

Cancer Management and Research

ISSN: 1179-1322 (Online) Journal homepage: www.tandfonline.com/journals/dcmr20

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To cite this article: Godwin Nimusiima, Sarad Pawar Naik Bukke, Awad Osman Abdalla Mohamed, John Martin Tumwebaza, Radiana Makuza Kabera, Joel Sebisaalu, Amina Abubakar, Patrick Kitheka Muasya, Bayapa Reddy Narapureddy, Nyakato Caroline, Silas Ojuka, John Isiiko & Tadele Mekuriya Yadesa (2026) Determinants of Adverse Events in Patients with Cancer Who Practiced Self-Medication: A Cross-Sectional Study in Southwestern Uganda, Cancer Management and Research, , 603947, DOI: 10.2147/CMAR.S603947

To link to this article: https://doi.org/10.2147/CMAR.S603947

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Published online: 02 Jun 2026.

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ORIGINAL RESEARCH

Determinants of Adverse Events in Patients with Cancer Who Practiced Self-Medication: A Cross-Sectional Study in Southwestern Uganda

Godwin Nimusiima[1], Sarad Pawar Naik Bukke[2], Awad Osman Abdalla Mohamed[3], John Martin Tumwebaza[1], Radiana Makuza Kabera[1], Joel Sebisaalu[1], Amina Abubakar[1], Patrick Kitheka Muasya[1], Bayapa Reddy Narapureddy[4], Nyakato Caroline[5], Silas Ojuka[5], John Isiiko[6], Tadele Mekuriya Yadesa[1,7]

[1]Department of Pharmacy, Mbarara University of Science and Technology, Mbarara, Uganda; [2]Department of Pharmaceutics and Pharmaceutical Technology, Kampala International University, Ishaka, Uganda; [3]Department of Anesthesia and Operations, King Khalid University, Abha, Saudi Arabia; [4]Department of Public Health, King Khalid University, Abha, Saudi Arabia; [5]Department of Pharmacy, Uganda Heart Institute, Kamapala, Uganda; [6]Department of Pharmacy, Uganda Cancer Institute, Mbarara, Uganda; [7]Department of Clinical Pharmacy and Pharmacy Practice, Kampala International University, Ishaka, Uganda

Correspondence: Tadele Mekuriya Yadesa, Email maatiikoo4@gmail.com

Background: Cancer therapies have been the cornerstone in cancer care. Co-morbidities and Adverse Events (AEs) often encourage some patients with cancer to resort to self-medication in search of relief or better symptom management. While self-medication is a key aspect of self-care and may offer some relief, it also poses risks, especially the potential for AEs. Limited data exist in Uganda, particularly at the Mbarara Regional Referral Hospital (MRRH) Cancer Unit, regarding the prevalence and determinants of AEs.

Objective: To determine the prevalence and factors associated with AEs among self-medicating cancer patients at the MRRH Cancer Unit.

Methods: A cross-sectional study was conducted from 1st of February to 31st of March 2025, among patients with cancer attending the MRRH Cancer Unit. Using Cochran's formula, the sample size was estimated to be 270 patients who were recruited using consecutive sampling technique. Data were collected using interviewer-administered questionnaires and patient records, with medication reconciliation performed to identify both prescribed and self-medicated drugs and herbal products. AEs were graded using the Common Terminology Criteria for AEs. Descriptive statistics and binary logistic regression tests were performed using STATA version 17.0 employing and binary logistic regression tests.

Results: Out of 270 participants, 218 (80.7%) experienced AEs. Grade 1 was the most common (49.8%) followed by grade 2 (41.4%), and grade 3 (8.8%). The determinants of AEs included the use of alkylating agents (AOR=3.6, 95% confidence interval CI: 1.02–12.51; p-value= 0.046), self-medication with drugs for acid-related disorders (AOR=7.9, 95% CI: 1.79–35.41; p-value=0.006) and herbal medicines use (AOR=2.1, 95% CI: 1.09–4.22; p-value=0.026).

Conclusion: AEs among self-medicating patients with cancer are highly prevalent at MRRH cancer unit. Therefore, implementing comprehensive medication review in this population, and applying active ADE risk classification and closer monitoring in high-risk patients, including those on any alkylating agents and those who use herbal products, is crucial to minimize the ADEs and ensure safe use these products.

Keywords: self-medication, determinants, chemotherapy, adverse events, cancer, Uganda

Introduction

Globally, the cancer burden is growing rapidly, amidst mounting need for health services.[1] By 2040, the global cancer burden is projected to reach 28.4 million cases, representing a 47% increase from 2020.[2] Cancer is the second-leading cause of death in the United States overall, and the leading cause among people younger than 85 years.[3] In Uganda, the incidence of cancer is on the rise, with cervical cancer, Kaposi sarcoma, breast cancer, prostate cancer, and non-Hodgkin lymphoma being the most prevalent types.[4] Cancer as a chronic condition leads to illness, disabilities, and financial burdens, significantly impacting the quality of life for individuals, families, communities and requiring individualized treatment.[5]

https://doi.org/10.2147/CMAR.S603947
Received: 16 February 2026
Accepted: 26 May 2026
Published: 3 June 2026

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Cancer treatment is complex, requiring multiple disciplines and different treatment modalities provided in diverse care settings.[6] Although significant efforts are made to reduce medical and social risks linked to cancer therapies, many treatments have been associated with long-term effects.[7] Moreover, patients with cancer often experience ADE, which further complicates their quality of care.[8] Co-morbidities and AEs often encourage some patients with cancer to resort to self-medication in search of relief or better symptom management.[9]

Self-medication, as defined by the World Health Organization (1998), is the "use of drugs to treat self-diagnosed disorders or symptoms or the intermittent or continued use of prescribed drugs for chronic or recurrent disease or symptoms". A study conducted in patients with cancer demonstrated that pain and fever are the most frequently reported symptoms leading to self-medication, followed by cough and cold.[10] Other patients tend to self-medicate in order to manage the AEs caused by their medication regimen.[11] While self-medication is a key aspect of self-care and may offer some relief, it also poses risks, especially the potential for AEs.[12]

