**Current Status and Future Prospects of Clinical Trials on CRS+HIPEC for Gastric Cancer Peritoneal Carcinomatosis**

Zhong-He Ji 1, Kai-Wen Peng 2, Yang Yu 1, Xin-Bao Li 1, Yutaka Yonemura 3, Yang Liu 3, Paul H Sugarbaker 4, Yan Li 1, 2\*

1 Department of Peritoneal Cancer Surgery, Beijing Shijitan Hospital, Capital Medical University. Beijing, 100038, China;

2 Department of Oncology, Zhongnan Hospital of Wuhan University, Hubei Key Laboratory of Tumor Biological Behaviors & Hubei Cancer Clinical Study Center, Wuhan 430071, China;

3 NPO Organization to Support Peritoneal Dissemination Treatment, Kishiwada, Osaka, Japan;

4 Washington Cancer Institution, Washington DC, USA.

**First author/ presenter address and email:**

**Submission author address and email:**

**Background**: Peritoneal carcinomatosis (PC) is the number one route among the three major forms of gastric cancer (GC) metastasis: blood-route metastasis, lymphatic metastasis, and seeding metastasis. Both institution-based and population-based clinical studies demonstrated a median overall survival (OS) of about 5 months for such patients. Currently, no standard treatment guidelines are available for this important problem. As a results, high-level clinical trials are in urgent need in order to develop optimal treatment strategies for this problem.

**Objectives**: This study is to review the currently available clinical trials on CRS+HIPEC for GC PC, published since 1991. These studies covers institution- and population-based studies on the epidemiology of GC PC, retrospective studies on CRS+HIPEC, and prospective studies on CRS+HIPEC. Survival and safety profiles are the key considerations in this review.

**Methods:** We reviewed the available clinical trials on cytoreductive surgery (CRS) plus hyperthermic intraperitoneal chemotherapy (HIPEC) for GC PC. Survival and safety are primary endpoints.

**Results:** The median OS of GC PC was 3.1 months in a large-sample institutional study, and 4.6 months in a population-based study. CRS+HIPEC could improve the survival of such patients. In three retrospective studies on PC, the median OS for 300 GC PC patients was about 13.0 months after CRS+HIPEC. In five prospective studies on 256 GC PC patients, the median OS was about 11.0 months vs. about 5.0 months for CRS+HIPEC vs. control. In retrospective studies on 1374 patients with GC PC, the median OS was about 11.3 months. CRS+HIPEC could double the OS in selected patients with GC PC. There is no statistically significant increase in serious adverse events directly attributed to CRS+HIPEC.

**Conclusions**: Adequate clinical evidence is now available to support the advantages of CRS+HIPEC over traditional treatments for GC PC. CRS+HIPEC should be advocated as the treatment of choice for selected patients with GC PC, in experienced treatment centers.

**Key words**: clinical trials; gastric cancer; cytoreductive surgery (CRS); hyperthermic intraperitoneal chemotherapy (HIPEC)

**Funds:** The Key Discipline Development Fund of Beijing Shijitan Hospital affiliated to the Capital Medical University (2016fmzlwk), and the Special Fund for the Capital Characteristic Clinical Medicine Development Project (Z161100000516077) (both to Yan Li).