



**21st European Congress
on Gynaecological Oncology**
Nov 2-5, 2019 | Athens, Greece



A photograph of the Parthenon in Athens, Greece, showing its iconic Corinthian columns against a clear blue sky with some white clouds. A red horizontal bar is overlaid across the middle of the image, containing the text "Best of ESGO 2019".

**Best of
ESGO 2019**



Overview: Best of ESGO 2019

The Best of ESGO 2019 project highlights the most relevant data presented at the world's biggest gynaecological oncology event in 2019: the 21st International Meeting of the European Society of Gynaecological Oncology.

The abstracts chosen for this presentation and discussion reflect the foremost clinical research and strategies in oncology that will impact our patient care.

The slides report the most recent relevant findings in the management of gynaecological malignancies presented in Athens, November 2019.



Radiotherapy instead of inguinofemoral lymphadenectomy in vulvar cancer patients with a metastatic sentinel node: results of Groinss-V II

-- *M. Oonk et al.*

Objectives & Methods

OBJECTIVES

At present, no generally established guidelines for the management of sentinel lymph node (SLN) micrometastasis (≤ 2 mm deposit) or isolated tumour cells (ITCs) (≤ 0.2 mm) in patients with invasive squamous cell carcinoma of the vulva (SCC).

The aim of the current study was to evaluate whether complete inguinofemoral lymphadenectomy (IFL) could be replaced by adjuvant radiotherapy in patients with early invasive vulvar SCC who had SLN micrometastatic disease.

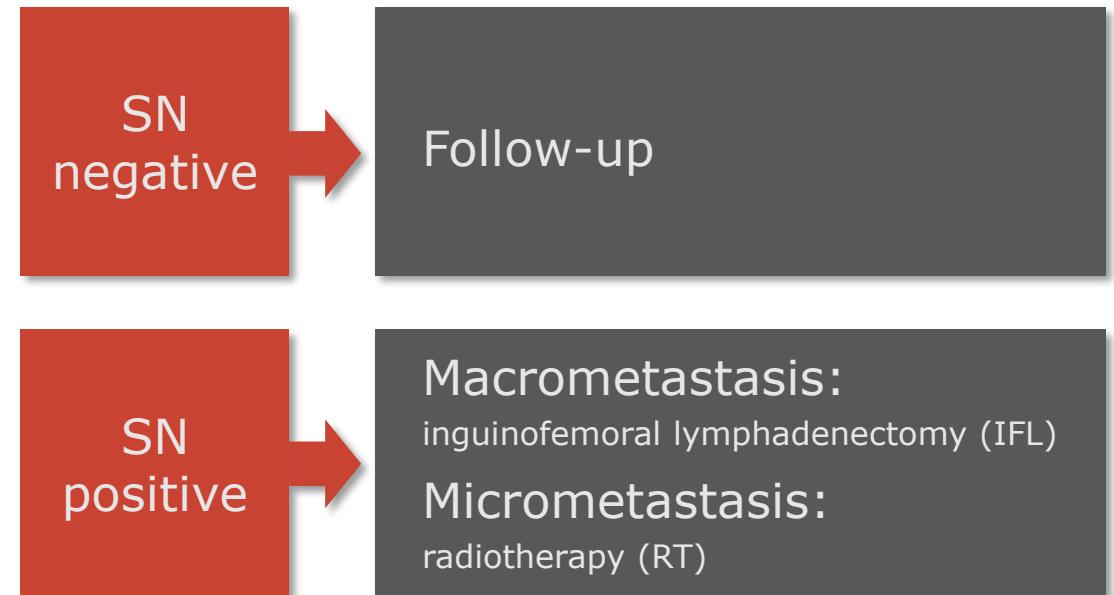
Objectives & Methods

METHODS

Prospective international multicenter phase II trial (2005-2016) with stopping rules for a number of groin recurrences

Inclusion:

- Primary macroinvasive SCC of the vulva
- Unifocal tumour < 4 cm
- No suspicious nodes at imaging



Results: Recurrence rate in patients with

MICROMETASTASES IN SLN

radiotherapy vs no adjuvant therapy vs IFL

- no adjuvant therapy > IFL ($P<0,05$)
- no adjuvant therapy > radiotherapy ($P<0,05$)
- IFL vs radiotherapy ($p>0,05$)

MACROMETASTASES IN SLN

radiotherapy vs IFL

- radiotherapy > IFL ($P<0,05$)

TREATMENT-RELATED MORBIDITY

- SN only < SN +RT < SN+IFL
- SN only < SN +RT < SN+IFL

Conclusions

Radiotherapy to the groins in patients with SN metastasis $\leq 2\text{mm}$ results in very low groin recurrence rate.

Radiotherapy to the groins is associated with minimal treatment-related toxicity in the majority of patients.

For patients with SN metastasis $>2\text{mm}$, radiotherapy with a total dose of 50Gy is no safe alternative for IFL.

Enhanced recovery after surgery in advanced ovarian cancer: a prospective randomized trial

-- JL. Sánchez-Iglesias *et al.*

Objectives & Methods (1/2)

OBJECTIVES

The primary goal of the study was to compare in a prospective randomized trial the enhanced recovery after surgery (ERAS) vs conventional perioperative care in terms of reduction in Median Length of Hospital Stay (LOH). The secondary outcomes were the type of intra- and postoperative complications, readmissions rate, and mortality within the 30-days follow-up period.

METHODS

Advanced ovarian carcinoma.
(FIGO Stage IIB-IVA)

Randomization

Conventional
perioperative care

Enhanced recovery
after surgery

49 patients with

- primary CRS (21)
- recurrent CRS (12)
- interval CRS (16)

50 patients with

- primary CRS (22)
- recurrent CRS (8)
- interval CRS (20)

Methods (2/2)

ERAS Protocol

Preoperative

- pre-admission counselling
- nutritional status assessment
- administration of 35mg of maltodextrin 3h before surgery
- no mechanical bowel preparation
- no preanesthetic sedatives

Postoperative

- early mobilization (24-48h)
- clear liquid intake (+6h) and protocolized diet
- early (24h) urinary catheter removal

Intraoperative

- ERAS based anesthetic protocol
- no nasogastric intubation
- no systematic use of drainages

Results

Overall compliance with the ERAS protocol was about 91 %.

No significant differences between the two groups related to operative time, blood loss, or cytoreduction rate.

The ERAS group had a median length of hospital stay of 2 days shorter as compared to the classic group (7 days vs 9 days, p=0,009).

No significant differences in the complications rate or re-interventions (30 days post-operative follow up period).

The ERAS group had a lower rate of readmissions as compared to the CM group (6% vs 20.4% p=0,03).

Conclusions

The ERAS protocol results in a shorter hospital stay due to earlier recovery, and a lower rate of readmissions with no increase in morbidity and mortality.



Ovarian cancer detection combining an innovative catheter for uterine and tubal lavage with ultra-sensitive TP53 sequencing

-- *P. Speiser et al.*

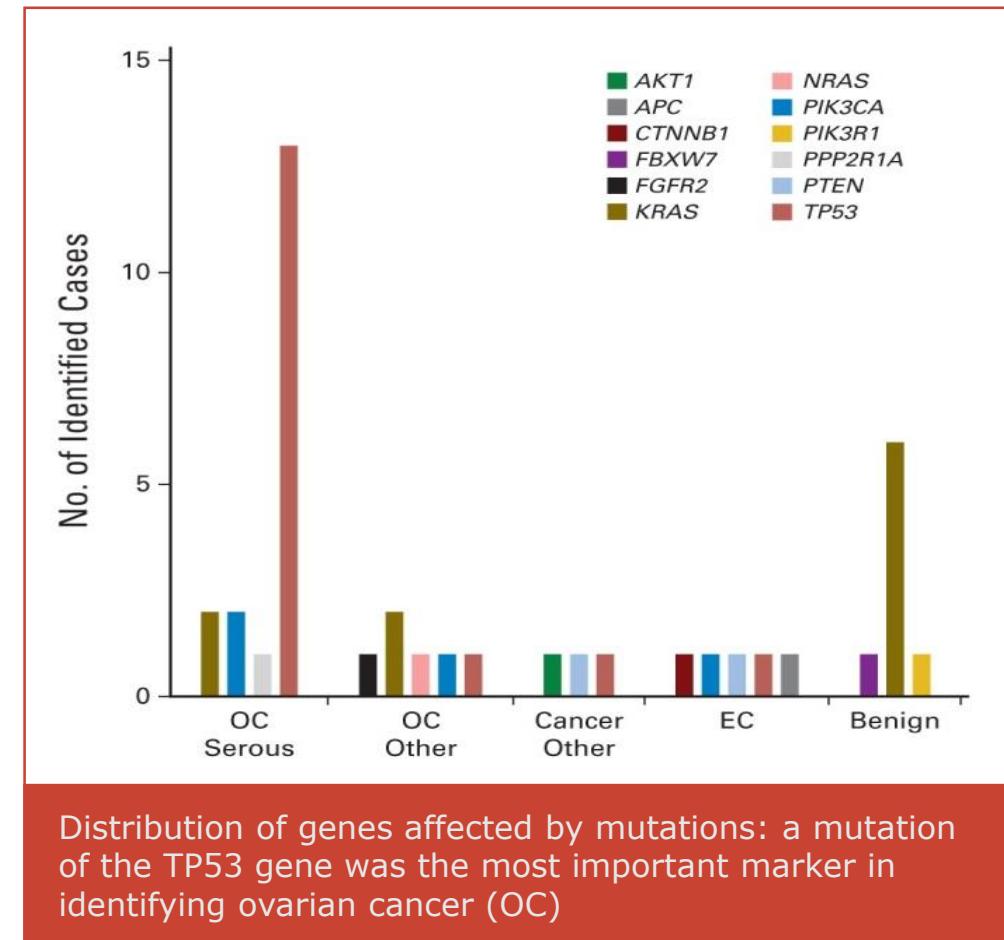
Objectives

To present rationale for the study aiming to investigate potential of Lavage Concept for the screening of BRCA 1 mutation carriers for occult high-grade serous carcinoma (HGSC) or serous tubal intraepithelial carcinoma (STIC) based on the 3 (already) finalized and published studies.

Background & Methods (1/3)

Proof of principle study n 1 (Maritschnegg E et al. J Clin Oncol. 2015):

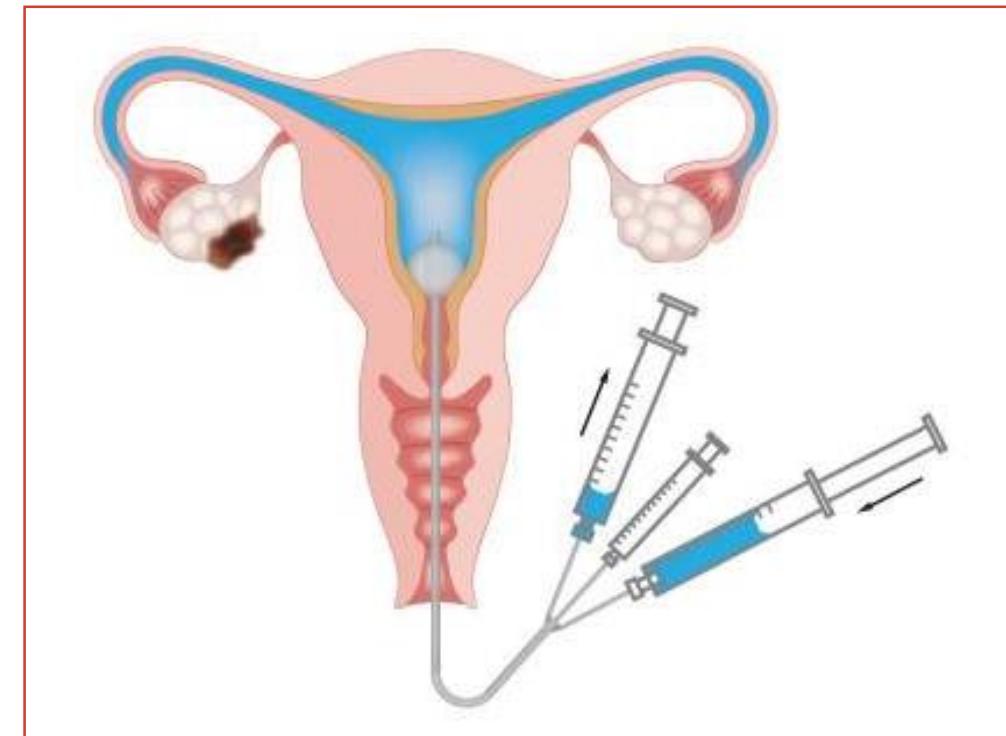
- Cells shed from Müllerian duct cancers, including OC and EC, can be collected through a lavage of the uterine cavity, in which tumour-specific mutations can be detected through massively parallel sequencing.
- 60% of patients with OC had mutations in their lavage samples detected with the NGS approach.
- Singleplex analysis of mutations previously determined in corresponding tumour tissue led to further identification in 24 (80%) of 30 patients with OC.



Background & Methods (2/3)

Proof of concept study n 2 (Maritschnegg E et al.
Int J Gynecol Cancer. 2018):

- Uterine and tubal lavage (UtL) performed with the new catheter fulfills all prerequisites for a screening test.
- Specimens can be collected reliably, even after a short training.
- The procedure was proven to be safe and feasible to use in a clinical or outpatient setting.
- The uterine and tubal lavage took 6.5 minutes on average.
- The amount of extracted DNA was above the lower limit for a sensitive, deep-sequencing mutation analysis in all cases.

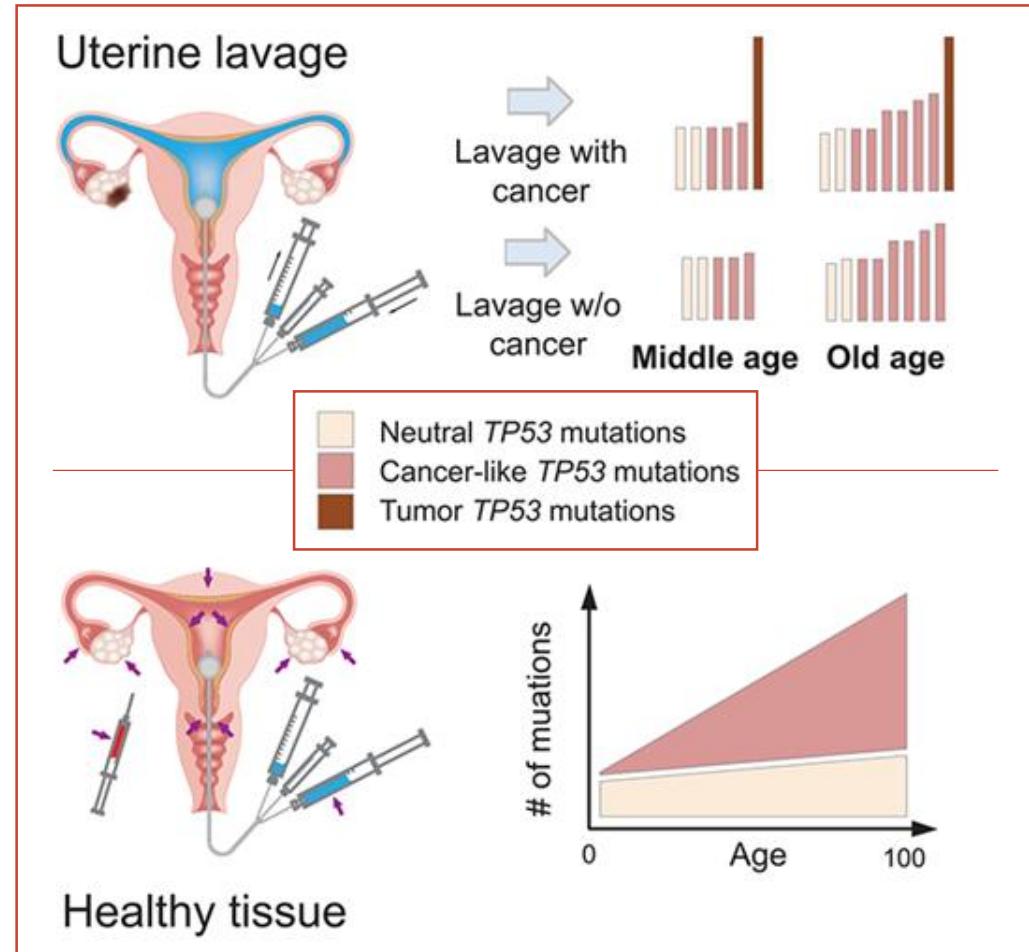


Sketch of the catheter for uterine and tubal lavage. It is carried out by passing a small catheter through the cervix, followed by concurrent flushing and aspiration with 10 mL of saline.

Background & Methods (3/3)

Proof of concept study n 3 (Salk JJ et al. Cell Rep. 2019):

- Ovarian cancer can be detected by ultra-accurate sequencing of uterine lavage DNA.
- However, low-frequency TP53 mutations also exist in normal tissue of healthy women.
- TP53 mutations are increasingly selected for with age, revealing somatic evolution.
- Age-associated, cancer-like mutations challenge specificity for cancer detection.



Results & Conclusions

Planned study: Uterine Lavage for Ovarian cancer Early detection – L.O.V.E. Trial
Phase II Study on Sensitivity and Specificity of the Lavage Concept

Aim of the study

- Investigate potential of Lavage Concept for the screening of BRCA 1 mutation carriers for occult HGSC or STIC

Eligibility criteria

- ages eligible for study: 35 years to 70 years

Inclusion criteria

- BRCA1 mutation carriers

Exclusion criteria

- pregnant, incapacity, tubal ligation

Study intervention

- yearly uterine and tubal lavage under local anesthesia

Study endpoint

- STIC or occult HGSC on RRSO
- Spontaneous HGSC development
- End of the study

Statistics

- Lifetime incidence for HGSC ~45%
- Occult HGSC or STIC at RRSO is 7%
- Specificity of $\geq 94\%$, sensitivity = 80%
- 150 events requiring ~2000 patients

Dose-dense neoadjuvant chemotherapy followed by sentinel node mapping and laparoscopic pelvic lymphadenectomy and simple trachelectomy in cervical cancer – update results

-- *H. Robova et al.*

Objectives & Methods

OBJECTIVES

Fertility-sparing surgery is safe only if tumour doesn't exceed 2 cm in the biggest diameter. When the tumor bigger, surgery must be more radical (abdominal trachelectomy type C2), but pregnancy results aren't promising.

