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Rapid oncological diagnosis of lung cancer: specific facility experience

Abstract

Introduction: In order to improve diagnosis procedure by public health service, an organizational solution called Rapid Oncological Path has been introduced. The introduction of this program caused criticism of the medical community, and state control authorities showed irregularities in its functioning in medical clinics. Its aim was to assess this process among lung cancer patients hospitalized in in our center, in the period of 9 months.

Material and methods: After the analysis of imaging tests, the patients were qualified for invasive tests (bronchoscopy, EBUS). Patients with histopathological diagnosis of NSCLC were subjected to molecular diagnostics. After completing the diagnosis and establishing the final diagnosis, the patient's forfeiture was presented at the clinical meeting.

Results: The analysis involved 209 patients who had a an oncological card (DILO) issued. 156 patients were diagnosed with lung cancer and qualified for the consulate. Among the histopathological types, NSCLC dominated — 80%. SCLC was 17% of the types. By the decision made on medical case conference, 135 patients have been qualified for casual treatment, among others 12% surgical treatment; 47% chemotherapy, 18% radiotherapy; 8% chemo-radiotherapy. An average waiting time for diagnosis process to begin, after DILO card has been issued was 16.33 (± 18.78) days, an average hospitalization and diagnosis time was 9.16 (± 6.61) days. Around 31.3 (± 14.93) days on average have passed from the start of diagnostical hospitalization until beginning of the causal treatment.

Conclusions: In a multi-specialist center, it is possible to develop a care model for lung cancer patients, consistent with Rapid Oncological Path.

Key words: rapid oncological diagnosis, lung cancer, DILO card (diagnosis and oncological treatment card)

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Introduction

Lung cancer is the most common type of tumour (1.2 million incidences per year). It occurs mainly among men; the highest estimated rate of occurrence is noted in Central and Eastern Europe (53.3/100,000) and in East Asia (50.4/100,000) [1]. In highly developed countries, lung cancer is the main cause of death among oncological patients [2]. In Poland, 21 556 people were diagnosed with lung cancer in 2013. It amounts to 14% of all malignant tumours noted in the country, making it the most commonly diagnosed oncological disease in Poland.

Cancerous diseases constitute the second most common cause of death among Polish people. Among these, lung cancer is ranked in the first place (24% deaths of oncological causes), right before colorectal cancer (7.6%) and breast cancer (6.2%). It is also noticeable that death rate among patients of both sexes in Poland exceeds the average rate of all European Union countries (20.6% for women and 56.4% for men). A standardised rate for 5- year survival of lung cancer throughout last decade is up to 13.4% [3].

The effectiveness of lung cancer therapy depends mainly on the primary clinical stage of the disease as well as on histopathological type of the tumour. In Poland, lung cancer is rarely recognised at an early stage. 80% of patients have been diagnosed at the 3rd or 4th stage of the disease.

In order to improve the diagnostic procedure and start the treatment, the Rapid Oncological Path has been introduced. It is an organisational

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solution that aims at leading the patient through respective diagnosis and treatment stages. It is dedicated to all patients that are suspected to have a malignant tumour or are diagnosed with it [4]. This programme has been launched on January 1st, 2015.

The introduction of amendments to the Act on healthcare services financed from public funds and certain other acts (Journal of Laws 2018 item 1532) [5] (introducing the oncology and queue package) caused a number of comments and doubts in the medical environment. The top state audit body (NIK — the Supreme Audit Office), during the activities checking the functioning of the programme in healthcare facilities, pointed out numerous errors [6, 7].

The oncological package has been introduced in the Department of Internal Diseases, Pneumology, Allergology and Clinical Immunology of the Military Institute of Medicine on July 1st, 2016.

It was focused on the assessment of rapid oncological diagnosis procedures in frames of "Oncological Package" among lung cancer patients who were hospitalised in the Department between July 1st, 2016 and March 3rd, 2018.

Material and methods

During the research period, a group of 209 patients has been diagnosed, including 136 men and 73 women, 68 ± 10 of age (SD).

