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Original Article

Role of Procalcitonin, qSOFA, and MASCC Score in Predicting Mortality and Intensive Care Unit Admission for Patients with Chemotherapy-Induced Febrile Neutropenia

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Abstract

Introduction Febrile neutropenia is one of the major complications in patients receiving chemotherapy. In terms of the burden of disease, including mortality, hospital admissions, intensive care unit (ICU) admissions, and financial burden, febrile neutropenia plays a major role in patients receiving chemotherapy.

Objective The study aimed to evaluate the role of procalcitonin (PCT), Quick Sequential Organ Failure Assessment score, and the Multinational Association of Supportive Care in Cancer (MASCC) score in predicting mortality and ICU admission.

Materials and Methods A prospective observational study was performed at two tertiary oncology centers. Forty-seven adult patients diagnosed with chemotherapy-induced febrile neutropenia were enrolled over 12 months. Demographic, clinical, and laboratory data were collected for each patient. Admission risk scores (qSOFA, MASCC, and Clinical Index of Stable Febrile Neutropenia [CISNE]) as well as PCT levels were collected. Statistical analyses were conducted using SPSS v 26 and a p-value <0.05 was considered statistically significant.

Results The majority of the cohort had solid malignancies ($n = 30$, 63.8%). Among culture-positive cases, 75% were infected with gram-negative organisms, followed by 25% with gram-positive organisms. The low and high risk scores for MASCC were found to be 57.4 and 42.6%, respectively. Respiratory rate, granulocyte colony-stimulating factor, systolic blood pressure, qSOFA, MASCC score, CISNE, oral mucositis, and gastrointestinal tract mucositis were significantly associated with mortality. Patients with PCT >1 ng/mL exhibited higher qSOFA and CISNE scores with p-values of 0.004 and 0.001, respectively, and lower MASCC scores ($p = 0.005$).

Conclusion PCT, qSOFA score, and MASCC score were effective in predicting mortality in patients with febrile neutropenia.

Keywords
- procalcitonin
- sepsis
- mortality
- qSOFA
- febrile neutropenia
- ICU admission

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Introduction

Febrile neutropenia (FN) is one of the major complications in patients receiving chemotherapy.[1] In terms of burden of disease, including mortality, hospital admissions, intensive care unit (ICU) admissions, and financial burden, FN plays a major role in patients receiving chemotherapy.[2] Starting empirical broad-spectrum antibiotics at the earliest with the diagnosis of FN is critical. Early diagnosis and identification of patients who would probably be needing in-patient services and ICU services is of utmost importance, not only in terms of mortality prevention but also to improve the overall quality of life of patients and to decrease the financial burden to the patient.[3]

In this study, we intend to evaluate the predictive performance of the Quick Sequential Organ Failure Assessment (qSOFA) score as a tool for screening of sepsis, ICU admission, and mortality in patients with FN, and also to compare qSOFA score with that of the Multinational Association of Supportive Care in Cancer (MASCC) risk index score in regards to illness severity. The results of this study help us in the identification of patients with FN who would require ICU admission at the point of first contact with the health care provider, which will thus prompt early interventions if and when required.

Materials and Methods

A prospective observational study of patients with FN was conducted at the Department of Medical Oncology at two tertiary care oncology hospitals—KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, and KLES Belgaum Cancer Hospital, Belgaum—over a 12-month period from February 2023 to January 2024. Diagnosis of FN was made on a standard clinical basis.

Selection Criteria

FN: a patient with an absolute neutrophil count <500 cells/mm^3, with an oral temperature >38.3°C or sustained temperature ≥ 38.0°C for greater than 1 hour.

Inclusion Criteria

- All patients presenting with chemotherapy-induced FN (CIFN).
- Age above 18 years.
- A patient who had not received any antibiotics prior to blood culture collection.
- Availability of complete clinical, laboratory, and follow-up data.

Exclusion Criteria

- Patients younger than 18 years.
- Prior administration of empirical antibiotics before the collection of blood culture.
- Incomplete clinical records.

Data Collection

A total of 47 patients with FN were enrolled in the study (►**Fig. 1**). Demographic, clinical, and laboratory data, along with cancer diagnosis, stage, chemotherapy regimens, and vital parameters, were recorded. At admission and before starting the empirical antibiotics, three sets of blood cultures along with culture from urine and any suspected site of infection were collected. All blood culture samples were collected as per the standard institutional protocol. After confirmation of neutropenia, procalcitonin (PCT) levels, the MASCC risk index, and qSOFA score were measured at baseline. Clinical, demographic, and oncologic data were collected, including age, gender, stage of malignancy, type of cancer, chemotherapy regimen, treatment, and the number of chemotherapy cycles completed.

