

Underreporting of Adverse Events and Improper Disposal of Oral Chemotherapy in the Community Oncology Setting

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Background

- Patients on oral chemotherapy regimens present a unique challenge relative to those on infusion chemotherapy, in that they have a greater responsibility in terms of medication management.¹
- The narrow therapeutic index and high toxicity profile of oral chemotherapy agents requires adequate patient education on proper disposal and reporting of side events.¹
- Early discontinuation of an oral chemotherapy, whether physician or patient initiated, can lead to improper disposal of potentially toxic oral chemotherapy agents,²⁻³ drug wastage due to accumulating medication after no longer taking them, and poorer outcomes related to their disease state.⁴⁻⁶
- In addition, adverse events (AEs) may go unreported because patients (1) do not want to compromise the effectiveness of their chemotherapy, (2) are unable to recognize the incipient adverse events, and (3) are unaware of an adverse event reporting system.⁷⁻⁹

Objective

- The objective of this study was to assess disposal techniques and adverse events reported by patients on oral chemotherapy.

Methods

- This prospective cohort study took place from December 2018 to May 2019. Patients were included if they were 18 years or older and receiving oral chemotherapy or hormonal therapy. Patients were prospectively followed for 6 months through monthly follow-up calls assessing mild, moderate, and/or severe adverse events from their oral chemotherapy. If patients discontinued therapy, additional questions were asked to assess the reason for discontinuation and methods for disposing of medication.

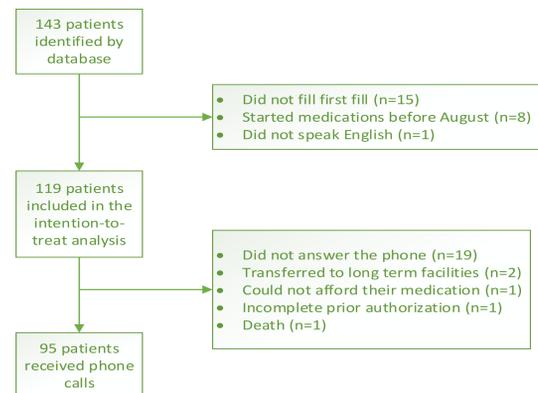


Figure 1. Patient Enrollment

Results

Table 1. Demographic and Clinical Characteristics

Baseline Characteristics (n=95)	
Sex, n (%)	
F	75 (79)
M	20 (21)
Age, n (mean)	
35-50	12 (12.6)
50-65	41 (43.2)
>=65	42 (44.2)
Race, n (%)	
White (Non-Hispanic)	61 (64.2)
Black (Non-Hispanic)	9 (9.5)
Hispanic	6 (6.3)
Asian	4 (4.2)
Other	15 (15.8)
Stage, n (%)	
0	2 (2.1)
I-II	47 (49.5)
III-IV	24 (25.3)
Not Noted	22 (23.1)
Tumor Type, n (%)	
Gastrointestinal	15 (16.8)
Genitourinary	6 (6.3)
Hematological	9 (9.5)
Breast	62 (65.3)
Brain	3 (3.2)

Table 2. Discontinuation Rates Leading to Disposal

Discontinuation of Chemotherapy (n=18)	
Reason, n (%)	
Physician Discontinuation (n=12)	
Side Effects	5 (41.6)
Drug Interaction/Contraindication	2 (16.7)
Therapy Completion	2 (16.7)
Disease Progression/Change in Therapy	1 (8.3)
Reason for discontinuation not provided	2 (16.7)
Patient Self-Discontinuation (n=6)	
Patient Declined Therapy	1 (16.7)
Side Effects	5 (83.3)

The primary reason for discontinuations were adverse events. While 66% of patients who discontinued their medications did so under physician consultation, 33% of patients who discontinued their medications did so on their own. Among patients who self discontinued, 83% of patients discontinued because of adverse events

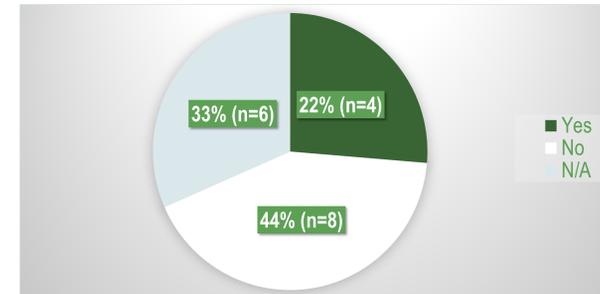


Figure 2. Disposal Technique: Of the 18 patients who discontinued therapy, 44% of patients improperly disposed of their medication, 22% disposed of their medication correctly, and the remaining of patients did not provide a response.

