



THIRD ANNUAL
ISSPP
Congress 2022

*International Society
for the Study of Pleura
and Peritoneum*



LATE BREAKING ABSTRACT | GASTRIC CANCERS SESSION

Adjuvant PIPAC During Laparoscopic Gastrectomy in High-Risk Gastric Cancer Patients: A Multicentre Phase I Study

Martin Graversen, MD, PhD

Odense PIPAC Center
Department of Surgery
Odense University Hospital
Denmark

Advancing Innovative Therapies for Cancers That Invade the Peritoneum and the Pleura

Disclosures

- I do not have any relevant financial relationships.

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

The off-label or investigational use of cisplatin and doxorubicin will be addressed.



**Karolinska
Institutet**

Region of
Southern Denmark
OUH
Odense
University Hospital



Peritoneal metastasis in gastric cancer (GC)

- Up to 50% at surgical exploration (serosal involvement)
- Up to 60% at time of death
- Systemic chemo less effective

Gastric cancer

- Data from Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC) in patients with manifest PM are promising
- **BUT**
- No data regarding the prophylactic setting

| PIPAC directed therapy in GAC-PM | N (PIPAC procedures) | Objective tumor response (PIPAC >1) |
|--------------------------------------|----------------------|-------------------------------------|
| Alyami (Eur J Surg Oncol 2021) | 42 (163) | (14.3% became resectable) |
| Di Giorgio (Surg Oncol 2020) | 28 (46) | 61.5% |
| Nadiradze (J Gastrointest Surg 2016) | 24 (60) | 50% |
| Ellebaek (Clin Exp Metastasis 2020) | 20 (52) | 72% |
| Gockel (J Gastric Cancer 2018) | 24 (46) | 79% |
| Khomyakov (Pleura Peritoneum 2016) | 31 (56) | 60% |
| Struller (Ther Adv Med Oncol 2019) | 25 | 36% (ITT) 100% (PP) |

Adjuvant pressurized intraperitoneal aerosol chemotherapy (PIPAC) during laparoscopic resection in high-risk gastric cancer patients: A Multicentre Phase-I Study

The PIPAC-OPC4 study



- DESIGN: Prospective, multicentre, non-randomised, non-blinded, open-label phase-I study
- HYPOTHESIS: **PIPAC procedure is feasible and safe in high-risk GAC patients undergoing laparoscopic D2 gastrectomy**