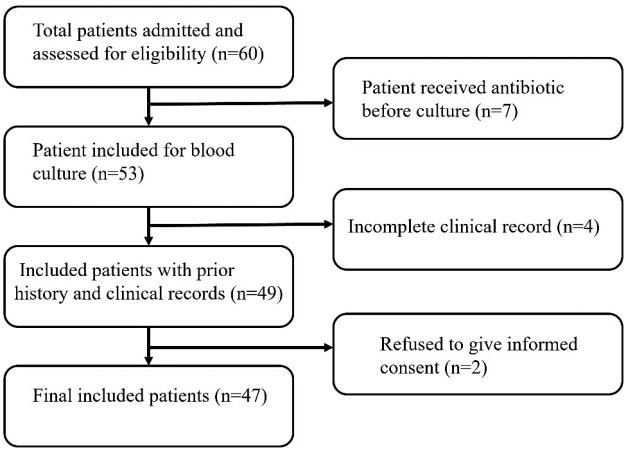

Fig. 1 Screening flow diagram of patients with febrile neutropenia.

Primary and Secondary Outcome Measures

The primary outcome measure was to evaluate the predictive performance of the qSOFA score as a screening tool for sepsis, mortality, and ICU admission in patients with FN, and the secondary outcome measure was to compare the qSOFA score and the MASCC risk index score as predictors of the severity of illness.

Statistical Analysis

Significance was assessed using a 5% level of significance, and a p-value <0.05 was considered statistically significant. Categorical variables were presented as proportions, while continuous variables were presented as mean and standard deviation. Comparison of categorical variables was analyzed using Fisher's exact test. Variables with statistical significance were tested by binary logistic analysis, together with the qSOFA score, and presented with the odds ratio. The area under the curve (AUC) for qSOFA was compared to assess the discriminating power of the qSOFA score to predict outcome.

Ethical Approval

All the patients have given their informed consent and were enrolled in the study. The study was carried out according to the regulations established by the Jawaharlal Nehru Medical College Institutional Ethics Committee (Ref- MDC/JNMCIEC/19) dated 03/02/2023. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national

research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Results

A total of 47 patients with FN caused by chemotherapy included in the study; the majority were aged between 50 and 60 years (42.55%), with 31.91% over 60 years and only 4.26% under 40 years of age. Gender distribution was nearly balanced with 51.06% male and 48.94% female. ICU was indicated in approximately 36.17% of cases, indicating a substantial burden of severe complications. The majority of patients were on palliative (46.81%) versus curative (27.66%) or adjuvant (17.02%) intent. Most patients (70.21%) were in hospital for less than 10 days, and a large proportion (85.11%) had received fewer than five cycles of chemotherapy. Thus, FN developed early in the course of treatment in many instances, and frequently in association with advanced disease or poor prognosis (►**Table 1**).

Table 1 Demographic characteristics of patients having neutropenia caused by chemotherapy

Characteristics	Number ($n=47$)	Percentage (%)
Age		
<40 y	2	4.26%
40–50 y	10	21.28%
50–60 y	20	42.55%
>60 y	15	31.91%
Gender		
Male	24	51.06%
Female	23	48.94%
Type of admission		
ICU	17	36.17%
No ICU	30	63.83%
Intention of treatment		
ADJ	8	17.02%
Curative	13	27.66%
NACT	4	8.51%
Palliative	22	46.81%
Duration of hospital stay		
<10 days	33	70.21%
10–20 days	10	21.28%
>20 days	4	8.51%
No. of chemotherapy cycles		
<5 cycles	40	85.11%
5–10 cycles	5	10.64%
>10 cycles	2	4.26%,

Abbreviations: ADJ, adjuvant therapy; ICU, intensive care unit; NACT, neoadjuvant chemotherapy.

Type of Malignancies

The majority of the study participants had solid malignancy ($n=30$, 63.8%). Hematologic malignancy was present in 36.2% ($n=17$) of the study participants. Among patients with solid malignancy, 23.3% ($n=7$) had breast cancer, followed by esophageal cancer and gastroesophageal junction cancer, each accounting for 10% ($n=3$), cervical cancer, colon cancer and neuroendocrine tumor, each accounting for 6.8% ($n=2$), and buccal mucosa cancer, rectal cancer, stomach cancer, Ewing sarcoma, muscle invasive bladder cancer, mixed germ cell tumor, non-small cell lung cancer, adrenal carcinoma, rhabdomyosarcoma, and seminoma, each 3.3% ($n=1$). In patients with hematological malignancy, 64.7% ($n=11$) had diffuse large B cell lymphoma, followed by 17.6% ($n=3$) multiple myeloma, 11.8% ($n=2$) acute myeloid leukemia, and 5.9% ($n=1$) small cell lymphoma.

