IGCS 2023
Annual Global Meeting
SEOUL

IGCS 2023 Abstracts:
Oral Presentations (Plenary Sessions)

Oral abstract presentations are included in the below sessions.
The sessions will be recorded for on-demand viewing via the IGCS 360 Educational Portal.

Plenary 01: Oral Abstract Presentations
Sunday, November 5, 2023, 9:00 – 10:30 AM
Auditorium

Plenary 03: Oral Abstract Presentations – Ovarian Cancer
Tuesday, November 7, 2023, 8:30 – 9:30 AM
Auditorium

PO001 / #381

Topic: ***AS03. Cervical Cancer***

IS MINIMALLY INVASIVE SURGERY SAFE FOR CERVICAL CANCER PATIENTS WITH A DIAMETER OF LESS THAN 2 CM? (MISAFE): GYNECOLOGIC ONCOLOGY RESEARCH INVESTIGATORS COLLBORATION STUDY (GORILLA-1003)

PLENARY 01: ORAL ABSTRACT PRESENTATIONS

Tae-Wook Kong[1], Jeeyeon Kim[1], Joo-Hyuk Son[1], A Jin Lee[2], Eun Jung Yang[2], Seung-Hyuk Shim[2], Nam Kyeong Kim[3], Yeorae Kim[3], Dong Hoon Suh[4], Dong Won Hwang[5], Soo Jin Park[5], Hee Seung Kim[5], Yoo Young Lee[6], Ji Geun Yoo[7], Sung Jong Lee[8], Suk-Joon Chang[1]
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Introduction: To identify clinicopathologic factors associated with disease recurrence for patients with 2018 FIGO stage IA with lymphovascular invasion (LVSI) to IB1 cervical cancer treated with minimally invasive surgery (MIS).

Methods: A total of 722 early-stage cervical cancer patients between January 2010 and February 2021 were identified. All possible clinicopathologic factors related to disease recurrence were analyzed. Disease-free survival (DFS) and overall survival (OS) rates were estimated using the Kaplan-Meier method. To determine prognostic factors for DFS, a Cox proportional hazard regression model was used.

Results: Of 722 patients, 49 (6.8%) showed disease recurrence (37 pelvis, 1 para-aortic lymph node, and 11 peritoneum). Five-year DFS and OS rates were 90.7% and 98.1%, respectively. In multivariate analysis, risk factors associated with disease recurrence were residual disease in the remaining cervix (OR, 4.693; 95% CI, 3.719 – 5.667; p = 0.002), intracorporeal colpotomy (OR, 2.960; 95% CI, 1.703 – 3.161; p = 0.017), and positive resection margin (OR, 3.415; 95% CI, 2.351 – 4.479; p = 0.024). The non-conization group had a higher percentage of stage IB1 (77.4% vs. 64.6%; p = 0.004) and larger tumor (16 mm vs. 10 mm; p < 0.001) than the conization group. Intracorporeal colpotomy and residual disease in the remaining cervix were independent variables associated with disease recurrence in patients undergoing MIS following conization.

Conclusion/Implications: During MIS, early-stage cervical cancer patients with tumors less than 2 cm can be vulnerable to peritoneal recurrences. Preoperative conization itself may not lower the disease recurrence in early-stage cervical cancer patients undergoing MIS.

PO002 / #156

Topic: ***AS03. Cervical Cancer***

EFFICACY AND SAFETY RESULTS FROM SKYSCRAPER-04: AN OPEN-LABEL RANDOMIZED PHASE 2 TRIAL OF TIRAGOLUMAB PLUS ATEZOLIZUMAB FOR PD-L1-POSITIVE RECURRENT CERVICAL CANCER

PLENARY 01: ORAL ABSTRACT PRESENTATIONS

Ritu Salani[1], Bradley Monk[2], Yong-Man Kim[3], Sharad Ghamande[4], Shaundra Hall[5], Domenica Lorusso[6], Lisa Barraclough[7], Lucy Gilbert[8], Adrián Guzmán Ramírez[9], Chien-Hsing Lu[10], Dominique Berton[11], Nicoletta Colombo[12], Youyou Hu[13], Venkatesh Krishnan[14], Yuning Feng[15], Nicole Kim[16], Marcela Castro[16], Yvonne Lin[16], Mary Mccormack[17]
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Introduction: Immune checkpoint inhibitors are active in advanced cervical cancer. SKYSCRAPER-04 (NCT04300647) evaluated dual blockade with tiragolumab (anti-TIGIT) and atezolizumab (anti-PD-L1) (tira+atezo), an approach hypothesized to overcome immune suppression and restore immune response.

