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PIPAC – CLINICAL EVIDENCE

PIPAC in Gastric Cancer

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Disclosures

- Consultant for J&J Ethicon, and Imugene, LTD.

This presentation and/or comments will be free of any bias toward or promotion of the above referenced company or its products and/or other business interests.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

This presentation has been peer-reviewed and no conflicts were noted.

The off-label or investigational use of Cisplatin, Doxorubicin, Oxaliplatin, Mitomycin, Carboplatin will be discussed.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:
The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

The following CLC & IB components will be addressed in this presentation:

- Sensitivity to ethnic differences in understanding of gastric cancer (GC) as a disease, cultural views of clinical trial enrollment.
- The importance of addressing cultural information in discussing PIPAC as an investigational option in care for GC and of having available in-language trial enrollment and consent process.
- Ethnic disparities in GC that adversely impact Asian/Hispanic/Black Americans compared to NHW.
- Adverse impact of GCPC on young adult patients with higher incidence or peritoneal metastases.

Peritoneal Metastasis in Gastric Cancer

- End-stage manifestation of GC in urgent need of more effective therapies
  - Median survival of 3.1 to 11.0 months
  - 5-year survival from time of GCPM diagnosis is <2%
- Most common site of metastasis
  - 43% present with synchronous PM
  - 56% recurrence after FLOT plus curative intent surgery
  - 60% at time of death
- Staging laparoscopy for presumed locally AGC
  - Occult microscopic disease (~40%)
  - Macroscopic peritoneal carcinomatosis (~15%)

Studies show 23%-56% of patients who undergo perioperative FLOT develop peritoneal recurrence within 2 years of radical resection

High Risk Patient Characteristics for GCPM

- GCPM disproportionately affects young patients and ethnic minorities
- Young adults ≤40 years old are more likely to present
  - Stage IV disease (42.9% vs. 21.4–36.7% GC $P < 0.0001$)
  - Synchronous peritoneal metastases (32.0% vs. 10.5–25.9% GC, $P < 0.0001$).
- Hispanic were more likely to have peritoneal metastases
  - 14.8% versus
  - 9.7% in Asian Americans
  - 7.5% in NHW.

California Cancer Registry (2000-2012)

California Cancer Registry (2004-2014)

Tumor Factors at Risk for Peritoneal Metastases

Increasing Association with Peritoneal Dissemination

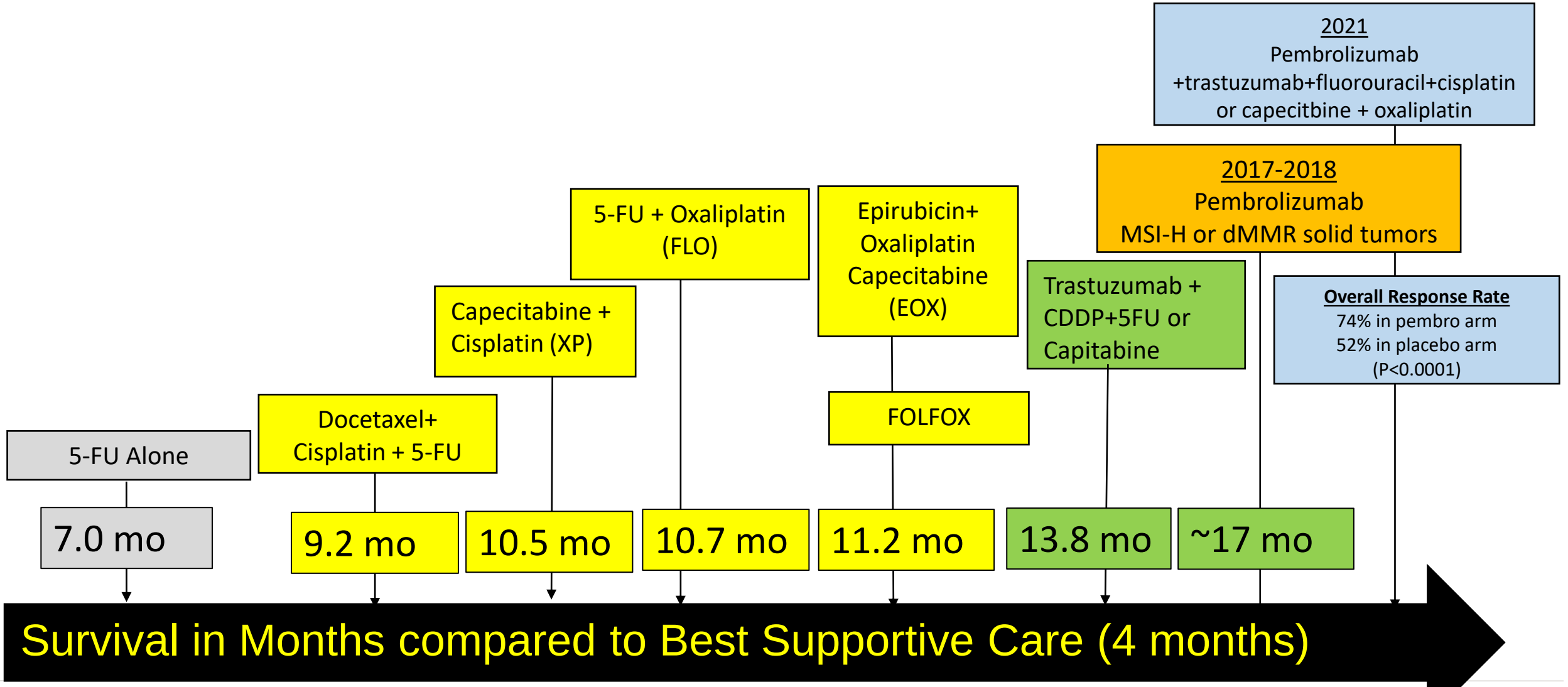
Borrmann R. Borrmann, 1926 [19]		**I**	**II**	**III**	**IV**
Lauren P. Lauren, 1965 [2]		**Intestinal**		**Mixed**	**Diffuse**
Singapore -Duke Z. Lei *et al*, 2013 [64]			**Metabolic** Metabolism pathways	**Proliferative** Intestinal histology *TP53* mutations High levels of CNA Cell cycle pathways	**Mesenchymal** Diffuse histology Loss of *CDH1* EMT/cell adhesion pathways Angiogenesis
TCGA The Cancer Genome Atlas Network, 2014 [3]	**EBV** EBV-CIMP PD-L1/2 expression *PIK3CA* mutations *JAK2* amplification IL-12 mediated signaling	**MSI** Hypermutation *MLH* silencing		**CIN** Intestinal histology *TP53* mutations High levels of CNA RTK-RAS activation Cell cycle pathways	**GS** Diffuse histology *CDH1, RHOA* mutations *CLDN18-ARHGAP* fusion Cell adhesion pathways
ACRG R. Cristescu *et al*, 2015 [4]		**MSI** Hypermutation *MLH1* loss	**MSS/TP53+** Intestinal histology	**MSS/TP53-** Intestinal histology *TP53* mutations Liver metastasis	**MSS/EMT** Diffuse histology Signet ring cell Peritoneal recurrence Early onset Loss of *CDH1* EMT pathways
Stromal/ vascular M. T. Uhlik *et al*, 2016 [74]		**I** High levels of lymphocytes Immature vascular markers	**VINI** Rudimentary vessels Immature stroma	**VM/I** Mature vascular markers Immune infiltrate	**VM**

