



A Study of Clinico-Hematological Profile of Patients with Febrile Neutropenia in Tertiary Care Centre

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ABSTRACT

INTRODUCTION:

Cancer has been raising rapidly and contributing more to morbidity and mortality worldwide. Chemotherapy induced myelosuppression leads to neutropenia in severe cases which associated with Febrile Neutropenia. It is major dose limiting complication. Multinational association for Supportive care in Cancer (MASCC) index widely used for stratifying patients on chemotherapy for clinical practice.

OBJECTIVE:

1. To describe the Clinical profile and Haematological Parameters in Patients with Febrile Neutropenia.
2. To describe the clinical profile with the bacterial and fungal spectrum and susceptibility patterns of pathogens in culture-positive febrile neutropenic patients.
3. To estimate the proportion of low-risk patients for serious complications of febrile neutropenia using the MASCC risk index (score ≥ 21 points).

METHODOLOGY:

Hospital based cross sectional study was conducted in the Department of Medicine, tertiary care centre, Mumbai for two years from September 2016 to Sep 2018. Sample Size of 100 was obtained based on Baskaran et al study. All patients with malignancies presenting with single oral temperature (T) equal to or more than 101°F or oral temperature (T) equal to or more than 100.4°F for one hour were included. Those who have not given consent were excluded. After obtaining the institutional ethical committee clearance, data was collected using structured proforma.

RESULTS:

The mean age of distribution of the patients were found to be 55.54 ± 14.76 , With minimum age 15 and maximum age 84. Majority patients presented with cough. The common comorbidity reported was Diabetes Mellitus (24%). The mean MASCC score was 22.67 ± 1.617 .

CONCLUSION:

Most patients with febrile neutropenia have comorbidity. The MASCC score was more in severely ill patients.

Keywords: Febrile, Neutropenia, Chemotherapy, Cancer

INTRODUCTION

The incidence of cancer is gradually escalating worldwide and thus contributes to significant morbidity and mortality. As per global burden of disease, 17.5 million cancer cases reported and 8.7

million cases resulted in mortality by 2015. There was 33% increase in incidence of cancer from the year 2005 to 2015 [1] and corresponding increase of cases receiving chemotherapy.

Chemotherapy-induced myelosuppression can lead to neutropenia, in which severe cases may be associated with fever and are called Febrile Neutropenia (FN).[2] It is the major dose-limiting complication, hence can result in chemotherapy reductions or treatment delays in subsequent cycles. This may adversely impact the treatment outcomes among cancer patients. [3,4]

Apart from the chemotherapy regimen, type and stage of tumour, and whether the neutropenia prophylaxis has been administered or not, there are various patient-level factors, that can be associated with increased risk of myelosuppression. These factors may include demographic parameters like age, gender, nutritional status of the affected person, presence of previous medical co-morbidities, and organ dysfunction at the time of initiation of chemotherapy. So, clinicians need to identify patients at high risk of developing febrile neutropenia, and manage them effectively.[5]

Multinational Association for Supportive Care in Cancer (MASCC) risk index in one such score, which has widely used in clinical practice for risk stratification of patients on chemotherapy. This score has been validated in multiple studies across the globe. [6,7]

A wide range of microorganisms can be responsible for febrile neutropenia. The proportion of people with a definitive localization of infection and with a microorganism isolated in culture, as reported by various studies is quite variable. There is also a general shift from the gram-positive organisms towards gram-negative bacterial predominance among febrile neutropenia patients in recent times. The antibiotic susceptibility pattern of the isolated organisms is also quite variable across the studies conducted in different health care institutions globally and even within different geographical localities in India. Serial studies conducted in a single institution have also documented a rapidly changing pattern of antibiotic susceptibility among febrile neutropenic patients. [8,9]

A thorough understanding of the clinical and microbiological profile, antibiotic sensitivity pattern in a particular setting may aid the clinicians in better decision making. With this setting, the present study was undertaken to describe the clinical and microbiological profile of febrile neutropenic patients

and to estimate the proportion of low-risk patients for serious complications of febrile neutropenia using the MASCC risk index.

