

Original Research Article

Comparison of cisplatin doublet therapy in non-small cell lung cancer

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Abstract

Introduction: Patients with lung cancer may be eligible for a variety of therapies, including surgery, radiation, chemotherapy, and targeted therapy, depending on their stage. Specific mutations have been identified thanks to breakthroughs in genetics and biomarker testing, allowing for more personalised treatment for particular patients. Nearly 40% of lung cancer patients who are newly diagnosed are in stage IV. The first-line treatment for stage IV non-small cell lung cancer is cytotoxic combination chemotherapy, which is determined by histology, performance status, and age vs. comorbidities. The American Society of Clinical Oncology recommends a platinum (cisplatin or carboplatin) with paclitaxel, gemcitabine, vinorelbine, docetaxel, pemetrexed, or irinotecan regimen.

Material and Methods: this study was done on 40 patients of non-small cell cancer who were divided into two groups of 20 patients each. One group was given cisplatin and paclitaxel while other was given cisplatin and gemcitabine. 32 male and 8 female patients in the age group 47-83 years were included in the study to compare and see the difference in overall survival and toxicity in two groups.

Result: overall survival in gemcitabine group was found to be 8.75 months and in paclitaxel group was found to be 8.05 months. Toxicities were found to be higher in gemcitabine group.

Conclusion: average overall survival was higher in gemcitabine group however it was not statistically significant from the other group. Toxicities were also found to be higher in gemcitabine group. Further larger studies are required to find a statistical significant conclusion.

Keywords: Cisplatin, Gemcitabine, Paclitaxel, Non-small cell lung cancer, Overall survival, Toxicities.

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1. Introduction

Lung Cancer is the leading cause of cancer-related mortality according to the GLOBCAN 2020 report. In India, lung cancer accounts for 5.9% of all cancers and 8.1% of all cancer-related deaths.¹ Prevalence of lung cancer in India appears to be increasing as compared to the west.² Tobacco smoking is the most common risk factor for lung cancer in both genders. In India bidi smoking is more prevalent form of smoked tobacco than cigarette.³

Treatment plan for lung cancer is based on its histologic type, extent of spread and performance status of the patient. Treatment Options include surgery, chemotherapy, and radiation therapy.⁴

Patients with untreated metastatic non-small cell lung cancer have a median survival of four to five months, with a 1-year survival rate of about 10 percent.⁵

Randomised studies have been done in the past to compare efficacy of chemotherapy with “best supportive care” and have shown that chemotherapy reduces symptoms and improves the quality of life.⁶

For the treatment of advanced stage non-small cell lung cancer, many agents are available including the taxanes (paclitaxel and docetaxel), vinorelbine and gemcitabine. These agents, when combines with a platinum compound (cisplatin/carboplatin), have resulted in high response rates and prolonged survival at 1-year in several studies.⁷⁻¹¹

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This has been demonstrated by the Cancer and Leukemia Group B (CALGB) 9730 trial¹² and further confirmed in a meta-analysis.¹³ Combination doublet chemotherapy is now an accepted standard of care for stage IV disease. But still the search for optimal regimen for advanced NSCLC continues.

2. Objectives of the Study

1. To compare the overall survival in NSCLC patients between those given cisplatin-paclitaxel versus those given cisplatin-gemcitabine.
2. To compare toxicity between the two regimens.
3. To compare the progression free survival between the two regimens.

3. Materials and Methods

The study was conducted at J. N. Medical College and Hospital, AMU. The study is a prospective study involving 52 patients diagnosed with Non-Small Cell Lung Cancer over a period of two years from November 2019 to November 2021. Proper written informed consent was taken from the patients in their own language and ethical clearance was taken from the institutional ethical committee.

3.1. Patient inclusion criteria

1. Patients with Biopsy Proven Non-Small Cell Lung Carcinoma
2. Patient's with Performance Score less than or equal to 3
3. Chemo Naïve Patients

3.2. Patient exclusion criteria

1. Patients with multiple co-morbidity
2. Patients refusing for chemotherapy
3. Patients with Performance Score more than 3
4. Patients who had previously received a chemotherapy for Non-small cell lung Cancer

3.3. Statistical analysis

In the present study, all the qualitative variables were analysed using Pearson Chi-Square test and all the quantitative variables were analysed using unpaired t-test and paired sample t-test. Tests were performed using computer program IBM SPSS version 25.0. P values < 0.05 were considered significant.

