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Prevalence and risk factors of chemotherapy-induced oral mucositis among adult cancer patients at the cancer unit of Mbarara Regional Referral Hospital

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Abstract

Background: Chemotherapy is a common treatment for cancer, but it is associated with adverse drug reactions like oral mucositis. This condition destroys basal cells in the oral mucosal layer, causing inflammation and ulceration. This can impact the patient's physical, emotional, and psychological well-being, affecting treatment outcomes and quality of life. This study aims to determine the prevalence, severity, and risk factors of chemotherapy-induced oral mucositis among adult cancer patients.

Methods: The study was a cross-sectional study conducted among adult cancer patients receiving chemotherapy at the cancer unit of Mbarara Regional Referral Hospital in southwestern Uganda. Data was collected through patient interviews, oral examinations, and patient chart reviews.

Results: Out of 268 patients, 115 (42.9%) experienced oral mucositis. Grade 2 oral mucositis was the most common (44.3%) followed by grade 1 (35.7%) and grade 3 (20.0%). Independent risk factors of chemotherapy-induced oral mucositis were female gender (Adjusted Odds Ratio (AOR) = 2.19, 95% confidence interval [CI]: 1.27–3.78; p-value = 0.005), poor oral hygiene (AOR = 3.70, 95% CI: 1.51–9.10; p-value = 0.04), and receiving chemotherapy containing an alkylating agent (AOR = 3.17, 95% CI: 1.63–6.19; p-value < 0.001).

Conclusion: The study found that two out of five chemotherapy patients developed oral mucositis, with nearly half being grade 2. The risk factors identified in our study were comparable to those reported in previous studies. Therefore, identification and assessment of cancer patients at high risk for chemotherapy-induced oral mucositis should be routinely done for proper and timely management.

KEYWORDS
cancer, chemotherapy, Mbarara, oral mucositis, prevalence

1 | INTRODUCTION

The burden of cancer and its associated mortality is rapidly growing worldwide.[1] According to the World Health Organization (WHO), nearly 10 million deaths were attributed to cancer in 2020.[2] It is projected that there will be about 26 million new cancer cases and 17 million cancer deaths per year by 2030.[3] In Uganda, approximately 32,000 new cases of cancer and 21,000 related fatalities were reported in 2018.[4]

Chemotherapy is the most common treatment modality for cancer, with approximately 57.7% of new cancer cases worldwide requiring chemotherapy. It is a form of treatment that uses drugs to kill cancer

cells or prevent them from proliferating in order to stop the growth of cancer cells.[5] Chemotherapy can be administered orally, intravenously, topically, or by injection, depending on the type and stage of the cancer being treated. It may be used alone or in conjunction with other therapies like biologic therapy, surgery, or radiation therapy.[6]

Due to their cytotoxic effects, cancer chemotherapy is limited by several adverse drug reactions.[7] An adverse drug reaction (ADR) is a reaction to a drug that is noxious and unintended and occurs at doses typically used in humans for the prevention, diagnosis, or treatment of disease or for altering any physiological function.[8] and it warrants prevention, specific treatment, a change of dose, or withdrawal of the drug product.[9] In addition to the high healthcare expenses associated with cancer treatment, it is estimated that more than half of cancer patients require hospitalization for further management as a result of chemotherapy-related adverse events.[10]

Many chemotherapeutic drugs target rapidly multiplying cancer cells, but they also affect rapidly multiplying normal tissues like bone marrow, oral mucosa, intestinal mucosa, hair follicles, and gonads. One of the significant adverse drug reactions from chemotherapy is oral mucositis, which results in the breakdown and atrophy of the basal cells of the mucosal covering layer this leads to mucosal inflammation and ulcerations which affects the function and integrity of the oral cavity as it is associated with pain and impairs functional activity like eating and swallowing as well as mental and emotional health. The risk of systemic infections is also increased which could affect treatment outcomes.[11–13]

It is estimated that oral mucositis can occur in 40% of patients receiving a standard dose of chemotherapy, in 75% of patients receiving high-dose chemotherapy, and in about 90% of patients who receive both chemotherapy and radiation treatments.[14] Oral mucositis in patients ranges in severity, depending on a number of distinct factors.[15] As a result, oral mucositis may lead to treatment interruptions, or even discontinuation, non-adherence to chemotherapy, and a marked reduction in the patient's quality of life.[16,17]

Despite the similarities in diagnosis and treatment, patients are not at equal risk of developing chemotherapy-induced oral mucositis as the toxicities of chemotherapeutic agents vary across individuals of different ages, ethnicities, races, and regions due to differences in pharmacogenetics and numerous related risk factors among various groups.[18]

Chemotherapy-induced oral mucositis has not been investigated in our setting. This study therefore aimed at establishing the prevalence of chemotherapy-induced oral mucositis, assessing its severity, and determining the risk factors among adult cancer patients at the cancer unit of Mbarara Regional Referral Hospital in South-Western Uganda.

