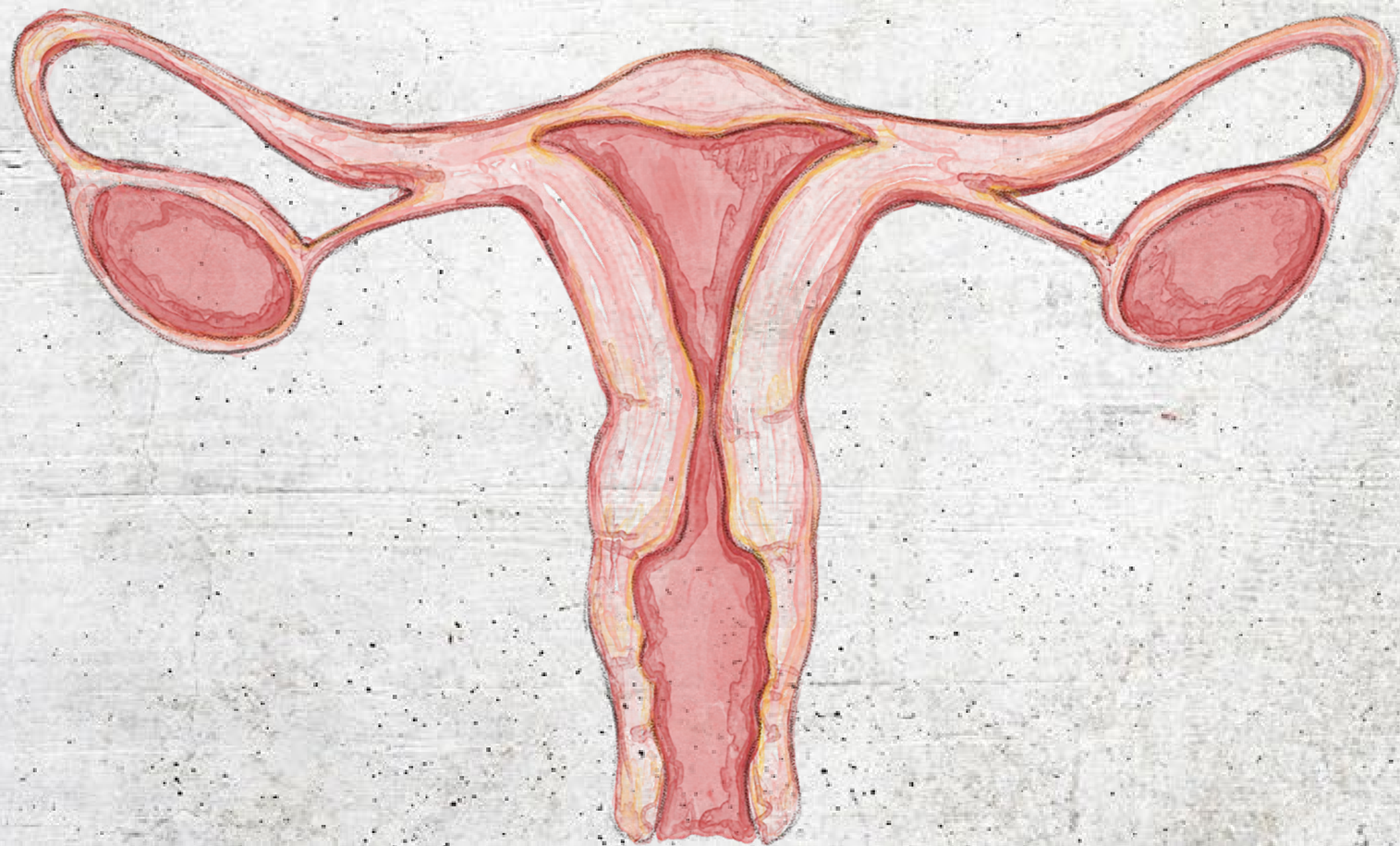
RGOQ
Regroupement des Gynécologues Oncologues du Québec

18E CONGRÈS ANNUEL

Revue du cancer de l'ovaire séreux de haut grade

Dre Jessica Ruel- Laliberté MD Msc
Fellow-CHUM



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Déclaration de conflits d'intérêts personnels

Je n'ai pas de conflits d'intérêts ou de biais commerciaux potentiels

RGOQ
Regroupement des Gynécologues Oncologues du Québec

Études qui seront présentées

01 SORAYA

02 MIRASOL

03 CHIPOR

SORAYA et MIRASOL

SORAYA

original reports

Efficacy and Safety of Mirvetuximab Soravtansine in Patients With Platinum-Resistant Ovarian Cancer With High Folate Receptor Alpha Expression: Results From the SORAYA Study

Ursula A. Matulonis, MD[1]; Domenica Lorusso, MD, PhD[2]; Ana Oaknin, MD, PhD[3]; Sandro Pignata, MD, PhD[4]; Andrew Dean, MBChB, MRCP, FRACP[5]; Hannelore Denys, MD, PhD[6]; Nicoletta Colombo, MD, PhD[7,8]; Toon Van Gorp, MD, PhD[9]; Jason A. Konner, MD[10]; Margarita Romeo Marin, MD, PhD[11]; Philipp Harter, MD, PhD[12]; Conleth G. Murphy, MD[13]; Jiuzhou Wang, PhD[14]; Elizabeth Noble, BS[14]; Brooke Esteves, BSN[14]; Michael Method, MD, MPH, MBA[14]; and Robert L. Coleman, MD[15]

Jusqu'à 80% des cancers épithéliaux de l'ovaire vont récidiver

Patientes développent éventuellement une résistance aux platins (PROC)

->Tx de chimiothérapie sans platins

->Taux de réponse faibles (10-30%) et toxicités qui peuvent être importantes

Le mivetuximab soravtansine (MIRV) est un anticorps conjugué composé d'un récepteur antifolate a (FRa)

FRa est une protéine membranaire qui se lie et transporte le folate dans les cellules. Ce récepteur est généralement surexprimé dans les tumeurs épithéliales, en particulier dans les tumeurs séreuses de haut grade de l'ovaire et de l'endomètre séreux

SORAYA

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Étude phase 2 simple brin
39 sites, 8 pays

PROC (6 mois)

Expression tumorale élevée de FRa, évaluée par le Test Ventana FOLR128, avec au moins 75 % des cellules de tumeur viable (méthode démontrée + fiable que celle utilisée dans FORWARD I)=36% des ptes *screenées* considérées +

Reçu une à trois lignes précédentes de thérapie anticancéreuse systémique (thérapies d'entretien incluses) et avaient toutes déjà reçu du BEV

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Critères d'exclusion:

-troubles cornéens, affections oculaires nécessitant un traitement continu

-neuropathie périphérique de grade > 1

-maladie pulmonaire interstitielle non infectieuse

MIRV à 6 mg/kg IV q. 3 semaines ad progression, toxicités inacceptables, décès

Examen ophtalmologique lors du screening et évaluation des symptômes oculaires avant chaque dose

Larmes artificielles lubrifiantes die et des gouttes de corticostéroïdes la veille ad J8 de chaque tx

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Issue primaire: ORR selon critères RECIST 1.1 (ORR de référence de 12 % pour la chimiothérapie à agent unique)

Issues secondaires: durée de réponse (définie comme le temps écoulé entre la réponse initiale complète ou partielle jusqu'à la progression de la maladie), PFS, OS

Évaluation radiologique (scan ou IRM) au screening puis q.6sem x 36 semaines, puis q.12 sem ad progression, décès ou début d'un nouveau traitement

