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Cost-effectiveness analysis of advanced stage non-small cell lung cancer treatment with cisplatin–vinorelbine and carboplatin–gemcytabine combination regimens

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Objectives. The aim of the work is to perform an incremental cost-effectiveness analysis of cisplatin–vinorelbine (PN) and carboplatin–gemcytabine (KG) treatment regimens used in advanced stage non-small cell lung cancer (NSCLC) treatment.

Material and methods. Medical records of 99 patients with advanced stage NSCLC were collected retrospectively at the Oncology Center in Bydgoszcz. The patients were treated with one of the regimens to be analysed between 2006 and 2011. The analysis was performed from the payer's perspective. Only direct medical costs were analysed. Costs of procedures were obtained from the hospital's price list of medical services as of June 30th, 2012. Incremental and one-way sensitivity analyses were performed.

Results. The average cost of chemotherapy treatment with the PN treatment regimen is higher than that with the KG treatment regimen (25,342.04 PLN and 19,546.80 PLN per patient, respectively). The average survival time of NSCLC patients treated with PN and KG treatment regimens was 12.91 and 10.11 months, respectively. The cost of drugs constitutes the largest part of the total cost of NSCLC treatment with either treatment regimen. The incremental cost-effectiveness ratio (ICER) is 24,836.76 PLN per additional life-year gained.

Conclusion. The analysis showed that the PN treatment regimen is more cost-effective in the treatment of advanced NSCLC, when compared to the KG treatment regimen.

Analiza efektywności kosztów leczenia chorych na zaawansowanego niedrobnokomórkowego raka płuca chemioterapeutykami zawierającymi cisplatynę–winorelbinę oraz karboplatynę–gemcytabinę

Cel pracy. W pracy porównano koszty i efekty dwóch alternatywnych chemioterapii opartych na schematach cisplatyna/winorelbina (PN) oraz karboplatyna/gemcytabina (KG) stosowanych w leczeniu zaawansowanego niedrobnokomórkowego raka płuca (NDRP).

Materiał i metody. Koszty oszacowano retrospektywnie na podstawie historii chorób 99 pacjentów leczonych w Centrum Onkologii w Bydgoszczy w latach 2006–2011. Analizę przeprowadzono z perspektywy płatnika. Analizowano jedynie bezpośrednie koszty medyczne. Punktem czasowym określenia cen był czerwiec 2012 r. W pracy zastosowano analizę efektywności kosztów, obliczono inkrementalny współczynnik efektywności kosztów (IWEK) oraz wykonano jednokierunkową analizę wrażliwości.

Wyniki. Droższą metodą i jednocześnie bardziej skuteczną okazał się schemat PN. Średni koszt leczenia jednego pacjenta schematem PN wyniósł 25 342,04 PLN, a średni czas przeżycia — 12,91 miesiąca. Średni koszt leczenia jednego pacjenta wg schematu KG wyniósł 19 546,80 PLN, a średni czas przeżycia — 10,11 miesiąca. Głównym składnikiem

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kosztów całkowitych w obu schematach jest koszt leków. Wynik przeprowadzonej analizy inkrementalnej przedstawiony w postaci IWEK informuje, że dodatkowy rok życia pacjentów z zaawansowanym NDRP leczonych droższym, ale skuteczniejszym schematem (PN), kosztuje 24 836.76 PLN.
Wnioski. Z przeprowadzonych badań wynika, że stosowanie schematu PN jest strategią bardziej efektywną kosztowo.

Key words: non-small cell lung cancer, cost-effectiveness analysis, cisplatin, vinorelbine, carboplatin, gemcytabine
Słowa kluczowe: rak płuca, analiza efektywności kosztów, cisplatyna, winorelbina, karboplatyna, gemcytabina

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Introduction

Lung cancer is the most common neoplasm in the world. Approximately 1.2 million new cases and 1.1 million deaths are recorded annually. In the last 60 years, the death rate caused by this disease has increased thirty times [1, 2]. In Poland, there are over 20 000 registered cases of people diagnosed with lung cancer every year, of which 80% are diagnosed with non-small cell lung cancer (NSCLC) [3]. The majority of patients are diagnosed with advanced stages of the disease (stage IIIA, IIIB or IV), and 50–55% of patients are diagnosed with metastatic NSCLC. These patients cannot be treated with radical surgery [4]. Due to late recognition of the disease, the majority of patients receive only symptomatic and palliative treatment. Patients are treated with chemotherapy in the advanced stages of the disease to relieve cancer complaints. More advanced stages of cancer are often the result of poor prognosis and require higher costs of treatment.

