GCC Cancer Treatment Protocol Guidelines for Breast and Colorectal Cancer

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Introduction

Due to the type and intensity of treatment received and other risk factors, many cancer patients experience a decrease of elements of the immune systems that make them more exposed to various infections. In the latter condition, the body in not able to fight against the causative agents effectively. One type of blood elements whose number commonly decreases during cancer is the group of neutrophil, which constitutes the first line of the body defence against diseases. The decline in the neutrophil number associated with fever is known as febrile neutropenia (FN). Neutropenia is considered as an oncology emergency and can lead to serious adverse consequences such as serious infection complications and death. (1, 2).

Abstract

Febrile neutropaenia (FN) is defined as an oral temperature of >38.3°C or two consecutive readings of >38.0°C for 2 hours and an absolute neutrophil count (ANC) of <0.5 x 10⁹/l, or expected to fall below 0.5 x 10⁹/l. Fever is one of the characteristic symptoms of FN and is usually associated with the presence of an infection caused by various microorganisms.

The incidence and epidemiology of FN are variable based on different factors: (type of cancer, the age/sex of the patient, chemotherapy type/number of cycles). FN remains one of the most common and risky complications of chemotherapy which occurred within 6–8 days with standard chemotherapy and it is occurred as about 7–8/1000 patients receiving treatment with chemotherapeutic agents. There is a clear relationship between the severity of neutropaenia (which directly influences the incidence of FN) and the intensity of chemotherapy. Currently, the different regimens are classified as producing a high risk (>20%), an intermediate risk (10%–20%) or a low risk (<10%) of FN.

The causative organisms including either bacteria, fungi or viruses. The bacteria Gram–positive (currently dominating) and Gram–negative (Dominant in the 1970s), are usually the main microorganisms responsible for FN and cause complicated infections.

Although the morbidity and mortality rates of FN have decreased over the years due to use of proper antibiotic treatment, preventive measures and use the standard–risk management plan as per guidelines but it is still one of oncological emergency. FN is responsible for considerable morbidity as 20%–30% of patient’s present complications that require in–hospital management, with an overall in–hospital mortality of ∼10%.

Keywords: Febrile Neutropenia, Cancer, Solid Tumour, Chemotherapy.
used to be non-pathogenic is eased and this associated with the increase of antibiotic multi–resistances constitute a serious public health concern at a global level. (3)

**Definition of Febrile Neutropenia**

Neutropenia is a condition characterised by low number of neutrophil (<500 cells/mm³), the most abundant circulating white blood cells that constitute the first line of the organism defence against infections. Febrile neutropenia refers to the occurrence of a fever (≥ 38.3°C) during a period of significant neutropenia (Fig. 1). (3)

There was a different definition that described FN reported by health institutions in different countries (Table 1).

**Incidence and Epidemiology**

The patients who were starting chemotherapy were believed to be at risk of developing FN at a rate of ≥ 10%. It was revealed that after the initial four chemotherapy cycles, cancer patients developed 3–4 grade neutropenia (absolute neutrophil count <1.0 × 10⁹ /L) and FN (absolute neutrophil count <0.5 × 10⁹ /L and fever ≥ 38 °C) with an incidence of 11% and 4.3% respectively.

<table>
<thead>
<tr>
<th>Source</th>
<th>Fever (°C)</th>
<th>Neutropenia (&lt;10⁹ cells/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bugs &amp; Drugs (2012)</td>
<td>≥38.3 oral temperature or ≥38.0 over 1 hour</td>
<td>ANC &lt;0.5 x 10⁹/L (500 cells/mm³)</td>
</tr>
<tr>
<td>Infectious Diseases Society of America (2011)</td>
<td>≥38.3</td>
<td>ANC &lt;0.5 or predicted decline to &lt;0.5 over next 48 hours</td>
</tr>
<tr>
<td>National Comprehensive Cancer Network (2011)</td>
<td>≥38.3 oral temperature, or ≥38.0 over 1 hour</td>
<td>ANC &lt;0.5 or &lt;1.0 with predicted decline to &lt;0.5 over next 48 hours</td>
</tr>
<tr>
<td>European Society of Medical Oncology (2010)</td>
<td>&gt;38.5 oral temperature or ≥38.0 for 2 hours</td>
<td>ANC &lt;0.5 or predicted decline to &lt;0.5</td>
</tr>
<tr>
<td>British Columbia Cancer Agency (2008)</td>
<td>≥38.3</td>
<td>ANC &lt;0.5</td>
</tr>
<tr>
<td>Japan Febrile Neutropenia Study Group, 2005</td>
<td>≥38.0 single oral or ear probe temperature or &gt;37.5 single axillary temperature</td>
<td>ANC &lt;0.5 or &lt;1.0 in subjects with predictably deteriorating clinical condition</td>
</tr>
</tbody>
</table>

