Original Article

Short-term Outcome of Hyperthermic Intraperitoneal Chemotherapy with Mitomycin-C: A Community Hospital Experience

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Key Words
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Purpose. Review and evaluating the safety and early result of hyperthermic intraperitoneal chemotherapy (HIPEC) performed in the community hospital.
Methods. Single institution retrospective analysis of patients who underwent HIPEC was invested.
Results. Five males and five female patients received HIPEC at our institution between June 15, 2022, and April 11, 2024. The mean patient age was 61.2 years old. The primarily occurring tumors were one appendiceal mucinous adenocarcinoma rupture; three right-sided colon cancer, and six left-sided colon cancer. Two of them are synchronous with peritoneal carcinomatosis.
Primary tumor was resected in all patients. All patients had cytoreduction surgery (CRS) with Mitomycin C HIPEC. The operative time was 420 ± 79.3 minutes. The blood loss was 15.5 ± 13.6 ml. Peritoneal carcinomatosis index (PCI) was 4 (interquartile range 2.3, 5.8). The CRS completion score (CC score) was 0 in six and 1 in four patients. Three patients had a body temperature of more than 38 °C, intraoperative. No acute renal failure or other morbidity, mortality was noted.
Mean carcinoembryonic antigen (CEA) drops from 15.4 ng/mL, preoperative, to 6.6 ng/mL, postoperative. Four patients noted recurrence after 5.34-19.6 months post-operation.
Conclusions. CRS with HIPEC in selective case is a safe procedure, and could be applied in community hospitals.

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The annual incidence of colorectal cancer (CRC) is increasing worldwide. It increased from approximately 5% to 15% of all cancers until 2016[1] and increased incidence to 44.7 per 100,000 persons in 2014[2] in Taiwan.

Generally, peritoneal metastasis (PM) is discovered in 5%-15% of patients during primary colorectal surgery[3,4] and in 20%-50% of patients with recurrence. Untreated CRC PM is associated with a dismal mean overall survival (OS) of approximately 3-6 months.[5] Traditional systemic chemotherapy for CRC PM is associated with a poor prognosis, with a median

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survival time of 5-7 months.[3] While treatment with modern systemic multi-chemotherapeutic regimens increases OS to 10-15 months, survival remains 30-50% lower than that in patients with stage IV CRC without PM.[5] This limited improvement is probably because the peritoneum-plasma barrier prevents chemotherapeutic drugs from entering the systemic circulation into the peritoneal cavity.[6]

In 1978, Dedirck et al. proposed intraperitoneal chemotherapy to achieve higher drug concentrations and a longer half-life in the peritoneal cavity.[7]

In 1980, Spratt first described a combination of cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC).[8] In 1990, Sugarbaker et al. established a peritonectomy procedure combined with HIPEC.[9,10] In 2003, Verwaal confirmed the benefit of CRC with HIPEC survival benefit, compared to systemic therapy alone (22.3 vs. 12.6 months).[11]

In Taiwan, few reports have provided HIPEC results for patients with CRC yet.[12-14] In this study, we reviewed our cases treated at the Department of Colorectal Surgery, China Medical University Hsinchu Hospital, to collect data for evaluation.

Patients and Methods

From June 15, 2022, to April 11, 2024, CRS with HIPEC was performed in ten patients in the Division of Colorectal Surgery, China Medical University Hsinchu Hospital. Histologically proven peritoneal metastases originate from colorectal cancer. The patients underwent thoracic and abdominal computed tomography to confirm peritoneal and other metastases before surgery. Positron emission tomography-computed tomography was also considered when computed tomography was difficult to perform or when non-abdominal metastasis was suspected. Multidisciplinary teamwork (MDT) discussions were routinely conducted before surgical planning.[13]

The exclusion criteria were unresectable peritoneal carcinomatosis, suspicious liver hilum involvement, extensive small bowel obstruction, or major vessel involvement. Those who underwent emergency surgery and those with poor overall system status at 2 or more points in the Eastern Cooperative Oncology Group were excluded. Those who had not been clearly concluded and those who agreed to undergo HIPEC surgery by a multidisciplinary team were excluded.