OBJECTIVE:

1. To describe the Clinical profile and Haematological Parameters in Patients with Febrile Neutropenia.
2. To describe the clinical profile with the bacterial and fungal spectrum and susceptibility patterns of pathogens in culture-positive febrile neutropenic patients of malignancies.
3. To estimate the proportion of low-risk patients for serious complications of febrile neutropenia using the Multinational Association for Supportive Care in Cancer (MASCC) risk index (score ≥ 2 points).

MATHODOLOGY:

Study setting:

Hospital based cross sectional study was conducted in the Department of Medicine, Indian Naval Hospital Ship, Asvini hospital, Mumbai which is a tertiary care centre. The study was done for a period of two years from September 2016 to Sep 2018.

Sample Size:

The sample size was attained based on Baskaran N.D et al study[10], the proportion of Febrile neutropenia was 43.1%, and with 95 % confidence interval and taking absolute precision of 10% the sample size calculated was 95 which is rounded off to 100.

Inclusion Criteria:

All patients with malignancies presenting with single oral temperature(T) equal to or more than 101°F or oral temperature (T) equal to or more than 100.4°F for one hour and absolute neutrophil count (ANC) of less than 500 cells/ cu.mm or predicted to decline <500 cells/cu.mm in next 48 hours were included.

Exclusion Criteria:

Patients who have not given consent were excluded.

Data Collection:

After obtaining the informed written consent, all the study subjects were evaluated by thorough clinical history, physical examination, and appropriate

investigations. All the relevant parameters were documented in a structured study proforma.

The following parameters were documented in the study proforma.

1. Personal particulars like Name, Age, Gender, occupation, Present, and Past History were documented. General and systemic examination was done, vitals recorded, the outcome was documented.
2. Haematological and biochemical investigations, Serum procalcitonin, Blood culture & Sensitivity, X-ray chest PA view, and USG Abdomen were done
3. The Multinational Association for Supportive Care in Cancer (MASCC) risk index score [11]
4. *Components of the multinational association for supportive care in cancer index*

Clinical characteristic	Score ^b
The burden of illness (1 of the 3 options only) ^a :	
No or mild symptoms	5
Moderate symptoms	3
Severe symptoms	0
No hypotension (systolic BP > 90 mmHg)	5
No chronic obstructive pulmonary disease	4
Solid tumour or no prior fungal infection in a patient with hematologic neoplasm	4
No dehydration (hydration with IV fluids not required)	3
Outpatient at the onset of fever	3
Age < 60 years	2

^aBurden of illness, no chronic obstructive pulmonary disease, and no dehydration are not objective criteria.

^bMaximum score: 26 (5 + 5 + 4 + 4 + 3 + 3 + 2). Low risk for complication = score \geq 21; high risk for complication = score < 21, BP = blood pressure; IV = intravenous.

Statistical analysis:

After collecting the data, it was entered in MS excel Windows10. Statistical analysis was done in SPSS 20. Continuous data were expressed in terms of Mean \pm Standard deviation and Compared by independent sample t test. Categorical variable were expressed in terms of numbers (percentages) and compared by the chi-square test.

RESULT

The mean age of the samples was 55.54 ± 14.76 . The minimum age was 15 and the maximum age was 84. 58% of participants were males and the remaining 42% participants were females. Among the study population, 53 % of the subjects were workers, 42% were homemakers and 5% were students.

The most common presentation was with cough is of 18% followed by thrombophlebitis 11%, Dysuria 10% etc (Table 1)

The most common comorbidity present was type 2 diabetes mellitus in 24% of the study subjects, followed by hypertension 21%. (Table 2)

Piperacillin + Tazobactam combination was the most common Prophylactic (Empirical) Antibiotic used in 56% of the study population, followed by Cefoperazone + sulbactam 12%. Concomitant steroid use was reported in 11%. (Table 3)

The mean MASCC score was 22.67 ± 1.614 among the study population. The minimum and maximum values were 20 and 26 among the study population. 12 patients had MASCC score less than 21 (High risk) and 88 patients had MASCC score equal to or greater than 21 (Low Risk). Among the study population, 96% of them recovered without any complications, and the remaining 4% met with mortality. Among the people who died, 3% belong to a low-risk group and 1% belong to high risk.

