### A Comparative Study Between Pemetrexed and Taxanes as First Line Treatment of Metastatic Lung Adenocarcinoma

Sarmad Qahtan Al-Salihi 101, Azhar Sabieh Al Zubaidi 102

### **Abstract**

**Background:** Adenocarcinoma of the lung is the most common type of lung cancer. Platinum agents in combination with other chemotherapy are currently the cornerstone for chemotherapy of advanced cases with metastasis.

**Objective:** To compare the response rate of pemetrexed doublets versus taxanes doublets in patients with metastatic lung adenocarcinoma.

**Patients and Methods:** This a prospective study that included 60 patients with pulmonary adenocarcinoma. Those patients received a platinum based doublet chemotherapy with additional treatment protocol; combined with either pemetrexed or taxanes (paclitaxel or docetaxel) with 30 patients in each arm. Tumor size, response rate and side effects of chemotherapy were evaluated in both arms.

**Results:** The median reduction in tumor size in pemetrexed and taxan arms were 4.72 cm2 and 6.53 cm2 respectively. Nausea, fatigue, constipation and anorexia were more common in pemetrexed arm, while leukopenia, arthralgia and peripheral neuropathy were more common in taxan arm. **Conclusion:** Serious side effects such as leukopenia, and peripheral neuropathy were more common in taxan than pemetrexed arm. Pemetrexed is preferable to use as a fist line treatment for patients with metastatic adenocarcinoma of the lung.

**Keywords:** Adenocarcinoma, Pemetrexed, Taxanes, metastatic lung cancer.

### **OPEN ACCESS**

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### Introduction

Adenocarcinoma of the lung, which falls under the category of non-small cell lung cancer (NSCLC) [1], is the prevailing form of lung cancer. The primary cause of this cancer type is cigarette smoking [2]. TNM staging [3] is used to determine the extent of the disease. Adenocarcinoma in situ and minimally invasive adenocarcinoma, although infrequent, constitute only 5% of

surgically removed adenocarcinomas [4]. The most frequently encountered invasive adenocarcinoma is categorized based on five distinct histological growth patterns: lepidic, acinar, papillary, micropapillary, or solid [5].

Historically, platinum doublet chemotherapy has served as the established initial treatment for individuals having metastatic lung adenocarcinoma lacking a

<sup>&</sup>lt;sup>1</sup>Oncology Teaching Hospital, Baghdad, Iraq

<sup>&</sup>lt;sup>2</sup> Baghdad Teaching Hospital, Baghdad, Iraq

defined mutation [6]. Extensive research has explored various combinations of third-generation drugs alongside platinum agents, such as cisplatin plus paclitaxel and cisplatin plus gemcitabine. These combinations have demonstrated comparable response rates and survival durations in patients with metastatic NSCLC. In cases where patients cannot put up with platinum agents, non-platinum treatments like gemcitabine plus docetaxel or gemcitabine plus vinorelbine may serve as reasonable alternatives [7,8].

was established that pemetrexed increases survival rate for patients with nonsquamous **NSCLC** first-line maintenance chemotherapy [7]. Single-agent immunotherapy such as nivolumab, atezolizumab and pembrolizumab have been found to prolong survival in general [9,10,11]. Extensive research has focused on innovative combination therapies advanced lung adenocarcinoma, which with a involve pairing chemotherapy checkpoint inhibitor. One notable example is mixture of pembrolizumab carboplatin and pemetrexed, which has been studied and approved as a first-line treatment option. Additionally, the combination of two checkpoint inhibitors, namely ipilimumab plus nivolumab, has demonstrated benefits in patients with a high tumor mutational rate (≥10 mutations per mega-base). It is crucial to select an approved targeted therapy as the initial treatment if the tumor harbors an tortious mutation [6]. The assessment of treatment response utilizes the response evaluation criteria in solid tumors (RECIST) criteria and employs a three-dimensional approach [12,13]. The current study aims to compare the response rate to platinum

doublets pemetrexed versus platinum doublets taxanes in first line treatment for patients with metastatic NSCLC adenocarcinoma subtype in Iraqi patients.

