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ASSESSMENT OF ADVERSE DRUG REACTIONS AND QUALITY OF LIFE IN CANCER PATIENTS RECEIVING PLATINUM ANALOGUES AND MONOCLONAL ANTIBODIES VISITING A TERTIARY CARE HOSPITAL: AN OBSERVATIONAL STUDY

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ABSTRACT The objective of this study is to evaluate the most common and immediate adverse drug reactions associated with platinum analogues and monoclonal antibodies, and to determine the safer therapeutic option based on the frequency and severity of adverse drug reactions in cancer patients. Additionally the study aims to facilitate evidence-based practice by assessing the safety profiles of platinum analogues and monoclonal antibodies and advancing findings to inform clinical decision-making for the best cancer treatment outcomes and to Identify the safer therapeutic options by assessing the safety profiles of platinum analogues and monoclonal antibodies in cancer patients, particularly with regard to age and gender as well as patient-specific factors. This study aims to assess adverse drug reactions and quality of life among cancer patients receiving platinum analogues and monoclonal antibodies in a tertiary care facility. A prospective study was conducted obtaining permission from the hospital administration at Apollo hospitals. A total of 120 cancer patients were enrolled in the study. Data was collected from all eligible participants using data collection forms including demographic details such as age, gender and comorbid conditions. FACT-G questionnaire was used to assess the quality of life and adverse drug reactions were recorded using an adverse drug reaction reporting form. Our study identified that platinum-based treatments were more frequently utilized but were associated with lower quality of life and more severe adverse drug reactions compared to monoclonal antibodies, which showed better quality of life.

KEYWORDS : Adverse Drug Reactions, Monoclonal Antibodies, Platinum Analogues, Quality of Life

INTRODUCTION

Cancer stands as one of the pre-eminent reasons for illness and death across the globe while continuously improving treatment approaches to provide better patient outcomes. In India, one out of every nine people will have cancer at some point in their lives [1]. By 2025, India's cancer burden is predicted to increase from 26.7 million DALYs (Disability adjusted mortality to incidence) in 2021 to 29.8 million [2] .There are various types of treatments include chemotherapy, targeted therapy, immunotherapy. Among various treatment approaches, monoclonal antibodies and platinum based chemotherapeutic agents play a crucial role in cancer treatment[3]. Monoclonal antibodies are able to act on cells to aid the immune system's fight against cancer cells by targeting specific antigen. Trastuzumab, rituximab are widely used.[4] Platinum analogues bind DNA to form interstrand and intra-strand cross-links, which lead to the inhibition of DNA synthesis and transcription.[5] Despite of their therapeutic effects, these agents are associated with adverse drug reactions (ADRs) including nephrotoxicity, infusion related reactions, gastrointestinal disturbances which can seriously impact patient safety and medication adherence.[6,7] Quality of Life consists of a person's elements of life such as emotional, social, physical and functions of their life. Cancer treatment might lead to adverse drug reactions (ADRs), which can negatively affect the patient's mental and physical health. This situation might cause QOL to decline, which makes it essential to recognize these effects and support patients [8] .This study aims to assess the impact of adverse drug reactions on the quality of life in patients receiving platinum analogues and monoclonal antibodies.

MATERIALS AND METHODS

The inclusion criteria of the study were patients of all ages and both genders with reported ADRs, including newly diagnosed patients and those in subsequent chemotherapy were included to provide comprehensive view of ADR. Patients who did not provide consent, those receiving only surgical, radiation without chemotherapy, clinically unstable patients, Pregnant or breastfeeding women were excluded.

Patients receiving platinum analogues and monoclonal antibodies, as monotherapy or in combination therapy were included. A separate data entry form was prepared to record patient demographic details, type of cancer, comorbid conditions, laboratory investigations are taken to assess ADRs. Chemotherapy-induced ADRs were evaluated using the Naranjo probability scale. There are four levels on the severity scale: 0 to 4.

The QOL of cancer patients were evaluated using the functional Assessment of Cancer Therapy (FACT-G Scale) [version 4.0]. It consists of four subscales being (e.g ability to perform daily activities) FWB; 7 items, score range 0-28 Physical well-being (e.g., fatigue, pain) PWB; 7 items, score range 0-28, Social/family well-being (e.g., relationships, support) SWB ; 7items, score range 0-28,Emotional wellbeing (e.g. Stress, anxiety) EWB ; 6 items , score range 0-28),Functional well-being Functional well-being (e.g., ability to perform daily activities) FWB; 7 items, score range 0-28. Each item is scored based on the patient response. All questions in the FACT-G use a 5- likert scale. Zero means nothing at all, while one means, A little while; 2 denotes somewhat; 3 denotes Significantly; 4 denotes A lot Higher scores correspond to a higher standard of living. Circle or place an X next to the number that describes the patient experience for the past 7 days. Higher scores indicate better quality of life.