The aim of the study was to verify if neoadjuvant chemotherapy (NAC) followed by simple trachelectomy could be an option for these patients.

Methods

LAP 3 – DOSE-DENSE CHEMOTHERAPY

- **Squamous cell cancer (SCC)**

Cisplatin 75mg/m² (day 1)

Ifosfamid 2g/m² max. 3 g (day 2)

- interval 10 days
- 3 cycles chemotherapy (dose-dense)

- **Adenocarcinoma (AC)**

Cisplatine 75mg/m² + Adriamycin 35mg/m²

(day 1)

- interval 10 days
- 3 cycles chemotherapy (dose-dense)

Interval between 1st day of chemotherapy
and surgery was 43 days (36-46 days)

40 patients with cervical cancer

(28 IB3 and 12 IB3)

MRI/US volumometry

More than 20 mm < 2/3 of stromal invasion

NAC - high dose density

Laparoscopic assessment of sentinel node

negative

positive

"parametrectomy"
+ laparoscopic
lymphadenectomy

open radical
hysterectomy C1/C2

negative

positive

Simple
trachelectomy

Open radical
hysterectomy C1/C2

Results

ONCOLOGICAL OUTCOME

- Recurrence rate 5/29 women (17.2%)
 - 4 local recurrences (3 AC, 1 SCC)
 - 1 distant recurrence - ovary (SCC)
- Mortality 3/29 women (10.3%) (2 SCC, 1 AC)

PREGNANCY OUTCOME

- 29 women (72.5%) – fertility was saved
 - (3 of them lost fertility after treatment of recurrence) – definitively fertility was saved in 26 women
- 23 pregnancies in 19 women (pregnancy rate 95%)
- 16 women delivered 19 babies

Conclusions

Oncological results in NAC followed by simple trachelectomy in cervical cancers bigger than 2cm are acceptable (mortality rate 10.3%) and pregnancy results are excellent (pregnancy rate 95.0%), but still it is experimental protocol for full instructed women.

Uterus-11 study: a randomized clinical trial on surgical staging versus CT-staging prior to primary chemoradiation in patients with FIGO 2009 stages IIB-IVA cervical cancer

-- *C. Kohler et al.*

Objectives & Methods

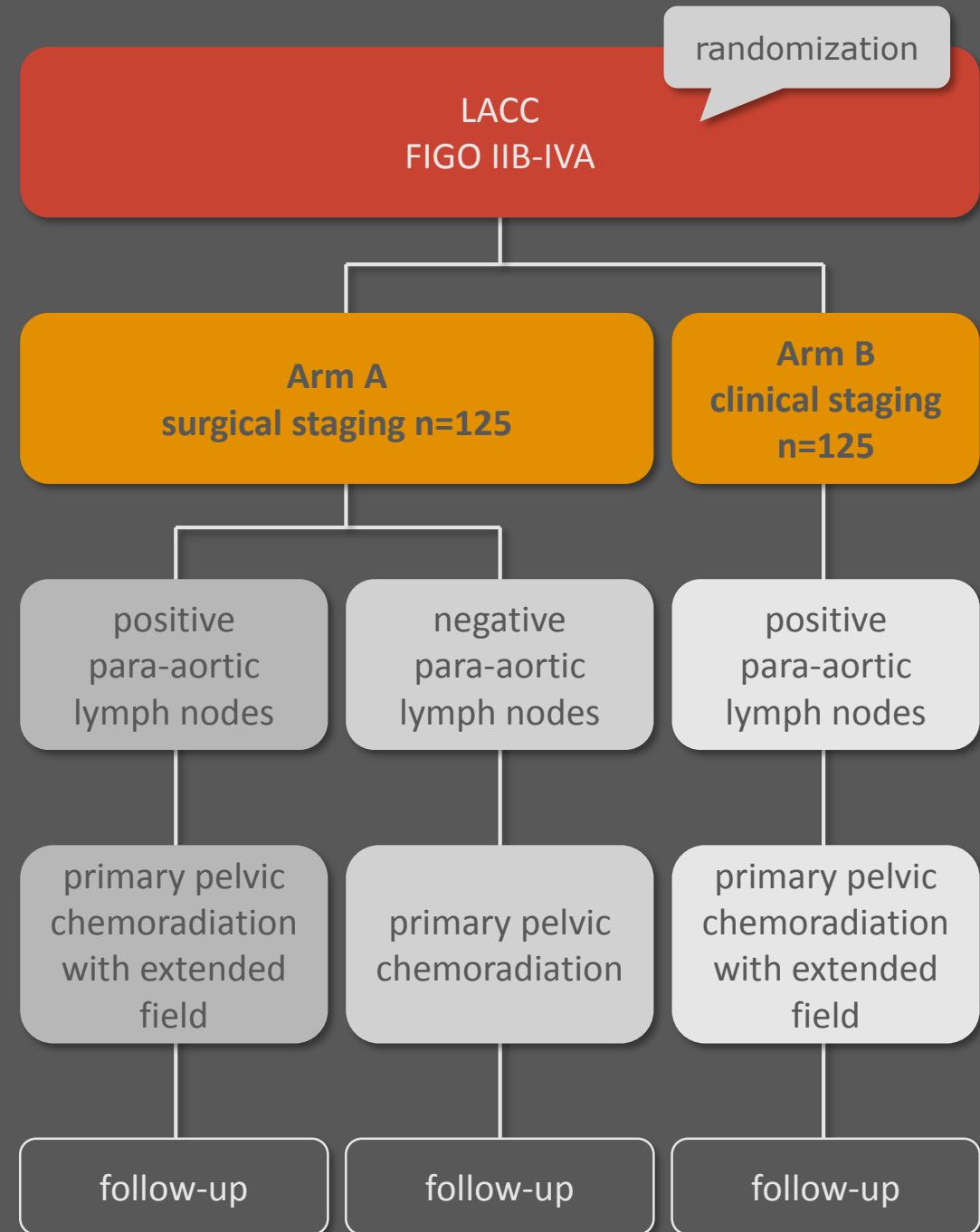
OBJECTIVES

- Surgical staging leads to upstaging in a relevant percentage of patients with locally advanced cervical cancer (LACC), but oncologic benefit is controversially discussed
- Well known limitations of imaging systems in detection of para-aortic lymph node involvement
- The only randomized clinical trial from Lai et al. failed, included a very small number of patients and had considerable problems
- Different level of recommendation in national and international guidelines

The aim of this study was to compare the oncological outcomes (OS and PFS) of the surgical staging with CT-staging prior to primary chemoradiation in patients with cervical cancer FIGO stages IIBb-IVA (2009)

Methods

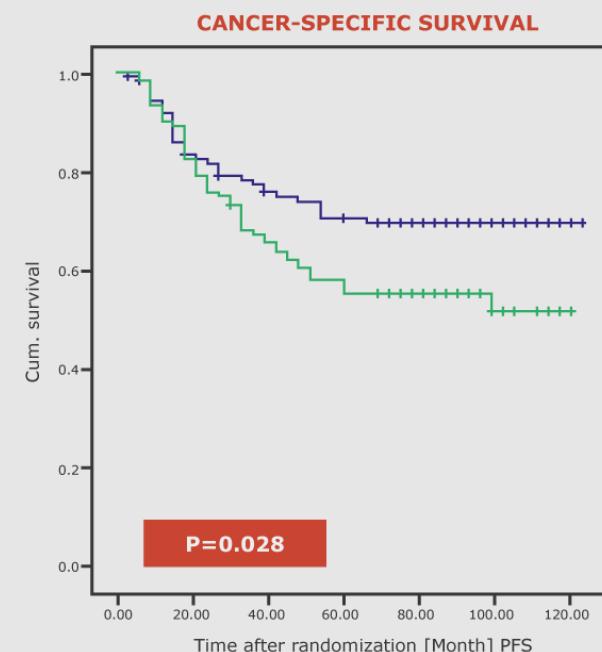
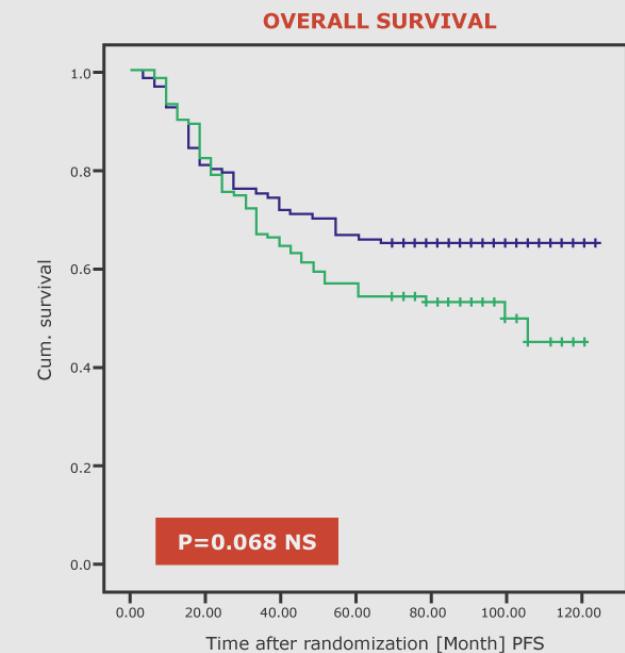
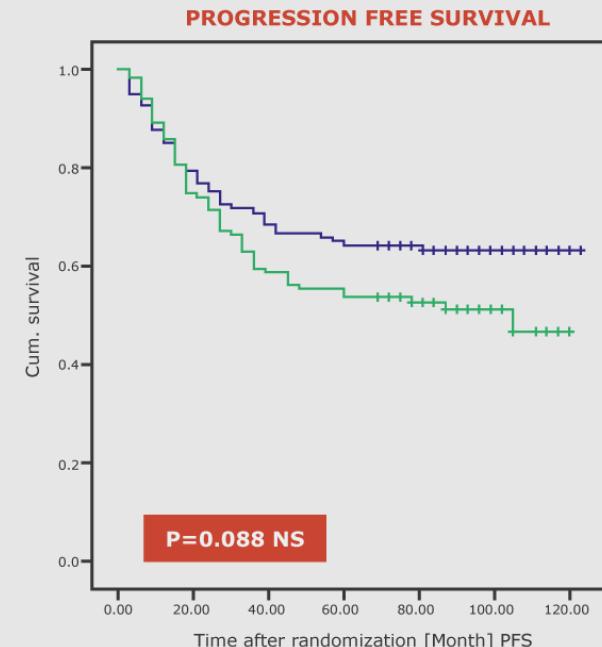
- Randomization of 255 LACC patients (FIGO2009 IIB-IVA)
- Arm A: surgical staging including pelvic and para-aortic lymphadenectomy and CR
- Arm B: clinical staging including CT-Abdomen and CT-guided biopsy of para-aortic lymph nodes if suspicious) followed by CR
- Chemoradiation consisted in pelvic external beam radiotherapy with weekly cisplatin ($40\text{mg}/\text{m}^2$) and brachytherapy
- Extended-field radiation was performed in cases of confirmed para-aortic metastases.



Results

UPSTAGING

- 40/121 (33%) patients were upstaged after surgical staging
- 7/114 (6%) patients had positive para-aortic CT-guided biopsy



Median FU:
90 months in both arms

- Arm A (surgical)
- Arm B (clinical)
- OP Staging
- Clin. Staging
- OP Staging censored
- Clin. Staging censored

Conclusions

It is the only adequately powered prospective randomized trial RCT where nearly all surgical staging procedures were done by minimally-invasive approach and exclusively modern radiation techniques were used.

Surgical staging performed by laparoscopy is safe and does neither delay primary chemoradiation nor increase early complication rate of primary chemoradiation.

There is a significant cancer-specific survival benefit in favour of laparoscopic staging compared to clinical staging.

There is urgent need to better maintenance therapy following primary chemoradiation in order to reduce rate of distant metastases.

SUCCOR study: an international european cohort observational study comparing minimally invasive surgery versus open abdominal radical hysterectomy in patients with stage IB1 cervical cancer operated in 2013-2014

-- *L. Chiva et al.*

Background

Minimally invasive surgery (MIS) was adopted as an alternative to laparotomy for radical hysterectomy in patients with early-stage cervical cancer before obtaining solid evidence regarding its effect on survival.

A recent randomized trial from Ramirez et al. (LACC trial) showed a survival advantage if radical hysterectomy was performed with open approach, compared with minimally-invasive approach.

Objectives & Methods

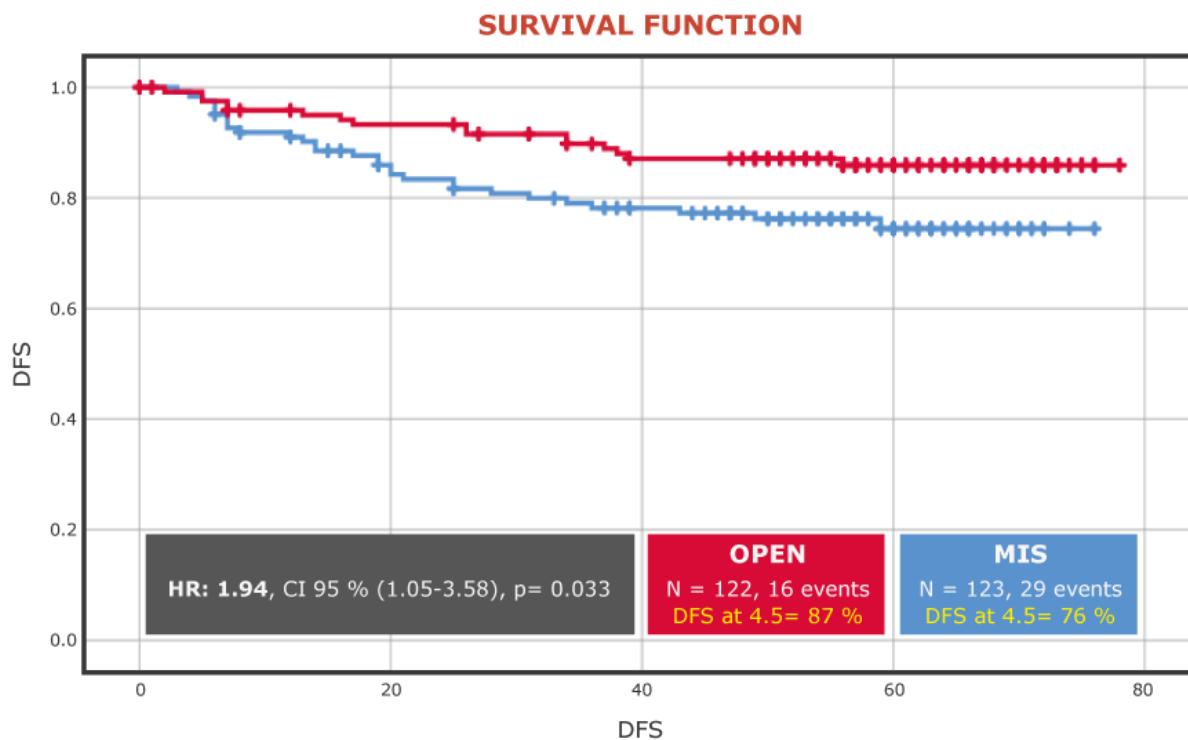
THE AIM OF THE STUDY WAS TO:

- Retrospectively compare DFS at 4.5 years in patients who underwent a laparoscopic or robotic radical hysterectomy (MIS) vs. abdominal radical hysterectomy (TARH) for stage IB1 cervical cancer in European countries (2013-2014).
- Explore causal association between specific surgical protective manoeuvres and risk of relapse (manipulator, vaginal closure, etc.).