Type of Organism

Among culture-positive study participants ($n=28$), 75% ($n=21$) were gram-negative organisms, followed by 25% ($n=7$) gram-positive infections (►**Supplementary Fig. S1**). In the gram-positive group, CoNS, *Staphylococcus saprophyticus*, and *Enterococcus faecium* each contributed 28.6% ($n=2$), and 14.2% ($n=1$) was *Staphylococcus epidermidis*. In the gram-negative group, 28.6% ($n=6$) *Escherichia coli* was present, followed by 23.8% ($n=5$) *Pseudomonas aeruginosa*, 19% ($n=4$) *Klebsiella pneumoniae*, 9.5% ($n=2$) in both *Acinetobacter lwoffii* and *Providencia rustigianii*, and 4.8% ($n=1$) in *Proteus vulgaris* and *Acinetobacter baumannii* complex.

Comparison of qSOFA and MASCC Scores

Low risk of qSOFA (0–1) score was recorded in 59.6% ($n=28$) of the study's patients (mean hospital stay: 9.5 ± 7.4). High risk of qSOFA (2 or more) was recorded in 40.4% ($n=19$) of the study's patients (mean hospital stay: 8.4 ± 5.8). Low risk of MASCC (≥21) was present in 53.2% ($n=25$) of the study's patients (mean hospital stay: 9.5 ± 7.5). High risk of MASCC (<21) was present in 46.8% ($n=22$) of the study's patients (mean hospital stay: 8.4 ± 5.8). When qSOFA and MASCC scores were compared using the chi-square test, statistically significant results were recorded ($p=0.000$), which shows that the variation between low- and high-risk categories in both qSOFA and MASCC is statistically significant.[4]

Clinical Index of Stable Febrile Neutropenia Score

The Clinical Index of Stable Febrile Neutropenia (CISNE) score stratifies the patients into low, intermediate, and high-risk categories using the aggregate score. Patients with an aggregate score of 0 are stratified as low risk, those with an aggregate score of 1 to 2 are stratified as intermediate risk, and those with a score of ≥3 are high-risk patients. In addition, 4.2% of patients ($n=2$) were in low risk, 40.4% of patients ($n=19$) were in intermediate risk, and 50.2% ($n=26$) were in the high-risk group.

Table 2 Comparison of study variables among survivors and nonsurvivors

Variables	Total ($N=47$)	Survivors ($N=34$)	95% CI	Non survivors ($N=13$)	95% CI	p-Value (Chi- square test)
Gram positive	6 (12.8%)	5 (14.7%)		1 (7.7%)		0.139
Gram negative	22 (46.8%)	11 (32.4%)		11 (54.6%)		0.160
Albumin	2.96 ± 0.71	3.20 ± 0.62	2.98–3.42	2.33 ± 0.56	1.99–2.67	0.312
GCS	13.59 ± 2.25	14.55 ± 1.43	14.05–15.05	11.07 ± 2.05	9.83–12.31	**0.000**
RR	19.12 ± 4.80	17.20 ± 4.01	15.80–18.60	24.15 ± 2.54	22.62–25.68	**0.001**
SBP	104.25 ± 19.42	112.05 ± 16.83	106.18–117.92	83.84 ± 6.50	79.91–87.77	**0.001**
qSOFA						
0	26 (55.3%)	26 (76.5%)		0 (0%)		**0.000**
1	2 (4.3%)	2 (5.9%)		0 (0%)		
2	6 (12.8%)	3 (8.8%)		3 (23.1%)		
3	13 (27.6%)	3 (8.8%)		10 (76.9%)		
MASCC	19.17 ± 5.63	21.52 ± 4.67	19.89–23.15	13.00 ± 2.16	11.73–14.27	**0.001**
CISNE						
0	2 (4.3%)	0 (0%)		2 (5.9%)		**0.001**
1–2	19 (40.4%)	0 (0%)		19 (55.9%)		
≥ 3	26 (55.3%)	13 (100%)		13 (38.2%)		
PCT	29.12 ± 38.81	11.30 ± 24.56	2.73–19.87	75.75 ± 29.34	58.02–93.48	0.377
Oral mucositis	28 (59.6%)	16 (47.1%)		12 (92.3%)		**0.004**
Git mucositis	19 (40.4%)	7 (20.6%)		12 (92.3%)		**0.000**

