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Clinico-epidemiological study of lung carcinoma: Five years retrospective study

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Abstract
Aims: The aim of this study was; statistical analysis of the clinico-epidemiological characteristics and different prognostic factors affecting the treatment outcome in the patients with NSCLC/SCLC and assessments the response and the adverse events of treatment.
Patients and Methods: This is a retrospective clinic-epidemiological study was carried out to evaluate the patients presented with NSCLC and SCLC and treated at Clinical Oncology Department Tanta University hospital during a period between January 2015 to December 2019 with a minimum follow up period of 6 months.
Results: The SCLC was represented in 14.4% of patients, while NSCLC was represented in 85.6%. Most of the patients were presented with stage IV (49.5%) while only (1.2%) of the patients were presented with stage I. lung cancer represented the 4th most common type of cancer in our department. Adenocarcinoma was prevelant among the non-smoker and smoker patients (53.4% and 45% respectively). (5.3%) of patients with SCLC had achieved CR while only (1.35%) of patients with NSCLC had achieved CR. At the end of this study, there were 48 patients (9.2%) alive and 473 patients (90.8%) dead.
Conclusion: In the realm of lung cancer prevention, the pivotal preventive strategy lies in the regulation of tobacco smoking. The prognosis for lung cancer sufferers tends to be unfavorable due to delayed detection and the limited scope for surgical intervention. The establishment of multidisciplinary cohorts is imperative for the purpose of deliberating on optimal therapeutic approaches for individual patients.

Keywords: Clinico-epidemiological, lung carcinoma

Introduction
Based on GLOBOCAN 2020 estimates, lung cancer is the most commonly diagnosed cancer worldwide [1]. In Egypt, lung cancers are the 5th most common malignancies (4.7%) [2]. In Gharbiah, trachea, bronchus and lung cancers account for 8.2% of malignancies in males versus 2.7% in females [3]. It is categorized into: small cell lung carcinoma accounts for 15% of cases, while non-small cell lung carcinoma represents 85% [4]. Non-small cell lung carcinomas can be further classified into adenocarcinoma, squamous cell carcinoma, and large cell carcinoma. It is observed that lung adenocarcinomas commonly exhibit mutations in the epidermal growth factor receptor (EGFR) and rearrangements in ALK [5]. The primary risk factor associated with the development of lung cancer is tobacco cigarette smoking [6].

Aim
The aim of this study was; statistical analysis of the clinico-epidemiological characteristics of the patients with NSCLC/SCLC, statistical analysis of the different prognostic factors affecting the treatment outcome in the patients with NSCLC/SCLC and assessments the response and the adverse events of treatment of the patients with NSCLC/SCLC.

Patients and Methods
This is a retrospective clinic-epidemiological study was carried out to evaluate the patients presented with NSCLC and SCLC and treated at Clinical Oncology Department Tanta University hospital during a period between January 2015 to December 2019 with a minimum follow up period of 6 months.

Inclusion criteria

Patients were eligible in the following conditions; Age: ≥18 years. Patients with sufficient follow-up data. Performance status: ≤ 2 score according to Eastern Cooperative Oncology Group (ECOG) performance scale, those with histologically or cytologically proven lung cancer, those with any TNM disease stage including patients presented with metastatic disease, those with initially adequate bone marrow, liver and kidney functions.

Methods

Through review of patient's files; patient age, gender, occupation (Workers, farmers, employees, driver, carpenterno and others), history of smoking (Type of tobacco, duration and time of cessation of smoking), family history of lung cancer, performance status, type of symptoms (Dyspnea, pain, cough, hemoptysis, dysphagia and anorexia) and its duration before diagnoses, history of other co-morbidities (Such hypertension, diabetes mellitus), surgical pathology reports, tumor site, tumor size, lymph node status, TNM disease stage, type of lung cancer and histological subtypes, tumor grade, presence or absence of metastases (Sites, numbers and presenting with or development of brain metastases) date of death or last follow up, date of distant metastases and local failure, response to treatment and its duration, timing of chemotherapy and/or radiotherapy treatment received (neoadjuvant or adjuvant), types of radical chemotherapy and/or radiotherapy treatment received and its doses, types and doses of palliative therapy received, acute and delayed adverse events of treatments and its grades were obtained for each patient.

