Impact of fertility preservation on ovarian cancer: clinical analysis and current understandings in Asia

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Introduction

35 y.o. female, Gravida 0 PMH: Endometriotic cyst of the right ovary

HPI: Laparotomy for the enlarged right ovarian cyst and emerged nodule

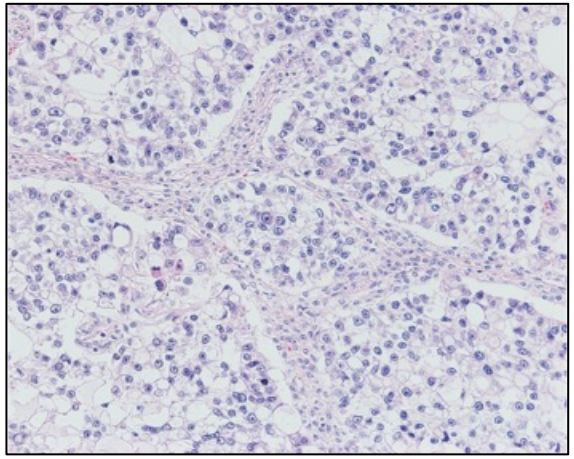
RSO + Omentectomy + Lymph node biopsy

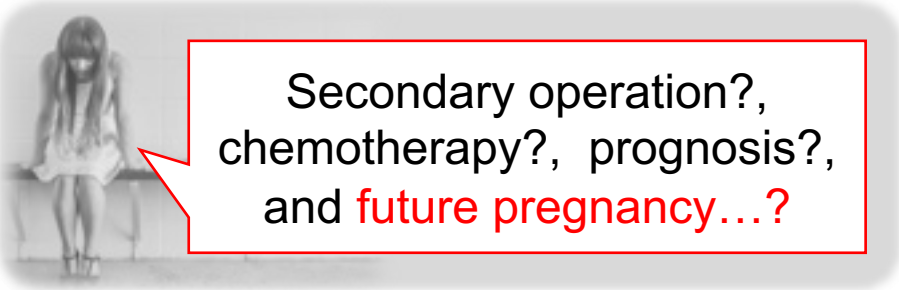
(intraoperative micro-rupture, frozen section: adenocarcinoma)

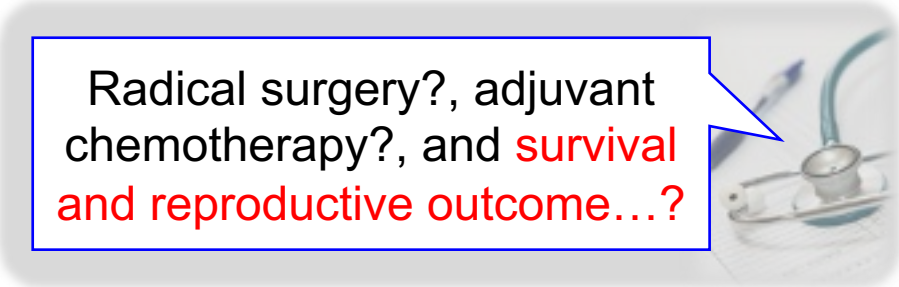
Pathology: **clear-cell carcinoma**, no preoperative capsule rupture

Ascites cytology: negative

FIGO Stage IC1 (pT1c1N0M0)







Recommendation of FSS in guidelines

JSGO
IA/IC1 Grade1 (non-CCC)

ACOG
IA Grade 1/2 (non-CCC)

ESMO
IA Grade 1/2 (non-CCC) without adhesion

Introduction

- Fertility preservation (FP) in ovarian cancer (OvCa) is an unmet medical need for survivor after the treatment including surgery and chemotherapy.

- We have reported the impact of fertility-sparing surgery (FSS) for early-stage OvCa using patients' cohort from multiple institutions.

1. Shigeyama M, ***Yoshihara M**, Kitami K, Mogi K, Uno K, Iyoshi S, Tano S, Yoshikawa N, Kajiyama H. Long-term post-recurrence survival outcomes in young women receiving fertility-sparing surgery for epithelial ovarian cancer. ***Eur J Obstet Gynecol Reprod Biol.*** 267, 221-225, 12, 2021.
2. ***Yoshihara M**, Tamauchi S, Iyoshi S, Kitami K, Uno K, Mogi K, Kajiyama H. Impact of incomplete surgery and adjuvant chemotherapy for the intraoperative rupture of capsulated stage I epithelial ovarian cancer: a multi-institutional study with an in-depth subgroup analysis. ***J Gynecol Oncol.*** 32(5), e66, 9, 2021.
3. Ikeda Y, ***Yoshihara M**, Yoshikawa N, Tamauchi S, Yokoi A, Nishino K, Niimi K, Kajiyama H. Is cystectomy an option as conservative surgery for young patients with borderline ovarian tumor? A multi-institutional retrospective study. ***Int J Gynaecol Obstet.*** 157(2), 437-443, 5, 2022.
4. ***Yoshihara M**, Tamauchi S, Iyoshi S, Kitami K, Uno K, Yoshikawa N, Ikeda Y, Kawai M, Nagasaka T, Kajiyama H. Does uterine preservation affect survival outcomes of patients with stage I ovarian sex cord-stromal cell tumours? A multi-institutional study. ***Eur J Obstet Gynecol Reprod Biol.*** 254, 52-56, 11, 2020.
5. **Yoshihara M**, Kajiyama H, Tamauchi S, Iyoshi S, Yokoi A, Suzuki S, Kawai M, Nagasaka T, Takahashi K, Matsui S, Kikkawa F. Impact of uterus-preserving surgery on Stage I primary mucinous epithelial ovarian carcinoma: A multi-institutional study with propensity score-weighted analysis. ***Int J Gynaecol Obstet.*** 150(2), 177-183, 8, 2020.
6. **Yoshihara M**, Kajiyama H, Tamauchi S, Suzuki S, Takahashi K, Matsui S, Kikkawa F. Prognostic factors and effects of fertility-sparing surgery in women of reproductive age with ovarian clear-cell carcinoma: a propensity score analysis. ***J Gynecol Oncol.*** 30(6), e102, 11, 2019.
7. Kajiyama H, **Yoshihara M**, Tamauchi S, Yoshikawa N, Suzuki S, Kikkawa F. Fertility-Sparing surgery for young women with ovarian endometrioid carcinoma: a multicenteric comparative study using inverse probability of treatment weighting. ***Eur J Obstet Gynecol Reprod Biol X.*** 4, 100071, 6, 2019.

- Here, we introduce our current findings that assessed the impact of FSS for young women and post-recurrence long-term prognosis of them.

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Study 1

Prognostic factors and effects of fertility-sparing surgery in women of reproductive age with ovarian clear-cell carcinoma: a propensity score analysis

Background

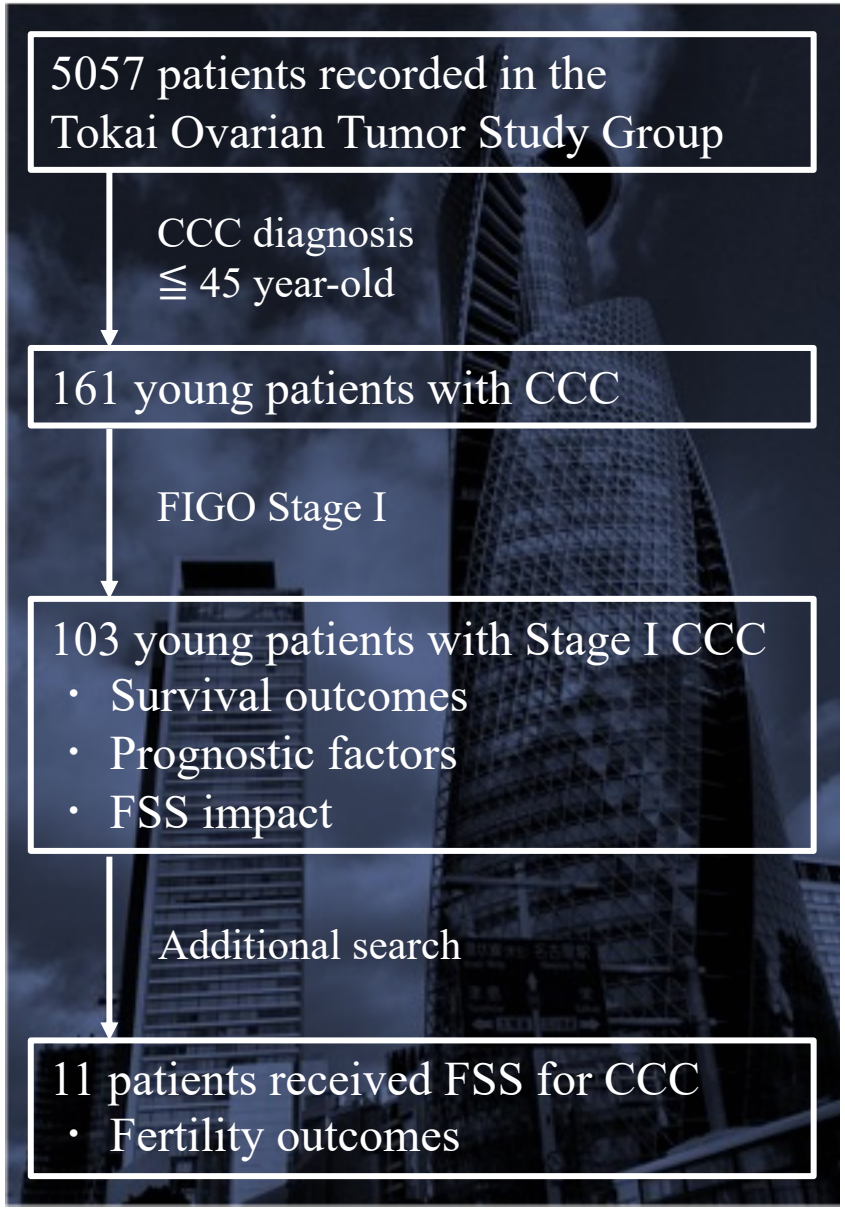
- Clear cell carcinoma (CCC) of the ovary is the second most frequent subtype of epithelial ovarian cancer (OvCa), accounting for 24.5% of all malignant neoplasm diagnosed in Japan.
- Previous studies have suggested that resistance to anti-neoplastic agents resulted in poorer prognosis compared with other histological types. Therefore, radical surgery for complete tumor resection has been done in the first place.
- However, we occasionally face young patients with CCC of the ovary in daily practice and some of them are diagnosed after the first limited operation.

- Based on the earlier reports, 3-17% of patients with epithelial OvCa are at reproductive age, for which treatment are the matter of growing concern.

- Here, we retrospectively identified the clinical and pathological features of the FIGO Stage I CCC patients at reproductive age and analyzed various prognostic indicators. We also focused on the fertility-sparing surgery and analyzed its effect on the prognosis of the patients including oncologic and reproductive outcomes.

