ESMO GUIDELINES:
REAL WORLD CASES

LATE STAGE OVARIAN CANCER

Sandro Pignata

IRCCS National Cancer Institute "Fondazione G. Pascale", Naples

ESMO WEBINAR SERIES

Programme

15 October 2024

10 min	**Welcome and introduction** Sandro Pignata
10 min	**Case Presentation** Maria Kfoury
20 min	**Presentation of the ESMO Clinical Practice Guideline for Critical Analysis of the Case** Antonio Gonzalez Martin
10 min	**Considerations Related to Guideline Implementation in Everyday Clinical Practice and Discussion** Benedetta Pellegrino
10 min	**Live Q&A and Discussion** All speakers

Sandro Pignata
Chair
Uro-Gynecological Department
Division of Medical Oncology
IRCCS National Cancer Institute "Fondazione G. Pascale"
Naples

Maria Kfoury
Speaker
Institut Paoli-Calmettes
Marseille

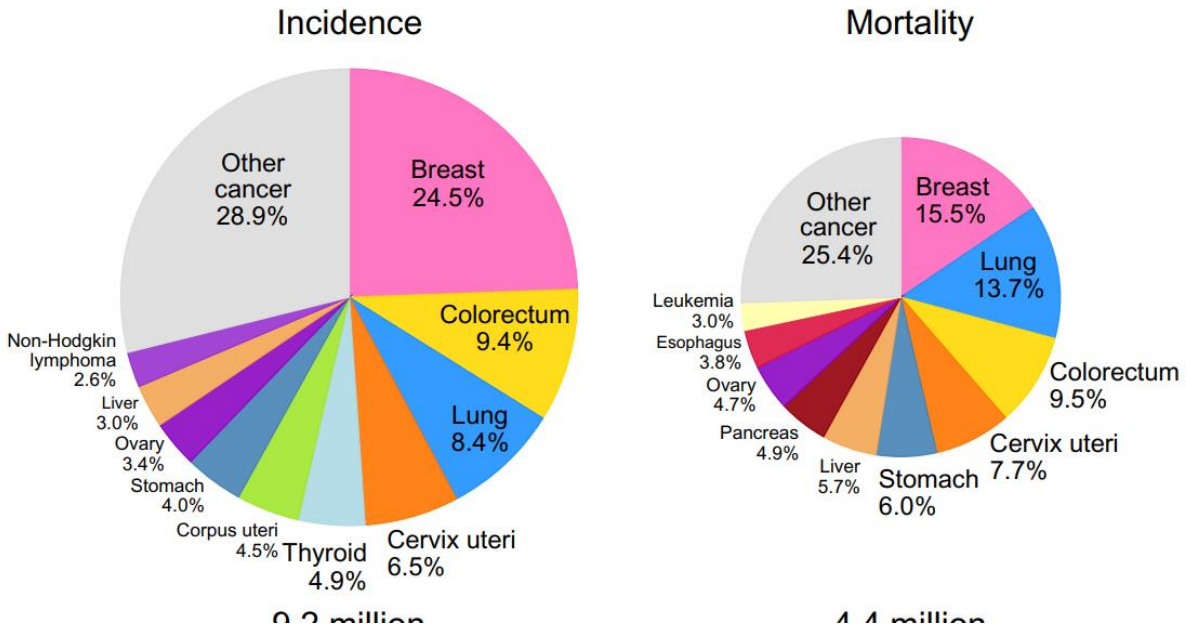
Antonio González-Martín
Speaker
Medical Oncology Department, Cancer Center Clínica Universidad de Navarra,
Madrid

Benedetta Pellegrino
Speaker
University Hospital of Parma

LEARNING OBJECTIVES

- Promote evidence-based quality cancer care by disseminating the ESMO Clinical Practice Guidelines (CPG) in the oncology community.
- Present a clinical case for each of the selected topics for discussion in the context of the ESMO CPG recommendations.
- Present and critically review the ESMO CPG recommendations for each selected cancer type.
- Discuss the case, the ESMO CPG recommendations, their impact on care and implementability in the daily practice setting under the guidance of a moderator senior expert, with participation of the guideline authors, practicing oncologists and young oncologists.
- Audit the fulfillment of the learning objectives and acceptability of the ESMO CPG recommendations by means of an online questionnaire.

EPIDEMIOLOGY



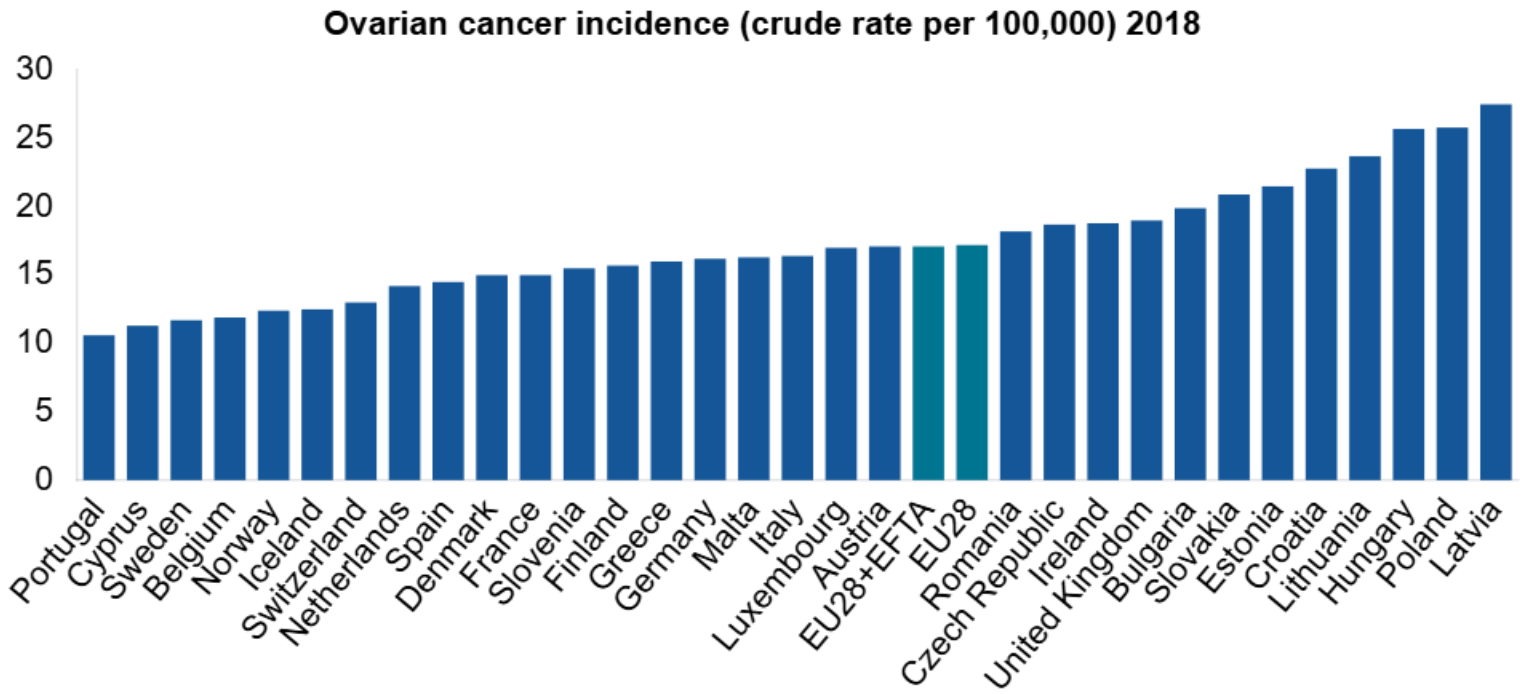
Globocan 2020

New cases 313,959 (1.6)

New deats 207,252 (2.1)

Sung et Al: Globocan CA CANCER J CLIN 2021;71:209–249

EPIDEMIOLOGY



The estimated number of new cases in Europe in 2020
66 693 with 44 053 deaths

EFPIA website
ECIS - European Cancer Information System. https://ecis. jrc.ec.europa.eu.

EPIDEMIOLOGY

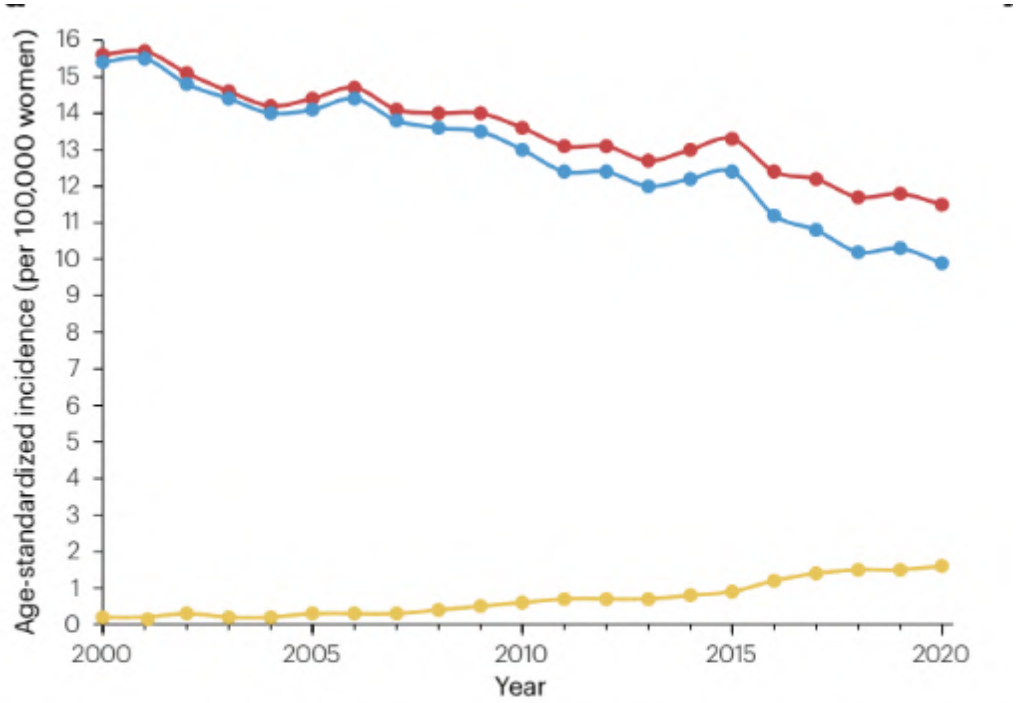


Fig. 2 | Age-standardized incidence rates of ovarian and ovarian plus serous fallopian tube cancers over time. a, USA – non-Hispanic white individuals (standardized to US 2000 population). **b**, Australia (standardized to Australian

Incidence is decreasing

Webb et ak Nature Reviews Clinical Oncology | Volume 21 | May 2024 | 389–400

EPIDEMIOLOGY

- No screening available
- 2/3 of the cases in an advanced stage

- BRCA carriers identification is the priority to decrease mortality

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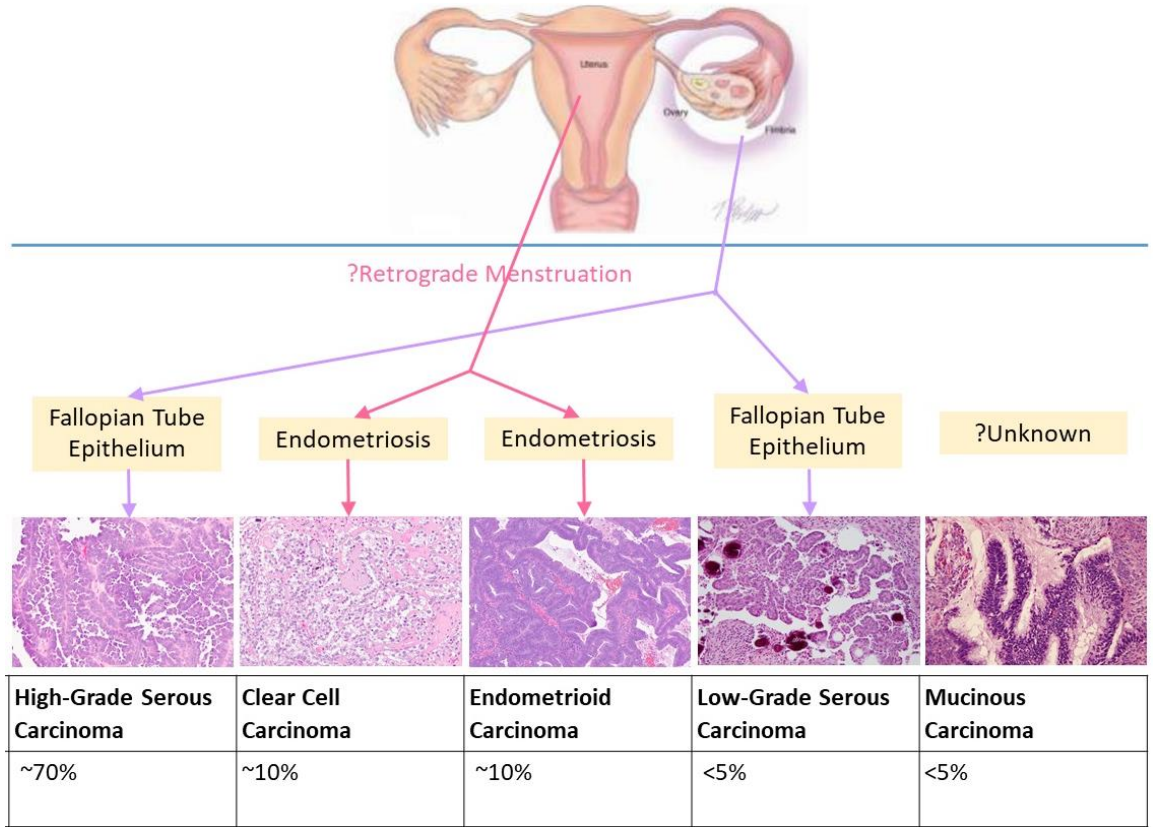
HISTOLOGY

What we call Ovarian cancer is more than one disease



High-Grade Serous Carcinoma	Clear Cell Carcinoma	Endometrioid Carcinoma	Low-Grade Serous Carcinoma	Mucinous Carcinoma
~70%	~10%	~10%	<5%	<5%

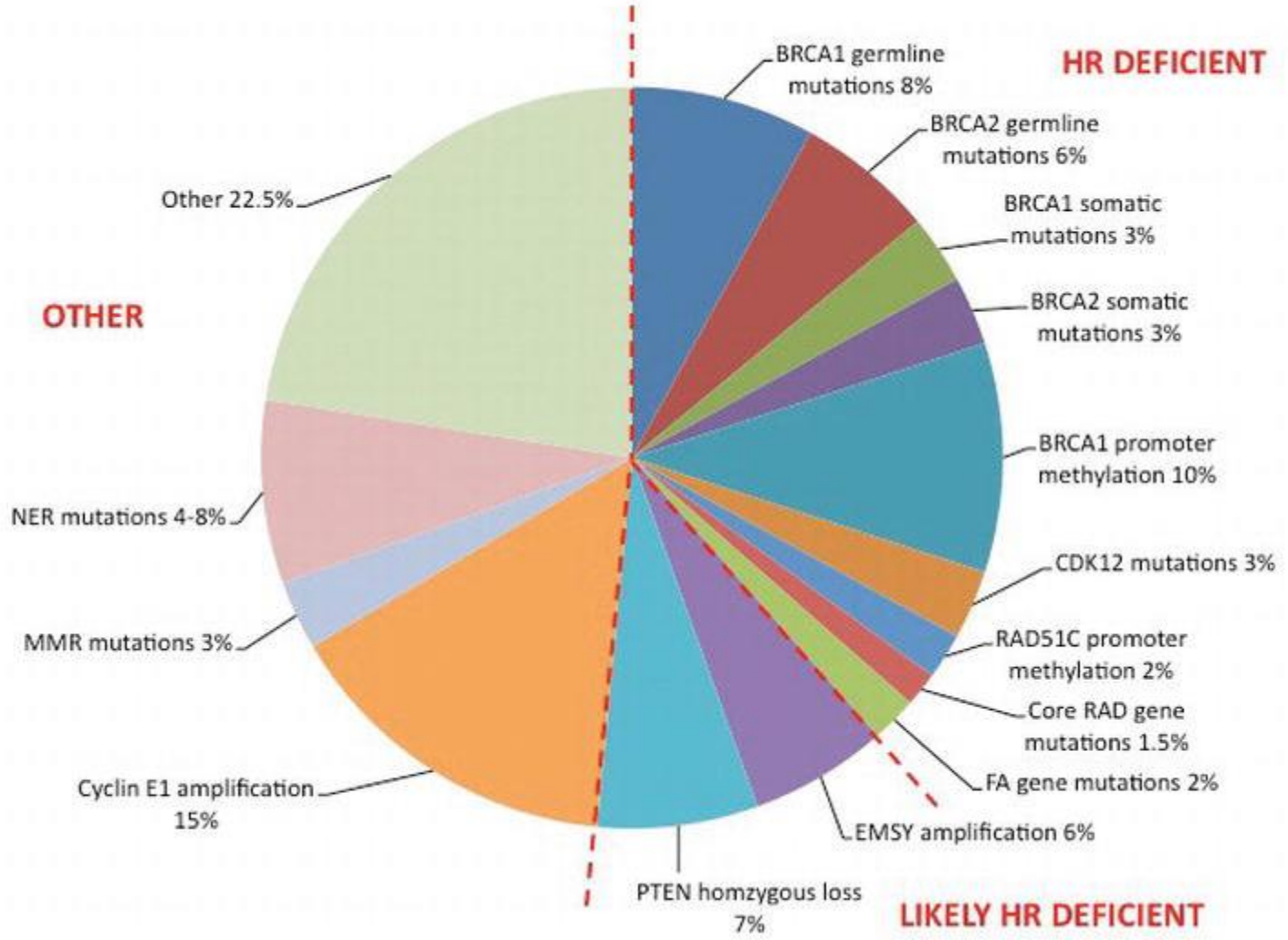
Epithelial ovarian cancer Lheureux et al. The Lancet 2019
bccancer.bc.ca http://www.bccancer.bc.ca/books/ovary

MOLECULAR PATHOLOGY

High grade	P53 BRCA NF1 RB1 CDK12 CCNE
Serous low grade	BRAF KRAS NRAS
Clear cell	ARID1 PIK3CA PTEN dMMR
Mucinous	KRAS HER2Ampl
Endometriod	ARID1 PIK3CA CTNN d MMRB1
Multiple subtypes with numerous molecular alterations	

MOLECULAR PATHOLOGY: HIGH GRADE

HR Proficient



MULTIDISCIPLINARY TEAM

- Gynecologist
- Medical Oncologyst

- Pathologist
- Molecular Pathologist
- Ereditary team

TOPICS IN THE EVERY DAY PRACTICE OF MTB

- Is cytoreductive surgery possible?
- Therapy according to histology and molecular alterations
- Maintenance single agent or in combination?
- How manage and delay resistance

ESMO GUIDELINES: REAL WORLD CASES

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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO GUIDELINES:
REAL WORLD CASES

LATE STAGE OVARIAN CANCER

Case presentation

Maria Kfoury

Medical Oncology Department

Institut Paoli-Calmettes, Marseille, France

October 15th, 2024

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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

DECLARATION OF INTERESTS

Maria Kfoury

Financial interest	Company/ organisation
Speaker	Astra Zeneca, Eisai, GSK
Travel and accomodation	Eisai, Janssen, Pfizer, GSK
Non financial interest	Committee member of ESMO Young Oncologists Committee