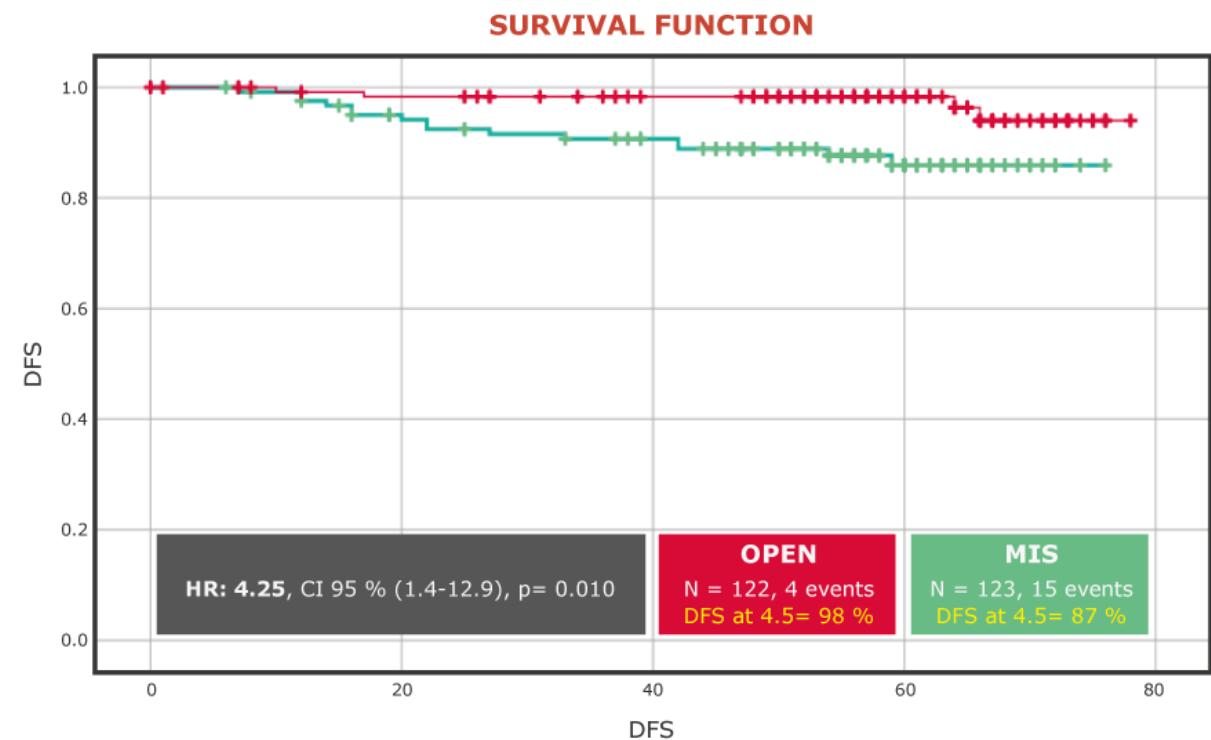
METHODS

- Retrospective observational cohort study across ESGO members (111 centres)
- A propensity matching score to balance all the relevant variables that were found significant to modify the rate of relapse (n=245 patients after 123 matchings)

Results (1/3)

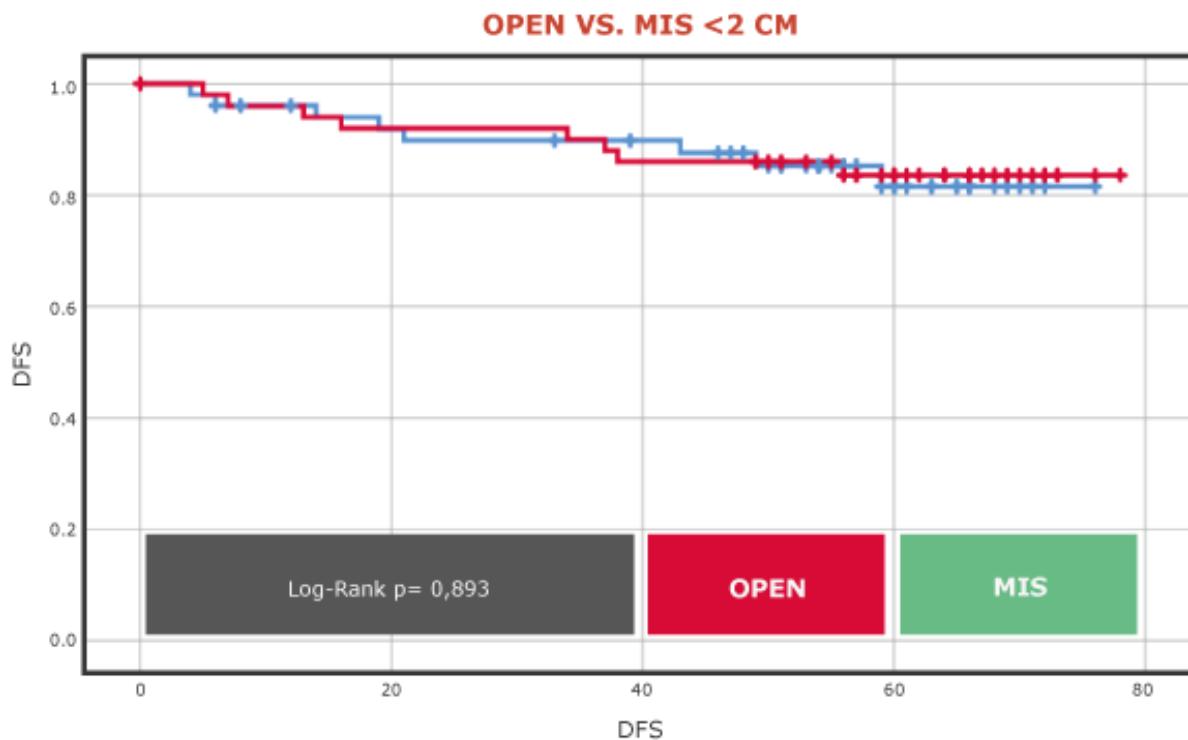


DFS in both groups open and MIS after propensity matching score

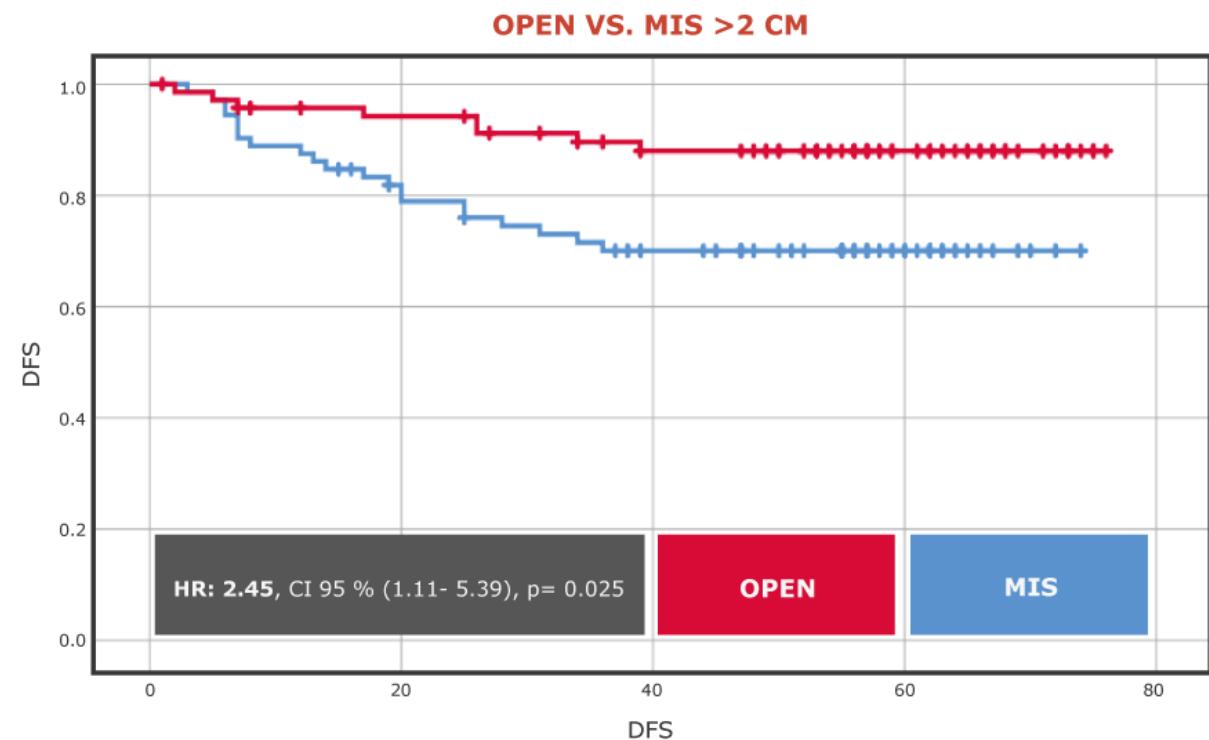


OS in both groups open and MIS after propensity matching score

Results (2/3)

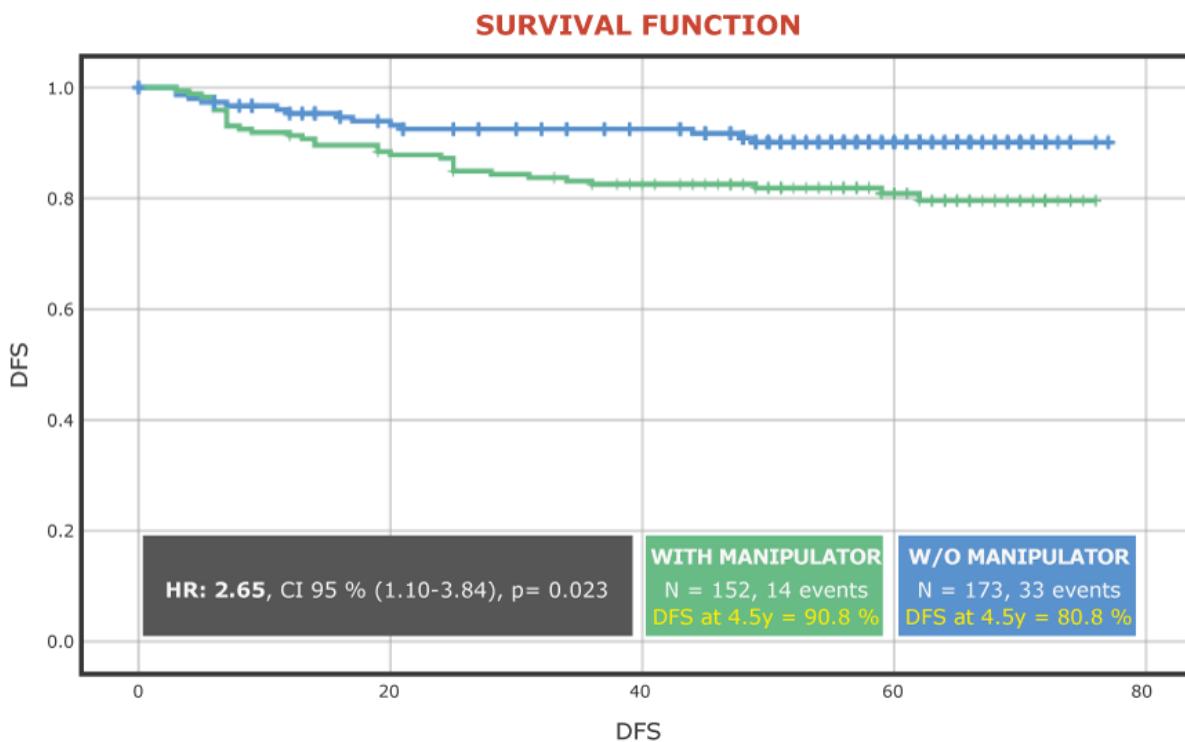


DFS in both groups open and MIS after propensity matching score in patients with tumour <2cm (MRI-US max diameter)

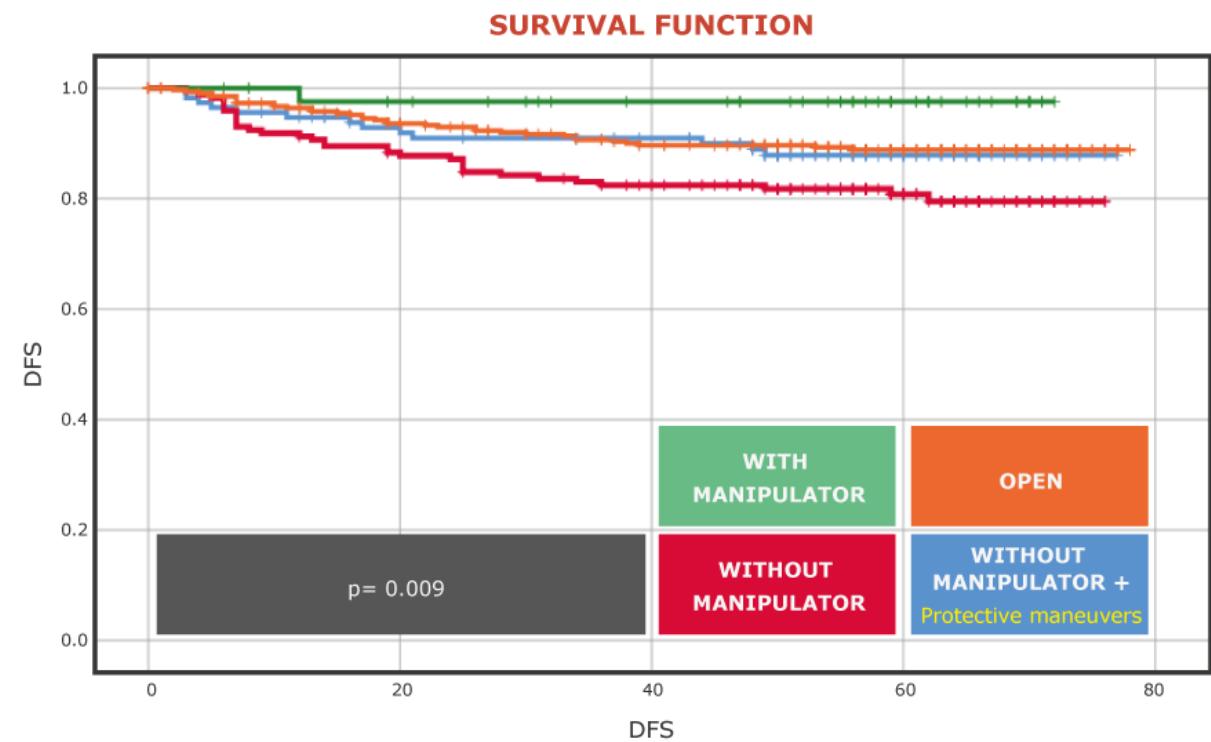


DFS in both groups open and MIS after propensity matching score in patients with tumour >2cm (MRI-US max diameter)

Results (3/3)



Impact of using manipulator on DFS in MIS



Protective score in MIS

Conclusions

Patients with IB1 <4cm cervical cancer that underwent radical hysterectomy by MIS showed a significantly higher risk of relapse and death.

Patients with tumours smaller than 2 cm and those with previous cone biopsy did not show differences in DFS by the surgical approach.

The use of a uterine manipulator in MIS impacted the DFS negatively in this population.

Patients that underwent radical hysterectomy by MIS without using a manipulator showed the same outcome that those operated by open surgery.

Protective maneuvers to avoid tumour spillage at the time of the colpotomy in MIS improved the DFS in these patients (e.g. vaginal cuff formation).

Phase III PAOLA-1/ENGOT-ov25 : maintenance olaparib with bevacizumab in patients with newly diagnosed, advanced ovarian cancer treated with platinum-based chemotherapy and bevacizumab as standard of care

-- *P. Harter et al.*

Background

First-line bevacizumab in combination with chemotherapy and followed by bevacizumab maintenance is the current standard of care for most patients with newly diagnosed advanced ovarian cancer (AOC).

The PARP inhibitor olaparib showed a PFS benefit as first-line maintenance monotherapy for patients with a BRCA mutation (BRCAm). It is also well known that homologous recombination repair deficiency (HRD) affecting response to olaparib is not limited to BRCAm and is present in ~50% of high-grade serous ovarian tumours.

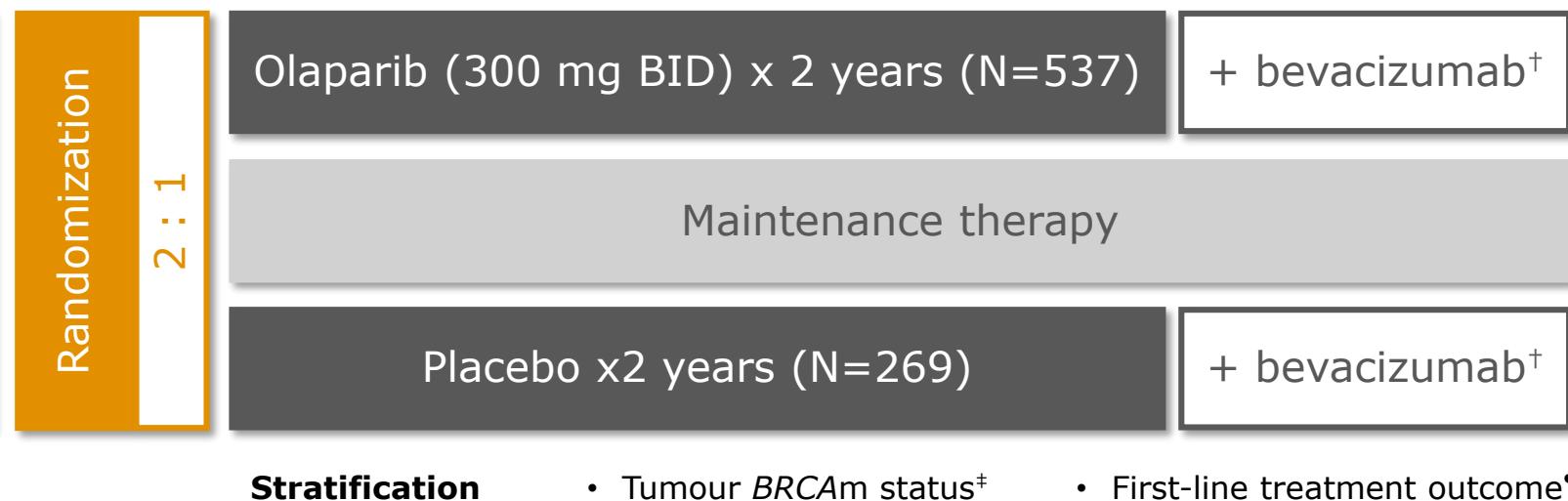
Objectives & Methods

The aim of the study was to evaluate the efficacy and safety of maintenance therapy with a PARP inhibitor in patients with AOC regardless of BRCA mutation status who are receiving first-line standard-of-care treatment including bevacizumab.

