

Pressurized intraperitoneal Aerosol chemotherapy as PIPAC / a generic drug delivery system

Pr Marc Pocard



INSERM U.1275 :

CAP Paris Tech : Carcinomatosis Peritoneum Paris Technology

Oncological surgical unit = Lariboisière/Bégin Hospitals, Paris, France

International Society for Study of Pleura and Peritoneum





U Inserm 1275
CArcinose Péritoine Paris-Techno



Marc POCARD



Inserm

Institut national
de la santé et de la recherche médicale



Links of interest 2016 - 2020

Honorary / Consultant :

GAMIDA, LEO Pharm, FISHER&PAYLER, NOVARTIS, ROCHE, SANOFI .

Award – congress – laboratory research grant :

ALLERGAN; AstraZeneca, BARD, CAPNOMED, ETHICON; FISHER&PAYLER, FUJINON; GAMIDA; INTEGRA, IPSEN; INTUITIVE surgical; LEO Pharm; NOVARTIS, RAND; ROCHE; STORZ; SANOFI

Intraperitoneal chemotherapy: limitations

Poor drug **distribution** within the peritoneal cavity

Limited **penetration** of drugs into tumor / normal tissue

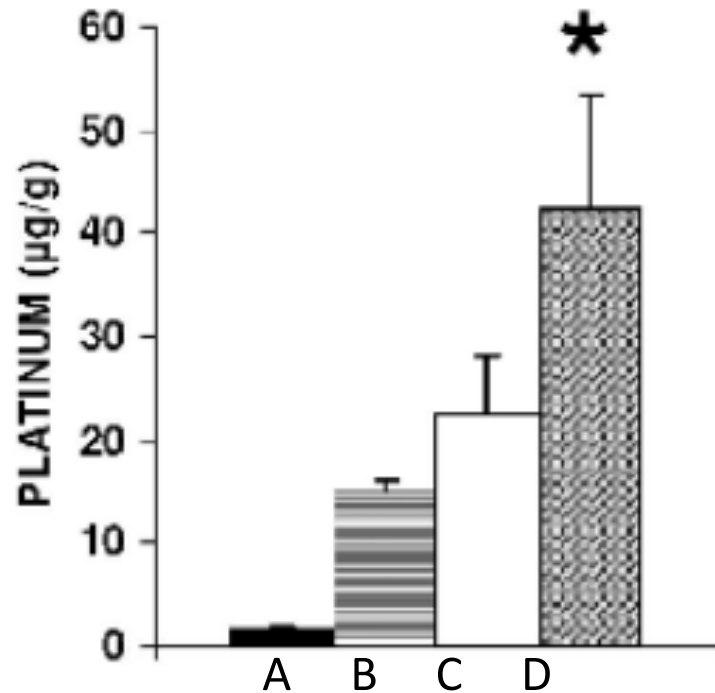
Escape into systemic circulation after regional delivery by capillary flow

Local toxicity: bowel perforation, abdominal pain, infection, obstruction

Inconvenience: Logistics, time, costs

Markman M. Intraperitoneal antineoplastic drug delivery: rationale and results.
Lancet Oncol. 2003 May;4(5):277-83. Review

Influence of intraperitoneal pressure on intratumoral platin concentration: rodent



A: iv administration
 B: conventional ip = same total dose as IAP
 C: conventional ip = same concentration as IAP
 D: pressurized ip (IAP: 22 mmHg)

Platinum concentration in peritoneal tumors after IV, IP, or IAP cisplatin treatment. Rats with 21-day-old carcinomatosis treated with cisplatin by intravenous (IV) or conventional intraperitoneal (IP) injection, or by a 1-hour intraperitoneal infusion with a sustained 22 mm Hg intra-abdominal pressure (IAP). For the conventional IP treatments, cisplatin was given either to obtain the same concentration (50 mg/L in 20 mL; 1 mg/rat; 3 mg/kg; horizontal bars) or the same total dose (7.5 mg/rat; 22.5 mg/kg; 375 mg/L in 20 mL; clear bars) as for the IAP treatment. * P < 0.05, Kruskal-Wallis test)



High Pressure Enhances the Effect of Hyperthermia in Intraperitoneal Chemotherapy With Oxaliplatin

An Experimental Study

Olivier Facy, MD,*† Sophie Al Samman, MD,† Guy Magnin, MD,‡ Francois Ghiringhelli, MD, PhD,* Sylvain Ladoire, MD, PhD,* Bruno Chauffert, MD,* Patrick Rat, MD,*† and Pablo Ortega-Deballon, MD, PhD*†

(*Ann Surg* 2012;256: 1084–1088)

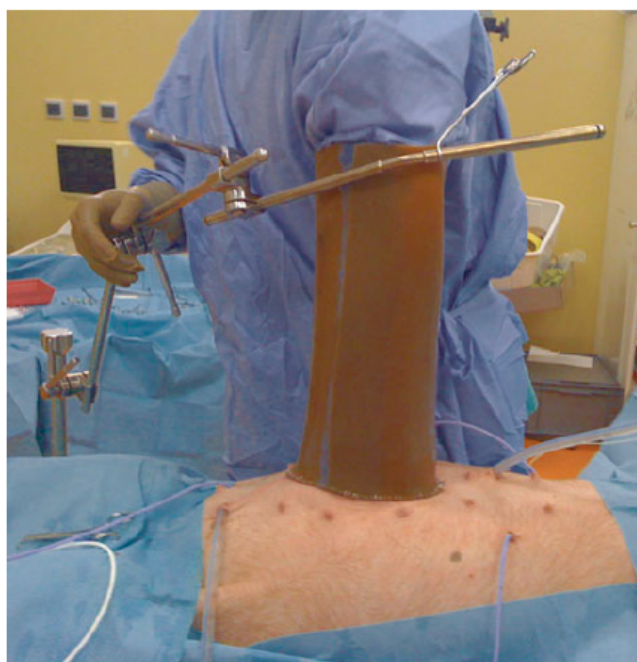
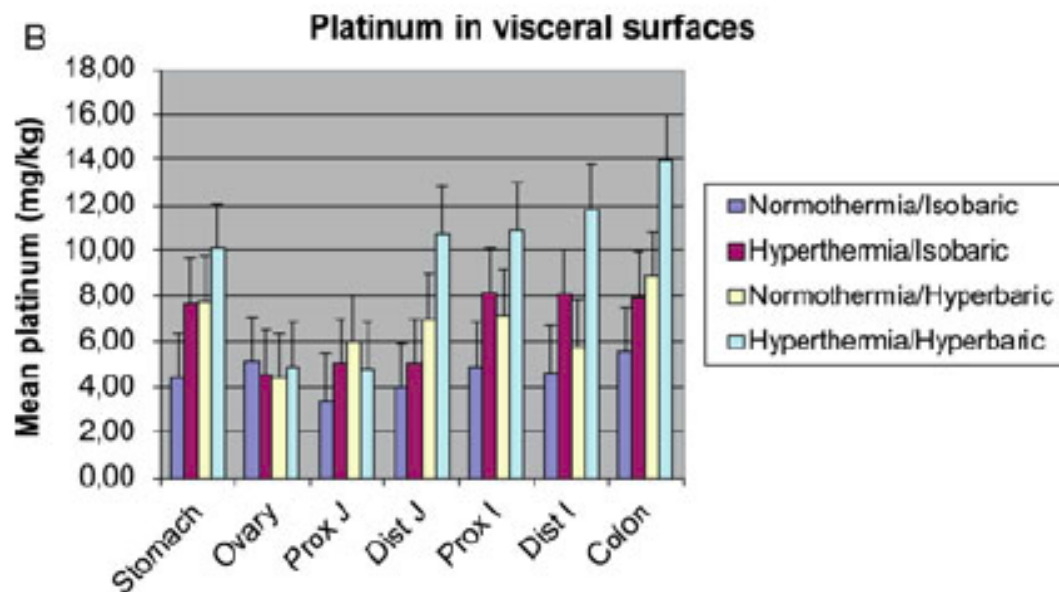
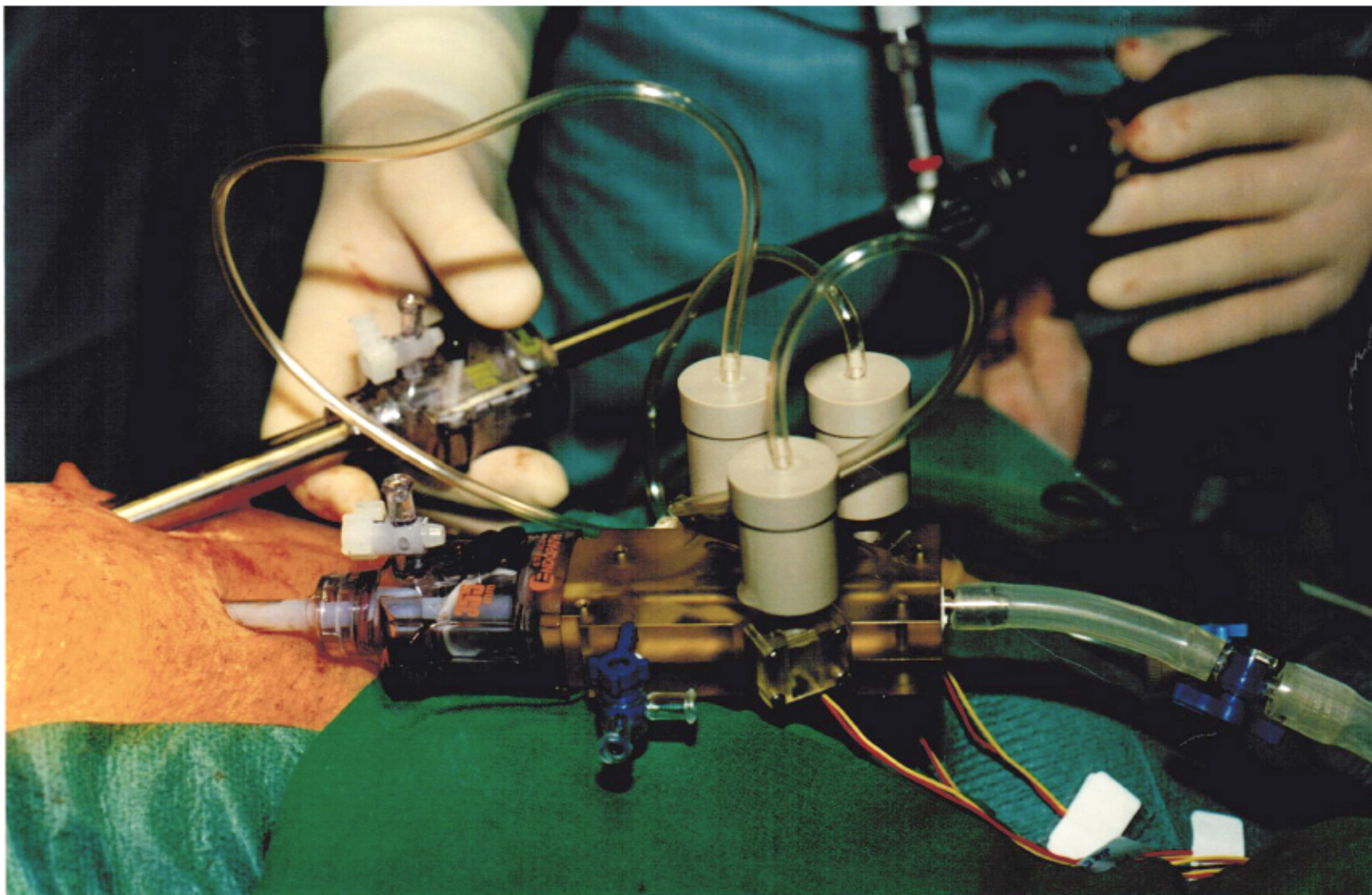


