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Epidemiological Studies and Evaluation of Adverse Drug Reactions Caused by Injection Pegfilgrastim

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Abstract

Injection Pegfilgrastim is used to decrease the incidence of the infection and manifest by febrile neutropenia non-myeloid cancer patients receiving myelosuppressive anti-cancer treatment. The studies on the efficacy and injection related ADR'S have been carried out because this injection has been mandatorily given to every cancer patient except blood cancer as a prophylactic purpose. Still, the point is safety and efficacy of this injection have not been approved in patients receiving both chemo and radiation therapy. So, studies have been carried out to prove its safety and efficacy. The study was conducted at Omega super specialty hospital, Hyderabad for a period of six months from August 2019 to January 2020.

Keywords

Injection pegfilgrastim, tumour, cancer, genes, drug, Breast, patients, Malignant.

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I. INTRODUCTION

Cancer is a cluster of diseases caused by an uncontrolled division of cells in any part of the body [1, 2]. Cancer consists of more than 100 different types of infections. It can develop in almost any part of our organization. Cells are the fundamental units that make up the human body. Cells in our collection are always multiplying and generating more new cells as our body needs them. Usually, cells decease after they get old or become damaged. Cancer usually occurs when genetic changes intervene in this orderly process. These cause the cells may grow uncontrollably. These cells may then form a mass, which is termed a tumour. Tumour either be cancerous or benign. Cancer that may be cancerous can become malignant, which means cancer may grow and move to the various parts of the body [3, 4].

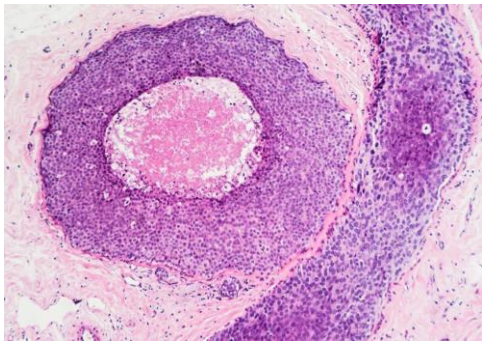

Figure 1: Cross-sectional image of cancer cell

On the other hand, a benign tumour means that cancer grows but doesn't spread to any part of the body. Particular sort of disease does not form a tumour. These include lymphoma, leukemia, and also myeloma. As a tumour grows in size, it may pass into the bloodstream or lymphatic system, which may carry cancerous cells to various parts of the

body. And during this process, the cancer cells may multiply, increase in size, and develop into new tumours. This process is commonly known as metastasis. Cancer or cancerous cells may grow and generate into the lymph nodes [5, 6]. These Lymph nodes are tiny, round, and somewhat curvy bean-shaped organs that help to fight off infections in our body. These are located in the form of groups in various parts of the body, like as the groin area, neck and under the arms. The figure1 shows the cross-sectional image of cancer cell. Cancer cells can also spread to various parts of the body penetrate through the bloodstream, which includes the brain, bones, liver, and lungs [7]. When cancer advances to different part of the body, it is still termed after the region where the tumour was initially formed. For example, if colon cancer metastasizes to the lungs, it is called metastatic colon cancer and not lung cancer [8, 9].

Genetic factors can also play an essential role in the formation of cancer. The genetic code of a person informs their cells when to multiply and when to expire. Any changes in these genes can result in faulty instructions, dominant to the formation of cancerous cells. Genes can also influence a cell's generation of proteins, and proteins help carry information for the cellular growth and division. Specific genes can also alter proteins that would repair damaged cells. These can lead to the development of tumour cells. Alteration in genes can also occur after birth, and individual factors such as sun exposure and smoking increase the risk of cancer. Other changes that can affect development in cancer growth can occur in the chemical signals, which determine how the body expresses specific genes.

i. Injection Pegfilgrastim

The brand name is Pegstim Injection and chemical name is 3-hydroxypropyl-N-metionyl-, 1-eter wit alpha-methyl-omega-hydroxypoly (oxy-1, 2-etanediyl). The injection pegfilgrastim has a molecular formula: C849-H1347-N223-O244-S9 and its molecular weight is 39000.0 Da (approximate, PEGylated). The figure 2 shows the molecular structure of injection pegfilgrastim.

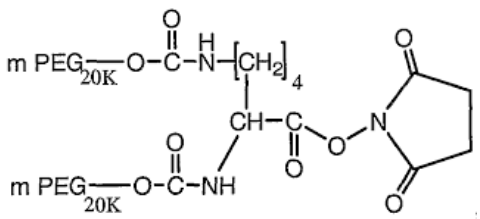

Figure 2: Molecular structure of pegfilgrastim[10]

Pegfilgrastim is a PEGylated form of G-CSF. It is used to lower the extent of the infection, as seen in febrile neutropenia, in individuals with non-myeloid cancer receiving myelosuppressive anticancer treatment [10]. Also evaluated was the resilience of pegfilgrastim to agitation and successive freezing cycles [15]. Some individuals or patients with higher risk factors can develop febrile neutropenia during myelosuppressive therapy, and they are susceptible to high risk of developing the infections. Although in many chemotherapy regimens, the risk of causing febrile neutropenia is below 20%, some diseases have higher chances of patients getting hospitalized and mortalities.

