E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.01.597

Research Article

Prospective Observational Study On Neurotoxicity Induced By Paclitaxel-Based Chemotherapy Regimens And Its Impact On Quality Of Life In Patients With Solid Tumors

Dr. M. Ramya[1], Chowdavaram Varshi[2], K. Naresh[3], B. Sowmya[4], K. swathi[5]
[1]Assistant Professor, Pharmacy Practice, Seven Hills College of Pharmacy, Tirupati, AP, India.
[2]Pharm D Intern, Seven hills college of Pharmacy, Tirupati, AP, India.
[3]Pharm D Intern, Seven hills college of Pharmacy, Tirupati, AP, India.
[4]Pharm D Intern, Seven hills college of Pharmacy, Tirupati, AP, India.
[5]Pharm D Intern, Seven hills college of Pharmacy, Tirupati, AP, India.
Email: [2]chowdavaramvarshireddy@gmail.com, [3]nareshnaresh77984@gmail.com, [4]sowmyachoti1218@gmail.com, [5]kswathi7870@gmail.com
Received: 11.04.26, Revised: 13.05.26, Accepted: 19.06.26

ABSTRACT
Context: Paclitaxel is a widely used chemotherapeutic agent for treating various solid tumors. However, its use is limited by Paclitaxel-induced neurotoxicity (PIN), which adversely affects patients' quality of life (QoL).
Aims: To evaluate incidence, severity, and impact of Neurotoxicity induced by Paclitaxel based chemotherapy regimens and its effect on the quality of life in patients with solid tumor [Head& Neck, Ovarian, Stomach, Endometrial, Pelvic, Breast cancers etc.]
Settings and Design: SVIMS –SPMC (W) TIRUPATI Hospital setting Prospective Observational study design.
Methods and Material:
✓ Patient documentation form
✓ EORTC Grading Scale (Quality of life tool)
✓ CTCAE Grading Scale (Neurotoxicity grading tool)
✓ Informed consent form
Statistical Analysis Used: Statistical analysis was done by performing the Chi-square test using SPSS software.
Results: Among 60 participants, females comprised 73.3%. Breast and ovarian cancers were the most prevalent diagnoses. Sensory neurotoxicity occurred in 44.5% of patients, with 6.6% experiencing severe symptoms. Higher grades of neurotoxicity significantly correlated with lower physical functioning scores ($p = 0.0232$). However, cognitive and social domains of QoL were not significantly affected.
Conclusions: Our study shows neurotoxicity severity varies with paclitaxel mono- and combination therapy. Sensory symptoms more significantly reduce quality of life. Patients with pronounced sensory toxicity may require alternative regimens, warranting further investigation. Regular monitoring and early intervention can reduce severity and improve treatment outcomes in patients receiving Paclitaxel-based regimens.

Keywords: Paclitaxel, Chemotherapy, Neurotoxicity, Peripheral Neuropathy, Quality Of Life, EORTC, CTCAE.

Key Messages: Paclitaxel-induced neurotoxicity is common and increases in severity with treatment, and as its severity rises, patients experience a significant decline in their quality of life.

INTRODUCTION

Cancer is a disease, characterized by the uncontrolled growth, ignoring the body's signal to stop, malignant cells multiply to form tumors in organs and tissues and leads to spread of abnormal cells, which can invade and damage surrounding tissues and organs[1]. It is a leading cause of death worldwide, accounting for nearly 9.7 million deaths in 2022[2].

Paclitaxel, a diterpenoid compound derived from Taxus brevifolia, is one of the most effective chemotherapeutic agents used in the management of solid tumors, including breast, ovarian, lung, and head and neck cancers. It

acts by stabilizing microtubules, thereby arresting cell division in the G2/M phase of the cell cycle, leading to apoptosis[3]. Despite its therapeutic efficacy, Paclitaxel-induced neurotoxicity (PIN) remains a major dose-limiting adverse effect[4]. Patients typically present with sensory, motor, and autonomic neuropathic symptoms that may persist long after therapy, reducing their quality of life (QoL)[5]. Given the clinical importance of Paclitaxel, this study aimed to evaluate the incidence and severity of neurotoxicity induced by Paclitaxel-based chemotherapy regimens and assess its correlation with QoL among patients with solid tumors[6].