2 | MATERIAL AND METHODS

2.1 | Study design and population

This was a cross-sectional study conducted among adult cancer patients receiving chemotherapy at Mbarara Regional Referral Hospital.

2.2 | Study setting

The study was conducted at the cancer unit of Mbarara Regional Referral Hospital which is a government-owned referral hospital located in Mbarara city approximately 268 km from Kampala the capital city. The hospital serves a population of approximately 4 million people and is a referral Centre for different districts in South Western Uganda.

The cancer unit of MRRH has a bed capacity of 38 beds with two specialist oncologists, one pharmacist, and seven nurses. On average 250 patients are initiated on chemotherapy every month from the cancer unit and about 600 patients receive chemotherapy every month from the cancer unit.

2.3 | Study period

The study was conducted for a period of 2 months from October 1, 2022, to November 30, 2022.

2.4 | Study participants

All patients who were receiving chemotherapy had previously received at least one cycle of chemotherapy in the last 4 weeks and were 18 years of age and above. Patients who had oral mucositis before initiation of chemotherapy were excluded.

2.5 | Sample size determination

The sample size for this study was determined using the Fisher's formula for estimation of sample size, $\mathbf{n = Z^2(p)(q)/d^2}$.[19] The Prevalence of chemotherapy-induced oral mucositis was accepted as **81.3%** from a study conducted in Ethiopia.[20] No recent or similar study was found in Uganda or from other neighboring countries. Adding 15% contingency for incomplete data or withdrawal from study, the sample size of the study was determined to be **268** adult cancer patients.

2.6 | Sampling technique

A consecutive sampling method was used to enroll 268 adult cancer patients receiving chemotherapy at the Mbarara Regional Referral Hospital cancer unit.

2.7 | Data collection procedure

Data was collected by patient interview, oral examination, and patient chart review. Research assistants, who included a clinical pharmacist, an internal medicine resident, a dental care practitioner, and nurses, were trained on the approved study protocol. The assessment of the severity of oral mucositis was done by an internal medicine resident after a thorough oral examination. Oral hygiene was assessed by a dental care practitioner, while patient interviews and chart reviews were

done by the clinical pharmacist and the nurses. A pretest of the data collection tool was conducted on 5% of the sample size (15 patients) before the actual data collection.

The data that was collected from the patient interview included patient demographics, other patient-related risk factors, and a history of oral mucositis. For very critically ill patients or patients not able to conduct the interview, data was collected from the caretaker who best knows the patient. The patient charts were reviewed for data on disease-related and treatment-related factors. Oral examination provided data on the severity of oral mucositis, the nature of the patient's oral hygiene, and the presence of oral infections secondary to oral mucositis.

The data on severity was collected using the WHO Oral Toxicity Scale Grading Tool, which assesses patients' ability to swallow and the general appearance of the mucosa in terms of color, swelling, and ulceration.[21] To assess the severity of oral mucositis, patients were first briefed on the intraoral examination. Using a light source, the inner parts of the mouth, which include the inner lips, the entire surface of the tongue, the soft and hard palate, and the oral mucosa, were examined. Oral hygiene was assessed using the simplified oral hygiene index,[22] with a score of 0–1.2 regarded as good; 1.3–3.0, fair; and 3.1–6.0, poor.[23]

The assessment for causality for oral mucositis was done using the Naranjo Adverse Drug Reaction Probability scale, with a score of less than 0 regarded as doubtful, a score of 1–4 as possible, a score of 5–8 as probable, and a score of 9 and above regarded as definite.[24]

To maintain the confidentiality of the data collected, the forms included unique patient identifiers, not patient names or chart numbers. Access to the data collected was restricted to only the study team and authorized people as per the approved protocol.

2.8 | Informed consent

Written Informed consent was sought from the participants before being interviewed for this study. For unconscious or critically sick patients unable to consent on their own, consent was sought from the caretaker before obtaining any information about the patient.

2.9 | Data management and analysis

The data collected during the study was entered in Microsoft Excel version 2016 and exported to SPSS software version 20 for analysis. The characteristics of the study population and the prevalence and severity of chemotherapy-induced oral mucositis were analyzed using descriptive statistics and presented with measures of central tendency, frequencies, and percentages. Univariate and multivariable logistic regression were used to determine the risk factors for oral mucositis. Variables with a p-value < 0.25 at univariate logistic regression were included in the multivariate logistic regression. A p-value < 0.05 and 95% confidence interval were used as cutoff points for determining the statistical significance of associations.