Abbreviations: CI, confidence interval; CISNE, Clinical Index of Stable Febrile Neutropenia; GCS, Glasgow Coma Scale; MASCC, Multinational Association of Supportive Care in Cancer; PCT, procalcitonin; qSOFA, Quick Sequential Organ Failure Assessment; RR, respiratory rate; SBP, systolic blood pressure.
Note: Statistically significant p-values are indicated in bold.

Comparison of Study Variables Among Survivors and Nonsurvivors

►**Table 2** shows the clinical and scoring characteristics of survivors and nonsurvivors of CIFN. Significant differences were shown in the Glasgow Coma Scale (GCS), respiratory rate (RR), systolic blood pressure (SBP), and risk stratification scores (qSOFA, MASCC, and CISNE). Survivors had a significantly higher GCS (mean 14.55 vs. 11.07; $p=0.000$), lower RR (17.20 vs. 24.15; $p=0.001$), and higher SBP (112.05 vs. 83.84 mmHg; $p=0.001$) compared to nonsurvivors. qSOFA scores of 2 and 3 were seen more in nonsurvivors ($p=0.000$), while MASCC scores were lower (13.00 vs. 21.52; $p=0.001$), reflecting a high severity, and MASCC scores were also at a higher risk. Further, all nonsurvivors were in the high-risk category (CISNE ≥ 3; $p=0.001$). Mucositis was also related to poor outcomes, whereby overall mucositis was seen in 92.3% of nonsurvivors ($p=0.004$), with oral mucositis (92.3%, $p=0.004$) and gastrointestinal tract (GIT) mucositis (92.3% GIT, $p=0.000$) as being potentially predictive of mortality rate.

Comparison of Study Variables Between ICU Admissions and non-ICU Admissions

►**Table 3** shows the relationships between clinical variables and ICU admission. Compared to those without ICU support, patients requiring ICU support demonstrated statistically significantly worse clinical parameters with lower GCS (11.11 vs. 15.00; $p=0.000$), higher RR (24.35 vs. 16.16; $p=0.000$), and lower SBP (85.88 vs. 114.66 mmHg; $p=0.000$). In addition, most patients admitted to the ICU had qSOFA scores of 2 to 3 ($p=0.000$). MASCC scores were also significantly lower (13.23 vs. 22.53; $p=0.000$). Also notable was that all patients admitted to the ICU scored high risk on the CISNE score chart ($p=0.000$). Mucositis was noted to be an important predictor for ICU need with oral and GIT mucositis in 94.1 and 88.2% of patients admitted to the ICU ($p=0.000$ for both), further emphasizing the association with increased disease severity.

PCT Levels

►**Supplementary Table S1** summarizes the clinical variables by PCT levels as ≤ 1 and >1 ng/mL groups. Patients with PCT >1 ng/mL had significantly worse clinical parameters with higher qSOFA scores ($p=0.004$), lower MASCC scores ($p=0.005$), and higher CISNE scores ($p=0.001$), highlighting a greater risk of adverse outcomes, including sepsis and ICU admission. Distribution of gram-positive and gram-negative infections did not differ significantly between the PCT groups ($p>0.05$). These findings are encouraging, as they indicate that elevated PCT is a useful biomarker for clinically identifying febrile neutropenic patients at high risk for severe clinical deterioration (►**Supplementary Table S1**).

Table 3 Comparison of study variables among study participants based on the ICU admissions