### **Patients and Methods** The Study Population

This is a prospective study including with patients metastatic pulmonary adenocarcinoma who were attending Oncology Teaching Hospital in Baghdad during the period from 1 January 2020 to 31 July 2020. Patients with histologically confirmed advanced pulmonary adenocarcinoma by trans-bronchial or transthoracic biopsy with metastases to bone, liver and brain, detected by computed tomography (CT) examination, were eligible for the study. The study included Eastern Cooperative Oncology Group (ECOG) Performance Status (PS)  $\leq 1$ , adequate hematopoietic, liver and renal functions, age less than 75 and stage IV lung tumor adenocarcinoma subtype. On the other hand, patients having PS 2 or more, patient positive for EGFR, those with incomplete radiological assessment, uncontrolled diabetes mellitus or peripheral neuropathy and renal or hepatic insufficiency were excluded from the study. Written informed consent following approval of the health authority from all participants was obtained before data collection after explaining the aim of the study.

### The Study Groups

History and physical examination including TNM staging were performed for all patient. All patients were given platinum based doublet chemotherapy 4-6 cycles according to national comprehensive cancer network Guidelines [14], with carboplatin AUC 5 i.v over 30 minutes (manufactured by Hospira),

combined with one of the following drugs: Group A: 30 patients treated with pemetrexed (manufactured by Lilly Pharma) 500mg/m<sup>2</sup> i.v over 10 minutes

Group B: 30 patients treated with taxanes, paclitaxel (manufactured by Hospira) 175mg/m<sup>2</sup> i.v over 3 hours or docetaxel (manufactured by Pfizer) 75mg/m<sup>2</sup> i.v over 60 minutes.

Treatment has been delayed 1 week for patients in any arm with grades 3–4 neutropenia, thrombocytopenia and anemia with hemoglobin less than 8 g/dl. Treatment discontinued if the patient has experienced decrease in his performance status, complication or progression.

The response of patients was evaluated according to RECIST guidelines. Clinical evaluation and CT scan were performed every 3 treatment cycles.

A patient was considered to have complete response when there is disappearance of all target lesions. A patient had partial response when there is at least 30% decrease in sum of the longest diameters of the target lesion. Stable disease indicates neither a shrinkage sufficient to qualify for partial response nor sufficient increment to qualify for progressive disease.

### **Statistical Analysis**

Data entry was performed using the SPSS software (vesion 24). Continuous data were

subjected to normality test. Mean and standard deviation (SD) was used to express the normally distributed data which were analyzed with Student t-test, while median and range were used to present non-normally distributed date. Those data were analyzed with Mann Whitney U test. Categorical variables were expressed as number and percentage, and were analyzed using the Chisquare ( $\chi 2$ ) test. Spearman's correlation test was used to explore the possible correlation of tumor reduction with other continuous variables. Null hypotheses of no difference were rejected if p-values were less than 0.05.

### **Results**

### **Demographic characteristics of patients**

The mean age of pemetrexed arm was 60.35±10.5 years which did not differ significantly from that of taxan (58.87±12.29 years). Likewise, the two arms were comparable in terms of weight, height and BMI without significant differences. Males and zero ECOG score were more frequent than females and ECOG 1 score representing 56.67% and 66.67% pemetrexed and taxan arms, respectively with no significant difference. In contrast, smokers were more frequent in taxan than pemetrexed arms (53.33% versus 26.67%) with a significant difference Table (1).

**Table (1):** Demographic characteristics of the patients.

Variables	Pemetrexed(n=30)	Taxan(n=30)	p-value
<b>Age, years</b> Mean±SD Range	60.35±10.5 37-77	58.87±12.29 34-74	0.703
<b>Gender</b> Male Female	17(56.67%) 13(43.33%)	20(66.67%) 10(33.33%)	0.426
<b>Weight, kg</b> Mean±SD Range	73.9±11.67 58-105	76.8±11.3 60-100	0.507
<b>Height, cm</b> Mean±SD Range	168.6±10.55 151-183	166.13±11.03 148-181	0.244
<b>BMI, kg/m²</b> Mean±SD Range	26.13±5.0 20.9-44.85	28.38±6.21 19.6-41.62	0.332
Smoking, pack/year Never Ex/current smokers	22(73.33%) 8(26.67%)	14(46.67%) 16(53.33)	0.035
ECOG Zero One	17(56.67%) 13(43.33%)	20(66.67%) 10(33.33%)	0.426

