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Application of a Chemotherapy Standard Form in Patients with Breast Cancer: Comparison of Private and Public Centers

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Abstract

Background: Medication errors are important in chemotherapy centers, which can cause excessive morbidity and extra cost for patients because of the high toxicity and low therapeutic index of antineoplastic agents. Using standardized forms for prescription and administration of medications is one of the ways of reducing medication errors in the chemotherapy process.
Objectives: In the current study, the authors aimed to evaluate the effects of the standard forms implementation and detect medication error and adverse drug event (ADE) rates involving in chemotherapy regimens used in breast cancer in the public/private outpatient chemotherapy settings.
Methods: A cross-sectional interventional study was performed prospectively at two adult outpatient cancer centers, Mashhad, Iran. To avoid errors, a standardized order sheet was established to document information regarding breast cancer chemotherapy. The effect of the standard sheet on decreasing errors in ordering and administering was evaluated. The epidemiology of the errors and adverse drug events was reported.
Results: Of the 217 visits (164 at a public hospital and 70 at a private clinic) of 84 adult patients (64 at the hospital and 20 at the clinic) involving 385 medications, 41% were associated with a medication error. Of these errors, 5% occurred in the private clinic compared to 95% of the errors occurring in the public hospital. A standardized approach helped to reduce errors in the selection of the regimen type. However, physicians did not calculate doses based on the standard sheets so the most common error type was improper dose prescription (38.2% of the 89 cited error types). The effect of standard sheets in the administration phase could not be assessed due to the incomplete data presented by nurses. 62% of the errors originated in the prescription phase of medication and 33% originated in the administration phase. The ADE rate was 9.6% but no life-threatening adverse drug event was recorded.
Conclusions: Based on the current study, the medication errors occurred more commonly in the public setting and the prescribing errors were the most common ones. Standardized order sheets would be very beneficial in minimizing the medication errors if are used accurately.

Keywords: Chemotherapy, Standard Form, Medication Errors, Adverse Drug Effects, Breast Cancer

1. Background

Adverse drug reactions and medication errors have been proposed as a critical problem to modern healthcare systems. Cancer chemotherapy regimens are highly beneficial medications; however, they must be used precisely because they can cause serious toxicities at food and drug administration (FDA)-approved dosages and with FDA-approved administration plans (1). Thus, the substantial toxicity or a suboptimal therapeutic response can arise from even slight changes in the programmed treatment. Therefore, additional precautions are essential for the prevention of medication errors related to chemotherapeutic agents (2).

The national coordinating council for medication error reporting and prevention (NCCMERP) defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare provider, pa-

tient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use"(3).

Antineoplastic drugs are the second most common cause of fatal medication error (4, 5). It is the right of each patient, once entering the system, to be ensured that both care and treatment are safe and effective (6). The important concern for any oncologist is administering these agents in the safest and most efficient manner. It is essential as chemotherapy protocols have become very complex consisting of multiple co-medications and in most cases, they are given to old age cancer patients with several comorbidities. Although all precautions are taken, there is still a potential for serious medical errors during chemotherapy (7-10).

If errors are not found out during each treatment, they may be repeated during the following chemotherapy treatments and go undetected throughout a whole treatment course. Chemotherapy must be viewed as "high-alert" medication in order to prevent medication error (11). To improve the pharmacotherapeutic process in oncology and hematology patients, antineoplastic-related medication error prevention must become a priority (12). To enhance the safety of chemotherapy administration, it is necessary to standardize chemotherapy protocols in an applicable way for enhancement of the chemotherapy administration safety (10). Using validated pre-printed form (13) has been recommended as a method of decreasing medication errors.

Data from the literature have revealed that standardized chemotherapy forms diminish the medication errors occurrence and improve oncology patient care (14-17).

The standard form is a written order form that consists of necessary variables for precise completion of chemotherapy orders, such as the diagnosis, regimen, height, weight, body surface area (BSA), route, frequency, duration of medication administration, and chemotherapy dose and calculation based on BSA. The inclusion of these variables diminishes the chance of a medication error (18).

