State of the Art – Gynaecological cancer
Ovarian and Endometrial Cancer

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01
Ovarian Cancer

Ovarian cancer in Germany

9.000 newly diagnosed **7.000 deaths**

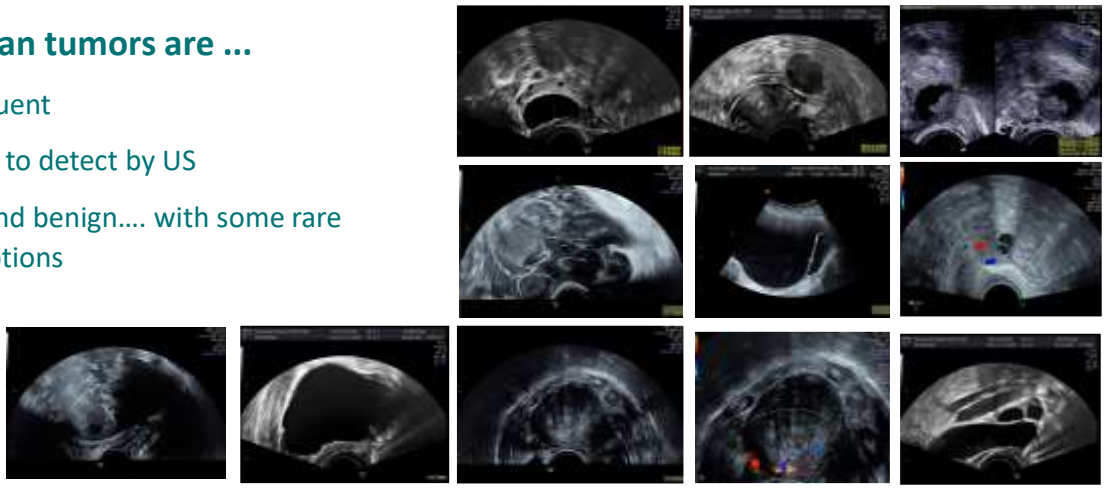
„RARE BUT DEADLY“

Ovarian cancer

- very limited symtoms
- 70% diagnosed at STAGE III
- no effective strategy for screening

Ovarian cancer and Screening

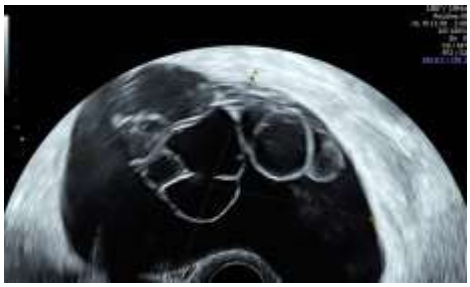
- **Ovarian tumors are …**
  - frequent
  - easy to detect by US
  - …. and benign…. with some rare exeptions



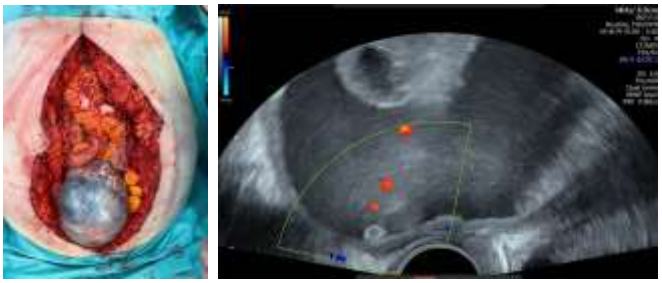
Ovarian cancer

2 different situations at the time of primary diagnosis

Early stage (I-IIA)
~ 25-30%

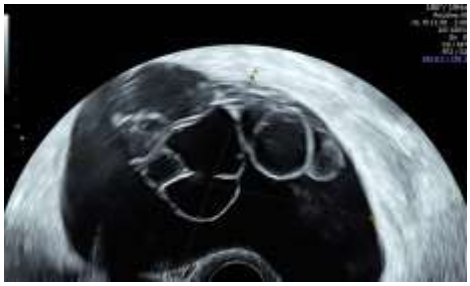


Advanced stage (IIB-IV)
~ 70-75%



Ovarian cancer – open questions in early stage

Early stage (I-IIA)
~ 25-30%



- **Radical surgical therapy?**
- **Relevance of the LND?**
- **Adjuvant therapy?**

Optimal staging - early stage OC

- longitudinal laparotomy, inspection and palpation of the entire abdominal cavity
- peritoneal cytology
- peritoneal biopsies
- bilateral salpingooporectomy
- hysterectomy
- omentectomy at least infracolic
- appendectomy (mucinous tumor type)
- lymphonodectomy pelvin and paraaortic

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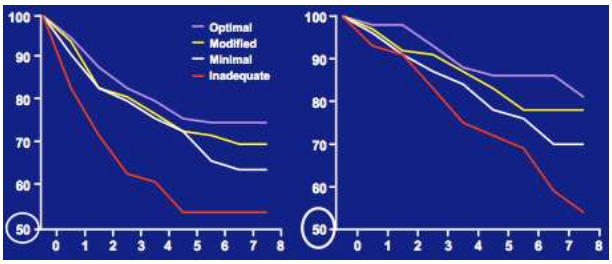
Incidence of occult intra-abdominal metastases at "early stage": 20-30%

- **Positive cytology 20 %**
- **Omentum majus 6 %**
- **Diaphragm 15 %**
- **Peritoneal biopsies 13 %**
- **Lymph nodes paraaortal 14 %**
- **Lymph nodes pelvin 8 %**

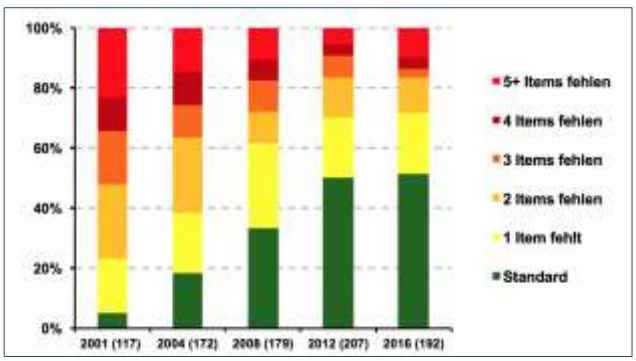
JB Trimbos Int J Gynecol Cancer 2000



Significant for OS and DFS in multivariate analysis : Staging: HR 2.05 and 1.99 (p=0.027/p=0.008)
ACTION/ICON1 Studien

Optimal staging in early stage OC – real world data

Staging-OP in FIGO I-IIA according to QS-OVAR (N=867)



Optimal staging in early stage OC – real world data

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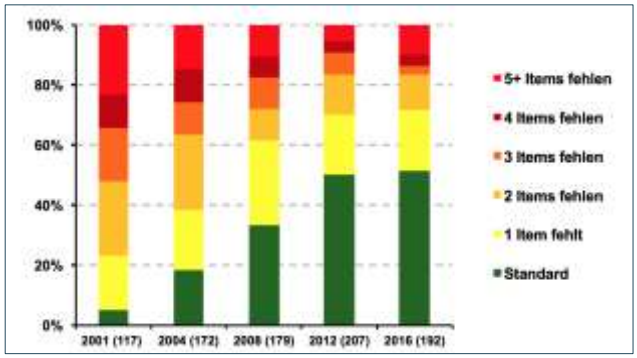
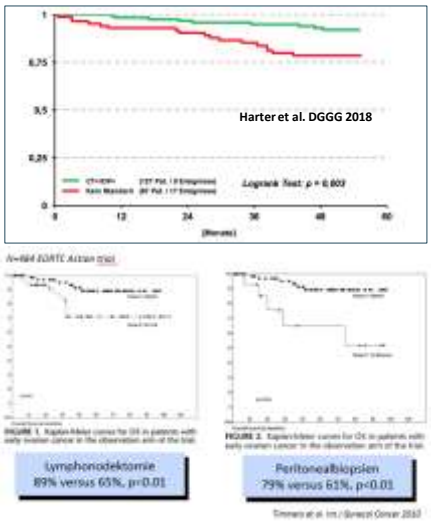
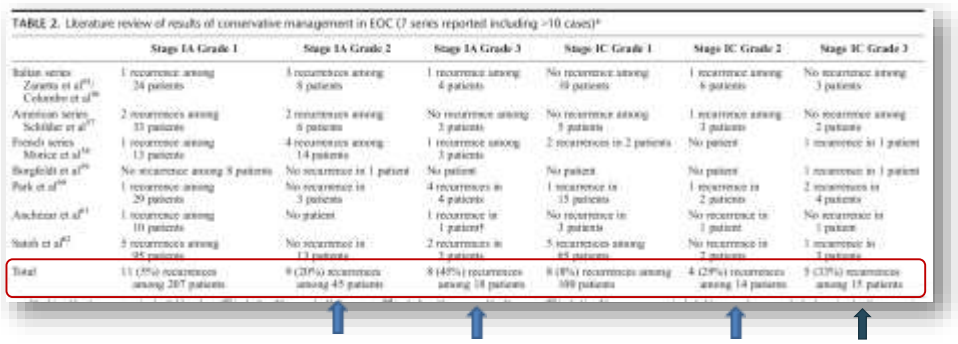


QS-OVAR Kohorte 2012: Treatment quality and survival (FIGO I IIA) (OP+: max. 1 missing)



Option for fertility sparing surgery?

