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Analysis of the use of novel antitumor drugs in lung cancer treatment at Nanjing Chest Hospital from 2019 to 2023

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Abstract: Objective To monitor the clinical use and trend of novel antitumor drugs in the treatment of lung cancer, and provide references for improving the standardization and rationality of drug use and the optimization of relevant medical insurance policies. **Methods** A retrospective method was used to analyze the number of novel antitumor drugs in the treatment of lung cancer, annual sales amount, defined daily doses (DDDs), defined daily cost (DDC), and ratio of sequence of consumption sum(B)/sequence of DDDs (A) in the Nanjing Brain Hospital (Thoracic Hospital Campus) from 2019 to 2023. **Results** From 2019 to 2023, the variety, consumption sum and constituent ratio of novel antitumor drugs in the treatment of lung cancer showed an increasing trend year by year, and the increase in consumption sum was stable. From 2019 to 2023, the varieties of novel antitumor drugs increased significantly, with the largest increase in the use of camrelizumab; the DDC of various varieties of new antitumor drugs showed a downward trend, among which the DDC of afatinib in small molecule targeted drugs had the largest decline; the largest decrease in DDC for monoclonal antibody drugs was camrelizumab, from 942.76 yuan to 123.85 yuan, with a B/A ratio greater than 1, indicating good synchronization. **Conclusion** The variety and quantity of novel antitumor drugs in this hospital have increased significantly, and the treatment payment of patients has decreased year by year.

Keywords: Lung cancer; Novel antitumor drugs; Defined daily doses; Consumption sum; Medication analysis

In recent years, with the accelerating pace of research, development, and marketing of new anti-tumor drugs, China has successively issued notices such as the *Guidelines for the Clinical Application of Novel Anti-tumor Drugs (2023 Edition)*[《新型抗肿瘤药物临床应用指导原则（2023 年版）》]and the *Administrative Regulations on the Clinical Application of Anti-tumor Drugs (For Trial Implementation)* [《抗肿瘤药物临床应用管理办法（试行）》], requiring medical institutions to strengthen management and promote rational use. Nanjing Brain Hospital (Thoracic Hospital Campus) is a specialized hospital for thoracic disease treatment in Nanjing, with 300 beds for lung cancer patients, serving patients from regions such as Jiangsu and Anhui. There is a significant demand for the application of new technologies and new drugs. To better dynamically monitor drug usage, the author, as a member of the hospital's anti-tumor drug rational use review panel, analyzed the usage of new anti-tumor drugs in the hospital from 2019 to 2023, hoping to provide reference data for improving the standardization and rationality of drug use in lung cancer treatment and for optimizing related medical insurance policies.

1 Data and Methods

1.1 Types of Drugs Analyzed

According to the *Guidelines for the Clinical Application of Novel Anti-tumor Drugs (2023 Edition)* issued by the National Health Commission of the People's Republic of China, new anti-tumor drugs are broadly classified by mechanism into small molecule targeted drugs, macromolecular monoclonal antibodies (mAbs), and other categories. Small molecule targeted drugs mainly include gefitinib, erlotinib, and afatinib. Macromolecule mAbs mainly include bevacizumab, cetuximab, and nimotuzumab. Other categories mainly include everolimus and recombinant human endostatin.

1.2 Methods

Data on the usage of new anti-tumor drugs from 2019 to 2023 were obtained from the Hospital Information Management System and the Rational Drug Use Monitoring System of the Nanjing Brain Hospital (Thoracic Hospital Campus). The data included drug name, specification, dosage form, unit, quantity, and cost. Microsoft Excel was used for statistical analysis, including drug quantity, annual sales amount, query of the defined daily dose (DDD), calculation of defined daily doses (DDDs, i.e., cumulative DDDs), defined daily cost (DDC), and ranking ratio (B/A). DDDs were referenced from the *Guidelines for the Clinical Application of Novel Anti-tumor Drugs (2023 Edition)* issued by the National Health Commission of the People's Republic of China, drug package inserts, the *New Pharmacology (18th Edition)*, and the *Pharmacopoeia of the People's Republic of China — Clinical Medication Guidelines*. DDDs was calculated separately for different specifications and dosages of the same drug to determine the final DDDs.

DDDs = total annual drug usage / DDD. A higher DDDs value reflects greater clinical preference. DDC = annual drug sales amount / DDDs. DDC represents the drug price level; a higher DDC value indicates a higher average daily cost. B/A = ranking of total drug consumption cost (B) / ranking of DDDs (A). This ratio reflects whether the sales amount is synchronized with the number of users. A B/A value ≥ 1 indicates good synchronization, low price, and high utilization rate for the drug; conversely, a B/A value < 1 indicates a higher economic burden for patients.

1.3 Statistical Methods

This study used Microsoft Excel 2024 for statistical analysis of the data. Statistical description was performed using frequencies and composition ratios.

2 Results

2.1 Sales Amount and Composition Ratio of New Anti-tumor Drugs in Lung Cancer Treatment

From 2019 to 2023, the types, sales amount, and proportion of total usage cost of new anti-tumor drugs used in lung cancer treatment at the Nanjing Brain Hospital (Thoracic Hospital Campus) showed an increasing trend year by year, with a stable growth rate in sales amount. There was a slight decrease in the amount growth rate in 2022 compared to 2021. The sales amount of large molecule monoclonal antibodies increased substantially, with the largest increase occurring in 2020. See **Table 1**.

2.2 Sales Amount and Ranking of New Anti-tumor Drugs in Lung Cancer Treatment

From 2019 to 2023, the number of new anti-tumor drug varieties increased from 11 to 19. Bevacizumab ranked first in sales amount for four consecutive years. Since its procurement in 2021, the sales amount of Sintilimab increased significantly. The annual sales amount of Anlotinib exceeded one million yuan for four years, while the sales amounts of Gefitinib, Crizotinib, and Ceritinib showed a decreasing trend year by year. See **Table 2**.

