MEDS Clinical Medicine (2026)
Clausius Scientific Press, Canada

DOI: 10.23977/medsc.2026.070205
ISSN 2616-1907 Vol. 7 Num. 2

Efficacy of Risk-Stratified Nursing Interventions on Chemotherapy-Induced Oral Mucositis in Acute Leukemia Patients

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Keywords: Acute leukemia; chemotherapy; Oral mucositis; Risk assessment; Stratified nursing; Precision nursing

Abstract: To evaluate the efficacy of risk assessment combined with stratified nursing interventions in preventing chemotherapy-induced oral mucositis (OM) in acute leukemia patients, this randomized controlled trial (N = 80) evaluated the clinical efficacy of a risk-stratified nursing framework in mitigating chemotherapy-induced oral mucositis (OM) in patients with acute leukemia. The experimental group (n = 40) received individualized prophylactic interventions based on baseline risk assessment, including cryotherapy, topical growth factor administration, nutritional optimization, and preemptive analgesia, whereas the control group (n = 40) received standard institutional care. The results demonstrated that risk-based stratification significantly reduced the incidence of OM (52.50% vs. 80.00%, P = 0.009) and alleviated its severity (P = 0.001). In addition, the experimental group showed significantly lower Visual Analogue Scale (VAS) pain scores (3.24±1.15 vs. 5.81±1.42), shorter mucosal healing time (6.52±1.83 vs. 10.28 ± 2.45 days), and higher scores in quality of life (EORTC QLQ-C30) and nursing compliance (all P < 0.05). These findings suggest that risk stratification enables early identification of high-risk patients, effectively reduces the incidence and severity of OM, and contributes to improved clinical outcomes and treatment tolerance in patients with acute leukemia.

1. Introduction

Acute Leukemia (AL) is a common hematologic malignancy. High-dose chemotherapy is essential for survival but is highly cytotoxic to the oral mucosa. Coupled with chemotherapy-induced myelosuppression, Oral Mucositis (OM) has become a prevalent and severe complication. Reported incidence rates reach 50%–80%, exceeding 90% in intensive regimens [1].

OM manifests as congestion, edema, ulceration, and intense pain, leading to dysphagia, malnutrition, and a high risk of sepsis due to bacterial translocation during neutropenia [2]. Severe OM (Grade III–IV) often necessitates chemotherapy dose reduction or discontinuation, negatively impacting prognosis and quality of life.

Traditional oral care relies on "one-size-fits-all" approaches (e.g., universal saline rinsing) and reactive symptom management [3]. This strategy lacks precision and fails to address individual risk factors such as chemotherapy intensity and baseline health status. Consequently, resources are often misallocated.

The "precision nursing" model advocates for evidence-based risk prediction and stratified interventions. This study evaluates a risk-assessment-guided, stratified nursing model for AL patients. We aim to determine its efficacy in reducing the incidence and severity of OM, thereby providing a more precise and efficient clinical protocol for managing chemotherapy-related oral complications.

2. Materials and Methods

2.1 Study Population

This study included patients with acute leukemia who received chemotherapy in the Department of Hematology of our hospital from January 2024 to October 2025.

(1) Inclusion Criteria:

1) Confirmed diagnosis of acute leukemia (via bone marrow aspiration, morphology, and immunophenotyping) scheduled for standard combination chemotherapy.

2) Age ≥ 18 years, with intact cognitive function and basic literacy skills.

3) Intact oral mucosa (absence of erythema, edema, ulceration, or fungal infection) confirmed by baseline oral clinical assessment.

4) Estimated life expectancy>3 months.

5) Provision of signed informed consent by the patient or their legal proxy.

(2) Exclusion Criteria:

1) Clinically significant dysfunction of major organs (cardiac, hepatic, or renal) or active systemic infection.

2) History of recurrent aphthous stomatitis, severe periodontal disease, or prior radiotherapy to the head and neck.

3) Psychiatric disorders precluding adherence to study protocols or clinical assessments.

