Original Article

Outcome and factors associated with aborted cytoreduction for peritoneal carcinomatosis

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Background: Cytoreductive surgery with hyperthermic intraperitoneal chemotherapy (CRS/HIPEC) offers a potential cure for peritoneal carcinomatosis (PC), whereas aborted cytoreduction is associated with a poor outcome. We evaluate factors associated with aborted CRS procedures.

Methods: An IRB approved retrospective review was performed from 12/2011 to 2/2016. Clinicopathologic variables and outcomes are described.

Results: Seventy-four patients underwent attempted CRS/HIPEC which was completed in 51 (69%) and aborted in 23 (31%). There was no difference in age, race, gender or prior treatment between groups. Patients who underwent aborted procedures had a higher peritoneal cancer index (PCI, 26.1±9.9 *vs.* 16.2±10.5, P=0.001). Overall survival (OS) was significantly improved for patients who underwent completed CRS/HIPEC (41.0±10.4 *vs.* 6.0±2.3 months, P<0.0001). Patients with an appendiceal and colorectal primary who underwent CRS/HIPEC had a significantly better outcome (median not reached *vs.* 6±5.4 months, P<0.0001, and 28.0±7.5 *vs.* 8.0±4.0 months, P<0.0001, respectively). Colorectal pathology (P=0.014) and PCI score (<0.0001) were independent predictors of aborted CRS procedures.

Conclusions: One-third of patients with PC had significant disease which prevented successful completion of CRS/HIPEC. PCI and colorectal primary tumor pathology were associated with a greater likelihood of aborted CRS procedures.

Keywords: Carcinomatosis; cytoreduction; hyperthermic intraperitoneal chemotherapy (HIPEC); colorectal cancer; aborted

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Introduction

Cytoreductive surgery with hyperthermic intraperitoneal chemotherapy (CRS/HIPEC) has improved the outcome for patients with peritoneal carcinomatosis (PC) from gastrointestinal malignancies (1,2). Cytoreduction involves the removal of all macroscopic disease within the abdominal cavity and often necessitates omentectomy, multivisceral resection and complex peritonectomy procedures. Intraperitoneal chemotherapy is administered to eradicate residual microscopic disease (3). The burden of disease, as measured by the peritoneal cancer index (PCI), and the completeness of cytoreduction score (CCR) are significant determinants of outcome after CRS/HIPEC (4-6).

The successful completion of CRS/HIPEC is dependent on several factors, notably tumor grade, histology and primary tumor location (7). Pre-operative cross sectional imaging provides anatomic detail of the distribution of disease within the abdominal cavity but may under represent the exact burden of disease (8). Unfortunately, approximately 20% of patients who undergo exploration are found to have advanced disease precluding successful completion of CRS/HIPEC (9,10).

The negative impact on patients with PC who undergo aborted CRS procedures is potentially immense. Aborted cytoreduction procedures are associated with potential morbidity, unnecessarily prolongs recovery and may delay the initiation or continuation of systemic chemotherapy. The outcome of patients who are found to have significant disease and undergo aborted CRS procedures is ill-defined. The purpose of this study is to examine the outcomes of patients who undergo aborted CRS procedures and identify factors associated with aborted CRS in a newly established peritoneal surface malignancy program.

Methods

We performed a retrospective review of patients who were referred for management of peritoneal surface malignancies from December 2011 to February 2016. Patients were considered for CRS/HIPEC if they had a good performance status (ECOG 0/1), no evidence of extraperitoneal disease as evidenced on computed tomography (CT) or magnetic resonance imaging (MRI) and were able to tolerate a major abdominal operation. Patients were discussed in multidisciplinary tumor board prior to consideration for CRS/HIPEC. Approval for this study was obtained from the University of Tennessee Health Science Center and St Jude Children's Research Hospital Institutional Review Boards.

At the time of exploration, the PCI score was calculated at the completion of adhesiolysis and prior to CRS/HIPEC (11). HIPEC was performed via a closed technique at the completion of cytoreduction. HIPEC was performed with mitomycin-C (40 mg at 42 ℃ for 90 minutes) or oxaliplatin (200 mg at 42 ℃ for 60 minutes) for appendiceal and colorectal pathology and cisplatin (100 mg/m^2 at 42 ℃ for 60 minutes) for ovarian, mesothelioma and desmoplastic small round cell tumor (DSRCT) pathologies. The adequacy of surgical debulking was defined by the CCR score (12). Gastrointestinal continuity, stoma creation (when necessary), and drain placement were performed at the completion of HIPEC.