FIGURE 1. Device for high-pressure intraperitoneal chemotherapy: a vertical latex expander is hermetically stapled to the skin and stabilized on the arm of a Thompson retractor. The expander is filled to a height of 25 cm with the liquid and allows access to the whole abdominal cavity. According to Pascal's principle, the pressure induced by the weight of the water column is uniformly transmitted to the entire abdominal cavity. Three thermal probes (blue on the picture) are placed to monitor the temperature within the abdomen, as well as in the outflow and the inflow catheters (transparent tubes).





Not a new idea: Pressure and aerosol using First prototype 1999

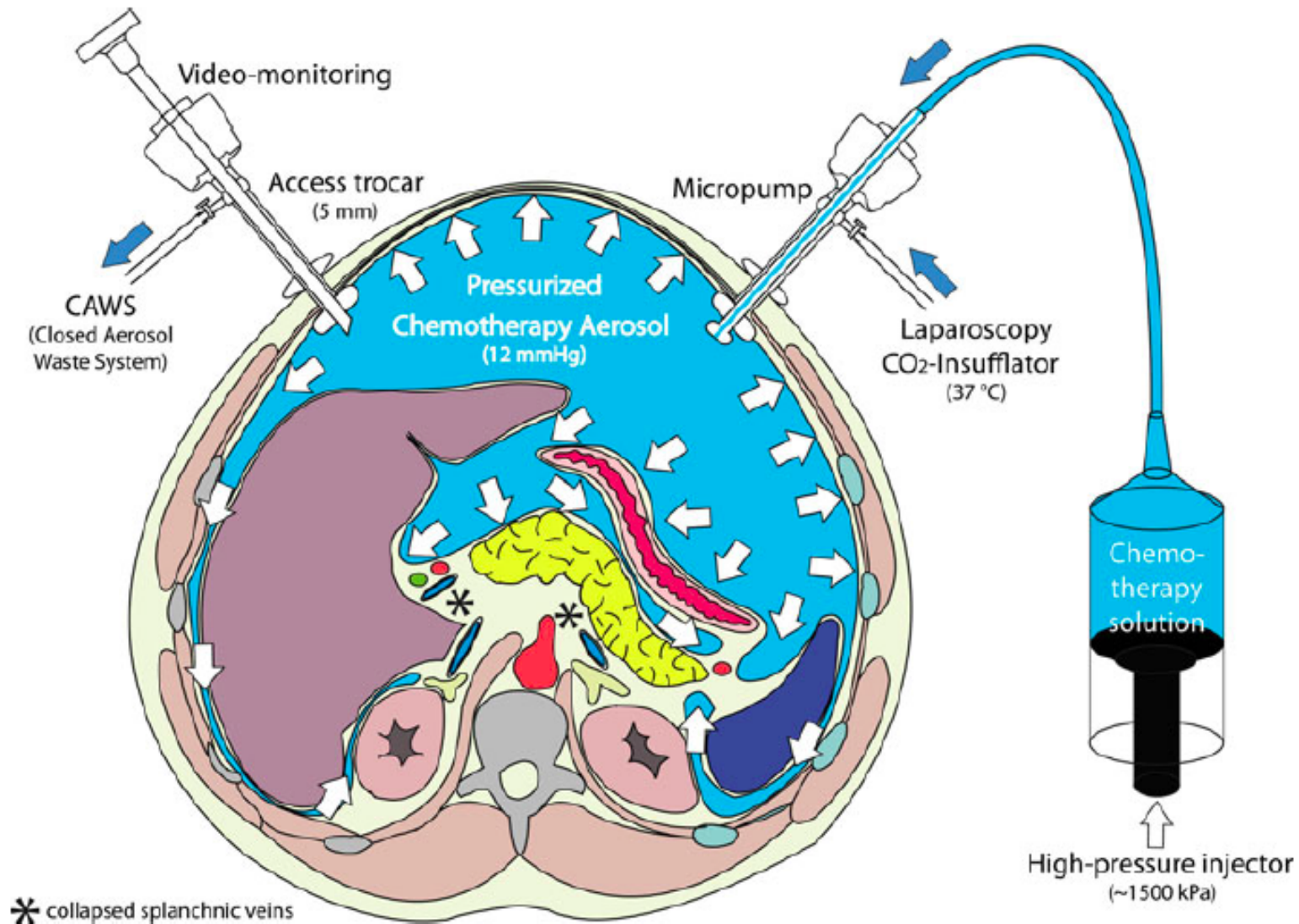


2010: 2nd generation prototype



- Technology is more simple
- Aerosol delivery system is derived from car industry, from a common rail injector
- Produced by CAPNOMED company
- Drug volumes up to 200 ml
- Certification as class 2A device

Pressurized intrapéritoneal Aerosol chemotherapy as PIPAC



1st PIPAC Nov 5th, 2011

Bielefeld Deutschland





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PIPAC

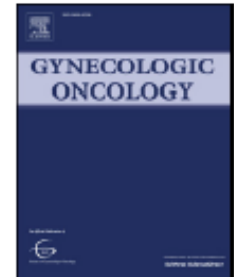


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Contents lists available at [ScienceDirect](#)

Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno



Activity of Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC) with cisplatin and doxorubicin in women with recurrent, platinum-resistant ovarian cancer: Preliminary clinical experience

Clemens B. Tempfer^{a,*}, Ilknur Celik^a, Wiebke Solass^b, Bernd Buerkle^a, Urs G. Pabst^b, Juergen Zieren^b, Dirk Strumberg^c, Marc-André Reymond^b

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^c Department of Hemato-Oncology, Ruhr University Bochum, Bochum, Germany

Gynecol Oncol.
2014;132(2):307-11

PIPAC medical plausibility

Applying an **aerosol** in the peritoneal cavity allows a more homogeneous distribution of the chemotherapeutic agent within the abdomen than a liquid solution.

An artificial **pressure** gradient is generated that overcomes tumoral interstitial fluid pressure, an obstacle in cancer therapy.