High Risk GC Subtypes

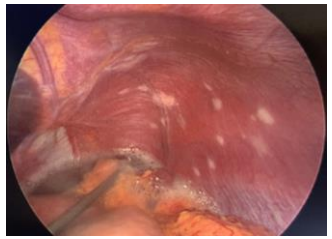
- Bormann: Type IV
- Lauren: Diffuse Type
- Singapore-Duke: Mesenchymal
- TCGA: GS
- ACRG: MSS/EMT
- Stromal/vascular: VM/I and VM

Chen Y et al. Cancers 2020.

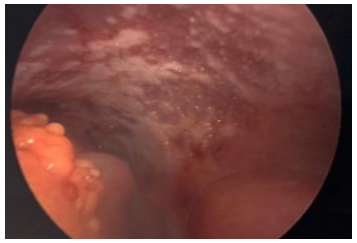
Systemic Therapies in Unresectable Metastatic GC



Peritoneal Directed Therapy for GC



Intent of Treatment
Palliative
Preventative
Curative ?



IP
Intraperitoneal Chemotherapy

Phase III Trial Comparing Intraperitoneal and Intravenous Paclitaxel Plus S-1 Versus Cisplatin Plus S-1 in Patients With Gastric Cancer With Peritoneal Metastasis: PHOENIX-GC Trial

- Trials have failed to demonstrate clear survival benefit
- However, responses were encouraging
- Patient selection and novel therapies are needed
- Several trials on-going