Methods: Eligible patients had measurable (per investigator assessment) PD-L1-positive recurrent/persistent cervical cancer after 1-2 prior chemotherapy lines (including ≥1 platinum-based regimen). Patients were randomized 3:1 to atezolizumab 1200mg with or without tiragolumab 600mg q3w until unacceptable toxicity/progression. Crossover to tira+atezo was permitted after unequivocal progression during single-agent atezolizumab. Stratification factors were ECOG PS, prior (chemo)radiotherapy, and disease status. The primary endpoint was independent review committee (IRC)-assessed confirmed objective response rate (ORR) per RECIST v1.1 in all treated patients randomized to tira+atezo. An ORR ≥21% (1-sample z-test p≤0.0245) was required to demonstrate statistically significant improvement versus a 14.6% historical reference [Chung, 2019]. Secondary endpoints included IRC-assessed progression-free survival, overall survival, and pre-crossover safety.

Results: Prior therapy in 171 treated patients included bevacizumab in 35%, (chemo)radiotherapy in 80%, and paclitaxel in 93%. IRC-assessed ORRs were 19.0% with tira+atezo and 15.6% with atezo alone (Table). In post hoc exploratory analyses of patients with measurable disease per IRC assessment, ORRs were 21.6% (tira+atezo) and 15.8% (atezo). There were no new safety signals. In a post hoc

follow-up analysis, 15% of patients remained on treatment and 15/45 initially randomized to atezo had crossed over to tira+atezo.

Table. Outcomes for pts with PD-L1-positive (TAP ≥5%) recurrent cervical cancer receiving tiragolumab + atezolizumab or atezolizumab alone

Endpoint	**Tira+atezo (n=126)**	**Atezo (n=45)**
Primary analysis (data cutoff Dec 8, 2021; median follow-up 8.5 months)		
IRC-assessed ORR, % (95% CI)	19.0 (12.6–27.0)	15.6 (6.5–29.5)
PD-L1$_{high}$ subgroup (n=105)	25.0 (15.8–36.3)	20.7 (8.0–39.7)
PD-L1$_{low}$ subgroup (n=66)	10.0 (3.3–21.8)	6.3 (0.2–30.2)
IRC-determined measurable disease subgroup (n=149)*	21.6 (14.4–30.4)	15.8 (6.0–31.3)
Median IRC-assessed PFS, months (95% CI)	2.8 (1.7–4.1)	1.9 (1.5–3.0)
Grade 3/4 adverse events, %	44	31
Grade ≥3 adverse events of special interest, %	8	11
Updated OS analysis (data cutoff Jun 30, 2022; median follow-up 10.4 months)		
Median OS, months (95% CI)	11.1 (9.6–14.5)	10.6 (6.9–13.8)

CI = confidence interval; OS = overall survival; PD-L1$_{high}$ = TAP ≥10%; PD-L1$_{low}$ = TAP 5–<10%; PFS = progression-free survival; TAP = PD-L1 tumor area positivity by SP263.
*Post hoc exploratory analysis.

Conclusion/Implications: The ORR with tira+atezo was numerically but not significantly higher than the historical benchmark. This is the first reported phase 2 cervical cancer trial targeting TIGIT and PD-L1 concurrently.

PO003 / #269

Topic: ***AS11. Ovarian Cancer***

IGNITE: A PHASE II SIGNAL-SEEKING TRIAL OF ADAVOSERTIB TARGETING RECURRENT HIGH GRADE SEROUS OVARIAN CANCER WITH CYCLIN E1 OVER-EXPRESSION WITH AND WITHOUT GENE AMPLIFICATION

PLENARY 01: ORAL ABSTRACT PRESENTATIONS

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Introduction: Cyclin E1 amplification and over-expression is associated with platinum resistance in high grade serous ovarian cancer (HGSC), and may predict response to WEE1 inhibition. Adavosertib, a WEE1 inhibitor, has activity in unselected women with recurrent ovarian and endometrial cancer. We aimed to evaluate the efficacy of adavosertib in women with recurrent platinum resistant HGSC (PR-HGSC) with cyclin E1 over-expression, with and without gene amplification.