2.3 DDDs and Ranking of New Anti-tumor Drugs in Lung Cancer Treatment

Bevacizumab ranked first for four consecutive years, indicating its widespread clinical application. The usage of Camrelizumab increased significantly; after its breakthrough from zero usage in 2020, it showed the largest increase in ranking among large molecule monoclonal antibodies. The usage of Gefitinib was stable, maintaining a ranking between 2nd and 5th in the first three years, but dropped to a lower ranking after 2023. **See Table 3.**

2.4 Changes in DDC and B/A of New Anti-tumor Drugs in Lung Cancer Treatment

From 2019 to 2023, the DDC of various new anti-tumor drugs used in lung cancer treatment showed a consistent downward trend. Among small molecule targeted drugs, Afatinib exhibited the largest decrease in DDC, with B/A values consistently >1, indicating good synchronization. The DDC of both Gefitinib and Erlotinib decreased, with B/A values significantly greater than 1. The DDC of Osimertinib decreased from over 500 to just over 100, indicating a reduced economic burden on patients. The drug with the largest decrease in DDC across all varieties was Camrelizumab . The DDC of Durvalumab and Rituximab both exceeded 1,000; the DDC of Crizotinib, Alectinib, and Ceritinib all exceeded 500, indicating a heavy economic burden on patients. See **Table 4.**

Tab.1 Composition ratio and increase of overall sales sum of different types of new antitumor drugs and traditional antitumor drugs in lung cancer treatment from 2019 to 2023

Item	2019		2020			2021			2022			2023		
	Amount (10,000 yuan)	Variety	Amount (10,000 yuan)	Variety	Increase (%)[a]	Amount (10,000 yuan)	Variety	Increase (%)[a]	Amount (10,000 yuan)	Variety	Increase (%)[a]	Amount (10,000 yuan)	Variety	Increase (%)[a]
New-type	891.17	11	1,146.79	15	28.68	1,504.85	16	31.22	1,397.32	18	-7.14	1,635.57	19	17.05
Small Molecule Targeted Drugs	506.25	8	562.02	9	11.01	770.71	6	37.13	616.91	10	-19.95	473.75	13	-23.21
Macromolecular mAb	203.87	2	401.20	4	96.79	415.93	8	3.67	536.84	7	29.06	829.15	5	54.45
Other	181.05	1	183.57	2		318.21	2		243.53	1		332.66	1	
Traditional anti-tumor drugs	2,243.94		1,462.22			1,196.81			1,085.92			1,096.84		
Total	3,135.11		2,609.01			2,701.66			2,483.24			2,732.41		
Composition ratio of usage amount (%)[b]	28.42		43.95			55.70			56.27			59.86		

Note: a, the growth rate of the current year's amount compared to the previous year; b, the proportion of new anti-tumor drugs in the total expenditure.

Tab.2 Sales sum and ranking of new antitumor drugs in lung cancer treatment from 2019 to 2023

Classification	Drug Name	2019		2020		2021		2022		2023	
		Amount (10,000 yuan)	Ranking	Amount (10,000 yuan)	Ranking	Amount (10,000 yuan)	Ranking	Amount (10,000 yuan)	Ranking	Amount (10,000 yuan)	Ranking
Macro-molecular mAb	Bevacizumab	203.09	2	388.64	1	606.18	1	509.48	1	571.92	1
	Durvalumab			9.65	12	89.26	5	27.13	11		
	Camrelizumab			1.98	13	43.78	7	31.04	10	26.27	8
	Nivolumab			0.93	14						
	Cetuximab	0.77	11			3.85	13				
	Sintilimab					1.71	14	42.23	6	95.80	6
	Rituximab					1.57	15	3.15	16		
	Pembrolizumab					14.33	11				
	Tislelizumab					10.03	12			132.41	4
	Nimotuzumab							1.15	18		
	Trastuzumab							2.75	17	2.75	12
Small Molecule Targeted Drugs	Anlotinib	208.23	1	148.49	4	142.68	3	192.66	3	202.43	3
	Alectinib					140.11	4	94.21	5	93.65	7
	Crizotinib	40.90	6	54.69	7			7.32	14	13.38	10
	Ceritinib	14.85	8	14.85	9	16.32	10	5.71	15	0.41	19
	Osimertinib	123.93	4	168.31	3			99.33	4		
	Gefitinib	64.82	5	56.51	6	17	9			1.48	17
	Almonertinib							37.44	7		
	Furmonertinib							9.56	13	115.23	5
	Afatinib	14.68	9	30.12	8	64.23	6	34.19	9	0.88	18
	Icotinib	35.65	7	63.89	5			19.56	12	20.91	9
	Erlotinib	3.19	10	14.46	10	35.59	8	36.88	8	1.94	16
	Lorlatinib									10.54	11
	Brigatinib									8.77	13
	Savolitinib									2.12	14
	Trametinib									2.03	15
	Apatinib			10.72	11						
Others	Everolimus					0.39	16				
	Recombinant Human Endostatin	181.06	3	183.55	2	317.81	2	243.53	2	332.66	2

Tab.3 DDDs and ranking of new antitumor drugs in lung cancer treatment from 2019 to 2023

