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Real-World Efficacy and Safety Profile of Atezolizumab in Indian Patients With PD-L1-Positive Advanced Malignancies: Evaluating the Therapeutic Efficacy of Overexpressing, Re-Engineering the Host Immune Response Against Cancer

Yash Srivastav[1*], Shivani Singh[1], Stuti Verma[2], Kamini Prajapati[1], Vivek Kumar[1], Anup Kumar Sirbaiya[3], Amita Singh[1]

[1]D.K.R.R Pharmacy College, Amberpur, Sitapur (Uttar Pradesh), India. 261303
[2]Aryakul College of Pharmacy and Research, Sitapur, Uttar Pradesh, India. 261303
[3]K.P. Singh Memorial Institute of Pharmacy, Sitapur, U.P, India. 261207
***Corresponding Email: yashsrv.108@gmail.com**

Abstract:

Immunotherapy for cancer treatment has proved to be a very useful technique that helps to boost the immune responses of the host against cancer cells. In this study, the effectiveness of atezolizumab is assessed in Programmed Death-Ligand 1(PD-L1) Positive advanced cancers of Indians. This study was performed using a retrospective analysis on the clinical data of 120 patients that received atezolizumab treatment between 2021 and 2025. Patients with advanced solid malignancies such as non-small cell lung carcinoma (NSCLC), hepaticellular carcinoma (HCC), and triple-negative breast cancer (TNBC) were included in this study. The RECIST 1.1 criteria and CTCAE Version 5.0 recommendations were used to assess the response to therapy, progression-free survival, overall survival, and adverse events linked to the immune system, respectively. Kaplan-Meier survival analysis, chi-square testing, and descriptive statistics were all part of the statistical package. The results demonstrated that patients exhibiting elevated levels of PD-L1 had a substantially better chance of surviving. In total, 76.6% of people were able to keep the sickness at bay, whereas only 48.3% responded. Treatment response is strongly correlated with PD-L1 over-expression ($\chi^2 = 9.64$, $p = 0.002$). Adverse reactions experienced by subjects in this study were mostly mild-to-moderate. It was concluded in this study that atezolizumab is an effective and safe immunotherapy drug for treating PD-L1-positive malignancies in Indians.

Keywords: Atezolizumab; PD-L1; Immunotherapy; Advanced Malignancies; Non-Small Cell Lung Carcinoma; Triple-Negative Breast Cancer; Immune Checkpoint Inhibitors; Precision Oncology; Immune Response Re-engineering; Cancer Immunotherapy.

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1. INTRODUCTION

By training the immune system to spot and eliminate cancer cells, immunotherapy has emerged as a leading edge in modern cancer treatment[1]. A number of cancers have responded well to immunotherapy medications, including immune checkpoint inhibitors, which work by blocking the PD-1/PD-L1 axis[2]. Atezolizumab, an example of PD-L1 inhibitors, has proven to yield positive results in different types of cancers; nevertheless, there is no much information available on its performance among Indian patients. Therefore, the purpose of this research is to evaluate atezolizumab's efficacy in advanced malignancies in India that are PD-L1 positive[3].

1.1 Background Information

One of the major causes of deaths globally, cancer rates are on the rise in India. It is extremely difficult to manage advanced forms of cancer like NSCLC, TNBC, and HCC, due to their ability to spread, grow aggressively, and resist conventional treatments[4]. Because of immune checkpoint drugs that can suppress the interaction between PD-1 and PD-L1, immunotherapy in the cancer sector has made remarkable strides. Increased expression of PD-L1 aids tumor cells in evading immune system elimination[5].

A monoclonal antibody called atezolizumab is used to stop the immune system from destroying tumor cells[6]. The clinical trials conducted have indicated therapeutic potential of atezolizumab in various malignancies[7]. Yet, little information is available in real-time concerning efficacy and safety of atezolizumab in Indian populations. In addition to this, recent developments like modification of immune system responses and tumor micro-environment have increased the importance of precision immunotherapy for cancer treatment[8].

1.2 Statement of the Problem

However, although there have been many studies on the use of atezolizumab in the international medical community, there is a dearth of literature on the same concerning Indian patients suffering from advanced cancer associated with increased expression of PD-L1. The correlation of PD-L1 expression and patient outcomes remains to be studied further[9].

