

## Research Status and Progress of Comprehensive Evaluation of Cancer Clinical Efficacy

Wang Ziyu<sup>1</sup>, Jiang Yuan<sup>2</sup>, Yuan Shengli<sup>3\*</sup>

<sup>1</sup>Qingdao University, Qingdao, Shandong, 266011, China

<sup>2</sup>Ludong Hospital (Shandong Provincial Hospital Group), Yantai, Shandong, 264000, China

<sup>3</sup>Qingdao Municipal Hospital, Qingdao, Shandong, 266011, China

\*Corresponding Author Email: A22631610@163.com

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**Abstract:** with the continuous deepening of people's understanding of tumors, the standardized treatment of early diagnosis and early treatment, and the gradual improvement of diagnosis and treatment, the mortality of tumors is gradually decreasing, and the survival time of patients is significantly extended. A variety of treatment methods (such as surgery, radiotherapy, chemotherapy, Chinese medicine treatment, biological treatment, endocrine treatment, etc.) Provide options for the treatment of tumors. However, how to adopt the most effective treatment strategy and obtain the best treatment effect has become one of the key issues in clinical research of tumors. Therefore, it is particularly important to objectively evaluate the efficacy of tumor treatment. This study reviewed the relevant literature in recent years, reviewed the comprehensive evaluation application and development of various indicators in the evaluation system of tumor efficacy in modern medicine, and researched the research status and progress of tumor efficacy evaluation system. It is hoped that this study will have a certain degree of understanding of the current status and trends of comprehensive evaluation of tumor clinical course.

### 1. Introduction

The incidence of tumors has been increasing year by year, and people's understanding of tumors and the effect of treatment have greatly improved. For most solid tumors, local treatment of the tumor, such as surgical resection or radiotherapy, is the standard treatment. The treatment of tumors has gradually changed from focusing on changes in local tumors to focusing on the patient's general condition, treatment response, and patient's quality of life[1]; however, for some patients with locally advanced tumors, when the tumor is locally infiltrated extensively, and adjacent important organs or tissues are complicated, it makes the local treatment more difficult. In this way, it is often difficult to effectively solve the tumor burden, and to ensure the integrity of normal anatomy and function, so as to "cure" the tumor. Therefore, adopting multi-disciplinary clinical comprehensive curative effect evaluation has become an effective and main way to evaluate the effect of tumor treatment. However, at present, there are still some problems in the comprehensive evaluation system of tumor efficacy. For example: the evaluation indicators are not completely unified; content differences in quality of life-based assessments; the weights of evaluation indicators in all stages of tumorigenesis have not been unified. And how to objectively reflect the actual effect of traditional Chinese medicine in treating tumors[2].

Therefore, it is particularly important to objectively evaluate the efficacy of tumor treatment. In this study, through literature review, a review of relevant research literature on the comprehensive evaluation of various indicators in the evaluation system of tumor efficacy in modern medicine, and its development, the research status and progress of tumor curative effect evaluation system were also studied.

## 2. Research Status of Comprehensive Evaluation of Cancer Clinical Efficacy

Although traditional Chinese medicine and modern medicine have different evaluation systems for tumor efficacy, they both advocate the use of comprehensive evaluation indicators. Selectively include tumor size, quality of life, time to treatment (TTP), median survival, tumor-bearing survival, overall survival, clinical benefit rate, health economics, immune function, and tumor markers to the tumor efficacy evaluation system, and determine the weight of each index in the evaluation system. This is a complex systems engineering, a comprehensive evaluation system with multiple fields, multiple levels, and multiple indicators. It is a dynamic process of continuous improvement.

### 2.1 Evaluation Criteria of Comprehensive Curative Effect of Current Tumor Treatment

#### 2.1.1 Digital Pain Scoring Method

According to the 2011 edition of the standardized diagnosis and treatment of cancer pain issued by the Ministry of Health, the digital pain score, the pain is expressed by a total of 11 numbers from 0 to 10 (0 means no pain, 10 means the most painful). Patients choose one of these 11 numbers according to their pain level, which is the NRS value.