Pegfilgrastimneeds less persistent dosing than filgrastim because the half-life of the drug is longer, and the elimination rate is slow. Pegfilgrastim and filgrastim have similar biological activity, stimulating the differentiation, activation and proliferation of neutrophils.

Pegfilgrastim was first developed by Amgen [29], and approved by the FDA in the year 2002 and is marketed as Neulasta®.Pegfilgrastim is administered subcutaneously.pegfilgrastim is a covalent filgrastim conjugator, and monometoxypolyethyleneglycol. Pegfilgrastim raises the half-life of terminal removal and reduces the drug's apparent serum clearance in patients with non-myeloid cancer.[11] There are several pegfilgrastim biosimilars with the same therapeutic indication that are approved by Health Canada, FDA and European Union (EU). These biosimilars are very similar to Neulasta (pegfilgrastim), in terms of both pharmacological and pharmacokinetic profile, the conditions of use, such as the therapeutic indications, dosing regimens, strengths, dosage forms, and routes of administration of these biosimilars are also similar to pegfilgrastim. Neulasta should not be indicated to individuals who are allergic to filgrastim.

To use pegfilgrastim safely, contact your health care professional if you have any of these following conditions: sickle cell disorder, kidney disease, chronic myeloid leukaemia, myelodysplasia and A latex allergy. It is unknown if pegfilgrastim can impair or harm an unborn baby. If the individual is pregnant or plans to become pregnant, it advised talking to the doctor before administering pegfilgrastim. The usual Adult Dose for Neutropenia for Chemotherapy is 6 mg subcutaneously per chemo cycle, for less than 12 year old the dose is 100 mcg/kg once per chemotherapy cycle and for 13 to 18 years' old who are greater than 45 kg: 6 mg once per chemotherapy cycle,

A severe side effect of pegfilgrastim, which is quite rare, is known as capillary leak syndrome. Side

effects include decreased urination, tiredness, dizziness, a light-headed feeling, Feeling of fullness and sudden swelling, puffiness. Medical conditions like cancer and certain medications like chemotherapy may reduce our body's ability to create an average amount of white blood cells. Based on comfort and patient adherence, pegfilgrastim for the prevention of chemotherapy-induced FN may be preferred to filgrastim 11 days. [12]. Always make sure to read the Patient Information Leaflet that is provided by the pharmacist before using pegfilgrastim and also before you get a refill. Consult your healthcare professional if you have any queries regarding the information present in the patient information leaflet. This medication should be kept at room temperature for about forty-eight to seventy-two hours. After this, if the drug is still unused, it is advised to discard it. Always consult your health care professional or pharmacist for information regarding the medicine.

ii. Objectives

- To carry out epidemiological studies on ADR'S and evaluate the drug injection. Pegfilgrastim safety and efficacy.
- To identify the number of cases that have been receiving injection pegfilgrastim.
- Assessing the ADR's and side effects of injection pegfilgrastim
- Evaluation of Patient's outcome.
- To evaluate the efficacy of injection Pegfilgrastim.

This paper is organized as follows: in section II the literature review is presented. Section III proposes the methodology used. Section IV presents the result and discussion is presented in section V. Finally, conclusions are summarized in section VI.

II. LITERATURE REVIEW

The literature related to our work carried out by various authors is reviewed as follows:

Gralow J R *et al*. (2020) [12]: Have investigated that 73.2 per cent of patients showed preference for oral rather than intravenous formulation prior to randomization. In a log-rank check, DFS didn't vary across the weapons. We found no evidence, either in the overall or subgroup study, of differences in efficacy through bisphosphonate forming.

Kahan Z *et al*. (2019) [13]: Security profiles were comparable across categories. No neutralizing antibodies were identified against pegfilgrastim. Treatment equivalence can be shown in that the duration of neutropenia between RGB-02 and Neulasta ® caused by chemotherapy. RGB-02 once-per-cycle administration and reference pegfilgrastim have shown similar effectiveness and safety profiles.

Hauber A B *et al*. (2018) [14]: Patients usually chose the prescribing method they had experience with. 55.5 percent favored an in-clinic injection and 28.0 percent favored the OBI for a less compromised option. Patients and physicians have reported that clinic visits for the administration of pegfilgrastim may be burdensome to return. The OBI, which requires adherence to the use of pegfilgrastim marketed without return visits.