Patient demographics, clinicopathologic data, and outcomes were collected in a prospectively maintained database. Detailed operative characteristics were recorded including procedures performed, PCI score, type and dose of chemotherapeutic agent used, duration of HIPEC, length of surgery, estimated blood loss (EBL), CCR score, need for intra-operative transfusion, extent of visceral resection, and number of anastomoses performed. Complications were graded according to the Clavien-Dindo classification schema (13).

Factors associated with aborted CRS were further analyzed including the distribution of disease and palliative procedures performed. Patients who underwent CRS/HIPEC were compared to those who underwent aborted CRS. Recurrence was defined as radiographic evidence of recurrent disease any time after CRS/HIPEC. Overall survival (OS) was defined as the duration from the date of CRS/HIPEC or aborted CRS to death or last follow up. For all outcomes, patients were censored at the time of most recent follow-up or death at the time of data collection. Categorical variables were summarized using percentages and compared using Chi-squared analysis. Continuous variables were summarized using the mean with standard deviation (SD) and analyzed with an independent, 2 tailed *t*-test. All P values were based on 2-tailed statistical analysis and a P value <0.05 was considered indicative of statistical significance. OS was compared between the two groups using the Kaplan-Meier method with the log rank test. All statistical analysis was performed using SPSS software, version 24 (IBM Corporation, Armonk, NY, USA).

Results

During the study period, 74 patients underwent evaluation for peritoneal surface malignancy and were scheduled for CRS/HIPEC. Of these, 51 patients (69%) underwent complete CRS/HIPEC and 23 patients (31%) underwent aborted CRS procedures. There were no significant differences between CRS/HIPEC and aborted CRS groups with respect to basic demographics including age, gender, race, or prior treatment (*Table 1*). Primary tumor histology differed between the groups as more patients with appendiceal primaries were able to undergo successful CRS/HIPEC, while a higher percentage of patients with colorectal pathology underwent aborted CRS (P=0.02).

The PCI score was higher for patients who underwent

Table 1 Demographic characteristics

Variable	All (N=74)	CRS/HIPEC (N=51)	Aborted CRS (N=23)	P value
Age	50.1±16.3	48.5±17.2	55.6±13.1	0.58
Race				0.81
Caucasian	48 [65]	33 [65]	15 [65]	
AA	24 [32]	16 [31]	8 [35]	
Other	2 [2]	2 [4]	0	
Female gender	46 [62]	34 [67]	12 [52]	0.23
Prior surgery				
Laparoscopy	19 [26]	13 [25]	6 [26]	0.96
Laparotomy	48 [65]	36 [71]	12 [52]	0.13
HIPEC	3 [4]	3 [6]	0	0.24
Neoadjuvant chemotherapy	59 [80]	40 [78]	19 [83]	0.68
Pathology				0.02
Appendix	26 [35]	20 [39]	6 [26]	
Colon	19 [26]	8 [16]	11 [48]	
Ovary	11 [15]	10 [20]	1 [4]	
DSRCT	8 [11]	7 [14]	1 [4]	
Mesothelioma	2 [3]	2 [4]	0	
Gastric	3 [4]	1 [2]	2 [9]	
Small Bowel	2 [3]	2 [4]	0	
Other	3 [4]	1 [2]	2 [9]	

Results reported as N [%] or mean (± SD). CRS/HIPEC, cytoreduction and hyperthermic intraperitoneal chemotherapy; IC, aborted/incomplete cytoreduction; AA, African American; HIPEC, hyperthermic intraperitoneal chemotherapy; DSRCT, desmoplastic small round cell tumor; SD, standard deviation.

aborted CRS procedures while those able to undergo CRS/HIPEC had a lower PCI score (26.1±9.9 *vs.* 16.2±10.5, P=0.001). Patients who were able to undergo complete CRS/HIPEC had significantly longer operative times, higher blood loss, were more likely to require transfusion, undergo multi-visceral resection, require an anastomosis and undergo a diverting ostomy as portion of their procedure (*Table 2*). There was no difference in hospital length of stay between groups.

