


COMBAT
Cancer with
Hyperthermia

COMBAT
MEDICAL

Clinical Evidence
PRS⁺Agitation
Optimising HIPEC Delivery

Agitation
with CO₂
improves drug
and heat
distribution



“ In our hospital we found the PRS⁺ Agitation the most appropriate HIPEC technique for maintaining thermal uniformity and for improving the distribution of the drug in the peritoneal cavity. The oncological effectiveness was shown by an increase in overall or progression free survival in the patients studied”

*Dr Pedro Villarejo- Campos,
Consultant Surgeon, Ciudad Real.*

COMBAT PRS⁺ Agitation. Clinical Overview

- Three ongoing, randomised controlled trials with over 300 patients in Colo-Rectal, Ovarian and Pancreatic Cancer
- A further series of multicentre trials in Gastric and Colo-Rectal Cancers to be announced
- PRS Registry (PRS⁺R) a real world data registry, sponsored by COMBAT, controlled by the PRS clinical working group. Outcomes of over 500 patients already presented
- Data continually assessed and presented at major congresses

Targeting Peritoneal Cancers with HIPEC + Agitation

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Analysis of the Survival of Patients Undergoing CRS + Closed Hipec with CO₂ Agitation System: A Multicentre Study

A. Gutierrez, R. Gómez, F. Pereira, I. Manzanedo, D. Padilla, E. García, E. Lopez-Tomassetti, L. González, E. Díaz, M. Pitarch, F. Ochando, F.J. Lacueva, M. Durán, A. González, P. Villarejo.

GECOP - VIII Reunion Internacional- Grupo Espanol de Cirugia Oncologica Peritoneal - 5-7th June 2019, Murcia, Spain

ESSO 9-11th October 2019 Rotterdam, Netherlands

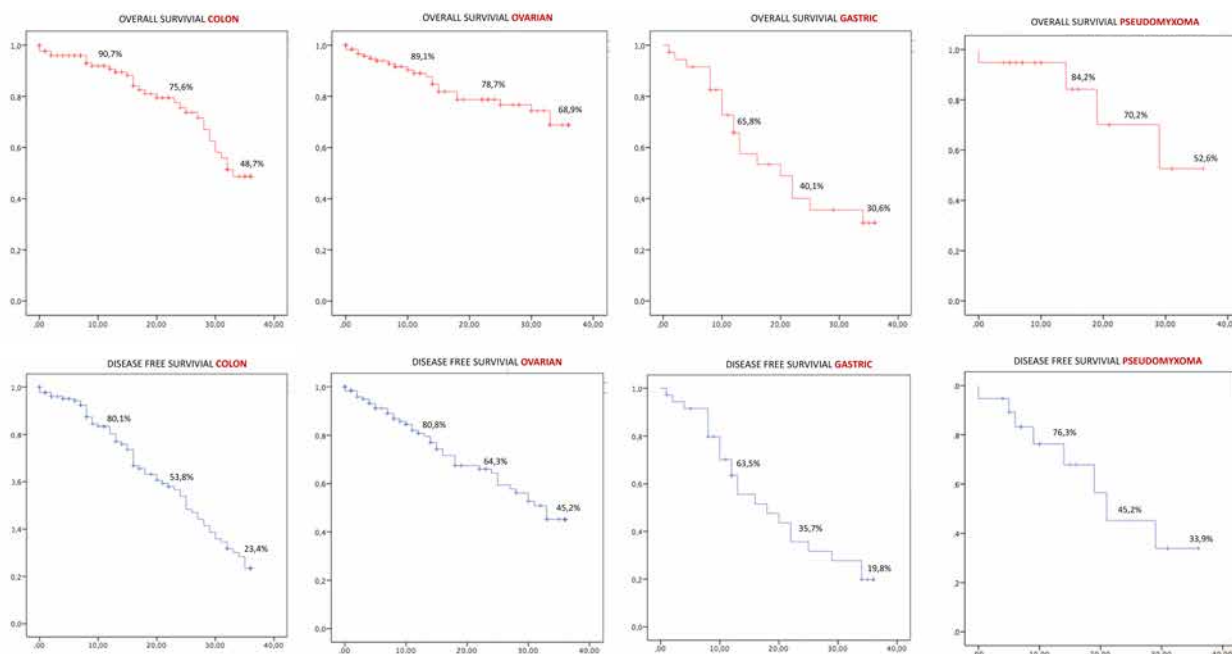
Objectives: There are 2 ways of carrying out HIPEC: the open (or “Coliseum”) technique and the closed technique. There is no study that demonstrates a greater long-term clinical benefit of either technique. In order to combine the potential benefits of both techniques, a closed technique HIPEC with CO₂ Agitation (PRS⁺A) was launched in 2011. The objective of this study is to analyse the survival results of this technique.

Methods: A multicenter, retrospective study based on a common prospective database of 482 patients, chosen without specific selection criteria and treated with the Closed PRS⁺A technique. A descriptive statistical analysis was performed for qualitative and quantitative variables and the Kaplan Meier method for calculating the survival function using the SPSS software for Mac.

