BMC Cancer

RESEARCH

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Factors associated with occurrence of drug therapy problems among patients with neoplasms of s-sectional studydigestive organs at Uganda Cancer Institute, Mbarara: a cros

Silas Ojuka[1†], Alex Duhimbaze[2†], Samuel Michael Nono[2], Moses Nangosya[2], John Isiiko[3] and Tadele Mekuriya Yadesa[2,4*]

Abstract

Background The global burden of neoplasms of digestive organs (NDOs) is on the rise. Various stakeholders have made significant efforts to ensure access to effective and relatively safe chemotherapy for the treatment of NDOs. However, the use of cancer chemotherapy has been associated with drug therapy problems (DTPs). These potentially compromise desired treatment outcomes. There is limited knowledge among stakeholders regarding the burden of DTPs among patients on cancer chemotherapy in Uganda.

Method This was a cross-sectional study which enrolled 196 participants with NDOs. It was conducted at Uganda Cancer Institute (UCI), Mbarara. Data was collected using a questionnaire and checklist. Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 22.0. The prevalence of DTPs was expressed as a percentage of the sample size. Factors associated with occurrence of DTPs were analyzed using logistic regression. Variables with p-values less than 0.25 at univariate analysis were subjected to multivariate analysis. Variables were considered statistically significant if p-values were less than 0.05 at 95% confidence interval.

Results Out of 196 participants 86 (43.9%) experienced DTPs. The most common DTPs were: need for additional therapy (135/535, 25.2%), unnecessary drug therapy (86/535, 16.1%) and adverse drug reactions (ADRs) (86/535, 16.1%). On performing logistic regression, female gender (aOR: 2.11; 95% CI: 1.01–4.42, $p=0.047$), unemployment (aOR: 7.17; 95% CI: 1.31–39.02, $p=0.023$) or older age (aOR: 2.67; 95% CI: 1.31–5.47, $p=0.007$) were significantly associated with occurrence of DTPs.

†Silas Ojuka and Alex Duhimbaze contributed equally to this work.

*Correspondence:
Tadele Mekuriya Yadesa
maatiikoo4@gmail.com

Full list of author information is available at the end of the article

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Conclusion This study demonstrates that the use of cancer chemotherapy to achieve desired therapy outcomes among patients with NDOs is still challenged by DTPs. The findings are suggestive of a gap in rational medicines use in the treatment of cancers in a LMIC setting.

Keywords Drug therapy problem, Neoplasm of digestive organ, Cancer, Chemotherapy

Background

Globally 4.8 million new cases and 3.4 million deaths from neoplasms of digestive organs (NDOs) were documented by the year 2018. This contributed to approximately 26% of all new cancer cases and 35% of all cancer related mortality worldwide [1]. In Uganda the prevalence of NDOs ranks second after prostate cancer among males and third after cervical and breast cancers among females [2, 3]. According to WHO classification, NDOs include cancers of the; esophagus, liver, stomach, gallbladder and bile duct, pancreas, small bowel, colon, rectum and anus [4]. Of these the commonest in Uganda are cancers of the; esophagus(28.8%), liver(25.8%) and stomach (18.4%) [5].

Risk factors such as older age, alcohol use, tobacco use, infectious causes, diet with carcinogenic contaminants and obesity account for over half of all the NDOs. In fact, it has been observed that variations in the occurrence of these risk factors have been widely associated with notable temporal changes in incidences of the primary kinds of neoplasms [1, 6]. NDOs are largely prevalent among older adults with more than half of the incidence occurring among individuals above 75 years. It is also important to note that most diagnoses of NDOs among older adults are made at advanced stages of the cancers [7].

DTPs are unfavorable patient experiences while on drug therapy which may compromise desired treatment outcomes [8]. They include; unnecessary drug therapy, adverse drug reactions, need for additional drug therapy, dose too high, dose too low and noncompliance [8–10].