2 analyses de sous-groupe prévues: nbr de lignes de tx et utilisation PARPi

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n=105

51 % avaient déjà reçu trois lignes de traitement

48 % avaient déjà reçu un PARPi

Suivi médian 13.4 mois

ORR 32,4 % (IC à 95 %, 23,6 à 42,2), cinq réponses complètes et 29 réponses partielles

Durée médiane de réponse 6,9 mois (IC à 95 %, 5,6 à 9,7)

TABLE 2. ORR and Subgroup Analysis in the Efficacy Evaluable Population

ORR	Investigator-Assessed	BICR-Assessed
Efficacy evaluable patients, No.	n = 105	n = 96
ORR, No. (%) [95% CI][a]	34 (32.4) [23.6 to 42.2]	29 (30.2) [21.3 to 40.4]
Best overall response, No. (%)		
CR	5 (4.8)	6 (6.3)
PR	29 (27.6)	23 (24.0)
SD	48 (45.7)	54 (56.3)
PD	20 (19.0)	9 (9.4)
NE	3 (2.9)	4 (4.2)
Tumor reduction, No. (%)	75 (71.4)	ND
Disease control rate, No. (%)	54 (51.4)	ND
CA-125 response[b]	n = 86	
No. (%) [95% CI]	40 (46.5) [35.7 to 57.6]	ND
ORR subgroup analysis		
Prior lines of therapy, No. (%) [95% CI][a]		
1 or 2	n = 51	n = 46
	18 (35.3) [22.4 to 49.9]	15 (32.6) [19.5 to 48.0]
3	n = 53	n = 49
	16 (30.2) [18.3 to 44.3]	14 (28.6) [16.6 to 43.3]
Prior exposure to PARPi, No. (%) [95% CI][a,c]		
Yes	n = 50	n = 47
	19 (38.0) [24.7 to 52.8]	14 (29.8) [17.3 to 44.9]
No	n = 51	n = 46
	14 (27.5) [15.9 to 41.7]	15 (32.6) [19.5 to 48.0]

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Événements indésirables liés au traitement

Retards (33%)

Réductions de dose (20%)

Arrêts de dose (9%) des patientes

original reports

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TABLE 5. Most Common (≥ 10%) TRAEs in the Safety Population

TRAEs	All Grades, No. (%)	Grades 3-4, No. (%)
Patients with any event	91 (86)	31 (29)
Blurred vision	43 (41)	6 (6)
Keratopathy[a]	31 (29)	9 (9)
Nausea	31 (29)	0 (0)
Dry eye	26 (25)	2 (2)
Fatigue	25 (24)	1 (1)
Diarrhea	23 (22)	2 (2)
Asthenia	16 (15)	1 (1)
Photophobia	14 (13)	0 (0)
Peripheral neuropathy	14 (13)	0 (0)
Decreased appetite	14 (13)	1 (1)
Neutropenia	14 (13)	2 (2)
Vomiting	12 (11)	0 (0)

SORAYA

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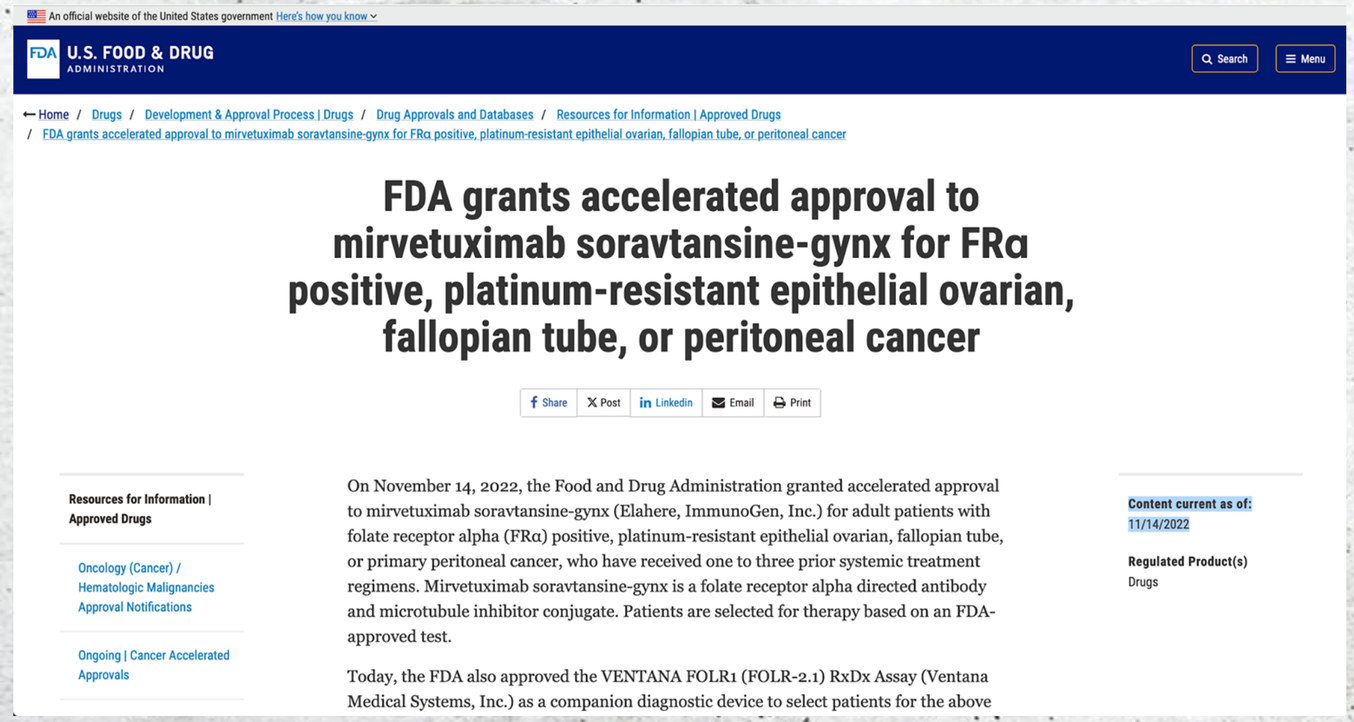
Événements oculaires observés chez environ 50 % des patientes étaient attendus sur la base d'essais cliniques antérieurs

1 arrêt pour situation oculaire urgente, sans séquelles permanentes



An official website of the United States government Here's how you know

FDA U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / Drugs / Development & Approval Process | Drugs / Drug Approvals and Databases / Resources for Information | Approved Drugs / FDA grants accelerated approval to mirvetuximab soravtansine-gynx for FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or peritoneal cancer

FDA grants accelerated approval to mirvetuximab soravtansine-gynx for FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or peritoneal cancer

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Resources for Information | Approved Drugs

Oncology (Cancer) / Hematologic Malignancies Approval Notifications

Ongoing | Cancer Accelerated Approvals

On November 14, 2022, the Food and Drug Administration granted accelerated approval to mirvetuximab soravtansine-gynx (Elahere, ImmunoGen, Inc.) for adult patients with folate receptor alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Mirvetuximab soravtansine-gynx is a folate receptor alpha directed antibody and microtubule inhibitor conjugate. Patients are selected for therapy based on an FDA-approved test.

Today, the FDA also approved the VENTANA FOLR1 (FOLR-2.1) RxDx Assay (Ventana Medical Systems, Inc.) as a companion diagnostic device to select patients for the above

Content current as of: 11/14/2022

Regulated Product(s)
Drugs

MIRASOL

LBA5507 Oral Abstract Session

Phase III MIRASOL (GOG 3045/ENGOT-ov55) study: Initial report of mirvetuximab soravtansine vs. investigator's choice of chemotherapy in platinum-resistant, advanced high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers with high folate receptor-alpha expression.

