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Cost-effectiveness analysis of the new oncological drug durvalumab in Italian patients with stage III non-small cell lung cancer

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Abstract

Background: The monoclonal antibody durvalumab, an immune-checkpoint inhibitor (ICI) antiprogrammed death ligand 1 (PD-L1), is available for unresectable stage III NSCLC patients as consolidation therapy following induction chemoradiotherapy, with very promising overall survival (OS) and progression-free survial (PFS) results in registration trials. The purpose of this study was to provide policymakers with an estimate of the cost-effectiveness of durvalumab in the treatment of non-small cell lung cancer (NSCLC).

Methods: The study developed a Markov model covering a 5-year period to compare costs and outcomes of treating PD-L1 positive patients with or without durvalumab. We conducted a series of sensitivity analyses (Tornado analysis and Monte Carlo simulation) by varying some parameters to assess the robustness of our model and identify the parameters with the greatest impact on cost-effectiveness.

Results: Prior to the release of durvalumab, the management of NSCLC over a 5-year period cost €33 317 per patient, with an average life expectancy of 2.01 years. After the introduction of the drug, this increased to €37 317 per patient, with an average life expectancy of 2.13 years. Treatment with durvalumab led to an incremental cost-effectiveness ratio (ICER) of €35 526 per year. OS is the variable that contributes the most to the variability of the ICER.

Conclusions: The study observed that durvalumab is a cost-effective treatment option for patients with unresectable stage III NSCLC.

KEYWORDS
cost-effectiveness analysis, durvalumab, economic burden of cancer, new oncologic drugs, NSCLC

INTRODUCTION

Today, lung cancer is the leading cause of cancer death in men and the second leading cause in women worldwide, after breast cancer.[1] The majority of lung cancers are non-small cell lung cancers (NSCLC), which account for approximately 87% of cases.[2]

In this context, new high-cost, personalized oncological drugs are being introduced, opening up promising prospects in terms of improvements in overall and progression-free survival (OS and PFS), while simultaneously raising concerns about their affordability for healthcare systems.[3]

To date, in line with current recommendations, these types of therapies are only reserved for unresectable stage IV eligible NSCLC patients.[4–6] A new monoclonal antibody, durvalumab, has now been approved by the American Food and Drug Administration (FDA) for inoperable stage III NSCLC patients as consolidation therapy following

induction chemoradiotherapy.[7] Durvalumab has also been approved by the European Medicines Agency (EMA) and the Italian Medicines Agency (AIFA) for the same patients as in the U.S., but with the restriction that they have to be PD-L1 positive,[8,9] with a two-year OS rate of 66.3% with durvalumab versus 55.6% in the placebo group, a median PFS of 17.2 months versus 5.6 months, and a three-year OS rate of 57% versus 43.5% in the placebo group.[10,11]

However, in tandem with this promising development, it is now also reasonable to expect a significant increase in expenditure for stage III NSCLC patients, thus heightening concerns about the sustainability of these therapies for oncological patients.

The cost-effectiveness of durvalumab has been investigated in two studies in the U.S.,[12,13] as well as in other studies in Europe.[14–16]

The aim of the present study was to analyze the potential cost-effectiveness of durvalumab consolidation therapy versus active follow-up (standard of care) after induction chemoradiotherapy for patients with unresectable stage III NSCLC and PD-L1 expression ≥1%. The aim is to provide policymakers with an estimate of its value in terms of NSCLC treatment costs and health outcomes.

METHODS

Context

A whole disease model (WDM)[17] was developed in a previous study,[18] starting from the NSCLC patient care pathway and implemented on the grounds of international evidence and guidelines.[4–6] The findings of this previous study, in terms of annual direct costs for each stage of disease, were used as input cost data for the present study.

Model structure

We used TreeAge Pro 2022 R1.2 (Figure 1) to create a Markov model with a 5-year time horizon. This was used to compare costs and outcomes for the treatment of patients with unresectable stage III NSCLC and PD-L1 ≥ expression of 1% with or without durvalumab[19] to reflect the EMA-approved indication for durvalumab as a consolidation therapy, administered every 2 weeks for up to 12 months or until disease progression, the initiation of an alternative cancer therapy, or toxic events, versus active follow-up (the standard of care as described by the previous PDTA Veneto program[6]), after induction chemoradiotherapy.