Patients who underwent CRS/HIPEC had a higher overall complication rate compared to those who underwent aborted procedures, although not statistically significant (43% *vs.* 22%, P=0.08). There was no difference in minor (Clavien-Dindo 1–2) or major (Clavien-Dindo 3–5) morbidity between groups (*Table 3*). Approximately one-quarter of patients in the CRS/HIPEC group required readmission within 30 days of operation.

Adjuvant systemic chemotherapy was administered to 65% of patients in the CRS/HIPEC group while only 48% of patients in the aborted CRS group were treated with palliative systemic chemotherapy. Adjuvant whole abdominal radiation was administered to 6 patients with DSRCT which is part of the consolidative treatment protocol for this rare pathology at St Jude Children's Research Hospital. Thirty-eight patients (75%) in the CRS/HIPEC group developed recurrence of disease with 14 (27%) developing distant disease (*Table 3*).

There was no difference in 30-day mortality between groups (*Table 3*). OS for all patients with PC evaluated for CRS/HIPEC was 22.8±3.0 months. The 1-, 3- and 5-year OS rates were 84%, 51% and 43% for CRS/HIPEC and were 27%, 0% and 0% for those who underwent aborted

Table 2 Operative characteristics

Variable	All (N=74)	CRS/HIPEC (N=51)	Aborted CRS (N=23)	P value
PCI	18.9±11.2	16.2±10.5	26.1±9.9	0.001
Cytoreduction				<0.001
CCR-0	33 [45]	33 [65]	0	
CCR-1	15 [20]	14 [28]	1 [4]	
CCR-2	6 [8]	4 [8]	2 [9]	
CCR-3	20 [27]	0	20 [87]	
Length of surgery (minutes)	457±202	553±147	233±120	<0.001
Blood loss (mL)	680±760	842±810	303±458	0.001
RBC transfusion	43 [58]	36 [71]	7 [30]	0.001
FFP transfusion	13 [18]	12 [24]	1 [4]	0.045
Multi-visceral resection	52 [70]	46 [90]	6 [26]	<0.001
≥4 organs	32 [43]	30 [59]	2 [9]	<0.001
Any anastomosis	38 [51]	35 [69]	3 [13]	<0.001
One	30 [41]	27 [53]	3 [13]	
Two	8 [11]	8 [16]	0	
Ostomy	19 [26]	14 [28]	5 [22]	0.60
Diverting	10 [14]	10 [71]	0	0.01
Reversal	6 [8]	6 [43]	0	0.07
Length of stay (days)	10.3±5.6	10.6±5.1	9.8±6.7	0.63

Results reported as N [%] or mean (± SD). CRS/HIPEC, cytoreduction and hyperthermic intraperitoneal chemotherapy; IC, aborted/incomplete cytoreduction; PCI, peritoneal cancer index score; CCR, Completeness of Cytoreduction; RBC, red blood cell; FFP, fresh frozen plasma; SD, standard deviation.

CRS. OS was 41.0±10.4 months for CRS/HIPEC versus 6.0±2.3 months for the aborted CRS group (P<0.0001, *Figure 1*). Patients with an appendiceal and a colorectal primary who underwent CRS/HIPEC had a significantly better outcome than those who underwent aborted CRS procedures (median not reached, >38 *vs.* 6±5.4 months, P<0.0001, *Figure 2* and 28.0±7.5 *vs.* 8.0±4.0 months, P<0.0001, *Figure 3*, respectively). On multivariable analysis, PCI score (P<0.0001) and colorectal primary (P=0.014) were independent predictors of aborted CRS. PCI score (P=0.002) was the only factor significantly associated with OS (*Table 4*). With a median follow up of 15 months (range, 0–58 months), 28% of patients who underwent CRS/HIPEC had no evidence of disease, 31% were alive with disease and 35% had died of disease. In contrast, 21% of the aborted CRS groups were alive with disease and 78% had died of progressive disease.