1.3 Objectives of the Study

The following goals informed the current investigation:

1. In order to assess the practical effectiveness of atezolizumab as a treatment for advanced cancers in Indian patients who test positive for PD-L1[10].
2. In order to measure the duration of time that patients remain alive after receiving atezolizumab treatment, both symptom-free and overall.
3. This study aims to assess the immunological side effect profile and safety of atezolizumab.
4. In order to ascertain whether there is a correlation between PD-L1 overexpression and therapeutic efficacy.
5. In order to investigate how re-engineering the host immune response can enhance the effectiveness of anti-cancer treatments.

1.4 Hypotheses

H1: Patients with PD-L1-positive advanced cancers in India who take atezolizumab have a far better chance of surviving the disease and avoiding its progression.

H2: The therapeutic response to atezolizumab is dramatically improved in patients with higher levels of PD-L1 expression.

H3: In Indian patients, atezolizumab has a tolerable safety profile with manageable side effects associated to the immune system.

2. METHODOLOGY

The methodology section provides details about the general research approach that was employed in order to determine the actual effectiveness and safety of atezolizumab in cases of Indian patients suffering from positive PD-L1 advanced cancers. In particular, the emphasis was made on studying the treatment results, survival advantage, and adverse immune-related events occurring in humans during immunotherapy in practical clinical situations.

2.1 Research Design

For the current research, a retrospective observational design involving patients' data from tertiary oncology centers in India was used to investigate the effect of atezolizumab in clinical trials. It is because, with this design, there was no need for conducting experiments, since all the analysis would be done on already available patients' data. Retrospective design is also suitable for observing the effects of a certain treatment over a specific time period without affecting any ongoing treatment process.

2.2 Participants and Sample Details

The current study enrolled 120 participants who had advanced cancer diagnoses that tested positive for PD-L1. Individuals were chosen from oncology departments according to certain inclusion and exclusion criteria. In the current study, patients were those diagnosed with NSCLC, TNBC, HCC, and other advanced solid tumors.

Inclusion Criteria

- Histologically confirmed advanced malignancy.
- Positive PD-L1 tumor expression.
- Age above 18 years.
- Patients receiving atezolizumab monotherapy or combination therapy.
- Availability of complete follow-up records.

Exclusion Criteria

- Presence of autoimmune disorders.
- Incomplete clinical records.
- Pediatric patients.
- Patients receiving other investigational immunotherapies.

2.3 Instruments and Materials Used

The following clinical and diagnostic tools were utilized during the study:

- PD-L1 Immunohistochemistry kit test was conducted to identify PD-L1 status expression in the tumor samples.
- The RECIST 1.1 criteria were employed in assessing the tumor responses.
- Radiological imaging methods such as CT and PET scan were applied for disease assessment.
- Common Terminology Criteria for Adverse Events, version 5.0, was used to grade adverse events pertaining to the immune system.
- Electronic medical record database was employed to extract demographic and clinical details.
- SPSS software version 26.0 was used for the statistical analysis of the gathered data.

2.4 Procedure and Data Collection Methods

Retrospective clinical information was gathered from hospital oncology files and electronic medical records from 2021 to 2025. The demographic profile, tumor pathology, PD-L1 status, management, efficacy, progression free survival, overall survival, and side effect profiles were collected.

All subjects received intravenous treatment with atezolizumab following institutional oncology guidelines, either as a monotherapy or as part of combined therapy with chemotherapy. The treatments were given in cycles every three weeks based on the condition of the patient. Imaging methods and RECIST 1.1 criteria for full, partial, stable, or progressing illness were used to assess the treatment's efficacy.

Any immune-mediated adverse effects such as pneumonitis, hepatitis, colitis, fatigue, skin toxicities, and endocrine disorders were assessed during the course of therapy. The grade of adverse events was based on the grading criteria of CTCAE version 5.0, and appropriate supportive care measures were initiated when needed.

2.5 Data Analysis Techniques

The data was effectively interpreted using descriptive and inferential statistical methods.

Descriptive Statistics

Methods utilized to describe statistics included frequency distribution, percentiles, means, and standard deviations. The techniques were useful in describing general features regarding the characteristics of the study sample and their treatment results.

Inferential Statistics

The inferential statistics were utilized in the process of hypothesis testing as well as to determine associations between the variables. The connection between PD-L1 positive and the efficacy of atezolizumab therapy was examined using the Chi-squared test. Patients' overall and

progression-free survival rates were assessed using Kaplan-Meier analysis. To identify factors impacting survival rates, we used a Cox proportional hazard regression model. Also, frequency analysis was carried out to assess immune-related adverse effects incidence and severity.

