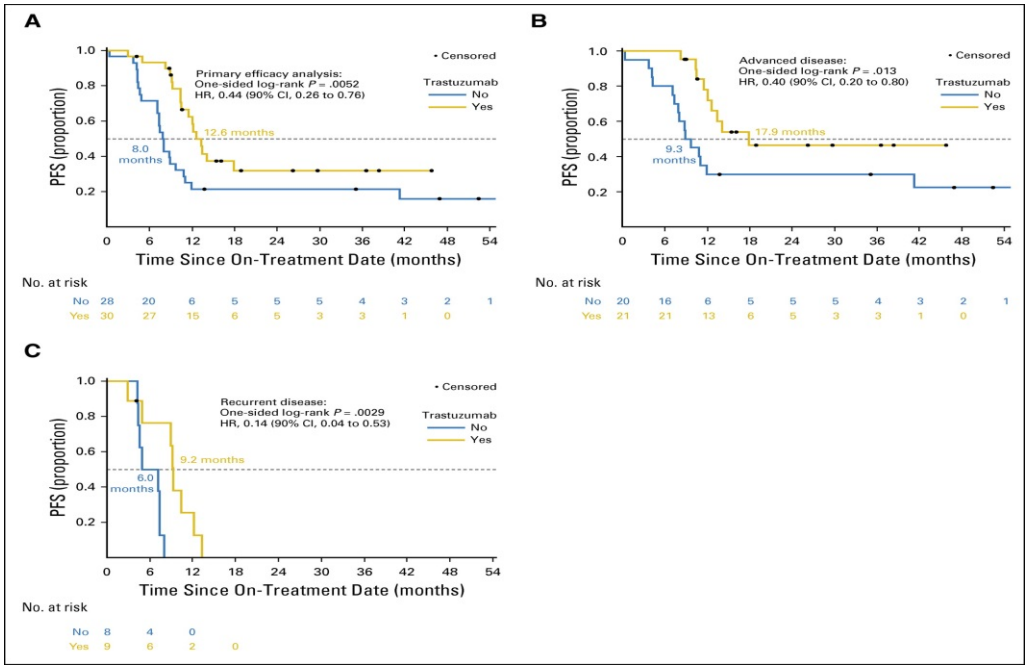
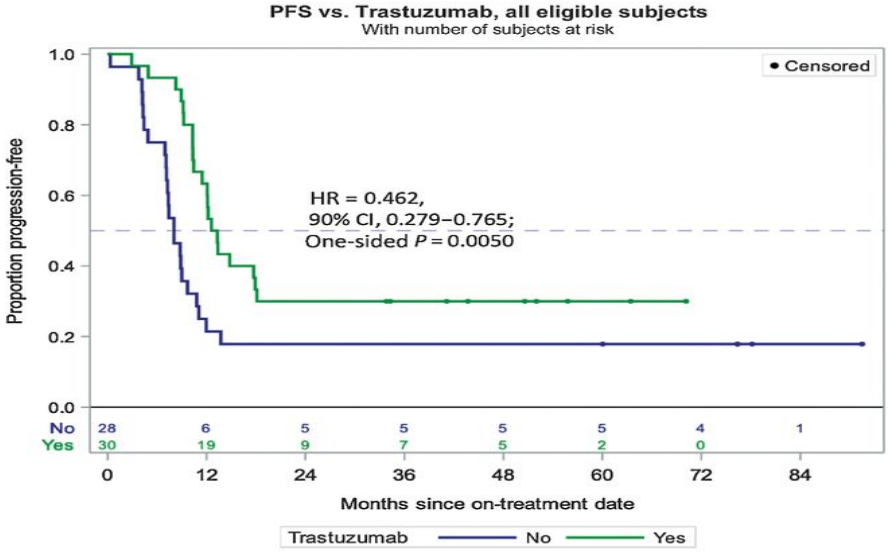
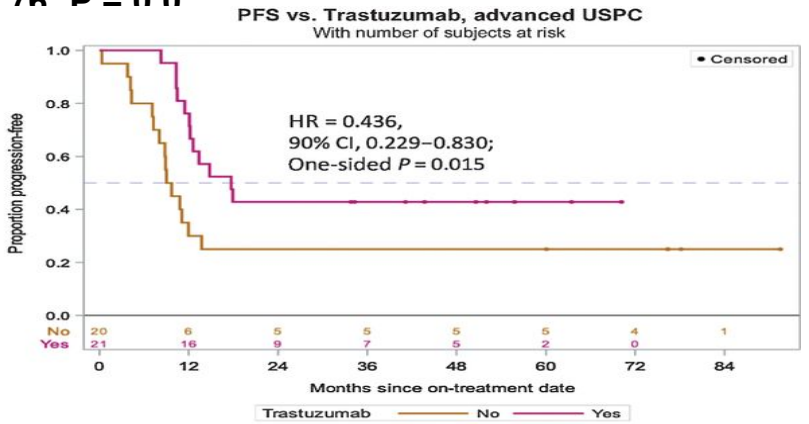


