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Toxicities, complications, and clinical encounters during intraperitoneal chemotherapy in 17 women with ovarian cancer

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A B S T R A C T

Purpose of the research: Intraperitoneal (IP) chemotherapy is a viable and superior treatment to standard intravenous (IV) chemotherapy in women with small volume residual ovarian cancer following optimal debulking. Despite this clinical advantage, widespread adoption of the treatment regimen has been hampered by concerns related to toxicities and complications. The purpose of this descriptive study was to describe nursing implications related to toxicities, complications and clinical encounters in 17 women with ovarian cancer who received IP chemotherapy.

Methods and sample: Women with ovarian cancer who received IP chemotherapy at one NCI-designated comprehensive cancer center were accrued. Data related to IP chemotherapy summary, clinical encounters and admissions were obtained through comprehensive chart audits.

Key results: Common treatment-related toxicities included nausea and vomiting, fatigue, hypomagnesia, pain, neuropathy, anemia, and constipation. Reasons for dose-modifications were multi-factorial, and were primarily related to catheter complications and chemotherapy toxicities. The number of clinical encounters was high, and they were primarily related to admissions for inpatient IP chemotherapy and follow-up clinic visits.

Conclusions: Treatment-related toxicities and complications were common in women with ovarian cancer who received IP chemotherapy. Use of IP chemotherapy results in multiple clinical encounters, such as outpatient clinic visits and inpatient admissions. Nursing is a critical part of the interdisciplinary approach in caring for women treated with IP chemotherapy. Interdisciplinary teams with high levels of knowledge and skills related to IP chemotherapy administration are needed to manage treatment-related toxicities and complications, and support multiple clinical encounters during treatment.

Introduction

In the United States, an estimated 22,280 women will be diagnosed with ovarian cancer in 2012 (Siegel et al., 2012). Despite the relatively modest incidence, ovarian cancer is highly aggressive. Most women are diagnosed with advanced disease, and approximately 79% present with regional or metastatic disease (Howlander et al., 2011). The reported five-year survival rate is 26.9% for distant (metastasized) disease (Howlander et al., 2011). Over the years, combined intraperitoneal (IP) and intravenous (IV) chemotherapy regimens have been explored as a viable treatment approach for women with optimally debulked stage III ovarian cancer. Approximately 20–30% of all women with ovarian cancer are appropriate candidates for IP chemotherapy (Armstrong et al., 2006).

The median progression-free survival rate in the pivotal phase 3 trial that compared IV chemotherapy with IV/IP combined treatment in patients with stage III ovarian cancer (Gynecologic Oncology Group – GOG 172) was 5.5 months, with an overall survival advantage of 16 months, both favoring the IV/IP combined regimen (Armstrong et al., 2006). Despite the observed therapeutic advantages for the combined IV/IP chemotherapy regimen, grade 3 and 4 toxicities as well as complications were common (Armstrong et al., 2006; Jaaback et al., 2011). These toxicities and complications

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pose a significant challenge for health-care professionals, including oncology nurses, to sustain optimal overall well-being of women during and after treatment. The purpose of this descriptive study was to describe nursing implications related to toxicities, complications and clinical encounters in a small cohort of women with ovarian cancer who received combined IP/IV chemotherapy.

Background

Findings from several randomized phase III clinical trials have clearly established that IP chemotherapy is superior to standard IV chemotherapy in the treatment of advanced epithelial ovarian cancer with small volume residual disease. A major obstacle to the widespread adoption of IP chemotherapy is the support needed to manage treatment-related toxicities and complications (Markman and Walker, 2006; Trimble et al., 2011). Rothenberg et al. reported that 96% of women who received IP chemotherapy reported at least one of the following grade 3 or 4 toxicities: neutropenia (79%), nausea (50%), vomiting (34%), and fatigue (24%). Side effects were also a common reason for treatment discontinuation (Rothenberg et al., 2003). In the GOG 172 study, 58% of women on the IP arm did not complete the six cycles of treatment because of toxicities (Armstrong et al., 2006). All categories of systemic toxicities, which included grade 3 and 4 fatigue and pain, were more common in the IP-treated group (Armstrong et al., 2006). Common post-treatment side effects included nausea and vomiting, constipation, diarrhea, and fatigue (Anderson and Hacker, 2008; Ryan and Duggan, 2010).

