

# Phase II Trial of Systemic Therapy Plus Intraperitoneal Paclitaxel in Gastric/GEJ Cancer Peritoneal Carcinomatosis - STOPGAP Trial

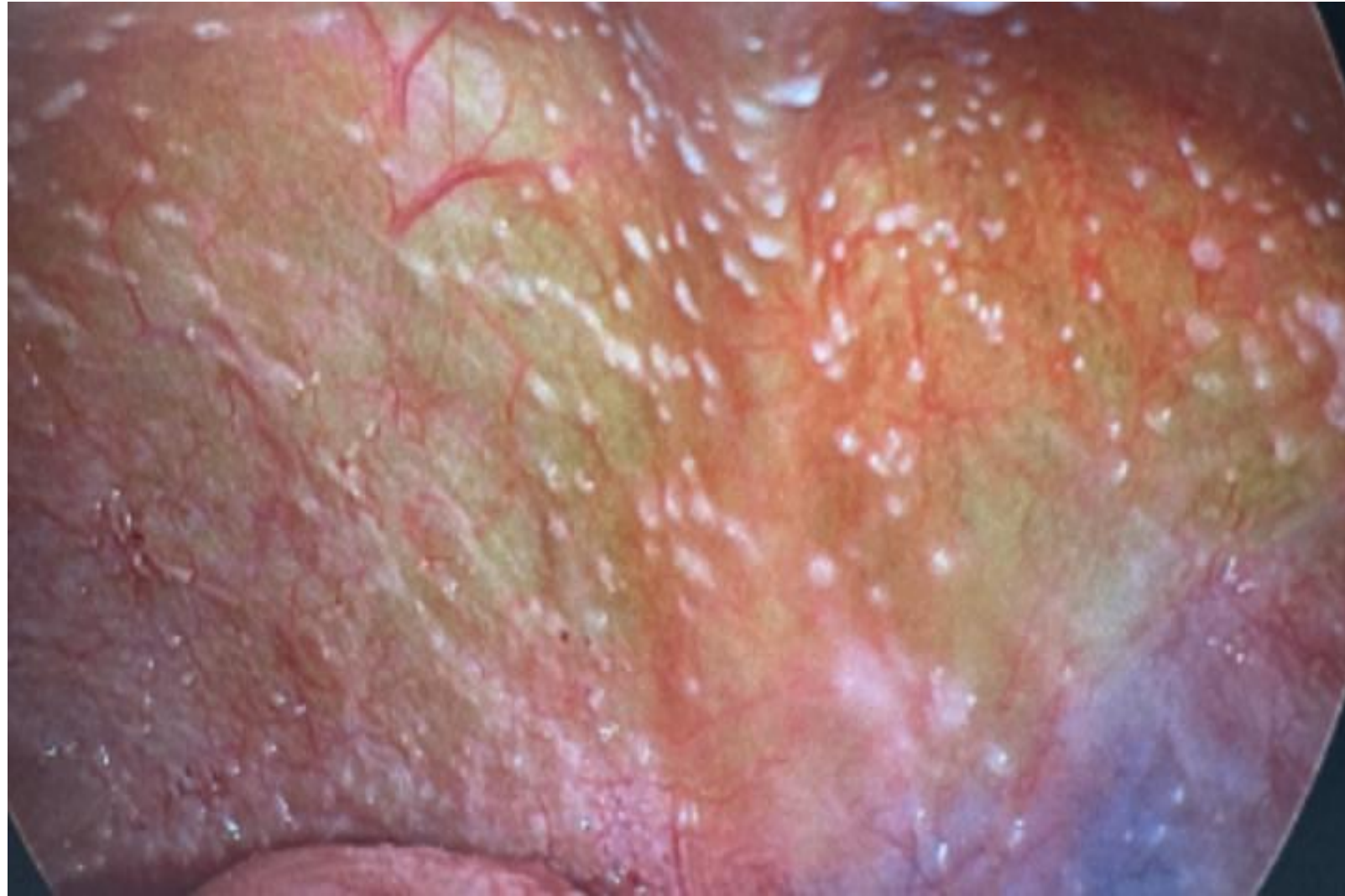
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# Disclosures

- Funding NIH (R01CA290115)
- US Patent- US25/60661
- Consultant or Advisory board- GE healthcare, On Target laboratories, Astra Zeneca

