RISK OF COMPLICATIONS ASSOCIATED WITH FEBRILE NEUTROPENIA AMONG PATIENTS UNDERGOING CHEMOTHERAPY USING MASCC RISK INDEX

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ABSTRACT

A descriptive study was done to assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy using MASCC risk index in a selected hospital, Pathnamthitta. The objectives of the study were to assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy and to find out the association between the risk of complications associated with febrile neutropenia and the selected baseline variables of the patients undergoing chemotherapy. Descriptive research design was used for the present study. Health promotion model by Nola. J. Pender was used as the conceptual framework for the study. The study was done among 30 patients. The samples were selected using non probability purposive sampling technique. Baseline data assessment proforma and MASCC risk index score were used as the tools for data collection. Descriptive and inferential statistics were used for data analysis. The study identified 56.7% of the samples as high risk group and 43.3% as low risk group. Significant association was found between the MASCC risk index score with type of cancer and history of prior stem cells or bone marrow transplantation. The study concluded that majority of the samples were belong to high risk. This shows patients undergoing chemotherapy have a greater risk for developing complications

associated with febrile neutropenia and prompt monitoring is required. MASCC risk index is a reliable tool for assessing the risk of complications among chemotherapy patients.

Key words: Febrile neutropenia ; Multinational Association of Supportive Care in Cancer (MASCC) risk index ; Chemotherapy.

INTRODUCTION

„The best preparation for tomorrow is doing your best today"

H.Jackson Brown

BACKGROUND OF THE PROBLEM

A cancer is an abnormal growth of cell. The cells have lost normal control mechanisms and thus are able to multiply continuously, invade nearby tissues, migrate to distant parts of the body, and promote the growth of new blood vessels from which the cells derive nutrients. Cancerous cells can develop from any tissue within the body[1].

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020. The most common cancer cases were breast (2.26 million cases), lung (2.21 million cases), colon and rectum (1.93 million cases), prostrate (1.41 million cases), skin non-melanoma (1.20 million cases), and stomach (1.09 million cases) [2].

The projected incidence of patients with cancer in India among males were 679,421(94.1 per 100,000) and among females 712,758(103.6 per 100,000) for the year 2020. One in 68 males were affected with lung cancer, and one in 9 Indians will develop cancer during their lifetime between (0-74 years of age)[2].

Cancer in all forms are causing about 12% of death throughout the world. In the developed counties cancer is the second leading cause of death accounting for 21% of all mortality. In the developing countries cancer is the 3rd cause of death and account for 9.45 % of all deaths[3].

In 2015, about 90.5 million people had cancer. As of 2019, about 18 million new cases occur annually. It caused about 8.8 million deaths (15.7% of deaths). The most common types of cancer in males are lung cancer, prostate cancer, colorectal cancer and stomach cancer. In females, the most common types are breast cancer, colorectal cancer, lung cancer and cervical cancer. If skin cancer other than melanoma were included in total new cancer cases each year, it would account for around 40% of cases. In children, acute lymphoblastic

leukemia and brain tumors are most common, except in Africa where non-Hodgkin lymphoma occurs more often. In 2012, about 165,000 children under 15 years of age were diagnosed with cancer. The risk of cancer increases significantly with age, and many cancers occur more commonly in developed countries. Rates are increasing as more people live to an old age and as lifestyle changes occur in the developing world[4].

Chemotherapy is an aggressive form of chemical drug therapy meant to destroy rapidly growing cancer cells in the body. It is usually used to treat cancer, as cancer cells grow and divide faster than other body cells[5]. Chemotherapy is generally given in cycles: a treatment period is followed by a recovery period, then another treatment period, and so on. Usually a patient has chemotherapy as an outpatient at the hospital, at a doctor's office or clinic, or at home. However, depending on which drugs are given and the patient's general health, the patient may need to stay in the hospital for a short time[6].

Chemotherapy is now used in the treatment of many solid tumors and is the primary therapy for leukemia and some lymphomas. The effect of chemotherapy is at the cellular level. All cells enter the cell cycle for replication and proliferation. The effects of the chemotherapeutic agents are described in relationship to the cell cycle.

The two major categories of chemotherapeutic drugs are cell cycle nonspecific and cell cycle phase- specific drugs[7].

Chemotherapy is the standard treatment for cancer. Myelosuppression is the major adverse effect of chemotherapy. Complications include potentially life threatening febrile neutropenia, intravenous antibiotic treatment and prolonged hospitalization[3].

The side effects of chemotherapy depend mainly on the drugs and the doses the patient receives. Most anticancer drugs affect cells that divide rapidly. These include blood cells, which fight infection, cells that help blood to clot and cells carry oxygen to all parts of the body. When blood cells are affected by anticancer drugs, patients are more likely to develop infections, may bruise or bleed easily, and may have less energy. Cells that line the digestive tract also divide rapidly. As a result of chemotherapy, patients can have side effects, such as loss of appetite, nausea and vomiting, hair loss, or mouth sores[6].

Neutrophil, a type of white blood cell (leukocyte) that is characterized histologically by its ability to be stained by neutral and functionally by its role in mediating immune responses against infectious microorganisms. Neutrophils, along with esinophils and basophils, constitute a group of white blood cells known as granulocytes. The granules of neutrophils typically stain pink or purple-blue following treatment

with a dye. About 50 to 80 percent of all the white bloods cells occurring in the human body are neutrophils[8].

Neutrophils play an essential role in the innate immune system by responding to invading pathogens by directly attacking bacterial cells or fungal hyphae and releasing cytokines to recruit inflammatory responses at the site of infection. Therefore, quantitative or qualitative deficits in neutrophils put a patient at risk for infections caused by bacterial and fungal organisms, in particular. Many cytotoxic chemotherapy agents act on the myeloproliferative cells of the bone marrow, in addition to their intended tumor cell targets, resulting in neutropenia. These agents also damage rapidly dividing cells; of particular concern are those cells lining gut mucosa because these cells act as an anatomic barrier to the bacterial organisms that colonize the GI tract. Therefore, patients receiving cytotoxic chemotherapy for malignancy are at high risk for infection-related complications, particularly caused by bacterial and fungal organisms. The degree and duration of neutropenia directly correlate with risk for infection; this relationship was initially described in patients with acute myeloid leukemia by Bodey et al in 1966. In addition to increased risk for infection, patients with neutropenia often have more subtle or delayed signs or symptoms of localized infection as a result of the inability to mount an inflammatory response. In fact, febrile neutropenia may be the only sign of infection in this population. Therefore, febrile neutropenia requires urgent and thorough evaluation and treatment [9].

Chemotherapy induced neuropenia is the most common side effect associated with administration of anti neoplastic drugs. Up to 25% of the patients under treatment with chemotherapy are likely to develop a febrile neutropenic episode, the percentage may even rise up to 96% with some type of cancer[3].

The Common Toxicity Criteria of the National Cancer institute developed a scale to grade neuropenia, based on the absolute neurophil count.(ANC) Grade I (ANC$\geq$ 1.5 to<2x 10^9/I), Grade II (ANC $\geq$ 0.5 to < 1.5 x10^9/I) , Grade III (ANC $\geq$ 0.5 to< 1x10^9/I), and Grade IV (ANC < 0.5 x 10^9/I)[3].

A patient with febrile neuropenia is very susceptible to suffer life threatening complications including death closely related to the duration and severity of the febrile neuropenia episode. The higher the duration of neuropenia, the higher the infection risk, so it is basic and important to determine the chemotherapy induced neuropenia duration at the onset of a febrile episode[3].

According to the ASCO guidelines fever is defines in neutropenic patients as a single oral temperature of > 38. 3 c (101 F) or temperature of >38.0 C sustained for >1 hour. Neutropenia as an absolute neutrophils count (ANC) < 500 cells /ml or an ANC that is expected to decrease to < 500 cells /ml during the next 48 hoursafter a chemotherapy[10].

Neutropenia may be accompanied by fever originating from an underlying infections. Fever may be the sole of indicator of an underlying infection in patients with chemotherapy induced neutropenia; other signs and symptoms of inflammation may be absent. Patients with neutropenia thus must be assessed for risk of severe infection immediately at presentation of fever. Febrile neutropenia is defined by an oral temperature greater than 101ºF from a single reading or an oral temperature of at least 100.4ºFsustained over a 1-hour period or reported from 2 consecutive readingsin a 2-hour period[11].

Febrile neutropenia (FN) is a serious complication often associated with cancer chemotherapy. Bone marrow suppression is the most common dose-limiting toxicity of traditional cytotoxic chemotherapy agents and has also been observed with targeted and immunological therapies. Consequences of febrile neutropenia can include dose reductions, treatment delays, and substantial impact on morbidity and mortality. Findings from a study across inpatient and outpatient care settings demonstrated a 16.8% risk of developing febrile neutropenia during a course ofchemotherapy. The Infectious Diseases Society of America defines neutropenia as an absolute neutrophil count (ANC) of 500 cells/mm^3 or less than 1,000 cells/mm^3 with an anticipated decline to less than 500 cells/mm^3 within 48 hours. Others define ANCs of less than 1,000 cells/mm^3 or 500 cells/mm^3 as moderate or severe neutropenia, respectively. Neutropenic patients are at increased risk of developing serious infections. Febrile neutropenia is described by clinical practice guidelines as neutropenia with a single oral or tympanic temperature greater than or equal to 101°F (38.3°C) or greater than or equal to 100.4°F (38°C) for at least one hour[12].

In a study conducted to validate MASCC risk index in predicting the complications with febrile neutropenia among patients undergoing chemotherapy correctly predicted the outcome of 123 patients. The study identified 93% of patients as low risk group. The study had positive predictive value of 93% with both sensitivity and specificity of 65 and 75% respectively. The MASCC risk score is a valuable tool in determining the outcome in patients with febrile neutropenia[13].

The Multinational Association for Supportive Care in Cancer (MASCC) risk index score was developed to identify patients with febrile neutropenia at low risk of serious medical complications or death. The MASCC score uses identifiablecharacteristics at the onset of febrile neutropenia to predict low risk of complications and the potential for successful outpatient management. The scoring points from each criterion met by the patient are added to produce a final score. Results from the initial validation set found that a MASCC score of 21 or higher identified low-risk patients with a positive predictive value of 91%, specificity of 68%, and

sensitivity of 71%. Since the development of the MASCC risk index score, several validationstudies have been published, all with a positive predictive value greater than 83%. The validation studies also showed a higher (greater than 90%) positive predictive value when fewer patients with hematologic malignancies were enrolled.

This finding indicates the need for additional caution when using the MASCC score in patients with a hematologic malignancy[14].

The morbidity and mortality rates of febrile neutropenia have decreased over the years as result of the use of appropriate antibiotic treatment, preventive measures , risk assessment procedures and adequate patient management plans . However, febrile neutropenia, mainly associated with complicated infections remains a significant threat and an oncological emergency. The threat is amplified with the continuing occurrence of antibiotic resistant microorganisms, which causes infections that are difficult to treat, leading to the death of millions of people worldwide [15].

Fever in cancer patients with chemotherapy – induced neutropenia remains a life-threatening complication. The accepted standard of care for such patients has been routine hospitalization for prompt administration of empiric, broad-spectrum anti-biotics, and close monitoring for development of complications until fever resolution and neutropenia recovery [16].

Preventing infections including febrile neutropenia is thus extremely important for a successful chemotherapy outcome. Nurses play an important role in the prevention, detection, and management of neutropenia, as well as provision of information to patients for ensuring better compliance rates [17].

Nurses should better indentify patients at risk for developing neutropenia and monitor patients who already have it for better initiation of interventions to improve patient care as well as improving QOL in patients with cancer receiving chemotherapy[17].

NEED AND SIGNIFICANCE OF THE STUDY

Neutropenia is one of the most serious and common complication develops during oncological treatment. Patients under chemotherapy are susceptible to infections because therapy directly affect the production of neutrophils. Reduction in these cells predisposes the body to bacterial invasion and proliferation, and inhibits appearance of any inflammatory respons[10].

Neutropenia is characterized by a reduction in neutrophils below normal counts, usually occurring within 7 to 12 days following cancer chemotherapy. It is diagnosed with a blood test that confirms an absolute neutrophil count (ANC) of less than 500 cells per micro liter following cytotoxic chemotherapy, or by an ANC expected to decrease to less than 500 cells per micro liter within 48 hours. Due to reduced levels of neutrophils in circulation, patients with neutropenia may have an impaired ability to fight against infections. Hence, even a minor infection of patients with neutropenia may become very serious. It is crucial to monitor patients for signs and symptoms of infection, which may present as fever, chills, or sweats[11].

The most serious and potentially life threatening complication of chemotherapy is febrile neutropenia, or the presence of fever in a patient with neutropenia. Febrile neutropenia is considered as an emergency because even previously stable patients can quickly become hemodynamically unstable and critically ill. Prompt assessment and interventions are necessary to reduce morbidity and mortality .Oncology nurses play critical role not only in the delivery of care, but also in patient education about the importance of recognizing and managing side effects and complications of cancer therapy[17].

Due to 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 neutrophils, which constitutes the first line of the body defense against diseases. The decline in the neutrophils 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[15].

Age is the most important patient related risk factor, increasing age is associated with the greatest risk of chemotherapy induced neutropenia. It is due to the immunosencence phenomenon [18]. Elderly patient have reduced bone marrow reserves or decline in renal and hepatic function and are more prone to develop treatment related complications [19].