Due to increasing costs of the NSCLC treatment, many pharmacoeconomic analyses are used to determine the most optimal therapy for cancer. Conducting a pharmacoeconomic analysis to select the most health-effective and financially efficient method of treatment is therefore crucial to effectively manage a limited healthcare budget [5].

Treatment regimens used in NSCLC differ in toxicity, health benefits and cost [6, 7], therefore a pharmacoeconomic analysis of alternative regimens has to be performed in order to find an optimal therapy, which is the one that is the most cost-effective, cures NSCLC most effectively and has the least undesirable effects.

In this work we perform a comparative study of two alternative chemotherapy regimens: cisplatin–vinorelbine (PN) and carboplatin–gemcytabine (KG), both of which are used to treat advanced stage NSCLC in the Oncology Center in Bydgoszcz. Both gemcytabine and vinorelbine have proved to be effective drugs in the treatment of lung cancer. However, there are few sources on the incremental analysis of the PN and KG treatment regimens used to treat NSCLC [8]. Therefore, the aim of the analysis is to establish which of the two regimens is a better method of treatment for NSCLC, in terms of its cost and health effects.

Material and methods

99 medical records of patients treated at the Oncology Center in Bydgoszcz between 2009 and 2011 were used in the analysis. There were three conditions that determined whether a patient was to be included in the analysis. He/she was:

— histopathologically diagnosed with NSCLC,
— diagnosed with cancer in one of the following stages: inoperable IIIA, IIIB, or IV,
— treated with a combination of first-line drugs: either PN or KG.

50 patients (35 male and 15 female) were treated with the PN regimen. The median age of those patients was 58 years. In the second group of patients there were 49 people (27 male and 22 female) who were treated with the KG regimen. Their median age was 60 years.

4 patients treated with the PN regimen (8% PN group) and 4 patients treated with the KG regimen (8% KG group) were diagnosed with inoperable stage III A cancer. 22 patients treated with the PN regimen (44% PN group) and 14 patients treated with the KG regimen (29% KG group) were diagnosed with stage III B cancer. 24 patients treated with the PN regimen (48% PN group) and 31 patients treated with the KG regimen (63% KG group) were diagnosed with stage IV cancer.

The cost-effectiveness analysis was performed from the payer's perspective. Individual costs that constitute the total cost of NSCLC treatment were determined in a contract made between the Oncology Center in Bydgoszcz and the NHF. The price of drugs was taken from the drug price list of the hospital pharmacy at the time of writing this work (June 2012). Therefore, the analysis did not consider any discounting of costs. Only the direct medical costs of treatment were analyzed. The analysis of the total cost was measured from the first chemotherapy cycle, and consisted of calculating the costs of drugs, radiotherapy, hospitalization, ambulatory treatment, diagnostic tests, medical examinations and treatment of hematologic complications.

The cost-effectiveness of NSCLC treatment was expressed in terms of incremental cost per additional life-year gained. Survival time was measured from the moment a patient started their chemotherapy treatment. Information

Tabela I. The components of the total cost of advanced stage NSCLC treatment in the PN and KG groups

Source of costs	PN			KG		
	Cost (PLN)	Average/patient (PLN)	% of total cost	Cost (PLN)	Average/patient (PLN)	% of total cost
Drugs	432 072,66	8 641,45	34,10	356 390,01	7 273,27	37,21
Radiotherapy	309 036,00	6 180,72	24,39	195 416,00	3 988,08	20,40
Hospitalization	229 632,00	4 592,64	18,12	183 664,00	3 748,24	19,18
Ambulatory	106 704,00	2 134,08	8,42	100 152,00	2 043,92	10,46
Diagnostics	139 531,20	2 790,62	11,01	85 130,80	1 737,36	8,89
Hematologic complications	7 868,14	157,36	0,62	1 057,68	21,59	0,11
Medical consultations	42 257,80	845,16	3,34	35 982,90	734,34	3,75
TOTAL	**1 267 101,80**	**25 342,04**	**100,00**	**957 793,39**	**19 546,80**	**100,00**

about the death of patients was collected from the National Cancer Registry of Poland. The average survival time was calculated by analyzing the date of death of 28 patients from the PN group and of 20 patients from the KG group.