Classification	Drug Name	2019		2020		2021		2022		2023	
		DDDS	Ranking	DDDS	Ranking	DDDS	Ranking	DDDS	Ranking	DDDS	Ranking
Macro-molecular mAb	Bevacizumab	4,200.00	4	11,356.00	1	19,840.00	1	18,016.00	1	20,876.00	1
	Durvalumab			48.91	12	454.35	10	140.00	14		
	Camrelizumab			21.00	13	2898.25	7	2,226.19	7	2,121.18	7
	Nivolumab			5.83	14						
	Cetuximab	9.84	11			52.45	14				
	Sintilimab					63.01	13	4,115.79	6	9,336.84	5
	Rituximab					11.11	16	22.22	18		
	Pembrolizumab					84.01	12				
	Tislelizumab					483.04	9			10,084.21	4
	Nimotuzumab							28.57	17		
	Trastuzumab							110.00	16	110.00	16
	Anlotinib	6761.62	1	84.528	11	9,957.70	3	10,420.94	2	10,934.93	3
Small Molecule Targeted Drugs	Alectinib					2,575.50	8	1,862.00	9	1,851.00	9
	Crizotinib	810.00	7	1,080.00	8			160.00	13	390.00	13
	Ceritinib	250.00	9	250.00	10	400.00	11	140.00	14	10.00	19
	Osimertinib	2,430.00	5	3,300.00	5			5,340.00	4		
	Gefitinib	5,221.00	2	9,691.00	2	4,200.00	5			576.00	12
	Almonertinib							1,063.50	11		
	Furmonertinib							810.00	12	5,974.50	6
	Afatinib	715.75	8	1,506.00	7	3,661.00	6	1,952.00	8	944.25	11
	Icotinib	1,855.33	6	3,325.00	4			1,638.00	10	1,751.33	10
	Erlotinib	175.00	10	1,988.00	6	5,012.00	4	5,194.00	5	2,037.00	8
	Lorlatinib									200.00	15
	Brigatinib									298.66	14
	Savolitinib									28.00	18
	Trametinib									61.00	17
	Apatinib			284.00	9						
Others	Everolimus					15.00	15				
	Recombinant Human Endostatin	5,071.76	3	6,610.59	3	11,445.88	2	8,770.59	3	11,980.59	2

Tab.4 DDC and B/A of various new antitumor drugs in lung cancer treatment from 2019 to 2023

Classification	Drug Name	2019		2020		2021		2022		2023	
		DDC/yuan	B/A	DDC/yuan	B/A	DDC/yuan	B/A	DDC/yuan	B/A	DDC/yuan	B/A
Macro-molecular mAb	Bevacizumab	483.55	0.5	342.23	1	305.53	1	282.79	1	273.96	1
	Durvalumab			1,973.17	1	1,964.56	0.5	1,937.85	0.78		
	Camrelizumab			942.76	1	151.06	1	139.43	1.43	123.85	1.14
	Nivolumab			1,594.38	1						
	Cetuximab	789.94	1			734.78	0.93				
	Sintilimab					271.16	1.08	102.60	1	102.60	1.2
	Rituximab					1,416.07	0.94	1,417.51	0.89		
	Pembrolizumab						0.92				
	Tislelizumab					207.61	1.33			131.31	1
	Nimotuzumab							402.50	1.058		
	Trastuzumab							250.00	1.06	250.00	0.75
Small Molecule Targeted Drugs	Anlotinib	307.96	1			143.29	1	184.88	1.5	185.12	1
	Alectinib					544.00	0.5	505.96	0.56	505.92	0.78
	Crizotinib	504.89	0.86	506.39	0.88			457.50	1.08	343.20	0.77
	Ceritinib	594.00	0.89	594.00	0.9	408.00	0.91	407.86	1.07	408.00	1
	Osimertinib	510.00	0.80					186.01	1		
	Gefitinib	124.15	2.5	58.31	3	40.49	1.8			25.69	1.42
	Almonertinib							352.05	0.64		
	Furmonertinib									192.87	0.83
	Afatinib	205.11	1.13	200.00	1.14	175.45	1	175.15	1.13	9.32	1.63
	Icotinib	192.15	1.17	192.15	1.25			119.41	1.2	119.40	0.9
	Erlotinib	182.29	1	72.74	1.67	71.00	2	71.00	1.6	9.51	2
	Lorlatinib									527.00	0.73
	Brigatinib									293.51	0.93
	Savolitinib									755.70	0.78
	Trametinib									332.55	0.88
	Apatinib			377.47	1.22						
Others	Everolimus					260.00	1.07				
	Recombinant Human Endostatin	357.01	1	277.66	0.67	277.67	1	277.67	0.67	277.67	1

3 Discussion

In the treatment of lung cancer, traditional anti-tumor chemotherapy drugs have significant toxic and side effects, and the 5-year survival rate for patients is relatively low [1]. New anti-tumor drugs, represented by tyrosine kinase inhibitors (TKIs) and monoclonal antibody immunosuppressants, have great application value and have achieved good clinical efficacy in the treatment of lung cancer [2-3]. Therefore, both the usage amount and the variety of new anti-tumor drugs in our hospital have shown a rapid increasing trend.

In patients with non-small cell lung cancer (NSCLC), epidermal growth factor receptor (EGFR) mutations are the most common driver oncogenes, with a detection rate as high as 50.2% in China [4]. The first-generation EGFR-TKIs used in our hospital include gefitinib, erlotinib, and icotinib [5]. Comprehensive analysis showed that in the early clinical stage, gefitinib were preferred, but as resistance to them increased, they were gradually replaced by icotinib. Multiple studies have shown no statistically significant differences among the three in terms of best overall response, median survival time, objective response rate, median progression-free survival, and 1-, 3-, and 5-year survival rates. From a safety perspective, erlotinib have the highest incidence of diarrhea and gastrointestinal symptoms. From a cost-effectiveness analysis, icotinib have a more obvious advantage [6].

The representative second-generation EGFR-TKI in our hospital is Afatinib, which have irreversible dual inhibition properties and can effectively inhibit tumor development. Compared with gefitinib and erlotinib, Afatinib show no significant difference in efficacy [7] but can significantly prolong progression-free survival [8] and reduce the development of acquired resistance in patients [9]. The adverse reactions of afatinib include paronychia,

skin toxicity, and stomatitis. although the incidence is higher than that of erlotinib hydrochloride and gefitinib, it has better tolerability and is often controllable at conventional doses [10]. Comprehensive analysis indicates that the economic advantage of afatinib is not obvious compared to gefitinib .