Results: Of the 482 patients included in the study, 66.4% were women. The average age was 59 years. The origin of carcinomatosis was colon (CO) in 210 cases, ovarian (OV) in 149, gastric (GA) in 49, pseudomyxoma (PM) in 32, mesothelioma in 10 and others in 18 cases. Four or more surgical procedures were performed in 215 patients. The morbidity of the series was 35.2% (170 patients), being 10% (51 patients) with type III / IV complications. Operative mortality was 1.6% (8 patients). None of the cases were directly related to the HIPEC procedure. The overall survival (OS) and Disease-Free Survival (DFS) of the series, with a median follow-up (FU) of 12 months was OS 86.1%, 70.6% and 54.1% at year 1, 2 and 3 respectively. For carcinomatosis of CO origin, with a median FU of 13 months OS was 90.7%, 75.6% and 48.7% at year 1, 2 and 3. For OV origin, with a median FU of 10 months OS was 89.1%, 78.7% and 68.9%. For GA origin, with a median FU of 12 months OS was 65.8%, 40.1% and 30.6%. For PM, with a median FU of 10 months OS was 84.2%, 70.2% and 52.6%.

Conclusions: Cytoreduction with the Closed HIPEC with CO₂ Agitation (PRS⁺A) is a safe technique with acceptable morbidity and mortality rates, similar to other surgical procedures of high complexity. The application of this treatment with specific care programs and by experienced multidisciplinary teams, **shows survival results clearly superior to standard treatments.**

Cancer Origin/Patient Number and Follow Up	Overall Survival	Disease Free Survival
Combined Series - 482 patients Median f/up 12 months	86.1% - Year 1 70.6% - Year 2 54.1% - Year 3	77.2% - Year 1 55.8% - Year 2 31.4% - Year 3
Colon (CO) Origin - 210 patients Median f/up 13 months	90.7% - Year 1 75.6% - Year 2 48.7% - Year 3	80.1% - Year 1 53.8% - Year 2 23.4% - Year 3
Ovarian (OV) Origin - 149 patients Median f/up 10 months	89.1% - Year 1 78.7% - Year 2 68.9% - Year 3	80.8% - Year 1 64.3% - Year 2 45.2% - Year 3
Gastric (GA) Origin - 49 patients Median f/up 12 months	65.8% - Year 1 40.1% - Year 2 30.6% - Year 3	63.5% - Year 1 35.7% - Year 2 19.8% - Year 3
Pseudomyxoma (PM) - 32 patients Median f/up 10 months	84.2% - Year 1 70.2% - Year 2 52.6% - Year 3	76.3% - Year 1 45.2% - Year 2 33.9% - Year 3



Morbimortality of Patients Undergoing CRS + Closed Hipec with CO₂ Agitation System: A Multicentre Study

A. Gutiérrez, L. Jiménez, F. Pereira, I. Manzanedo, D. Padilla, S. Sánchez, E. López-Tomassetti, L. González, I. Fabra, A. Titos, E. Marcello, A. Calero, B. Rufián, P. A. Cascales, P. Villarejo

GECOP - VIII Reunion Internacional- Grupo Espanol de Cirugia Oncologica Peritoneal - 5-7th June 2019, Murcia, Spain

ESSO 9-11th October 2019 Rotterdam, Netherlands

Objectives: There are two ways of carrying out Hyperthermic IntraPERitoneal Chemotherapy: the open (or “Coliseum”) technique and the closed technique. There is no study that demonstrates a greater long-term clinical benefit of either technique. In order to combine the potential benefits of both techniques, a closed technique HIPEC with CO₂ Agitation (PRS⁺A) was launched in 2011. The objective of this study is to analyze the morbidity and mortality results of this technique.

Methods: A multicenter, retrospective study based on a common prospective database of 482 patients, chosen without specific selection criteria and treated with the Closed HIPEC with CO₂ Agitation (PRS⁺A) technique. Intraoperative and postoperative complications were classified according to the Clavien-Dindo 2004 scale. A descriptive statistical analysis was performed for qualitative and quantitative variables.

Results: Of the 482 patients included in the study, 66.4% were women. The average age was 59 years. The origin of carcinomatosis was colon in 210 cases, ovarian in 149, gastric in 49, pseudomyxoma in 32, mesothelioma in 10 and others in 18 cases. 4 or more surgical procedures were performed in 215 patients. A total of 170 patients (35%) presented some type of complication, with type III / IV in 51 patients (10%). During the HIPEC procedure, complications occurred in 9 patients (1.9%): Other complications included 6 hyperglycemias (higher than 400), one case of severe metabolic acidosis, one case of a severe allergic reaction to oxaliplatin and one of hypercapnia. These complications did not cause an increase in ICU stay. No statistical increase in risk was found during the HIPEC procedure related to the drug used, the age of the patient, the PCI or the number of surgical procedures performed. Operative mortality was 1.6% (8 patients), none of which were directly related to the HIPEC procedure.

