Clinical and Experimental Health Sciences

The Prevalence of Drug-Drug Interactions and Reported Therapy Related Side-Effects in Oncology Out-Patients

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ABSTRACT

Objective: The use of multiple medications in cancer patients is unavoidable; thus, adverse drug-drug interactions are frequent. This study aims to assess the prevalence of potential drug interactions in oncology patients visiting the outpatient chemotherapy unit.

Method: Demographic and health-related information of patients visiting an outpatient chemotherapy unit was recorded using a pre-prepared form. A comprehensive list of all concurrently used medications was compiled and checked for interactions with the Micromedex online drug interaction tool.

Results: A total of 179 adult patients were included. We recorded an average of 9.3 drugs per patient with 79 patients using more than 10 drugs. A total of 1671 drugs including 303 chemotherapeutic agents were assessed for drug-drug interactions. A total of 374 interactions, of which 203 were significant, were recorded in 118 (65.9%) patients with an average of 3.2 interactions per patient. Only 46 major interactions were recorded for anticancer agents. Cyclophosphamide (n=13) and cisplatin (n=12) were involved in most interactions. The number of interactions correlated with the number of drugs used (p=.001) and the presence of comorbidities (p=.002). The presence of comorbidities increased the risk of interaction by 1.21 (p=.04). Recorded side effects were not correlated to drug interactions.

Conclusion: Medication review in cancer patients is essential in establishing all medications used by patients. Routine assessment in terms of potential drug interactions and evaluation of these interactions by a qualified pharmacist may help in optimizing patient outcomes.
Keywords: Cancer patients, Antineoplastic agents, Drug-drug interaction, Side effects, Polypharmacy.

1. INTRODUCTION

Cancer is a major life-threatening condition with a high rate of mortality and morbidity and increasing prevalence around the world. The treatment of cancer involves the use of highly toxic medications with low therapeutic index and serious adverse effects. The rate of drug-related problems is high in cancer patients due to the concurrent use of many drugs. These drugs are used for cancer treatment, side effect management, palliative and supportive care, and comorbidity treatment. Drug-drug interactions make up an important part of the drug-related problems seen in these patients (1,2).

There are different forms of drug interactions. These interactions can be with food, disease, laboratory analysis and other drugs. Drug-drug interactions can lead to changes in the therapeutic effects or adverse effects of drugs. The outcome of interactions is variable. Outcomes are often clinically insignificant, occasionally beneficial or harmful (3,4). Clinically significant interactions are those that have negative impact on patient outcomes (3) which are estimated to be between 3% and 20% (4). Drug interactions can lead to an increase in side effects already present with cancer medications (5). Assessment of drug interactions is fundamental in cancer patients for optimal management of pharmacotherapy. A systematic review of patients' medications at the beginning and with any change in regimen is necessary to prevent interactions (5,6).

The number of drugs used by a patient is an independent factor that increases the risk of drug interactions (7,8). Approximately, at least one drug-drug interaction may be present in the majority of the patients undergoing treatment for cancer. Some of these interactions may require medical intervention. Most potential drug-drug interactions are not detected or prevented due to the inefficient professional relationship between pharmacists and other health care providers. The most common consequences of interactions are gastrointestinal toxicity, QT prolongation, and central

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nervous system depression. Most interactions are reported to involve unavoidable supportive care medications including antiemetics, analgesics and steroids. The combination of these medication increases the risk of interactions (6,9–11).

In oncology, the main function of a pharmacist is to conduct a comprehensive medication review to prevent drug-related problems. The integration of clinical pharmacy services in the care of oncology patients optimizes therapeutic outcomes by improving medication appropriateness, reducing adverse drug events, increasing patient satisfaction, and reducing health expenditure (1,10,12)

This study aimed to determine the rate and significance of potential drug-drug interactions between concurrently used medications by cancer patients visiting the outpatient chemotherapy unit. And also to assess the rate of chemotherapy-related side effects and their relation to potential drug interaction.