PIPAC medical plausibility

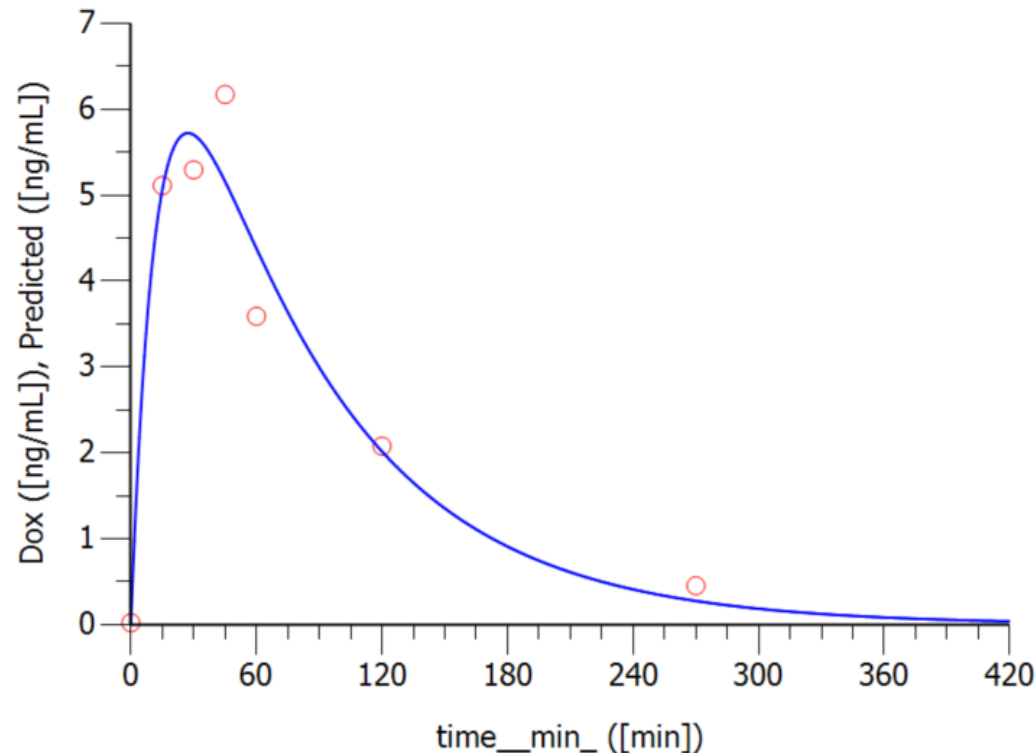
This results in a higher tissue drug concentration compared to IV chemotherapy or IP chemotherapy with liquids. Therefore, only a **low dose** (10%-20% of a normal systemic dose) needs to be applied.

Organ toxicity and adverse events remain low, therapy is well tolerated.

Staging laparoscopy is performed anyway; there are no catheter-linked complications

PIPAC: Systemic uptake (Doxorubicin)

Pharmacokinetic profile in peripheral venous blood (typical profile)
after PIPAC with Doxorubicin [Dox] 1,5 mg/m² KOF for 30 min. with i. -abd. Pressure of 12 mmHg.



Systemic doxorubicin exposure during PIPAC, showing a typical pharmacokinetic profile in peripheral venous blood after PIPAC with doxorubicin 1.5 mg/m² body surface for 30 min at an intraabdominal pressure of 12 mmHg. Peak doxorubicin plasma concentrations were low (4.0–6.2 ng/ml). Line predicted profile. Dots experimental values.

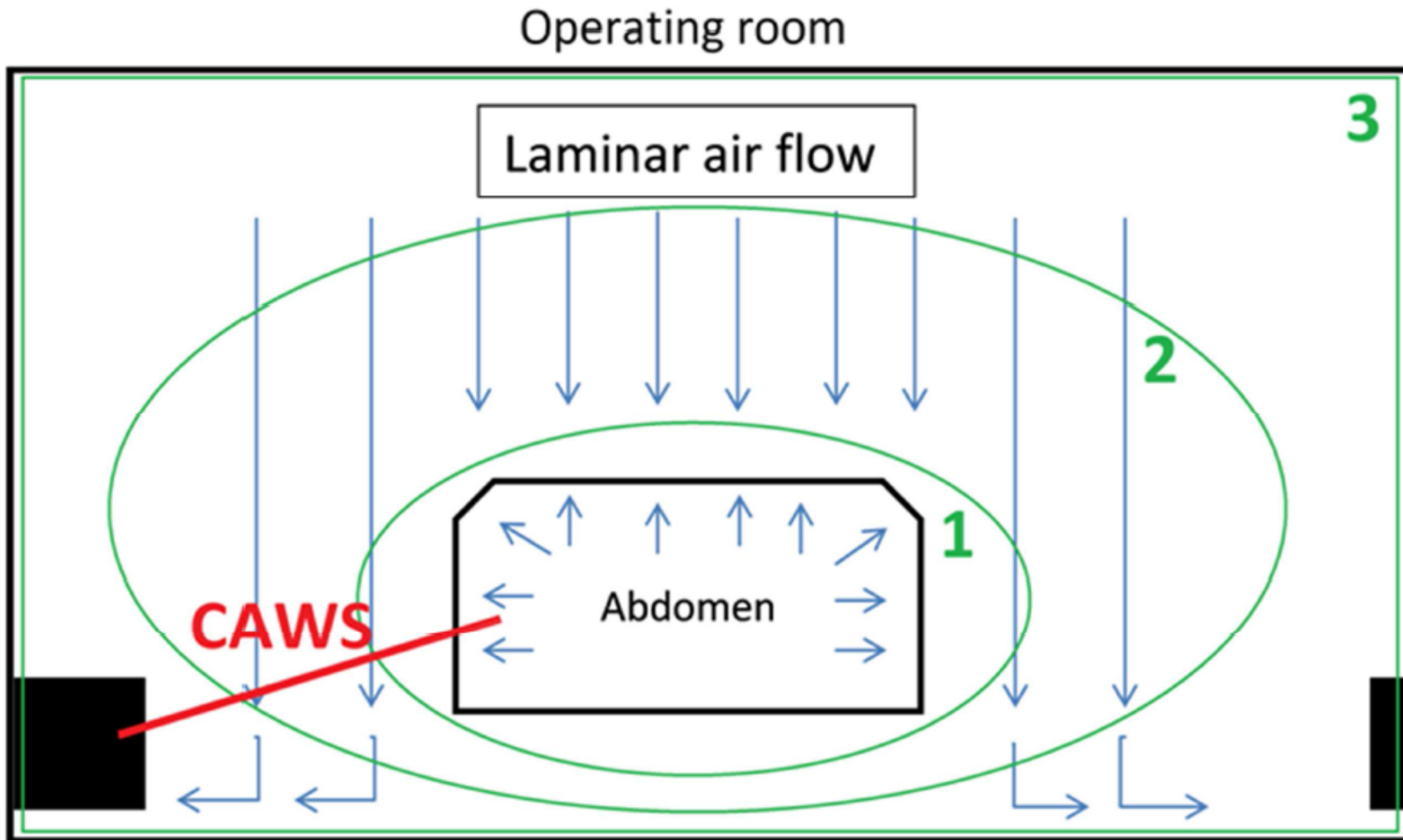
PIPAC: occupational health safety program



1. Risk management program started in 2011
 - Substances and amount
 - Identification of potential hazards and possible contamination pathways
2. Design of simulations in the operating room
3. Working out a safety protocol, health workers training
4. Repeated workplace measurements under real conditions
5. Mathematical simulations (worst case scenario)
6. Critical Incident Reporting System (CIRS)
7. Biological assessment after 500 and 1500 PIPACs
8. Regulatory approval of safety guidelines for PIPAC

Inhalation risk: Safety concept

National Center for Pleura and Peritoneum 2018





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Workplace measurements: air

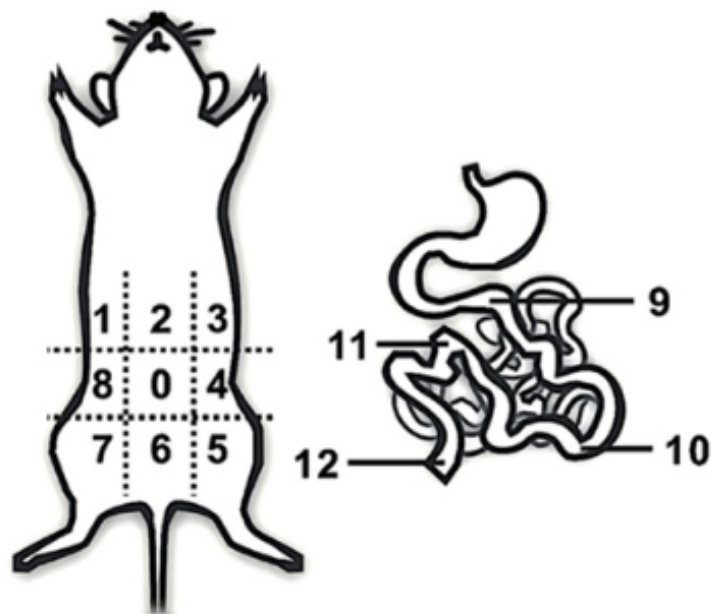


- No contamination detected in any hospital
(Lowest sensitivity: **0.004 pmol/m³**)