The pathologic stage was determined according to AJCC TNM staging 2010.

Diagnostic work up

All patients were subjected to the following

Full history taking, clinical (general and local) examinations. Laboratory investigations

- Imaging studies
- Pathological diagnosis
- Follow-up

Statistical method of analysis

Data was gathered, encoded, and inputted into a computer prior to undergoing analysis utilizing the Statistical Package for Social Science software, specifically version 21.0. Qualitative data was portrayed through frequency distribution accompanied by its respective percentage, whereas quantitative data was illustrated by median, means, and standard deviation. The comparison of qualitative data was executed through Chi-squared test and Fisher's t-test, while ANOVA was utilized for quantitative data comparison.

The evaluation of clinical response was conducted in accordance with the revised response evaluation criteria within solid tumors (RECIST) guideline, version 1.1. The overall survival denoted the duration from the initial diagnosis date to the recorded date of demise or final follow-up. Disease-free survival (DFS) was calculated starting from the treatment date until the documentation of disease recurrence or the final follow-up date. Loco-regional recurrence was delineated as the presence of a tumor in the lung or mediastinum, as identified through clinical, radiological, or pathological examinations. Distant metastases were identified as the presence of a tumor in any other region.

An analysis of the various prognostic factors influencing the treatment was carried out through univariate analysis based on Kaplan-Meier, with survival curve disparities assessed utilizing the Log-rank test. Multivariate analyses were computed in alignment with the Cox regression model. A significance level cut-off point was set at P-values of <0.05.

The Chi-square test was employed to ascertain the potential relationship between two categorical variables. Monte Carlo testing was utilized to predict potential outcomes of uncertain events. Fisher's exact test was conducted to establish the presence of a statistically significant association between two categorical variables. ANOVA testing was implemented to examine variations among the means of more than two groups.

Results

This is a retrospective clinic-epidemiological study was carried out at Clinical Oncology Department Tanta University hospital during a period between January 2015 to December 2019. The aim of this study was analysis of the clinico-epidemiological characteristics of the patients with NSCLC/SCLC., analysis of the different prognostic factors affecting the treatment outcome, assessments the response to treatment and its adverse events. About twenty eight of the patients were never smoker, while 71.6 were smoker ex-smoker. The most common tumor grade of all patients was grade II (48%), while poorly differentiated grade III represented in 19.6%.The majority of studied patients were presented with ECOG PS 2.The SCLC was represented in 14.4% of patients, while NSCLC was represented in 85.6%.Most of the patients were presented with advanced stage IV (49.5%) while only (1.2%) of the patients were presented with early stage I. The tumor site was in (48.4%) of the patients in the right lung, while it was in (33.8%) of the patients in the left lung, while bilateral lung tumor was represented in (4.2%). About 13.8% of the patients were complained from weight loss more than 5% of their weight at presentation (table 1).

Most of studied patients were coming from El Gharbia governrate (70.1%) followed by Kafr EL sheikh, EL Bhera El Menofia governorate (10.9%, 6.3% and 5.6% respectively).

El mahlla and Tanta centres were the main centres of El Gharbia governorate that most of the patients coming from there (31.5% and 28.2% respectively).

Lung cancer and colon cancer (7.2%, 7.1%, 5.8%, 5.1% respectively). Consequently, lung cancer represented the 4th most common type of cancer in our department.

Adenocarcinoma pathological type was prevelant among the non-smoker and smoker patients (53.4% and 45% respectively) (p=0.086). Twenty percent of smoker patients were SCLC while none of non-smoker patients had presented with SCLC (p<0.001).There was statistically significant difference of the percent of squamous cell carcinoma between non-smoker and smoker patients (29% Vs 20.4%, p=0.033) (table 2).

Surgical resection had performed for (22.7%) of patients presented with SCLC while (11.4%) of patients presented with NSCLC were surgically resected. Neoadjuvant chemotherapy had received in (22.7%) of patients with SCLC while it was received in only (9%) of patients with

NSCLC (p<0.001). Concurrent chemo radiation therapy was administered in (44%) of patients with SCLC while it was administered in (33.6%) of patients with NSCLC.