**Table 1. Published definition of febrile neutropenia.** (5)

Schelenz et al. 2011, demonstrated the variability of the incidence of FN according to several factors including cancer type, chemotherapy regimen, antibiotic treatment, age and sex. Patients suffering from both solid tumours and FN and receiving a routine care at a local cancer centre in the UK were investigated over a one year period. It was shown that the incidence of FN over the 12 months period was 19.4 per 1000 oncology admissions. The cancer types that were most associated with FN were breast, lung, ovarian and oesophageal malignant tumours, accounting for 27%, 16%, 13% and 13% respectively. With regards to the age and sex, the mean age was 63 years (71.9% were at least 60 years old) and 56% of patients was female. Table 2 provides more information about the type of cancer and patients screened as well as the outcomes of the study.

The epidemiology of FN is also variable according to several factors. It has been reported that 50% of deaths

<table>
<thead>
<tr>
<th>Underlying cancer</th>
<th>No. (%)</th>
<th>Death No. (%)</th>
<th>Age (%) &gt;60 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer</td>
<td>9/32 (28.1)</td>
<td>0/9 (0)</td>
<td>5/9 (56)</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>5/32 (15.6)</td>
<td>1/5 (20)</td>
<td>5/5 (100)</td>
</tr>
<tr>
<td>Oesophageal cancer</td>
<td>5/32 (15.6)</td>
<td>0/5 (0)</td>
<td>4/5 (80)</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td>4/32 (12.5)</td>
<td>2/4 (50)</td>
<td>3/4 (75)</td>
</tr>
<tr>
<td>Brain tumour</td>
<td>2/32 (6.3)</td>
<td>2/2 (100)</td>
<td>2/2 (100)</td>
</tr>
<tr>
<td>Sarcoma</td>
<td>2/32 (6.3)</td>
<td>0/2 (0)</td>
<td>0/2 (0)</td>
</tr>
<tr>
<td>Pancreatic cancer</td>
<td>1/32 (3.1)</td>
<td>1/1 (100)</td>
<td>1/1 (100)</td>
</tr>
<tr>
<td>Bladder cancer</td>
<td>1/32 (3.1)</td>
<td>0/1 (0)</td>
<td>1/1 (100)</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>1/32 (3.1)</td>
<td>0/1 (0)</td>
<td>1/1 (100)</td>
</tr>
<tr>
<td>Thyroid cancer</td>
<td>1/32 (3.1)</td>
<td>0/1 (0)</td>
<td>1/1 (100)</td>
</tr>
<tr>
<td>Melanoma</td>
<td>2/32 (3.1)</td>
<td>0/1 (0)</td>
<td>0/1 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>6/32 (18.8)</td>
<td>23/32 (71.9)</td>
</tr>
</tbody>
</table>

**Table 2: Distribution of cancer type, mortality and febrile neutropenia.** (8)
in patients receiving chemotherapy for solid tumors is attributable to FN. In patients being administrated chemotherapy for acute leukemia, FN represents 50% to 75% of deaths. The rapid administration of antibiotics has triggered a response rate of up to 60% to 70% and reduced the mortality to 10%. In the USA, a mortality rate associated with grade 3 and 4 neutropenia ranging from 3.4% to 10.5% with an overall mortality ranging from 6.8% to 9.5% was reported. (6)

There have been some significant advances in the prevention and treatment of FN that have led to a decrease in the number of death. However, the condition remains one of the most worrying complications of chemotherapy. (7)

In patients suffering of solid tumours and some haematological malignancies, the overall mortality rates are 5% and 11% respectively. This increases to 15% in patients with confirmed bacteraemia related to Gram—negative bacteria, whereas Gram—positive bacteraemia accounts for 5%. The group of patients which is at a higher risk of FN and which exhibits the worst morbidity and mortality rates is constituted by the elderly patients. In the study of Schelenz et al. 2011, conducted in the UK, it was shown that the epidemiology of FN varies according to e.g. the type of cancer and the age. The total mortality rate was 18.8%, and 83% of the patients who died were aged 60 or over. No FN related death was observed with patients suffering from melanoma, thyroid cancer, colorectal cancer, bladder cancer, and sarcoma and oesophageal cancer. The rest of the types of cancer exhibited a variable mortality rate (Table 2).