A cost-effectiveness analysis was performed by calculating the incremental cost-effectiveness ratio (ICER). ICER is an equation that measures the difference in costs and health effects of two or more analyzed treatment regimens.

A one-way sensitivity analysis was performed to determine how a change in individual costs that constitute the greatest share of the total cost of NSCLC treatment would affect the result of the incremental analysis.

Results

A detailed list of all the components of the total cost of treatment of advanced stage NSCLC in each analyzed group is shown in table I.

Drug costs constitute the largest share of the total cost of advanced stage NSCLC treatment, regardless of the regimen used (34.10% and 37.21% of the total cost of treatment when the PN and KG treatment regimen is used, respectively). Table II lists all the component costs of the total pharmacotherapy cost in each analyzed group, which are the costs of: the first and subsequent chemotherapy lines, cytostatic drugs preparation, infusion liquids, and drugs used to treat undesirable effects.

The doses of regimen PN are cisplatin 75–100 mg/m^2 day 1, vinorelbine 25–30 mg/m^2 day 1, 8 of a cycle repeated every 21 days. Due to frequently-observed severe side effects in patients, the cisplatin dose was often reduced. The actual average daily cisplatin dose in one chemotherapy cycle was 153.38 mg per patient, and that of vinorelbine was 90.62 mg per patient. Six patients had poor cisplatin tolerance, so it was replaced with a less toxic drug, namely carboplatin. Each of those six patients received a carboplatin dose of between 230 and 350 mg/m^2.

The doses of regimen KG are carboplatin 300––350 mg/m^2 or by rule Calverta AUC 6, day 1, gemcytabine 1000–1250 mg/m^2 day 1, 8 of a cycle repeated every 21 days. The dose was often reduced due to the bad general condition of the patients. The carboplatin dose was personalized and depended on the individual patient's creatinine clearance. The actual average carboplatin dose in one chemotherapy cycle was 500.53 mg per patient, and that of gemcytabine was 3045.63 mg per patient. The rest period between each cycle of chemotherapy treatment with either regimen was 21 days. Patients had an average of between 2 and 6 cycles of treatment.

In case of early recurrence or resistance to first-line chemotherapy treatment, patients received second and/or subsequent lines of chemotherapy. In total, patients from the PN group were treated with 37 different chemotherapy cycles, and patients from the KG group were treated with 23 different chemotherapy cycles. The most frequently administered drugs in subsequent lines of chemotherapy were docetaxel, erlotynib, and pemetrexed. The cost of the second and subsequent lines of chemotherapy is high and has a significant impact on the total cost of pharmacotherapy, regardless of whether a patient was treated with the PN or KG combination regimen as the first line of chemotherapy (tab. II). Moreover, costs of subsequent lines of chemotherapy with the PN treatment regimen are higher than those of subsequent lines of chemotherapy with the KG treatment regimen, due to a more frequent use of the former method of treatment. Some of the possible reasons for the more frequent use of subsequent lines of chemotherapy with the PN, as opposed to with the KG, treatment regimen could be a poor response to the former treatment regimen, or a good general condition of patients from the PN group, which allows them to be treated with more cytostatic drugs.

Table II shows that the costs of preparation of cytostatic drugs used in the PN and KG treatment regimens are comparable. The cost of pharmacotherapy (which includes the costs of drugs used to reduce adverse effects of NSCLC treatment, adjunctive drugs, and infusion fluids) constitutes a small share of the total cost of drugs in both treatment

Table II. The components of the total pharmacotherapy cost in the PN and KG groups