According to the WHO pain grading standard, it is divided into 4 levels, of which 0 is no pain (no pain symptoms, and life is completely self-care); 1 ~ 3 is divided into mild pain (pain is relieved without analgesics, and most of life can take care of itself); 4 ~ 6 points of moderate pain (pain medication is needed to relieve pain, and the living part can take care of itself); 7 ~ 10 points are divided into severe pain (pain cannot be relieved, analgesics cannot completely relieve pain, and reliance on stronger analgesics)[3].

#### 2.1.2 Karst Score (Kps)

KPS, also known as the Karst score (see Table 1), consists of a total of 11 registrations that use 0 to 100 points for physical activity. 0 means death and 10 means normal. The higher the KPS score, the better the patient's physical condition and the more able to tolerate the side effects of various treatments on the body.

Table 1 Kps Score Sheet

Scores	Physical condition	Scores	Physical condition
0	Death	10	Critically ill, near death
20	Severely ill, requiring hospitalization and active treatment	30	Serious life can not take care of themselves
40	Can't take care of yourself and need special care	50	Often need care
60	Life can take care of itself for the most part, but occasionally need help	70	Can take care of themselves but cannot maintain normal life and work
80	Barely living a normal life with some symptoms or signs	90	Able to live a normal life with mild symptoms and signs
100	Normal, asymptomatic and signs	/	/

#### 2.1.3 Local Effect

According to the solid tumor response evaluation standard (RECIST version 1.1) published by the European Journal of Cancer in 2009, the efficacy evaluation of bone metastases (see Table 2) is divided into complete response (CR); partial response (PR); stable disease (SD); disease Progress (PD)[4].

Objective efficiency: ORR = (CR + PR) / (CR + PR + SD + PD) \* 100%;

Disease control rate (clinical benefit rate): DCR = (CR + PR + SD) / (CR + PR + SD + PD) \* 100%.

Table 2 Efficacy Evaluation

Efficacy	Standard
CR	Cure
PR	Lesion no longer expands, marginal sclerosis
SD	No obvious enlargement of the lesion
PD	Lesions have further expanded and bone destruction has become more pronounced

Note:CR:complete response;PR:partial response;SD:stable disease;PD:progressive disease.

## 2.2 Curative Effect Evaluation Indicators At the Current Stage of Tumor Treatment

The complete killing of tumor cells is the ideal standard pursued by modern oncology, but theory and practice prove that this goal is almost impossible to achieve. Combined with literature research, this study summarizes the current evaluation indicators for tumor treatment in the literature [5], as shown in Figure 1.