Table 5 list the distribution of disease and palliative procedures performed for the two most common pathologies (colorectal N=11, appendix N=6) who underwent aborted cytoreduction. The decision to abort cytoreduction and not proceed with CRS/HIPEC was made with a second surgeon. The reasons for aborted CRS included significant disease burden precluding a CCR score 0/1 resection (N=21) and hemodynamic instability (N=2). The PCI score for those undergoing aborted CRS was 32.2±6.4 for appendix pathology and 21.2±10.0 for colorectal pathology. Involvement of more than 9 regions, the porta hepatis, lesser omentum and widespread small intestine serosa/mesentery involvement were common factors associated with aborted cytoreduction. Palliative HIPEC (in the absence of extensive cytoreduction) was performed for two patients with refractory ascites who had required multiple paracentesis procedures prior to

Table 3 Outcome characteristics

Variable	All (N=74)	CRS/HIPEC (N=51)	Aborted CRS (N=23)	P value
Any complication	27 [37]	22 [43]	5 [22]	0.08
Minor	16 [22]	13 [26]	3 [13]	0.23
Major	12 [16]	9 [18]	3 [13]	0.62
Rehab transfer	4 [5]	4 [8]	0	0.17
Re-admission	17 [23]	13 [26]	4 [17]	0.44
Mortality (30 day)	4 [5]	2 [4]	2 [9]	0.40
Mortality (90 day)	2 [3]	0	2 [9]	0.03
Adjuvant radiation	6 [8]	6 [12]	0	0.09
Adjuvant chemotherapy	44 [60]	33 [65]	11 [48]	0.16
Recurrence	38 [51]	38 [75]	–	NS
Distant metastasis	14 [19]	14 [27]	–	NS
Follow up status				0.005
NED	15 [20]	14 [28]	0	
AWD	20 [27]	16 [31]	5 [22]	
DOD	36 [49]	18 [35]	18 [78]	
DOC	3 [4]	3 [6]	0	
Follow up (months)	18.6±14.3	23.7±14.2	7.5±6.5	<0.001

Results reported as N [%] or mean (± SD). CRS/HIPEC, cytoreduction and hyperthermic intraperitoneal chemotherapy; IC, aborted/incomplete cytoreduction; NED, no evidence of disease; AWD, alive with disease; DOD, dead of disease; DOC, dead of other cause; SD, standard deviation.

consideration for CRS/HIPEC.

Discussion

As we reviewed our early institutional experience managing peritoneal surface malignancies, we identified that almost one-third of patients were found to have advanced disease precluding complete cytoreduction. We identified that the burden of disease and a colorectal primary tumor conferred a negative impact in this population. Less than half of the patients who underwent aborted CRS received palliative chemotherapy. The outcome for this population was poor with approximately 80% of aborted cytoreduction patients eventually succumbing to progressive disease.

Other institutions have reported similar outcomes for those who undergo aborted CRS procedures. Authors from the Netherlands reported that up to 25% of colorectal patients with PC underwent "open and close" procedures (10). The primary reason for aborted CRS was widespread disease and a preoperative stoma and an ASA score of 3 were associated with increased risk of open and close procedures. Given the poor prognosis for those undergoing aborted procedures, one would expect patients to suffer a rapidly progressive clinical course. Rodt and colleagues noted, however, that a nontherapeutic laparotomy did not negatively impact the clinical course of those found to have advanced disease precluding successful completion of CRS/HIPEC (14). In their series, the median survival was 12.7 months for colorectal cancer patients and 88% of patients received palliative chemotherapy. We observed that only about half of the patients who underwent aborted CRS procedures went on to receive palliative chemotherapy and the outcome was worse—6 months for appendiceal adenocarcinoma pathology and 8 months for colorectal pathology. The Dutch similarly observed that patients with PC who underwent aborted CRS procedures fared worse (10). They noted that approximately 50% were found to have widespread peritoneal disease precluding successful