Methods

- This is a regional population-based study between January 1986 and March 2017.
- Using data of the patients with CCC, patients at the age of less than or equal to 45 years old were collected under the central pathological review system based on the Tokai Ovarian Tumor Study Group, consisting of Nagoya University Hospital and the thirteen affiliated institutions.
- Total recorded study population was 5057 ovarian cancer patients during the study period and 161 of them were CCC patients of less than or equal to 45 years old.



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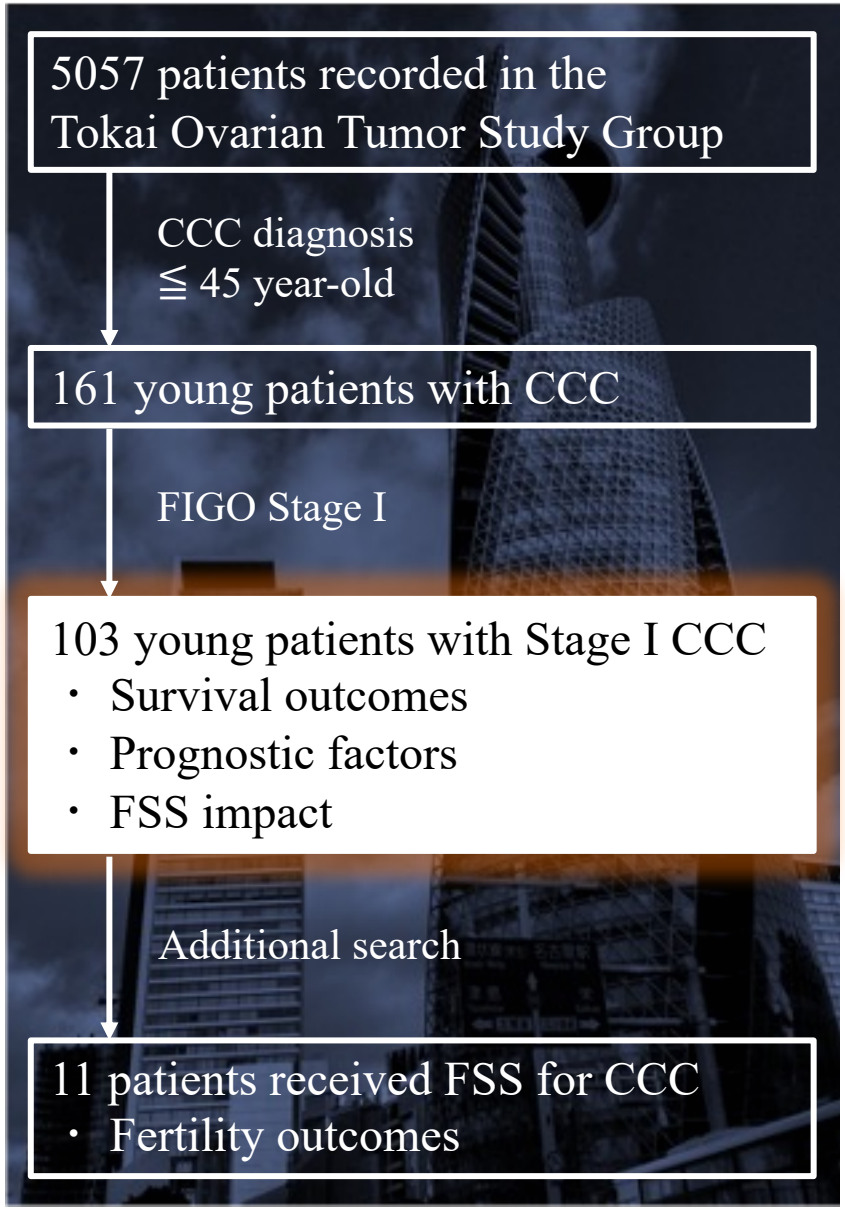
- Total recorded study population was 5057 ovarian cancer patients during the study period and 161 of them were CCC patients of less than or equal to 45 years old.

- Firstly, we explored the FIGO Stage I CCC patients at their reproductive age.
- Baseline data and prognostic factors were evaluated with uni- and multivariate analysis.



Results

Table 1. Baseline charactersitics of the Stage I CCC patients (n = 103)

Age, year (Range)	39.3 (26-45)	CA125, IU/mL (SD)	127.7 (274.5)
Nullipara, n (%)	23 (33.3)		
BMI, kg/m^2 (SD)	21.0 (3.3)	Radical surgery, n (%)	56 (54.4)
Endometriosis, n (%)	45 (57.0)		
		Adjuvant chemotherapy, n (%)	
FIGO stage, n (%)		None	13 (12.6)
IA	28 (27.2)	Conventional platinum based	27 (26.2)
IC1	49 (47.6)	Taxane plus platinum	63 (61.2)
IC2	16 (15.5)		
IC3	10 (9.7)		
Tumor size, cm (SD)	12.0 (4.6)		

Results

Table 2. Recurrence-free survival (n = 103)

	Univariate analysis		Multivariate analysis	
Categories	**HR**	**p value**	**HR**	**p value**
Age	1.006	0.923		
BMI	0.905	0.423		
Endometriosis	1.104	0.874		
FIGO stage				
IA/IC1	referent			
IC2/IC3	5.531	< 0.001	9.185	0.002
Tumor size	0.971	0.681		
CA125*	1.151	0.485		
Radical surgery	1.239	0.946		
Adjuvant chemotherapy	2.674	0.646		

*Logarithmic transformed

Results

Table 3. Overall survival (n = 103)

	Univariate analysis		Multivariate analysis	
Categories	**HR**	**p value**	**HR**	**p value**
Age	1.060	0.383		
CA125*	1.113	0.636		
Radical surgery	0.795	0.658		
Adjuvant chemotherapy	24.359	0.363		

*Logarithmic transformed

In young patients with Stage I CCC,

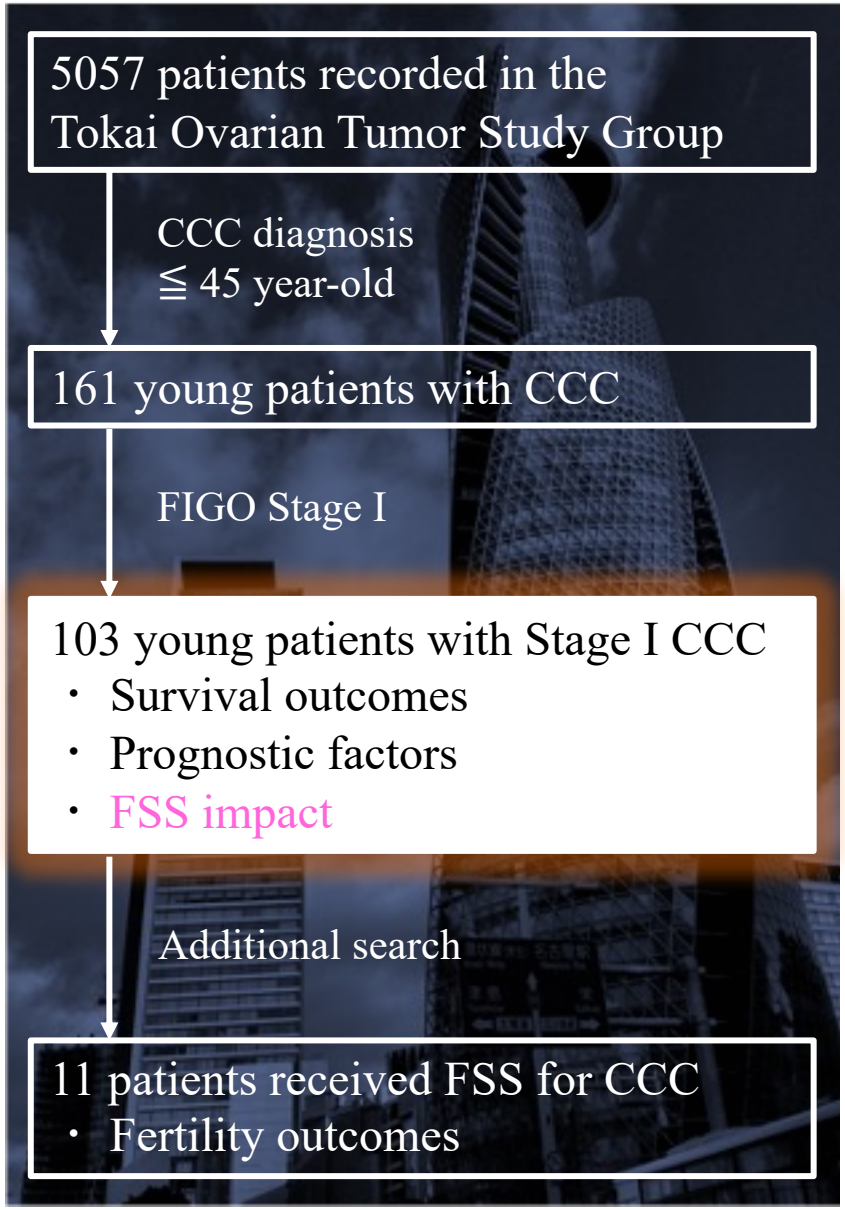
Stage IC2/IC3 =
<u>preoperative capsule rupture and/or positive ascitic cytology</u>

is the only independent prognostic factor for their survival.

Methods

- This is a regional population-based study between January 1986 and March 2017.
- Using data of the patients with CCC, patients at the age of less than or equal to 45 years old were collected under the central pathological review system based on the Tokai Ovarian Tumor Study Group, consisting of Nagoya University Hospital and the thirteen affiliated institutions.
- Total recorded study population was 5057 ovarian cancer patients during the study period and 161 of them were CCC patients of less than or equal to 45 years old.

- Next, we focused on surgical procedure and analyzed the effect of fertility-sparing surgery (FSS) in this cohort.