3 | RESULTS

3.1 | Participants' characteristics and clinical information

A total of 268 adult cancer patients were enrolled in this study. The enrolled patients consisted of 46.3% ($n = 122$) females and 53.7% ($n = 144$) males, with patients' ages ranging from 18 to 91 years, with a mean (SD) of 56.96 (15.78) years. Of these patients, 51.1% ($n = 131$) had a normal weight, while 28% ($n = 75$) were underweight, 15.3% ($n = 41$) were overweight, and 5.6% ($n = 15$) were obese. A positive history of smoking was present in 30.6% (82) of patients, and 46.6% ($n = 125$) had a positive history of alcohol consumption. The oral hygiene was found to be good in 53.4% ($n = 143$), fair in 35.8% ($n = 96$), and poor in 10.8% ($n = 29$). Among the types of cancers, 83.6% ($n = 224$) of the patients had a carcinoma, 9% ($n = 24$) had a sarcoma, 6% ($n = 16$) had lymphoma, and only 1.4% ($n = 4$) of the patients had a melanoma. 37.3% ($n = 100$) had stage IV cancer, 39.2% ($n = 105$) had stage III, 14.6% ($n = 39$) stage II and only 2.2% ($n = 6$) had stage I.

The most common cancer was breast cancer (18.3%), esophageal cancer (12.7%), prostate cancer (10.1%), stomach cancer (8.6%), colorectal cancer (7.8%) and 4.1% of the patients had Kaposi sarcoma (Figure 1).

Note that, 34% of the patients had a comorbid disease, and the most common diseases were hypertension (41.8%), peptic ulcer disease (26.4%), HIV/AIDS (24.2%), and diabetes mellitus (11%) (Figure 2).

The average number of chemotherapy cycles received was 3.3 (Table 1), and the average number of days to mucositis occurrence from the last chemotherapy cycle was 8 (Table 2).

3.2 | Prevalence of chemotherapy induced oral mucositis

The overall prevalence of oral mucositis after receiving chemotherapy was 42.9% (Figure 3). Note that, 60% of these patients had active oral mucositis at the time of this study, whereas 40% had recovered. All patients had received at least one cycle of chemotherapy with 70.5% of the patients having received chemotherapy for at most 1 year and 29.5% for more than 1 year. The causality assessment for oral mucositis was done using the Naranjo scale which showed that 48.7% of the cases were possible ADRs as 51.3% were probable ADRs. The mean score was 4.4 with a range of 2–7 and a mode score of 5.

3.3 | Severity of oral mucositis

Using the WHO Oral Toxicity Scale Grading of Oral Mucositis, most of the oral mucositis cases were of grade 2 (44.3%) followed by grade 1 (35.7%) and grade 3 (20.0%), and no patient had grade 4 mucositis (Figure 4).

Most patients on taxane-based chemotherapy (61.5%), platinum analogs (40.8%), vinca alkaloids (71.4%), cytotoxic antibiotics (66.7%),

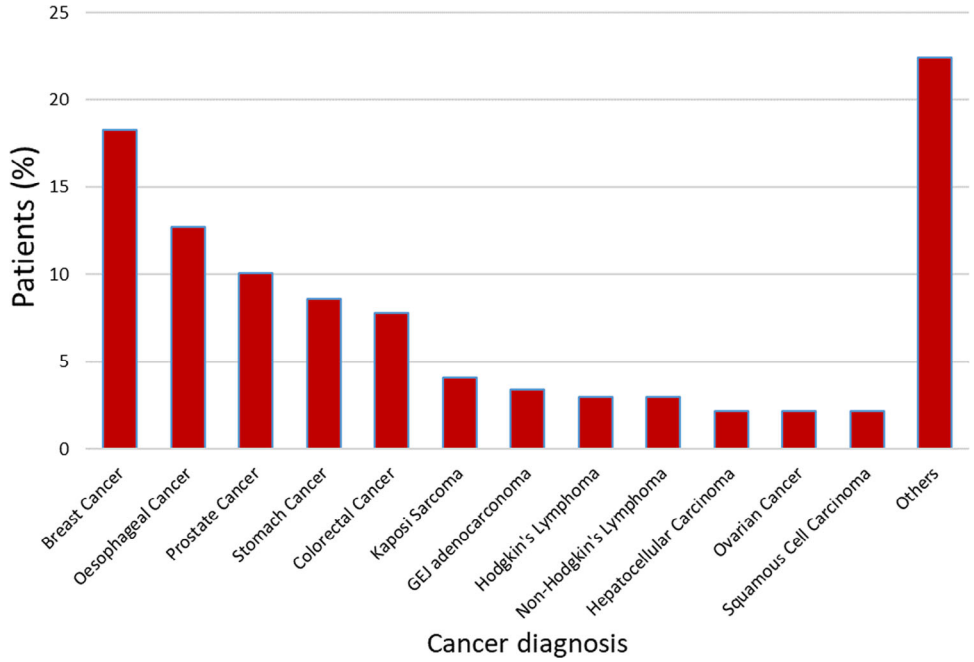

FIGURE 1 Common Cancer diagnosis among patients receiving chemotherapy at Mbarara Regional Referral Hospital Cancer Unit.