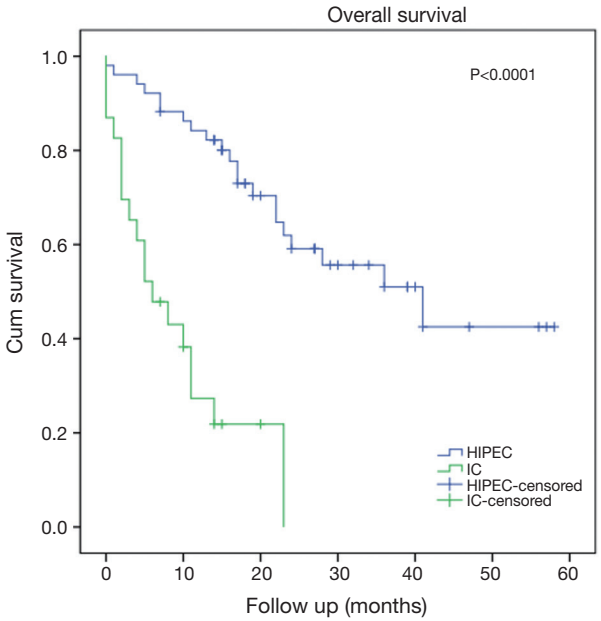

Figure 1 OS CRS/HIPEC versus aborted cytoreduction. OS, overall survival; CRS/HIPEC, cytoreduction and hyperthermic intraperitoneal chemotherapy; IC, aborted/incomplete cytoreduction.

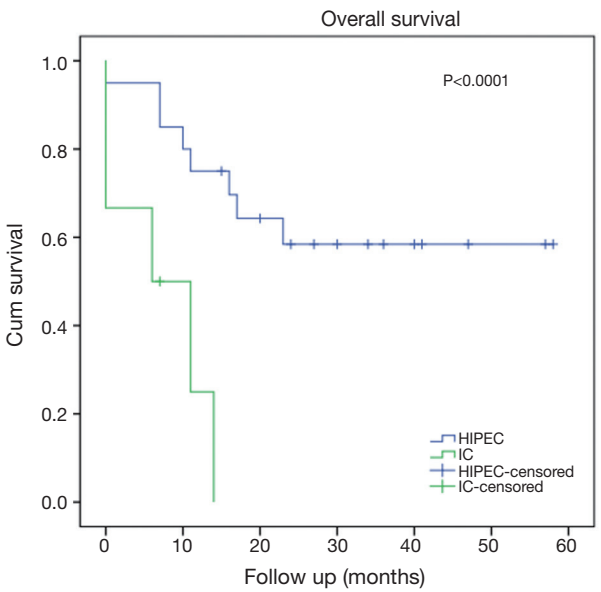

Figure 2 OS CRS/HIPEC versus aborted cytoreduction for appendix pathology. OS, overall survival; CRS/HIPEC, cytoreduction and hyperthermic intraperitoneal chemotherapy; IC, aborted/incomplete cytoreduction.

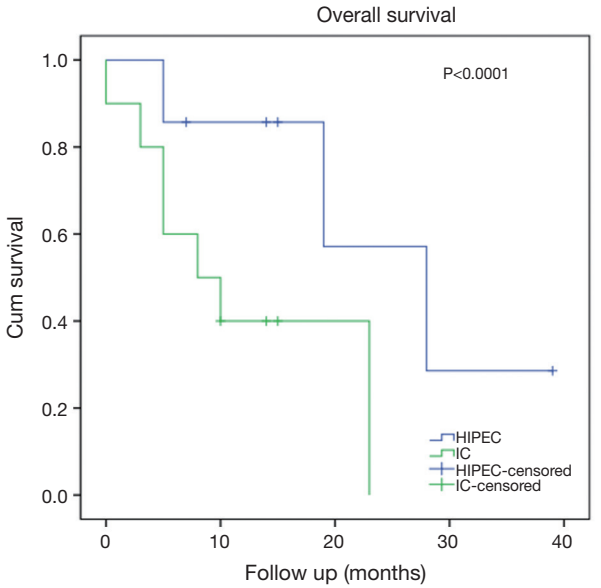

Figure 3 OS CRS/HIPEC versus aborted cytoreduction for colorectal pathology. OS, overall survival; CRS/HIPEC, cytoreduction and hyperthermic intraperitoneal chemotherapy; IC, aborted/incomplete cytoreduction.

CRS/HIPEC. The median survival was 11.2 months for patients treated with palliative chemotherapy compared to 2.7 months with palliative care alone.