Chemotheapy has significant and predictable toxicities, the most serious of which are likely to develop while the patient is at home between treatment cycles. Neutropenic sepsis or febrile neutropenia is a life threatening complication of cancer. The incidence varies and depends on the myelosuppressive nature of the chemotherapy agent being given, the performance status of the patient and the extend of co – morbidconditions[20].

Oncology nurses practices in different work settings like acute care centers, ambulatory clinics, diagnostic centers, chemotherapy and radiation therapy facilities. Oncology nurses play a variety of roles in the care of patients. The change to outpatient administration of chemotherapy has increased the necessity for the accurate and through patient and family education. This require nurses to understand the possible side effects of each antineoplastic agents and the self care activities to decrease the severity [21].

Nurses are expected to be experts in assessing a patient"s physical and emotional status, must aware about the expected outcomes and possible complications[21].

Oncology nurses play critical role not only in the delivery of care , but also in patient education about the importance of recognizing and managing side effects and complications of cancer therapy . Reducing the risk of chemotherapy induced neutropenia and its complications with supportive care measures can improve patient outcomes, quality of life, and reduce financial burden for both patient and the medical system [17].

STATEMENT OF THE PROBLEM

A descriptive study to assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy using MASCC risk index in a selected hospital, Pathanamthitta District.

OBJECTIVES

1. To assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy in a selected hospital.

2. To find out the association between the risk of complications associated with febrile neutropenia and the selected baseline variables of the patients undergoing chemotherapy in a selected hospital.

CONCEPTUAL DEFINITIONS

1. **Febrile neutropenia**

Febrile neutropenia is the development of fever, single oral temperature $\geq 38.3\ ^0C$ ($\geq 101\ ^0$ F) or a temperature of $38.0\ ^0$ C ($100.4\ ^0$ F) sustained over 1 hour period. It is often associated with other signs of infection in a patient with neutropenia which is characterized by a reduction in neutrophils below normal counts, (ANC<500 Cells/micro liter) usually occurring within 7 – 12 days following cytotoxic chemotherapy[22].

2. MASCC risk index

A numerical tool used to assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy with a total score of 26 and graded as low risk score(> 21) and high risk score (<21)[23] .

OPERATIONAL DEFINITION

- **Risk of complications**

The personal risk of developing complications associated with febrile neutropenia which includes death, intensive care unit admission, confusion, cardiac complications, respiratory failure, hypotension, bleeding and other serious medical complications among patients undergoing chemotherapy which is assessed using MASCC risk index.

ASSUMPTION

Patients undergoing chemotherapy have an increased risk of developing complications associated with febrile neutopenia.

CONCEPTUAL FRAMEWORK

A conceptual frame work is a discussion of the relationship of the concept that underlines the study problem and supports the rationale for conducting the study [24].

Conceptualization refers to the process of developing and refining abstract. Theories and conceptual models are the primary means of providing a conceptual context for a study. The conceptual framework provides for systematic approach to the nursing research [24].

The theoretical framework of the present study is based on the "Health promotion Model" (HPM) by Nola .J. Pender in 1987.The model describes the multi - dimensional nature of the persons as they interact within their environment to pursue health[24].

Prior related behavior

Prior related behavior refers to frequency of the same or similar behavior in the past. This includes direct and indirect efforts on the likelihood of engaging in health promoting behaviors[24]. In this study prior related behaviors the occurrence of complications associated with febrile neutropenia among patients undergoingchemotherapy in the past.

Personal factors

Personal factors refers to the biological, psychological and socio cultural factors which are predictive of a given behavior and are shaped by the nature of the target behavior being considered [24]. In this study personal factors are the selected base line variables of patients undergoing chemotherapy which are subdivided as biological, psychological and socio cultural factors.

Biological factors

Biological factors are considered to be any non-social factor that influences the development of a person"s body and brain[24].In this study biological factors are age, gender, duration of chemotherapy, type of cancer, type of chemotherapy, history of radiation therapy, history of prior stem cell or bone marrow transplantation and co- morbidity.

Psychological factors

The Psychological factors are the factors that talk about the psychology of an individual that drive his actions to seek satisfaction[24]. In this study no psychological factors are identified.

Socio-cultural factors

Socio cultural factors are customs, lifestyles and values that characterize a society[24]. In this study no socio cultural factors are identified.

Perceived benefits of action

Perceived benefits of action are anticipated positive outcomes that will result from health behavior[24]. In this study perceived benefits of action is preventing the occurrence of complications after chemotherapy.

Perceived barriers to action

Perceived barriers to action are anticipated, imagined or real blocks and personal costs of undertaking a given behavior[24]. In this study perceived barriers to actions are immune suppression, infection, nutritional status general health and well being of the patients undergoing chemotherapy.

Perceived self-efficacy

Perceived self-efficacy is judgment of personal capability to organize and execute a health-promoting behavior[24]. In this study perceived self-efficacy refers to the strong personal feelings of the patient receiving chemotherapy that he is able to prevent the risk of complications associated with febrile neutropenia.

Activity related effect

An activity-related affect describes subjective positive or negative feelingsthat occur before, during and after a particular behavior. It is cognitively labeled, remembered and continued[24]. In this study the activity related effect is the positive feelings of the patient receiving chemotherapy towards self monitoring of the signs and symptoms related to neutropenia and its associated complications.

Interpersonal influences

It is the thoughts or beliefs about the behaviors, attitudes and belief of others[24].In this study interpersonal influence are the support given by the family , friends, consultant, nursing staff and researcher to the patients undergoing chemotherapy.

Situational influences

Situational influences are personal perceptions and cognitions of any given situation or context that can facilitate or impede behaviors [24]. In this study situational influences are home environment, frequent hospital visit and hospitalizations of patients undergoing chemotherapy.

Commitment to plan of action

The commitment to plan of action describes the concept of intention and identification of a planned strategy that leads to implementation of health behavior[24.] In this study commitment to plan of action is the desire of patients undergoing chemotherapy to observe on occurrence of manifestations of febrile neutropenia and its complications.

Competing demands

Competing demands are alternative behavior over which individuals have low control, because there are environmental contingencies such as work or family care responsibilities, home situations etc[24]. In this study competing demands includesscheduled cycle of chemotherapy regimen.

Competing preferences

Competing preferences are alternative behaviors over which individuals exert relatively high control[24]. In this study competing preferences are the personal preference or choices of patients undergoing chemotherapy.

Health –promoting behavior

A health promoting behavior is an end point or action outcome that is directed towards attaining positive health outcomes such as optimal well being, personal fulfillment and productive living[24]. In this study health promoting behavior is the, assessment, early identification and prompt reporting of the manifestation of febrile neutropenia and its related complications.
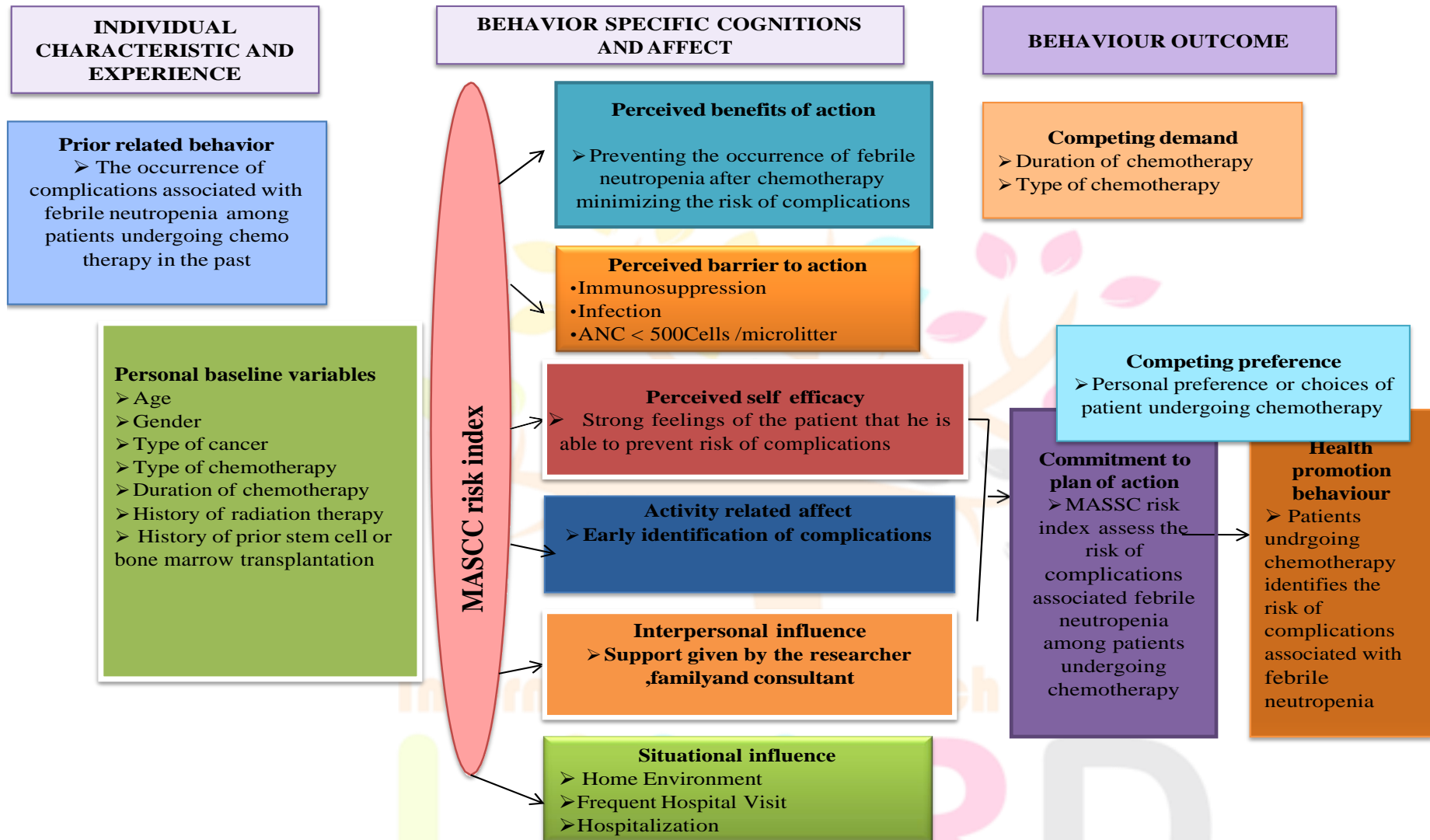
INDIVIDUAL CHARACTERISTIC AND EXPERIENCE

BEHAVIOR SPECIFIC COGNITIONS AND AFFECT

BEHAVIOUR OUTCOME

Prior related behavior
➢ The occurrence of complications associated with febrile neutropenia among patients undergoing chemo therapy in the past

Personal baseline variables
➢Age
➢Gender
➢Type of cancer
➢Type of chemotherapy
➢Duration of chemotherapy
➢History of radiation therapy
➢ History of prior stem cell or bone marrow transplantation

MASCC risk index

Perceived benefits of action
➢Preventing the occurrence of febrile neutropenia after chemotherapy minimizing the risk of complications

Perceived barrier to action
•Immunosuppression
•Infection
•ANC < 500Cells /microlitter

Perceived self efficacy
➢ Strong feelings of the patient that he is able to prevent risk of complications

Activity related affect
➢**Early identification of complications**

Interpersonal influence
➢**Support given by the researcher ,familyand consultant**

Situational influence
➢ Home Environment
➢Frequent Hospital Visit
➢Hospitalization

Competing demand
➢Duration of chemotherapy
➢Type of chemotherapy

Competing preference
➢Personal preference or choices of patient undergoing chemotherapy

Commitment to plan of action
➢MASSC risk index assess the risk of complications associated febrile neutropenia among patients undergoing chemotherapy

Health promotion behaviour
➢ Patients undrgoing chemotherapy identifies the risk of complications associated with febrile neutropenia

Figure 1: Conceptual Framework Pender"s Health Promotion Model – 1996

REVIEW OF LITERATURE

"Optimismis the faith that leads to achievement; nothing can be donewithout hope and confidence".

Helen Keller

Researcher never conducts a study in an intellectual vacuum. The studies are usually undertaken within the context of an existing knowledge base. Researchers undertake a literature review to familiarize themselves with that knowledge base[25].

Review of literature involves systematic identification, location, scrutiny and summary of written materials that contains information on research problem.It is a systematic research of a published work to gain information about a research topic. The review of literature is a key step in research process. It is based on an extensive survey of books, journals and international nursing indices[26].

The review of literature of the present study is organized under following sections.

Section I : Literature related to cancer and chemotherapy.

Section II : Literature related to febrile neutropenia and MASCC risk index.

SECTION I : Literature related to cancer and chemotherapy

A prospective cohort study was conducted to describe the frequency and severity of patient reported chemotherapy side effects in routine care. The study was done among 449 patients who were diagnosed with breast, lung or colorectal cancerundergoing chemotherapy. Side effects were identified by patient self report. The frequency, prevalence and incidence rate of side effects were calculated by type and grade of cancer and cumulative incidence curves for each side effects were computed. The study result showed that 86% of the patients reported at least one sideeffect during the study period and 24% reported grade IV side effect (dyspnea and fatigue). Fatigue was the most common side effect (85%) followed by diarrhea and constipation (74%) prevalence and incidence rates were similar across side effects and cancer types. The study stated the significance of observational data in clinical practice and in providing routine care[27].