AEs, as defined by National Cancer Institute, "are undesired effects of a drug or other type of treatment".[13] Patients receiving cancer treatment face the risk of various AEs that can lead to significant morbidity, mortality, and costs related to their treatment.[14] In patients with cancer, severe AEs, including iatrogenic harm due to drug–drug interactions, have been linked to self-medication practices.[15] A prospective study indicated that 1.7% of AEs were associated with self-medication.[16] Medications such as quinolones, opioids, and other agents like St. John's Wort and garlic used in self-medication can produce unexpected or dangerous effects when combined with cancer therapies.[17] One study found a higher risk of death among breast patients with cancer who self-medicated with Graviola or Alenda. The higher morbidity and mortality associated with self-medication in patients with cancer is explained by the increased risk of drug–drug and drug–herbal interactions that may increase the serum concentration of chemotherapeutic agents leading to serious toxicities including to the vital organs like heart, kidneys, and the liver.[18]

Given these risks, there is limited knowledge about AEs in self-medicating patients with cancer in resource-limited settings, particularly at the cancer unit of MRRH. Additionally, this study explored the determinants of AEs, with the goal of identifying opportunities for intervention and education to improve patient safety. The objectives of this study included: assessing the occurrences, types, and determinants of AEs in self-medicating patients with cancer at the cancer unit of MRRH.

Methods and Materials

Study Design

A cross-sectional study was conducted among adult patients with cancer attending cancer unit at Mbarara Regional Referral Hospital. This study assessed AEs in patients who self-medicated over the past 4 weeks.

Study Setting and Period

This study was conducted at the Cancer Unit of Mbarara Regional Referral Hospital (MRRH) from 1st of February to 31st of March 2025. MRRH is a government aided and a teaching facility for the Mbarara University of Science and Technology (MUST), with a total bed capacity of 350 beds, serving a population of over four million people from the Districts of Mbarara, Buhweju, Bushenyi, Mitoma, Ntungamo, Kazo, Kiruhura, Ibanda, Isingiro, Rubirizi, Rwampara, Sheema, and Mbarara City in South Western Uganda. The MRRHCU has a bed capacity of 38 beds (20 and 18 beds for adult and pediatric patients, respectively) with two clinic days (Tuesday and Thursday) on the adult wing attending to averagely 70 patients per clinic day. Financial year ending June 2023, they recorded 750 new cases, approximating 75 new patients per month. Mbarara Regional Referral Hospital Cancer Unit (MRRHCU) utilizes a variety of anti-cancer agents including monoclonal antibodies, antimetabolites (methotrexate, capecitabine), antitumor antibiotics (bleomycin), plant alkaloids (Vincristine and docetaxel) alkylating agents (cyclophosphamide) and endocrine therapies (Goserelin, bicalutamide) among other therapies in management of cancer. The unit is staffed with 13 health personnel (two (2) medical oncologists, two (2) medical officers, one (1) oncology pharmacist, one (1) pharmacist, and seven (7) Nurses.

Target Population

All adult out-patients above 18 years of age receiving anticancer therapy at MRRHCU.

Study Population

- Adult Self-medicating patients with cancer who were receiving anti-cancer therapy at MRRHCU and met the inclusion criteria.
- Medical records of patients with cancer were used for the study.

Inclusion Criteria

- Self-medicating adult patients with cancer aged 18 years and above.
- Patients with confirmed cancer diagnosis.
- Patients currently on any cancer treatment.

Exclusion Criteria

- Patients who did not provide comprehensive information
- Patients who were unconscious or critically sick patients unable to consent on their own.
- Patients without the required laboratory test results for screening of ADRs

Sample Size Determination

The sample size was determined by using Cochran formula; $N \geq Z^2P\ (1\text{-}P)/d^2$.[19] A margin of error of 6% was selected based on feasibility and resource considerations while maintaining acceptable statistical power. The prevalence of AEs among patients with cancer was determined based on a similar study conducted in Kenya, which reported a prevalence of 100%.[20] Because of the prevalence 100%, this makes direct statistical computation impractical, a conservative prevalence of 50% was adopted to ensure maximum variability and obtain an adequate sample size. Added 1.5% for contingency for incomplete data or withdraw from the study. The final sample size of the study was (n) 270 adult patients with cancer.

Sampling Techniques and Participant Enrolment

A consecutive sampling technique was used to recruit adult patients with cancer who self-medicated and were receiving cancer treatment at the cancer unit during the study and data collection period. In this approach, patients who meet the eligibility criteria based on the screening tool were enrolled. Data was gathered over a one-month period on clinic days (Tuesdays and Thursdays) until the target sample size is reached. Patient files were be organized to include only those attending during the study period until the sample size is attained.

Identification of Self-Medicating Patients

The principal investigator and the oncology resident screened patients to identify those who self-medicated while undergoing anticancer therapy. Medication reconciliation was performed on patients who reported self-medication to identify both the drugs and herbs they had used. They were then subjected to eligibility screening tool which screened the patients according to predefined inclusion and exclusion criteria. Patients who meet the eligibility criteria were enrolled for the study.

Data Collection Tools

Both English and Runyankole questionnaires were developed and pre-tested on 5% of the sample size (14 patients) at MRRHCU before actual data collection. The questionnaire, which includes a checklist of AEs, is adopted from a similar study conducted in the Netherlands.[21] A data collection form was used to extract information from the patients' medical records. ONCOassist® software was used to categorize and grade the severity observed AEs according to Common Terminology Criteria for AEs (CTCAE) version 5.[22] The grades were defined as follows: grade 1 for mild or asymptomatic, grade 2 for limiting instrumental activities of daily living, grade 3 for hospitalization without life-threatening conditions, grade 4 for life-threatening risk, and grade 5 for death.[23]

Data Collection Procedure

Before the study begun, two research assistants, who were registered oncology nurses, received training on data collection protocols, ethical considerations and AE detection and documentation.

Eligible patients were interviewed using a questionnaire to gather information on self-medicated drugs, as well as their baseline socio-demographic, medical history and AEs. All patients who attended the clinic, were subjected to a preliminary screening tool and assessed for eligibility as potential study participants. Data was collected every week on clinic days (Tuesday and Thursday) until the sample size is attained.