Aapro M *et al*. (2017) [15]: Clinical care should be given for treatment with curative purpose, control of dose intensity using G-CSF to avoid dose delays / reduction. Within this era of targeted therapies more trials with G-CSF are still required. With current guidelines, these recommendations will be used to improve the use of pegfilgrastim in clinical practice.

Fust K *et al*. (2017)[16]: The comparators either were more pegfilgrastim or had lower costs but higher ICERs than pegfilgrastim PPs. From a Belgian payer's point of view, PP with pegfilgrastim is cost-effective in patients with stage II breast cancer or NHL at €30,000 / QALY compared to other prophylactic approaches

Cerchione C *et al*. (2017)[17]: Pegfilgrastim has been associated significantly with lower incident levels of FN-related chemotherapy complications and fewer days of FN hospitalization. For patients with indolent NHL, primary prevention with pegfilgrastim in the front-line treatment with bendamustine plus rituximab tends to decrease the occurrence of FN related chemotherapy complications and days of hospitalization. This is also welltolerated and can improve the ability to sustain the normal treatment schedule.

McBride A *et al*. (2017) [18]: Cost savings achieved with filgrastim-sndz compared to reference filgrastim using ASP+CPT. Similar to cost savings compared with pegfilgrastim, filgrastim-sndz saved on pegfilgrastim-injector. Prophylaxis with filgrastimsndz, is a biosimilar filgrastim, was consistently correlated with the high cost savings over prophylaxis with reference filgrastim, pegfilgrastim, and pegfilgrastiminjector, throughout various administration scenarios.

Naeim A *et al*. (2013) [19]: The mean length of filgrastim prophylaxis in the sample was 4.8 days, in the comparative efficacy analysis. The mean length of prophylaxis of pegfilgrastim in the study was 1.0 day, consistent with the prescribed dose of pegfilgrastim. Pegfilgrastim prophylaxis was associated with a reduced risk of neutropenia in this comparative efficacy review and decreased hospitalization due to neutropenia postchemotherapy.

Burris HA *et al*. (2010)[20]: In the breast and lymphoma trials, the absolute neutrophil count profile for patients on Sameday was higher, greater and longer than that for patients on the next day, although the results for neutropenia length were not lower than the results for the next day. Pegfilgrastim was given 24 hours after completion of the chemotherapy for patients undergoing pegfilgrastim with chemotherapy.

Danova M *et al*. (2009) [21]: Pegfilgrastim was cost-effective in comparison to six-day filgrastim in Italy under base-case assumptions. The equivalent marginal cost-effectiveness ratio with pegfilgrastim was won Euro 409 per year of life and received Euro 429 per year of quality-adjusted existence. At the current official price in Italy, primary prophylaxis with pegfilgrastim improved health outcomes for the payer of the National Health Service with a very limited cost increase. Even if the model considered very low filgrastim.

Scholz M *et al*. (2009) [22]: Dosage and timing had a significant impact on the efficacy of filgrastim schedules whereas pegfilgrastim was irrelevant for the timing effect. We conclude that the efficacy of filgrastim application during chemotherapy is highly dependent upon its scheduling. Timing is an optimum. Dose separation is better applied than concentrated. The effectiveness of pegfilgrastim depends less on the timing.

Bruns I *et al*. (2008) [23]: Pegylated G-CSF and unconjugated G-CSF mobilized CD34(+) and hematopoietic stem cells with different molecular phenotypes and functional properties. The study revealed that stimulation with pegylated-G-CSF results in a distinct expression of key regulatory genes and distinct cognitive properties of activated hematopoietic stem cells as well as their progeny, a finding that may be essential for the application of these cells in the transplantation of stem cells in blood.

Balducci L *et al*. (2007) [24]: Proactive application of pegfilgrastim resulted in a substantially lower occurrence of febrile neutropenia in patients with both solid tumors and NHL compared with reactive application. It is the first, randomized, prospective study evaluating support for growth factors in traditional elderly patients with cancer. Proactive use of pegfilgrastim successfully demonstrated a lower incidence of febrile neutropenia and other side effects in older patients with either solid tumor's or NHL undergoing mild-moderate chemotherapy regimens.

Kuderer N M *et al*. (2007) [25]: In studies requiring secondary G-CSF prophylaxis in controls and in the three trials with reciprocal prophylactic antibiotics in both treatment arms, substantial reductions were observed in FN with G-CSF. Studies have shown that prophylactic use of G-CSF reduces the risk of febrile neutropenia and deaths caused by chemotherapy, which include infectious mortality, while increasing RDI and musculoskeletal pain.