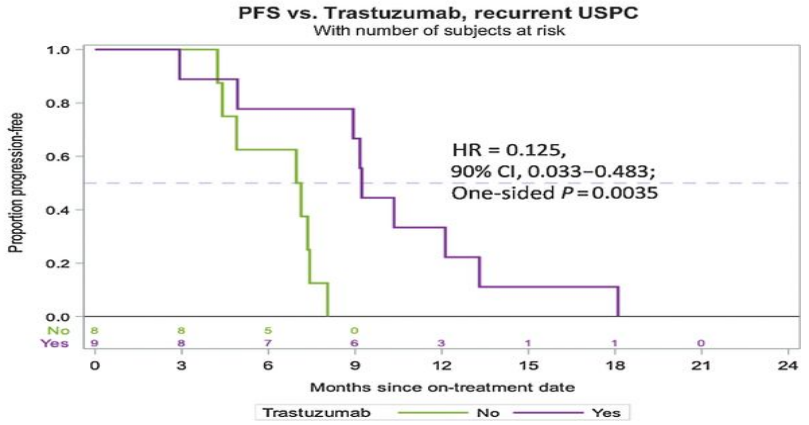
Fig 2. Progression-free survival (PFS). (A) Median progression-free survival was improved by 4.6 months in patients (n = 58) who received trastuzumab with carboplatin-paclitaxel (12.6 months) compared with those who received carboplatin-paclitaxel alone (8.0 months; P = .005; hazard ratio [HR], 0.44; 90% CI, 0.26 to 0.76). (B) The addition of trastuzumab benefitted patients (n = 41) with advanced disease in the primary treatment setting (17.9 v 9.3 months; HR, 0.40; 90% CI, 0.20 to 0.80; P = .013). (C) The addition of trastuzumab also benefitted patients (n = 17) with recurrent disease after zero, one, or two lines of prior chemotherapy (9.2 v 6.0 months; HR, 0.14; 90% CI, 0.05 to 0.54; P = .003). In total, there were 40 progression events; among those who remained alive and progression free, five were in the control arm and 13 were in the experimental arm.

Published in: Amanda N. Fader; Dana M. Roque; Eric Siegel; Natalia Buza; Pei Hui; Osama Abdelghany; Setsuko K. Chambers; Angeles Alvarez Secord; Laura Havrilesky; David M. O'Malley; Floor Backes; Nicole Nevadunsky; Babak Edraki; Dirk Pikaart; William Lowery; Karim S. ElSahwi; Paul Celano; Stefania Bellone; Masoud Azodi; Babak Litkouhi; Elena Ratner; Dan-Arin Silasi; Peter E. Schwartz; Alessandro D. Santin; *JCO* **2018,** 36, 2044-2051.
DOI: 10.1200/JCO.2017.76.5966

Updated PFS analyses continue to support the addition of trastuzumab to the treatment of advanced/recurrent USC. Left: Median PFS was 8.0 months in patients who received CP and 12.9 months in patients who received CP+T (HR = 0.46; 90% CI, 0.28–0.76; P = 0.0







Amanda N. Fader et al. Clin Cancer Res 2020;26:3928-3935

Clinical Cancer Research
AACR American Association for Cancer Research

Endometrial Cancer

Phase 2 trial of Ribociclib and letrozole in ER positive endometrial cancer or ovarian cancer

Colon-Otero et al: ESMO Open October 2020 http://dx.doi.org/10.1136/esmoopen-2020-000926

Total Patients PFS ≥24 weeks	**11/40 (27.5%)**
Ovarian group	**4/20 (20.0%)**
Low-grade serous	3/3 (100.0%)*
High-grade serous	1/17 (5.9%)
Endometrial group	**7/20 (35.0%)**
Grade 1 to 2	***5/11 (45.5%)***
High-grade	2/9 (22.2%)

