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Use of a Validated Assessment Tool Demonstrates the Frequency of Patient-experienced, Regimen-related Side Effects Associated With the Treatment of Common Solid Tumors

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ABSTRACT

Although side effects associated with chemotherapy-based regimens have been well described, a disconnect exists between the incidence and severity of side effects noted by professional caregivers and those noted by patients. To better determine the true incidence of chemotherapy-related side effects, we evaluated patients being treated with standard regimens for breast, colon, ovarian, or non-small cell lung cancer (NSCLC), using a validated, patient-reported outcomes assessment instrument: Patient Care Monitor© (PCM).

The study enrolled 384 patients. PCM was used to prospectively assess symptom distress of 6 targeted side effects—nausea/vomiting (NV), oral mucositis (OM), diarrhea, fatigue, peripheral neuropathy (PN), cognitive dysfunction (CD)—for each chemotherapy cycle on a scale of 0 to 10 (severe distress=10). Patients were considered to have moderate-to-severe side effects if the maximum score was ≥4 during the first 3 cycles of chemotherapy. Patients received their planned chemotherapy and supportive care deemed appropriate by their physicians.

The frequency of patient-described, moderate-to-severe side effects was substantial and varied by diagnosis and chemotherapy regimen. Among patients with breast cancer (n=187), fatigue (57%), chemotherapy-induced nausea and vomiting (CINV) (43%), and OM (31%) were most commonly reported, whereas fatigue (54%), CINV (36%), and PN (26%) were most often cited by patients with colon cancer (n=89). Patients with NSCLC (n=43) reported fatigue (65%), PN (38%), OM (25%), and NV (30%) most frequently. CINV was a consistent finding among all regimens, ranging in frequency from 30% among NSCLC patients to 43% in patients with breast cancer, despite the ubiquitous use of standard antiemetic protocols.

The side-effect burden associated with chemotherapy remains, despite advances in supportive care. Notably, the self-reported incidence of studied side effects generally exceeds the rates typically cited in the literature. This underscores the need for oncology nurses to continue their important role in monitoring and assessing consequences of chemotherapy. The study results also point to a need for more effective supportive care strategies along with new tools to help predict individual risk for chemotherapy-related side effects that may allow for more tailored supportive care interventions in advance of treatment and, thus, a more optimized patient treatment plan.

BACKGROUND

- Despite improvements in supportive care technology and therapeutics, moderate-to-severe side effects remain a problem for patients, families, and clinicians because they interfere with patient function, and are costly and disruptive to practice efficiency
  - Palonosetron, a second generation 5-HT3 antiemetic, demonstrated significant improvement in CINV, especially chemotherapy-induced nausea[1]
  - Aprepitant, the first NK1, in combination with a 5-HT3 and dexamethasone, improved the rate of CINV in patients receiving highly emetogenic chemotherapy regimens[2]
  - Octreotide LAR was demonstrated to be effective in reducing diarrhea in chemotherapy patients[3]
- PCM©, a validated, patient-reported outcomes assessment instrument, was used to evaluate patients with breast, colon, ovarian, and NSCL cancers for chemotherapy-related side effects[4]
- One study goal was to evaluate side effects to determine the current incidence and severity of side effects in patients receiving chemotherapy

  - Another goal was to determine whether the occurrence of side effects could be predicted using predictive genomic models

METHODS

- Patients (N=374) were evaluated if they had a cancer diagnosis of breast, colon, NSCL, or ovarian cancer and either were receiving or had received a selected chemotherapy regimen (Tables 1 and 2)
- PCM was used to evaluate side effects (CINV, Fatigue, OM, Diarrhea, PN, CD) using a 0-10 point scale. Scores ≥4 were consistent with moderate-to-severe side effects in patients with colon, breast, NSCL, and ovarian cancers receiving standard chemotherapies for each tumor site (Figure 1)

RESULTS

- Total of 384 patients were enrolled over a 8-month period (9 were excluded and 1 voluntarily withdrew from study)

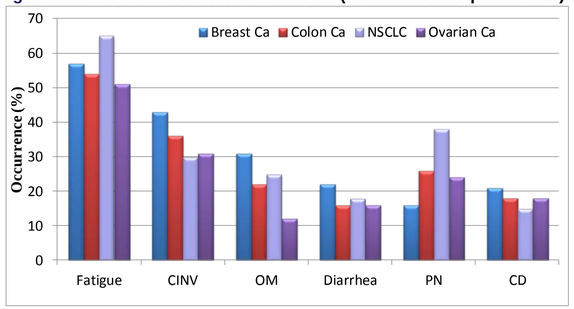
Table 1: Patient Demographics

Demographic	Breast Cancer n=187(%)	Colon Cancer n=89(%)	NSCL Cancer n=43(%)	Ovarian Cancer n=55(%)
Age Groups (yrs)				
18-35	13(7)	2(2)		2(4)
36-55	103(55)	33(37)	6(14)	14(25)
56-64	49(26)	26(29)	11(26)	16(29)
65+	22(12)	28(31)	26(60)	23(42)
Sex				
Female	187(100)	42(47)	19(44)	55(100)
Male		47(53)	24(56)	
Ethnicity				
African American	39(21)	24(27)	7(16)	5(95)
Asian	2(1)		1(2)	
White	51(27)	35(39)	17(40)	33(60)
Not Documented	95(51)	30(34)	18(42)	17(31)

Table 2: Top Treatment Regimens Used

Diagnosis	Chemotherapy Regimen Evaluated	Utilization Rate (%)
Breast Cancer	AC +/- docetaxel	2
	Carboplatin/Docetaxel +/-Bevacizumab	13
	Docetaxel + Cyclophosphamide +/- Bevacizumab	25
	Dose-Dense AC + Paclitaxel	57
Colon Cancer	FOLFIRI +/- Bevacizumab	20
	MFOLFOX6 +/- Bevacizumab	75
NSCLC	Pemetrexed +/- Bevacizumab	9
	Carboplatin/Pemetrexed +/- Bevacizumab	37
	Carboplatin/Paclitaxel +/- Biologic	21
	Cisplatin/Pemetrexed	14
	Weekly Carboplatin/Paclitaxel +/- Pemetrexed	14
Ovarian Cancer	Carboplatin/Docetaxel +/-Bevacizumab	13
	Carboplatin/Paclitaxel +/- Biologic	75

Figure 1: Moderate-to-Severe Side Effects (PCM© ≥4 on 10-point scale)



- Approximately 59% and 41% of patients with breast cancer received highly or moderately high emetogenic chemotherapy regimens
- Of those receiving AC-based regimens, 91% received standard antiemetic supportive care with a 5HT3+Dex+NK1, as well as standard prevention and/or management of other side effects
- Of all the patients with reported moderate-to-severe CINV, 100% experienced moderate-to-severe nausea, while only 10% experienced moderate to severe vomiting

CONCLUSIONS

- The self-reported incidence of side effects remains high and may even be understated, given the reporting through only the first 3 cycles of chemotherapy, and demonstrates the need for continued monitoring and assessment of consequences of chemotherapy-induced side effects by oncology nurses
- More effective supportive care strategies along with new tools are needed to help predict individual risk for chemotherapy-related side effects. This would allow for more tailored supportive care interventions in advance of treatment and, thus, a more optimized patient treatment plan

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