3.4. Baseline investigations

The following investigations were performed:

3.4.1. Routine investigations

These were performed prior to giving each cycle of chemotherapy to the patient

1. Hemogram including HB%, Complete Blood Count, Differential Blood Count and Platelet Counts
2. Renal Function Test including Serum Creatinine and

Blood Urea.

3. Random Blood Sugar level
4. Liver Function Test- SGOT, SGPT, Alkaline Phosphatase and S. Bilirubin
5. Electrolyte comprising of Sodium, Potassium and Calcium
6. Weight and Height Measurement at the time of each cycle
7. Chest X-Ray
8. ECG if required
9. Vitals and General examination of the patient
10. Sputum for AFB analysis
11. Thoracocentesis
12. Bronchoscopy , FNAC and biopsy

3.5. Measurement of the performance score

Zubrod scale alternatively known as Eastern Cooperative Oncology Group (ECOG) score was used for scoring in which 0 represents no restriction of function and 5 represents death. Therefore higher the Zubrod score, the more restricted the patient with greater disability.

3.6. Outcome measurements

Patient outcome was measured at the time of 4th and 6th chemotherapy cycle and at one year on the basis of:

1. Overall Survival: It is defined as the time from subject randomisation to the time of death from any cause (Federal Drug Administration, US Dept. of Health and Human Services, 2007)¹⁴ and is the definitive end point where life expectancy and treatment options are limited. Provided that the quality of life is not compromised, OS represents the greatest clinical benefit for the patient.
2. Toxicity due to Chemotherapeutics measured according to the ECOG common toxicity criteria¹⁵
3. Progression Free Survival

Progression-free survival (PFS), the time from treatment initiation until disease progression or worsening, may be used as a direct or surrogate measure of clinical benefit for drug approvals, depending on the disease and response observed, while overall survival (OS), the duration of patient survival from the time of treatment initiation, is a universally-accepted direct measure of clinical benefit.

3.7. Plan of study

52 patients were taken up for study. 12 patients were withdrawn from the study due to death before starting treatment and loss to follow up. 20 patients (Group 1/PC) were given Cisplatin (75 mg/m²) & Paclitaxel (175 mg/m²) on day 1. 20 patients (Group 2/GC) were given Cisplatin (75mg/m²) on day 1 & Gemcitabine (1200 mg/m²) on day 1 and day 8 in our respiratory indoor ward. Simultaneously, proton pump inhibitors, antacids, analgesics, antipyretics, iron preparations and multivitamins along with protein supplements were given as and when required. Blood

transfusion was advised in case of poor levels of Hb% (<10mg/dL). Patients were discharged after completion of each cycle with symptomatic medications to be taken at home and to report immediately in case of any deterioration. Relevant investigations along with CECT thorax was done to assess the disease progression at the time of 4th cycle, 6th cycle, and at 1 year. Any sign of toxicity was noted and treatment of toxicities was done. Opinion from respective physicians was also taken while management of systemic side effects.

4. Observation and Results

4.1. Study results

The male to female ratio in the study was found to be 32:8 i.e. 80% were males while 20% were females (**Figure 1**). The ratio in each group was same- 16:4 (80% males and 20% females).

The age group of patients in the study was between 47-83 years. In Gemcitabine group it was 48 – 80 years, mean age was 61.0 years (SD-9.6) and in the Paclitaxel group it was between 47 – 83 years, mean age was 63.25 years (SD-10.8). There was no significant difference in the age of the patients (p value- 0.746) as shown in **Table 1**.