Conclusions: Cytoreduction with the closed HIPEC technique with CO₂ Agitation (PRS⁺A) is a **safe technique, with acceptable morbidity and mortality rates**, similar to other surgical procedures of high complexity.



Intraperitoneal Chemotherapy Hyperthermia (HIPEC) for Peritoneal Carcinomatosis of Ovarian Cancer Origin by Fluid and CO₂ Recirculation Using the Closed Abdomen Technique (PRS-1.0 COMBAT): A Clinical Pilot Study

Susana Sánchez-García, Pedro Villarejo-Campos, David Padilla-Valverde, Mariano Amo-Salas & Jesús Martín-Fernández.

International Journal of Hyperthermia, 2016, 32.5,488-495

Background: This paper reports a study of 21 patients with peritoneal carcinomatosis from ovarian cancer who underwent cytoreductive surgery and HIPEC by means of PRS-1.0 Combat a new model for closed abdomen HIPEC aimed at improving fluid distribution with assistance from a CO₂ recirculation system. This new technology has been previously shown to be successful in an experimental study (pig model) performed by our group and has been approved for use in our hospital.

Methods: Twenty-one patients with peritoneal carcinomatosis of ovarian cancer origin were included in the study. Cytoreductive surgery and HIPEC were performed by a closed abdomen fluid and CO₂ recirculation technique using the PRS-1.0 Combat model. We analysed the intraoperative safety tolerance and post-operative morbidity and mortality during the first 30 days.

Results: Between November 2011 and March 2014, 21 patients with epithelial ovarian cancer, International Federation of Gynecology and Obstetrics stage II–IV, were included in the study. During the procedure there were no significant haemodynamic or analytical disturbances. Complication rates were 38.1% and 57.14% for grade III/IV and minor (grade I/II) complications, respectively. Post-operative mortality was 4.76% (one patient). Complete cytoreductive surgery and intraperitoneal chemotherapy improved overall survival and disease-free survival in women with advanced ovarian cancer. The association of intra-abdominal hyperthermia with chemotherapy (HIPEC) increased the therapeutic benefit.

Conclusions: This study has shown that closed abdomen intraperitoneal chemohyperthermia by a fluid and CO₂ recirculation system (PRS⁺-1.0 Combat) can be a safe and feasible model for the treatment of peritoneal carcinomatosis of ovarian cancer.

Security and Efficiency of A Closed-System, Turbulent-Flow Circuit for Hyperthermic Intraperitoneal Chemotherapy After Cytoreductive Ovarian Surgery: Perioperative Outputs

Javier Pascual-Ramírez, Susana Sánchez García, Francisco González Ruiz de la Herrán, Pedro Villarejo Campos, Carlos López de la Manzanar Cano, Javier Haya Palazuelo, David Padilla Valverde, Jesús Martín Fernández

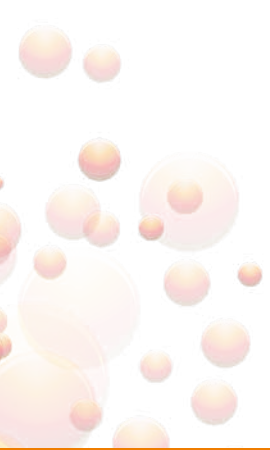
Gynecologic Oncology July 2014, Volume 290, Issue 1, pp 121–129

Objective: To present physiologic intraoperative data and immediate postoperative outcomes of patients diagnosed with epithelial ovarian cancer submitted to cytoreductive surgery and hyperthermic peritoneal intraoperative chemotherapy (HIPEC) with a closed-circuit, turbulent-flow system.

Materials and Methods: A closed-circuit system with CO₂ turbulent-flow was used for paclitaxel HIPEC during 60 min for patients diagnosed with stage II or higher and recurrent epithelial ovarian cancer. Perioperative hemodynamic and metabolic statuses were followed, as well as physiologic recovery during the first 12 postoperative hours. A non-parametric statistical analysis was performed.

Results: At the end of the hyperthermia phase, temperature was 37.7 ± 0.6 °C, heart rate 88 ± 19 bpm, cardiac index 2.8 ± 0.5 L min⁻¹ m⁻², stroke volume variation 14.6 ± 3.6 % and extravascular lung water 8.7 ± 1.9 mL kg⁻¹. No hyperdynamic status was recorded. The length of stay in the ICU was 2½ days, and 12.7 ± 7 days in hospital. Average postoperative intubation time was 11.7 ± 17.4 h. At the ICU admission time, glucose, lactic acid and hemoglobin were the only values out of range, but close to normal. SOFA median was 3 at admission and 0 the following day.

Conclusion: A turbulent-flow, closed-circuit use for hyperthermic peritoneal intraoperative chemotherapy resulted in no hyperdynamic response or coagulopathy, had good tolerance and promoted early physiologic recovery.