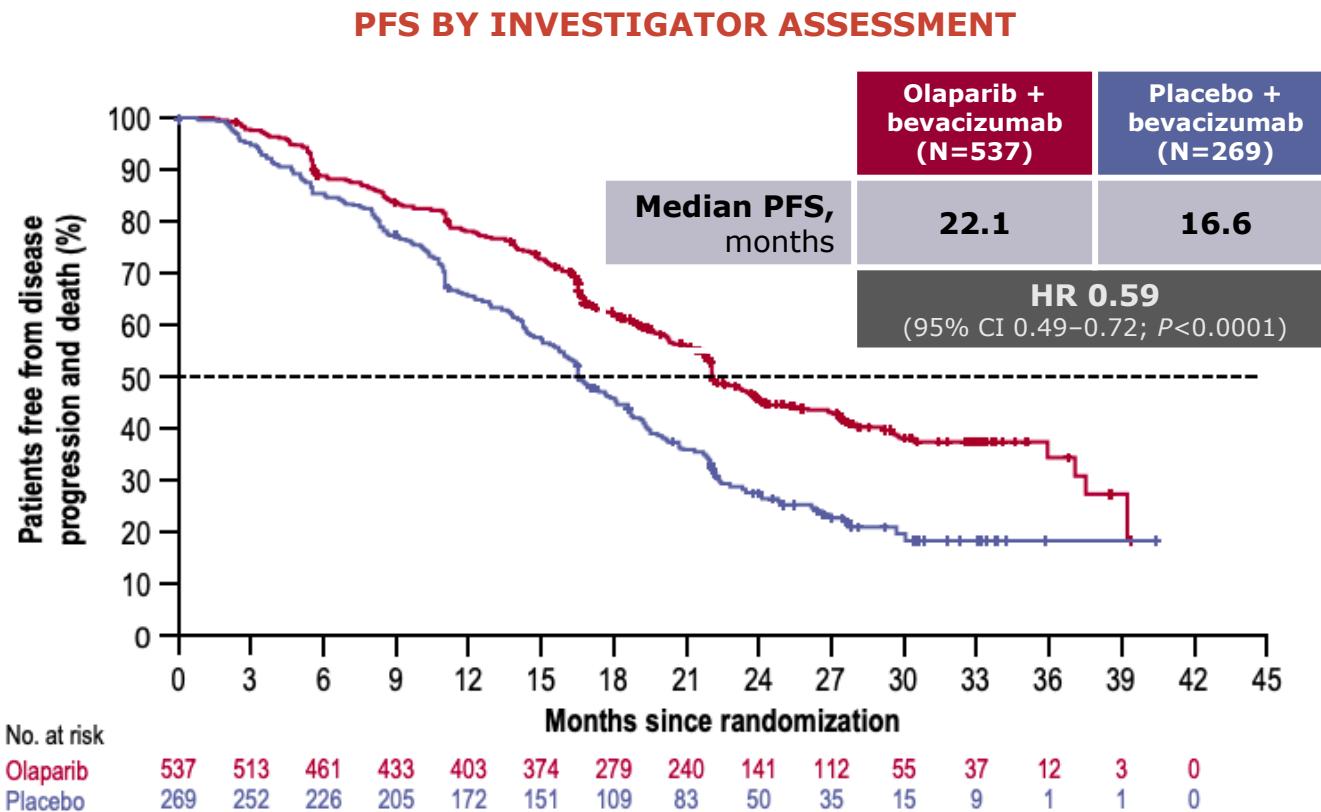
METHODS

FIRST LINE

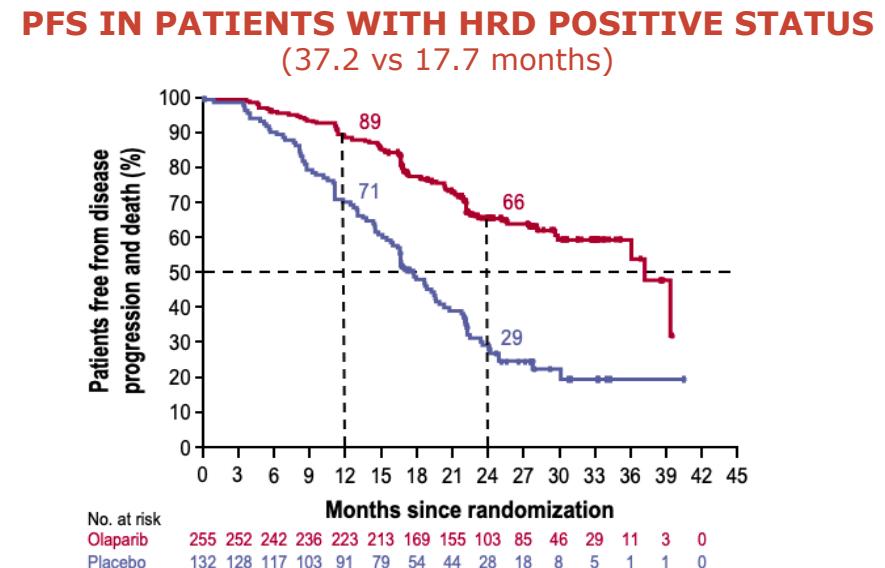
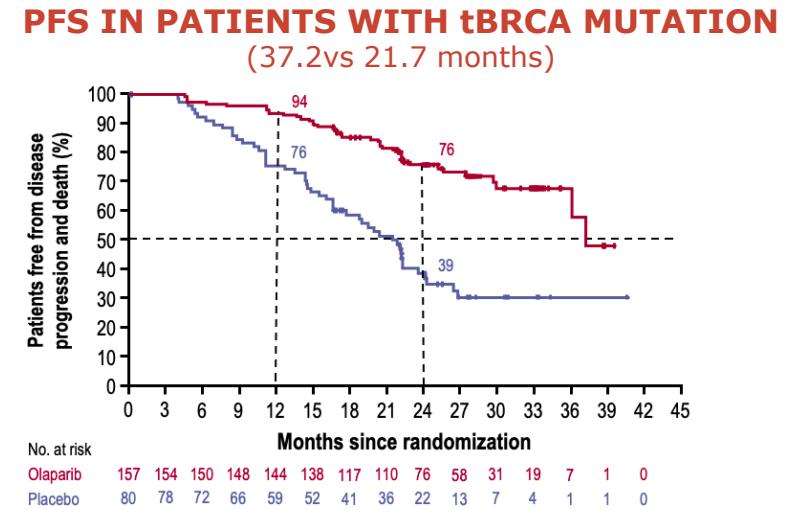
- FIGO stage III–IV
- Surgery (upfront or interval)
- Platinum–taxane based chemotherapy
- ≥3 cycles of bevacizumab
- NED/CR/PR



Results



PFS was significantly increased in the olaparib arm (22.1 vs 16.6 months), HR 0.59 (95% CI 0.49–0.72; $P<0.0001$) (59% maturity)



Conclusions

Addition of olaparib to bevacizumab maintenance therapy following first-line standard-of-care bevacizumab maintenance treatment led to a statistically significant and clinically meaningful PFS benefit in patients with advanced ovarian cancer. The PFS benefit in patients with a tBRCAm and in HRD-positive patients was substantial.

Exploratory subgroup analyses showed that all patients had PFS benefits regardless of disease stage and previous NACT; further biomarker analyses in both subgroups are ongoing.

The safety profile of olaparib in combination with bevacizumab was generally consistent with previous trials of each drug and the addition of olaparib did not impact on bevacizumab tolerability and HRQoL.

Results from neoadjuvant chemotherapy followed by radical surgery compared to chemoradiation for stage IB2-IIIB cervical cancer -EORT GCG 55994

-- S. Greggi et al.

Objectives & Methods

Conflicting evidence exists on the value of neoadjuvant chemotherapy followed by surgery compared to concomitant chemoradiation (CT-RT) in stage IB2-IIIB cervical carcinoma

The aim of the study was to compare OS and PFS of patients with stage IB2, IIA, or IIB cervical cancer treated with neoadjuvant cisplatin-based chemotherapy followed by radical hysterectomy vs standard therapy comprising concurrent radiotherapy and cisplatin-based chemotherapy.

METHODS

CERVICAL CARCINOMA

FIGO Stage IB2,
IIA >4cm, IIB

Randomization

Arm 1: N=314
NACT + Surgery

Arm 2: CTRT N=312

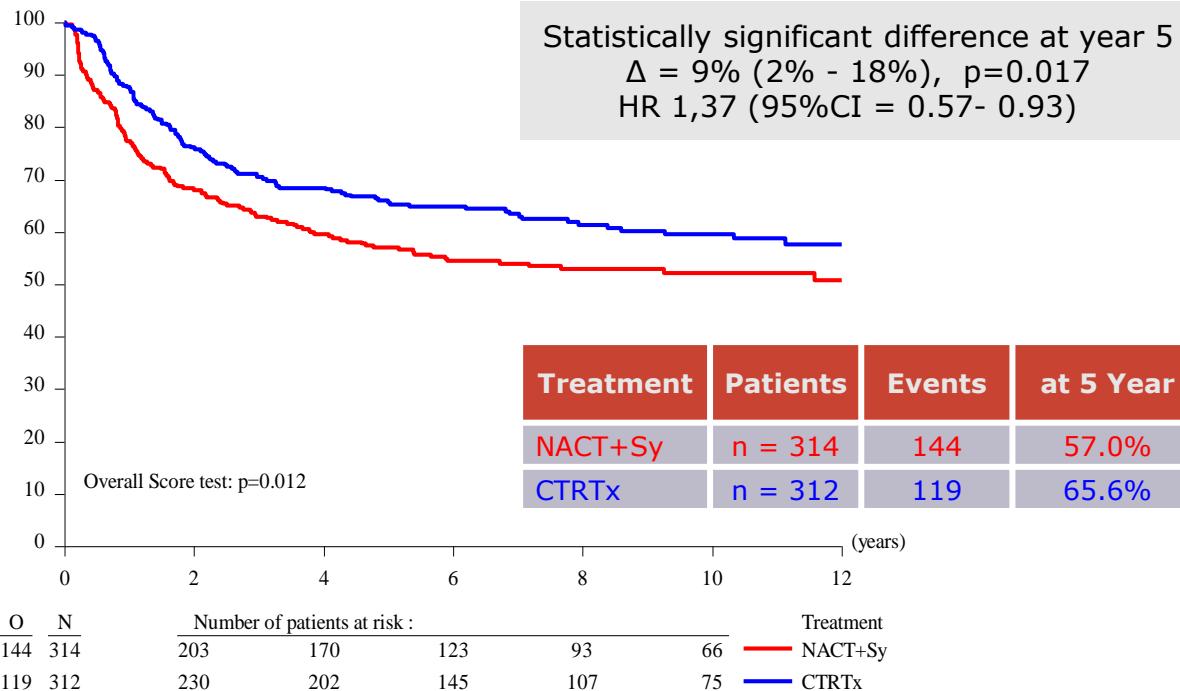
Neoadjuvant cisplatin-based chemotherapy
($\geq 225 \text{ mg/m}^2$) followed by rad. hysterectomy

Concomitant radiation and chemotherapy
45-50 Gy plus boost + weekly $\geq 40 \text{ mg/m}^2$ cisplatin

Results

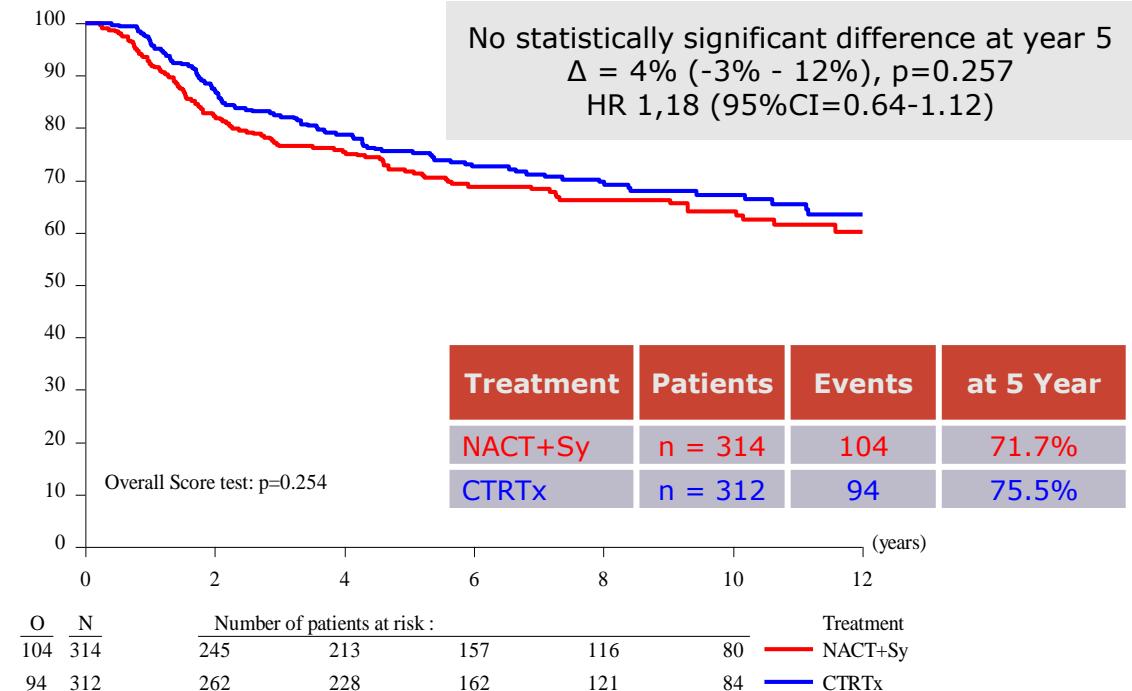
Similar results in eligible and per protocol population

PROGRESSION FREE SURVIVAL



- 626 pts
- median FU = 8.7 yrs
- no difference in baseline clinical characteristics

OVERALL SURVIVAL



Acceptable toxicity in both arms: G3-4 short-term tox > in the NACT+S arm, long-term > in the CTRT arm

Conclusions

These preliminary results revealed no difference in 5-year OS between NACT+S and CTRT.

PFS benefit interpreted with caution (potential delayed detection of rec/pr following RT). Nevertheless, a significant (7-9%) advantage in PFS for CTRT detected in both, mostly due to Stage IIB.

Trend for better results for NACT+S in stage Ib2, for CTRT in Stage IIB

Quality of life analysis is not yet available.

Child development at 6 years after maternal cancer diagnosis and treatment during pregnancy

-- *T. Vandenbroucke et al.*

Objectives & Methods

OBJECTIVE

The goal of this study was to assess

- cognitive development
- health problems and
- cardiac structure/function

in children after 6 years who were born to mothers with cancer during pregnancy compared to a control group from healthy mothers with uncomplicated pregnancies.

METHODS

Data from the registry of the International Network of Cancer, Infertility and Pregnancy 132 children at the age of 6 born after an uncomplicated pregnancy and delivery (73,5% prenatally exposed to chemotherapy) compared to 132 children of a control group.

Results

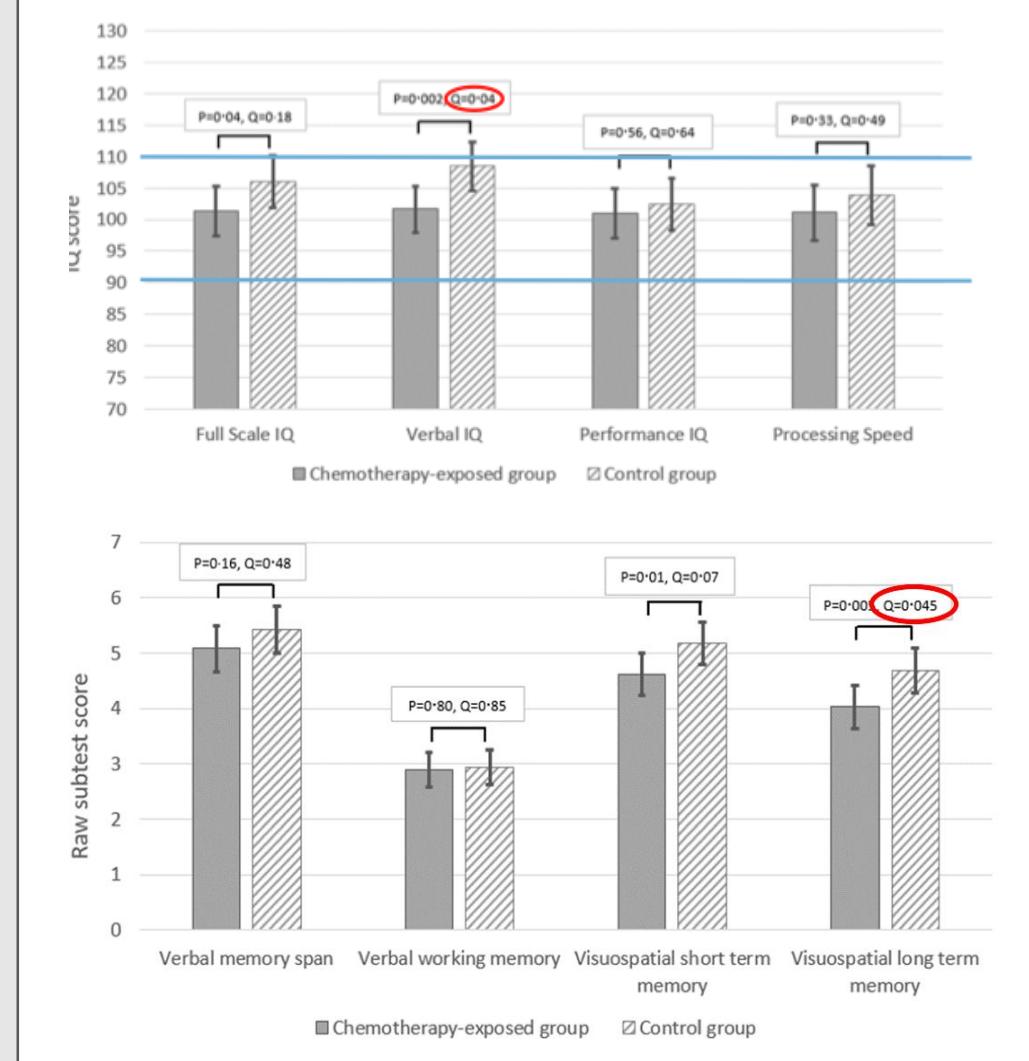
HEALTH PROBLEMS

- Children in the treatment group were 3 times more likely to wear glasses (14.9% vs 4.2%)
- Cisplatin lead to hearing loss in 3 out of 14 children

CARDIAC FUNCTION

- No difference in cardiac evaluation

COGNITIVE DEVELOPMENT



- Although within normal ranges, the mean Verbal IQ score was lower (6 points) ($p<0,05$)
- Lower score for visuospatial long-term memory ($p<0,05$)

Conclusions

Special attention for the evaluation and additional stimulation of early language development in these children may be advised to prevent delay in language development and verbal intelligence.

On the value of a prognostic Tumour Score in locally advanced cervical cancer

-- JC. Lindegaard *et al.*

Objectives

The FIGO score in cervical cancer doesn't incorporate certain aspects such as proximal versus distal parametrial invasion, unilateral versus bilateral involvement or organ infiltration on MRI.

The aim of the study was to investigate the performance of a simple but wide-ranging tumour score (T-score) for reporting and prognostication in locally advanced cervical cancer (LACC).

Tumour score (T-score): degree of involvement of 8 anatomical locations (cervix, left parametrium, right parametrium, vagina, bladder, ureters, rectum and uterine corpus) scored according to a ranked ordinal scale with 0–3 points. The total sum of points constituted the T-score.

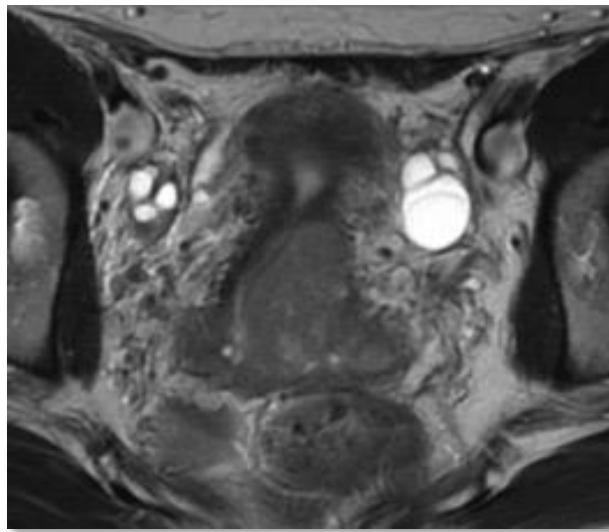
Methods (1/2)

- 400 patients with LACC (2005-2018) with FIGO 2009 stage distribution IB-IIA 9%, IIB 61% and III-IV 30%.
- full diagnostic work up including MRI, PET-CT and clinical examination.
- external beam radiotherapy ± concomitant cisplatin and image-guided adaptive brachytherapy
- T-score was calculated by summing up predefined criteria.