Schippinger W *et al*. (2006) [26]: The frequency of chemotherapy delays and dose reductions between the two G-CSF treatment groups was not significantly different. Such results from the study indicate a trend towards pegfilgrastim superiority over filgrastim in reducing the occurrence of febrile neutropenia in patients with taxane and epirubicin chemotherapy regimens who are diagnosed with breast cancer.

III. METHODOLOGY

The study structure carried out is a prospective and observational study to study the ADR'S occurring in different cancer patients, recording them, and analyzing them. A count of 150 patients was included in the research, and they have been observed thoroughly.

i. Study design

The study structure carried out is as prospective and observational studies, on epidemiological research and evaluation of injection pegfilgrastim and its ADR's.

***Study Site*:** The study was conducted at Omega super specialty hospital, MLA colony, Banjara Hills.

Study period: The study was conducted for a period of six months from August 2019 to January 2020.

Sample Size: A total of 150 subjects that were admitted in various wards were analyzed during the study period based. The 150 subjects were enrolled based on inclusion and exclusion criteria; of these, 50 were diagnosed with colon cancer, 50 were diagnosed with rectal cancer, and 50 were diagnosed with breast cancer.

ii. Study Criteria

Inclusion criteria

- Patients receiving injection PEGFILGRASTIM are to be included.
- Patients of both the genders
- Patients of all ages above 25 years are included.

Exclusion criteria

- Pregnant, lactating women
- Pediatrics patients
- Patients who are not receiving INJECTION PEGFILGRASTIM are excluded.

iii. Study material: All relevant and necessary data for this study was collected from-

- Patient case notes
- Treatment chart
- Laboratory reports

- Interviewing Patient/ Patient caretaker
- Interviewing Healthcare Professionals

iv. Study procedure

A prospective and observational study was conducted to analyze the adverse effects of various subjects who were taking injection pegfilgrastim in different hospital wards by regular ward rounds and case record reviews. The patients were diagnosed with colon, rectal and breast cancer. The enrolled patients were taken follow-up from the day of admission until the day of discharge or patient-specific conditional outcome and the relevant study data, including laboratory investigations, recent medical history of the patient from the Patient's case record, and medical history from case record form.

IV. RESULTS

During the study period, appropriateness based on dose administered ,and therapeutic efficacy of this drug were studied and adverse drug reaction of this drug in Breast Cancer patients was found to be Leukocytosis (37%), Weakness (22%), Body pains (8%), Giddiness(7%), Legs pain (6%),Fever (5%),Back pain; Bone pain; Joint pain ;Motions (4%); Headache ;Loss of Appetite(3%), Nausea(2%),Tiredness(2%), Others (4%) and adverse drug reaction of this drug in Colon Cancer patients was found to be Leukocytosis (38%), Weakness(20%), Body pains(16%), No complaints(14%), Loss of Appetite(5%), Fever(4%), Giddiness(1%), Stomach pain(1%), Back pain (1%)and adverse drug reaction of this drug in Rectal Cancer patients was found to be Leukocytosis (47%), No complaints (20%), Weakness(12%), Loss of Appetite (8%), Body pains (5%), Vomitings (5%), Stomach pain; Back pain; Nerve tingling (2%), Giddiness(1%). Since this drug is mandatory for every cancer patient, special caution should be taken to prevent drug interactions. After interrogating every cancer patient, we found that these adverse effects occur as soon as after administration and only last for 3-4 days. We can overcome it by taking nutritious food and the medication is considered healthy.

i. Age-Wise Distribution

Of the enrolled 50 breast cancer patients, recording the age-wise distribution of subjects with the class size of 10years, it was seen that majority of subjects belonging to the age group of 41-50 years, with the mean age value of 50.54 years.

Table 1: Age-wise distribution of Breast Cancer patients

Age groups	Number of subjects	Percentage
31-40	3	6%
41-50	24	48%
51-60	13	26%
61-70	10	20%

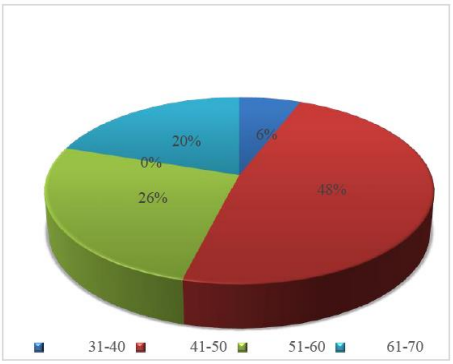

Figure 3: Pictorial Representation of Age-Wise Distribution in Breast Cancer

ii. Sites of Breast Cancer

Of the enrolled 50 breast cancer patients, regarding the site-wise distribution of breast cancer subjects, a majority of breast cancer site was found to be the left side, then right followed by bilateral.