Unnecessary drug therapy was defined as patient being prescribed a drug without an indication for the drug at the time, use of many drugs for treatment of a condition that could be resolved with non-drug therapy or fewer drugs. Use of drugs of addiction, recreational drugs and treating avoidable adverse reaction was also considered unnecessary drug therapy. Needs additional therapy was defined as evidence-based requirement to start therapy for a condition that is not being treated, for prophylactic purposes or to take advantage of synergistic effect of adding another drug. Ineffective drug therapy was defined us a patient being prescribed a drug product that is unable to achieve the desired treatment outcomes. Dosage too low was defined as; a prescribed dose being below the therapeutic dose, the prescribed dosage interval being longer than is appropriate to produce the desired therapeutic response or the duration of the prescribed drug therapy being shorter than what is appropriate. Adverse drug reaction (ADR) was defined as a noxious and unintended effect of drug which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. Dosage too high was defined as the prescribed dose being more than is appropriate, the dosing frequency being too short for the patient or duration of drug therapy being longer than the appropriate length of time [11].

Generally, DTPs are a major public health concern which have had an upward trend over the years. Despite half the number of DTPs being avoidable, they cause 5–10% of hospital admissions [12]). DTPs are a global concern, both in low-income economies and high-income settings. In the USA, the prevalence of DTPs has been estimated to be 89.5% [8]. In Spain drug related mortality has been observed to be as high as 18.4% [13]. A systematic review demonstrated that the average fatality rate for patients hospitalized from DTPs in Africa was approximately 5.7% with an average rate of 2.7% [14]. DTPs significantly increase financial cost of health care. For instance, in Europe treating a patient who develops an ADR may cost between €174 and €8,515 [15].

Chemotherapy plays a significant role in management of NDOs and other cancers. However, cancer chemotherapy has been associated with numerous DTPs [16, 17]. DTPs can be responsible for prolonged hospitalization, increase in overall health care expenses and patient mortality [12]. In Uganda the burden of NDOs ranks highly after cervical and breast cancers in females and prostate cancer in males [2]. During patient therapy DTPs may impede achievement of desired treatment outcomes among patients with NDOs. In light of this there is need for clinicians and researchers to study the burden of DTPs among patients on treatment for highly prevalent cancers like NDOs.

Methods

Study aim

To assess prevalence and factors associated with DTPs among patients with NDOs at UCI Mbarara, south-western Uganda.

Study design

This was a cross-sectional study where quantitative methods of analysis were applied.

Study setting

The study was conducted at UCI Mbarara a public, specialized, tertiary care medical facility owned by the Uganda Ministry of Health. Located in the city of Mbarara, UCI Mbarara is a cancer treatment, research, and teaching center affiliated with the Mbarara University School of Medicine and the Mbarara Regional Referral Hospital. The UCI Mbarara has two units, the pediatric and adult units. The pediatric unit accommodates 20 beds and so does the adult unit. These facilities were created in 2017 and provide cancer patients with both inpatient and outpatient care. In addition, the UCI Mbarara employs five nurses, one pharmacist, two oncologists, and one oncology pharmacist [18].

Characteristics of participants

Study population

All patients who visited UCI Mbarara between September 2023 and December 2023 were included in the study population. The study included all patients aged 18 and above with confirmed NDO who were prescribed at least one antineoplastic medication from UCI Mbarara during the study period. The study excluded those patients with NDO who had not yet begun taking an antitumor medication. The study also excluded patients who were unable to communicate and those who were transferred or released within 24 h of being included.

Sample size calculation

Utilizing a single population proportion calculation, the sample size for the study was calculated using the Cochrane formula: $n_o = Z^2P(1\text{-}P)/d^2$.

Where;

n_o= sample required.

Z= critical value for 95% confidence interval (1.96).

d is the precision. (5%) = 0.05,

P= prevalence rate = 71% (0.71) Adopted from a study done in Ethiopia [19].

$n_o = 1.96^2 \times 0.71(1\text{-}0.71)/0.05^2$ = 317participants.

The UCI Mbarara serves a total of 400 cancer patients which is less than 10,000 therefore, the finite population correction formula was applied;

$$n = \frac{no}{1 + (no - 1)/N)}$$

Where:

N is the size of the population.

n is the actual sample size.

n = 317/1+ ((317-1)/400) =177participants.

On adding 10% of the sample size for contingency an actual sample size of 196 participants was obtained.