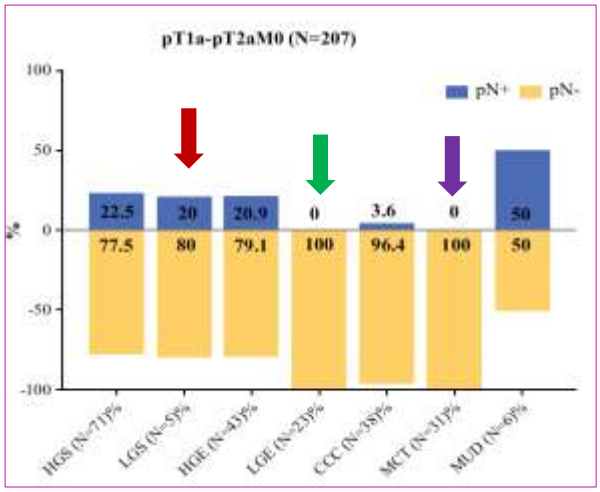
- no randomized trials
- adequate staging required
- individual appoach for unilateral tumor
- FIGO IA grade 1 (and possibly 2) serous, mucinous, endometrioid
- FIGO IC G1 ???



Morice, Denschlag et al. Int J Gynecol Cancer 2011

High rate of recurrence in potentially curative situation !

Relevance of LND - early stage OC




SURGICAL ONCOLOGY

ORIGINAL ARTICLE – GYNECOLOGIC ONCOLOGY

Stage- and Histologic Subtype-Dependent Frequency of Lymph Node Metastases in Patients with Epithelial Ovarian Cancer Undergoing Systematic Pelvic and Paraaortic Lymphadenectomy

- low grade endometrioid: no LN metastasis
- low grade mucinös: pT1-2a: no LN metastasis
- *CAVE: low grade serous: high rate of positive LN 20-73%*

LND may be omitted in certain histological subtyps

Adjuvant Tx - early stage OC

Early stage (I-IIA)
~ 25-30%

FIGO IA, G1 → no adjuvant chemo Tx

FIGO IA, G2, FIGO IB G1/2 → pt containig chemo Tx optional

all FIGO IC, FIGO IA/B G3 → pt containig chemo Tx

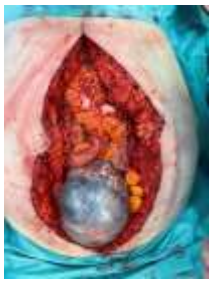
Limited data on certain subtypes → adjuvant chemo Tx to be discussed individually:
- clear cell carcinoma FIGO IA-IC1
- mucinous carcinoma FIGO IB/C G 1/2

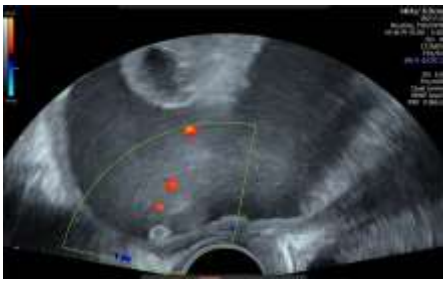
Chemo Tx should contain pt, 6 cycles

Ovarian cancer - Standard of care in advanced stage

- **Radical surgical therapy → intraabdominal complete resection**
- **First line med. Tx**
- **Maintenance Tx / BRCA / HRD diagnostic**

Advanced stage (IIB-IV)
~ 70-75%





Optimal surgery – advanced stage OC

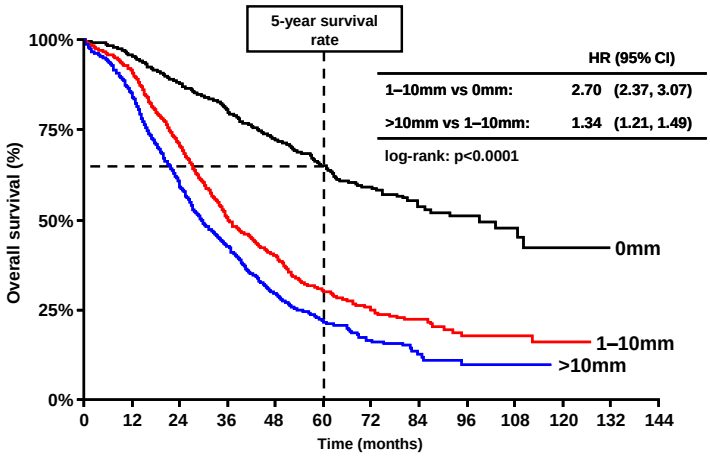
FIGO IIB-IV

- longitudinal laparotomy, inspection and palpation of the entire abdominal cavity
- **Complete resection** → multivisceral surgey (BSO, hysterectomy, resection of bowl, spleen, liver, peritonectomy, ……
- No LNE!

Complete resection rate in specialized centers in Germany: 60-70%

Residual Tumor at the end of surgery – the most important prognostic factor !

The impact of residual tumour on outcome in advanced ovarian cancer
Data from an individual patient meta-analysis of three randomised phase III trials with 3,126 patients

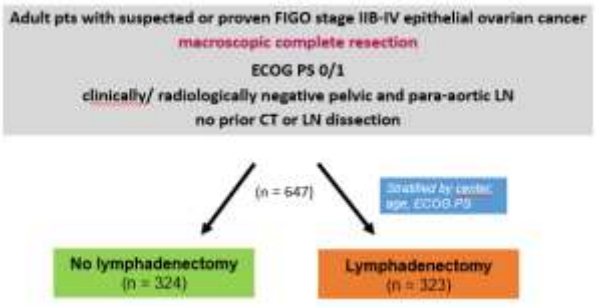


Complete debulking is important… because it saves the patients life !!!

10 % debulking improve OAS by approx 2,3 mths

du Bois A, et al. Cancer 2009;15:1234–44

How about LNE in advanced stage?



LION (AGO-OVAR OP.3)

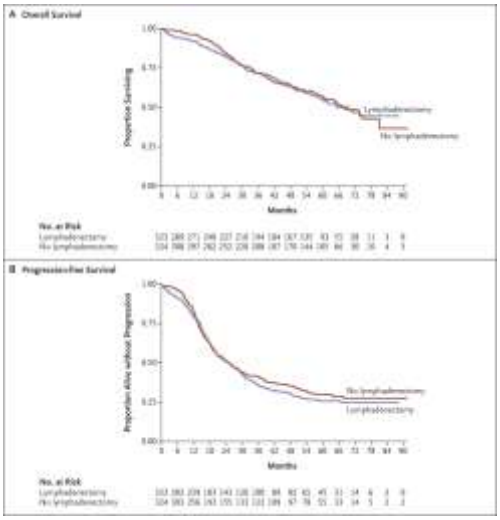
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial of Lymphadenectomy in Patients with Advanced Ovarian Neoplasms

P. Harter, J. Sehouli, D. Lorusso, A. Reuss, I. Vergote, C. Marth, J.-W. Kim, F. Raspagliesi, B. Lampe, G. Aletti, W. Meier, D. Cibula, A. Mustea, S. Mahner, I.B. Runnebaum, B. Schmalfeldt, A. Burges, R. Kimmig, G. Scambia, S. Greggi, F. Hilpert, A. Hasenburg, P. Hillemanns, G. Glorda, I. von Leffern, C. Schade-Brittinger, U. Wagner, and A. du Bois

In conclusion, in this trial involving patients with macroscopically complete resection of advanced ovarian cancer and clinically negative lymph nodes, systematic pelvic and paraaortic lymphadenectomy was not associated with better outcomes than no lymphadenectomy and was associated with a higher incidence of postoperative complications.

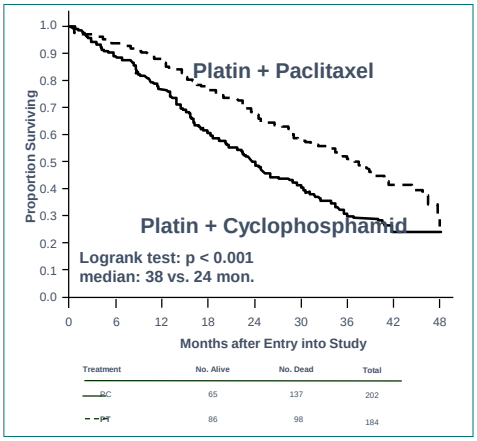


No LNE in advanced OC

N Engl J Med 2019; 380:822-832

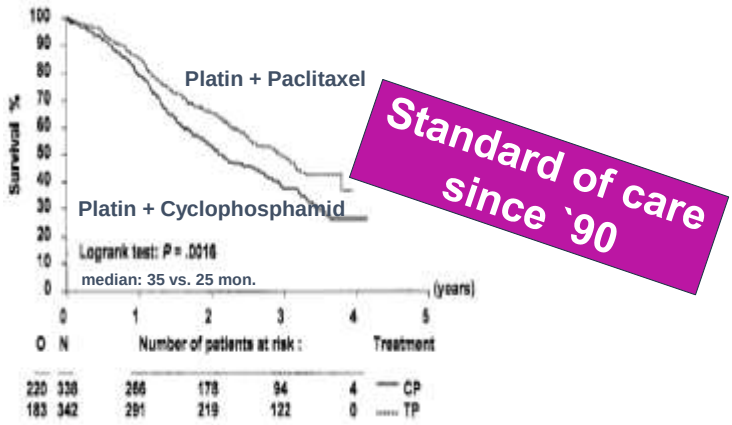
Adjuvant CTx in OC

GOG 111: 410 Pat. FIGO III-IV TuR > 1cm



WP McGuire et al.; N Engl J Med 334 (1996)