SUBJECTS AND METHODS

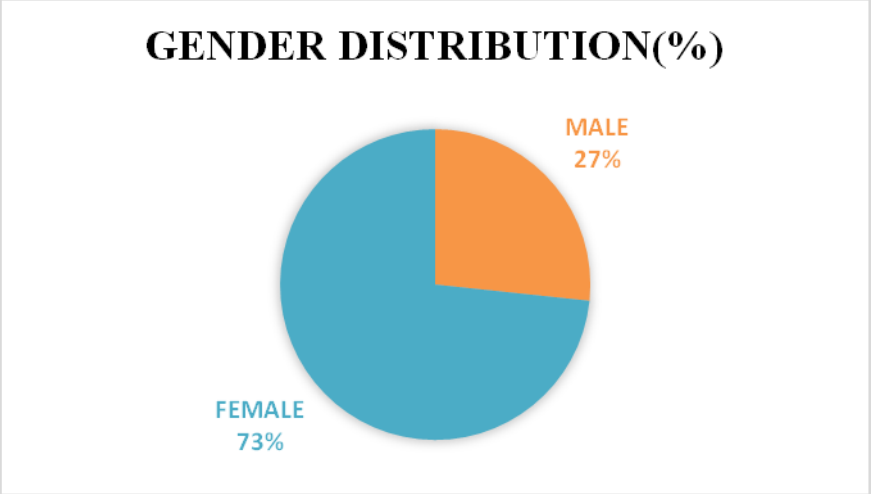
Study Design and Site: A hospital-based prospective observational study was conducted in the Department of Medical Oncology, SVIMS–Sri Padmavati Medical College for Women, Tirupati, Andhra Pradesh.
Study Duration: Six months (December 2024 – May 2025).
Sample Size: A total of 60 patients diagnosed with solid tumors and receiving Paclitaxel-based chemotherapy were enrolled.
Inclusion Criteria: Patients aged ≥18 years, diagnosed with solid tumors, receiving Paclitaxel-based chemotherapy, and provided written informed consent.
Exclusion Criteria: Patients with pre-existing peripheral neuropathy, those receiving non-Paclitaxel regimens, or pregnant/lactating women.
Data Collection Tools: CTCAE (v5.0) for grading neurotoxicity and EORTC QLQ-C30 for assessing quality of life.
Statistical Analysis: Data were analyzed using SPSS software. Descriptive statistics summarized demographics. Chi-square test evaluated relationships between neurotoxicity and QoL, with $p < 0.05$ considered significant.

RESULTS

Frequency of Gender Distribution

The present study includes a total of 60 participants who received Paclitaxel based chemotherapy regimens amongst these, 16 subjects were males with proportion of 26.7% and 44 subjects were females with a majority proportion of 73.3%.

Figure 1: Pie Diagram of Gender Distribution



Frequency of Age Distibution

The study includes a total of 60 participants who received Paclitaxel based chemotherapy regimens amongst these, 1 subject(1.66%) was under the age group of <29 years, 5 subjects(8.33%) were under the age group of 30-39 years , 10 subjects (16.66%) were under the age group of 40-49 years, 23 subjects(38.33%) were under the age group of 50-59 years, 14 subjects (23.33%) were under the age group of 60-69 years , 5 subjects (8.33%) were under the age group of 70-79 years, 2 subjects(3.33%) were under the age group of >80 years.