About five percentage of patients with SCLC had achieved CR while only (1.35%) of patients with NSCLC had achieved CR.

At the end of this study, there were 48 patients (9.2%) alive and 473 patients (90.8%) dead. The median overall survival time for all the patients was 16.0 (1.0 - 47.0), the median disease free survival time for all the patients was 13.0 (4.0 - 31.0) while the median progression free survival time for all the patients was 6.0 (1.0 - 23.0).

Analysis of prognostic factors that significantly affecting the OS in the univariate analysis and revealed that ECOG PS (≥3), Pathological (High grade), Surgery, Pretreatment weight loss (>5%), not responder, Radical radiotherapy, CCRTH and SCLC was significantly affecting OS (table 3).

Analysis of prognostic factors that significantly affecting the DFS in the univariate analysis and revealed that, Pathological (High grade) (p= 0.004) and neoadjuvant chemotherapy (p0.032) was significantly affecting DFS (table 4).

As regard the local tumor recurrence, 27 patients were complained from only local tumor recurrence and the site of recurrence most commonly in tumor bed (38.5%) followed by bronchial stump and pleural effusion (17.9% and 17.9% respectively). On the other hand, concerning with distant metastasis, 36 patients were developed only distant metastasis with brain, liver and adrenal gland with most common site of distant metastasis in brain (20.8%) and 12 patients develop local recurrence and distant failure.

Grade 3-4 haematological toxicity was developed in 52 patients (13%) and anaemia was the most common grade 3-4 toxicity in studied patient (8.5%). Nausea and vomiting was the most common non haematological toxicity developed in studied patients (7.5%) followed neuropathy (6.25%) and by fatigue (5.5%).

The most common grade 3-4 toxicity of RTH in studied patient was oesophagial toxicity (6.2%) followed by pulmonary toxicity (4.3%).

Discussion

Lung cancer is the most commonly diagnosed cancer in men globally and the third most commonly diagnosed cancer in women [7]. It leads to approximately 2 million cases and 1.76 million deaths annually, making it the primary cause of cancer-related morbidity and mortality. Recent data from the World Health Organization in May 2014 revealed that lung cancer caused 4,429 deaths in Egypt, accounting for 0.96% of total deaths and ranking Egypt 111th worldwide [8]. The national cancer registry from the National Cancer Institute in 2007 documented that lung cancer represented 2.8% of all malignancies in Egypt [9].

This clinicoepidemiological investigation of lung carcinoma found that the median age of patients was 60 years, with a mean age of 60.31±10.57 years. Male patients comprised 74.1% of the study population, while females made up 25.9%, resulting in a male-to-female ratio of 2.9 to 1. Age is a well-known risk factor for lung cancer, with most patient cohorts falling between 60 and 70 years of age, indicating that lung cancer predominantly affects the elderly. Nevertheless, cases have been reported in individuals under 40 years, showing distinct disease patterns, with a higher likelihood of adenocarcinoma subtype in younger age groups [10]. A common global trend in lung cancer is the noticeable gender disparity favoring males [11]. The pivotal role of smoking as the primary cause of lung cancer is widely acknowledged [12].

Our research revealed that approximately 71.6% of lung cancer patients were either current or former smokers. Among these patients, 85% were cigarette smokers, while 15% were goza smokers. Furthermore, more than half of the patients were current smokers. These findings align with previous studies indicating that over two-thirds of lung cancer cases can be linked to smoking [13].

Non-small cell lung cancer (NSCLC) was predominant in 85.6% of our patient cohort, while small cell lung cancer (SCLC) accounted for 14.4% of cases [14]. Consistent with Xie1 *et al*., who reported 85% NSCLC and 15% SCLC cases, adenocarcinoma was the most frequently diagnosed histopathological subtype of NSCLC, representing 55.4% of cases, followed by squamous cell carcinoma (26.7%) and large cell carcinoma (8.7%). This trend mirrors global data showing a decline in squamous cell carcinoma prevalence across various patient cohorts. The exact reasons for this shift remain unknown but could be attributed to changes in tobacco manufacturing practices, such as reduced tar content and improved filters, as well as increased efforts in smoking cessation programs [15].