DIAGNOSIS

Dec 2020

Patient profile

- 52-year-old female
- No personal history
- Father : lung cancer

Initial presentation

- Persistent abdominal pain and constipation

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Apr 2021

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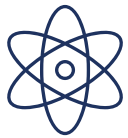

Diagnostic work-up

- CA-125: 1305 U/ml (normal <35 U/ml)
- CA19-9: 7,8 U/ml (normal < 37 U/ml)
- ACE: 0,8 µg/l (normal < 5 ug/L)

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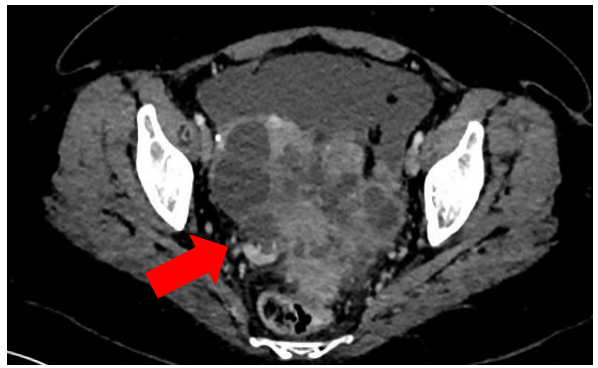
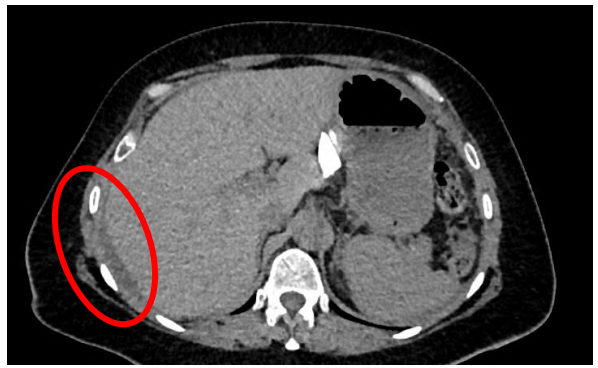
- **CT scan**
  - Multilocular pelvic mass
  - Peritoneal carcinomatosis, extended to the diaphragmatic dome with liver scalloping
  - Moderate ascites
  - No suspicious lesion at the thoracic level





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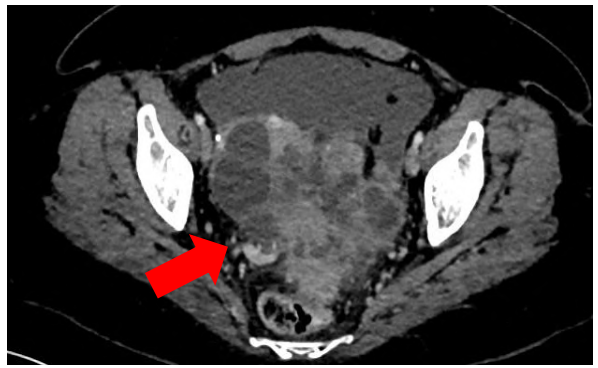

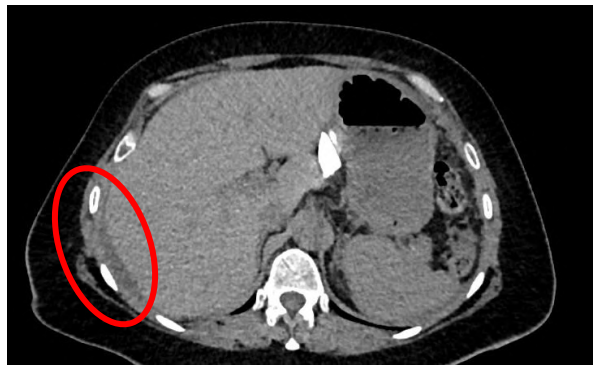

→ **Referral to a specialised cancer center**

DIAGNOSIS

May 2021

Exploratory Laparoscopy

- **Unresectable abdominal and pelvic carcinomatosis**
  - Multiple nodules on the right diaphragmatic dome, small bowel, parieto-colic groove
- The adnexa are not visible
- Moderate ascites
- Peritoneal cancer index: **17/33**

- Multiple peritoneal biopsies and peritoneal washing

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Pathology report

- **High-grade serous ovarian adenocarcinoma**
  - PAX8+, *WT1*+, *TP53* mutated
  - Positive peritoneal biopsy and cytology

- FIGO stage IIIC

- **Tumor *BRCA* testing**
- **HRD testing**

FIGO, International *Federation* of Gynecology and Obstetrics; HRD, homologous recombination deficiency

NEO-ADJUVANT CHEMOTHERAPY

May 2021

Neo-adjuvant chemotherapy

- Carboplatin AUC 5 and paclitaxel 175 mg/m²
  - Q3W for 3 cycles

- Monitoring of CA-125
  - Cycle 1: 1691 U/ml
  - Cycle 2: 1060 U/ml
  - Cycle 3: 260 U/ml

AUC, area under the curve; Q3W, 3-weekly..

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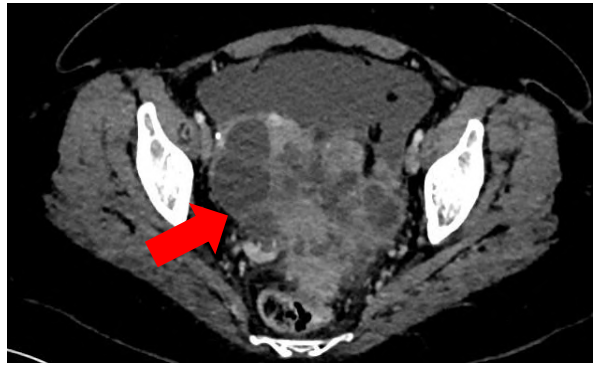
Jul 2021

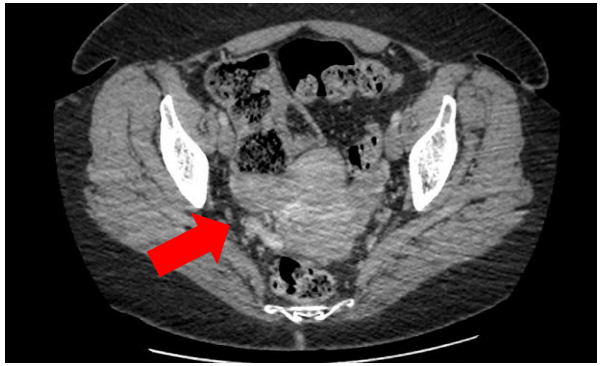
Assessment after 3 cycles

- **CT scan**
  - Partial response of pelvic mass and peritoneal carcinomatosis
  - Regression of ascites

- **KELIM score**
  - 0.65 : Unfavorable



Baseline (Apr 2021)



After 3 cycles (Jul 2021)

AUC, area under the curve; KELIM, ELIMination rate constant K; Q3W, 3-weekly..

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NGS (70% tumor cells)

- ***BRCA1* mutation (AF 70%)**
- *TP53* mutation (AF 60%)

Validated HRD test (70% tumor cells)

- Genomic instability score: 3.8 (**high**)

AF, Allelic frequency; AUC, area under the curve; KELIM, ELIMination rate constant K; Q3W, 3-weekly..

INTERVAL CYTOREDUCTIVE SURGERY

Aug 2021

Exploratory laparoscopy

- Resectable carcinomatosis
  - Peritoneal cancer index: 6/36

CC0, no macroscopic residual disease; PAX8, paired box gene 8.

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Interval cytoreductive surgery

- Hysterectomy with bilateral adnexectomy
- Resection of peritoneal nodules
- Douglasectomy, omentectomy, appendectomy

Complete resection CC0

CC0, no macroscopic residual disease

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Pathology report

- High-grade serous ovarian carcinoma
- Persistence of carcinomatous masses measuring 0.1 to 1.5 cm on:
  - The uterus, both ovaries, prevesical peritoneal nodule, and the Douglas
- Significant scarring extending over 7 cm on the omentectomy
- All other samples are void of tumor

Chemotherapy response score 2

CC0, no macroscopic residual disease

ADJUVANT AND CHOICE OF MAINTENANCE THERAPY

Sep 2021

MDT

- Choice of adjuvant / maintenance therapy
  - PARP inhibitor alone versus olaparib + bevacizumab

MDT, multi-disciplinary tumor board

ADJUVANT AND CHOICE OF MAINTENANCE THERAPY

Sep 2021

MDT

- Choice of adjuvant / maintenance therapy
  - PARP inhibitor alone versus olaparib + bevacizumab

- **In favor of PARP inhibitor alone**
  - No macroscopic residual disease
  - NGS: *BRCA1 mutation*
  - Homologous Recombination Deficiency

- **In favor of olaparib + bevacizumab**
  - Interval surgery after neo-adjuvant chemotherapy
  - Unfavorable KELIM score: 0.65
  - Chemotherapy response score: 2
  - No contra-indication to bevacizumab

KELIM, ELIMination rate constant K; MDT, multi-disciplinary tumor board; NGS, next-generation sequencing

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Adjuvant chemotherapy

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Dec 2021

Maintenance therapy

- Olaparib 300 mg BID

- Bevacizumab 15 mg/kg
  - Q3W

Genetic counselling results

- Germline *BRCA 1* mutation

AUC, area under the curve; BID, bi-daily; Q3W, 3-weekly

ADJUVANT AND MAINTENANCE THERAPY

Sep 2021

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Maintenance therapy

- Olaparib 300 mg BID
- Bevacizumab 15 mg/kg
  - Q3W

Overall tolerance

- Hypertension grade 2 and proteinuria grade 2
  - Controlled with ACE inhibitors
- Anemia grade 1
  - Well tolerated

No interruptions
No dose adjustments

ACE, angiotensin-converting enzyme; AUC, area under the curve; BID, bi-daily; Q3W, 3-weekly

FIRST PLATINUM-SENSITIVE RECURRENCE

May 2023

- No symptoms
- CA-125: 39 U/ml (normal < 35)

FIRST PLATINUM-SENSITIVE RECURRENCE

Jun 2023

- No symptoms
- CA-125: 39 U/ml (normal < 35)

- CA-125: 51 U/ml (normal < 35)
- CT scan
  - No evidence of recurrence

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Aug 2023

- No symptoms
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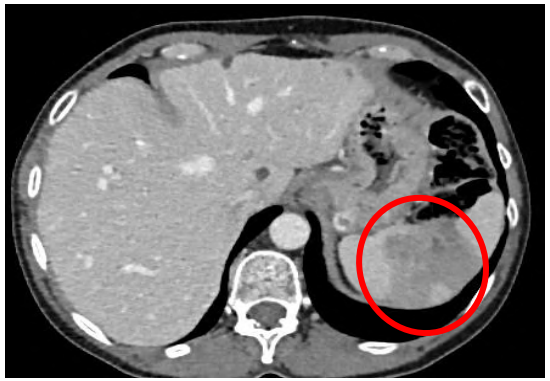
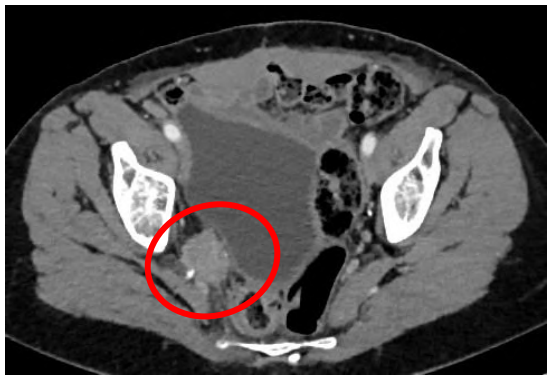
  - Appearance of nodules at the splenic hilum and at the right pelvic ureter in favor of a recurrent peritoneal carcinomatosis.
  - No supra-diaphragmatic lesions





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Aug 2023

MDT

- Positive AGO score
  - ECOG PS 1
  - Ascites < 500 ml
  - CC0 at first surgery

- Secondary cytoreductive surgery

AGO, Arbeitsgemeinschaft Gynaekologische Onkologie; CC0, no macroscopic residual disease; ECOG PS, Eastern Cooperative Oncology Group Performance Status.

SECONDARY CYTOREDUCTIVE SURGERY

Sep 2023

Exploratory laparoscopy

- Resectable carcinomatosis

Pathology report

- Resected lesions are compatible with the known high-grade serous adenocarcinoma of ovarian origin

Laparoconversion for cytoreductive surgery

- Resection of all visible lesions
- Splenectomy
- Ureteral reimplantation

Complete resection CC0

CC0, no macroscopic residual disease

ADJUVANT AND MAINTENANCE THERAPY

Oct 2023

- Carboplatine AUC 5
  + Pegylated Liposomal Doxorubicin 30 mg/m²
  Q4W
  6 cycles

Apr 2024

- **CT scan**
  - No evidence of recurrence
- CA-125 normal

AUC, Area Under Curve; Q4W, 4-weekly

ADJUVANT AND MAINTENANCE THERAPY

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- Carboplatine AUC 5
  + Pegylated Liposomal Doxorubicin 30 mg/m²
  Q4W
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Enrolment in TEDOVA/ GINECO-OV244b/ ENGOT-ov58 trial

- Randomized phase II trial
- Patients with positive HLA-A2 phenotype
- Maintenance therapy with neo-epitope based vaccine OSE2101 alone +/- Pembrolizumab
  versus best supportive care

- **Randomized to OSE2101 + Pembrolizumab**

AUC, Area Under Curve; Q4W, 4-weekly

FOLLOW UP

TEDOVA/ GINECO-OV244b/ ENGOT-ov58 trial

May 2024

Cycle 1

OSE 2101 5 mg SC, Q3W

Pembrolizumab 400 mg, Q6W

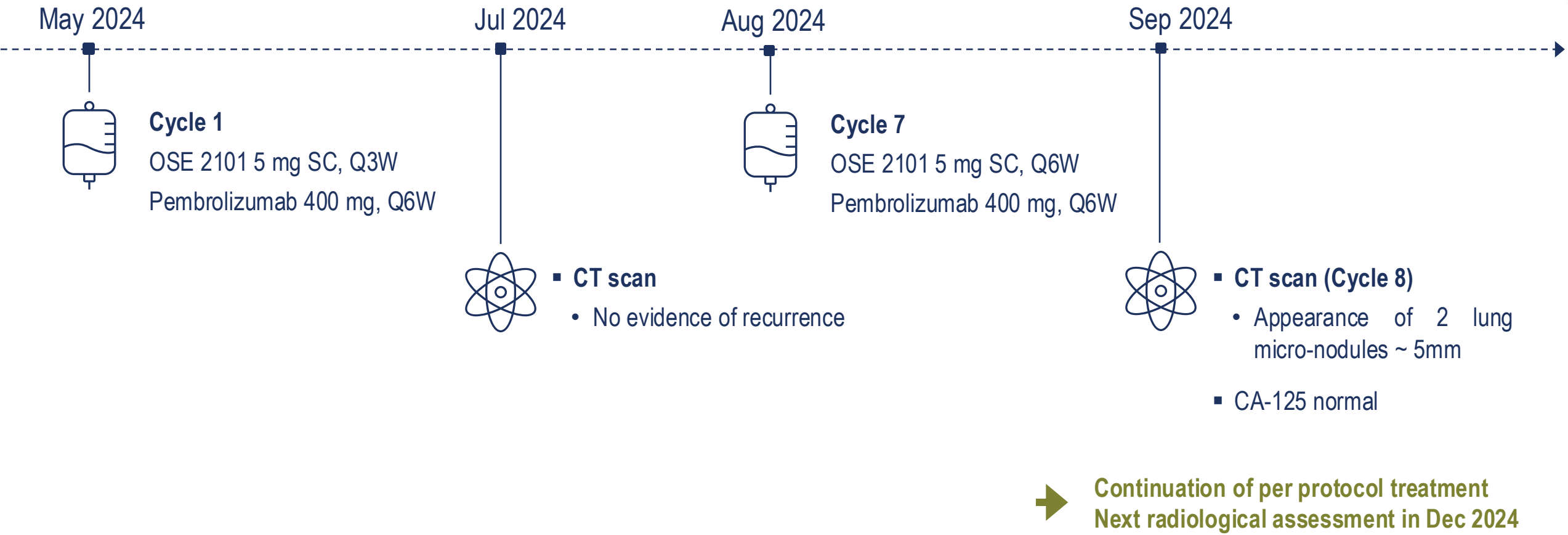
Jul 2024

- **CT scan**
  - No evidence of recurrence

Q3W, 3-weekly; Q6W, 6-weekly, SC, sub-cutaneaous

FOLLOW UP

TEDOVA/ GINECO-OV244b/ ENGOT-ov58 trial



Continuation of per protocol treatment
Next radiological assessment in Dec 2024

Q3W, 3-weekly; Q6W, 6-weekly, SC, sub-cutaneaous

ESMO GUIDELINES: REAL WORLD CASES

Maria Kfoury

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CRITICAL ANALYSIS OF THE CASE

Parallel presentation of the ESMO CPG recommendations, flow charts, MCBS, section by section

Antonio González-Martín ND, PhD

Cancer Center Clínica Universidad de Navarra

DECLARATION OF INTEREST

Financial interest	Company/organisation
Educational and advisory activities	Alkermes, Amgen, AstraZeneca, Clovis, Genmab, GSK, HederaDx, Abbvie/Immunogen, Incyte, Illumina, Mersana, MSD, Novartis, Novocure, Oncoinvent, PharmaMar, Regeneron, Roche, SOTIO, SUTRO, Seagen, Takeda, Tubulis, Zailab
Principal investigator	PRIMA
Non-financial interests	Chairman of GEICO, Chairman of ENGOT (2018-2020)

EPITHELIAL OVARIAN CANCER

Most patients diagnosed at advanced stage due to the lack of reliable early diagnostic tests

1. Ovarian cancer: second most lethal gynaecological malignancy worldwide behind cervical cancer and first in developed countries[1]
2. Currently no reliable screening method for ovarian cancer
3. Most women diagnosed based on symptoms, with majority presenting at advanced stage (70%-80%)

1. Sung H, et al. CA Cancer J Clin 2021;71:209249

DIAGNOSTIC WORK-UP

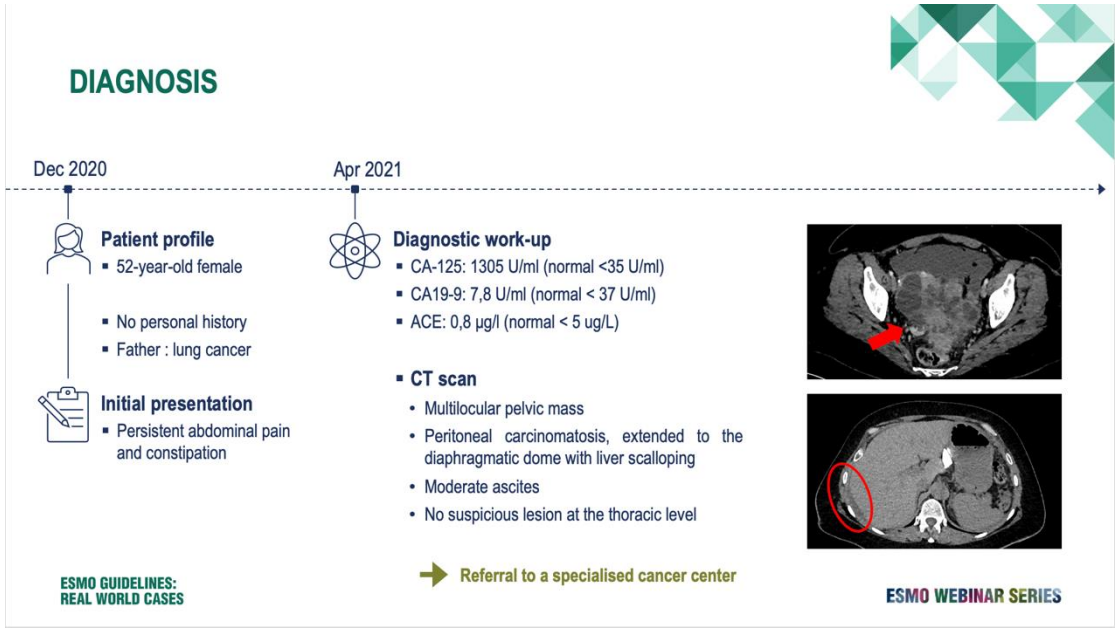


Table 1. Diagnosis of EOC

Work-up if EOC is suspected

- Detailed history and clinical examination
- Serum CA-125
- Serum CEA and CA 19-9, in the case of MC, and endoscopy, if either or both are elevated
- Transabdominal and transvaginal US by expert examiner *
- CT of thorax, abdomen and pelvis
- Pathological examination of adequate tumour sample from diagnostic biopsy or surgical specimen
- Cytological assessment of pleural effusion if present

***IOTA simple rules risk model or IOTA-ADNEX model.**

ADNEX, Assessment of Different NEoplasias in the adneXa; CA 19-9, carbohydrate antigen 19-9; CA-125, cancer antigen 125; CEA, carcinoembryonic antigen; IOTA, International Ovarian Tumor Analysis; MC, mucinous carcinoma; US, ultrasound.
González-Martín A, et al. Ann Oncol 2023;34:833-48.