As a newly established peritoneal surface malignancy center, an aggressive attempt to resect all visible disease was made as evidenced by the high proportion of patients who underwent ureteral catheter placement, the length of surgery and associated procedures performed before the decision to abort cytoreduction. Similar to more established centers, at the time of exploration we calculated the burden of disease (PCI) after adhesiolysis and then began to resect disease, focusing efforts on the pelvis or diaphragm as these areas are most difficult to clear (15). Despite our sincere efforts, many of these patients were ultimately deemed unresectable due to significant disease burden and underwent aborted cytoreduction. For these patients, the decision to abort cytoreduction was made with a second surgeon. Our inexperience and judgement may have negatively affected outcome, offering CRS/HIPEC to some patients who may have been deemed to be unresectable by more experienced centers. Polanco and colleagues noted that 180 procedures are required to maximize operative outcomes and achieve the lowest risk of incomplete cytoreduction (16). The high incidence of aborted CRS procedures in our first 74 CRS/HIPEC attempts highlights

Table 4 Multivariable factors associated with aborted cytoreduction and OS

Variable	Odds ratio	95% CI		P value
		Low	High	
Aborted cytoreduction				
Age	1.02	0.97	1.08	0.39
PCI	1.13	1.05	1.21	<0.0001
Colon	10.56	1.78	62.81	0.014
Appendix	0.82	0.15	4.48	0.59
OS				
Age	1.01	0.98	1.03	0.62
PCI	1.06	1.02	1.09	0.002
Colon	0.58	0.24	1.40	0.23
Appendix	1.54	0.63	3.72	0.34

OS, overall survival; PCI, peritoneal cancer index score.

the importance of the cytoreduction "learning curve" and also resulted in a re-evaluation of our preoperative assessment of patients with PC.

As demonstrated above, the accurate preoperative determination of patients who are ideal candidates for CRS/HIPEC remains a challenge. Cross sectional imaging has limited sensitivity in detecting peritoneal metastases, often underrepresenting the actual burden of disease (17). Selective use of diagnostic laparoscopy as a screening method may more accurately predict optimal candidates for CRS/HIPEC. Since review of this early experience of aborted CRS procedures, we have begun to perform diagnostic laparoscopy more liberally as a screening method for high-grade appendiceal and colorectal pathologies. Diagnostic laparoscopy is safe with low morbidity, even in the setting of prior operation and allows complete peritoneal assessment in most patients (18). The use of diagnostic laparoscopy earlier in our experience may have prevented several of the aborted cytoreduction procedures. Diffusion-weighted MRI is another method to screen potential CRS/HIPEC candidates as preoperative MRI correlates well with surgical PCI and postoperative resection status (19,20).

Disease burden, as determined by the PCI score, has been validated as a useful surrogate for successful completion of CRS/HIPEC and has a significant impact on outcome (21). We identified PCI score to be an independent predictor of OS for patients who undergo aborted cytoreduction and an important determinant of likelihood of successful completion of CRS/HIPEC. Consistent with others, we consider a PCI score of 20 as a general cut off for proceeding with CRS/HIPEC (22). We identified that the median PCI score was 10 points higher for those who underwent aborted cytoreduction procedures. Some have reported that long-term survival is possible for patients with a high PCI if able to achieve complete cytoreduction (23). We did not observe this trend, however, as advanced disease precluding a CCR 0/1 resection was the primary indication for aborted cytoreduction in 21 patients (91%). Two patients were aborted because of hemodynamic instability, one of whom underwent eventual successful CRS/HIPEC 6 months later and the other who developed recurrent disease and remains on palliative chemotherapy.

Primary tumor pathology has a significant effect on overall outcome and successful completion of CRS/HIPEC. The outcome for appendiceal primary tumors is generally more favorable than for PC from other pathologies (21). We identified a survival advantage for appendiceal primaries who were successfully able to undergo CRS/HIPEC (*Figure 2*). Colorectal primary tumors were the second most common pathology treated accounting for 25% of patients in this series. There were a disproportionately higher percentage of patients with colorectal pathology who underwent aborted procedures, which was identified as an independent predictor of worse outcome (*Table 4*, *Figure 3*). Several factors have been associated with increased risk of aborted CRS for colorectal peritoneal metastases including extensive disease at the porta hepatis (24), PCI score (25), extensive