CT or analysis of provided results has been performed for each patient. Further diagnosis was implemented based on those results, aiming at a collection of tissue material. It was gathered by invasive diagnostic methods: forceps biopsy *via* bronchoscopy, transbronchial biopsy during endobronchial ultrasound (EBUS); lung biopsy monitored by USG or CT. Molecular diagnosis has been performed on patients with histopathological recognition of non-small cell lung cancer (adenocarcinoma, carcinoma NOS (not otherwise specified), large cell carcinoma (LCC): the presence of EGFR mutations (epidermal growth factor receptor); rearrangement of the ALK gene (anaplastic lymphoma kinase) and in the case of the negative ones, test for the evaluation of PD-L1 expression [8]. Molecular studies were performed at the Department of Genetics and Clinical Immunology at the National Institute of Tuberculosis and Lung Diseases in Warsaw.

Once the diagnosis was finished and final recognition established, a particular case has been presented during a clinical assembly (medical case conference, interdisciplinary group of specialists consisting of an oncologist, radiotherapist, cardiothoracic surgeon, radiologist, pneumologist) in order to define further treatment.

Basic statistical descriptive methods determining average values and standard deviation (SD) for patients' age and specific dates of respective diagnosis stages, have been used in the analysis. Moreover, a percentage value for each histopathological type of cancer has been established.

The survival rate based on the disease's stage and type of treatment applied has been determined with the Kaplan-Meier estimator. Statistical significance of differences between the groups in survival was calculated with the log-rank test. In our analysis, p-value below 0.05 was a cutoff for statistical significance.

Descriptive statistics and testing of hypotheses were used for the analysis using STATISTICA software (StatSoft Inc,version 12).

Results

Two hundred and nine patients with diagnosis and an oncological treatment card (DILO) have been analysed. One hundred twenty and two cards have been issued by family doctors. Nine of the cards have been issued by specialists from the Pulmonology Clinic and 79 of them in the hospital.

For 53 patients, the card has been closed due to: death (13 cases); normal medical image of CT of chest (10 cases); focal abnormalities without any symptoms of tumour (29 cases); congenital defect (pulmonary sequestration) (1 case).

One hundred fifty and six patients have been diagnosed with lung cancer and qualified for medical case conference (including 102 men 69 ± 10 of age [SD] and 54 women 68 ± 8 of age SD).

Non-small cell lung cancer (NSCLC) was the most common of all histopathological types — 80% (124 patients). Small cell lung cancer (SCLC) type constituted 17% of all the 27 patients. The remaining 1% of histopathological types are: metastatic carcinoma — anaplastic breast cancer (2 cases); mixed cancer — NSCLC and SCLC (2 cases) and undefined (1 case).

Based on numerous clinical data, lung cancer patients have been defined and assigned to specific disease stages:

— 1st stage: 17 patients (11%),
— 2nd stage: 12 patients (8%),
— 3rd stage: 57 patients (36%),
— 4th stage: 70 patients (45%).

Table 1. Histological subtypes of lung cancer of the studied group

Lp.	Histological subtypes of lung cancer	Number of cases (% of total)
1	Squamous cell carcinoma	61 (49%)
2	Adenocarcinoma	48 (39%)
3	Non-small cell cancer — unspecified	6 (5%)
4	Carcinoma NOS (not otherwise specified)	5 (4%)
5	Neuroendocrine carcinoma	4 (3%)