A descriptive cross sectional study was done among 110 patients diagnosed with breast cancer and was receiving chemotherapy with Docetaxel, Epirubicin and Cyclophosphade. The purpose of the study was to assess the relationship between chemotherapy induced adverse side effects and health related quality of life among patients diagnosed with breast cancer. The study highlighted the negative effect of nausea, peripheral neuropathy, anorexia, myalgia and edema on health related qualityof life [28].

A retrospective observational study was carried out to assess the clinical manifestations, risk factors, diagnosis, treatment regimen and the adverse effects associated with chemotherapy. The study was conducted among 353 patients diagnosed with breast cancer and are receiving chemotherapy with Doxorubicin, Cyclophosphide, Paclitaxel, 5Fluorouracil. The demographic and laboratory data were collected from the case sheets. The result showed that 344 patients developed adverse effects. Identified 1157 adverse effects among these patients. (Cardiac 16.5%, Hematological 60.55%, Gastrointestinal 22.6%) The higher incidence of adverse effects was reported among age group between 49 to 58 years and the least were reported among 18 to 28 years[29].

A cross sectional study was conducted on knowledge of adverse effects of chemotherapy and the self care ability of patients to manage the adverse effects in Odisha, India. 100 patients who were in the daycare centre to receive chemotherapy were selected by using purposive sampling technique. Datacollection was done by face to face interview using structured questionnaire. The result showed that 58% of the patients had above average level of knowledge regarding chemotherapy and side effect. Knowledge of the adverse effects of chemotherapy is positively related to self practices and not associated with demographic variables. The study concluded that it is essential to enhance awareness about adverse effects of chemotherapy for better self care practice[30].

A retrospective cohort study was conducted from 2009 to 20220 to develop and validate a normogram for predicting the risk of febrile neutropenia among 1554patients affected with cancer and were receiving the first cycle of Etopoiside – basedchemotherapy. Variables used to predict neutropenia were karnofsky performance status such as co-morbidity of heart disease recent surgeries, administration of alkayating agents, total bilirubin and lymphocyte count. The study concluded that the early identification and screening of the potential risk of neutropenia in the first cycle of treatment for patients using Etoposide – based chemotherapy should be done [31].

A retrospective cohort study was conducted in the emergency department of a tertiary medical hospital from January to December 2008. The study was done among 81 patients receiving chemotherapy. The aim of the study was to assess the occurrence of febrile neutropenia. The study result showed that 78 patients had febrile neutropenia and 25 patients developed serious complications after chemotherapy. The study concluded that early administration of antibiotics helps to prevent febrile neutropenia and further complications[32].

A retrospective study was conducted to explore the safety of pre operative chemotherapy and clarify whether pre operative chemotherapy with Oxaliplatin + S- 1(SOX) regimen and its adverse events are associated with high risk of post operative complications. The study was conducted among 343 gastric cancer patients from July 1 2008 to31 January 2020. The patients were selected using consecutive sampling technique. In total, surgical complications were found in 34.1% patients however the patients who received 5 – 6 cycles were more prone to post operative complication. The study concluded that the occurrence of post operative complications was not influenced by pre operative SOX chemotherapy[33].

A prospective observational single center study was conducted to examine the relationship between Cefipme exposure and clinical efficacy or neurotoxicity among 76 febrile neutropenia patients from August 2019 until October 2020. The result showed that no Cefipime related break through infection occurred during Cefipime treatment. Patients with neurotoxicity showed significant trend for higher through concentrations. The study concluded that real world clinical data showing that high Cefipime dosages efficacious and safe in febrile neutropenic patients[34].

A reterospective cohort study was carried out to assess the side effect of adjuvant chemotherapy and its impact on outcome in elderly breast cancer patients. 128 elderly patients were included in this study. The study assessed the dose the dose, reductions or interruptions of chemotherapy and side effects .The study result revealed that 19 patients developed cardiotoxicity while the dosage of chemotherapy was reduced in 23 patients (18.0%) and 14 (10.9%) had premature interruptions. The study concluded the need of reduction or discontinuation of chemotherapy due to side effects. This will cause potentially worsening outcomes[35].

A prospective cohort study was conducted on outcomes in critically ill patients with cancer- related complications in intensive care units in Brazil. The study was conducted among 2,028 patients. Data collection was done by secondary analysis of two prospective cohorts of cancer patients. Multivariable logistic regression analysis was used to identify variables. The study result showed that 456(23%) had cancer related

complications, 45% need vasopressors, 70% need mechanical ventilation,12% of patients need dialysis. Hospital mortality rates were also higher in patients with cancer related complications. Chemo/radiation therapy –induced toxicity (6%), venous thromboembolis (5%), respiratory failure (4%), gastrointestinal involvement (3%) and vena cava syndrome (2%) were the most frequent cancer related complications identified. The study concluded that the prognostic impact of cancer related complications was variable[36].

A prospective cohort study was done to assess the length of stay among cancer patients with febrile neutropenia. This study was conducted in a single tertiary hospital in southern Brazil from 2009 to August 2011. 307 patients with febrile neutropenia were evaluated. The overall length of hospital stay was 16 days. The study revealed that hematologic neoplasms, high- dose chemotherapy regimens, prolonged periods of neuropenia, and bloodstream infection with gram negative multi drug resistant bacteria were the predictors of prolonged length of stay amongadult cancer patients with febrile neutropenia[37].

A cross-sectional study was performed over a period of 6 months on patients hospitalized in the Hematology-Oncology Center of Omid Hospital, Isfahan, Iran. The information was collected by filling the designed data abstraction form. A total of 115 oncology patients were admitted with or encountered to febrile neutropenia. This equates to a cumulative incidence of 1.26% of febrile neutropenia cases per 1000 oncology admissions. The average age was 49.5 ± 18.02 years (range 18–85 years), with 42.6% of patients being female. The most frequently prescribed antibiotic agents were Meropenem (91.3%) and Vancomycin (47.82%) alone or in combination. Empiric antifungal agents initiated in 20.86% of cases, and there were no patients needed antiviral treatment. From all positive cultures, Gram-positive microorganisms were the most found pathogen. Female (42.6%) and patients lymphopenia (26.5%) were the most noted predictors. Neutropenia (81.7%) was the most reported risk factors for serious complications[10].

A retrospective analysis was conducted on 43 non-transplant febrile neutropenic patients with concurrent cutaneous lesions, as determined by dermatopathologic studies at Songklanagarind Hospital in Thailand over a five-year period. The mean age was 39 years (SD: 18.8). Approximately 60% of the samples were male. The mostcommon underlying disease was a hematologic neoplasm. Twenty-one participants had developed febrile neutropenia within 7.5±8.7 days after presenting with skin lesions. Twenty-two participants had skin lesions 9.0±11.1 days after diagnosing febrile neutropenia. Cutaneous manifestations were mostly in the form of multiple lesions (67.4%), of which the most common were nodular skin lesions (37.2%) presenting on the

lower extremities of the body (58.1%). The dermatopathologic diagnoses included infections which were almost all fungal and leukemia cutis. The development of skin lesions after febrile neutropenia proved to be a statisticallysignificant risk factor for fungal infection (OR 8.13, P = 0.009), whereas age (over 40 years) proved to be a statistically significant protective factor (OR 0.20, P = 0.04). The study concluded that there are a variety of cutaneous manifestations in febrile neutropenia, of which the most common were cutaneous nodular skin lesions in the lower extremities. The most frequent infection was fungal in patients under 40 years of age who had developed skin lesions after febrile neutropenia [38].

A prospective cross-sectional study was conducted among 113 female patients diagnosed with cancer breast over a 2-year period. Socio-demographic, clinical and haematological data were obtained using semi-structured interviews and from medicalcase files. Blood samples for complete blood count parameters were collected 2 weeks after each course of chemotherapy. The National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03 was used to assess the occurrence febrile neutropenia, neutropenia and their severity. The result showed that incidence of neutropenia and febrile neutropenia among the patients were 31.9% and 5.3%, respectively. Throughout all courses of chemotherapy (n = 502), there were 57 (11.4%) neutropenic episodes with 6.6% mild, 3.4% moderate and 1.4% severe neutropenia. The incidence of neutropenia decreased with increasing chemotherapy courses, with a rate of 14.2% and 4.9% after the first and last course, respectively. Factors associated with the risk of developing neutropenia include increasing age (p = 0.014), Eastern Cooperative Oncology Group performance score $\geq$ 1 at presentation(p = 0.033) and presence of bone metastasis (p = 0.002). The present study concluded that one in three breast cancer patients developed neutropenia while on chemotherapy but no independent risk factors were identified for febrile neutropenia among these patients. This study has, therefore, provided the preliminary data necessary for further independent validation of the identified risk factors for febrile neutropenia[39].

An observational study was conducted in the oncology department of Jinnah PGMC, Karachi, Pakistan for a period of1 year. The study was done among 316 patients. The samples were selected using non- probability convenience sampling technique. Patients were divided into two group based on their gender. Group 1 consisted ofmale and group 2 consisted of female patients. The study result showed that febrileneutropenia was found among 96 (56.11%) male patients and 70 (47.3%) female patients. The study concluded that majority of the male cancer patients developed febrile neutropenia . Only few female patients developed febrile

neutropenia[40].

A retrospective study was conducted to assess the risk factors for febrile neutropenia in patients with bone and soft tissue sarcoma (BSTS) among 35 samples in between 2007 and 2014. The incidence of febrile neutropenia, risk factors and blood culture result were analyzed. The study result revealed that 57 % patient had febrile neutropenia, 24% of courses of systemic chemotherapy and blood culture result showed that 33.3% patient had febrile neutropenia. The study concluded that the patients with bone and soft tissue sarcoma had high risk of febrile neutropenia during chemotherapy [41].

A study was conducted to assess chemo radiation related febrile neutropenia prophylaxis among 219 older adults at Chittaranjan National Cancer Institute, West Bengal from September 2011 to January 2016. The study result revealed that 38.4% developed febrile neutropenia. Multiple logistic regression revealed geriatric assessment (G8) score and tumor stage are significant predictors of febrile neutropenia while on antibiotics (p< 0.0001). The study concluded that G8 score and burden are significant predictors of efficacy of antibiotic prophylaxis among older adults receiving chemoradiation. Older patients having poor outcome due to poor G8 score and advanced tumors [42].

Section II: Literature related to febrile neutropenia and MASCC risk index.

A prospective study was carried out to validate the Multi National Association Of Supportive Care Of Cancer (MASCC) Risk index score in an attempt to accurately predict the risk for development febrile neutropenia and its associated serious complications among patients who were receiving chemotherapy. The study was conducted between November 2000 and July 2002. The MASCC risk index score was calculated among 64 patients with 80 febrile neutropenic episodes. Patients with a score ≥ 21was considered as low risk and patients with a score ≤ 21 were considered as high risk. The result of the study revealed that out of the 80 febrile neutropenic episodes, 58 were classified as low risk and 22 were classified as high risk. The study further concluded that they were correctly predicted 98.3 %of the low risk and 86.3% of the high risk patients. The study had a positive predictive valve of 98.3% and a negative predictive value of 80.4% with both specificity and sensitivity of 95%. The MASCC risk index correctly identified low and high risk patients[43].

A study was conducted to support the use of MASCC risk index to determine the management of febrile neutropenia. The study was carried out among 83 patients. A total of 100 febrile neutropenic episodes occurring in 83 patients were treated over a 6months" period. Patients treated for solid tumors or lymphomas with low risk febrile neutropenia (MASCC score ≥ 21) were managed better with oral antibiotics like Ciprofloxacin, Doxycycline and Amoxiclav. These patients were discharged early from hospital also. The median duration of hospitalization was 2.5 days compared to 6.5 days in high risk episodes. 90% of episodes were low risk of which 83.3% received oral antibiotics and the success rate was 94.5%. The positive predictive value of the MASCC score was 96.7%. The study concluded that MASCC risk index is safe and feasible in the management of febrile neutropenic patients with solid tumors or lymphomas .Patients predicted with low risk can be managed safely with oral antibiotics and early hospital discharge[44].

A prospective study was conducted among 100patients with acute neutropenic fever. The study was done between January 2017 and February 2019 at a tertiary cancer hospital in England. Patients with low-risk febrile neutropenia consecutively managed in an emergency ambulatory unit were prospectively analyzed. Eighty-one patients were females and the median age was 51 years (range 17–79 years).Patients with a fever >38.0°C and an absolute neutrophil count <1.0 × 10^9/L were included. All patients with a Multinational Association for Supportive Care in Cancer score ≥21 and a National Early Warning Score ≤3 were included for the study. Complications were classified as serious if the patient developed persistent hypotension, respiratory failure, intensive care unit admission, altered mental status, disseminated intravascular coagulation, renal failure requiring renal replacement therapy, electrocardiogram changes requiring ant dysrhythmic treatment, and 30-day mortality. The study concluded that outpatient ambulatory care for emergency patients with low-risk febrile neutropenia can be delivered in a safe and effective fashion. Collaboration between acute care physicians and oncologists is required to develop local models based on national guidelines to facilitate individualized care for emergency oncology patients[45].

A descriptive study was done to assess the risk of febrile neutropenia among patients undergoing chemotherapy. The study was conducted among 100 patients selected by convenience sampling technique. The findings of the study revealed that 58 % of the patients were on high risk for developing febrile neutropenia and 42% were on low risk for getting febrile neutropenia. The study concluded that special precautions to befollowed to prevent the infection along with administration of biological therapies to boost

the immune system of patients receiving chemotherapy[46].