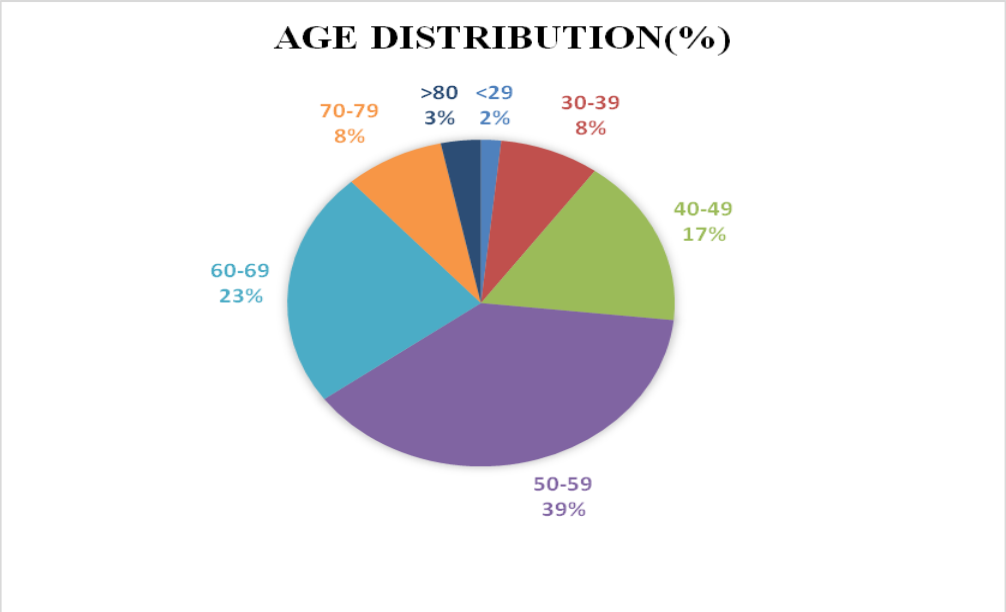


Figure 2: Frequency of Age Distribution of the Patients

Gender Distribution According to Diagnosis

In this study among the 60 participants, the number of male and female patients diagnosed with Buccal mucosal cancer was 2 and 2 respectively. Number of female patients diagnosed with Ovarian cancer was 18, Cervical cancer was 12, Breast cancer was 6, Hard palate cancer was 2, and Endometrial cancer, Vulva cancer, Metastatic adenoid cystic carcinoma, Unknown (SCLN) was 1 patient each. The number of male patients diagnosed with Stomach cancer was 2, Urinary bladder cancer, Lung cancer, Right foot melanoma, Sinonasal cancer, Laryngeal cancer, Pancreatic cancer, GE junction cancer, Penis cancer, Tongue cancer, Glottis cancer, Mouth cancer, Unknown (SCLN) cancer was 1 patient each.