The mean of Haemoglobin was 10.37 ± 1.98 . The minimum level was 5.60 and the maximum level was 15. The mean of ANC was 412.0 ± 90.79 . The minimum level was 110 and the maximum level was 600. The mean of S Procalcitonin was 8.04 ± 7.08 . The minimum level was 0.08 and the maximum level was 34.86. (Table 4)

E.Coli and S.Aureus were the most common organism isolated in blood culture in 7% of the population each. S.Epidermidis, K.Pneumoniae, and

S.Pneumonia were isolated in 4% of the subjects each. MRSA was isolated in 3% of the subjects and P. Aeruginosa was isolated from 2% of the subjects. (Table 5)

In urine culture, 86% had no growth. The most common organism isolated was E.coli in 10% of the subjects. Pseudomonas aeruginosa was the most common organism isolated in sputum culture, followed by Klebsiella pneumoniae 2%. MRSA was isolated in 5% of the Skin swab/Pus culture specimens. MRSA was the most common organism isolated in I.V Access catheter tip culture and S.Aureus was isolated in 4% of the specimens.

Among the study participants 12 had high risk, among them 9 died. Rest 88 had low risk of which 6 died. And this difference is statistically significant. (Table 6)

DISCUSSION

The study population included 100 patients with febrile neutropenia. The mean age of the study participants was 55.54 ± 14.76 . Literature had reported varying ages for the incidence of FN. A similar observation was seen in a study done by Tamai et al [12].

The majority of the participants were males (58%). Our results were consistent with the studies done by Karanwal AB et al [13], Jacob LA et al [14], Pinto J et al in 2017, reported that a slightly higher male predominance (59%) was seen [15].

In the present study, the most common presentation was cough in 18% of the patients, followed by 13% who had loose stools. In the study reported by Karanwal AB et al, cough and dyspnoea were reported in 30.4% and 22% of the study population [13]. Diarrhoea was reported in 22% of study participants.

Among the study population, PICC was present in 33% of the population and 9% had chemoport. The perianal abscess was present in 4% of the subjects. Baskaran N et al PICC infection in 33% and perianal abscess in 6.9% of study participants [10]. Peripherally inserted central catheters (PICC) are commonly employed in cancer patients and in 2 cohorts the incidence of PICC-related BSIs was very low (0.05 per 1000 catheter days), although the

incidence of localized PICC-associated infections and thrombosis was high [16].

The most common comorbidity present was Type 2 diabetes mellitus in 24% of the study subjects, followed by hypertension among 21%. Jacob LA et al reported that comorbidity was present in 58.6% of the study participants [14]. Also, a statistically significant difference in comorbidity was reported between participants with haematological malignancy and solid tumour in their study. Whereas Bhaskaran ND et al reported that comorbid conditions were present in 17.2% of the study participants [10]. Park Y et al reported diabetes in 16.6% and hypertension in 14.7% of the study participants [17]. Marc Gregory Y et al reported that asthma and cardiovascular disease were present among 1.7% and 8% of the participants respectively [18]. Lustberg MB et al reported that risk factors for febrile neutropenia include older age, comorbidities, and a history of multiple cytotoxic chemotherapy regimens [19]. Hosmer W et al, in a predictive model of Increased risk of FN with comorbidities reported that the risk for FN increased with the number of comorbidities (one comorbid condition, odds ratio [OR] = 1.13, P = 0.02; two comorbid conditions, OR= 1.39, P < 0.001; three comorbid conditions, OR= 1.81, P < 0.001) [20].