Patients were enrolled as study participants by the principal investigator and research assistants upon voluntarily consenting to participate in the study by consenting. An interview was carried out using a questionnaire and a data collection tool to gather information on medication history and self-medication, followed by screening for AEs. Patients who reported having self-medicated in past four weeks were assessed to identify the medications they used and any associated AEs.

Minimizing Recall and Social Desirability Bias

To minimize recall bias, patients were interviewed about the self-medicated drugs they used and the AEs they experienced within the past month. The questions were framed as research-oriented and non-judgmental. The interviews were conducted in a neutral private setting to reduce fear of judgment. Participants were assured of anonymity and confidentiality in the informed consent.

AEs Screening

AEs were screened in only individuals who reported having self-medicated in the past 4 weeks. The results were analyzed for the frequency and severity of AEs. The study included AEs documented in patients' medical records and those reported directly by the patient, while excluding AEs that required laboratory analysis or measurement devices for detection. Once AEs were identified and validated, they were categorized according to their severity, which was classified based on the Common Terminology Criteria for AEs.

Data Analysis

Stata version 17.0 software program was used for quantitative analysis (descriptive statistics, and logistic regression analysis). In descriptive analysis, the prevalence of AEs among self-medicating patients with cancer was calculated by dividing the number of patients who has at least one clinically significant AE by the total number of patients to be studied, and were expressed as a percentage. The severity of AEs in self-medicating patients with cancer were categorized using the Severity Scale, specifically the CTCAE. In descriptive analysis, determinants of AEs among self-medicating patients with cancer such as patients' demographics, disease related, type of anti-cancer and type of self-medicated drug variables were presented using mean, median with interquartile range and percentages (%). In inferential statistics, bivariate and multivariate logistic regression were employed to determine the independent determinants of AEs. Variables with $p < 0.25$ in the bivariate analysis were included in the multivariate logistic regression. In the multivariate model, P values <0.05 were considered statistically significant.

Data Quality Control

The research team comprised two research assistants, a pharmacy student and a pharmacy intern. To ensure accuracy of the collected data, they were trained on the data collection protocols and ethical considerations and undertook the Responsible Conduct of Research training and held a valid certificate of completion before the study started. Questionnaires were developed in both English and Runyankole, and a pre-test was conducted with 20 patients at MRRHCU to ensure the tool's feasibility before actual data collection. Close supervision and monitoring of the data collection process was routinely done by the principal investigator to ensure completeness of the data.

Data Quality Assurance

AE severity score was assessed at different times, the test–retest reliability was measured by having the same principal investigator (PI) assess the same AEs at two different times during the pretest. High correlation in scores would indicate

consistent results over time. Oncology pharmacist was engaged to review the data collection tools (AE and self-medication data collecting tools) and grading tools to verify that they all include all necessary items for accurately capturing AE severity based on clinical standards of Common Terminology Criteria for AEs.

Ethical Consideration

This study was conducted in accordance with the declaration of Helsinki. The study protocol was approved by the Research Ethical Committee of Mbarara University of Science and Technology (MUST-REC), with ref no. MUST-2024-1962. Administrative clearance was sought from the Department of Pharmacy, Faculty Research Committee and Hospital Director MRRH before starting the study. Informed consent was sought from the participants before being interviewed for this study. We maintained confidentiality by ensuring participants' names did not appear on data collection tools; instead, each form carried a unique identifier. All the data collected was kept under lock and key to restrict access apart from the study team. The computer for data analysis was password protected.

Results

Patients' Demographic Characteristics

A total of 270 self-medicating adult patients with cancer who received anticancer therapy were enrolled in this study. The majority of patients were males (n = 169, 62.5%). The mean age was 58.6 years (±16.2), with 49.6% of the patients aged 60 years and above. The median body surface area (BSA) was 1.6m^2, with an interquartile range (IQR) of 1.5 to 1.7 m^2. Body Mass Index (BMI) categories showed over 55.1% of the participants had a normal weight, while 16.6% were underweight as shown in Table 1 below.

Clinical and Medication-Related Characteristics

The median time since cancer diagnosis among the 270 participants was 2 years (IQR:1.0 to 2.0 years). Regarding chemotherapy cycles received, the median cycle was 4 (IQR: 3.0 to 5.0 cycles). Cancer staging data indicated that the

Table 1 Patient's Characteristics of Adult Patients with Cancer at Oncology Unit of MRRH

Characteristics	**Category**	**Frequency (%) N = 270**
Age category (years) Mean ± SD= (58.6±16.2)	18–39	38(14.1)
	40–59	98(36.3)
	≥60	134(49.6)
Gender	Male	169(62.5)
	Female	101(37.4)
Body Mass Index (BMI, Kg/m^2)	Underweight	45(16.6)
	Normal weight	149 (55.1)
	Overweight	52(19.2)
	Obesity	24(8.9%)
BSA (m^2)	<1.5	66(24.4)
	1.5–1.8	174(64.4)
	1.9–2.1	30 (11.1)

Abbreviations: SD, Standard Deviation; IQR, Interquartile Range.

Table 2 Clinical Characteristics of Adult Patients with Cancer at the Oncology Unit of MRRH

Characteristics		Category	Frequency (%) N = 270
Time since Cancer Diagnosis (years), median (IQR) Mean ± SD (1.6 ±0.6)			2.0 (1.0, 2.0)
Chemotherapy cycles received median (IQR), Mean ± SD (4.4 ± 2.7)			4 (3.0, 5.0)
Cancer stage		Early stage	67 (24.8)
		Advanced stage	198 (73.3)
		Not staged	5 (1.9)
Comorbidities	HIV	Yes	46 (17.0)
		No	224 (83.0)
	Hypertension	Yes	29 (10.7)
		No	241 (89.3)
	Diabetes Mellitus	Yes	5.0 (1.9)
		No	265 (98.1)
	Others*	Yes	9 (3.3)
		No	261(96.7)

Notes: *Heart failure (1), Acute kidney failure (1), Typhoid, Sepsis (2), Hepatitis B (2), Pneumonia (1), Anaemia (1), Asthma (1).
Abbreviations: HIV, Human Immunodeficiency Virus; SD, Standard Deviation; IQR, Interquartile Range.

majority of participants (43.0%) were at stage 4, while a small proportion (1.9%) were not staged. Comorbidities were present in 29.3% of participants, with HIV and hypertension being the most common, as shown in Table 2 below.