Experimental pharmacokinetics evaluation of chemotherapy delivery by PIPAC for colon cancer: first evidence for efficacy

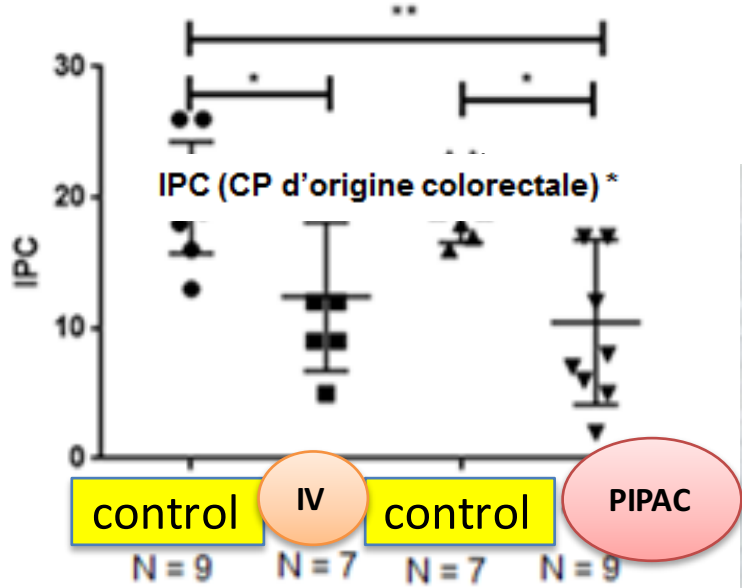
Pleura and Peritoneum 2017; aop

PCI for mice

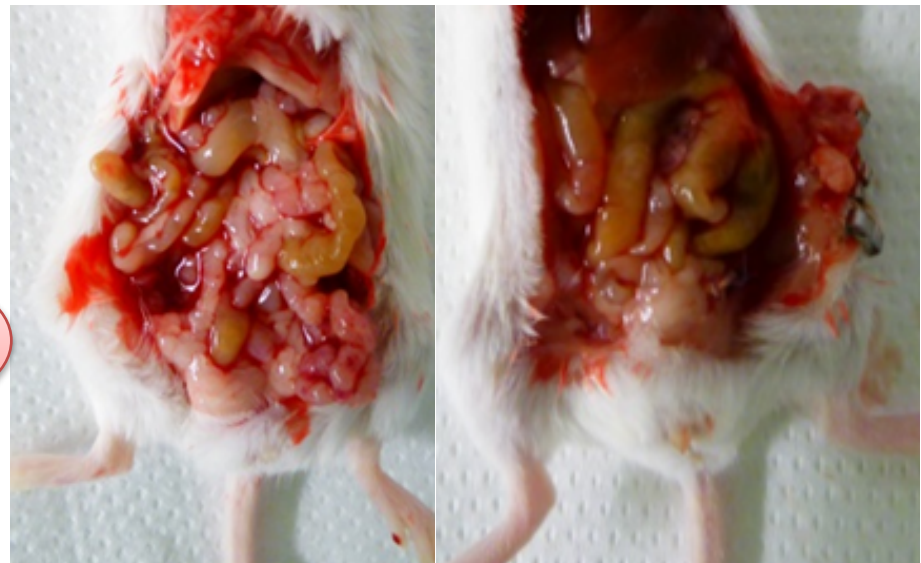


		Score	Tumor size
0	Central abdomen		
1	Right upper quadrant		
2	Epigastric region	0	no macroscopic lesion
3	Left upper quadrant		
4	Left middle quadrant	1	Lesion from 1 to 2 mm, 1 to 2 sites
5	Left lower quadrant		
6	Pubic region		
7	Right lower quadrant	2	Lesion from 2 to 4 mm, 1 to 2 sites
8	Right middle quadrant		
9	Proximal jejunum		
10	Distal jejunum	3	lesion over 4 mm or more than 10 sites
11	Proximal ileum		
12	Distal ileum		

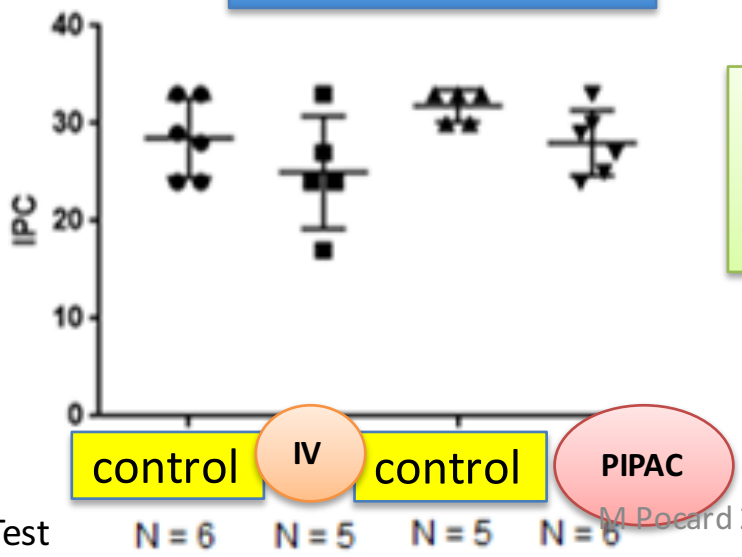
PCI colon CT26



PCI evaluation



PCI ovarian Ovar

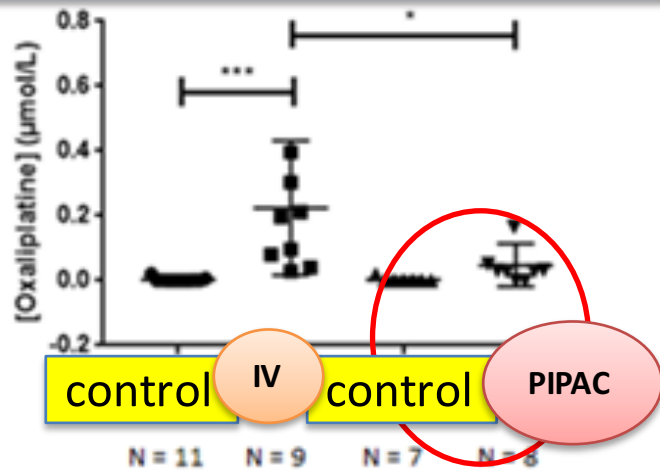


PIPAC is effective as IV Oxapiplatin in a murin model of colon cancer carcinomatosis

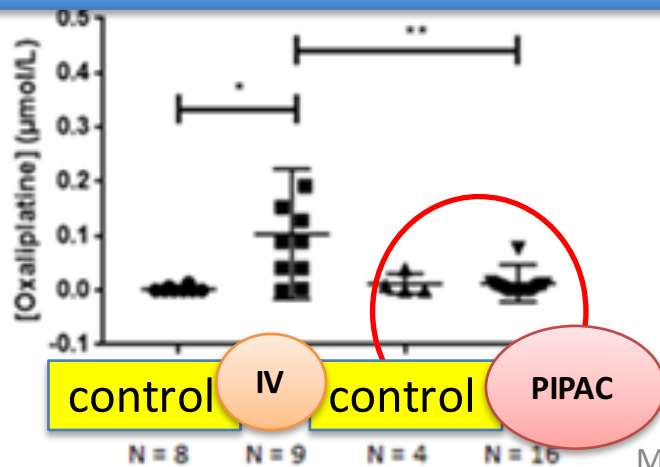
*Kruskal-Wallis Test

Oxaliplatin drugs concentration in blood

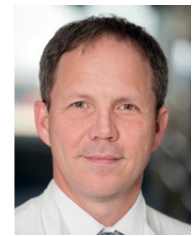
Oxaliplatin in blood colon CT26



Oxaliplatin in blood ovarian OVcar



→ The PIPAC decreases the concentration of oxaliplatin in the blood compared to IV, with less systemic absorption, for Colon and ovarian carcinomatosis mice model