Piperacillin+Tazobactam combination was the most common Prophylactic (Empirical) Antibiotic used in 56% of the study population. Bhaskaran ND et al reported that antibiotic prophylaxis was provided for 11.2% of the study participants [10]. Several controlled clinical trials and meta-analyses have demonstrated a significant reduction in the risk of FN in patients randomized to receive primary prophylaxis with granulocyte colony-stimulating factors following the initiation treatment with chemotherapy. However, they have been associated with additional toxicity and the emergence of antibiotic-resistant bacteria [21]. Kuderer NM et al in a systematic review reported that prophylactic G-CSF reduces the risk of FN and early deaths, including infection-related mortality while increasing RDI and musculoskeletal pain [22]. Fluoroquinolone prophylaxis especially with Levofloxacin has also been found to be a useful prophylactic agent [23].

The mean MASCC score was 22.67 ± 1.614 among the study population. The minimum and maximum

values were 20 and 26 among the study population. 12 patients had MASCC score less than 21(High risk) and 88 patients had MASCC score equal to or greater than 21(Low Risk). Patients with a MASCC score of 21 or greater are considered low risk, and patients with lower scores are considered higher risk and need more intensive management [19]. The mean MASCC score was 22.67 ± 1.614 in the current study. 88 patients (88%) had MASCC scores greater than or equal to 21(Low Risk). 12 patients (12%) had a score less than 21(High risk). In this study, only one patient (1%) among the high-risk group died. Yapici O et al reported that prolonged neutropenia and MASCC score <21 were found to be significantly associated with mortality ($P < 0.001$) in their study[24].

The mean of Hemoglobin was 10.37 ± 1.98 . The mean of ANC was 412.0 ± 90.79 . The mean hemoglobin was 10.37 ± 1.98 g/dl and the mean ANC was 412.0 ± 90.79 cell/ μ l. Whereas Karanwal AB et al reported mean Hb level as 6.8g/dl [13]. Patil VN et al reported mean HB level as 7.9(3.1-14.5) g/dl [11]. The mean of ANC was $411.48 \pm 91.46/\text{mm}^3$. But this was far higher compared to Karanwal AB et al [13] who reported ANC level as $120/\text{mm}^3$. Park Y et al <100 cells/ mm^3 was found in 63.3% of the study participant [17]. Kim DY et al reported that the median ANC in their study was 130(40-380)/ mm^3 [25]. Nordwig J et al reported that older age (>60 years) and baseline anemia, hypoalbuminemia, and leukocytosis, as well as comorbidity and disseminated disease stage, are independent risk factors for infections [26]. Anaemia in cancer patients is a significant prognostic factor and has shown to be a strong predictor of poorer survival in this patient group [27].

In the current study, positive bacterial culture was found in 31% of the participants. E.Coli and S.Aureus were the most common organism isolated in blood culture in 7% of the population each. A study by Karanwal AB et al demonstrates that gram-negative organisms are still the predominant pathogens causing bacteremia in FN patients [13]. The most common organisms were: Escherichia coli (43%). Jacob AL et al reported that the culture positivity rate was 21.3%, blood being the most common site of positive culture (14.7%) [14]. 56.25% of the positive cultures yielded Gram-negative bacteria, 31.25% Gram-positive, and 12.5% mixed (both Gram-positive and Gram-negative) [14].

Staphylococcus aureus was the most common Gram-positive organism and K. pneumonia, E. coli, and Acinetobacter the most common Gram-negative organisms isolated in FN patients [14]. Roongpoovapatr P et al documented that gram-negative bacteria were the most frequently isolated pathogens (63.9%), followed by Gram-positive bacteria (29.9%) and fungi (6.2%). Escherichia coli (46.8%) and coagulase-negative Staphylococcus (27.6%) were the most common isolates among Gram-negative and Gram-positive bacteria, respectively [27]. Patil VN et al reported that the majority of isolates were Gram-negative organisms (50 cases, 72%) [11]. In the present study Pseudomonas aeruginosa was the most common organism isolated in sputum culture, followed by Klebsiella pneumoniae in 2%, Acinetobacter baumannii, and P. Jerovocii in 1% each. Whereas Lakshmaiah V et al reported that sputum culture was positive in 7/108 (7.41%) of FN episodes [28]. The most common isolate in sputum was P. aeruginosa and E. coli followed by K. pneumoniae, A. baumannii, and S. aureus. Skin swab/ Pus culture was done in 13 subjects.