PIPAC C/D (off-label) after esophagojejunal anastomosis

Cisplatin 10.5 mg/m², doxorubicin 2.1 mg/m²

Flow 0.5-0.7 ml/s, max 300 PSI, diffusion time 30 minutes

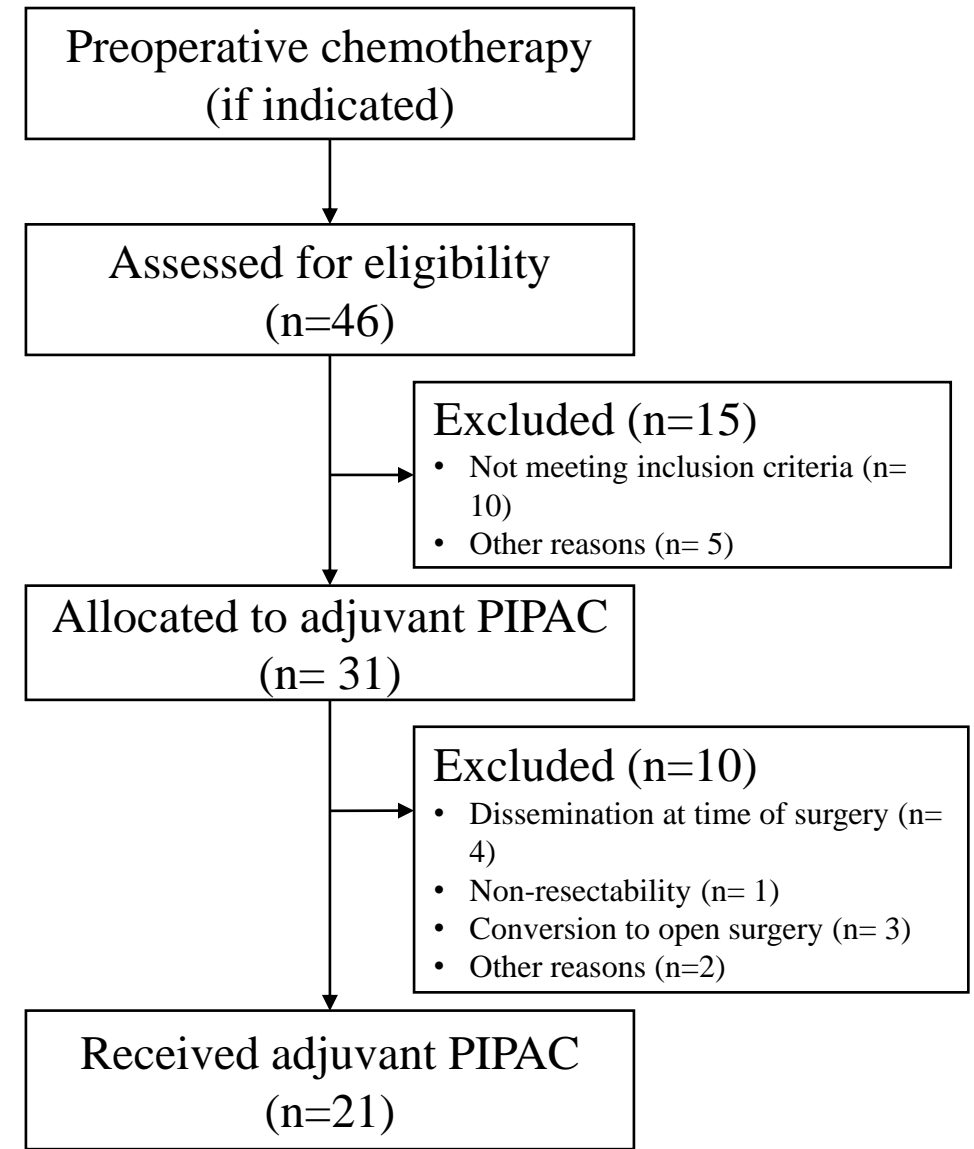
High-risk GC definition & outcomes

Poorly cohesive adenocarcinomas or clinical stage: cTany + cN2-3 or cT3-T4 + cNany or GAC patients with preoperative positive peritoneal cytology submitted to laparoscopic gastrectomy (+/- neoadjuvant treatment).