Medical records included patient demographics, cancer-associated treatment history, HIPEC-associated operative details, hospital stay course, postoperative complications, and recurrence.

The peritoneal cancer index was measured via abdominal exploration during surgery. The abdominal cavity was divided into 13 compartments and subdivided into 0-3 points according to the size of peritoneal metastasis (0 points, absence of tumor; 1 point, tumor less than 0.5 cm; 2 points, tumor from 0.5 cm to 5 cm; and 3 points, tumor larger than 5 cm). The scores ranged from 0 to 39.[15]

Completeness of cytoreduction after surgery was subdivided according to the size of the residual tumor (CC-0, complete removal of visible tumor; CC-1, remnant tumor less than 0.25 cm; CC-2, residual tumor between 0.25 cm and 2.5 cm; and CC-3, visible tumor larger than 2.5 cm in diameter).[11]

Complications were classified into five grades according to the Clavien-Dindo grade classification.[16]

The surgical procedure was similar to that of the laparoscopic examination. As suggested by Sugarbaker, CRS is performed to remove cancer cells by mechanical means using the naked eye and to minimize the peritoneal cancer index score.[10,11]

HIPEC was prepared using a Dutch regimen.[11,17] There are three shots of mitomycin C with 17.5 mg/m^2 of body surface area (BSA), 8.8 mg/m^2 BSA, and 8.8 mg/m^2 BSA into circulating normal saline every 30 minutes. The amount of circulating solution was calculated as 2.5 L/m^2 BSA normal saline and adjusted according to the abdominal cavity volume. It was circulated through a HIPEC pump (The RanD Performer® HT perfusion device (RanD Co. Ltd., Italy) through four tubes into the abdominal cavity, two in and two out, and in the four quadrants of the abdominal cavity. It was circulated at a rate of 1,000 mL/min for 90 min while maintaining the temperature between 43 °C and 44 °C.

After 90 min of HIPEC treatment, the mixed chemotherapeutic solution was removed. The Jackson-Pratt drainage tubes were left in place for further use

but were removed when there was no color change in the drainage tube and the number of ascites decreased. The first three days after the operation, drainage ascites was collected as contaminated and biomedical waste.

The patient's central body and inflow and outflow temperatures were checked every 5 min, and the target temperature was controlled through the inlet temperature of the HIPEC pump.

Patients were transferred to the intensive care unit or general ward depending on vital signs and clinical examination results. Water intake was initiated on the day after surgery if the patient tolerated it. Oral intake was steady after tolerance to water intake.

The primary outcomes were surgical time, blood loss, hospitalization, and complications.

Results

Between June 15, 2022, and April 11, 2024, ten patients received HIPEC at our institution. There were five males and five female patients (Table 1, 2). Two of the patients were first diagnosed as having colon cancer synchronous with intraperitoneal metastasis, one ruptured appendical mucinous adenocarcinoma, and the remaining seven patients had previous surgical intervention, but cancer recurrence with peritoneal metastasis had been noted during the follow-up periods. The mean patient age was 61.2 years old. The average body mass index was 26 ± 1.9 kg/m^2. The American Society of Anesthesiologists physical status classification (ASA) was II in four patients and III in six. The Charlson comorbidity index (CCI) was 6.6 ± 1.6. For the primarily occurring tumors, there was one appendiceal mucinous adenocarcinoma rupture, three had right-sided colon cancer, and six had left-sided colon cancer.