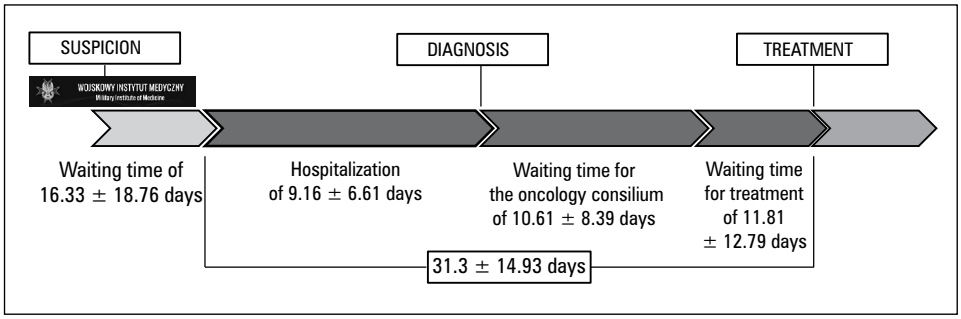

Figure 1. Diagnostic path time

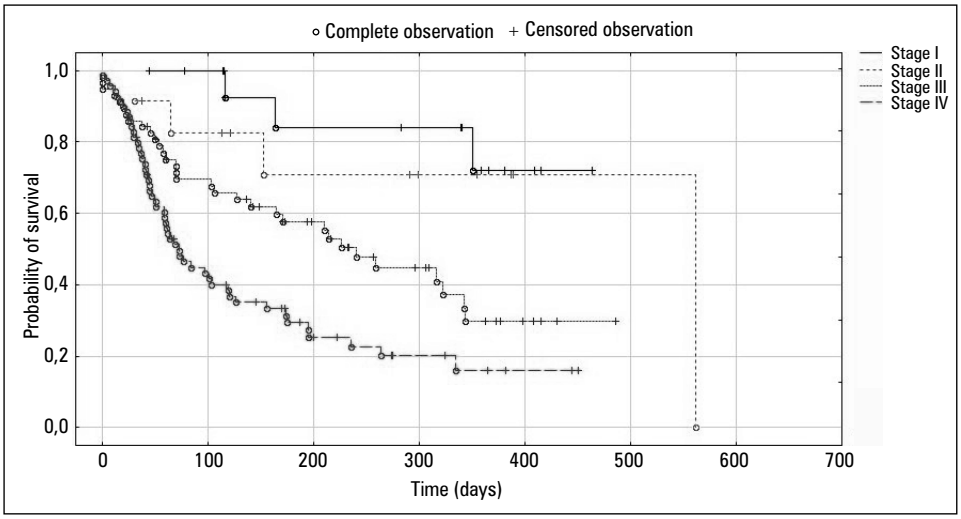

Figure 2. Estimated survival curves for stage I, stage II, stage III and stage IV patients with lung cancer (p-value 0.00001, log-rank test)

Histological subtypes of lung cancer of the studied group are shown in Table 1.

A molecular lung cancer diagnosis for EGFR gene mutation, rearrangement of ALK gene and expression of PD-L1 have been performed. In none of the above cases was the mutation confirmed.

135 patients have been qualified for casual treatment, basing on the decision made at the medical case conference. Among others:

— 19 patients for a surgery (12%),
— 74 patients for chemotherapy (19%),
— 29 patients radiotherapy (19%),
— 13 patients chemo-radiotherapy (8%).

Twenty one subjects have been disqualified from casual treatment and qualified for palliative therapy instead.

An average (SD) waiting time for the diagnosis process to begin, after DILO card has been issued was 16.33 ± 18.78 days. The average (SD) hospitalisation and diagnosis time was 9.16 ± 6.61 days. Around 31.3 ± 14.93 days on average (SD) have passed from the start of diagnostic hospitalisation until the beginning of the causal treatment (Fig. 1).

Patients' survival time, based on the disease stage and applied treatment, has been analysed: survival time from the moment of diagnosis: me-