Some pain and discomfort is expected with infusion of up to two liters of fluid into the abdominal cavity, and reported rates of pain and discomfort can be as high as 85.7% (Ryan and Duggan, 2010). Varying degrees of pain during IP treatment have been reported, with 24.5% of women reporting mild pain that was relieved by opioids and did not cause any limitations in daily activity (Almadrones, 2007). In contrast, 11% of women reported severe pain during the infusion requiring opioids and treatment discontinuation (Almadrones, 2007). The GOG 172 study reported that abdominal symptoms were significantly worse in the IP arm during treatment and 3–6 weeks after treatment, but were similar 12 months after treatment (Armstrong et al., 2006). Other chemotherapy-related toxicities that are specific to the agents used in IP infusions (cisplatin and paclitaxel) include neurotoxicity, anorexia, alopecia, and tinnitus (Hydzik, 2007; Lowe et al., 2007; Ryan and Duggan, 2010). In the GOG 172 study, neurotoxicity was worse in the IP arm 3–6 weeks after treatment and remained increased 12 months after treatment (Armstrong et al., 2006).

Catheter and infusion-related complications are also common reasons for treatment discontinuation. Catheter-related complications include access device blockage, internal kinking of the catheter, port infections, catheter migration, bowel perforation, rectal fistula, bowel adhesions, retrograde flow of fluid into port pocket, fluid leakage from port septum and port access difficulty (Armstrong et al., 2006; Echarri et al., 2011; Helm, 2012; Lesnock et al., 2010; Robinson and Beyer, 2010). Complications that commonly arise during IP infusions include pain, burning sensations and peritonitis (Naumann et al., 2009; Ryan and Duggan, 2010). Post-infusion abdominal distention results in bloating, pressure, and discomfort that may not dissipate until 48 h after IP administration and/or after IP fluids are absorbed (Marin et al., 2007; Ryan and Duggan, 2010). Approximately 34% of patients in the GOG 172 study experienced catheter-related complications (Armstrong et al., 2006). Fully implanted IP access device complications occur at an overall rate of 6.8% to 40.5%, and are primarily responsible for the failure to complete planned IP chemotherapy in 1.9% to 2.6% of patients (Helm, 2012). Overall rates for superficial and deep infections can be as high as 20.5%, and rates for catheter obstructions vary from 2.1% to 22% (Helm, 2012). In the GOG 172 study, leakage was a reason for treatment discontinuation for 12.5% of patients (Armstrong et al., 2006).

The amount of resources used to implement IP chemotherapy is also a relevant topic of discussion, particularly when national health care expenditures are forecast to increase in the coming years. Although studies have explored the feasibility of IP chemotherapy administration in outpatient settings (Berry et al., 2009), it has traditionally been given partially in hospital settings. It is expected that expenditures for inpatient treatments are higher compared with outpatient treatments. A GOG study explored the cost effectiveness of IP compared with IV chemotherapy for women with stage III ovarian cancer. The cost effectiveness model incorporated toxicities, costs of adverse events, caregiver costs, charges associated with serious adverse events and hospitalizations. Findings suggest that costs for IP chemotherapy were higher than IV chemotherapy, and that the cost appears to be related to inpatient treatment (Havrilesky et al., 2008). In outpatient settings, treatments were estimated to be more cost effective, if aggressive supportive measures (i.e. scheduled hydration and granulocyte colony-stimulating factors) were given (Berry et al., 2009; Havrilesky et al., 2008).