The number of patients with adenocarcinoma and squamous cell carcinoma in Gemcitabine group was 10 (50%) and 10 (50%) while in paclitaxel group it was 9 (45%) and 11(55%) respectively.(**Figure 2**)

None of the patients had 0 or 5 performance score on ECOG scale, 9 patients (22.5%) had score 1, 15 patients (37.5%) had score 2, and 16 patients (40%) had score 3. The difference in the performance score was not significant between the two groups. (p value= 0.843).(Table 2)

The patients with different stages of the disease in Gemcitabine and Paclitaxel groups respectively are shown in **Table 3**. (P value= 0.731) 34 (85%) patients had a previous smoking history while 6 patients (15%) were non-smokers (**Figure 3**) 6 (15%) patients out of 40 had previous history of Anti tubercular treatment (ATT) in the past. 2 patients were on ATT when the diagnosis of carcinoma was made and ATT was stopped after ruling out tuberculosis.

Overall Survival was measured using Unpaired t-Test and was not found to be significantly different between the two groups (p value=0.631). Average survival of the patients in Gemcitabine group was found to be 8.75 Months (SD=4.33) and in Paclitaxel group 8.05 months (SD=4.8) (**Figure 4**).

The toxicities were compared using unpaired t-test and were not found to be significantly different at 4th cycle (p value= 0.442) and at 1-year (p value= 0.675) but it was statistically significant at 6th cycle (p value = 0.026) between the two groups. Paclitaxel group had significantly lesser toxicity score than Gemcitabine group at 6th cycle but at 1

year the toxicity scores between the two groups were not significantly different.

Almost all the patients had a decrease in the Hb% from their pre-treatment levels. 14 (35 %) patients had to be given blood transfusion. The average Hb level after 4th cycle, 6th cycle and at 1- year (values in mg/dl) shown in **Table 5**.

The average hemoglobin level at 4th cycle, 6th cycle and at 1-year did not differ significantly throughout the follow up.(**Figure 5**)

The average total leucocyte count at pre-treatment, 4th cycle, 6th cycle and at 1 year did not differ significantly throughout the follow up.(**Table 6; Figure 6**)

The average platelet counts of patients in cisplatin-gemcitabine group were significantly lower than those in cisplatin-paclitaxel group at the 4th cycle (p value=0.0001) and at the 6th cycle (p value = 0.002). Then at 1 year the difference in platelet counts of patients in both groups was not statistically significant (p value = 0.217). (**Table 7; Figure 7**)

Out of 40 patients most of the patients gave history of nausea and vomiting at one or more occasions during the treatment. 32 (80%) patients required active treatment for the same.

Numbness and tingling sensation was a frequent complaint by patients. 7 (35%) patient in gemcitabine group complained of numbness and tingling and 4 (20%) patients in paclitaxel group. However, it was not found to be statistically different (p value = 0.365).

Alopecia was one side effect present universally in all patients although the degree of alopecia varied from patient to patient in each group.

2(10%) patients on paclitaxel complained of skin rashes although they did not require any active treatment for this.