Prostate cancer was the most commonly diagnosed, accounting for 26.3% of cases, followed by breast cancer at 13.7%. Esophageal and gastric cancers were also prevalent, representing 10.4% and 8.1% of cases, respectively, as illustrated in Figure 1 below.

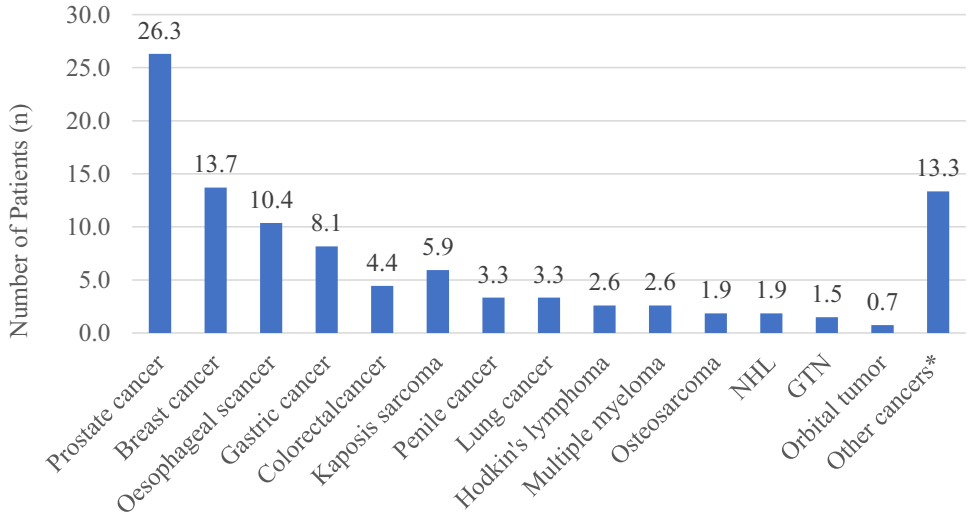


Figure 1 Commonly diagnosed cancers among patients with cancer at the oncology unit of MRRH. *Tongue tumors (3), urothelial carcinoma (2), Head and Neck cancers (2), Nasopharyngeal carcinoma (2). Papillary Thyroid Carcinoma (2), Dermato fibrosarcoma (1), Choriocarcinoma (1), Cervical cancer (1) Acute myeloid leukemia (1), Gastrointestinal Stromal Tumors (1), Germ cell tumor (1), Chronic lymphocytic leukemia (1), Mucoepidermoid (1), Myxoid lipoma (1).

https://doi.org/10.2147/CMAR.S603947

Taxanes were the most frequently prescribed chemotherapy class, used in 126 cases (46.7%), platinum analogs and antimetabolites followed, prescribed in 99 (36.7%) and 86 (31.9%) cases, respectively (Figure 2).

Self-Medication-Related Characteristics

Most of the patients with cancer were self-medicating to manage pain (56.3%), followed by Epigastric discomfort (27.8%) and cough (18.2%). Over 500 drugs were reported to be used for self-medication. The most commonly used drugs were analgesics (47.8%) and antibiotics (27.4%), which are classified as N02 and J01, respectively, according to the ATC drug classification. Regarding duration of self-medication, a duration of the self-medication was considered from the starting to stopping the self-medication or up to the data collection date if not stopped. Accordingly, majority self-medicated for 1 to 6 months (46.7%). Data from herbal use indicated that almost half of the participants used herbs, as illustrated in Table 3 below.

Prevalence of AE Among Self-Medicating Patients with Cancer

Out of 270 participants enrolled in this study, 218 (80.7%: 95% CI: 75.5–85.3) experienced an AE as illustrated in Figure 3 below.

Characteristics of AEs Among Self-Medicating Patients with Cancer

A total of 331 AEs were reported in this study. Gastric ulcers were the most frequently reported, accounting for 18.4% of all events, followed by nausea at 11.8% and vomiting at 6.9% as illustrated in Figure 4 below.

Severity of AEs Among Self-Medicating Patients with Cancer

According to the Common Terminology Criteria for AEs, most AEs were Grade 1 (49.8%), followed by Grade 2 (41.4%) and Grade 3 (14%). Gastric ulcers were most frequently reported at Grade 1 (10%) and Grade 2 (6%), while nausea and vomiting predominated at Grade 3 (3.9%) as illustrated by the Figure 5 below.

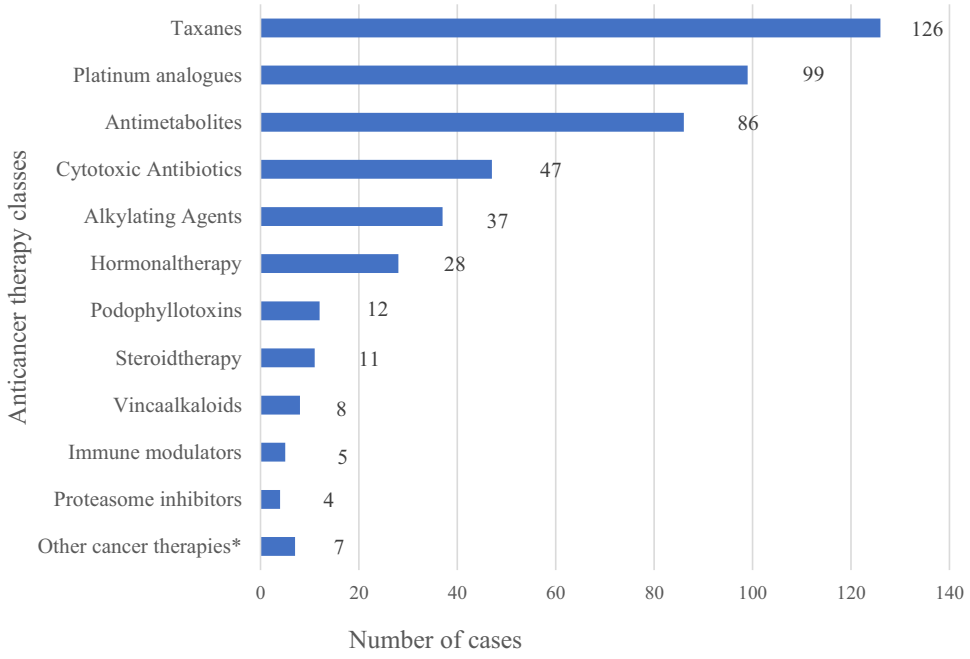


Figure 2 Common classes of anticancer drugs prescribed for patients with cancer at the oncology unit of MRRH. *Camptothecin (3), Monoclonal antibodies (3), Tyrosine kinase inhibitors (1).