DRUGS			Cost (PLN)			
			PN		KG	
			Total	Average/Patient	Total	Average/patient
CHEMOTHERPY	Cytostatics of 1st line	Cisplatin vial 100 mg — 70,20 PLN	17 958,56	359,17	–	–
		Vinorelbine vial 50 mg — 79,38 PLN	25 463,52	509,27	–	–
		Carboplatin vial 450 mg — 85,10 PLN	822,63	16,45	16 902,56	344,95
		Gemcytabine vial 1000 mg — 54,43 PLN	–	–	29 673,60	605,58
	Cytostatics of subsequent chemotherapy		339 639,05	6 792,78	271 584,80	5 542,55
	Compounding of cytostatics		35 880,98	717,62	31 207,77	636,89
PHARMACOTHERAPY OF ADVERSE DRUG REACTION	Analgetic		413,34	8,27	295,68	6,03
	Antiemetic		2 305,50	46,11	1 766,99	36,06
	Antidiarrheal		4,13	0,08	0,39	0,01
	Laxative		42,70	0,85	21,81	0,45
	Diastolic		18,75	0,38	-	-
	Antitussive		159,04	3,18	99,4	2,03
	Expectorants		17,12	0,34	-	-
	Anticoagulants		484,46	9,69	895,11	18,27
	Antihaemorrhagics		101,23	2,02	75,70	1,55
	Psychotropics		55,56	1,11	71,60	1,46
	Other drugs		6 468,96	129,38	3 419,60	69,79
Infusion fluids			2 237,13	44,75	375,00	7,65
TOTAL			**432 072,66**	**8 641,45**	**356 390,01**	**7 273,27**

regimens. Almost six times more infusion fluids were used in the PN treatment regimen, mainly due to the necessity of body rehydration and prevention of cisplatin-induced nephrotoxicity.

Radiotherapy constitutes a significant share of the total cost of the advanced stage NSCLC treatment in both of the analyzed groups, and was administered in addition to chemotherapy treatment, or to treat the side effects of an unsuccessful chemotherapy treatment. The total cost of radiotherapy in the KG group amounts to 195 416.00 PLN (3 988.08 PLN/patient) and is significantly lower than in the PN group, which amounts to 309 036.00 PLN (6 180.72 PLN/patient). The difference in the total radiotherapy cost between the two analyzed groups is the result of the higher total number of radical radiotherapy cycles which patients from the PN group received, and also due to the higher cost of this, as opposed to the palliative radiotherapy cycle.

The cost of hospitalization includes "hotel" costs. Patients were admitted to hospital to receive radiation therapy, cytostatic drugs, or due to the patient's bad general condition. The total length of hospital stay of patients from the PN group was longer than that of patients from the KG group.

The total length of hospital stay of patients from the PN group was 450 days, 272 of which they spent on the Chemotherapy Ward, and 178 of which they spent on the Radiotherapy or Brachytherapy Ward. The average length of hospital stay was 9 days per patient from the PN group.

The total length of hospital stay of patients from the KG group was 365 days, 204 of which they spent on the Chemotherapy Ward, and 161 of which they spent on the Radiotherapy or Brachytherapy Ward. The average length of hospital stay was 7.45 days per patient from the KG group.

The cost of ambulatory treatment constitutes a large part of the total cost of the NSCLC treatment (8.42% and 10.46% of the total cost of treatment with the PN and KG treatment regimen, respectively). The cost of diagnostic tests also constitutes a large part of the total cost of the NSCLC treatment (11.01% and 8.89% of the total cost of treatment with the PN and KG treatment regimen, respectively). The cost of ambulatory care services included the costs of diagnostic procedures and cytostatic drug administration. The cost of ambulatory care was similar in both groups.

Diagnostic tests are divided into laboratory and imaging tests. The total cost of diagnostic tests was higher in the

Table III. The costs of individual diagnostic tests in the analyzed groups

Type of test	Average price (PLN)	PN		KG	
		Total cost (PLN)	Average cost/patient (PLN)	Total cost (PLN)	Average cost/ patient (PLN)
Laboratory					
Hematology	9,43	6 934,00	138,75	7 570,00	154,48
Biochemistry	6,42	11 545,50	230,84	11 924,00	243,38
Immunology	10,00	20,00	0,40	10,00	0,20
Tumor markers	25,00	525,00	10,50	850,00	17,34
Imaging					
CT	429,00	63 390,5	1 267,81	28 468,00	580,98
RTG	25,75	1 585,00	31,70	1 250,00	25,50
USG	70,00	1 750,00	35,00	1 960,00	40,01
RM	572,00	9 592,00	191,84	1 056,00	21,55
PET/CT	4 100,00	32 800,00	656,00	16 400,00	334,69
Scintigraphy	308,00	2 833,60	56,67	1 848,00	37,71
Bronchoscopy	220,00	880,00	17,60	1 320,00	26,94
BAC/USG	100,00	400,00	8,00	300,00	6,12
Other	287,66	7 275,60	145,51	12 174,80	248,46
TOTAL		**139 531,20**	**2 790,62**	**85 130,80**	**1 737,36**

PN group, which was the result of the more frequent use of PET and CT type imaging tests, which are by far the most expensive types of imaging tests see table III.