PATHOLOGY AND MOLECULAR BIOLOGY (I)

- Definitive diagnosis of ovarian cancer **requires pathological examination by an expert pathologist** of tumour samples from either a **diagnostic biopsy or, preferably, a surgical specimen**

Table 2. Pathology and molecular biology of EOC subtypes

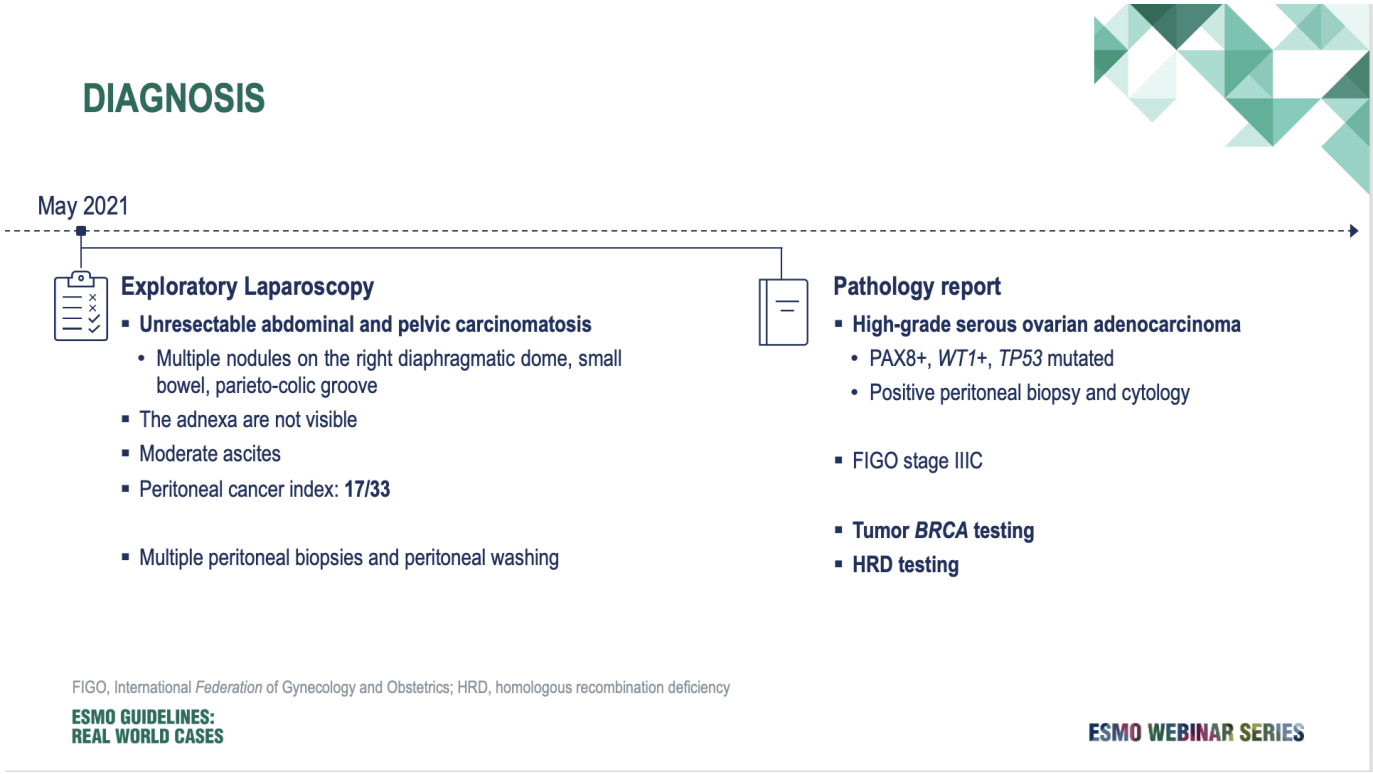
	70% cases →	HGSC	EC	CCC	LGSC	MC
IHC staining	p53	Abnormal	Abnormal/normal	Normal	Normal	Normal
	p16	+	–	–		
	WT-1	+	–	–	+	–
	ER	+/–	+	–	+	–
	PAX8	+	+		+	–
	Vimentin		+			
	HNF1β			+		
	CDK2					+
Molecular alterations (decreasing prevalence from top to bottom)		*TP53* *BRCA1/2* HRD	*CTNNB1* *ARID1A* *PTEN* *KRAS* *TP53* (high-grade EC) MSI/dMMR	*ARID1A* *PI3KCA* *PTEN* MSI/dMMR	*KRAS* *BRAF* *RAF*	*CDKN2A* *KRAS* *HER2*

CCC, clear-cell carcinoma; CDX2, homeobox protein CDX-2; dMMR, mismatch repair deficiency; EC, endometrioid carcinoma; HGSC, high-grade serous carcinoma; HNF1β, hepatocyte nuclear factor-1β; HRD, homologous recombination deficiency; LGSC, low-grade serous carcinoma; MC, mucinous carcinoma; MSI, microsatellite instability; PAX8, paired box gene 8; WT-1, Wilms tumour 1.

González-Martín A, et al. Ann Oncol 2023;34:833-48.

STAGING AND RISK ASSESSMENT

- All patients with ovarian cancer should be surgically staged according to the revised **2014 FIGO staging system for EOC** [I, A]
- When the disease appears suitable for cytoreduction as assessed by imaging, and there are no surgical or medical contraindications, **surgical staging (through midline laparotomy or initial laparoscopy)** should be carried out to explore the extent of the disease in the abdomino-peritoneal cavity and **assess the likelihood of achieving optimal cytoreduction (no gross residual)**



FIGO, International Federation of Gynecology and Obstetrics.
González-Martín A, et al. Ann Oncol 2023;34:833-48.

PATHOLOGY AND MOLECULAR BIOLOGY (II)

- All patients with **high-grade ovarian** cancer should be **tested for germline and/or somatic *BRCA1/2*-muts** at diagnosis [I, A]
- **Testing for HRD** is recommended in **advanced high-grade cancers** [I, A]

Table 2. Pathology and molecular biology of EOC subtypes

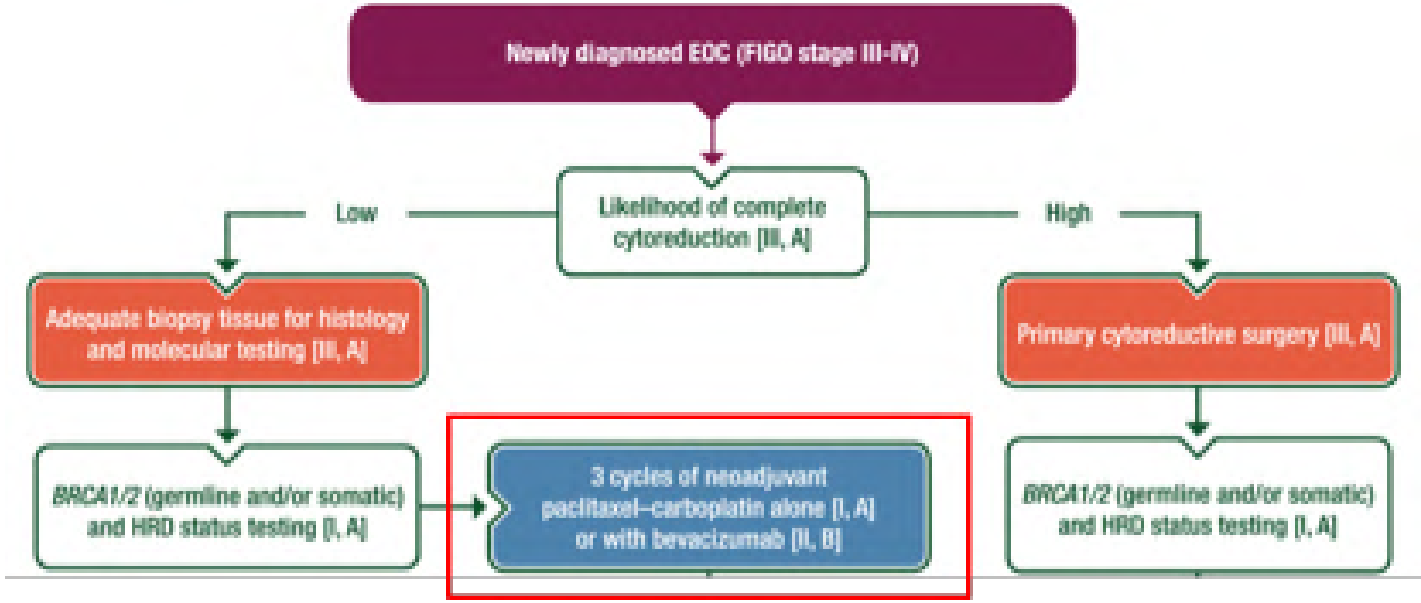
		HGSC	EC	CCC	LGSC	MC
IHC staining	p53	Abnormal	Abnormal/normal	Normal	Normal	Normal
	p16	+	−	−		
	WT-1	+	−	−	+	−
	ER	+/−	+	−	+	−
	PAX8	+	+		+	−
	Vimentin		+			
	HNF1β			+		
	CDX2					+
Molecular alterations (decreasing prevalence from top to bottom)		*TP53*	*CTNNB1*	*ARID1A*	*KRAS*	*CDKN2A*
		BRCA1/2	*ARID1A*	*PIK3CA*	*BRAF*	*KRAS*
		HRD	*PTEN*	*PTEN*	*RAF*	*HER2*
			KRAS	MSI/dMMR		
			TP53 (high-grade EC)			
			MSI/dMMR			

CCC, clear-cell carcinoma; CDX2, homeobox protein CDX-2; dMMR, mismatch repair deficiency; EC, endometrioid carcinoma; HGSC, high-grade serous carcinoma; HNF1β, hepatocyte nuclear factor-1β; HRD, homologous recombination deficiency; LGSC, low-grade serous carcinoma; MC, mucinous carcinoma; MSI, microsatellite instability; PAX8, paired box gene 8; WT-1, Wilms tumour 1.

González-Martín A, et al. Ann Oncol 2023;34:833-48.

MANAGEMENT OF ADVANCED EOC

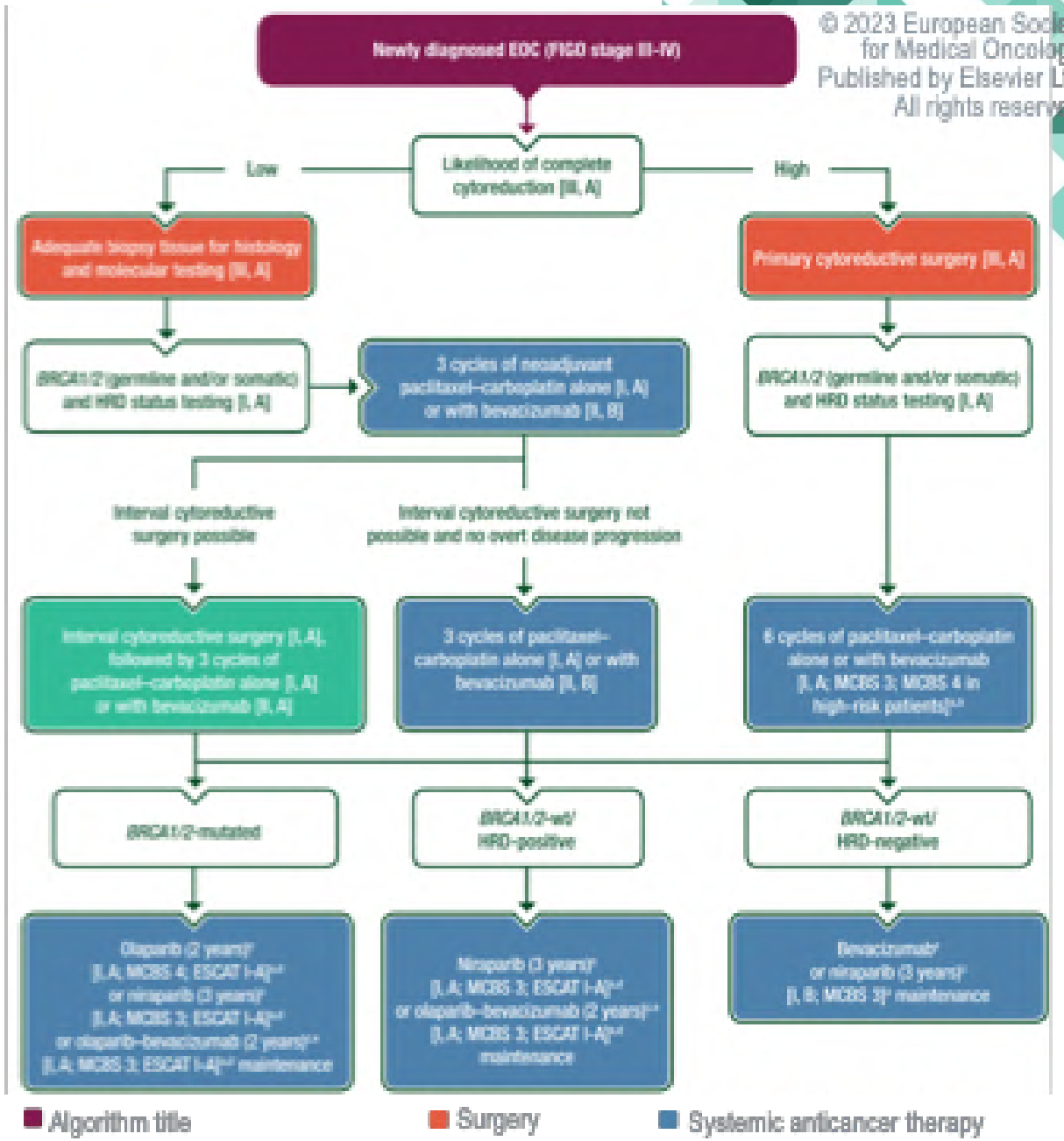
- Patients with advanced EOC should be evaluated for PCS by a **specialised team**, with the aim of achieving complete cytoreduction (absence of all visible residual disease) [III, A]
- When **complete cytoreductive surgery is feasible, PCS is recommended** [III, A]; otherwise, obtaining adequate biopsy tissue for histology and molecular testing is recommended [III, A]
- When **complete cytoreductive surgery is not feasible**, NACT for 3 cycles followed by ICS and 3 cycles of paclitaxel-carboplatin are recommended [I, A]



ICS, interval cytoreductive surgery; NACT, neoadjuvant ChT; PCS, primary cytoreductive surgery.
González-Martín A, et al. Ann Oncol 2023;34:833-48.

MANAGEMENT OF ADVANCED EOC

- Systemic therapy decisions should be informed by *BRCA1/2*-mut (germline and/or somatic) and HRD status testing carried out at primary diagnosis [I, A]

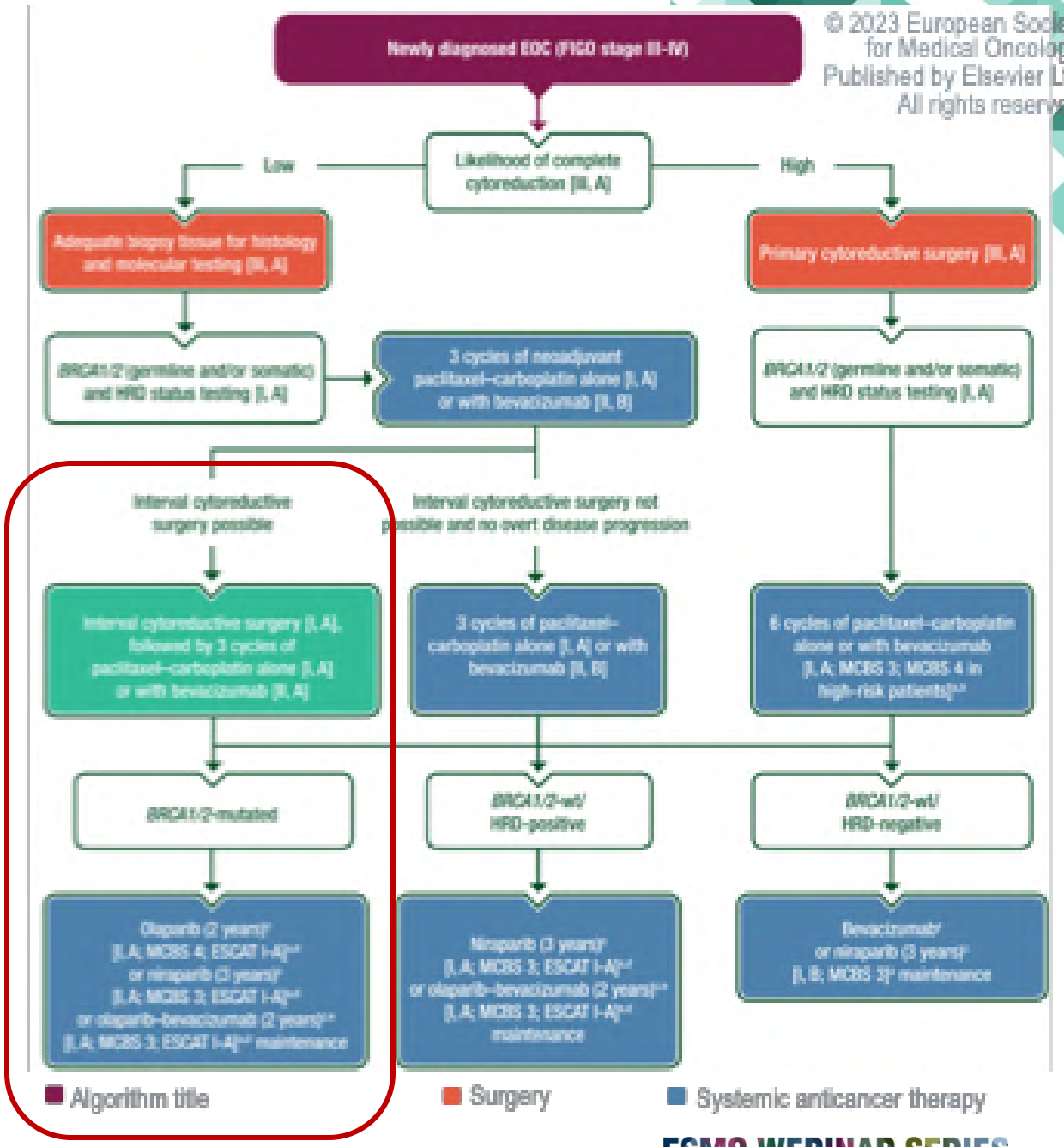


AUC, area under the curve; ChT, chemotherapy; FIGO, International Federation of Gynecology and Obstetrics; HRD, homologous recombination deficiency; PARPi, poly (ADP-ribose) polymerase inhibitor.