HIPEC
Heated IP Chemotherapy

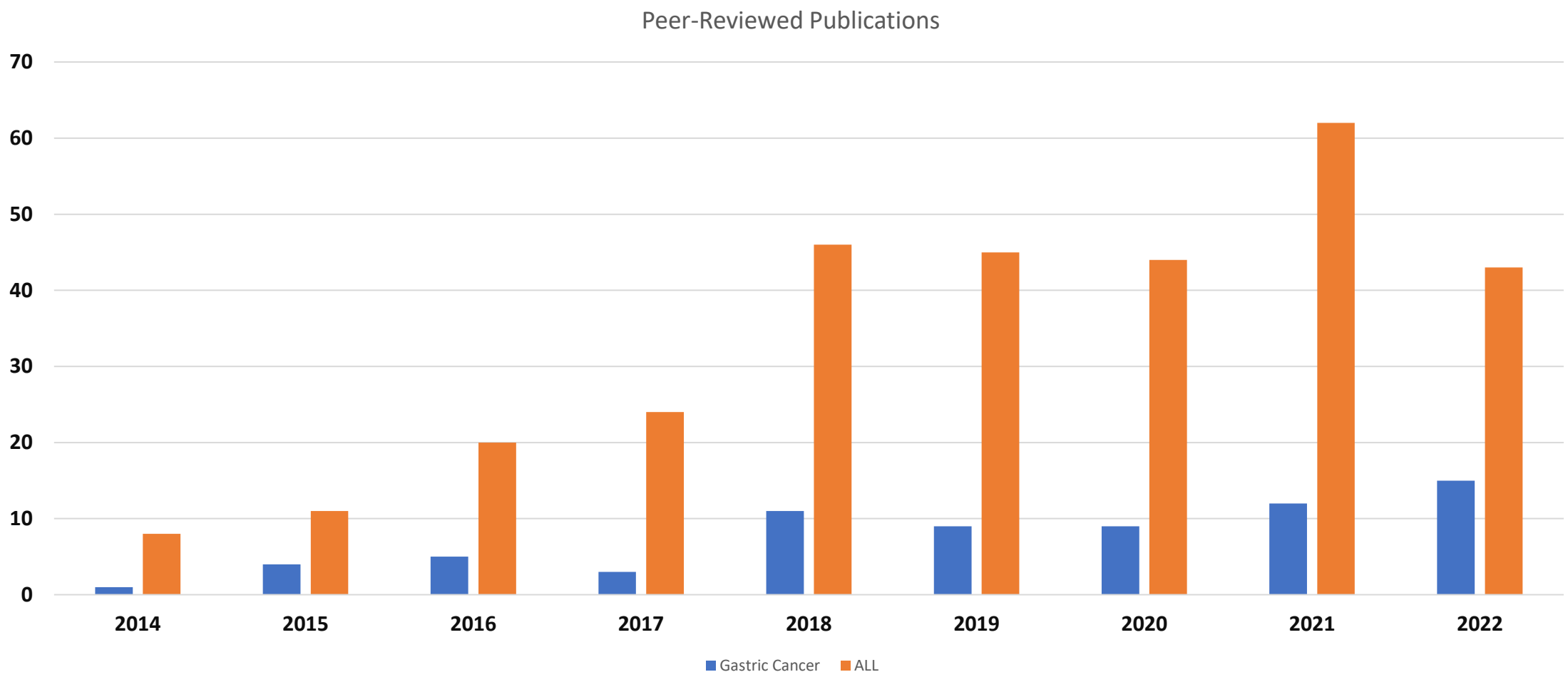
The Thirty-Year Experience - A Meta-analysis of Randomized and High Quality Non-Randomized Studies of Hyperthermic Intraperitoneal Chemotherapy in Gastric Cancer

- 30 years of clinical trials failed to achieve survival benefit for single dose HIPEC except
- May benefit patients with occult disease
- 18 vs 12 mo improved median OS with HIPEC+CRS vs CRS alone showing more promise
- PERISCOPE II trial, COETH Italian Trial are on-going

PIPAC
Pressurized Aerosolized IP Chemo

?

Increasing Number of PIPAC Studies Reported



Summary of PIPAC from International Trials

Peritoneal Cancer

Pressurised intraperitoneal aerosol chemotherapy: rationale, evidence, and potential indications

Mohammad Alyami, Martin Hübner*, Fabian Grass, Naoual Bakrin, Laurent Villeneuve, Nathalie Laplace, Guillaume Passot, Olivier Glehen, Vahan Kepenekian*

Prospective									
PIPAC OV-1[47]	Ovarian	64	130	11/64 (17%)	43/53 (81%)	4/53 (8%)	8/53 (15%)	0/53	0/53
PIPAC GA-1[48]	Gastric	25	43	NA	12/25 (48%)	NA	4/25 (16%)	0/25	0/25
PIPAC GA-2[49]	Gastric	31	56	0	15/31 (48%)	1/31 (3%)	4/31 (13%)	0/31	0/31
PIPAC OPC-1[43]	Various	35	129	0	30/35 (86%)	2/35 (6%)	4/35 (11%)	1/35 (3%)	0/35
Subtotal, weighted means	–	155	358	8·5%	69·4%	5·9%	13·9%	0·7%	0
Retrospective									
Tempfer and colleagues[38]	Ovarian	21	34	3/21 (14%)	8/18 (44%)	3/18 (17%)	3/18 (17%)	2/18 (11%)	0/18
Tempfer and colleagues[39]	Ovarian	99	252	17/99 (17%)	50/82 (61%)	5/82 (6%)*	17/82 (21%)	3/82 (37%)	0/82
Nadiradze and collaegues[52]	Gastric	25	60	1/25 (4%)†; 3/24 (13%)‡	17/24 (71%)	3/60 procedures (5%)	6/24 (25%)	1/24 (4%)	2/24 (8%; nr)
Odendahl and colleagues[53]	Various	91	158	NA†; 5/91 (6%)‡	48/91 (53%)	3/91 (3%)	8/91 (9%)	1/91 (1%)	3/91 (3%; 2r, 1nr)
Robella and colleagues[40]	Various	14	40	0	14/14 (100%)	0	0/14	0/14	0/14
Demtröder and colleagues[54]	Colorectal	17	48	0†; 6/17 (35%)‡	14/17 (82%)	0	4/17 (24%)	0/17	0/17
Graversen and colleagues[55]	Pancreatic	5	16	0	5/5 (100%)	0	0/5	0/5	0/5
Hübner and colleagues[56]	Various	44	91	2/44 (4%)	30/42 (71%)	1/42 (2%)	0/42	0/42	1/42 (3%; nr)
Alyami and colleagues[58]	Various	73	164	NA	45/73 (62%)	NA	14/73 (195)	0/73	5/73 (7%; 1r, 4nr)
Khosrawipour and colleagues[57]	Pancreatic	20	41	0†; 3/20 (15%)‡	10/20 (50%)	0	0/20	0/20	1/20 (5%; nr)
Falkenstein and colleagues[58]	Biliary tract	13	17	2/13 (15%)	5/11 (45%)	0	0/11	0/11	0/11
Kurtz and colleagues[59]	Various	71	142	8/71 (11%)	39/63 (62%)	7/142 (5%)	1/63 (16%)	0/63	1/63 (16%; nr)
Gockel and colleagues[60]	Gastric	28	46	3/28 (11%)†; 2/24 (8%)‡	14/24 (58%)	NA	0/24	0/24	0/24
Horvath and colleagues[61]	Pancreatic	12	23	0	6/12 (50%)	0	0/12	0/12	0/12
Jansen-Winkeln and colleagues[62]	Various	62	111	5/59 (8%)†; 4/54 (7%)‡	33/54 (61%)	7/54 (13%)	NA	NA	NA
Giger-Pabst and colleagues[39]	Mesothelioma	29	74	7/29 (24%)	20/22 (91%)	0	1/22 (5%)	2/22 (9%)	1/22 (5%; r)
Subtotal, weighted means	–	624	1317	10·5%†	62·6%	Not pooled (data heterogeneity)	10·4%	1·7%	r: 0·8%; nr: 1·9%