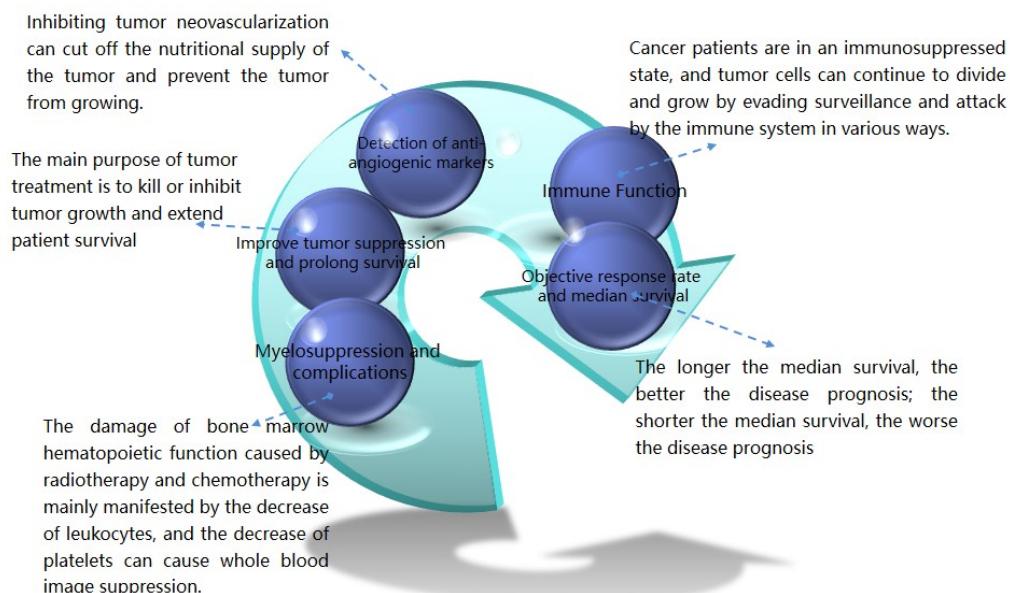


Fig.1 Comprehensive Evaluation Index of Current Solid Tumors

## 2.3 Evaluation of the Efficacy of Tumor Immunotherapy

From the perspective of the characteristics of the tumor itself, immunotherapy can use multiple ways or means to control the collective immune system, so as to play a better killing effect on the tumor. In recent years, with the rapid development of cell biology, immunology, and genetic engineering technology, human beings have explored the correlation between tumor cell genes, immune system and microenvironment, and immunotherapy strategies have emerged one after another. DCs loaded with various antigens can intervene in anti-tumor immune responses of varying degrees. DC cells can induce tumor-specific CTL cells after transfection with PEG-10; The use of HBV-specific T cells can effectively control the progression of hepatitis B virus infection and hepatitis B virus-related tumors; The use of NK and NKT cells isolated from peripheral blood for cellular immunotherapy can strengthen the immune system's ability to resist hepatitis C virus and its related HCC [7].

## 2.4 Research Status of Comprehensive Efficacy Evaluation of Tcm in Treating Tumors

The concept of TCM treatment of tumors is based on the macro-adjustment of the balance of the human body's internal environment as a starting point. The evaluation of the curative effect includes

the content that reflects the quality of life of the patient, such as physical function, subjective feelings and conscious symptoms. At present, the academic world has not formed a unified evaluation system for the efficacy of traditional Chinese medicine tumor treatment. In recent years, TCM oncologists have put forward many creative suggestions for constructing TCM tumor efficacy evaluation systems, and have carried out targeted research, and have obtained some research results with reference value. The “Traditional Chinese Medicine Tumor Efficacy Evaluation of Solid Tumors (Draft)” developed by Chen, D and others will evaluate the efficacy of traditional Chinese medicine for advanced lung cancer in terms of total efficacy (100%) = tumor change (30%) + clinical symptoms (15%) + physical condition ( 15%) + survival (40%), and compared with the curative effect evaluation standard of RECIST based on the curative effect evaluation standard, 191 patients with intermediate and advanced stage NSCLC were evaluated, and it was found that the comprehensive index evaluation method can better reflect the curative effect of traditional Chinese medicine treatment [8].

### **3. Research Progress of Comprehensive Evaluation of Tumor Clinical Efficacy**

In addition to the traditional evaluation of the efficacy of tumors, the evaluation of the efficacy of tumors also begins to consider the economic burden and clinical benefits of patient treatment. The evaluation target involves multiple levels of medical supplier and demand side, such as patients themselves, clinical staff, caregivers and medical tests. We are also trying to explore how to use these indicators to comprehensively evaluate the clinical efficacy of tumors, in order to more comprehensively evaluate the treatment effect and provide a more scientific clinical decision basis. In previous clinical studies, objective tumor remission rate and chemotherapy completion rate have been used as the main evaluation indicators of anti-tumor Chinese medicine and radiotherapy and chemotherapy synergistic drugs. However, the positive rate in actual clinical research is not high, and satisfactory results have not been obtained. Evaluation of quality of life in clinical research has gradually risen due to its role in the evaluation of tumor efficacy. Modern medicine has also paid more and more attention to changes in patients' quality of life under the mind-body health model. Whether it is a tumor disease or a corresponding treatment, it will have a comprehensive impact on the social life and family life of patients [9]. Attention to quality of life efficacy indicators will be the trend of clinical research on new tumor drugs in the future. When selecting the endpoints for clinical research, we should consider the importance of the indicators and choose the indicators that can reflect the advantages of chemotherapy. Cytotoxic drugs have the advantage of shrinking tumors, but they also produce a series of adverse reactions. Therefore, in a period of time, clinical research in modern medicine has used the objective response rate and disease stability rate as the main efficacy indicators. At present, the research progress of clinical comprehensive curative effect evaluation of tumor is mainly reflected in several directions as shown in Figure 2.