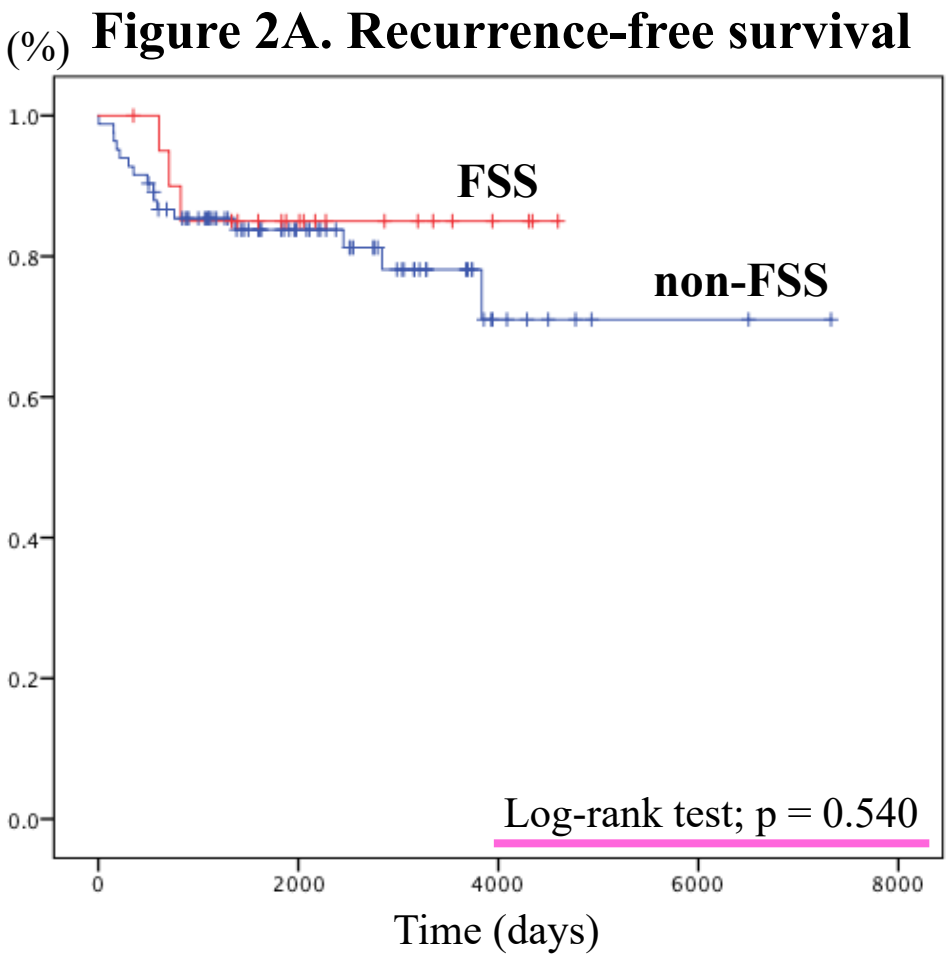
Results

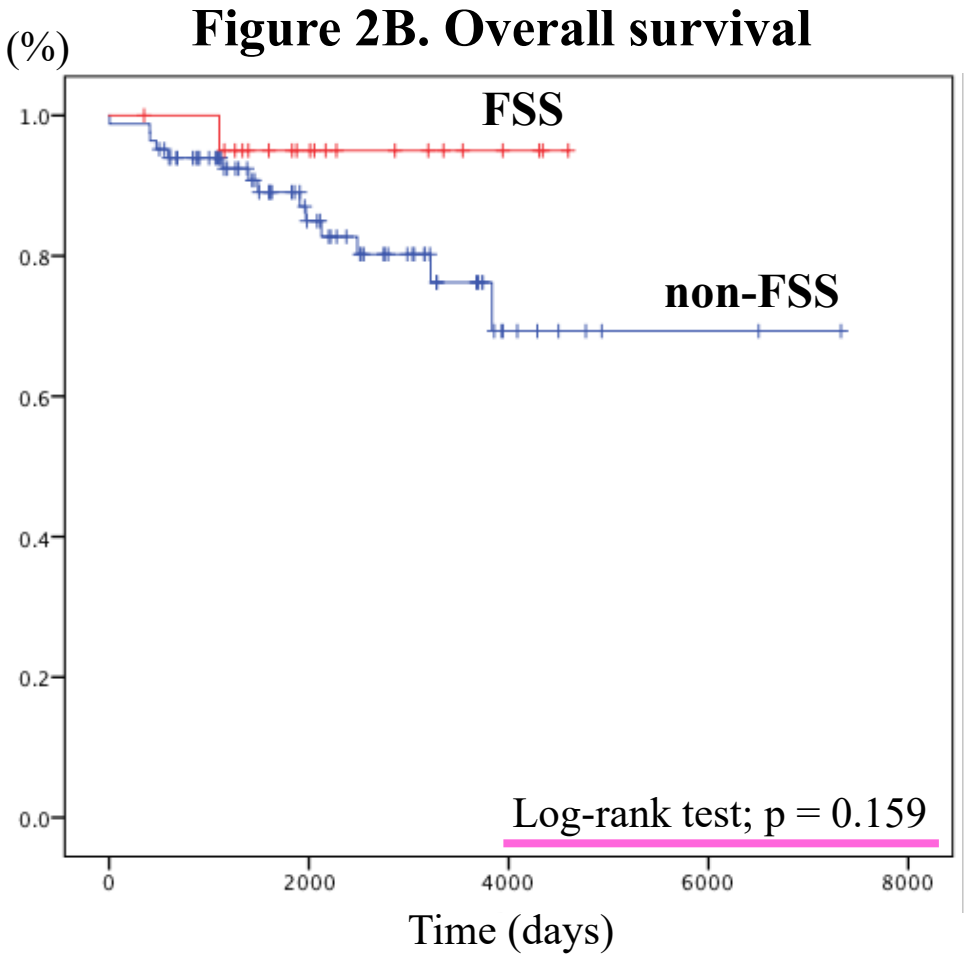
Table 4. (n = 103)

Categories	FSS (n = 21)	non-FSS (n = 82)	p value
Age, year (SD)	35.4 (3.8)	40.3 (3.6)	0.001
Nullipara, n (%)	3 (27.3)	20 (24.4)	0.356
BMI, kg/m^2 (SD)	21.1 (3.1)	21.0 (3.4)	0.937
Endometriosis, n (%)	13 (61.9)	32 (39.0)	0.296
FIGO stage, n (%)			
IA/IC1	18 (85.7)	59 (72.0)	0.265
IC2/3	3 (14.3)	23 (28.0)	
= preoperative capsule rupture and/or positive result of ascitic cytology			
Tumor size, cm (SD)	11.3 (4.7)	12.2 (4.5)	0.477
CA125, IU/mL (SD)	74.0 (67.8)	141.9 (305.3)	0.315
Adjuvant chemotherapy, n (%)			
None	3 (14.3)	10 (12.2)	0.943
Conventional platinum based	5 (23.8)	22 (26.8)	
Taxane plus platinum	13 (61.9)	50 (61.0)	

Paired *t*-test or Chi-square test are used as appropriate.

Results





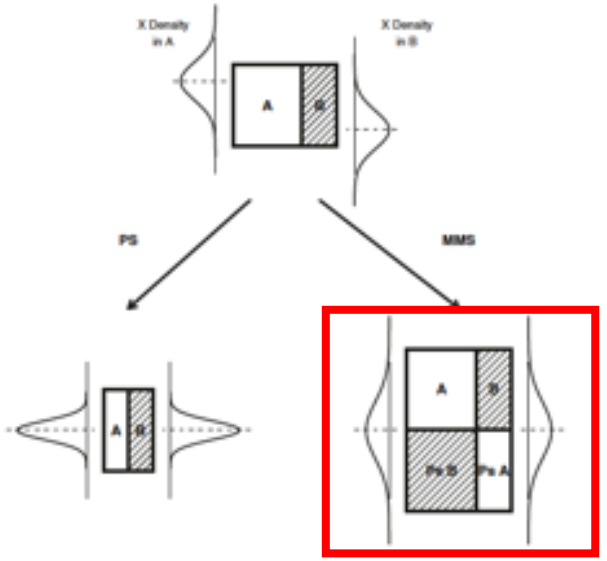
There were no significant survival outcomes between FSS and non-FSS groups.

Results

- Baseline imbalance between patients with and without FSS was adjusted using an inverse probability of treatment weighting (IPTW) using propensity scores composed of independent clinical variables.

Independent variables

- Age (year)
- Parity (n)
- BMI (kg/m^2)
- Endometriosis (n)
- Tumor size (cm)
- CA125 (U/mL)
- Cytology (n)
- Chemotherapy (n)