### Therapeutic and clinical characteristics of the Patients

The most common comorbidity was hypertension (HTN) accounting for 36.67%% and 46.67% of patients in pemetrexed and taxan arms respectively, with no significant differences. Patients in pemetrexed arm had remarkably smaller initial and final tumor

size (28.37±28.78 cm<sup>2</sup> and 22.52±36.7 cm<sup>2</sup>, respectively) than those in taxan arm (40.52±37.55 cm<sup>2</sup> and 35.83±25.76 cm<sup>2</sup>, respectively). However, the differences were significant only in final reading. The vast majority of patients in both arms received 6 cycles treatment Table (2).

**Table (2):** Therapeutic and clinical characteristics of the patients.

Variables	Pemetrexed (n=30)	Taxan (n=30)	p-value
Comorbidities No comorbidity Hypertension Diabetes mellitus Others	16(53.33%) 11(36.67%) 3(10%) 1(5%)	12(40%) 14(46.67%) 8(26.67%) 1(6.67%)	0.301 0.432 0.095 0.916
Initial tumor size, cm <sup>2</sup> Mean±SD Range	28.37±28.78 3.0-132	40.52±37.55 3-132	0.240*

Final tumor size, cm <sup>2</sup> Mean±SD Range	22.52±36.7 0-167	35.83±25.76 1.12-99	0.023*
Treatment cycles 4 6	4(13.33%) 26(86.67%)	4(13.33%) 26(86.67%)	1.00

<sup>\*</sup> Mann Whitney U test

### **Reduction in tumor size**

The median reduction in tumor size in pemetrexed arm was 4.72 cm<sup>2</sup> (range -66.5-95.22 cm<sup>2</sup>) compared with 6.53 cm<sup>2</sup> (range -

 $50.0-88.0 \text{ cm}^2$ ) in taxan arm. Statistically, there was no significant difference between the two arms (p= 0.657) Figure (1).

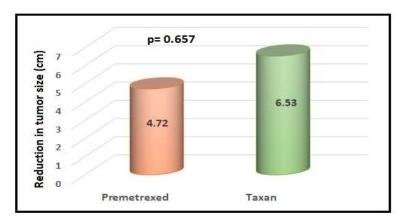


Figure (1): Median reduction in tumor sizes in pemetrexed and taxan treated arms.

### Response to treatment

The response rate was in favors of pemetrexed arm in which there was only 4 (13.33%) non-responders compared to 10

(33.33%) among taxan arm with no significant differences (p= 0.211) (Figure 3-2). Interestingly, there was only one patients with complete remission in taxan Figure (2).

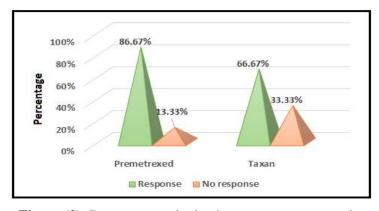


Figure (2): Response rate in the three treatment protocols.

Correlation of tumor reduction with other variables

Spearman's correlation test was used to explore the possible correlation between tumor reduction and other continuous variables. In general, none of the included variables had a significant correlation with tumor reduction Table (3).

**Table (3):** Spearman's correlation between tumor reduction with other continuous variables.

Variable	Pemetrexed		Taxan	
	R	p-value	r	p-value
Age	-0.007	0.977	-0.025	0.929
Weight	0.121	0.612	0.445	0.096
Height	0.023	0.923	-0.103	0.715
BMI	0.078	0.744	0.380	0.163
No. of cycles	0.289	0.216	0.085	0.763

## Association of tumor reduction with gender, smoking, and co-morbidity

There was no significant effect of gender, smoking habit or the presence of comorbidity on the reduction rate. However, patients with ECOG 0 score in pemetrexed arm had significantly higher reduction size  $13.05\pm35.6$  cm<sup>2</sup> than those with ECOG 1 (- $4.94\pm15.25$  cm<sup>2</sup>) as shown in Table (4).