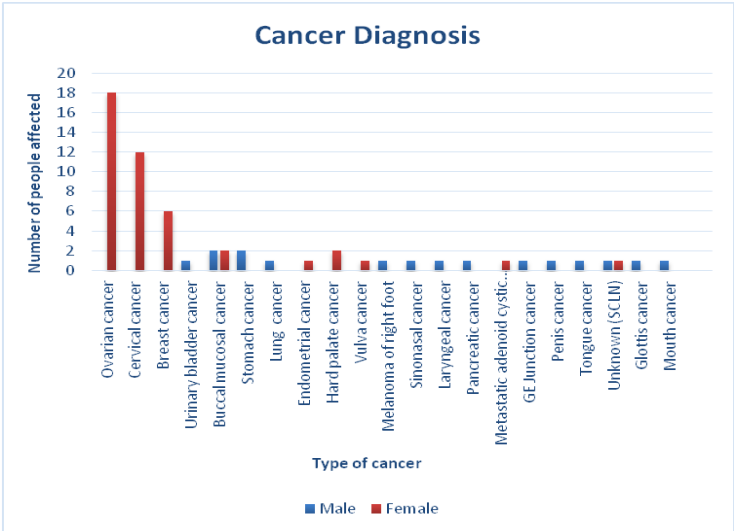


Figure 3: Frequency Distribution of Patients According to Diagnosis

Frequency Distribution According To Neurotoxicity Assessement

Sensory Symptoms

This study includes a total of 60 participants who received Paclitaxel based chemotherapy regimens amongst them a proportion of 55.41% of patients has experienced Grade 0 neurotoxicity (no sensory symptoms), 24.58% of the patients has experienced Grade 1 neurotoxicity (mild sensory symptoms), 13.33% of the patients has experienced Grade 2 neurotoxicity (moderate sensory symptoms), 6.66% of the patients has experienced Grade 3 neurotoxicity (severe sensory symptoms).

We have used Chi-square test for Independence to find the statistical significance and we understood that about half of those patients has Grade 0 sensory neurotoxicity. The obtained P-value 0.000019 is found to be less than the standard value of 0.05 therefore implying that this is statistically significant result.

Table 4.1: Frequency Distribution of Sensory Neurotoxicity

GRADE	Q1	Q2	Q3	Q4	Mean	%	Chi-square (χ^2)	Degree of Freedom	P-value
GRADE 0	21	23	44	45	33.25	55.41			
GRADE 1	23	17	9	10	14.75	24.58			
GRADE 2	10	13	6	3	8	13.33			
GRADE 3	6	7	1	2	4	6.66	37.78	9	0.000019
Total	60	60	60	60	60	100			

Motor Symptoms

Out of 60 participants who received Paclitaxel based chemotherapy regimens, a proportion of 50% of patients experienced Grade 0 neurotoxicity(no motor symptoms), 28.8% of the patients has experienced Grade 1 neurotoxicity(mild motor symptoms), 15.55% of the patients has experienced Grade2 neurotoxicity(moderate motor symptoms), 5.55% of the patients experienced Grade 3 neurotoxicity(severe motor symptoms)

We have used Chi-square test for Independence to find the statistical significance and we understood that about half of those patients has Grade 0 motor neurotoxicity. The obtained P-value 0.030 is found to be less than the standard value of 0.05 therefore implying that this is statistically significant result.

Table 4.2: Frequency Distribution of Motor Neurotoxicity

GRADE	Q1	Q2	Q3	AVG	%	Chi-square (χ^2)	Degree of freedom	P-value
GRADE 0	25	25	40	30	50			
GRADE 1	18	23	11	17.33	28.88			
GRADE 2	13	7	8	9.33	15.55			
GRADE 3	4	5	1	3.33	5.55	14.01	6	0.030
total	60	60	60	60	100			

Autonomic Symptoms

Out of 60 participants who received Paclitaxel based chemotherapy regimens, a proportion of 43.75% of patients experienced Grade 0 neurotoxicity(no autonomic symptoms), 34.58% of the patients has experienced Grade 1 neurotoxicity(mild autonomic symptoms), 16.66% of the patients has experienced Grade2 neurotoxicity(moderate autonomic symptoms), 5% of the patients experienced Grade 3 neurotoxicity(severe autonomic symptoms)

We have used Chi-square test for Independence to find the statistical significance and we understood that the obtained P-value 0.199 is found to be more than the standard value of 0.05 therefore implying that this is not statistically significant result.

Table 4.3: Frequency Distribution of Autonomic Neurotoxicity

GRADE	Q1	Q2	Q3	Q4	AVG	%	Chi-square (χ^2)	Degree of freedom	P-value
GRADE 0	29	23	28	25	26.25	43.75			
GRADE 1	23	20	15	25	20.75	34.58			
GRADE 2	8	14	12	6	10	16.66			
GRADE 3	0	3	5	4	3	5	12.27	9	0.199
Total	60	60	60	60	60	100			

Average of Neurotoxicty Assessment

Out of 60 participants who received Paclitaxel based chemotherapy regimens, major proportion of the patients did not experience any sort of Neurotoxic symptoms being it sensory (33.25), motor (30), or autonomic (26.25). As a result, they are categorized into Grade 0.