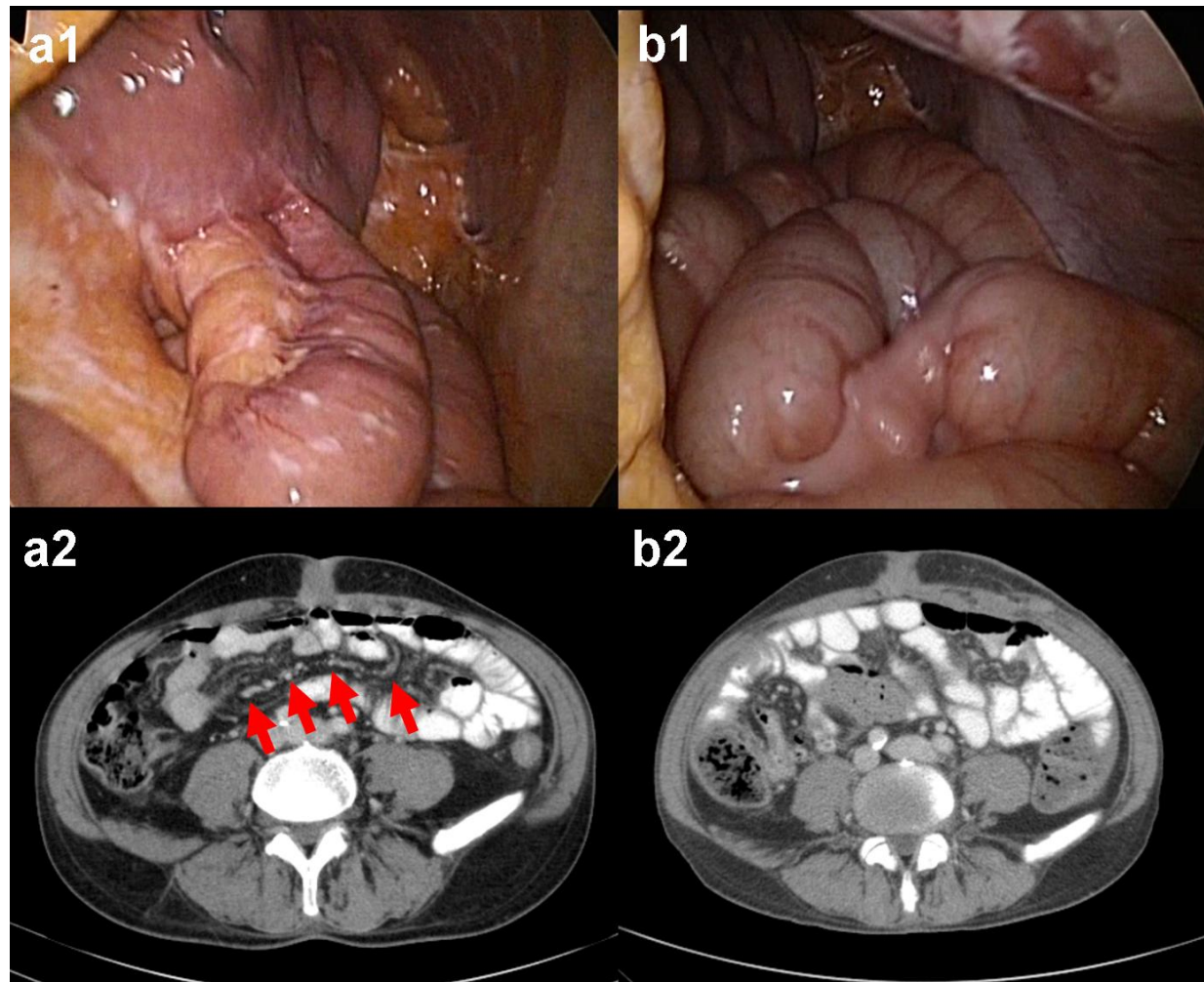


Intraperitoneal Chemotherapy of Peritoneal Carcinomatosis Using Pressurized Aerosol as an Alternative to Liquid Solution: First Evidence for Efficacy

Wiebke Solass, MD¹, Reinhold Kerb, MD^{2,3}, Thomas Mürdter, PhD^{2,3}, Urs Giger-Pabst, MD⁴, Dirk Strumberg, MD⁵, Clemens Tempfer, MD, MBA⁶, Jürgen Zieren, MD⁴, Matthias Schwab, MD^{2,3}, and Marc André Reymond, MD, MBA⁴

¹Institute of Pathology, Ruhr-University Bochum, Bochum, Germany; ²Dr. Margarete Fischer-Bosch Institute of Clinical Pharmacology, Stuttgart, Germany; ³Department of Clinical Pharmacology, University Hospital, Tübingen, Germany; ⁴Department of Surgery, Marienhospital Herne, Ruhr-University Bochum, Bochum, Germany; ⁵Department of Internal Medicine, Oncology and Hematology, Marienhospital Herne, Ruhr-University Bochum, Bochum, Germany; ⁶Department of Gynaecology and Obstetrics, Marienhospital Herne, Ruhr-University Bochum, Bochum, Germany

Efficacy: CT-scan (RECIST) and laparoscopy



PIPAC # 1

PIPAC # 4

53 y.o. patient with signet ring gastric cancer, S/P gastrectomy and chemotherapy (3rd line situation by PCI 19). Patient is alive 90 Monate after diagnosis, and 6 months after PIPAC #1 with complete radiological and histological remission. Karnofsky 100%.



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European Journal of Surgical Oncology

journal homepage: www.ejso.com



Multicenter comprehensive methodological and technical analysis of 832 pressurized intraperitoneal aerosol chemotherapy (PIPAC) interventions performed in 349 patients for peritoneal carcinomatosis treatment: An international survey study

Maciej Nowacki ^{a, *}, Mohammad Alyami ^{b, d, e, m}, Laurent Villeneuve ^{c, d, e},
Frederic Mercier ^{b, e}, Martin Hubner ^f, Wouter Willaert ^g, Wim Ceelen ^g, Marc Reymond ^h,
Denis Pezet ⁱ, Catherine Arvieux ^j, Vladimir Khomyakov ^k, Laura Lay ^l, Sergio Gianni ⁿ,
Wojciech Zegarski ^a, Naoual Bakrin ^{b, d, e}, Olivier Glehen ^{b, d, e}

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

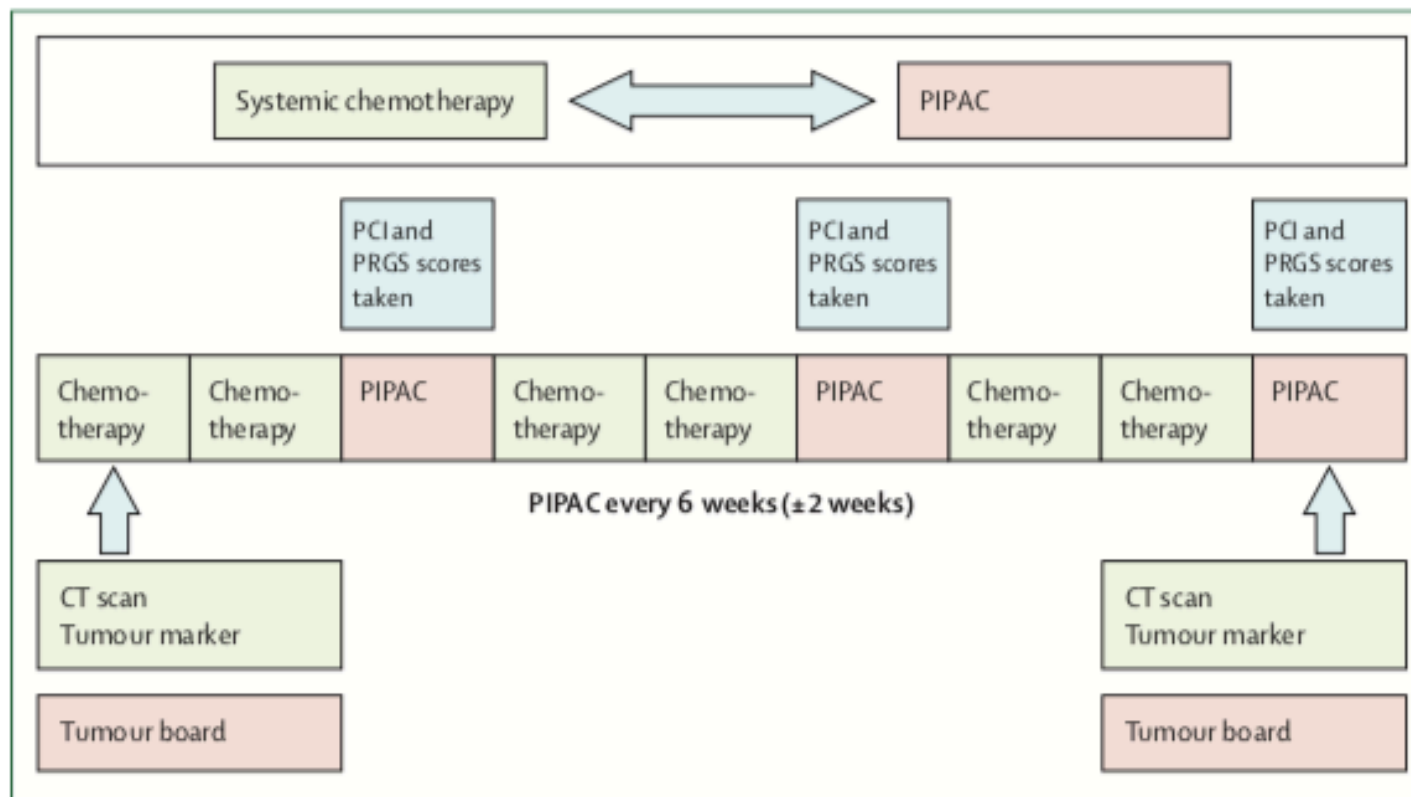


Figure 3: Concomitant systemic and intraperitoneal treatment

Suggested treatment schedule for PIPAC every 6 weeks (± 2 weeks), alternating with systemic chemotherapy.