4) Inability to complete the study due to voluntary withdrawal, inter-hospital transfer, or rapid clinical deterioration.

(3) Sample Size and Grouping: Based on the formula for comparing two independent proportions, an alpha of 0.05 (two-tailed) and a power (1-β) of 0.80 were set. Accounting for a 20% attrition rate, at least 40 patients were required per group. Using a random number table, 80 eligible patients were randomized into a Control Group (n=40) and an Observation Group (n=40).

(4) Ethical Approval: The study followed the Declaration of Helsinki and was approved by the hospital's Ethics Committee. Data were used strictly for research purposes with patient privacy protected.

2.2 Intervention Methods

2.2.1 Control Group (Routine Nursing)

Patients received standard hematological nursing care. Before chemotherapy, they received routine health education on correct tooth brushing, and soft-bristled toothbrushes were provided. During chemotherapy, patients performed oral rinsing with 0.9% sodium chloride or 0.12% chlorhexidine 3–4 times daily. For Oral Mucositis (OM), symptomatic treatment (topical medication, antifungal therapy, or analgesics) was provided per physician orders.

2.2.2 Observation Group (Risk Assessment + Stratified Nursing)

In addition to routine care, this group received a stratified nursing intervention model based on risk assessment:

Step 1: Risk Assessment: Using evidence-based literature and the Delphi method, we developed an "Acute Leukemia Chemotherapy Oral Mucositis Risk Scale." It evaluates five key factors: age, chemotherapy intensity, baseline leukocyte count, oral hygiene, and nutritional status (BMI and albumin). Assessments were performed by trained nurses 1 day before the first chemotherapy session.

Step 2: Risk Stratification: Based on scores, patients were categorized as Low-risk, Moderate-risk, or High-risk.

Step 3: Stratified Care:

Low-risk: Routine preventive care and hygiene education. Nurses used the "Teach-back" method to ensure correct Modified Bass brushing. Rinsing was mandatory upon waking, before sleep, and around meals. Diet focused on high-protein, vitamin-rich, cool, and soft foods.

Moderate-risk: Increased monitoring (≥ twice daily). Oral rinsing was upgraded to alternating 5% sodium bicarbonate and normal saline to alkalize the oral environment. Oral cryotherapy (ice chips) was implemented 5 minutes before and 30 minutes after infusion of specific high-dose drugs (e.g., methotrexate) to induce local vasoconstriction.

High-risk: All moderate-risk interventions plus proactive, multi-dimensional care: use of composite medicated mouthwash; prophylactic topical recombinant human epidermal growth factor (rhEGF) spray; early nutritional support (enteral or parenteral if necessary); pain management with topical lidocaine gel; and psychological counseling to alleviate anxiety.

2.3 Outcome Measures

(1) Data were collected by two blinded quality control nurses.

(2) Primary Outcome: Incidence and severity of OM, graded by WHO criteria (Grade 0–IV). Total incidence = (Grade I–IV cases) / Total cases × 100%.

(3) Secondary Outcomes:

1) **Pain Intensity:** Evaluated using the Visual Analogue Scale (VAS), with scores ranging from 0 (no pain) to 10 (excruciating pain).

2) **Health-related Quality of Life (HRQoL):** Assessed via the EORTC QLQ-C30 questionnaire to evaluate functional and symptomatic dimensions.

3) **Mucosal Healing Duration**: The number of days from the clinical detection of ulceration to complete mucosal re-epithelialization.

4) **Nursing Adherence Rate**: Defined as the percentage of patients maintaining full or partial adherence to the stratified nursing interventions.

2.4 Statistical Analysis

SPSS 26.0 was used. Continuous data are presented as Mean ± SD (t-test) or Median/IQR (Mann-Whitney U test). Categorical data are presented as frequencies/percentages (Chi-square or Fisher's exact test). Ordinal data (e.g., OM grades) were analyzed using the Wilcoxon rank-sum test. $P < 0.05$ was considered statistically significant.

3. Results

3.1 Baseline Characteristics

Eighty patients undergoing chemotherapy for acute leukemia were randomized into a control group (n=40) and an observation group (n=40).