2. METHODS

This prospective study was carried out in the outpatient chemotherapy delivery unit of Medipol Mega university hospital between January and April 2017. Ethics approval was obtained from Istanbul Medipol University Non-Invasive Clinical Trial Ethics Committee with Reference No: 18/2017 before the commencement of the study.

Adult cancer patients visiting the unit for treatment, who gave consent, were included in the study. The patients' demographics and health-related data including primary cancer site, the presence of comorbidities, and home medications were recorded using a pre-prepared form by 5th-year pharmacy students. Treatment protocols administered in the unit during the patients' visits were recorded from the unit's patient records. Under the supervision of a clinical pharmacist, a comprehensive list of all medications used by each patient was compiled and checked for clinically significant potential drug-drug interactions using the Micromedex online drug interaction checker (Access date: January – April 2017). Interactions were classified as contraindicated, major, moderate, minor, and unknown. Contraindicated and major interactions were considered significant interactions. Treatment-related side effects experienced by patients were also recorded and classified based on Common Terminology Criteria for Adverse Events (CTCAE) v5.0. These side effects were compared with major interactions involving chemotherapy agents and the possible significance of interactions were assessed.

Statistical analysis was done with SPSS 22.0 (Statistical Package for the Social Sciences) program. Spearman test and Pearson test were used to analyse correlations between numerical data and categorical data respectively. A logistic regression test was done to predict clinical risk factors. The results with p<.05 in the 95% confidence range were considered significant.

3. RESULTS

A total of 179 patients were included in the study. The majority of the patients were female (n=97, 54.2%). We classified our patients into three groups based on their ages (13). Most patients were in the 31-60 age group. The mean age was 55.8 ± 14.6. Some patients (n=81) reported having at least one comorbidity. Only four of these patients reported not using any medication for their comorbidities. The most common comorbid diseases reported were hypertension (n=35), diabetes (n=29) and hyperlipidemia (n=12). Demographic and health-related data of patients and distribution of interactions are given in Table 1.

Table 1. *Demographic data of patients and distribution of interactions*

Demographic details		Patients with interactions	Patients without interactions	Total n (%)
Gender	Male	54	28	82 (45.8)
	Female	64	33	97 (54.2)
Age	18-30	6	1	7 (3.9)
	30-60	58	38	96 (53.6)
	>60	54	22	76 (42.5)
Comorbidities	None	58	40	98 (54.7)
	At least 1	60	21	81 (45.3)
Number of medications used	< 5	8	23	31 (17.3)
	6-10	42	27	69 (38.5)
	>10	68	11	79 (44.2)
Presence of side effects	None	79	51	130 (72.6)
	At least one	39	11	49 (27.4)

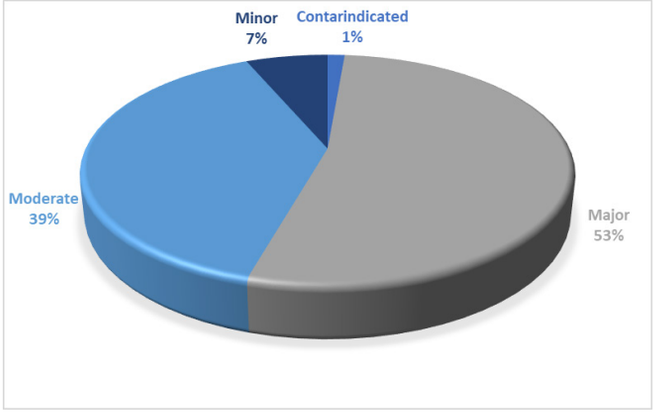

Figure 1*. Types of interactions*

The most common cancer sites were breast (C50) (n=49), lung (C35) (n= 37), and colon (C18) (n=15). At least one-cite metastasis was present in 24 patients. During their visits, most patients (n=163) received chemotherapy drugs while 16 patients received only palliative medications. The most received chemotherapy agents were paclitaxel (n=35), trastuzumab (n=27) and carboplatin (n=22). Cancer-related data and distribution of interactions are given in Table 2.