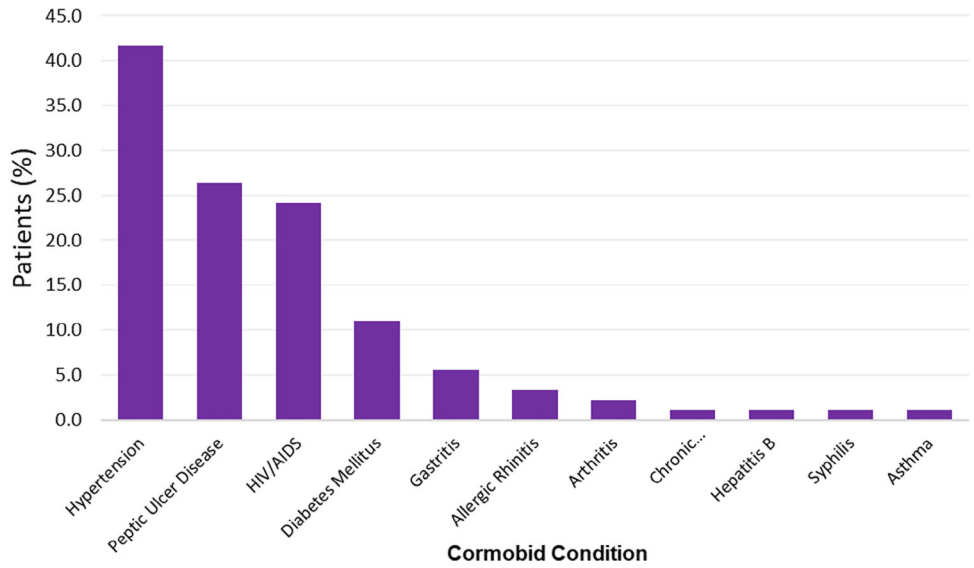

FIGURE 2 Common comorbid condition among cancer patients receiving chemotherapy at Mbarara Regional Referral Hospital Cancer Unit.

and podophyllotoxins (60%) developed grade 2 oral mucositis. Grade 1 oral mucositis was reported more among patients on antimetabolites (38.3%), alkylating agents (39.5%), and anthracyclines (38.2%) (Table 3).

3.4 | Factors associated with chemotherapy induced oral mucositis

Among 21 independent variables that were tested for association with incurring oral mucositis at univariate logistic regression, 7 showed statistical significance which includes: female gender (Crude Odds Ratio-COR = 2.35, 95% confidence interval [CI]: 143–3.86; *p*-value < 0.001), history of alcohol consumption (COR = 1.78, 95% CI: 1.09–2.90; *p*-value = 0.021), fair oral hygiene (COR = 1.71, 95% CI: 1.01–2.90; *p*-value = 0.046), poor oral hygiene (COR = 3.53, 95% CI: 1.53–8.18; *p*-value = 0.003), receiving taxane chemotherapy (COR = 0.48, 95% CI: 0.29–0.79; *p*-value = 0.004), antimetabolites (COR = 2.00, 95% CI: 1.22–3.28; *p*-value = 0.006), alkylating agents (COR = 3.48, 95% CI: 1.88–6.46; *p*-value < 0.001), and anthracyclines (COR = 2.15, 95% CI: 1.20–3.86; *p*-value = 0.011).

TABLE 1 Number of chemotherapy cycles received by the time of onset for oral mucositis.

Number cycles	Frequency; *n*(%)
1	26 (23.6)
2	16 (14.5)
3	20 (18.2)
4	20 (18.2)
5	15 (13.6)
6	7 (6.4)
7	3 (2.7)
8	3 (2.7)

TABLE 2 Time in days to occurrence of oral mucositis from the last chemotherapy cycle.