The probabilities of death and progression for patients receiving durvalumab were computed using the hazard ratios estimated in the study led by Antonia and colleagues.[10] Five-year survival was estimated from data observed[20] in the two years following diagnosis by assuming a linear time trend.

Based on the probabilities in the literature, patients could be classified as "surgical" or "nonsurgical".[21–24]

We also performed a series of sensitivity analyses by varying some parameters to assess the robustness of our model and to identify the parameters that have the greatest impact on cost-effectiveness. We particularly focused on durvalumab-related variables such as the probability of being a stage III PD-L1 positive patient, the hazard ratios for death (OS HR), and for progression-free survival (PFS HR)[10] (Table 1). To address the uncertainty of durvalumab-related variables concurrently, we ran a probabilistic sensitivity analysis by means of a random 1000-fold resampling from the assigned probability distributions (Monte Carlo simulation). The percentages of patients receiving durvalumab were assigned beta distributions.

An annual 3.7% risk of natural death was also applied to all the people in the model, based on the life tables and mean age of NSCLC patients from the Veneto region.[25]

Tables 2–3 show the baseline probabilities of survival and death prior to the administration of durvalumab at different times after diagnosis.

Costs

The study was conducted from the perspective of the Italian National Health Service, only taking into account the direct costs incurred by the regional government of the Veneto Region. Costs (in Euros) are drawn from official reimbursement tariffs that were in effect in 2017.[30,31]

We assumed that each progression from stage III to stage IV or from stage IV to tumor-related death occurs in the sixth month of the year. In the year when progression occurred, we stopped the follow-up costs after 6 months and applied a cost that included restaging and surgical/medical treatments for the remaining 6 months. In the case of death by natural causes, we stopped the follow-up and any potential medical treatments at six months, while in the case of NSCLC-related death, we stopped medical therapy costs 6 months beforehand (no treatment costs were applied because the patients were expected to die by the end of the sixth month), and we applied the cost of 3 months of palliative care. The cost associated with supportive care is €1775.66 and includes hospitalization, hospice, and outpatient care.[32]

Table 4 illustrates the overall stage-specific costs of the first two years of management as calculated by our model prior to the introduction of durvalumab. A normal distribution with a mean of €5000 was instead assigned to the monthly cost of durvalumab.

Finally, future costs were discounted at a 3% rate.

Cost-effectiveness analysis

The incremental cost-effectiveness ratio (ICER) was calculated as the difference in costs for the two branches, divided