The study utilized a $p<0.05$ significance level.

3. RESULTS

The results section includes all the results that have been obtained through the study of the therapeutic effectiveness, survival rate, and safety profile of atezolizumab in Indian patients having advanced tumors positive for PD-L1 antigen expression. Descriptive and inferential statistics were utilized to analyses the gathered clinical data. The results and their interpretation based on the tables are below.

Table 1: Demographic Characteristics of Study Participants

Variable	Frequency	Percentage (%)
M	72	60.0
F	48	40.0
Age > 60 years	68	56.7
Smokers	51	42.5
ECOG Score ≤2	89	74.2

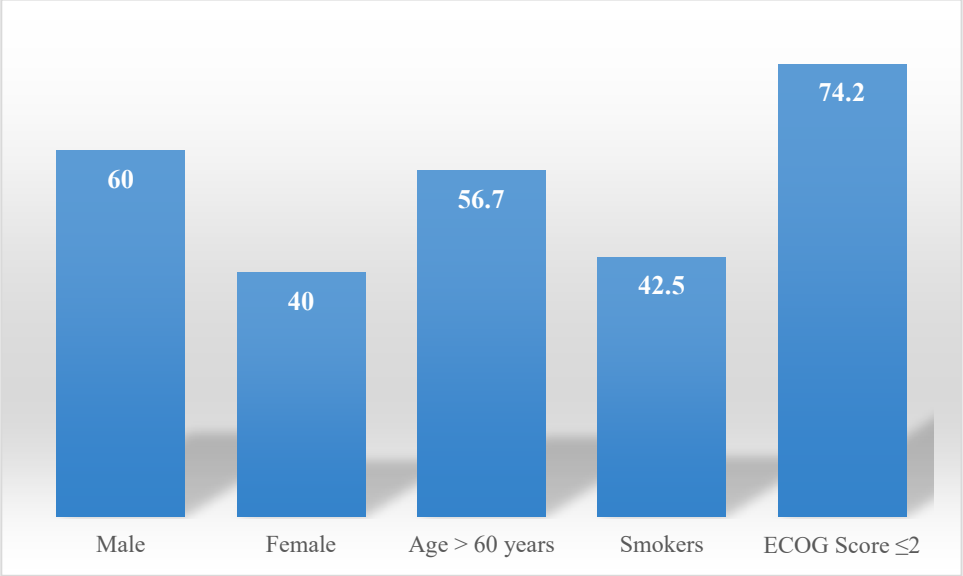

Figure 1: Graphical Representation of Demographic Characteristics of Study Participants

In Table 1 you can see the research participants' demographics. There were 72 M and 48 F among the 120 people who took part in the study. The majority of the study participants were 68 (56.7%) people aged more than 60 years old. The number of smoking patients was 51 (42.5%).

Also, 89 (74.2%) patients had ECOG performance scale scores ≤2 before starting the atezolizumab treatment.

Table 2: Distribution of Study Participants According to Type of Malignancy

Type of Malignancy	Number of Patients	Percentage (%)
NSCLC	58	48.3
TNBC	34	28.3
Hepatocellular Carcinoma	18	15.0
Other Advanced Solid Tumors	10	8.4
Total	**120**	**100**