Time of onset (days)	Frequency; *n*(%)
2	1(0.9)
3	11(9.6)
4	1(0.9)
5	22(19.1)
7	44(38.3)
8	1(0.9)
10	15(13.0)
14	19(16.5)
21	1(0.9)

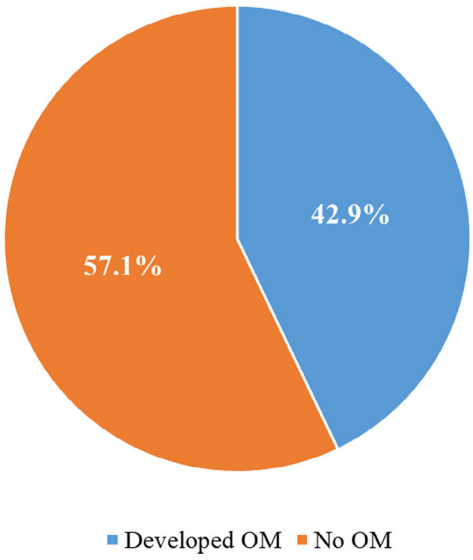

FIGURE 3 Prevalence of chemotherapy-induced oral mucositis among patients receiving chemotherapy at Mbarara Regional Referral Hospital cancer unit.

Seven variables including body surface area, comorbidity status, white blood cell count, time since first chemotherapy, receiving a platinum analog, vinca alkaloid, and podophyllotoxin, were excluded from multivariate analysis as each showed a *p*-value > 0.25 at univariate analysis.

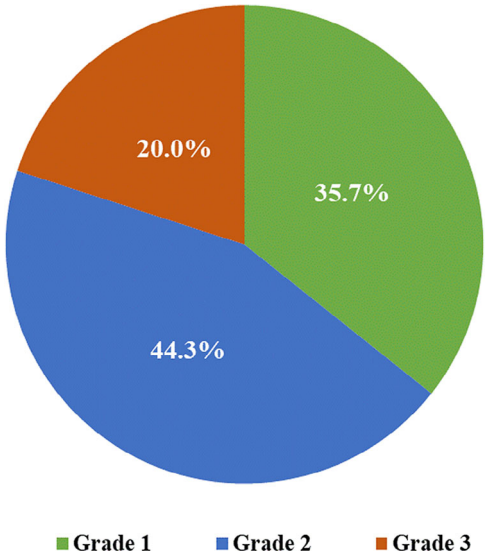

FIGURE 4 Grades of oral mucositis among patients who developed oral mucositis after receiving chemotherapy at Mbarara Regional Referral Hospital cancer unit.

TABLE 3 Grade of oral mucositis among patients according to the class of chemotherapy received at Mbarara Regional Referral Hospital cancer unit.

	WHO oral mucositis grade; *n* (%)		
Class of chemotherapy	Grade 1	Grade 2	Grade 3
Taxane	11(28.2)	24 (61.5)	4 (10.3)
Platinum analogs	16 (32.7)	20 (40.8)	13 (26.5)
Antimetabolites	23 (38.3)	20 (33.3)	17 (28.3)
Alkylating agents	15 (39.5)	14 (36.8)	9 (23.7)
Anthracyclines	13 (38.2)	13 (38.2)	8 (23.5)
Vinca alkaloids	1 (14.3)	5 (71.4)	1 (14.3)
Cytotoxic antibiotics	1 (16.7)	4 (66.7)	1 (16.7)
Podophyllotoxin	2 (40.0)	3 (60.0)	0

Fourteen variables all of which had a *p*-value < 0.25 were included in multivariate logistic regression analysis. Age of the patient, body mass index, history of smoking, history of alcohol consumption, stage of cancer, neutrophil count, receiving a taxane, antimetabolite, anthracycline, cytotoxic antibiotic and number of chemotherapy cycles received showed no significant association with the occurrence of oral mucositis after chemotherapy.

Three variables maintained their statistical significance during multivariate regression and these included the female gender (AOR = 2.19, 95% CI: 1.27–3.78; *p*-value = 0.005) compared to the male gender, poor oral hygiene (AOR = 3.70, 95% CI: 1.51–9.10; *p*-value = 0.04) compared to good oral hygiene, and receiving chemotherapy containing an alkylating agent (AOR = 3.17, 95% CI: 1.63-6.19; *p*-value < 0.001) compared to chemotherapy regimen without one. Female patients had about 2.19 times higher odds of experiencing oral mucositis after chemotherapy compared to males. Patients who had poor oral hygiene

TABLE 4 Univariate and multivariate logistic regression of factors associated with the occurrence of oral mucositis among patients receiving chemotherapy at Mbarara Regional Referral Hospital cancer unit.