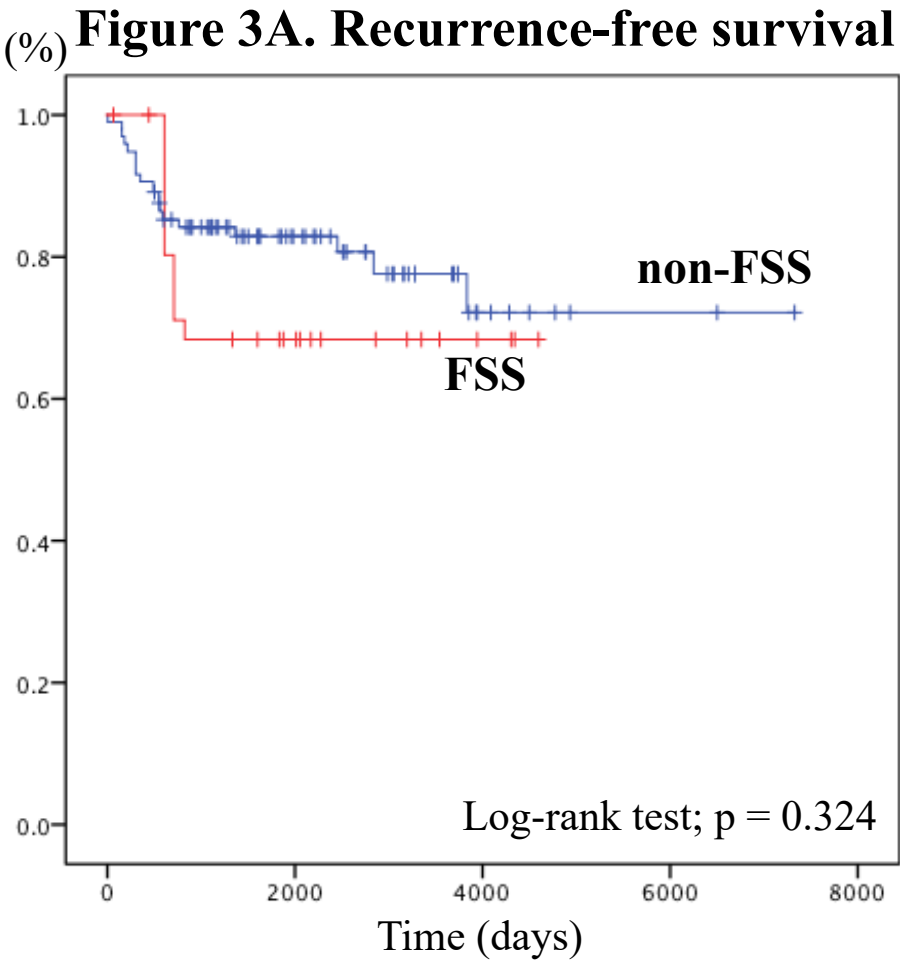
Propensity score

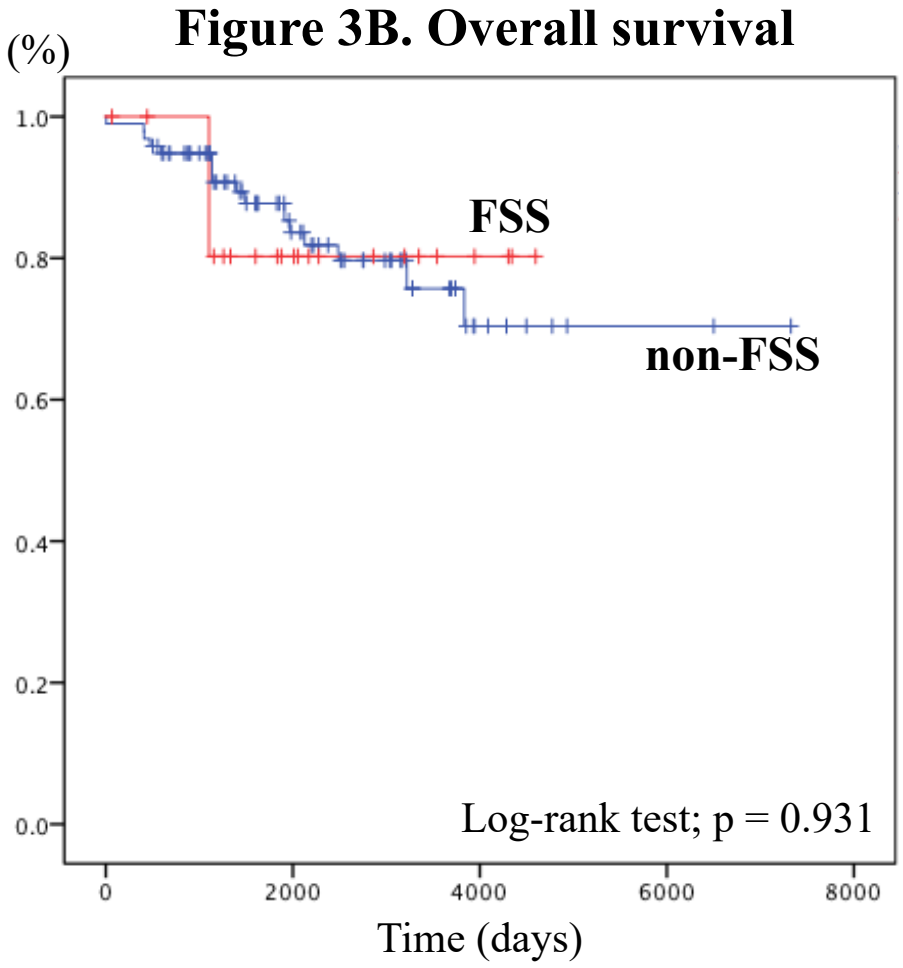
FSS	n = 21
non-FSS	n = 82

IPTW

FSS	n = 76
non-FSS	n = 103

Results



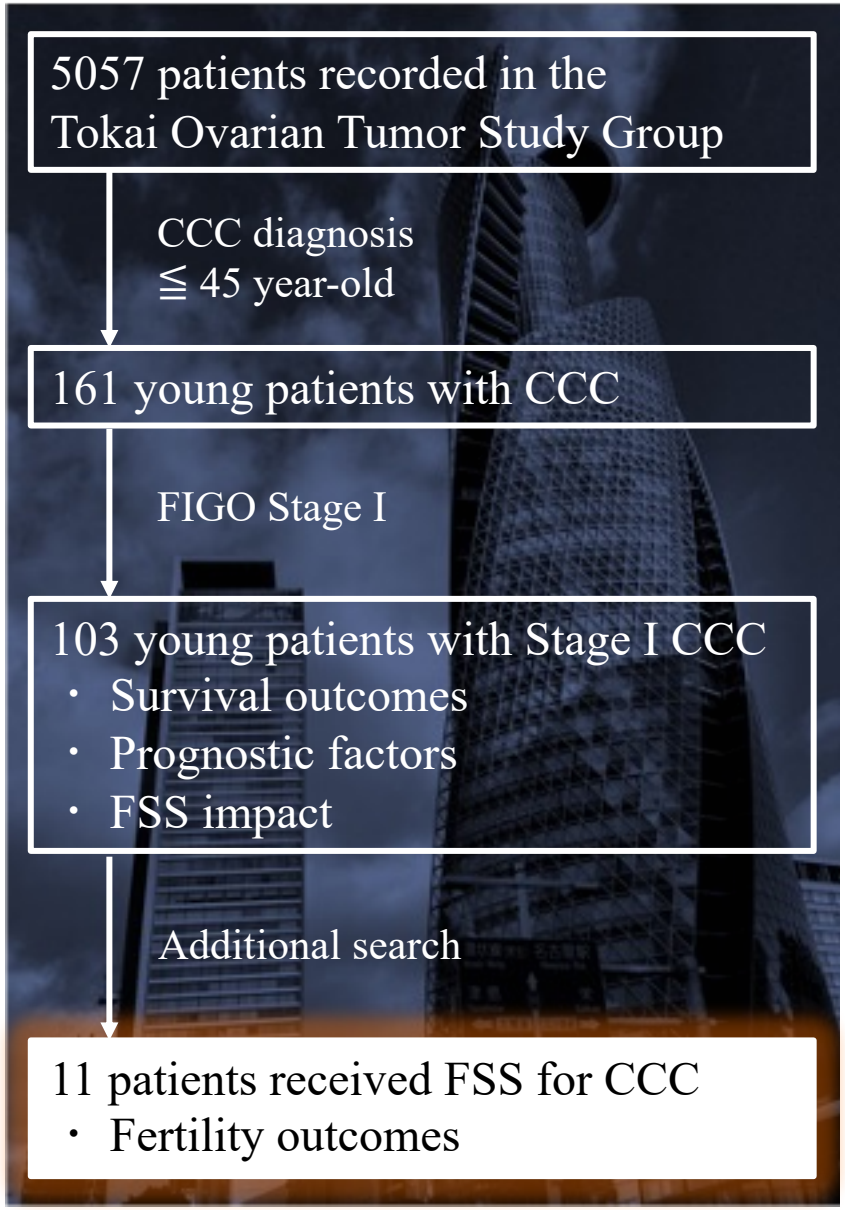


After adjustment, there were also no significant survival outcomes between the two groups.

Methods

- This is a regional population-based study between January 1986 and March 2017.
- Using data of the patients with CCC, patients at the age of less than or equal to 45 years old were collected under the central pathological review system based on the Tokai Ovarian Tumor Study Group, consisting of Nagoya University Hospital and the thirteen affiliated institutions.
- Total recorded study population was 5057 ovarian cancer patients during the study period and 161 of them were CCC patients of less than or equal to 45 years old.

- Finally, we conducted an additional investigation to clarify the reproductive and obstetric outcomes of the CCC patients who underwent FSS.



Results

Table 6. Reproductive outcomes of the patients received FSS (n = 11)

Age, yr (Range)		34.3 (26-39)
BMI, kg/m2 (SD)		21.4 (3.49)
Endometriosis, n (%)		7 (63.6)
Stage, n (%)	IA	5 (45.5)
	IC1	5 (45.5)
	IC3	1 (9.0)
Chemotherapy, n (%)	Taxan+Platinum	9 (81.8)
Menstruation, n (%)		11 (100.0)
POF, n (%)		1 (9.1)
Infertility treatment, n (%)	IVF	3 (27.3)
Pregnancy, n	Total	10
	Normal	5
	Spontaneous abortion	3
	Artificial abortion	1
	Ectopy	1
Delivery, n	Vaginal delivery	3
	Caesarean section	2
Neonate, n	Healthy	5
	Abnormal	0

Conclusion 1

- This is the first retrospective cohort study, using the adjusted population with IPTW method, to figure out the effect of FSS in patients with Stage I CCC of the ovary compared with conventional surgical procedures.

- Despite some limitations of this study, such as small number and variation of the patients, we endeavored to minimize the imbalances of the groups, resulting in clarifying this therapeutic effect.

Yoshihara M, Kajiyama H, et al. ***J Gynecol Oncol.*** 2019.

Study 2

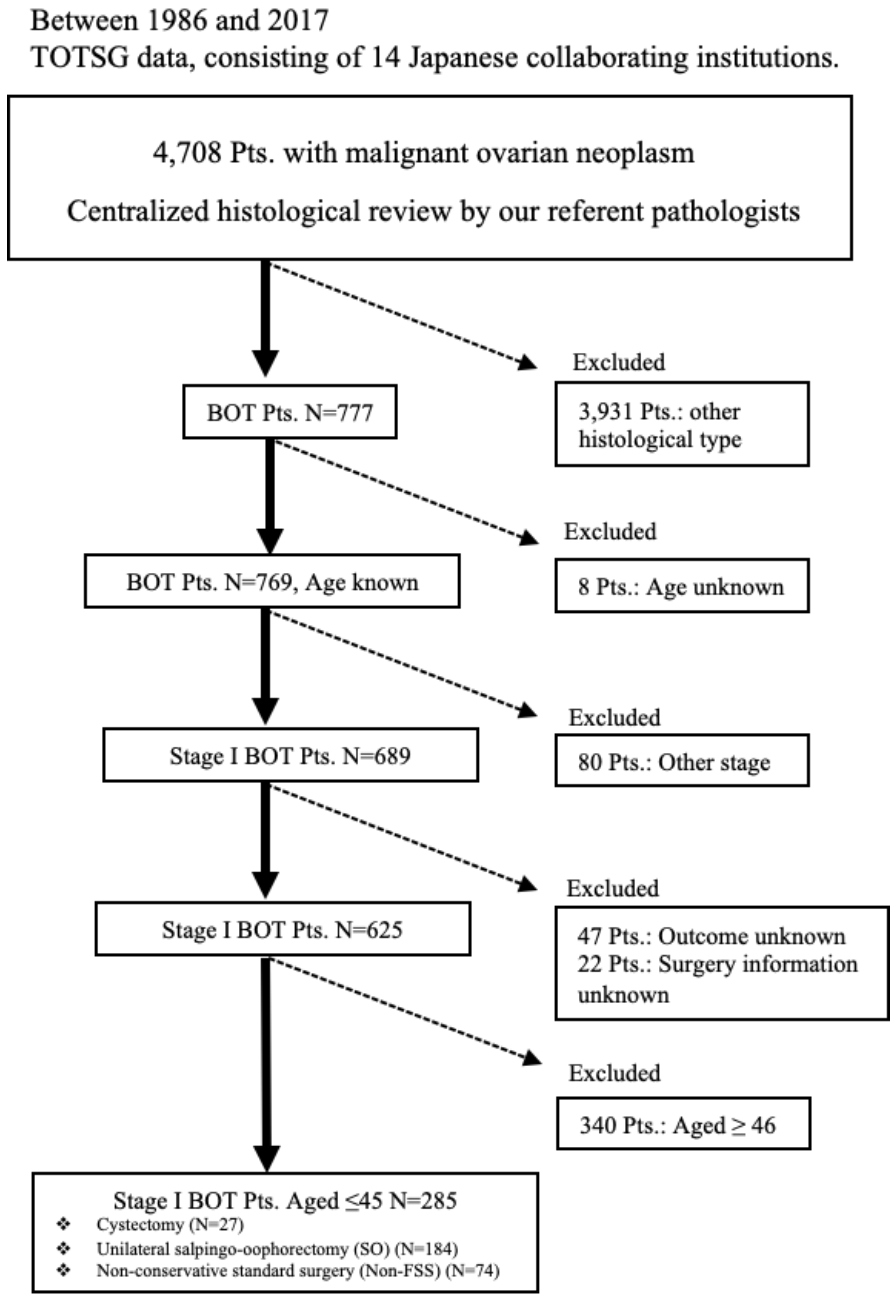
Prognostic factors and effects of fertility-sparing surgery in women of reproductive age with ovarian clear-cell carcinoma: a propensity score analysis

Background and Methods

- Borderline ovarian tumors (BOT) are more common in women of reproductive age, often leading to the choice of fertility-sparing surgery (FSS) in young patients with early-stage BOT, as it does not impair long-term survival despite the risk of recurrence.
- Standard procedures for FSS include unilateral salpingo-oophorectomy and omentectomy, but cystectomy may be the only option for those with prior ovary removal or bilateral ovarian involvement.