In this study, TNM stages I, II, III, and IV were distributed as 1.2%, 12.1%, 37.2%, and 49.5% respectively. Siang *et al*. [16] presented findings from Malaysia that align with our outcomes; the majority of lung cancer diagnoses occur at advanced stages, either locally advanced or with distant metastasis, with 75-88% falling into stage III or IV. Merely around 12% of cases are identified early enough to undergo potentially curative surgical resection. Results emerging from the 2015 Korean Association of Lung Cancer Registry (KALC-R) study in South Korea, [17] involving 2,657 lung cancer patients, disclosed that TNM stages I, II, III, and IV were distributed at 21.5%, 14.4%, 35.9%, and 28.3% respectively.

Within our study, 56.8% of patients manifested lung cancer in the right lung, 33.8% in the left lung, 5.2% in the main bronchus, and 4.2% in both lungs. Li *et al*. [18] observed that 59.86% of lesions resided on the right side, 39.79% on the left side, and 0.35% bilaterally. Ibrahim *et al*. [19] communicated that the tumor site was predominantly in the upper lobe in 49.4% of instances, lower lobe in 26.6%, and main bronchus in 18.2%. Mandal *et al*. [20] documented that the right lung (60.3%) was the primary site, followed by the left lung (39.1%) and both lungs (0.6%).

In the current study, a majority of patients (70.1%) originated from El Gharbia governorate, with El Mahalla and Tanta serving as the primary cities of origin. Breast cancer emerged as the most prevalent cancer type (46.5%), with lung cancer ranking fourth (10.1%) during the research duration. The sole documented incidence rates stem from a cancer registry within a Nile Delta district (Gharbiah governorate). The most recent internal reports from this registry date back to 2002. (4) Subsequent incidence rates up to 2007 were published in Volumes IX and X of Cancer Incidence in Five Continents,(22) marking the conclusion of registry operations due to sustainability challenges. Among males, the most common cancer sites include the liver (18.7%), bladder (12.7%), non-Hodgkin's lymphoma (11.0%), and the trachea, bronchus, and lung (8.2%), collectively representing 50.6% of all male cancer cases.

Among females, prevalent sites comprise the breast (38.8%), non-Hodgkin's lymphoma (8.5%), liver (4.6%), and ovary (4.5%), accounting for 56.4% of female cancer cases. No data regarding both sexes combined are provided. Studies drawing on Gharbiah data up to 2007 are restricted to specific cancer sites and do not offer a comprehensive representation of Egypt, originating solely from a single delta governorate's registry without broader implications. The current situation of cancer at the national level [13]. The National Population-Based Registry Program of Egypt (NCRP) 2008-2011 [23, 24] documented the predominant cancers in Egypt as liver (23.81%), breast (15.41%), bladder (6.94%), Brain (5.29%), non-Hodgkin lymphoma (4.64%), and lung including trachea, bronchus tumors (4.22%). Significant associations were observed between SCLC prevalence and smoking ($p<0.001$), while such correlation was not significant for other histopathological types ($p>0.05$). Khuder [25] highlighted that all histologic types of lung cancer between 1970 and 1999 were notably linked to cigarette smoking, particularly squamous cell carcinoma (SQC) and SCLC compared to large cell cancer and adenocarcinoma. Zeng *et al*. [26] discovered that squamous cell carcinoma (39.38%) was the main lung cancer histological type among male smokers, followed by adenocarcinoma (29.85%). Conversely, among non-smokers, adenocarcinoma accounted for 53.86% and SCC for 16.64%. Among female lung cancer patients, adenocarcinoma (65.79%) was the primary histological subtype, followed by (10.21%). Mandal *et al*. [20] revealed that approximately 91.9% of squamous cell carcinoma patients had a smoking history.

The study presented the primary treatment modalities for NSCLC patients as surgery (11.4%), radiotherapy (definitive and adjuvant) (5.3%), chemotherapy (neo. Adj. and adjuvant) (21.1%), concurrent chemoradiation therapy (33.6%), and best supportive care (4.6%). Kim *et al*. [27] indicated that in NSCLC patients, surgery was performed on 47.2% of patients, followed by chemotherapy (27.9%), radiation therapy (23.7%), and concurrent chemoradiation (1.3%) post-diagnosis. In contrast, chemotherapy (69.8%) was the most prevalent treatment for SCLC patients, with 9.3% undergoing surgery and none receiving concurrent chemoradiation.