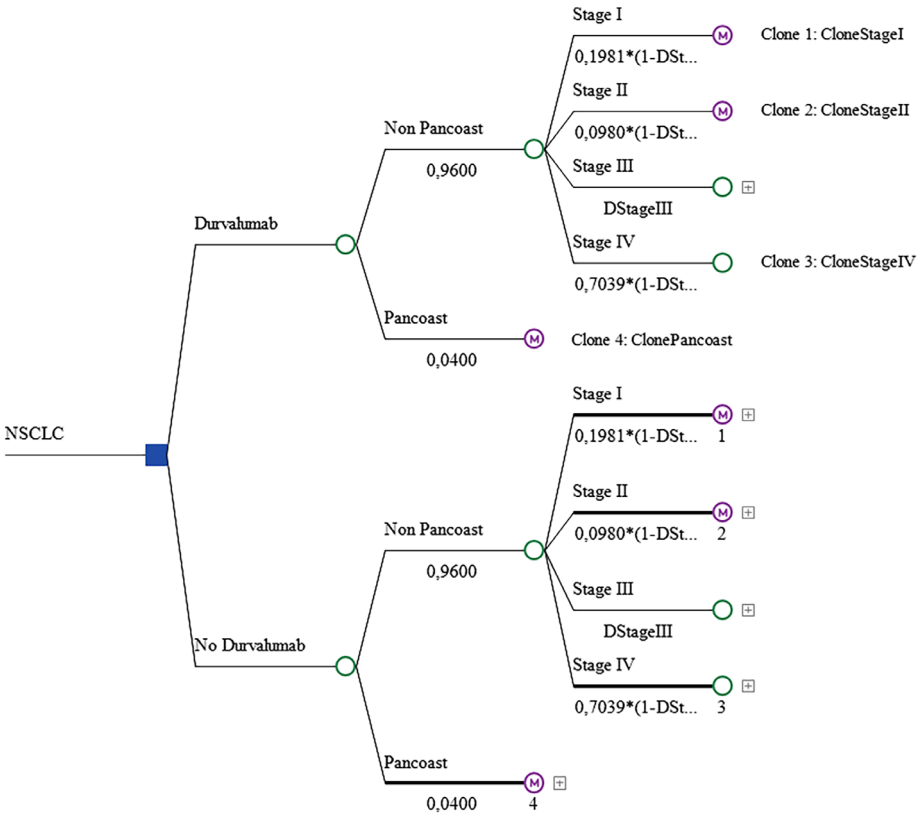

FIGURE 1 TreeAge pro model for the durvalumab cost-effectiveness analysis

TABLE 1 Durvalumab-related variables incorporated into our TreeAge Markov model and tested in the sensitivity analysis

	Value	Range	Distribution	Source
Percentage of stage III patients	21.2%	20.0–29.0%	Beta (21.2, 88.8)	19
HR OS in patients treated with durvalumab	0.68	0.47–0.99	Beta (68.0, 32.0)	10
HR PFS in patients treated with durvalumab	0.51	0.41–0.63	Beta (51.0, 49.0)	10

Abbreviations: HR, hazard ratio; OS, overall survival; PFS, progression-free survival

TABLE 2 Probabilities of death and progression one year after diagnosis, before durvalumab

	Post-surgery mortality rate (only for surgical patients)	Natural mortality rate	Tumor-related mortality rate	Overall mortality rate	Recurrence rate	Source
I	1.50%	3.07%	0.72%	5.00%	5.00%	19,26
II	1.37%	3.07%	6.07%	10.00%	10.00%	22,24
III	7.14%	3.07%	23.00%	26.87%	18.00%	25,27
IV	1.90%	3.07%	53.18%	57.07%	-	21,23
Pancoast	3.17%	3.07%	33.22%	38.00%	22.00%	24,25,28,29

TABLE 3 Probabilities of death and progression five years after diagnosis, before durvalumab

	%	Stable	Progressions	Deaths
I	14.8%	64.7%	7.7%	27.6%
II	7.3%	33.8%	15.7%	50.5%
III	21.2%	16.9%	11.6%	71.6%
IV	52.6%	9.8%	0.1%	90.1%
Pancoast	4.0%	25.3%	9.1%	65.6%
Total	100.0%	64.0%	5.2%	30.7%

by the difference in life years. The cost-effectiveness of durvalumab in comparison to standard therapy was determined using acceptability thresholds of €25 000 and €50 000 per life year gained.

RESULTS

Prior to the introduction of durvalumab, the management of NSCLC cost €33 183 per patient over a 5-year period, with an average life expectancy of 2.01 years. After the

TABLE 4 Mean per-patient costs of care for NSCLC by disease stage (€) for the first and second year of management, before the introduction of durvalumab

	N (n, %) [14, 15]	First year costs	Second year costs
Stage I	352	20 222	2722
	14.81%		
Stage II	174	23 935	6333
	7.33%		
Stage III	504	23 027	7365
	21.22%		
Stage IV	1250	22 915	13 396
	52.63%		
Pancoast	95	31 749	7116
	4%		
Total	2374	22 968	8307
	100%		

introduction of the drug into the study, the cost increased to €37 317 (+€4134) with a life expectancy of 2.13 years (Tables 5). The average incremental cost-effectiveness ratio (ICER) stood at €35 526 per year gained.

When only stage III PD-L1 patients were considered, the average durvalumab cost per patient was €55 101, whereas the cost of the best standard therapy amounted to €35 639, a difference of +€19 462 and 0.54 life years gained with the new drug. In this case, the ICER resulted in a gain of €35 501 per year.