- Research comparing the outcomes of cystectomy and salpingo-oophorectomy in early-stage BOT is limited, necessitating accurate risk estimation for recurrence in cystectomy patients.

- In this study, we evaluated the impact of cystectomy on tumor relapse in young stage I BOT patients.



Results

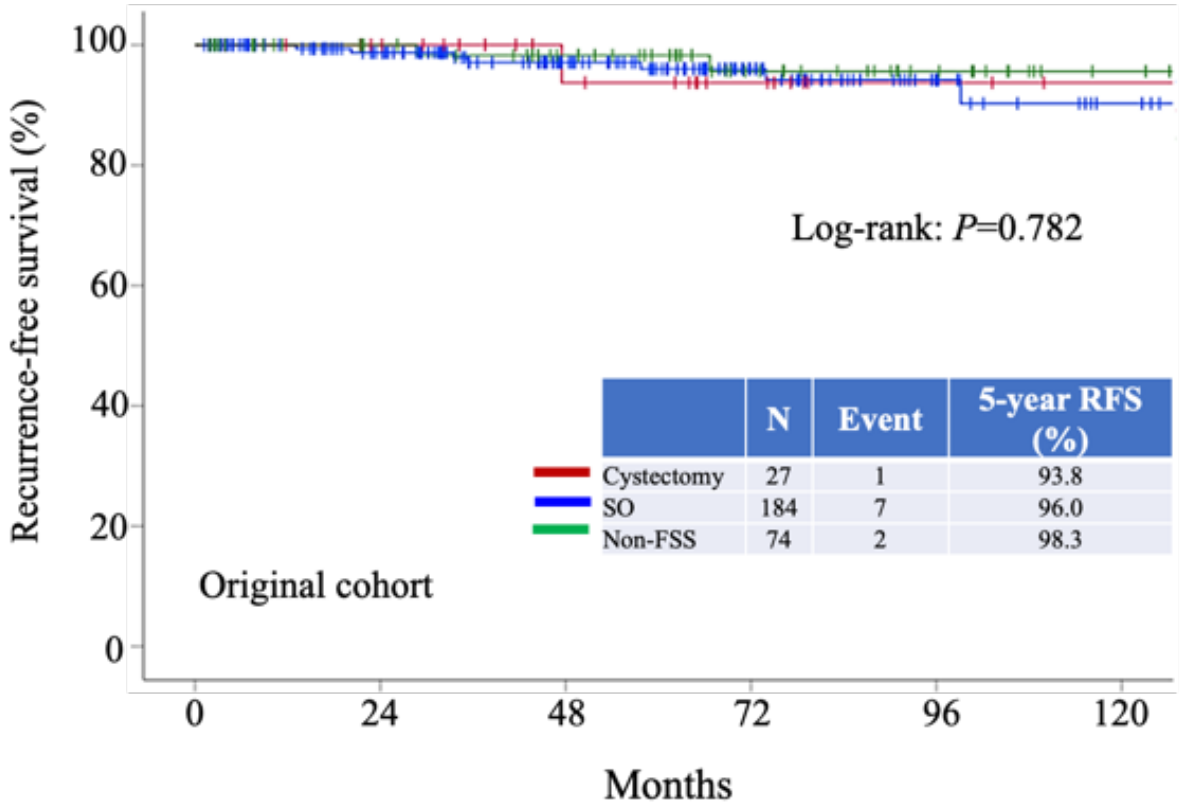
		Cystectomy		SO		Non-FSS		*P*-value[#1]	*P*-value[#2]
		N	%	N	%	N	%		
Total	**285**	27		184		74			
Age (median/mean/SD)		27/28.4/5.4		30.5/30.7/7.3		40/38.2/5.8		0.111	<0.0001
Substage (FIGO 2014)									
IA	174	10	37.0	123	66.8	41	55.4	<0.0001	0.0005
IB	12	4	14.8	2	1.1	6	8.1		
IC	99	13	48.1	59	32.1	27	36.5		
Histological type								0.1029	0.0832
Mucinous	156	16	59.3	140	76.1	49	66.2		
Serous	95	10	37.0	36	19.6	21	28.4		
Endometrioid	25	0	0.0	4	2.2	4	5.4		
Mixed	7	0	0.0	3	1.6	0	0.0		
Others	2	1	3.7	1	0.5	0	0.0		
Ascites volume (mL)								0.7342	0.0681
< 100	230	25	92.6	153	83.2	52	70.3		
100-499	21	0	0.0	10	5.4	11	14.9		
500-1,000	6	1	3.7	2	1.1	3	4.1		
> 1,000	8	0	0.0	7	3.8	1	1.4		
NA	20	1	3.7	12	6.5	7	9.5		
Preoperative CA125 value (U/mL)								0.5596	0.3937
≤ 35	134	15	55.6	90	48.9	29	39.2		
> 35	135	10	37.0	86	46.7	39	52.7		
NA	16	2	7.4	8	4.3	6	8.1		
Chemotherapy								0.4243	0.4518
No	252	23	85.2	166	90.2	63	85.1		
Yes	33	4	14.8	18	9.8	11	14.9		

Results

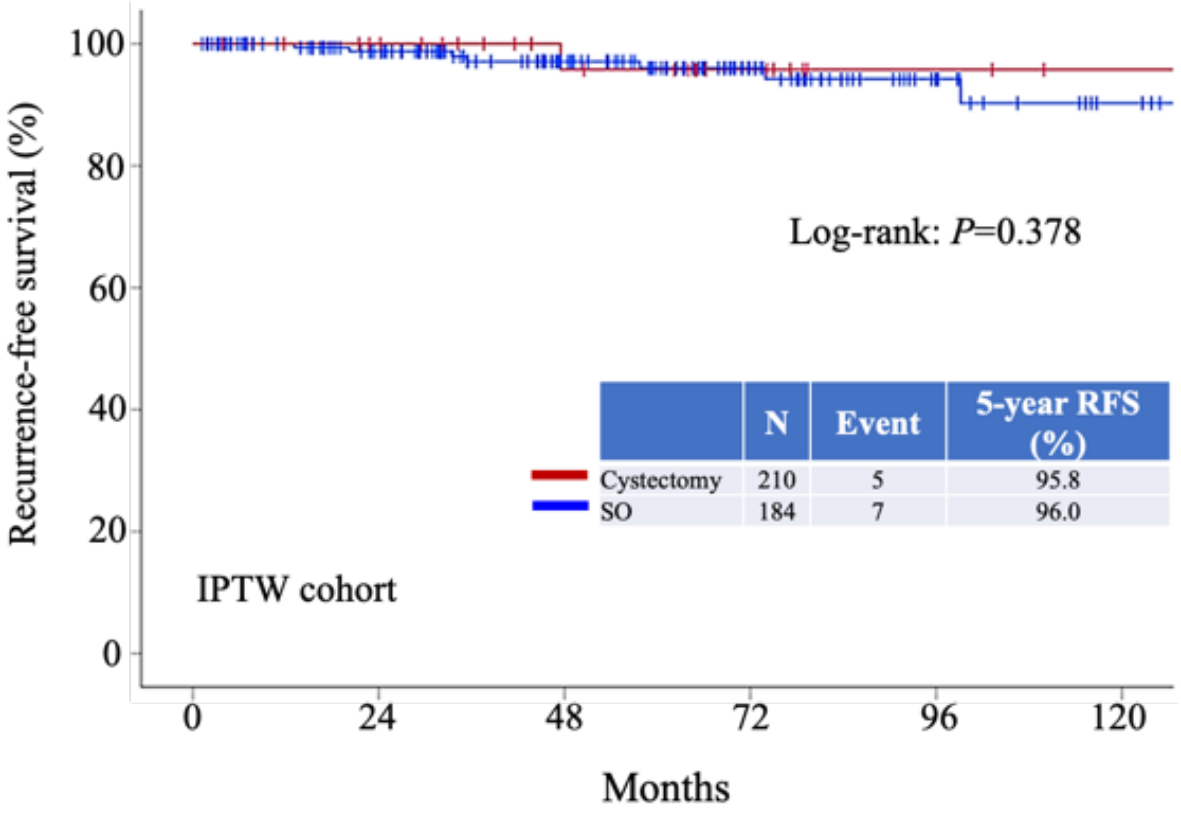
Variable	RFS		
	HR	95% CI	*P*-value
Model 1 (Original cohort)			
Age	1.091	0.989-1.203	0.083
Surgery (Cystectomy vs. SO)	1.276	0.150-10.864	0.823
Sub-stage (IC vs. IA-B)	1.276	0.150-10.864	0.557
Histological type (mucinous vs. non-mucinous)	2.650	0.323-21.762	0.364
Chemotherapy (yes vs. no)	1.414	0.168-11.867	0.750
Model 2 (IPTW cohort)			
Age	1.091	1.000-1.191	0.051
Surgery (Cystectomy vs. SO)	0.742	0.225-2.453	0.625
Sub-stage (IA-B vs. IC)	0.319	0.069-1.478	0.144
Histological type (mucinous vs. non-mucinous)	3.245	0.4124-25.570	0.264
Chemotherapy (yes vs. no)	8.648	2.568-29.124	0.000

In multivariate models, surgical method did not affect recurrence-free survival.

Results



	N	Event	5-year RFS (%)
Cystectomy	27	1	93.8
SO	184	7	96.0
Non-FSS	74	2	98.3



	N	Event	5-year RFS (%)
Cystectomy	210	5	95.8
SO	184	7	96.0

There was no significant difference between cystectomy and SO groups.