Table 2: Site-wise distribution of Breast Cancer

Sites of breast cancer	Number of cases
Right breast cancer	22
Left breast cancer	24
Bilateral breast cancer	4

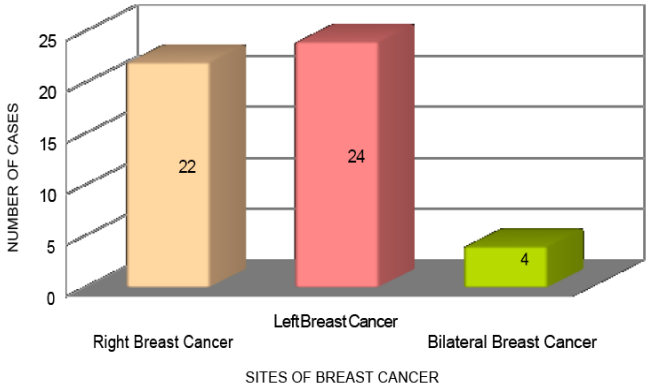

Figure 4: Graphical Representation of site-Wise Distribution

iii. Type of Tumour

Of the enrolled 50 breast cancer patients, the nature-wise distribution of tumor of subjects, it was seen that majority of the subject nature of tumor was found to be Benign.

Table 3: Nature-wise distribution of Tumour in Breast Cancer.

Type of Tumour	Number of Cases	Percentage
Malignant	19	38%
Benign	31	62%

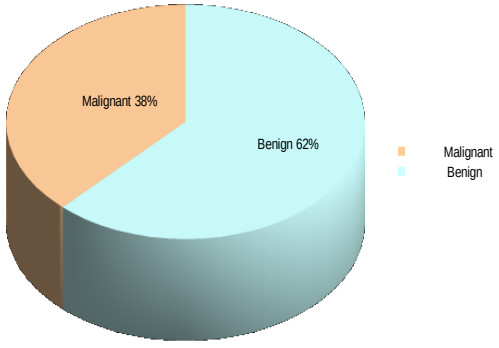

Figure 5: Pictorial Representation of Nature-Wise Distribution of Tumour

iv. Injection Pegfilgrastim Adverse Drug Reactions in Breast Cancer

Of the enrolled 50 breast cancer patients, the adverse drug reactions caused by the drug pegfilgrastim were found to be of the majority of subjects experienced the leukocytosis, weakness and body pains majorly, then giddiness, legs pain, fever, back pain, bone pain, joint pain, motions moderately and headache, loss of appetite, nausea, tiredness minorly.

Table 4: Injection pegfilgrastim ADR'S.

Type of adverse drug reaction's	Number of Patients
Leukocytosis	50
Weakness	30
Body pain	11
Giddiness	9
Legs pain	8
Fever	7
Back Pain, Bone Pain, Joint Pain, Motions	5
Headache, Loss of Appetite	4
Nausea	3
Tiredness	2
Others	6

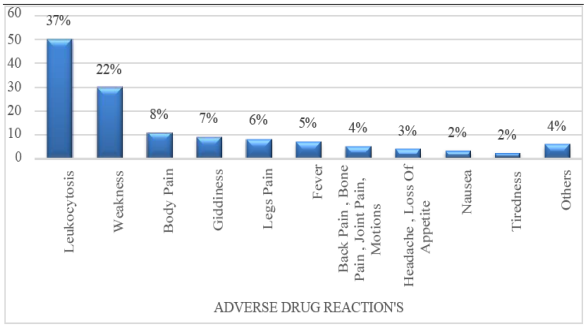

Figure 6: Graphical Representation of Injection pegfilgrastim ADR'S in Breast Cancer

v. Gender

A total of 50 colon cancer patients were enrolled, gender-wise distribution was done during the study period, of majority are males, and the minority are females.

Table 5: Gender-wise distribution of Colon Cancer patients

Gender	Number of subjects	Percentage
Female	17	34%
Male	33	66%

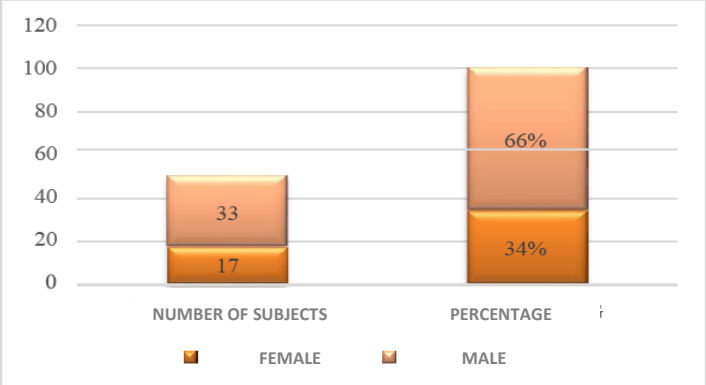

Figure 7 Graphical Representation of Gender-wise distribution of Colon Cancer patients

vi. Age-Wise Distribution

Of the enrolled 50 colon cancer patients, recording the age-wise distribution of subjects with the class size of 10years, it was seen that majority of subjects belong to the age group of 41-50 and 61-70.