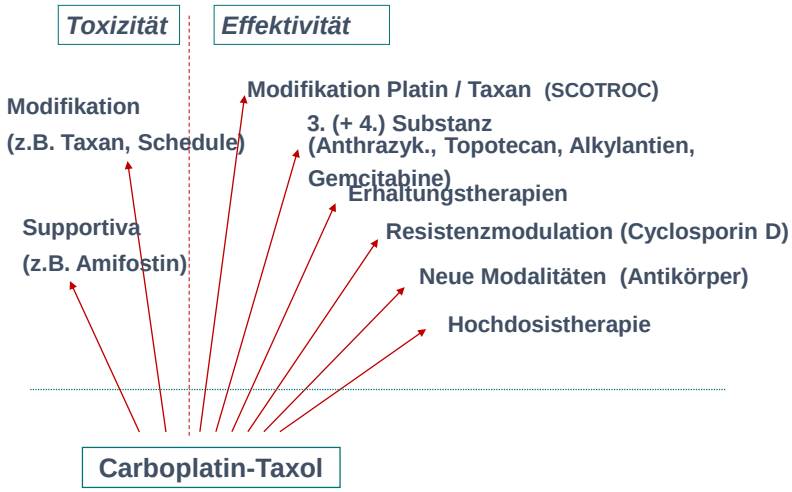
OV-10: 680 Pat. FIGO IIB-IV alle TuR



Standard of care since `90

MJ Piccart et al.; J Natl Cancer Inst 92 (2000)

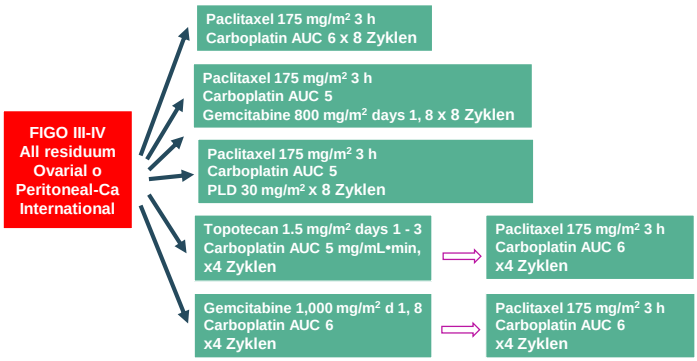
Standard Med Tx – Optimizing CTx



Despite radical cytoreductive surgery and ‚optimal CTx' approx. 2/3 of all patients with operable ovarian cancer will experience relapse.

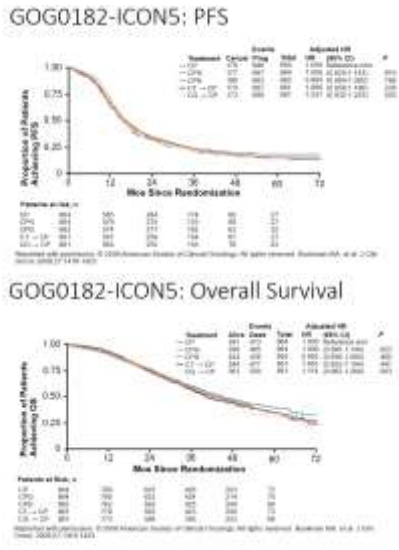
Is adding of a third drug better ?

Is more better? - GOG 182



Interval cytoreduction allowed, no second-look surgery
Endpoints: PFI, survival, response
n > 4,000 patients

NO !



Bookman, ASCO 2006, #5002

Ovarian cancer - Standard of care in advanced stage

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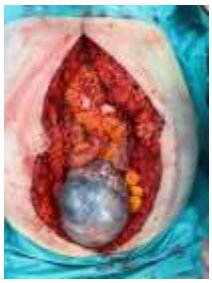
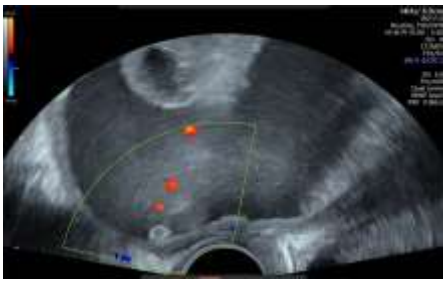
Advanced stage (IIB-IV)
~ 70-75%



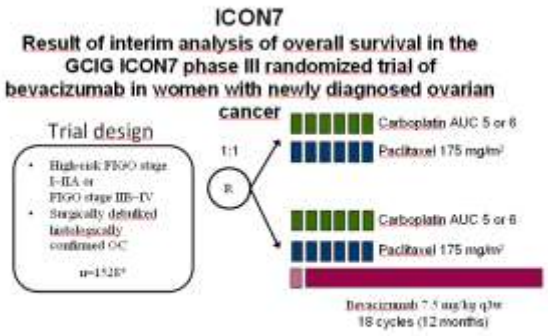


Maintenance therapy – an old concept

Will 12 months of paclitaxel prolong survival in patients with clinical complete remission after primary treatment ?

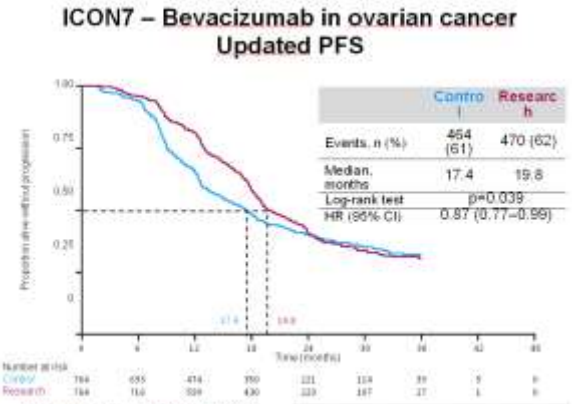
No positive evidence for CTx maintenance Tx in advanced OC

ICON 7 - Design



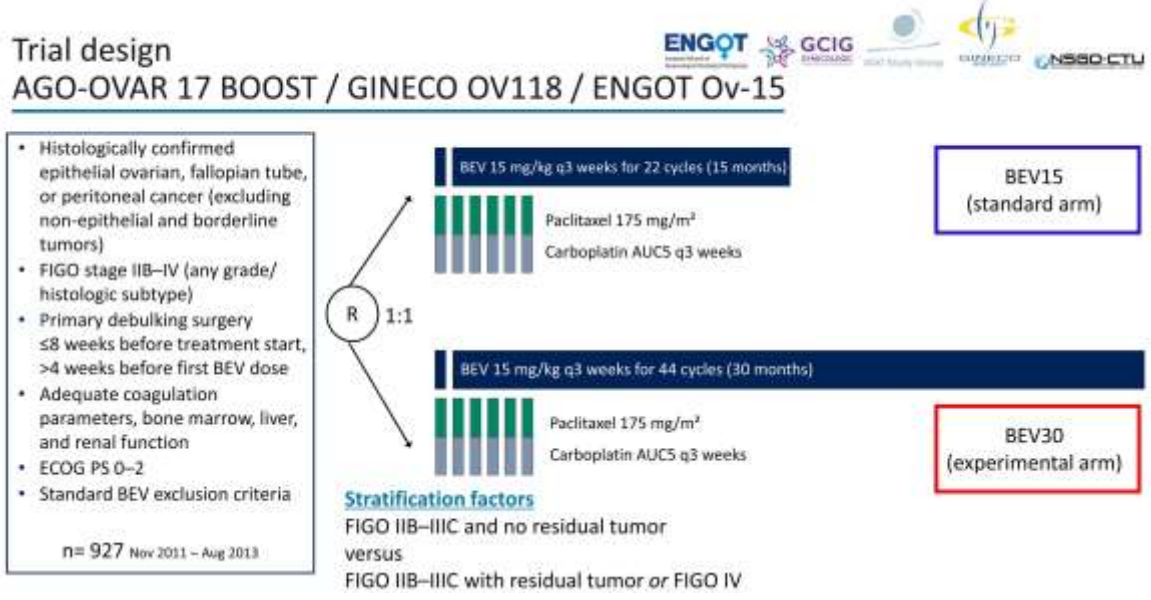
•Kristensen et al., J Clin Oncol 29: 2011 (suppl; abstr LBA5006)

•*Dec 2006 to Feb 2009



•Kristensen et al., J Clin Oncol 29: 2011 (suppl; abstr LBA5006)

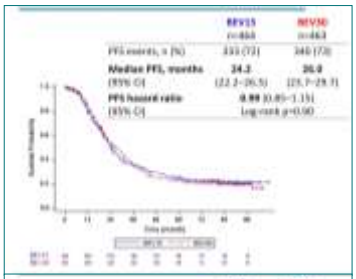
BEV - Optimizing Duration of Tx



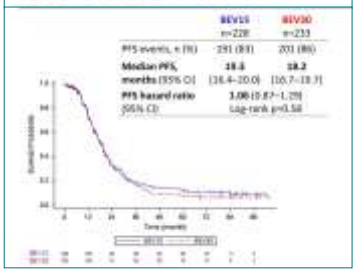
Jacobus Pfisterer et al. ASCO 2021, oral abstract 5501