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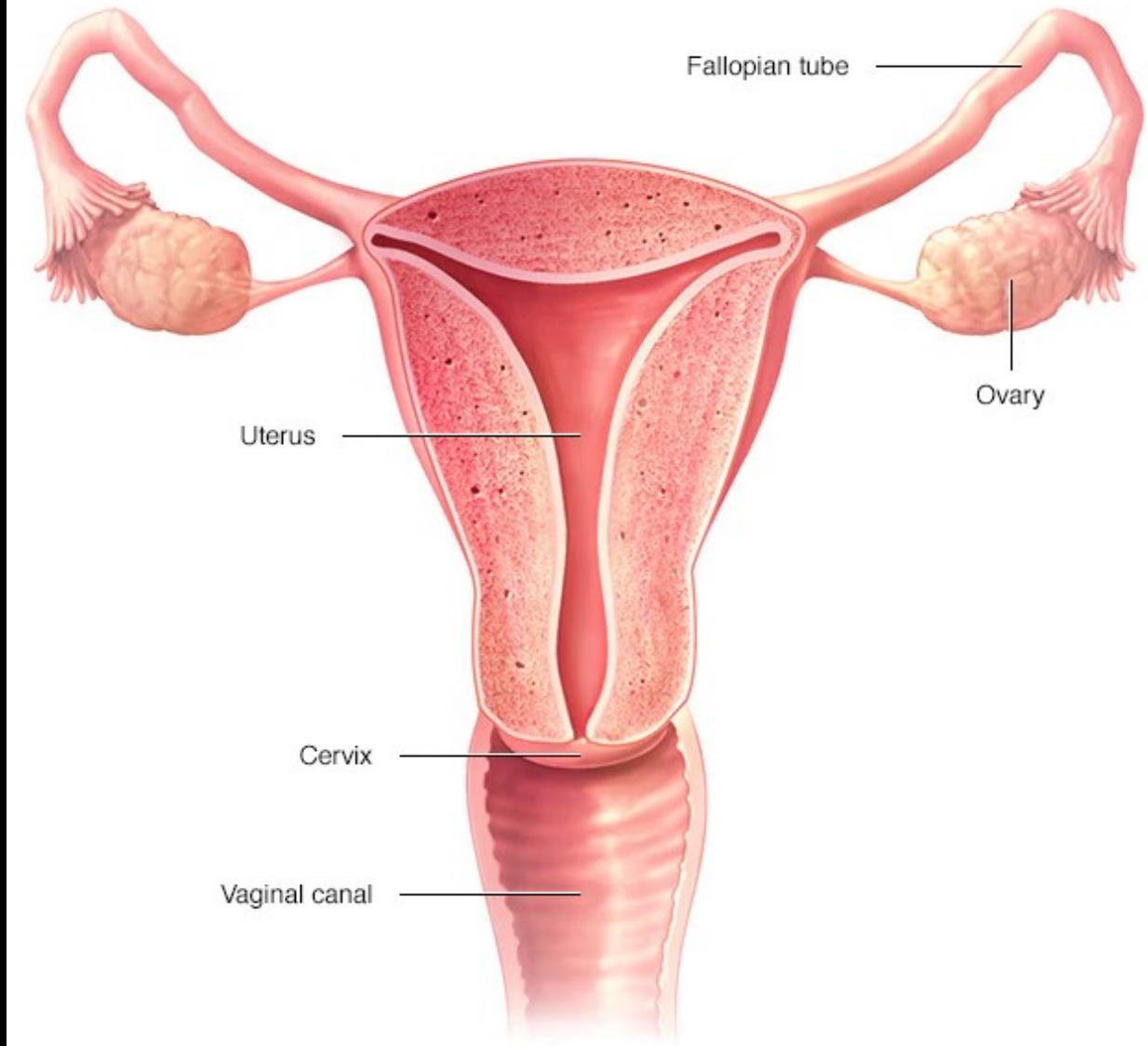
Ovarian Cancer



Ovarian Cancer

Standard of care

- Debulking laparotomy vs neo-adjuvant chemotherapy with interim debulking
- Paclitaxel and carboplatin +/- bevacizumab
- IP chemotherapy (HIPEC with interim debulking)
- PARP plus/minus bevacizumab maintenance
- Platinum sensitive vs resistant

Ovarian Cancer

What is new

- PARP inhibitors
- Debulking surgery in platinum sensitive relapse

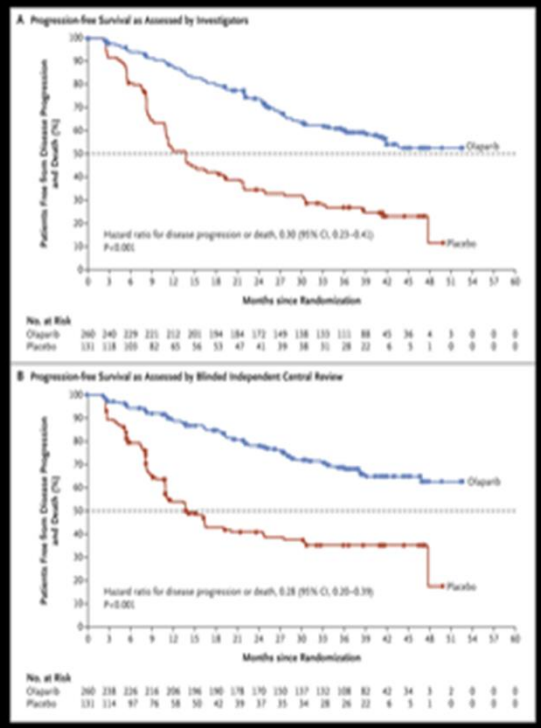
Clinical trials of parp inhibitors in epithelial ovarian cancer: who, when, how?

Ovarian Cancer Clinical Setting

Population	Phase	Upfront maintenance	Plat Sens Rec (maintenance post chemo)	Plat Sens Rec (treatment)	Plat Res Rec (treatment)
BRCA mutated	III	SOLO-1 (olaparib)	SOLO-2 (olaparib)		
	II				Study 42 (olaparib)
Anyone	III	PAOLA-1 (olaparib/bev) VELIA (veliparib) PRIMA (niraparib)	Study 19 (olaparib) NOVA (niraparib) ARIEL3 (rucaparib)	AVANOVA2 (niraparib/bev) GY-004 (olaparib vs other) SOLO3 (olaparib vs non-plat chemo)	
	II	OVARIO (niraparib/bev)		LIGHT study (olaparib) ARIEL2/Study 10 (rucaparib)	QUADRA (niraparib) CLIO (olaparib vs. chemo)

SOLO-1 Trial

Kaplan–Meier Estimates of Progression-free Survival.