Results

Report	Year	N	Surgery		Recurrence			
			SO	Cystectomy	SO		Cystectomy	
			Total	N	N	%	N	%
Maneo	2004	62	28	34	3	10.7	8	23.5
Boran	2005	62	40	22	1	2.5	3	13.6
Romagnolo	2006	53	32	21	7	21.9	6	28.6
Yinon	2007	62	40	22	11	27.5	5	22.7
Wong	2007	116	78	38	2	2.6	2	5.3
De Iaco	2009	85	50	35	10	20.0	12	34.3
Park	2009	184	128	56	3	2.3	6	10.7
Kanat-Pektas	2011	55	36	19	1	2.8	2	10.5
Koskas	2011	74	47	27	3	6.4	8	29.6
Song	2011	155	117	38	7	6.0	5	13.2
Total		908	596	312	48	8.1	57	18.3

Considering literatures, cystectomy is considered a feasible treatment when it is the only option to preserve patients' fertility.

Conclusion 2

- In clinical practice, it is critical to conserve the endocrine and/or reproductive function of young women with gynecologic borderline and malignant tumors.
- In this situation, it would be less risky to adopt oophorectomy than cystectomy without fear of recurrence at least in the ipsilateral ovary.

- Nevertheless, how can we treat women with BOT if they have already lost the other ovary and have only the tumor-sided ovary? Alternatively, how should we carry out fertility-preserving treatment for young patients with bilateral BOT?

- Ovarian tumorectomy /cystectomy is the only treatment option to satisfy patients' strong hope to preserve their reproductive function.

- Even though the surgical technique is feasible, cystectomy may be associated with the possible existence of an occult tumor in the remaining ovary.

Study 3

Long-term post-recurrence survival outcomes in young women receiving fertility-sparing surgery for epithelial ovarian cancer

Background and Methods

- There are few reports describing prognostic value of FSS for long-term survival after developing recurrent tumor of epithelial OvCa.
- As we cannot conduct a prospective randomized trials to assess prognostic impact of FSS due to an ethical aspect, it is one of the biggest clinical challenges to decide performing FSS with consideration of long-term prognosis for young women with epithelial OvCa.

- We previously reported less significant clinical impact of unilateral salpingo-oophorectomy for post-recurrence survival in patients of all ages with epithelial OvCa; however, which insufficiently indicated pure effect of FSS for young fertile women.
- In this study, we investigated long-term post-recurrence survival outcomes in young women receiving FSS to verify the feasibility of the limited surgery for epithelial OvCa.

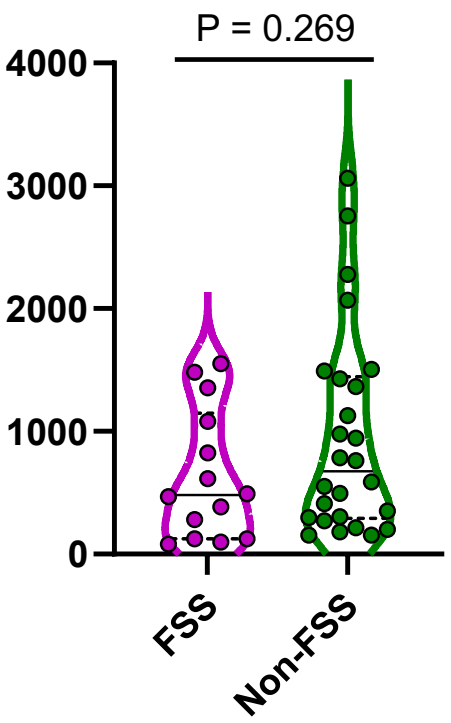
- We performed a regional multicenter retrospective study from January 1986 and March 2020, using clinical data corrected under the central pathological review system. Patients with recurrent tumor after surgery for stage I epithelial OvCa, aged equal or younger than 45 years were included for this study. We evaluated effect of FSS regarding long-term post-recurrence survival with statistical adjustment of propensity score-based method.

Results

Category	FSS (n = 14)	Non-FSS (n = 26)	P-value
Age, years (SD)	31.3 (6.5)	38.8 (4.9)	<0.001
CA-125, IU/mL (SD)	146.371 (107.7)	210.35 (289.1)	0.432*
Stage, n (%)			
IA	4 (28.6)	5 (19.2)	0.808
IC1	4 (28.6)	7 (26.9)	
IC2	1 (7.1)	1 (3.8)	
IC3	5 (35.7)	13 (50.0)	
Histology, n (%)			
Serous	2 (14.3)	2 (7.7)	0.286
Clear-cell	2 (14.3)	13 (50.0)	
Mucinous	4 (28.6)	4 (15.4)	
Endometrioid	5 (35.7)	6 (23.1)	
Others	1 (7.1)	1 (3.8)	

Category	FSS (n = 14)	Non-FSS (n = 26)	P-value
Lymph node sampling, n (%)	2 (14.3)	21 (80.8)	<0.001
Adjuvant chemotherapy, n (%)	10 (71.4)	26 (100.0)	0.004
Disease-free interval, days (SD)	640.3 (530.9)	951.1 (830.1)	0.214
Site of recurrence, n (%)			
Peritoneum	8 (57.1)	11 (42.3)	0.510
Ovary	4 (28.6)	-	-
Lymph node	3 (21.4)	9 (34.6)	0.484
Extra-peritoneum	4 (28.6)	12 (46.2)	0.329

Results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2000
1000
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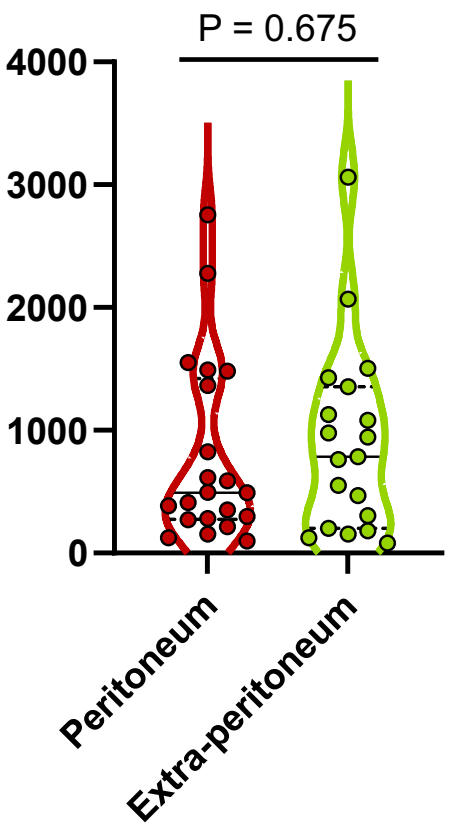
FSS
Non-FSS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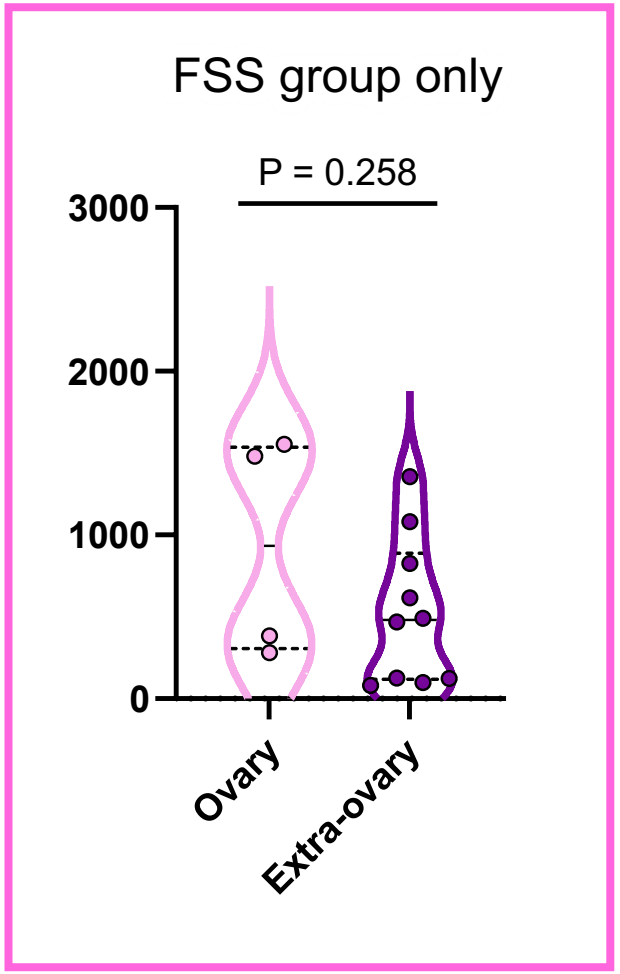
Peritoneum
Extra-peritoneum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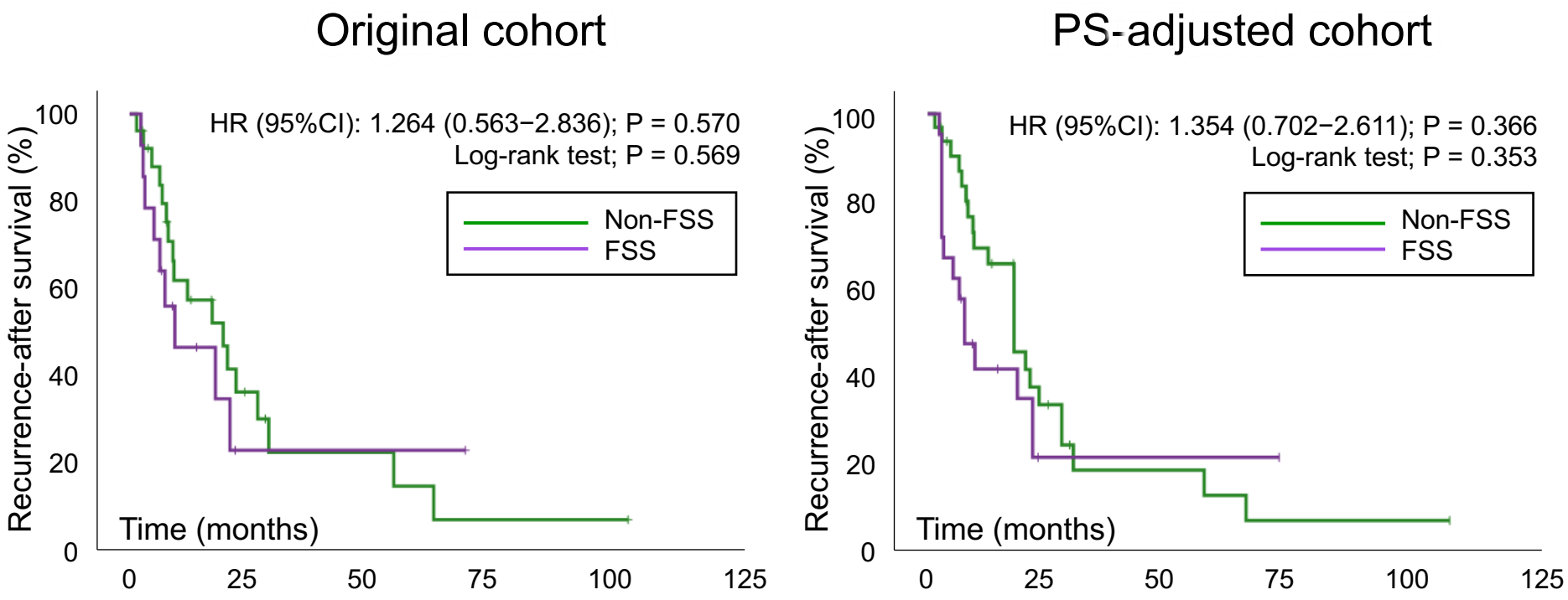
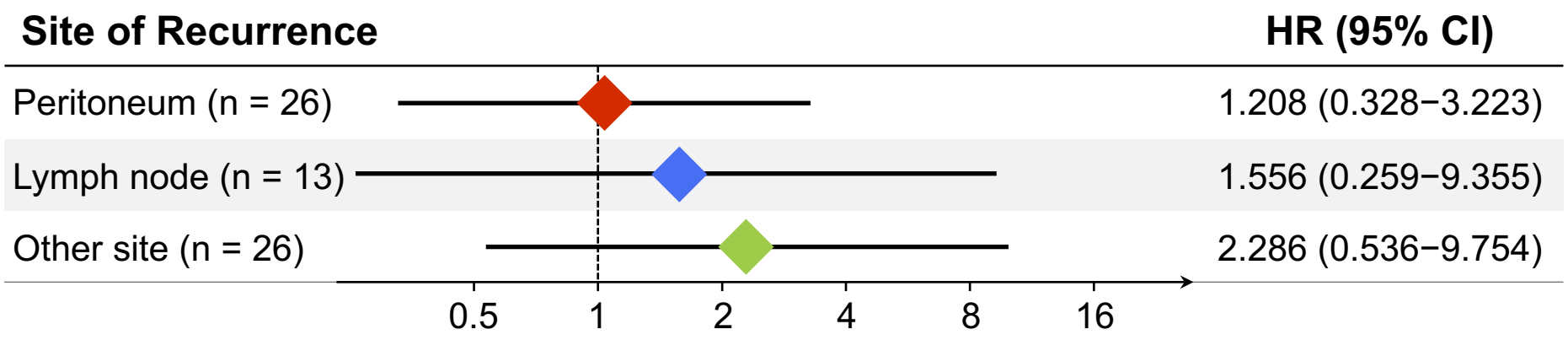
Ovary
Extra-ovary