Medianes F-UP 85 mths

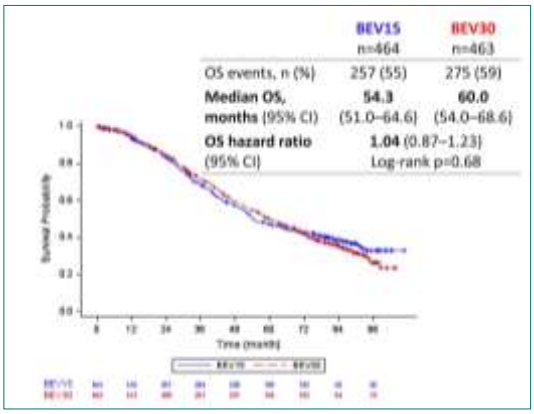
PFS



PFS
High-risk Gruppe
III+TR
IV



OS

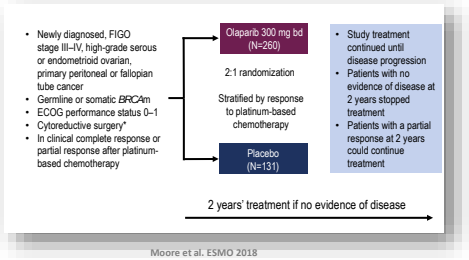


Bev 15 mths still standard of care

Jacobus Pfisterer et al. ASCO 2021, oral abstract 5501

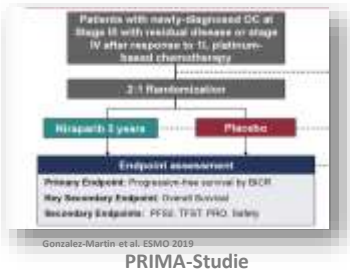
PARPi – first line Tx FIGO III/IV

SOLO1



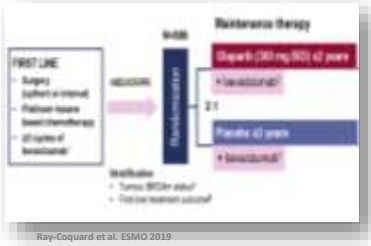
Moore et al. ESMO 2018

PRIMA



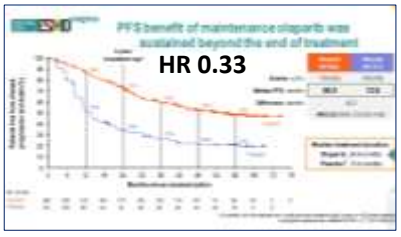
Gonzalez-Martin et al. ESMO 2019

PAOLA

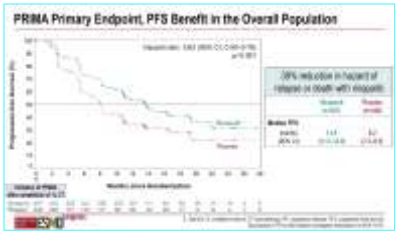


Ray-Coquard et al. ESMO 2019

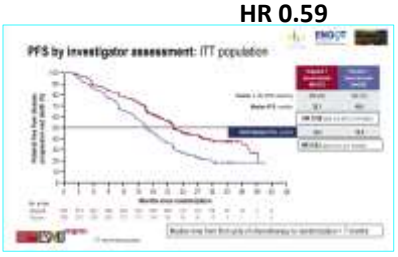
PRIMA-Studie



HR 0.62



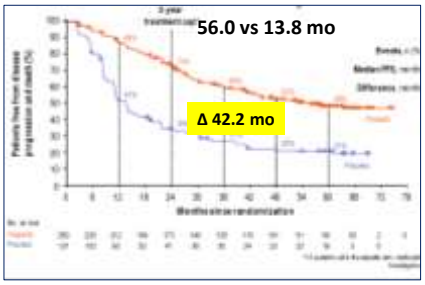
HR 0.59



Moore et al. ESMO 2018 & Banerjee et al. ESMO 2020

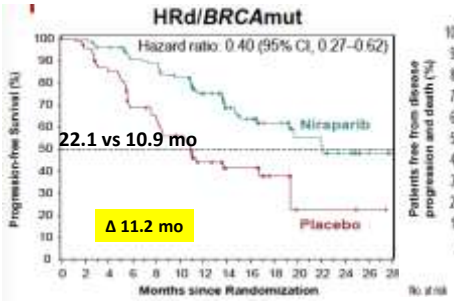
BRCA-Mutation

SOLO1



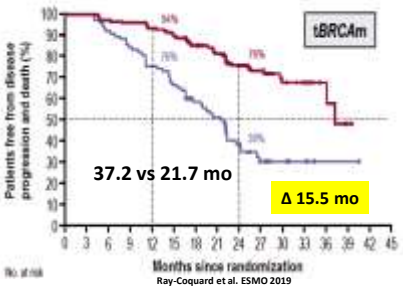
Banerjee et al. ESMO 2020

PRIMA



Gonzalez-Martin et al. ESMO 2019

PAOLA

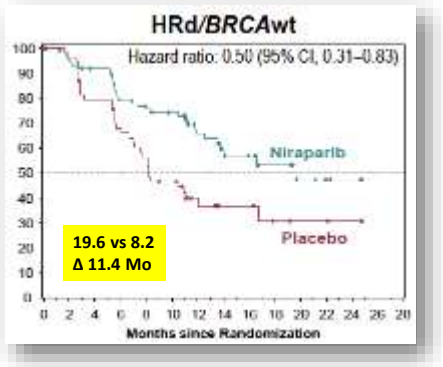


Ray-Coquard et al. ESMO 2019

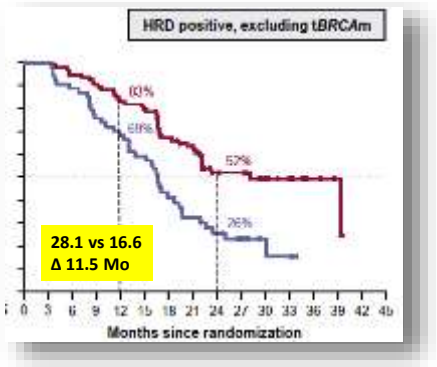
HR 0.33m(0.25-0.43) | **HR 0.40 (0.27-0.62)** | **HR 0.33 (0.25-0.45)**

HRD-positiv- BRCAwt

PRIMA



PAOLA



HR 0.50 (0.31-0.83) | **HR 0.43 (0.28-0.66)**

	PRIMA	PAOLA
Medianes PFS –	HRd/BRCAwt: 19.6/ 8.2 mo	HRd/BRCAwt: 28.1/ 16.6 mo
HR	HRd/BRCAwt: 0.50 (s)	HRd/BRCAwt: 0.43 (s)

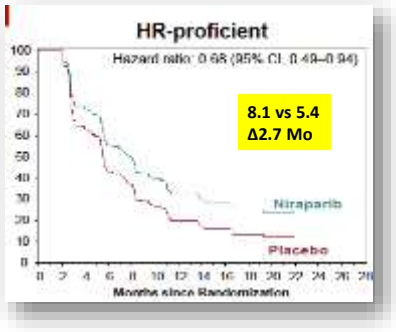
„Die Zulassung für Olaparib Filmtabletten in Kombination mit Bevacizumab in dieser Indikation ist auf Patienten mit positivem HRD Status beschränkt und erfolgte auf Basis einer präspezifizierten Subgruppenanalyse."

Gonzalez-Martin et al. ESMO 2019

Ray-Coquard et al. ESMO 2019

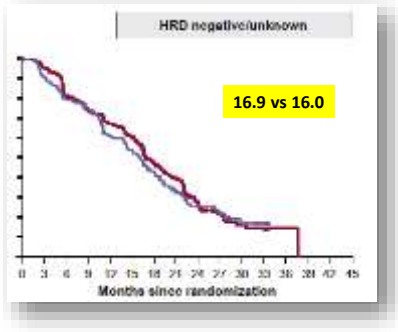
HRD-proficient/negative

PRIMA



HR 0.68 (0.49-0.94)

PAOLA



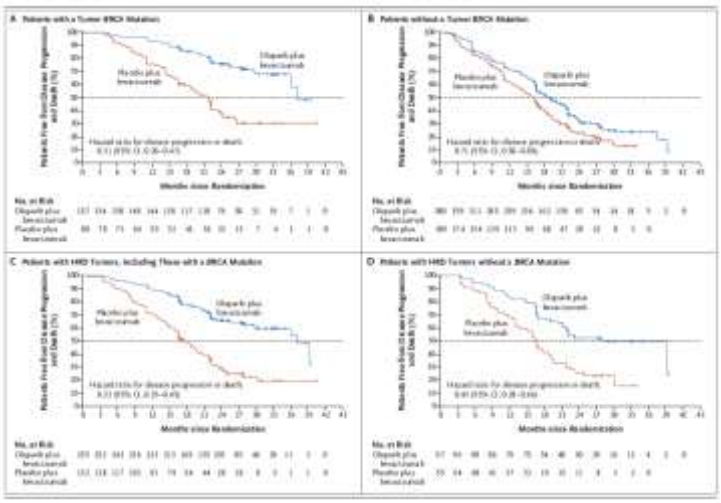
HR 0.92 (0.72-1.17)

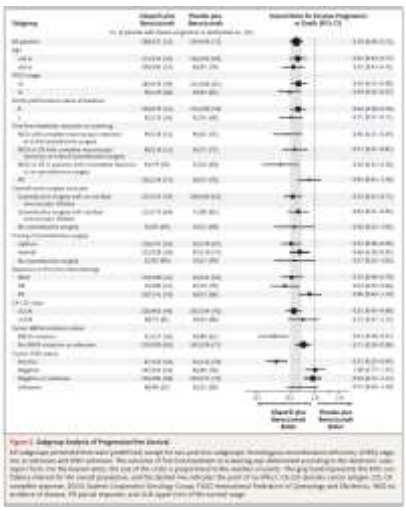
	PRIMA	PAOLA
Medianes PFS –	HRp: 8.1 / 5.4 mo	HRp: 16.9 / 16.0 mo
HR	HRp: 0.68 (s)	HRp: 0.92 (ns)

Gonzalez-Martin et al. ESMO 2019

Ray-Coquard et al. ESMO 2019

PARPi + Antiangiogenetic Tx?