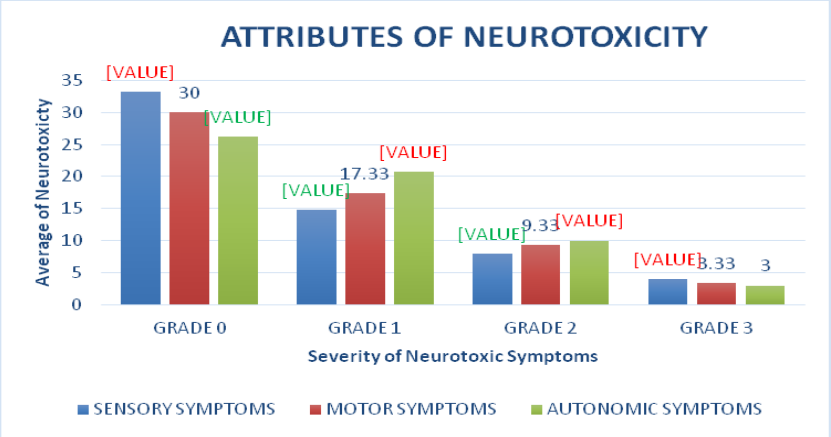


Figure 5.4.4: Bar Graph representation of Attributes of Neurotoxicity

Frequency Distribution According to Quality-of-Life Assessment

Physical Functioning

Out of 60 participants who received Paclitaxel based chemotherapy regimens, a proportion of 41.38% of patients has claimed that Paclitaxel based chemotherapy has 'not at all' affected their physical functioning, 27.21% of the patients claimed that 'a little' of their physical functioning has affected, 22.5% of the patients has claimed that 'quite of bit' of their physical functioning has affected, 8.88% of the patients claimed that their physical functioning has been affected 'very much'.

We have used Chi-square test for Independence to find the statistical significance and we understood that the obtained P-value 0.0232 is found to be less than the standard value of 0.05 therefore implying that this is statistically significant result.

Table 5.1: Frequency Distribution of Physical Functioning

GRADE	Q1	Q2	Q3	Q4	Q5	Q6	AVG	%	Chi-square (χ^2)	Degree of freedom	P-value
NOT AT ALL	35	25	15	21	26	27	24.83	41.38	27.75	15	0.0232
A LITTLE	10	19	23	18	13	15	16.33	27.21			
QUITE A BIT	12	6	17	15	16	15	13.5	22.5			
VERY MUCH	3	10	5	6	5	3	5.33	8.88			
Total	60	60	60	60	60	60	60	100			

Social Functioning

Out of 60 participants who received Paclitaxel based chemotherapy regimens, a proportion of 67.5% of patients has claimed that Paclitaxel based chemotherapy has 'not at all' affected their social functioning, 20.83% of the patients claimed that 'a little' of their social functioning has affected, 6.66% of the patients has claimed that 'quite of bit' of their social functioning has affected, 5% of the patients claimed that their social functioning has been affected 'very much'.

We have used Chi-square test for Independence to find the statistical significance and we understood that the obtained P-value 0.925 is found to be more than the standard value of 0.05 therefore implying that this is not statistically significant result.

Table 5.2: Frequency Distribution of Social Functioning

GRADE	Q1	Q2	AVG	%	Chi-square (χ^2)	Degree of freedom	P-value
NOT AT ALL	41	40	40.5	67.5	0.471	3	0.925
A LITTLE	12	13	12.5	20.83			
QUITE A BIT	3	5	4	6.66			
VERY MUCH	4	2	3	5			
Total	60	60	60	100			

Cognitive Functioning

Out of 60 participants who received Paclitaxel based chemotherapy regimens, a proportion of 70.55% of patients has claimed that Paclitaxel based chemotherapy has 'not at all' affected their cognitive functioning, 21.1% of the patients claimed that 'a little' of their cognitive functioning has affected, 6.66% of the patients has claimed that 'quite of bit' of their cognitive functioning has affected , 1.66% of the patients claimed that their cognitive functioning has been affected 'very much'.