ECR
Résultats présentés ASCO 2023

PROC avec une expression élevée de FRa (test Roche FOLR1) même définition que Soraya
1 à 3 lignes de tx antérieurs
PARPi ou **utilisation de BEV non obligatoire**
Randomisées 1:1

MIRV 6 mg/kg, poids corporel idéal ajusté, q.21j versus chimiothérapie: paclitaxel, caelyx , ou topotécan

Issue primaire: PFS

Issues secondaires: ORR, OS, issues rapportées par les patientes

MIRASOL

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n=453

227 MIRV, 226 chimio

Suivi médian 13.1 mois

Les caractéristiques de base étaient bien équilibrées dans tous les bras ;
Nombre de lignes de tx antérieur: 14 % une, 39 % deux et 47 % trois lignes
62 % avaient déjà reçu du BEV

55 % avaient déjà reçu un PARPi

41% taxol hebdo, 36% caelyx, 23% topotecan

MIRASOL

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PFS 5.6m MIRV vs 3.98m SS

ORR 42.3% MIRV vs 15.9% SS

5.3% de réponse complète dans le groupe MIRV

mOS 16.5m MIRV vs 12.7m SS

Efficacy Endpoints	MIRV (n=227)	IC (n=226)	Hazard Ratio	P-value
mPFS (INV) (months, 95% CI)	5.62 (4.34, 5.95)	3.98 (2.86, 4.47)	0.65 (0.52, 0.81)	, 0.0001
mPFS (BICR) (months, 95% CI)	5.91 (4.93, 6.97)	4.34 (3.52, 4.99)	0.72 (0.56, 0.92)	0.0082
ORR (INV) (95% CI)	42.3 (35.8, 49.0)	15.9 (11.4, 21.4)	NA	, 0.0001
Complete response % (n)	5.3 (12)	0	NA	NA
Partial response % (n)	37.0 (84)	15.9 (36)	NA	NA
ORR (BICR) (95% CI)	36.1 (29.9, 42.7)	14.6 (10.3, 19.9)	NA	, 0.0001
mOS (months, 95% CI)	16.46 (14.46, 24.57)	12.75 (10.91, 14.36)	0.67 (0.50, 0.88)	0.0046

MIRASOL

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Événements oculaires (MIRV vs chimio tous grades 56 % vs 9 % ; grade 3+ 14 % vs 0 %)

Événements gastro-intestinaux (MIRV vs chimio tous grades 70 % vs 66 % ; grade 3+ 13 % vs 15 %)

Profil d'événements indésirables supérieur groupe MIRV

EI grade 3+ survenus pendant le traitement (42 % MIRV vs 54 %)

EI graves (24 % MIRV vs 33 %)

Arrêts dus à des événements indésirables (9 % MIRV vs 16 %)

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LBA5507 Oral Abstract Session

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Traitement démontrant un bénéfice sur la survie dans une étude de phase 3 pour les patientes avec un cancer de l'ovaire résistant aux platins

- est-ce cliniquement significatif 1.6m de PFS?

Approuvé FDA

- coût?, accès aux tests du folate?

Bénéfice statistiquement significatif sur PFS, ORR, OS

Profil d'effets indésirables supérieur à la chimio

- sera intéressant de voir les issues rapportés par les patientes dans l'article

Événements oculaires à surveiller

Résultats semblables entre la population ayant reçu ou pas du BEV

Article non publié

CHIPOR

CHIPOR

#876

HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY IN PLATINUM-SENSITIVE RELAPSED EPITHELIAL OVARIAN CANCER: THE CHIPOR RANDOMISED PHASE III TRIAL

[1]Jean-Marc Classe*, [2]Pierre Meeus, [3]Eric Leblanc, [4]Romuald Wernert, [5]François Quenet, [6]Frédéric Marchal, [7]Gilles Houvenaeghel, [8]Anne-Sophie Bats, [8]Fabrice Lécuru, [9]Gwenaël Ferron, [10]Cécile Brigand, [1]Dominique Berton, [9]Laurence Gladieff, [11]Florence Joly, [2]Isabelle Ray Coquard, [12]Sylvaine Durand-Fontanier, [13]Emilie Brument, [14]Bernard Asselain, [1]Loïc Campion, [15]Olivier Glehen. *[1]ICO René Gaudducheau, Saint Herblain, France; [2]Centre Léon Bérard, Lyon, France; [3]Centre Oscar Lambret, Lille, France; [4]Centre Paul Papin, Angers, France; [5]ICM Val d'Aurelle, Montpellier, France; [6]Institut de Cancérologie de Lorraine, Vandoeuvre-Lès-Nancy, France; [7]Institut Paoli Calmettes, Marseille, France; [8]HEGP, Paris, France; [9]Institut Claudius Regaud – IUCT Oncopole, Toulouse, France; [10]Institut CHU Hautepierre, Strasbourg, France; [11]Centre François Baclesse, Caen, France; [12]CHU Dupuytren, Limoges, France; [13]Unicancer, Paris, France; [14]ARCAGY-GINECO Group, Paris, France; [15]Hôpital Lyon Sud, Pierre Benite, France*

Évaluation de la CHIP en cancer de l'ovaire épithélial récidivant

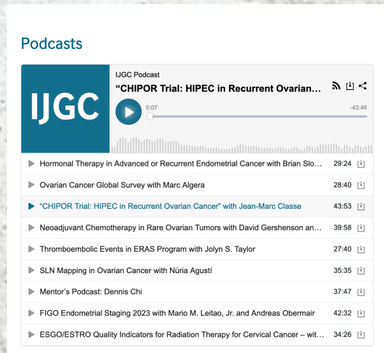
2009 études rétrospectives 1re récidive >12 mois semblait avoir un bénéfice associé à la cytoréduction 2daire

Équipe Nantes: tenté d'avoir une bourse (1M euro) en 2009 sur cytored secondaire +/- CHIP

Bourse refusée puisqu'ils évaluaient 2 traitements considérés non standards à ce moment (cytored 2nd et CHIP)

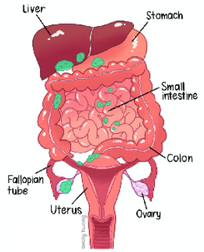
Bourse obtenue en 2010 avec OS comme issue primaire et chimiothérapie comme tx standard de la récidive dans les 2 bras

ARTICLE NON PUBLIÉ, résultats présentés



Ovarian Cancer

DESKTOP III



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 2, 2021 VOL. 385 NO. 23

Randomized Trial of Cytoreductive Surgery for Relapsed Ovarian Cancer

P. Harter, J. Sehouli, I. Vergote, G. Ferron, A. Reuss, W. Meier, S. Greggi, B.J. Mosgaard, F. Selle, F. Guyon, C. Pomel, F. Lécuru, R. Zang, E. Avall-Lundqvist, J.-W. Kim, J. Ponce, F. Raspagliesi, G. Kristensen, J.-M. Classe, P. Hillemanns, P. Jensen, A. Hasenburg, S. Ghaem-Maghami, M.R. Mirza, B. Lund, A. Reinthaller, A. Santaballa, A. Olaitan, F. Hilpert, and A. du Bois, for the DESKTOP III Investigators*

ABSTRACT

BACKGROUND

Treatment for patients with recurrent ovarian cancer has been mainly based on systemic therapy. The role of secondary cytoreductive surgery is unclear.

METHODS

We randomly assigned patients with recurrent ovarian cancer who had a first relapse after a platinum-free interval (an interval during which no platinum-based chemotherapy was used) of 6 months or more to undergo secondary cytoreductive surgery and then receive platinum-based chemotherapy or to receive platinum-based chemotherapy alone. Patients were eligible if they presented with a positive

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Harter can be contacted at p.harter@kem-med.com or at the Department of Gynecology and Gynecologic Oncology, Kliniken Essen-Mitte, Henricistr. 92, 45136 Essen, Germany.