González-Martín A, et al. Ann Oncol 2023;34:833-48.

MANAGEMENT OF ADVANCED EOC

- Maintenance treatment with either Olaparib for 2 years [I, A; MCBS 4 ; ESCAT I-A] or niraparib for 3 years [I, A; MCBS 3; ESCAT I-A] or Olaparib-bevacizumab for 2 years [I, A; MCBS 3 ; ESCAT I-A] can be recommended for *BRCA 1/2 mutated* tumours
- Rucaparib 2 years is also included in the updated Guideline Pocket Version



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González-Martín A, et al. Ann Oncol 2023;34:833-48.

PATIENT'S DISEASE

Factors to be considered beyond molecular subtype

Molecular biology

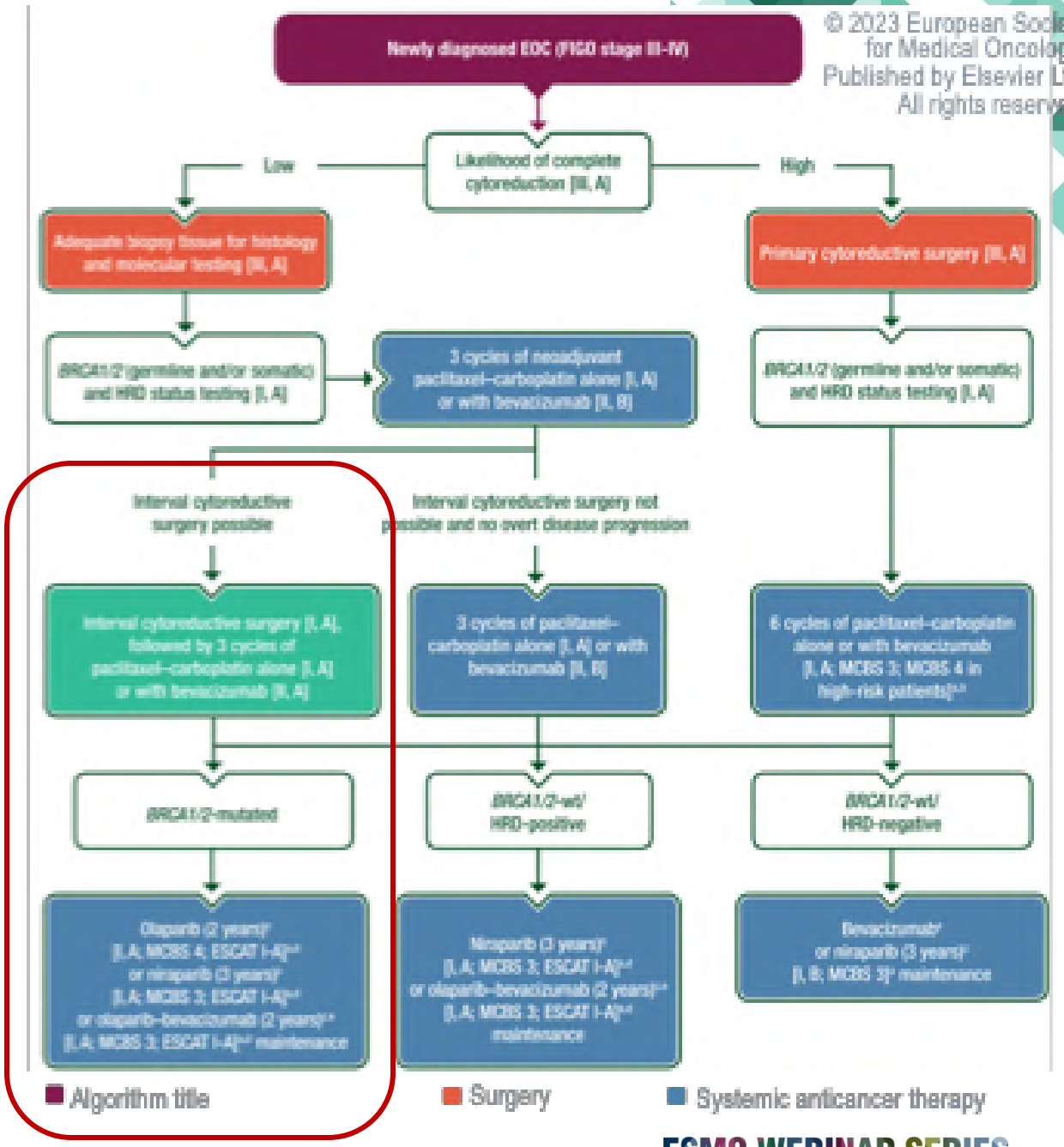
- BRCA1 MUTATION
- HRD-positive (GIS score high)

Response to NACT

- Radiological partial response
- Unfavourable KELIM (0.65)
- Laparoscopic partial response (PCI 6/36)
- CRS2

Outcome of surgery

- Optimal (no gross-residual)



AUC, area under the curve; ChT, chemotherapy; FIGO, International Federation of Gynecology and Obstetrics; HRD, homologous recombination deficiency; PARPi, poly (ADP-ribose) polymerase inhibitor.

González-Martín A, et al. Ann Oncol 2023;34:833-48.

MDT: ADJUVANT AND CHOICE OF MAINTENANCE THERAPY

Sep 2021

MDT

- Choice of adjuvant / maintenance therapy
  - PARP inhibitor alone versus olaparib + bevacizumab

- **In favor of PARP inhibitor alone**
  - No macroscopic residual disease
  - NGS: *BRCA1 mutation*
  - Homologous Recombination Deficiency

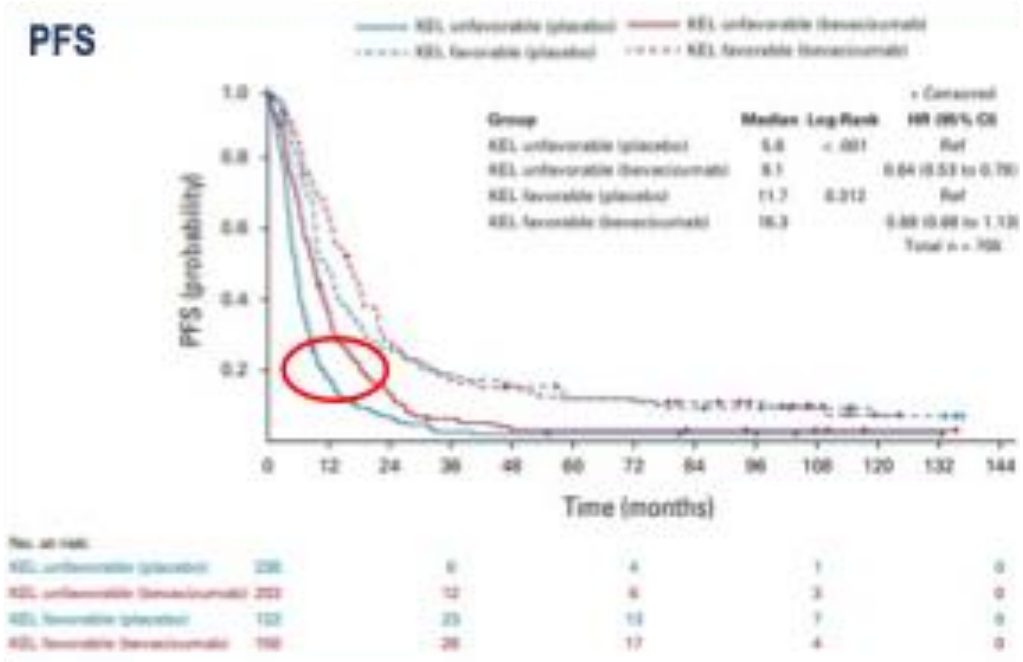
- **In favor of olaparib + bevacizumab**
  - Interval surgery after neo-adjuvant chemotherapy
  - Unfavorable KELIM score: 0.65
  - Chemotherapy response score: 2
  - No contra-indication to bevacizumab

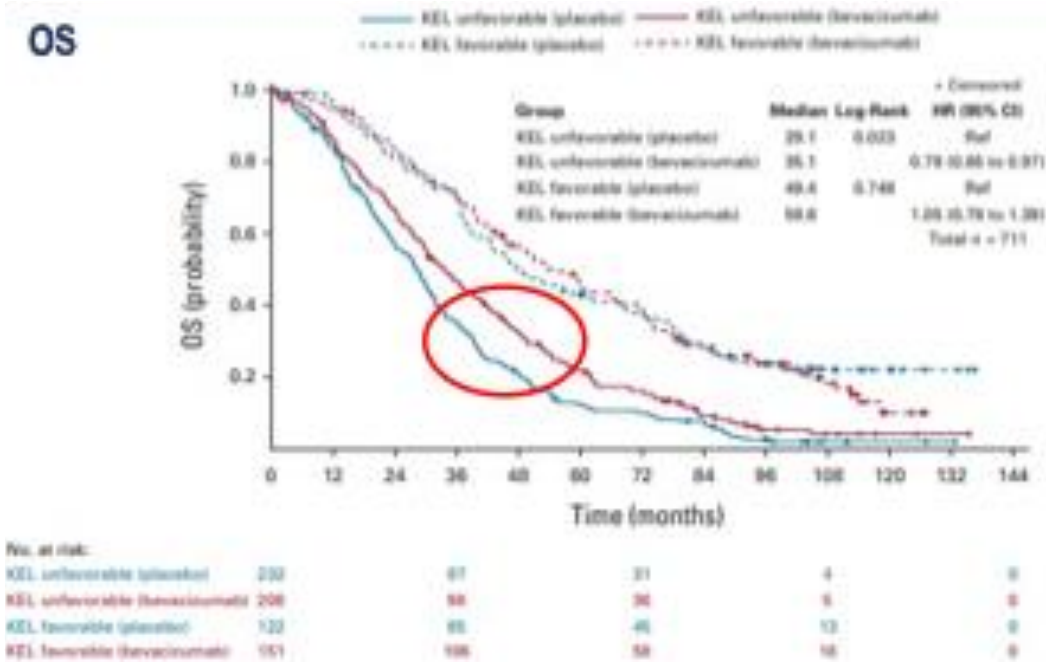
KELIM, ELIMination rate constant K; MDT, multi-disciplinary tumor board; NGS, next-generation sequencing

CHOICE OF MAINTENANCE IN BRCA+ TUMOURS

Role of Bevacizumab: KELIM (exploratory analysis from GOG-218)

Kaplan–Meier curves according to treatment arm (bevacizumab concurrent-maintenance vs placebo) in patients with favourable or unfavourable KELIM (KEL) score, in the population with high-risk disease (stage IV + stage III operated with suboptimal surgery)[1]





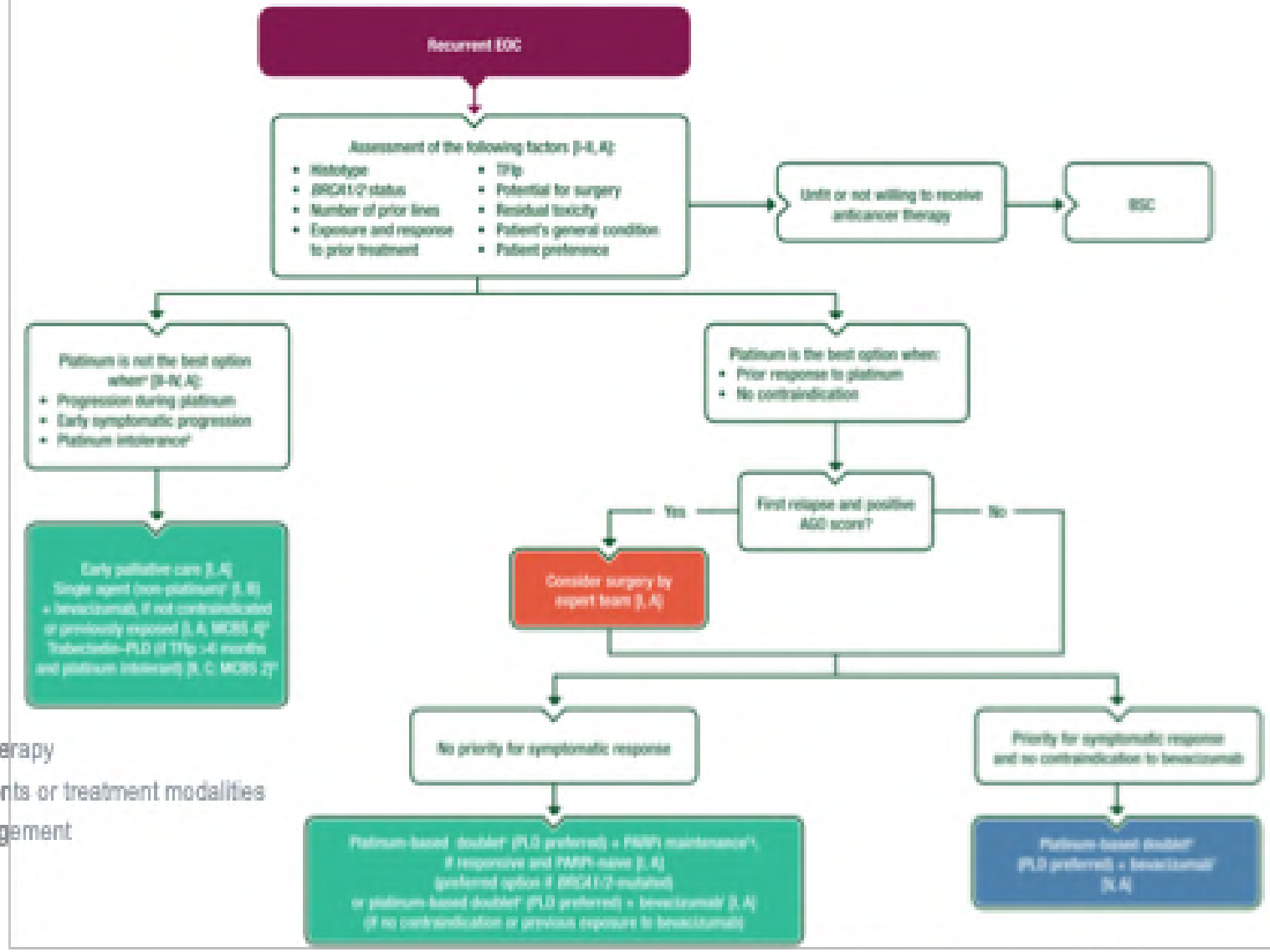
Graphs reproduced with permission[1]

HR, hazard ratio; HRD, homologous recombination deficiency; KELIM, ELIMination rate constant K; mPFS, median PFS (months); Ref, reference.

1. You B, et al. J Clin Oncol 2022;40:3965-74.

MANAGEMENT OF RECURRENT DISEASE

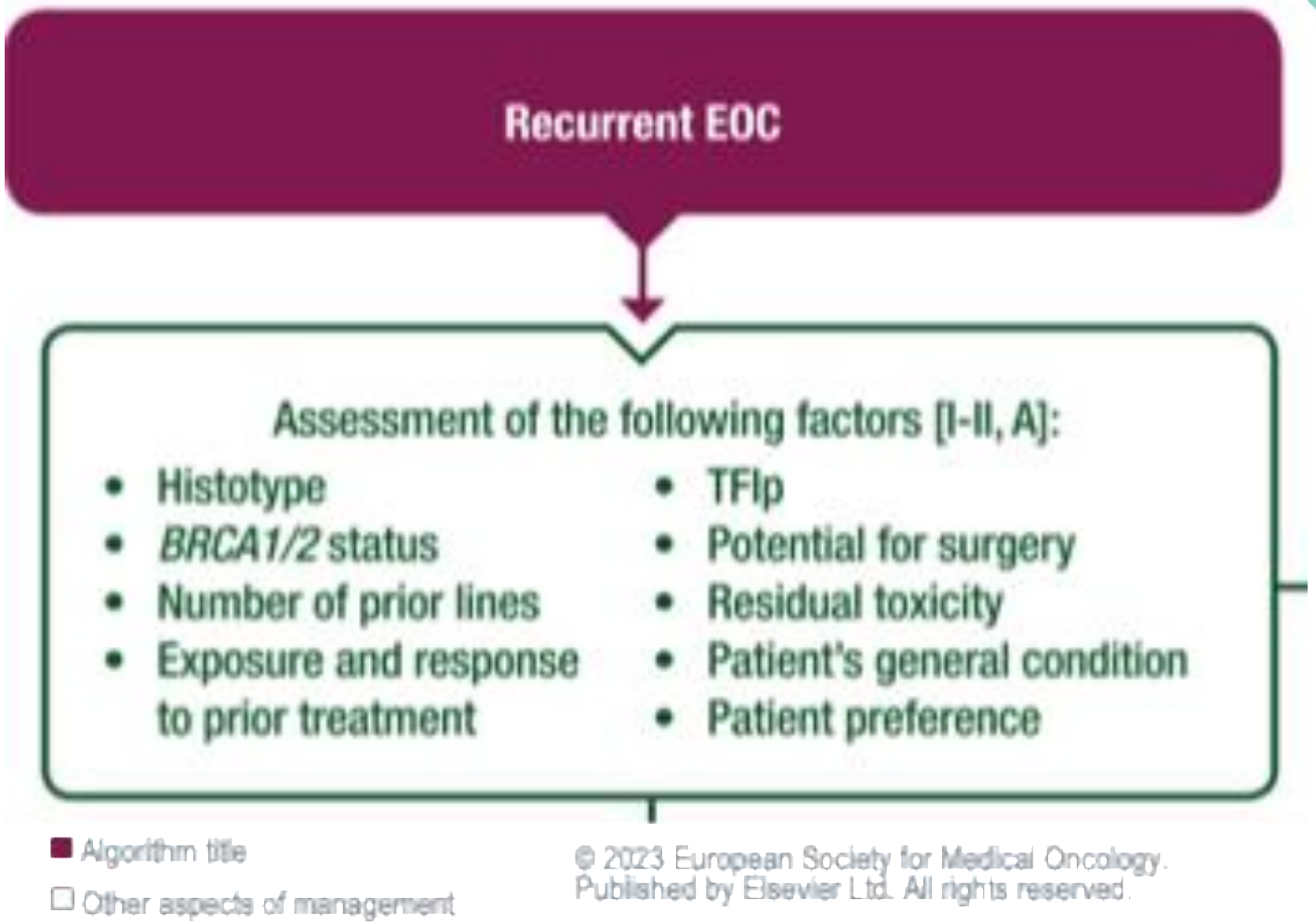
- Patient had recurrent disease (21-month PFI) with LIMITED peritoneal carcinomatosis



MANAGEMENT OF RECURRENT DISEASE

Patient assessment

- High-grade serous
- Tumour *BRCA1-mut*
- One prior line
- Good response to prior platinum-based therapy
- TFIp 21 months
- No residual toxicity
- Good general condition

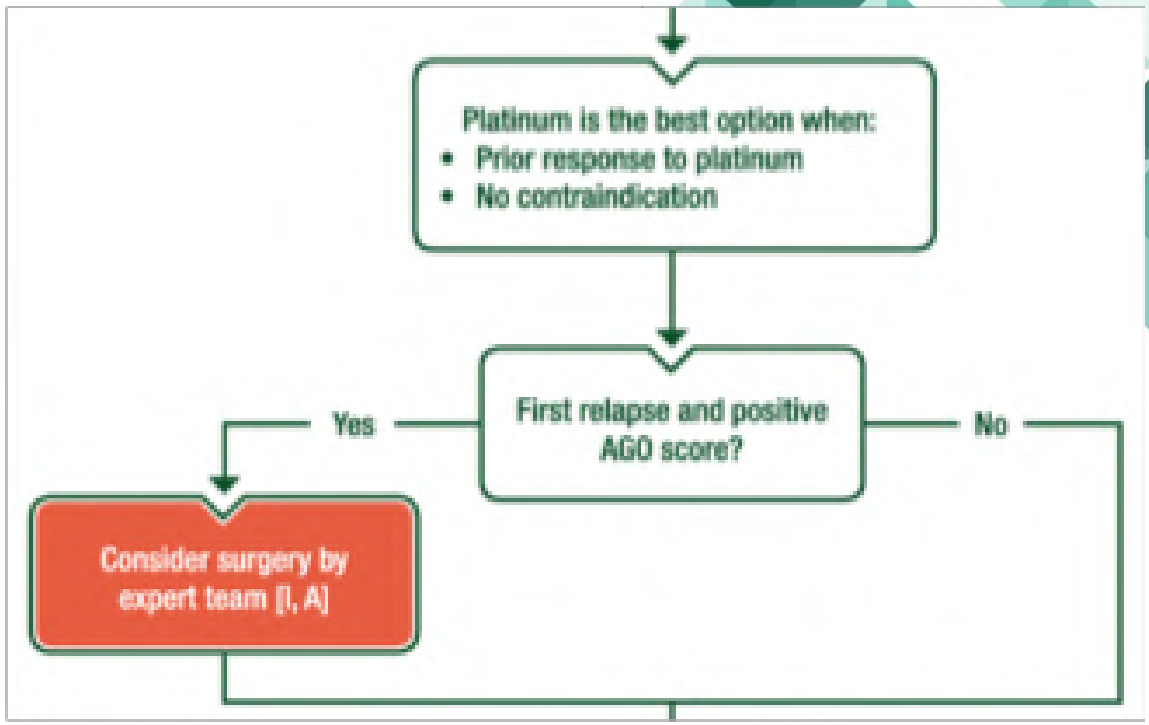


TFIp, treatment-free interval from last platinum.
González-Martín A, et al. Ann Oncol 2023;34:833-48.