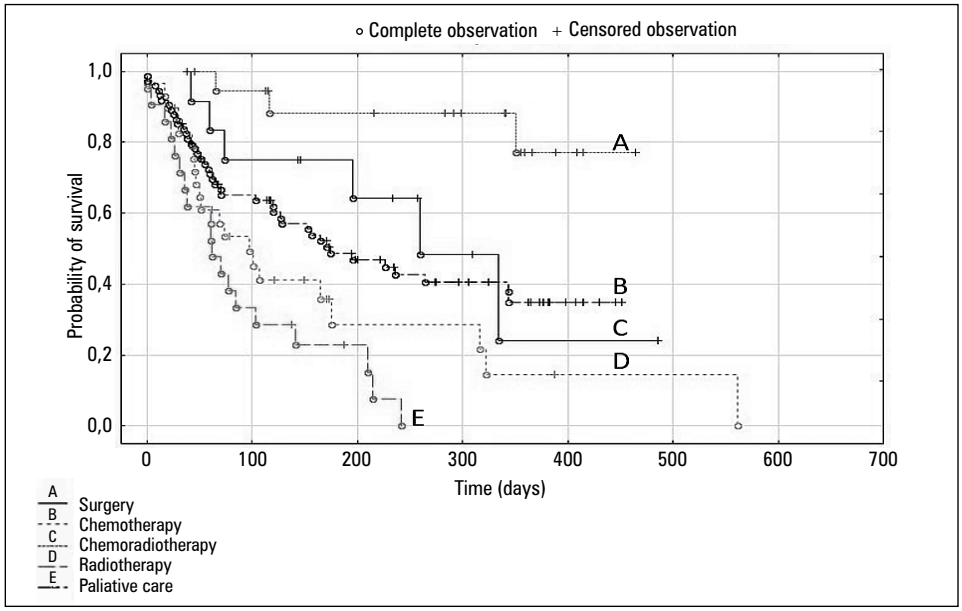

Figure 3. Estimated survival curves for patients with lung cancer depending on the type of treatment (p-value 0.0003, log-rank test)

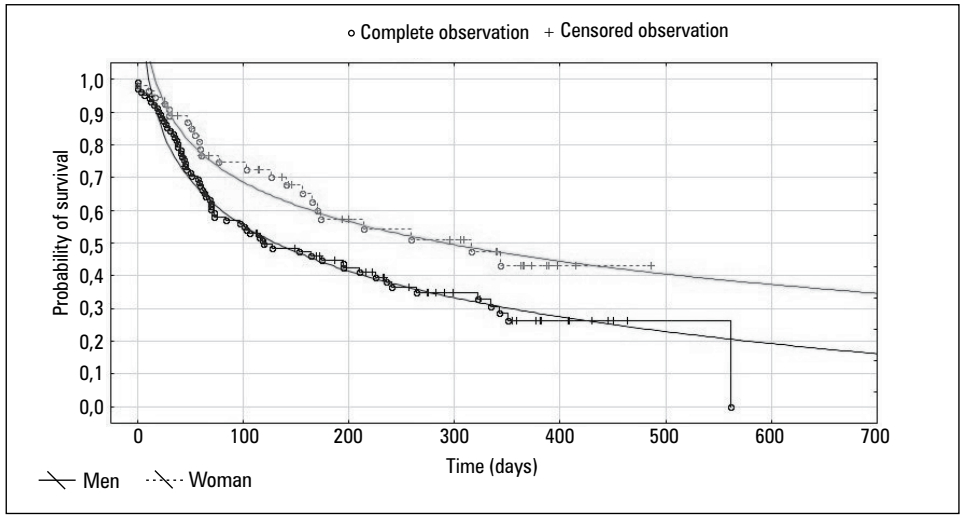

Figure 4. Gender-specific survival probability curves for non-small cell lung (p-value 0.029, log-rank test)

dian 118 days, IQR 223.5. The longest survival time was observed in case of 1st stage patients, and the most effective type of treatment was a surgery: average survival median 340 days; IQR 250. Median survival for women was 144.5 days (IQR 257) and for men 109.5 days (IQR 193). Estimated 1-year survival time for men: 29.34%, for women: 46.06% (Figs 2–4).