Overall, although evidence suggests that IP chemotherapy has an overall survival advantage compared to standard IV therapy, this advantage is achieved at the expense of significantly higher rates of treatment-related toxicities, complications, reduced quality of life (QOL) during treatment, and potentially higher resource use based on cost. The administration of IP chemotherapy requires extra time, space, and resources than are typically required for IV administration. As the adoption of IP chemotherapy into standard practice for women with ovarian cancer increases worldwide, it is critical to understand women's experiences related to toxicities and complications during IP chemotherapy, and to describe the amount of health care resources utilized by patients during treatment. Explorations of women's experiences in receiving IP chemotherapy for the treatment of ovarian cancer can expand this understanding.

Materials and methods

The study design and protocol were reviewed and approved by the Institutional Review Board prior to study initiation. Women with ovarian cancer who were undergoing IP chemotherapy treatment, had a prognosis of 6 months or greater, and were 18 years or older were eligible to participate in the study. All participants provided informed consent prior to enrollment. Seventeen women with ovarian cancer who received IP chemotherapy were recruited from the Surgical and Medical Oncology ambulatory clinics of one NCI-designated comprehensive cancer center. Data related to the IP chemotherapy summary and clinical encounters (ambulatory encounters and hospital admissions) were collected for each patient using chart audit forms developed by the investigators. Data were collected during IP chemotherapy and 6–12 months following IP treatment in an attempt to describe each patient's experience. All patients received combined IV/IP chemotherapy using the modified Armstrong protocol (day 1 inpatient IV paclitaxel at 135 mg/m^2 over 24 h; day 2 inpatient IP cisplatin at 75–100 mg/m^2 over 1 h; day 8 outpatient IP paclitaxel 60 mg/m^2) given every 3 weeks for a total of six planned cycles. Each patient was followed throughout the planned six cycles of IP chemotherapy or one month following treatment discontinuation.

Instruments

Basic demographic data obtained for patients included age, race/ethnicity, education, marital status, co-morbidities, employment,

symptoms before diagnosis, and genetic counseling. IP chemotherapy summary, toxicities, and clinical encounters (ambulatory encounters and hospital admissions) were captured using a Demographic and Chart Audit Data Form. Patient medical charts were manually reviewed, and data relevant to the study were documented in the Demographic and Chart Audit Data Form. Disease-related data obtained using the chart audit form included disease stage and previous treatments.

Statistical analysis

Chart audit data were entered into a relational database (Access) and audited for accuracy. Using SPSS v. 15.0, summary statistics were computed on the Demographic and Treatment Data Tool and the chart audit data on IP chemotherapy summary and clinical encounters (ambulatory encounters and hospital admissions) for all patients.

Results

Table 1 presents basic demographic and disease-related data for the 17 women with ovarian cancer enrolled in the study. The mean age was 58, and the majority of women reported being of mixed race/ethnicity (76%). Women in this study were highly educated (82% reported completing college and/or graduate degrees), and the majority were married. Most women were retired (37%); three patients were working full time. Reported co-morbidities were related to metabolic, respiratory, and cardiovascular ailments. The majority of women reported experiencing symptoms prior to diagnosis, and these symptoms included abdominal bloating, pain, constipation, fatigue, and decreased appetite (see Table 2).

Table 1
Demographics and clinical characteristics ($N = 17$).

Variable	Frequency	Percent
Age (mean = 58.8, range 42–72)		
Race/ethnicity		
Caucasian	1	5.9
Asian/Pacific Islander	1	5.9
Hispanic	1	5.9
American Indian/Alaskan native	1	5.9
Mixed/other	13	76.4
Education		
No high school	2	11.8
High school	1	5.9
College	6	35.3
Graduate/professional	8	47.1
Marital status		
Married	15	88.2
Divorced	1	5.9
Widowed	1	5.9
Co-morbidities (45 responses)		
Cardiovascular	11	24.4
Endocrine/metabolic	4	2.2
Respiratory	2	8.8
Other	27	59.9
None	1	4.4
Employment		
Full time	3	18.8
Homemaker	4	25.0
Retired	6	37.5
Disabled	3	18.8
Missing[a]	1	5.9

[a] Missing data due to incomplete patient record.