PIPAC=pressurised intraperitoneal aerosol chemotherapy. PCI=peritoneal cancer index. PRGS=peritoneal regression grading score.

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

	Colorectal cancer		Gastric cancer		Ovarian cancer		Peritoneal mesothelioma		Biliary tract cancer		Appendiceal cancer	
	PIPAC	HIPEC	PIPAC	HIPEC	PIPAC	HIPEC	PIPAC	HIPEC	PIPAC	HIPEC	PIPAC	HIPEC
High risk for peritoneal metastasis after primary tumour resection	USC	USC	USC	USC	-	-	-	-	?	?	-	-
Upfront or interval situation and resectable peritoneal metastasis	USC	PCI ≤ 15	USC; PCI > 6	USC; PCI ≤ 6	USC	+	USC	+	USC	USC	-	+
Synchronous or recurrent peritoneal metastasis as sole metastatic site and unresectable disease, or patient not eligible for extensive cytoreductive surgery or HIPEC and with 2nd or 3rd line of systemic chemotherapy	+	-	+	-	+	-	+	-	+	-	+	-
Refractory ascites	+	-	+	-	+	+/-	+	-	+	-	+	-
Systemic chemotherapy intolerance	+	-	+	-	+	-	+	-	+	-	+	-
Unfavourable histology	+*§	-*	+*§	-*	+†§	+†	+‡§	+/-‡	+§	-	+*§	-*

PIPAC=pressurised intraperitoneal aerosol chemotherapy. HIPEC=hyperthermic intraperitoneal chemotherapy. USC=under study condition. PCI=peritoneal cancer index. *Signet ring histology. †Clear cell carcinoma, undifferentiated ovarian cancer. ‡Sarcomatoid or biphasic peritoneal mesothelioma. §Unfavourable histology is an additional argument to introduce PIPAC earlier in the treatment strategy.

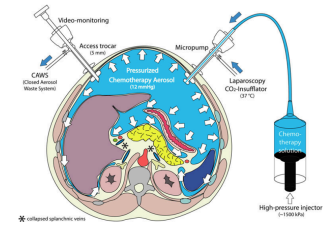
Table 3: Potential indications for the use of PIPAC and HIPEC

PIPAC: completed/ongoing 13 clinical trials

1	Recruiting	<u>Efficacy and Safety of PIPAC/PITAC in Gastric, Ovarian, Colorectal Cancer and Mesothelioma With Pleural Carcinomatosis.</u> Conditions: Colorectal Cancer; Ovarian Cancer; Gastric Cancer; Mesothelioma Intervention: Procedure: pressurized intraperitoneal/intrathoracic aerosol chemoTx	Switzerland
2	Recruiting	<u>Study of Efficacy and Safety of Laparoscopic Intra-abdominal Chemotherapy (PIPAC) Performed in Patients With Peritoneal Carcinomatosis From Colorectal, Ovarian, Gastric Cancer and Primary Peritoneal Tumors</u> Condition: Peritoneal Carcinomatosis Intervention: Drug: Pressurized IntraPeritoneal Air-flow Chemotherapy (PIPAC)	Singapore
3	Recruiting	<u>Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC) Applied to First Platinum-Resistant Recurrence of Ovarian Tumor</u> Condition: First Platinum-resistant Recurrent of Epithelial Ovarian Cancer Intervention: Device: Pressurized intraperitoneal aerosol chemotherapy with cisplatin and doxorubicin	Italy
4	Recruiting	<u>Treating Peritoneal Carcinomatosis With PIPAC</u> Condition: Peritoneal Carcinomatosis Intervention: Drug: PIPAC	Denmark
5	Completed	<u>Intraperitoneal Aerosol Chemotherapy in Gastric Cancer</u> Condition: Gastric Cancer Intervention: Drug: doxorubicin and cisplatin	France
6	Completed	<u>Intraperitoneal Aerosol High-pressure Chemotherapy for Women With Recurrent Ovarian Cancer</u> Condition: Recurrent Ovarian Cancer Intervention: Drug: chemotherapy with doxorubicin and cisplatin	Belgium
7	Recruiting	<u>A Study With Intraperitoneal Cisplatin and Doxorubicin in Recurrent Ovarian Cancer and Peritoneal Carcinomatosis</u> Condition: Ovarian Cancer Interventions: Drug: Cisplatin and doxorubicin; Procedure: Cisplatin and doxorubicin	Germany

La PIPAC à la française, permet un contrôle solide de la carcinose gastrique sans morbidité surajoutée dans plus de la moitié des cas.

M Pocard, I Jouvin, G Mariano G, C Eveno, J-M Gornet , T André.



Méthode :

Etude rétrospective monocentrique des patients consécutifs traités par PIPAC pour MPG à l'Hôpital Lariboisière 2017 - 2018

- Soit : PIPAC avec Oxaliplatine
- Soit : PIPAC avec Doxorubicine et Cisplatine

Inclusion : Etat général conservé / OMS 0 – 1 et 2 / PAS d'occlusion / ascite oui / neuropathie oui / gastrectomie antérieure oui / linite oui /

Exclusion : nutrition parentérale / Occlusion /

Résultats

75 PIPACs ont été réalisées
pour 27 patients
d'âge médian de 58 ans (ext 28 – 72).

Tous ont eu au moins une PIPAC,
85% au moins 2 (n=23),
63% au moins 3 (n=17) (extr 1 – 6).

Résultats de 75 PIPAC pour métastases péritonéales gastriques

La morbidité majeure a été de 1,4% : (1 éviscération),

Pas de mortalité.

Le nombre de jour d'hospitalisation est de **2 jours** (décision liée au PMSI)

La majorité des patients a considéré la PIPAC comme plus facile à supporter que la chimiothérapie IV

La qualité de vie (QLQ C-30) est stabilisée pendant le traitement

Utilisation initiale de l'Oxaliplatine : puis bascule vers Doxo
Cisplatine devant la douleur post opératoire moindre et le nombre
de patient ayant une neuropathie après la première ligne de
chimiothérapie IV

Résultats de 75 PIPAC pour métastases péritonéales gastriques

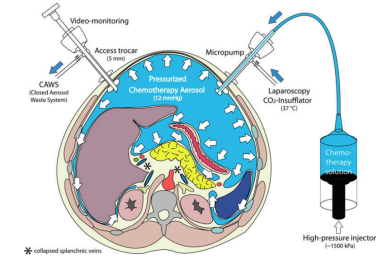
La durée maximale du contrôle a été de 11 mois,
avec une patient en attente de sa septième PIPACs.

La durée médiane entre les 2 PIPACs a été de 47 jours
(extr 31 – 67).

Pour deux patients, le contrôle de la maladie a autorisé une proposition de chirurgie secondaire de cytoréduction avec CHIP.

Conclusion

- Un traitement palliatif de PIPACs « à la française », est possible et contrôle la maladie probablement aussi bien qu'une chimiothérapie iv, avec moins d'effets secondaires.



Fava et al. *World Journal of Surgical Oncology* (2018) 16:62
<https://doi.org/10.1186/s12957-018-1363-0>

World Journal of
Surgical Oncology

CASE REPORT

Open Access



Neoadjuvant intraperitoneal chemotherapy followed by radical surgery and HIPEC in patients with very advanced gastric cancer and peritoneal metastases: report of an initial experience in a western single center

Un troisième patient traité à l'Hôpital St Louis chimio et Bégin pour PIPAC est en cours de discussion pour une tentative de chirurgie et CHIP du fait de la très bonne réponse



Equipe à Moscou cohorte de 134 patients Vladimir Khomiakov, survie médiane de 16 mois avec chimio IV et PIPAC contre 7 mois pour chimiothérapie systémique.