Hyperthermic Chemotherapy Intra-Abdominal Laparoscopic Approach: Development of A Laparoscopic Model Using CO₂ Recirculation System and Clinical Translation in Peritoneal Carcinomatosis

Susana Sánchez-García, David Padilla-Valverde, Pedro Villarejo-Campos, Esther P. García-Santos, Jesús Martín-Fernández, University General Hospital, Ciudad Real, Spain

International Journal of Hyperthermia, 2017, 33:6, 684-689

Introduction: Hyperthermic intraperitoneal chemotherapy (HIPEC) is an effective treatment for peritoneal carcinomatosis (PC). Laparoscopic surgery is performed in the treatment of colorectal and appendiceal cancer, and PC from diverse origin in selected patients. HIPEC management by laparoscopic approach after cytoreductive surgery (CRS) completed locoregional treatment of PC and may be feasible and safe after appropriate patient selection.

Objective: Development of an experimental model of HIPEC by laparoscopic approach, with CO₂ recirculation. Clinical translation in two patients with PC and low peritoneal cancer index.

Material and methods: We performed CRS in a porcine model of 5 pigs (35–38 kg) by laparoscopic approach. Laparoscopic HIPEC by CO₂ recirculation system was performed; laparoscopic access was used for catheter input and output placement (Paclitaxel 175mg/m² for 60min at 42 °C). The experimental variables were: blood gases, haemodynamic and intra-abdominal and central temperature. Clinical model application was performed in three cases with PC from colorectal origin.

Results: No statistically significant differences was found in blood gases, haemodynamic or temperature in the experimental study. In clinical study, there were no technical complications during laparoscopic-HIPEC approach, and we observed no changes in haemodynamic variables during the procedure.

Conclusions: CRS and HIPEC laparoscopic model by CO₂ recirculation system is a safe and feasible technique in selected patients, that include low PC index, local and accessible tumour recurrences or high-risk of PC tumours.



Laparoscopic Gastrectomy and Adjuvant Hyperthermic Intraperitoneal Chemotherapy (HIPEC) Using Closed System with Turbulent-Flow Circuit: Technical Aspects and Preliminary Results of A Pilot Study

Daniele Bernardi, Emanuele Asti, Michele Punturieri, Alberto Luporini, Luigi Bonavina

European Surgery, (May 2018). <https://doi.org/10.1007/s10353-018-0538-9>

Background: Intraoperative hyperthermic chemotherapy (HIPEC) is increasingly used in combination with cytoreductive surgery for the treatment of peritoneal carcinomatosis. The potential survival benefit of adjuvant HIPEC after curative gastrectomy has not been conclusively demonstrated. We describe a newly developed closed system for HIPEC and report the preliminary results of a pilot study.

Method: Patients with locally advanced gastric carcinoma at a high risk for peritoneal recurrence were identified from a prospectively collected database. Laparoscopic total or subtotal gastrectomy combined with standard D2 lymphadenectomy was performed. Immediately after resection and 15 min before HIPEC treatment, intravenous induction chemotherapy with folinic acid and 5-fluorouracil was administered. A closed-system HIPEC with turbulent-flow circuit (Combat PRS⁺, Peritoneal Recirculation System), was used to perfuse the peritoneal cavity with a solution of oxaliplatin and glucose for 60 min. After washout of the peritoneal cavity and re-establishment of pneumoperitoneum, a Roux-en-Y esophagojejunostomy or gastrojejunostomy was performed.

Results: Between June 2017 and February 2018, 6 patients were treated according to this protocol. No major postoperative complications occurred. There were no intra- or postoperative complications related to the HIPEC procedure. All patients are alive and disease free at 3–11 months of follow-up.

Conclusion: The preliminary results of this pilot study indicate the safety and feasibility of the closed HIPEC system with CO₂ recirculation in selected patients undergoing laparoscopic total or subtotal gastrectomy for locally advanced gastric carcinoma.

Experimental Development of an Intra - Abdominal Chemohyperthermia Model Using A Closed Abdomen Technique and the PRS⁺ - 1.0 COMBAT CO₂ Recirculation System

Susana Sánchez-García, David Padilla-Valverde, Pedro Villarejo-Campos, Jesús Martín-Fernández , Marta Rodríguez-Martínez.
University General Hospital, Ciudad Real, Spain

Surgery 2014;155:719-25

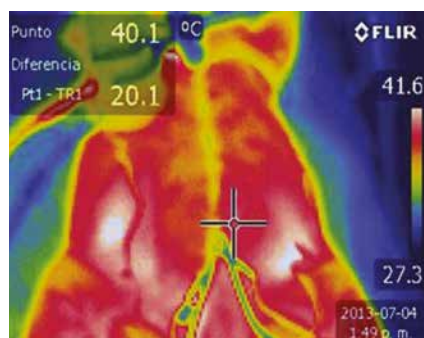
Background: Cytoreductive surgery with hyperthermic intraperitoneal chemotherapy is the best operative treatment currently available for patients with peritoneal carcinomatosis of ovarian origin. The open abdomen technique is the classic technique for hyperthermic intraperitoneal chemotherapy. We developed a closed abdomen model that improves temperature control and increases exposure of peritoneal surfaces to the drug by recirculating the perfusate.