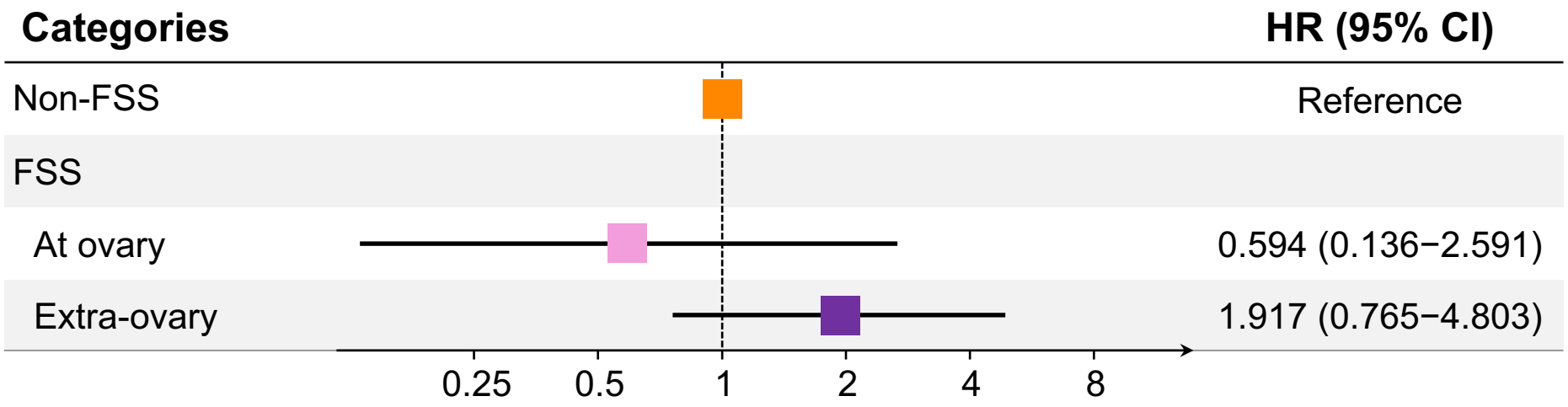
Results



Patients with FSS was not associated with poorer prognosis for recurrence-after survival.

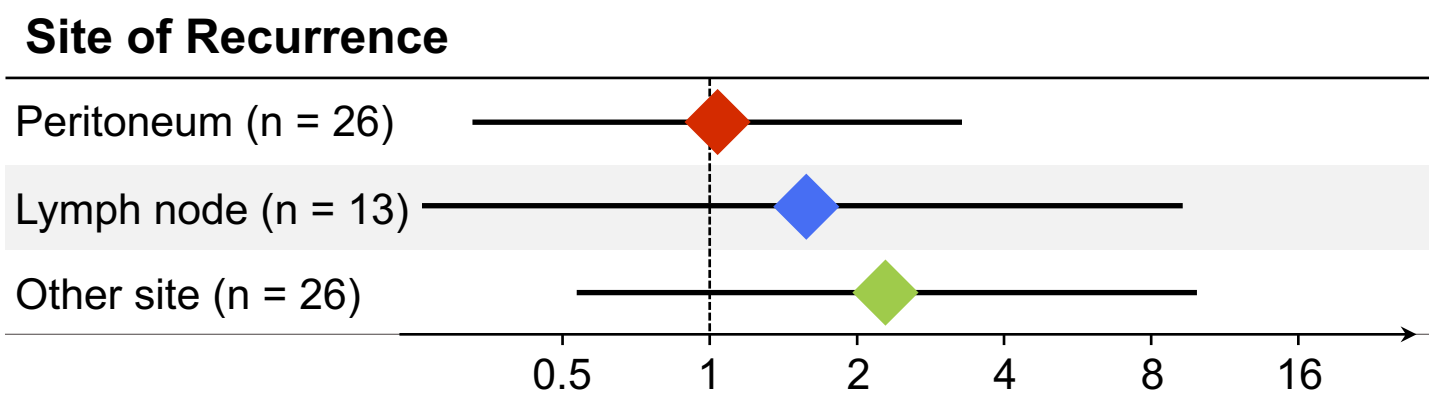
Results

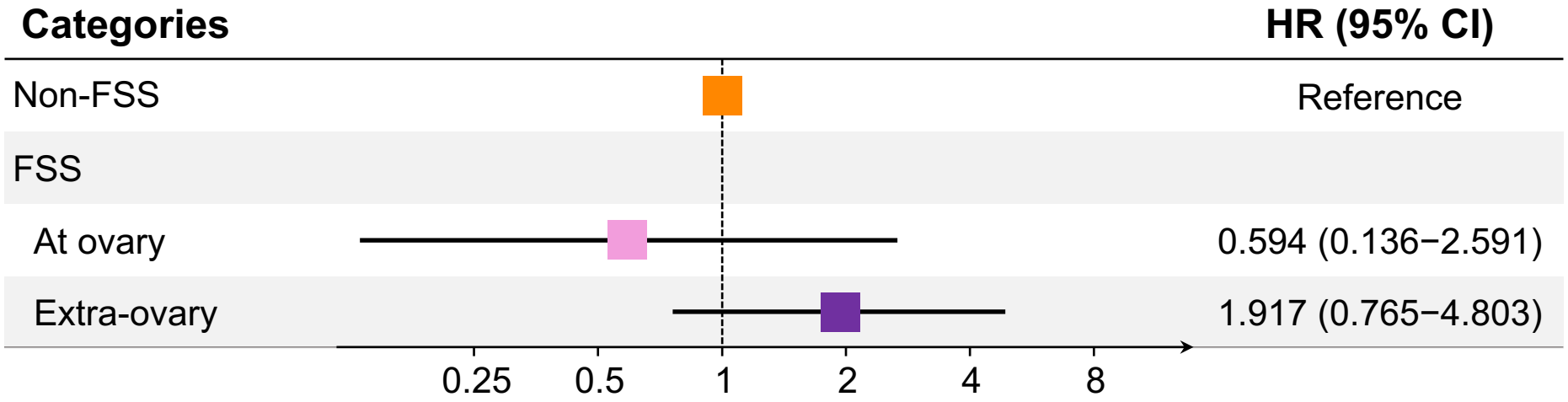




FSS did not have a significant prognostic impact despite recurrence site including spared ovary.