Methods: IGNITE is a multicentre, Phase 2 trial with 2 cohorts of PR-HGSC patients. Cohort 1 were cyclin E1 amplified (≥8 copies by FISH) and over-expressed (H-score>50), and Cohort 2 were non-amplified. Adavosertib 300mg PO was given daily on days 1-5 and 8-12 q21-day cycle (dose was reduced to 200mg after n=71 due to safety concerns). The primary endpoint was clinical benefit (CB) defined as no progression for ≥ 18 weeks. Here we present the 18-week CB rate (CBR) and overall response rate (ORR), with data cut-off of Apr-2023.

Results: From Jan-2020 to Oct-2022, 80 patients (Cohort 1 n=21; Cohort 2 n=59) were accrued. Median age was 64 years (range 42-84), 83% had ≥2 prior chemotherapy lines. For Cohort 1, ORR=38% and CBR=53%. For Cohort 2, ORR=45% and CBR=48%. Treatment related adverse events occurred in 78 patients (97%). Dose reduction was required in 36 (45%) patients, mostly for neutropenia or diarrhoea. Four patients (5%) died from treatment (sepsis n=3; thrombocytopenia n=1).

Table 1: Response and clinical benefit (amplified – all patients)

Response	Response evaluable patients (n = 21)	RECIST measurable patients (n = 20)
CR	0	0
PR	7 (33%)	7 (35%)
CA125 50% Response	1 (5%)	0
SD	7 (33%)	7 (35%)
No CA-125 response and no PD	0	0
PD	6 (29%)	6 (30%)
OR (CR/PR/CA-125 50% response)	**8/21 (38% [18, 62])**	**7/20 (35% [15, 59])**
CB (No PD>18 weeks)	**10/19[a] (53% [29, 76])**	**10/19 (53% [29, 76])**

[a]Two patients were not considered evaluable for clinical benefit (discontinued treatment due to toxicity n=1; withdrew consent prior to week 18 n=1)

Table 2: Response and clinical benefit (non-amplified – all patients)

Response	Response evaluable patients (n = 58)	RECIST measurable patients (n = 49)
CR	3 (5%)	3 (6%)
PR	18 (31%)	18 (37%)
CA125 50% Response	5 (9%)	0
SD	16 (28%)	16 (33%)
No CA-125 response and no PD	4 (7%)	0
PD	12 (21%)	12 (24%)
OR (CR/PR/CA-125 50% response)	**26/58 (45% [32, 58])**	**21/49 (43% [29, 58])**
CB (No PD>18 weeks)	**26/54[a] (48% [34, 62])**	**23/46 (50% [35, 65])**

[a]Four patients were considered not evaluable for clinical benefit (Withdrew consent n=2; missing data n=1; discontinued treatment prior to week 18 per SMC recommendation, no further tumour assessment n=1)

Conclusion/Implications: Adavosertib demonstrated activity in biomarker selected patients with PR-HGSC. Study accrual was halted early due to concern regarding rates of myelotoxicity.

PO008 / #393

Topic: ***AS11. Ovarian Cancer***

TIMED ADOPTIVE T-CELL THERAPY DURING CHEMOTHERAPY IN PLATINUM SENSITIVE RECURRENT EPITHELIAL OVARIAN CANCER, THE OVACURE PHASE I/II TRIAL.

PLENARY 03: ORAL ABSTRACT PRESENTATIONS – OVARIAN CANCER

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Introduction: T-cell infiltration correlates with epithelial ovarian cancer (EOC) survival, suggesting that EOC may be sensitive to ACT with autologous TIL. Carboplatin-paclitaxel (CP) chemotherapy lowers tumor induced immune-suppressive myeloid-cells, thereby creating a window-of-opportunity for TILs. IFNα may support the TIL.