Table 6: Age-wise distribution of Colon Cancer patients

Age group	Number of subjects	Percentage
31-40	8	16%
41-50	14	28%
51-60	8	16%
61-70	14	28%
71-80	6	12%

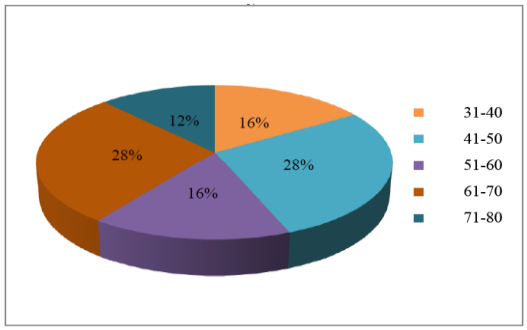

Figure 8: Pictorial Representation of Age-Wise Distribution of Colon cancer patients

vii. Types of Tumour

Of the enrolled 50 colon cancer patients, the nature-wise distribution of tumor of subjects, it was seen that majority of the subjects nature of tumor was found to be Malignant.

Table 7: Nature-wise distribution of Tumour in Colon Cancer

Type of tumour	Number of cases	Percentage
Malignant	44	88%
Benign	6	12%

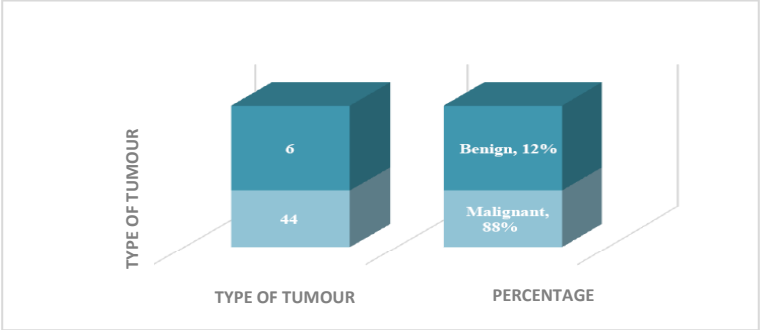

Figure.9: Graphical Representation of Nature-Wise Distribution of Tumor.

viii. Injection.Pegfilgrastim Adverse Drug Reaction's In Colon Cancer

Of the enrolled 50 colon cancer patients, the adverse drug reactions caused by the drug Pegfilgrastim were found to be, of them majority of the subjects experienced the Leukocytosis, weakness, body pains majorly, and moderately people have no complaints and loss of appetite, fever, giddiness, stomach pain minorly.

Table 8: Injection. Pegfilgrastim ADR'S..

Types of adverse drug reaction's	Number of patients
Leukocytosis	50
Weakness	26
Body pains	21
No complaints	18
Loss of Appetite	6
Fever	5

Giddiness	2
Stomach pain	2
Back Pain,	1

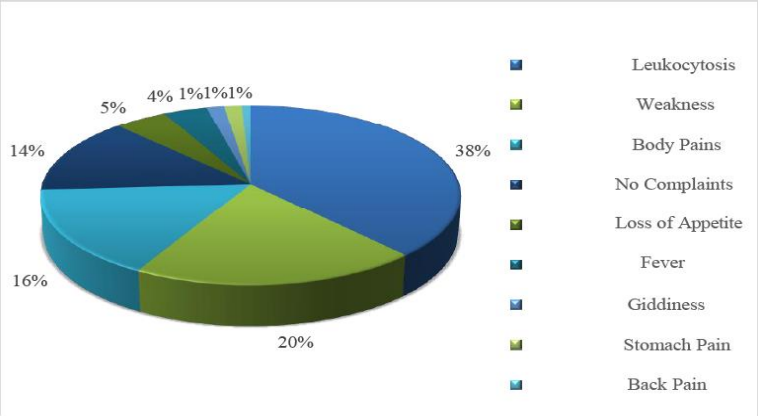

Figure10: Pictorial Representation of Injection. Pegfilgrastim ADR'S in Colon Cancer patients.

ix. Age –Wise Distribution

Of the enrolled 50 rectal cancer patients, recording the age-wise distribution of subjects with the class size of 10 years, it was seen that majority of the subjects belong to the age group of 51-60.

Table 9: Age –wise distribution of Rectum Cancer patients.