Baseline data including gender, age, disease type (AML/ALL), and chemotherapy regimen showed no statistically significant differences between the two groups (P>0.05). The groups were comparable. (See Table 1.)

Table 1. Baseline characteristics of patients in the two groups

Characteristics	Observation group (n=40)	Control group (n=40)	Statistic (t/x^2)	*P* value
Sex, n (%)			$x^2 = 0.050$	0.823
Male	22 (55.00)	21 (52.50)		
Female	18 (45.00)	19 (47.50)		
Age (years), Mean ± SD	45.25 ± 12.31	46.12 ± 11.84	$t = -0.322$	0.748
Disease type, n (%)			$x^2 = 0.237$	0.626
AML	28 (70.00)	26 (65.00)		
ALL	12 (30.00)	14 (35.00)		
Chemotherapy regimen, n (%)			$x^2 = 0.275$	0.600
Standard chemotherapy	30 (75.00)	28 (70.00)		
Intensive chemotherapy	10 (25.00)	12 (30.00)		

Abbreviations: AML = acute myeloid leukemia; ALL = acute lymphoblastic leukemia.

3.2 Incidence and Severity of Oral Mucositis (OM)

The total incidence of OM in the observation group was 52.50% (21/40), significantly lower than the 80.00% (32/40) in the control group (x^2=6.766, *P*=0.009).

Regarding severity, the observation group mainly developed Grade I and II OM, with no cases of Grade IV. In contrast, the control group showed a 25.00% (10/40) incidence of Grade III/IV OM. The OM severity in the observation group was significantly lower than that in the control group (Z=-3.245, *P*=0.001). (See Table 2.)

Table 2. Incidence and severity of oral mucositis in the two groups [*n* (%)]

Group	n	Grade 0	Grade I	Grade II	Grade III	Grade IV	Overall incidence
Observation group	40	19 (47.50)	15 (37.50)	5 (12.50)	1 (2.50)	0 (0.00)	21 (52.50)
Control group	40	8 (20.00)	10 (25.00)	12 (30.00)	7 (17.50)	3 (7.50)	32 (80.00)
x^2							6.766
P value							0.009

Note: Overall incidence includes Grade I–IV oral mucositis.

3.3 Pain Scores (VAS) and OM Healing Time

Among patients with OM, the peak VAS pain score in the observation group (n=21) was (3.24±1.15) , significantly lower than 5.81±1.42 in the control group (n=32) (t=-7.025, P<0.001).

The mean OM healing time was 6.52±1.83 days in the observation group, significantly shorter than 10.28±2.45 days in the control group (t=-6.110, P<0.001). (See Table 3.)

Table 3. Comparison of pain scores (VAS) and healing time of oral mucositis (Mean ± SD)

Group	Patients with OM (n)	Maximum pain score (VAS)	Healing time (days)
Observation group	21	3.24 ± 1.15	6.52 ± 1.83
Control group	32	5.81 ± 1.42	10.28 ± 2.45
t		-7.025	-6.110
P value		<0.001	<0.001

Abbreviation: VAS = Visual Analog Scale.

3.4 Quality of Life and Adherence

Baseline EORTC QLQ-C30 scores showed no significant difference before chemotherapy (P>0.05). After the chemotherapy cycle, the observation group achieved a higher quality of life score (78.50±8.24) compared to the control group (65.45±9.12) (t=6.721, P<0.001). (See Table 4.)

Regarding adherence, the observation group showed a significantly higher total adherence rate (95.00%, 38/40) compared to the control group (77.50%, 31/40) (x^2=5.165, P=0.023). (See Table 5.)

Table 4. Comparison of quality of life scores (EORTC QLQ-C30) before and after chemotherapy (Mean ± SD)

Group	n	Before chemotherapy	After chemotherapy	*t*	*P* value
Observation group	40	55.32 ± 6.15	78.50 ± 8.24	-14.281	<0.001
Control group	40	54.89 ± 6.42	65.45 ± 9.12	-5.996	<0.001
Between-group t value		0.306	6.721		
Between-group P value		0.760	<0.001		

Abbreviation: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30.