CONCLUSION:

It is very important to diagnose early and treat the serious infections which cause morbidity and mortality in neutropenic patients. Due to inadequate clinical and microbiological data it was a great problem in diagnosis Febrile neutropenic patients and for treatment. Because of all these factors antibiotic therapy was still considered as standard therapy. But this approach leads to antibiotic resistance. So it is advisable for the tertiary care centre to follow their own type of infection and follow empirical therapy.

LIMITATIONS

The key limitation of the current study is the relatively smaller sample size of the study. Hence there is a high probability of chance occurrence of many of the findings. The generalizability of the study findings is limited, as the profile of the subjects with FN can be quite variable across the settings.

RECOMMENDATIONS

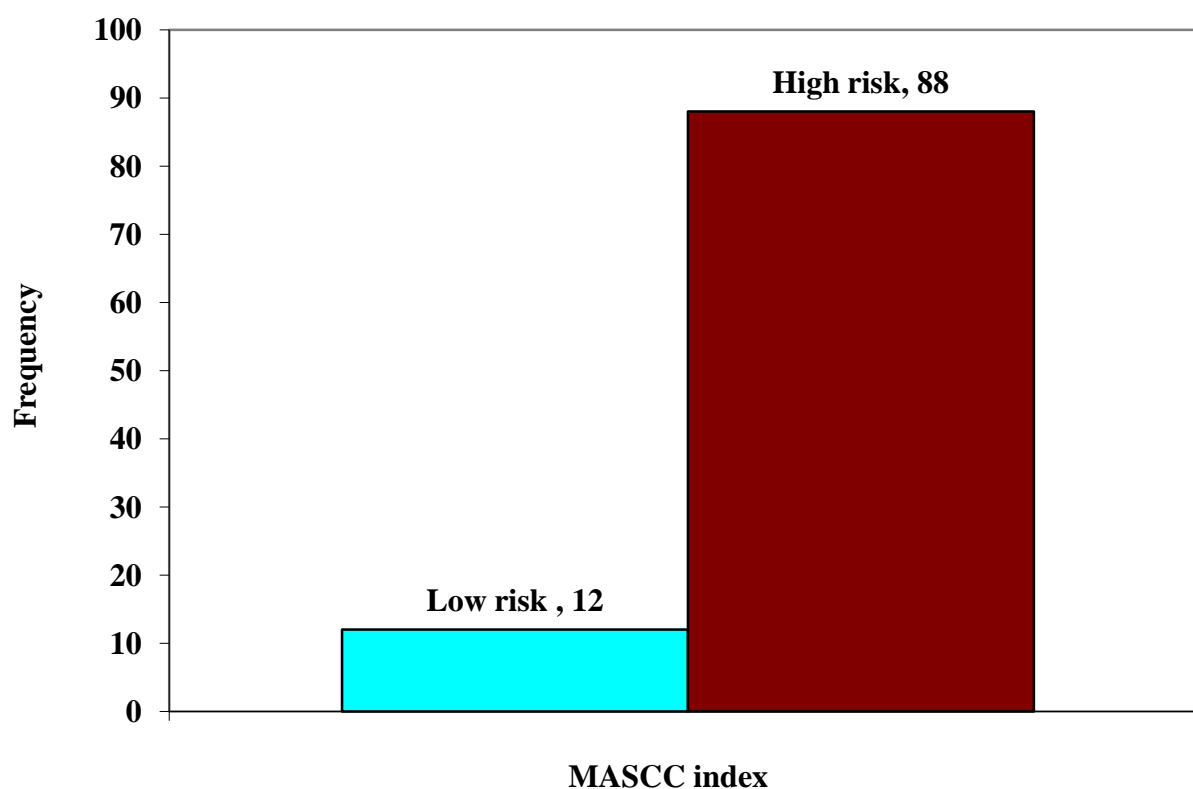
There is a need to setup Febrile Neutropenia (FN) surveillance system in all the health care settings, administering cancer chemotherapy. Periodic analysis of the surveillance data can aid the clinicians in

changing the profile of the FN patients, microbiological profile, and their antibiotic susceptibility pattern. The antibiotic treatment regimens should be used rationally, based on culture and sensitivity pattern, to avoid inadvertent development of antibiotic resistance.