Risk Stratification

According to National Comprehensive Cancer Network (NCCN) guideline patients who develop neutropenia can be categorized as at low risk or high risk of complications. The practical implication of risk assessment is to allow the development and implementation of a management plan to be applied to the particular FN case (e.g. type of treatment, outpatient or hospitalization). (2)

The National Comprehensive Cancer Network (NCCN) and other institutions have issued guidelines for the stratification of FN risks and encourage the usage of the Multinational Association for Supportive Care in Cancer (MASCC) index to identify patients according to the MASCC scores, a patient with a score <26 is to be considered at low risk and treated as an outpatient, whereas a patient with a score >21 is at high risk and should be hospitalized (Figure 2, & Table 3).

Pathophysiology

Neutropenia is most commonly seen as a result of cytotoxic therapy although the ANC of individuals can drop significantly through cancer’s direct interaction with haematopoiesis (e.g. leukemia) or the bone marrow metastatic replacement. (10)

The types of chemotherapy that can highly induce neutropenia include products such as the anthracyclines, taxanes, topoisomerase inhibitors, platinum’s, gemcitabine, vinorelbine, and certain alkylating like cyclophosphamide and ifosfamide. (11)

Lewis et al., 2011, (10) reported that the nadir in ANC happens 5 to 10 days after the last dose in most outpatients undergoing chemotherapy regimens. Inpatient medications provided for the treatment of e.g. hematologic malignancies usually results in a severe and long term neutropenia. The intensity and length of FN are important risk factors for complications. Other risk elements are e.g. the speed of the ANC decline, previous history of FN or current immunosuppression pre—treatment, augmentation in alkaline phosphatase, bilirubin, or aspartate aminotransferase levels, low glomerular filtration rate and cardiovascular comorbidities.

Microorganisms

The microbiological profile of FN associated infections has evolved internationally over the years. It has been stated that in the 1060 and 1970s Gram—negative microorganisms were mainly reported (60 to 70%), whereas in the 1980s and 1990s, Gram—positive bacteria dominated (55 — 70%). (3, 12, 13) The mechanisms behind this shift in not well known but may be attributed to factors such as the type of treatment that have undergone various modifications as a result of modernization. The intensification of cancer treatment have resulted in the occurrence of more severe oral mucositis and diarrhea that cause significant damage of mucosal barriers and an
Table 3: Characteristics of patients at risk for complications from febrile neutropenia (9)
(Includes data from the NCCN guidelines and other sources)

<table>
<thead>
<tr>
<th>Low risk (most of the factors listed below)</th>
<th>High risk (any of the factors listed below)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No high risk factors</td>
<td>MASCC risk index score ≥21</td>
</tr>
<tr>
<td>MASCC risk index score ≥21</td>
<td>MASCC risk index score &lt;21</td>
</tr>
<tr>
<td>Outpatient status at time of development of fever</td>
<td>Inpatient status at time of development of fever</td>
</tr>
<tr>
<td>No associated acute comorbid illness independently indicating inpatient treatment or close observation</td>
<td>Insignificant clinical comorbidity or medically unstable, including:</td>
</tr>
<tr>
<td>Anticipated short duration of severe neutropenia (≤100 cells/mL for &lt;7 days)</td>
<td>Anticipated prolonged severe neutropenia (≤100 cells/mL for ≥7 days)</td>
</tr>
<tr>
<td>Good performance status (ECOG 0-1)</td>
<td>Uncontrolled/progressive cancer; pneumonia or other complex infections at clinical presentation; alemtuzumab therapy; mucositis grade 3-4</td>
</tr>
<tr>
<td>No hepatic insufficiency</td>
<td>Hepatic insufficiency (five times ULN for aminotransferases)</td>
</tr>
<tr>
<td>No renal insufficiency renal</td>
<td>Insufficiency (creatinine clearance &lt;30 mL/minute)</td>
</tr>
<tr>
<td>&lt;60 years</td>
<td></td>
</tr>
<tr>
<td>Cancer partial or complete remission</td>
<td></td>
</tr>
<tr>
<td>No focal findings of infection</td>
<td></td>
</tr>
<tr>
<td>Temp &lt;39 °C</td>
<td></td>
</tr>
<tr>
<td>Normal chest x ray</td>
<td></td>
</tr>
<tr>
<td>Absence hypotension</td>
<td></td>
</tr>
<tr>
<td>Respiratory rate ≤ 24</td>
<td></td>
</tr>
<tr>
<td>No chronic lung disease or diabetes</td>
<td></td>
</tr>
<tr>
<td>No dehydration/confusion</td>
<td></td>
</tr>
<tr>
<td>No history of fungal infection or antifungal therapy in past six months</td>
<td></td>
</tr>
</tbody>
</table>

