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BRIEF ARTICLE

Hyperthermic intraperitoneal chemotherapy for gastric and colorectal cancer in Mainland China

Tao Suo, Haile Mahteme, Xin-Yu Qin

Tao Suo, Xin-Yu Qin, Department of General Surgery, Zhongshan Hospital, Fudan University, General Surgery Institute of Fudan University, Shanghai 200032, China
Haile Mahteme, Department of Surgical Sciences, Uppsala University, SE75185 Uppsala, Sweden
Author contributions: Suo T and Qin XY designed the study; Suo T performed the search of the literature and analyzed the data; Suo T and Mahteme H wrote the paper; Qin XY revised the paper before submission.
Correspondence to: Xin-Yu Qin, MD, PhD, Department of General Surgery, Zhongshan Hospital, Fudan University, General Surgery Institute of Fudan University, 180 Fenglin Road, Xuhui District, Shanghai 200032, China. qin.xinyu@live.cn
Telephone: +86-21-64041990 Fax: +86-21-64037224
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Abstract

AIM: To investigate the current status of peritoneal carcinomatosis (PC) management, as well as the usage of cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) in mainland China.

METHODS: A potentially curative therapeutic strategy for selecting patients with PC, known as "Techniques", consists of CRS in combination with HIPEC. A systemic search of published works and clinical trials was performed. Additional papers were retrieved by cross-checking references and obtaining information from Chinese oncologists and relevant conferences. One hundred and one papers and one registered clinical trial on HIPEC were included.

RESULTS: A literature review identified 86 hospitals in 25 out of all 31 areas of mainland China that perform HIPEC. The earliest report included in our survey was published in 1993. Different approaches to HIPEC have been utilized, i.e. palliative, prophylactic, and possibly curative treatment. Only one center has consistently performed HIPEC according to the "Sugarbaker Protocol", which involves evaluating the extent of PC with peritoneal cancer index and the results of CRS with the completeness of cytoreduction. Positive preliminary results were reported: 7 of 21 patients with PC survived, free of tumors, during an 8-43-mo follow-up period. Hyperthermic strategies that include HIPEC have been practiced for a long time in mainland China, whereas the "Sugarbaker Protocol/Techniques" has been only rarely implemented in China. The Peritoneal Surface Oncology Group International hosts a biannual workshop with the intent to train more specialists in this field and provide support for the construction of quality treatment centers, especially in developing countries like China, whose population is huge and has a dramatically increased incidence of cancer.

CONCLUSION: To popularize Sugarbaker Protocol/Techniques in mainland China in PC management arising from gastric cancer or colorectal cancer will be the responsibility of the upcoming Chinese Peritoneal Surface Oncology Group.

Key words: Peritoneal carcinomatosis; Hyperthermia; Prophylactic strategy; Sugarbaker Protocol/techniques; Mainland China

Peer reviewer: Dr. Oliver Mann, MD, Senior Attending Physician and Deputy Director, Department of General, Visceral and Thoracic Surgery, University of Hamburg, Martini Str. 52, D-20246 Hamburg, Germany

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INTRODUCTION

China has a population of more than 1.3 billion, which makes it the largest developing country in the world with a consequently huge medical burden. The incidence of gastrointestinal cancer in China has been rapidly increasing in recent years[1]. In 2004-2005 alone, there were 428 380 newly reported cases of gastric cancer (GC) and 339 308 GC-related deaths. Furthermore, in the same period of time, there were 197 873 newly reported cases of colorectal cancer (CRC), including cancers of anal canal, and 101 684 CRC-related deaths[2]. Although the incidence of GC has decreased for both men and women in some areas of China, the incidence of CRC has annually increased by 4.2% in Shanghai, which is higher than the observed global rate of increase. Notably, a report of 1075 cases of CRC in China has revealed that advanced stage Ⅲ and Ⅵ cases account for 46.8% of all reported cases[3].

The peritoneum is one of the most commonly affected sites in patients with recurrent GC or CRC. One study performed on a Chinese population found that even early GC has a 1.63% (4/308) rate of peritoneal recurrence[4]. The natural course of peritoneal carcinomatosis (PC), including those arising from GC and CRC, is only 6-8 mo[5,6]. In regard to the traditional treatment and follow-up, PC is considered to be a terminal event of systemic metastasis. Over the past two decades, "Sugarbaker Protocol/Techniques", i.e. surgical removal of all macroscopic PC in combination with hyperthermic intraperitoneal chemotherapy (HIPEC), has emerged as a potential curative treatment option for some patients. It becomes increasingly acceptable as a standard method of treatment for certain local peritoneal surface diseases. In recent years, many institutions all over the world have applied this combined modality treatment and have achieved exciting results[7-14].