Methods: We used a porcine model with 12 female, Large White pigs-4 in the open technique group and 8 in the closed technique CO₂ group. We performed cytoreductive surgery and hyperthermic intraperitoneal chemotherapy for 60 minutes using paclitaxel (175 mg/m²) at an input temperature of 42°C. Perfusate recirculation was performed under controlled pressure (range 12–15 mmHg). The infusion of 0.7l of CO₂ via a separate intraperitoneal infusion catheter mixed the perfusate within the peritoneal cavity. Intra-abdominal temperature was assessed using 6 intra-abdominal temperature probes and 2 temperature probes in the inflow and outflow circuits. Drug distribution was assessed using methylene blue staining.

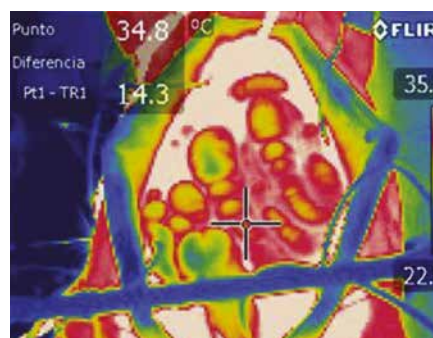
Results: Intra-abdominal temperatures remained constant and homogeneous in all intra-abdominal quadrants with a constant input temperature of 42°C and a minimum output temperature of 41.4°C. The infused CO₂ caused the fluid to bubble and created agitation inside the abdominal cavity to facilitate a homogeneous distribution of the drug-containing perfusate.

Conclusion: The closed recirculation hyperthermia with intraperitoneal chemotherapy technique developed in this study is safe and feasible and may provide a more homogeneous delivery of heated chemotherapy to the peritoneal cavity in patients with peritoneal malignancies.

Closed Technique + Agitation



Open Technique



Thermographic images from the closed CO₂ technique using the **COMBAT HIPEC + Agitation** technique in a porcine model. Image shows a more homogeneous delivery of heated chemotherapy (left) in comparison to the open technique (right).

Usefulness of Thermographic Analysis to Control Temperature Homogeneity in the Development and Implementation of A Closed Recirculating CO₂ Chemohyperthermia Model

David Padilla-Valverde ^a, Susana Sanchez-Garcia ^a, Esther Garcia-Santos ^a, Carlos Marcote-Ibañez ^b, Mercedes Molina-Robles ^c, Jesus Martin-Fernandez ^a and Pedro Villarejo-Campos ^a

^a Department of Surgery, Faculty of Medicine, University General Hospital, Ciudad Real, Spain; ^b Department of Interne Medicine, Marques de Valdecilla, University General Hospital, Santander, Cantabria, Spain; ^c Department of Interne Medicine, Santa Barbara Hospital, Puertollano, Ciudad Real, Spain

International Journal of Hyperthermia, 2017 Vol. 33, No. 2, 220–226

Purpose: To determine the effectiveness of thermography to control the distribution of abdominal temperature in the development of a closed chemohyperthermia model.

Materials and methods: For thermographic analysis, we divided the abdominopelvic cavity into nine regions according to a modification of carcinomatosis peritoneal index. A difference of 2.5°C between and within the quadrants, and thermographic colours, were used as asymmetric criteria. Preclinical study: Rats Model: Six athymic nude rats, male, rnu/rnu. They were treated with closed technique and open technique. Porcine Model: 12 female large white pigs. Four were treated with open technique and eight with closed recirculation CO₂ technique. Clinical Pilot Study, EUDRACT 2011-006319-69: 18 patients with ovarian cancer were treated with cytoreductive surgery and hyperthermia intraperitoneal chemotherapy, HIPEC, with a closed recirculating CO₂ system. Thermographic control and intra-abdominal temperature assessment was performed at the baseline, when outflow temperature reached 41°C, and at 30'.

Results: The thermographic images showed a higher homogeneity of the intra-abdominal temperature in the closed model respect to the open technique. The thermogram showed a temperature distribution homogeneity when starting the circulation of chemotherapy. There was correlation between the temperature thermographic map in the closed porcine model and pilot study, and reached inflow and outflow temperatures, at half time of HIPEC, of 42/41.4 °C and 42 ± 0.2/41 ± 0.8 °C, respectively. There was no significant impact to the core temperature of patients after reaching the homogeneous temperature distribution.

Conclusions: To control homogeneity of temperature distribution is feasible using infra-red digital images in a closed HIPEC with CO₂ recirculation.

Clinical Trials

COMBAT PRS⁺ is currently being evaluated in the following trials:

HIPEC OVA

HIPEC PANCREAT

HIPEC T4

See pages 13-14 for clinical trial protocols.
A further series of trials to be announced.