*A list of the investigators in the DESKTOP III trial is provided in the Supplementary Appendix, available at NEJM.org.

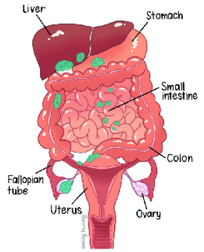
- ECR évaluant la cytored 2nd dans les cancers de l'ovaire récidivants
- Issue 1re: OS
- Autres issues : qualité de vie, PFS, résection complète comme facteur pronostique, complications

Critère d'inclusion:

- Cancer épithélial de l'ovaire récidivant sensible au platins
- PFI (intervalle sans platins) >/= 6 mois
- Score AGO: ECOG 0, Aucune tumeur résiduelle après chirurgie primaire, Absence d'ascite (< 500 ml)
- Une résection complète de la tumeur par laparotomie médiane semble possible

Ovarian Cancer

DESKTOP III



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PFI > 12 mois 75%

Complete Gross Resection (CGR) 75%

Bénéfice de survie > 12 mois pour les patients avec CGR vs patientes sans chirurgie (médiane 61.9 contre 46.2 mois)

Les patientes ayant subi une intervention chirurgicale avec une résection incomplète ont OS pire (médiane 27.7 mois) que le groupe sans chx

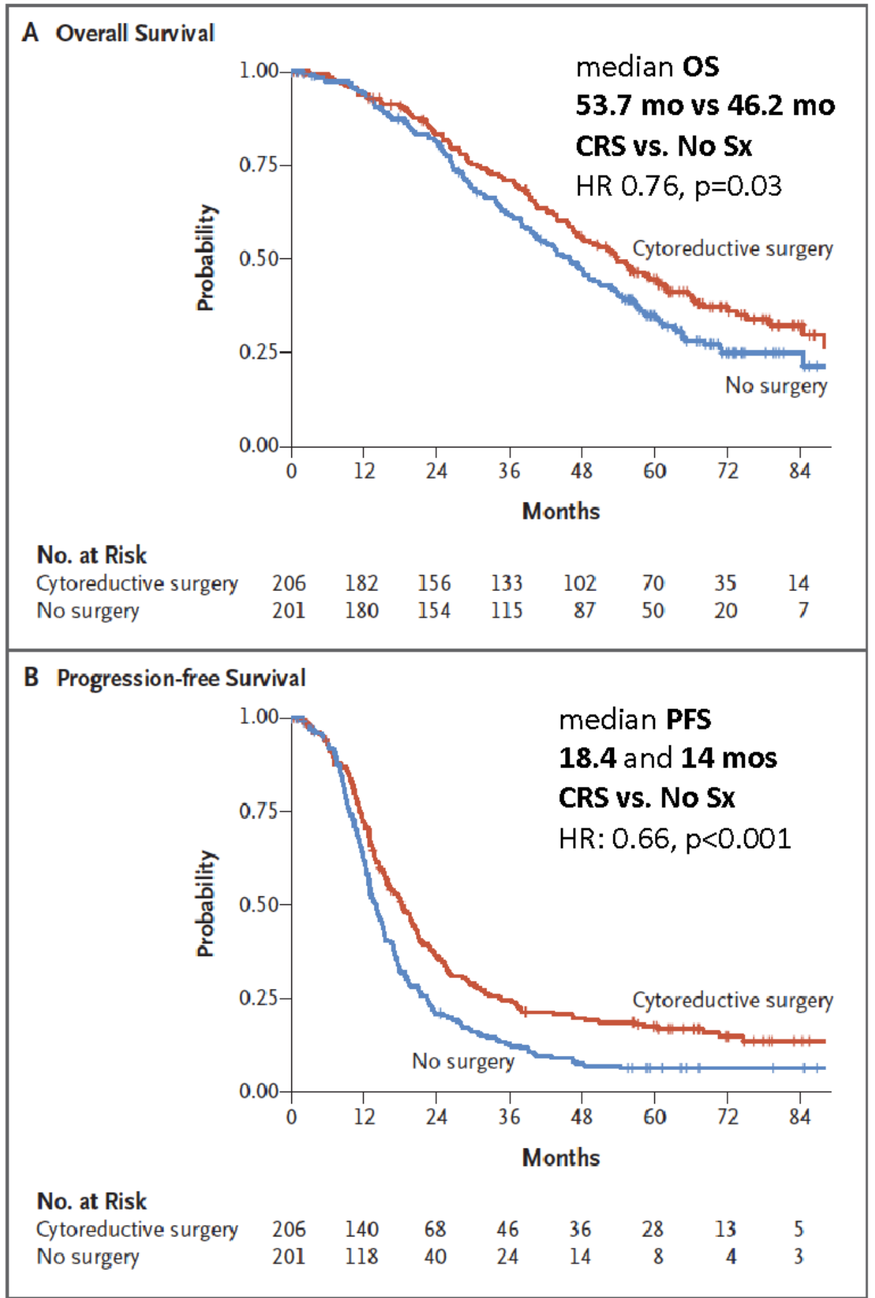


Figure 2. **Kaplan–Meier Estimates of Overall Survival and Progression-free Survival.**

Tick marks indicate censored data.

SOC-1, Shi, 2021

- RCT in China to compare secondary debulking vs chemotherapy in patients with recurrent OC using the iModel

Eligibility
•Pts with 1st relapsed EOC after >6m platinum-free interval if iMODEL score predicted a potential R0 & combined with PET-CT image

Study Design
Phase III, RCT, Surgery + Chemo Vs Chemo

Co-primary end points: PFS and OS

iModel (calculated using six variables):
- FIGO stage
- residual disease after primary surgery
- platinum-free interval
- ECOG status
- CA 125 at recurrence
- resence of ascites

An iMODEL score of 4·7 or lower predicted a potentially complete resection.

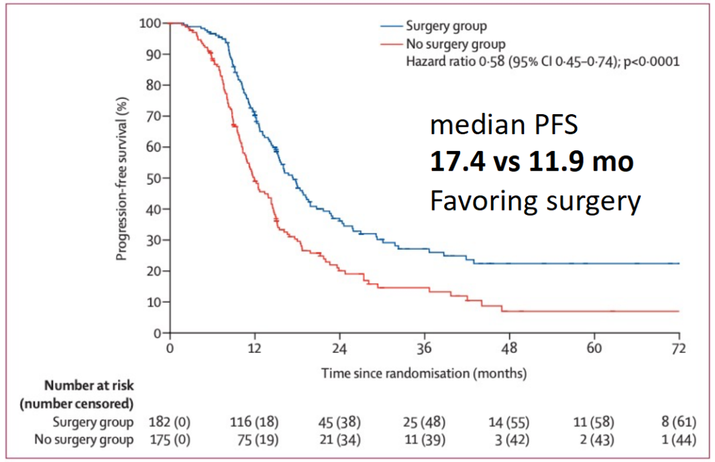
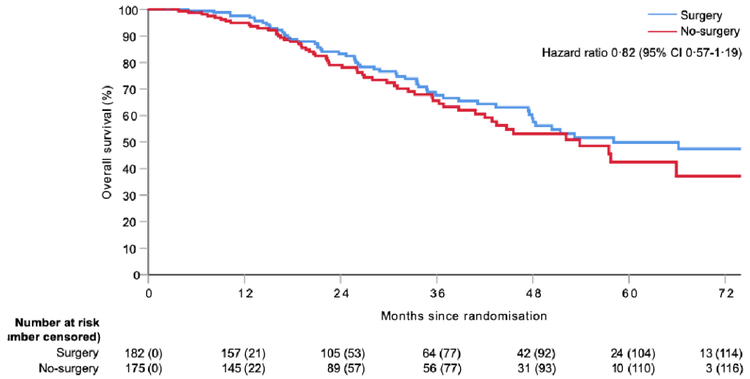
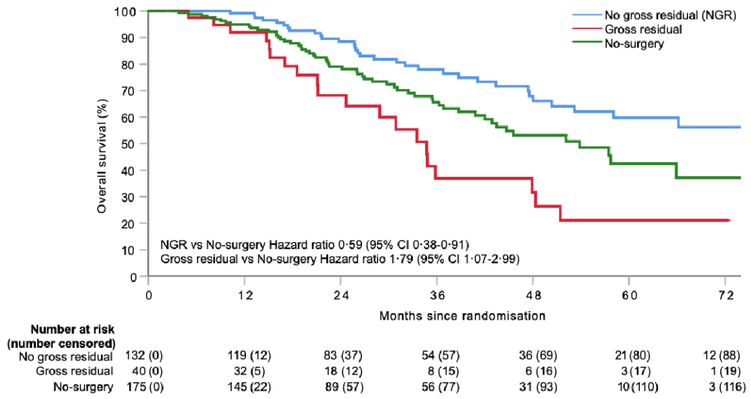