Table 2: *Patient and interaction distribution based on primary cancer type.*

Cancer type	Code	Sex		Total number of patients		Metastasis		Comorbidity		Average number of total drugs used	Average number of chemotherapy drugs used	Total number of interactions	Significant interactions (n)	Chemotherapy-related major interaction (n)
		Male (n)	Female (n)	n	%	None	At least one site	None	At least one					
Gastric	C16	2	2	4	2.2	4	0	3	1	7.3	2.0	1	1	0
Colon	C18	9	6	15	8.4	12	3	7	8	10.5	2.2	25	11	0
Rectal	C20	4	1	5	2.8	4	1	2	3	10.8	2.2	27	14	0
Liver	C22	3	2	5	2.8	4	1	3	2	11.2	1.4	19	17	1
Pancreas	C325	2	2	4	2.2	3	1	1	3	11.3	2.0	3	2	0
Lung	C35	26	11	37	20.7	33	4	20	17	10.7	1.8	99	56	6
Breast	C50	3	46	49	27.4	37	12	29	20	7.4	1.5	83	40	15
Ovary	C56	0	8	8	4.4	7	1	5	3	8.5	1.9	9	7	2
Prostate	C61	6	0	6	3.3	6	0	2	4	8.3	1.5	13	7	2
Testis	C62	3	0	3	1.7	3	0	3	0	7.7	2.0	1	1	0
Kidney	C64	1	2	3	1.7	3	0	0	3	8.0	1.0	4	1	0
Brain	C71	3	3	6	3.3	6	0	4	2	6.8	1.7	1	1	0
NHL	C85	5	0	5	2.8	5	0	2	3	12.8	2.6	15	8	7
MM	C90	1	2	3	1.7	3	0	2	1	10.0	1.3	15	8	2
AML	C92	2	2	4	2.2	4	0	1	3	9.5	1.0	18	8	0
Others		12	10	22	12.4	21	1	14	8	82.8	9.3	41	21	9
Total		82	97	179	100	155	24	98	81	-	-	374	203	44

AML – acute myelomonocytic leukemia; MM – Multiple myeloma; NHL – Non-Hodgkin lymphoma

Table 3. *Major drug-drug interactions involving agents used for cancer treatment*

Chemotherapy drug	Interacting drug (n)	Frequency (44)	Outcome of interaction
Cyclophosphamide	Allopurinol	6	Increase in cyclophosphamide toxicity
	Doxorubicin	6	Increase in cardiomyopathy risk
	Hydrochlorothiazide	1	Increase in cyclophosphamide effect and myelosuppression
Cisplatin	Furosemide	10	Increase in nephrotoxicity and ototoxicity risk
	Vinorelbine	2	Increase in granulocytopenia risk
Doxorubicin	Aprepitant	5	Increase in doxorubicin effect
	Dexamethasone	3	Decrease in doxorubicin effect
Methotrexate	Trimethoprim	1	Increase in methotrexate toxicity
Paclitaxel	Levonorgestrel	1	Increase in paclitaxel toxicity
Pazopanib	Lansoprazole	1	Reduction in pazopanib bioavailability
	Calcium Carbonate	1	Reduction in pazopanib bioavailability
	Magnesium Hydroxide	1	Reduction in pazopanib bioavailability
Pemetrexed	Diclofenac	1	Increase in pemetrexed toxicity
Tamoxifen	Domperidone	1	Increase in QT elevation risk
	Goserelin	1	Increase in QT elevation risk
Trastuzumab	Epirubicin	1	Increase in cardiac dysfunction risk
Vincristine	Filgrastim	1	Increase in severe peripheral neuropathy risk
	Dexamethasone	1	Decrease in serum vincristine levels

A comprehensive list of all medications used by each patient was compiled. The average number of total drugs used was 9.3 drugs per patient with 79 patients using more than 10 drugs. The use of at least one home medication was recorded in 134 patients with an average of 4.1. Fifty-eight of these patients were using only cancer-related medications while 76 patients were using cancer-related medications and/or medications for their comorbidities. A total of 303 chemotherapy medications were administered to 163 patients during their visit.