K Moore et al. N Engl J Med 2018;379:2495-2505.

The NEW ENGLAND JOURNAL of MEDICINE

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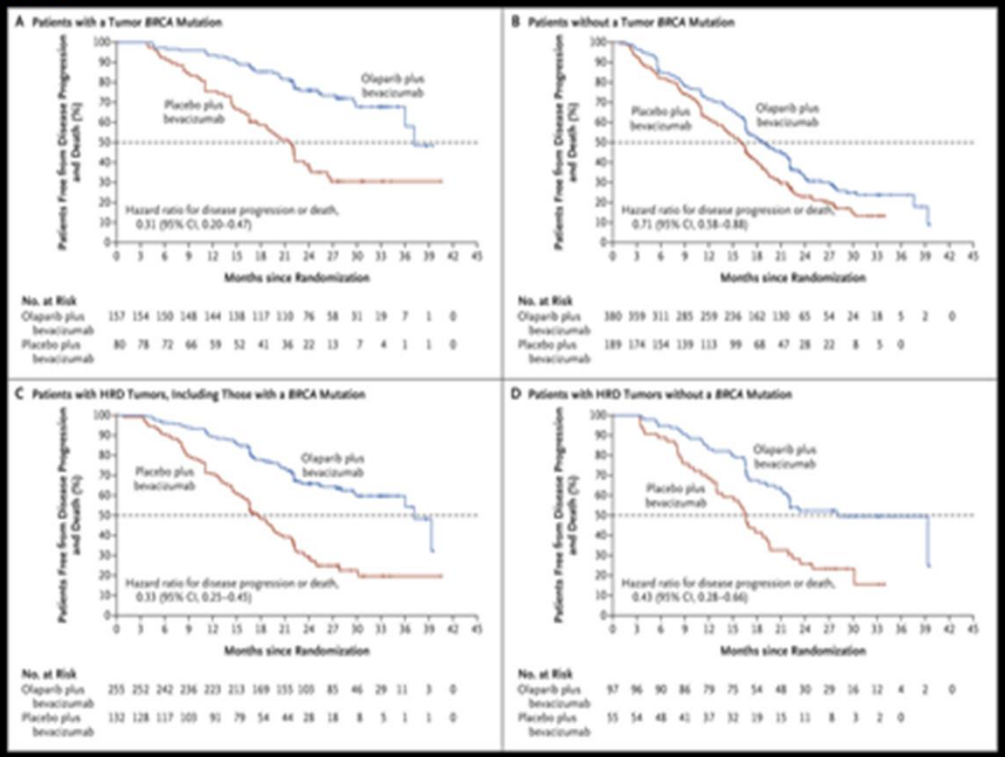
PAOLA-1 Trial

Kaplan–Meier Estimates of Investigator-Assessed Progression-free Survival, According to Tumor *BRCA* Mutation Status and Homologous-Recombination Deficiency (HRD) Status.

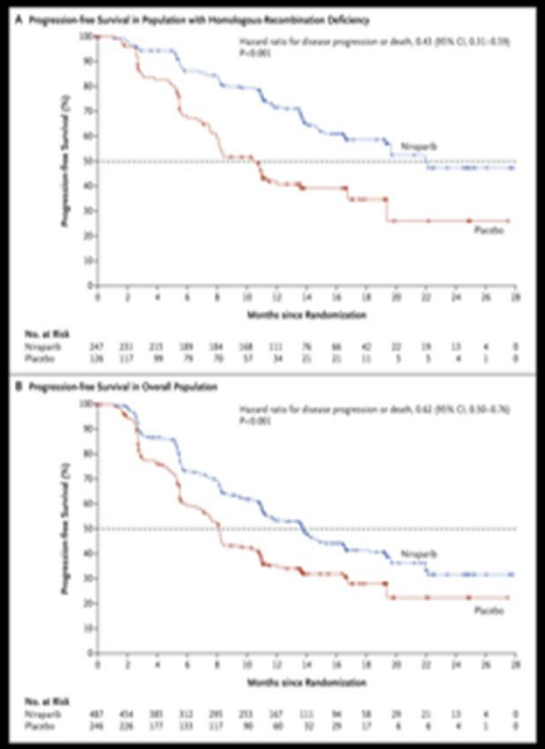


I Ray-Coquard et al. N Engl J Med 2019;381:2416-2428.

The NEW ENGLAND JOURNAL of MEDICINE

PRIMA Trial

Progression-free Survival in the Two Primary Populations.