2. Objectives

The goal of this study was to evaluate the effects of the chemotherapy standard form and identify the rates and types of medication errors in relation to the early detection of toxicity and adverse drug reactions in outpatients with breast cancer.

3. Methods

3.1. Study Design

This was a cross-sectional interventional study carried out on patients receiving breast cancer chemotherapy in the outpatient settings between January 2015 and June 2015 at two oncology centers, Omid Oncology center as a teaching hospital, and a private clinic in Mashhad, Iran.

3.2. Inclusion Criteria

All patients with breast cancer, regardless of their stages and grades, were included in this study. Patients aged less than 17 or more than 70 years old, patients using herbal drugs, and patients with renal, heart, and liver impairment were not included in the study.

A standard chemotherapy form was prepared based on the available recommendations (19) and all breast cancer chemotherapy regimens were included in the form.

Physicians selected the appropriate regimen for each patient in these pre-printed forms. Then, nurses received standard forms to be used in the administration process. At the end of the study, all standard forms were collected and medication errors and possible side effects were evaluated. Since physicians did not document doses in the standard forms, patient files containing regimen details were examined. In addition, the patient's height, weight, and BSA were revised and BSA was recalculated to detect any error in the calculation of BSA. With respect to the available BSA calculating devices, all the calculations were based on the Du Bois formula. The Du Bois formula is the western standard formula for BSA calculation, which is validated largely and its accuracy has been confirmed more than other available formulas (20). Doses were recalculated according to the right BSA to detect any medication error.

Any medication order that was more than 10 percent over or under the calculated dose or defined duration was defined as dosing or duration error (21, 22).

3.3. Statistical Analysis

The results are shown as means $\pm$ standard deviation (SD) or number (percentages) for nominal variables. Kolmogorov-Smirnov test was used to assess the normality of the distribution of the variables. Data analysis was performed using the SPSS 16.0 statistical package. Univariate associations were assessed using the Chi-square test. Independent sample t-test was used to compare variables between the two groups. Statistical significance was set at $P < 0.05$.

Table 1. Patients' Characteristics and Demographic Data

Variable	Frequency (%)
Gender	
Female/male ratio	81/3 (96.4/3.6)
Involved breast	
Right	32 (38.1)
Left	49 (58.33)
Both	3 (3.57)
Family history	
First degree relative	6 (7.1)
Second-degree relative	7 (8.3)
Multiple relative	6 (7.1)
No relatives	65 (77.4)
Metastasis status	
Positive	3 (3.6)
ER status	
Positive	62 (73.8)
PR status	
Positive	63 (75)
HER2 status	
Positive	51 (60.07)

Abbreviations: ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor.

4. Results

During the 6-month prospective study, 84 adult breast cancer patients and 217 cycles with a total of 385 drugs were observed. The mean patient age was 46.17 $\pm$ 9.5 years and the male/female ratio was 3/81. The mean weight of patients was 69.5 $\pm$ 14.11 kg. There were no significant differences in patients' demographic data between the two groups. The demographic data of the patients are summarized in Table 1.

89 medication errors (41% of the cycles or 23.11% of the drugs) were recorded totally. 63% of them were errors in order writing (predominantly wrong doses) and 37% were nurse administration errors. The various types of errors included under- and overdosing (38.2% of the errors or 8.8% of the drugs), incorrect duration of infusion (31.4% of the errors or 11.7% of the drugs), no recalculation of BSA (24.8% of the errors or 23.8%/files) and other incidents, such as stopping infusion pump (5.6% of the errors).

84 patients' files containing the patient's height, weight, and BSA were reviewed and BSA was recalculated to detect any error in the calculation of BSA. 23.8% of the BSA calculated by the physicians differed from new recalculations by 2% to 27%.