A total of 1671 drugs were assessed for drug-drug interactions. These included 303 chemotherapeutic agents, 555 reportedly used home medications and 813 palliative care and pre-medication agents. A total of 374 interactions were recorded in 118 (65.9%) patients with an average of 3.2 interactions per patient. Recorded interactions included five contraindicated, 198 major, 146 moderate, and 24 minor interactions as shown in Figure 1. Contraindicated interactions were recorded between palliative care medications which include ondansetron-posaconazole (n=3), fluconazole-granisetron (n=1) and fluconazole – ondansetron (n=1). Only 44 major interactions involved anticancer agents. A list of these interactions is given in Table 3. The most used anticancer agents included paclitaxel (n=35), trastuzumab (n=27), carboplatin (n=22), fluorouracil (n=19), bevacizumab (n=18), cisplatin (n=17) and cyclophosphamide (n=15). Cyclophosphamide (n=13) and cisplatin (n=12) were involved in most interactions.

The presence of comorbidities significantly correlated to the total number of drugs used (r=0.3; p=.001) and the number of total (r=0.23; p=.002), major (r=0.16; p=.03) and moderate interactions (r=0.2; p=.005). The presence of comorbidity increased the risk of interaction by 1.21 (p=.04). The number of interactions also correlates with the total number of drugs used (r=0.5; p=.001).

***Table 4**. Side effects reported by patients*

MedDRA SOC	CTCAE Term	Frequency
Blood and lymphatic system disorders	Anemia	1
	Neutropenia	2
	Thrombocytopenia	1
Ear and labyrinth disorders	Vertigo	1
Gastrointestinal disorders	Abdominal distension	1
	Abdominal pain	2
	Constipation	6
	Diarrhoea	3
	Dyspepsia	1
	Mucositis oral	4
	Nausea	23
	Rectal ulcer	1
	Salivary duct inflammation	3
	Stomach pain	1
	Toothache	2
	Vomiting	3
General disorders and administration site conditions	Fatigue	16
	Hot flashes	5
	Pain	4
Immune system disorders	Allergic reaction	3
	Anaphylaxis	1
Infections and infestations	Nail infection	4
Metabolism and nutrition disorders	Anorexia	1
	Arthralgia	1
	Hypercalcemia	1
	Hypokalemia	1
Nervous system disorders	Headache	2
	Hypersomnia	1
	Syncope	1
Psychiatric disorders	Anxiety	3
	Hallucinations	1
	Insomnia	3
Reproductive system and breast disorders	Vaginal dryness	1
Respiratory, thoracic, and mediastinal disorders	Hoarseness	1
Skin and subcutaneous tissue disorders	Alopecia	4
	Skin rash	1
	Palmar-plantar erythrodysesthesia syndrome	1
Vascular disorders	Flushing	2
	Hypertension	1
	Hypotension	1

MedDRA SOC – Medical Dictionary for Regulatory Activities System Organ Class: CTCAE-Common Terminology Criteria for Adverse Events

The therapy-related side effects experienced by patients were recorded. A total of 115 side effects were reported by 49 patients, with an average of 2.3 events per patient. Most reported side effects were gastrointestinal-related (n=50). Details are given in Table 4. We evaluated the possible influence of interactions on reported side effects. A possible interaction-related increase in side effects was noticed in only three patients. Two patients using cyclophosphamide and allopurinol reported having nausea and one patient using paclitaxel and Levonorgestrel reported having five different side effects which included nausea, vomiting, neutropenia, fatigue, and hair loss.