A real world data registry, sponsored by COMBAT, controlled by the PRS Clinical group and renowned GECOP Surgical oncology Group. Anonymous patients' data with cancer from over 6 different origins have been collected, analysed and presented. We continue to collate and present data in order to optimise treatment and inform future trials.

PRS⁺R

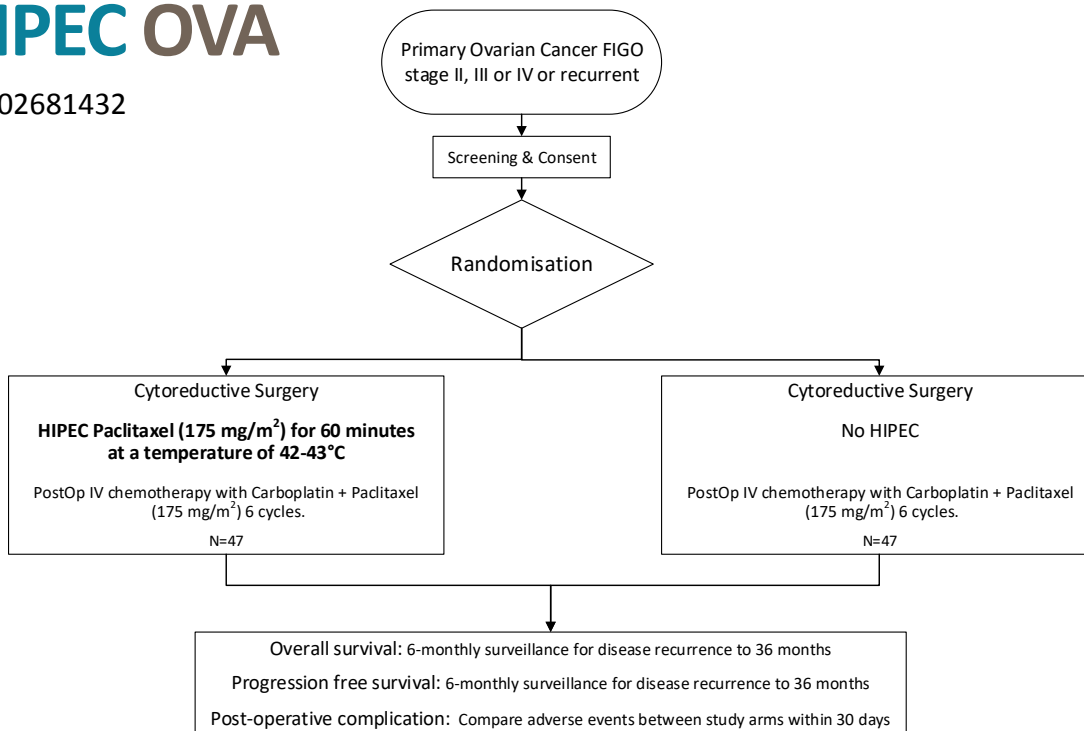
COMBAT will continue to update its summary of clinical evidence as more data is published and presented.

We partner with a global network of distributors to ensure that the **COMBAT PRS⁺** is available to patients in as many countries as possible and are constantly working towards increasing its availability on an international level. If you would like to speak to your in country distributor or if you are interested in finding out about distribution opportunities please contact COMBAT Medical directly.

For more information on the clinical programme or clinical evidence please contact us or see www.combatcancer.com