Medical consultations and treatment of hematological complications constitute a small portion of the total cost of NSCLC treatment. However, it should be noted that a significantly higher number of patients treated with the PN, as opposed to KG, treatment regimen suffered from leucopenia or anemia, which requires the transfusion of a red blood cell concentrate. Despite their low cost of treatment, hematological complications present a big challenge due to their negative effect on patients' quality of life.

An incremental cost-effectiveness analysis was performed to compare the cost and health effects of using the PN and KG treatment regimens in NSCLC. The results of the analysis are shown in table IV.

The analysis shows that the PN treatment regimen is more effective but also more expensive than the KG treatment regimen. Moreover, the difference between the two treatment regimens regarding survival rates is small. The result of the incremental analysis measured in the incremental cost-effectiveness ratio shows that NSCLC treatment with the more expensive but also more effective treatment regimen (namely, PN treatment regimen) costs an additional 2 069.73 PLN per life-month gained, which is an additional 24 836.76 PLN per life-year gained.

A one-way sensitivity analysis was performed to measure how a ±10% change in each individual direct cost of advanced stage NSCLC treatment would affect the result of the incremental analysis (fig. 1).

The results of the analysis show that a change in the costs of radiotherapy and drugs would have the greatest impact on the result of the incremental analysis. Furthermore, a change in the costs of diagnostic tests and hospitalization would have a significant impact on the result of the incremental analysis, and a change in the remaining individual direct costs that constitute the total cost of treatment would not have a significant impact on the result of the incremental analysis.

Discussion

It is estimated that NSCLC diagnostic procedures and treatment account for 20% of the total cost of health care services that deal with all types of malignant tumors, and for approximately 2% of global health care costs [9]. Only 13–15% of patients live up to five years after being diagnosed with NSCLC [10].

Table IV. The result of the incremental cost-effectiveness analysis, the average cost of NSCLC treatment per patient, and the average survival rate in each of the analyzed groups

Regimen	Life expectancy (months)	Cost per life-year gained (PLN)	ICER (PLN/month)
PN	12,91	25 342,04	2 069,73
KG	10,11	19 546,80	

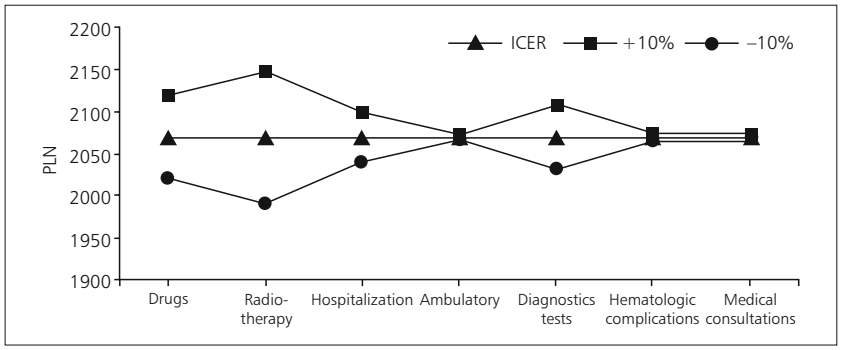

Figure 1. The one way sensitivity analysis

In highly economically developed countries, expenses for health care services are increasing. Any method of treatment should be pharmacoeconomically evaluated. Conducting a cost-effectiveness analysis, which consists of assessing the health effectiveness of a given method of treatment in relation to its cost, is crucial in choosing the most appropriate pharmacotherapy.

One randomized clinical research which compares effectiveness of the PN and the KG treatment was found among the available published results of research studies. It was written by Thomas P, Robinet G, Gouva S et al. [11]. They describe a case where a total of 100 patients with stage IV or stage III NSCLC were randomized. The time to progression was similar in both groups (140 days in the KG group and 148 days in the PN group). Overall, survival rates were 11.1 months in the KG regimen and 10.1 months in the PN regimen. Survival rates of both regimens were found within a similar range of effectiveness. The results of the cited research differ from the results of our study. Both studies indicate a small difference between the PN and the KG group regarding survival rates, but our research shows that the PN treatment regimen is more effective, whereas the other research shows that the KG treatment regimen is more effective. The difference might be due to different patient selection criteria. Our study also includes patients with stage III A cancer, whereas the only eligible patients from the clinical research were the ones with stage IIIB and IV cancer.