In the current study, the median overall survival (OS), locoregional recurrence-free survival (LRFS), distant metastasis-free survival (DMFS), and progression-free survival (PFS) were 16, 13, 19, and 6 months, respectively. The 2-year OS, LRFS, DMFS rates were 33.8%, 49.9%, 43.8%, respectively. Li Ma, *et al*. (30) reported that the 2-year OS, PFS, LRFS, and DMFS rates were 84.2%, 42.5%, 70.0%, and 50.9%, respectively. Komaki *et al*. [31] noted a median overall survival of 14.8 months and a 5-year survival rate of 9.5%. Tumor grade (low & intermediate vs. high, $p<0.001$), surgery (yes vs. no, $p<0.001$), pretreatment weight loss (<5% vs. >5%, $p<0.001$), response to treatment (present vs. absent, p=0.022), radical radiotherapy (yes vs. no, p=0.007), and initial treatment with concurrent chemoradiotherapy (yes vs. no, p=0.001) were identified as survival-affecting factors in multivariate analyses. These findings align with Urvay *et al*. [32], who found that performance status did not impact survival in NSCLC patients. Young age, stage IIIA, radiotherapy dosage, and concomitant chemoradiation were prognostic factors for survival in their study cohort.

Treatment with the new classes of therapy (targeted therapies) has recently become accessible for clinical application. Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs) have displayed notable efficacy in a subgroup of patients harboring an activating EGFR mutation in late-stage lung carcinoma [35]. A response rate of up to 70% has been documented with a singular EGFR TKI agent, contrasting with a 30-40% response rate from traditional platinum doublet chemotherapy. Scarce instances are documented in the body of literature where EGFR TKIs have been employed in the neoadjuvant context before definitive surgical intervention [36, 37]. Despite the robustness of the current investigation due to its extensive participant pool and a longitudinal examination spanning five years, it is not without significant limitations. To begin with, the retrospective nature of the study is susceptible to uncontrolled biases related to patient selection, referrals, and treatment regimens, potentially influenced by variations in patient access to healthcare facilities. Disparities in the staging distribution, histological characteristics, treatments, and other variables identified in the data may signal the presence of such biases, consequently impacting the variations in survival rates. Furthermore, as the data solely originates from a singular institution, the applicability of the results may be restricted, necessitating further investigations from multiple establishments to corroborate our observations. Additionally, owing to the retrospective data gathering process, we acknowledge a shortfall in the information available from medical records, particularly regarding smoking history, tobacco exposure duration, body mass indices, details on other potential risk factors like water pipe smoking, occupational exposure to potential carcinogens, or the utilization of electronic nicotine delivery systems. Finally, certain data elements that could complement or elucidate the findings are absent, such as those pertaining to the assessment of inflammatory, immunological, and metabolic markers.

Table 1: Clinical characteristics of 521 patients with lung cancer

	No.	%
Age (Years)		
<60	208	39.9
≥60	313	60.1
Mean ± SD.	60.31±10.57	
Median (Min. - Max.)	60.0 (21.0 - 88.0)	
Sex		
Male	386	74.1
Female	135	25.9
Smoking history		
Never smoker	148	28.4

Smoker/ex-smoker		373	71.6
ECOG PS			
0-1		85	16.3
2		436	83.7
Tumor grade			
Grade 1 (Well differentiated)		169	32.4
Grade 2 (Moderately differentiated)		250	48.0
Grade 3 (Poorly differentiated)		102	19.6
Pathological types			
SCLC		75	14.4
NSCLC		446	85.6
Adeno		247	55.4
Squamous		119	26.7
Large cell		39	8.7
Others		41	9.2
TNM staging	T stage		
	T1	14	2.7
	T2	142	27.3
	T3	233	44.7
	T4	132	25.3
	N stage		
	N0	65	12.5
	N1	97	18.6
	N2	216	41.5
	N3	143	27.4
	M stage		
	M0	263	50.5
	M1	258	49.5
Stage at diagnosis			
1		6	1.2
IIA		36	6.9
IIB		27	5.2
IIIA		61	11.7
IIIB		35	6.7
IIIC		98	18.8
IV		258	49.5
Site of tumor			
Right upper lobe		192	36.9
Left upper lobe		128	24.6
Right lower lobe		60	11.5
Left lower lobe		48	9.2
Right middle lobe		44	8.4
Main bronchus		27	5.2
Both lung		22	4.2
Pretreatment weight loss			
<5%		449	86.2
>5%		72	13.8