**Table (4):** Association of tumor reduction with gender, smoking and comorbidity.

Variables	Pemetrexed	Taxanes	
Gender			
Males	4.22±38.89	4.72±22.1	
Females	8.29±7.58	4.62±53.85	
p-value	0.624	0.859	
Smoking			
Yes	6.1±14.66	-5.02±24.79	
No	4.42±82.67	11.69±37.48	
p- value	0.479	0.121	
Comorbidity			
Yes	8.76±36.46	8.03±44.96	
No	1.49±17.89	2.47±26.87	
p-value	0.625	0.776	
ECOG			
0	13.05±35.6	3.67±33.37	
1	-4.94±15.25	6.72±38.53	
p-value	0.031	0.440	

<sup>\*</sup> Non-parametric Mann Whitney test was used for comparison

### Side effects of the treatment

A total of 12 side effects were reported for the two arms., seven of which differed significantly between arms. Nausea, fatigue, constipation and anorexia were more common in pemetrexed arm (P<0.05), while leukopenia, arthralgia, and peripheral neuropathy were more common in taxan arm (P<0.05) Table (5).

Effects	Pemetrexed (n=30)	Taxan (n=30)	p-value
Leukopenia	0(0%)	18(60%)	< 0.001
Neutropenia	12(40%)	16(53.33%)	0.433
Nausea	27(90%)	16(53.33%)	0.004
Vomiting	18(60%)	18(60%)	1.0
Alopecia	24(80%)	21(70%)	0.265
Diarrhea	7(33.33%)	8(26.67%)	0.599
Arthralgia	0(0%)	16(53.33%)	< 0.001
Peripheral neuropathy	0(0%)	16(53.33%)	< 0.001
Anemia	24(80%)	24(80%)	1.0
Fatigue	24(80%)	0(0%)	< 0.001
Constipation	12(40%)	0(0%)	< 0.001
Anorexia	24(80%)	0(0%)	< 0.001

**Table (5):** Side effects of the three treatment arms.

### **Discussion**

Not only does pemetrexed have less toxicity that taxan, but may also it is better than other chemotherapies. In their study, Scagliotti et al. conducted a comparison between the effectiveness of cisplatin/pemetrexed and cisplatin/gemcitabine as first-line treatments for patients with non-small cell lung cancer (NSCLC) [15]. The overall survival (OS) was found to be equal in both treatment arms, with a duration of 10.3 months. However, when analyzing the nonsquamous subgroups, observed survival that was was extended significantly with cisplatin/pemetrexed. Specifically, in patients with adenocarcinoma, the survival duration was 12.6 months compared to 10.9 months with cisplatin/gemcitabine. In the case of large cell histology, the survival was 10.4 months with cisplatin/pemetrexed, while it was 6.7 months with cisplatin/gemcitabine.

According to the result of the current study, all demographic characteristics were comparable between the pemetrexed and taxan arms with no significant differences, except smoking habit which is more frequent among taxan arm with a significant difference (P=0.035). An American study including 1370 patients with NSCLC demonstrated no prognostic effect of smoking status on treatment response or overall survival rates [16]. Thus, smoking is undoubtly the main risk factor adenocarcinoma, but may have less important role in the response to chemotherapy.

Clinically, the mean final tumor size in taxan arm was larger than that of pemetrexed arm. However, when the reduction rate in tumor size was calculated, there was no significant differences between the two arms. Interestingly, the response rate in pemetrexed arm was better than that of taxan arm (86.67% versus 66.67%) although the difference was not significant.

Global studies on this matter have yielded contradictory outcomes. In a randomized, multi-centric study, the combination of carboplatin and pemetrexed was compared to carboplatin and docetaxel in patients diagnosed with advanced non-small cell lung cancer (NSCLC). The group of patients

treated with carboplatin and pemetrexed exhibited a longer median survival without experiencing significant toxicity, as did the patients in the carboplatin and docetaxel group. The median overall survival was comparable between the two groups, along with similar response rates. As a result, the authors concluded that carboplatin and pemetrexed could serve as a suitable first-line treatment regimen for non-squamous NSCLC [17]. Another retrospective analysis of a large multi-centric study comparing pemetrexed to docetaxel revealed overall response rates of 9.1% and 8.8% (P = 0.105), respectively [18].