4. DISCUSSION

Drug-drug interactions can occur in most patients treated with more than one medication. The clinical significance of these interactions varies based on the severity and time to unset, in addition to patient and/or therapy-related factors. The outcomes of most interactions are unnoticed and unrecorded in the clinical setting. The use of multiple medications in cancer patients increases their susceptibility to drug interactions and outcomes in these patients may be devastating. In this study, we evaluated the incidence and significance of potential drug interaction that may be present in all concurrently used medications. The incidence of drug interactions was 65.95% in our study population with most interactions occurring in our female patients. This may be due to the study's higher number of female patients. Most of them had other diseases and thus polypharmacy was present in many. Similar studies have a comparable number of drug-drug interactions (1,8,14–17).

The presence of comorbidities was recorded as an independent factor that increased drug-drug interaction. Also, the frequency of interactions increased as the concurrent number of drugs used increased. The presence of comorbidities necessitates the use of other medications. Comorbidities and polypharmacy are usually associated with a higher incidence of drug interactions (18,19). A study revealed that interactions were more in patients receiving 7 or more medications (8). This is similar to our result as interactions were more common in patients receiving more than five drugs. The selection of chemotherapy regimens with drugs that have more interacting potential also predisposes patients to interactions (20). Comorbidities and polypharmacy are more common in elderly patients. We recorded at least one interaction in 22 patients above 60 years. Studies carried out mainly in geriatric cancer patients have revealed high incidences of drug-drug interactions and risk increases with the presence of comorbidities and polypharmacy (11,21,22).

We prepared a comprehensive medication list of all patients which included all medications the patients were taking at home. Most of these medications were involved in drug interactions. A study revealed a high prevalence of drug interactions among medications independently dispensed to the same set of cancer patients by a hospital pharmacist and

community pharmacist (23). There is a need for optimum medication reconciliation and surveillance in cancer patients due to the use of various sets of medications at the different levels of health care.

We also evaluated the frequency of reported chemotherapy side effects. Side effects were reported by 27.4% of the patients. This rate is lower when compared to other studies. In their retrospective study, Bayraktar et al reported a total of 9080 chemotherapy-related side effects in 347 patients (14). A similar study also recorded high levels of side effects in geriatric patients (24). Both studies recorded all symptoms that may be attributed to chemotherapy from doctor-filled patient information charts. This may have given them the opportunity to gain more verified data. The other study was mainly on geriatric patients who are more liable to side effects. Also, improvements in clinical practice aimed at improving better use of drugs, adequate prophylaxis and improving quality of life over the years may have led to decrease in the incidence of side effects.

Assessment of drug interactions in cancer patients is essential for the management of pharmacotherapy. To prevent interactions, routine evaluation of all patients' medications is required (5,25). The use of a computer-aided interaction check system in the prescription system has been shown to reduce incidences of interactions. These systems provide accurate proactive information enhancing quick decision-making (26,27). This can help in the early identification of possible threatening interactions. But the significance of identified interactions to individual patients' therapeutic outcomes needs to be assessed and verified by a qualified pharmacist. The positive impact of clinical pharmacy services on patient outcomes under different conditions has been shown in various studies (12, 28).

This study had some limitations. It was a single center study and as such there were limited number of patients. Only patient reported-therapy side effects were evaluated in terms of possible association to drug interactions. Clinical proof of this association was not established. Also patients were not monitored for clinical outcomes that may be associated to drug interactions. No interventions were made for all interactions.

5. CONCLUSION

Drug-drug interactions are quite common in cancer patients. Pharmacists can improve therapy by identifying potential drug interactions and drug-related problems in cancer patients. A clinical pharmacist as a member of a multidisciplinary healthcare team can ensure the provision of the safest chemotherapy regimens, effective treatment of comorbidities, and effective supportive and palliative care through comprehensive medication management.

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Acquisition of data for the study: ZYC, EGE
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