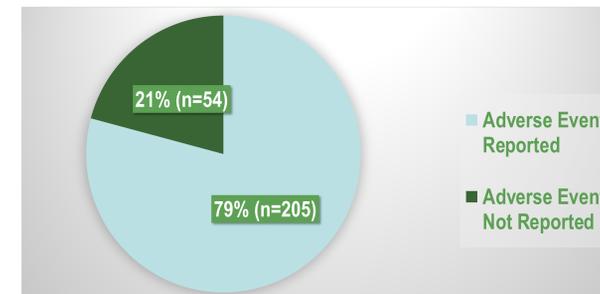


Figure 3. Total Adverse Events and Reporting of Oral Chemotherapy: Among the total study population (n=95), 259 AEs were reported. Two hundred and five (79%) of AEs were reported by patients and 54 (21%) were unreported by patients to their oncologist.

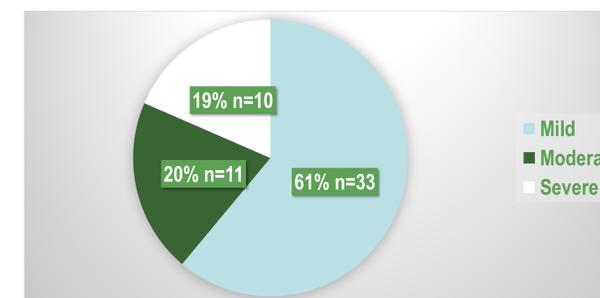


Figure 4. Unreported Adverse Events by Severity: Of the 54 unreported AEs experienced, 33 (61%) were categorized as mild, 11 (20%) were categorized as moderate, and 10 (19%) were categorized as severe.

Table 3. Unreported Adverse Events During Follow-Up Calls

Adverse Events (AEs)	Severity of AE			Number of AEs (n=259)	Number of Unreported AEs
	Mild (n=164)	Moderate (n=73)	Severe (n=22)		
Hot flash	63	18	3	84	
Unreported to oncologist	12	4	1		17
Fatigue	23	27	5	55	
Unreported to oncologist	6	3	3		12
Joint/Back/Musculoskeletal pain	33	12	9	54	
Unreported to oncologist	6	0	4		10
Nausea and vomiting	17	2	3	22	
Unreported to oncologist	4	1	1		6
Diarrhea	5	4	1	10	
Unreported to oncologist	1	1	1		3
Edema	6	4	0	10	
Unreported to oncologist	2	1	0		3
Alopecia	7	1	0	8	
Unreported to oncologist	1	0	0		1
Rash	1	0	0	1	
Unreported to oncologist	1	0	0		1
Loss of appetite & weight loss	0	1	0	1	
Unreported to oncologist	0	1	0		1
Number of events unreported per AE severity	33	11	10		54

The AEs with the highest number of unreported moderate to severe complications includes fatigue (n=6, 50%), hot flashes (n=5, 29%), joint/back/musculoskeletal pain (n=4, 40%), and nausea and vomiting (n=2, 33%).

Discussion

- Previous literature has shown that adherence to oral chemotherapy regimens is relatively high.¹⁰⁻¹¹ Data regarding discontinuations related to adherence was consistent with what has been previously reported.¹⁰⁻¹¹ The majority of patients who discontinued their medications did so under the direction of their physician, with the primary reasoning being adverse events.
- Data presented from this study shows a gap in patient understanding of how to correctly dispose of oral chemotherapy agents. These results are consistent with previous literature that indicates a lack of proper disposal technique among patients on oral chemotherapy agents.²⁻³
- Interventions to educate patients on appropriate oral chemotherapy management should include components about the importance of proper handling and storage of these medications, and the risks associated with incorrect disposal. Additionally, healthcare professionals may consider following up with patients who will be discontinuing medications under physician directions, to re-educate them on how they can dispose of left-over medications.
- Adverse events due to oral chemotherapy were not consistently reported to healthcare providers. Adverse events not reported by patients were of various severity grades including, mild, moderate and severe. The majority of patients who did not report their adverse events experienced those that were mild in nature however, over one-third of those not reported were in the moderate and severe categories.
- Data from this study are consistent with previous research and shows the continued need for intensive patient education regarding adverse events due to oral chemotherapy, how to distinguish adverse events from underlying clinical conditions, and the importance of reporting them to healthcare providers for proper management.¹¹⁻¹²

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