Table 2
Women's reported symptoms before diagnosis.

Variable	Frequency	Percent
Type of symptoms (52 responses)		
Bloating	13	25
Abdominal pain	9	17.3
Constipation	5	9.6
Fatigue	4	7.7
Urinary frequency	4	7.7
Back pain	3	5.8
Decrease appetite	3	5.8
Anxiety	2	3.8
Vaginal bleeding	2	3.8
Depression	1	1.9
Diarrhea	1	1.9
Other	5	9.6

Treatment-related toxicities and complications

Table 3 presents findings from the chart audits in relation to IP chemotherapy summary, which includes toxicities and complications. The most commonly reported symptoms related to combined IV/IP chemotherapy treatment included nausea and vomiting, fatigue, hypomagnesia, pain, neuropathy, anemia, and constipation. IP-related complications included swelling and redness around the IP port and leakage at the port site. Reasons for dose-modifications were multi-factorial, and included renal function abnormalities, slow port infusion, tinnitus, IP port malfunction, and IP port access problems.

Clinical encounters during treatment

Table 4 presents chart audit findings regarding ambulatory encounters for patients during IP chemotherapy treatment. The 17 women enrolled on the study had a total of 475 scheduled and unscheduled ambulatory encounters, of which the majority were scheduled (80.6%). The majority of encounters were in the medical oncology clinic and urgent care settings. Reasons for encounters were primarily related to routine follow-up visits, scheduled treatments, consultations, and symptom management.

Table 5 presents findings related to hospital admissions for patients while on study. A total of 75 scheduled and unscheduled

Table 3
Women's reported toxicities during treatment.

Variable	Frequency	Percent
Toxicity recorded during treatment (185 responses)		
Nausea/vomiting	25	9.0
Fatigue	24	8.7
Hypomagnesia	22	8.0
Neuropathy	13	4.7
Pain	13	4.7
Anemia	12	4.4
Constipation	10	3.6
Diarrhea	8	2.9
Abdominal pain	7	2.5
Anxiety	7	2.5
Neutropenia	6	2.2
Rash	5	1.8
Appetite problems	5	1.8
Hypokalemia	4	1.5
Dehydration	2	0.7
Hypophosphatemia	2	0.7
Sleep changes	2	0.7
Abdominal bloating	1	0.4
Fever	1	0.4
Other	14	5.1

Table 4
Scheduled and unscheduled clinical encounters.

Variable	Frequency	Percent
Encounter type (475 responses)		
Scheduled	408	85.8
Unscheduled	67	14.2
Provider of services (941 responses)		
MD	387	41.1
Advanced practice nurse/physician assistant	132	14.0
Supportive care	23	2.4
Other	38	4.0
Encounter location (424 responses)		
Clinic	388	91.5
Phone call	15	3.5
Urgent care/emergency triage center	13	3.0
Other	8	2.0
Department (416 responses)		
Medical oncology	282	67.7
GYN oncology	93	22.3
Supportive care	18	4.3
Cardiology	12	2.8
Endocrinology	5	1.2
Neurology	4	0.9
Gastroenterology	2	0.8
Reason for encounter (537 responses)		
Routine follow-up visit	195	36.3
Scheduled IP chemo	117	21.7
Scheduled chemotherapy	65	12.1
Consultation	55	10.2
Symptom management	40	7.4
Routine Post-op visit	29	5.4
Supportive services	14	2.6
Wound problems	8	1.4
Labs	5	1.0
Education	5	1.0
Scheduled imaging	3	0.9

Table 5
Scheduled and unscheduled inpatient admission and complications.[a]