Sampling method

Files of patients who met the study criteria were arranged in ascending order using patient file numbers. Systematic sampling was used for selection of participants. From the stack of files every second file was chosen to obtain the sample size.

Data collection methods and procedures

Consent of study participants was obtained in writing. Data was collected using a pretested questionnaire and checklist. The questionnaire was used to interview participants while the checklist was used to obtain data from patient files. Adherence to medication was assessed using questions adopted from Hill-Bone medication adherence scale [20]. Only patients whose drug therapy was indicated and safe were assessed for adherence to medication. Males and females were considered non-adherent if they scored < 29.1 and < 32.3, respectively [20]. The Naranjo scale was used to assess causality of suspected adverse drug reactions. A physician confirmed that the event is not of any other cause except the drug in question. Cases where causality score was at least 9 were described as definite, a score of 5 to 8 was described as probable while 1 to 4 was described as possible [21].

Drug therapy problem was defined as an unfavorable occurrence experienced by a patient and is associated with drug therapy [11] . DTPs may actually or potentially impede achievement of set goals of therapy. For purposes of this study UpToDate application was used as a reference tool for drug information necessary for diagnosing DTPs. The pharmacist who was also the principal investigator made the diagnosis of DTPs. A physician on the research team confirmed that prescriptions that the pharmacist determined had DTPs did not, in fact, have any clinical justification for not following standard treatment protocols. This is because clinicians may not always document reasons for not prescribing in accordance with standard protocols. Uganda Cancer Institute cancer treatment guidelines were used to determine the occurrence of the DTPs [22].

Data analysis

Data analysis was done using SPSS version 22.0 software. The prevalence of DTPs was expressed as a percentage of the sample size. Factors associated with occurrence of DTPs were analyzed using logistic regression. Variables with p-values less than 0.25 at univariate analysis were further subjected to multivariate logistic regression analysis. Variables were considered statistically significant if p-value was less than 0.05 at 95% confidence interval.

Table 1 Socio-demographic characteristics of study participants (*N* = 196)

Variable	Category	Frequency (%)
Sex	Male	130(66.3)
	Female	66(33.7)
Age	18 to 59 years	103(52.6)
	60 years and above	93(47.4)
Nutrition status	Underweight (BMI < 18.5)	83(42.3)
	Normal (BMI 18.5–24.9)	88(44.9)
	Overweight or Obese (BMI > 25.0)	25(12.7)
Marital status	Single	19(9.7)
	Married	118(60.20
	Separated	19(9.7)
	Divorced / Widow	40(20.4)
Religious affiliation	Catholic	77(39.3)
	Anglican	95(48.5)
	Muslim / Other	24(12.3)
Highest level of education	No formal education	49(25.0)
	Primary	106(54.1)
	O level	41(20.9)
Employment status	Employed	17(8.7)
	Unemployed	179(91.3)