Kristjanson (2015) (13) reported that the common bacteria isolated from blood cultures are coagulase-negative staphylococci and Viridans group streptococci and that the frequency of antibiotic-resistant Gram-negative bacterial infections is increasing. The Gram-positive bacteria commonly reported in FN associated infections are coagulase-negative staphylococci, Staphylococcus aureus, including methicillin-resistant isolates, Enterococcus species, including those which are resistant to vancomycin, Viridans group streptococci, Streptococcus pneumoniae (increasing macrolide resistance), Group A β-haemolytic streptococci such as Streptococcus pyogenes.

For Gram-negative microorganisms associated with FN infections, different types of bacteria have also been reported including e.g. Escherichia coli (most common elevated risk of local Gram-positive microbial infections. Also, the increased use of partially or totally implantable intravenous catheters may have contributed to the occurrence of staphylococcal infections. (3)
GNB), species of Klebsiella, Enterobacter, Citrobacter, and Acinetobacter as well as Stenotrophomonas maltophilia, and Pseudomonas aeruginosa.

A broad range of antibiotics are used to treat cancer patients who exhibit a febrile condition and there are many resistant microorganisms that cause further complications. Antibiotic resistance is a current serious international public health concern and special care with regards to resistant microorganisms is need. Well-known resistant bacteria associated with cancer patient febrile infections include e.g. methicillin-resistant Staphylococcus aureus (MRSA), coagulase-negative staphylococci, vancomycin-resistant enterococci, viridians group streptococci, ciprofloxacin-resistant Escherichia coli, and Pseudomonas aeruginosa. (14)

Some FN infections are not associated with bacteria but other types of microorganisms such fungi mainly may also be present. It is estimated that more than 20% of all neutropenic patients may develop systemic fungal infections whose causative agents include Candida, Aspergillus, Fusarium, Scedosporium species mainly (90%). (12)

**Management**

Before administrating any treatment to FN patients, it is important to consider carefully the medical history of the patient and proceed to various examinations and tests in order to provide the best treatment option. The vast majority of FN cases, as managed according to the algorithm set out in (Fig. 3), respond promptly to empirical therapy, suffering no major complications (Table 4).

**Low-risk patients**

A recent review has concluded that inpatient oral antibacterial therapy can be safely substituted for conventional intravenous (i.v.) treatment in some low-risk FN patients, namely those who are haemodynamically stable, do not have acute leukaemia or evidence of organ failure and do not have pneumonia, an indwelling venous catheter or severe soft tissue infection. (9)
Table 4: Examples of screening recommendations and treatment for febrile neutropenia patients. (2, 5)

| Investigations | • CBC and differential  
|               | • Transaminases, bilirubin, alkaline phosphatase  
|               | • Electrolytes  
|               | • Creatinine and urea  
|               | • Blood and urine cultures  
|               | • Sputum gram stain and culture if productive  
|               | • AST  
|               | • Nasopharyngeal swab for viral respiratory panel PCR, if respiratory symptoms are present  
|               | • Chest x-ray (should be obtained even in the absence of pulmonary symptoms or signs) |
| Monotherapy   | • Cefipime 2 grams IV every 8 hours.  
|               | • Carbapenem monotherapy is an alternative to piperacillin-tazobactam. In order to prevent the selection of carbapenem resistance, carbapenems should not be used in first line unless there is a known or suspected infection with ESBL/AmpC cephalosporinase-producing organisms or a penicillin allergy.  
|               | • Ceftazidime monotherapy is not recommended, as it: 1. Has no reliable Gram positive (Enterococci, Streptococci, Staphylococci) activity compared to piperacillin-tazobactam, 2. May promote antimicrobial resistance (ESBL and AmpC cephalosporinases), 3. Is not optimal in patients with profound (<0.1 x 109/L)/prolonged neutropenia |
| Combination Therapy | • Piperacillin-tazobactam 4.5 grams IV every 8 hours is the treatment of choice.  
|                   | • β-Lactam plus an aminoglycoside plus vancomycin is recommended until C&S results are available in patients who are hemodynamically unstable or have septic shock. In such circumstances, vancomycin 15 mg per kg IV every 12 hours should be administered, in combination with either gentamicin 5-7 mg/kg IV every 24 hours or tobramycin 7 mg/kg IV every 24 hours |
| Recommendations for the Use of Vancomycin | • Empiric vancomycin should not be used routinely, but should be considered in the following circumstances: Concern of a major β-lactam allergy, Obvious IV catheter/tunnel infection, Gram stain of culture reveals gram-positive organism, with organism not yet identified, Known colonization with MRSA or penicillin-resistant S. pneumonia o Hypotension/shock, Quinolone antibiotic prophylaxis of Skin or soft tissue infection of Pneumonia o Hemodynamic instability  
|                   | • Vancomycin therapy should be stopped on day 2 or 3 if cultures are negative for β-lactam resistant Gram positive organisms. |
| Anti-fungal therapy | • Fluconazole, Voriconazole, Posaconazole, Amphotericin B, Itraconazole, Posaconazole, Caspofungin |