Figure 1: Gender distribution

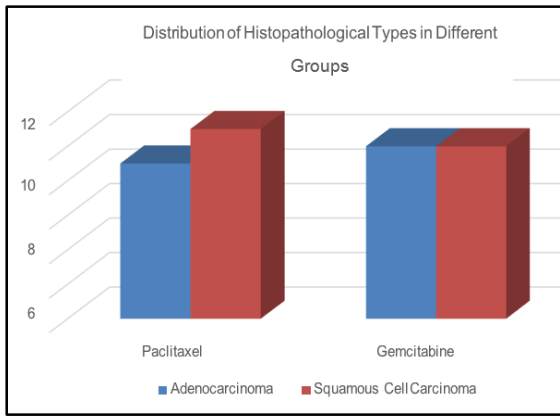


Figure 2: Distribution of histopathological types

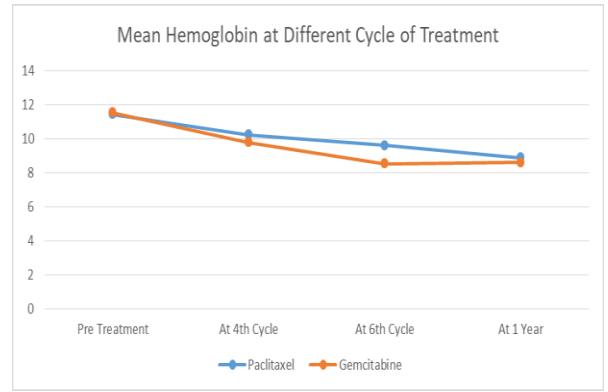


Figure 5: Comparison of hemoglobin levels

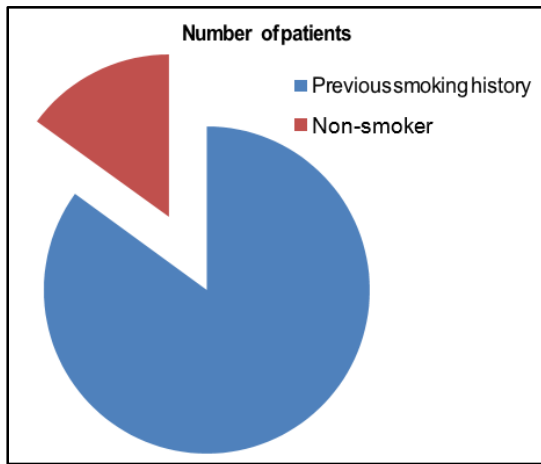


Figure 3: Distribution of smoking pattern

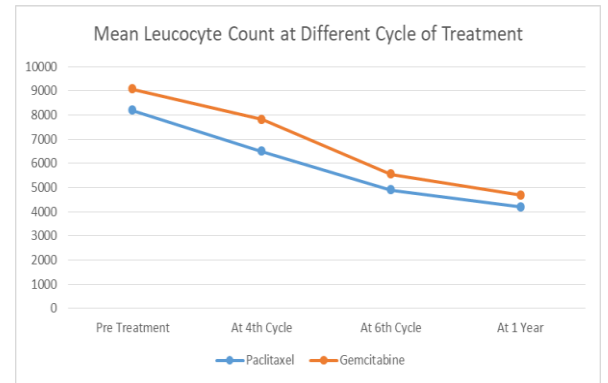


Figure 6: Comparison of total leucocyte counts

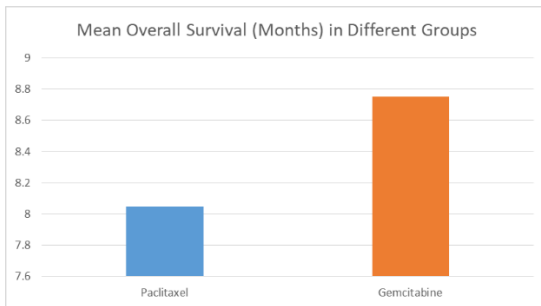


Figure 4: Comparison of mean overall survival

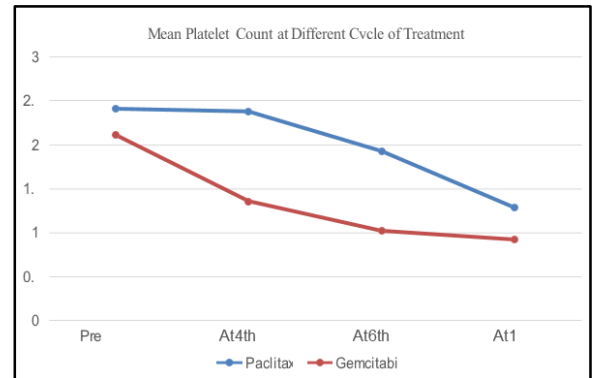


Figure 7: Comparison of platelet counts

Table 1: Distribution of age in each group

Age	Group						P-Value
	Paclitaxel		Gemcitabine		Total		
	Cases	(%)	Cases	(%)	Cases	(%)	
45-55 Year	6	30.00	7	35.00	13	32.50	0.746
56-65 Year	7	35.00	8	40.00	15	37.50	
66-75 Year	2	10.00	3	15.00	5	12.50	
76-85 Year	5	25.00	2	10.00	7	17.50	
Total	20	100.00	20	100.00	40	100.00	