# Peritoneal Carcinomatosis

30%-40%

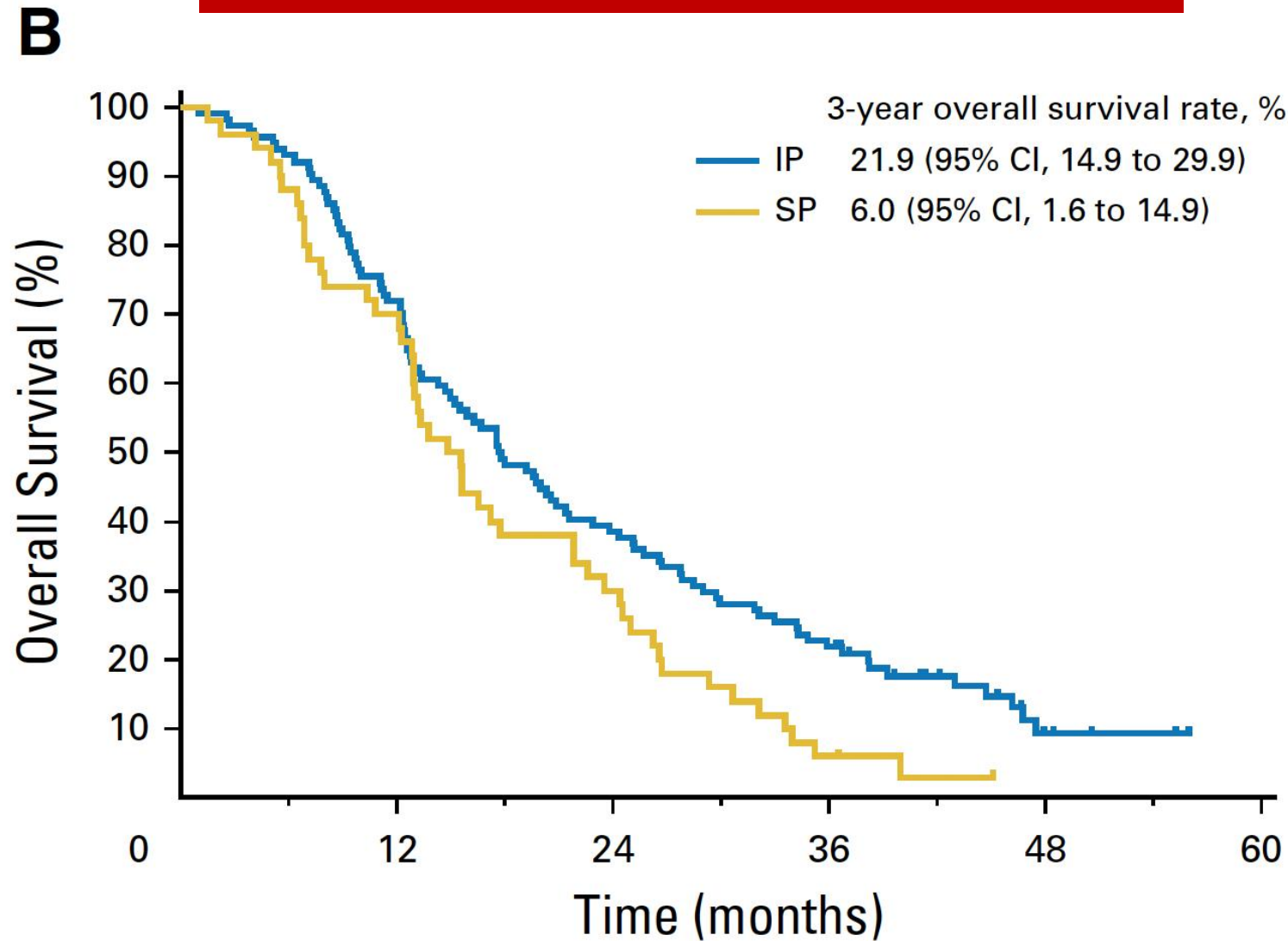


- Poor survival (6-13 months)
- Poor response to systemic therapy
- **Better therapies are needed!!**