A retrospective analysis of prospective data of febrile neutropenia patients at a tertiary care oncology teaching hospital was done between 2007– 2012. The aim of the study was the assess the pattern of prevention, source of infection, management and outcome and to identify the factors that may correlate with outcome. A standard form was filled for each patients. MASCC score was retrospectively calculated. Failure of therapy was defined as death, organ failure, shifting from OPD in patients or requirement of intensive care support. The result revealed that 388 febrile neutropenia episodes was identified (256 in hematological and 132 in solid tumor patients) 156 episodes were high risk by MASCC score[47].

A retrospective observational case series was conducted to characterize febrile neutropenia patients were admitted in pulmonology department among 78 lung cancer patients. The result shows that 42 cases of febrile neutropenia were revised, corresponding to 36 patients were male, with a mean age of 66.71± 9.83 years. The study concluded that lower performance status, severe anemia and infections by gram negative agents seen to be associated with worse outcomes in febrile neutropenic patients[48].

A retrospective study was conducted to discover how the MASCC risk score of 21 or greater correlated with complications among 198 episodes of febrile neutropenia patients with solid tumor in 4 community hospitals in between October 2008 to November 2010. The study result shows that 42.3% had complications, misclassifying to low risk 69 episodes with complications. The study concluded that MASCC risk score 21 or greater could not be used as a criterion for no complications[49].

A study was conducted to develop and validate prognostic model for chemotherapy induced febrile neutropenia. The study comprised of 1001 episodes febrile neutropenia among 718 derivation set, 283 for the validation set. The study result showed that unfavorable outcome occurred in 5.9% of the low risk group classified by the new prognostic model was in 12.2% classified by MASCC risk index. The study concluded that new prognostic model can classify patients with febrile neutropenia into three class of increasing adverse outcomes and bacteremia. Early discharge could be possible for class I patients, short term observation could safely manage class II patients, and in patient admission is warranted for class III patients[50].

A study was conducted to evaluate the association of MASCC among patients with febrile neutropenia from November 2011 to till December 2013. The study was conducted among 226 patients. The result shows 58.4% were categorized as low risk while 41.5% as high risk patients according to MASCC risk index score. In low risk group 93% had uncomplicated infection while 7% are complicated infection. The study concluded that the MASCC risk score is valuable tool in determining outcome in patients with febrile neutropenia[13].

A retrospective study was conducted to determine the risk for poor clinical outcomesamong 550 cancer patients with febrile neutropenia in between April 2018 and April 2019. The study result showed that patient with procalcitoin (PCT) levels < 0.25ng/ml, those with levels ≥ 0.25 ng/ml had significantly higher 14 day mortality rate, a higher blood stream infection rate and a longer hospital length of stay. Procalcitoin level was significantly better predictor of blood stream infection than MASCC score. The study concluded that procalcitoin level is superior to MASCC index in predicting blood stream infection [51].

A prospective and observational study was conducted to compare the efficacy of risk assessment models among 53 neutropenic fever where the patients recruited throughout a 9 month period for the histologic diagnosis of malignancy, neutropenic febrile secondary to chemotherapy and or radiotherapy and≥ 18 years of age were considered as an inclusion criteria in a reference treatment center . The study result revealed that sensitivity, specificity, PPV,NPV, and the accuracy of the model were respectively 100,75.0,86.8, 100 and 90.6%.The study concluded that MASCC risk index score had sensitivity and specificity to predict the absence of complications .[16]

A descriptive and non- experimental study was conducted among 200 patients receiving chemotherapy to investigate the frequency, severity and distress of symptoms that chemotherapy induced in cancer patients. The sample consisted of patients having received their third cycle of chemotherapy. Eligibility criteria were adult patients (≥ 18 years) with a cancer diagnosis, admitted for chemotherapy treatment to a chemotherapy clinic as outpatients. Data was collected usingMemorial Symptom assessment Scale and questionnaire for collecting the demographic and clinical characteristics. The result of the study showed that majority of the patients was males (63.5%). Their mean age was 58.95 (SD= 9.95, range- 29- 79). The most prevalent physical symptoms were numbness/tingling in the hands/feet (54%), followed by lack of energy (46%). Feeling nervous (52%) and having trouble sleeping (41%) were the two most common psychological symptoms. The study further concluded that cancer patients undergoing chemotherapy experience various symptoms in high prevalence,

and the symptoms are severe. Nurses should consider these findings and plan appropriate, individualized care plans and nursing interventions in order to alleviate the symptoms and improve patients" quality oflife[52].

A retrospective observational study was done among 32 patients receiving chemotherapy. The study was done to determine door-to-assessment, door-to- treatment and door-to-investigation intervals for patients with febrile neutropenia whopresented to the inpatient oncology ward, the outpatient oncology day unit and the emergency department. Patients diagnosed with solid tumors and who were admitted with febrile neutropenia between January and December 2010 were identified, and paper and electronic medical records were analyzed to determine door to: assessment, treatment and investigation intervals. Patients in this series were assessed quicker and received the first dose of antibiotics faster when they presented to an oncology ward rather than the emergency department. The study findings suggested that patients presenting with presumed neutropenic fever should be assessed rapidly and should receive the first dose of antibiotics promptly. The policies that have beenimplemented need to become more rigid and strategies have to be initiated in order to decrease the door to needle time, including the introduction of a stringent protocolthat allows for immediate cannulation and antibiotic delivery by healthcare professionals and improved education in all grades of staff. In addition, dedicated

„acute oncology assessment areas" with point-of-care may be set up, which would allow for immediate management of any patients presenting with complications both of their underlying neoplasm and the treatment they are receiving for it[53].

A retrospective cohort study was conducted to assess the risk stratify outpatients with cancer and febrile neutropenia among 193 hospitalized patients. The data collection methods were patient demographics, cancer characteristics microbiological profile, MASCC score, utilization of critical care therapies, documentation of goal of care (GOC) and inpatient death outcomes associated with low (>21) versus high risk <21 MASCC scores, 52% (n =101) had a risk score (<21). The result showed that twenty one percent required immediate / ICU less of care and 12% died in the hospital. Those with a low risk score were 33% less likely to requires intermediate / ICU care 19% less likely to die in the hospital compared to those with high score. The study concluded that MASCC score helps to identify the high risk for complications. These helps to manage the potential consequence and early management[54].

A prospective observational study was conducted in the inpatients and outpatients oncology department from October 2016 to March 17. The study was done among

200 patients who receiving chemotherapy. The tools used for the study are demographic information and MASCC risk index score to predict the patients risk of developing chemotherapy induced febrile neutropenia. The results of the study revealed that 19 patients developed 22 episodes of chemotherapy induced febrile neutropenia. The overall occurrence of chemotherapy induced febrile neutropenia during the study period was 9.5%. The high incidence of chemotherapy induced febrile neutropenia was observed among males (57.89%), age group between 45-60 (52.63%), stage III patients (42.10%), solid tumor (73.60%), double chemotherapy regimen (59.1%). The high incidence of febrile neutropenia was developed during first cycle. The length of hospitalization has been prolonged for all patients who developed chemotherapy induced febrile neutropenia[55].

A descriptive study was conducted among 51 staff nurses between January 2012 and May 2012, at oncology adult inpatient units of a university hospital in Turkey. The aim of the study was to determine nurses" knowledge and infection control care practices among neutropenic patients because neutropenia-associated infections can prolong hospitalization, increase re-admission, mortality and morbidity rates. Data were collected using a questionnaire on socio demographic characteristics, knowledge on neutropenia and infection control care practices. Each nurse was observed by researcher three times for infection control care practices. The result of the revealed that the mean score of nurses" knowledge was 21.3 ± 2.4 (min.17; max. 27). For all three observations hand hygiene adherence was found low both in medication preparation, administration and vital signs assessment. The study concluded that nurses" knowledge related with neutropenia and care of neutropenic patient was foundabove average but their infection control care practices were found insufficient[56].

SUMMARY

This chapter deals with review of literature. Section one deals with literature related cancer and chemotherapy and section two deals with febrile neutropenia and MASCC risk index. The literature says that cancer is the leading causes of mortality and morbidity globally. Chemotherapy is the standard treatment for cancer .consider as the important cause of death. The reviewed literature were regarding the risk of febrile neutropenia patients receiving chemotherapy and related to the risk stratification of high and low risk febrile neutropenic patients. Early risk identificationhelps proper management in the patient receiving chemotherapy.

METHODOLOGY

Research methodology is the science of studying how research is done scientifically. It is a way to systematically solve the research problem. It includes the steps, procedures and strategies for gathering and analyzing the data in a research investigation. It deals with defining the problem, formulation of hypothesis, methods adopted for data collection and statistical techniques used for analyzing the data[57].

This chapter deals with the methodology adopted by the investigator for the present study to assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy using MASCC risk index.

RESEARCH APPROACH

Research approach means the description of the plan to investigate the phenomenon under study.[57]

Quantitative research approach was adopted in the present study.

RESEARCH DESIGN

The term „Research design" refers to the master plan specifying the methods and procedure for collecting and analyzing the needed information in research study. It is the overall plan for answering the research questions for testing the research hypothesis .[26]

In the present study, descriptive research design was used to assess the risk of complications associated with febrile neutropenia among patients undergoingchemotherapy using MASCC risk index.

VARIABLES

Variables are the qualities, properties or characteristics of person, things or situation that can change or vary [26].

The main types of variables under the present study were:

1. Baseline variables

2. Research variables

Baseline variables

These are characteristics and attribute of the study subjects which the researcher attempt to study and present in the research findings [26]. In the present study, baseline variable are age, gender, type of cancer, type of chemotherapy, duration of chemotherapy, history of radiation therapy and history of prior stem cell or bone marrow transplantation.

Research variables

These are qualities, attributes, properties or characteristics that are observed or measured in a natural setting without manipulating and establishing cause and effect relationship[26]. In the present study, research variable is the risk of complications associated with febrile neutropenia.
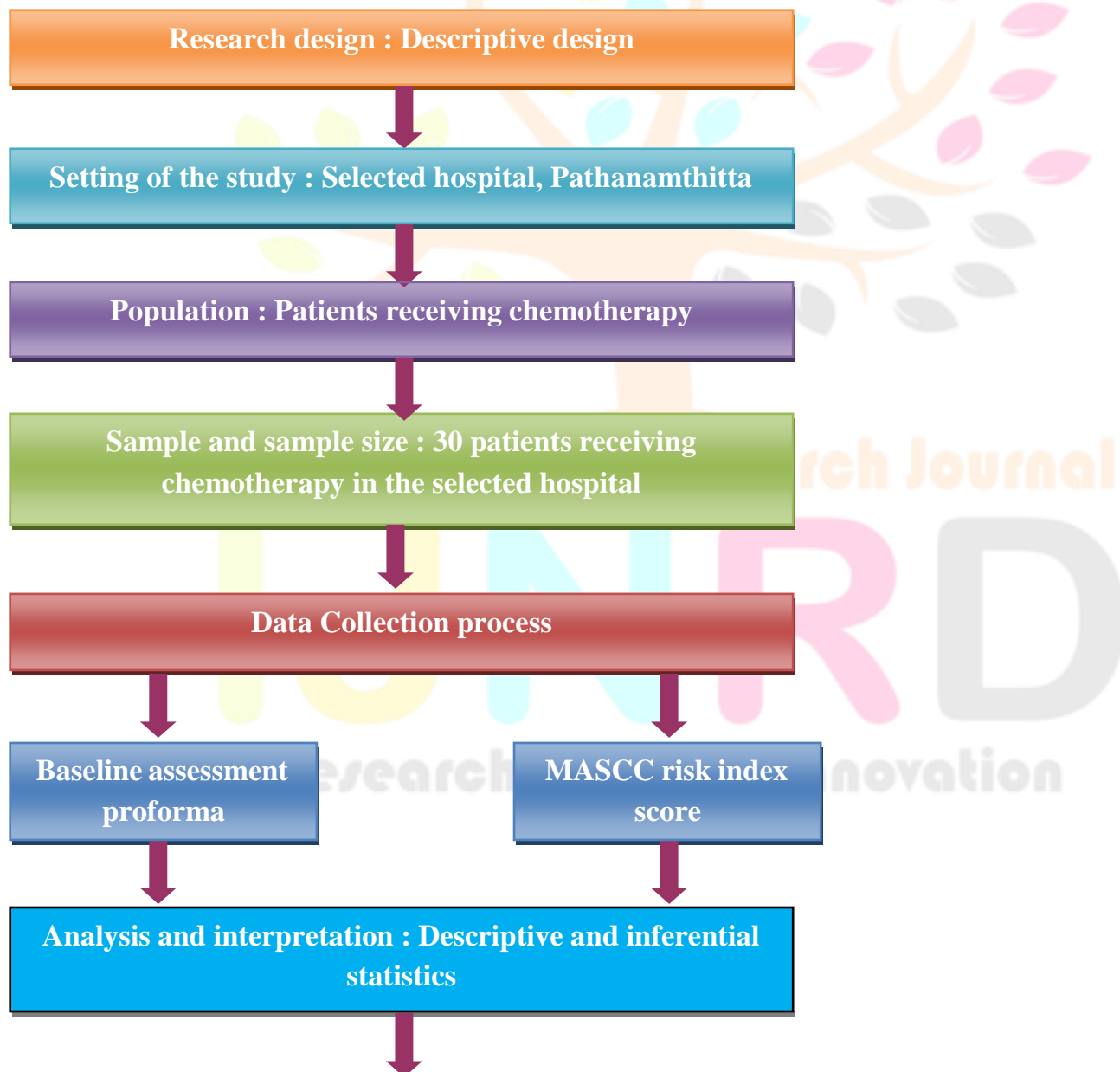
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┌─────────────────────────────────────────────────┐
│     Research design : Descriptive design        │
└─────────────────────────────────────────────────┘
                        ↓
┌─────────────────────────────────────────────────┐
│  Setting of the study : Selected hospital,       │
│                 Pathanamthitta                   │
└─────────────────────────────────────────────────┘
                        ↓
┌─────────────────────────────────────────────────┐
│   Population : Patients receiving chemotherapy   │
└─────────────────────────────────────────────────┘
                        ↓
┌─────────────────────────────────────────────────┐
│   Sample and sample size : 30 patients receiving │
│      chemotherapy in the selected hospital       │
└─────────────────────────────────────────────────┘
                        ↓
┌─────────────────────────────────────────────────┐
│            Data Collection process               │
└─────────────────────────────────────────────────┘
          ↓                           ↓
┌──────────────────────┐    ┌──────────────────────┐
│ Baseline assessment  │    │  MASCC risk index    │
│      proforma        │    │       score          │
└──────────────────────┘    └──────────────────────┘
          ↓                           ↓
┌─────────────────────────────────────────────────┐
│  Analysis and interpretation : Descriptive and   │
│            inferential statistics                │
└─────────────────────────────────────────────────┘
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Communication of findings

↓

Reporting

Figure 2: Schematic representation of the study

SETTING OF THE STUDY

Setting is the physical location and condition in which data collection takes place[26]. The present study was conducted in MGM Muthoot Hospital Kozhencherry,Pathanamthitta district.

