

Development and evaluation analysis of the questionnaire of "eight methods of tumour pathogenesis" based on the Delphi questionnaire method

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Abstract

Objective: The Delphi questionnaire was used to evaluate and analyse 109 symptoms of 8 categories in the pool of Chinese medical evidence of tumours, and was used to formulate the "Tumour Disease Mechanism Evaluation Scale", with the aim of establishing a unified and standardized criterion for the clinical diagnosis of tumours. **Methods:** The questionnaire content of the "Eight Methods of Tumour Disease Mechanisms" was formulated by collating disease entries through literature review. Experts' opinions were collected through the Delphi method, and the degree of coordination and concentration of experts were statistically analysed after the collection. **Results:** Through two rounds of Delphi questionnaire analysis, experts' enthusiasm was 100%, the authority coefficient of the first-level index was 0.685, the second-level index was 0.065 and 0.593, and six indexes with poor correlation were deleted. **Conclusion:** The experts participating in this survey are representative, with high motivation and good coordination of their opinions on the questionnaire entries, and the "Tumour Disease Mechanism Identification and Evaluation Scale" formulated using this questionnaire has practical value.

Keywords: Delphi questionnaire; tumour; disease mechanism identification; evaluation of questionnaire.

Introduction

A tumor is a new growth of tissue caused by the abnormal proliferation of cells due to the influence of various physical and chemical factors, resulting in the loss of normal regulation in local tissues. Tumors are classified into benign and malignant types, with malignant tumors commonly referred to as cancer [1]. In recent years, due to the increasing incidence and mortality rates, malignant tumors have become a major global public health issue [2]. In addition to conventional treatments, the integration of traditional Chinese medicine (TCM) offers new opportunities for malignant tumor therapy. TCM interventions can reduce the adverse effects of conventional treatments, such as chemotherapy and radiotherapy, while improving patients' quality of life and prolonging survival [3-5]. However, the field of TCM currently lacks standardized and unified syndrome differentiation methods and corresponding scales to evaluate the clinical efficacy of TCM treatments [6].

Syndrome differentiation and treatment (treatment based on syndrome differentiation) is the core of TCM clinical practice, and the accuracy of syndrome differentiation determines the effectiveness of medication [7]. However, long-term clinical practice has revealed that the accuracy of syndrome differentiation is closely related to the physician's knowledge, clinical experience, and the patient's basic condition. To better guide TCM clinical diagnosis and treatment of malignant tumors, improve the accuracy of syndrome differentiation, and further explore the syndrome patterns of malignant tumors, we aim to develop the "Tumor Pathomechanism Identification and Assessment Scale". This scale will be applied to the TCM clinical diagnosis and evaluation of treatment efficacy in malignant tumor patients.

Through a literature review, we identified eight pathomechanisms associated with malignant tumors and compiled a pool of 103 syndrome-related items. These items were incorporated into a questionnaire based on the "Eight Methods of Tumor Pathomechanism". Subsequently, the Delphi method was used to survey 45 experts through a questionnaire, and the results are reported below.

1. Materials and Methods

1.1 Literature Review

A literature search was conducted in databases such as CNKI, VIP, and Wanfang using the keywords "Traditional Chinese Medicine," "syndrome differentiation and treatment," "malignant tumor," and "syndrome." The relevant literature was reviewed and summarized, resulting in the identification of eight pathomechanisms related to malignant tumors, including Qi deficiency, blood deficiency, Yang deficiency, and Yin deficiency, among others. A total of 109 symptoms associated with malignant tumors were extracted, covering the common symptoms observed in clinical practice across different ages, genders, and stages of malignant tumor patients (see Table 1).

Table 1 Primary indicators

oil level indicator tap-changer	two grade index evaluation	oil level indicator tap-changer	two grade index evaluation
deficiency of vital energy	vertigo blurred vision and weariness	stagnation of the circulation of vital energy	Distending pain in the chest and abdomen
	Short of breath and lazy		Emotional sensitivity, good sighing
	spontaneous perspiration		anxiety and irritability
	Easy cold		Bitter mouth and dry throat or accompanied by vomiting
	Pale (fat) tongue, tender and white fur		Dull tongue
	feeble pulse		wiry and rapid pulse
	Pale or yellowish complexion		dizziness
	Cough, gasp, or saliva clearing		Chronic cough or asthma
	he stomach is bloated		Belching and hiccups
	Continuous pain		The stomach is bloated
deficiency of yang	Weak bowel movements, frequent urination at night	phlegmatic hygrosis	Bad stool
	Pulse sinking or delayed		Tongue edge tooth marks, thin white or thin yellow, white or yellow greasy
	Pale face, fear of cold limbs cold		small and wiry pulse
	It is easy to have diarrhea after entering cold food		Heavy head and body
	Warm like press, heat pain reduction		Chest duct fullness and tightness