Figure 2: **Progression-free survival in the intention-to-treat population**





Conclusion:
Secondary CytoreducL on in selected pts resulted in a dramaL cally significant extension of median PFS and OS with acceptable complicaL ons

Source: Highlights of Practice Changing Papers in 2021, 2022 Fellows educational course

GOG 213, Coleman et al, 2019

pas de différence de survie dans GOG 213

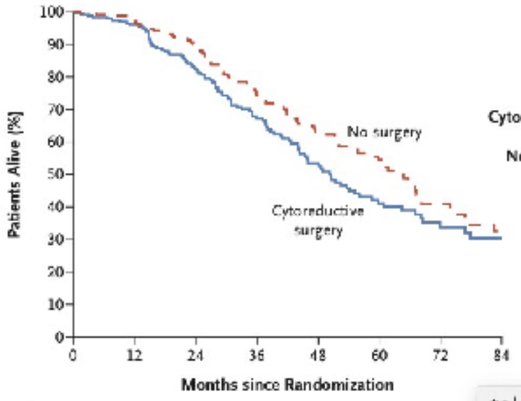
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Secondary Surgical Cytoreduction for Recurrent Ovarian Cancer

- **Study Design:** multicenter, RCT
- **Objective:** To determine whether secondary cytoreduction would increase OS among women with platinum sensitive, recurrent ovarian cancer who otherwise were considered to be surgical candidates in a Randomized control trial
- Primary Endpt: OS
- Secondary Endpt: PFS

A Overall Survival

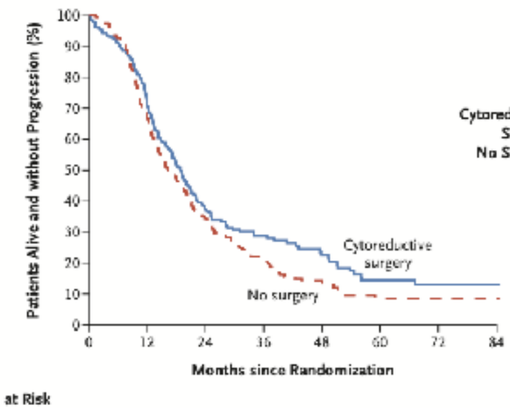


	No. of Deaths	No. of Patients	Median Overall Survival mo
Cytoreductive Surgery	105	240	50.6
No Surgery	92	245	64.7

No. at Risk								
Cytoreductive surgery	240	205	157	98	67	41	23	14
No surgery	245	217	172	124	75	50	28	16

tel:0%2012%2024%2036%2048%

B Progression-free Survival



	No. of Events	No. of Patients	Median Progression-free Survival mo
Cytoreductive Surgery	163	240	18.9
No Surgery	191	245	16.2

No. at Risk								
Cytoreductive surgery	240	152	68	38	22	13	10	6
No surgery	245	153	68	36	19	8	6	5

Limitations
- Inherent Bias in patient selection for surgery
- Survival benefit of Bev ?
- Median OS 3x longer than expectec
  - Was improvement in clinical care, ?Parp-i

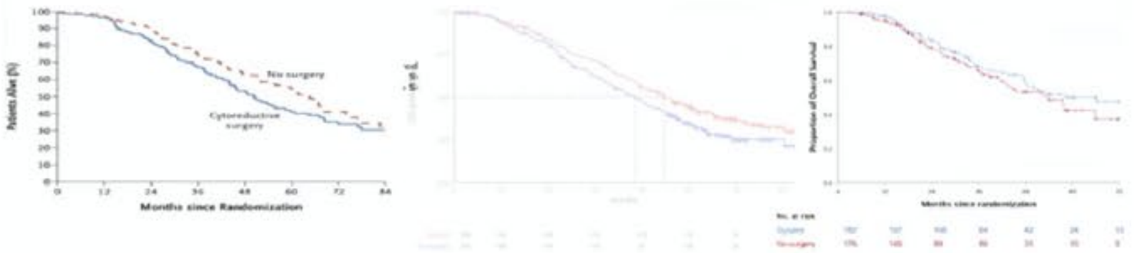
pts with platinum-sensitive, recurrent ovarian cancer did not have longer OS after secondary debulking vs chemo alone
?was this influenced by bev

Source: Highlights of Practice Changing Papers in 2021, 2022 Fellows educational course

Surgery is Beneficial in the "Right" Patients

	GOG-213	AGO DESKTOP-3	SGOG SOC-1
OS – Surgery (median)	53.6 mos	53.7 mos	58.1 mos
OS - No Surgery (median)	65.7 mos	46.0 mos	53.9 mos
HR, 95% CI	1.28 (0.92-1.78) P = NS	0.75 (0.58-0.96) P = 0.04	0.82 (0.57-1.19) P = NS

GOG-213 DESKTOP III SOC-1



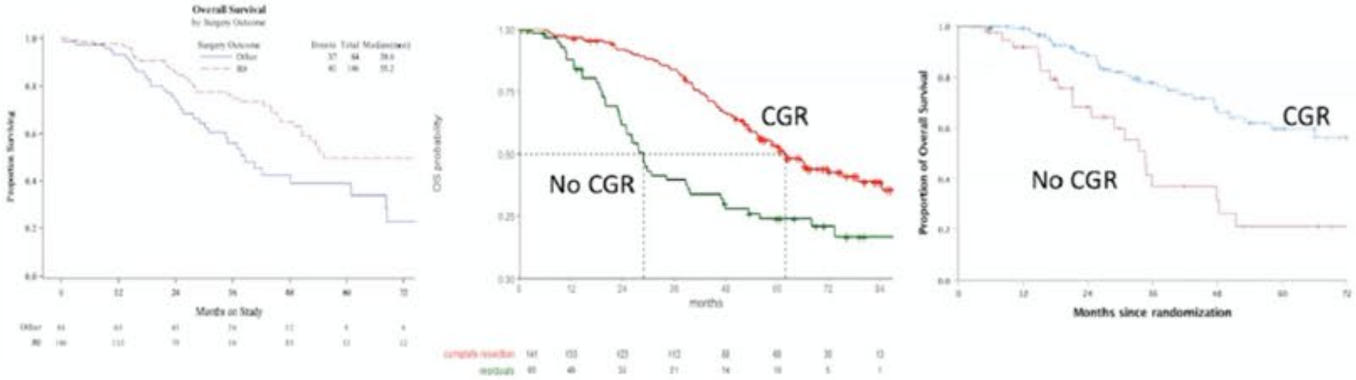
IGCS | xDigital

Robert L. Coleman, MD

18

Surgery is NOT Beneficial when no CGR

GOG-0213 DESKTOP-3 SOC-1



Potential harm to incorrectly identified patients places a premium on selection if undertaken