Primary tumor resection (PTR) was performed in all patients, including two with synchronous peritoneal metastases, to nearly obstruct the cancer. Between the PTR to the HIPEC period, six patients were exposed to adjuvant chemotherapy, and three patients were exposed to targeted with chemotherapy, respectively. One patient initially underwent liver resection and radiofrequency ablation for liver metastasis, later developed peritoneal metastasis, and was enrolled in the HIPEC study. One patient with local recurrence underwent colon tumor resection; the pelvic tumor required resection again because left ovary metastasis with pelvic peritoneal metastasis was noted. Targeted therapy with chemotherapy was initiated first, and HIPEC was enrolled later. Two patients underwent oophorectomy during PTR (Table 2).

Preoperative carcinoembryonic antigen (CEA) was 15.4 ng/mL (interquartile range, 3.8-34.2 ng/ml), and it was 6.6 ng/mL (IQR, 5-7.5 ng/ml) three to four weeks post operation (Table 2).

All CRS patients had CRS treated with HIPEC. The operative time was 420 ± 79.3 minutes. The average blood loss was 15.5 ± 13.6 ml. Four patients underwent concurrent surgery, including one patient who underwent tumor resection with right ureteroureterostomy, one patient who underwent RSO, one patient who underwent partial cystectomy, and one patient who underwent RH for locally advanced appendiceal cancer (Table 3).

In our case series, PCI was less than 10 (Table 1, 3). The CRS completion score (CC score) was 0 in six and 1 in four patients. After 6-18.4 months of follow-up of the four CC-1 patients, no peritoneal metastasis was noted. However, the patient died of cholangitis, and the liver metastasis progressed after two rounds of TACE therapy.

During the operation, three patients had a body temperature of more than 38 °C. The symptoms subsided after hydration and supportive treatment.

No oliguria or acute renal insufficiency was observed after the surgery. The average urine output during the operation day was 2641 ± 1420.3 ml. Although one patient underwent partial cystectomy and two patients had a history of benign prostate hypertrophy, the others were removed with a Foley catheter on POD 0-2 days.

Postoperatively, the flatus, oral water sip, and oral intake diet were on POD 1-5, 0-3, and 1-4. The drain was removed 3-7 days later. The ICU and total hospital stay were 0-1 and 5-7 days (Table 3). The nasogastric tube was only inserted in 4 patients, POD 0-3 days later.

Table 1. Patient list

Patient	Age	Sex	Primary cancer	PTR	Primary pT	Primary pN	Primary stage	Histology	Differentiation	Previous target ± chemotherapy	Previous OP	PCI	CC	Post-HIPEC	Recurrent (months)
1	50	M	Sigmoid	AR	T4b	N0	2C	Adenocarcinoma	Moderate	XELOX		6	0	Panitumumab + FOLFIRI	19.6
2	50	F	Descending	AR	T3	N2a	3C	Adenocarcinoma	Moderate	FOLFOX, Xeloda, Panitumumab + FOLFIR	LSO	4	0	Panitumumab + FOLFIRI	5.4
3	73	M	Sigmoid	AR + parital cystectomy	T3	N1a	3B	Adenocarcinoma	Moderate	FOLFOX		7	0	Cetuximab + FOLFIRI	6.9
4	71	M	Hepatic flexure	RH	T4b	N2a	3C	Mucinous adenocarcinoma	Moderate	FOLFOX		7	1	Bevacizumab + FOLFIRI	
5	58	F	Transverse	Palliative LH + LSO	T4a	N0	4C	Serrated adenocarcinoma	Moderate	Bevacizumab + FOLFOXIRI		5	1	Bevacizumab + FOLFIRI	
6	66	F	Transverse	RH	T4a	N2a	3C	?	?	FOLFOX		4	0	Bevacizumab + FOLFIRI	8.5
7	72	F	Transverse	RH	T4a	N0	4C	Adenocarcinoma	Moderate	FOLFOX		1	1	Cetuximab + FOLFOX	
8	66	M	Splenic flexure	Subtotal colectomy	T4b	N1	4A (liver)	Adenocarcinoma	Moderate	Bevacizumab + FOLFOX	Liver resection	3	1	TACE 2 times	
9	57	F	Sigmoid	AR + RSO	T4a	N1	3B	Adenocarcinoma	Moderate	FOLFOX		2	0	Not yet	
10	49	M	Appendical (rupture)	LA	T3	N1	3B	Adenocarcinoma	Poor	0		0	0	Not yet	