Exposure variables		Outcome variable					
Variables	Categories	No OM Frequency (%)	'Presence of OM' Frequency (%)	COR (95% CI)	*p*-Value	AOR (95% CI)	*p*-Value
Gender	Female	57 (46)	and 67 (54.0)	**2.35 (1.43–3.86)**	**0.001**	**2.19 (1.27–3.78)**	**0.005**
	Male	96 (66.7)	48 (33.3)	1.00		**1.00**	
Age in years	<65	97 (53.3)	85 (46.7)	1.64 (0.96–2.78)	0.069	1.64 (0.91–2.98)	0.102
	> = 65	56 (65.1)	30 (34.9)	1.00		1.00	
BMI	Normal	86 (62.8)	51 (37.2)	1.00		1.00	
	Underweight	41 (54.7)	34 (45.3)	1.39 (0.79–2.48)	0.250	1.67 (0.86–3.22)	0.129
	Overweight	19 (46.3)	22 (53.7)	1.953 (0.96–3.95)	0.063	1.90 (0.85–4.24)	0.119
	Obese	7 (46.7)	8 (53.3)	1.93 (0.66–5.63)	0.230	1.88 (0.56–6.32)	0.310
BSA	Normal	75 (59.1)	52 (40.9)	1.00			
	Small	69 (56.1)	54 (43.9)	1.13 (0.68–1.87)	0.636		
	Large	9 (50.0)	9 (50.0)	1.44 (0.54–3.88)	0.468		
History of smoking	Yes	52 (63.4)	30 (36.6)	0.67 (0.40–1.17)	0.166	0.85 (0.43–1.68)	0.636
	No	101 (54.3)	85 (45.7)	1.00		1.00	
History of alcohol consumption	Yes	62 (49.6)	63 (50.4)	**1.78 (1.09–2.90)**	**0.021**	1.36 (0.74–2.48)	0.325
	No	91 (63.6)	52 (36.4)	1.00		1.00	
Oral hygiene	Good	93 (65.0)	50 (35.0)	1.00		1.00	
	Fair	50 (52.1)	46 (47.9)	**1.71 (1.01–2.90)**	**0.046**	1.69 (0.95–3.00)	0.076
	Poor	10 (34.5)	19 (65.5)	**3.53 (1.53–8.18)**	**0.003**	**3.70 (1.51–9.10)**	**0.04**
Comorbidity status	Yes	48 (52.7)	43 (47.3)	1.43 (0.86–2.40)	0.304	1.39 (0.75–2.56)	0.291
	No	105 (59.3)	72 (40.7)	1.00		1.00	
WBC count	Normal	112 (56.3)	87 (43.7)	1.00			
	Low	9 (50.0)	9 (50.0)	1.29 (0.49–3.38)	0.608		
	High	32 (62.7)	19 (37.3)	0.76 (0.41–1.44)	0.405		
Stage of cancer	I	2 (33.3)	4 (66.7)	1.00		1.00	
	II	24 (61.5)	15 (38.5)	0.31 (0.05–1.92)	0.209	0.33 (0.04–2.49)	0.283
	III	56 (53.3)	49 (46.7)	0.44 (0.08–2.49)	0.352	0.49 (0.07–3.44)	0.472
	IV	60 (60.0)	40 (40.0)	0.33 (0.06–1.91)	0.217	0.58 (0.08–4.12)	0.587
Time since the first chemotherapy	< = I year	106 (56.1)	83 (43.9)	1.00			
	> 1 year	47 (59.5)	32 (40.5)	0.87 (0.51–1.48)	0.607		
Neutrophil count	Normal	114 (57.0)	86 (43.0)	1.00		1.00	
	Low	6 (35.3)	11 (64.7)	2.43 (0.87–6.83)	0.092	2.04 (0.66–6.34)	0.217
	High	33 (64.7)	18 (35.3)	0.72 (0.38–1.37)	0.320	1.24 (0.58–2.66)	0.578
Taxane	Yes	79 (66.9)	39 (33.1)	**0.48 (0.29–0.79)**	**0.004**	1.35 (0.52–3.55)	0.539
	No	74 (49.3)	76 (50.7)	1.00		1.00	
Platinum analogs	Yes	64 (56.6)	49 (43.4)	1.03 (0.63–1.68)	0.898		
	No	89 (57.4)	66 (42.6)	1.00			
Antimetabolites	Yes	54 (47.4)	60 (52.6)	**2.00 (1.22–3.28)**	**0.006**	1.47 (0.82–2.63)	0.193
	No	99 (64.3)	55 (35.7)	1.00		1.00	
Alkylating agents	Yes	19(33.3)	38 (66.7)	**3.48 (1.88–6.46)**	**<0.001**	**3.17 (1.63–6.19)**	**<0.001**
	No	134 (63.5)	77 (36.5)	1.00		1.00	
Anthracyclines	Yes	25 (42.4)	34 (57.6)	**2.15 (1.20–3.86)**	**0.011**	0.91 (0.29–2.79)	0.866
	No	128 (61.2)	81 (38.8)	1.00		1.00	

(Continues)

TABLE 4 (Continued)