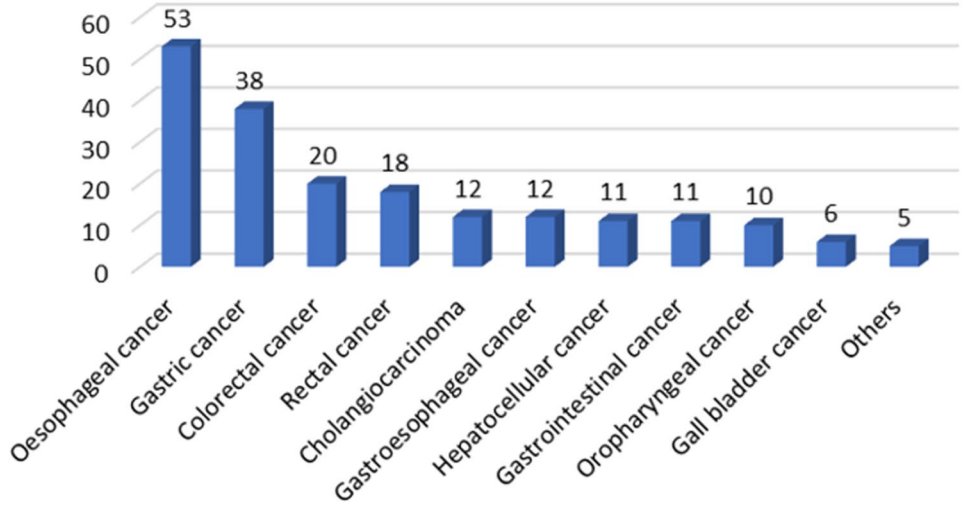


Fig. 1 Distribution of NDOs among patients receiving care from UCI Mbarara

Results

Characteristics of study participants

The study included 196 participants with NDOs receiving care from UCI Mbarara, majority of whom were male; 130/196(66.3%). The mean age of the participants was 58 years (SD = 12.96). Over a half, 103/196(52.6%), were adults while majority, 116/196(60.2%) were married. The mean BMI was 19.74 (SD = 4.45); with majority of the patients, 90/196(45.9%) having normal BMI, 87/196(44.4%) being underweight while 19/196(9.7%) were overweight or obese. Most of the participants, affiliated with Anglican and Catholic religions, 95/196(48.5%) and 77/196(39.3%) respectively. More than half, 106/196(54.1%) had primary level education as their highest level of education while majority 180/196(91.8%) were unemployed (Table 1).

Frequency distribution of NDOs among patients receiving care from UCI Mbarara

The commonest cancers among the participants were esophageal, gastric and colorectal cancers with proportions of 53/196(27.0%), 38/196(18.9%) and 20/196(10.2%) respectively (Fig. 1).

Prevalence of patients with DTPs

A total of 86 (43.9%) out of 196 participants experienced at least one DTP (Fig. 2).

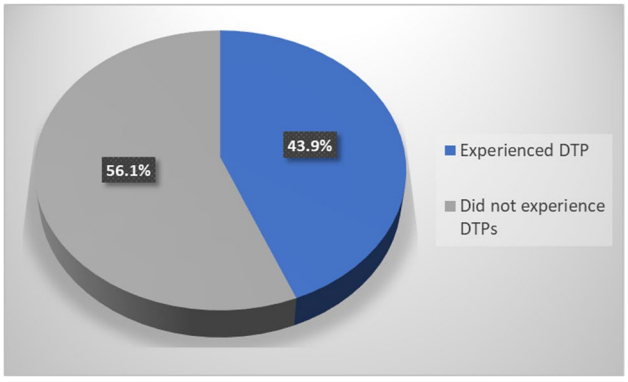


Fig. 2 Prevalence of DTPs in patients with NDO

Frequency distribution of DTPs among patients with NDOs receiving care from UCI Mbarara

The most common drug therapy problems were; need for additional therapy 135/535 (25.2%), unnecessary drug therapy 86/535(16.1%) and ADRs 86/535(16.1%) (Fig. 3). The overall mean ± standard deviation of the number of DTPs was 2.73 ± 0.49 per patient.

Factors associated with DTPs among patients with NDOs receiving care from UCI Mbarara

On performing logistic regression being female (aOR: 2.11; 95% CI: 1.01–4.42, $p = 0.047$), unemployed (aOR: 7.17; 95% CI: 1.31–39.02, $p = 0.023$) or of older age (aOR: 2.67; 95% CI: 1.31–5.47, $p = 0.007$) were significantly associated with occurrence of DTPs (Table 2).

Discussion

In the current study the prevalence of DTPs was 43.9%. An assessment of DTPs among patients with cervical cancer at Kenyatta National Hospital demonstrated a higher prevalence of 93.8% [23]. However, the study from Kenya enrolled fewer participants than the current study. This difference in sample size could probably explain the difference in study findings. Higher prevalences of 90.1% and 62.1% were also reported in previous studies conducted among older patients on chemotherapy in Singapore and Canada respectively [24, 25]. This difference could be attributed to the fact that participants in the previous studies were largely older adults. In the current study it was also observed that older age was significantly associated with occurrence of DTPs. This is probably because older adults are more likely to have lower metabolic rates, have comorbidities and be on multiple drugs. This makes them prone to experiencing ADRs [26, 27].