# Systemic Therapy Plus Normothermic Intraperitoneal Paclitaxel

## PHOENIX- GC

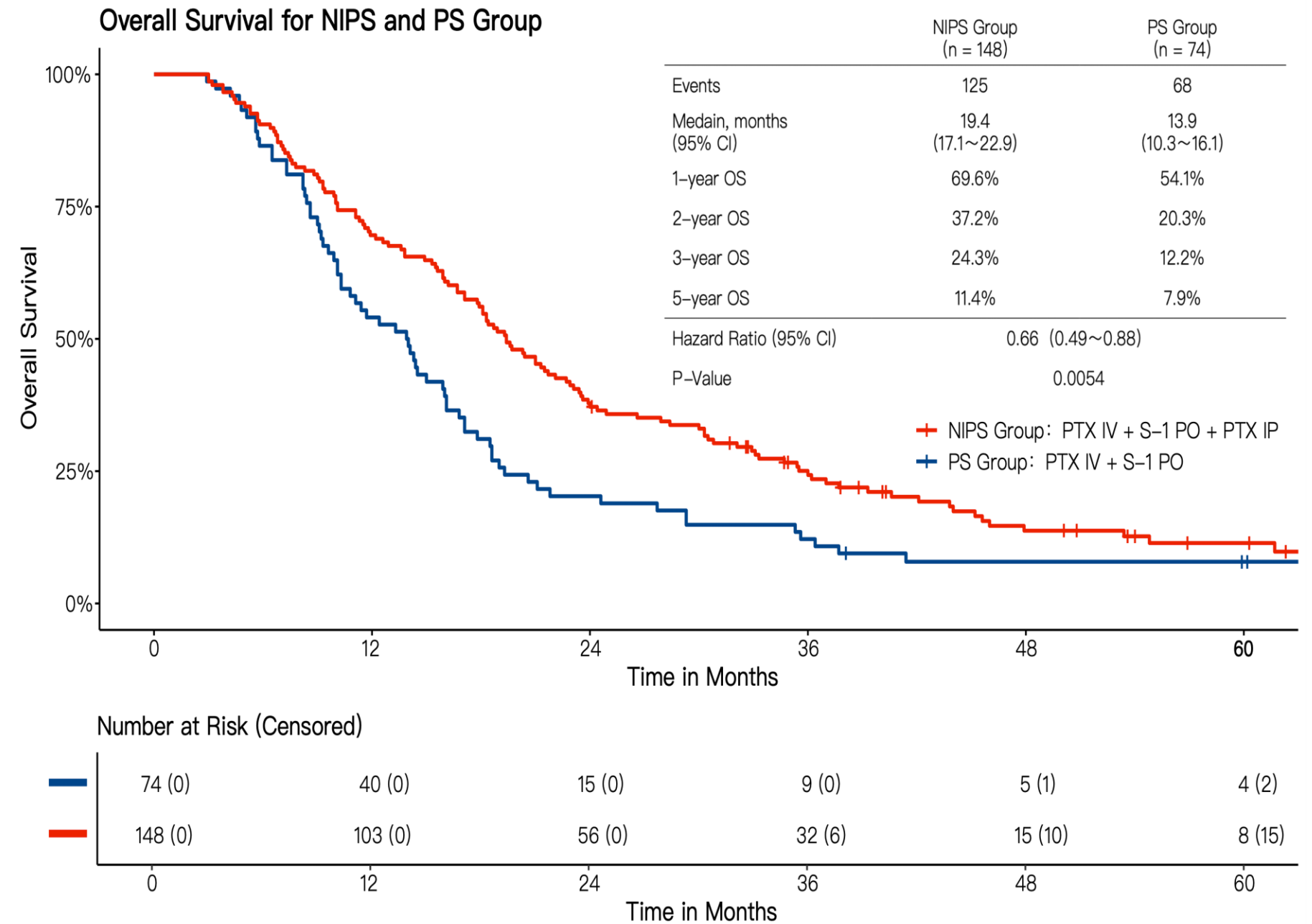
3-yr OS rate - 22% vs. 6%



No. at risk	0	12	24	36	48	60
IP	114	82	44	25	4	0
SP	50	35	15	3	0	0

## DRAGON-01

Median OS 13.9 vs. 19.4 months



RESEARCH

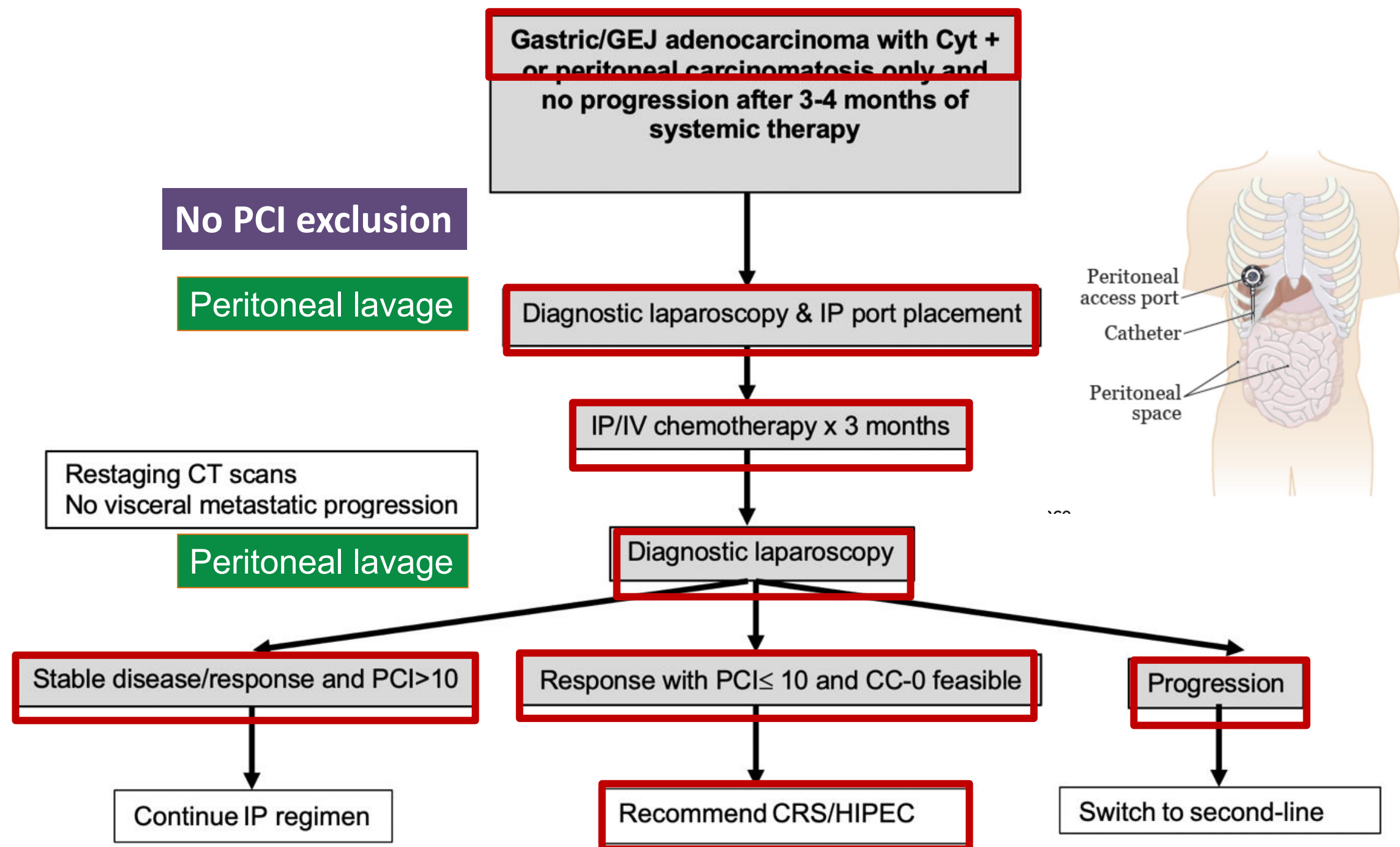
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# Phase II clinical trial of sequential treatment with systemic chemotherapy and intraperitoneal paclitaxel for gastric and gastroesophageal junction peritoneal carcinomatosis - STOPGAP trial

Maheswari Senthil<sup>1\*</sup> and Farshid Dayyani<sup>2</sup>

# STOPGAP I- Iterative Paclitaxel NIPEC



<b>Leucovorin</b>	20mg/m2	IV
<b>5-FU</b>	400mg/m2	IV
<b>Paclitaxel</b>	50mg/m2	IV
<b>Paclitaxel</b>	40mg/m2	<b>IP</b>

Targeted agents allowed ( Nivo, Trastuzumab etc.)  
Days 1&8, Q 3 weeks cycle for 4 cycles

Primary end point

- 1-year PFS

Secondary Endpoint

- Overall Survival
- PRO -QOL – EuroQol-5D-5L

# Patient Demographics

Enrollment period – May 2021- August 2025  
42.4% underwent CRS

Characteristics	All (n=33)	No CRS (n=19)	CRS (n=14)	P-Value
<b>Age - Median( range)-yr</b>	<b>50 (30-75)</b>	<b>47 (30-73)</b>	<b>56 (32-75)</b>	<b>0.43</b>
<b>Sex-no. (%)</b>				
<i>Male</i>	17 (51.5)	14 (73.7)	3 (21.4)	
<b><i>Female</i></b>	<b>16 (48.5)</b>	<b>5 (26.3)</b>	<b>11 (78.6)</b>	<b>0.003</b>
<b>Race or Ethnicity- no. (%)</b>				0.071
<i>Non-Hispanic white</i>	9 (27.2)	4 (21.1)	5 (35.7)	
<b><i>Hispanic</i></b>	<b>13 (39.4)</b>	<b>5 (26.3)</b>	<b>8 (57.1)</b>	
<i>African American or Black</i>	1 (3)	1 (5.3)	0 (0)	
<i>Asian</i>	9 (27.3)	8 (42.1)	1 (7.1)	
<i>Pacific Islander</i>	1 (3)	1 (5.3)	0 (0)	