yin deficiency	Long clear urination or frequent urination at night, loose stool or diarrhea	blood stasis	Nauseous and stupid
	The tongue is light and fat with teeth on the edge, and the fur is white and smooth		Vomiting sputum and excessive sputum
	Pulse sinking late or weak		Sticky stool, thin loose stool
	Lethargy, dizziness and lethargy		Tongue light fur white greasy tooth marks
	spontaneous perspiration		Pulse slip or dull
	The mouth is weak and not thirsty		dizzy
	Phlegm and saliva are clear and thin		The eyes turned yellow
	soreness and weakness of waist and knees		enclosed mass
	Urine dripping, urine flow gradually thin, oligoedema of urine		Sticky mouth, weak mouth thirsty or thirsty not to drink
	impotence		hypersalivation
	The throat is dry and the mouth is dry		tenesmus
	dysphoria in chestpalms-soles		The tongue is pale and the fur is white and thick
	night sweat		The pulse is slippery, the pulse string is slippery, the pulse is moist
	Short yellow urine, dry stool		Tingling, radiating pain
	Red tongue with little moss		The mass is hard and dark or purple in color
	thready rapid pulse		Blue lip nails
	become thin		Dark blood or clots

	dizziness and tinnitus		Dark purple tongue or ecchymosis, petechiae, tortuous sublingual vein
	insomnia and dreamful sleep		uneven pulse
	Dry cough with little sputum or bloodshot sputum		darkish complexion
	Noisy, acid reflux		scaly dry skin, a symptom of blood stasis; pellagra
	soreness and weakness of waist and knees		Purpura subcutanea
	dull pain		numbness of limb
	The tongue is dry and cracked, and the fur is thin and white		The pulse is heavy, the pulse is mixed, the pulse is astringent, the pulse is fine astringent or firm
	The mouth is dry and bitter		Lumps pain at night
	Pulse depth count		Pale complexion, lips and nails
	Surface tumors are red, swollen, burning pain, often accompanied by ulcers and red blood		feel dizzy
	Afternoon tidal fever, persistent low or high fever		insomnia and forgetfulness
heat toxin	Dry cough, cough yellow sputum or pus blood smelly sputum	deficiency of blood	Palpitation and palpitation
	Bad breath, dry mouth, swollen gums, sore throat		pale tongue with moist coating
	The urine is red and congealed		A breakdown of pulse
	reddened tongue		The blood is pale

rapid pulse	Faint pain
Irritability, restlessness or even delirium	Limb numbness and clonus
Yellow eyes or accompanied by bitter mouth, sticky mouth	White fur, thin white fur
Burning pain in the chest and hypochondrium	Thin pulse, thin pulse
The tongue is red and the fur is yellow and dry or thick and greasy	weak pulse
The number of slips or strings	weak

1.2 Delphi Questionnaire Method

1.2.1 Questionnaire Design

The questionnaire includes the basic information of the experts and an informed consent form, an introduction to the questionnaire items, and the questionnaire table. An expert opinion collection form is attached to allow experts to record personal opinions beyond the table and to supplement or correct the content of the questionnaire. In the first round of the questionnaire, we used a 10-point scale, where experts could rate the importance of each item from 1 to 10: 1 (basically irrelevant), 2 (very unimportant), 3 (unimportant), 4 (somewhat important), 5 (moderately important), 6 (relatively important), 7 (important), 8 (very important), 9 (extremely important), and 10 (critical). In the second round of the questionnaire, based on expert suggestions, we adjusted the scale to a 1-5 rating system: very unimportant (1 point), unimportant (2 points), neutral (3 points), important (4 points), and very important (5 points).

1.2.2 Expert Team Selection

The experts participating in the questionnaire were from the Traditional Chinese Medicine Department of the Second Affiliated Hospital of the Air Force Medical University and the Affiliated Hospital of Shaanxi University of Chinese Medicine. All experts were senior clinicians with over 10 years of experience in traditional Chinese medicine or integrated Chinese and Western medicine oncology. They held associate senior titles or higher and had extensive experience in the diagnosis and treatment of malignant tumors using traditional Chinese medicine or integrated Chinese and Western medicine approaches.

1.2.3 Evaluation Method

Excel software was used to organize and summarize the questionnaire data. After verification, SPSS 26.0 software was employed for statistical analysis. The boundary value method was used to screen the indicators, and items that did not meet the requirements were eliminated. The first round of survey results was analyzed using this method, and the second round of the questionnaire was designed based on the results. If a consensus was not reached after two rounds, a third round of questionnaires could be conducted until consultation, feedback, and analysis led to a unified expert opinion, resulting in the final evaluation indicators.