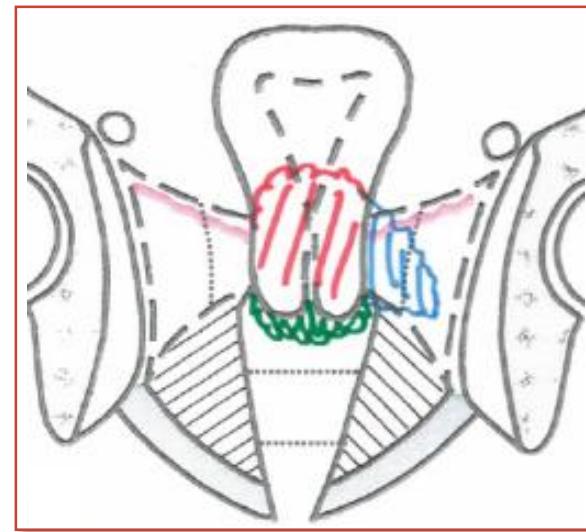
Methods (2/2)

Clinical example of calculation of the T-score in a LACC stage IIB using the integrated information from clinical examination and MRI.

MRI



CLINICAL EXAMINATION

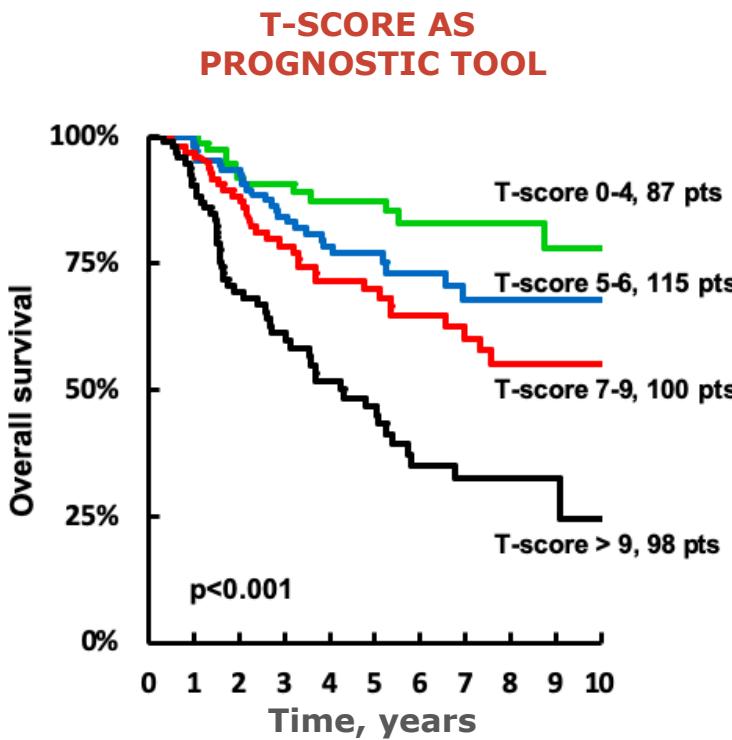


Stage IIB
T-score = 7

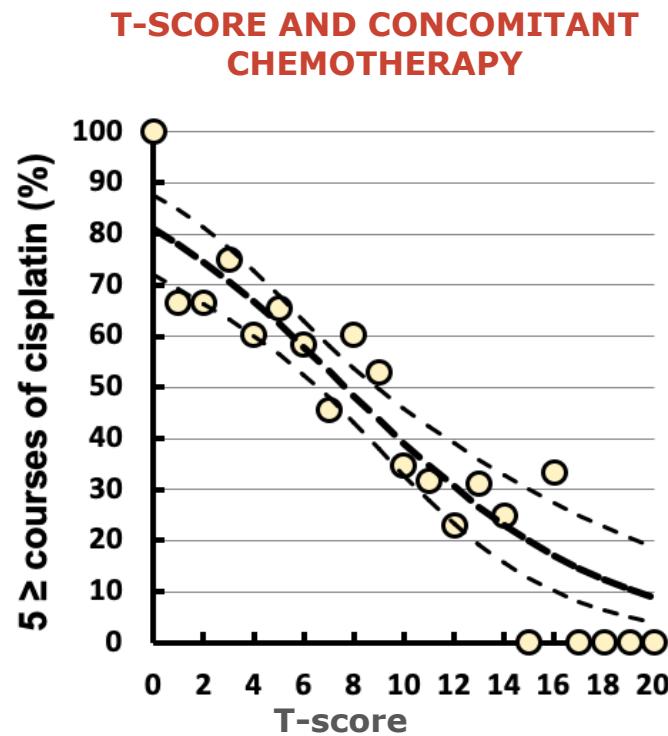
Location	Scale	Score
Uterine cervix	<20 mm	0
	20-40 mm	1
	>40 mm	2
	Disrupted	3
Parametrium left	Not involved	0
	Proximal	1
	Distal	2
	Pelvic wall	3
Parametrium right	Not involved	0
	Proximal	1
	Distal	2
	Pelvic wall	3
Bladder	Not involved	0
	Bladder wall	1
	Bullous edema	2
	Mucosa	3
Ureter	Not involved	0
	Unilateral	1
	Bilateral	2
Rectum	Not involved	0
	Mesorectum	1
	Rectal wall	2
	Mucosa	3
Uterine corpus	Not involved	0
	Lower third	1
	Middle third	2
	Upper third	3
Vagina	Not involved	0
	Upper third	1
	Middle third	2
	Lower third	3
Total score		7

Results

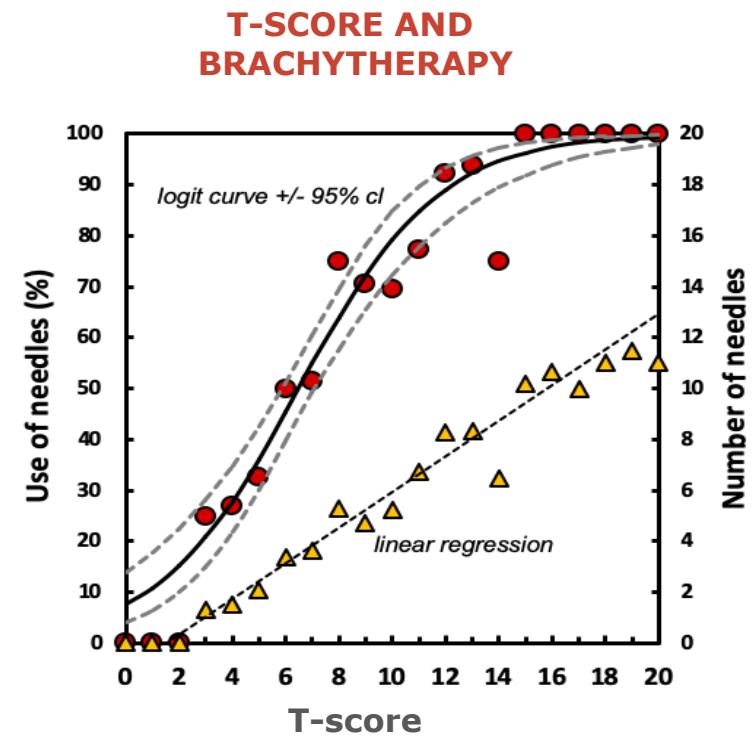
- The median T-score was 6 (range 0–20).



The T-score outperformed FIGO stage for both survival and local control.



The likelihood of receiving full course concomitant chemotherapy decreased significantly with T-score with only about 50% of the patients being able to receive ≥ 5 courses when T-score = 8.



Prediction of the use of interstitial needles for brachytherapy increased sharply with 45% and 90% of patients with T-score of 6 and 12 requiring needles, respectively.

Conclusions

Important prognostic information from MRI and clinical evaluation are missing in the FIGO classification.

The T-score may predict the ability of patients to undergo concomitant chemotherapy and the need for interstitial brachytherapy.

The T-score is a powerful full prognostic factor for survival and local control.



Frozen section examination of sentinel lymph nodes can be used as a decisional tool in the surgical management of early cervical cancer

-- *A. Rychlik et al.*

Objectives

Sentinel lymph node (SLN) biopsy is an important tool in the management of early-stage cervical cancer and takes place to decrease the risk of lymphadenectomy related complications. However, the accurate assessment of the SLN is still under debate.

The main aim of this study was to evaluate the clinical usefulness and role of frozen section for the histo-pathologic analysis of sentinel lymph nodes in early-stage cervical cancer.

Methods

METHODS

178 early-stage (IA1-IB2 FIGO 2018) cervical cancer patients (2001-2018) enrolled, but **only patients with bilateral mapping were analyzed**

SLN biopsy and frozen section analysis were used

Combined technique with filtered Technetium-99 microsulfur colloid and blue dye in most cases

Results

by patient with bilateral mapping (including micrometastases, excluding ITC)

Bilateral mapping in 153 patients (86.7%)

19 patients (12.4%) had SLN involvement: 13 with macrometastases, 3 with micrometastases and 3 with isolated tumour cells (ITC)

3 pts out of 13 with macrometastases and 3pts out of 3 with ITC were missed;
no pt with micrometastases was missed.

Sensitivity 81.2% (95% CI 57.0–93.4), NPV 97.9% (95% CI 93.9–99.3)

Only 3 patients with macrometastases out of 153 were wrongly oriented

Different surgical strategies used today

Traditional Surgical Approach

Radical hysterectomy with pelvic node dissection +/- SLN

Define pathology

LN negative

Surveillance

LN positive

CRT

10 % have combined treatment

Surgical Approach 2 Steps

Nodal assessment (SLN +/- PLND)

Define Pathology (Ultrastaging)

(S)LN negative

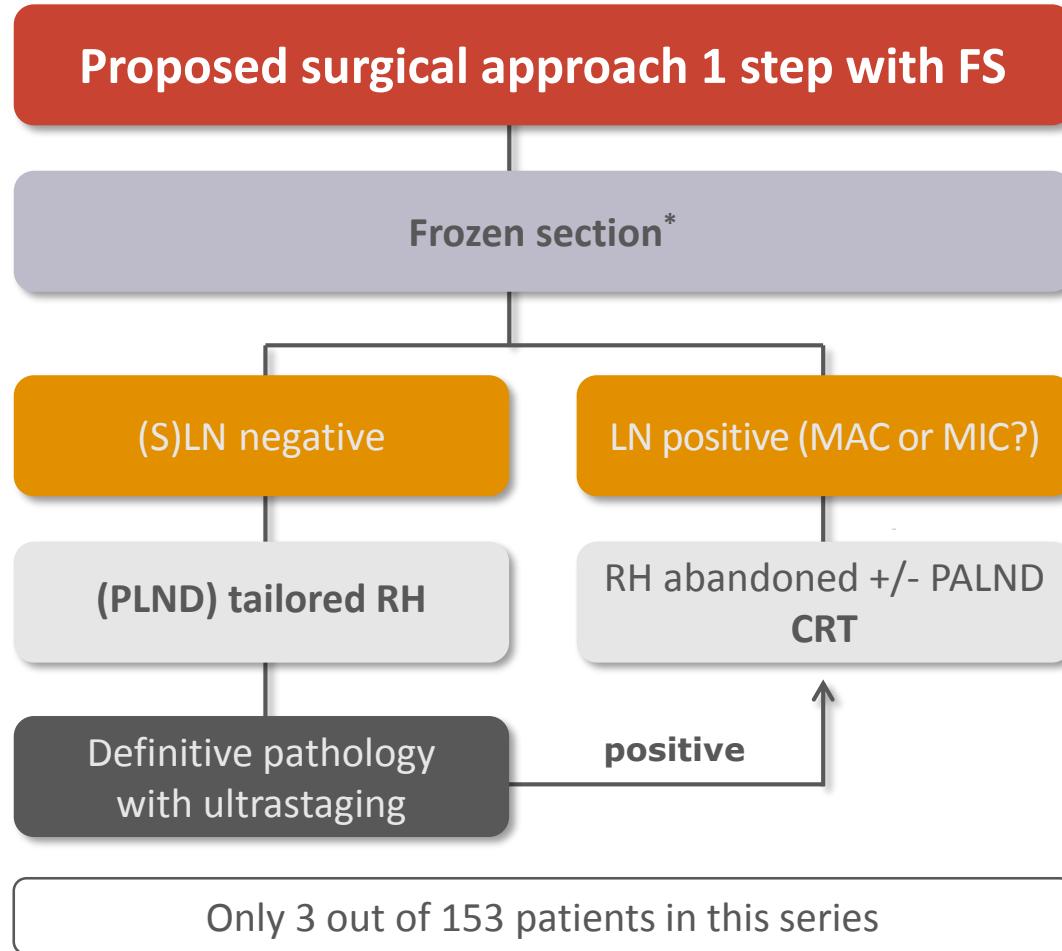
(PLND) tailored RH

LN positive (MAC or MIC?)

RH abandoned +/- PALND
CRT

90 % have two surgeries

Different surgical strategies used today



FS is an accurate and useful tool to evaluate SLNs in early-stage cervical cancer. With a NPV in the order of 97%, FS allowed to detect the vast majority of lymph nodal metastases.

Out of 153 patients, 150 were correctly orientated.

This study has provided an evidence that implementing FS of SLN in the surgical management of early stage cervical cancer can impact the intraoperative decision.

* FS of Full dissection if SLN detection fails

Niraparib therapy in patients with newly diagnosed advanced ovarian cancer after chemotherapy: PRIMA/ENGOT-OV26/GOG-3012 Study

-- *A. González-Martín et al.*

Objectives

Niraparib has shown progression-free survival (PFS) benefit in recurrent ovarian cancer (OC) after platinum-based chemotherapy (CT) in all patients regardless of BRCA status.

The efficacy of niraparib in patients with newly diagnosed advanced ovarian cancer after a response to first-line platinum-based chemotherapy was unknown.

The aim of this study was to show the efficacy and safety of niraparib after first line chemotherapy in newly diagnosed advanced ovarian cancer patients.

Methods

KEY INCLUSION CRITERIA

- High grade serous or endometrioid pathology
- Stage III: primary debulking surgery (PDS) with visible residual disease post surgery, NACT, or inoperable
- Stage IV: PDS regardless of residual disease, NACT, or inoperable
- CR or PR following platinum first-line treatment

KEY EXCLUSION CRITERIA

- Patients with Stage III disease who have had complete cytoreduction (i.e., no visible residual disease) after PDS

733 patients with newly-diagnosed OC at high risk for recurrence after first line platinum-based chemotherapy

Randomization
2 : 1

484 patients with niraparib

244 patients with placebo

Primary Endpoint:
Progression-free survival

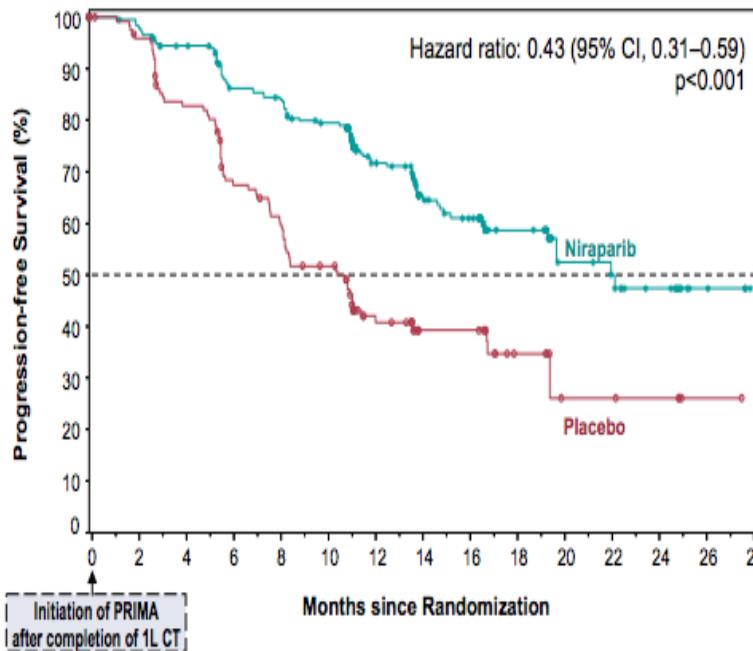
Key Secondary Endpoint:
Overall Survival

Patient characteristics were well balanced across each arm.