# Tumor Characteristics

Characteristics	All (n=33)	No CRS (n=19)	CRS (n=14)	P-Value
<b>Tumor type - no.(%)</b>				0.60
<b><i>Diffuse</i></b>	<b>23 (69.7)</b>	<b>12 (63.2)</b>	<b>11 (78.6)</b>	
<i>Intestinal</i>	0 (0)	0 (0)	0 (0)	
<i>Mixed type</i>	2 (6.1)	1 (5.3)	1 (7.1)	
<i>Not reported</i>	8 (24.2)	6 (31.5)	2 (14.3)	
<b>Grade - no.(%)</b>				0.74
<b>1</b>	2 (6.1)	2 (10.5)	0 (0)	
<b>2</b>	2 (6.1)	1 (5.3)	1 (7.1)	
<b>3</b>	<b>29 (87.8)</b>	<b>16 (84.2)</b>	<b>13 (92.9)</b>	
<b>Signet ring- no.(%)</b>				0.20
<b><i>Present</i></b>	<b>27 (81.8)</b>	<b>14 (73.7)</b>	<b>13 (92.9)</b>	
<i>Absent</i>	6 (18.2)	5 (26.3)	1 (7.1)	

# Treatment Characteristics

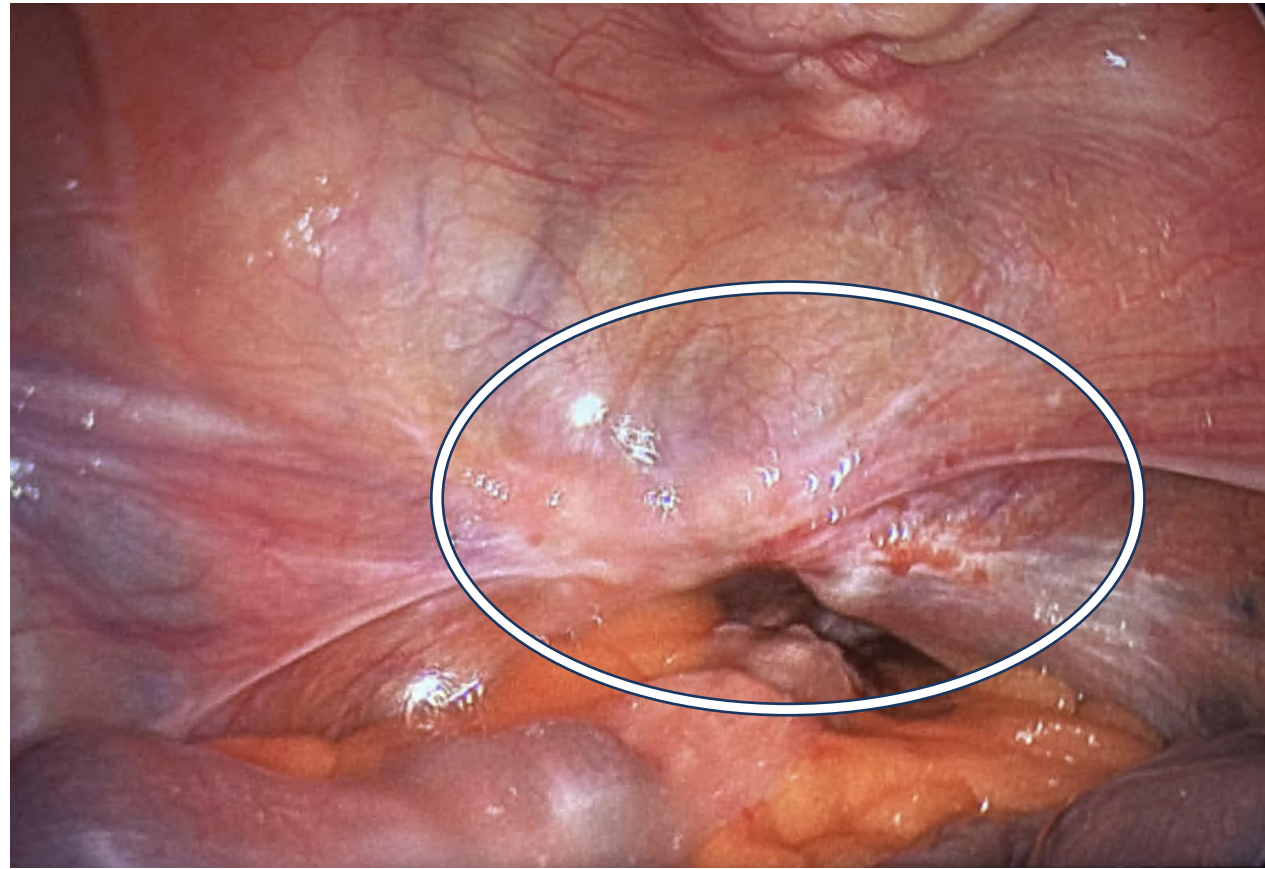
Characteristics	All ( n=33)	No CRS (n=19)	CRS (n=14)	P-Value
PCI at enrollment - Median (Range)	8 (0-36)	12 (0-36)	5 (0-24)	0.01
PCI at Enrollment – no. (%)				0.09
0	4 (12.1)	1 (5.3)	3 (21.4)	
1-6	10 (30.3)	4 (21.1)	6 (42.8)	
7-14	10 (30.3)	6 (31.5)	4 (28.6)	
>15	9(27.3)	8(42.1)	1(7.1)	
Cycles of IP PTX	4 (2-9)	4 (2-9)	4 (4)	