Variables	Total ($N = 47$)	ICU admission	Non-ICU admission ($N = 30$)	p-Value (Chi- square test)
Gram positive	6 (12.8%)	1 (7.1%)	5 (38.5%)	0.067
Gram negative	22 (46.8%)	13 (92.9%)	9 (64.3%)	0.082
Albumin	2.96 ± 0.71	2.50 ± 0.58	3.22 ± 0.65	0.318
GCS	13.59 ± 2.25	11.11 ± 2.08	15.00 ± 0.00	**0.000**
RR	19.12 ± 4.80	24.35 ± 2.39	16.16 ± 2.90	**0.000**
SBP	104.25 ± 19.42	85.88 ± 10.64	114.66 ± 15.02	**0.000**
qSOFA				
0	26 (55.3%)	0 (0%)	26 (86.7%)	**0.000**
1	2 (4.3%)	0 (0%)	2 (6.7%)	
2	6 (12.8%)	5 (29.4%)	1 (3.3%)	
3	13 (27.6%)	12 (70.6%)	1 (3.3%)	
MASCC	19.17 ± 5.63	13.23 ± 2.90	22.53 ± 3.66	**0.000**
CISNE				
0	2 (4.3%)	0 (0%)	2 (6.7%)	**0.000**
1–2	19 (40.4%)	0 (0%)	19 (63.3%)	
≥ 3	26 (55.3%)	17 (100%)	9 (30%)	
PCT	29.12 ± 38.81	66.28 ± 36.27	8.07 ± 19.89	0.223
Oral mucositis	28 (59.6%)	16 (94.1%)	12 (40%)	**0.000**
GIT mucositis	19 (40.4%)	15 (88.2%)	4 (13.3%)	**0.000**

Abbreviations: CISNE, Clinical Index of Stable Febrile Neutropenia; GCS, Glasgow Coma Scale; GIT, gastrointestinal tract; ICU, intensive care unit; MASCC, Multinational Association of Supportive Care in Cancer; PCT, procalcitonin; qSOFA, Quick Sequential Organ Failure Assessment; RR, respiratory rate; SBP, systolic blood pressure.
Note: Statistically significant p-values are indicated in bold.

ROC Analysis—qSOFA and Mortality

The receiver operating curve between qSOFA and mortality is shown in ►**Supplementary Fig. S2**. The AUC was 0.912 ($p = 0.000$), which indicates that the qSOFA score demonstrates a good discriminatory ability to predict mortality among patients with CIFN.

Multivariate Analysis

Multivariate analysis showed that RR, qSOFA, ICU admission, CISNE, and GIT mucositis were independent risk factors associated with mortality. Multivariate analysis showed that PCT, GCS, RR, SBP, qSOFA, MASCC, oral mucositis, GIT mucositis, and CISNE were independent risk factors associated with ICU admission. Multilevel modeling (►**Table 4**) indicated that being admitted to the ICU was independently predicted by lower MASCC scores and presence of oral mucositis. Elevated PCT levels were significantly correlated with lower MASCC scores, and significant presence of oral mucositis was also associated with more drastic changes from baseline PCT levels. This reinforces the ability to integrate the use of validated clinical scoring systems with biomarkers to help stratify patients at risk and promote early intervention. MASCC and oral mucositis were independent risk factors associated with high PCT.

Discussion

This prospective study examined the predictive ability of PCT, MASCC, CISNE, and qSOFA scores to evaluate inpatient ICU admission and mortality in patients with CIFN. Higher levels of PCT (>1 ng/mL) were significantly associated with higher qSOFA and CISNE scores, lower MASCC scores, and poorer clinical outcomes. In multivariate regression analysis, independent predictors of ICU admission included RR, GIT mucositis, qSOFA, and PCT, and CISNE and MASCC were useful to further stratify the risk of complications and mortality. These results indicate that utilizing a combination of clinical scores and biomarkers provides a better model of early risk stratification in CIFN patients.

Our results are consistent with increasing evidence confirming the predictive ability of scoring systems and biomarkers in CIFN.[5] Most comparative studies have shown a clear benefit in using CISNE over MASCC to predict serious complications in hospitalized patients.[6–8] Shakinah et al[9] found a higher area under the ROC curve (AUROC) for CISNE versus MASCC in solid (0.80 vs. 0.68) and hematologic malignancies (0.85 vs. 0.65), which suggests that CISNE is better able to discriminate between patients who will and will not have complications. Anderson et al[10] also support the prognostic value of MASCC as they demonstrated that

Table 4 Multivariate analysis of survivors, ICU admissions, and PCT levels

Multivariate analysis	Survivors (*p*-value)	ICU admission (*p*-value)	PCT (*p*-value)
Respiratory rate	0.006	0.000	NS
qSOFA	0.010	0.000	NS
ICU admission	0.001	–	NS
CISNE	0.019	0.001	NS
GIT mucositis	0.045	0.015	NS
PCT	NS	0.017	–
GCS	NS	0.001	NS
SBP	NS	0.008	NS
MASCC	NS	0.000	0.026
Oral mucositis	NS	0.026	0.037

Abbreviations: CISNE, Clinical Index of Stable Febrile Neutropenia; GCS, Glasgow Coma Scale; GIT, gastrointestinal tract; ICU, intensive care unit; MASCC, Multinational Association of Supportive Care in Cancer; PCT, procalcitonin; qSOFA, Quick Sequential Organ Failure Assessment; SBP, systolic blood pressure.

low MASCC scores were associated with gram-negative bacteremia and increased mortality.