Median follow up of 13.8 months

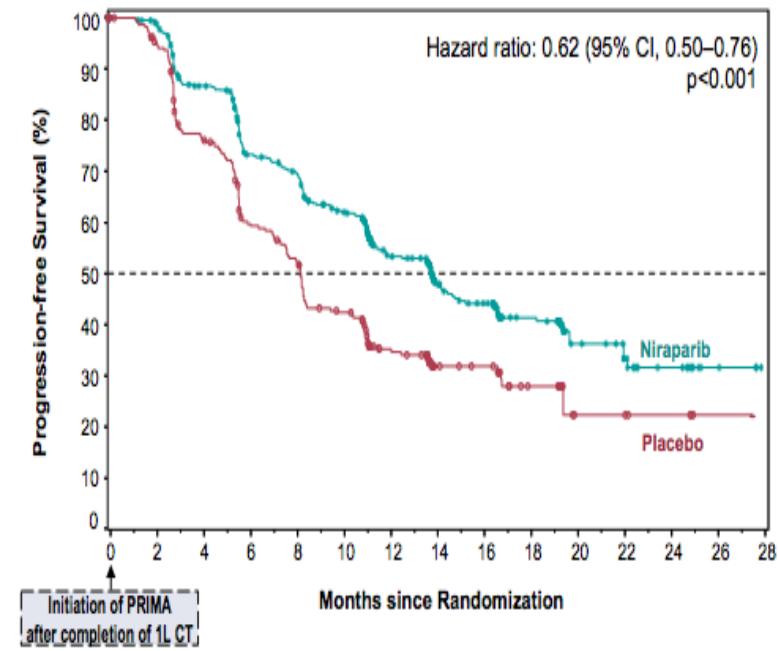
Results (1/2)

PFS BENEFIT IN THE HR-DEFICIENT POPULATION



57% reduction in hazard of relapse or death with niraparib	
Niraparib (n=247)	Placebo (n=126)
Median PFS	
months (95% CI) 21.9 (19.3–NE)	10.4 (8.1–12.1)
Patients without PD or death (%)	
6 months	86%
12 months	72%
18 months	59%

PFS BENEFIT IN THE OVERALL POPULATION



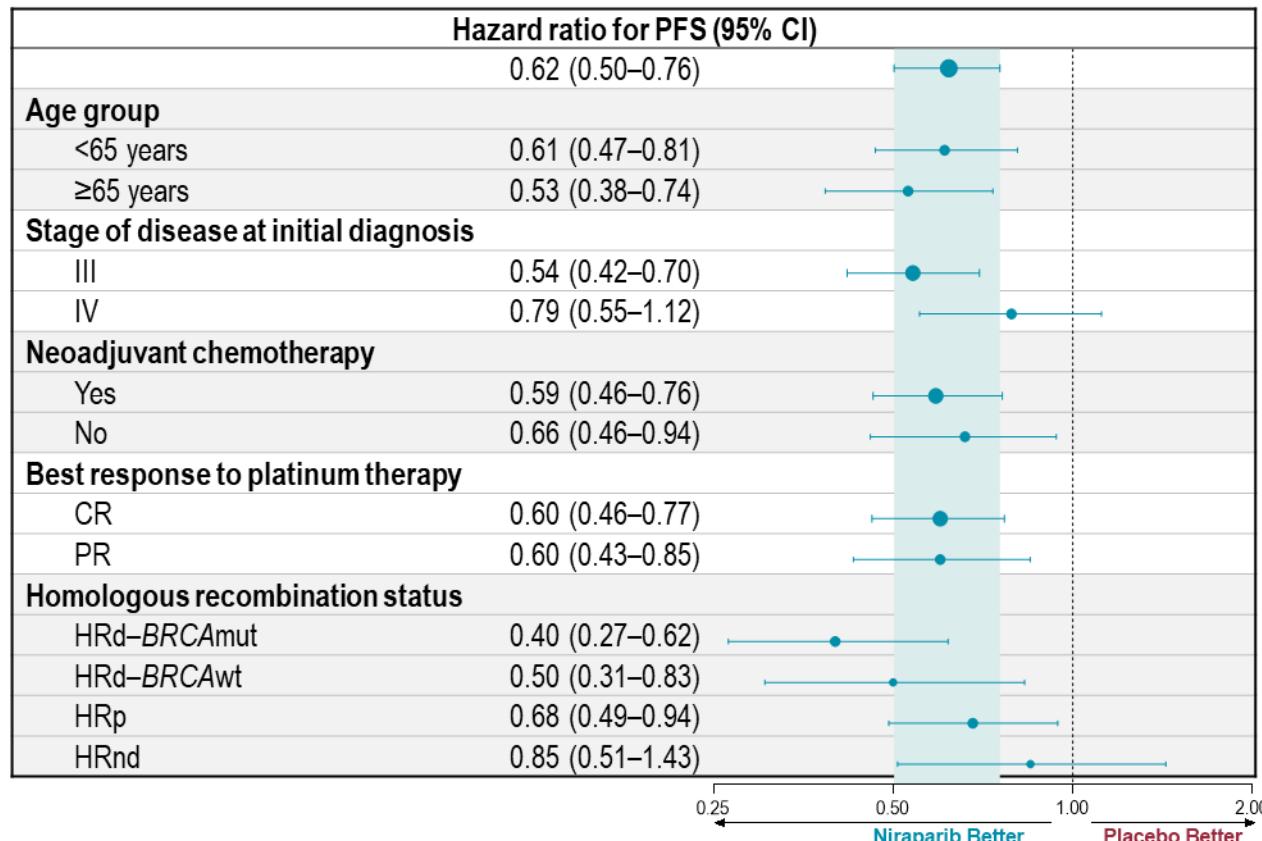
38% reduction in hazard of relapse or death with niraparib	
Niraparib (n=487)	Placebo (n=246)
Median PFS	
months (95% CI) 13.8 (11.5–14.9)	8.2 (7.3–8.5)
Patients without PD or death (%)	
6 months	73%
12 months	53%
18 months	42%

Niraparib reduced the risk of relapse or death by 57% and **prolonged median PFS from 10.4 to 21.9**.

Niraparib reduced the risk of relapse or death of 38% and **prolonged median PFS from 8.2 months to 13.8 months**.

Results (2/2)

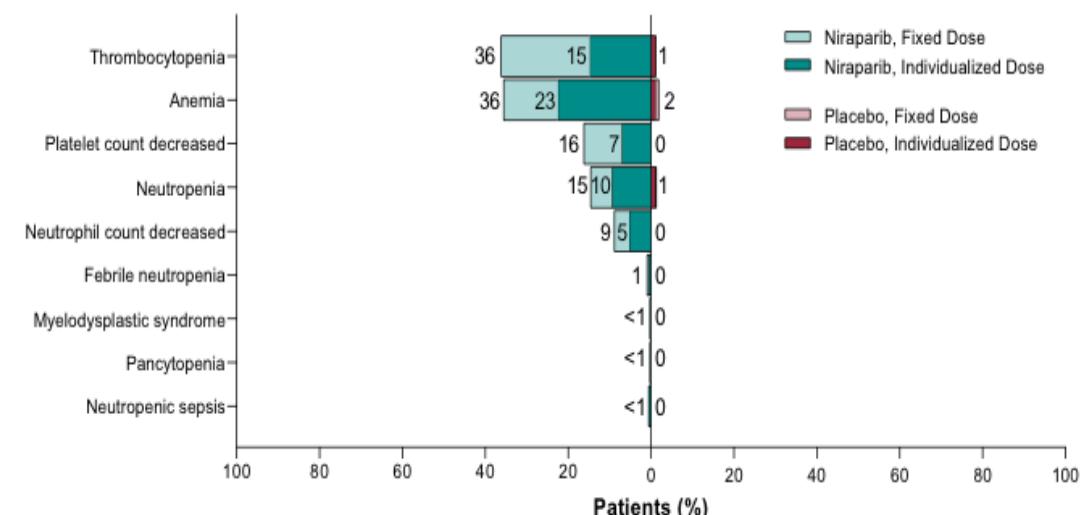
PFS BENEFIT IN PRE-SPECIFIED GROUPS



- Niraparib provided similar clinical benefit in the HRd subgroups (BRCAmut and BRCAwt)
- Niraparib also provide benefit in the HR-proficient subgroup with a 32% risk reduction in progression or death

TREATMENT EMERGENT ADVERSE EVENTS (TAETS)

- manageable and consistent with the PARP inhibitor class, most commonly reversible myelosuppression.
- discontinuation due to TAETs was 12.4%
- no death due to treatment



- Incidence of grade ≥3 hematologic TEAEs were lower in patients who received an individualized dose of niraparib

Conclusions

- Niraparib therapy in patients with advanced ovarian cancer provided a clinically significant improvement in PFS after response to first-line platinum-based chemotherapy in all patients.
- Niraparib demonstrates benefit in patients across biomarker subgroups
- Patients with ovarian cancer at the highest risk of early disease progression (NACT, partial responders to first-line platinum chemotherapy) had significant benefit
- No new safety signals were observed, and quality of life was maintained
- Niraparib monotherapy after first-line platinum-based chemotherapy should be considered a new standard of care

Maintenance olaparib after platinum-based chemotherapy in patients with newly diagnosed advanced ovarian cancer and a BRCA mutation: efficacy by the timing of surgery and residual tumor status following upfront or interval cytoreductive surgery in the phase III SOLO1 trial

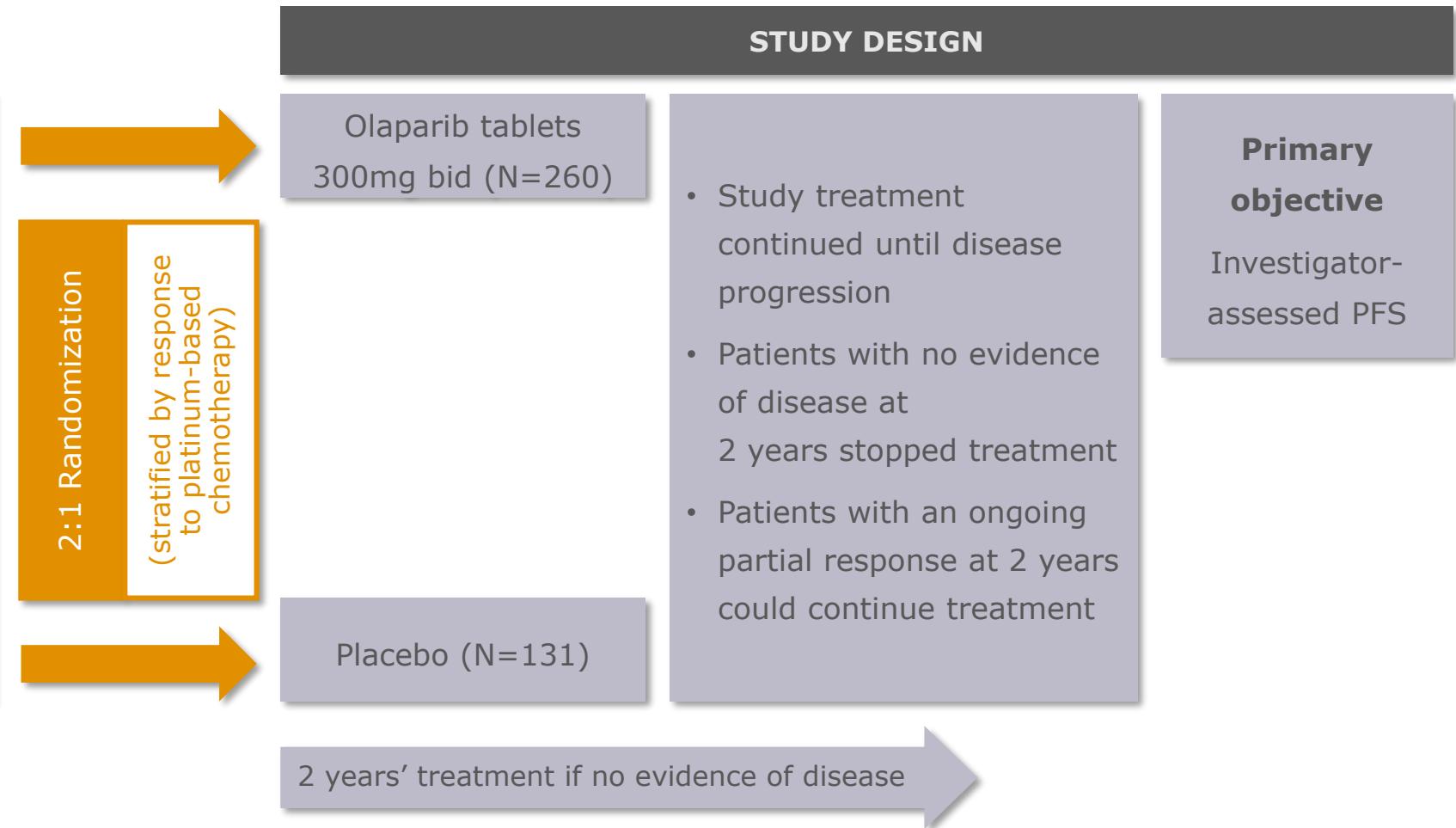
-- *N. Colombo et al.*

Objectives

- The Phase III SOLO1 trial evaluated maintenance therapy with the PARP inhibitor olaparib in women with primary, advanced ovarian cancer (OC) and a BRCA1 or BRCA2 mutation (BRCAm) who were in clinical complete or partial response following platinum-based chemotherapy
- Maintenance with olaparib provided a substantial PFS benefit versus placebo (HR 0.30; 95% CI 0.23–0.41; $P<0.001$)
- The probability of progression free of disease or being alive at 3 years was 60.4% with olaparib versus 26.9% with placebo
- SOLO1 recruited patients regardless of prior surgical status.
- **The main aim of this study** was to analyze the efficacy of olaparib in stage III OC patients who underwent upfront surgery and had no residual macroscopic disease.

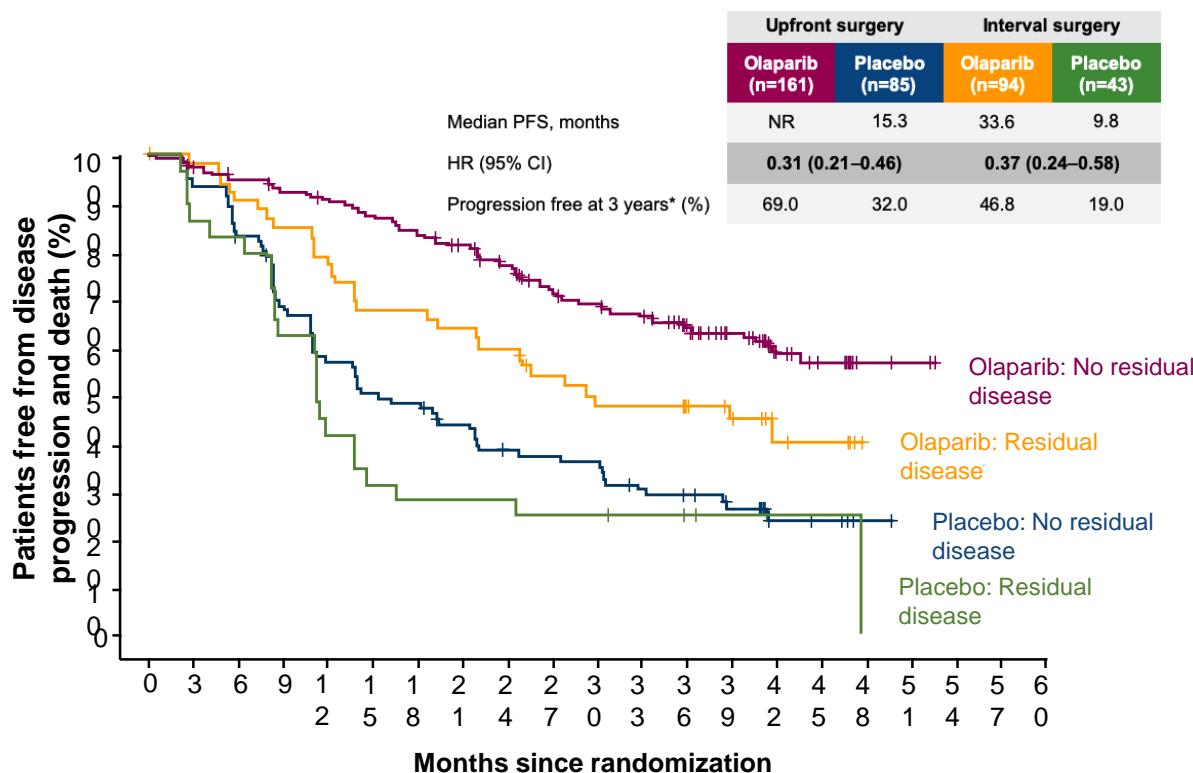
Methods

- Newly diagnosed, FIGO stage III-IV, high grade serous or endometrioid ovarian, primary peritoneal or fallopian tube cancer
- Germline or somatic BRCAm
- Cytoreductive surgery
- In clinical complete response or partial response after platinum based chemotherapy



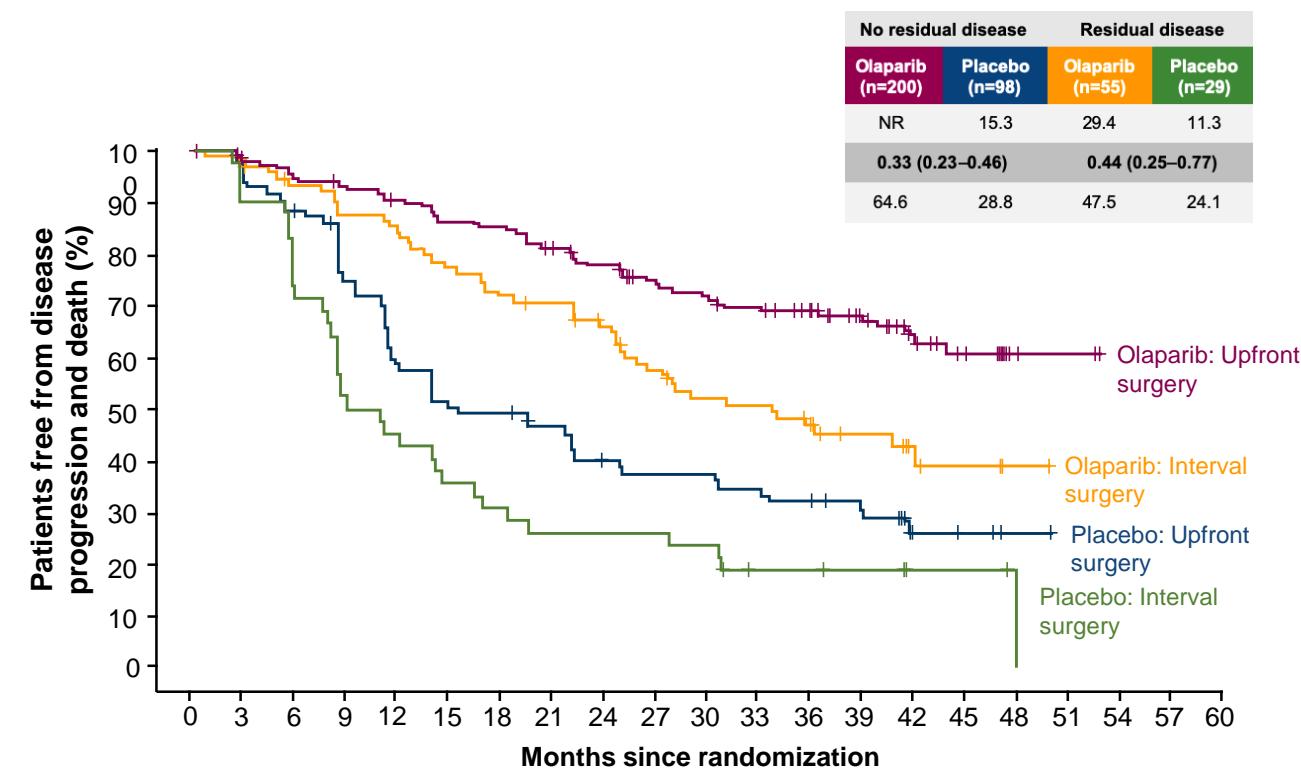
Results

PFS BASED ON TIMING OF SURGERY



PFS was significantly improved regardless of the timing of surgery

PFS BASED ON RESIDUAL DISEASE STATUS FOLLOWING SURGERY



PFS was significantly improved regardless of the residual disease status after surgery

Conclusions

Consistent with the PFS benefit seen in the overall population in SOLO1, maintenance olaparib provided a substantial PFS benefit across all patient subgroups including:

- Patients with a complete cytoreduction
- Patients who had undergone upfront surgery and had no residual disease

A substantial PFS benefit was seen regardless of the timing of surgery or residual disease status after surgery, indicating that all patients with newly diagnosed, advanced high-grade ovarian cancer and a BRCAm are at high risk of progression and achieve substantial benefit from maintenance olaparib

Surgical algorithm for sentinel lymph nodes detection in early-stage cervical cancer: Insights of SENTICOL I and II cohorts

-- *F. Lécuru et al.*

Objectives

OBJECTIVES

The aim of the study was to describe and assess a surgical algorithm for sentinel lymph nodes (SLN) detection in early-stage cervical cancer to improve lymph node staging.