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Table 3 Self-Medication-Related Characteristics of Adult Patients with Cancer Receiving Cancer Treatment at the Oncology Unit of MRRH

Characteristics	Category	Frequency (%)
Reasons for Self-medicating	Pain	152 (56.3)
	Gastric ulcers	75 (27.8)
	Cough	49 (18.2)
	Common cold	25 (9.3)
	Nausea and Vomiting	20 (7.4)
	Fever	18 (6.7)
	Others*	60 (22.2)
ATC classification of Drugs used for Self-Medication	*Analgesics* (N02)	129 (47.8)
	Antibiotics (J01)	74 (27.4)
	Anti-inflammatory drugs (M01)	64 (23.7)
	Drugs for acid-related disorders (A02)	48 (17.8)
	Antihistamines (R06)	41 (15.2)
	Vitamins and minerals (A11/A12)	27 (10.0)
	Antiprotozoals (P01)	23 (8.5)
	Nasal decongestants (R01)	18 (6.7)
	*Antiemetics (*A04)	17 (6.3)
	*Corticosteroids (*H02)	9 (3.3)
	Others[#]	42 (15.6)
Duration of Self-medication	<1 month	103 (38.2)
	1–6 months	126 (46.7)
	7–12 months	27 (10.0)
	>12 months	14 (5.2)
Herbal use	Yes	149 (55.2)
	No	121 (44.8)

Notes: *Diarrhoea (12), numbness (10), cancer (9), allergies (9), anorexia (8), scaly skin (4), erectile dysfunction (4), alopecia (3), ocular pruritis (4), constipation (3), urethral discharge (2), dermatitis (2), fatigue (1), edema (1), hypertension (1). [#]C03: Diuretics (2), N05: Psycholeptics (2), A06: Laxatives (6), N03: Antiepileptics (6), N06: Psychoanaleptics (5), G04: Urologicals (4), A03: Drugs for functional gastrointestinal disorders (6), D11: Dermatological Preparations (3), R05: Cough and cold preparations (3), P02: Anthelmintic (3), N05: Anadverse eventsthetics (2), M03: Muscle relaxants (3), A07: Antidiarrheals (3), V03: All other therapeutic products (3), S01: Ophthalmologicals (3) J02: Antimycotics for systemic use (2)

Determinants of AEs Among Self-Medicating Patients with Cancer

At univariate logistic regression, 8 variables which were identified with potential association with AEs included age above 60 category (COR = 0.3, 95% CI: 0.10–1.08): p-value = 0.066, anthracyclines category (COR = 1.9, 95% CI: 0.64–5.70): p-value = 0.243, alkylating agents category (COR = 3.0, 95% CI: 0.89–10.24):p-value = 0.076, antimetabolites category (COR = 2.2, 95% CI: 0.98–4.7):p-value = 0.033, taxanes category (COR=0.5,9 5% CI:0.28–0.98): p-value = 0.039, hormonal therapy category (COR = 0.4, 95% CI: 0.16–0.88):p-value = 0.023, A02 category (COR = 6.7, 95% CI: 1.56–28.51):p-value = 0.010, herbal use category (COR = 1.8, 95% CI: 0.98–3.55):p-value = 0.053. Variables

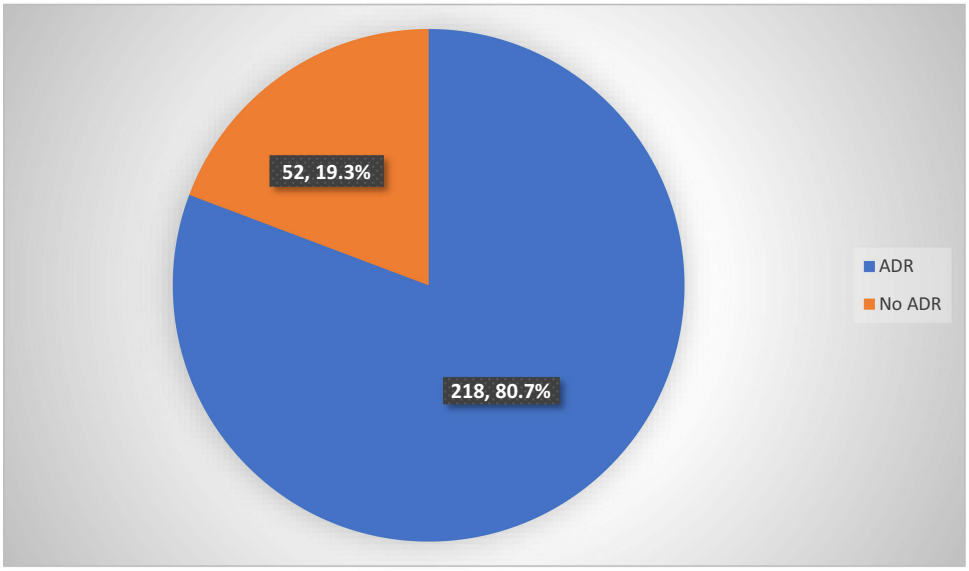


Figure 3 Prevalence of AEs among Self-medicating patients with cancer.

which showed a p-value > 0.25 at univariate regression were excluded from multivariate regression, and only those which had a p-value < 0.25 were included. In the multivariate logistic regression, three variables remained statistically significant, which included alkylating agents' category (AOR = 3.6, 95% CI: 1.02–12.51): p-value= 0.046, A02 category (AOR = 7.9, 95% CI: 1.79–35.41): p-value = 0.006 and herbal use category (AOR = 2.1, 95% CI: 1.09–4.22): p-value = 0.026, as illustrated by Table 4 below.