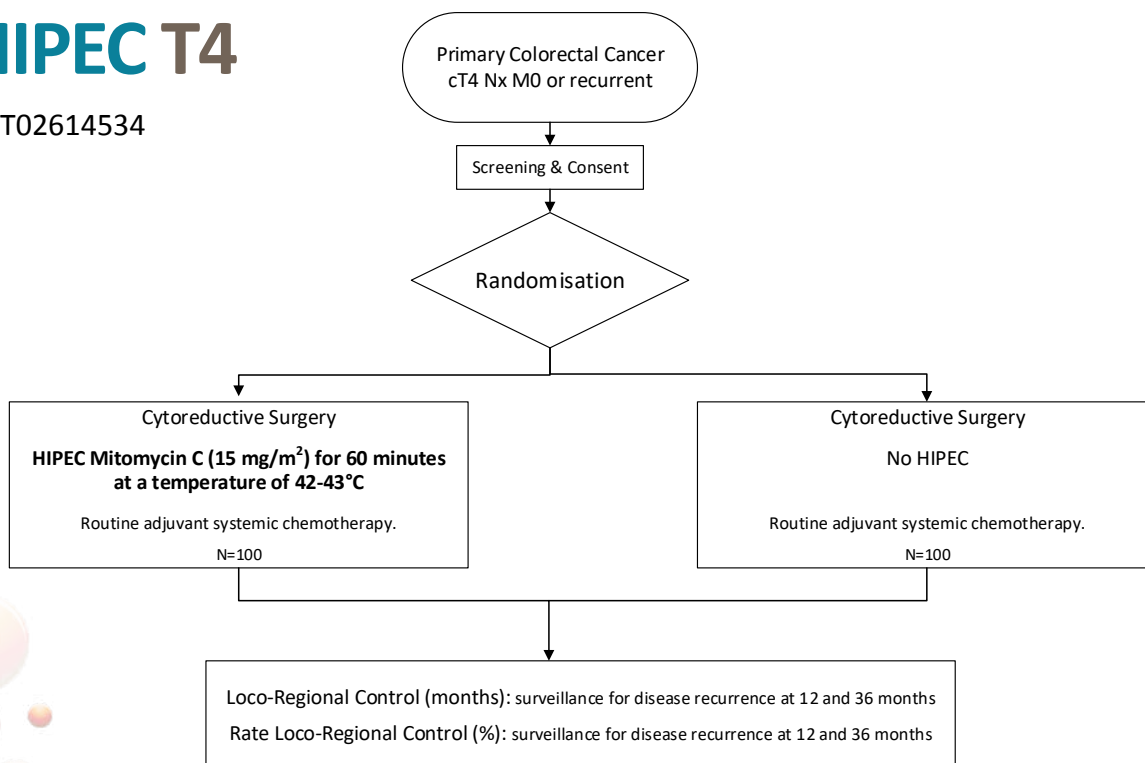
HIPEC OVA

NCT02681432



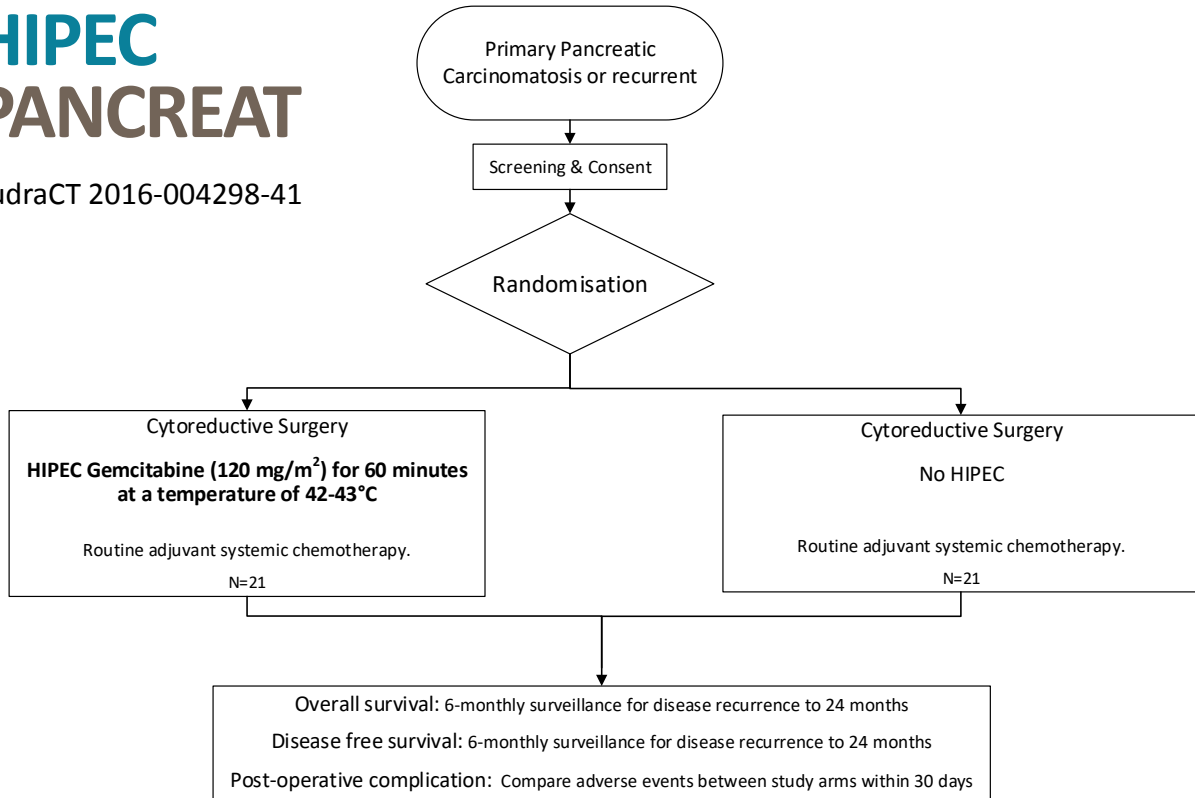
HIPEC T4

NCT02614534



HIPEC PANCREAT

EudraCT 2016-004298-41



HIPEC + Agitation

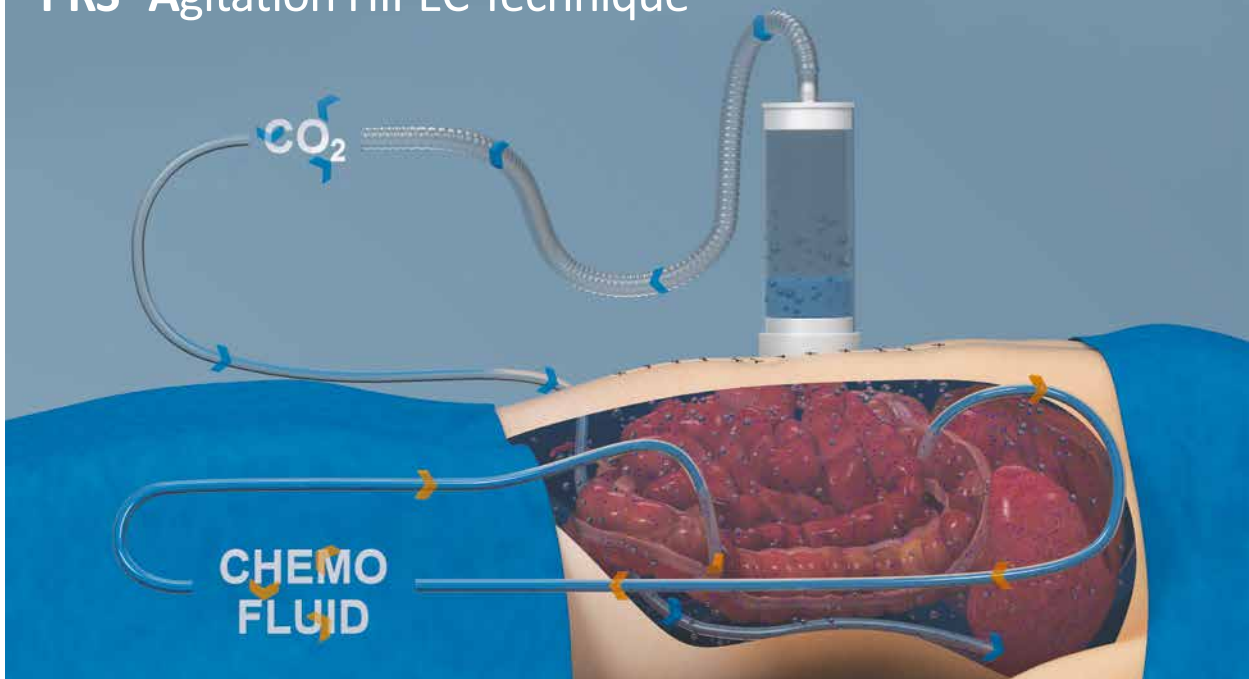
Developed in collaboration with surgeons to optimise **Efficacy, Safety** and **Delivery** of the HIPEC technique.

The **COMBAT PRS+** utilises an innovative patented agitation system to optimise the HIPEC treatment. Combined with the patented aluminium coated heat exchanger the PRS+ offers unparalleled heat control. The Agitation with CO₂ and accurate heat control improves drug and heat distribution in the abdominal cavity.

The PRS+ operating systems are compatible with all other open and closed HIPEC delivery techniques giving the surgeons and healthcare professionals the flexibility to choose the most suitable technique for the patient and the disease.



PRS+ Agitation HIPEC Technique



HIVEC delivered by BRS



COMBAT Medical is dedicated to optimising the treating of many cancers. The BRS is a chemohyperthermia system used for treating Non Muscle Invasive Bladder cancer (NMIBC).

The BRS has been used in over 40,000 treatments to date and is now used routinely in over 200 centres across 40 countries. 867 patients are in randomised controlled HIVEC trials and evidence has already been presented on over 500 patients while we await results of larger scale trials.

For further information please contact COMBAT Medical or see www.combatcancer.com



Introduction to COMBAT BRS



COMBAT Medical