# STOPGAP I - Safety and Feasibility

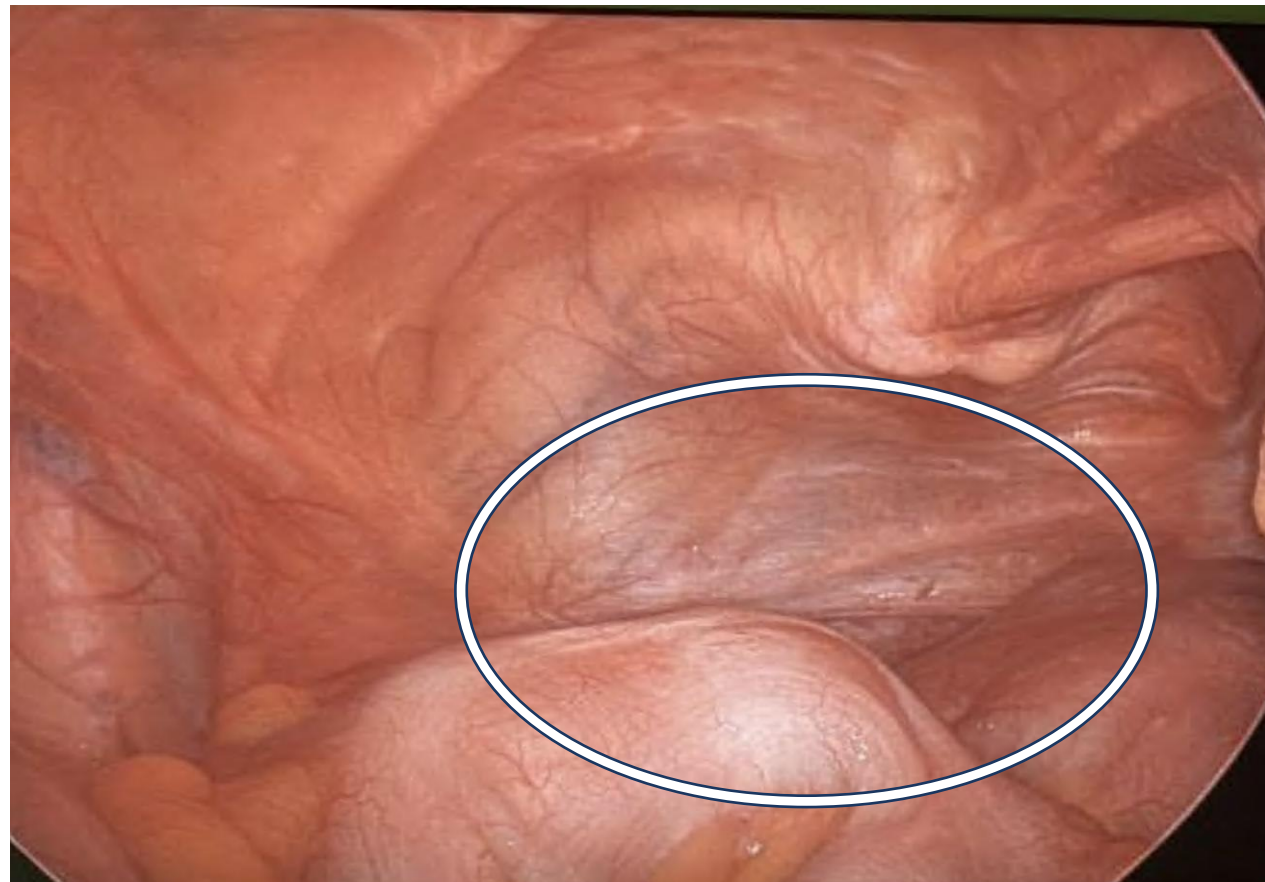
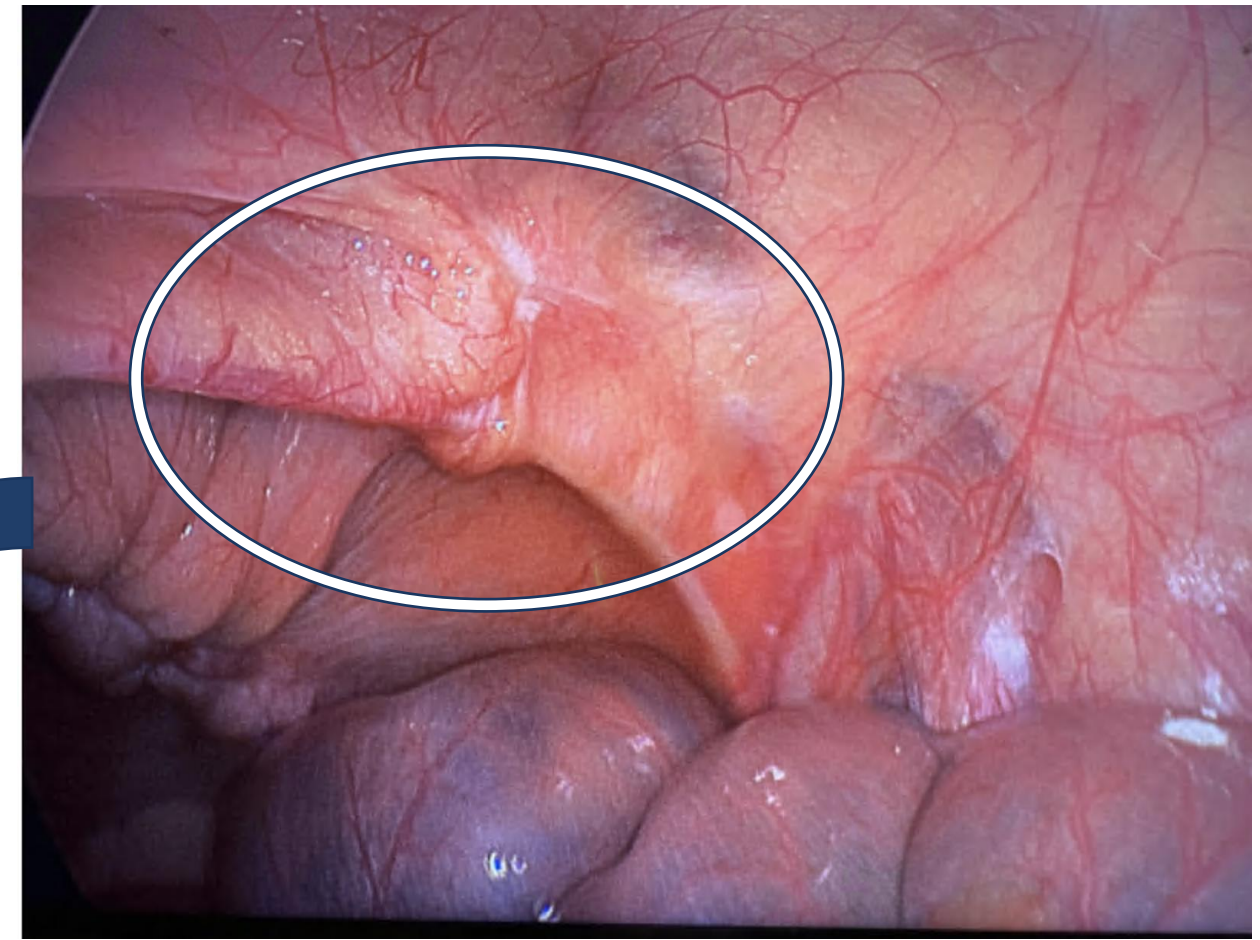
- **29/33 (87.9%)** patients completed at least four cycles of treatment
- **4/33 (12.1%)** patients discontinued treatment due to disease progression
- Grade 3 or higher TRAE occurred in **14/33 (42.4%)** patients
- No anastomotic leaks or 30 day-readmission in CRS group