Table 2: Relation between history of smoking and pathological types

Pathological types	Smoking				χ^2	P
	Smoker (n = 373)		Nonsmoker (n = 148)			
	No.	%	No.	%		
Small cells carcinoma	75	20.1	0	0.0	34.763*	<0.001*
Adenocarcinoma	168	45.0	79	53.4	2.955	0.086
Squamous cell carcinoma	76	20.4	43	29.1	4.528*	0.033*
Large cell carcinoma	23	6.2	16	10.8	3.301	0.069
Others	31	8.3	10	6.8	0.353	0.552

Table 3: Multivariate COX Regression analysis of prognostic factors affecting OS

	Sig.	HR	LL - UL 95%C.I
ECOG PS (≥3)	0.046*	1.308	1.005 - 1.702
Pathological (High grade)	0.006*	1.430	1.109 - 1.845
Surgery	<0.001*	0.102	0.060 - 0.172
Pretreatment weight loss (>5%)	0.317	1.203	0.837 - 1.730
Brain metastases	0.697	1.058	0.798 - 1.403
Disease stage (Advanced)	0.089	1.556	0.935 - 2.589
Non responder	0.002*	1.516	1.168 - 1.967

Radical radiotherapy	0.011*	0.341	0.148 - 0.784
Neo. Adj. CTH	0.620	1.090	0.774 - 1.536
Adj. CTH	0.682	0.935	0.680 - 1.288
CCRTH	<0.001*	0.205	0.159 - 0.265
SCLC	<0.001*	2.204	1.500 - 3.237

Table 4: Multivariate COX Regression analysis of prognostic factors affecting DFS

	Sig.	HR	LL - UL 95%C.I
Pathological (High grade)	0.038*	2.895	1.061 -7.900
Pretreatment weight loss (>5%)	0.847	0.902	0.319 - 2.552
Neo. Adj. CTH	0.028*	2.072	1.083 - 3.965
SCLC	0.282	1.553	0.696 - 3.464

Conclusion

Lung cancer remains a significant public health concern globally, particularly among men, and is a leading cause of cancer-related morbidity and mortality. Our study's clinicoepidemiological investigation in Egypt highlights several critical aspects of lung cancer. The median age of patients was 60 years, predominantly affecting older adults, with a marked male predominance. Smoking was identified as a primary risk factor, with a substantial proportion of patients being current or former smokers, primarily cigarette smokers.

Non-small cell lung cancer (NSCLC) was the most common type, with adenocarcinoma being the predominant histopathological subtype. Our findings also indicated that the majority of lung cancer cases were diagnosed at advanced stages, reflecting the global trend and underscoring the need for early detection efforts.

Geographically, the majority of patients in our study were from the El Gharbia governorate, with significant associations between smoking and small cell lung cancer (SCLC). Treatment modalities varied, with concurrent chemoradiation therapy being a common approach for NSCLC patients, while chemotherapy was prevalent for SCLC patients. Survival rates in our cohort were lower compared to some international data, indicating potential areas for improvement in treatment and early detection.

Despite the strengths of our study, including a large participant pool and a longitudinal approach, limitations such as the retrospective design and single-institution data highlight the need for broader, multi-institutional studies. Future research should aim to address these limitations and explore additional risk factors and biomarkers to enhance our understanding and management of lung cancer.

Overall, our study contributes valuable insights into the epidemiology, risk factors, and clinical characteristics of lung cancer in Egypt, emphasizing the critical need for enhanced early detection, targeted therapies, and comprehensive national cancer registries to improve patient outcomes.

Conflicts of interest

There are no conflicts of interest.

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