The third-generation EGFR-TKIs in our hospital include almonertinib, osimertinib, and furmonertinib . Data from **Table 3** and **Table 4** showed that almonertinib have a B/A < 1, and their DDC value was much higher than that of osimertinib. The DDDs of osimertinib are significantly higher than those of almonertinib. Osimertinib can penetrate the blood-brain barrier and reduce tumor progression. They have been recommended by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology as the first-line preferred treatment for advanced NSCLC with EGFR mutations [11]. They have been approved by the National Medical Products Administration of China, the U.S. Food and Drug Administration, and the European Medicines Agency for adjuvant therapy after NSCLC surgery [12]. Due to the long treatment course, their usage is high. Furmonertinib, as the second domestically developed third-generation EGFR-TKI, have shown a significant increase in usage ranking for NSCLC patients resistant to first-generation EGFR-TKIs and those with brain metastases. Compared with gefitinib, its clinical efficacy is favorable, with the longest progression-free survival reported to date, making it highly favored in clinical practice. Therefore, its usage ranking is rising rapidly.

Approximately 3% to 5% of NSCLC patients harbor anaplastic lymphoma kinase (ALK) fusion positivity. The first approved inhibitor (ALK-TKI), crizotinib, broke the situation where ALK-positive advanced NSCLC patients could only receive chemotherapy, marking a watershed in treatment. It is more effective than the standard regimen (pemetrexed plus platinum) in controlling brain metastases and has better efficacy [13]. Patients with ALK-positive NSCLC who develop resistance are switched to second-generation ALK-TKIs for treatment, with representative drugs including ceritinib and alectinib . Data indicate that our hospital prefers alectinib, possibly related to its better blood-brain barrier penetration rate and greater breakthrough in controlling brain metastases [14]. As the first approved second-generation ALK inhibitor, literature reports highlight significant safety concerns with ceritinib [12]. Concerns about the safety of this drug and the economic burden on patients may be the main reasons affecting the clinical use of ceritinib in our hospital.

Bevacizumab has ranked first for many consecutive years in both sales amount ranking and DDDs, indicating its very wide clinical use. Looking at the disease types in lung cancer treatment, the incidence of adenocarcinoma is higher than that of squamous cell carcinoma. Bevacizumab was approved for the treatment of adenocarcinoma earlier, holds a high therapeutic status, and has many approved indications, covering patients from treatment to maintenance throughout the entire disease cycle. Clinically, bevacizumab is often used alone or in combination with TKIs. Bevacizumab can also play a role in patients resistant to EGFR, significantly improving progression-free survival, increasing the overall disease control rate, and exerting a lasting and significant anti-tumor effect. However, anti-vascular endothelial growth factor monoclonal antibodies represented by Bevacizumab, when combined with chemotherapy, have not improved the overall survival of patients with small cell lung cancer (SCLC). Targeted drugs are less effective in SCLC than in NSCLC. Only anlotinib is recommended for the third-line or later treatment of advanced SCLC [15]. Anlotinib can inhibit multiple targets, including fibroblast growth factor receptors, vascular endothelial growth factor receptors, and platelet-derived growth factor receptors. They are used in advanced metastatic NSCLC patients who have progressed after receiving at least two prior systemic chemotherapy regimens [12, 16-17]. Since their introduction to our hospital in 2019, their DDDs have shown an increasing trend year by year. Although the DDC value has been decreasing annually, it remains relatively high, leaving room for further reduction.

In recent years, targeted therapy for lung cancer has advanced rapidly, but in the field of SCLC, few targeted drugs have been approved. Immunotherapy offers more treatment possibilities for SCLC patients, who are prone to relapse, have low survival rates, and high metastasis rates [18]. The increase in DDDs for immune checkpoint inhibitors is much greater than that for small molecule targeted drugs. It is evident that an increasing number of lung cancer patients are receiving immunotherapy. Programmed death receptor inhibitors, represented by camrelizumab, have been approved by the U.S. Food and Drug Administration as the first-line treatment of choice for patients with extensive-stage SCLC [19-20]. Data show that camrelizumab has the largest increase in usage. Its DDC also shows the largest decrease. The reason may be that camrelizumab was included in the national negotiated medical insurance drug list in 2022, resulting in significant clinical efficacy and a reduced economic burden on patients, leading to a rapid increase in clinical usage.

In summary, as new anti-tumor drugs continue to provide increasing benefits to patients in lung cancer treatment, especially oral drugs which are more convenient to administer than chemotherapy and have fewer side effects, they are unanimously recommended by both patients and clinicians. The DDC of various drugs has been trending downwards, but it still remains at a relatively high level, placing a considerable burden on patients and medical insurance. To achieve better treatment outcomes and reduce the economic pressure on patients, the procurement of new anti-tumor drug varieties included in the national negotiated medical insurance list is continuously increasing. Clinically, the use of new anti-tumor drugs should be further standardized to truly achieve "safety, efficacy, and economy," providing patients with higher quality medical services.

Conflict of Interest None

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·肺癌专题·论著·

2019—2023年南京市胸科医院新型抗肿瘤药物在肺癌治疗中的使用分析

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摘要：目的　通过监测在肺癌治疗中新型抗肿瘤药的临床使用情况和用药趋势，为提升药物使用的规范化和合理性以及相关医保政策优化提供参考。**方法**　采用回顾性方法分析南京脑科医院胸科院区2019至2023年在肺癌治疗中新型抗肿瘤药物数量、年销售金额、用药频度（DDDs）、限定日均费用（DDC）及药品销售金额排序（B）/DDDs排序（A）情况。**结果**　2019至2023年新型抗肿瘤药物在肺癌治疗的品种、使用金额、构成比呈逐年上升趋势，且使用金额的增幅稳定。2019至2023年，新型抗肿瘤药物品种显著上升，其中卡瑞利珠单抗注射液使用量上升幅度最大；新型抗肿瘤药物各品种的DDC呈现下降趋势，其中小分子靶向药物中马来酸阿法替尼片的DDC下降幅度最大；单克隆抗体类药物DDC下降幅度最大的是卡瑞利珠单抗注射液，从942.76元降至123.85元，B/A均>1，提示同步性良好。**结论**　该院2019至2023年肺癌治疗中新型抗肿瘤药物品种数量均大幅度增加，患者治疗付费逐年下降。