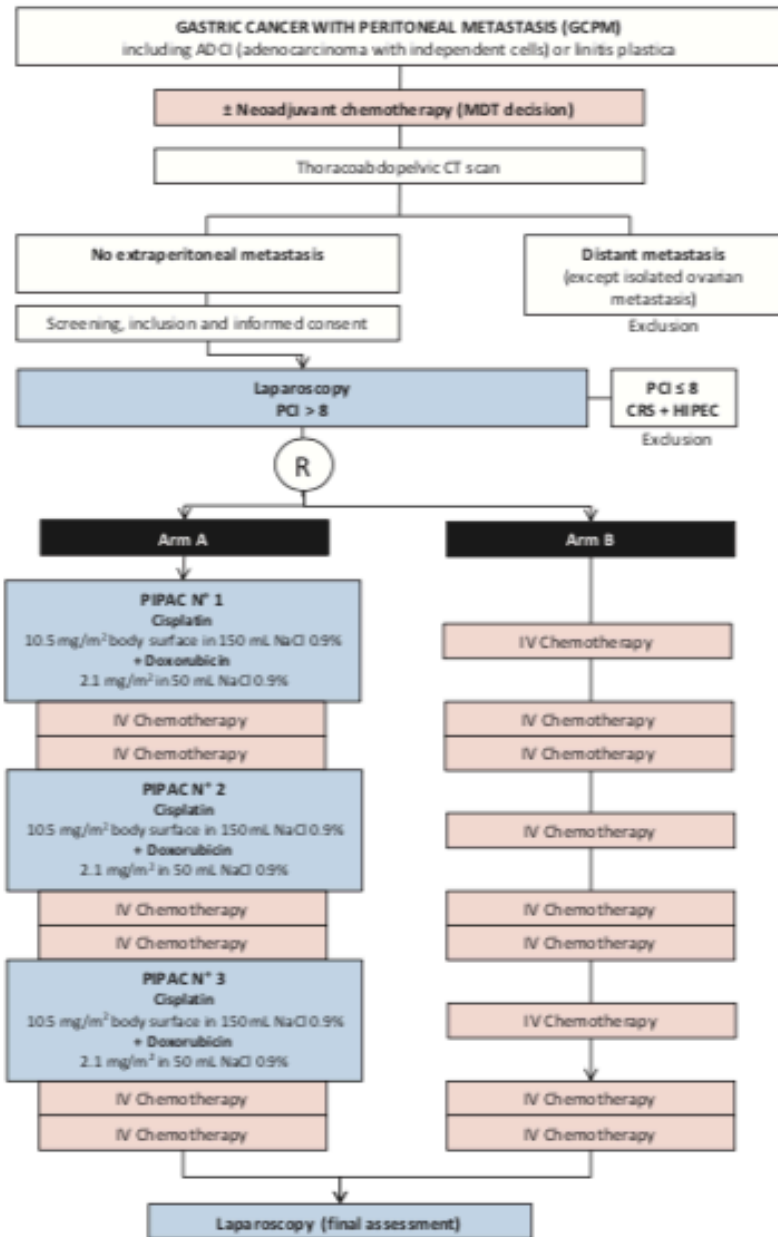


Figure 1: PIPAC EstoK 01 study flow-chart.

Chemo versus Chemo + PIPAC

Clarisse Eveno*, Ingrid Jouvin and Marc Pocard
**PIPAC EstoK 01: Pressurized IntraPeritoneal Aerosol
 Chemotherapy with cisplatin and doxorubicin
 (PIPAC C/D) in gastric peritoneal metastasis: a randomized
 and multicenter phase II study**

Chemo versus PIPAC

ANTICANCER RESEARCH 35: 2309-2314 (2015)

Low-dose Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC) as an Alternative Therapy for Ovarian Cancer in an Octogenarian Patient

URS GIGER-PABST¹, WIEBKE SOLASS², BERND BUERKLE³,
MARC-ANDRÉ REYMOND¹ and CLEMENS B. TEMPFER³

*Departments of ¹Surgery, and ³Obstetrics and Gynecology, Ruhr University Bochum, Bochum, Germany;
²Institute of Pathology, Medical School Hannover, Hannover, Germany*

PIPAC as neoadjuvant before cytoreductive surgery and HIPEC

Girshally et al. *World Journal of Surgical Oncology* (2016) 14:253
DOI 10.1186/s12957-016-1008-0

World Journal of
Surgical Oncology

RESEARCH

Open Access



Pressurized intraperitoneal aerosol
chemotherapy (PIPAC) as a neoadjuvant
therapy before cytoreductive surgery and
hyperthermic intraperitoneal chemotherapy

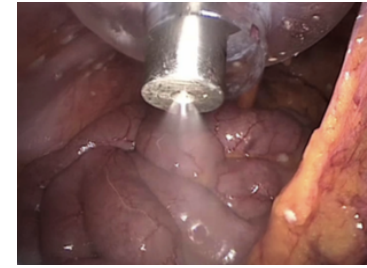
Ramy Girshally^{1,2}, Cedric Demtröder^{1,2}, Nurettin Albayrak¹, Jürgen Zieren^{1,2}, Clemens Tempfer^{1,2}
and Marc A. Reymond^{3*}

My clinical experience

- Quality of life is stabilized during the PIPAC courses
- Nutritional status is stabilized during the PIPAC courses
- Symptoms could disappear for some patient

- The major problem is to go inside the abdomen without making any bowel traumatic lesion
- The PIPAC is a non eventful procedure

- Stopping a PIPAC course for holidays, or to make a stopping procedure is not a good idea because when carcinomatosis coming to be clinically present, new PIPAC course is inefficient
- Important ascites (> 4 liters) is not well controlled by PIAPC

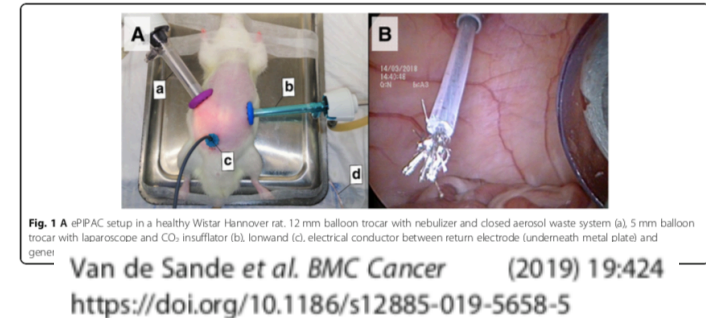


PIPAC For what ?

- In case of inefficacy of systemic chemotherapy for peritoneal metastasis and/or ascites control, on gastric or ovarian cancer
 - 1 PIPAC every 6 or 8 weeks /
 - Evaluated criteria : quality of life
- Associated with a systemic chemotherapy at the first line as palliation, including at first diagnosis ?
 - 1 PIPAC / 1 IV cycle / 2 PIPAC / 2 IV cycle, ...
 - Evaluated criteria : OS or DFS
- Associated with an intensive anticancer strategy for non resectable carcinomatosis in a patient affected by a gastric carcinomatosis
 - 1 PIPAC / 1 IV cycle / 2 PIPAC / IV etc
 - Evaluated criteria : secondary CCO resection

New ideas are coming

Different animals models are available:
mice / rat / pseudoperitoneal cavity



Different drugs could be tested

Nanotherapy

Immunotherapy

Virus therapy

DE GRUYTER

Pleura and Peritoneum 2018; 20180112

Leen Van De Sande, Martin Graversen, Martin Hubner, Marc Pocard, Marc Reymond, Marco Vaira, Sarah Cosyns, Wouter Willaert and Wim Ceelen*

Intraperitoneal aerosolization of albumin-stabilized paclitaxel nanoparticles (Abraxane™) for peritoneal carcinomatosis – a phase I first-in-human study

Individualization of treatment based on genetic testing

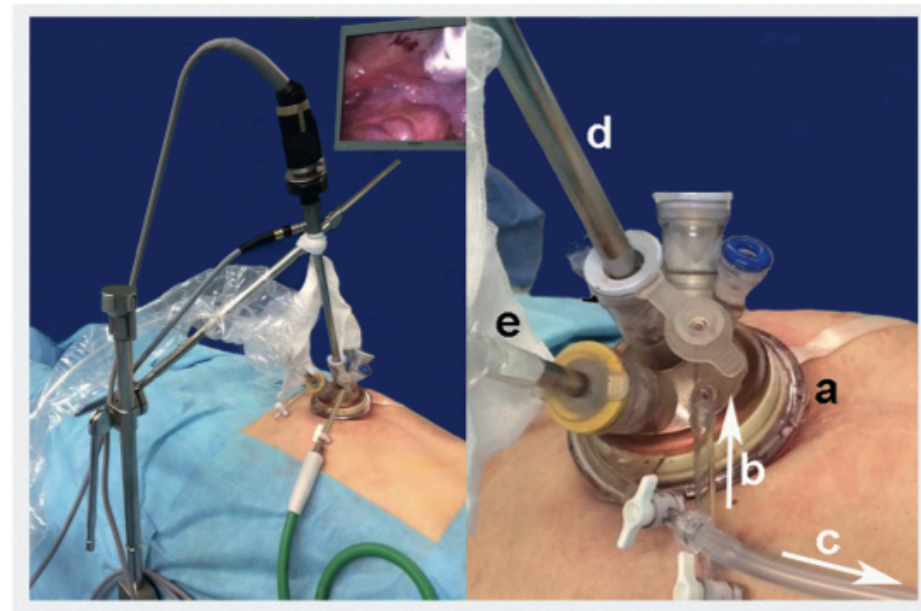
Single-port access technology

DE GRUYTER

Pleura and Peritoneum 2016; 1(4): 217–222

Marco Vaira*, Manuela Robella, Alice Borsano and Michele De Simone

Single-port access for Pressurized IntraPeritoneal Aerosol Chemotherapy (PIPAC): technique, feasibility and safety



Hyperthermia : New PIPAC technology

Surg Endosc

DOI 10.1007/s00464-015-4738-0



Feasibility of hyperthermic pressurized intraperitoneal aerosol chemotherapy in a porcine model