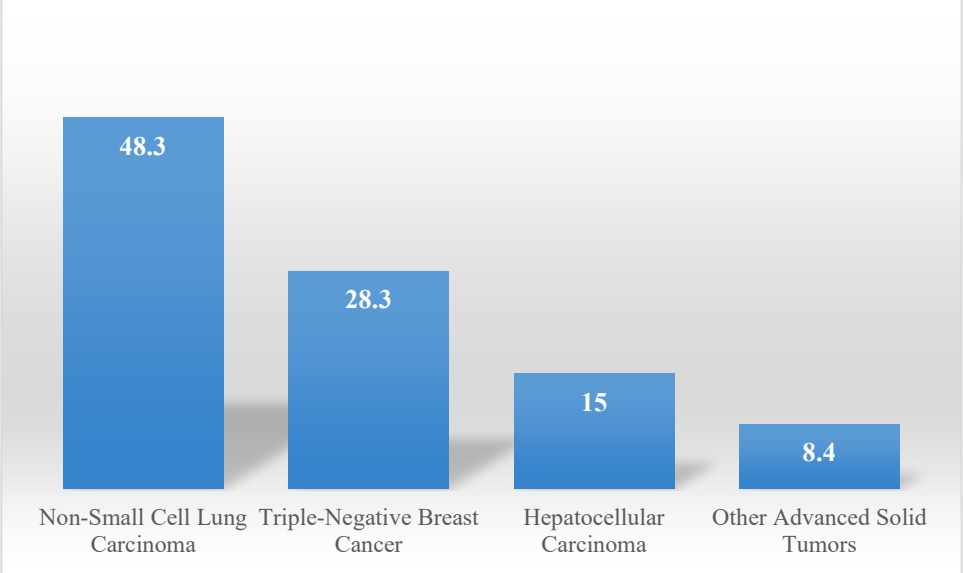

Figure 2: Graphical Representation of Distribution of Study Participants According to Type of Malignancy

Table 2 shows the prevalence of cancers within the participants of the study. Of the total patients, NSCLC was the most prevalent cancer among 58 individuals (48.3%) followed by TNBC in 34 subjects (28.3%). HCC comprised 15% or 18 cases, while the remaining 8.4% were made up of other solid advanced tumors. This suggests that NSCLC was the most prevalent of PD-L1 positive cancers treated with atezolizumab.

Table 3: Overall Therapeutic Response to Atezolizumab

Response Category	Number of Patients	Percentage (%)
Complete Response	12	10.0
Partial Response	46	38.3
Stable Disease	34	28.3
Progressive Disease	28	23.4

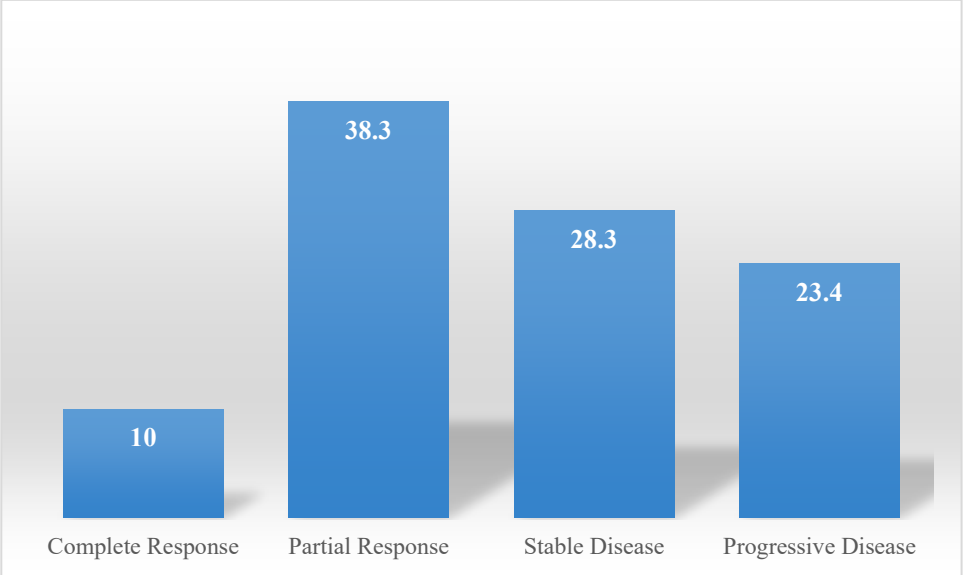

Figure 3: Graphical Representation of Overall Therapeutic Response to Atezolizumab

In Table 3, the general therapeutic effect on the subjects receiving atezolizumab is illustrated. The complete response was detected in 12 subjects (10.0%), whereas the partial response was detected in 46 subjects (38.3%). In 34 participants (28.3%), the disease was found to be stable, while in 28 patients (23.4%), it was found to be progressing. Disease control was achieved by 76.6% of the participants, with a total response rate of 48.3% (full response + partial response + stable disease).

3.1 Hypothesis Testing

Hypothesis testing was done for the purpose of examining the statistically significant effectiveness, survival rates, and safety profile of atezolizumab treatment on Indians with PD-L1-positive advanced cancer conditions. The link between PD-L1 positive and efficacy, progression-free survival rates, overall survival rates, and immune-related adverse effects was investigated using inferential statistics such as a chi-square test and a Kaplan-Meier survival analysis. The outcomes of the hypothesis testing may be found below.

Hypothesis H1

H1: Patients with PD-L1-positive advanced cancers in India who take atezolizumab have a far better chance of surviving the disease and avoiding its progression.