We have used Chi-square test for Independence to find the statistical significance and we understood that the obtained P-value 0.9981 is found to be more than the standard value of 0.05 therefore implying that this is not statistically significant result.

Table 5.3: Frequency Distribution of Cognitive Functioning

GRADE	Q1	Q2	Q3	AVG	%	Chi-square (χ^2)	Degree of freedom	P-value
NOT AT ALL	44	41	42	42.33	70.55	0.479	6	0.9981
A LITTLE	11	14	13	12.66	21.1			
QUITE A BIT	4	4	4	4	6.66			
VERY MUCH	1	1	1	1	1.66			
Total	60	60	60	60	100			

Average of Ouality of Life Assessment

Out of 60 participants, a major proportion of the patients has claimed that receiving Paclitaxel based chemotherapy has not at all affected their day-to-day Quality of life being it whether physical (24.83), social (40.5) or cognitive (42.33) functioning.

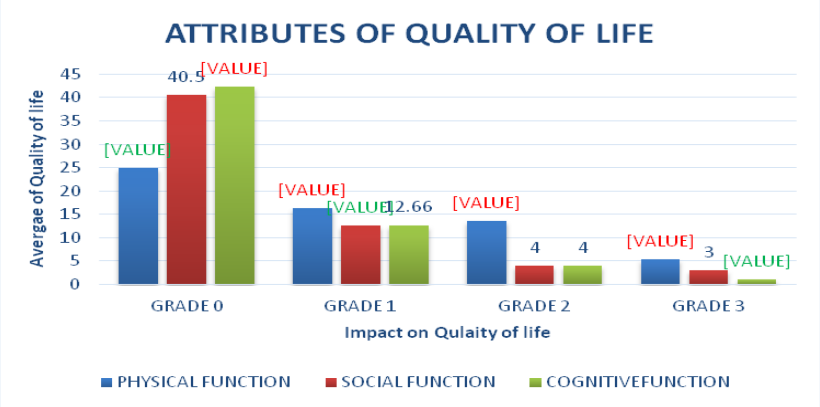


Figure 5.4: Bar Graph representation of Attributes of Quality of life

DISCUSSION

The study demonstrated that Paclitaxel-induced neurotoxicity has a measurable negative impact on patient quality of life. The majority of cases were mild to moderate, with sensory neuropathy being the most common presentation. These findings align with those reported by Cimbro et al. (2024) and Ahmed et al. (2021), who observed similar dose-dependent trends. Preventive measures, including dose modification and neuroprotective agents such as glutathione and

vitamin E, can mitigate toxicity and enhance patient comfort.