The commonest DTP observed in this study was need for additional drug therapy. However, similar studies conducted among oncology patients in referral hospitals in Kenya and Ethiopia reported ADRs as the commonest DTPs [16, 28]. This difference may be attributed to the fact that some patients may have had non oncology conditions. These may have required alternative expert health care consultation from other specialties who had not been accessed by the time of data collection [29, 30]. In healthcare settings in sub-Saharan Africa there is significant delay in honoring of consults made from one clinic to another. This could be due to poor ratio of specialists to patients within the healthcare system [31, 32]. In a retrospective review of cancer patients, it was observed that delay in treatment was often due to delay in being reviewed by the consulted expert. Some delays were due to diagnostic errors by the referring physician, delay in correct diagnosis, referral and appropriate response to pathology reports [29].

In the current study it was also noted that ADRs and unnecessary drug therapy were also relatively frequent. This is because they both came second on the frequency distribution. Similarly a study among patients with cancer in China reported that majority of them experienced ADRs [33]. This comparable finding could be because patients with pathologies affecting organs that are

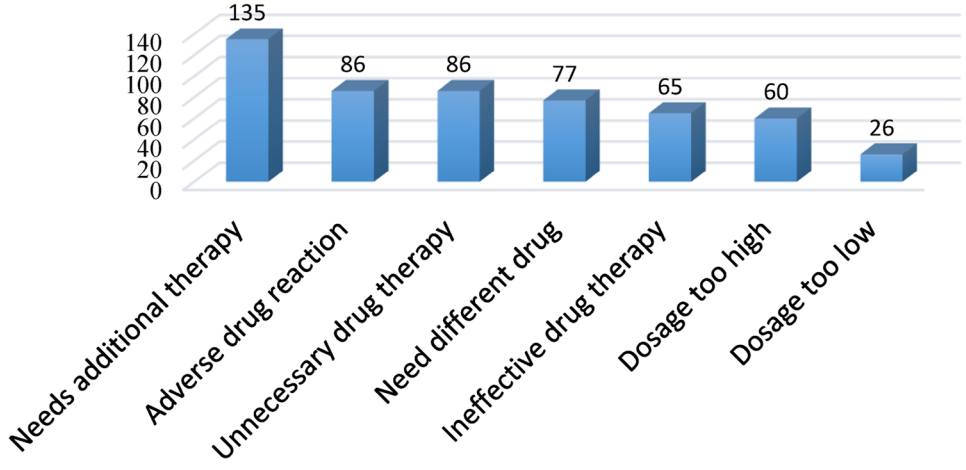


Fig. 3 Types of DTPs among patients with NDOs receiving care from UCI Mbarara

Table 2 Univariate and multivariate analysis of factors associated with DTPs among patients with NDOs receiving care from UCI Mbarara