关键词：肺癌；新型抗肿瘤药；用药频度；销售金额；用药分析
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Analysis of the use of novel antitumor drugs in lung cancer treatment at Nanjing Chest Hospital from 2019 to 2023

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Abstract: Objective　To monitor the clinical use and trend of novel antitumor drugs in the treatment of lung cancer, and provide references for improving the standardization and rationality of drug use and the optimization of relevant medical insurance policies. **Methods**　A retrospective method was used to analyze the number of novel antitumor drugs in the treatment of lung cancer, annual sales amount, defined daily doses (DDDs), defined daily cost (DDC), and ratio of sequence of consumption sum (B) /sequence of DDDs (A) in the Nanjing Brain Hospital (Thoracic Hospital Campus) from 2019 to 2023. **Results**　From 2019 to 2023, the variety, consumption sum and constituent ratio of novel antitumor drugs in the treatment of lung cancer showed an increasing trend year by year, and the increase in consumption sum was stable. From 2019 to 2023, the varieties of novel antitumor drugs increased significantly, with the largest increase in the use of camrelizumab injection; the DDC of various novel antitumor drugs showed a downward trend, among which the DDC of afatinib dimaleate tablets in small molecule targeted drugs had the largest decline; the largest decrease in DDC for monoclonal antibody drugs was camrelizumab injection, from 942.76 yuan to 123.85 yuan, with a B/A ratio greater than 1, indicating good synchronization. **Conclusion**　The variety and quantity of novel antitumor drugs in this hospital have increased significantly, and the treatment payment of patients has decreased year by year.

Keywords: Lung cancer; Novel antitumor drugs; Defined daily doses; Consumption sum; Medication analysis

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近年来，随着新型抗肿瘤药物研发、上市速度不断加快，国家相继颁发了《新型抗肿瘤药物临床应用指导原则（2023年版）》《抗肿瘤药物临床应用管理办法（试行）》，要求医疗机构要强化管理，促进合理使用。南京脑科医院胸科院区是南京市胸部疾病治疗专科医院，有300张肺癌收治床位，能够覆盖江苏、安徽等地区患者，对新技术、新药的应用有很大的需求。笔者作为医院抗肿瘤药物合理使用点评小组成员，为了更好地动态监测药物使用，就2019年至2023年医院新型抗肿瘤药物使用情况进行分析，期望为在肺癌治疗中药物使用的规范化和合理性的提升，以及为相关医保政策的优化提供参考数据。

1　资料与方法

1.1　*药物分析种类*　中华人民共和国国家卫生健康委员会发布的《新型抗肿瘤药物临床应用指导原则（2023年版）》根据机制大致分为小分子靶向药物、大分子单克隆抗体和其他类，其中小分子靶向药物主要包含吉非替尼片、盐酸厄洛替尼片和马来酸阿法替尼片等，大分子单克隆抗体包含贝伐珠单抗注射液、西妥昔单抗注射液和尼妥珠单抗注射液等，其他类主要是依维莫司片、重组人血管内皮抑制素注射液。

1.2　*方法*　从南京脑科医院胸科院区医院信息管理系统和合理用药监测系统获取2019至2023年新型抗肿瘤药物使用数据，包括药物名称、规格、剂型、单位、数量及金额，使用Excel统计分析，包括药品数量、年销售金额、查询药物限定日剂量（defined daily dose，DDD）、计算用药频度（defined daily doses，DDDs，即累计DDD数）、日均费用（daily drug cost，DDC）、排序比（B/A）等，DDD参照中华人民共和国国家卫生健康委员会发布的《新型抗肿瘤药物临床应用指导原则（2023年版）》、药品说明书、《新编药物学（第18版）》《中华人民共和国药典·临床用药须知》。同一药物不同规格剂量分别计算DDDs，确定最终DDDs。DDDs=药品年用药总量/DDD，值越大，反映临床倾向性越大。DDC=药品年销售金额/DDDs，DDC代表药品价格水平，DDC值越大，日均费用越高。B/A=总用药金额排序（B）/DDDs排序（A），反映的是销售金额与用药人数是否同步，其值≥1代表该药有良好的同步性，价格低，利用度高；反之，其值<1表示患者经济负担高。

1.3　*统计学方法*　本研究使用Microsoft Excel 2024对数据进行统计分析。以频数和构成比进行统计学描述。

2　结　果

2.1　*新型抗肿瘤药物在肺癌治疗中的销售金额与构成比*　2019至2023年南京脑科医院胸科院区新型抗肿瘤药物在肺癌治疗的品种、销售金额、使用金额构成比呈逐年上升趋势，且销售金额的增幅稳定。金额增幅2022年较2021年出现小幅下降。大分子单克隆抗体的销售金额大幅增长，其中2020年增幅最大。见表1。

2.2　*新型抗肿瘤药物在肺癌治疗中的销售金额和排序情况*　2019至2023年，新型抗肿瘤药物品种由11种增至19种，贝伐珠单抗注射液销售金额连续4年居首，信迪利单抗注射液自2021年采购以后，销售金额大幅度增加。盐酸安罗替尼胶囊四年销售金额均超百万，而吉非替尼片、克唑替尼胶囊和塞瑞替尼胶囊的销售金额呈逐年下降趋势。见表2。