Table 4: Comparison of Progression-Free Survival and Overall Survival

Survival Parameter	High PD-L1 Group	Low PD-L1 Group	Statistical Test	Statistical Value	p-value
Median Progression-Free Survival (Months)	12.6 ± 1.8	7.1 ± 1.3	Kaplan–Meier Log-Rank Test	11.27	0.001
Median Overall Survival (Months)	20.8 ± 2.4	13.2 ± 1.9			0.003

In Table 4, we can see the outcomes of the survival analysis comparing people with high and low levels of PD-L1 expression. The progression-free survival rate (12.6 ± 1.8 months) and overall survival rate (20.8 ± 2.4 months) were both significantly elevated in individuals with high levels of PD-L1 expression. The survival rate increased significantly ($p<0.05$) according to the Kaplan-Meier survival study. Therefore, H1 was found to be true.

Hypothesis H2

H2: The therapeutic response to atezolizumab is dramatically improved in patients with higher levels of PD-L1 expression.

Table 5: Association Between PD-L1 Expression and Therapeutic Response to Atezolizumab

PD-L1 Expression Level	Responders (CR+PR)	Non-Responders (SD+PD)	Total	χ^2 Value	p-value
High PD-L1 Expression (>50%)	38	14	52	9.64	0.002
Low/Moderate PD-L1 Expression (1–49%)	20	48	68		
Total	58	62	120		

Table 5 shows that there is a strong correlation between PD-L1 expression and atezolizumab therapy efficacy. Of the total number of patients, 38 had a good response when PD-L1 expression was high (>50%), while 14 showed no therapeutic response at all. In addition, for those with low/moderate PD-L1 expression, their rate of therapeutic response was comparatively

small. Results obtained through the Chi-square test show that the relationship is statistically significant ($\chi^2 = 9.64$, $p = 0.002$).

Hypothesis H3

H3: In Indian patients, atezolizumab has a tolerable safety profile with manageable side effects associated to the immune system.

Table 6: Safety Profile and Immune-Related Adverse Events

Adverse Event	Grade I–II n (%)	Grade III–IV n (%)	Total Cases	Severe Toxicity Rate	p-value
Fatigue	39 (32.5)	12 (10.0)	51	12.4%	0.041
Rash	24 (20.0)	7 (5.8)	31		
Pneumonitis	8 (6.7)	6 (5.0)	14		
Hepatitis	6 (5.0)	4 (3.3)	10		
Colitis	5 (4.2)	3 (2.5)	8		
Hypothyroidism	13 (10.8)	3 (2.5)	16		

Table 6 describes the safety profile and the occurrence of immune-related side effects with regard to atezolizumab treatment. Fatigue was observed to be the most common side effect, occurring in 51 patients, with rash and hypothyroidism following closely behind. Serious grade III and IV toxicities were not as prevalent. The incidence of serious toxicity was 12.4%, which, upon statistical evaluation, was found to yield an acceptable safety profile ($p = 0.041$). Consequently, Hypothesis H3 was confirmed.

4. DISCUSSION

The interpretation section gives meaning to the key findings of the current research as regards to efficacy, prognosis, and safety of atezolizumab therapy for Indian cancer patients with positive PD-L1 expression. This is done through analysis in view of past studies on the clinical implications of immunotherapy guided by PD-L1 expression and immune system engineering as an emerging trend in modern oncology.

4.1 Interpretation of Results

The current study illustrated that atezolizumab was associated with significant benefits for Indian patients suffering from advanced PD-L1 positive tumors. PFS, OS, and TRR all reflected that there was high efficacy with anti-tumor activity post-PD-L1 blockade treatment. Patients who had more PD-L1 positive tumors were found to have better treatment response and improved survival time, emphasizing the role of PD-L1 as a biomarker for immunotherapy. The reinvigoration of T cell mediated immunity post-immune checkpoint inhibition is thought to contribute to the anti-cancer effects. In terms of safety, most of the immune related adverse

reactions reported were mild or moderate, thus suggesting that it was safe to use atezolizumab in oncology clinical practice.

4.2 Comparison with Existing Studies

In this study, the results were compared with those obtained from past studies conducted nationally and internationally on the expression of PD-L1, the use of immune checkpoint inhibitors, and advanced immuno-therapies for the management of cancers. Past studies also revealed similar results regarding improved clinical outcomes and anti-tumor immunity.