Based on the result of the current study, reduction in tumor size inversely associated with ECOG in pemetrexed arm. In ECOG 1 group, there was a slight increase in tumor size compared with initial size. In contrast, the tumor size greatly reduced in ECOG 0 group. Thus, the large tumor burden may associate with some signs and symptoms for the disease and affect ECOG score.

Another interesting finding in the present study was that pemetrexed treatment was associated with more frequent nausea (the nausea may be attributed to the cisplatin base), fatigue, constipation and anorexia, while taxane arm was associated with more frequent leukopenia, arthralgia and peripheral neuropathy. In the Hanna's study [19], hematologic toxicity in patients treated with docetaxel was greater than those treated with pemetrexed.

#### **Conclusions**

Pemetrexed arm seems to have a better response rate and toxicity profile than taxan arm although the difference was not a significant. In terms of side effect, serious side effects such as leukopenia, and peripheral neuropathy were more common in taxan than pemetrexed with significant differences.

### Recommendations

The study recommends using pemetrexed as a fist line treatment for patients with adenocarcinoma unless otherwise a patients had adverse reaction to the drug. Also, it is better to avoid using taxanes in patient with chronic disease due to side effects of taxanes.

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**Ethical clearance:** This study was conducted according to the approval of College of Medicine/ University of Diyala and in accordance with the ethical guidelines of the Declaration of ethical committee of the College ( Document no.2023SQA769).

### Conflict of interest: Nil

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# دراسة مقارنة بين البيميتريكسيد والتاكسان كعلاج أولي لسرطان الرئة الغدي النقيلي سرمد قحطان الصالحي ، أزهر صبيح الزبيدي ٢

### الملخص

خلفية الدراسة: سرطان الرئة الغدي هو النوع الأكثر شيوعا من سرطان الرئة. تعتبر الادوية البلاتينية مع العلاجات الكيميائية الأخرى حاليًا حجر الزاوية في العلاج الكيميائي للحالات المتقدمة التي تعاني من ورم خبيث.

اهداف الدراسة: لمقارنة معدل استجابة ثنائيات البيميتريكسيد مقابل ثنائيات التاكسان في المرضى الذين يعانون من سرطان الرئة الغدى النقيلي.

المرضى والطرائق: شملت هذه الدراسة الاستطلاعية ٢٠ مريضا يعانون من سرطان غدي رئوي. تلقى هؤلاء المرضى علاجًا كيميائيًا مزدوجًا قائمًا على البلاتين مع بروتوكول علاج إضافي؛ تم دمجه مع البيميتريكسيد أو التاكسان (باكليتاكسيل أو دوسيتاكسيل) مع ٣٠ مريضًا في كل مجموعة. تم تقييم حجم الورم ومعدل الاستجابة والأثار الجانبية للعلاج الكيميائي في كلا االمجموعتين.

النتائج: بلغ متوسط الانخفاض في حجم الورم في مجموعتي البيميتريكسيد والتاكسان ٤,٧٢ سم٢ و٦,٥٣ سم٢ على التوالي. كان الغثيان والتعب والإمساك وفقدان الشهية أكثر شيوعًا في مجموعة البيميتريكسيد، بينما كانت قلة الكريات البيض والألم المفصلي والاعتلال العصبي المحيطي أكثر شيوعًا في مجموعة التاكسان.

الاستنتاجات: ظهرت الآثار الجانبية الخطيرة مثل نقص الكريات البيض، والاعتلال العصبي المحيطي أكثر تواترا في مجموعة التاكسان مقارنة بمجموعة البيميتريكسيد. يفضل استخدام البيميتريكسيد كعلاج خط اول للمرضى الذين يعانون من سرطان غدى منتشر في الرئة.

الكلمات المفتاحية: سرطان الغدة الدرقية, بيميتريكسيد, تاكسانات, سرطان الرئة النقيلي

alsalihi\_iraq@yahoo.com البريد الإلكتروني:

تاریخ استلام البحث: ۹ حزیران ۲۰۲۳

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المستشفى الاورام التعليمي - بغداد - العراق مستشفى بغداد التعليمي - بغداد - العراق