# IP PTX Treatment Response



PCI decreased  
from **19** to **10**



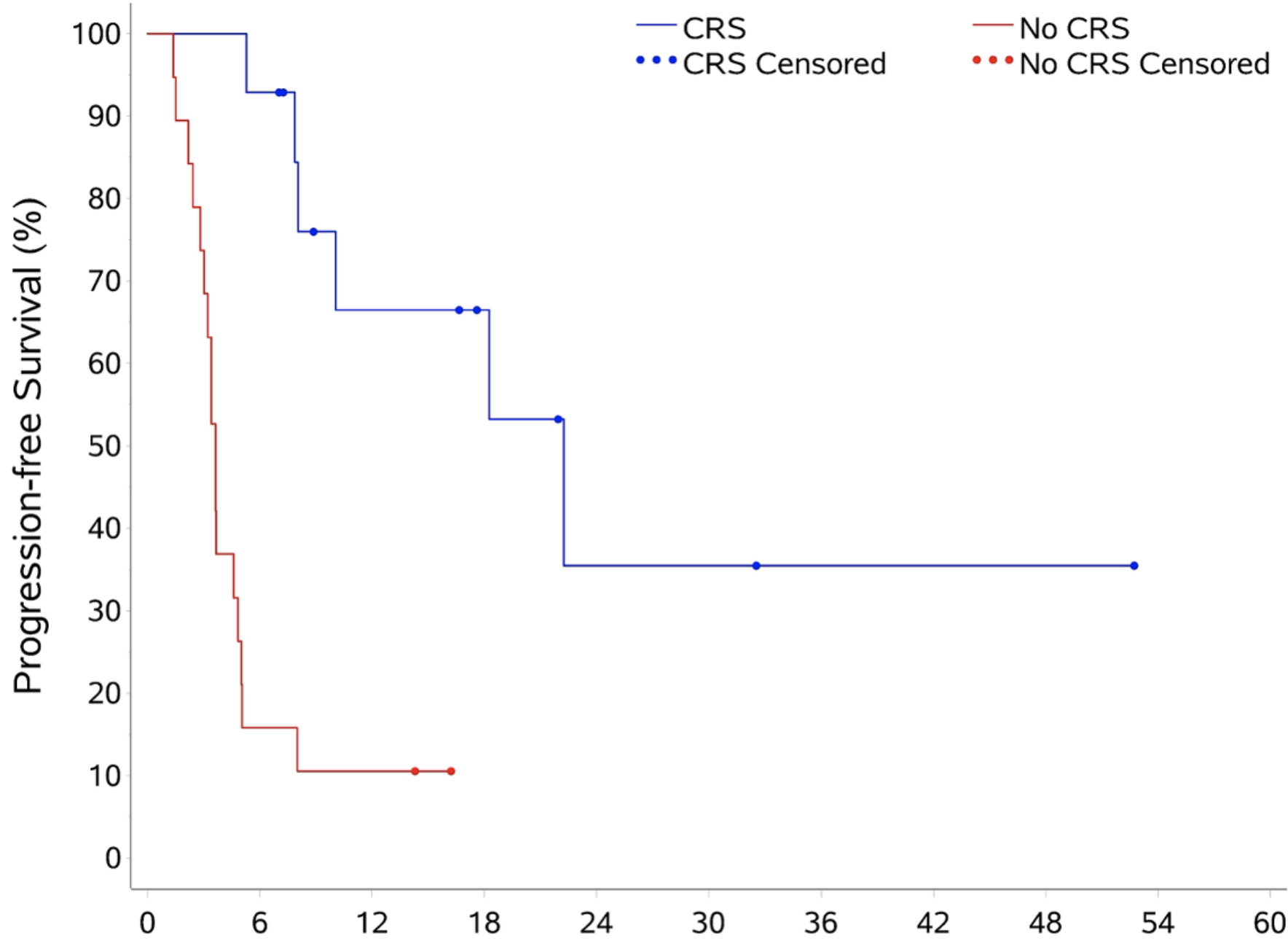
# STOPGAP | Survival

	Median PFS from diagnosis	Median PFS On study	Median OS from diagnosis	Median OS On study
<b>All patients (n=33)</b>	<b>12.1 (9.7-22.1)</b>	<b>5.3 (3.6-18.3)</b>	<b>17.8 (13.9-25.3)</b>	<b>11.4 (7.9- 21.5)</b>
<b>No CRS* (n=19)</b>	9.3 (7.1-11.4)	3.6 (2.8-4.8)	14.2 (11.0-16.2)	7.7 (5.2-11.1)
<b>CRS (n=14)</b>	<b>26.7 (12.5-NA )</b>	<b>22.2 (8.0-NA)</b>	<b>37.8 (17.4- NA )</b>	<b>33.3 (11.6-NA )</b>