METHODS (1/2)

Data from two prospective multicentric trials on SLN biopsy for cervical cancer (SENTICOL I & II) re-evaluated

305 early stage cervical cancer (stage IA1 with lymphovascular space invasion to stage IIA1) patients with SLN biopsy and full pelvic lymphadenectomy (PLND)

Combined technique: Patent blue and radioactive tracer

No positive lymph nodes on the preoperative evaluation clinically and radiologically by CT and/or MRI

Objectives & Results

METHODS (2/2)

The surgical algorithm was retrospectively applied and consisted in exploration of the following area:



RESULTS (1/2)

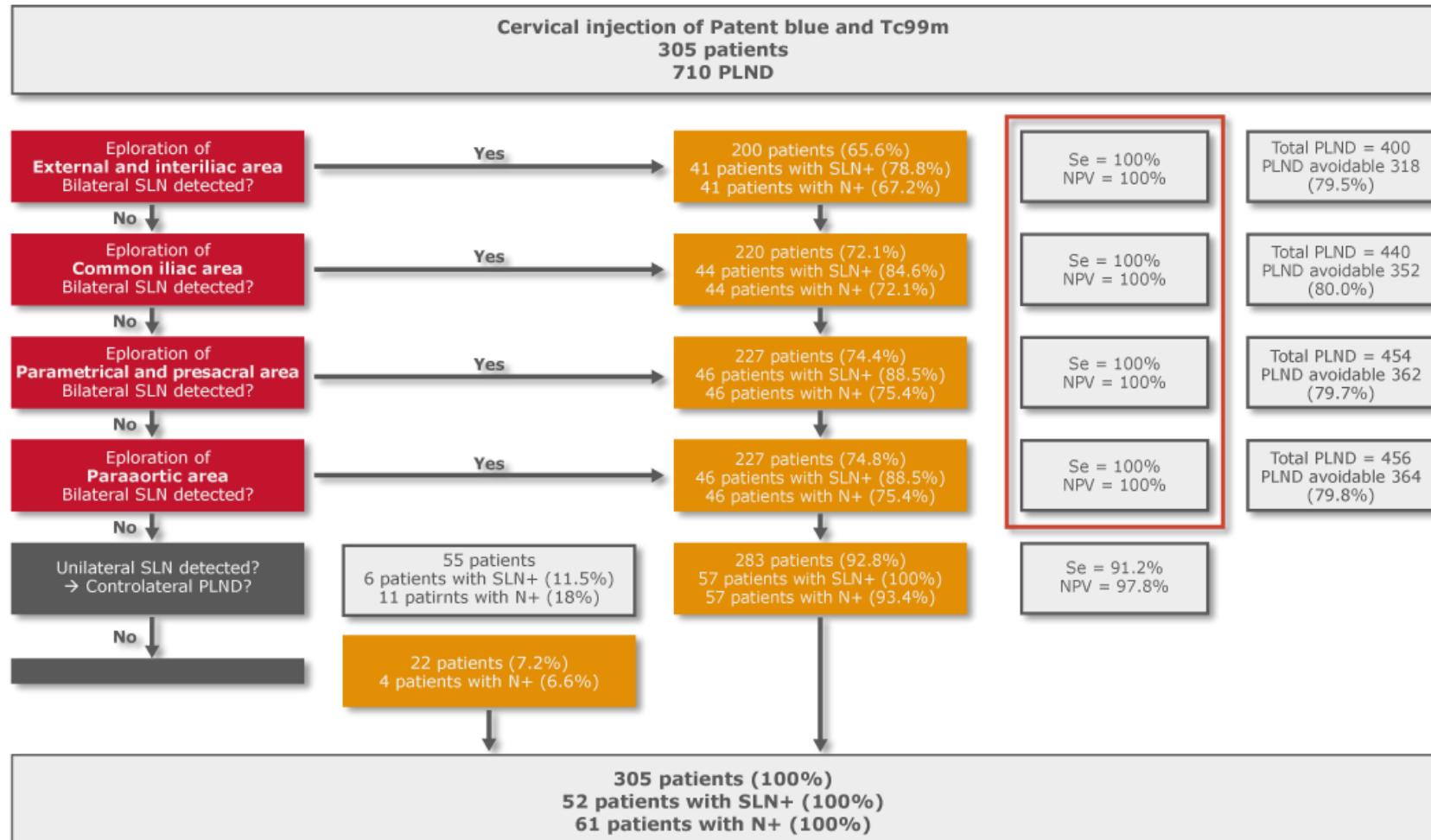
Most of the patients were stage IB1 (86,3%), with squamous cell carcinoma (74,1%) and treated with minimally invasive surgery (91%).

Total Patients: 305

- Patients with SLN+: 52 (17%)
- Patients with node+: 61 (20%)

86% of positive lymph nodes were located at the external/ interiliac area

Results (2/2)



Conclusions

This multicentric evaluation validates the use of a surgical SLN algorithm in early-stage cervical cancer.

In case of bilateral negative SLN, full lymphadenectomy could be omitted (negative predictive value: 100%).

This algorithm permits to identify all patients with nodal spread and may imply a decrease of unjustified PLND.



Detection of mRNA of CDKN2A, MKI67 and TOP2A in liquid-based cytology as biomarker of high-grade lesions of uterine cervix

-- *N. Carreras et al.*

Objectives

The expression of host-cell genes involved in cervical carcinogenesis induced by high-risk human papillomavirus (HR-HPV) may be useful to identify patients harbouring HSIL lesions.

Identifying of HSIL could help to select patients who might benefit from an immediate colposcopy or further treatment.

The aim of the study was to evaluate the performance of mRNA detection of three biomarkers (CDKN2A, MKI67 and TOP2A) in liquid-based cytology to identify high-grade squamous intraepithelial lesions (HSIL).

Methods

Observational prospective study including 250 patients referred to colposcopy that underwent:

1. liquid-based cytology
2. HR-HPV testing;
3. colposcopy, and at least one biopsy'
4. CDKN2A, MKi67 and TOP2A mRNA detection in LBC specimens by reverse transcription and quantitative polymerase chain reaction.

243 (97.2%) samples with adequate material

Results

FIVE STUDY GROUPS WERE IDENTIFIED

1. CONTROL GROUP (n=35) HR-HPV negative Normal/ASC-US cytology Negative biopsy	2. HPV positive group (n=49) HR-HPV positive Normal/ASC-US/LSIL cytology Negative biopsy	3. LSIL GROUP(n=38) HR-HPV positive Normal/ASC-US/LSIL cytology LSIL/CIN1 biopsy	4. HSIL GROUP (n=105) HR-HPV positive HSIL/CIN2-3 biopsy	5. DISCORDANT GROUP (n=17) HR-HPV positive HSIL cytology LSIL/CIN1 biopsy
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ΔCt Mean comparison between study groups

	Control group	HSIL group	p^a
ΔCt TOP2A	4.03 (3.54 – 4.51)	2.61 (2.17 – 3.05)	0.0004
ΔCt MKi67	4.63 (3.94 – 5.32)	2.95 (2.54 – 3.37)	0.0001
ΔCt CDKN2a	0.35 (-0.36 – 1.07)	-1.17 (1.52 – -0.81)	0.0000

Significantly higher expression of the three biomarkers in HSIL group compared to control group (p<0.05)

- TOP2A: sensitivity: 72%, specificity: 66,7%

ΔCt Mean comparison between discordant and HSIL group

	HSIL group	Discordant group	p^b
ΔCt TOP2A	2.61 (2.17 – 3.05)	2.99 (2.22 – 3.76)	0.4988
ΔCt MKi67	2.95 (2.54 – 3.37)	3.57 (2.70 – 4.44)	0.2583
ΔCt CDKN2a	-1.17 (1.52 – -0.81)	-0.97 (-1.92 – -0.22)	0.6780

Patients with discordant results between cytology and biopsy, showed higher expression of all biomarkers compared with the control group (p<0.05)

Conclusions

mRNA detection of CDKN2A, MKi67 and TOP2A in liquid-based cytology samples showed similar sensitivity than Pap-test to identify women with HSIL.

Sexual activity and vaginal functioning in patients with locally advanced cervical cancer following definitive radio-chemotherapy and image-guided adaptive brachytherapy (EMBRACE study)

-- *K. Kirchheimer et al.*

Objectives & Methods

OBJECTIVES

EMBRACE: prospective, observational, multicenter study on image-guided brachytherapy in locally advanced cervical cancer.

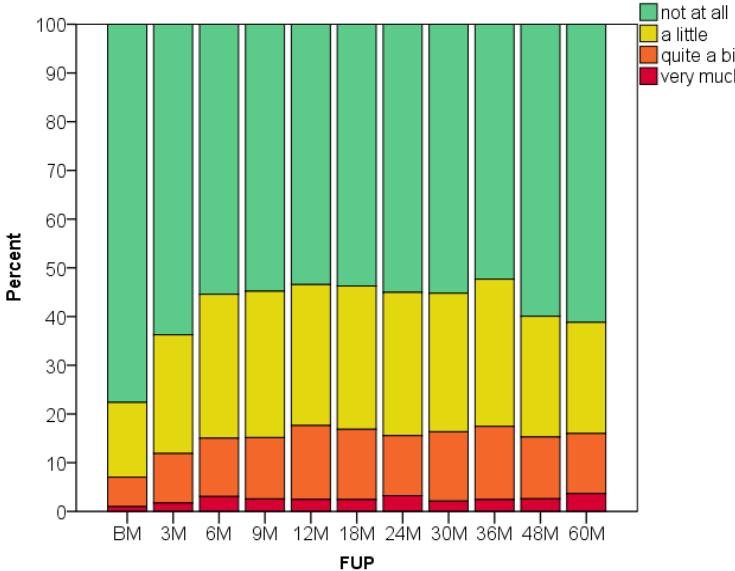
The aim of the current study was to **evaluate the pattern of sexual activity and its associations to sexual/vaginal functioning** within EMBRACE study.

METHODS

Prospective assessment with EORTC quality of life questionnaire CX24 at baseline prior to treatment, every 3 months after treatment 1st year, every 6 months 2nd + 3rd year, yearly thereafter (2008-2015).

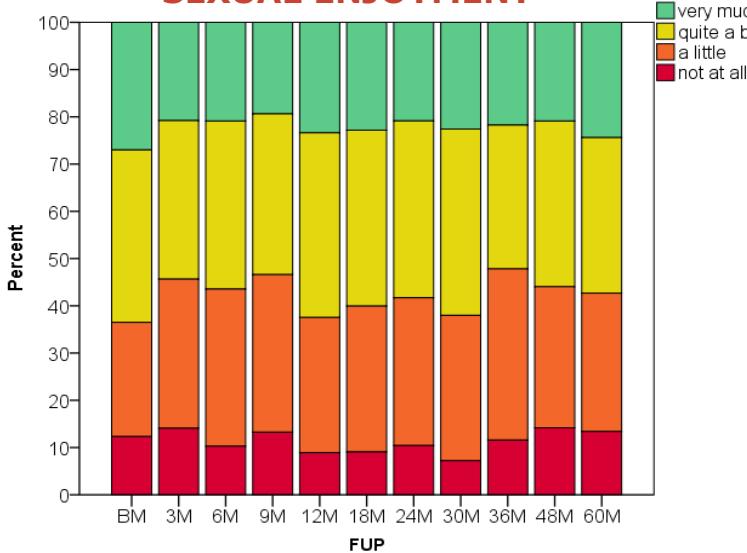
Results

SEXUAL ACTIVITY



- increases after treatment
- reaches a plateau at 6 months.

SEXUAL ENJOYMENT



- 37-48% of patients report to have 'not at all' or 'a little' sexual enjoyment
- no time trends visible.

Pain during intercourse is significantly correlated with vaginal tightening, shortening and dryness.

Vaginal dryness:

- Increase after treatment,
 - No improvement later.

Pain during intercourse:

- Increase after treatment,
 - slightest improvement over time.

Vaginal shortening:

- Steep increase after treatment,
 - No improvement later,
 - "a little" vaginal shortening seems to be gradually increasing.

Vaginal tightening:

- Steep increase after treatment,
 - No improvement later,
 - Reflect fibrotic vaginal changes, irreversible.

Conclusions

- >50% of the women are sexually active after treatment;
- ~1/3 report sexual functioning problems;
- Sexual enjoyment is compromised in ~50% of sexually active patients;
- Treatment-induced vaginal changes (dryness, shortening, tightening) are associated with dyspareunia.

Efforts to prevent vaginal morbidity and provide sexual rehabilitation programs are warranted.

TP53 mutations in cell-free DNA as early marker of therapy response in platinum-resistant ovarian cancer

-- *A. Vanderstichele et al.*

Objectives & Methods

OBJECTIVES

Detecting tumour-specific genetic alterations in cell-free DNA (cfDNA) obtained from cancer patients allows for a quantification of the tumoral fraction, i.e. the circulating tumour DNA (ctDNA).

This hypothesis was tested on cfDNA samples collected in GANNET53 trial investigating the addition of Hsp90-inhibitor ganetespib to standard paclitaxel weekly regimen (P +/-G) in platinum-resistant ovarian cancer (PROC);

- Cohort: 133 patients were randomized (90 P+G vs 43 P);
- Primary endpoint: PFS;
- Results: addition of ganetespib to paclitaxel did NOT improve PFS.

Objectives & Methods

The aim of this study was to explore the predictive role of early negatigation of TP53 mutations in circulating tumour DNA (ctDNA) in outcome / therapy response.

METHODS

- Archival FFPE tissue (central review + somatic TP53 / BRCA sequencing);
- Blood samples for plasma extraction (EDTA) at start and during treatment.

Results

ctDNA was detectable in 64.6% of baseline samples. Baseline CA125 did not differ between cases with and without detectable ctDNA at baseline.

- Detection of ctDNA predicted a **worse overall survival**.
- ctDNA **negative status after 4 weeks** of treatment predicts **better overall survival**;
 - Paclitaxel mono + ctDNA negative: PFS HR 0.65 (0.33-1.29) / OS HR 0.28 (0.16-0.65).
- ctDNA **negative status after 4 weeks** of treatment predicts **better response rate**;
 - ORR 40.5% in ctDNA negative \Leftrightarrow 16.1% in ctDNA positive ($p=0.047$).
- Highest objective response rate (ORR) was in patients where ctDNA was detectable and disappeared.
- Patients, where ctDNA remained or became detectable, had worst ORR.

Conclusions

Quantification of TP53 mutations in cfDNA of platinum-resistant ovarian cancer patients has prognostic value at baseline.

Favorable early changes during treatment may predict therapeutic response (early identification of non-responders).

Prognostic relevance of the molecular classification in high-risk endometrial cancer: Analysis of the PORTEC-3 trial

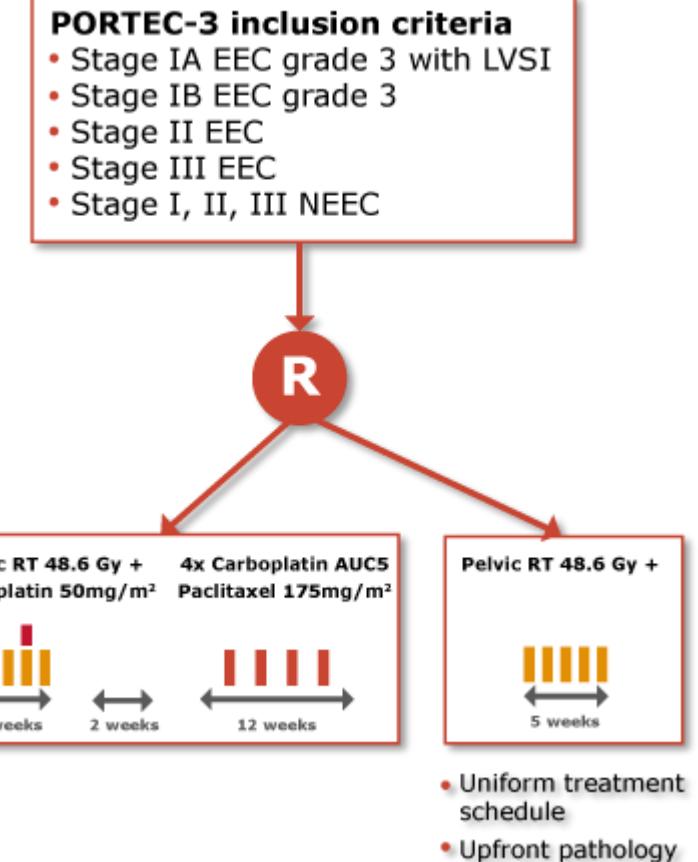
-- *A. Leon-Castillo et al.*

Objectives & Methods

OBJECTIVES

PORTEC-3 trial investigated the benefit of combined adjuvant chemotherapy and radiotherapy versus pelvic radiotherapy alone for women with high-risk endometrial cancer (HREC).