Ethics Statement and Informed Consent Statement:

Ethical approval was obtained, and informed consent was taken from all the participants.

Study Design

A six months, prospective, observational study was carried out at the cancer department of a tertiary care hospital in Hyderabad, Telangana.

After obtaining approval from the institutional ethics committee, the study was started in the hospital, Hyderabad, Telangana

Statistics

Data were analyzed using Microsoft office Excel.

RESULTS AND DISCUSSION

120 patients met the inclusion and exclusion criteria for this prospective observational study. In this study, we looked at how adverse drug reactions (ADRs) affected the quality of life (QOL) of patients receiving platinum-based therapies and monoclonal antibodies.

This study suggests that ADRs from platinum-based therapies can potentially have a greater impact on the daily lives of patients than monoclonal antibodies. The monoclonal antibodies might have a more positive effect, while platinum-based treatments might be more difficult. Combination therapy seemed to strike a balance between treatment efficacy and side effects, resulting in a moderate effect on overall well-being.

In queue with Vinod Kumar et al. and other studies, this study shows that the prevalence of cancer is higher in women (56.66%) than in men (43.33%) [9] This suggests that, in comparison to men, women were disproportionately impacted by cancer.

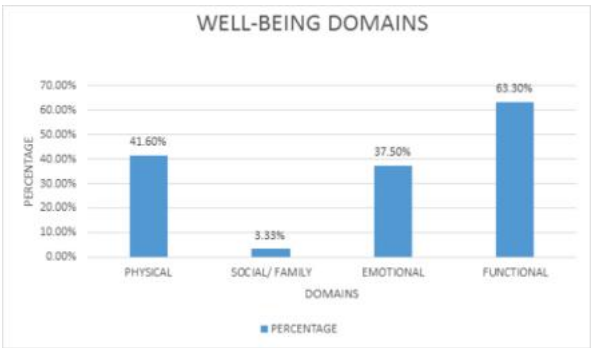

Figure 1:- Percentage of Patients Affected in Different Well-being Domains Due to Chemotherapy

Figure 1 illustrates the percentage of patients affected in different well-being domains due to chemotherapy. In the present study, the most affected well-being domains were functional well-being (FWB), followed by physical well-being (PWB), emotional well-being (EWB), and social well-being (SWB). This contrasts with the study by Anna Lewandowska et al, [10] which found that physical activity showed the greatest decline.

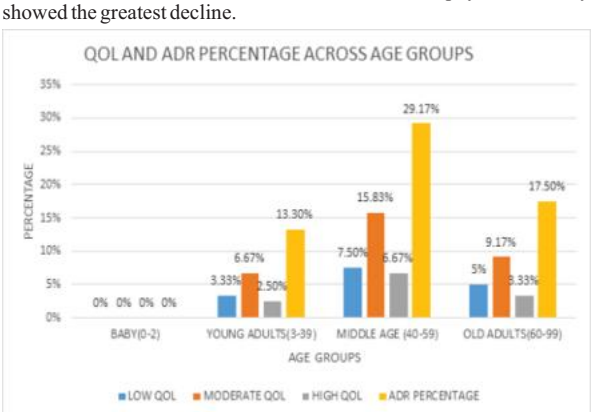

Figure 2:- Quality of Life and Adverse Drug Reaction S in Different Patients Across Different Age Groups

Figure 2 shows the quality of life and adverse drug reactions among patients across different age groups.Our findings align with the study by Sapan Kumar Behar et al., which showed that ADRs were most common in the 41–60 age group and lowest in the 0–2 age group[11] . The high incidence in middle-aged individuals may be due to cancer diagnosis patterns and potential underreporting in pediatric populations. In our study, middle-aged adults had the highest percentage of QOL levels, followed by older adults and young adults, which contrasts with the study of Gopala Kirshan et al. [12]