Table 2: Comparison of ECOG performance score in both groups

Mean \pm SD	Group		P- Value
	Paclitaxel	Gemcitabine	
ECOG Performance Score	2.15 \pm 0.81	2.20 \pm 0.77	0.843

Table 3: Stage-wise distribution in both groups

Stage	Group						P- Value
	Paclitaxel		Gemcitabine		Total		
	Cases	(%)	Cases	(%)	Cases	(%)	
Stage III	15	75.00	13	65.00	28	70.00	0.731
Stage IV	5	25.00	7	35.00	12	30.00	
Total	20	100.00	20	100.00	40	100.00	

Table 4: Number of patients requiring Blood Transfusion in both groups

Gemcitabine group	9 (45%)
Paclitaxel group	5(25%)

Table 5: Comparison of mean Hb level in both groups

Hemoglobin	Mean \pm SD		P-Value
	Group		
	Paclitaxel	Gemcitabine	
Pre Treatment	11.42 \pm 1.77	11.53 \pm 1.35	0.819
At 4 th Cycle	10.22 \pm 1.38	9.77 \pm 1.52	0.355
At 6 th Cycle	9.59 \pm 1.60	8.53 \pm 1.28	0.067
At 1 Year	8.87 \pm 0.74	8.61 \pm 1.85	0.735

Table 6: Comparison of mean total leucocyte count in both groups

Total Leucocyte Count (cells per mm ³)	Mean \pm SD		P-Value
	Group		
	Paclitaxel	Gemcitabine	
Pre Treatment	8195.00 \pm 3345.93	9065.00 \pm 3037.01	0.395
At 4 th Cycle	6500.00 \pm 2813.20	7815.79 \pm 3494.32	0.217
At 6 th Cycle	4892.31 \pm 758.79	5550.00 \pm 1535.10	0.176
At 1 Year	4185.71 \pm 1083.86	4687.50 \pm 1725.80	0.52

Table 7: Comparison of mean platelet count in both groups

Platelet Count (Lacs per mm ³)	Mean \pm SD		P- Value
	Group		
	Paclitaxel	Gemcitabine	
Pre Treatment	2.40 \pm 1.25	2.11 \pm 1.08	0.429
At 4 th Cycle	2.37 \pm 0.86	1.35 \pm 0.68	0.0001
At 6 th Cycle	1.92 \pm 0.65	1.01 \pm 0.73	0.002
At 1 Year	1.28 \pm 0.58	0.91 \pm 0.54	0.217

Table 8: Comparison of toxicities in both groups

Toxicity	GC	PC
Weight loss	5.8%	5.3%
Respiratory Infections	10%	5%
Allergic Skin Rash	-	10%
Numbness	35%	20%
Nausea	++	++
Alopecia	++	++

Weight loss was a universal side effect. Most of the time it was due to poor dietary intake either because of nausea and vomiting or due to dysphagia and oral ulcers. In the Gemcitabine group it was 5.8% (± 2) while in the paclitaxel group it was 5.3% (± 1.6) ($p=0.4$).

3 patients had to be treated for pneumonia, 1 requiring hospital admission. 2 patients (5%) belonged to the Gemcitabine group and 1 (2.5%) belonged to the Paclitaxel group. Other infections encountered during treatment were diarrhoea and fungal infections.

5. Discussion

This study was carried out with 40 patients who were diagnosed as NSCLC with both histological and radiological confirmation. Two groups were formed, each of 20 patients and two drug regimens were started separately in each group. One group was given Cisplatin and Gemcitabine (Group 1/GC) and the second group was given Cisplatin and Paclitaxel (Group 2/PC). The cost of treatment and side effects were explained to the patients beforehand. The main aim of the study was to find any difference in overall survival and progression free period, and to compare the toxicity between the two drug regimens.

The average overall survival in GC 8.75 (± 4.33) months, was more than PC 8.05 (± 4.80) months, however it was not different significantly (p value= 0.631).