IGCS Summary Slides, 2020 Rob Coleman

CHIPOR

#876

HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY IN PLATINUM-SENSITIVE RELAPSED EPITHELIAL OVARIAN CANCER: THE CHIPOR RANDOMISED PHASE III TRIAL

[1]Jean-Marc Classe*, [2]Pierre Meeus, [3]Eric Leblanc, [4]Romuald Wernert, [5]François Quenet, [6]Frédéric Marchal, [7]Gilles Houvenaeghel, [8]Anne-Sophie Bats, [8]Fabrice Lécuru, [9]Gwenaël Ferron, [10]Cécile Brigand, [1]Dominique Berton, [9]Laurence Gladieff, [11]Florence Joly, [2]Isabelle Ray Coquard, [12]Sylvaine Durand-Fontanier, [13]Emilie Brument, [14]Bernard Asselain, [1]Loïc Campion, [15]Olivier Glehen. *[1]ICO René Gaudducheau, Saint Herblain, France; [2]Centre Léon Bérard, Lyon, France; [3]Centre Oscar Lambret, Lille, France; [4]Centre Paul Papin, Angers, France; [5]ICM Val d'Aurelle, Montpellier, France; [6]Institut de Cancérologie de Lorraine, Vandoeuvre-Lès-Nancy, France; [7]Institut Paoli Calmettes, Marseille, France; [8]HEGP, Paris, France; [9]Institut Claudius Regaud – IUCT Oncopole, Toulouse, France; [10]Institut CHU Hautepierre, Strasbourg, France; [11]Centre François Baclesse, Caen, France; [12]CHU Dupuytren, Limoges, France; [13]Unicancer, Paris, France; [14]ARCAGY-GINECO Group, Paris, France; [15]Hôpital Lyon Sud, Pierre Benite, France*

CHIPOR trial (NCT01376752): Multicenter randomized phase III trial

Median laparotomy
Complete resection

- First relapse of epithelial ovarian cancer
- PFI ≥6 months
- Response to 6 cycles of platinum-based chemotherapy
- Complete surgery achievable

N=415

SURGERY

CC0/1

Randomization during surgery

R 1:1

HIPEC
(cisplatin 75 mg/m^2 41°C for 60 min)
n=207

No HIPEC
n=208

SOC maintenance therapy

Stratification:
- **Center**
- **Residual disease (none vs <0.25 cm)**
- **PFI (6–12 vs >12–18 vs >18 months)**
- **Planned PARP inhibitor (yes vs no)[a]**

[a]Added Oct 8, 2020

CC0 = no macroscopic residual; CC1 = residual <0.25 cm; PFI = platinum-free interval; SOC = standard of care

ESGO European Society of Gynaecological Oncology | 24th European Congress on Gynaecological Oncology | Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Présentation de Pierre Meeus, ESGO 2023

CHIPOR

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Randomisation intra-op après cytoreduction CC0-CC1

Facteurs de stratification: centre, cytoréduction (no residual disease vs residual <2.5mm), intervalle sans chimio à la récidive (6–12 vs 12–18 vs >18 mois) et l'utilisation de PARPi

Issue 1re: OS

Issues secondaires: PFS, QoL, morbidité/mortalité 60j post-op

Follow-up 6 ans initialement prévu

Amendement de l'étude pour suivi ad décès

Amendement sur utilisation des PARPi

Completeness of cytoreduction score

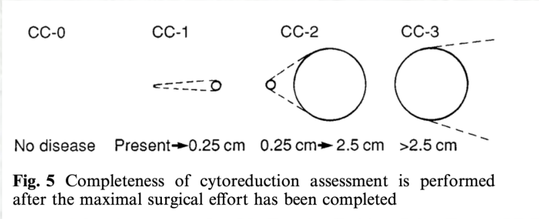

Fig. 5 Completeness of cytoreduction assessment is performed after the maximal surgical effort has been completed

P.H. Sugarbaker 1999

Population

Characteristics	No HIPEC (n=208)	HIPEC (n=207)
Median age (IQR), years	**59** (53–67)	**62** (55–68)
FIGO stage III/IV at primary treatment, %	84%	88%
Bevacizumab (first-line setting), n (%)	73 (35%)	64 (31%)
Median PFI (IQR), months	**17.8** (11.8–25.3)	**17.4** (10.6–26.6)
High-grade serous or grade 3 endometrioid, n (%)[a]	**165 (82%)**	**159 (79%)**
Completed 6 cycles of chemotherapy, n (%)	189 (91%)	188 (91%)
Surgery to CC0, n (%)	**180 (87%)**	**180 (87%)**

[a]Missing in 7 patients in the No HIPEC arm and 6 in the HIPEC arm
IQR = interquartile range

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No. of patients (%)		No HIPEC (n=208)	HIPEC (n=207)
Maintenance bevacizumab		16 (8%)	7 (3%)
BRCA mutation status	Known	164 (79%)	167 (81%)
	Mutated	51/164 (31%)	48/167 (29%)
Maintenance PARP inhibitor *		46 (22%)	35 (17%)

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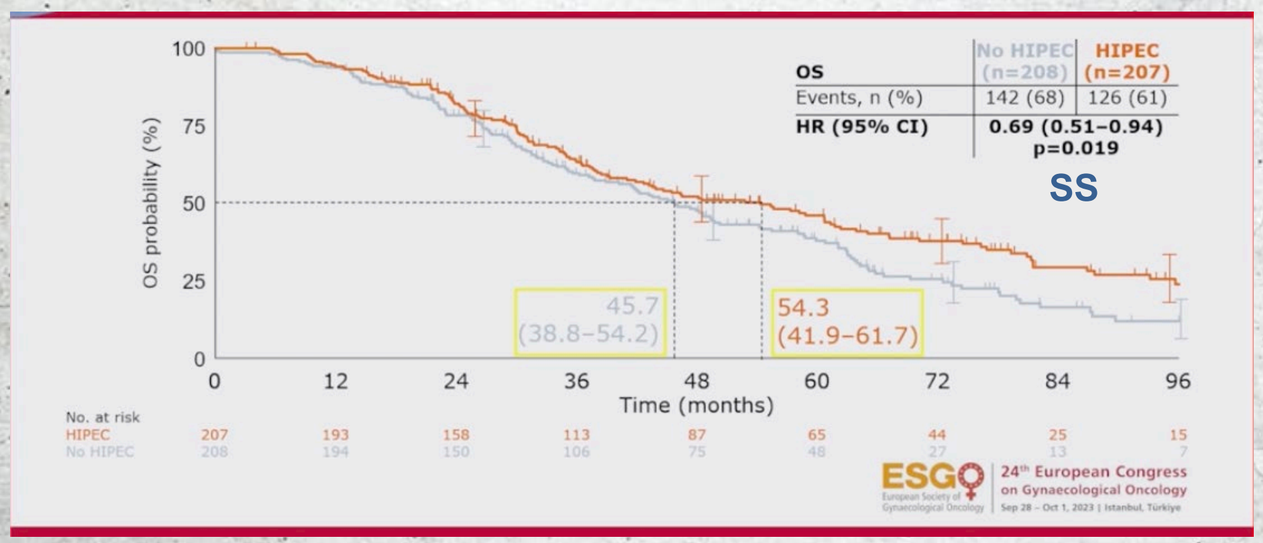
Chirurgie