The purpose of this survey was to investigate the current status of PC treatment, as well as the frequency of cytoreductive surgery (CRS) and HIPEC utilization in China, as determined by a review of the English and Chinese literature. We sought to identify the number of specialized centers that use this approach in the treatment of GC and CRC. We examined the logic behind the decision to pursue HIPEC and/or CRS and the location of the hospitals that reported the use of the technique. We sought to evaluate the popularity of these strategies and quantified the patients who were involved therein in order to determine the frequency with which this approach was utilized. The design, methodology, and results of those clinical trials are not analyzed and discussed in this report.

MATERIALS AND METHODS

An electronic search was conducted using English and/or Chinese language restrictions and Medline databases (from 1949 to January 2010) on PubMed[15], Cochrane databases[16], and other databases for registered clinical trials[17-19]. We used the following search strategy: (China or Chinese) and (cancer or tumor or carcinoma or malign*) and (mesothel* or periton*) and (heat* or hyper*) and chemotherapy.

The Chinese National Knowledge Infrastructure (CNKI) database[20] and the Chongqing Weipu Information Company (CQVIP) database[21] encompass 95.96% and 83.86% of all significant Chinese journals, respectively. The following search strategy was used for our investigation of the Chinese literature: (associated with abdomen) and (associated with cancer) and (associated with heat or hyperthermia) and (chemotherapy) and (associated with surgery and operation).

In order to supplement the electronic search, additional studies about registered clinical trials in China and intraperitoneal chemotherapy were retrieved by cross-checking references. Chinese oncologists and relevant conferences provided the information as well.

The reference lists of the obtained articles were also examined so as to identify further relevant citations. The first author performed electronic searches in January 2010. All of the abstracts of citations identified by the search were then scrutinized by the first author to determine their eligibility for this study.

Selection criteria

All reported cases with < 10 subjects, cases that lacked a description of the detailed process, cases without follow-up, and cases with brief reports that lacked abstracts and reviews were excluded. If a series of trials at the same center had been documented, we focused on the most recent results. Papers on the same trial published in different languages were considered to be one publication. As mentioned in the introduction, the quality of these clinical trials and their HIPEC technologies are not evaluated or discussed in this paper.

The included papers and clinical trials were categorized into three groups according to the purpose of treatment (Table 1) as follows.

Perioperative prophylactic strategy: intraoperative and early postoperative HIPEC for patients without visible peritoneal metastasis at the time of primary tumor surgery.

Palliative strategy: HIPEC after palliative operation without an attempt to eliminate visible peritoneal tumors or without surgery.

CRS and HIPEC: use "Sugarbaker Protocol", with an attempt to eliminate PC as a potentially curative strategy, following the HIPEC to control residual diseases. An evaluation of the PC and peritoneal cancer index (PCI), in addition to the extent of the CRS and the completeness of cytoreduction (CCR), was included in this category[9].

RESULTS

Initially, we obtained 629 records from the CQVIP database, 439 records from the CNKI database, 86 records from Medline, and 11 records from the clinical trial registration database. All 715 abstracts about GC and CRC were skimmed. Ultimately, 101 papers and one registered

Table 1 Hospitals performing HIPEC in different areas of Mainland China

Areas in mainland China	Hospitals	No. of trials	No. of trials (No. of patients)			No. of trials for different types of HIPEC			No. of trials that were performed for reasons other than HIPEC		
			GC	CRC	GC and CRC	iHIPEC	pHIPEC	iHIPEC, pHIPEC	Prophylactic	Palliative	Curative
Beijing	1	1	1 (169)			1			1		
Shanghai[1]	4	4	3 (30, 52, 104)		1 (25)	2		2	4	1	
Tianjin	2	2	1 (41)		1 (32)		2		2		
Chongqing	1	1	1 (54)				1		1		
Guangdong[1]	9	13	5 (63, 61, 25, 32, 44)	5 (44, 35, 20, 53, 358)	3 (30, 72, 157)	5	6	2	12	2	
Guangxi[1]	4	4	3 (29, 30, 35)	1 (68)		4			4	1	
Anhui[1]	5	5	3 (278, 25, 42)	1 (32)	1 (80)	1	4		5	1	
Zhejiang	9	10	8 (58, 135, 43, 40, 31, 32, 146, 45)		2 (76, 81)	4	6		10		
Jiangsu	8	10	8 (31, 38, 45, 46, 100, 25, 29, 32)		2 (58, 49)	3	7		10		
Henan[1]	11	13	9 (35, 34, 43, 50, 234, 49, 29, 32, 30)	2 (52, 87)	2 (48, 29)	5	7	1	11	3	
Hebei[1]	2	4	3 (30, 68, 37)	1 (68)		3	1		4	1	
Shandong[1]	5	7	5 (34, 45, 72, 53, 32)		2 (21, 63)	2	5		5	4	
Fujian	2	2	2 (68, 304)				2		2		
Hubei	4	4	2 (23, 56)		2 (68, 17)	2	1	1	3		1
Hunan	1	1	1 (35)				1		1		
Liaoning[1]	4	5	3 (128, 198, 17)	2 (35, 138)		3	2		4	2	
Jilin	1	2	1 (35)	1 (18)			2		1	1	
Shaanxi	2	2	1 (160)	1 (40)		1	1		2		
Ningxia	1	1	1 (82)			1			1		
Gansu[1]	2	2	2 (25, 50)				1	1	2	1	
Neimeng	2	2	1 (36)		1 (24)	1	1		2		
Sichuan	2	2	2 (33, 71)			1	1		2		
Jiangxi	2	2	1 (96)		1 (30)	2			2		
Yunnan	1	1			1 (25)			1	1		
Xinjiang	1	1	1 (136)			1			1		
Total[1] (trial number)	86	101	68	14	19	42	51	8	91	17	1