The errors observed in the public hospital were significantly higher than those occurring in the private clinic ($P < 0.01$). Table 1 shows the error comparison in both outpatient locations. Concerning the duration of infusion, the frequency of errors was 2 times higher in the infusion time of > 1 hour (7.9%) than the short-duration infusions (3.8%). This indicates duration as a possible determinant in the causation of errors, and the difference observed was statistically significant on multivariate analysis ($P < 0.01$). 21 adverse effects were recorded during the study period as follows: extravasation (38.1%), headache (52.4%), and backache (9.5%). No interventions were made on them. Using the standard forms made physicians select all regimens based on standards and it omitted errors in this part. However, they did not calculate doses according to the standard forms. In the administration phase, nurses did not enter information accurately and in some parts, the forms were incomplete.

5. Discussion

To the best of our knowledge, this is the first study to evaluate breast cancer chemotherapy standard forms in chemotherapy outpatient locations and describe the epidemiology of errors and adverse drug events. There are limited studies reporting errors related to chemotherapeutic agents in inpatient or outpatient settings (21-24). The error rate in the present study was 41% of the visits. Rinke et al. in a study on adult and paediatric patients reported one percent error rate (22), whereas Walsh et al. reported an 8.1% error rate in the outpatient setting (24). The error rate in Dhemaji's study was reported as 11% (25). By assessing the standard forms, it was concluded that physicians selected all the regimens according to the standards. It means that these forms made this part of prescribing flawless. However, they did not write doses in the forms and documented doses in the patient's files. By reviewing patients' files, it was observed that the most common error was the dose calculation, which implied the importance of the standard forms. In the administration phase, nurses did not use the standard forms properly and even they were incomplete in some parts so the evaluation of the standard forms effect in this phase was not possible. However, in some parts such as selecting the type and volume of diluents, there were no medication errors. To sum up, the standard forms could be very effective if they were used accurately.

In the present study, it was observed that 63% of the errors occurred during prescribing and 37% occurred during the administering phase of chemotherapy. Fyhr and Akselsson noted that prescribing errors (42%) occurred more

Table 2. Comparison of Errors in the Two Centers[a,b]

Error Type	Public Hospital, N = 79	Private Clinic, N = 5	Total, N = 84
Improper dose	30 (88.23)	4 (11.77)	34 (38.2% of the errors)
No recalculation of BSA	22 (100)	0	22 (24.8% of the errors)
Incorrect physician ordering	0	0	0
Incorrect duration of infusion	27 (96.42)	1 (3.58)	28 (31.4% of the errors)
Incorrect type of solution	0	0	0
Incorrect volume of solution	0	0	0
Wrong route	0	0	0
Wrong patient	0	0	0
Wrong drug	0	0	0
Others	5 (100)	0	5 (5.6% of the errors)

Abbreviation: BSA, body surface area.
[a]Values are expressed as No. (%).
[b]Independent sample t-test (P value: < 0.01)

Table 3. Epidemiology of Medication Errors in Chemotherapy in Comparison with the Published Literature

Variables	Study				
	Fyhr and Akselsson	**Rinke et al.**	**Dhamij et al.**	**Walsh et al.**	**This Study**
Year	1996 - 2008	1999 - 2004	2012	2008	2015
Length of the study	12 y	5 y	8 mo	9 mo	6 mo
Design	Retrospective	Retrospective	Retrospective	Retrospective	Prospective
Patients age, y	All ages	< 18	< 18	All ages	17 <, 70 >
ME rate, %	NS	1	11	8.1	41
ADE rate, %	NS	0.016	0.4	1.1	9.6
Errors in ordering, %	42	10	13	36	62
Errors in administering, %	16	48	43	56	37
Dosing error rate, %	45	22.9	9	NS	38.2
Rate of error in the duration of infusion	NS	NS	26	NS	31.4
Wrong route	NS	12.2	NS	NS	0
Wrong patients	0.08	NS	NS	NS	0
Wrong drug	30	NS	NS	NS	0
Reference	(23)	(22)	(21)	(24)	

Abbreviations: ADE, adverse reaction error; ME, medication error; NS, not specified.

than administering errors (16%) (23). However, some studies reported conversely (21, 22, 24).