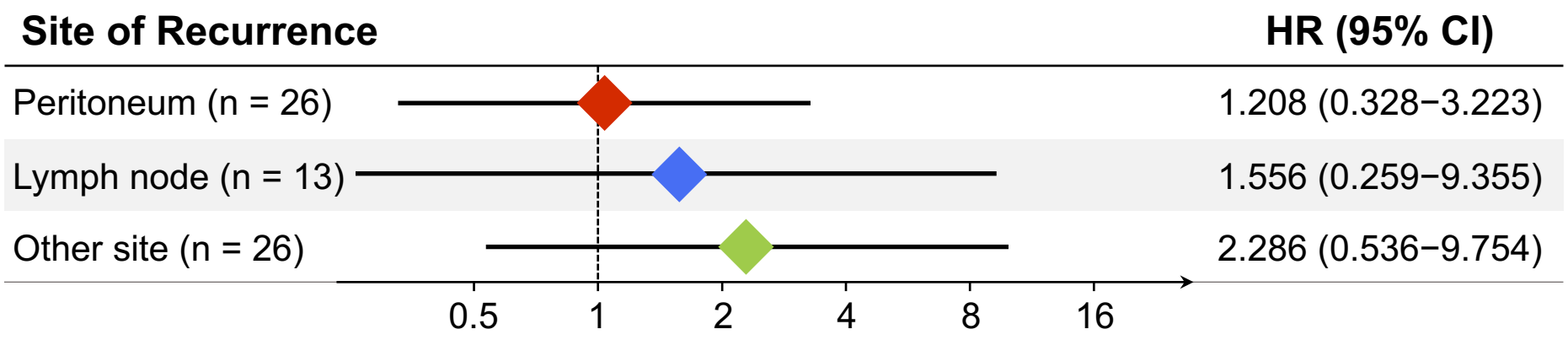
Results

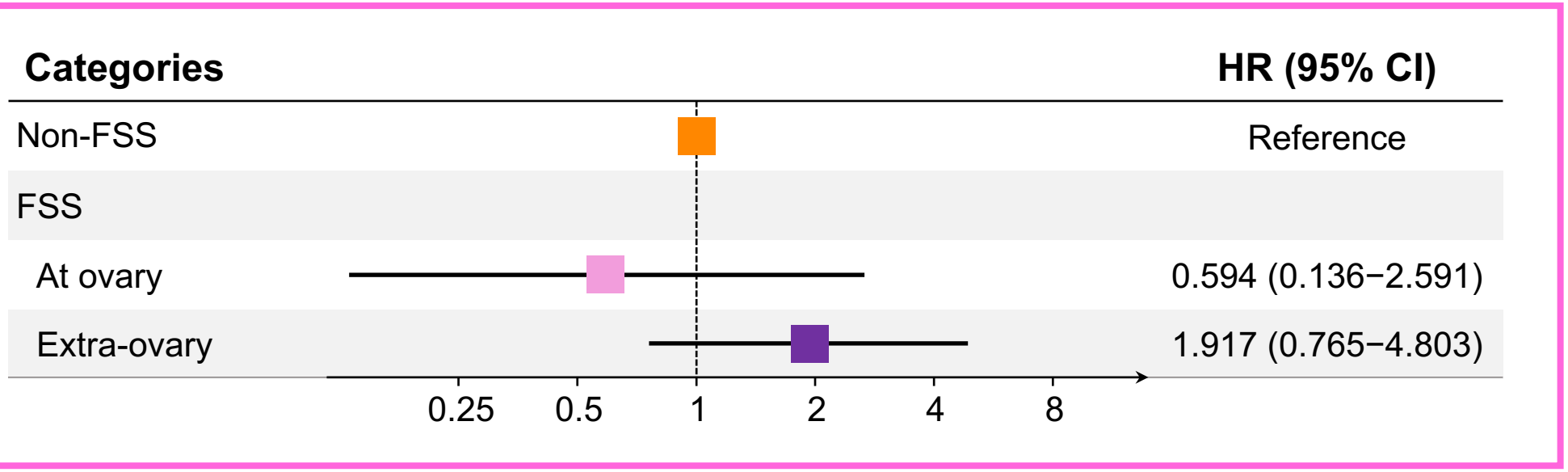




FSS did not have a significant prognostic impact despite recurrence site including spared ovary.

Results





FSS did not have a significant prognostic impact despite recurrence site including spared ovary.

Conclusion 3

- There was no significant difference of long-term post-recurrence survival outcomes between patients of epithelial OvCa with and without FSS in young women of reproductive age.
- Moreover, recurrence at spared ovary also presented no significant impact on prognosis for recurrence-after survival.
- Based on our findings, FSS seemed to be a feasible therapeutic option even in terms of prognosis after recurrence.

- To our best knowledge, this analysis contained small sample number, but one of the largest clinical studies to evaluate post-recurrence survival outcomes of FSS compared to radical surgery in young fertile women.

- We hope that our results will be further validated in future studies with more accumulation of clinical data of FSS for OvCa.

ASGO Special Task Force

Fertility Preservation in Gynecologic Oncology

Prof. Nao Suzuki

Prof. Hiroaki Kajiyama

Vision:

Aiming to Improve Cancer Survivorship among AYA Gynecologic Cancer Patients in Asia

◆ **Gynecologic oncologists (as primary physicians)**

1. **Comprehensively management** of fertility preservation (FP) for AYA patients with gynecologic cancer.
2. **Collaboration** with Reproductive Endocrinologists (REI) to understand the content related to reproductive medicine (ART, FP, etc).

Organizer :

Chair : **Nao Suzuki (St. Marianna University, Japan)**
Co-Chair: **Dr. Hiroaki Kajiyama (Nagoya University, Japan)**
Leader: Masato Yoshihara (Nagoya University, Japan)

- It remains unclear whether FP techniques are safely administered for patients with gynecologic malignancy with good prognosis.
- To meet the issue, we are trying to survey the current understandings and real-world clinical practice in Asian countries.

1. **Making questionnaires**
2. **Making draft of background of paper**

TASK No.1

- 2023/3-6 Making questionnaires
- 2023/7 ASGO STF-FP web-meeting
- 2023/7-11 Discuss via email and send
- **2023/12 ASGO in Taiwan Onsite-meeting**

TASK No.2

- 2023/6-11 Making draft of background of paper
- **2023/12 ASGO in Taiwan Onsite-meeting**

TASK No.3

- 2024/1-4 Summarize answer of the questionnaires
- 2024/5-6 ASGO STF-FP web-meeting
- 2024/5-8 Discuss results and issues to be resolved
- 2024/9-11 Reviewing the paper
- 2024/12 ASGO 2024 Onsite-meeting

1. **Making questionnaires**
2. **Making draft of background of paper**

TASK No.1

- 2023/3-6 Making questionnaires
- 2023/7 ASGO STF-FP web-meeting
- a email and send
- **Taiwan Onsite-meeting**

5 categories: 127 questions !

Members form 10 countries !!

TASK No.2

- 2023/6-11 Making draft of background of paper
- **2023/12 ASGO in Taiwan Onsite-meeting**

TASK No.3

- 2024/1-4 Summarize answer of the questionnaires
- 2024/5-6 ASGO STF-FP web-meeting
- 2024/5-8 Discuss results and issues to be resolved
- 2024/9-11 Reviewing the paper
- 2024/12 ASGO 2024 Onsite-meeting

Questionnaires for OvCa

Ovarian cancer	
	Prevalence, registry system
1	What is the definition of AYA in your country?
2	Does your country (or organization) have a registry documenting outcomes of OvCa patients receiving FP? (Yes/No)
3	Does your country's registry document the number of OvCa patients from 2015 to 2020 (and what percentage of them in AYA)? (Yes/No)
4	Does your country's registry document the number of OvCa patients receiving FP from 2015 to 2020? (Yes/No)
	Surgery (indication and procedure), chemotherapy, follow-up management
1	By what age can FSS be performed for OvCa?
2	For what histology and stage is FSS applicable for OvCa?
3	Is omentectomy and lymphadenectomy necessary for FSS? (Yes/No)
4	Is bilateral oophorectomy (uterine-preservation) feasible option as FSS? (Yes/No)
5	What is the criteria for adjuvant chemotherapy after FSS?
6	How long should patients receiving FSS be followed-up after initial treatment?
	Ovarian function (FSH, AMH, AFP count), IVF-ET, ovarian preservation, ex vivo oocyte pick-up
1	Is ovarian function (FSH, AMH, AFP count) regularly assessed before and after FSS? (Yes/No)
2	Is ovarian preservation indicated? (Yes/No)
3	Is ex vivo oocyte pick-up indicated during FSS? (Yes/No)
4	Are pregnant patients receiving FSS managed in an advanced medical institution? (Yes/No)
5	Is secondary staging surgery including hysterectomy indicated after the delivery? (Yes/No)

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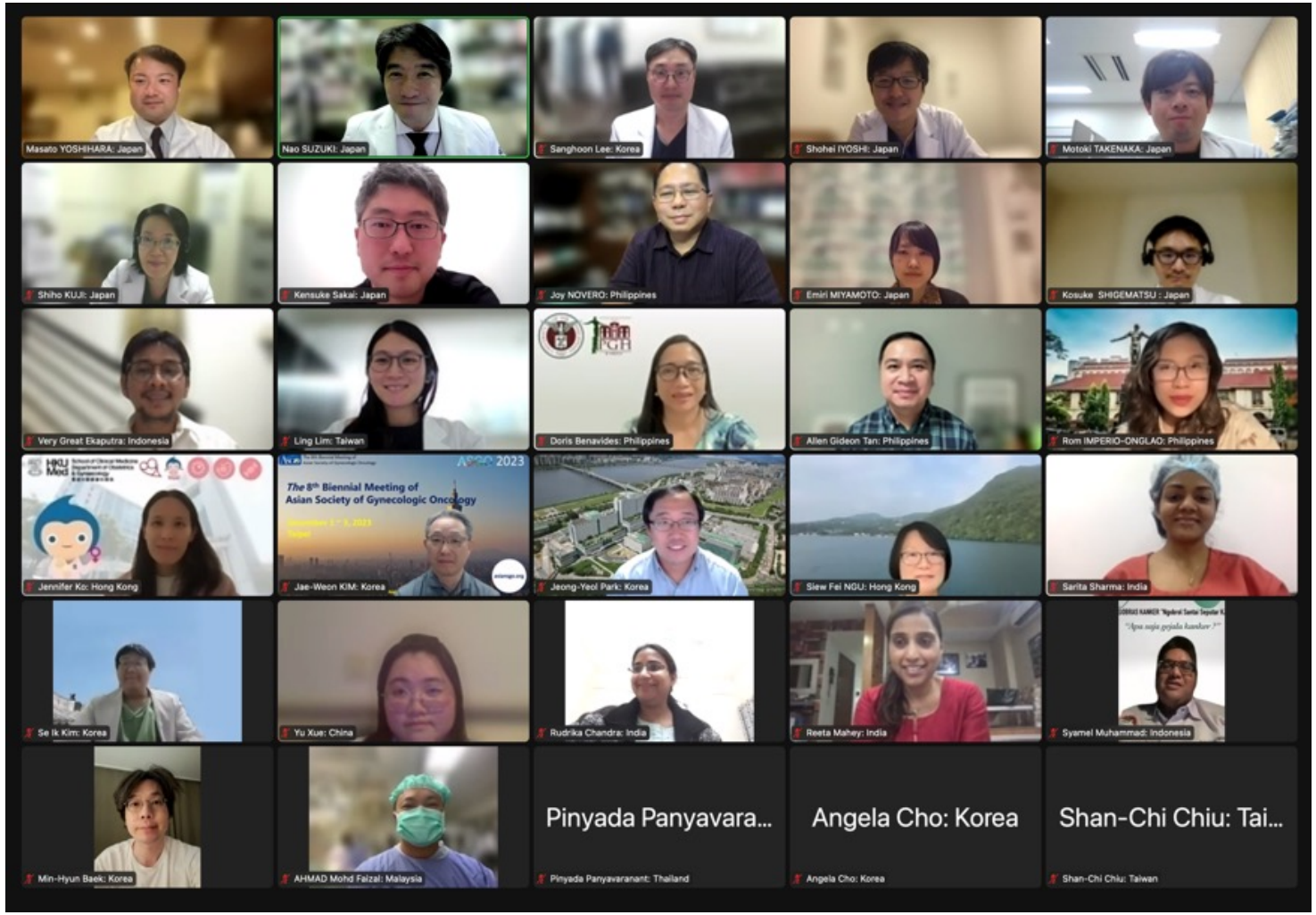
Thank you for your attention!!



Kick-off meeting of ASGO STF-FP Feb 2. 2023