COMBAT Medical is an innovative company committed to investing in research and development, clinical trials and evidence-based studies to demonstrate the effectiveness of our technology and create a solid foundation for its use.

COMBAT is continuously adding to its HIPEC bibliography of evidence across a number of disease areas.

In use since 2012, the COMBAT PRS⁺ (Peritoneal Recirculation System) is a CE marked, patented, technically advanced system to optimise the delivery and penetration of the chemotherapy into tumour cells. Using a closed system plus automatic agitation to ensure homogeneous drug and thermal distribution throughout the abdominal cavity and peritoneal surfaces maximising safety and patient outcomes. Hyperthermia is characterised by intrinsic anti-tumour activity which has led to its use in helping to treat many types of cancer.



Technical Specifications:

Equipment external dimensions:

Height 890mm Width 420mm Depth 350mm

Equipment weight:

PRS system 32.6kg plus stand

Safety alarms:

High temperature alarm

High pressure alarm

Auto safety cut off

Safety lock

Electrical risk classification:

Class I, Type B

Fluid ingress protection:

IPX2

Certification:

IEC/UL 60601 - 1; IEC 60601 - 1 - 2;

EN 60601 - 1 - 2; EN 60601 - 1

Function mode:

Continuous delivery at set temperature
between 20°C to 43°C ± 1°C

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Twitter: @CombatCancer

Visit: www.combatcancer.com

Manufactured by **BIO**surgical
part of the **COMBAT** group

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