Recent studies have discovered and confirmed four different molecular subclasses in EC, with each having a distinct prognosis; POLE-ultramutated, microsatellite unstable, copy-number low, and copy-number high.



Objectives & Methods

The aim of this study:

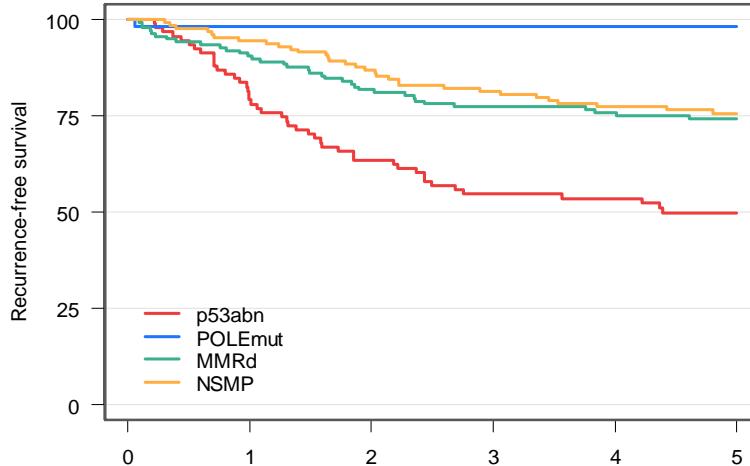
- evaluate the prognostic significance of the molecular classification in HREC using tissues from consenting PORTEC-3 trial participants
- evaluate molecular subclass specific benefit of combined chemotherapy and radiotherapy.

METHODS

- tissue samples obtained from 410 of the 660 participants in the PORTEC-3 trial
- tumours classified into four molecular subgroups of endometrial cancer with prognostic value:
 - 92 (22%) samples were p53 mutant staining (p53abn)
 - 2 (13%) POLE ultramutated (POLEMut)
 - 137 (33%) MMR deficient (MMRd)
 - and 129 (32%) no specific molecular profile (NSMP).
- treatment well balanced between molecular subgroups

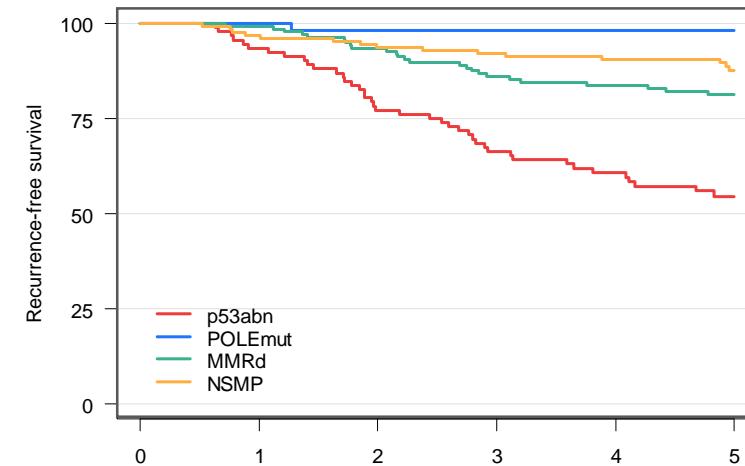
Results

RECURRENCE-FREE SURVIVAL (RFS)



Five-year RFS for patients with *POLE*mut, p53abn, MMRd and NSMP EC was 98%, 50%, 74% and 76%, respectively ($p<0.0001$)

OVERALL SURVIVAL (OS)



OS for patients with *POLE*mut, p53abn, MMRd and NSMP EC was 98%, 55%, 81% and 88% ($p<0.0001$).

- p53abn was the strongest prognostic factor for decreased survival, while pathogenic *POLE* EDM was the strongest favourable factor
- Patients with p53abn HREC had significant benefit of combined adjuvant chemotherapy and radiotherapy (5-year RFS with CTRT 61% versus 37% for RT, log-rank $p=0.015$).

Conclusions

The **molecular classification** provides **better risk stratification** than histopathology alone.

Patients with **POLEmut HREC** have **excellent clinical outcome**, suggesting these should be **classified as low-risk**, independent of other pathologic variables.

P53abn EC is the strongest predictor of poor clinical outcome, and these patients had significant benefit from added chemotherapy.

Molecular characteristics should be incorporated in clinical diagnostics and decision making and future trials should address molecular subgroup-based treatments.

When to stop futile treatment towards end of life in gynaecological cancer patients: A population-based study in Oslo county, Norway

-- *K. Lindemann et al.*

Objectives & Methods

OBJECTIVES

Gynaecological cancer patients have a high symptom burden, especially when it comes to the recurrent setting. By using palliative chemotherapy, only half of the patients experience an improvement in quality of life.

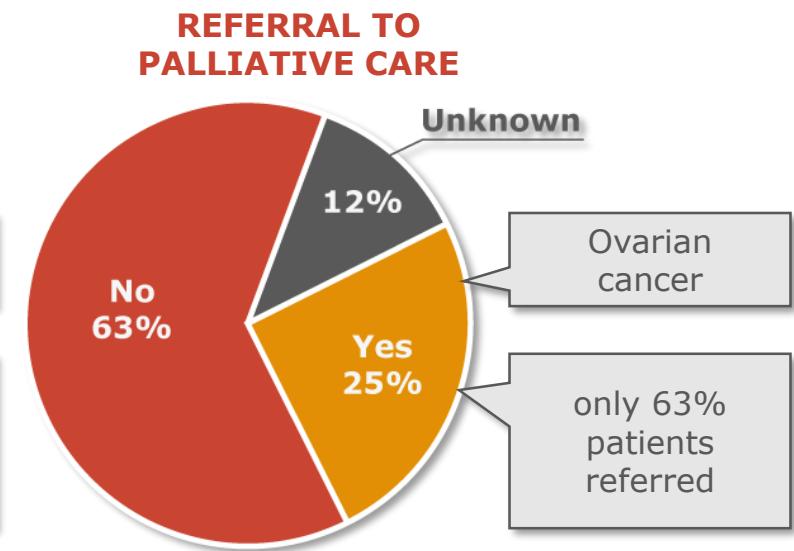
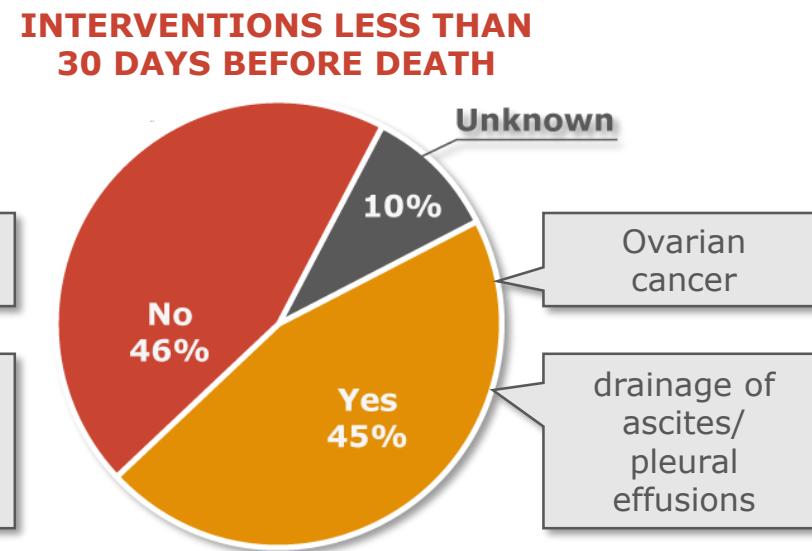
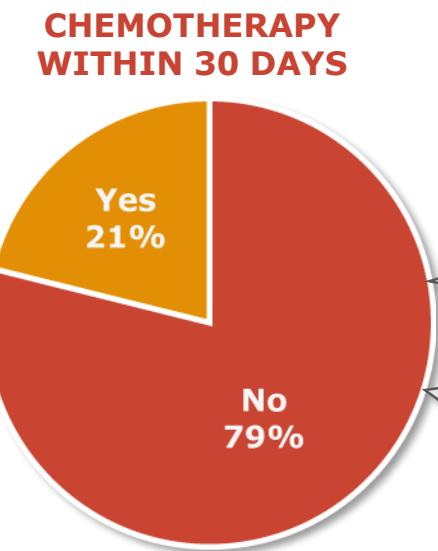
The aim of the study was to evaluate the provided end of life care in patients with gynaecological cancer as well as to identify possible gaps and patterns.

METHODS

- retrospective observational study
- patients who died of gynaecological cancer in Oslo county, Norway, 2015-201

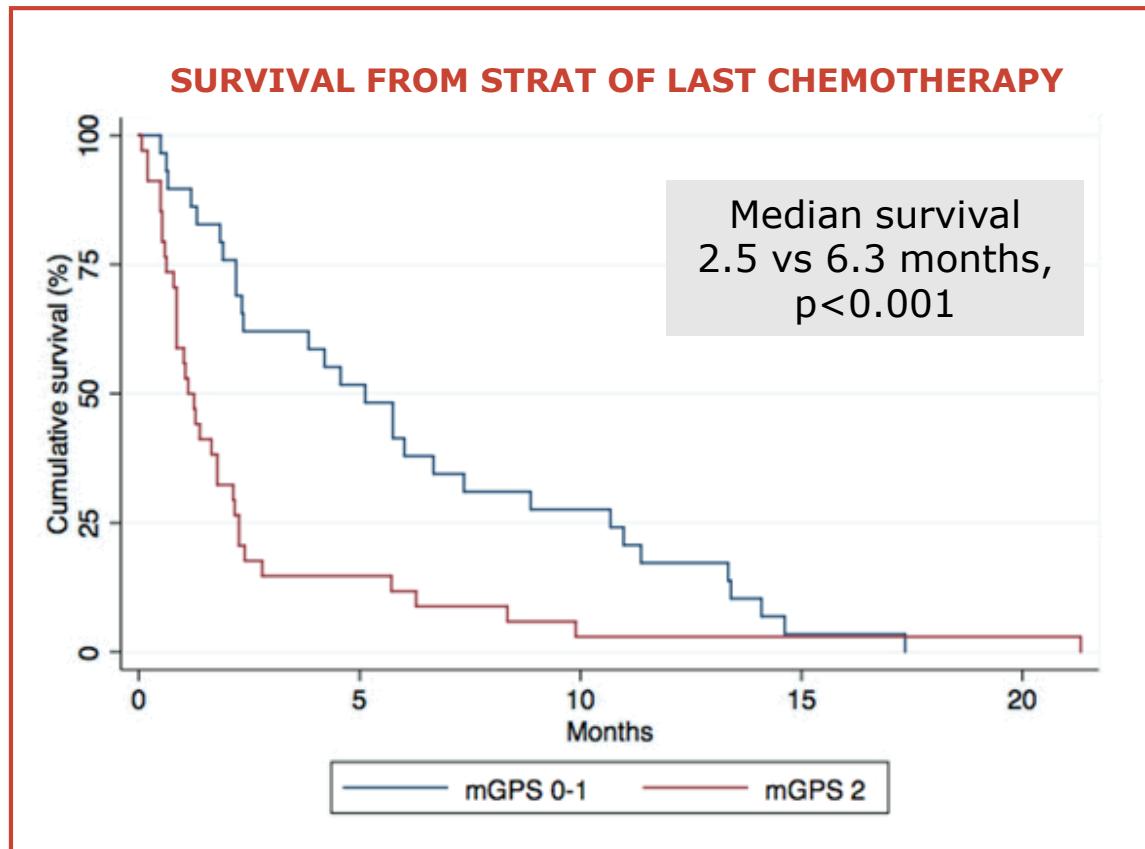
Results (1/2)

- 163 patients; 61% with ovarian-, 23% with endometrial-, 13% with cervical cancer and 3% with other gynaecological cancers.
- 29% patients with ovarian cancer received more than 3 lines of treatment.
- 9-25% of the patients died in nursing homes where no structured palliative care is offered
- Although approximately 60% of patients wish to die at home, only about 10% did so in the end.



Results (2/2)

MODIFIED GLASGOW PROGNOSTIC SCORE (MGPS) AS PROGNOSTIC FACTOR FOR SURVIVAL



	mGPS score
CRP ≤ 10 mg/L and albumin ≥ 35 g/L	0
CRP ≤ 10 mg/L and albumin < 35 g/L	0
CRP > 10 mg/L and albumin < 35 g/L	1
CRP > 10 mg/L and albumin < 35 g/L	2

- The modified Glasgow prognostic score (mGPS), a CRP-albumin-ratio, was evaluated as a possible prognostic score before the start of a palliative chemotherapy. Patients with a higher score had a significantly higher possibility to receive chemotherapy although those were the patients with poorer health status.

Conclusions

All gynaecological cancer patients should be referred early to palliative care to avoid futile treatment at the end of life.

The mGPS seems to be a useful tool to evaluate whether the patients will benefit of a palliative chemotherapy, or not.

The patients needs and expectations should be taken into consideration when it comes to making decisions about end of life treatment to provide a good end of life care.

List of studies (1/5)

RADIOTHERAPY INSTEAD OF INGUINOFEMORAL LYMPHADENECTOMY IN VULVAR CANCER PATIENTS WITH A METASTATIC SENTINEL NODE: RESULTS OF GROINSS-V II

MHM Oonk, B Slomovitz, P Baldwin, H van Doorn, J van der Velden, J de Hullu, B Slangen, K Gaarenstroom, I Vergote, M Brannstrom, E van Dorst, W van Driel, R Hermans, D Nunns, M Widschwendter, D Nugent, C Holland, P DiSilvestro, A Sharma, R Mannel, D Boll, A Covens, D Cibula, D Provencher, D Luesley, P Ellis, T Duncan, M Tjiong, D Cruickshank, P Kjolhede, C Levenback, J Bouda, K Kieser, I Runnebaum, C Palle, N Spirtos, D O'Malley, M Leitao, M Geller, K Tamussino, K Dhar, D Tobias, C Borgfeldt, T Myers, J Lea, J Bailey, P Persson, B Monk, C Creutzberg, A van der Zee

ENHANCED RECOVERY AFTER SURGERY IN ADVANCED OVARIAN CANCER: A PROSPECTIVE RANDOMIZED TRIAL

JL Sánchez-Iglesias, M Carbonell Socias, A Pérez Benavente, NR Gómez-Hidalgo, S Manrique Muñoz, M García Gorriz, R Burgos Peláez, H Segurola Gurrutxaga, P Gutierrez Barceló, C Pérez Barragan, M Pamies Serrano, S Serrano Castro, AA Scaillet Hopuberechts, AM Álvarez López, D Monroy Parada, Y Cossío Gil, A Gil-Moreno

OVARIAN CANCER DETECTION COMBINING AN INNOVATIVE CATHETER FOR UTERINE AND TUBAL LAVAGE WITH ULTRA-SENSITIVE TP53 SEQUENCING

P Speiser, E Maritschnegg, F Heitz, N Pecha, J Bouda, F Trillsch, C Grimm, A Vanderstichele, C Agreiter, P Harter, E Obermayr, I Vergote, R Zeillinger, JJ Salk, RA Risques, AGO Austria

DOSE-DENSE NEOADJUVANT CHEMOTHERAPY FOLLOWED BY SENTINEL NODE MAPPING AND LAPAROSCOPIC PELVIC LYMPHADENECTOMY AND SIMPLE TRACHELECTOMY IN CERVICAL CANCER: UPDATE RESULTS

H Robova, L Rob, MJ Halaska, M Hruda, T Pichlik, J Drozenova, P Skapa

List of studies (2/5)

24 UTERUS-11 STUDY: A RANDOMIZED CLINICAL TRIAL ON SURGICAL STAGING VERSUS CT-STAGING PRIOR TO PRIMARY CHEMORADIATION IN PATIENTS WITH FIGO2009 STAGES IIB-IVA CERVICAL CANCER

S Marnitz-Schulze, A Tsunoda, P Martus, MV Vieira, R Affonso, JS Nunes, V Budach, A Schneider, H Hertel, A Mustea, J Sehouli, A Plaikner, A Ebert, C Köhler

SUCCOR STUDY. AN INTERNATIONAL EUROPEAN COHORT OBSERVATIONAL STUDY COMPARING MINIMALLY INVASIVE SURGERY VERSUS OPEN ABDOMINAL RADICAL HYSTERECTOMY IN PATIENTS WITH STAGE IB1 (FIGO 2009, <4 CM) CERVICAL CANCER OPERATED IN 2013–2014

L Chiva, V Zanagnolo, A Kucukmetin, G Chakalova, F Raspagliesi, F Narducci, T Toptas, M Meydanli, A Fagotti, D Cibula, D Wydra, R Póka, R Jach, M Tavares, K Tamussino, D Haidopoulos, J Ponce, I Berlev, F Roldán, S Domingo, I Zapardiel, E Goncalves, M Malzoni, O Arencibia, K Kukk, H Haller, G Vorgias, F Ghezzi, F Guyon, S Herrero, J Haesen, JG Feron, J Minguez, E Chacon, D Vazquez, T Castellanos, J Arevalo, N Martin Calvo, JL Alcazar

PHASE III PAOLA-1/ENGOT-OV25 TRIAL: OLAPARIB PLUS BEVACIZUMAB AS MAINTENANCE THERAPY IN PATIENTS WITH NEWLY DIAGNOSED, ADVANCED OVARIAN CANCER TREATED WITH PLATINUM-BASED CHEMOTHERAPY PLUS BEVACIZUMAB

P Harter, MA Mouret-Reynier, S Pignata, C Cropet, A González-Martin, G Bogner, K Fujiwara, I Vergote, N Colombo, J Mäenpää, A Floquet, A El-Balat, D Lorusso, EM Guerra Alia, M Fabbro, B Schmalfeldt, AC Hardy Blessard, I Runnebaum, E Pujade-Lauraine, I Ray-Coquard

RESULTS FROM NEOADJUVANT CHEMOTHERAPY FOLLOWED BY SURGERY COMPARED TO CHEMORADIATION FOR STAGE IB2-IIIB CERVICAL CANCER: EORTC55994

S Greggi, G Kenter, I Vergote, D Katsaros, J Kobierski, LFAG Massuger, PA van Doorn, F Landoni, J van de Velden, N Reed, C Coens, I van Luijk, P Ottevanger, N Colombo, A Casado Herraez

List of studies (3/5)

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