Discussion

The prevalence of AEs among self-medicating patients with cancer at the MRRH Oncology Unit was 80.7%. Currently, there is limited literature that specifically quantifies AEs in self-medicating patients with cancer, despite the widespread nature of this practice. However, studies conducted in similar population report comparable findings. For instance, a study in Indonesia reported a closely similar prevalence of 80%, suggesting that AEs are common across different anticancer therapies.[24] In Kenya, a study among cervical patients with cancer found a relatively higher prevalence of 100%,[20] while a study in France reported a lower prevalence of 72.4%.[25] The higher prevalence in the Kenyan study may be attributed to its focus on patients with cervical cancer only, laboratory confirmation and a smaller sample size. Similarly, the lower prevalence reported by Le Saux et al may be explained by the study's restriction to patients with advanced (stage IIIB–IV) or recurrent epithelial ovarian cancer, as well as its smaller sample size. Additionally, the difference could be attributed to our inclusion of self-medicating patients with cancer and multiple chemotherapeutic drug classes, which have greater potential of predisposing the patients to AEs. Furthermore, these studies focused on patient population with specific types of cancer unlike our study which included all patients with different cancer diagnosis, this still explains the difference in the prevalence.

Gastric ulcers were the most frequently experienced AE (18.4%), followed by nausea (11.8%) and vomiting (23%). Similar findings have been reported in previous studies. For instance, a study in Japan reported severe gastric and duodenal ulcers following chemotherapy with mFOLFOX6 and bevacizumab.[26] Another study reported that nausea and vomiting were among the most common AEs, affecting up to 80% of patients receiving chemotherapy.[27]

The severity of AEs among self-medicating patients with cancer was graded using the CTCAE. The majority were Grade 1 (47%), followed by Grade 2 (39%) and Grade 3 (14%), with no Grade 4 or 5 events observed. These findings from similar population closely align with those reported by Le Saux et al, where most AEs were of Grade 1–3 severity, although a few grades 4 and 5 events were also noted. The slight difference may be attributed to the exclusion criteria in

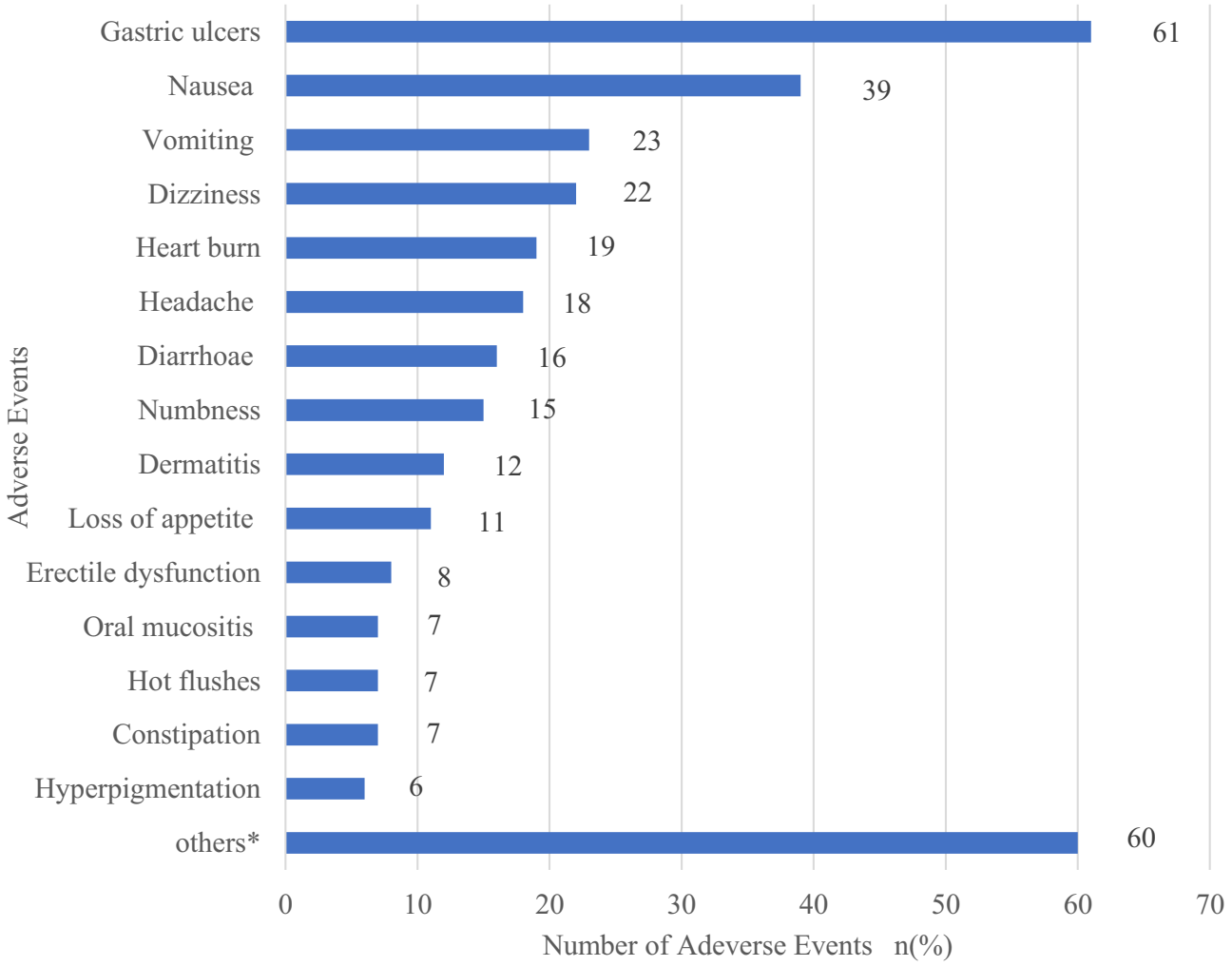


Figure 4 Characteristics of AEs among self-medicating patients with cancer. *Fatigue (6) sedation (6) loss of appetite (5) alopecia (5) blurred vision (4) polyuria (4) vaginal dryness (4) bloating (6) edema (3) haemorrhoids (3) insomnia (2) hypotension (2) nail disorders (2) palpitation (2) restlessness (2) urine discolouration (2) fall (1) flatulence (1) glossitis (1).