Age groups	Number of subjects	Percentage
21-30	1	2%
31-40	7	14%
41-50	9	18%
51-60	11	22%
61-70	8	16%
71-80	9	18%
81-90	4	8%
91-100	1	2%

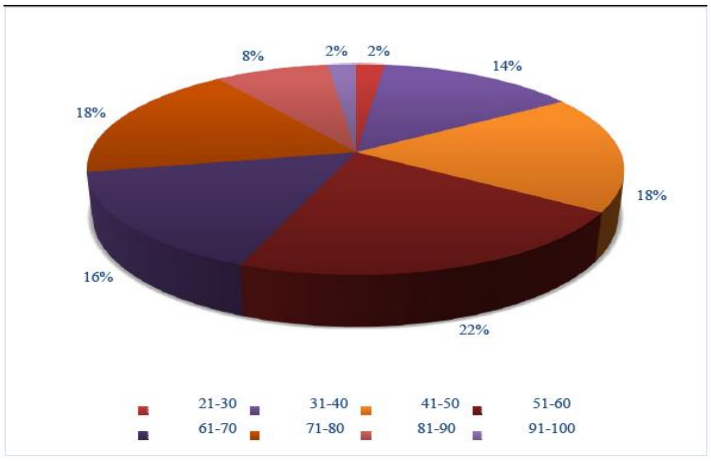

Figure.11: Graphical Representation of Age-wise Distribution of Rectal Cancer patients

x. Gender

A total of 50 rectal cancer patients were enrolled, gender-wise distribution was done during the study period, of majority are found to be females, and the minority are males.

Table 10: Gender- wise distribution of Rectal Cancer patients.

Gender	Number of subjects	Percentage
Female	26	56%
Male	24	48%

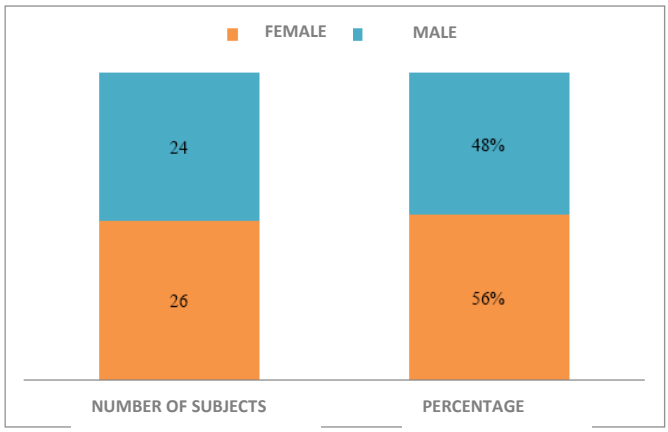

Figure 12: Graphical representation of Gender-wise distribution of Rectal Cancer patients.

xi. Type of Tumour

Of the enrolled 50 rectal cancer patients, the nature-wise distribution of tumor of subjects, it was seen that majority of the subject's nature of the cancer was found to be **Malignant.**

Table 11: Nature- wise distribution of Tumor in Rectal Cancer patients.

Type of tumour	Number of cases	Percentage
Malignant	26	52%
benign	24	48%

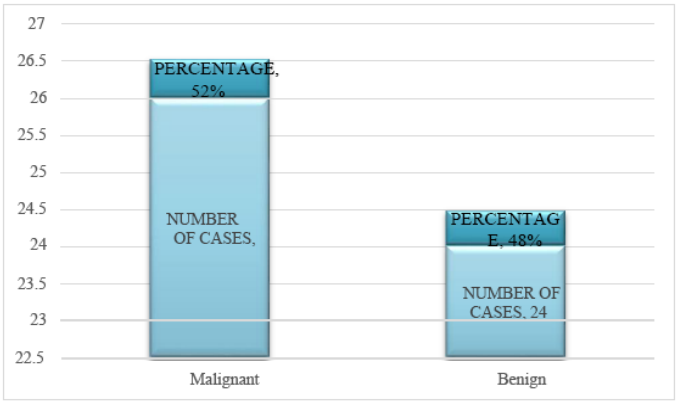

Figure.13: Graphical representation of Nature-wise distribution of Tumor

xii. Injection Pegfilgrastim Adverse Drug Reaction'sin Rectal Cancer

Pains, vomiting's and stomach pain, back pain, nerve tingling's, and giddiness minorly Of the enrolled 50 rectal cancer patients. The adverse drug reactions caused by the drug Pegfilgrstim were found to be, of the majority of subjects experienced the leukocytosis, no complaints, weakness majorly, and moderately people experience loss of appetite.

Table 12: Injection Pegfilgrastim ADR'S.