Discussion and conclusions

It has been estimated, taking demographic processes into consideration exclusively, that between 2016 and 2029 the number of patients diagnosed with lung cancer will increase in Poland from 180 300 to 213 100 (18%). The most rapid growth will be observed in wielkopolskie voivodship [10] (22.3%), pomorskie (22.3%), podkarpackie (22.2%) and małopolskie (21.8%). The smallest growth, on the other hand, will be noticed in łódzkie (11.6%) and śląskie (13.4%) voivodships [9]. Malignant lung tumour will be the most common type of cancer in 2029. Simultaneously, the costs of treatment of lung cancer patients grow methodically. Between 2005 and 2014, the expenses of the National's Health Fund (NFZ) on patients starting their lung cancer treatment had been growing. In 2015, NFZ spent more than 48.1 million PLN for medicine packages for non- small lung cancer patients, which consti-

tuted only 3.74% of expenses for all medicine packages for oncological diseases [10].

Introducing the DILO card by the legislator was aimed to improving conditions of patients suspected of cancer or diagnosed with it within the healthcare system. Thanks to the card, the diagnosis procedure and oncological treatment are meant to be clearly defined and the patient is entitled to complex medical care during every stage of the disease [11].

Within this medical package, maximum waiting time in terms of each stage of patients' treatment has been defined (35 days for initial diagnosis, 28 days for further one, 14 days for medical case conference and beginning of the treatment) [11].

Analysis of the diagnosis and treatment conducted by the Watch Health Care Foundation (WHC) assessed that for patients with a DILO card, it takes approximately 8.7 weeks (2.2 months) between the moment the cancer has been recognised and the beginning of the palliative radiotherapy. In the previously researched period (September 2016), time designated for initial and further diagnosis for patients with a DILO card was approximately 5.8 weeks, which is a 2.9-week decrease. 14 days is a period defined by the Ministry of Health as time for performing the first surgery since the medical case conference. In case of lung cancer patients with a DILO card, 2.7 weeks is the waiting time for the surgery, and molecular disease-specific treatment takes up about 1 week. Overall waiting time does not exceed the limit of 7 weeks defined by the Ministry of Health [12].

Within the analysed group, an average (SD) time between the beginning of hospitalisation and the beginning of the casual treatment (oncological treatment) was determined as 31.3 ± 14.93 days (4.5 weeks). Once again waiting time does not exceed the limit of 7 weeks defined by the Ministry of Health.

NFZ data have shown that in 2017 there were 9589 institutions providing medical services based on a DILO card. A high number of available facilities such as this increases the accessibility of these kind of services, but at the same time, it disperses diagnosis process and treatment between numerous facilities. It makes proper monitoring of service quality and coordination of the process more complicated [10].

Correlation of time limits within the oncological package adjusted to fit with the patient's actual path; shows why meeting the deadlines of each stage defined by the oncological package regulations does not necessarily have to result in shortening a real waiting time from suspicion to treatment. Within the package, keeping the time limits is mandatory only with regard to specific stages of diagnosis and treatment. Within those limits, time is measured from the moment the patient was placed on the waiting list. The time between stages is not taken into consideration. This restriction also refers to the beginning of the "path". It means that some time might pass from the moment the card has been issued by the specialist (in case of disease suspicion) to the moment the patient is entered on the initial diagnosis waiting list. The beginning of the treatment within the oncological package does not have to equal a surgery, application of medications or radiotherapy. This package also includes a medical consultation — some other operations might be performed then, among others: a consultation with further preparation or treatment planning [13].

A full-time control on every stage was performed within a group of patients diagnosed and treated in the Military Institute of Medicine. It resulted in a realisation of all diagnostic procedures as well as the implementation of casual treatment in a significantly shorter period of time than the one originally estimated (4.5 weeks). It indicates the need for development of multi-speciality cancer centres and their promotion in the public healthcare system.

An alternative solution is the introduction of coordination between service providers who execute only some parts of the diagnostic "path" by, e.g., imposing obligation to lead the patient through the whole "path" of diagnosis. It is also essential to take responsibility for oncological patients in case any treatment complications occur. Those patients are most often left on their own, and it is difficult for them to function in the healthcare system.

Implemented diagnosis and treatment must be also analysed in terms of their effectiveness. One of the parameters that might be applied is based on survival rate or number of repeated hospitalisations, due to ineffective diagnosis (neoplasms of uncertain behaviour and unspecified sites of middle ear, respiratory system and chest organs). In 2017, in the study authors' center, 19% of oncological patients have been repeatedly hospitalised due to ineffective lung cancer diagnosis (Table 2).