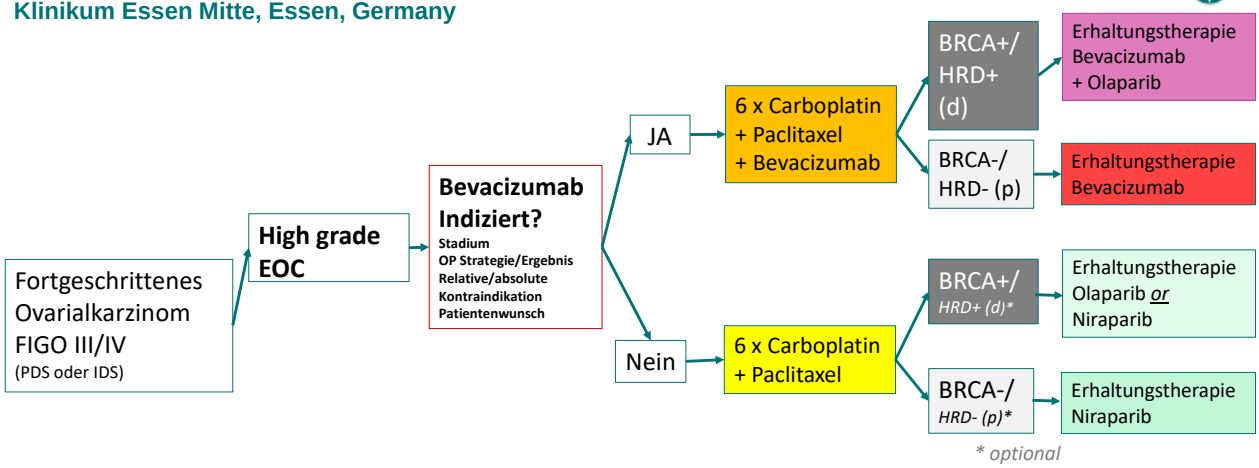




PAOLA-1, NEJM 381; 25 (2019)

Option for an Algorithm: Maintenance Tx in advanced O

Klinikum Essen Mitte, Essen, Germany



And many more aspects - we did not talk about...

Newly diagnosed OC

- Early detection and Screening
- Genetics, genetic risk factors, prevention strategies
- NACT – an option for selected patients?
- Dose dense CTx
- Endoscopic surgery?
- Specific needs in comorbid patients?

Recurrent disease

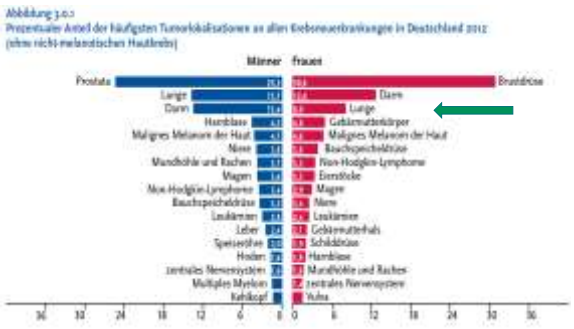
- Is surgery still an option?
- What is the best medical strategy?
- pt again – mono CTx / combined CTx ?
- PARPi after PAPRi ?

02
Endometrial Cancer

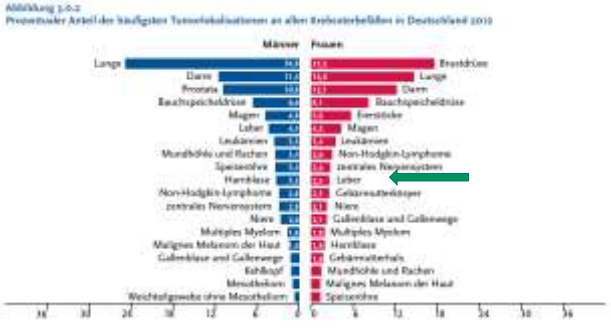
Endometrial cancer (EC)

Germany: Approx. 11.000 new cases / year, approx. 2.500 deaths / year

1/49 women will develop EC

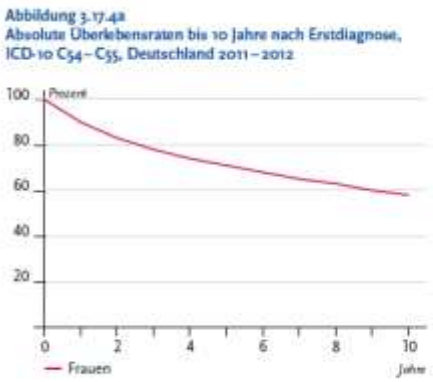


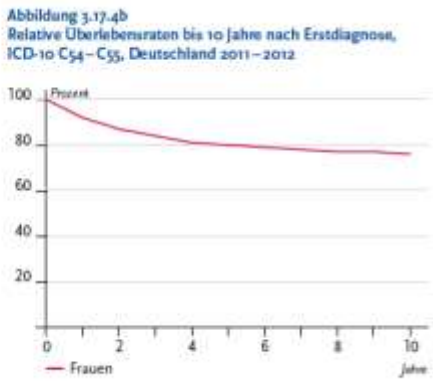
1/200 women will die because of EC

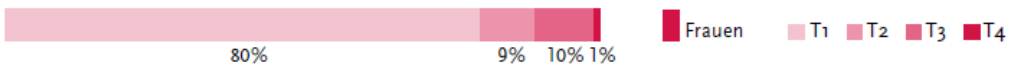


Robert-Koch-Institut 2015

Endometrial cancer (EC)
Good prognosis because of early detection



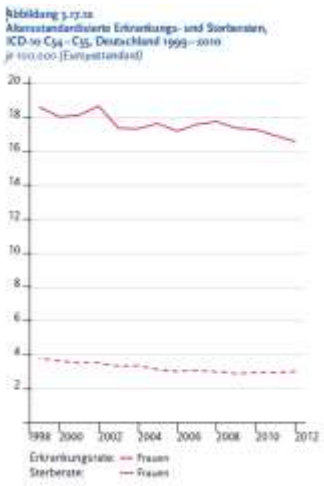


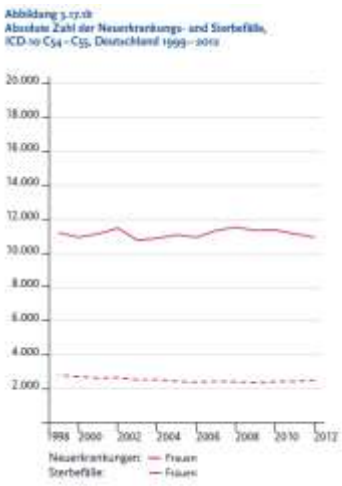


Verteilung der T-Stadien bei Erstdiagnose, ICD-10 C54 – C55, Deutschland 2011 – 2012

Robert-Koch-Institut 2015

Endometrial cancer (EC)
Good prognosis because of early detection





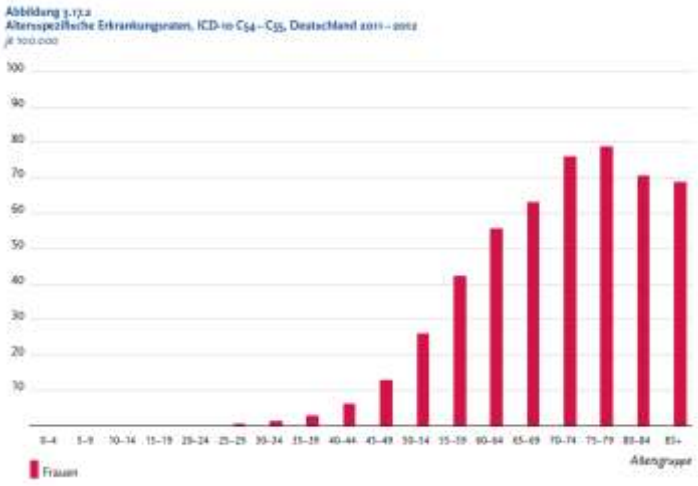
Absolute Zahl der Neuerkrankungs- und Sterbefälle, ICD-10 C54 – C55, Deutschland 1999 – 2012

But: high incidence – not improved since decades !!!

No improvement for outcome!!!