POPULATION

The term „population" refers to the aggregate of totality of all objects, subjects or numbers that confirm to set of specification. It is the entire aggregation of cases in which a researcher is interested.[58]

In the present study population is the patients receiving chemotherapy.

Accessible population is an aggregate of cases that confirm to designated criteria and are accessible for a study [58].

In the present study accessible population is the patients receiving chemotherapy in the selected hospital, Pathanamthitta district.

SAMPLE AND SAMPLING TECHNIQUESAMPLE

Sample is the subset of the population selected to participate in the research study and sampling is the process of selecting a portion of the population to represent the entire population. It is chosen to represent the population and is used to make generalizationabout the population.[25]

In the present study sample consists of the patients receiving chemotherapy in the selected hospital Pathanamthitta, District.

The sample size was 30.

SAMPLING TECHNIQUE

A carefully carried out sampling process helps to draw sample that represents the characteristics of the population from which the sample is drawn[25].

Non probability purposive sampling technique was adopted for the present study.

INCLUSION CRITERIA

The characteristics that people in the population must possess are referred to asinclusion criteria [59].

The present study included patients:

- of both genders.

- belongs to the age group of more than 18 years.

- receiving any cycle of chemotherapy.

- diagnosed with any type of malignancy and undergoing any type ofchemotherapy.

- receiving chemotherapy as inpatients and or outpatients in the selectedhospital.

EXCLUSION CRITERIA

The study excludes the patients who were:

- not willing to participate in the present study.

TOOL / INSTRUMENTS

The instruments are a vehicle that could obtain data pertinent to the study and at the same time add knowledge to the discipline[58]. It consist of defining the construct to be measured, formulating the items, for content validity ,developing instructions for respondents pre testing and testing the reliability and conductingthe pilot study[25].

The present study was primarily concerned with assessing the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy using MASCC risk index in a selected hospital, Pathanamthitta district . Experts from medical, nursing education, and nursing services were consulted for the development of the tool.

DEVELOPMENT AND SELECTION OF THE TOOL

The tool was developed based on objectives of the study. The following methods wereused:

1. Review of relevant literature (books, journals, reports, and articles, publishedunpublished studies).

2. Consultation with subject experts.

3. Consultation with statistician for the preparation of the plan for statistical analysis.

4. Consultation with language experts.

5. Personal experience and observation of the investigator.

DESCRIPTION OF THE TOOL

The tool was developed to assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy.

The tool used for the present study comprised of two sections:

Section A : Baseline assessment proforma.

Section B: Multinational Association of Supportive Care in Cancer (MASCC) risk index .

- **SECTION A** : Baseline assessment proforma - The tool consist of seven items which included age, gender, type of cancer, type of chemotherapy, duration of chemotherapy, history of radiation therapy and history of prior stem cell or bone marrow transplantation.

SECTION B: The Multi National Association of Supportive Care in Cancer (MASSC)   risk index is an internationally validated   scoring system which can be used among cancer patients with febrile neutropenia. The MASCC risk index score accurately predict on patients who are at low or high risk for development of serious medical complications associated with chemotherapy induced febrile neutropenia .The maximum score is 26. The tool is identified as a reliable tool for determining patients at low risk of chemotherapy induced febrile neutropenia and its associated complications based on a cut off at 21 points. MASCC score $\geq$ 21 shows low risk for complications and a MASCC score < 21 shows high risk for complications. The tool consist of 7 items which includes burden of illness (symptoms and severity), blood pressure (hypotension), COPD, solid tumors, outpatient status at time of presentation, fluid status and age.

MASCC score $\geq$ 21- Low risk for complications related to febrile neutropenia. The patient can be treated as outpatient with oral antibiotics and there is a 91% chance of positive resolution without complications.

 MASCC score < 21- High risk for complications related to febrile neutropenia. The patient needs hospitalization and IV antibiotics. There is 64% of resolution without adverse outcome.

CONTENT VALIDITY

Validity refers to the degree to which an instrument measures what it is supposed to be measured. It is a criterion for evaluating the quality of a measure or an instrument adequately encompasses the pertinent range of subject matter [59]. The prepared instruments along with statement of problem, objectives, operational definitions, baseline assessment proforma and MASCC risk index score were submitted to experts from

medical, nursing education and statistics. It was also given for language validation. Suggestions and recommendations given by the subject experts were accepted and necessary modifications were done before finalizing the tools. MASCC risk index score was used without any modifications.

RELIABILITY OF THE TOOL

The reliability of the research instrument is defined as the extent to which instrument yields the same results on repeated measures[58].Reliability of the entire tool was analyzed using Cronbach"s alpha ($\alpha = 2r/l+r$) an "α" value of the tool was calculated as 0.70. It showed that tool were reliable. The calculation were verified and accepted by the statistician.

PILOT STUDY

Pilot study is a small scale version, or trial run, done as a preparation for major study[58]. The purpose of pilot study was to find out the feasibility of the study, clarity of the language of tool.

The pilot study was conducted between the to 28- 12-2020 to 24 - 01-2021. Ethical clearance and permission from the concerned authorities were obtained before conducting the study. 6 samples were selected using non probability purposive sampling technique. The investigator introduced herself to the samples. A written informed consent was obtained from the samples. Data was collected by using baseline assessment proforma and MASCC risk index.

Data analysis was done using descriptive and inferential statistics .The analysis of the study revealed that objectives of the study could be fulfilled and the study was found to be feasible. Based on this information, the investigator proceeded with the final study.

DATA COLLECTION PROCESS

Data collection procedure is a process of gathering information to address the researchproblem.[59]

Data collection was done in the selected hospital, Pathanamthitta from 27. 12. 21 to a period of 2 months. Ethical clearance and permission from the concerned authorities were obtained before conducting the study. Thirty samples satisfying the inclusion and exclusion criteria were selected using non probability purposive sampling technique. The inpatients were met at their respective rooms and the outpatients were met in a room next to the oncology outpatient department as per their convenience before or after consulting the oncologist. The investigator introduced herself to the subjects and explained the purpose of the study .Individual informed written consent was obtained from the subjects and assured anonymity and confidentiality of the information provided by them. Data collection was done using the baseline assessment proforma and MASCC risk index.

PLAN FOR DATA ANALYSIS

Analysis is the systematic organization and synthesis of research data and the testing of hypothesis using that data[58]. The collected data were organized, tabulated and summarized by preparing the master data sheet. Frequency and percentage distribution were used to analyze the selected baseline variables of the patients undergoing chemotherapy.

1. Percentage and frequency were used to describe risk of complications associated with febrile neutropenia among patients undergoing chemotherapy.

2. Chi –square test was used to find out the association between risk of complications of febrile neutropenia and selected baseline variables of the patients undergoing chemotherapy.

SUMMARY

The research methodology is making an overall plan for a research problem to solve it in a systematic and scientific manner. This chapter dealt with the description of the research approach and design, variables, setting and sampling. It also included the preparation and implementation of the tools for the study and also dealt with the pilot study, method of data collection and data analysis.

ANALYSIS AND INTERPRETATION

This chapter deals with the analysis and interpretation of data obtained from the study conducted among 30 patients receiving chemotherapy from the selected hospital, Pathanamthitta district.

OBJECTIVES:

1. To assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy.

2. To find out the association between MASCC risk scores and the selected baseline variables of the patients undergoing chemotherapy.

ORGANIZATION OF THE STUDY FINDINGS

The data collected were organized, tabulated, analyzed and interpreted by usingdescriptive and inferential statistics and is presented under following sections.

Section 1: Description of baseline variables of patients undergoing chemotherapy. Section 2: Assessment of risk of complications associated with febrile neutropeniaamong patients undergoing chemotherapy. Section 3: Association between the MASCC risk scores and selected baselinevariables of patients.

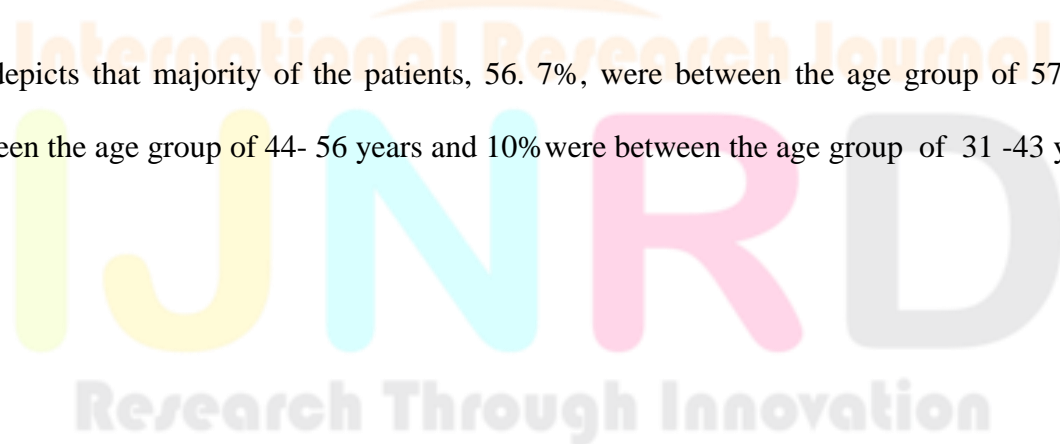## SECTION I: DESCRIPTION OF BASELINE DATA OF PATIENTSUDERGOING CHEMOTHERAPY

Table 1: Frequency and percentage distribution of patients undergoingchemotherapy according to the age.

(N = 30)

Age	Frequency	Percentage (%)
31-43 years	3	10
44- 56 years	10	33.3
57 – 70 years	17	56.7

The above data depicts that majority of the patients, 56. 7%, were between the age group of 57- 70 years, 33.3% were between the age group of 44- 56 years and 10% were between the age group of 31 -43 years.

Gender (N=30)

47%   FemaleMale
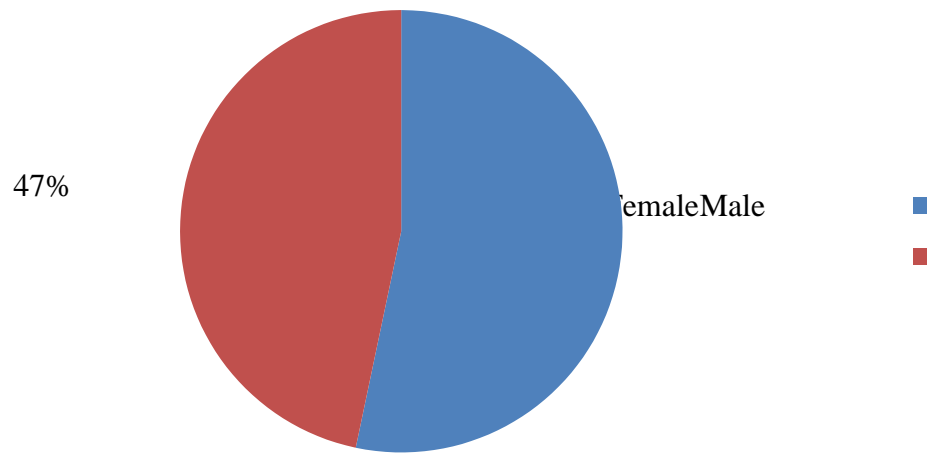
Fig 3: Frequency and percentage distribution of patients undergoingchemotherapy according to the gender.

The above data depicts that 53.3% of the patients were females and 46.7%of the patients were males.