### High-risk patients

Patients with FN who are at high risk as assessed by the MASCC criteria (<21), or have high–risk features as judged by the admitting doctor, should be admitted and commenced on broad spectrum i.v. antibiotics, since the risk of bacterial sepsis is very high. (9)

### Role of Filgrastim (G–CSF) in the management of Febrile Neutropenia

Filgrastim (recombinant human granulocyte colony stimulating factor, rG-CSF) is a hematopoietic growth factor which regulates the production and function of neutrophils.

Several meta–analyses indicate that primary prophylaxis with GCSF (i.e. G–CSF administered immediately after cycle 1 of chemotherapy) reduces the
risk of FN by at least 50% in patients with solid tumours without significantly affecting tumour response or overall survival. Most guidelines recommend that G-CSF be administered prophylactically if the risk of FN is >20% for all planned cycles of treatment.

The standard Dose of G-CSF is 5 μg/kg/day of G-CSF subcutaneously (s.c.) 24–72 h after the last day of chemotherapy until sufficient/stable post–nadir ANC recovery (achieving a target ANC of >10–109/l is not necessary).

Pegfilgrastim which is a PEGylated form of the recombinant human granulocyte colony–stimulating factor (GCSF) analog filgrastim, injected s.c. as a single dose of either 100 μg/kg (individualised) or of a total dose of 6 mg (general approach), is considered equally effective. The equivalent dose of filgrastim is 5μg/kg/day for ∼10 days. (9)

Duration of Therapy

If the ANC is ≥0.5 × 109/l, the patient is asymptomatic and has been afebrile for 48 h and blood cultures are negative, antibacterial can be discontinued if the ANC is ≤0.5 × 109/l, the patient has suffered no complications and has been afebrile for 5–7 days, antibacterial can be discontinued except in certain high-risk cases with acute leukaemia and following high–dose chemotherapy when antibacterial are often continued for up to 10 days, or until the ANC is ≥0.5 × 109/l. Patients with persistent fever despite neutrophil recovery should be assessed by an ID physician or clinical microbiologist and antifungal therapy considered (Fig. 4). (9)

Prevention

Since FN in cancer patients is usually a direct consequence of chemotherapy, an evaluation of risks factors associated with FN is necessary before any attempt to prevent the occurrence of the condition. It is difficult to prevent the occurrence of FN, but measures can be taken to decrease the risks of infections, the first action being the maintenance of a good hygiene (e.g. body, environment, and food) for both patients and medical staff.

In the elderly patients (aged 65 and over), there is an elevated risk of FN occurrence and particular consideration should be given to this category of patients. Additional FN risks include e.g. the level of the disease, history of FN episodes, lack of prophylaxis and treatment related to other adverse medical condition such as diabetes, cirrhosis that include the use of immunosuppressive agents. (15) Lustberg 2012, (1) also reported that one important factor that can help in the prevention of FN is the education of patients and their families as it can raise the awareness of individuals about the types of activities that should be avoided or done to minimize the FN occurrence risk and infectious complications during neutropenia.

In general, when preventive strategies are applied, many risk factors are reduced, and most patients are able to receive safely and complete the chemotherapy regimen of choice for their malignancy. (9)

References