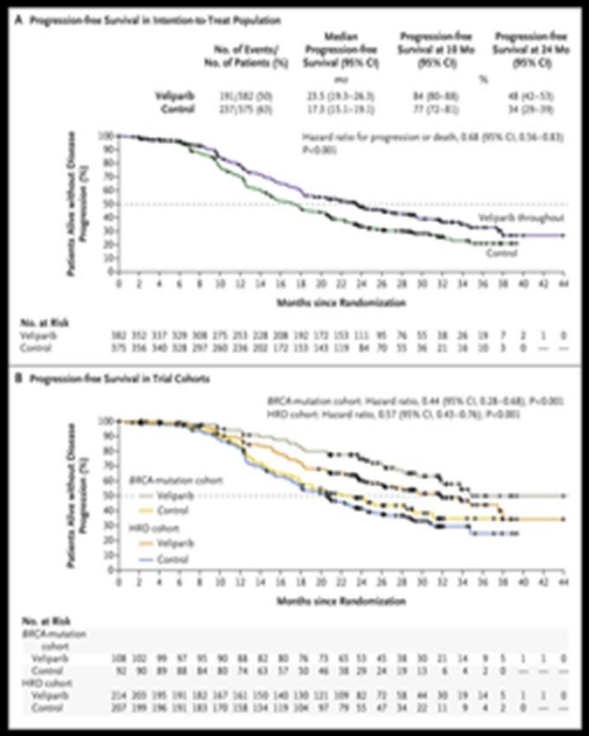


A González-Martín et al. N Engl J Med 2019;381:2391-2402.

The NEW ENGLAND JOURNAL of MEDICINE

VELIA Trial

Kaplan–Meier Estimates of Progression-free Survival in the Veliparib-Throughout Group and Control Group.



RL Coleman et al. N Engl J Med 2019;381:2403-2415.

The NEW ENGLAND JOURNAL of MEDICINE

A Comparison of Three PARP Inhibitors in Patients with Ovarian Cancer.*

Table 1. A Comparison of Three PARP Inhibitors in Patients with Ovarian Cancer.*

Trial Drug	Overall Population†			Mutated *BRCA*‡			HRD§			No HRD¶		
	Control	Treatment	Hazard Ratio (95% CI)	Control	Treatment	Hazard Ratio (95% CI)	Control	Treatment	Hazard Ratio (95% CI)	Control	Treatment	Hazard Ratio (95% CI)
	median			*median*			*median*			*median*		
Niraparib												
Duration of progression-free survival	8.2 mo	13.8 mo	0.62 (0.50–0.75)	10.9 mo	22.1 mo	0.40 (0.26–0.62)	10.4 mo	21.9 mo	0.43 (0.31–0.59)	5.4 mo	8.1 mo	0.68 (0.49–0.94)
P value			<0.001						<0.001			
Veliparib												
Duration of progression-free survival	17.3 mo	23.5 mo	0.68 (0.56–0.83)	22.0 mo	34.7 mo	0.44 (0.28–0.68)‖	20.5 mo	31.9 mo	0.57 (0.43–0.76)	NR	NR	0.81 (0.60–1.09)
P value			<0.001			<0.001			<0.001			
Olaparib plus bevacizumab												
Duration of progression-free survival	16.6 mo	22.1 mo	0.59 (0.49–0.72)	21.7 mo	37.2 mo	0.31 (0.20–0.47)	17.7 mo	37.2 mo	0.33 (0.25–0.45)	16.2 mo	16.6 mo	1.00 (0.75–1.35)**
P value			<0.001									

* Evaluations were performed in 733 patients who received niraparib in the PRIMA trial,[4] in 1140 patients who received veliparib in the VELIA trial,[5] and in 806 patients who received olaparib in the PAOLA-1 trial.[6] HRD denotes homologous-recombination deficiency, PARP poly(adenosine diphosphate [ADP]–ribose) polymerase, and NR not reported.
† In all three trials, patients with *BRCA* mutations were overrepresented, as compared with the overall population of patients with ovarian cancer. The outcome for the overall population was favorable for each of the PARP inhibitors listed here.
‡ In all three trials, the PARP inhibitor substantially improved the duration of progression-free survival in patients with *BRCA* mutations.
§ In all three trials, the PARP inhibitor substantially improved the duration of progression-free survival in the HRD cohort.
¶ The effect of the PARP inhibitor among patients in the no-HRD cohort was more limited than in the other subgroups, and the size of the between-group difference was modest.
‖ The patients who were included in this comparison could have either tumor (somatic) or germline *BRCA* mutations.
** Patients who had unknown HRD status were excluded from this comparison.

DL Longo. N Engl J Med 2019;381:2471-2474.