PIPAC=pressurised intraperitoneal aerosol chemotherapy. CTCAE=Common Terminology Criteria for Adverse Events. NA=not available. r=death related to PIPAC procedure. nr=death not related to PIPAC procedure. *CTCAE grade 3 or 4. †Primary non-access (during first PIPAC), ‡Secondary non-access (during repeated intended PIPAC).

Table 1: **Feasibility, safety, and tolerance of PIPAC**

- Over 42 Clinical Trials
- Over 800→12,500 procedures in 40 countries
- Over 528 stomach cancer patients
- Safe and feasible
- 79% stable disease or decreased ascites
- 10-20 months survival
- May prolong survival
- On-going trials in Europe and Singapore

❖ **Phase I Device Registry trial open in U.S. at COH, Northwell, Mayo Clinic (T. Dellinger, PI)**

Lancet Oncol 2019; 20 e368-77

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In Combination with Systemic Chemotherapy

Pressurized intraperitoneal aerosol chemotherapy (PIPAC) for unresectable peritoneal metastasis from gastric cancer

Inclusion Criteria:
- Unresectable PM
- ECOG status <2

Exclusion Criteria:
- Bowel obstruction
- Extra peritoneal disease
- History of allergic reaction to platinum agents or doxorubicin

PIPAC AGENTS
- Cisplatin (7.5 mg/m^2 of body surface in 150 ml NaCl 0.9%)
- Immediately followed by doxorubicin (1.5 mg/m^2 in 50 ml NaCl 0.9%).
- The system was then kept in steady state for 30 min (application time).

Treatment Plan
- The goal was to repeat PIPAC every 6–8 weeks for at least three procedures
- Delay of the systemic chemotherapy is 2 weeks before and after each PIPAC procedure.

Outcomes
- 163 PIPAC Procedures in 42 Consecutive Patients
- Synchronous PM (76.2%)
- Median PCI 17 (1-39); 8 with ascites (0.5-4L)
- Median LOS =3 d (2-56)
- Median time to systemic chemotherapy 14 days
- CTCAE 3-4 6.1% in 5 procedures
  - Intestinal obstruction
  - Allergic reaction
  - PE
  - 30-day mortality 2 patients (4.7 %)
  - OS 19.1 mo
  - 6 patients resectable after 3 PIPACs

M. Alyami et al. 2021

In Combination with Systemic Therapy

Systemic chemotherapy and pressurized intraperitoneal aerosol chemotherapy (PIPAC): A bidirectional approach for gastric cancer peritoneal metastasis

A. DiGorgio et al. 2020

- Forty-six PIPAC procedures
- mean of 1.7 PIPAC /patient
- Median time to systemic chemo after PIPAC = 6 days (range 4-7).
- Two grade 3-4 CTCAE toxicity events
- Thirteen patients repeated PIPAC.
- A pathological response in 61.5% of patients
  - one with pCR
  - 7 with pPR
- Median OS was 12.3 months in the overall population
  - 15.0 months in patients undergoing more than one PIPAC procedure.

Table 3
Operative outcomes in patients

Patient	Setting	I PIP			Survival	
		PS			OPS	OS
1	First line	0			22.0	30.4
3	Third line	0			13.7	24.5
5	Third line	0			6.8	21.4
7	Third line	0			8.3	18.0
11	First line	0		3)	5.8	10.8
16	First line	1		3)	3.1	11.1
17	First line	0			4.1	7.8
18	Second line	0			5.4	15.0
19	Second line	1		2)	10.4[a]	20.3[a]
21	Maintenance	1			5.4	14.9
23	First line	1		HIPEC	10.3[a]	16.8[a]
25	Maintenance	1			6.9	11.8
26	Third line	1			7.1	12.6
					6.9 ± 5.0	15.0 ± 6.3

I.V. CHT = Intravenous Chemoth … essed as mean (max); OPS = Overall Procedure Survival (i.e. from firs …

[a] Alive.

[b] 2 cases of rapid disease progression.

PIPAC-OPC4 Study – Results at ISSPP Congress

Adjuvant Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC) During Laparoscopic ion in High-risk Gastric Cancer Patients: A Multicentre Phase-I Study (the PIPAC-OPC4 Study) (NCT0404709

Inclusion: Diffuse cancer (signet ring cells predominant) or clinical stage: cTany + cN2-3 or cT3-T4 + cNany or GAC patients with preoperative positive peritoneal cytology submitted to laparoscopic gastrectomy (neoadjuvant treatment).