GC: Gastric cancer; CRC: Colorectal cancer; PC: Peritoneal carcinomatosis; HIPEC: Hyperthermic intraperitoneal chemotherapy; iHIPEC: Intraoperative HIPEC; pHIPEC: Postoperative HIPEC. [1]A trial including both prophylactic and palliative strategies was counted twice according different purposes of HIPEC.

clinical trial on HIPEC in China were identified. Among these, nine papers were obtained from Medline with English abstracts and five were published in English[9,22-29].

Based on the aforementioned criteria, we included 86 hospitals in mainland China whose doctors have extensive experience with HIPEC. The hospitals were located in 25 of the 31 areas of mainland China. In total, these institutions reported 101 clinical trials, and the earliest report was published in 1993. Among the included trials, 68 investigated GC, 14 studied CRC, and 19 examined both. In these trials, as a prophylactic strategy, intraoperative and postoperative HIPEC were used, and some centers used HIPEC for patients who were considered to have no chance of surviving surgery. Forty-two trials involved the use of intraoperative HIPEC, 51 utilized postoperative HIPEC, and eight studies adopted both strategies. Ninety-one trials were performed with prophylactic goals and 17 with palliative goals. Only one trial utilized CRS and HIPEC as two parts of a potentially curative strategy. The doctors in these studies adhered to the "Sugarbaker Protocol" in 21 cases that included 12 patients with GC and 5 patients with CRC (registered trial NCT00454519)[9]. The authors reported positive preliminary results: 7 of the 21 patients with PC survived and were tumor-free during an 8-43-mo follow-up.

Mitomycin C (MMC), Cisplatin (DDP) and 5-Fu are commonly used alone or in combination with HIPEC to treat GC and CRC. The dosage ranges of these treatments extensively vary across trials. The usage of some other drugs, such as Mitomycin C adsorbed on activated carbon particles (MMC-CH) and Tegafur, has been reported in some trials that examined GC. One trial reported on the combination of IL-2 with HIPEC.

The HIPEC centers located in different areas of mainland China and their respective reports are presented in Table 1.

DISCUSSION

Intraoperative intraperitoneal chemotherapy with heat is regarded as a typical prophylactic strategy for advanced GC in China. Among the 101 trials included in this survey, 91 utilized HIPEC for prophylactic purposes. Two other registered trials sponsored by two university hospitals in Shanghai are currently recruiting participants. Chinese authors have also performed a Cochrane review in order

to assess the efficacy and safety of intraperitoneal chemotherapy for GC. Fewer trials have been performed to examine HIPEC for CRC. Some centers have reported their results after performing HIPEC on patients who were not suited for surgical treatment. This survey reveals that hyperthermic treatment, intraperitoneal chemotherapy and HIPEC are popularly accepted in China as therapies for GC and CRC. The "Sugarbaker Protocol" has been implemented in China, although its application has been limited. In the only trial that examined CRS and HIPEC (21 reported cases), the extent of PC with PCI and the result of CRS with CCR were evaluated. The preliminary results are positive, and these authors have concluded that CRS and HIPEC are relatively safe treatment options for selecting patients with PC originating from the gastrointestinal tract and gynecological malignancies, and result in improved outcomes. On the basis of these results, their registered phase Ⅱ randomized clinical trial is still recruiting participants.