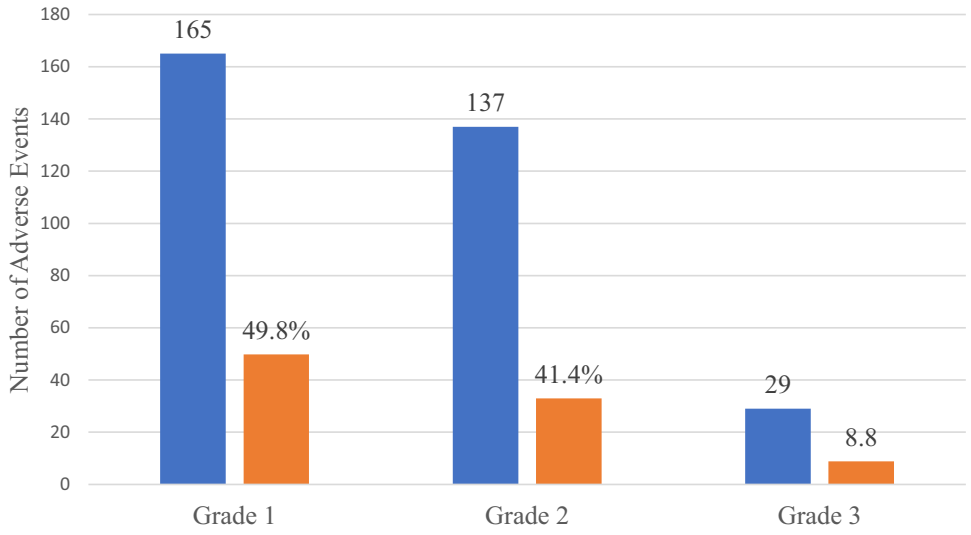


Figure 5 Severity of adverse events among self-medicating patients with cancer. Grade 1: Mild, no intervention required; Grade 2: Limits age-appropriate instrumental activities of daily living; Grade 3: Requires medical intervention.

https://doi.org/10.2147/CMAR.S603947

Table 4 Univariate and Multivariate Logistic Regression of Factors Associated with Adverse Events Among Self-Medicating Patients with Cancer Receiving Cancer Treatment at MRRH

Variable	Category	Adverse Events		COR (95% C.I)	P-value	AOR (95% C.I)	P-value
		No n (%)	Yes n (%)				
Age	18-39	3 (7.9)	35 (92.1)	1			
	40-59	20 (20.4)	78 (79.6)	0.3 (0.09–1.20)	0.093		
	≥60	29 (21.4)	105 (78.4)	0.3 (0.10–1.08)	0.066		
Gender	Male	36 (21.3)	133 (78.7)	1			
	Female	16 (15.8)	85 (84.2)	1.4 (0.75–2.75)	0.272		
BMI	Normalweight	29 (19.5)	120 (80.5)	1			
	Underweight	7 (15.6)	38 (84.4)	1.3 (0.53–3.23)	0.555		
	Overweight	11 (21.2)	41 (78.8)	0.9 (0.41–1.96)	0.793		
	Obesity	5 (20.8)	19 (79.2)	0.9 (0.32–2.66)	0.875		
Comorbidities	No	40 (20.9)	151 (79.1)	1			
	Yes	12 (15.2)	67 (84.8)	1.5(0.72–3.0)	0.277		
Anthracyclines	No	48 (20.3)	188 (79.7)	1			
	Yes	4 (11.8)	30 (88.2)	1.9 (0.64–5.70)	0.243		
Platinum analogs	No	36 (21.1)	135 (78.9)	1			
	Yes	16 (16.2)	83 (83.8)	1.4 (0.72–2.65)	0.327		
Alkylating agents	No	49 (21.0)	184 (79.0)	1			
	Yes	3 (8.1)	34 (91.9)	3.0 (0.89–10.24)	0.076*	3.6 (1.02–12.51)	**0.046**
Antimetabolites	NO	42 (22.8)	142 (77.2)	1			
	Yes	10 (11.6)	76 (88.4)	2.2 (1.07–4.72)	0.033*	2.2 (0.98–4.7)	0.056
Taxanes	No	21 (14.6)	123 (85.4)	1			
	Yes	31 (24.6)	95 (75.4)	0.5 (0.28–0.98)	0.039		
Hormonal therapy	No	42 (17.4)	200 (82.6)	1			
	Yes	10 (35.7)	18 (64.3)	0.4 (0.16–0.88)	0.023*	0.4 (0.16–1.03)	0.060
Analgesics (N02[1])	No	28 (19.9)	113 (80.1)	1			
	Yes	24 (18.6)	105 (81.4)	1.1 (0.59–1.99)	0.794		
Antiprotozoals (P01[1])	No	48 (19.4)	199 (80.6)	1			
	Yes	4 (17.4)	19 (82.6)	1.1 (0.37–3.52)	0.812		
Drugs for acid-related disorders (A02[1])	No	50 (22.5)	172 (77.9)	1			
	Yes	2 (4.2)	46 (95.8)	6.7 (1.56–28.51)	0.010*	7.9 (1.79–35.41)	**0.006**
Herbal use[#]	No	35 (23.5)	114 (76.5)	1			
	Yes	17 (14.1)	104 (85.9)	1.8 (0.99–3.55)	0.053*	2.1 (1.09–4.22)	**0.026**

Notes: [#]Use in the last 1 month; *Variables included in multivariate regression analysis; Bold: statistically significant variables at multivariate regression.
Abbreviations: BMI, Body Mass Index; COR, Crude Odds Ratio; AOR, Adjusted Odds Ratio; C.I., Confidence Interval.

https://doi.org/10.2147/CMAR.S603947

our study, which omitted AEs that required laboratory confirmation, unlike the study by Le Saux et al. Similarly, a study conducted in Thailand reported that most AEs were of mild-to-moderate severity (Grades 1–2), despite conducted in ambulatory home setting.[28] In contrast to our findings, a study conducted in Ethiopia reported that the majority of AEs were of Grades 3–4 severity.[29] This notable difference may be attributed to the inclusion of laboratory-based AEs in their assessment, which were excluded in our study.