Table 5. Comparison of compliance with nursing intervention between the two groups [*n* (%)]

Group	n	Complete compliance	Partial compliance	Non-compliance	Overall compliance
Observation group	40	25 (62.50)	13 (32.50)	2 (5.00)	38 (95.00)
Control group	40	15 (37.50)	16 (40.00)	9 (22.50)	31 (77.50)
x^2					5.165
P value					0.023

4. Discussion

4.1 Proactive value of risk assessment in preventing oral mucositis (OM)

Patients with acute leukemia face dual challenges: the disease itself and intensive chemotherapy. They often suffer from profound and prolonged myelosuppression and neutropenia. This destroys the mucosal immune barrier, leading to a very high risk of OM [4]. Our study showed a significantly lower incidence of OM in the observation group ($P<0.05$). This confirms the value of proactive risk assessment. Traditional oral care is passive, focusing on "problem-solving" after OM occurs. In contrast, we introduced quantitative risk assessment before chemotherapy. We analyzed multiple factors, including age, chemotherapy intensity, baseline white blood cell count, and nutritional status. This evidence-based mechanism allows nurses to identify high-risk patients before mucosal damage occurs. We shifted from "passive treatment" to "active prevention," which effectively reduced the overall incidence of OM during chemotherapy [5].

4.2 Stratified nursing intervention reduces OM severity and promotes healing

Our results showed not only a lower incidence of OM but also milder cases (Grade I–II) in the observation group compared to the control group (Grade III–IV). Furthermore, ulcer healing time was significantly shorter in the observation group ($P<0.05$). This is due to targeted interventions based on stratified nursing.

First, we implemented oral cryotherapy for high-risk patients. Local cold exposure constricts capillaries, reducing chemotherapy drug concentration in the oral mucosa. This prevents drug-induced toxicity in basal epithelial cells[6]. Second, we applied recombinant human epidermal growth factor (rhEGF) to high-risk patients. rhEGF promotes mitosis, accelerating epithelial cell migration, proliferation, and granulation tissue formation. Finally, stratified nursing avoids the "one-size-fits-all" approach. It matches nursing resources to the patient's risk level. This prevents over-treatment for low-risk patients and ensures intensive care for high-risk patients, maximizing nursing efficiency.

4.3 Impact on pain and quality of life

Severe OM causes intense pain, leading to dysphagia and malnutrition. This triggers a vicious cycle: "pain–malnutrition–delayed healing–emotional distress." In our study, the observation group reported significantly lower VAS pain scores and higher quality of life (EORTC QLQ-C30) and treatment adherence ($P<0.05$). Proactive pain management (e.g., topical lidocaine) and psychological support broke this cycle. Effective pain control improved oral nutritional intake, which further supported tissue repair and immune recovery [6]. These physiological improvements enhanced patient confidence and treatment adherence, leading to a better quality of life during chemotherapy.

4.4 Limitations and future perspectives

This study has some limitations. First, it was a single-center study with a limited sample size ($N=80$), which may lead to selection bias. We did not perform subgroup analyses for different leukemia subtypes or specific targeted chemotherapy regimens. Second, the follow-up period ended only one week after chemotherapy, lacking data on long-term oral health. Future studies should conduct multi-center, large-scale randomized controlled trials (RCTs). Furthermore, we could integrate digital tools (e.g., mobile apps or AI image recognition) to provide seamless "in-hospital to home" continuing care.

5. Conclusion

In summary, risk-based stratified nursing is effective for patients with acute leukemia undergoing chemotherapy. It allows for precise identification of high-risk patients and the implementation of targeted preventive strategies. This model reduces the incidence and severity of OM, alleviates oral pain, accelerates ulcer healing, and improves treatment adherence and quality of life. This approach is scientific, proactive, and highly practical. It optimizes the allocation of nursing resources and is recommended for clinical practice in hematology-oncology.

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