There are many studies found in the available literature, which compare cost and effectiveness of carboplatin and cisplatin in different treatment combinations. One of them is a study that compares the cost of treatment with a PN regimen to the cost of treatment with a PG (cisplatin/gemcytabine) regimen. According to that study, in Poland advanced stage NSCLC treatment is less expensive with the PN rather than PG treatment regimen, mainly due to the high cost of gemcytabine. However, after the patent protection for gemcytabine expired, its cost significantly decreased. The pharmacoeconomic analysis showed that the hospitalization cost is higher when the PN treatment regimen is used. Similar results were obtained from other research studies [12, 13]. Although carboplatin and cisplatin are both platinum derivatives, the results of the pharmacoeconomic analysis of the PG treatment regimen cannot be compared with those obtained from the pharmacoeconomic analysis of the KG treatment regimen performed in this work, because carboplatin and cisplatin differ in toxicity and anticancer activity, which influences the cost and health effectiveness of cancer treatment.

Slightly different results were obtained from a retrospective pharmacoeconomic analysis conducted from the perspective of the German Health Care System, in which PN, PG and KT (Carboplatin/Paclitaxel) treatment regimens were examined. The treatment with the PG regimen proved to be the cheapest, and the treatment with the KT regimen, the most expensive method of treatment. The incremental analysis showed that in Germany, in comparison with the PN treatment regimen, the PG treatment regimen is a better method of treatment in terms of cost and health effectiveness [14]. Similar results were obtained from research studies conducted in Italy [15]. The cost of treatment with the PG regimen was over 10% lower than with the PN regimen. Nevertheless, it is difficult to compare the results conducted in Poland with those carried out in different countries, due to the different drug prices in each country, different healthcare systems, as well as the difference in the amount of money set aside by the Ministry of Health for a more expensive but also more health-effective method of treatment.

The aim of this work was to compare the cost and health effectiveness of chemotherapy treatment with the PN and KG treatment regimens. The analysis shows that advanced stage NSCLC treatment with the PN treatment regimen is more expensive but also has more health benefits (it increases the average survival time by 2.8 months as compared to the KG treatment regimen). However, it is important to note that the median age of the patients from the KG group was slightly higher than that of the patients from the PN group (60 and 58 years of age, respectively). Furthermore, there

were more patients with stage IV cancer in the KG group, a fact that might have had an influence on the survival rate of patients from the KG group. The KG treatment regimen, which is the less toxic (and therefore better tolerated) of the two analyzed treatment regimens, is used to treat patients at high risk of the undesirable effects of chemotherapy. All individual direct costs that constitute the total cost of treatment with the PN treatment regimen are higher than the corresponding costs of the total cost of treatment with the KG treatment regimen. It must be noted that the total cost of advanced stage NSCLC treatment was higher when the PN treatment regimen was used, mainly due to the higher number of subsequent lines of chemotherapy and radiation therapies administered in the PN group. The higher number of subsequent lines of chemotherapy and radiotherapies administered in this group might indicate a possible better general condition of patients from the PN group, or a possible worse response to chemotherapy when the PN treatment regimen was used.

According to the one-way sensitivity analysis, a change in the costs of radiotherapy and drugs would have the greatest impact on the result of the incremental analysis.

In order to determine whether a more health effective but also more expensive method of treatment is cost-effective, it is essential to calculate the break-even point for that method of treatment. In year 2012 in Poland, the break-even point for any medical procedure was 99 543.00 PLN per additional life-year gained [16]. As the incremental cost-effectiveness analysis showed, the total cost of the advanced stage NSCLC treatment with the PN treatment regimen is 24 836.76 PLN per additional life-year gained, which is a cost that is significantly below the break-even point. Therefore, the advanced stage NSCLC treatment with this regime is highly cost-effective.

Conclusions

1. The PN treatment regimen is more effective and more expensive than the KG treatment regimen, but the difference between the two treatment regimens regarding survival rates is small and clinically insignificant.
2. The cost of drugs constitutes the largest part of the total cost of NSCLC treatment with either treatment regimen.
3. A calculated ICER is 24 836.76 PLN per one year of life gained.
4. The advanced stage NSCLC treatment with the PN treatment regimen is highly cost-effective.

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