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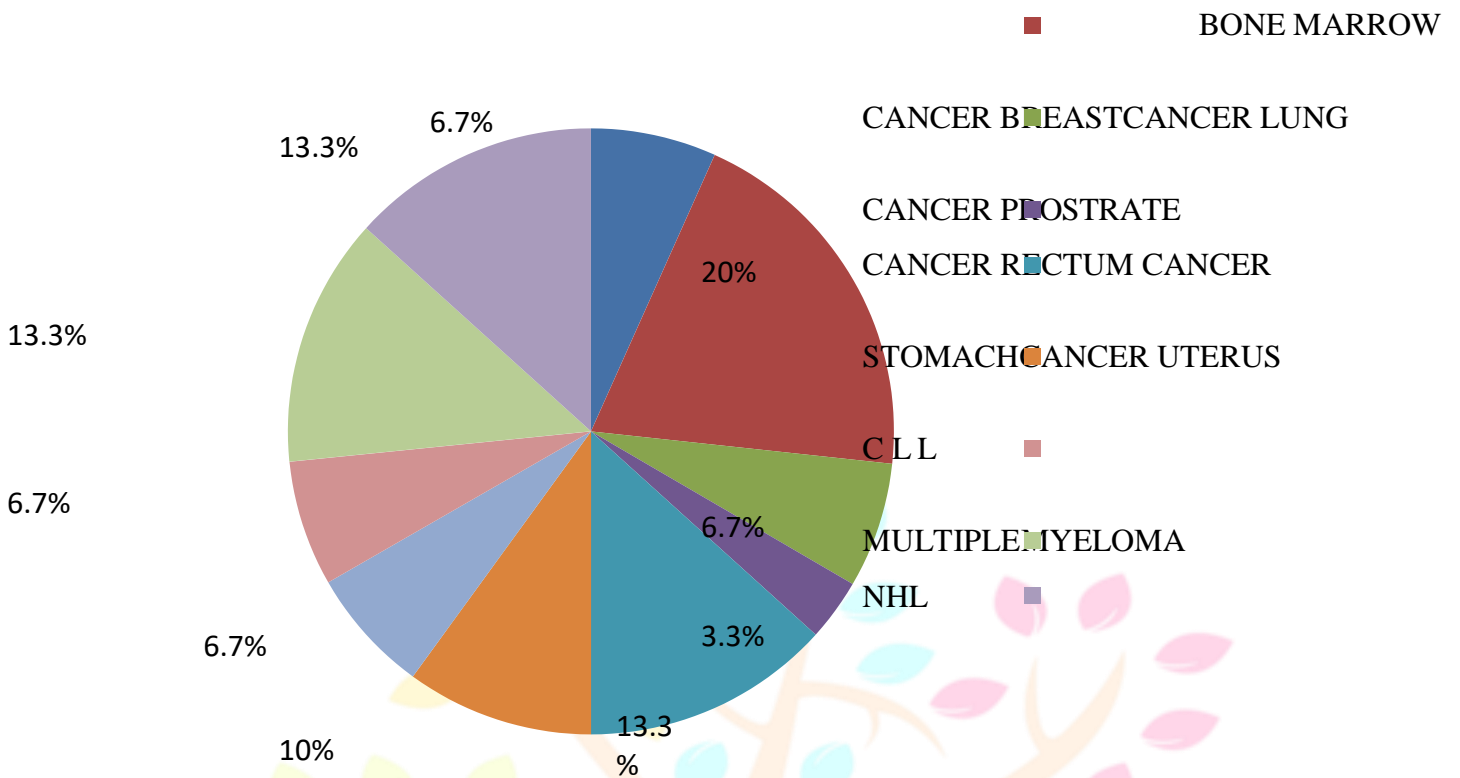**Type of Cancer**   **(N=30)**

■   BONE MARROW

CANCER BREASTCANCER LUNG

CANCER PROSTRATE

CANCER RECTUM CANCER

STOMACHCANCER UTERUS

C L L   ■

MULTIPLE MYELOMA

NHL   ■

Pie chart labels: 6.7%, 13.3%, 13.3%, 6.7%, 6.7%, 10%, 13.3%, 3.3%, 6.7%, 20%

Fig 4 :   **Frequency and percentage distribution of patients according to thetype of cancer**

The   above data depicts that   20% of the patients were having cancer breast,

13. 3% of the patients were having cancer rectum, 13.3 % were having multiple myeloma, 13. 3% were having

non Hodgkins lymphoma, 10% were having cancer stomach, 6.7 % were having cancer uterus, 6.7% were

having chronic lymphocytic leukemia, 6.7% were having bone marrow cancer, 6.7% were having lung cancer

and

3.3 % were having cancer prostrate.

Type of Chemotherapy **(N=30)**
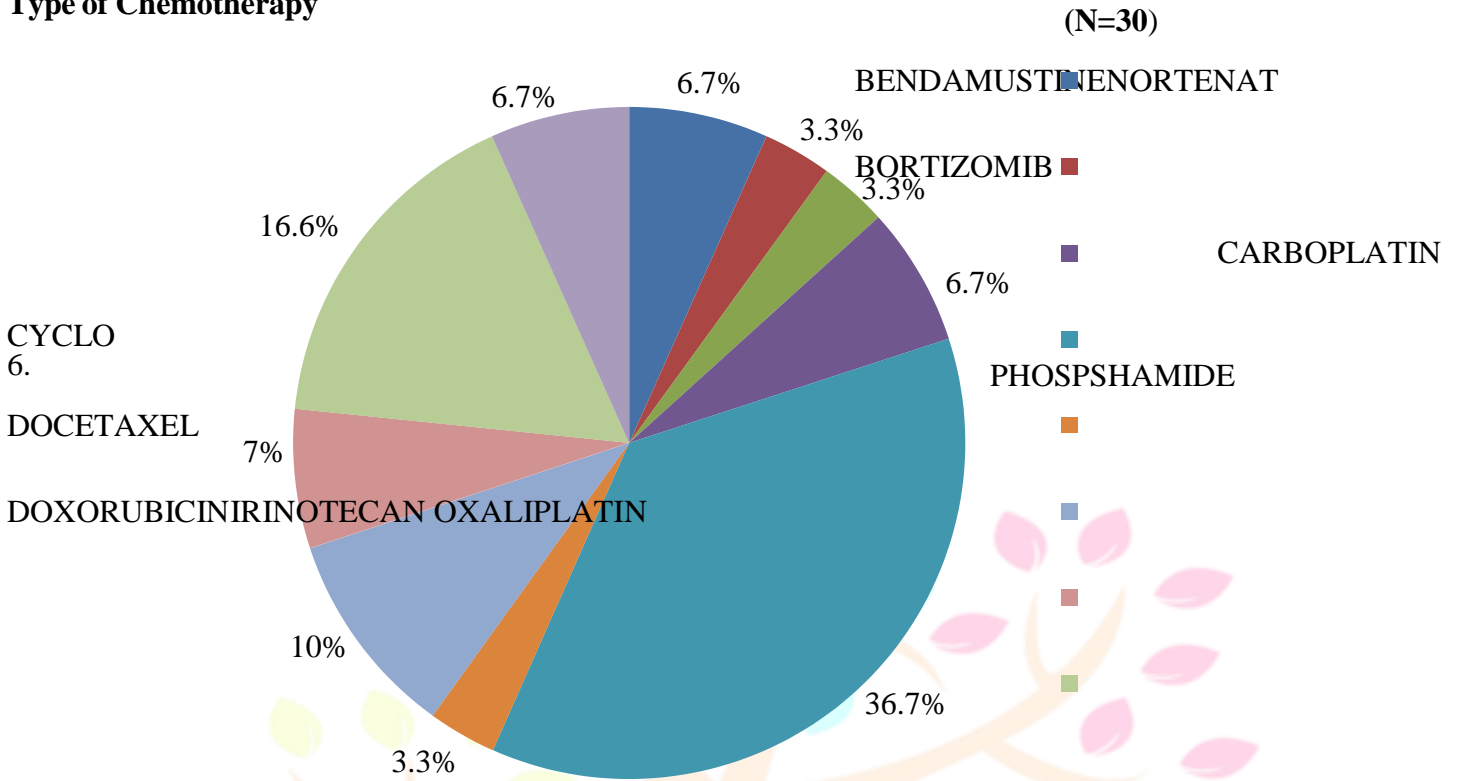
Fig 5: **Frequency and percentage distribution of patients according to the typeof chemotherapy**

The above data depicts that 36 .7% of the patients were on Cyclophosphamide,

16 .6% were on Oxaliplatin, 10% were on Doxorubicin, 6.7% were on Bendamustine,

6.7% were on Carboplatin, 6.7% were on Irinotecan, 6.7% were on Rituximab, 3.3% were on Bortenat, 3.3%
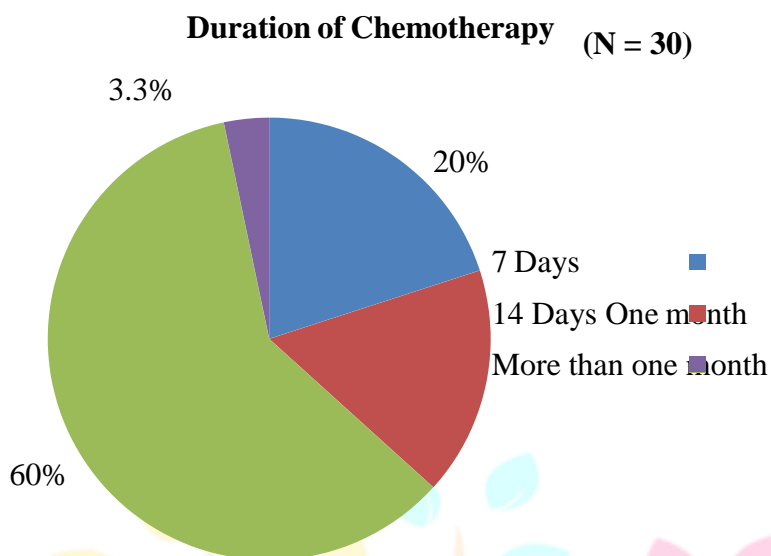
were on Bortezomib and 3.3% were on Docetaxel .
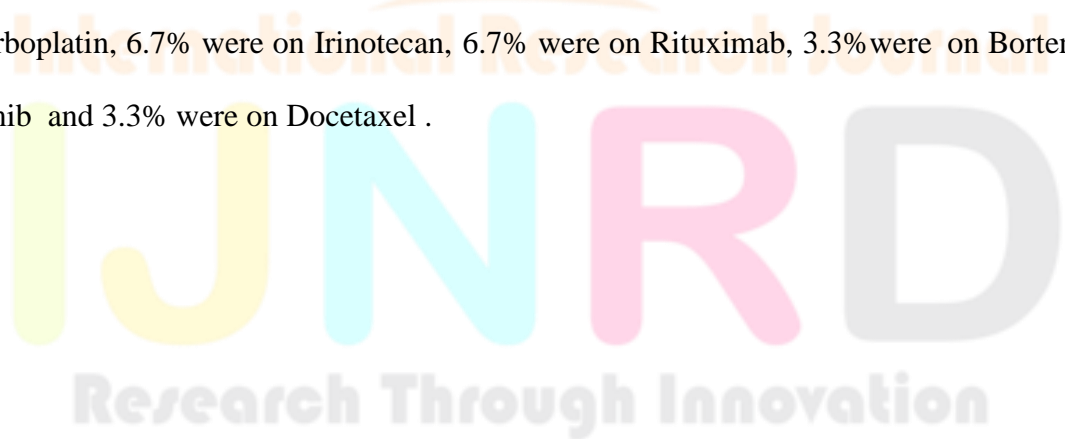
Fig 6: Frequency and percentage distribution of patients according to duration of chemotherapy

The above data revealed that 60% of the patients were had one month interval, 20 % were had 7 days interval,

16 .7% were had 14 days interval and 3.3% were had more than one month interval.
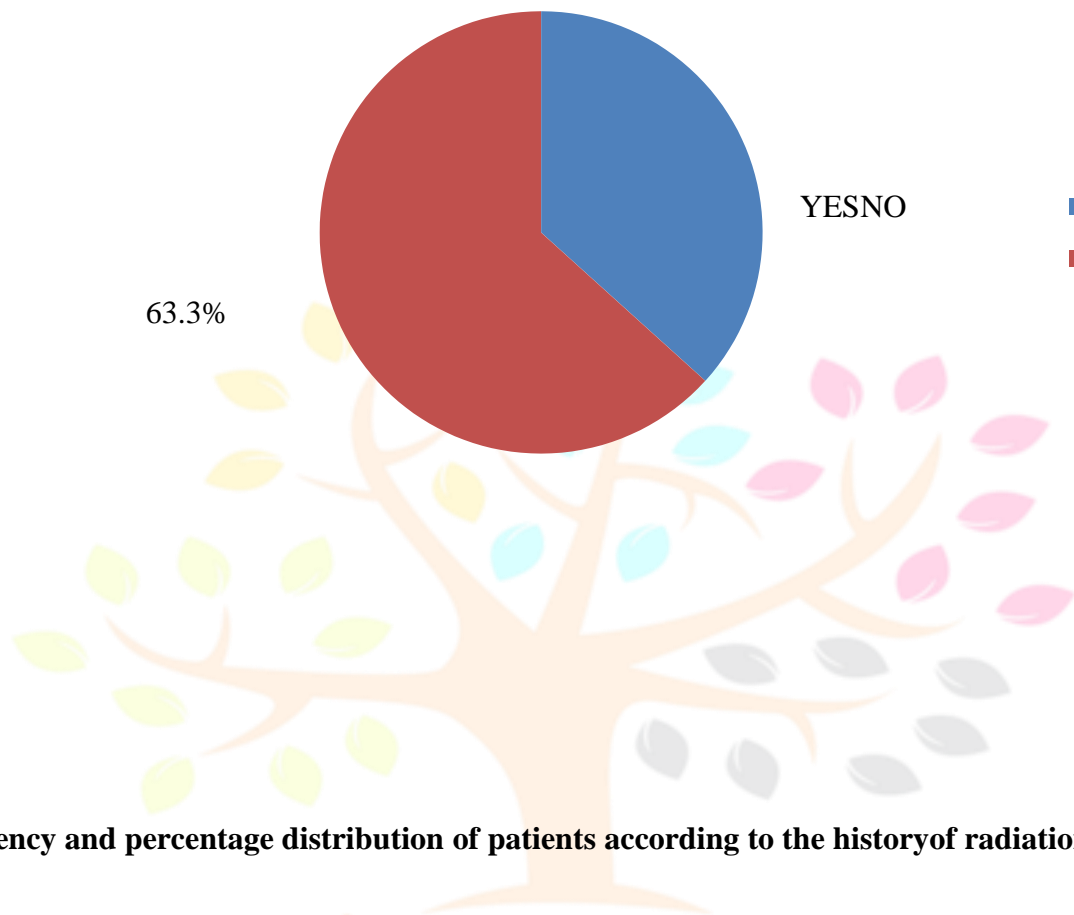
History of Radiation Therapy

(N=30)

Fig 7: Frequency and percentage distribution of patients according to the history of radiation.