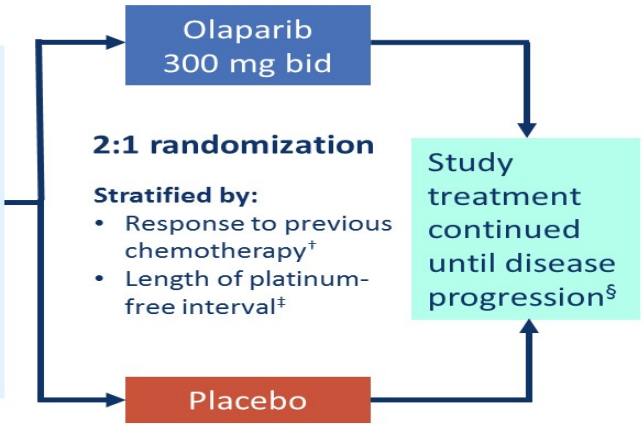
The NEW ENGLAND JOURNAL of MEDICINE

FDA approvals for parp inhibitors in epithelial ovarian cancer

Population	Ovarian Cancer Clinical Setting: Upfront maintenance	Plat Sens Rec (maintenance post chemo)	Plat Sens Rec (treatment)	Plat Res Rec (treatment)
BRCA mutated	olaparib			olaparib 3 or more prior chemo rucaparib 2 or more prior chemo
BRCA or HRD	olaparib + bevacizumab			niraparib 3 or more prior chemo
Anyone	niraparib	olaparib niraparib rucaparib		

SOLO2: study design

Eligible patients had:
- Relapsed, high-grade serous or endometrioid ovarian cancer*
- BRCAm
- Received ≥2 previous lines of platinum-based chemotherapy
- Responded to most recent platinum regimen



Primary endpoint
- Investigator-assessed PFS

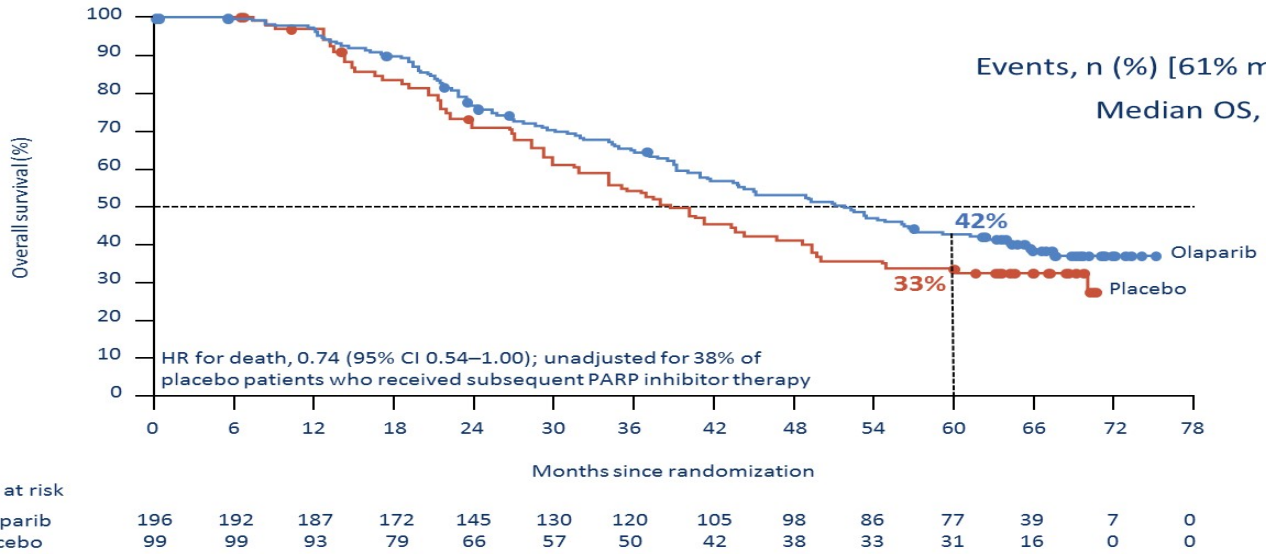
Time-dependent secondary endpoints
- **Overall survival**
- PFS2
- TFST
- TSST
- TDT
- HRQoL¶

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

SOLO2: final analysis of OS

Median OS improved by 12.9 months with maintenance olaparib over placebo, despite 38% of placebo patients receiving subsequent PARP inhibitor therapy



No. at risk

Olaparib	196	192	187	172	145	130	120	105	98	86	77	39	7	0
Placebo	99	99	93	79	66	57	50	42	38	33	31	16	0	0

	Olaparib (N=196)	Placebo (N=99)
Events, n (%) [61% maturity]	116 (59)	65 (66)
Median OS, months	51.7	38.8
HR 0.74		
95% CI 0.54–1.00; *P*=0.0537		

38% of placebo patients and 10% of olaparib patients received subsequent PARP inhibitor therapy*

OS analysis per eCRF in the full analysis set†
HR 0.70 (95% CI 0.52–0.96)

OS analysis in the Myriad gBRCAm subgroup†
HR 0.71 (95% CI 0.52–0.97)

*According to medical review of PARP inhibitor use; †Not adjusted for multiplicity
CI, confidence interval

SOLO2: AEs of special interest – primary and final analyses*,†

	Olaparib (N=195)		Placebo (N=99)	
	Primary	Final	Primary	Final
Mean total treatment duration (SD), months	17.4 (9.8)	**29.1 (24.7)**	9.0 (8.1)	**13.1 (18.6)**
MDS/AML, n (%) During the safety follow-up period (TEAE) After the safety follow-up period (non-TEAE)	4 (2)	**16 (8)** **7 (4)** **9 (5)**	4 (4)	**4 (4)** **0** **4 (4)**
Pneumonitis, n (%)	3 (2)	**3 (2)**	0	**0**