REFERENCES

1. World Health Organization. Health topics: cancer. Available from: https:// https://search.app/gJAUHaeYGVbsZTz5A
2. Siegel, et al. (2023). *Cancer statistics*, 2023. CA: A Cancer Journal for Clinicians, 73(1), 17–48. https://doi.org/10.3322/caac.21660
3. Horwitz SB,et al. *Taxol (paclitaxel): mechanisms of action*. Ann Oncol. 1994;5 Suppl 6:S3-6. PMID: 7865431https://pubmed.ncbi.nlm.nih.gov/7865431/
4. Scripture CD,et al. *Peripheral neuropathy induced by paclitaxel: recent insights and future perspectives*. Curr Neuropharmacol. 2006 Apr;*4*(2):165-72. doi: 10.2174/157015906776359568. PMID: 18615126
5. Nayak MG, et al. Quality of Life among Cancer Patients. Indian J Palliat Care. 2017 Oct-Dec;23(4):445-450. doi: 10.4103/IJPC.IJPC_82_17. PMID: 29123353;
6. Ahmed A, et al. *Evaluation of Paclitaxel Induced Neurotoxicity and its Impact on the Quality of Life in Breast Cancer Patients*. Esculapio - JSIMS. 2023 Jul. 12 [cited 2024 Dec. 19];*17*(4):362-6. Horwitz SB,et al. *Taxol (paclitaxel): mechanisms of action*. Ann Oncol. 1994;5 Suppl 6:S3-6. PMID: 7865431https://pubmed.ncbi.nlm.nih.gov/7865431/
7. Scripture CD,et al. *Peripheral neuropathy induced by paclitaxel: recent insights and future perspectives*. Curr Neuropharmacol. 2006 Apr;*4*(2):165-72. doi: 10.2174/157015906776359568. PMID: 18615126
8. Zhao YX, Yu XC, Gao JH, Yao M, Zhu B. Acupuncture for paclitaxel-induced peripheral neuropathy: a review of clinical and basic studies. J Pain Res. 2021 Apr 15;14:993-1005. doi:10.2147/JPR.S296150.
9. Gale, et al. (2022, October). *Overview of cancer*. *Merck Manual Consumer Version*. Merck Sharp & Dohme LLC. https://www.merckmanuals.com/home/cancer/overview-of-cancer/overview-of-cancer
10. DeCensi,et al. (2023*). Therapeutic cancer prevention: Achievements and ongoing challenges – A focus on breast and colorectal cancer*. British Journal of Cancer, *129*(10), 1459–1465. https://doi.org/10.1038/s41416-023-02466-3
11. Nayak MG, et al. Quality of Life among Cancer Patients. Indian J Palliat Care. 2017 Oct-Dec;23(4):445-450. doi: 10.4103/IJPC.IJPC_82_17. PMID: 29123353;
12. Timmins, et al. (2021d). *Weekly Paclitaxel-Induced Neurotoxicity in Breast Cancer: Outcomes and Dose response*. The Oncologist, *26*(5), 366–374.
13. Ahmed A, et al. *Evaluation of Paclitaxel Induced Neurotoxicity and its Impact on the Quality of Life in Breast Cancer Patients*. Esculapio - JSIMS. 2023 Jul. 12 [cited 2024 Dec. 19];*17*(4):362-6.
14. Pabst,et al. (2020d). *Persistent taxane-induced neuropathy in elderly patients treated for localized breast cancer*. The Breast Journal, *26*(12), 2376–2382.
15. Cimbro, et al. (2024). *Early taxane exposure and neurotoxicity in breast cancer patients*. Supportive Care in Cancer, *32*(10)
16. Wu S,et al. *An up-to-date view of paclitaxel-induced peripheral neuropathy*. J Cancer Res Ther. 2023 Dec 1;*19*(6):1501-1508. doi: 10.4103/jcrt.jcrt_1982_22. Epub 2023 Dec 28. PMID: 38156915.
17. Scripture, et al. (2006). *Peripheral neuropathy induced by paclitaxel*: *Recent insights and future perspectives*. Current Neuropharmacology, *4*(2), 165–172.
18. Horwitz, et al. (1994). *Taxol (paclitaxel): Mechanisms of action*. Annals of Oncology, *5*(Suppl 6), S3–S6
19. Abbas,et al. (2018*). An Overview of Cancer Treatment Modalities*. InTech. doi: 10.5772/intechopen.76558
20. Brown, et al. (2023). *Updating the definition of cancer*. Molecular Cancer Research, *21*(11), 1142–1147.
21. Nayak,et al. (2017). *Quality of Life among Cancer Patients*. *Indian Journal of Palliative Care*, *23*(4), 445-450.
22. Sharifi-Rad,et al. (2021). *Paclitaxel: Application in modern oncology and nanomedicine-based cancer therapy*. Oxidative Medicine and Cellular Longevity, 2021, 3687700
23. Afifi,et al. (2023). *Understanding breast cancer aggressiveness and its implications in diagnosis and treatment*. Journal of Clinical Medicine, *12*(4), 1375