PC is usually regarded as a disseminated, lethal stage of disease and a situation that necessitates palliative care. Based on the studies that are examined in this survey, we found that most authors still consider PC to be an incurable disease. If doctors do not implement the recent advanced treatment for loco-regional disease, their patients can not benefit from this. CRS followed by HIPEC changes the situation and provides selected patients with a chance for possible long-term survival. This novel approach would represent not only a technological advancement but also a paradigm shift in the conception of treatment. The efforts of the Peritoneal Surface Oncology Group International (PSOGI) and their biannual workshop support such progress. This group has cooperated with numerous individuals from the United States, Europe, Korea and Japan, who all have a common interest in the prevention and treatment of peritoneal surface malignancy. The latest reports from their 2008 meeting provide additional supporting evidence of the efficacy of "Sugarbaker Protocol"[11-13,30-39].

On one hand, the international community insists that CRS followed by HIPEC is effective for selected patients and will continue to improve with additional research. On the other hand, the "Sugarbaker Protocol" is not widely accepted in China, wherein the general population carries a heavy cancer-related medical burden. For example, only one researcher from China registered for the 7th Uppsala Workshop (2010-03-03 in Sweden). Notably, the most effective strategy will be beneficial for the patients and will be supported by academic researches. By sharing their experiences, these professionals from all over the world can work together to improve the treatment methods available for PC and prolong the patient survival. Another important issue is the dissemination of useful information by PSOGI and the biannual workshop. More specialists need to be trained and funding will be necessary in order to build high-quality centers. The necessary skills should be improved and constructed for specialized institutes[40], and collaborations with well-established centers that perform the techniques will be essential for the implementation of this strategy in the developing countries. As expected, 20% of the world's population would benefit from this technique if this approach was established in China.

This report is based on a comprehensive literature review and may also provide some advice to doctors and clinical researchers in China. The professionals that are involved in GC and CRC treatment and research must assimilate new concepts that are supported by strong evidence and rapidly apply the related techniques to patients in need. These doctors must publish the results they obtained from clinical practice in English as well as in Chinese, and furthermore, the results should be presented at conferences and in the medical literature. This hard work and collaboration will facilitate the fight against cancer.

As we mentioned in the introduction, this report did not include all of the clinical trials that relate to HIPEC and have been published in Chinese. The authors selected certain hospitals that met established criteria. These hospitals should be dedicated as HIPEC and CRS centers and potential collaborators with PSOGI in the near future.

Hyperthermic strategies have been practised for a long time in mainland China, whereas the "Sugarbaker Protocol" is only rarely implemented. The PSOGI hosts a biannual workshop with the intent to train more specialists in this field and provide support for the construction of quality treatment centers, especially in the developing countries like China.

COMMENTS

Background

According to the traditional treatment and follow-up, peritoneal carcinomatosis (PC) is considered to be a terminal event of systemic metastasis. Over the past two decades, "Sugarbaker Protocol/Techniques", i.e. surgical removal of all macroscopic PC in combination with hyperthermic intraperitoneal chemotherapy (HIPEC), has emerged as a potential curative treatment option for some patients. It becomes increasingly acceptable as a standard method of treatment for certain local peritoneal surface diseases by many institutions all over the world, and has achieved exciting results. Hyperthermic strategies have been practiced for a long time in mainland China, whereas the "Sugarbaker Protocol" is only rarely implemented.

Research frontiers

Over the past two decades, "Sugarbaker Protocol/Techniques" has emerged as a potential curative treatment option for some patients. It becomes increasingly acceptable as a standard method of treatment for certain local peritoneal surface diseases. In recent years, many institutions all over the world have applied this combined modality treatment and have achieved exciting results.

Innovations and breakthroughs

This study investigated the current status of PC treatment, as well as the frequency of cytoreductive surgery (CRS) and HIPEC utilization in China, as determined by a review of the English and Chinese literature.

Applications

The Peritoneal Surface Oncology Group International hosts a biannual workshop with the intent to train more specialists in this field and provide support for the construction of quality treatment centers, especially in the developing countries like China. As expected, 20% of the world's population would benefit from this technique if this approach was established in China.

Terminology

PC: most PCs come from gastric, colorectal, appendicle and ovarian cancers. Peritoneal Surface Malignancy/Oncology: include not only PC, but malignancies other than epithelial cancer, such as sarcomatosis and malignant peritoneal

mesothelioma. Sugarbaker Protocol: surgical removal of all macroscopic PC in combination with HIPEC, has emerged as a potential curative treatment option for some patients.

Peer review

The authors present a very important work on HIPEC procedures in mainland China. Standard operating procedures by the Peritoneal Surface Oncology Group are stated to be necessary. However, it is not quite correct, that HIPEC with or without CRS could ever be done in a curative intention, since the patients treated are all in a metastasized situation and any treatment will be palliative. It would be very interesting if the authors can present an analysis of the many prophylactic HIPEC procedures that seem to have taken place in China. Overall, the presented manuscript gives interesting and so far unknown information.

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