Types of adverse drug reaction's	Number of patients
leukocytosis	50
No complaints	21
Weakness	13
Loss of appetite	9
Body pains	6
Vomiting's	5

Stomach pain, back pain nerve tingling's	2
Giddiness	1

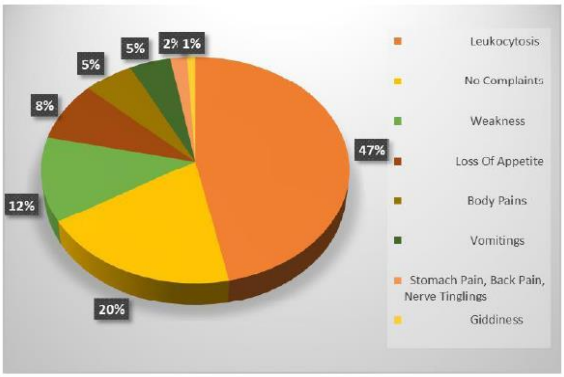

Figure 14: Pictorial representation of Injection Pegfilgrastim ADR'S in Rectal Cancer patients.

V. DISCUSSION

It is a prospective observational study conducted to carry out epidemiological and evaluation of Injection. Pegfilgrastim caused ADR'S in various cancer patients who were carried out in a cancer hospital by assessment of their case sheets.

The enrolled patients to whom this drug was given were taken followed right from the day of admission for their 1st chemotherapy cycle till up to the 8th chemotherapy cycles, patient-specific conditional outcome and the relevant study data including laboratory investigations, medication history of patient right from the diagnosis of cancer were documented in case report form.

A total of 150 subjects of various cancers were analyzed during the study to whom this drug Inj Pegfilgrastim was given were examined during the study period. Of these 50 subjects belong to breast cancer, 50 subjects belong to colon cancer, 50 subjects belong to rectal cancer.

A total of 150 subjects were enrolled (based on Inclusion and Exclusion criteria). The Age-wise distribution of subjects with a class size of 10 yrs.' shows that the majority of subjects belong to the age group.

The drug Injection Pegfilgrastim drug was given mandatorily to all cancer patients. Still, its safety and efficacy had not been established, so these studies were conducted to find the effectiveness and safety of this drug Injection Pegfilgrastim. In this study, cancer included breast cancer, Colon cancer, rectal cancer, and the Injection causing ADR'S were recorded.

During the study period, appropriateness based on dose administered ,and therapeutic efficacy of this drug were studied and adverse drug reaction of this drug in Breast Cancer patients was found to be Leukocytosis(37%), Weakness (22%), Body pains (8%), Giddiness(7%), Legs pain (6%),Fever (5%),Back pain; Bone pain; Joint pain ;Motions (4%); Headache ;Loss of Appetite(3%), Nausea(2%),Tiredness(2%), Others (4%) and adverse drug reaction of this drug in Colon Cancer patients was found to be Leukocytosis(38%), Weakness(20%), Body pains(16%), No complaints(14%), Loss of Appetite(5%), Fever(4%), Giddiness(1%), Stomach pain(1%), Back pain (1%)and adverse drug reaction of this drug in Rectal Cancer patients was found to be Leukocytosis(47%), No complaints (20%), Weakness(12%), Loss of Appetite (8%), Body pains (5%), Vomiting's (5%), Stomach pain; Back pain; Nervetingling's(2%), Giddiness(1%). Since this drug is mandatory for every cancer patient, special caution should be taken to prevent drug interactions. After interrogating every cancer patient, we found that these adverse effects occur as soon as after administration and only last for 3-4 days. We can overcome it by taking nutritious food and the medication is considered healthy.

VI. CONCLUSION

The current observational study was carried out to evaluate the efficacy of Injection.Pegfilgrastim and to carry out epidemiological studies and evaluation of Injection. Pegfilgrastim caused Adverse drug reactions. This Injection. Pegfilgrastim is long acting form of drug, Filgrastim. This drug is called as "Colony stimulating factor". And is used to stimulate bone marrow. It is used as prophylaxis that will stimulate growth of WBC which helps our body to fight against infection. On the basis of preliminary evaluation significantly high number of subjects were identified with different types of ADR's.

Literature was evaluated to retrieve the efficacy and safety of Injection. Pegfilgrastim, but clear specification about the safety, efficacy, of Injection. Pegfilgrastim was not established and was not clearly reported by other investigators. In the following study site, it was seen that higher number of subjects

were enrolled as this drug was mandatorily given to all cancer patients i.e. Breast cancer, colon cancer, rectal cancer except blood cancer. The literature review based ADR'S were more compared to the one experienced by subjects in studies.

Based on the observational studies conducted on Injection. Pegfilgrastim and analyzed in following study period concluded that this drug is mandatory for every cancer patient, special caution should be taken to prevent drug interactions. After interrogating every cancer patient, we found that these adverse effects occur as soon as after administration and only last for 3-4 days. We can overcome it by taking nutritious food and the medication is considered healthy.

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