- PIPAC with doxorubicin (2 surface in 50ml sali
- PIPAC cispl face in 150ml sa
- 0.5-0.8 ml/s imum pressure of 300 pressure per re inch and 30 minutes of simple diffusion.

Primary Ou

- CTCAE version 5.
- ons Dindo-Clavien classification

ry Outcome Measures

Length of stay

- Amount of time the patient is hospitalized
- The rate of positive peritoneal lavage before / after surgery
- The number of patients that receive adjuvant systemic chemotherapy

COMPLETED- RESULTS TO BE PRESENTED AT THE GASTRIC CANCER SESSION AT THE ISSPP CONGRESS 2022

Odense PIPAC Center, Denmark; PI: . SB Ellebaek, MD PhD

Cost-Effectiveness of PIPAC in GCPM

- **Economic modeling -** The outcomes of interest OS, QoL, total costs for each strategy (drug, surgery fee, drug fee, etc) and incremental cost per QALY gained.
- **Upfront therapy:** Combination of PIPAC C/D with first-line systemic chemotherapy (Oxaliplatin in combination with Capecitabin versus first-line palliative chemotherapy alone.
- **Second-line therapy** (salvag situation): PIPAC alone versus second-line chemotherapy (Ramucirumab monotherapy).

Second-line therapy	P	l-line erapy	Incremental
Total costs per patient		06	(£21,474)
Effectiveness			
Mean Overa		4.3	3.16
Tot	0.45	0.25	0.19
	Dominant		
ffective at £20,000	**100%**		
y of being cost-effective at £30,000	**100%**		
Probability of being cost-effective at £50,000 WTP	**100%**		

- **PIPAC C/D plus chemotherapy is a cost-effective**
- **PIPAC C/D alone as a second-line therapy has the potential to reduce costs and improve clinical outcomes for patients with GCPM**

M. Javanbakht et al. 2022

Phase 1 Study of PIPAC with Oxaliplatin plus Nivolumab in Patients with GCPC . (NCT03172416)

Phase I study: 3 + 3 dose escalation and cohort expansion design

- The pre-planned dose levels of PIPAC oxaliplatin
  - 45mg/m2 (Cohort 1)
  - 60mg/m2 (Cohort 2)
  - 90mg/m2 (Cohort 3)
  - 120mg/m2 (Cohort 4)
  - 150mg/m2 (Cohort 5)
- PIPAC every 6 weeks **with 240mg IV nivolumab every 2 weeks**

Primary Outcome Measures

- Safety Profile and tolerability of PIPAC with oxaliplatin
- Safety Profile and tolerability of PIPAC with oxaliplatin in combination with IV nivolumab

Secondary Outcome Measures

- **Clinical response** of PIPAC with oxaliplatin (and plus nivolumab)–**PCI score**
- **Pathological response** of PIPAC with oxaliplatin (and plus nivolumab)-**PRGS**
- **Blood Cmax** of oxaliplatin administered via PIPAC
- Pharmacokinetics of PIPAC Oxaliplatin

National University Singapore, PI: Jimmy So, MD

Clinical Trials of PIPAC in GC

Title	Conditions	Phase
• Adjuvant PIPAC in Gastric Cancer Patients	GC	
• Neoadjuvant Chemotherar	GC	
• Intraperitoneal Aerosol C	GC	
• Oncological Benefits of	C	
• Pressurized Intraperitor	C	
• PIPAC in Multimodal Th	C	
• Neoadjuvant Systemic a	C	
• PIPAC for the Treatment	C	
• Study of Efficacy and Sa Carcinomatosis From Co	C and other	
• PIPAC Nab-pac for Stom	C and other	
• Intraperitoneal Aerosoli	C and other	
• International Registry o	C and other	
• PIPAC With Nab-paclitax	C and other	
• Pressurized Intraperiton	C and other	
• Pressurized Intraperitonea Peritoneal Carcinomatosis	GC and other	
• Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC) in Gastric Carcinomatosis. Phase II Randomized Study	Gc and other	

Total of 16 trials registered on clinicaltrials.gov

Completed 3

Recruiting 8

Active not recruiting 2

Unknown 2

Suspended 1

Multi-institutional Phase I Device Registry Trial for PIPAC in US

Safety and efficacy of pressurized intraperitoneal aerosolized chemotherapy (PIPAC) in gynecologic, colorectal, appendiceal, and gastric patients with peritoneal carcinomatosis (PC)

Phase I pilot study

Arm 1	Ovarian cancer Uterine cancer Gastric cancer	*Cisplatin 10.5 mg/m²* *+ Doxorubicin 2.1 mg/m²* *IP q6weeks*
Arm 2	Colorectal cancer Appendiceal cancer	*Oxaliplatin 90 mg/m² IP* *+ 5-Fluorouracil/leucovorin IV* *q6 weeks*
Arm 3	Colorectal cancer Appendiceal cancer	*Mitomycin C (MMC) (dose-finding) starting at 7 mg/m2, escalate to 25 mg/m2 q6 weeks*

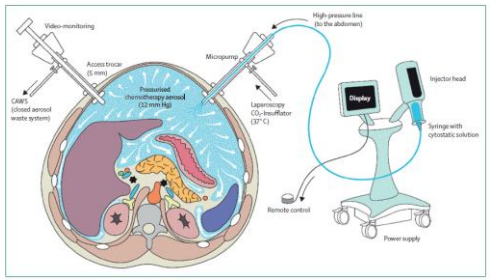

Figure 2: Schematic of PIPAC set-up
A hermetically sealed 10-12-mm trocar and a 5-mm balloon trocar are inserted. The liquid chemotherapy regimen is vaporised using a standard injector connected to a nebuliser. Reprinted from Hübner and colleagues[4] with permission from Médicine et Hygiène. PIPAC=pressurised intraperitoneal aerosol chemotherapy.