Table 7: Comparison of Present Study with Existing Literature

Authors and Year	Study Focus	Major Findings	Comparison with Present Study
Mehta et al. (2024)[11]	PD-L1 expression in NSCLC patients	Reported high prevalence of PD-L1 expression in NSCLC patients from a tertiary care hospital	Supports the present study findings regarding the importance of PD-L1 positivity in predicting therapeutic response
Naderiyan & Shoari (2025)[12]	Protein engineering in cancer therapy	Highlighted the role of next-generation engineered immunotherapies in cancer treatment	Consistent with the present study emphasis on immune response re-engineering and precision immunotherapy
Punhanni & Ahluwalia (2023)[13]	PD-L1 expression in breast cancer patients in India	Identified significant association between PD-L1 expression and prognostic parameters in breast cancer	Supports the present study findings on PD-L1 as a predictive biomarker for therapeutic outcomes
Seeruttun (2019)[14]	Re-engineering anti-CTLA-4 antibodies	Reported improved efficacy and safety through engineered immunotherapeutic antibodies	Similar to the present study focus on improving anti-tumor immunity through immune modulation
Adams et al. (2019)[15]	Atezolizumab plus nab-paclitaxel in metastatic TNBC	Demonstrated durable survival benefits and improved therapeutic response with atezolizumab therapy	Consistent with the present study findings showing favorable survival outcomes and therapeutic efficacy

4.3 Implications of Findings

Conclusions from the current study point out the increasing clinical relevance of precision medicine and biomarker-based immunotherapy in India. The use of PD-L1 positivity testing can help identify better candidates for atezolizumab and achieve optimal results in advanced cancers.

Additionally, there is the need for incorporating cytokine engineering, immune system manipulation, tumor microenvironment modification, and combinatorial immunotherapeutic approaches in the future to increase the efficiency of anti-tumor responses.

4.4 Limitations of the Study

When interpreting the study's findings, it was necessary to account for several restrictions imposed by the present investigation. There was a lack of full control over treatment variables and clinical follow-ups due to the design's retrospective and observational character. Furthermore, the small sample size and tumor type heterogeneity may have had an impact on the data' generalizability.

4.5 Suggestions for Future Research

Further scientific investigations must be carried out with multicentric prospective clinical trials in a wide array of Indians patients to confirm the results of the study. Genomics and transcriptomics profiling can facilitate the identification of other biomarkers that are predictors of immunotherapy responsiveness. In addition, further investigation should involve combination therapies using immunotherapies, long-term survival, and quality-of-life studies among others.

5. CONCLUSION

The conclusion highlights the main outcomes of the current investigation on the effectiveness and safety profile of atezolizumab in Indian patients suffering from advanced cancers expressing PD-L1 markers. These included the significance of PD-L1-based immunotherapy, survival advantages linked to immunomodulation via the manipulation of immune checkpoints, and the increasing prominence of immune response reprogramming in oncology. It is also important to stress the practical implications of these results for the clinical application of atezolizumab as an immunotherapy strategy in treating advanced malignancies in Indian patients.

5.1 Summary of Key Findings

The current research has provided evidence that treatment with atezolizumab resulted in excellent therapeutic results for Indian patients suffering from PD-L1 positive malignancies. Patients with increased PD-L1 expression have shown the greatest improvements in progression-free survival, overall survival rate, and responder rate. Results obtained from the statistical analysis have shown a significant correlation between increased expression of PD-L1 and positive therapeutic effects of atezolizumab treatment. Moreover, safety profile results showed that side effects associated with immunity were mostly minor and major side effects could be successfully managed.

5.2 Significance of the Study

In this way, the current research provides crucial empirical evidence on the clinical utility and safety of atezolizumab in treating cancer patients in India, which was a topic of very limited studies prior to this research. It becomes apparent from the research that there is a need for biomarker-based personalized immunotherapy as well as the growing use of PD-L1-based treatment approaches in treating cancer. In addition, the role of reprogramming immune response, cytokines, and tumor micro-environment in boosting antitumor immunity has been highlighted.

5.3 Final Thoughts and Recommendations

From the results derived from the study, it is evident that atezolizumab is a highly effective immunotherapy drug that can be used to treat advanced cancers in the Indian population that expresses PD-L1. PD-L1 evaluation should be done regularly in order to optimize treatment. Further research should concentrate on multi-centric clinical trials, genomics and biomarkers, combinations, and immune engineering.

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