Table 5 Disease distribution and palliative procedures performed for aborted cytoreduction patients with appendiceal and colorectal pathology

Variable	Colorectal (N=11)	Appendix (N=6)
Age (years)	54.4±12.2	57.5±11.3
PCI	21.2±10.0	32.2±6.4
Operative length (minutes)	269±119	202±99
Blood loss (mL)	493±618	72±45
Hospital stay (days)	7.7±5.6	11.3±9.3
Palliative chemotherapy	8 [73]	2 [33]
Disease distribution		
Right diaphragm	8 [73]	6 [100]
Involvement of >9 regions*	7 [64]	6 [100]
Fused pelvis	7 [64]	6 [100]
Left diaphragm	6 [55]	6 [100]
Small bowel serosa/mesentery	6 [55]	6 [100]
Lesser omentum	5 [45]	6 [100]
Porta hepatis	5 [45]	6 [100]
Falciform ligament	3 [27]	6 [100]
Omental mass	6 [55]	5 [83]
Ascites	3 [27]	4 [67]
Retroperitoneal involvement	3 [27]	2 [33]
Peri-aortic lymphadenopathy	2 [18]	–
Liver metastasis	1 [9]	–
Palliative procedures		
Ureteral stent placement	8 [73]	6 [100]
Omentectomy	5 [45]	2 [33]
Adhesiolysis >2 hours	5 [45]	–
Peritoneal biopsy	4 [36]	4 [67]
Stoma placement	4 [36]	1 [17]
Colon resection	2 [18]	–
Splenectomy	2 [18]	–
Rectal resection	1 [9]	–
Small bowel resection	1 [9]	–
Gynecologic procedure	1 [9]	–
Intestinal bypass	1 [9]	–
HIPEC	1 [9]	1 [17]

Results reported as N [%] or mean (± SD). *, based on PCI score of 13 regions. PCI, peritoneal cancer index score; HIPEC, hyperthermic intraperitoneal chemotherapy; SD, standard deviation.

small bowel involvement (7), liver metastasis as well as involvement of the lesser sac and diaphragm (26). Indeed, several of these factors were present for both appendiceal and colorectal primaries (*Table 5*). Of note, palliative HIPEC was performed in two patients with refractory malignant ascites as HIPEC is effective in controlling ascites even when complete cytoreduction is not feasible (27).

There are several limitations to this early experience. As previously described, the liberal use of screening laparoscopy may have avoided an unnecessary laparotomy in many of the patients described in this series. As a newer peritoneal surface malignancy program, our volume, while steadily increasing, is less than more established centers and these data presented highlight some of our institutional learning curve experiences. Nonetheless, as our experience has grown, so also has our awareness of proper patient selection, clinical judgement and technical proficiency. Kusamura and colleagues noted that approximately 80–100 cases were necessary to achieve short-term prognostic gains with approximately 140–150 cases necessary to gain competence in CRS and HIPEC (28). Lastly, many patients were referred from both community and academic oncology practices. Upon review of records, it was not always clear why some patients did or did not receive neoadjuvant or adjuvant/palliative therapy as part of their treatment. This underscores the significance of a multidisciplinary treatment approach for the management of PC and standardization of treatment recommendations.

Conclusions

Complete cytoreduction and HIPEC offers the possibility for cure for appropriately selected patients with PC. The burden of disease and CCR has a profound impact on survival with less disease and complete cytoreduction conferring the best outcome. Colorectal adenocarcinoma patients who undergo aborted cytoreduction procedures have the worst outcome. While approximately half of the patients who undergo aborted cytoreduction procedures are treated with palliative chemotherapy, the outcome remains poor and underscores the importance of proper patient selection.

Acknowledgements

None.

Footnote

Conflicts of Interest: This work was presented in part at the 11th Annual Regional Therapies Meeting, February 13–15, 2016, Phoenix, AZ, and the American College of Surgeons Clinical Congress, October 17–20, 2016, Washington, DC, USA.

Ethical Statement: Approval for this study was obtained from the University of Tennessee Health Science Center (17-05132-XP) and St Jude Children's Research Hospital Institutional Review Boards (XPD17-069). Informed consent was not required as this was a retrospective study.

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