Methods: This phase I/II OVACURE trial (NCT04072263) studied the feasibility and safety of TIL during CP +/- IFNα in patients with recurrent platinum-sensitive EOC. Sixteen patients were enrolled. Patients received CP iv q3 weeks, 6x and TIL iv 2 weeks after the 2nd, 3rd and 4th CP +/- IFNα 12 weeks around the TIL infusion. CP +/- IFNα were used for lymphodepletion instead of IL-2. Patients who received 3 TIL cycles were evaluable. Secondary, signs of activity, immunomodulation, and T-cell reactivity were studied.

Results: Fourteen patients were evaluable. Median age: 63 years (29-77), 13 HGSOC and 1 LGMOC. TIL could successfully be cultured for all patients. Addition of TIL during CP did not add toxicity, while additional IFNα resulted in grade 3 thrombocytopenia in the first 2 patients. Therefore, it was decided to continue treatment without IFNα. CP reduced plasma IL-6 levels and circulating myeloid-cell numbers. The optimal myeloid/lymphocyte ratio reduction was obtained 1-2 weeks after the 2nd CP. Interestingly, the platinum-free interval (PFI) exceeded the previous PFI after similar CP in 2 patients, including an ongoing PFI which increased from 8 to currently 43+ months.

Conclusion/Implications: Combined treatment with CP chemotherapy and timed TIL did not increase toxicity and may result in clinical benefit for patients with EOC.

PO009 / #424

Topic: ***AS11. Ovarian Cancer***

INNOVATIVE ACADEMIC HOMOLOGOUS RECOMBINATION DEFICIENCY TESTS AVAILABLE IN ADVANCED OVARIAN CANCER: THE EUROPEAN ENGOT INITIATIVE

PLENARY 03: ORAL ABSTRACT PRESENTATIONS – OVARIAN CANCER

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Introduction: Recently the PAOLA-1/ENGOT-ov25 phase-3 study (Ray-Coquard ESMO-2022) showed that the addition of olaparib maintenance to 1st-line platinum-based therapy and bevacizumab improved survival of advanced ovarian cancer (AOC) patients with HRD positive tumors independently of BRCA status (Myriad myChoice test). The aim of the European ENGOT initiative was to evaluate various academic HRD assays on PAOLA-1 tumor samples.

Methods: The novel HRD tests were initially assessed on 85 samples from PAOLA-1 BRCA-wild-type patients and results were correlated with Myriad test. Subsequently, >350 PAOLA-1 samples selected on the basis of tumor DNA availability were tested. Statistics were performed independently (v26.0-SPSS). The ability of each test to predict 1st-line olaparib maintenance efficacy versus placebo was evaluated on PAOLA-1 patient progression-free survival according to HRD/BRCA status.

Results: From 12/2019 to 09/2022 a total of 8 European academic laboratories representing 6 countries completed the clinical validation process on the PAOLA-1 samples. Despite the variety of methodological approaches and some differences in the distribution of HRD status, all of tests were clinically validated (Table 1) and did not differ significantly from Myriad test results. Progression-free survival hazard ratio

between olaparib and placebo arms depending on the assay was between 0.30 and 0.50 for HRD positive patients and between 0.88 and 1.15 for HRD negative patients.

Table 1. HRD clinically validated tests from 8 academic laboratories and the reference myChoice Myriad HRD test

HRD assay	Affiliation	Technical sum-up	HRDpos[1]/total No (%)	HRDpos[1] & BRCAwt[2] 0.35<HR of PFS<0.55
ICH	Humanitas University, Milano	SCNA[3] and SNV[4] (378 genes)	228/399 (57.1)	yes
Geneva	Geneva University Hospitals	Oncoscan SNP[5] assay	252/469 (53.7)	yes
ShallowHRDv2	Institut Curie, Paris	Low coverage WGS[6]	228/449 (50.7)	yes
GIScar	Centre F. Baclesse, Caen	Instability score: 127 gene panel	258/469 (55.0)	yes
Leuven HRD	Catholic University, Leuven	NGS[7] SNP + gene panel	254/468 (54)	yes
GIInger	Centre Léon Berard, Lyon	Low coverage WGS + 28 gene panel	266/469 (56.7)	yes
BRCA-like	Köln University and Netherlands Cancer Institute	Low coverage WGS	298/469 (63.5)	yes
NOGGO GIS	Berlin La Charité and Hamburg University	NGS SNP 57 gene panel	188/383 (49.1)	yes
MyChoice HRD CDx	Myriad Genetics	BRCA1/2 and GIS[8]	242/469 (51.6)	yes