Median f/u 10 months

\*P<0.001 CRS vs. no CRS

# Progression Free Survival On Study

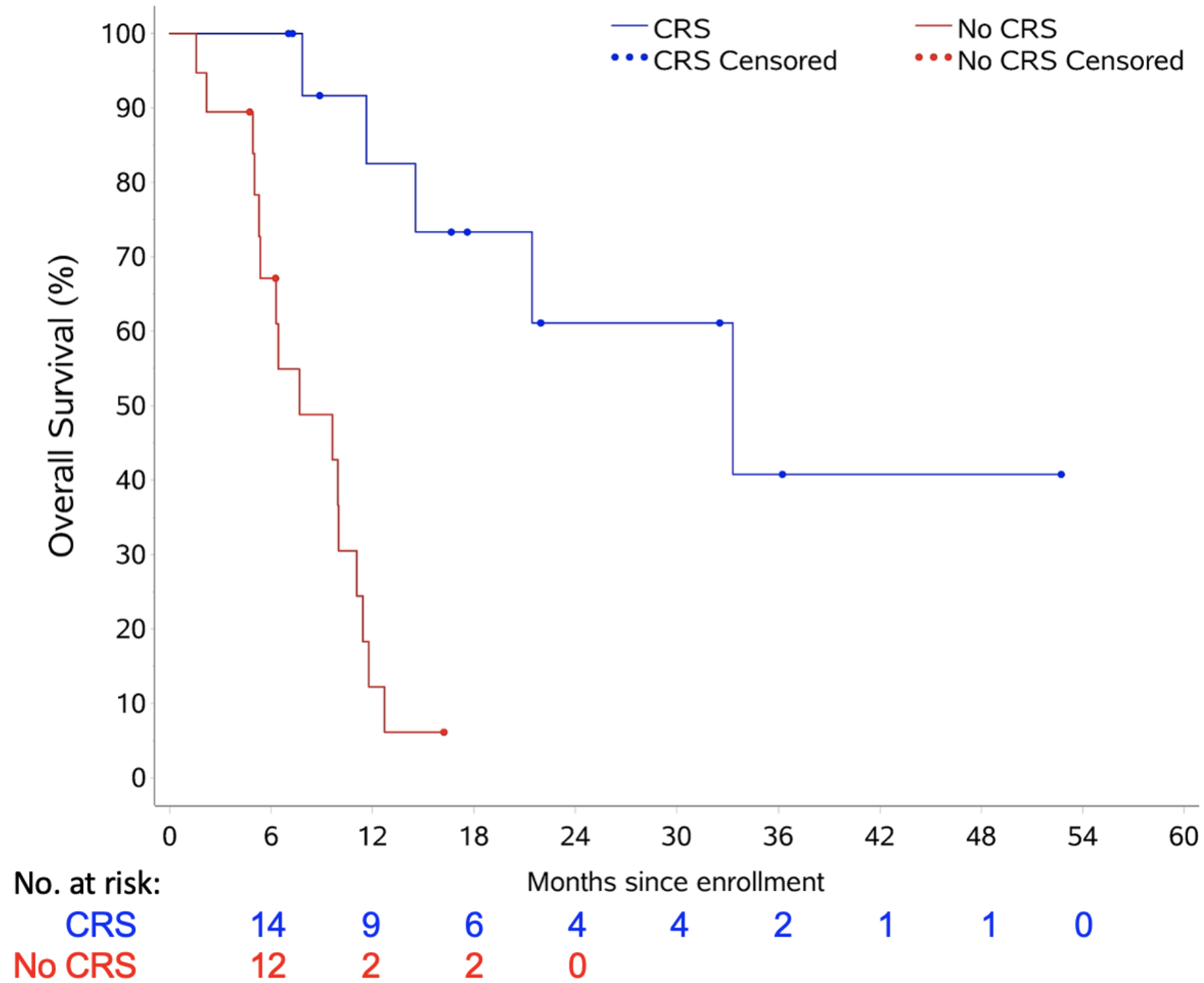


No. at risk:

	0	6	12	18	24	30	36	42	48	54
<b>CRS</b>	19	13	7	5	2	2	1	1	1	0
<b>No CRS</b>	19	3	2	0	0	0	0	0	0	0

	<b>No CRS N=19</b>	<b>CRS N=14</b>
<b>Median PFS, mos</b>	<b>3.6</b>	<b>22.2</b>
<b>95% CI</b>	<b>2.8-4.8</b>	<b>8.0-NA</b>
<b>P</b>	<b>&lt;0.001</b>	

# Overall Survival On Study



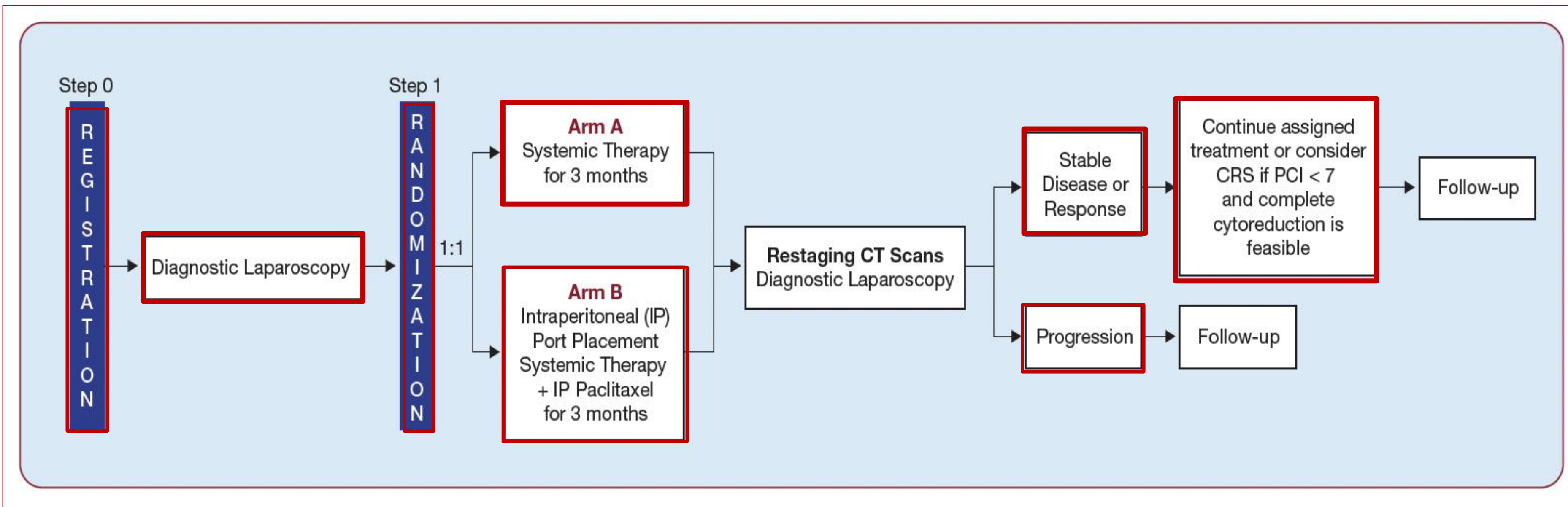
	No CRS N=19	CRS N=14
Median OS, mos	7.7	33.3
95% CI	5.2-11.1	11.6-NA
P	<b>&lt;0.001</b>	