No. of patients (%)	No HIPEC (n=208)	HIPEC (n=207)
Median duration of surgery (IQR), min	218 (160–282)	337 (272–407)
Digestive tract resection	78 (38%)	85 (41%)
Stoma diversion	10 (4.8%)	20 (9.7%)
Grade ≥3 morbidity	41 (20%)	82 (40%)
Blood disorders	16 (8%)	28 (14%)
Digestive tract disorders	14 (7%)	18 (9%)
Mortality	3 (1.4%)	0

Présentation de Pierre Meeus, ESGO 2023

Résultats

Survie globale, ITT



Endpoint		HIPEC (n=207)	No HIPEC (n=208)
OS	Events, n (%)	126 (61)	142 (68)
	Median, months (95% CI)	54.3 (41.9–61.7)	45.8 (39.9–54.2)
	HR (95% CI)*	0.69 (0.50–0.94), p=0.020	
Global PFS	Events, n (%)	180 (87)	184 (88)
	Median, months (95% CI)	10.2 (9.3–12.1)	9.8 (8.8–11.9)
	HR (95% CI)*	0.82 (0.64–1.06)	
Peritoneal PFS	Events, n (%)	151 (73)	157 (75)
	Median, months (95% CI)	13.1 (10.7–16.3)	12.2 (9.8–13.1)
	HR (95% CI)*	0.71 (0.54–0.94)	
Postoperative adverse events, n (%)	Grade 3/4	32 (15)	22 (11)
	Grade 3/4 renal toxicity	8 (4)	1 (, 1)
	Grade 5	0	3 (1)
Gastrointestinal stoma, n (%)		20 (10)	10 (5)

*Stratified on stratification factors. HR = hazard ratio.

Présentation de Pierre Meeus, ESGO 2023

CHIPOR- Conclusion

Conclusion

- Adding HIPEC to cytoreductive surgery after 6 cycles of second-line chemotherapy for patients with first late relapse of ovarian cancer significantly improves OS (HR: 0.69 [95% CI 0.51–0.94], p=0.019)
- CHIPOR is the largest prospectively randomized trial showing an OS benefit from HIPEC in relapsed ovarian cancer
- PFS and TTST are also significantly improved with HIPEC
- This treatment must be performed in specialized centers

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CHIPOR

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Article non publié

Données à analyser selon l'utilisation des PARPi (n=46 no HIPEC et n=35 HIPEC), du BEV et selon l'intervalle sans platins

Recrutement de 10 ans

Défis d'implantation:

-accès au plateau technique pour la cytoréduction secondaire et CHIP (perfusionniste, USI, etc.)

-importance de la sélection des patientes (CC0-CC1)

RGOQ

Regroupement des Gynécologues Oncologues du Québec

MERCI

Références

- HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY IN PLATINUM-SENSITIVE RELAPSED EPITHELIAL OVARIAN CANCER: THE CHIPOR RANDOMISED PHASE III TRIAL. Présentation de Pierre Meeus, ESGO 2023. 10.1136/ijgc-2023-ESGO.43
- MIRVETUXIMAB SORAVTANSINE DEMONSTRATES LONGER OVERALL SURVIVAL AND PROGRESSION-FREE SURVIVAL BY PRIOR LINES OF THERAPY VS CHEMOTHERAPY IN PLATINUM-RESISTANT OVARIAN CANCER AND HIGH FOLATE RECEPTOR ALPHA EXPRESSION IN THE MIRASOL TRIAL. 10.1136/ijgc-2023-ESGO.44
- Zivanovic O, Chi DS, Zhou Q, Iasonos A, Konner JA, Makker V, Grisham RN, Brown AK, Nerenstone S, Diaz JP, Schroeder ED, Langstraat CL, Paroder V, Lakhman Y, Soldan K, Su K, Gardner GJ, Andikyan V, Guo J, Jewell EL, Long Roche K, Troso-Sandoval T, Lichtman SM, Moukarzel LA, Dessources K, Abu-Rustum NR, Aghajanian C, Tew WP, Beumer J, Sonoda Y, O'Cearbhaill RE. Secondary Cytoreduction and Carboplatin Hyperthermic Intraperitoneal Chemotherapy for Platinum-Sensitive Recurrent Ovarian Cancer: An MSK Team Ovary Phase II Study. J Clin Oncol. 2021 Aug 10;39(23):2594-2604. doi: 10.1200/JCO.21.00605. Epub 2021 May 21. PMID: 34019431; PMCID: PMC8330970.
- Coleman RL, Spirtos NM, Enserro D, Herzog TJ, Sabbatini P, Armstrong DK, Kim JW, Park SY, Kim BG, Nam JH, Fujiwara K, Walker JL, Casey AC, Alvarez Secord A, Rubin S, Chan JK, DiSilvestro P, Davidson SA, Cohn DE, Tewari KS, Basen-Engquist K, Huang HQ, Brady MF, Mannel RS. Secondary Surgical Cytoreduction for Recurrent Ovarian Cancer. N Engl J Med. 2019 Nov 14;381(20):1929-1939. doi: 10.1056/NEJMoa1902626. PMID: 31722153; PMCID: PMC6941470.
- Harter P, Sehouli J, Vergote I, Ferron G, Reuss A, Meier W, Greggi S, Mosgaard BJ, Selle F, Guyon F, Pomel C, Lécuru F, Zang R, Avall-Lundqvist E, Kim JW, Ponce J, Raspagliesi F, Kristensen G, Classe JM, Hillemanns P, Jensen P, Hasenburg A, Ghaem-Maghami S, Mirza MR, Lund B, Reinthaller A, Santaballa A, Olaitan A, Hilpert F, du Bois A; DESKTOP III Investigators. Randomized Trial of Cytoreductive Surgery for Relapsed Ovarian Cancer. N Engl J Med. 2021 Dec 2;385(23):2123-2131. doi: 10.1056/NEJMoa2103294. Erratum in: N Engl J Med. 2022 Feb 17;386(7):704. PMID: 34874631.
- Shi T, Zhu J, Feng Y, Tu D, Zhang Y, Zhang P, Jia H, Huang X, Cai Y, Yin S, Jiang R, Tian W, Gao W, Liu J, Yang H, Cheng X, Zang R. Secondary cytoreduction followed by chemotherapy versus chemotherapy alone in platinum-sensitive relapsed ovarian cancer (SOC-1): a multicentre, open-label, randomised, phase 3 trial. Lancet Oncol. 2021 Apr;22(4):439-449. doi: 10.1016/S1470-2045(21)00006-1. Epub 2021 Mar 8. PMID: 33705695.
- Matulonis UA, Lorusso D, Oaknin A, Pignata S, Dean A, Denys H, Colombo N, Van Gorp T, Konner JA, Marin MR, Harter P, Murphy CG, Wang J, Noble E, Esteves B, Method M, Coleman RL. Efficacy and Safety of Mirvetuximab Soravtansine in Patients With Platinum-Resistant Ovarian Cancer With High Folate Receptor Alpha Expression: Results From the SORAYA Study. J Clin Oncol. 2023 May 1;41(13):2436-2445. doi: 10.1200/JCO.22.01900. Epub 2023 Jan 30. PMID: 36716407; PMCID: PMC10150846.
- Moore KN, Oza AM, Colombo N, Oaknin A, Scambia G, Lorusso D, Konecny GE, Banerjee S, Murphy CG, Tanyi JL, Hirte H, Konner JA, Lim PC, Prasad-Hayes M, Monk BJ, Pautier P, Wang J, Berkenblit A, Vergote I, Birrer MJ. Phase III, randomized trial of mirvetuximab soravtansine versus chemotherapy in patients with platinum-resistant ovarian cancer: primary analysis of FORWARD I. Ann Oncol. 2021 Jun;32(6):757-765. doi: 10.1016/j.annonc.2021.02.017. Epub 2021 Mar 2. PMID: 33667670.