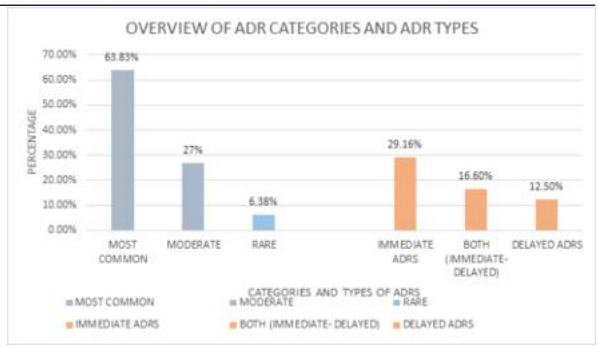

Figure 3:- Overview of ADRs Categories and ADRs Types in Different Patients

Figure 3 presents the distribution of adverse drug reaction categories and types among the study population.Our findings are almost in agreement with the data reported by Chopra et al confirming that the majority of reactions fall into Most Common (63.83%) then Moderate (27%) and Rare (6.38%). Both studies showed a similar pattern with common, manageable reactions dominating the clinical picture. [13] In addition, Immediate ADRs were more common than delayed ADRs in our study (29 cases, 16.6%), which is similar to studies conducted by Rosa M. Moreno Rodríguez et al. [14]

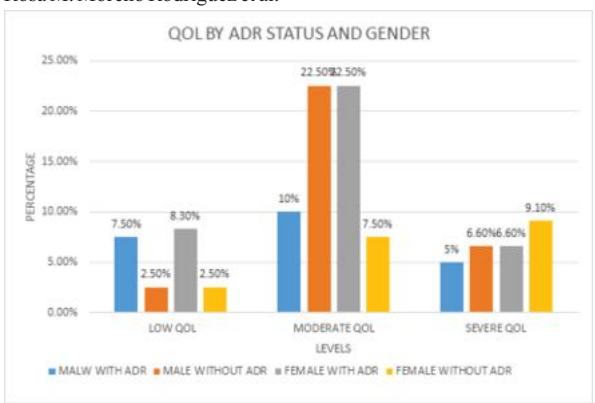

Figure 4:- Quality of Life by Adverse Drug Reaction's Status and Gender of Different Patients

Figure 4 demonstrates the quality of life based on adverse drug reaction status and gender among patients**.** 10% of the majority of male patients who experience (ADRs) have a moderate quality of life (QOL). At 22.5%, the majority of people without ADRs also enjoy a moderate quality of life. The QOL is low in 7.5% of male patients with ADRs and high in 5%. Just 2.5% of male patients without ADRs have a low QOL, whereas 6.6% have a good QOL. This indicates that both groups have a decent quality of life (QOL), with male patients who do not have ADRs often having a greater QOL than those who do. Notably, Quality of Life (QOL) is good for the majority of female patients who do not experience ADRs (9.1%), whereas it is moderate for the majority of female patients who do experience ADRs (22.5%). This indicates that individuals without ADRs typically have a high quality of life (QOL), while those with ADRs typically have a moderate QOL. These findings are in agreement with the study conducted by Deepthi chopra et al, which supports the observed impact of adverse drug reactions on the quality of life in patients.[13]

Gastrointestinal tract system up is most affected followed by skin, CNS, others. This is similar to the findings of Keshri et al., (16)which reveals the gastrointestinal tract is most commonly affected. Another study by Shrestha et al, found that hematological ADRs are common. [15]

In our study, severity levels 2 and 3 were the most common on the severity scale, which is similar to findings in chopra et al.[13]

Francisco et al. found that patients receiving monoclonal antibodies had better QOL outcomes in various subscales compared to those on chemotherapy alone[16], which is similar to our study.

Limitations

* The fact that the study was single-centered and only lasted six months is one of its major shortcomings.

* Better results may be obtained by patients who monitor their quality of life over time.
* Financial circumstances were not taken into consideration when evaluating the quality of life of cancer patients. Patients with higher incomes may be less affected emotionally and socially. This could therefore suggest changes in QOL.

Future Research

Pediatric patients were not included in our study due to the relatively short study period. A more nuanced understanding should be developed through future research to include children. A larger sample size and longer duration of the study would also provide more accurate data. Long-term follow-up with patients would be useful in evaluating the sustainability and durability of such treatment outcomes. Patient counselling in future studies may enhance treatment compliance better.

CONCLUSION

In our study females are prone to cancer. ADRs are commonly occurred in 40-59 years. Therapy groups were analysed in our study 49.2% patients who received platinum based therapies. Patients who experienced adverse drug reactions (ADRs) from platinum-based therapies were reported a poorer quality of life (QOL) than those who experienced ADRs from monoclonal antibody treatments. This study revealed that cancer patients experience many symptoms which affect their QOL. Nausea, vomiting, chills, fever, shivering are common and immediate ADRs. Our research showed that both platinum-based medicines and monoclonal antibody treatments significantly reduced the functional well-being of a major portion of patients. Based on our sample size, Monoclonal antibodies showed a comparatively better safety profile.

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