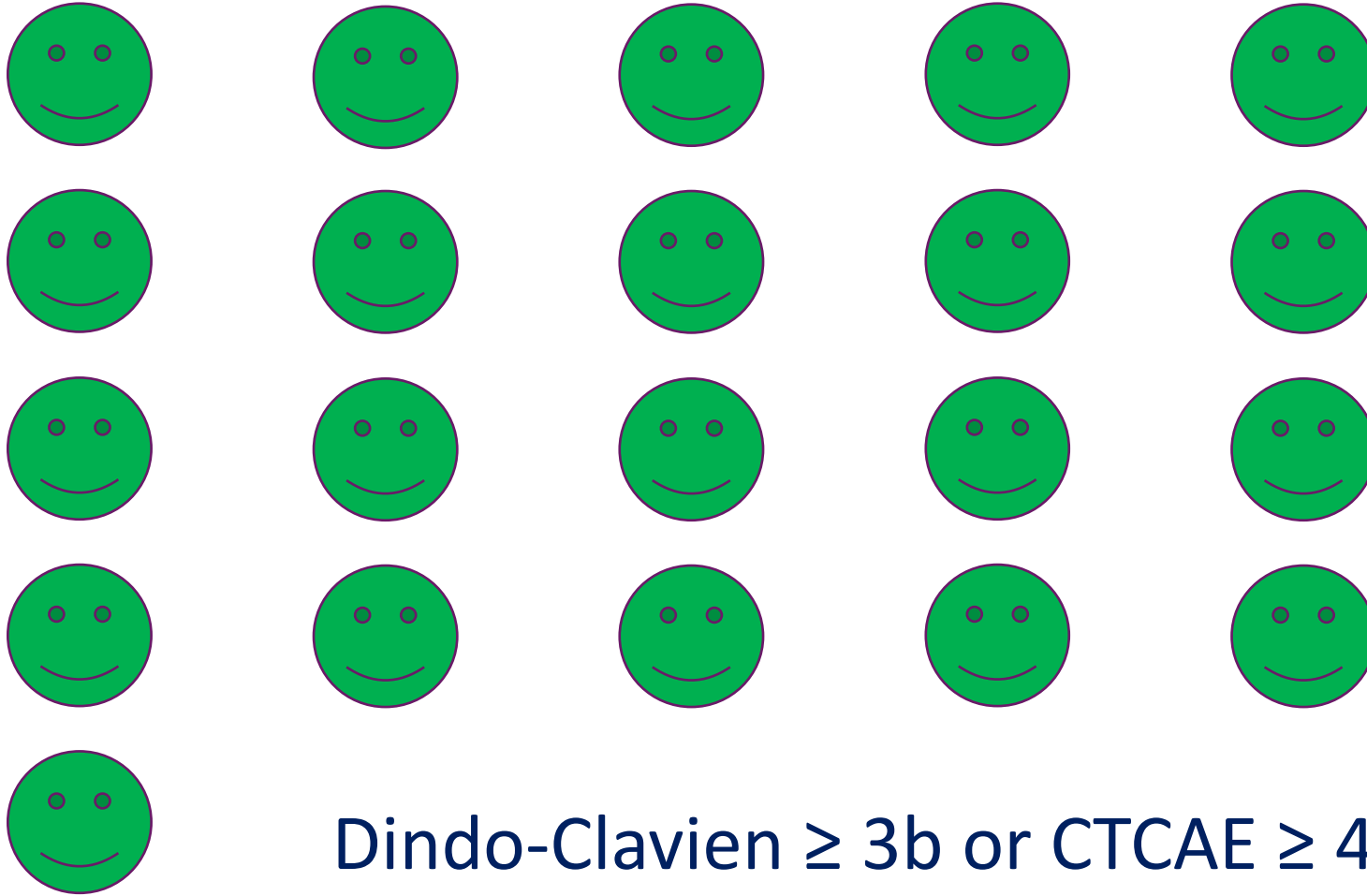
PIPAC is considered safe and feasible if $\leq 20\%$ of the patients have serious surgical complications or medical AEs equalling Dindo-Clavien $\geq 3b$ or CTCAE ≥ 4 .

Study population

| Variable | Value |
|-----------------------------|------------|
| Age, median years (range) | 61 (24-76) |
| Sex, m/f | 13/8 |
| Preoperative chemo, n (%) | 20 (95) |
| Poorly cohesive type, n (%) | 14 (67) |