The Tornado diagram shows that overall survival, rather than progression-free survival, is the variable that contributes most to the incremental cost-effectiveness ratio's variability (Figure 2). Figure 3 depicts the cost-effectiveness of the simulations in the probabilistic sensitivity analysis, with the majority of them placed above the threshold of €25 000 (a) per life year gained, but below

TABLE 5 Average costs (€) and life years five years after diagnosis, estimated via 10 000 simulations. 95% credibility intervals are reported within parentheses

(I) Average costs and survival for all NSCLC patients				
	Durvalumab	**No durvalumab (status quo)**	**Difference**	**ICER**
Average cost	37 317 (35 882–38 918)	33 183 (33 141–33 226)	4134 (2741–5692)	35 526
Average survival (years)	2.13 (2.10–2.26)	2.01 (2.01–2.02)	0.12 (0.09–0.24)	
(II) Average costs and survival for stage III patients				
Average cost	55 101 (48 475–62 246)	35 639 (35 493–35 780)	19 462 (12 982–26 466)	35 501
Average Survival (years)	2.85 (2.74–2.98)	2.31 (2.30–2.31)	0.54 (0.44–0.67)	

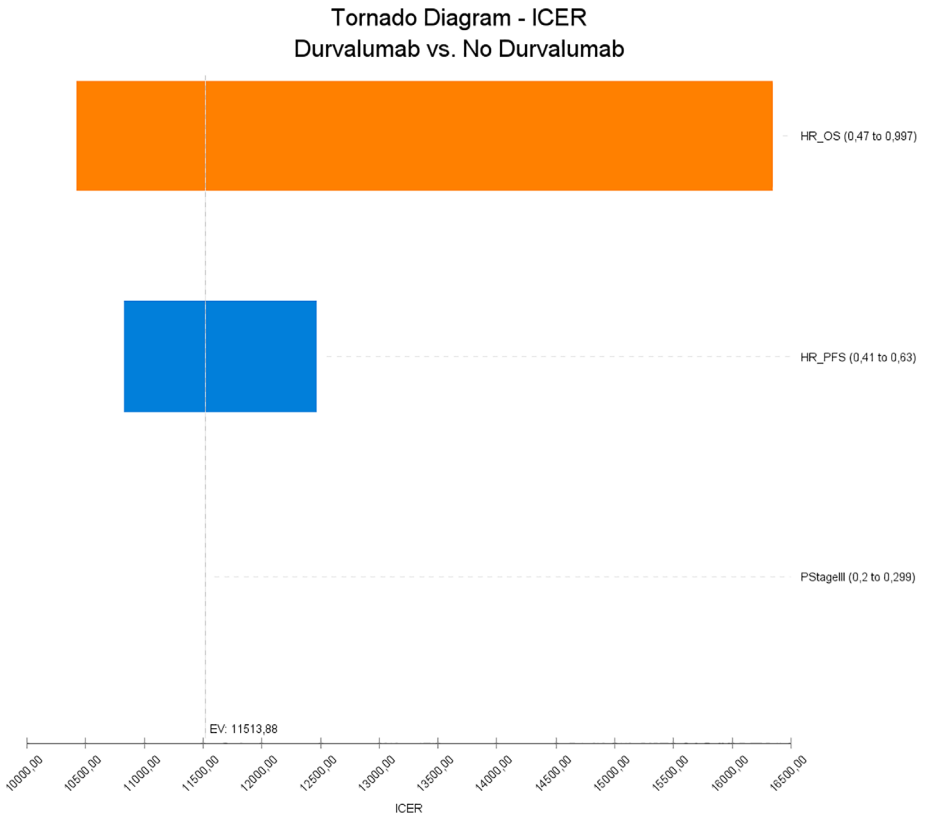

FIGURE 2 Tornado diagram showing the most influential variables of cost-effectiveness of durvalumab. The vertical line cuts the values chosen for the study or those reported by the literature/Delphi survey: As these values vary, so does the ICER