2.3　*新型抗肿瘤药物在肺癌治疗中的DDDs情况和排序*　贝伐珠单抗注射液连续4年居于首位，说明其

表1　2019至2023年不同类型新型抗肿瘤药和传统抗肿瘤药在肺癌治疗中的总体销售金额构成比及增幅

Tab.1　Composition ratio and increase of overall sales sum of different types of new antitumor drugs and traditional antitumor drugs in lung cancer treatment from 2019 to 2023

分类	2019年		2020年			2021年			2022年			2023年		
	金额（万元）	品种	金额（万元）	品种	增幅[a]（%）	金额（万元）	品种	增幅[a]（%）	金额（万元）	品种	增幅[a]（%）	金额（万元）	品种	增幅[a]（%）
新型抗肿瘤药	891.17	11	1 146.79	15	28.68	1 504.85	16	31.22	1 397.32	18	−7.14	1 635.56	19	17.05
小分子靶向药物	506.25	8	562.02	9	11.01	770.71	6	37.13	616.91	10	−19.95	473.75	13	−23.21
大分子单克隆抗体	203.87	2	401.20	4	96.79	415.93	8	3.67	536.84	7	29.06	829.15	5	54.45
其他	181.05	1	183.57	2		318.21	2		243.53	1		332.66	1	
传统抗肿瘤药	2 243.94		1 462.22			1 196.81			1 085.92			1 096.84		
金额合计	3 135.11		2 609.01			2 701.66			2 483.24			2 732.40		
使用金额构成比（%）[b]	28.42		43.95			55.70			56.27			59.86		

注：[a]增幅为当年与前一年相比金额的增长幅度；[b]为新型抗肿瘤药在总使用金额中的比例。

在临床应用广泛。卡瑞利珠单抗注射液使用量显著上升，2020年零突破后，在大分子单抗排名中上升幅度最大。吉非替尼片用量稳定，前3年保持2~5位，2023年下降靠后。见表3。

2.4　新型抗肿瘤药物在肺癌治疗中的DDC及B/A情况变化及排序情况　2019至2023年新型抗肿瘤药物在肺癌治疗中，多数品种的DDC均一路走低趋势。在小分子靶向药范围内马来酸阿法替尼片的DDC的下降幅度最大，B/A均>1，提示同步性良好。吉非替尼片和盐酸厄洛替尼片DDC都有下降，且B/A远大于1。甲磺酸奥希替尼片DDC由500多降至100多，说明患者经济负担变轻。DDC下降幅度最大的是卡瑞利珠单抗注射液，度伐利尤单抗注射液、利妥昔单抗注射液的DDC均超1 000；克唑替尼胶囊、盐酸阿来替尼胶囊、塞瑞替尼胶囊的DDC均超过500，说明患者的经济负担重。见表4。

表2　2019至2023年各新型抗肿瘤药物在肺癌治疗中的销售金额及排序

Tab.2　Sales sum and ranking of new antitumor drugs in lung cancer treatment from 2019 to 2023

分类	药品名称	2019年		2020年		2021年		2022年		2023年	
		金额（万元）	排序	金额（万元）	排序	金额（万元）	排序	金额（万元）	排序	金额（万元）	排序
大分子单克隆抗体	贝伐珠单抗注射液	203.09	2	388.64	1	606.18	1	509.48	1	571.92	1
	度伐利尤单抗注射液			9.65	12	89.26	5	27.13	11		
	卡瑞利珠单抗注射液			1.98	13	43.78	7	31.04	10	26.27	8
	纳武利尤单抗注射液			0.93	14						
	西妥昔单抗注射液	0.77	11			3.85	13				
	信迪利单抗注射液					1.71	14	42.23	6	95.80	6
	利妥昔单抗注射液					1.57	15	3.15	16		
	帕博利珠单抗注射液					14.33	11				
	替雷利珠单抗注射液					10.03	12			132.41	4
	尼妥珠单抗注射液							1.15	18		
	曲妥珠单抗注射液							2.75	17	2.75	12
小分子靶向药物	盐酸安罗替尼胶囊	208.23	1	148.49	4	142.68	3	192.66	3	202.43	3
	盐酸阿来替尼胶囊					140.11	4	94.21	5	93.65	7
	克唑替尼胶囊	40.90	6	54.69	7			7.32	14	13.38	10
	塞瑞替尼胶囊	14.85	8	14.85	9	16.32	10	5.71	15	0.41	19
	甲磺酸奥希替尼片	123.93	4	168.31	3			99.33	4		
	吉非替尼片	64.82	5	56.51	6	17.00	9			1.48	17
	甲磺酸阿美替尼片							37.44	7		
	甲磺酸伏美替尼片							9.56	13	115.23	5
	马来酸阿法替尼片	14.68	9	30.12	8	64.23	6	34.19	9	0.88	18
	盐酸埃克替尼片	35.65	7	63.89	5			19.56	12	20.91	9
	盐酸厄洛替尼片	3.19	10	14.46	10	35.59	8	36.88	8	1.94	16
	洛拉替尼片									10.54	11
	布格替尼片									8.77	13
	赛沃替尼片									2.12	14
	曲美替尼片									2.03	15
	甲磺酸阿帕替尼片			10.72	11						
其他	依维莫司片					0.39	16				
	重组人血管内皮抑制素注射液	181.06	3	183.55	2	317.81	2	243.53	2	332.66	2

表3　2019至2023年各新型抗肿瘤药物在肺癌治疗中的DDDs及排序

Tab.3　DDDs and ranking of new antitumor drugs in lung cancer treatment from 2019 to 2023

分类	药品名称	2019年		2020年		2021年		2022年		2023年	
		DDDs	排序	DDDs	排序	DDDs	排序	DDDs	排序	DDDs	排序
大分子单克隆抗体	贝伐珠单抗注射液	4 200.00	4	11 356.00	1	19 840.00	1	18 016.00	1	20 876.00	1
	度伐利尤单抗注射液*			48.91	12	454.35	10	140.00	14		
	卡瑞利珠单抗注射液			21.00	13	2 898.25	7	2 226.19	7	2 121.18	7
	纳武利尤单抗注射液			5.83	14						
	西妥昔单抗注射液	9.84	11			52.45	14				
	信迪利单抗注射液					63.01	13	4 115.79	6	9 336.84	5
	利妥昔单抗注射液					11.11	16	22.22	18		
	帕博利珠单抗注射液					84.01	12				
	替雷利珠单抗注射液					483.04	9			10 084.21	4