The dosing error rate in the present study was more than the mean dosing error rate in similar studies and because of our fewer observations, it should be considered very important.

The incorrect calculation of doses of drugs included both over and underdosing. However, these errors did not lead to serious side effects but it could be vital because if the dose is too low, it will be ineffective or less effective against the tumor, whereas, at excessive doses, the toxicity will be intolerable to the patient (26).

It was observed that in some cases, physicians had not measured weight for new regimens and just used the primary weight. In the case of weight changes in the patients, it could be culminated in over and underdosing due to the incorrect calculation of BSA.

Chemotherapy medications, which were associated with infusion errors, were those infused over a prolonged duration (more than an hour). Comparing with short in-

fusion time (less than one hour), the error rate was two times higher for longer duration infusions (> 1 hour) (3.8% vs. 7.9%), which was significantly different on the univariate analysis. Similar results have been reported by Dhamij et al. (21). In some patients, infusion pump malfunction caused disturbances in a constant rate of infusion and according to the "Applied Pharmacology", a change in the infusion rate will result in a change in the steady-state plasma concentrations (27). Therefore, assurance of precise working of infusion pumps is very necessary for all drugs, especially chemotherapy agents.

The ADE rates comprised 9.7% of the visits, which were more than in similar studies. It would be due to more errors happening in our study. ADE did not lead to death or serious incidents and just exacerbated as extravasation, headache, and backache.

To compare the public hospital and the private clinic, errors and ADE occurring in the hospital were significantly more than errors and ADE in the clinic, which may indicate the better use of the standard forms in the clinic.

It is of utmost importance to reduce the potential for errors in the prescribing and administering stages. This could be done using electronic chemotherapy order forms, which can reduce medication errors (MEs), especially by including exact medication names. Moreover, the ordering program was designed to calculate the BSA by inserting height and weight, reducing the potential for a manual miscalculation. Then, based on this calculated BSA, the computer program calculated the total necessary doses (28).

A study conducted in order to compare the traditional unstandardized blank order sheets, the standard written forms, and electronic chemotherapy forms. The results showed that the preparation of a standard chemotherapy order form significantly enhances its completeness. The electronic forms also show an additional progress over handwritten standard forms regarding the completeness, reduction of chemotherapy order clarifications, calculation of BSA, and chemotherapy doses (28).

Patients are the last line of defenses against an error, so they should be well educated about their chemotherapy regimens (29). To be informed of their treatment, they would be able to involve in the detection and prevention of errors (30). There are lots of evidence that patients have repeatedly noticed, detected, and reported errors and adverse events (31-33). Schulmeister specifies the number of examples in which the errors were identified by patients themselves. For example, patients recognized wrong drugs, wrong doses, or infusion pump malfunction (34). A study also reported patients identifying missed doses of premedication, incorrect infusion intervals, leaking infusions, and mistaken doses of oral antineoplastic agents (30). Training and educating nurses who administer antineoplastic drugs and making update references available are other ways to reduce the number of MEs (21).

5.1. Conclusion

In conclusion, based on our findings, most of the medication errors occurred in the public settings and most of these errors came from the error in dose calculation by the oncologists in the prescription phase. As the standard dosing regimens are completely defined in the prepared forms, adherence to the chemotherapy standard form can significantly reduce the medication errors in the public and private oncology settings.

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Footnotes

Authors' Contribution: Study concept and design: Maryam Mousavi, acquisition of data: Mahsa Rouhani, Soodabeh Shahidsales, Yasha Makhdoumi, Amir Amirabadi, Mohammad Mahdi Kooshyar, analysis and interpretation of data: Maryam Mousavi, drafting of the manuscript: Mahsa Rouhani, critical revision of the manuscript for important intellectual content: Maryam Mousavi, Sepideh Elyasi.

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