Variable	Category	DTP (%)		cOR	95% CI	*p*-value	Aor	95% CI	*p*-value
		Yes	No						
Sex	Male	52(40.0)	78(60.0)	REF	-	-	REF	-	-
	Female	34(51.5)	32(48.5)	1.59	0.88–2.89	0.131	2.11	1.01– 4.42	**0.047**
Nutrition status	Normal	44(50.6)	43(49.4)	REF	-	-	REF	-	
	Underweight	35(38.9)	55(61.1)	1.79	0.97–3.29	0.060	1.64	0.80–3.38	0.170
	Overweight/ obese	7(36.8)	12(63.2)	0.75	0.29–1.92	0.552	0.67	0.21–2.55	0.500
Age	18 to 59 years	33(32.0)	70(68.0)	REF	-	-	REF	-	
	60years and above	53(57.0)	40(43.0)	2.36	1.33–4.20	0.004	2.67	1.31–5.47	**0.007**
Religious affiliation	Catholic	35(45.0)	42(55.0)	REF	-	-			
	Anglican	42(44.0)	53(56.0)	0.95	0.52–1.74	0.878			
	Others	9(38.0)	15(63.0)	0.70	0.25–1.97	0.497			
Marital status	Single	7(36.8)	12(63.2)	REF	-	-			
	Married	52(44.1)	66(55.9)	1.22	0.45–3.32	0.702			
	Separated	27(45.8)	32(54.2)	1.25	0.34–4.59	0.749			
Family history of cancer	Yes	8(38.1)	13(61.9)	REF	-	-			
	No	78(44.6)	97(55.4)	1.27	0.64–2.60	0.484			
Highest level of education	Informal education	26(53.0)	23(47.0)	REF	-	-			
	Primary	37(35.0)	69(65.0)	0.66	0.33–1.30	0.231			
	Secondary/tertiary	23(56.0)	18(44.0)	1.09	0.47–2.51	0.832			
Employment status	Employed	3(17.6)	14(82.4)	REF	-	-	REF	-	
	Unemployed	105(58.7)	74(41.3)	6.63	1.47–29.80	0.014	7.17	1.31–39.02	**0.023**
Tobacco use	Yes	23(39.0)	36 (61.0)	0.83	0.40–1.40	0.375	0.67	0.17–2.55	0.560
	No	63 (46.0)	74 (54.0)	REF	-	-	REF	-	-
Cancer staging	I and II	14 (35.0)	26 (65.0)	REF	-	-	REF	-	-
	III and IV	72 (46.2)	84 (53.8)	1.56	0.23–1.35	0.193	0.51	0.17–1.48	0.220
Polypharmacy	Yes	43 (43.9)	55 (56.1)	REF	-	-	REF	-	-
	No	43 (43.9)	55 (56.1)	1.00	0.57–1.75	0.094	1.00	0.73–1.37	0.500
Medication adherence level	Low a	13 (29.5)	31 (70.5)	REF	-		REF	-	
	Medium	38 (46.3)	44 (53.7)	2.06	0.90–4.49	0.065	2.15	0.83–5.56	0.120
	High	35 (50.0)	35 (50.0)	2.38	1.07–5.57	0.032	2.58	0.98–6.74	0.050
Stress	Yes	6 (27.3)	16 (72.7)	REF	-	-	REF	-	
	No	80 (46.0)	94 (54.0)	1.83	0.99–3.36	0.051	3.01	0.93–9.65	0.060
Experience of prescriber	More than 5 years	19 (30.6)	43 (69.4)	REF	-	-	REF		
	Less than 5 years	68 (50.7)	66 (49.3)	1.81	0.99–3.36	0.051	1.63	0.75–3.50	0.210
Perceived workload of the prescriber	Too Much	33 (43.4)	43 (56.6)	REF			REF	-	
	Much	46 (44.2)	58 (55.8)	1.03	0.57–1.88	0.910	1.29	0.46–6.33	0.420
	Less	7 (43.8)	9 (56.3)	1.01	0.48–3.01	0.983	2.62	0.45–6.07	0.430
Knowledge of patient on drugs	Fair	41 (43.2)	54 (56.8)	REF	-	-	REF	-	-
	Poor	45 (44.6)	56 (55.4)	1.06	0.60–3.45	0.841	1.38	0.61–3.13	0.430
Comorbid conditions	None	29 (42.6)	39 (57.4)	REF	-	-	REF	-	-
	One	15 (51.7)	14 (48.3)	1.44	0.60–3.44	0.411	1.23	0.24–3.55	0.690
	More than one	42 (38.5)	67 (61.5)	0.1	0.53–1.85	0.972	0.91	0.41–2.02	0.810

Bold: Statistically significant (*p* value<0.05)

involved in drug metabolism are more likely to experience ADRs compared to those with normal organ function [34]. The fact that NDOs affect function of organs that may directly or indirectly affect drug metabolism could have played a role in compounding the burden of ADRs in this study. Given the known association of chemotherapy with occurrence of numerous ADRs [35] the observed relatively high rate of ADRs in the current study could have been contributed to by the combined effect of both chemotherapy and NDOs. Unnecessary drug therapy was also relatively common in the current study. This could have been due to inadequate number of specialists within the healthcare system [32].