Exposure variables		Outcome variable					
Variables	Categories	No OM Frequency (%)	'Presence of OM' Frequency (%)	COR (95% CI)	*p*-Value	AOR (95% CI)	*p*-Value
Vinca alkaloids	Yes	8 (53.3)	7 (46.7)	1.18 (0.41–3.34)	0.762		
	No	145 (57.3)	108 (42.7)	1.00			
Cytotoxic antibiotics	Yes	3 (33.3)	6 (66.7)	2.75 (0.67–11.25)	0.159	2.54 (0.54–11.91)	0.238
	No	150 (57.9)	109 (42.1)	1.00		1.00	
Podophyllotoxins	Yes	5 (50.0)	5 (50.0)	1.35 (0.38–4.76)	0.645		
	No	148 (57.4)	110 (42.6)	1.00			
Chemotherapy cycles	< = 3	66 (64.1)	37 (35.9)	1.00			
	>3	86 (52.8)	77 (47.2)	1.60 (0.96–2.65)	0.070	1.52 (0.86–2.68)	0.150

showed about 3.70 times higher odds of getting oral mucositis. As compared to other chemotherapy regimens, patients receiving regimens containing an alkylating agent had about 3.17 times higher odds of developing oral mucositis (Table 4).

4 | DISCUSSION

During this study, the prevalence of chemotherapy-induced oral mucositis was determined to be 42.9%. This prevalence is considerably lower than those previously reported in other countries; 90.16% in Thailand,[25] 81.3% in Ethiopia,[20] 51.7% in Turkey,[26] 71.7% in South Africa,[27] 75.% in Taiwan.[28] This difference in prevalence can be explained by the fact that most of these studies were conducted in specific types of cancers, unlike this study which included all patients with cancer. This is because oral mucositis may be more prevalent in specific cancers compared to the others in different populations.[29] Additionally, a more prevalent use of chemoradiation in some of the previous studies might contribute to the risk of developing oral mucositis.[30] Some of these studies also were prospective in nature and had a high detection rate for ADRs,[31] compared to our study design which was cross-sectional. It could also be explained by better pharmacovigilance systems in different countries compared to the one in our settings which lead to better detection and reporting of ADRs. However, the current prevalence is higher than the prevalence reported of 6.3% in Brazil,[32] and 22.3% reported in Italy.[33] This could be partly explained by different study designs used and the different and ever-changing treatment protocols in different cancers that are associated with varying risks of developing ADRs like oral mucositis.[34,35] The severity of oral mucositis among patients was done using the WHO oral toxicity scale which combines both the objective and subjective variables to measure anatomical, symptomatic, and functional components of oral mucositis.[21,36,37]The findings on the severity of chemotherapy-induced oral mucositis vary across different studies. In this study, most patients (80%) developed a mild form of oral mucositis of grades 1 and 2 as compared to 20% who developed severe oral mucositis of grades 3 and 4. These findings are comparable to those reported in South Africa,[27] which showed 70.7% of patients developed mild oral mucositis, and in Thailand which reported mild oral mucositis in 70.5%.[25] However, the current incidence of severe oral mucositis was considerably lower to 46% in Europe[38] and 52.5% in a clinical trial conducted in France.[39] The higher incidence of severe oral mucositis in previous studies might be explained by the prospective design which provides real-time reporting of occurrence and assessment of severity as compared to our study which assessed patients at the time of hospital visit where the severe form could have resolved already. Moreover, a higher rate of concurrent use of chemotherapy and radiotherapy in previous studies might have resulted in severe forms of oral mucositis.[40] A study in Europe, for example, involved the use of high-dose chemotherapy which has been shown to result in severe forms of ADRs as compared to standard doses.[41] The current lower prevalence of severe oral mucositis could be because more patients were on standard doses of chemotherapy with no patient receiving radiotherapy concurrently and more so, partly because there was delayed reporting from the time oral mucositis occurred. Therefore, patients and caretakers should be taught proper assessment so that at the time of the hospital visit, there are clear records.

The risk factors identified in this study were generally comparable to those reported in previous studies.[26,42] On univariate logistic regression, female gender, history of alcohol consumption, poor oral hygiene, taxane chemotherapy, antimetabolites, alkylating agents, and anthracyclines were all associated with chemotherapy-induced oral mucositis. Only female gender, poor oral hygiene, and alkylating agents were identified as independent risk factors on multivariate logistic regression.