AR, anterior resection; CC, completeness of cytoreduction; HIPEC, Hyperthermic intraperitoneal chemotherapy with Mitomycin-C; LA, laparoscopic appendectomy; LH, left hemicolectomy; LSO, left salpingo-oophorectomy; OP, operation; PCI, peritoneal cancer index; PTR, primary tumor resection; RH, right hemicolectomy; RSO, right salpingo-oophorectomy; TACE, transarterial chemoembolization.

Table 2. Patient characteristics

Age (years)	61.2 ± 9.6
Sex (n)	
Female	5
Male	5
BMI	26 ± 1.9
ASA (n)	
2	4
3	6
CCI	6.6 ± 1.6
preOP CEA (U/mL) [IQR]	15.4 [3.8, 34.2]
postOP CEA (U/mL) [IQR]	6.6 [5, 7.5]
PTR~HIPEC (months)	15.1 ± 12.3
Primary cancer (n)	
Appendical	1
Right-side colon	3
Left-side colon	6
AJCC stage	
II	1
III	6
IV	3
Extra-peritoneal metastasis	1 (liver)
Histology	
Adenocarcinoma	8
Mucinous adenocarcinoma	1
Unknwon	1
Differentiation	
Moderate	8
Poor	1
Unknown	1
Carcinomatosis Dx~HIPEC (months)	1.6 ± 0.9
Previous chemotherapy exposure (n)	
1 regimen	8
3 regimen	1
Previous cancer-related extra-PTR surgery (n)	
Oophorectomy	3
Liver resection	1
Post-operation	
Follow-up (months)	12 ± 8.5
Expire (n)	1
Postoperative 1st-line treatment (n)	
TACE	1 (2 times) (folfiri)
Panitumumab + FOLFIRI	2
Cetuximab + FOLFOX/FOLFIRI	2
Bevacizumab + FOLFIRI	3
Recurrent (n)	4
Recurrent (months)	10.1 ± 6.5

Values are presented as the patient numbers, or the mean ± standard deviation, or the median [quartile 1 to quartile 3]. BMI, body mass index; ASA, American Society of Anesthesiology physical status classification; CCI, Charlson Comorbidity Index; preOP, pre-operative; postop, post-operative;CEA, CarcinoEmbryonic Antigen; PTR, primary tumor resection; HIPEC, Hyperthermic IntraPEritoneal Chemotherapy with Mitomycin-C; AJCC, American Joint Committee on Cancer staging system; Dx, diagnosis; TACE, transarterial chemoembolization.

There was only one case of urinary tract infection (Table 3). There was no other surgical morbidity or mortality.

After discharge, two patients waited for further treatment suggestions and decisions regarding MDT. One patient underwent TACE. Seven patients underwent targeted chemotherapy. Four patients noted recurrence after 5.34-19.6 months post-operation.

Discussion

In this study, we report our preliminary experience.

CRC metastasis to the peritoneum is no longer viewed as a terminal event in selected patient groups. Better response rates to multidrug chemotherapy and

Table 3. Surgery and hospital stay outcomes

Surgical detail	
OP time (minutes)	420 ± 79.3
Blood loss (ml)	15.5 ± 13.6
PCI [IQR]	4 [2.3, 5.8]
CC [IQR]	0 [0, 1]
Surgical method	
CRS + HIPEC (n)	10
+ Partial cystectomy	1
+ Right oophoretomy	1
+ Right ureteroureterostomy	1
+ Right Hemicolectomy	1
BT low (°C)	35.7 ± 0.4
BT high (°C)	37.5 ± 1.1
Hospital stay	
Total hospital stay (days)	5.5 ± 1.0
ICU stay (days)	0.6 ± 0.5
Flatus/defecation (POD)	2.7 ± 1.3
Try water (POD)	1.0 ± 0.9
On diet (POD)	2.1 ± 0.9
Remove drain (POD)	4.5 ± 1.3
Complication related to HIPEC (n)	
UTI	1 (POD 28)