DTPs were more likely to occur among female patients compared to their male counterparts. This finding in the current study could be due to poor adherence to

treatment among female patients. Female patients may poorly adhere to treatment due to various reasons. Firstly, because they are more likely to delay to accept the diagnosis [36]. Secondly, females in sub-Saharan Africa are also significantly burdened by numerous responsibilities in their homes [37]. Furthermore, in previous studies it was observed that more reports on ADRs were received from female patients [38]. This could be because females are more likely to report noxious experiences from treatment than males [39]. Due to the fact that females are also more likely to be on more medicines than males they face an increased the risk of experiencing ADRs and other medication related problems [40].

Older patients were also more likely to experience DTPs compared to their younger counterparts. High prevalences of DTPs have similarly been reported in studies done among older adults [24, 25]. A systematic review on DTPs among older adults also reported a higher average number of DTPs per patient of (4.16) compared to an average of 1.56 observed in the current study [41]. It is possible that older age is significantly associated with occurrence of DTPs because older adults are more likely to be on numerous medications. This is because they are more likely to have multiple comorbidities compared to other age groups [26, 42–44]. Older adults are also more likely to have compromised function of metabolic organs. They are therefore prone to experiencing ADRs [26, 27] and having more advanced forms of diseases [45].

In the current study unemployment was significantly associated with occurrence of DTPs. This could be because unemployment, a common challenge in LMICs, is associated with poor socioeconomic status which affects adherence to treatment [46]. Poor socioeconomic status is also associated with high disease burden [47, 48]. In such a setting patients are trapped in a vicious cycle of frequently catching disease, failing to access proper and safe treatment and then remaining chronically diseased. Due to poor socioeconomic status among the unemployed patients are prone to having multiple comorbidities and therefore may resort to using herbal medicines or concomitant use drugs of various drugs that may have overlapping adverse effects [49–51].

Conclusion

This study highlights the burden of DTPs among patients receiving care for NDOs in a LMIC setting. It makes an effort to demonstrate that, even in cases when medications are readily available and accessible, DTPs which have been established to be notorious for undoing desired therapy outcomes can still occur. This study also shows that vulnerabilities like unemployment, female sex or being of older age may be significantly associated with occurrence of DTPs among patients receiving care for NDOs. The findings are suggestive of a gap in rational medicines use in the treatment of cancers in a LMIC setting. They also justify the necessity of a multidisciplinary team that includes clinical pharmacists to provide holistic care to each patient.

Limitations

In the current study the assumption was made that the prescriber fully documented their assessment of the patient including indication for prescribed medicines. This might have not been the case all the time. It is possible that some prescriptions appeared to have DTPs and yet they were made with justifiable clinical judgement. There was an attempt to remedy this limitation by having a physician on the research team who made a clinical assessment of each participant. Additionally, the participants' word was taken for it regarding whether they were using any other forms of therapy that were not prescribed at the study setting. This was prone to biases like recall bias, cognitive bias and social desirability bias.

Abbreviations

ADR	Adverse Drug Reaction
BMI	Body Mass Index
DTP	Drug Therapy Problem
LMIC	Low- and Middle-Income Country
NDO	Neoplasm of Digestive Organ
UCI	Uganda Cancer Institute

Acknowledgements

Not applicable.

Authors' contributions

AD conceptualized and collected data for the study. SMN and MN contributed to data generation and data analysis. SO provided main ideas for the study and also wrote the manuscript. SO, JI and TMY critically reviewed the manuscript. JI and TMY supervised the research process. All authors read and approved the final manuscript.

Funding

This study was done for academic purposes and was fully funded by the student who is also the principal investigator.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

Approval to conduct the study was obtained from Mbarara University of Science and Technology Research Ethics Committee (Reference number: MUST-2023-842). Written informed consent was obtained from the patients prior to participating in the study. This study was conducted in compliance with the declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

[1]Department of Pharmacy, Uganda Heart Institute, Kampala, Uganda
[2]Department of Pharmacy, Mbarara University of Science and Technology, Mbarara, Uganda

[3]Department of Pharmacy, Uganda Cancer Institute, Mbarara, Uganda
[4]Department of Clinical Pharmacy and Pharmacy Practice, School of Pharmacy, Kampala International University, Ishaka, Uganda

Received: 19 October 2024 / Accepted: 25 January 2026
Published online: 06 February 2026

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