Females were at about 2.35 times higher odds of developing oral mucositis compared to males. This finding was consistent with several previous studies.[29,43–47] This increased risk of cytotoxicity and oral mucositis has been linked to hormonal changes in females that exert direct and indirect effects on the physiology of the oral cavity contributing to the development of oral mucositis.[48,49] A number of sex-related physiological differences such as differences in the pharmacokinetics and pharmacodynamics of drugs in females as compared to males,[50] lead to differences in activity of enzymes that may

predispose females to an increased risk of developing ADRs.[51] Sex hormones like estrogens and progestins have also been shown to have an important role in the occurrence of ADRs by influencing immune responses, affecting the distribution, metabolism, and hepatic and renal clearance of drugs which increase the risk of developing drug-related toxicities.[52] This may explain the increased risk of developing chemotherapy-induced oral mucositis among female patients. Therefore, risk assessment for oral mucositis is recommended at every visit for timely management of oral mucositis among female cancer patients.

Patients with poor oral hygiene were found to have about 3.70 times higher odds of developing chemotherapy-induced oral mucositis when compared to those whose oral hygiene was good. This is in line with other studies among cancer patients,[30,53–56] that revealed that poor oral hygiene is an independent risk factor for the development of oral mucositis. Having and maintaining proper oral hygiene is fundamental in oral care,[57] as it helps to remove plaque and other debris that can contribute to the development of oral mucositis.[58] Studies have also shown that the incidence and severity of mucositis can also be decreased with intensive oral care.[59] This highlights the importance of effective patient oral health education,[60] especially when receiving chemotherapy, and also the adoption of a multidisciplinary approach to the care of patients on chemotherapy.[61] Healthcare practitioners managing patients on chemotherapy, should provide oral care education; and a multidisciplinary approach of care which includes dental care practitioners should be adopted in patients who may be found at high risk of incurring chemotherapy-induced oral mucositis.

Receiving an alkylating agent in the chemotherapy regimen increased the odds of getting oral mucositis by 3.17 times. Alkylating agents are a class of antineoplastic drugs that stop protein synthesis by inhibiting the transcription of DNA into RNA and examples include cyclophosphamide, ifosfamide, melphalan, and dacarbazine among others.[62] The findings of this study were in agreement with several studies.[41,63–66] The cytotoxicity of alkylating agents could be because these agents cause DNA damage in fast-growing cells like in the oral mucosa and inhibit normal cellular replication, transcription, and translation.[67] Alkylating agents also promote molecular changes which lead to cell death by inducing oxidative stress through glutathione depletion, lipid peroxidation, and an increase in reactive oxygen species,[68] and in addition, these events cause inflammation,[69] that contribute to alkylating agent-related toxicities like oral mucositis. It is therefore essential for clinicians to use targeted treatment of cancer cells where available which protects normal cells and closely monitor patients initiated on alkylating agents especially those other risk factors for oral mucositis in order to institute proper and timely management.

In previous studies, other various factors were identified to be independent risk factors for chemotherapy-induced oral mucositis but, in our study, these factors were not found to be statistically significant on multivariate logistic regression analysis. Case in point, history of alcohol drinking,[53,70] receiving antimetabolite or anthracycline chemotherapy,[34,71–77] age of the patient,[25,26,78–82] history of smoking,[82,83] body surface area and body mass index of the patient.[84–87] This shows that the etiology of chemotherapy-induced oral mucositis is multifactorial and differences in populations such as genetic differences in populations, differences in treatment protocols and guidelines, differences in study designs, and differences in the distribution of comorbidities and other risk factors may predispose patients to a different extent. A larger prospective, multicentered study is recommended to investigate fully these factors in our setting.

4.1 | Limitations of the study

The severity of oral mucositis was assessed only based on the grade of oral mucositis at the time of data collection. This could have captured the grade when mucositis is not yet at its peak or when it is already resolving. A prospective study design or using a patient-reported adverse event take-home tool to ably monitor the grade of oral mucositis in real-time.

The study did not capture other treatment alternatives, like herbal medicines and other self-medications, that the patients could have used. These drugs could have contributed to both the development of oral mucositis and its resolution. In future studies, a comprehensive tool to capture both the prescribed and non-prescribed medication histories should be used.

5 | CONCLUSION

About two out of five patients on chemotherapy developed oral mucositis and nearly half of which were rated as grade 2. Being female, having poor oral hygiene, and receiving an alkylating agent were identified as independent risk factors for chemotherapy-induced oral mucositis. The current prevalence shows that there is a significant burden of chemotherapy-induced oral mucositis among cancer patients and routine identification and assessments for patients at high risk should done so that there is proper and timely management. Even though the severity of oral mucositis was found to be mild in the majority of patients, it still substantially affected the patients and a prospective study is recommended to better report the severity of chemotherapy-induced oral mucositis.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

ETHICS STATEMENT

The study protocol was approved by the Research Ethical Committee of Mbarara University of Science and Technology (MUST-2022-573) and the Faculty Research Committee of the Faculty of Medicine, MUST. The study was also conducted in compliance with the Declaration

of Helsinki, and the confidentiality of the patients' information was protected.

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