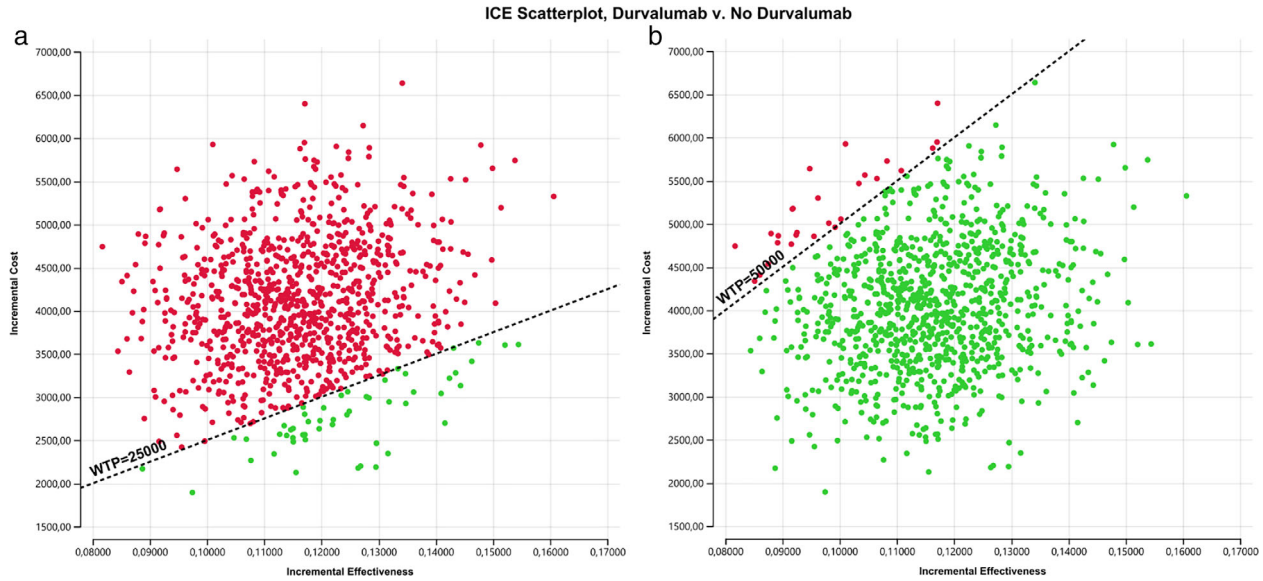

FIGURE 3 The results of a probabilistic sensitivity analysis with 10 000 simulations. The oblique dashed lines represent the (a) €25 000 and (b) €50 000 willingness-to-pay thresholds

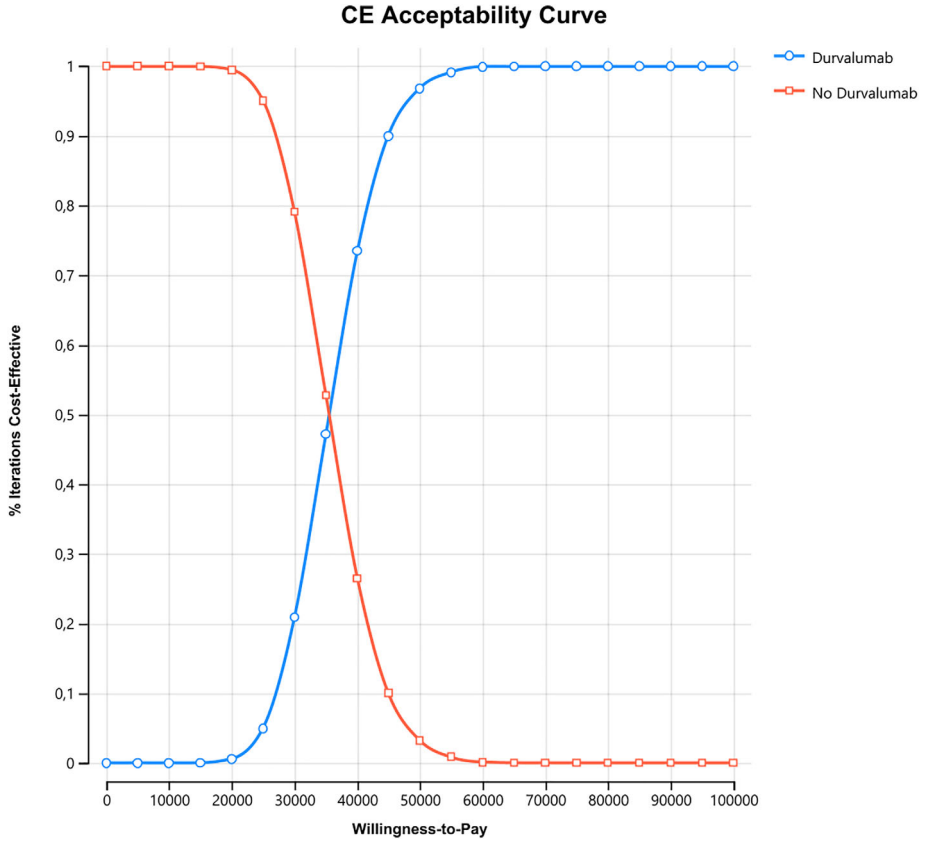

FIGURE 4 Acceptability curve showing the percentages of cost-effective iterations for different willingness-to-pay values

the threshold of €50 000 (b) per life year gained (willingness-to-pay).