MANAGEMENT OF RECURRENT DISEASE

Surgery for relapse

- Patients with first relapse of ovarian cancer after >6 months of last platinum administration should be evaluated by a gynaecological oncology centre experienced in surgery for ovarian cancer to identify **potential candidates for surgical cytoreduction** [I, A][1]
- In patients with a **positive AGO score –** defined as having complete resection at primary surgery (alternatively FIGO stage I-II), good performance status (ECOG 0) and absence of ascites (<500 ml) – the **likelihood of achieving a complete resection is 76%**[2]
- **DESKTOP III demonstrated a benefit in OS** and PFS for patients with positive AGO score optimally debulked at secondary cytoreduction[3]



Our patient management

- **Exploratory laparoscopy**
- **Resectable carcinomatosis**
- **Complete cytorreduction**

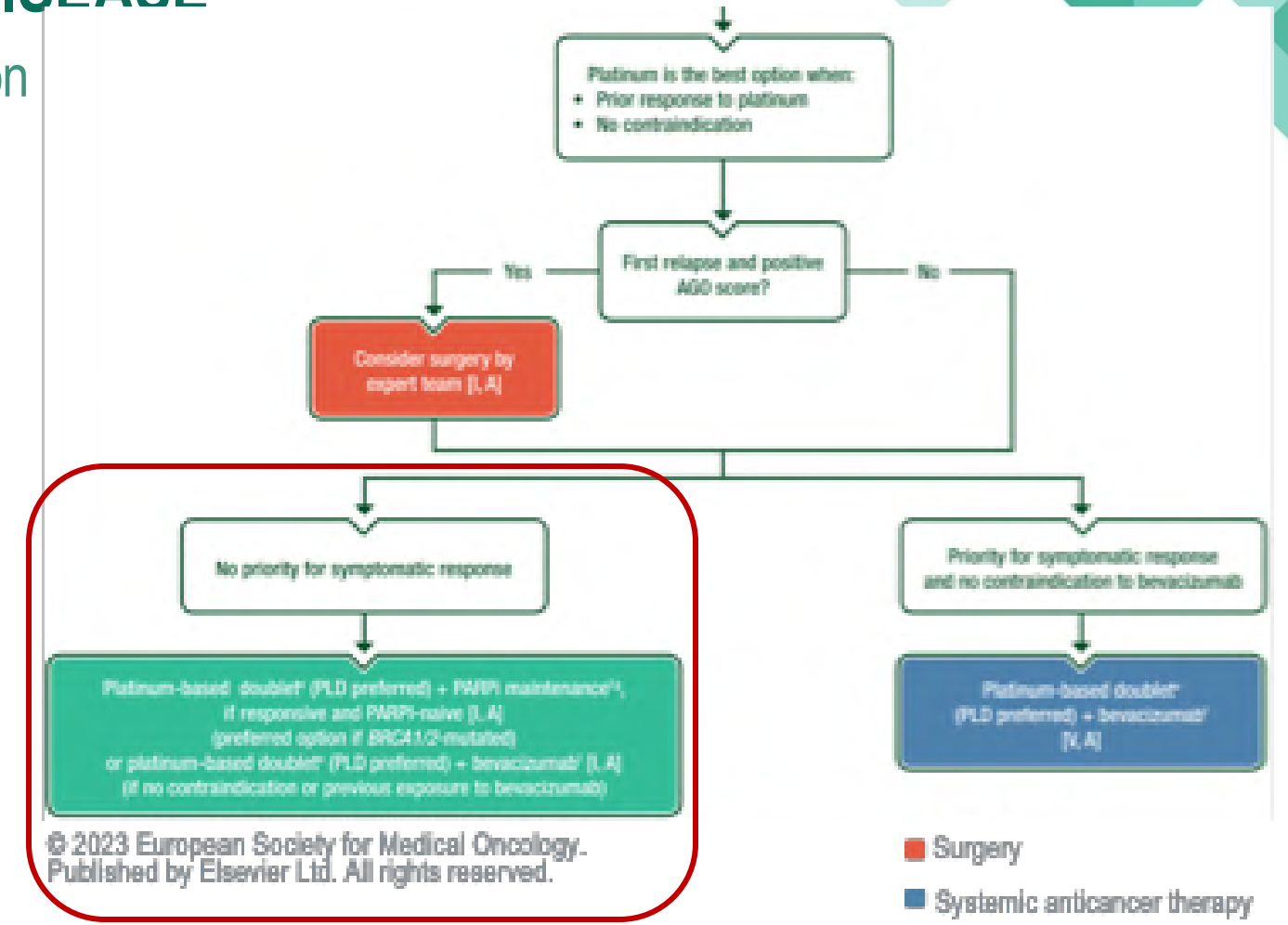
AGO, Arbeitsgemeinschaft Gynaekologische Onkologie; ECOG, Eastern Cooperative Oncology Group; FIGO, International Federation of Gynecology and Obstetrics.

1. González-Martín A, et al. Ann Oncol 2023;34:833-48; 2. Harter P, et al. Int J Gynecol Cancer 2011;21:289-95; 3. Harter P, et al. N Engl J Med 2021;385:2123-31.

MANAGEMENT OF RECURRENT DISEASE

Systemic therapy when platinum is an option

- For patients **with no priority for symptomatic response**, a platinum-based doublet (PLD, preferred)
- PARPi maintenance if responsive and PARPi-naïve or platinum-based doublet (PLD, preferred) with bevacizumab (if no contraindication or previous exposure to bevacizumab).



AGO, Arbeitsgemeinschaft Gynaekologische Onkologie; AUC, area under the curve; PARPi, poly (ADP-ribose) polymerase inhibitor; PLD, pegylated liposomal doxorubicin; Q4W, 4-weekly. González-Martín A, et al. Ann Oncol 2023;34:833-48.

MANAGEMENT OF RECURRENT DISEASE

ESGO-ESMO-ESP consensus conference recommendations on ovarian cancer: pathology and molecular biology and early, advanced and recurrent disease

Recommendation 16.5: For patients eligible for platinum and prior use of bevacizumab and PARPis, a platinum-based ChT should still be recommended [I, B] and rechallenge options of maintenance agents could be considered (see recommendations 16.9, 16.11).

Consensus: 97% (29) yes, 0% (0) no, 3% (1) abstain (30 voters)

J Ledermann et al. Ann Oncol 2023

MANAGEMENT OF RECURRENT DISEASE

ESGO-ESMO-ESP consensus conference recommendations on ovarian cancer: pathology and molecular biology and early, advanced and recurrent disease

Recommendation 16.9: Bevacizumab rechallenge in combination with platinum should be considered in patients already pre-treated with bevacizumab in the first line [I, A].

Consensus: 91% (29) yes, 6% (2) no, 3% (1) abstain (32 voters)

J Ledermann et al. Ann Oncol 2023

MANAGEMENT OF RECURRENT DISEASE

Bevacizumab Rechallenge

Carboplatin-based doublet plus bevacizumab beyond progression versus carboplatin-based doublet alone in patients with platinum-sensitive ovarian cancer: a randomised, phase 3 trial

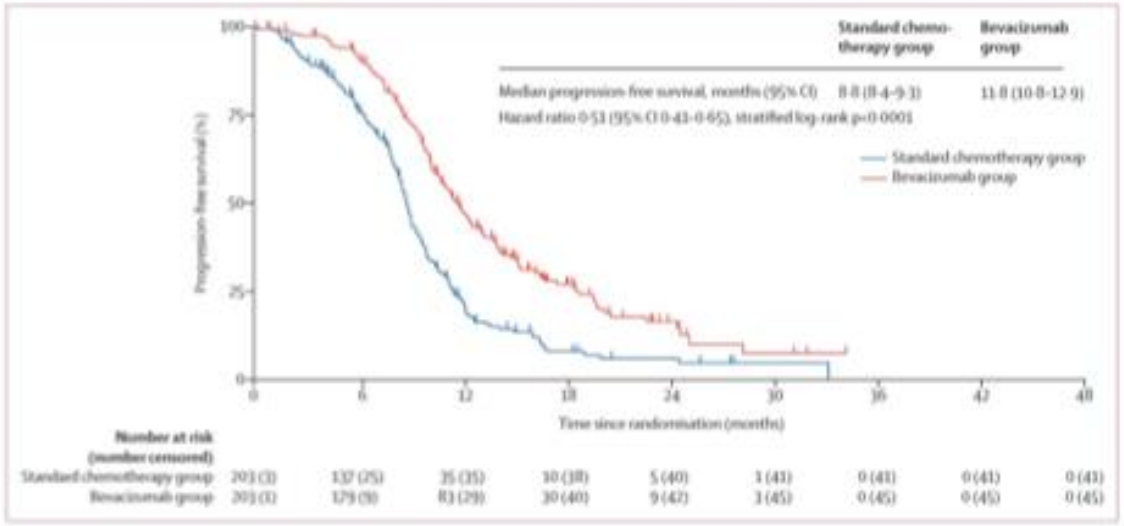


Figure 2: Kaplan-Meier estimated curves of progression-free survival

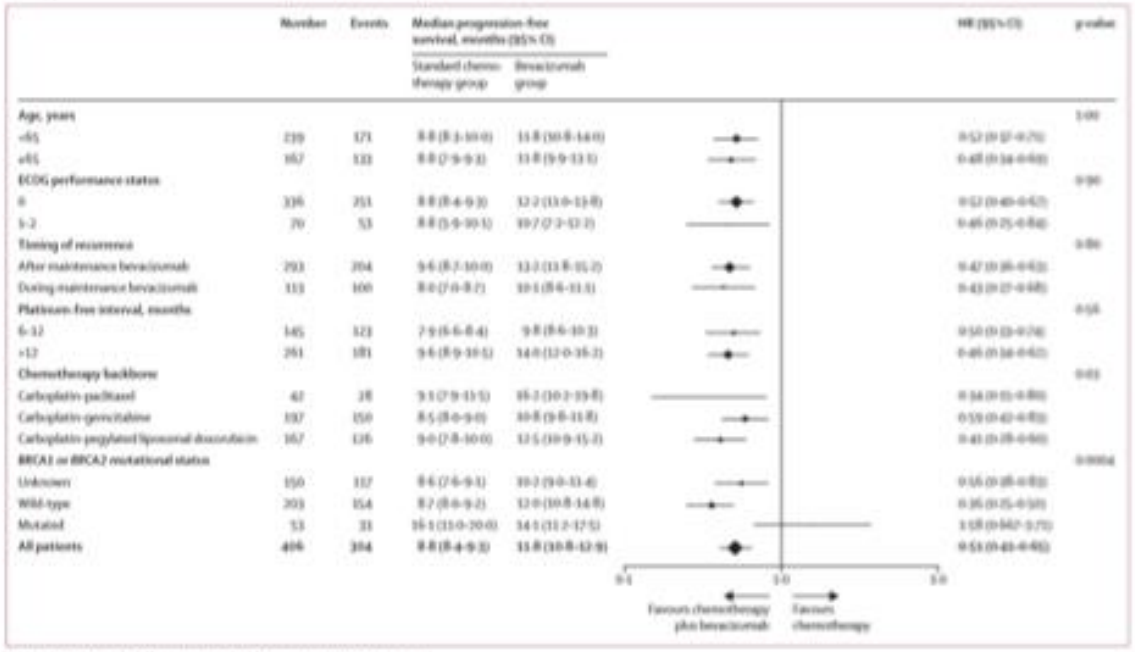


Figure 3: Forest plot of subgroup analysis of progression-free survival

Sandro Pignata et al. Lancet Oncol 2021; 22: 267–76

MANAGEMENT OF RECURRENT DISEASE

ESGO-ESMO-ESP consensus conference recommendations on ovarian cancer: pathology and molecular biology and early, advanced and recurrent disease

Recommendation 16.11: Patients in response to platinum-based ChT after prior PARPi maintenance therapy may be considered for a PARPi-maintenance rechallenge given a duration of prior PARPi exposure of 18 months in the first line and 12 months in further lines or 12 months and 6 months for patients with a *BRCA*-mut or *BRCA*-wt status, respectively [II, B].

Consensus: 94% (29) yes, 0% (0) no, 6% (2) abstain (31 voters)

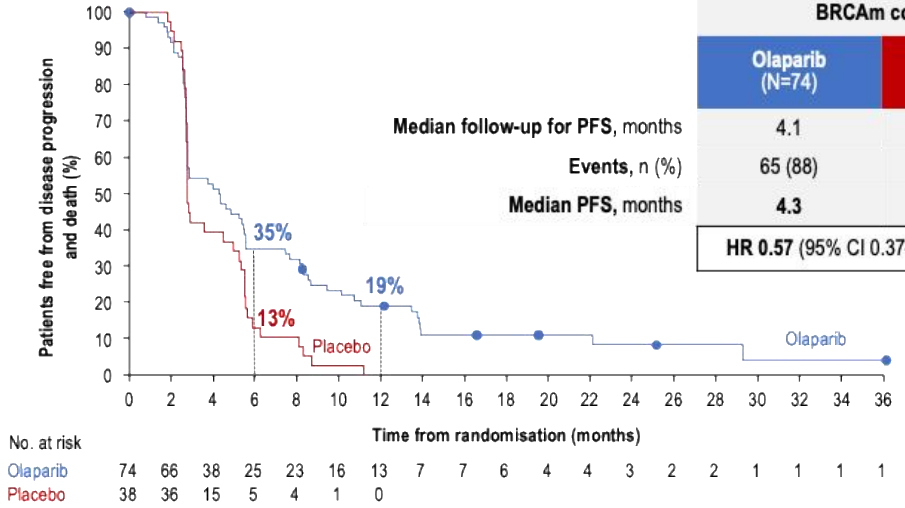
J Ledermann et al. Ann Oncol 2023

MANAGEMENT OF RECURRENT DISEASE

PARPi Rechallenge in BRCAm

A statistically significant PFS benefit was observed with olaparib in the BRCAm cohort

A proportion of patients derived clinically relevant long-term benefit

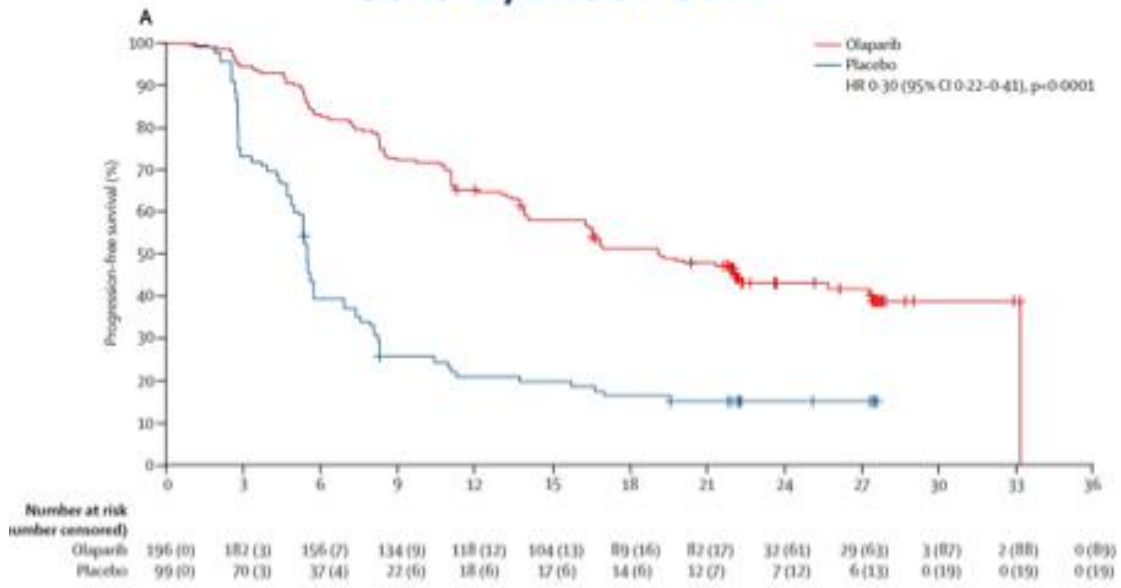


BRCAm cohort	Olaparib (N=74)	Placebo (N=38)
Median follow-up for PFS, months	4.1	2.8
Events, n (%)	65 (88)	38 (100)
Median PFS, months	**4.3**	**2.8**
HR 0.57 (95% CI 0.37–0.87); *P*=0.022		

CI, confidence interval.