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Figure 1: Frequency distribution of study population based on MASCC index score**Table 1: Descriptive analysis of clinical symptoms (N=100)**

System	Frequency (N)	Percentages (%)
Cough	18	18
Dyspnea	8	8
Constipation	2	2
Loose stools	13	13
Vomiting	3	3
Dysuria	10	10
Haematuria	2	2
Abscess at chemoport site	3	3
Abscess at PICC site	5	5
Furuncle	3	3
Thrombophlebitis	2	2
Oral mucositis	11	11
Sorethroat	10	10
Headache	3	3

Table 2: Frequency distribution of co-morbidities(N=100)

Co-morbidities	Frequency (N)	Percent (%)
Hypertension	21	21
DM Type 2	24	24
Asthma/COPD	12	12
Hypothyroidism	5	5
Immunosurveillance	1	1
Chronic kidney disease	4	4
Coronary artery disease	2	2
Cerebrovascular accident	3	3
Nil	28	28

Table 3: Descriptive analysis of Prophylactic (Empirical) Antibiotic in study population

Parameter	Frequency (N)	Percent (%)
Piperacillin+Tazobactam	56	56
Cefoperazone+sulbactam	12	12
Meropenam+Teicoplanin	10	10
Cefepime+Tazobactam	6	6
Meropenam+Teicoplanin+Caspofungin	5	5
Piperacillin +Tazobactam+ Amikacin	3	3
Teicoplanin	3	3
Piperacillin +Tazobactam+ Amikacin+Caspofungin	2	2
Piperacillin+Tazobactam+Trimethoprim+Sulfamethoxazole	1	1
Cefepime+Tazobactam+Caspofungin	1	1
Piperacillin+Tazobactam+Fluconazole	1	1

Table 4: Descriptive analysis for Hb, TLC, ANC, Platelet count, Bilirubin, SGOT, SGPT, PT, APTT, INR in study population (N=100)

Parameter	Mean \pm STD	Median	Min	Max
Hb	10.37 \pm 1.988	10.20	5.60	15.00
TLC	931.7 \pm 276.7	980.00	220.00	1900.00
ANC	412.0 \pm 90.79	440.00	110.00	600.00
Platelet count	17649 \pm 86425	150000	30000	540000

S.Bilirubin	0.933 ± 0.722	0.75	0.20	3.40
SGOT	42.99 ± 29.93	35.00	12.00	212.00
SGPT	46.15 ± 26.06	44.00	12.00	203.00
PT	13.79 ± 3.359	12.80	12.00	35.00
APTT	33.27 ± 30.74	28.85	25.00	334.00
INR	1.160 ± 0.292	1.04	0.92	2.97

Table 5: Descriptive analysis of Culture in study population (N=100)

Type of Samples	Growth Present		Growth Absent	
	Frequency	Percent (%)	Frequency	Percent (%)
Blood culture	31	31	69	69
Urine culture	14	14	86	86
Stool culture (indication only in 15 samples)	4	4	11	11
Sputum culture (indication only in 23 samples)	13	13	10	10
Skin swab/ Pus culture (indication only in 13 samples)	13	13	0	0
I.V Access catheter tip culture (indication only in 43 samples)	9	9	34	34

Table 6: Association between the patient status and the MASCC score index

MASCC index	Survived	Died	P Value
High risk (<21)	6(7%)	9(75%)	<0.001
Low risk (>21)	82(93%)	3(25%)	
Total	88(100)	12(100)	