MDS/AML

- **Actively solicited throughout study treatment and follow-up**
- **Incidences should be interpreted in the context of their late onset‡ and the longer OS observed with olaparib vs placebo**
- **Association with the number of prior platinum regimens, olaparib treatment and other potential risk factors is being explored**

In patients with newly diagnosed ovarian cancer and a BRCAm, at median follow-up of 65 months, MDS/AML occurred in 1% of olaparib patients and no placebo patients[1]

*Includes AEs that occurred outside safety follow-up period (during treatment and up to 30 days after discontinuation); †New primary malignancies (excluding hematologic malignancies) occurred in one olaparib patient (1%) and one placebo patient (1%) in the primary analysis, and in eight olaparib patients (4%) and two placebo patients (2%) in the final analysis; ‡After the safety follow-up period
AML, acute myeloid leukemia; MDS, myelodysplastic syndrome

1. AstraZeneca data on file for the SOLO1 trial (NCT01844986)

Randomized controlled phase III study evaluating the impact of secondary cytoreductive surgery in recurrent ovarian cancer: the final analysis of AGO DESKTOP III / ENGOT ov20

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C. Pomel (GINECO), F. Lecuru (GINECO), R. Zang (SGOG, China),
E. Avall-Lundqvist (NSGO), JW Kim (KGOG, Korea), J. Ponce (GEICO, Spain),
F. Raspagliesi (MITO), S. Ghaem-Maghami (NCRI, UK),
A. Reinthaller (A-AGO, Austria), **P. Harter (AGO, PI)**

ENGOT European Network of Gynaecological Oncological Trial groups

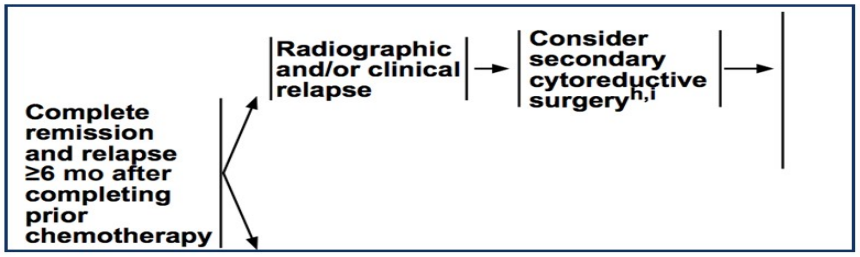
GYNECOLOGIC CANCER INTERGROUP An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

AGO Study Group

PRESENTED AT: 2020 ASCO ANNUAL MEETING #ASCO20

PRESENTED BY: Andreas du Bois
AGO & KEM Essen, Germany

Background

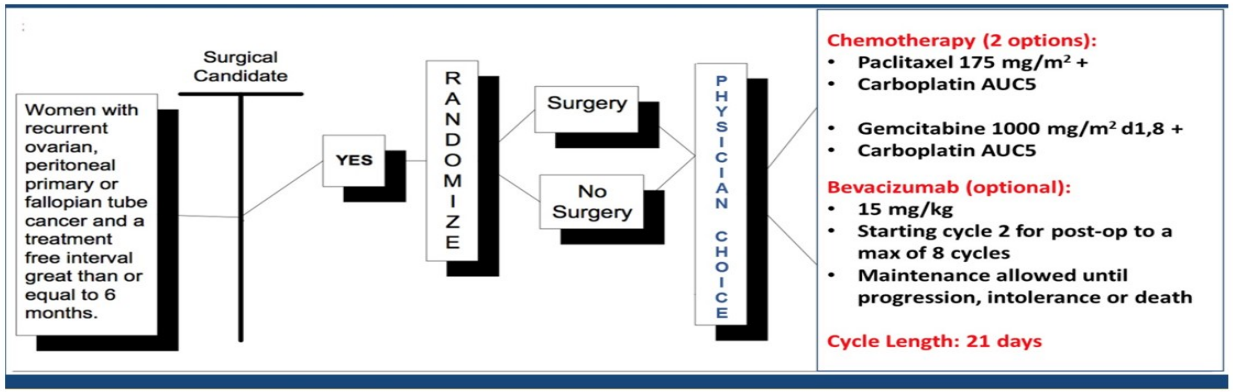


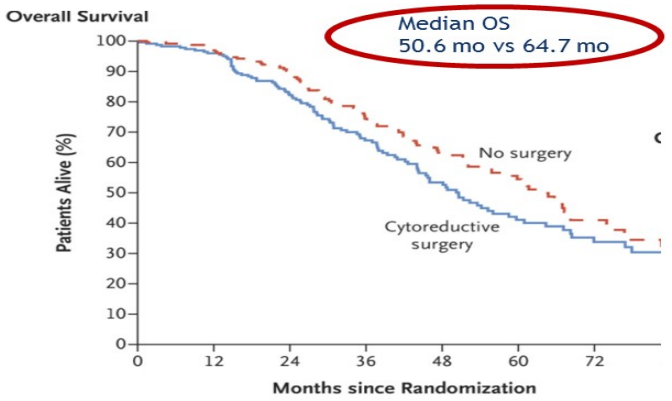
- Controversial
- 600 + retrospective series
- 5 randomized trials