SORAYA

original reports

Efficacy and Safety of Mirvetuximab Soravtansine in Patients With Platinum-Resistant Ovarian Cancer With High Folate Receptor Alpha Expression: Results From the SORAYA Study

Ursula A. Matulonis, MD[1]; Domenica Lorusso, MD, PhD[2]; Ana Oaknin, MD, PhD[3]; Sandro Pignata, MD, PhD[4]; Andrew Dean, MBChB, MRCP, FRACP[5]; Hannelore Denys, MD, PhD[6]; Nicoletta Colombo, MD, PhD[7,8]; Toon Van Gorp, MD, PhD[9]; Jason A. Konner, MD[10]; Margarita Romeo Marin, MD, PhD[11]; Philipp Harter, MD, PhD[12]; Conleth G. Murphy, MD[13]; Jiuzhou Wang, PhD[14]; Elizabeth Noble, BS[14]; Brooke Esteves, BSN[14]; Michael Method, MD, MPH, MBA[14]; and Robert L. Coleman, MD[15]

FORWARD I

MIRV à la chimio au choix de l'investigateur chez les patientes avec PROC n'a pas atteint son objectif principal (survie sans progression)

Le test utilisé pour déterminer l'expression du Fra était différent

Des résultats supérieurs pour le MIRV par rapport à la chimiothérapie ont été observés dans tous les critères d'évaluation secondaires dans la population réellement FRα élevée

Moore et al. Phase III, randomized trial of mirvetuximab soravtansine versus chemotherapy in patients with platinum-resistant ovarian cancer: primary analysis of FORWARD I. Ann Oncol. 2021 Jun;32(6):757-765.

CHIPOR

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Mai 2011-2021

415 ptes randomisées

Les caractéristiques de base étaient équilibrées entre les bras de traitement

Suivi médian 6.2 ans, 272 patientes (65%) décédées

Cytored 2nd CC0: plus de 85%

Insulte rénale: pas d'utilisation de thiosulfate de sodium en France au début de l'étude

Pas de mortalité dans le groupe HIPEC à 30 jours (3 décès dans le groupe no HIPEC)

Endpoint		HIPEC (n=207)	No HIPEC (n=208)
OS	Events, n (%)	126 (61)	142 (68)
	Median, months (95% CI)	54.3 (41.9–61.7)	45.8 (39.9–54.2)
	HR (95% CI)*	0.69 (0.50–0.94), p=0.020	
Global PFS	Events, n (%)	180 (87)	184 (88)
	Median, months (95% CI)	10.2 (9.3–12.1)	9.8 (8.8–11.9)
	HR (95% CI)*	0.82 (0.64–1.06)	
Peritoneal PFS	Events, n (%)	151 (73)	157 (75)
	Median, months (95% CI)	13.1 (10.7–16.3)	12.2 (9.8–13.1)
	HR (95% CI)*	0.71 (0.54–0.94)	
Postoperative adverse events, n (%)	Grade 3/4	32 (15)	22 (11)
	Grade 3/4 renal toxicity	8 (4)	1 (, 1)
	Grade 5	0	3 (1)
Gastrointestinal stoma, n (%)		20 (10)	10 (5)

*Stratified on stratification factors. HR = hazard ratio.

original reports abstract

Secondary Cytoreduction and Carboplatin Hyperthermic Intraperitoneal Chemotherapy for Platinum-Sensitive Recurrent Ovarian Cancer: An MSK Team Ovary Phase II Study

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PURPOSE The purpose of this phase II study was to evaluate hyperthermic intraperitoneal chemotherapy (HIPEC) with carboplatin for recurrent ovarian cancer during secondary cytoreductive surgery.

MATERIALS AND METHODS Patients were intraoperatively randomly assigned to carboplatin HIPEC (800 mg/m^2 for 90 minutes) or no HIPEC, followed by five or six cycles of postoperative IV carboplatin-based chemotherapy, respectively. Based on a binomial single-stage pick-the-winner design, an arm was considered winner if ≥ 17 of 49 patients were without disease progression at 24 months post-surgery. Secondary objectives included postoperative toxicity and HIPEC pharmacokinetics.

RESULTS Of 98 patients, 49 (50%) received HIPEC. Complete gross resection was achieved in 82% of the HIPEC patients and 94% of the standard-arm patients. Bowel resection was performed in 37% of patients in the HIPEC arm compared with 65% in the standard (P = .008). There was no perioperative mortality and no difference in use of ostomies, length of stay, or postoperative toxicity. At 24 months, eight patients (16.3%; 1-sided 90% CI, 9.7 to 100) were without progression or death in the HIPEC arm and 12 (24.5%; 1-sided 90% CI, 16.5 to 100) in the standard arm. With a medium follow-up of 39.5 months, 82 patients progressed and 37 died. The median progression-free survival in the HIPEC and standard arms were 12.3 and 15.7 months, respectively (hazard ratio, 1.54; 95% CI, 1 to 2.37; P = .05). There was no significant difference in median overall survival (52.5 *v* 59.7 months, respectively; hazard ratio, 1.39; 95% CI, 0.73 to 2.67; P = .31). These analyses were exploratory.

CONCLUSION HIPEC with carboplatin was well tolerated but did not result in superior clinical outcomes. This study does not support the use of HIPEC with carboplatin during secondary cytoreductive surgery for platinum-sensitive recurrent ovarian cancer.

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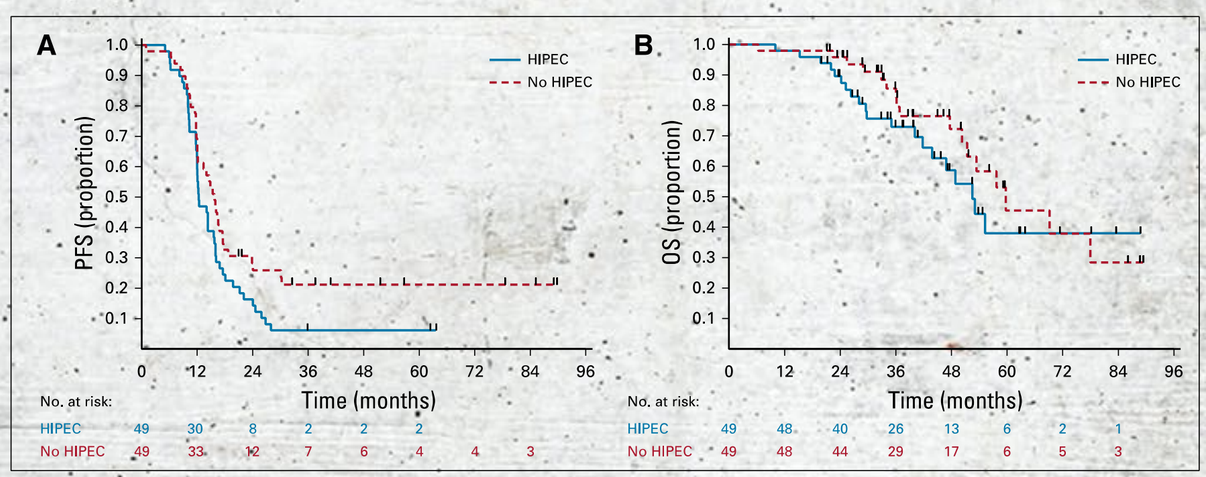
Cytoréduction 2nd +/-CHIP au Carbo suivi chimiothérapie en post-op

PFS 12.3 vs 15.7m SS favorisant groupe sans CHIP



verall survival; PFS, progression-free survival.