The predominance of Grade 1 and 2 AEs suggest that, for AEs among self-medicating patients with cancer, they are generally mild and manageable, rarely requiring treatment interruption. However, even mild AEs warrant attention, as they may progress to clinically significant complications or interfere with treatment, particularly in vulnerable patient populations. Moreover, severe AEs can compromise treatment effectiveness, reduce patient survival, and diminish quality of life. They may also necessitate dose reductions, treatment delays, or even discontinuation of anticancer therapies.[30]

At multivariate regression analysis, the use of alkylating agents, self-medication with drugs for acid-related disorders (A02), and herbal medicines, were identified as statistically significant determinants ($p < 0.05$).

Patients receiving alkylating agents were 3.6 times more likely to develop AEs. This finding is consistent with previous studies indicating association of AEs with alkylating agents. A registry-based study reported that alkylating agents (excluding platinum derivatives) were associated with serious AEs in 32.6% of patients, and overall, 91.9% of patients who received these agents experienced at least one adverse event.[31] Ingrand et al further linked the occurrence of AEs to the clinical context, particularly advanced disease with metastasis, which is consistent with our study where 73% of patients had advanced disease. Alkylating agents have also been linked to gastrointestinal tract toxicities, including mucositis, stomatitis, esophagitis, and diarrhea,[32] which were among the most reported AEs in our study.

Additionally, a study conducted at Mbarara Regional Referral Hospital found that treatment regimens containing alkylating agents were significantly associated with higher odds of developing oral mucositis.[33] These gastrointestinal tract AEs associated with the use of alkylating agents may contribute to increased self-medication with proton pump inhibitors as observed in this study.

Herbal medicine use was significantly associated with a twofold increase in the risk of AEs. This finding suggests the possibility of herb–drug interactions or direct toxicities associated with complementary and alternative therapies. A similar study raised safety-related concerns, including herb–drug interactions, toxic effects of certain herbal components, and alterations in the response of cancer cells to chemotherapy, either through pharmacological synergy or increased chemosensitivity.[34,35] In a study conducted in Iran, each additional herbal medicine used was associated with a 15% increase in the odds of a clinically relevant herb–drug interaction.[36]

In the current study, the most commonly reported herbal products were graviola (Annona muricata), beetroot (Beta vulgaris), sweet wormwood (Artemisia annua), and blackjack (Bidens pilosa), with most patients self-medicating with more than two herbal medicines. Additionally, a study conducted among patients with breast cancer found that self-medication with herbal products such as graviola was associated with an increased risk of AEs including death.[18] Likewise, Ramos-Esquivel et al (2017) reported that patients taking two or more herbal or conventional medications had a 2.5-fold higher risk of clinically significant interactions. With these findings, the lack of patient education regarding herbal medicine use may increase the frequency and severity of these undesirable effects. Therefore, implementing active ADE risk classification and closer monitoring in high-risk patients, including those on any alkylating agents and those who use herbal products, as well as targeted staff training on self-medication, and medication safety in cancer patients would be crucial to ensure safe and informed use.

The analysis revealed a strong and statistically significant association of nearly eightfold between drugs for acid-related disorders (A02) use, which consisted of proton pump inhibitors and anti-acids. This significant association likely reflects the clinical context in which A02 drugs are self-medicated to manage AEs of cancer medication particularly gastric ulcers, identified in our study as the most frequently reported adverse event among self-medicating patients with cancer. However, some AEs were reported in patients who self-medicated with A02 drugs including headache (6%) and diarrhea (3%). These findings closely align with other studies. One study reported that self-medication with proton pump inhibitors was associated with AEs, with diarrhea and headache occurring in 1–3% of cases.[37] Another study reported that PPIs were associated with AEs, particularly headaches.[38] With the increased self-medication of drugs for acid-related disorders among patients with cancer, future studies should focus on the AEs associated with these drugs in this population.

Limitations of the Study

The current study has strengths in including a relatively larger sample size, which increased the statistical power, improved the precision of prevalence estimates, and allowed for more reliable identification of determinants of AEs among self-medicating cancer patients. However, reliance on medical records and patient recall may have introduced bias or resulted in incomplete data. Conducting a prospective study in this subgroup would enable comprehensive data collection while minimizing recall bias.

Conclusion

The study found that about 4 out of 5 self -medicating patients with cancer experienced AEs. The majority of these AEs were mild. AEs among self-medicating patients with cancer were associated with receiving alkylating agents, herbal medicines use and self-medication with drugs for acid-related disorders. The frequent use of herbal medicines underscores the potential for drug–herb interactions, which may compromise safety and treatment outcomes. Establish routine medication reconciliation protocol in oncology outpatient clinics, comprehensive medication review including self-medicated drugs and over-the-counter products ensures a complete medication profile and medication safety. Moreover, implementing active ADE risk classification and closer monitoring in high-risk patients, including those on any alkylating agents and those who use herbal products, as well as targeted staff training on self-medication, and medication safety in cancer patients would be crucial to ensure safe and informed use.

Abbreviations

AE, Adverse Event; ATC, Anatomic and Therapeutic Classification; BMI, Body Mass Index; BSA, body surface area; CTCAE, Common Terminology Criteria for AEs; HIV, Human Immunodeficiency Virus; MRRH, Mbarara Regional Referral Hospital; MRRHCU, Mbarara Regional Referral Hospital Cancer Unit; MUST, Mbarara University of Science and Technology.

Data Sharing Statement

The data set and data collection tools used in this study are available upon reasonable request from the corresponding author.

Ethics Approval and Consent to Participate

The study was conducted in compliance with the declaration of Helsinki and confidentiality of the patients' information was protected. The study protocol was approved by the Research Ethical Committee of Mbarara University of Science and Technology (MUST-REC), with ref no. MUST-2024-1962. Administrative clearance was sought from the Department of Pharmacy, Faculty Research Committee and Hospital Director MRRH before starting the study. A written informed consent was obtained from the participants before being interviewed for this study.

Acknowledgments

We thank the administrative and technical staff of Mbarara Regional Referral Hospital Cancer Unit for their great cooperation while conducting this study. The authors also extend their appreciation to the Deanship of Research and Graduate Studies at King Khalid University for support given to this project through Large Research Project under grant number RGP2/639/46.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agreed to be accountable for all aspects of the work.

Funding

There is no funding to report.

Disclosure

The authors declare that they have no competing interests in this work.

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