Pujade et al. ESMO 2021

SOLO-2 /ENGOT-OV21



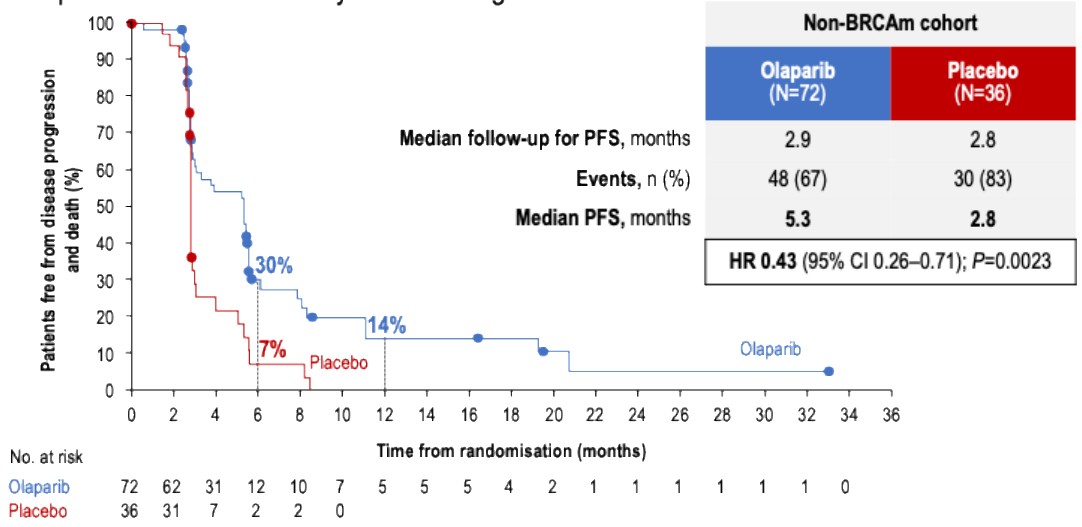
Pujade-Laurine et al. Lancet Oncol 2017

MANAGEMENT OF RECURRENT DISEASE

PARPi Rechallenge in non-BRCAm

A statistically significant PFS benefit was observed with olaparib in the non-BRCAm cohort

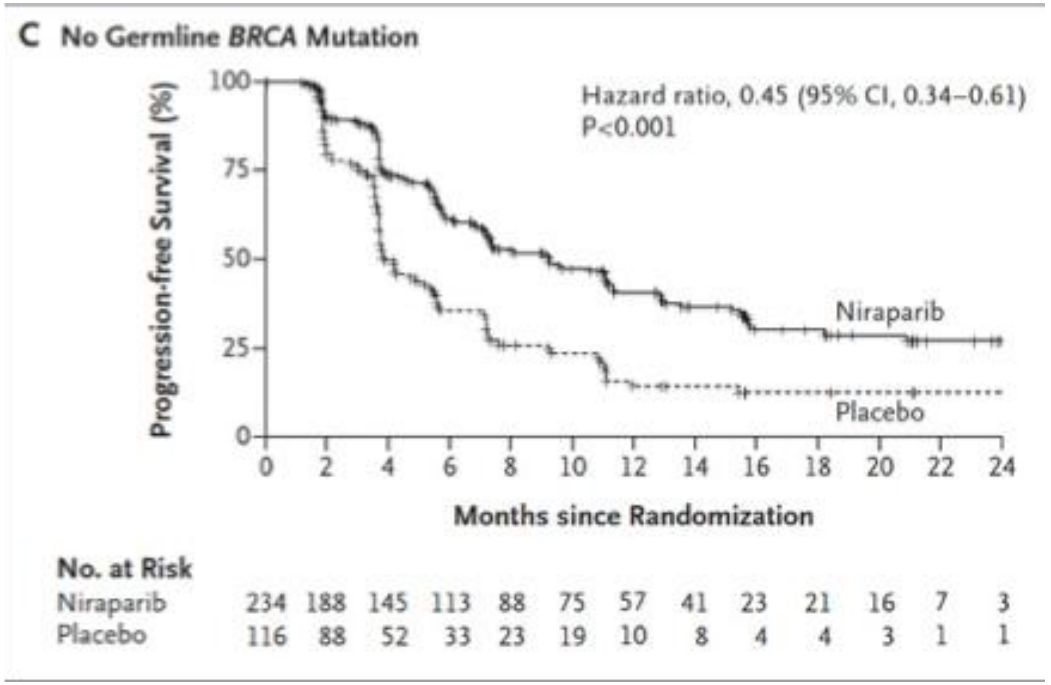
A proportion of patients derived clinically relevant long-term benefit



	Non-BRCAm cohort	
	Olaparib (N=72)	Placebo (N=36)
Median follow-up for PFS, months	2.9	2.8
Events, n (%)	48 (67)	30 (83)
Median PFS, months	**5.3**	**2.8**
HR 0.43 (95% CI 0.26–0.71); *P*=0.0023		

Pujade et al. ESMO 2021

NOVA /ENGOT-OV16



Mirza et al. N Eng J Med 2016

ADJUVANT AND MAINTENANCE THERAPY

Oct 2023

- Carboplatine AUC 5
  + Pegylated Liposomal Doxorubicin 30 mg/m²
  Q4W
  6 cycles

Apr 2024

- **CT scan**
  - No evidence of recurrence
- CA-125 normal

Enrolment in TEDOVA/ GINECO-OV244b/ ENGOT-ov58 trial

- Randomized phase II trial
- Patients with positive HLA-A2 phenotype
- Maintenance therapy with neo-epitope based vaccine OSE2101 alone +/- Pembrolizumab
  versus best supportive care

- **Randomized to OSE2101 + Pembrolizumab**

AUC, Area Under Curve; Q4W, 4-weekly

TAKE HOME MESSAGES

- Advanced epithelial ovarian cancer still a devastating disease for many; extensive research needed
- Surgery by a specialised team still a cornerstone in management of advanced ovarian cancer
- *BRCA* and HRD testing mandatory for selection of maintenance therapy in first line

- PARPi (± bevacizumab) considered standard of care as maintenance after response to platinum-based therapy, or NED after primary surgery
  - Magnitude of benefit depends on *BRCA* and HRD status
  - KELIM can help select patients with greater benefit from bevacizumab but confirmation in randomised clinical trial eagerly awaited
- Recurrent disease is a clear medical unmet need

HRD, homologous recombination deficiency; KELIM, ELIMination rate constant K; NED, no evidence of disease; PARPi, poly (ADP-ribose) polymerase inhibitor.

ESMO GUIDELINES: REAL WORLD CASES

Thank You!

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CLINICAL MANAGEMENT OF HRD POSITIVE OVARIAN CANCER

Emphasizing Specialized Care and Multidisciplinary Approaches

Benedetta Pellegrino, MD, PhD
Practising Oncologist Working Group
University Hospital of Parma

15° October 2024

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DECLARATION OF INTERESTS

B. Pellegrino reports research grants from Roche and Lilly; other support from Daiichi-Sankyo, Gilead, Pfizer, Lilly and Novartis; and personal fees from MSD outside the submitted work.

The ESMO POWG serves to identify the practice needs of oncologists who are hospital and office-based by developing educational services, practice tools and quality indicators that will facilitate the implementation of best practice at the point of care.

The POWG members are relevant stakeholders to the ESMO Guidelines Webinars as experts who are consulting and implementing the guidelines in their daily practices

For more information about the ESMO POWG visit **esmo.org**

ESMO > About ESMO > Organisational Structure > Educational Committee

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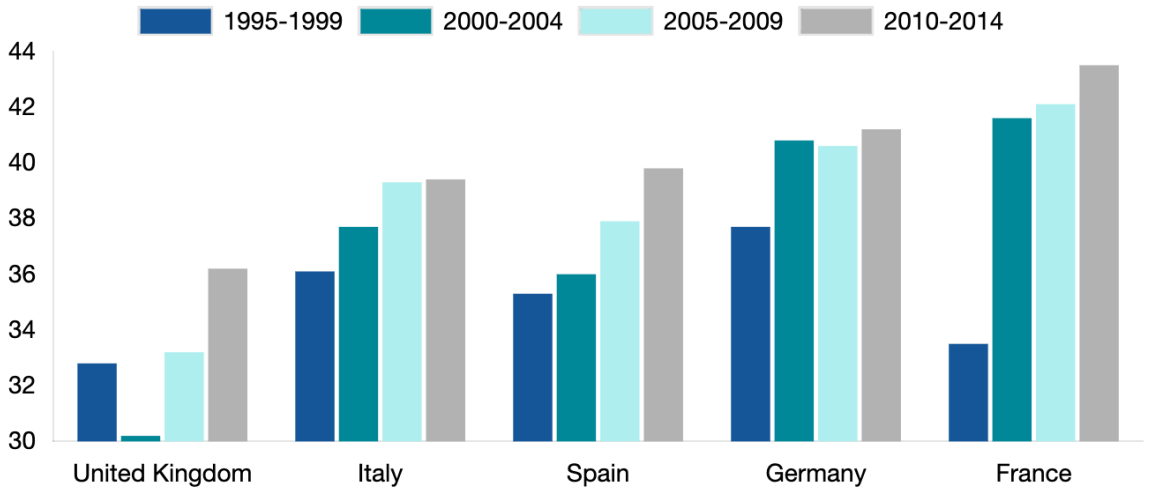
INTRODUCTION TO OVARIAN CANCER

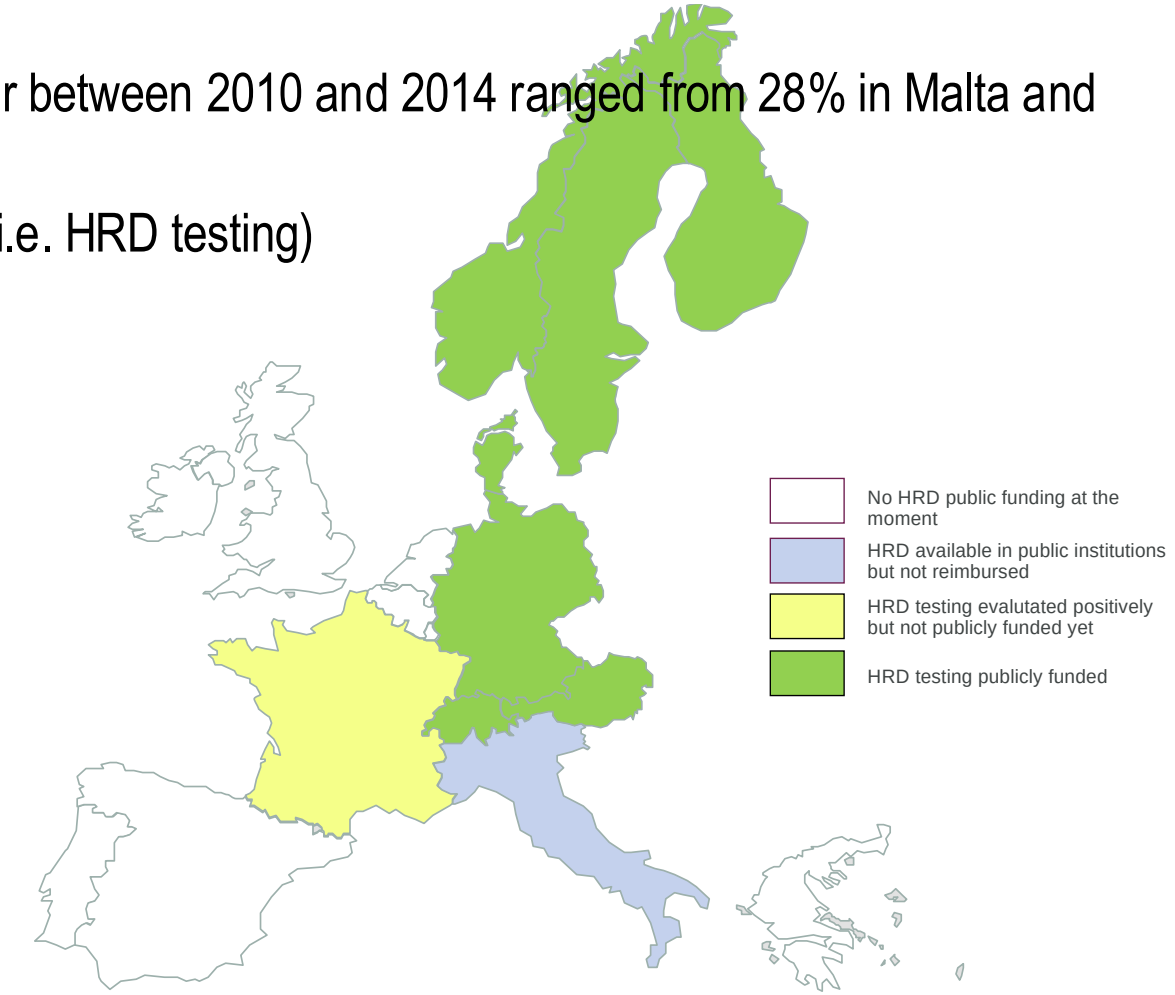
Ovarian Cancer is a rare disease

INTRODUCTION TO OVARIAN CANCER

5ys OS for Ovarian Cancer vary widely across Europe

- The 5-year age-standardized survival for ovarian cancer between 2010 and 2014 ranged from 28% in Malta and 46.5% in Sweden.
- This could be due to different regulations/organization (i.e. HRD testing)





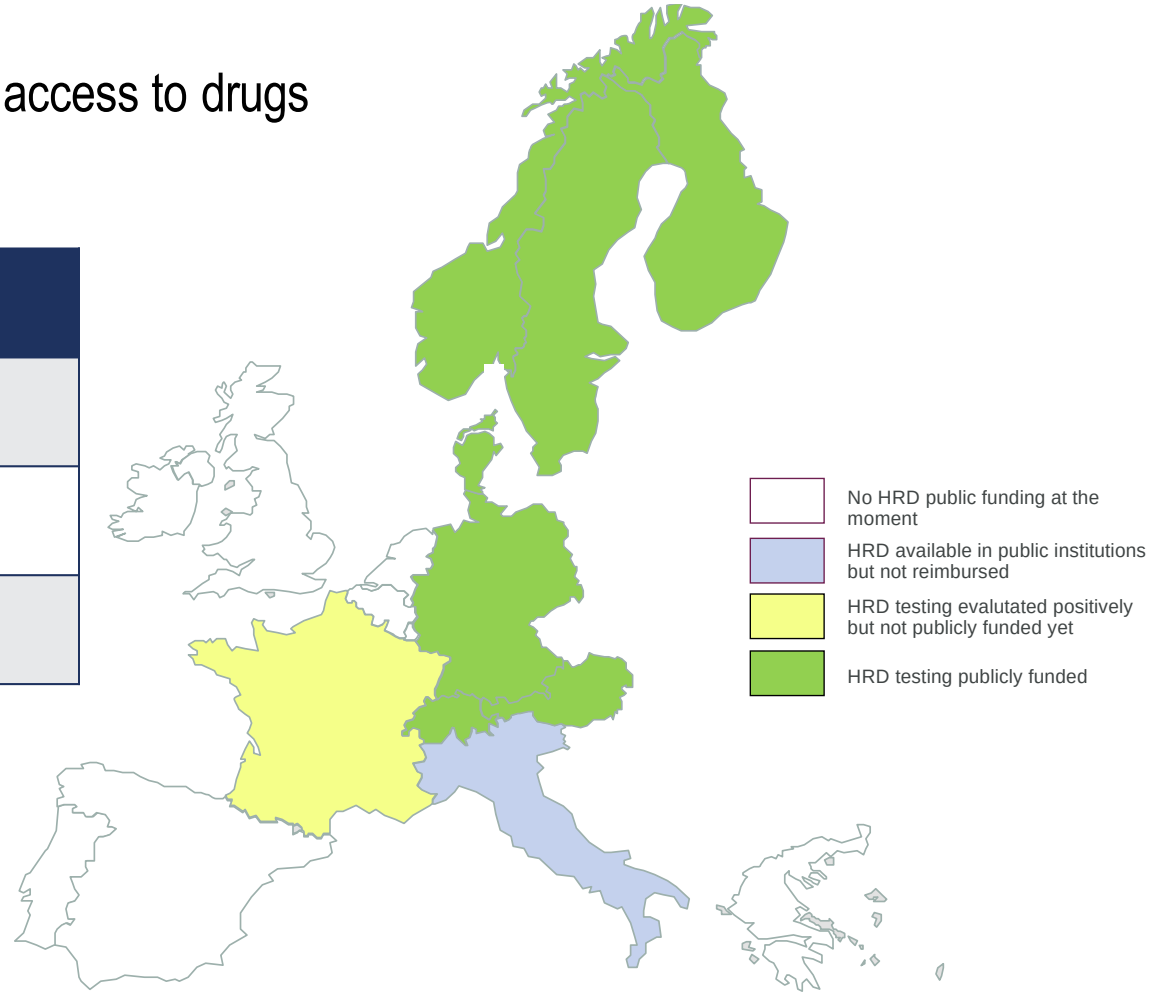
EFPIA website

INTRODUCTION TO OVARIAN CANCER

Genomic HRD predicts PARPi Response in Late-Stage Ovarian Cancer

- Differences in HRD testing availability may influence the access to drugs

Trial	Population	PFS in HRD-Positive	PFS in HRD-Negative
PAOLA	Advanced Ovarian Cancer	37.2	16.9
PRIMA	Advanced Ovarian Cancer	24.5	8.4
ATHENA	Newly Diagnosed Ovarian Cancer	28.7	12.1



Ray-Coquard I, NEJM 2019
Gonzalez-Martin A, EJM 2023
Monk B, JCO 2022

CASE PRESENTATION

BRCA1-mutated Late-Stage Ovarian Cancer Patient

CASE PRESENTATION

BRCA1-mutated Late-Stage Ovarian Cancer Patient

NGS (70% tumor cells)

- ***BRCA1* mutation (AF 70%)**
- *TP53* mutation (AF 60%)

Validated HRD test (70% tumor cells)

- Genomic instability score: 3.8 (**high**)

Neo-adjuvant chemotherapy

- Carboplatin AUC 5 and paclitaxel 175 mg/m²
  - Q3W for 3 cycles

Exploratory laparoscopy

§ Resectable carcinomatosis

- Peritoneal cancer index: 6/36

Interval cytoreductive surgery

§ Hysterectomy with bilateral adnexectomy

§ Resection of peritoneal nodules

§ Douglasectomy, omentectomy, appendectomy

Complete resection CC0

CASE PRESENTATION

BRCA1-mutated Late-Stage Ovarian Cancer Patient

Exploratory laparoscopy

§ Resectable carcinomatosis
- Peritoneal cancer index: 6/36

Interval cytoreductive surgery

§ Hysterectomy with bilateral adnexectomy

§ Resection of peritoneal nodules

§ Douglasectomy, omentectomy, appendectomy

Complete resection CC0

Pathology report

§ High-grade serous ovarian carcinoma

§ Persistence of carcinomatous masses measuring 0.1 to 1.5 cm on:
- The uterus, both ovaries, prevesical peritoneal nodule, and the Douglas

§ Significant scarring extending over 7 cm on the omentectomy

§ All other samples are void of tumor

Chemotherapy response score 2

CASE PRESENTATION

BRCA1-mutated Late-Stage Ovarian Cancer Patient

Pathology report

§ High-grade serous ovarian carcinoma

§ Persistence of carcinomatous masses measuring 0.1 to 1.5 cm on:

- The uterus, both ovaries, prevesical peritoneal nodule, and the Douglas

§ Significant scarring extending over 7 cm on the omentectomy

§ All other samples are void of tumor

Chemotherapy response score 2

Adjuvant chemotherapy

§ Carboplatin AUC 5 and paclitaxel 175 mg/m²

- Q3W for 3 cycles

§ Bevacizumab 15 mg/kg

- Q3W starting with cycle 5 and 6

§ CA-125: 21 U/ml (normal < 35)