Finally, Figure 4 depicts the probabilities of durvalumab treatment being cost-effective at different willingness-to-pay thresholds.

DISCUSSION

The present study found that durvalumab treatment could be cost-effective at a willingness-to-pay (WTP) threshold of €50 000 for YLL.

Criss and colleagues[12] determined that durvalumab is cost-effective compared to no consolidation therapy at a willingness-to-pay (WTP) threshold of $100 000 (equivalent to €91 450) per quality-adjusted life year (QALY), with an estimated ICER of $67 421 (€61 656) per QALY. In reality, these results differ significantly from ours, in addition to the difference in the outcome (YLLs and QALYs), probably due to a different estimate of the drug's cost or the U.S. healthcare's insurance-based reimbursement system, which is hardly comparable to the Italian universal healthcare coverage.

On the other hand, studies focusing on the European perspective indicated that durvalumab consolidation therapy in unresectable stage III NSCLC is cost-effective, backing our results. Among them, a British study by Dunlop et al. supported its routine use, validating the original cost-effectiveness analysis by benchmarking it against more mature (4 years) survival data from the PACIFIC study, with an estimated ICER of £22 665 per quality-adjusted life year gained, which falls within the higher level of the willingness-to-pay threshold used by the UK's National Institute for Health and Care Excellence (NICE) for cost-effectiveness (£30 000).[14] Moreover, an Italian study by Armeni et al. that was published in 2020 found that durvalumab consolidation therapy is cost-effective when offered with a discount of at least 13% off the list price, with an ICER of €42 322/QALY gained when official Italian prices are taken into consideration.[15] Finally, a recent study by Giuliani et al. demonstrated that durvalumab could be considered cost-effective, with an ICER of €3717 per month of PFS gained.[16,33]

As reported by other studies,[34,35] the costs of cancer care have risen dramatically in the past decade. Specifically, the prevalence of patients undergoing new oncological therapies and associated spending have more than doubled. This trend is expected to continue in the foreseeable future.[36] This means that very promising new oncological therapies, such as durvalumab, are being introduced. These therapies extend cancer patient survival, but they also place a heavy financial burden on national healthcare systems, jeopardizing their long-term viability.

These economic evaluations have the potential to support the fundamental role of primary prevention campaigns, such as those against tobacco smoke, and political interventions to reduce pollution worldwide. In fact, we can significantly reduce healthcare costs by lowering the incidence of lung cancer. In addition, screening strategies should be concretely debated, especially in countries such as Italy, where lung cancer incidence is already decreasing[37] because significantly more than half of NSCLC cases are diagnosed at advanced stages.[19] Lung cancer screening was recently proposed for patients considered to be at risk, but no consensus has yet been reached.[38,39] Furthermore, its cost-effectiveness value should be revised to account for the costs of advanced stages, including the innovative high-cost targeted therapies that go along with them.

In conclusion, this study has demonstrated that durvalumab therapy could be cost-effective at a willingness-to-pay (WTP) threshold of €50 000 per life year gained. Cost-effectiveness thresholds are typically used to assess whether an intervention is worthwhile and should reflect health opportunity costs. A previous study conducted in 2019,[40] estimating the marginal cost of a life year in Sweden's public healthcare sector, derived a marginal cost per life year of about EUR 39000 with a wide range of uncertainty (95% CI: 21, 151–235, 192). Our threshold falls within this range. The strength of this study lies in the availability of a whole disease model.[18] In fact, economic evaluation is usually "piecewise" in nature, involving an estimation of the expected costs of the interventions and health outcomes at an isolated point within a broader pathway of care. By limiting the scope of the economic analysis to a single decision point, further adoption decisions along the disease pathway and their knock-on effects, are frequently viewed as unrelated to the issue of the decision under consideration. In light of these concerns, this article puts forward a different approach—whole disease modeling, that is, the notion of modeling the "bigger picture" by simulating whole disease and treatment pathways within a single model.[17]

A limitation that must be mentioned in relation to this study is that it only addresses the direct costs of NSCLC, disregarding the burden of indirect costs, which can be predictably high.

CONFLICT OF INTEREST

The authors declare no conflict of interests.

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