- EORTC 55963: (N ~ 700) (closed for futility 10/2002);
- **GOG 213: (N: 945, 485 surgery randomization)**
- **DESKTOP III:**
- **SOC-I [Abs 6001 ASCO 2020!!]**
  - **Opened 3/2013 (N: 357); Primary endpoint: OS**
  - **iModel for resection (Stage, residual disease after primary surgery, PFI, PS, CA125, Ascites at recurrence)**

-SOCceR
  - Opened 6/2012 (N ~ 230)

What about GOG 213??





- No specific eligibility criteria for surgery "although must be considered suitable for complete gross surgical resection"
- Protocol guidance around carcinomatosis, ascites and parenchymal organ disease

Coleman et al NEJM 2019
Coleman ASCO 2018

Design: AGO DESKTOP III
(ENGOT-ov20; NCT01166737)

Sponsor: AGO
ENGOT Model A

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*

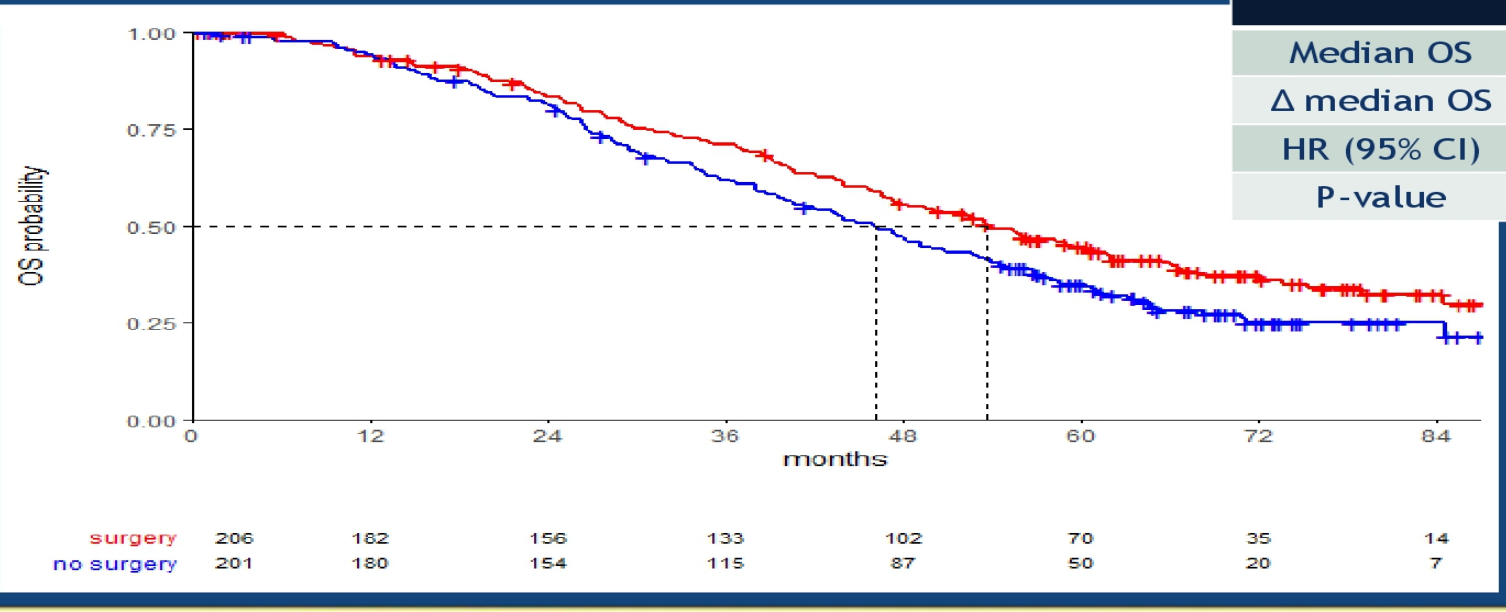
No OP → **Immediate Platinum-based Combination therapy** *strongly recommended* → *OP Allowed 3rd line*

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

PRESENTED BY: Andreas du Bois
AGO & KEM Essen, Germany

AGO DESKTOP III: Outcome 1 (OS, ITT population)

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



	surgery	no surgery
Median OS	53.7 mos	46.0 mos
Δ median OS	7.7 mos	
HR (95% CI)	0.75 (0.58 - 0.96)	
P-value	0.02	

CONCLUSIONS

SUBTITLE HERE

- Reasons to be hopeful for HPV vaccination prevention effectiveness
- Multiple new promising treatments for cervical cancer
- Subtypes of endometrial cancer amenable for individualized treatment
- PARP inhibitors prolong overall survival in BRCA mutated tumors.
- Debulking surgery in platinum sensitive relapses may be of benefit in selected subsets.

QUESTIONS & ANSWERS

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