Maintenance therapy

§ Olaparib 300 mg BID

§ Bevacizumab 15 mg/k

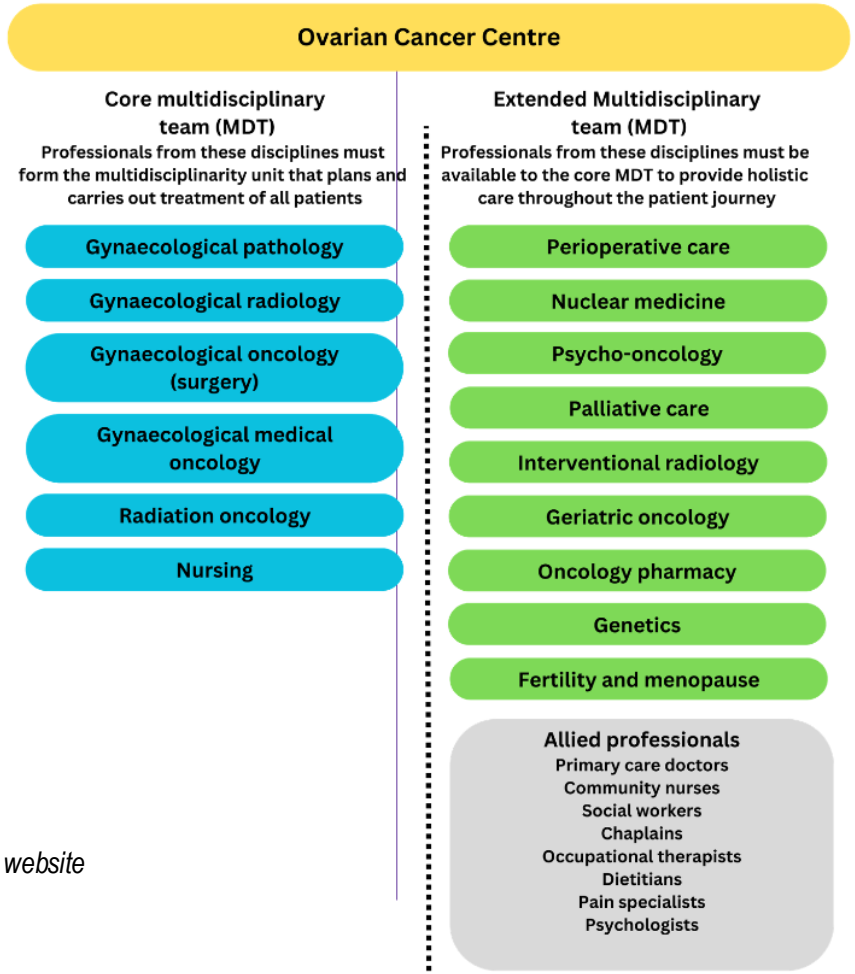
- Q3W

CLINICAL MANAGEMENT FOR A PO

Issues and challenges

IMPORTANCE OF SPECIALIZED OVARIAN CANCER UNITS

A minimum of 20 surgeries with the aim of complete cytoreductive for advanced ovarian cancer should be carried out at the centre (intermediate target 50, optimal target 100)



ECO website

Access to information and patient advocacy
Patient involvement in decision making; advocacy at national and European Network and Gynaecological Cancer Advocacy Groups; transparency of hospital organisational performance

Administration
Care pathways; data and performance management including audit outcomes; MDT performance; unit/ hospital accreditation

Research, registries, training and education
A target of 5 % of ovarian cancer patients entered into clinical trials

IMPORTANCE OF SPECIALIZED OVARIAN CANCER UNITS

Benefits of accessing to a certified ovarian cancer unit

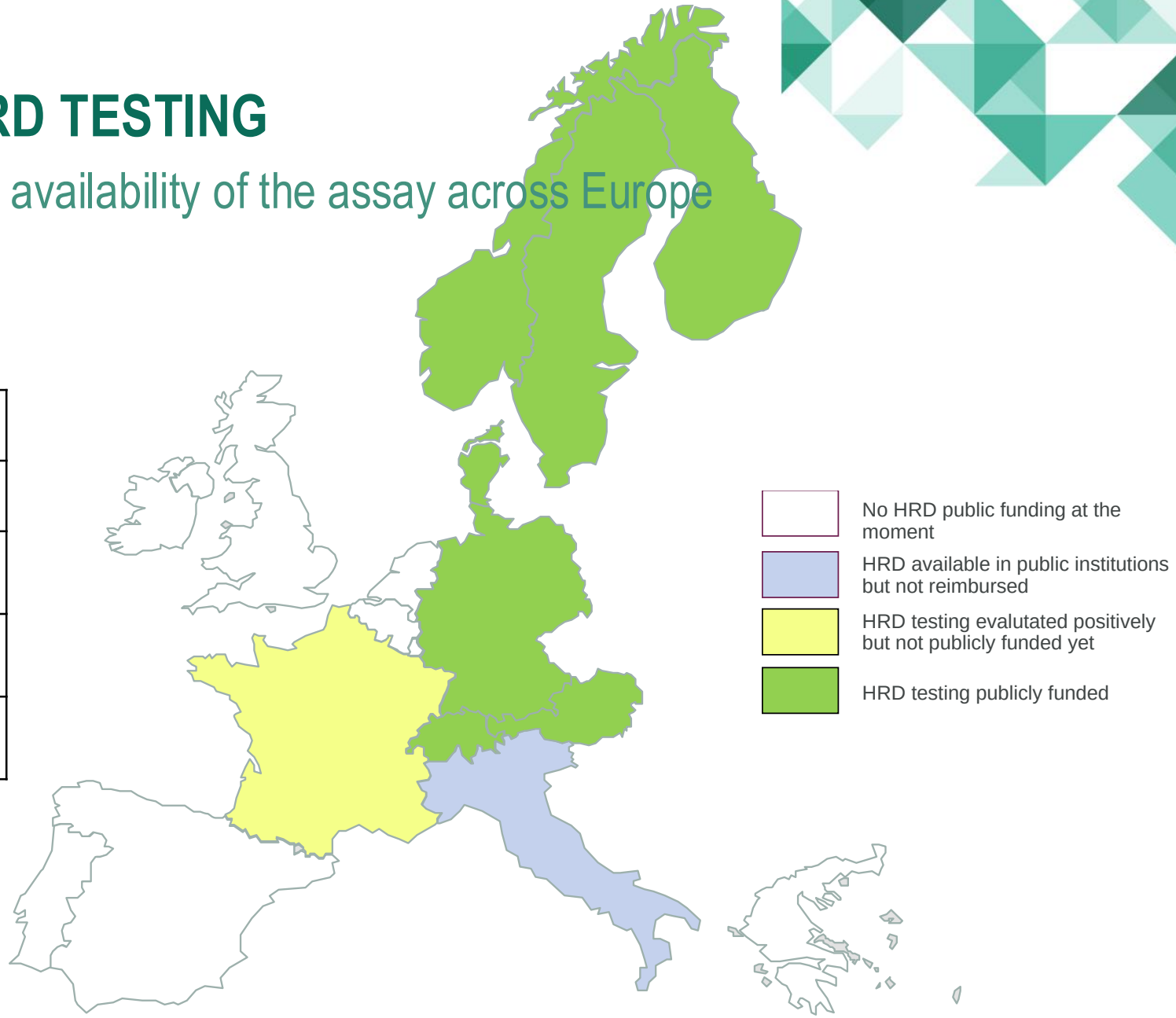
- 1. Standardized Care
  2. Access to Multidisciplinary Teams
  3. Enhanced Patient Outcomes
- 4. Access to Clinical Trials
  5. Expertise in Rare Diseases
  6. Advanced Diagnostic Tools
  7. Comprehensive Support Services
- 8. Patient Education and Resources
  9. Quality Assurance and Improvement
  10. Networking and Collaboration
  11. Improved Referral Pathways

ECO website

CHALLENGES IN GENOMIC HRD TESTING

Academic HRD tests may increase the availability of the assay across Europe

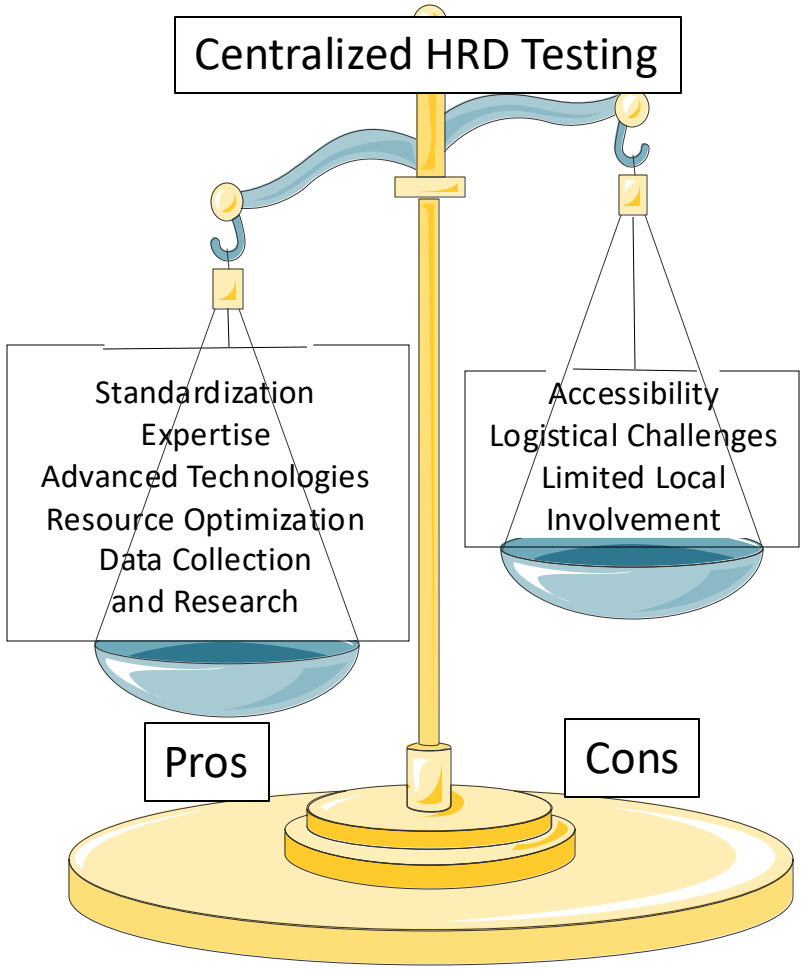
Analysis of concordance of HRR status between academic genomic HRD assays and Myriad.		
	LAB1 (CI 95%)	LAB2 (CI 95%)
Number of samples evaluated for HRR	92	92
Agreement rate	0.92 (0.87-0.98)	0.87 (0.81-0.94)
K- Cohen	0.84 (0.72 – 0.96)	0.74 (0.60 – 0.88)

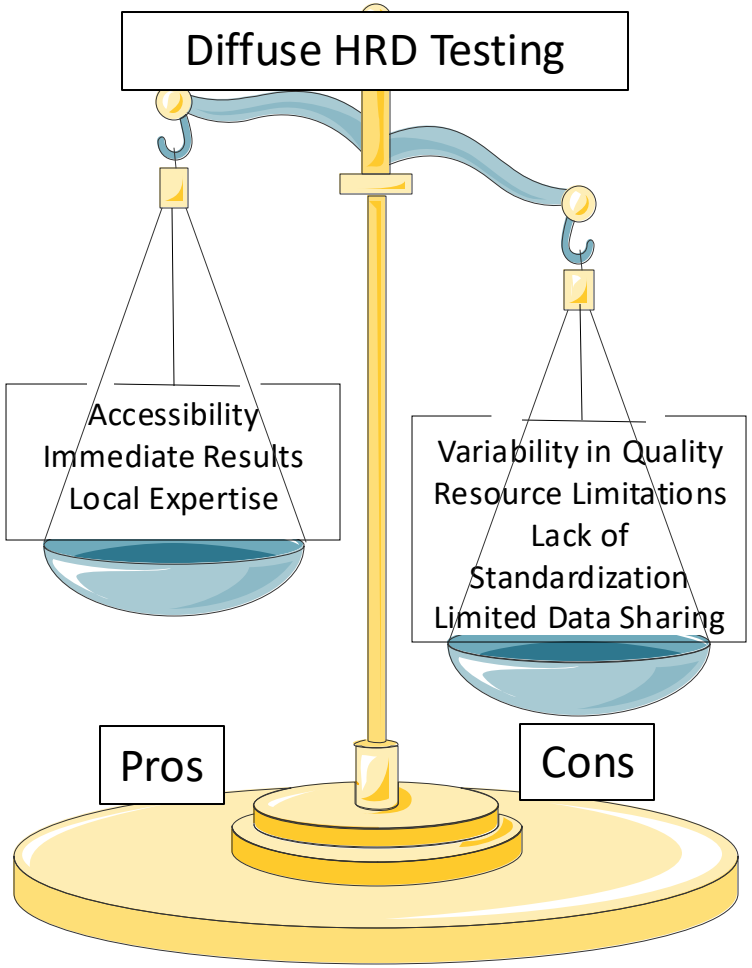


Capoluongo & Pellegrino et al, ESMO Open 2022

CHALLENGES IN GENOMIC HRD TESTING

Pros and cons of centralized vs. diffuse testing approaches

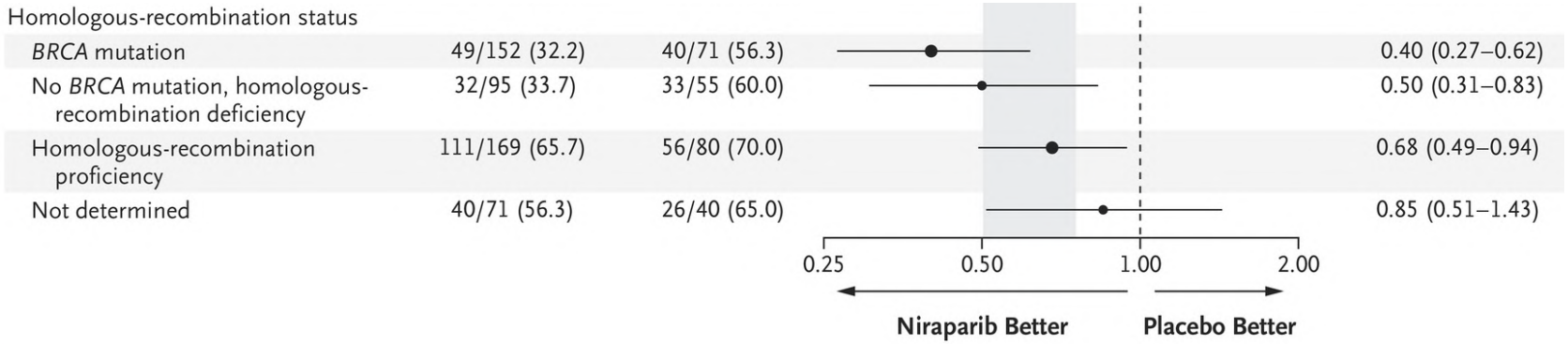




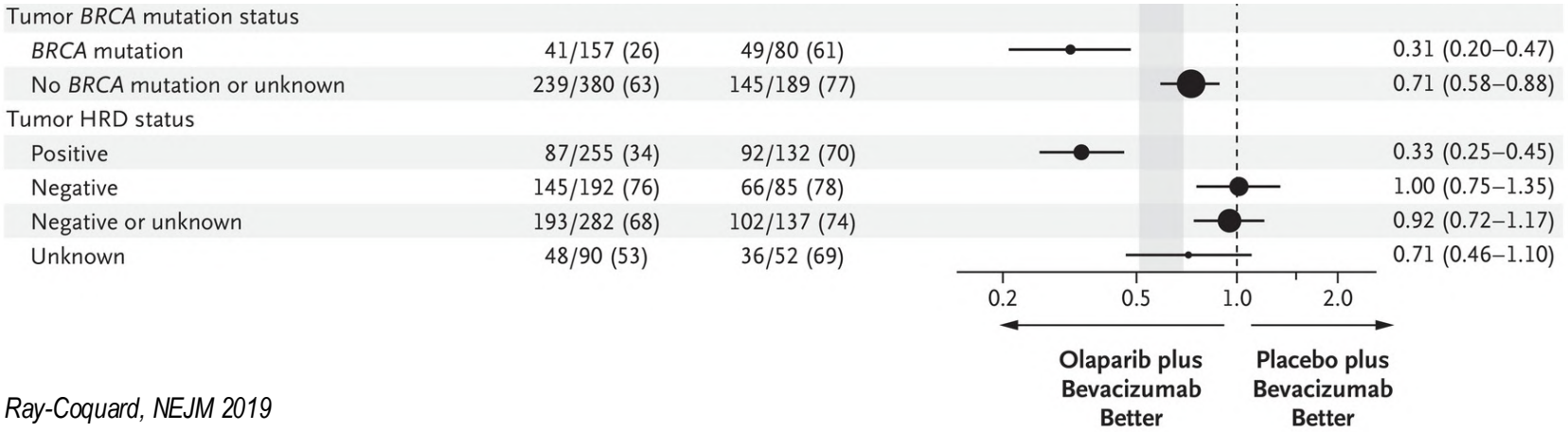
HRD IS ASSOCIATED WITH MAGNITUDE OF RESPONSE IN BRCA1/2-WT HGSOVC

In PRIMA trial, HRP HGSOC also benefited from PARPi as first-line maintenance treatment

PRIMA trial



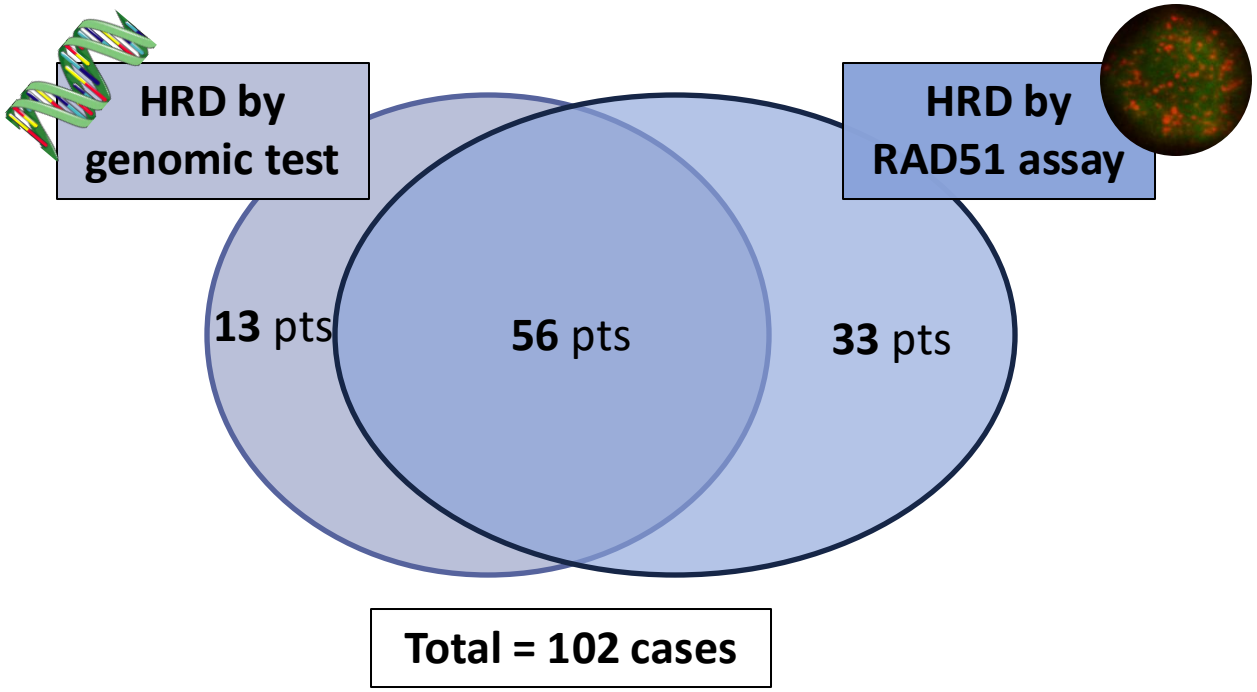
PAOLA trial



Gonzalez-Martin, NEJM 2019; Ray-Coquard, NEJM 2019

RAD51 ASSAY INCREASES THE NUMBER OF HRD OVARIAN CANCER PATIENTS COMPARED TO GENOMIC HRD TEST

Combined genomic and functional assay could increase the number of patients who may benefit from PARPi