Registration

< 6 weeks prior to therapy

Protocol Therapy

PIPAC Week 0

PIPAC Week 6

PIPAC Week 12

DLT period

AE monitoring - 18 weeks

Follow-up

Every 12 weeks

Time to progression (PD also monitored at any time during study)

1 year

Progression-free survival

- Indications for GC PC Patients:
  - Biopsy proven GC PC
  - High burden of peritoneal disease
  - Progressed on systemic therapy
- Laparoscopic procedure
- Repeat 3 times every 6 weeks
- Short hospital stay ~24 hr

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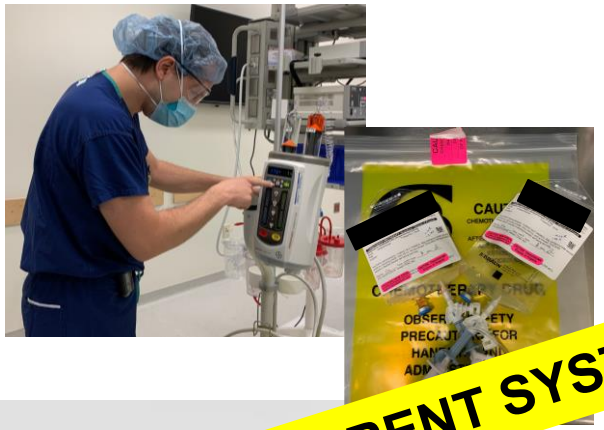
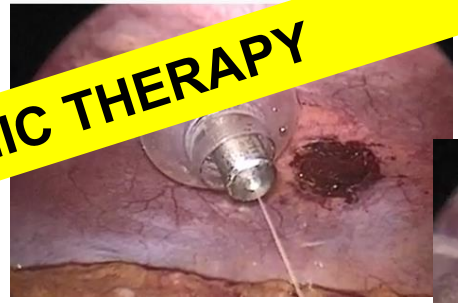
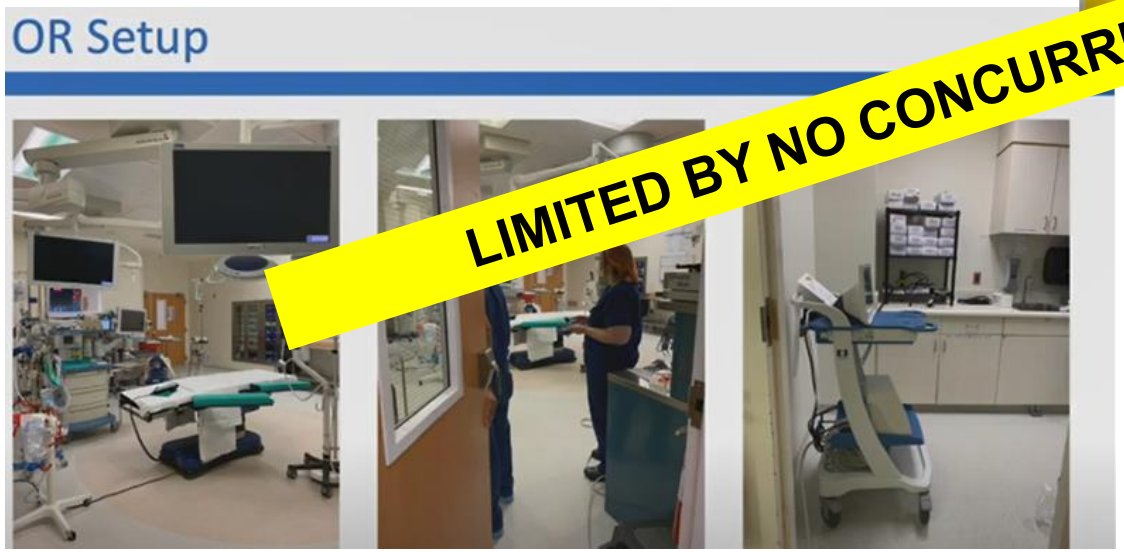
First US GC Patient Undergoing PIPAC with COH TEAM