The above data depicts that majority of the patients 63.3% were not received radiation and 36.7% were received radiation.
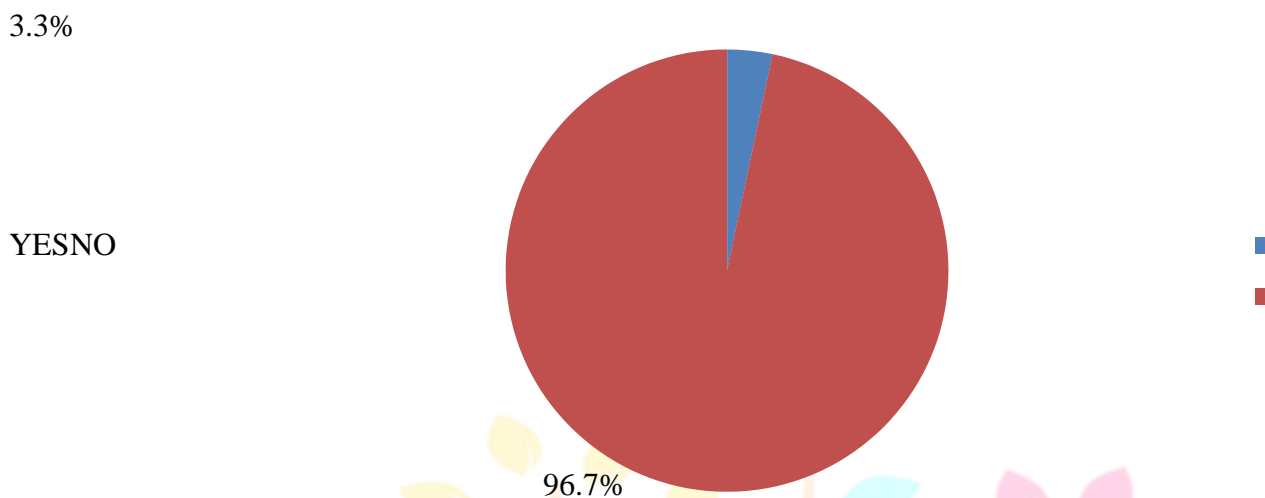
History of Bone Marrow Transplantation

(N=30)

3.3%

YESNO

96.7%

Fig 8: Frequency and percentage distribution of patients according to the prior history of stem cell or bone marrow transplantation.

The above data depicts that 96.7% of patients were not having history of prior stem cell or bone marrow transplantation and 3.3% of patients were having historyof prior stem cell or bone marrow transplantation.

SECTION : 2 ASSESSMENT OF RISK OF COMPLICATIONS ASSOCIATED WITH FEBRILE NEUTROPENIA AMONG CHEMOTHERAPY PATIENTS USING MASCC RISK INDEX SCORES

Risk of complications associated with febrile neutropenia among chemotherapy patients were assessed using MASCC risk index and analyzed using descriptive statistics.

Table 2: Distribution of samples based on the risk of complications associated with febrile neutropenia (N = 30)

Level of risk	Frequency	Percentage (%)
Low	13	43.3
High	17	56.7

The above data shows that majority, 56.7% of patients were at high risk and 43.3% of patients were at low risk for developing complications related to febrile neutropenia.

Table 3: Chi square value showing association between MASCC risk index score with age of patients (N = 30)

Sl. No	Demographic variables	MASCC risk score High f	%	Low f	%	χ^2
1	Age in years 31-43					1.701 NS
	44-56	2	6.7	1	3.3	
	57-70	4	13.3	6	20	
		11	36.7	6	20	

NS – Not significant

Table 3 depicts that there is no significant association between MASCC risk index score and age.

Table 4: Chi square value showing association between MASCC risk index scorewith gender of patients

(N = 30)

Sl. No	Demographic variables	MASCC risk score				χ^2
		High		Low		
		f	%	f	%	
2	Gender					0.475 NS
	Male Female	10	33.3	6	20	
		7	23.3	7	23.3	

NS – Not significant

Table 4 depicts that there is no significant association between MASCC risk indexscore and gender.

Table 5 : Chi square value showing association between MASCC risk indexscore with type of cancer.

(N = 30)

Sl. No	Demographic variables	MASCC risk score				χ^2
		High		Low		
		f	%	f	%	
3	Type of cancer Bone marrow Cancer					11.674*
	breast Cancer lung Cancer prostate	1	3.3	1	3.3	
	Cancer rectum Cancer stomach	5	16.7	1	3.3	
	Cancer uterus	1	3.3	1	3.3	
	Chronic lymphocytic leukemia	1	3.3	0	0	
	Multiple myeloma	3	10	1	3.3	
	Non-hodgkin lymphoma	2	6.7	1	3.3	
		0	0	2	6.7	
		1	3.3	1	3.3	
		0	0	4	13.3	
		3	10	1	3.3	

* p value = 0.043

Table 5 depicts that there is significant association between MASCC risk index scoreand type of cancer

(p<0.05).

Table 6: Chi square value showing association between MASCC risk indexscore with selected type of chemotherapy.

Sl.No (N = 30)

Demographic variables	MASCC risk score				χ^2
High			**Low**		
	f	%	f	%	
4 Type of chemotherapy					4.776 NS
Bendamustine	1	3.3	1	3.3	
Bortenat	0	0	1	3.3	
Bortezomib	0	0	1	3.3	
Carboplatin	1	3.3	1	3.3	
Cyclophosphamide	6	20	5	16.6	
Docetaxel	1	3.3	0	0	
Doxorubicin	2	6.7	1	3.3	
Irinotecan	1	3.3	1	3.3	
Oxaliplatin	4	13.3	1	3.3	
Rituximab	1	3.3	1	3.3	

NS – Not significant

Table 6 depicts that there is no significant association between MASCC risk indexscore and type of chemotherapy.

Table 7: Chi square value showing association between MASCC risk indexscore with duration of chemotherapy.

(N = 30)

Sl. No	Demographic variables	MASCC risk score				χ^2
		High		**Low**		
		f	%	f	%	
5	Duration of chemotherapy					3.213 NS

	High	Low	
7 days	2	6.7	4	13.3
14 days	4	13.3	1	3.3
1 month	10	33.3	8	26.6
More than one month	1	3.3	0	0

NS – Not significant

Table 7 depicts that there is no significant association between MASCC risk indexscore and duration of chemotherapy.

Table 8: Chi square value showing association between MASCC risk index scorewith history of radiation

(N = 30)

Sl. No	Demographic variables	MASCC risk score				χ^2
		High		Low		
		f	%	f	%	
6	History of radiation					0.889
	Yes No	5	16.7	6	20	NS
		12	40	7	23.3	

NS – Not significant

Table 8 depicts that there is no significant association between MASCC risk indexscore and history of radiation.

Table 9: Chi square value showing association between MASCC risk index scorewith history of bone marrow or prior stem cell transplantation.

(N = 30)

Sl. No	Demographic variables	MASCC risk score				χ^2
		High		Low		
		f	%	f	%	
7	History of bone marrow or prior stem cell transplantationYes					1.353*
		0	0	1	3.3	
	No	17	56.6	12	40	

*p value = 0.045

Table 9 depicts that there is significant association between MASCC risk index scoreand history of bone marrow or prior stem cell transplantation (p<0.05).

SUMMARY

This chapter dealt with analysis and interpretation of data obtained from 30 patients who were diagnosed as having chemotherapy induced febrile neutropenia regarding their selected baseline variables and MASCC risk index scores.

RESULTS

This chapter presents the major results of the study. The aim of the present study was to assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy using MASCC risk index.

This chapter is organized mainly under two headings –objectives and major findings of the study.

OBJECTIVES OF THE STUDY

1.   To assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy.

2.   To find out the association between the risk of complications associated with febrile neutropenia and the selected baseline variables of the patients undergoing chemotherapy.

MAJOR FINDINGS OF THE STUDY

Baseline Data Assessment

In the present study, distribution of the patients according to age revealed that 56. 7%, were between the age group of 57- 70 years , 33.3% were between the agegroup of 44- 56 years and 10 % were between the age group of 31 -43 years . Distribution of patients according to gender revealed that 53.3% were females and 46.7% were males.

Distribution of patients according to type of cancer revealed that 20% were having cancer breast, 13. 3% were having cancer rectum, 13.3 % were having multiple myeloma, 13. 3% were having Non-Hodgkins lymphoma, 10% were having cancer stomach, 6.7 % were having cancer uterus, 6.7% were chronic having lymphocytic leukemia, 6.7% were having bone marrow cancer,6.7% were having lung cancer and 3.3 % were having cancer prostrate .

Distribution of patients according to the type of chemotherapy revealed that, 36 .7% were on Cyclophosphamide, 16 .6% were on Oxaliplatin, 10% were on Doxorubicin,6.7% were on Bendamustine, 6.7% were on Carboplatin, 6.7% were on Irinotecan, 6.7% were on Rituximab, 3.3% were on Bortenat,3.3% were on Bortezomib and 3.3% were on Docetaxel.

Distribution of patients according to the duration of chemotherapy revealed that, 60% of patients were having one month interval, 20% were having 7 days interval, 16 .7% were having 14 days interval and 3.3% were having more than one month interval.

Distribution of patients according to the history of radiation revealed that majority of the patients 63.3% were not received radiation and 36.7% of patients were received radiation.

Distribution of patients according to the history of prior stem cell or bone marrow transplantation revealed that majority of the patients 96.7% were not had prior history or stem cell or bone marrow transplantation and only few patients 3.3% were had prior history of prior stem cell or bone marrow transplantation.

Distribution of patients according to the MASCC risk index score revealed that majority of the patients 56.7% were belonged to high risk category and 43.3% of patients were belonged to low risk category.

To find out the association between the MASCC risk scores and the selected baseline variables of patients undergoing chemotherapy

The second objective is to find out the association between the MASCC risk score and the selected baseline variables of patients with febrile neutropenia .The selected baseline variables of the study included age, gender, type of cancer, type of chemotherapy, duration of chemotherapy, history of radiation therapy and history of prior stem cell or bone marrow transplantation .

The computed chi square value of the selected baseline variables were as follows : 1.701 for age, .475 for gender, 11.674 for type of cancer, 4.776 for type of chemotherapy, 3.213 for duration of chemotherapy, .889 for history of radiation and 1.353 for history of prior stem cell or bone marrow transplantation .

The present study showed that there was a significant association between MASCC risk index scores and the selected baseline variables type of cancer and history of bone marrow or prior stem cell transplantation at P < 0.05 % level of significance. There was no association found between MASCC risk index scores and selected baseline variables with age, gender, type of chemotherapy, duration of chemotherapy and history of radiation.

SUMMARY

This chapter dealt with the analysis and interpretations of the data collected from thirty patients undergoing chemotherapy regarding risk of complications associated with febrile neurtopenia using MASCC risk index scores.

DISCUSSION, SUMMARY AND CONCLUSION

This chapter gives a brief account of the present study including discussion of the findings in accordance with objectives of the study, summary, possible implications of the results, recommendations, limitations and conclusion drawn from the findings.

DISCUSSION

Discussion refers to the findings of the study or how it differs from previous literature [22]. The study was intended to evaluate the risk of complications associated with febrile neutropenia among patients receiving chemotherapy.

The results of the study   have been discussed under the following sections :

.   **SECTION I**: Description of baseline variables of patients undergoing chemotherapy.

SECTION II: Assessment of risk of complications associated with febrile neutropenia among patients undergoing chemotherapy.

SECTION III: Association between the risk of complication associated with febrile neutropenia and the selected baseline variables of patients undergoing chemotherapy.

SECTION 1: Description of baseline variables of patients undergoing chemotherapy

The baseline variables selected for the present study were age, gender, type of cancer, type of chemotherapy, duration of chemotherapy, history of radiation and history of prior stem cell or bone marrow transplantation.