	RAD51 assay		
Genomic HRD test	**HRD (%)**	**HRP (%)**	**Total (%)**
HRD+ (%)	56 (63)	13 (41)	69 (57)
HRD- (%)	33 (37)	19 (59)	52 (43)
Total (%)	89 (100)	32 (100)	121 (100)

Cohen/Conger's Kappa 0.193

Pellegrino&Capoluongo, under review

CASE PRESENTATION

BRCA1-mutated Late-Stage Ovarian Cancer Patient

Jun 2023

§ No symptoms

§ CA-125: 39 U/ml (normal < 35)

§ CA-125: 51 U/ml (normal < 35)

§ CT scan

- No evidence of recurrence

Aug 2023

§ No symptoms

§ CA-125: 155 U/ml (normal < 35)

§ CT scan :

- Appearance of nodules at the splenic hilum and at the right pelvic ureter in favor of a recurrent peritoneal carcinomatosis.
- No supra-diaphragmatic lesions

Aug 2023

MDT

§ Positive AGO score

- ECOG PS 1
- Ascites < 500 ml
- CC0 at first surgery

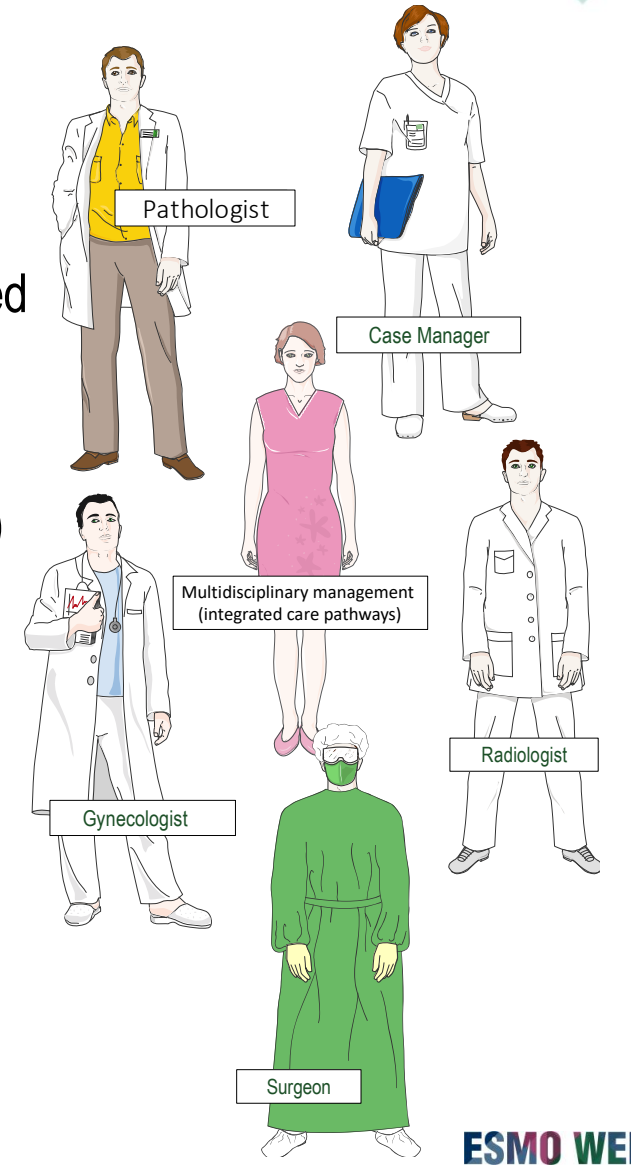
§ Secondary cytoreductive surgery

INTERVAL SURGERY AND SECONDARY REDUCTIVE SURGERY

The multidisciplinary approach

Multidisciplinary management (integrated care pathways)

- Gynecologist with expertise in advanced laparotomic surgery (expecially peritoneal surgery). Two gynecologists needs to be involved for at least 50% of their timetable in Ovarian Cancer surgery.
- Expert radiologist with experience in RM
- Pathologist (with access to intra-operative frozen section consultation)
- Case Manager
- On demand: urologist, epatobiliary surgeon, vascolar surgeon



ESMO –ESGO Consensus Conference Reccomendation for Ovarian Cancer

Emilia Romagna Consensus Conference for Ovarian Cancer Treatment

SURGERY ISSUES

Selection criteria for upfront surgery

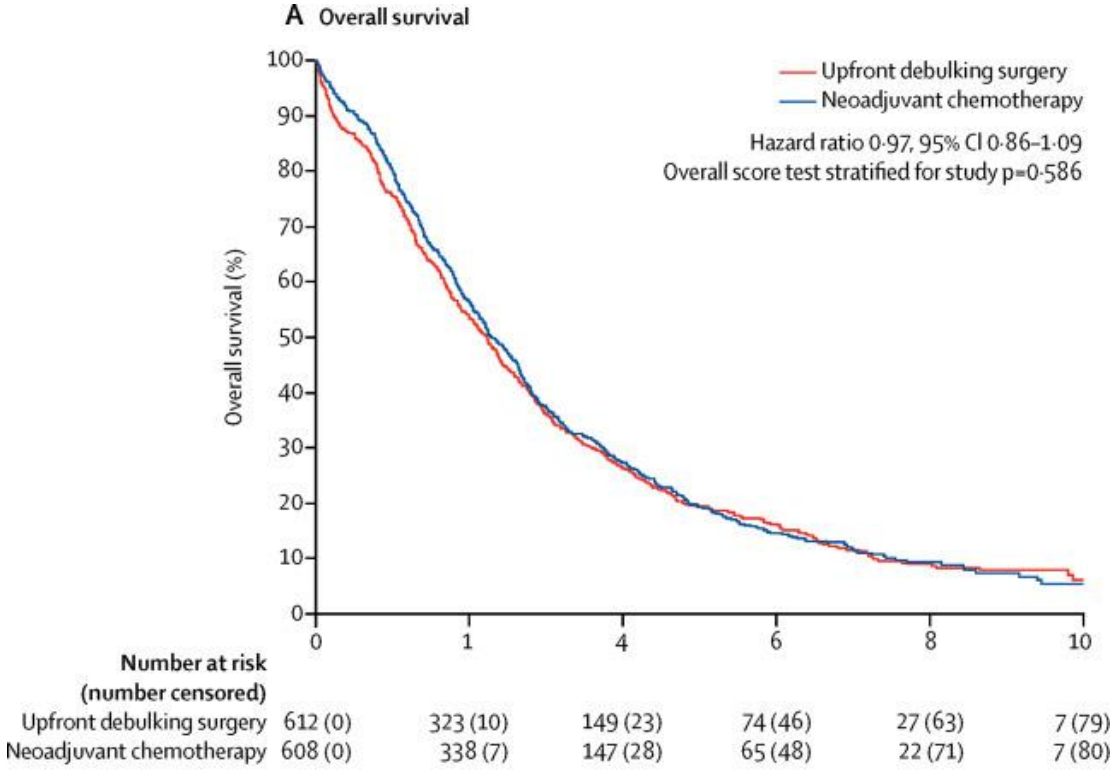
- Complete resection of all macroscopic disease has been shown to be the single most important independent prognostic factor in advanced EOC and careful evaluation of patients before surgery is essential to defining the management plan.
- **Exclusion criteria**:
  - Chest
    - Multiple parenchymal pulmonary nodules
    - Multifocal mediastinal adenopathy
    - Cardiac involvement
  - Abdomen/Pelvis
    - Unresectable porta hepatis or gallbladder fossa disease
    - Lesser sac involvement
    - Stomach parenchymal disease at lesser or greater curvature
    - Involvement of celiac trunk and root of mesenteric artery
    - Extensive serosal involvement of the small and large bowel
    - Multifocal bone involvement

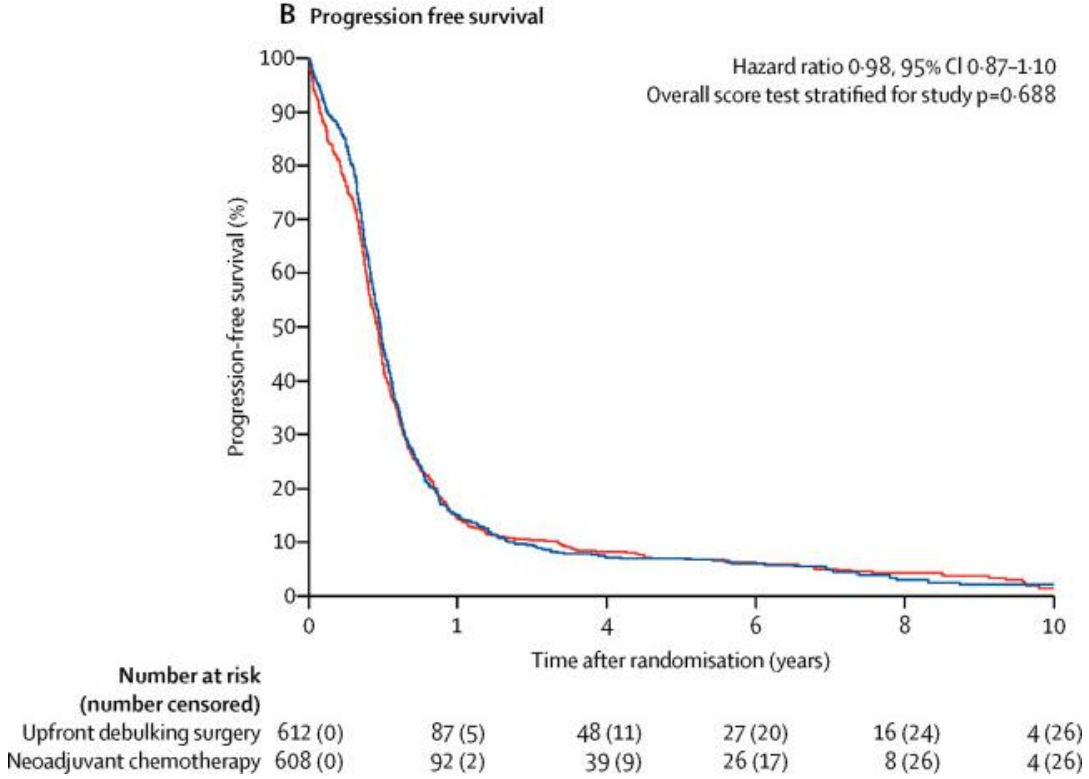
ESMO –ESGO Consensus Conference Reccomendation for Ovarian Cancer

NEO-ADJUVANT VS UPFRONT SURGERY

Pooled analyses of EORTC55971 and CHORUS trials

If resection of all macroscopic disease cannot be obtained based on pre-operative staging with an acceptable operative morbidity, neoadjuvant chemotherapy with carboplatin/paclitaxel is an acceptable option.

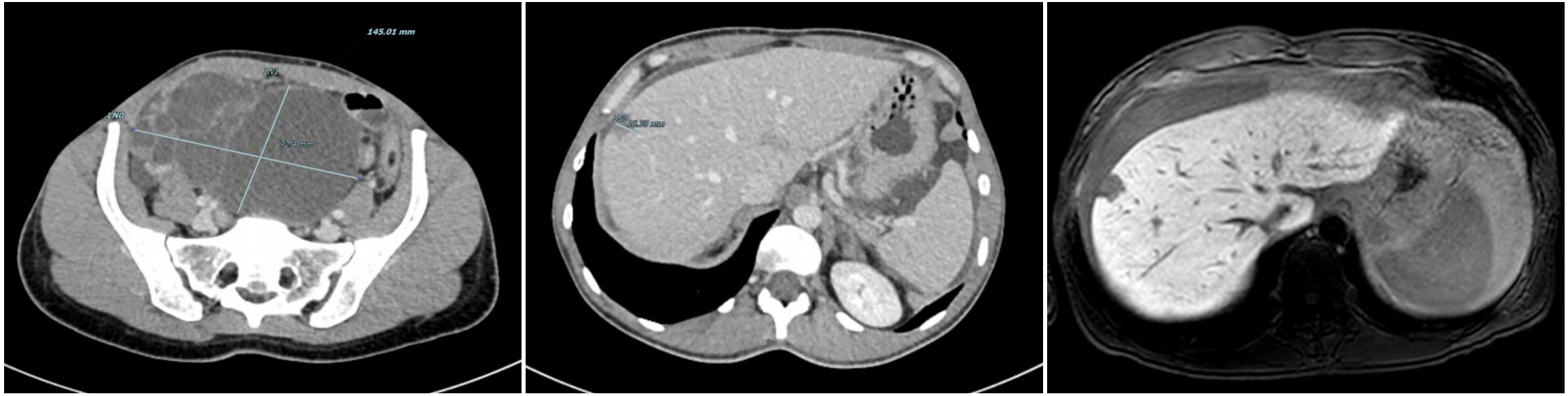




SURGERY ISSUES

Preoperative diagnostic work-up

- Preoperative diagnostic work-up includes: CT, PET-CT, or whole-body MRI.
- If carried out by an experienced sonographer, ultrasound has an invaluable role in estimating the malignant potential and histopathological features of ovarian cysts but also in assessing tumour extent in the pelvis and abdominal cavity.
- Diagnostic laparoscopy can provide a definitive histopathological diagnosis and detailed information about the intra-abdominal disease burden (e.g. Fagotti scoring system). After laparoscopy, a high rate of port-site metastases are observed, but do not worsen the prognosis.



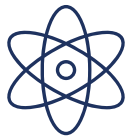
CASE PRESENTATION

BRCA1-mutated Late-Stage Ovarian Cancer Patient

Oct 2023

§ Carboplatine AUC 5
+ Pegylated Liposomal Doxorubicin 30 mg/m²
Q4W
6 cycles

Apr 2024



§ **CT scan**
- No evidence of recurrence

§ CA-125 normal

Enrolment in TEDOVA/ GINECO-OV244b/ ENGOT-ov58 trial

§ Randomized phase II trial
§ Patients with positive HLA-A2 phenotype
§ Maintenance therapy with neo-epitope based vaccine OSE2101 alone +/- Pembrolizumab
versus best supportive care

§ **Randomized to OSE2101 + Pembrolizumab**

AUC, Area Under Curve; Q4W, 4-weekly

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ECO website

IMPORTANCE OF SPECIALIZED OVARIAN CANCER UNITS AND COOPERATIVE RESEARCH GROUP

A target of 5% of ovarian cancer patients entered into clinical trials

Ovarian Cancer Centre

Core multidisciplinary team (MDT)
Professionals from these disciplines must form the multidisciplinarity unit that plans and carries out treatment of all patients

- Gynaecological pathology
- Gynaecological radiology
- Gynaecological oncology (surgery)
- Gynaecological medical oncology
- Radiation oncology
- Nursing

Extended Multidisciplinary team (MDT)
Professionals from these disciplines must be available to the core MDT to provide holistic care throughout the patient journey

- Perioperative care
- Nuclear medicine
- Psycho-oncology
- Palliative care
- Interventional radiology
- Geriatric oncology
- Oncology pharmacy
- Genetics
- Fertility and menopause

Allied professionals
Primary care doctors
Community nurses
Social workers
Chaplains
Occupational therapists
Dietitians
Pain specialists
Psychologists

Access to information and patient advocacy
Patient involvement in decision making; advocacy at national and European Network and Gynaecological Cancer Advocacy Groups; transparency of hospital organisational performance

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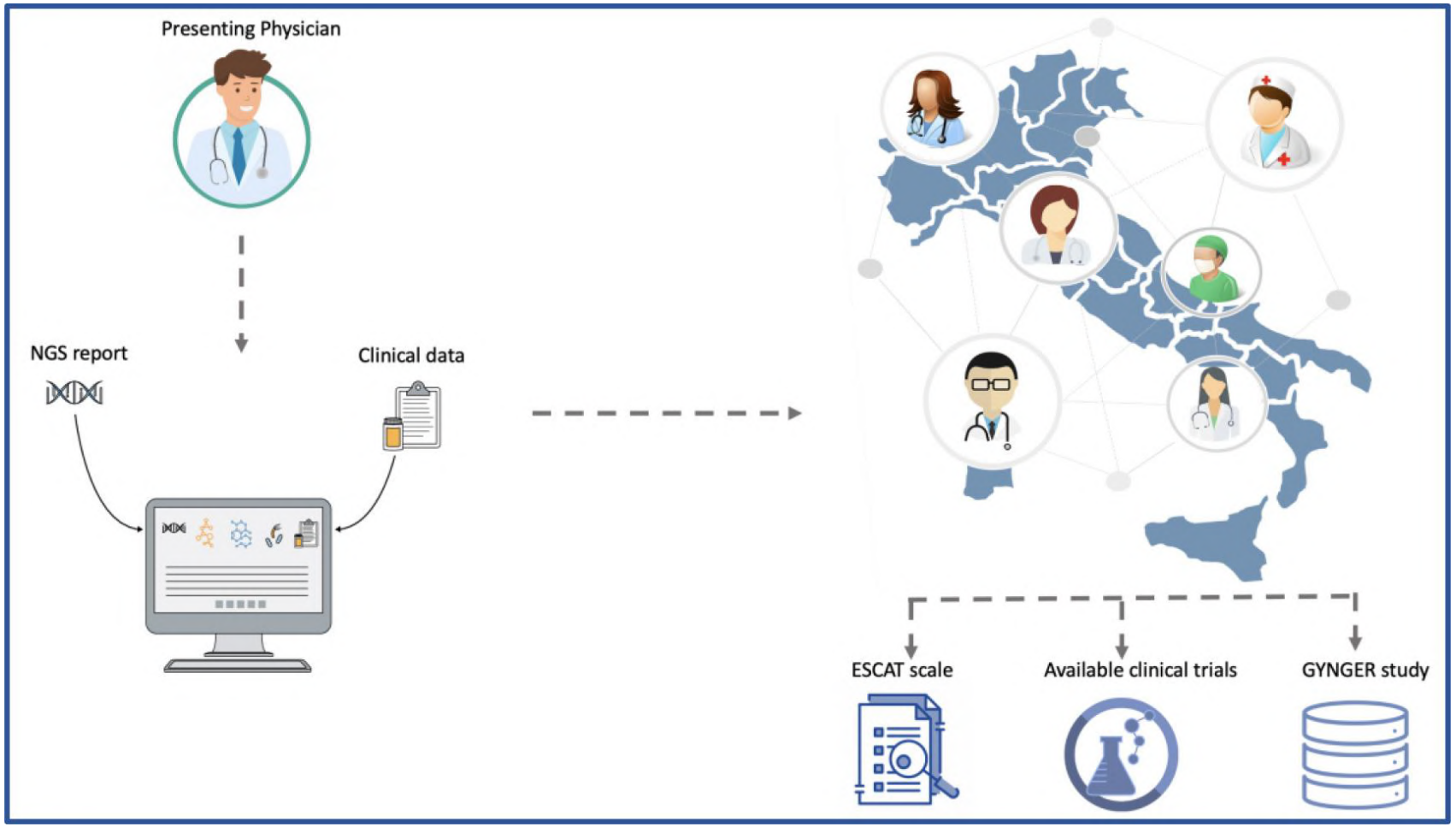
IMPORTANCE OF SPECIALIZED OVARIAN CANCER UNITS AND COOPERATIVE RESEARCH GROUP

The experience of MITO Tumor Molecular Board



MITO website

ESMO GUIDELINES: REAL WORLD CASES

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