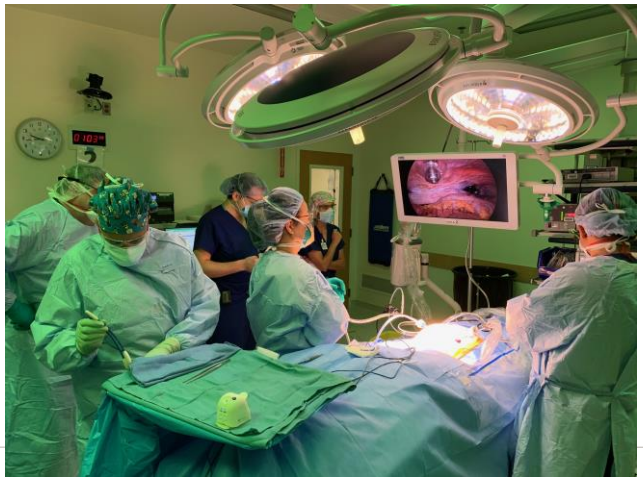


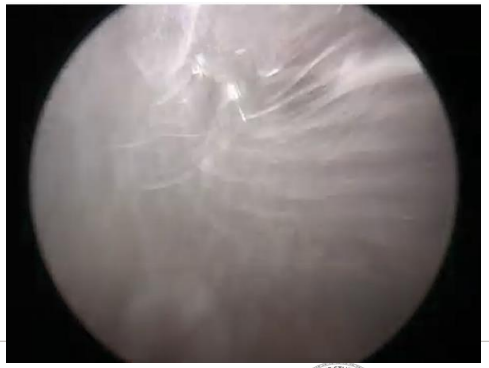
Intra-abdominal view





LIMITED BY NO CONCURRENT SYSTEMIC THERAPY





Extra-abdominal view

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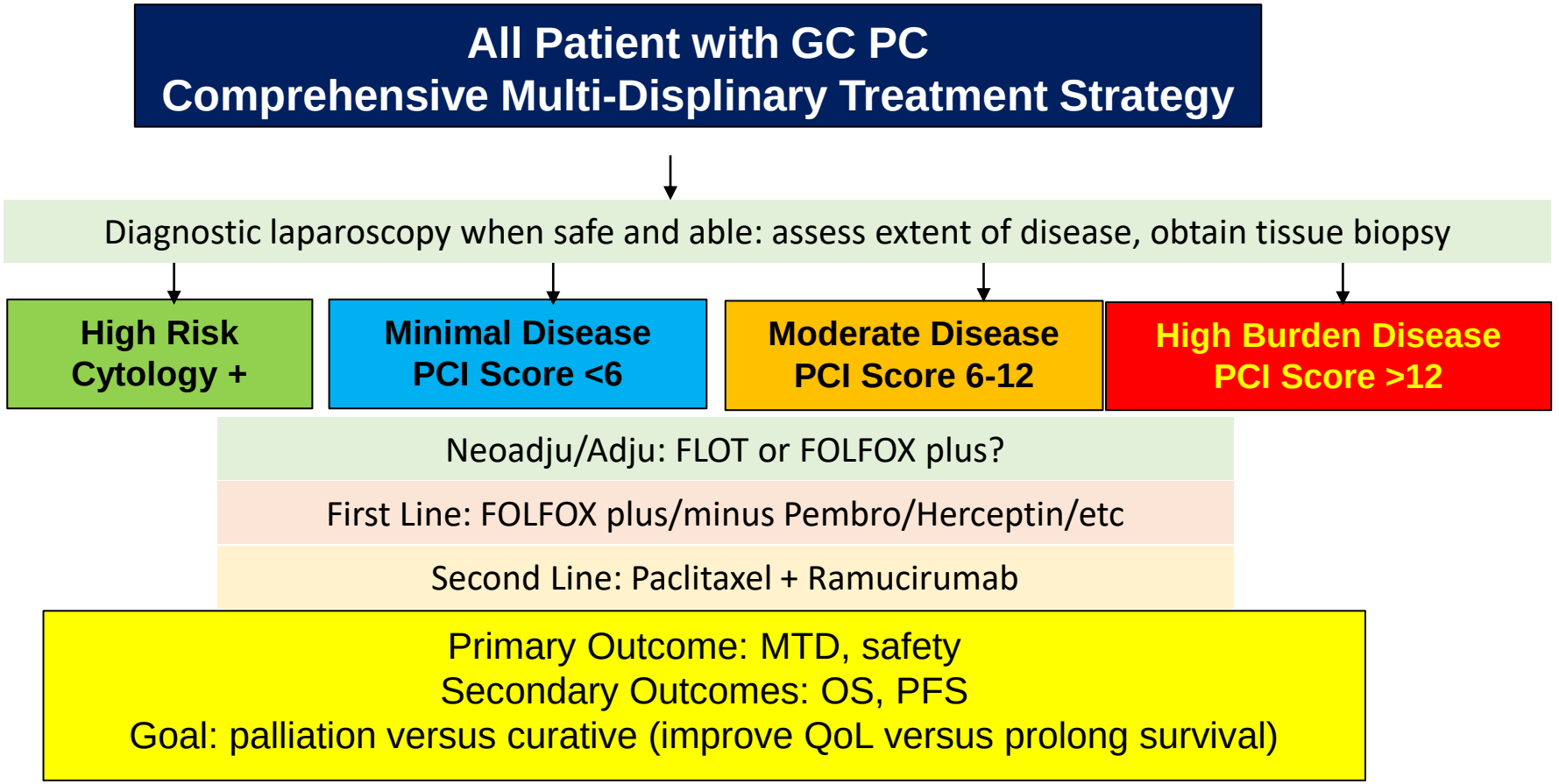
Considerations for Application of PIPAC in GC

- Timing of PIPAC (First-line, second-line, third line, adjuvant, prophylactic)
- PIPAC Drug / Dose Selection
- Dosing Schedule between IV and PIPAC dosing
- Patient Selection-
  - Age ?
- Disease Selection (Burden of PC/MA)
  - Other Sites of Metastases
- Other Considerations



Exploratory Measures: peritoneal TME changes over the course of therapy

Specimen collection: primary tumor, PM, peritoneal fluid, peripheral blood

Proposal for phase I dose-escalation trial to evaluate the safety and tolerability of docetaxel PIPAC in combination with first-line standard of care therapy in gastric cancer patients with peritoneal metastases