Variable	Frequency	Percent
Admission type		
Scheduled	66	59.5
Unscheduled	9	8.1
Missing[b]	36	32.4
Admission location		
Cancer center	98	88.3
Other facility	8	7.2
Missing[b]	5	4.5
Reason for admission[c]		
IP chemotherapy	71	42.5
IV chemotherapy	66	39.5
Additional surgical procedures	20	12.0
Symptom management/complications	10	6.0
Complications[c]		
Myelosuppression	7	7.0
Fistula	6	6.0
Catheter problems	5	5.0
Infection	5	5.0
Dehydration	3	3.0
Bowel obstruction	2	2.0
Intraabdominal abscess	1	1.0
Other	16	16.0
Discharge status		
Home-independent	54	48.6
Home–home care assistance	48	43.2
Inpatient facility-rehab/SNF	5	7.2
Missing[b]	4	3.6

[a] 111 Response unless otherwise indicated.
[b] Missing data due to incomplete patient record.
[c] More than one reason indicated.

admissions occurred for patients, and the majority were scheduled (59.5%). Patients were primarily admitted to the cancer center (88.3%); only 7.2% were admitted to outside facilities. Beyond scheduled admissions for IP chemotherapy treatments, the most common reasons for admission included additional surgical procedures (12%), complications (3.6%), and symptom management (2.4%). In terms of complications-related admissions, myelosuppression was the most common, followed by fistula, catheter problems, infections, dehydration, bowel obstructions, and sepsis. Patients were either discharged independently or with home care assistance.

Discussion

The delivery of IP chemotherapy requires the placement and use of IP access devices, which often have complications and adverse effects. As a result, dose delays, treatment discontinuation, higher resource utilization and potential increases in cost of care can occur (Helm, 2012). All of these developments can cause additional suffering to patients and their families and potentially jeopardize the patient's life. In this study, we aimed to describe treatment-related toxicities, complications, and clinical encounters during combined IP chemotherapy. Treatment-related toxicities, as expected, were common in this cohort of women, and these symptoms were commonly reported in several phase III clinical trials, including the GOG 172 study (Armstrong et al., 2006; Jaaback et al., 2011; Markman and Walker, 2006; Rothenberg et al., 2003; von Gruenigen et al., 2009, 2010). Our findings related to complications were also confirmed by other studies (Helm, 2012; Markman and Walker, 2006).

Few studies have explored the level of multiple clinical encounters needed during IP chemotherapy. In this study, a total of 475 scheduled and unscheduled outpatient encounters were documented for the 17 women who were followed while receiving IP chemotherapy. The finding that the majority of the encounters were scheduled confirms the high level of healthcare use that is required to care for patients receiving IP chemotherapy. For scheduled and unscheduled admissions, we were also able to document that IP chemotherapy infusion, additional surgical procedures, complications, and symptom management were the top reasons for hospital admissions among the 17 women. These findings are not surprising, given that clinical trial results show that women who received combined IV/IP chemotherapy are more likely to experience high levels of treatment-related toxicities and complications (Armstrong et al., 2006; Jaaback et al., 2011; Landrum et al., 2008; Lesnock et al., 2010; Markman and Walker, 2006; Rothenberg et al., 2003). Further studies should be conducted to explore the impact of IP chemotherapy administration on inpatient and outpatient clinical encounters and its impact on nursing resources.

Discussion over the relative value of IP chemotherapy persists based on concerns related to toxicities, complications and resource utilization. It has been recommended that IP chemotherapy should only be offered in institutions where the requisite knowledge, skills and experience of the health care team is available (Echarri et al., 2011; Markman and Walker, 2006). Because IP administration is more complex and time consuming, is associated with more significant toxicities, and is both physically and emotionally more challenging for patients, this is an important recommendation (Echarri et al., 2011). An interdisciplinary approach to caring for

patients is critical for comprehensive support of women and their families in an effort to minimize the adverse effects associated with IP therapy for ovarian cancer. Oncology nurses can play an important role in this interdisciplinary care approach.