The rate of repeated hospitalisation in Poland differs depending on the region. It happens most often in wielkopolskie voivodship (49%) and the least often – in kujawsko-pomorskie (20%). On average, 32% of patients with suspicion or

Table 2. Analysis of hospitalization codes

CD-10 Diagnosis Codes	2015	2016	2017
C34	49	50	105
D38	301	232	200
Sum	350	282	305
Second hospitalizations	81	88	59

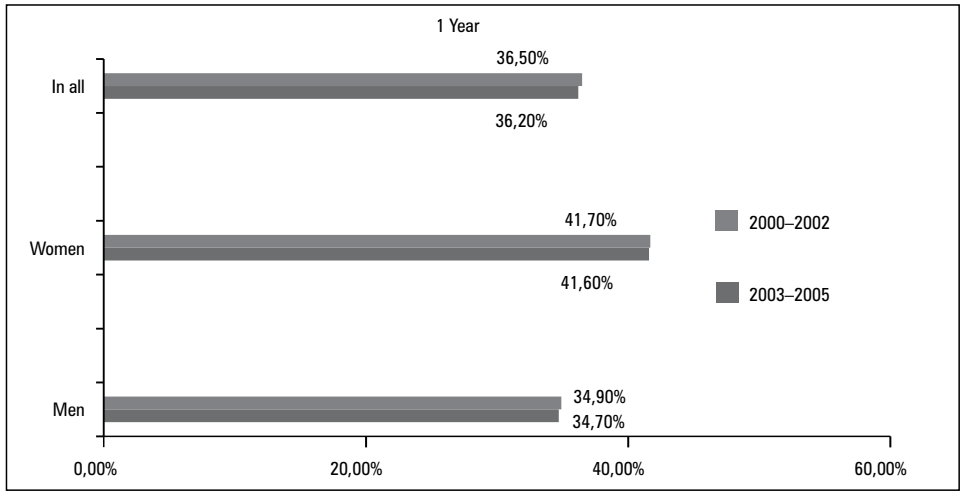

Figure 5. Indicators of 1-year relative survival in patients with lung cancer in Poland [3]

diagnosis of lung cancer has been hospitalised twice in 2014 [10].

Among patients who have been diagnosed with lung cancer between 2000 and 2001, 1-year survival rate was 34.7% for men and 41.6% for women. Between 2003 and 2005 this rate was at the level of 34.9% for men and 41.7% for women (Fig. 5).

In the examined group, the tendency was similar — survival rate was higher for women and lower for men.

Lung cancer is a growing problem not only in Poland. The risk of cancer can be reduced by influencing carcinogenic factors that can be modified. The most influential factor is smoking. Smokers are about 15–30 times more prone to get a cancer [14]. Third-person exposure (passive smoking) also increases the risk of lung cancer [15]. Implementation of prevention actions (banning advertisements, raising cigarette prices) that result in decrease of smoking rate, especially among the youth, could influence society's health [14]. Also, damaging habits can also be substituted with less harmful ones (e.g. replacing cigarettes with e-cigarette) [16].

Considering worsening air quality (heavy metals) and its documented effect on respiratory system diseases, including its impact on carcinogenesis, it is important to take up actions aimed at the protection of the environment and limitation of air pollution [16, 17].

Despite the fact that the oncological package has existed for 3 years now, it is still subject to varied opinions. The Ministry of Health claims it has improved diagnosis and treatment procedures, but the medical community expresses its doubts and indicates bureaucracy problems as well as the fact that the situation of patients has not been improved [18, 19].

The authors' experience corresponds with the Supreme Audit Office's report and shows that it is possible to develop a care model for lung cancer patients, consistent with the Rapid Oncological Path. Also, making treatment more personalised will give patients a sense of security at every stage of the disease [7].

Conflict of interest

The authors declare no conflict of interest.

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