[1]HRDpos: Test HRD positive; [2]BRCAwt: BRCA wild type; [3]SCNA: Somatic Copy Number Alteration; [4]SNV: Single Nucleotide Variant; [5]SNP: Single Nucleotide Polymorphism;[6]WGS: Whole Genome Sequencing; [7]NGS: Next-Generation Sequencing; [8]GIS : Genomic Instability Score

Conclusion/Implications: The ENGOT HRD initiative is a unique collaboration of European academic laboratories involved in gynaecology oncology translational research. A total of 8 innovative HRD tests achieved a clinical validation from AOC tumor samples of the phase 3 PAOLA-1 study.

PO010 / #673

Topic: ***AS11. Ovarian Cancer***

A SINGLE-ARM, PHASE II STUDY OF NIRAPARIB AND BEVACIZUMAB MAINTENANCE IN PATIENTS WITH PLATINUM-SENSITIVE, RECURRENT OVARIAN CANCER PREVIOUSLY TREATED WITH A PARP INHIBITOR (KGOG 3056/NIRVANA-R)

PLENARY 03: ORAL ABSTRACT PRESENTATIONS – OVARIAN CANCER

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Introduction: The aim of NIRVANA-R trial is to investigate the efficacy of niraparib in combination with bevacizumab as a maintenance therapy in platinum-sensitive ovarian cancer patients who were previously treated with a PARPi. Here, we report the results from first stage of NIRVANA-R.

Methods: This study included patients with platinum-sensitive recurrent ovarian cancer who received at least 2 previous courses of platinum- containing therapy and had been treated with a PARPi. Patients who had responded to the last platinum regimen were eligible to participate in this study. Forty-four patients will be recruited. All enrolled patients are treated with niraparib and bevacizumab for maintenance therapy until disease progression. The primary endpoint of the study is 6-month progression-free survival (PFS) rate. A Simon 2-stage design was utilized. Target accrual was 22 patients in the first stage; ≥10 patients with progressive disease within 6 months was required to proceed to second stage.

Results: Thirty three of 44 planned patients have been enrolled. Median age was ( ) years old, high grade serous ( ). Median prior lines of therapy ( ); prior bevacizumab ( ). Of the 22 patients from 1st stage, 8 had progressived disease within 6 months. The efficacy boundary to proceed to 2nd stage was met. Data will be updated at the late breaking abstract deadline.

Conclusion/Implications: Our findings indicate encouraging safety and activity of niraparib + bevacizumab as a maintenance therapy in platinum-sensitive ovarian cancer patients who were previously treated with a PARPi. Complete interim analysis results will be reported.

PO013 / #435

Topic: ***AS11. Ovarian Cancer***

ROLE OF LYMPHADENECTOMY (LND) IN ADVANCED OVARIAN CANCER (OC) –A SUBGROUP ANALYSIS OF THE PATIENTS EXCLUDED FROM THE ORIGINAL LION TRIAL (THE CHARITÉ COHORT)

PLENARY 03: ORAL ABSTRACT PRESENTATIONS – OVARIAN CANCER

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Introduction: The results of the prospective randomized phase-III LION-trial failed to demonstrate a therapeutic benefit from LND in tumor-free operated advanced OC patients with macroscopically normal appearing LN. Patients were randomized intraoperatively with exclusion of those thought by the surgeon not to be fully operable or with suspicious/bulky LN by inspection or palpation. We wished to address the surgical and survival outcomes of this excluded group in a single center.

Methods: This is a monocentric analysis in a tertiary ESGO-accredited center of excellence for OC. A total of 202 patients were screened for the original study; 120 were excluded, and 82 included in the final LION analysis. Excluded cases were retrospectively analyzed according to the same endpoints (PFS and OS) of the LION-trial with a subsequent comparison analysis.

Results: Overall, 195 patients were included in the present analysis. Rate of CR was with 45% significantly lower in the intraoperatively excluded patients vs the tumor-free operated patients of the original LION analysis. This had a significantly negative impact on OS and PFS. Only 60% of the screening failed patients had histologically positive LN in final pathology. There was no significant difference in PFS or OS between the tumor-free operated screening failed patients versus those randomized, regardless of their histological LN-status and whether an LND was performed.