At the same time, the emergence of targeted drugs has brought many challenges to the RECIST criteria for evaluation of solid tumors. For example, when targeted drugs are used to treat malignant tumors, the tumor size does not change, but its metabolism decreases. Taking size as an evaluation criterion does not accurately reflect the effect of treatment, and traditional Chinese medicine is facing the same confusion in treating tumors. In addition to survival time, the efficacy judgment needs to introduce a reasonable quality of life concept. Some scholars believe that the evaluation of the efficacy of malignant tumors should include three elements: quality of life, survival time, and tumor remission rate, but there is currently no evaluation standard that includes the above three elements. With the development of biological technology and molecular imaging, researchers have successfully applied specific antibodies in combination with contrast agents to target lesions to reflect changes in the molecular level of living tissues. Soria, J. C. et al. used a 1.5 TMR device to scan a nude mouse model of small cell lung cancer inoculated with the brain, which showed that the tumor was significantly strengthened after intravenous injection of single crystal iron oxide particles combined with human tumor-specific antibodies, and the degree of enhancement was related to tumor cells [10]. In addition, some researchers incubated iron oxide particles coated with integrin receptor  $\alpha v\beta 3$  antibodies with isolated vascular endothelial cells and performed MRI to reflect the

expression level of integrin receptor  $\alpha v\beta 3$ . The latter is closely related to tumor micro-angiogenesis, but currently, monoclonal antibodies and contrast agents combined with targeted MRI are still in the clinical research stage [11].

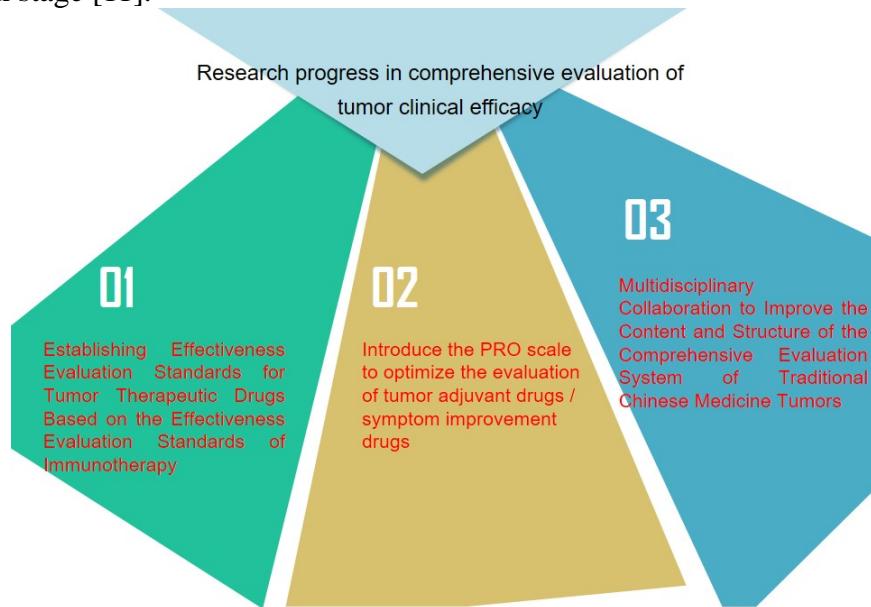


Fig.2 Research Progress in Comprehensive Evaluation of Tumor Clinical Efficacy

#### 4. Conclusion

With the in-depth study of the evaluation of tumor efficacy, I believe that traditional Chinese medicine and modern medicine will be more objective, comprehensive and standardized in the selection and application of evaluation indicators and the effectiveness of clinical evaluation. Practice has shown that medicine is diverse. The curative effect evaluation system is a cross-disciplinary, unified weights and measures system across various medicines. Because of this, we can use this “fair scale” to weigh the advantages and disadvantages and characteristics of different disciplines and various therapies. With the transformation of the modern medical model from the biomedical model to the bio-psychosocial model, modern medicine has gradually paid more attention to human psychological and social factors. Regardless of Western medicine or Chinese medicine, the end point of evaluating the efficacy of treating tumors should be how to maximize the benefits for patients. That is to achieve the maximum tumor remission rate on the basis of satisfactory quality of life and longer survival time, instead of simply emphasizing tumor shrinkage, regression and tumor-free survival time. Therefore, based on this consensus, through extensive and intensive exchanges and cooperation between Chinese and Western medical oncologists, it should be possible to establish a tumor efficacy evaluation system that reflects the characteristics of Chinese and Western medicine and is more conducive to academic exchanges between Chinese and Western medicine.

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