Robert-Koch-Institut 2015

Endometrial cancer (EC)
A disease of elderly and very old women



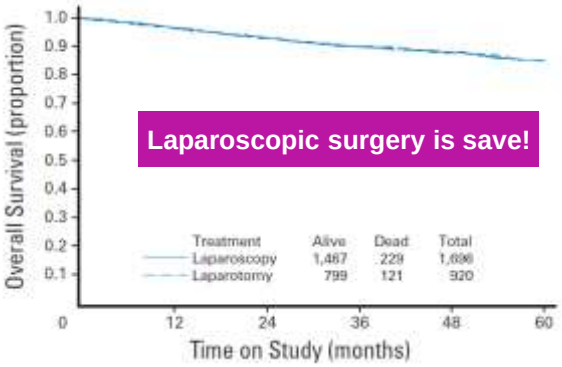
Robert-Koch-Institut 2015

After more than 30 years - New aspects in EC

- New surgical strategies → Sentinel LNE, robotic surgery
- Molecular diagnostics → new classification of EC
- New options for medical treatment → immunooncological Tx and others

Standard of care EC since decades

- **Hysterectomy and BSO**, radical hysterectomy only for selected cases, Lymphonodectomy in selected cases
- Option for adj. Tx in according to stage (RTx, CTx)



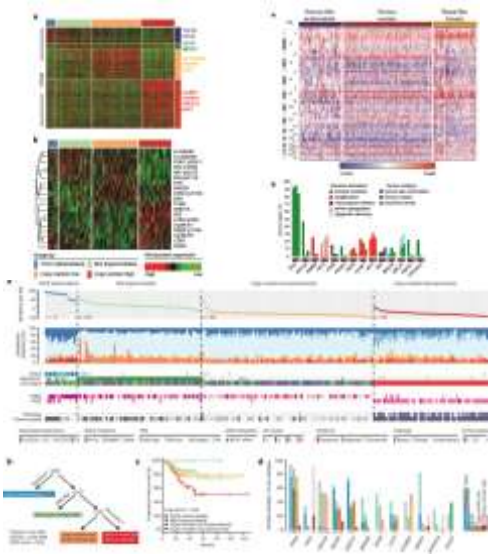
Walker et al. JCO 2012
Walker et al. JCO 2009

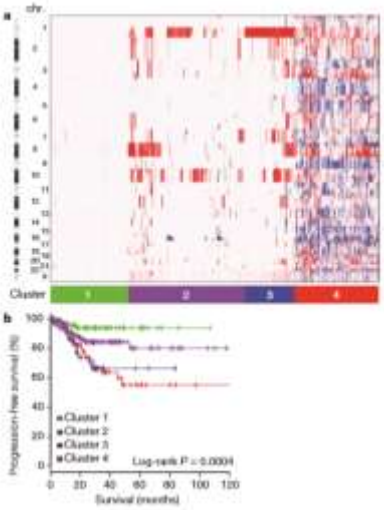
New options for surgical Tx in EC

After more than 30 years - New aspects in EC

- New surgical strategies → Sentinel LNE, robotic surgery
- **Molecular diagnostics → new classification of EC**
- New options for medical treatment → immunooncological Tx and others

Ready for primetime - The Cancer Genome Atlas Research Network, Endometrial cancer

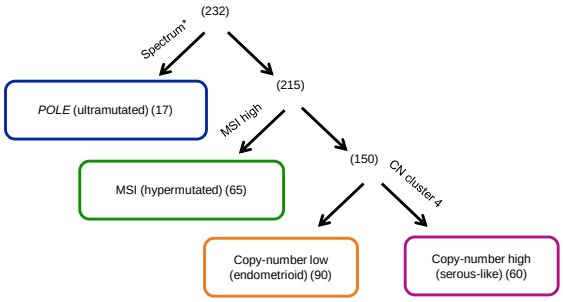


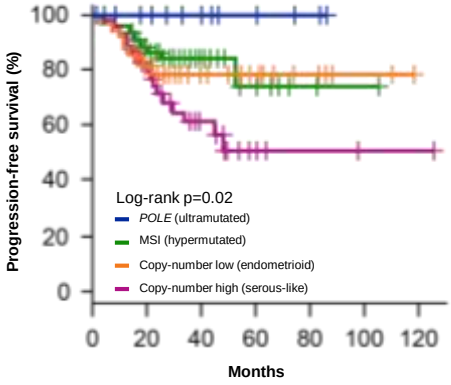


Kandoth et al., TCGA, Nature, 497: 67-73, 2013

The Cancer Genome Atlas – Molekular subtyps

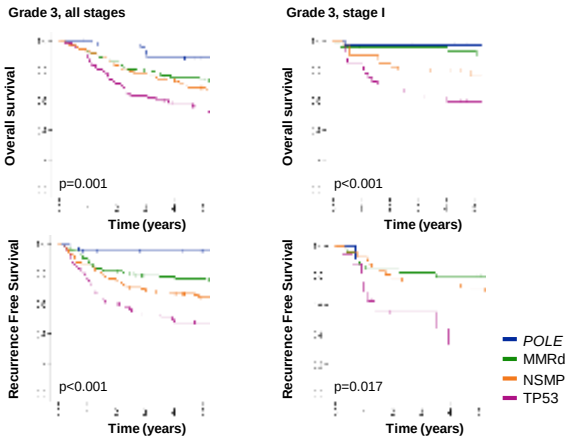
KANDOTH C ET AL. NATURE. 2013;497:67-73





45

Molecular classification of high grade endometrial cancer



n=381; international collaboration

Conclusions

- Grade 3 endometrial cancer is **not a homogeneous 'high risk' cohort**
- TGCA molecular groups have clear prognostic impact in high-grade EC
- Prognostic strength of molecular classification is independent of stage
- POLE almost zero events in grade 3 disease

→ Molecular subtyping should be performed prior to definite surgical therapy

Bosse et al, Am J Surg Pathol 2018

2020 ESGO / ESTRO / ESP

RISK GROUPS /GUIDELINES FOR MANAGEMENT OF PATIENTS WITH ENDOMETRIAL CANCER

Risk group	Molecular classification unknown	Molecular classification known*†
Low	► Stage IA endometrioid + low-grade‡ + LVSI negative or focal	► Stage I–II **POLEmut** endometrial carcinoma, no residual disease ► Stage IA **MMRd/NSMP** endometrioid carcinoma + low-grade‡ + LVSI negative or focal
Intermediate	► Stage IB endometrioid + low-grade‡ + LVSI negative or focal ► Stage IA endometrioid + high-grade‡ + LVSI negative or focal ► Stage IA non-endometrioid (serous, clear cell, undifferentiated carcinoma, carcinosarcoma, mixed) without myometrial invasion	► Stage IB **MMRd/NSMP** endometrioid carcinoma + low-grade‡ + LVSI negative or focal ► Stage IA **MMRd/NSMP** endometrioid carcinoma + high-grade‡ + LVSI negative or focal ► Stage IA **p53abn** and/or non-endometrioid (serous, clear cell, undifferentiated carcinoma, carcinosarcoma, mixed) without myometrial invasion
High–intermediate	► Stage I endometrioid + substantial LVSI regardless of grade and depth of invasion ► Stage IB endometrioid high-grade‡ regardless of LVSI status ► Stage II	► Stage I **MMRd/NSMP** endometrioid carcinoma + substantial LVSI regardless of grade and depth of invasion ► Stage IB **MMRd/NSMP** endometrioid carcinoma high-grade‡ regardless of LVSI status ► Stage II **MMRd/NSMP** endometrioid carcinoma
High	► Stage III–IVA with no residual disease ► Stage I–IVA non-endometrioid (serous, clear cell, undifferentiated carcinoma, carcinosarcoma, mixed) with myometrial invasion, and with no residual disease	► Stage III–IVA **MMRd/NSMP** endometrioid carcinoma with no residual disease ► Stage I–IVA **p53abn** endometrial carcinoma with myometrial invasion, with no residual disease ► Stage I–IVA **NSMP/MMRd** serous, undifferentiated carcinoma, carcinosarcoma with myometrial invasion, with no residual disease
Advanced metastatic	► Stage III–IVA with residual disease ► Stage IVB	► Stage III–IVA with residual disease of any molecular type ► Stage IVB of any molecular type

Concin N, *et al. Int J Gynecol Cancer* 2020;**0**:12–39. doi:10.1136/ijgc-2020-002230

Molecular subtype stratified response to adjuvant therapy (learning from PORTEC-3): Canadian Cohorts (SGO 22) & Future directions

MMRd EC

No benefit from the addition of adjuvant chemotherapy to radiation in ESMO high risk and ESMO high, advanced and metastatic risk groups combined

NO CHEMO!!!

p53abn EC

Adjuvant chemotherapy resulted in a statistically significant improvement in DSS and OS in ESMO high risk and ESMO high, advanced and metastatic risk groups combined compared to radiation only

45% UNDER treated
NEED Chemo
Some PARP?

NSMP EC

Patients who had radiation only appeared to have improved outcomes in ESMO high risk and ESMO high, advanced and metastatic risk groups combined compared to chemoradiation

RT better?
AI / progestin?