Conclusion/Implications: Our findings confirm the lack of therapeutic LND in advanced OC even in patients with suspicious LN. Non-tumor-free operated patients had worse outcome. We demonstrated that intraoperative LN evaluation by the surgeon is subjective and inaccurate.

PO014 / #364

Topic: ***AS11. Ovarian Cancer***

LAPAROSCOPIC CYTOREDUCTION AFTER NEOADJUVANT CHEMOTHERAPY (LANCE): FEASIBILITY PHASE OF A RANDOMIZED TRIAL

PLENARY 03: ORAL ABSTRACT PRESENTATIONS – OVARIAN CANCER

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Introduction: In patients who respond to neoadjuvant chemotherapy (NACT) for advanced-stage epithelial ovarian cancer (EOC), minimally invasive surgery (MIS) may reduce the morbidity of surgery. Studies evaluating oncologic outcomes of minimally invasive interval cytoreductive surgery are largely retrospective.

Methods: LANCE is a prospective, multicenter, international, randomized trial evaluating whether MIS is non-inferior to laparotomy in terms of disease-free survival, among patients with stage IIIC and IV EOC with normalization of CA125 after 3-4 cycles of NACT. The planned 100 patients were enrolled in a lead-in phase to assess the feasibility of the trial with respect to cross-over among those assigned to MIS, complete gross resection, and recruitment. Patients were randomized (1:1) to undergo open or MIS (laparoscopic or robotic) surgery. Surgeons applied maximal effort to resect all visible tumor, conversion to open surgery was performed when necessary to attain complete resection.

Results: From September 2020-February 2023, 100 patients were randomized (51 open, 49 MIS). The mean age was 62 years, 67% had stage IIIC, and 54% received 3 cycles of NACT. Six patients randomized to MIS (12.2%;95%CI: 4.6-24.8%) underwent conversion to open surgery. Surgeons achieved complete gross resection in 87.5% (95%CI: 74.8-95.3%) and 83% (95%CI: 69.2-92.4%) of patients assigned to MIS and open (p=0.6). There were three (6.3%) intraoperative complications in the MIS group and three (6.4%) in the open group. Two patients (4.1%) in the MIS group experienced grade 4-5 adverse events following

surgery.

Table 1: Demographic and clinical characteristics (n = 100)

	OPEN (n = 51)		Minimally Invasive (n = 49)	
Characteristic	**N**	**%**	**N**	**%**
Age (Years)				
Mean (SD)	63 (10.2)		61.4 (9.5)	
Ethnicity				
Hispanic or Latino	14	29.1	18	36.7
Not Hispanic or Latino	34	70.8	31	63.3
Missing or unknown	1		0	
Race				
White or Caucasian	46	90.2	44	89.8
Black or African American	3	5.9	0	0
Asian	1	1.9	3	6.1
Other	1	1.9	2	4.1
Disease primary site				
Ovary	40	78.4	43	87.8
Fallopian tube	2	3.9	0	0
Peritoneum	9	17.6	6	12.2
BRCA status				
Negative	25	75.8	25	73.5
BRCA1	5	15.1	3	8.8
BRCA2	3	9.1	6	17.6
Unknown/Missing	18		15	
Stage				
IIIC	34	66.7	33	67.3
IV	17	33.3	16	32.6
HIPEC				
No	37	78.7	39	81.2
Yes	10	21.3	9	18.7
Missing or unknown	4		1	
Residual disease				
R0	39	83	42	87.5
< 5mm	3	6.4	3	6.2
>5 - 10 mm	3	6.4	3	6.2
> 1cm	2	4.3	0	0
Missing or unknown	4		1	
Intraoperative Complication				
No Complications	44	93.6	45	93.7
EBL > 2000 ml	0	0	1	2.1
Vascular Injury	0	0	1	2.1
Organ Injury	3	6.4	1	2.1
Missing or unknown	4		1	

Conclusion/Implications: Evaluation of MIS interval cytoreductive surgery is feasible, enrollment is ongoing in a definitive trial.