# STOPGAP I – Conclusions

- **Systemic therapy plus intraperitoneal chemotherapy is safe and feasible**
- **Cytoreduction in appropriately selected patients is associated with significantly better survival**
- **Ongoing EA 2234 STOPGAP II trial will provide critical evidence about the benefits of IP therapy and the role of CRS in gastric PC**

# EA 2234 STOPGAP II Schema

Gastric/ GEJ cancer with synchronous Cyt+ or peritoneal carcinomatosis (MSS) and have received 3-6 months of 1L systemic therapy





UPMC LIFE CHANGING MEDICINE



Memorial Sloan Kettering Cancer Center

Yale University School of Medicine



UT Southwestern Medical Center



VANDERBILT UNIVERSITY MEDICAL CENTER

RUTGERS Robert Wood Johnson Medical School



UC Irvine Health

Wake Forest Baptist Medical Center

UNIVERSITY OF IOWA HOLDEN COMPREHENSIVE CANCER CENTER

University of Cincinnati Medical Center | UC Health

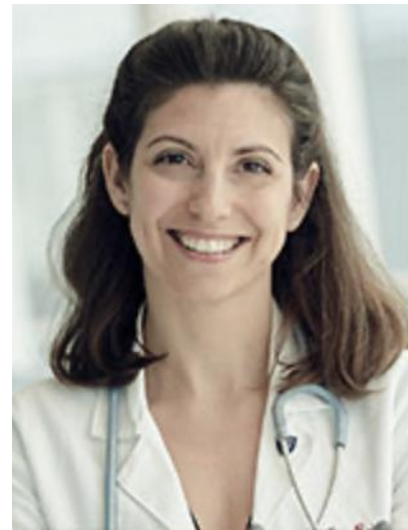


THE OHIO STATE UNIVERSITY WEXNER MEDICAL CENTER

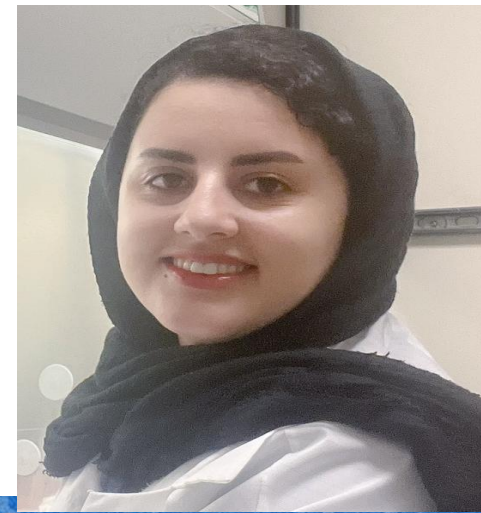
UW Medicine

KU MEDICAL CENTER The University of Kansas





**Sincere thanks to our patients, families, and my incredible team !!!**



# Back Up Slides

# Characteristics of CRS Group

Characteristics	Alive (n=9)	Dead (n=5)	P-Value
Alive without disease	8 (88.9)	NA	
Alive with disease	1 (11.1)	NA	
<b>PCI at enrollment</b>			0.01
Median (Range)	3 (0-9)	8 (6-24)	
0	3 (33.3)	0 (0)	
1-6	5 (55.6)	1 (20)	
7-14	1 (11.1)	3 (60)	
>15	0 (0)	1 (20)	
<b>PCI at CRS</b>			0.48
Median (Range)	1 (0-7)	2 (0-10)	
0	5 (55.6)	2 (40)	
1-6	3 (33.3)	2 (40)	
7-14	1 (11.1)	1 (20)	
>15	0 (0)	0 (0)	

# Resection CRS Group

Characteristics	Alive (n=9)	Dead (n=5)
<b>Primary Resection</b>		
Total gastrectomy	5 (55.6)	3 (60)
Subtotal Gastrectomy	4 (44.4)	2 (40)
<b>Additional Organ resections</b>		
Colon	2 (22.2)	1 (20)
Pancreas/spleen	1 (11.1)	2 (40)
Ovaries	5 (55.6)	2 (40)
Diaphragm	1 (11.1)	0 (0)
Small bowel	1 (11.1)	2 (40)
Peritoneum	4 (44.4)	3 (60)

# Pathologic Characteristics of CRS

Characteristics	Alive (n=9)	Dead (n=5)	P-Value
<b>Pathology</b>			
Tumor			0.03
yPT0	0 (0)	0 (0)	
yPT1	0 (0)	1 (20)	
yPT2	0 (0)	0 (0)	
yPT3	6 (66.7)	0 (0)	
yPT4	3 (33.3)	4 (80)	
<b>Node</b>			0.14
yPN0	1 (11.1)	2 (40)	
yPN1	5 (55.6)	0 (0)	
yPN2	1 (11.1)	2 (40)	
yPN3	2 (22.2)	1 (20)	
<b>Metastasis</b>			0.58
yPM0	6 (66.7)	2 (40)	
yPM1	3 (33.3)	3 (60)	



# THANK YOU!

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