In a previous study by Schiller et al., 2002,¹⁶ comparison was done between four chemotherapy regimens for advanced non-small cell lung cancer, and the overall survival was not found to be statistically significant between the groups of patient given cisplatin-gemcitabine vs those given cisplatin-paclitaxel, which is in accordance with our study result. In the group of patient who received cisplatin and paclitaxel, the median survival was 7.8 months and in the group of patients who received cisplatin and gemcitabine, the median survival was 8.1 months.¹⁶ Though poor performance score is also related to poor survival outcome (Aisner J and Hansen HH, 1981; Gatzemeier U et al., 1998),^{17,18} there was no significant difference in the performance scores among the two groups ($p= 0.843$). So the result cannot be attributed to the difference in PS.

The mean progression free survival in the cisplatin-plus-paclitaxel group was 5.10 (± 3.49) months and in the cisplatin-plus-gemcitabine group was 6.25 (± 3.82) months. It was not found to be significant in our study (p value= 0.327). However, in the study by Schiller et al., 2002¹⁶ where the sample size was 1155 patients, the median time to the progression of disease was 3.4 months in the cisplatin-plus-paclitaxel group, as compared with 4.2 months in the cisplatin-plus-gemcitabine group with a p value= 0.001 .

The toxicity levels were significantly higher in GC at 6th cycle as compared to PC ($p= 0.026$). The toxicity levels at 1 year were higher in the GC group, but it was not statistically

significant (p value= 0.675). The predominant side effect was hematological toxicity (92 %). The difference in anemia was not significant in both the groups at 4th cycle (p value = 0.355), 6th cycle (p value= 0.07) and at 1-year (p value= 0.735). In both the groups, fall in total leucocyte count was observed with treatment but no significant difference between the two groups was observed at 4th cycle (p value= 0.217), 6th cycle (p value= 0.176) and 1 year (p value = 0.52). Thrombocytopenia was significantly more in patients of GC group at 4th (p value= 0.0001) and 6th cycle (p value = 0.002). However no significant difference was observed in platelet levels at 1 year (p value = 0.217). In the study by Schiller et al., 2002,¹⁶ patients given cisplatin-plus-gemcitabine had significantly more anemia and thrombocytopenia than those given cisplatin-plus-paclitaxel.

Better tolerability of chemotherapeutic agent seen in the current study could be due to the genetic differences in the cohort of patient in India and West.

Increased rates of myalgias and neurotoxicity were observed in paclitaxel- treated patients in West. There was significant amount of weight loss in patients in GC group ($p=0.04$). This result could be due to the poor financial status of patients opting for the GC regime wherein the initial weight is lower than the PC group with better nutrition to start with. Unlike some previous studies no comparison was made between the level of drug in blood and toxicity.

Studies done on chemotherapeutic agents in NSCLC earlier included various other criteria to determine the outcome and included many more number of patients. The method of assessing toxicity and their management was in accordance with the recommendations.

Further observations which could be done to reach a precise conclusion would include:

1. Remission rates of the drugs
2. Quality of Life (QoL)
3. Response Rates
4. Assessment of cost-benefit ratio

6. Conclusion

Although OS is considered as the traditional gold standard end point, as it has the advantage of being unambiguously defined and important to the patient's perspective, some of its limitations are problematic. This study found that average overall survival was higher in patients of gemcitabine group however it was not statistically significant from the other group. Toxicities were also found to be higher in patients of gemcitabine group.

As a result of development of more effective agents, OS has improved in many types of cancer and its measurement now requires increasingly longer follow-up periods. If regulatory approval of a new agent is on the basis of a demonstrated improvement in OS, patients will be required to wait a long time, longer than in previous years, for access

to treatments that are more effective than those currently available.

7. Limitations of Study

1. The study could further be strengthened by increasing the number of patients enrolled. Calculation of outcome according to sex, age, stage of disease, PS and smoking history can further enlighten the subject and better decision can be made in the choice of chemotherapy.
2. The toxicities also vary with the dosage of drug but were not assessed in the current trial.
3. The relation between race or genetic and outcomes in terms of survival and toxicity profile can guide the choice of chemotherapeutics by the oncologist especially when cost is a major concern in countries like ours.

8. Conflict of Interest

The authors report no conflict of interest

9. Source of Funding

This study received no funding.

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