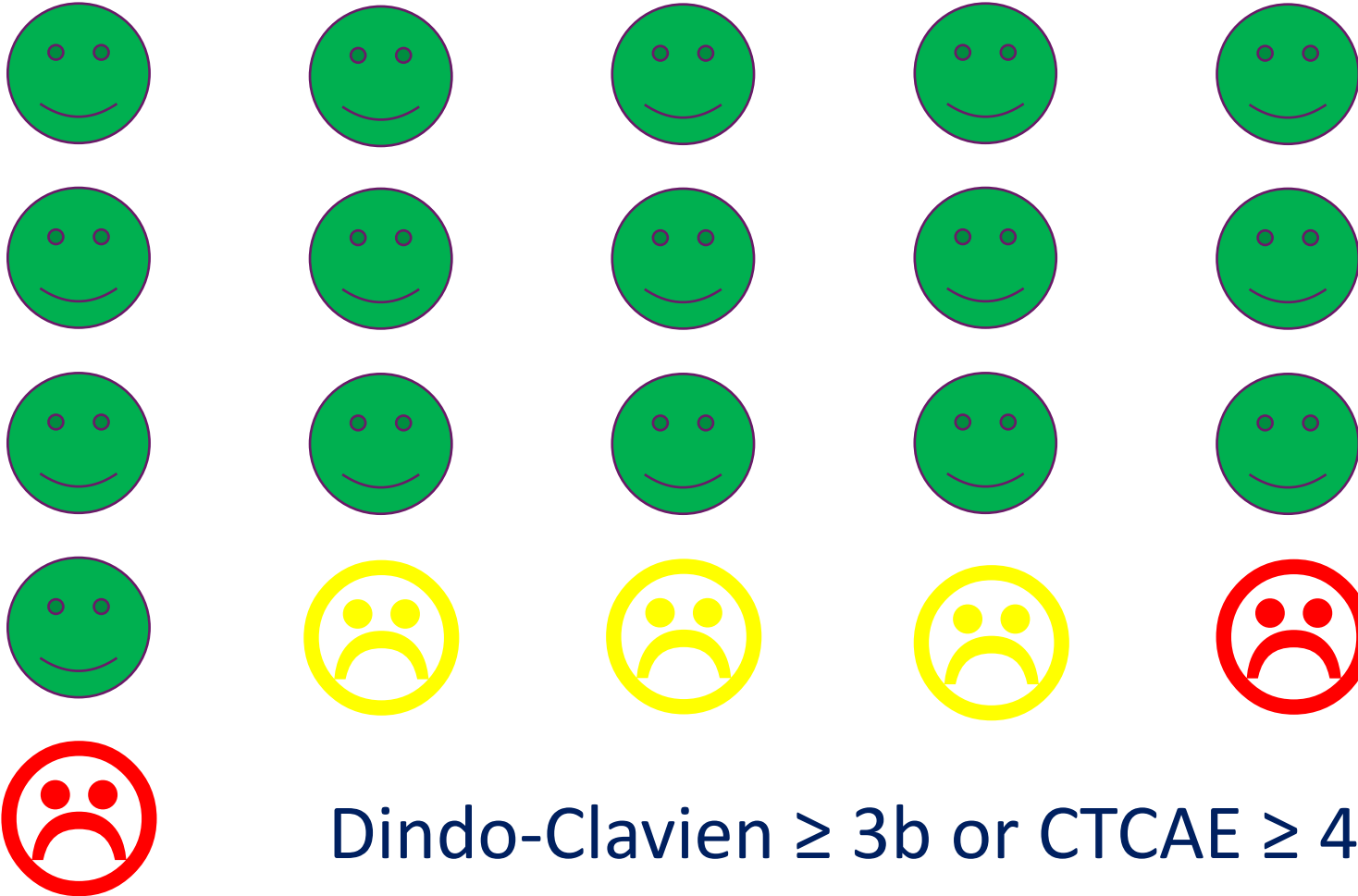


Main outcome



Dindo-Clavien $\geq 3b$ or CTCAE ≥ 4

Main outcome



1 duodenal blow out
1 anastomotic leakage
3 bowel obstructions
No CTCAE ≥ 4

Dindo-Clavien ≥ 3b or CTCAE ≥ 4

Secondary outcomes

| Variable | Value |
|--|----------|
| Length of stay, median days (range) | 6 (4-26) |
| Pre-resection positive lavage cytology, n | 1 |
| Post-resection positive lavage cytology, n | 0 |
| Patients who received postoperative chemo, n (%) | 15 (71) |

Conclusion

- ✓ **HYPOTHESIS: PIPAC procedure is feasible and safe in high-risk GAC patients undergoing laparoscopic D2 gastrectomy**

**The Efficacy of Pressurised Intraperitoneal aerosol chemotherapy (PIPAC) combined with CURative intent minimally invasive radical resection in high-risk gastric cancer patients.
A Multicentre Phase-II Randomized Study (EPICURE trial)**

EPICURE trial

High-risk GAC → Neoadj. chemo → Laparoscopy + PL + biopsy → Resectable → **RANDOM**

1:1 randomization, n= 320

Primary outcome

Overall DFS at 12 months

Secondary outcomes

mOS

Peritoneal DFS within 12 months

Complications/toxicity, lavage cytology, QoL...

Thank You!

Information/participation in EPICURE

Martin.graversen@rsyd.dk

Michael.bau.mortensen@rsyd.dk



**Karolinska
Institutet**