续表

分类	药品名称	2019年		2020年		2021年		2022年		2023年	
		DDDs	排序	DDDs	排序	DDDs	排序	DDDs	排序	DDDs	排序
	尼妥珠单抗注射液							28.57	17		
	曲妥珠单抗注射液							110.00	16	110.00	16
小分子靶向药物	盐酸安罗替尼胶囊	6 761.62	1	84.53	11	9 957.70	3	10 420.94	2	10 934.93	3
	盐酸阿来替尼胶囊					2 575.50	8	1 862.00	9	1 851.00	9
	克唑替尼胶囊	810.00	7	1 080.00	8			160.00	13	390.00	13
	塞瑞替尼胶囊	250.00	9	250.00	10	400.00	11	140.00	14	10.00	19
	甲磺酸奥希替尼片	2 430.00	5	3 300.00	5			5 340.00	4		
	吉非替尼片	5 221.00	2	9 691.00	2	4 200.00	5			576.00	12
	甲硝酸阿美替尼片							1 063.50	11		
	甲硝酸伏美替尼片							810.00	12	5 974.50	6
	马来酸阿法替尼片	715.75	8	1 506.00	7	3 661.00	6	1 952.00	8	944.25	11
	盐酸埃克替尼片	1 855.33	6	3 325.00	4			1 638.00	10	1 751.33	10
	盐酸厄洛替尼片	175.00	10	1 988.00	6	5 012.00	4	5 194.00	5	2 037.00	8
	洛拉替尼片									200.00	15
	布格替尼片									298.66	14
	赛沃替尼片									28.00	18
	曲美替尼片									61.00	17
	甲硝酸阿帕替尼片			284.00	9						
其他	依维莫司片					15.00	15				
	重组人血管内皮抑制素注射液	5 071.76	3	6 610.59	3	11 445.88	2	8 770.59	3	11 980.59	2

表 4　2019 至 2023 年各新型抗肿瘤药物在肺癌治疗中的 DDC 及 B/A

Tab.4　DDC and B/A of various new antitumor drugs in lung cancer treatment from 2019 to 2023

分类	药品名称	2019年		2020年		2021年		2022年		2023年	
		DDC(元)	B/A	DDC(元)	B/A	DDC(元)	B/A	DDC(元)	B/A	DDC(元)	B/A
大分子单克隆抗体	贝伐珠单抗注射液	483.55	0.50	342.23	1	305.53	1	282.79	1	273.96	1
	度伐利尤单抗注射液			1 973.17	1	1 964.56	0.50	1 937.85	0.78		
	卡瑞利珠单抗注射液			942.76	1	151.06	1	139.43	1.43	123.85	1.14
	纳武利尤单抗注射液			1 594.38	1						
	西妥昔单抗注射液	789.94	1			734.78	0.93				
	信迪利单抗注射液					271.16	1.08	102.60	1	102.60	1.20
	利妥昔单抗注射液					1 416.07	0.94	1 417.51	0.89		
	帕博利珠单抗注射液						0.92				
	替雷利珠单抗注射液					207.61	1.33			131.31	1
	尼妥珠单抗注射液							402.50	1.06		
	曲妥珠单抗注射液							250.00	1.06	250.00	0.75
小分子靶向药物	盐酸安罗替尼胶囊	307.96	1			143.29	1	184.88	1.50	185.12	1
	盐酸阿来替尼胶囊					544.00	0.5	505.96	0.56	505.92	0.78
	克唑替尼胶囊	504.89	0.86	506.39	0.88			457.50	1.08	343.20	0.77
	塞瑞替尼胶囊	594.00	0.89	594.00	0.90	408.00	0.91	407.86	1.07	408.00	1
	甲磺酸奥希替尼片	510.00	0.80					186.01	1		
	吉非替尼片	124.15	2.50	58.31	3	40.49	1.8			25.69	1.42
	甲磺酸阿美替尼片							352.05	0.64		
	甲磺酸伏美替尼片									192.87	0.83
	马来酸阿法替尼片	205.11	1.13	200.00	1.14	175.45	1	175.15	1.13	9.32	1.63
	盐酸埃克替尼片	192.15	1.17	192.15	1.25			119.41	1.20	119.40	0.90
	盐酸厄洛替尼片	182.29	1	72.74	1.67	71.00	2	71.01	1.60	9.51	2
	洛拉替尼片									527.00	0.73
	布格替尼片									293.51	0.93
	赛沃替尼片									755.70	0.78
	曲美替尼片									332.55	0.88
	甲磺酸阿帕替尼片			377.47	1.22						
其他	依维莫司片					260.00	1.07				
	重组人血管内皮抑制素注射液	357.01	1	277.66	0.67	277.67	1	277.67	0.67	277.67	1

3 讨 论

肺癌治疗中，传统抗肿瘤化疗药物毒副反应大，患者5年存活率较低[1]。以酪氨酸激酶抑制剂（tyrosine kinase inhibitor，TKI）、单克隆抗体免疫抑制剂为代表的新型抗肿瘤药物的应用价值大，在肺癌的治疗中取得了良好的临床疗效[2-3]，因此本院新型抗肿瘤药物无论是使用金额还是品种种类都趋于快速上升趋势。