Nurses experienced in administering IP chemotherapy are an essential part of an interdisciplinary IP chemotherapy team. Nurses require expertise in managing the "technical" aspects of IP administration, such as port access. Nurses can also meet the challenge of supporting women's physical and emotional demands while undergoing IP therapy. Published data suggest that health care provider inexperience in managing IP catheters or administering IP therapy can affect the success of IP chemotherapy administration (Potter and Held-Warmkessel, 2008). Therefore, nurses who are responsible for administering IP chemotherapy should have the knowledge and skills needed to manage and administer IP chemotherapy. This knowledge should include pre-infusion protocols, such as IV pre-hydration, pre-infusion anti-emetic regimen, having women void prior to administration to minimize discomfort, and warming the chemotherapy solution to help with abdominal discomfort during infusion (Marin et al., 2007). Nurses should also be aware of strategies that can assist with successful access of IP ports, such as proper positioning of patients (lying flat with head of bed slightly elevated) and applying local anesthetics to reduce access discomfort (Echarri et al., 2011; Ryan and Duggan, 2010). During infusion, nurses should be aware of the proper positioning of patients to facilitate breathing as the abdomen distends, as well as strategies to reduce discomfort, such as reducing flow rates (Potter and Held-Warmkessel, 2008). Furthermore, institutions should provide nurses with adequate training and establish standard procedures and protocols for managing patient needs during IP chemotherapy.

Nursing also plays an essential role in the education and coordination of care for women who are receiving IP chemotherapy. Conducting educational sessions prior to the first IP infusion with patients and family would foster the patient's sense of preparedness and alleviate anxiety (Potter and Held-Warmkessel, 2008). Key components of education should include the following: rationale for treatment, information on insertion of IP port, chemotherapy agent used, potential toxicities, management of toxicities, reportable signs and symptoms of complications, and contact numbers for the health care team (Anderson and Hacker, 2008; Echarri et al., 2011; Marin et al., 2007; Potter and Held-Warmkessel, 2008; Ryan and Duggan, 2010). Although IP chemotherapy-related toxicities and complications are not completely avoidable, evidence-based nursing protocols and careful techniques can keep these adverse effects to a minimum, which will allow women to receive the best possible clinical benefits from their treatment.

Nursing research can inform the development of interventions to support women in ovarian cancer during IP chemotherapy treatments. An IP chemotherapy research agenda should include the following: (1) further prospective and longitudinal studies that describe toxicities and complications over-time; (2) needs assessment for women with ovarian cancer during IP chemotherapy; (3) studies that explore the extent of nursing-related resource utilization for treating women with IP chemotherapy; (4) studies that explore the long-term HRQOL and functional implications in IP chemotherapy; and (5) pilot studies that test the feasibility of nursing interventions to support women during IP chemotherapy, which will lead to larger, comparative clinical trials to test the efficacy of the interventions.

A major limitation of this study is the small number of women who participated in the study. Therefore, study findings must be interpreted with caution, and findings cannot be generalized to women with ovarian cancer beyond the 17 patients who participated in the study.

The study was conducted in one comprehensive cancer center; thus, findings also may not be generalizable to other institutions and settings. The relatively short follow-up after treatment completion also limits the generalizability of the study, since findings may only be applicable to women's experience during IP chemotherapy. The study pre-dates an electronic medical record system at the study site. As a result, the number of complications may be underestimated, and the severity of patients' situations may be undocumented. Nevertheless, this descriptive analysis confirms the high toxicity and complication burden carried by women treated with IP chemotherapy, and provides preliminary insight into the level of multiple clinical encounters necessary for patient care while on treatment. Further research is needed to replicate the findings in a large, prospective longitudinal study where specific cost implications can be addressed.

In conclusion, findings from the current analysis provide valuable information for oncology nurses who routinely care for women with ovarian cancer receiving IP chemotherapy. Results can aid in the development of evidence-based supportive care protocols for the management of IP chemotherapy-related adverse events, and provide nursing administration with the knowledge to anticipate and prepare for the high levels of nursing care required for successful IP chemotherapy administration.

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