In the present study,   the distribution of patients according to age revealed that 56. 7% of patients were between the age group of 57- 70 years, 33.3% were between the age group of 44- 56 years and 10 % were between the age group of 31 -43 years .

Distribution of patients according to gender revealed that 53.3% were females and 46.7 % were males.

Distribution of patients according to the type of having cancer revealed that 20% were having cancer breast, 13. 3% were having cancer rectum, 13.3 % were having multiple myeloma, 13. 3% were having Non-hodgkins lymphoma , 10% were having cancer stomach , 6.7 % were having cancer uterus, 6.7% were having chronic lymphocytic leukemia , 6.7% were having bone marrow cancer, 6.7% were having lung cancer and 3.3 % were having cancer prostrate.

Distribution of patients according to the type of chemotherapy revealed that 36.7% were on Cyclophosphamide, 16.6% were on Oxaliplatin, 10% were on Doxorubicin , 6.7% were on Bendamustine, 6.7% were on Carboplatin, 6.7% were on Irinotecan, 6.7% were on Rituximab, 3.3% were on Bortenat,3.3% were onBortezomib and 3.3% were on Docetaxel.

Distribution of patients according to the duration of chemotherapy revealed that, 60% of patients were having one month interval, 20% were having 7 days interval, 16.7% were having 14 days interval and 3.3% were having more than one month interval.

Distribution of patients according to the history of radiation revealed that majority of the patients 63.3% were not received radiation and 36.7% of patients werereceived radiation.

Distribution of patients according to the history of prior stem cell or bone marrow transplantation revealed that majority of the patients 96.7% were not had prior history or stem cell or bone marrow transplantation and only few patients 3.3% were had history of prior stem cell or bone marrow transplantation.

A prospective cross sectional study was conducted for 2 years among 113 patients diagnosed with breast cancer and was receiving chemotherapy. The purpose of the study was to assess the incidence of chemotherapy induced febrile neutropenia and its associated factors. The occurrence of febrile neutropenia and its severity was assesses during The National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03. Semi structured interview was conducted to collect the socio demographic, clinical and hematological data. The result of the study revealed that incidence of neutropenia and febrile neutropenia among the patients was 31.9%and 5.3 respectively. Increasing age and bone metastasis were identified as the

factors increases the risk of febrile neutropenia. The study provided preliminary data necessary for further independent validation of the identified risk factors of febrile neutropenia[39]

An observational study was carried out among 316 patients for a period of 1 year. The aim of the study was to evaluate the frequency of febrile neutropenia between genders and find out association with hematological parameters. Samples were selected using non-probability convenience sampling technique. The study findings revealed that 56.11% of the males (n=168)and 47.3% of females (n= 148) developed febrile neutropenia. The study further concluded that there was no significant difference in the occurrence of febrile neutropenia between two genders[40].

A retrospective cohort study was done between January 2006 to December 2011 among adult patients who underwent mylosuppressive chemotherapy for metastatic cancers of the breast, colon, rectum, lungs, ovaries and prostrate. The study was done to identify the occurrences of febrile neutropenia in each cycle of chemotherapy starting from the 1chemotherapy course. The study concluded that febrile neutropenia is a frequent complication associated with significant morbidity, mortality, economic cost and careful consideration should be given in the treatment.[60]

The findings of the above mentioned studies support the findings of the present study in terms of selected baseline variables of patients with febrile neutropenia.

SECTION II : **Assessment of risk of complications associated with febrile neutropenia among patients undergoing chemotherapy**.

The MASCC risk index is an internationally validated scoring system that identifies the risk of complications associated with febrile neutropenia in patients undergoing chemotherapy.

In the present study MASCC risk index score of the patients revealed that out of 30 patients selected, majority 56.7% were classified under high risk group, and 43.3%were classified under low risk group.

A prospective study was carried out to validate the Multi National Association of Supportive Care Of Cancer (MASCC) Risk index score in an attempt to accurately predict the risk for development febrile neutropenia and its associated serious complications among patients who were receiving chemotherapy. The study was conducted between November 2000 and July 2002. The MASCC risk index score was calculated among 64 patients with 80 febrile neutropenic episodes. Patients with a score ≥ 21was considered as low risk and patients with a score ≤ 21 were considered as high risk. The result of the study revealed that out of the 80 febrile neutropenic episodes, 58 were classified as low risk and 22 were classified as high risk. The study further concluded that they were correctly predicted 98.3 %of the low risk and 86.3% of the high risk patients. The study had a positive predictive valve of 98.3% and a negative predictive value of 80.4% with both specificity and sensitivity of 95%. The MASCC risk index correctly identified low and high risk patients.[43]

A descriptive study was conducted among 100 samples using non probability convenience sampling technique. The aim of the study was to find out risk of complications associated with febrile neutropenia. The finding of the study revealed that 58% were on high risk and 42% were on low risk for complications associated febrile neutropenia. The study concluded that special precautions to be followed to prevent the infection along with administration of biological therapies to boost the immune system and also emphasis the importance of educating the health care personnel regarding febrile neutropenia risk assessment and its management [46]

A prospective multinational study was carried out to develop an internationally validated scoring system to identify low risk group among patients with febrile neutropenia. 756 patients were included in the study. The study results showed that Multinational Association of Supportive Care in Cancer risk index on score >/21 identified low risk patients with a positive predictive value of 91%, specificity of 68% and sensitivity of 71%. The study concluded that MASCC risk index accurately identifies patients at low risk [23].

A study was conducted to support the use of MASCC risk index to determine the management of febrile neutropenia. The study was carried out among 83 patients A total of 100 febrile neutropenic episodes occurred in 83 patients were treated over a 6 months period. Patients treated for solid tumors or lymphomas with low risk febrile neutropenia (MASCC score ≥ 21) were managed better with oral antibiotics like Ciprofloxacin, Doxycycline and Amoxiclav. These patients were discharged early from hospital also. The

median duration of hospitalization was 2.5 days compared to days in high risk episodes. 90% of episodes were low risk of which 83.3% received oral antibiotics and the success rate 94.5%. The positive predictive value of the MASCC score was 96.7%. The study concluded that MASCC risk index is safe and feasible in the management of febrile neutropenic patients with solid tumors or lymphomas .Patients predicted with low risk can be managed safely with oral antibiotics and early hospital discharge[44]

The findings of the above mentioned studies supports the findings of the present study in terms of using MASCC risk index scores for patients in assessing the risk of complications secondary to chemotherapy induced febrile neutropenia and classifying the patients as high and low risk groups .

SECTION III: Association between the MASCC risk index scores and the selected baseline variables of patients.

The selected baseline variables of the present study included age, gender, type of cancer, type of chemotherapy, duration of chemotherapy, history of radiation therapy and history of prior stem cell or bone marrow transplantation.

The present study showed that there was a significant association between MASCC risk index scores with selected baseline variables type of cancer and history prior stem cell or bone marrow transplantation. There was no association between MASCC risk index scores and selected baseline variables such as age, gender, type of chemotherapy, duration of chemotherapy and history of radiation.

Summary

The present study was done to assess the risk of complications associated withfebrile neuropenia among patients receiving chemotherapy in a selected hospital.

The objectives of the study were to assess the risk of complications associated with febrile neutropenia among patients undergoing chemotherapy and to find out the association between the risk of complications associated with febrile neutropenia and the selected baseline variables .

The review of literature were taken from books, journals, unpublished dissertations, thesis, and web resources. A descriptive research design was used for the present study. The tool consisted of base line data assessment proforma and MASCC risk index scores. The validity and reliability of the tool were tested and found reliable. Pilot study was conducted among 6 patients. Non-probability purposive sampling technique

was used for the sample selection. Pilot study revealedthat the objectives of the study could be fulfilled. Based on the information the investigator proceeded with the final study. The main study was conducted in the selected hospital Pathanamthitta district. The subjects satisfying inclusion and exclusion criteria were selected using non probability purposive sampling technique. The study was conducted among 30 patients who were receiving chemotherapy inthe oncology outpatient department, oncology wards and medical intensive care units of the selected hospital . The investigator introduced herself to the subjects andexplained the purpose of the study. Individual informed written consent was obtained from the subjects and assured anonymity and confidentiality of the study.

Data was systematically tabulated to facilitate data analysis. The collected datawere analyzed by using descriptive and inferential statistics. In the present study MASCC risk index score of the patients revealed that out of 30 patients selected, majority 56.7% were classified under high risk group, and 43.3% were classifiedunder low risk group.

The analysis of the association of selected baseline variables with MASCC risk index scores revealed significant association between type of cancer.

Conclusion

Febrile neutropenia is one of the most prominent complications of cancer chemotherapy and leads to decreased efficacy. Febrile neutropenia occurs during a chemotherapy cycle. The Multinational Association of Supportive Care in Cancer (MASCC) risk index scores is an internationally validated scoring system which identifies low risk patients who can potentially be treated as an outpatient with early antibiotic therapy. Early identification of fever, sepsis and timely administration of antibiotic are highly recommended in the management of febrile neutropenia. Hence, concurrent over viewing of system should be integrated by health care facilities.

Optimal management of febrile neuropenia has been clearly documented in a care bundle introduced by Fouks, that documented on improvement in compliance with the neurtopenic care pathway from 19% to 94 % along with benefit in terms of decreased hospital stay from 13.4 days to 6 days and decreased mortality from 7% to 4%.

Specific guidelines for nurses regarding the prevention and management of febrile neuropenia have been recommended. These include:

a. Developing and reinforcing the implementation of patient care pathways designed to prevent and mange febrile neuropenia.

b. Providing appropriate education on febrile neuropenia for health professionals, patients and families.

c. Providing patients with verbal and written information on the early signs offebrile neuropenia.

The present study revealed that risk of complications associated with febrile neutropenia among patients undergoing chemotherapy. Distribution of patients according to the MASCC risk index score revealed that majority of the patients 56.7% were belonged to high risk category and 43.3% were belonged to low risk category.

The present study showed that there was a significant association between MASCC risk index scores with selected baseline variable type of cancer. There was no association between MASCC risk index scores and selected baseline variablessuch as age, gender, type of chemotherapy, history of radiation duration of chemotherapy and history prior stem cell or bone marrow transplantation.

Nursing implications

The study findings of the present study have several implications in the field of nursing service, nursing education, nursing administration and nursing research.

Nursing service

1. This study brings awareness among nurses regarding the early identification of risk of complications associated with febrile neutropenia among patientsundergoing chemotherapy.

2. This study sensitizes the nurses regarding the possible risk of complications among patients undergoing chemotherapy.

3. This study strengthen the knowledge of nurses regarding the assessment on risk of complications associated with febrile neutropenia among patients undergoing chemotherapy .

4. The study emphasizes the need for adequate patient/family education regarding assessment of febrile neutropenia and its associated complications

5. This study emphasizes the need for highly trained oncology nurses for conducting routine and emergency assessment on patients receiving chemotherapy.

Nursing Education

1. This study brings awareness among nurse educators and nursing students regarding the of risk of complications associated with   febrile neutropenia among patients undergoing chemotherapy .

2. This study helps the nurse educators to prepare the student nurses with adequate knowledge and skill to perform the assessment on risk of complications associated with febrile neutropenia among patients undergoing chemotherapy.

3. Nurse educators can organize periodic workshops on chemotherapy, patient assessment, complications of chemotherapy and its management and prevention.

Nursing Administration

1. The study findings can be used by nursing authorities to organize in-service education programmes to update the knowledge of nurses on risk of complications associated with febrile neutropenia among patients undergoing chemotherapy .

2. Nurse administrators can make policies and protocols for early identification of risk of complications associated with febrile neutropenia among patients undergoing chemotherapy.

3. Nurse administrators can monitor and supervise the practices of nurses in carrying out the assessment regarding complications associated with febrile neutropenia among patients undergoing chemotherapy .

4. Nurse administrators can do periodic auditing and evaluation on nurses" knowledge and skill on assessment of complications associated with febrile neutropenia among patients undergoing chemotherapy .

5. Nurse administrators can suggest for developing guidelines, policies and care bundles for the prevention, management and early identification of febrile neutropenia and its associated complications among patients undergoing chemotherapy.

Nursing Research

1. There is a need for extensive and intensive research in this area so that strategies can be implemented in educating nurses regarding chemotherapycomplications and its management and prevention among patients undergoing chemotherapy.

2. Researchers can use the present study as a reference material so that it act as avenue for further studies in this area .

Limitations

1. The study was limited to thirty patients receiving chemotherapy.

2. The study was limited to patients who were receiving chemotherapy in oncology outpatient department, oncology wards and medical intensive care unit of the selected hospital.

3. The study was limited to a shorter period of time.

4. Generalization was limited due to sample size and sampling technique

5. The study was assessed only the risk of complications associated with febrile neutropenia among patients undergoing   chemotherapy using   MASCC risk index scores

6. The study was given only some descriptive data.

Recommendations

1. Similar study can be conducted on larger samples so that findings can begeneralized.

2. Similar study can be conducted for a longer period of time.

3. Similar study can be conducted considering complications other than febrile neuropenia among patients receiving chemotherapy.

4. Similar study can be conducted to identify high risk factors among patients for developing febrile neutropenia.

5. Similar study can be conducted to assess the occurrence of febrile neutropenia and its complications with selected chemotherapeutic agents.

6. Similar study be conducted using different assessment tools for febrileneutropenia.

SUMMARY

This chapter dealt with discussion of the findings in accordance with objectives of the study , summary ,possible implications of the results, recommendations , limitations , and conclusions drawn from the findings .

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