非小细胞肺癌（non-small cell lung cancer，NSCLC）患者中表皮生长因子受体（epidermal growth factor receptor，EGFR）突变是最常见的驱动癌症基因，在我国检出率高达50.2%[4]。本院一代EGFR-TKI有吉非替尼片、盐酸厄洛替尼片和盐酸埃克替尼片[5]。经综合分析，临床早期倾向选用吉非替尼片，随其耐药性增高逐渐被盐酸埃克替尼片所替代。多项研究显示，三者在最佳疗效、中位生存期、肿瘤客观缓解率、中位无进展生存期以及1、3、5年生存率上无统计学差异。从安全性角度分析，盐酸厄洛替尼片的腹泻、消化道症状发生率最高，从成本效用分析，盐酸埃克替尼片优势更明显[6]。

本院二代EGFR-TKI代表是马来酸阿法替尼片，其具有不可逆的双重抑制性，能有效抑制肿瘤发展。与吉非替尼片、盐酸厄洛替尼片相较，马来酸阿法替尼片疗效无明显差异[7]，但能显著延长肿瘤无进展生存期[8]，减少患者的获得耐药性[9]。马来酸阿法替尼片不良反应有甲沟炎、皮肤毒、口腔炎等，发生率虽高于盐酸厄洛替尼片和吉非替尼片，但耐受性更好，常规剂量常可控[10]。经综合分析，马来酸阿法替尼片经济学优势较吉非替尼片不明显。

本院三代EGFR-TKI有甲磺酸阿美替尼片、甲磺酸奥希替尼片和甲磺酸伏美替尼片。从表3、4数据看，甲磺酸阿美替尼片B/A<1，DDC值远高于甲磺酸奥希替尼片，甲磺酸奥希替尼片DDDs明显高于甲磺酸阿美替尼片。甲磺酸奥希替尼片可穿透血脑屏障，降低肿瘤进展，已被美国国立综合癌症网络临床实践指南推荐作为EGFR突变的晚期NSCLC一线首选[11]。获得中国药品监督管理局、美国食品药品管理局和欧洲药品管理局批准，用于NSCLC术后辅助治疗[12]，治疗周期长，因此使用量高。甲磺酸伏美替尼片作为第二个国内原研三代EGFR-TKI，对一代EGFR-TKI耐药和有脑转移的NSCLC患者，其使用量名次明显上升，临床疗效对比吉非替尼片，无进展生存期目前最长，深受临床青睐，因此使用量名次上升快速。

大约有3%~5%的NSCLC患者存在间变性淋巴瘤激酶（anaplastic lymphoma kinase，ALK）融合阳性。首个获批抑制剂（ALK-TKI）克唑替尼胶囊，打破了ALK阳性晚期NSCLC患者仅能化疗的局面，成为治疗的分水岭，其比标准方案（培美曲塞+铂类）更能控制脑转移，疗效更好[13]。耐药后的ALK阳性NSCLC的患者更换二代ALK-TKI治疗，代表药有塞瑞替尼胶囊、盐酸阿来替尼胶囊。数据显示本院更倾向选盐酸阿来替尼胶囊，可能与其拥有较好的血脑屏障渗透率，在控制脑转移方面有较大突破有关[14]。作为首个获批的二代ALK抑制剂，据文献报道塞瑞替尼胶囊安全性问题突出[12]。对该药安全性顾虑和对患者经济负担顾虑，可能是影响本院塞瑞替尼胶囊临床使用的主要原因。

贝伐珠单抗注射液无论是金额排序、DDDs均连续多年居首，可见临床使用甚广。从肺癌治疗病种看，腺癌发病率高于鳞癌，贝伐珠单抗注射液治疗腺癌获批时间早，治疗地位高，获批适应证多，能够覆盖患者从治疗到维持整个疾病周期。临床通常单用贝伐珠单抗注射液或者与TKI联合使用。贝伐珠单抗注射液对EGFR耐药的患者也能发挥一定的作用，能明显改善肿瘤无进展生存期，提高疾病总控制率，抗肿瘤作用持久而显著。然而以贝伐珠单抗注射液为代表的抗血管内皮生长因子的单克隆抗体联合化疗并未提高小细胞肺癌（small cell lung cancer，SCLC）患者的肿瘤总生存期。靶向药物在SCLC应用中不及NSCLC，仅盐酸安罗替尼胶囊被推荐用于晚期SCLC三线及以上治疗[15]。盐酸安罗替尼胶囊能抑制成纤维细胞因子受体、血管内皮生长因子受体，及血小板衍生生长因子受体等多靶点，用于至少接受过2种系统化疗后出现进展的晚期转移NSCLC患者[12,16-17]。自2019年本院引进后，其DDDs呈逐年递增趋势，尽管DDC值在逐年下降，却仍偏高，下降空间尚有。

近几年肺癌靶向治疗进展迅猛，但在SCLC领域，获批的靶向药物较少。免疫治疗为易复发、低生存、转移率高的SCLC患者带来了更多治疗的可能[18]。免疫检查点抑制剂DDDs增幅比小分子靶向药物增幅大得多。可见越来越多的肺癌治疗患者接受免疫治疗。

以卡瑞利珠单抗注射液为代表的程序性死亡受体抑制剂被美国食品药品管理局批准作为广泛期SCLC患者一线治疗首选[19-20]。数据显示，卡瑞利珠单抗注射液使用增长幅度最大。DDC下降幅度也是最大，其原因可能是2022年卡瑞利珠单抗注射液被纳入国家谈判医保目录药品，临床疗效显著，患者经

济负担减轻，因此临床使用量增长迅速。

综上所述，由于新型抗肿瘤药物在肺癌治疗中使患者获益不断增加，特别是口服药物较化疗给药方便，副作用低，受到患者和临床的一致推荐，多数品种DDC均呈一路走低趋势，但仍处于高位，患者和医保的负担较重。为达到更好的治疗效果、减轻患者经济压力，采购国家医保谈判目录的新型抗肿瘤药物品种在不断增加，临床应进一步规范新型抗肿瘤药物的使用，真正做到“安全、有效、经济”，为患者提供更优质的医疗服务。

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