For the predictive value of qSOFA, Kim et al[11] found that qSOFA was significantly associated with ICU admission and mortality in FN, though they reported a lower AUC (0.651).[9,11] The reports of Kim et al[11] showed low sensitivity but high specificity, which suggests that qSOFA is a useful triage tool. In our population, the qSOFA score was associated with mortality and showed an AUC of 0.912, highlighting its excellent predictive ability. In regard to PCT, Chaftari et al[12] reported that PCT levels were significantly associated with bloodstream infection rates, 14-day mortality, and hospital length of stay. PCT also had superior predictive ability to MASCC in diagnosing bacteremia and provides additional information to clinical scoring systems. In our study, we found that elevated levels of PCT were independently predictive of ICU admission and worsened risk scores, suggesting that PCT provides value for early identification of risk factors.[13,14]

Many studies support the significance of clinical variables reported in our study. Using prognostic factors, Babu et al[15] found that prolonged and severe neutropenia, hypokalemia, hypotension, and pneumonia were significantly associated with mortality, similar to our identification of hypotension and mucosal injuries as important in those patients. Horasan et al[16] also found MASCC score, ICU admission, and specific pathogens in blood culture to be predictors of mortality. Like our multivariate analysis, Horasan et al[16] also found them to be independent risk factors. In addition, similar to our findings regarding systemic compromise and inflammatory response, Kim et al[11] and Cetintepe et al[17] confirmed that inflammatory markers, number of platelets, and SOFA scores were useful prognostic markers for identifying mortality and whether patients with FN would need ICU care.

Although there is wide agreement in the literature, there has also been evidence that qSOFA and MASCC scores do not always predict patient outcomes.[18–20] In their study by Moon et al,[18] qSOFA was less sensitive in the emergency department. CISNE was moderately predictive (AUROC: 0.66). These findings were at odds with our present findings, in which qSOFA had high sensitivity and specificity (AUC: 0.912). The differences in study settings and populations most likely explain this deviation.

Gram-positive and gram-negative organisms were present in 25 and 75% of the culture-positive study participants. *Escherichia coli* was the most common isolate (21.4%). Among culture-positive isolates, 32.1% had multidrug resistance. Mortality was significantly associated with GCS, RR, SBP, qSOFA, MASCC score, CISNE, oral mucositis, and GIT mucositis. ICU admissions were significantly associated with GCS, RR, SBP, qSOFA, MASCC, CISNE score, oral mucositis, and GIT mucositis. PCT levels were significantly associated with qSOFA, MASCC, and CISNE. RR, qSOFA, ICU admission, and CISNE were independent risk factors associated with mortality. The predominant organisms found among ICU patients were gram-negative, with *E. coli* being a frequently isolated organism.[21] Multidrug resistance was also prevalent, especially among *Acinetobacter baumannii* and *Klebsiella pneumoniae*. The factors associated with mortality and ICU admission were GCS, RR, SBP, and qSOFA scores. The factors that were also associated with mortality included mucositis.[21] Some other factors associated with mortality were invasive mechanical ventilation, septic shock, or use of continuous renal replacement therapy. PCT levels were associated with qSOFA, MASCC, and CISNE scores. However, qSOFA values demonstrated insensitivity in predicting severe acute cholangitis and mortality.[21]

Conclusion

This study highlights the clinical relevance of qSOFA and MASCC scores for early risk stratification in cases of CIFN. In particular, qSOFA (high scores) and CISNE (high scores) were found to be independent predictors of ICU admission and mortality. Based on these findings, the study further supports implementing these measures into a routine assessment, so

that appropriate actions can be taken quickly to improve patient outcomes. Mucositis was also found to be a vital clinical signal of poor prognosis and can inform more comprehensive supportive care approaches for high-risk patients.

Authors' Contributions

M.D. : conceptualization, manuscript writing and editing, literature search, data acquisition, data analysis.
R.B. : conceptualization, manuscript editing.
K.M.: literature search, data acquisition, manuscript editing, and manuscript review. The manuscript has been read and approved by all the authors and the requirements of authorship have been fulfilled. All the authors believe that the manuscript is of honest work.

Patient Consent

All the patients have given their informed consent.

Funding

None.

Conflict of Interest

None declared.

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