*POLE*mut EC

Small number of disease related events in this subtype, even in ESMO high risk group
Most deaths were non-cancer related

44% *POLE*mut EC were possibly overtreated

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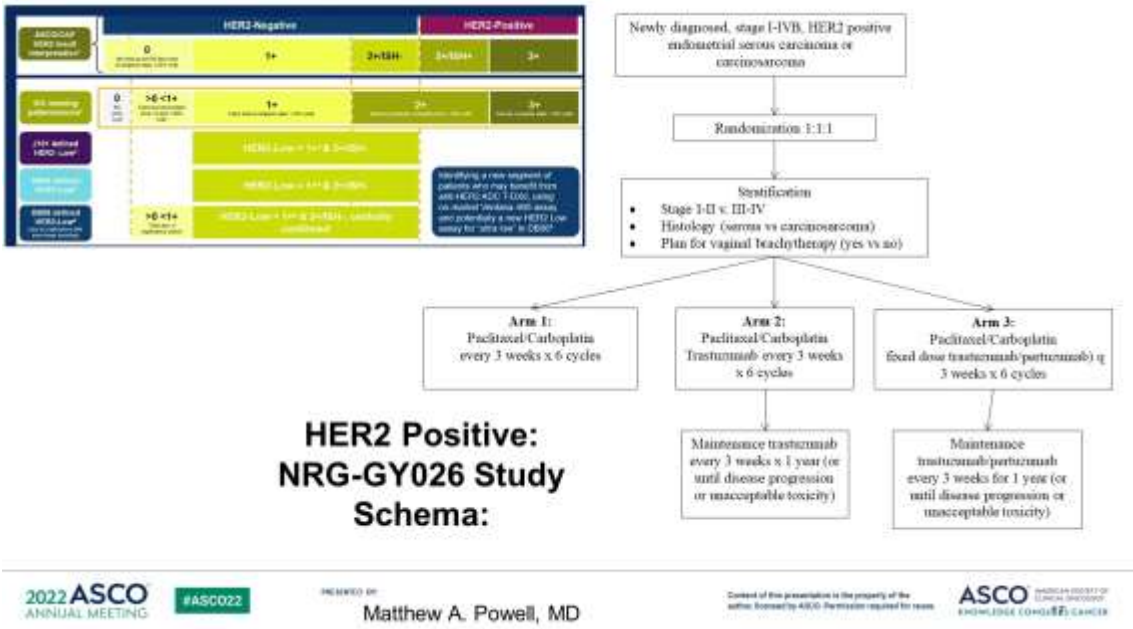
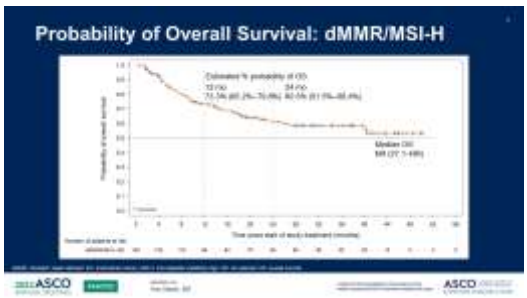
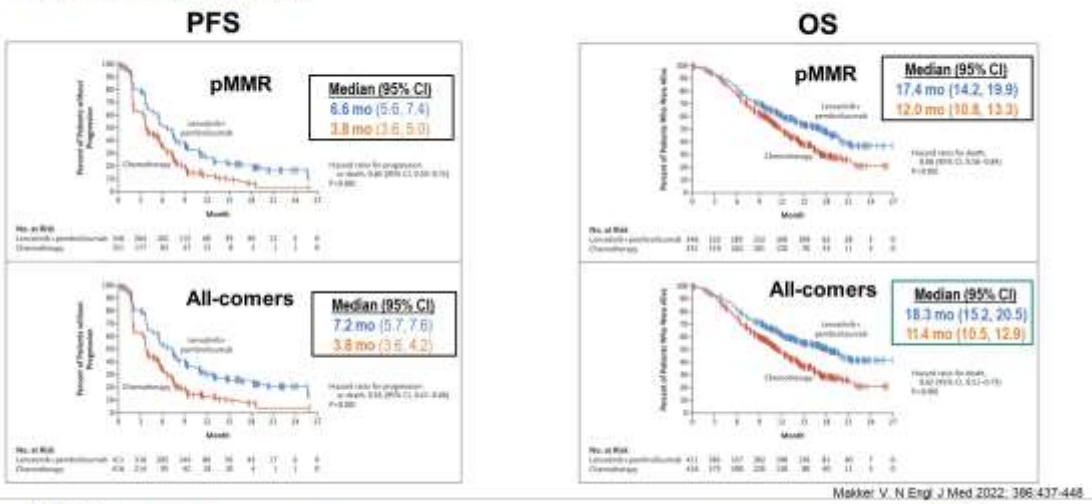


Dostarlimab in recurrent EC – GARNET Trial



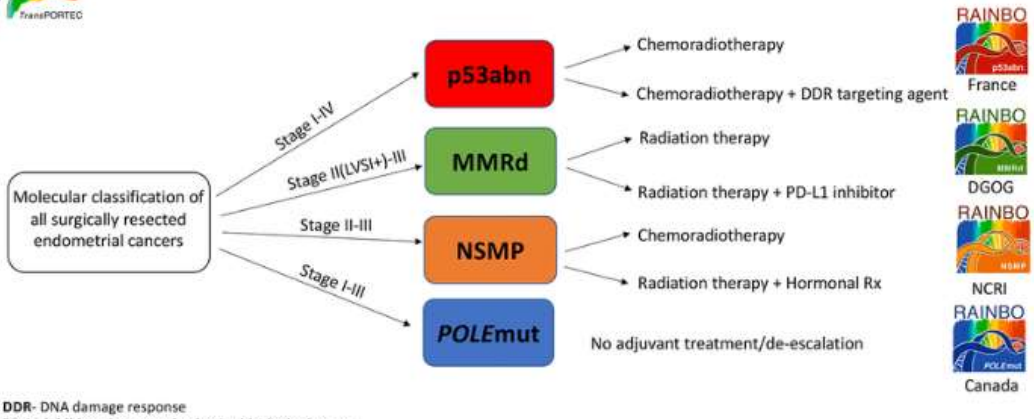
Study 309/Keynote-775: Lenvatinib and Pembrolizumab vs. Physician's Choice Chemotherapy



Makker V. N Engl J Med 2022; 386:437-448

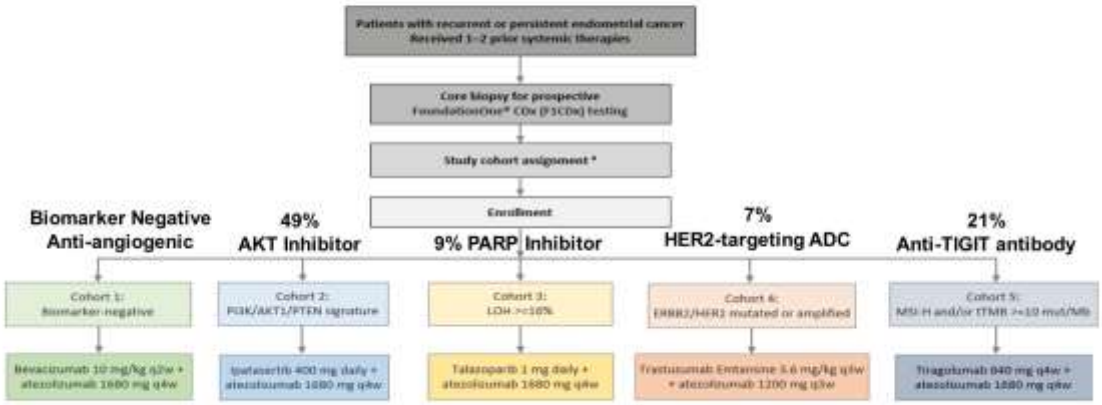
2022 ASCO ANNUAL MEETING #ASCO22 PRESENTED BY Melissa A. Geller, MD

TransPORTEC RAINBO Umbrella Trial



DDR- DNA damage response
PD-L1 inhibitor- immune checkpoint blockade therapy

A Phase IB/II Multi-Cohort Study of Targeted Agents with Atezolizumab for Patients with Recurrent or Persistent Endometrial Cancer Alliance Foundation Trial EndoMAP NCT04486352



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Melissa A. Geller, MD

2022 ASCO ANNUAL MEETING

Randomized Phase III Study of Maintenance Selinexor vs Placebo in Endometrial Cancer (ENGOT-EN5/GOG-3055/SIENDO): Impact of Subgroup Analysis and Molecular Classification

Vicky Makker[1], J Alejandro Pérez-Fidalgo[2], Alice Bergamini[3], Daniel Spitz[4], Toon Van Gorp[5], Jalid Sehouli[6], Jaroslav Klat[7], Tamar Perri[8], Amit Oza[9], Estrid Høgdall[10], Jason Konner[11], Eva M Guerra-Alia[12], Francesco Raspagliesi[13], Stéphanie Henry[14], Bradley J. Monk[15], Jerónimo Martínez[16], Brian Slomovitz[17], Sharon Shacham[18], Mansoor Raza Mirza[19], Ignace Vergote[5]

[1]Memorial Sloan Kettering Cancer Center, [2]Hospital Clínico Universitario de Valencia, Valencia and GEICO, [3]MITO and Department of Obstetrics and Gynecology, San Raffaele Scientific Institute, [4]Florida Cancer Specialists, Sarah Cannon Research Institute, [5]BGOG and Leuven Cancer Institute, University Hospitals Leuven, Leuven, Belgium, [6]NOGGO and Department of Gynecology, European Competence Center for Ovarian Cancer, Charité Comprehensive Cancer Center, Charité–Berlin University of Medicine, [7]CEEGOG and University Hospital Ostrava, [8]ISGO and Sheba Medical Center, [9]Princess Margaret Cancer Centre, University Health Network, [10]Department of Pathology, Herlev Hospital, University of Copenhagen, Copenhagen, Denmark, [11]Memorial Sloan Kettering Monmouth, [12]Hospital Universitario Ramón y Cajal, Madrid and GEICO, [13]MITO and Fondazione IRCCS Istituto Nazionale dei Tumori– Milano, S.C. Ginecologia Oncologica, [14]BSGO and Université Catholique de Louvain, CHU UCL Namur Site Ste Elisabeth, Service d'onco-hématologie (SORMN), Place Louise Godin 15 B-5000 Namur, [15]GOG Foundation, University of Arizona, Creighton University, Phoenix, AZ USA, [16]Hospital Virgen de la Arrixaca, Murcia and GEICO, [17]Gynecologic Oncology, Mount Sinai Medical Center; Obstetrics and Gynecology, Florida International University, [18]Karyopharm Therapeutics [19]Rigshospitalet, Copenhagen University Hospital, Denmark

Vicky Makker, M.D.