Values are presented as the patient numbers, or the mean ± standard deviation, or the median [quartile 1 to quartile 3]. OP, operation; ml, mL; PCI, peritoneal cancer index; IQR, interquartile range; CC, completeness of cytoreduction; CRS, cytoreduction; HIPEC, Hyperthermic Intraperitoneal Chemotherapy with Mitomycin-C; BT, body temperature; ICU, intensive care unit; POD, post-operative day; UTI, urinary tract infection.

biological agents have enabled some patients to become surgical candidates for CRS/HIPEC.[18]

Despite the failure of the PRODIGE 7 trial,[19] a meta-analysis showed that HIPEC is still a suggestion for CRC PM.[20] Survival benefits exist that prolonged OS from 5-7 months[3] to 54.3 months,[18] or hazard ratio (HR) 0.53, 95% confidence interval (CI) 0.38-0.73, compared with cytoreduction with palliative chemotherapy.[20] Thus, HIPEC is still recommended and reserved by the American Society of Clinical Oncology (ASCO),[21] the European Society for Medical Oncology (ESMO),[22] and Taiwanese guidelines.[23] The 2022 Peritoneal Surface Oncology Group International (PSOGI) also reached a consensus on HIPEC that CRS/HIPEC can be conditionally recommended for CRC PM.[24]

CRS/HIPEC is a complex procedure that demands meticulous postoperative care; therefore, physicians and patients predominantly consider it in academic centers. However, a well-functioning CRS/HIPEC program at a non-academic hospital with advanced services may expand accessibility and lead to favorable outcomes.[25]

CRS/HIPEC is an aggressive treatment modality that is often associated with high-grade complications. Most morbidities and mortalities are associated with extensive surgical procedures concurrent with high-dose chemotherapy.

Chua et al. reported major morbidity rates ranging from 12% to 52% in high-volume centers. The mortality rate after CRS/HIPEC ranges from 0.9% to 5.8%.[26] The morbidity may be up to 56.3% in patients with CRC PM receiving CRS/HIPEC.[27]

Despite extensive peritonectomies,[10] chemotherapeutic agents and procedures are not a union worldwide. Yurttas sorted the points and reported them in a systemic review.[28] To date, the most commonly used agent is Mitomycin C (MMC), with or without other compounds. This accounts for two-thirds of the literature. The secondary drug was oxaliplatin (L-OHP), which accounted for approximately one-fourth of the total. We use the Dutch regimen as a single agent for MMC at our institute.[11,17]

In the pharmacodynamic study, 62% of the MMC was retained inside the body after 90 min.[29] However, only marrow toxicity attributable to MMC was noted to be approximately 19%, as reported by Verwaal.[11] The serum plasma level is 1/27 of the peritoneal MMC fluid, with a peak of 0.25 (±0.06) μg/ml at 30 minutes after HIPEC.[29] Though the complication rate of CRS/HIPEC is high, systemic toxicity via MMC is low.

In our case series, we did not perform extensive peritonectomy. Extensive surgery was performed in only one case of partial cystectomy, one case of right hemicolectomy with bowel anastomosis, and one case of ureteroureteral resection with anastomosis. This may explain the low mortality rate observed in this study. This finding also confirmed the low toxicity of the Dutch regimen.

In addition, a nasogastric tube is generally noted in CRS/HIPEC because of gastric spasms induced by chemotherapeutic agents. However, performing the procedure without extensive peritonectomy or intra-abdominal organ resection is unnecessary. Six of the ten patients did not have an NG tube in our series. Considering the low MMC toxicity, we suspect that it may not irritate gastric spasms. In addition, we did not wash out the HIPEC solution before the end of the surgery. However, we collected three days of Jackson-Pratt (JP) draining ascites for biomedical waste treatment. Finally, we did not note dysuria and failed to observe acute renal insufficiency in this case series.