Kevin M Sullivan[1], Raghav Sundar[2], Joseph Chao[1], Samuel Klempner[3], Daneng Li[1], Alexander Jung[1], Sue Chang[1], Rifat Mannan[1], Paul Frankel[1], Wei Peng Yong[2], I Benjamin Paz[1], Thanh Hue Dellinger[1], Mustafa Raoof[1], Jimmy So[2], Yuman Fong[1], Yanghee Woo[1]

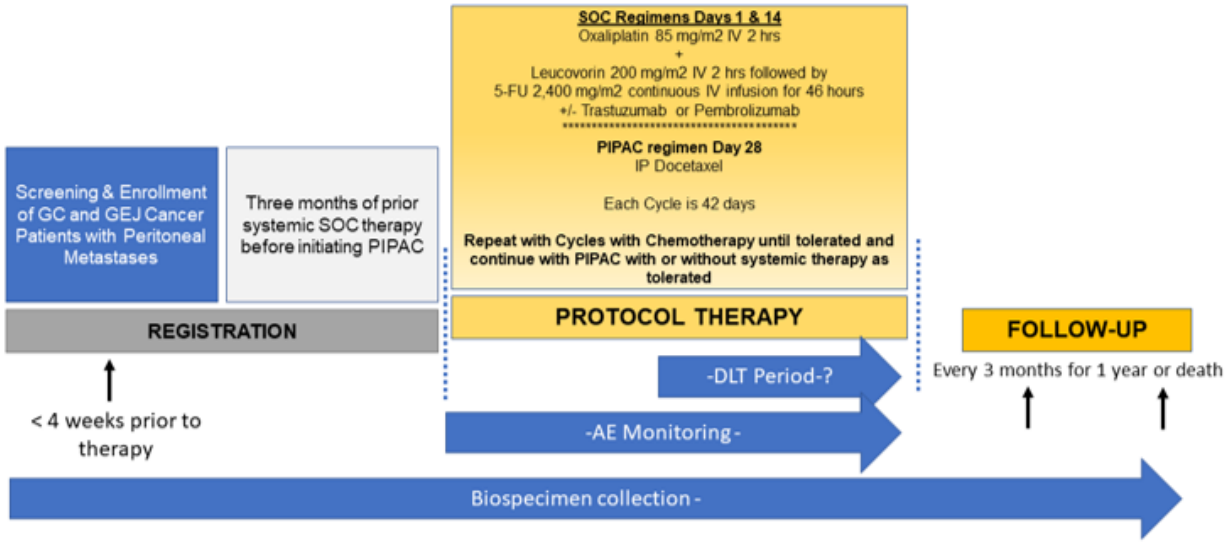
[1] City of Hope National Medical Center, Duarte, CA, [2] National University of Singapore, Singapore, Singapore, [3] Massachusetts General Hospital, Boston, MA

BACKGROUND

- Peritoneal metastases (PM) from gastric cancer (GC) often progress within 3 months of standard of care first line systemic chemotherapy
- PIPAC has demonstrated safety in clinical trials in gastric, gynecologic, appendiceal, and colorectal PM outside of the U.S.
- Cisplatin/doxorubicin PIPAC in patients with unresectable GC showed overall survival (OS) of 19 months and 14.3% of patients became resectable with <10% major complications (Alyami M et al. Eur J Surg Oncol 2021)
- A phase II study of cisplatin/doxorubicin PIPAC in 25 patients showed 40% complete response, partial response, or stable disease, including 36% histologic complete or major regression. (Struller F et al. Ther Adv Med Oncol 2019)
- Safety of docetaxel PIPAC in combination with systemic therapy has not been established.

METHODS

- Eligibility: Patients with GC PM who have received ≥ 3 months of first-line therapy consisting of IV oxaliplatin and fluorouracil (5-FU) plus leucovorin +/- trastuzumab or pembrolizumab
- Exclusion criteria: extraperitoneal disease, progression, contraindications for laparoscopy, poor performance status, or bowel obstruction
- Dose escalation schedule follows the 3+3 design (lead-in cohort 50 mg/m2, then 75, 100, and 125 mg/m2) plus SOC chemotherapy



RESULTS

- Primary endpoint: incidence and severity of AEs and dose limiting toxicity (DLT)
- Secondary endpoints:
  - Peritoneal tumor response (by peritoneal regression grade score)
  - PCI score
  - Imaging [RECIST 1.1]
  - Progression free and OS rates
- Exploratory endpoints: Longitudinal blood, urine and tissue specimens collected for translational correlatives including pharmacokinetics, circulating biomarkers, immune profiling, and single-cell multi-omics studies.

CONCLUSIONS

The goal of this phase I trial is to evaluate the safety, tolerability and MTD of combination docetaxel PIPAC and systemic therapy for GC PM in the first line setting.

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Future Direction

- PIPAC to delivery other chemotherapeutic agents and different combinations
- PIPAC to deliver novel targeted agents such as OV, CAR-T, BiTE therapy, and other immunotherapeutic agents

- Clinical Trials to move PIPAC from end-stage setting to early PM, locally advanced disease, prophylactic

- Novel delivery methods?
- Development of liquid biopsies for patient selection
- Integration into best practices into GC care

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Thank you for your attention and participation!

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