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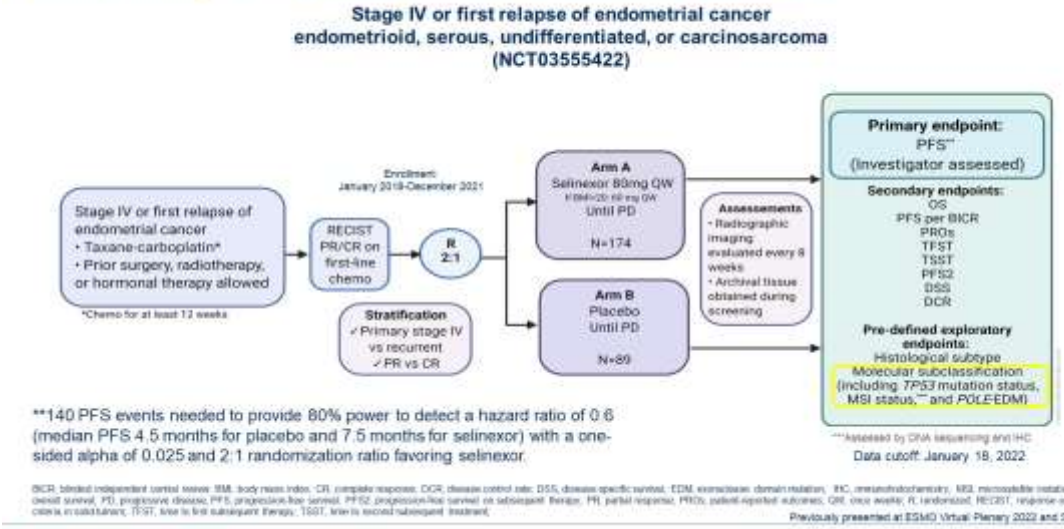
Vicky Makker, M.D., ENGOT-EN5/GOG-3055/SIENDO

Trial Design ENGOT-EN5/GOG-3055/SIENDO



BICR, blinded independent central review; BMI, body mass index; CR, complete response; DCR, disease control rate; DSS, disease specific survival; EDM, exonuclease domain mutation; IHC, immunohistochemistry; MSI, microsatellite instability; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS2, progression-free survival on subsequent therapy; PR, partial response; PROs, patient-reported outcomes; QW, once weekly; R, randomized; RECIST, response evaluation criteria in solid tumors; TFST, time to first subsequent therapy; TSST, time to second subsequent treatment

Previously presented at ESMO Virtual Plenary 2022 and SGO 2022

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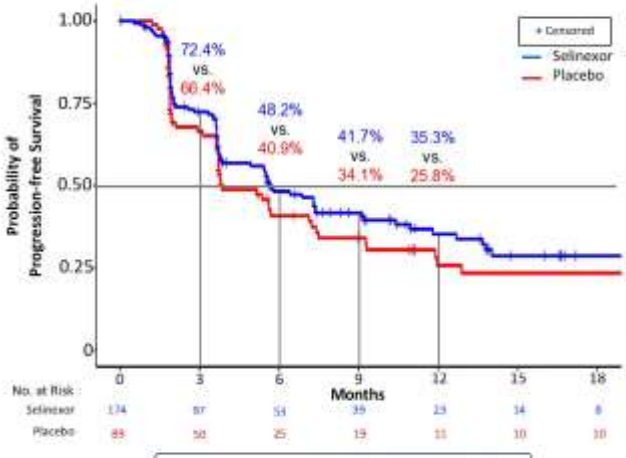
Presented by: Vicky Makker, M.D., ENGOT-EN5/GOG-3055/SIENDO

ASCO KNOWLEDGE CONQUERS CANCER

Primary Endpoint: PFS in ITT Population



Median PFS

Selinexor (n=174): 5.7 mo (95% CI 3.81-9.20)

Placebo (n=89): 3.8 mo (95% CI 3.68-7.39)

Audited* (by electronic case report form)

HR = 0.705 (95% CI 0.499-0.996)

One-sided P value = 0.024

Unaudited* (by interactive response technology)

HR = 0.76 (95% CI 0.543-1.076)

One-sided P value = 0.063

*In 7 patients (2.7% of 263), the stratification factor of CR/PR was incorrect and was corrected by the investigators prior to database lock and unblinding. The statistical analysis was validated by the independent ENGOT statistician and approved by the IDMC.

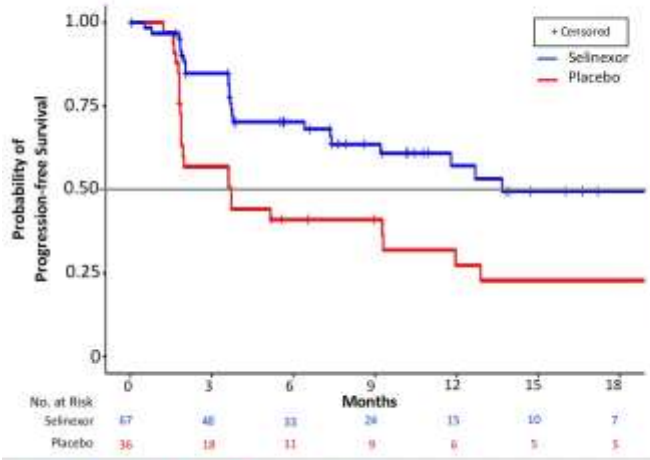
CI, confidence interval; HR, hazard ratio; mo, months; PFS, progression-free survival

2022 ASCO ANNUAL MEETING #ASCO22

Presented by: Vicky Makker, M.D., ENGOT-EN5/GOG-3055/SIENDO

ASCO KNOWLEDGE CONQUERS CANCER

Preliminary Analysis of a Prespecified Exploratory Subgroup PFS: Patients with p53 wild-type EC



Median PFS

Selinexor (n=67): 13.7 mo (95% CI 9.20-NR)

Placebo (n=36): 3.7 mo (95% CI 1.87-12.88)

Audited

HR = 0.375 (95% CI 0.210-0.670)

Nominal one-sided P value = 0.0003

Unaudited

HR = 0.407 (95% CI 0.229-0.724)

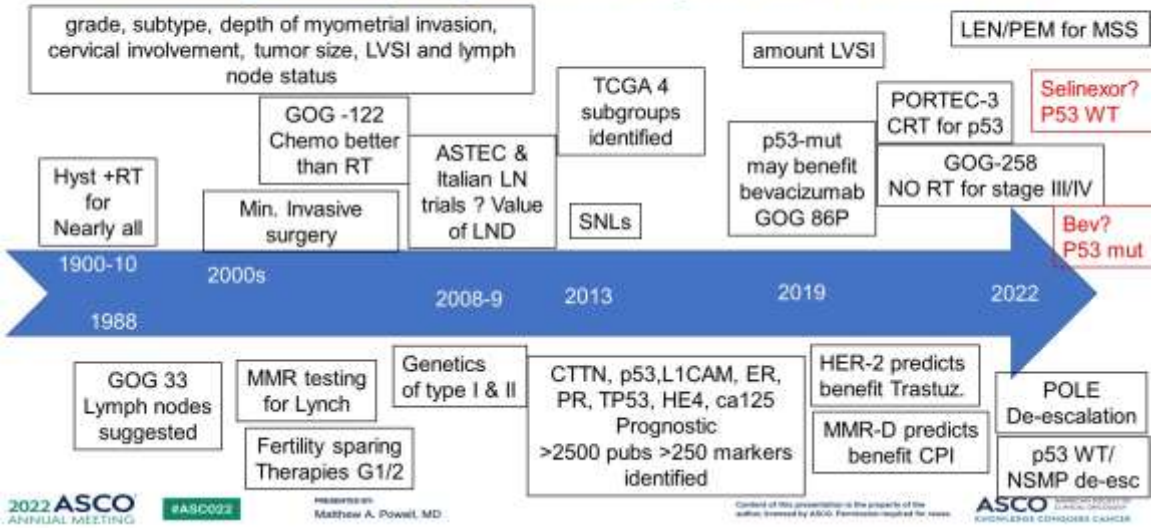
Nominal one-sided P value = 0.0008

CI, confidence interval; HR, hazard ratio; mo, months; PFS, progression-free survival

2022 ASCO ANNUAL MEETING #ASCO22

Vicky Makker, M.D., ENGOT-EN5/GOG-3055/SIENDO

History of management of Endometrial Cancer: Journey from prognostic to predictive markers



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Matthew A. Powell, MD

"Before I came here I was confused about this subject. Having listened to your lecture I am still confused. But on a higher level."

Enrico Fermi
1901 - 1954

Prof. Dr. med. Gerhard Gebauer, MHM, MBA
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