The three hyperthermic temperatures were higher than 38 °C. The patients recovered after conservative treatment.

Except for the less extensive surgical procedure, our PCI was relatively smaller than those in other studies.[12-14] In our institute, more severe PM was associated with distal unresectable lesions, poor patient condition, no conclusion of staged surgery, and rejection of CRS/HIPEC treatment after MDT discussion. Therefore, extensive pneumonectomy was not performed in this case series.

However, it also showed better results (PCI < 10), as reported by Rivard.[30] We think it is reliable for clinical benefit in CRC patients with PM.

One patient with ruptured appendiceal mucous adenocarcinoma was referred from another hospital for further surgical intervention. CRS/HIPEC was performed simultaneously with RH. Although the com-

plete result of CAIRO 6[31] and the failure of COLOPEC[32,33] have not been reported, aggressive intervention is under consideration in young patients (49 years) with ruptured mucous adenocarcinoma with early recurrence.

Herein, we report the short-term results of CRS/HIPEC using a Dutch regimen. Without extensive peritonectomy, with good nutritional and physical status of the patients, dedicated surgical procedures, and meticulous postoperative care, CRS/HIPEC has been adopted in non-academic community hospitals.

Conclusions

CRS with HIPEC is safe and requires a short hospital stay for selected patients. It can also be used in community hospitals.

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None.

Conflict of Interesting

None.

Authors' Contributions

Drs. Jau-Jie You, Chu-Cheng Chang, and Ming-Yin Shen conceptualized and designed the study, collected data, performed statistical calculations, carried out the initial analyses, drafted the initial manuscript, and revised the manuscript. Drs. William Tzu-Liang Chen, Yen-Chen Shao, and Yu-Hao Su reviewed and revised the manuscript. All authors have approved the final manuscript as submitted and agreed to be accountable for all aspects of this study.

Data Availability Statement

The datasets presented in this article are not readily available because data release is not permitted by China Medical University Hsinchu Hospital. Requests to access the datasets should be directed to Dr. Ming-Yin Shen at mingyin.shen@gmail.com.

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原　著

社區醫院執行熱灌注腹腔化療的短期結果

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目的　審查和評估在社區醫院進行的熱灌注腹腔化療的安全性和早期結果。

方法　對敝院進行熱灌注腹腔化療的患者進行回顧性分析。

結果　在 2022 年 6 月至 2024 年 4 月期間，敝院共有五名男性和五名女性患者接受了熱灌注腹腔化療。患者的平均年齡為 61.2 歲。主要的腫瘤型態包括一例破裂穿孔的闌尾黏液性腺癌；三例右側結腸癌，六例左側結腸癌。其中兩例診斷時已同時有腹膜癌轉移。

所有患者的原發腫瘤都有切除。患者接受了腫瘤細胞減積手術合併 Mitomycin C 熱灌注腹腔化療。手術時間為 420 ± 79.3 分鐘，失血量為 15.5 ± 13.6 ml。腹膜癌指數 (PCI) 為 4 (四分位距 2.3，5.8)。腫瘤細胞減積手術完成評分 (CC 評分) 中，六例為 0，四例為 1。三例患者術中體溫超過 38 ℃。未有急性腎功能衰竭或死亡病例。

癌胚抗原平均值從術前的 15.4 ng/mL 降至術後的 6.6 ng/mL。四名患者在術後 5.34-19.6 個月內出現復發。

結論　適當選擇病人，腫瘤細胞減積手術合併熱灌注腹腔化療是一種可以在社區醫院執行的安全手術。

關鍵詞　腫瘤細胞減積手術、熱灌注腹腔化療、社區醫院。