Do Hyun Jung^{1,2} · Sang Yong Son^{1,3} · Aung Myint Oo^{1,4} · Young Suk Park¹ ·
Dong Joon Shin¹ · Sang-Hoon Ahn^{1,5} · Do Joong Park^{1,5} · Hyung-Ho Kim^{1,5}

Surg Endosc

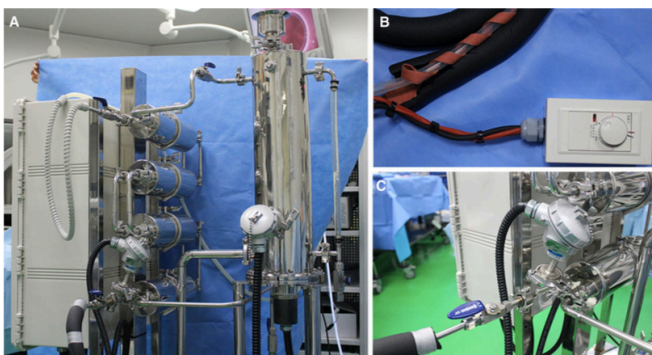


Fig 2 A A heater to create hyperthermic capnoperitoneum, B a CO₂ gas delivery line covered with a heating line, C a temperature-monitoring unit was located at the outflow pipe of the heating units where the CO₂ gas delivery line connected to the heating units

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Electrostatic : New PIPAC technology

Ann Surg Oncol
DOI 10.1245/s10434-016-5108-4

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY



ORIGINAL ARTICLE – TRANSLATIONAL RESEARCH AND BIOMARKERS

In Vivo Feasibility of Electrostatic Precipitation as an Adjunct to Pressurized Intraperitoneal Aerosol Chemotherapy (ePIPAC)

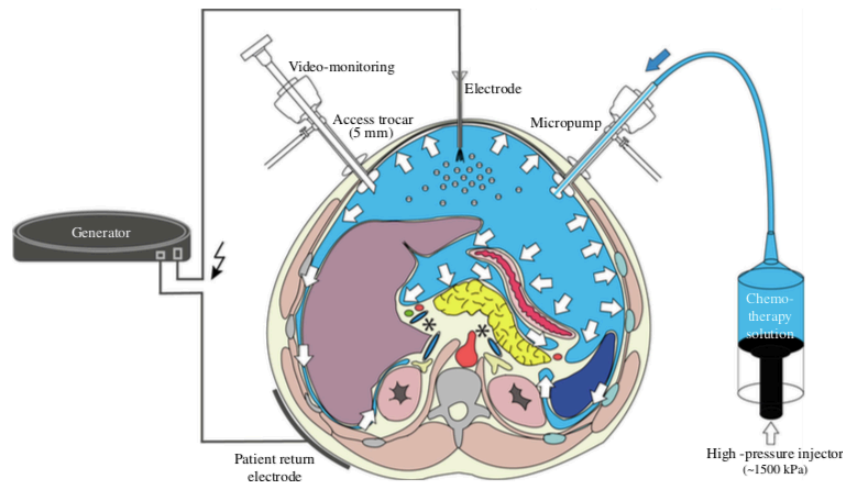
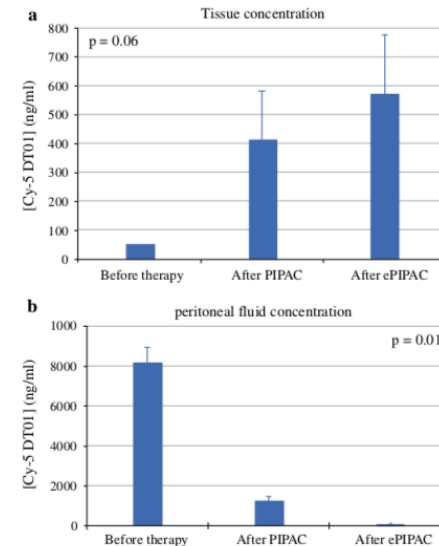
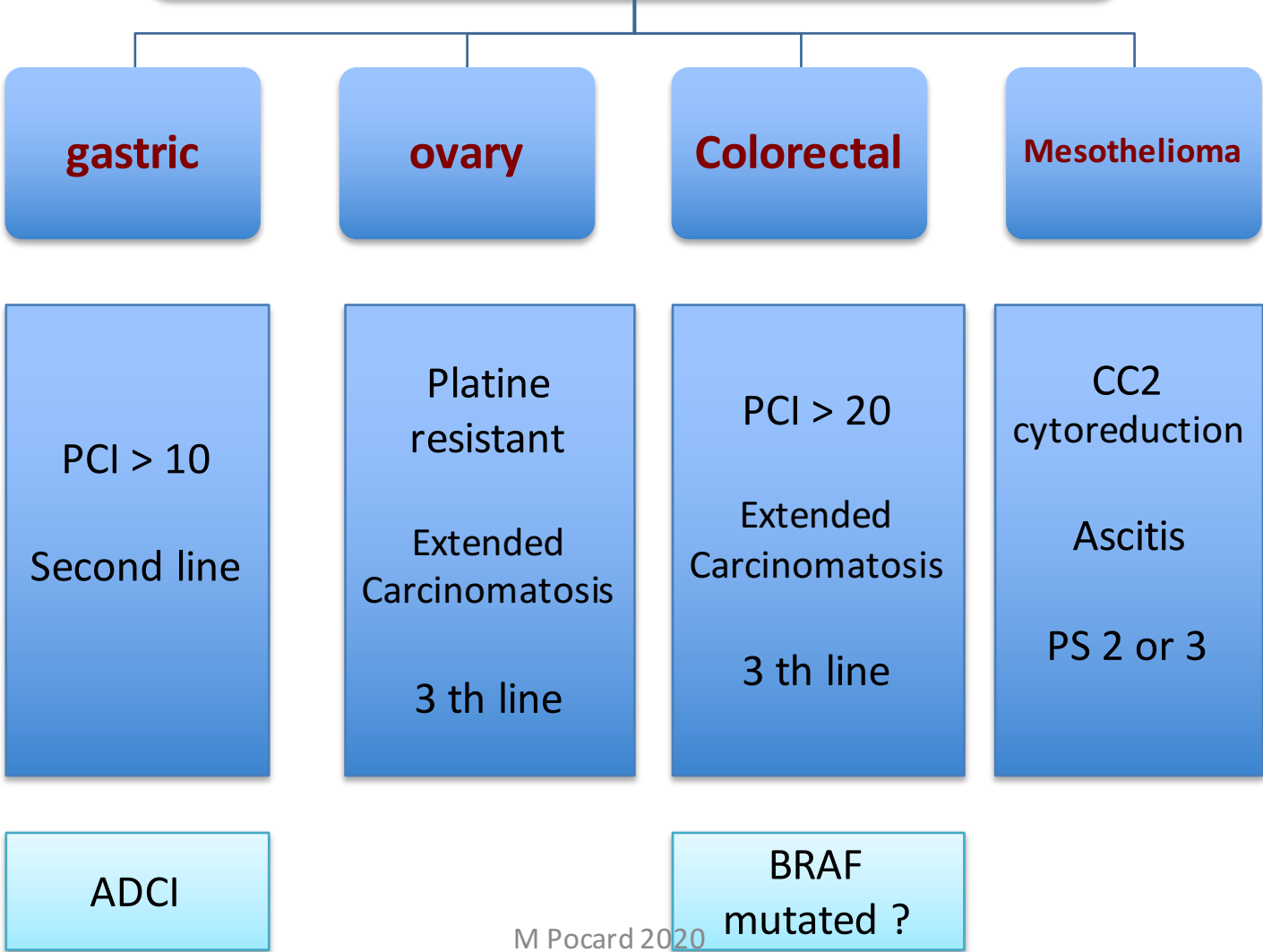


FIG. 1 Principle of electrostatic precipitation ePIPAC. **a** Technical setting for ePIPAC, including high-pressure injector containing therapeutic solution micropump generating pressurized intraperitoneal aerosol, brush electrode for electrostatic loading of therapeutic

aerosol, and return electrode (solid plate). **b** Intraoperative view of abdomen showing micropump producing aerosol and electrode actively loading this aerosol with electrostatic charges, leading to precipitation of aerosol particles



Palliation with PIPAC indications Lariboisière – Paris



Take home messages

PIPAC is not a therapy but a drug delivery system

Innovative technologies for intraperitoneal drug delivery
(taking advantage of physical laws) open new research
avenues in peritoneal diseases

Available clinical evidence shows that PIPAC is feasible, safe
and well tolerated

Preliminary oncological results call for further comparative
clinical studies



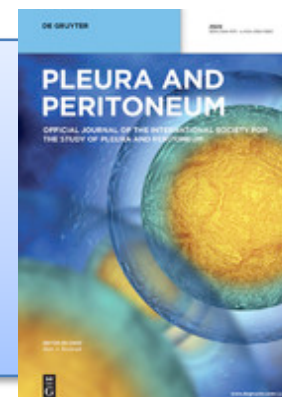
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