2. Data Analysis Process

2.1 Expert Enthusiasm Coefficient

The response rate (Response Rate = Number of Responses / Number of Questionnaires Sent × 100%) reflects the enthusiasm coefficient of the experts, indicating their level of attention to this questionnaire survey. Starting from January 2023, questionnaires were distributed and collected via email, postal mail, and in-person delivery during the survey process. By March 2023, in both rounds of the questionnaire survey, 45 questionnaires were distributed and 45 were collected, resulting in an expert enthusiasm coefficient of 100% for each round. This demonstrates a high level of attention from the experts toward this survey. (See Table 2)

Table 2-1 Questionnaires returned

	amount shipped out	recycling quantity	Expert positive coefficient
first round	45	45	100%
the second round	45	45	100%

2.2 Expert Authority Coefficient

The expert authority coefficient (Cr) is primarily determined by two factors: the basis of the expert's judgment (Ca) and the expert's familiarity with the issue (Cs) [8,9]. Generally, an expert authority coefficient greater than 0.7 is considered to indicate a high level of expert authority. The calculation of the expert authority coefficient for this questionnaire survey is as follows [10].

$$C_r = \frac{C_s + C_a}{2}$$

(公式)

Table 2-2 Quantitative calculation table of expert familiarity

knowledge	be unfamiliar with	unfamiliar	anthriscus sylvestris	be familiar with	very familiar
number of people	0	0	2	6	37
Expert familiarity weight	0.2	0.4	0.6	0.8	1.0
Coefficient of expert familiarity	$C_s = (2 \times 0.6 + 6 \times 0.8 + 37 \times 1) / 45 = 0.96$				

Table 2-3 Quantitative calculation of expert judgment basis

criterion	strong		middle		inferior		Score/number of people
	number of people	assignment	number of people	assignment	number of people	assignment	
practical experience	37	0.5	7	0.4	1	0.3	21.6/45=0.48
theoretical analysis	35	0.3	6	0.2	4	0.1	12.1/45=0.27
Understanding of domestic and foreign counterparts	35	0.1	8	0.1	2	0.1	4.5/45=0.1
intuition	18	0.1	25	0.1	2	0.1	4.5/45=0.1
Total Ca							0.95

According to the statistical data, the expert authority coefficient (Cr) for the participants in the questionnaire survey is calculated as $(0.96 + 0.95) / 2 = 0.955$. This indicates that the reliability and authority of this Delphi study are relatively high.

2.3 Expert Coordination and Consensus

In terms of expert coordination and consensus in this study, it is necessary to calculate the coordination coefficient (Kendall's W), the coefficient of variation (CV), the mean expert score (X), and χ^2 . Generally, the W value should range between 0 and 1, with a higher W value indicating better coordination. The CV value should be less than 0.25, reflecting a high level of

consensus among expert opinions [11].

Based on the results of the first round of the survey, for the primary indicators, the expert scores were greater than 4.00, the coefficient of variation was less than 0.25, and the coordination coefficient was 0.685, indicating a relatively high level of consensus among experts. Therefore, a second round of consultation was not conducted for these indicators. However, for the secondary indicators, the expert scores were all less than 4.00, the coefficient of variation was greater than 0.25, the coordination coefficient was 0.065, χ^2 was 99.185, and the P-value was 0.01 ($P < 0.05$), showing statistical significance. These results indicate that the experts had a low level of agreement on the first-round indicators, and the coordination among experts was also low, with inconsistencies in their opinions on the questionnaire content. Therefore, a second round of the questionnaire survey was necessary. (See Tables 2-4) Based on expert feedback, the questionnaire was adjusted and optimized before being resent to the experts.

According to the results of the second round of the survey, the mean expert score was greater than 4.00, the coefficient of variation was less than 0.25, the coordination coefficient was 0.593, χ^2 was 907.256, and the P-value was 0.01 ($P < 0.05$), showing statistical significance. These results indicate that the experts had a high level of agreement on the second-round indicators, and the coordination among experts was also high. Therefore, a third round of the survey was not required, and the questionnaire survey was concluded. (See Table 2-5)

Table 2-4 shows the degree of coordination of expert opinions in the first round of consultation

Evaluation content	CV	W	X2	P
oil level indicator tap-changer	0.063-0.112	0.685	41.118	<0.05
two grade index evaluation	0.294-0.789	0.065	99.185	<0.05

Table 2-5 shows the degree of coordination of expert opinions in the second round of consultation

Evaluation content	CV	W	X2	P
two grade index	0.043-0.144	0.593	907.256	<0.05

2.4 Modification and Refinement

In this study, the "threshold method" was used for indicator screening, and two formulas were applied to calculate the thresholds. For the full score frequency and arithmetic mean, the threshold was generally calculated using the formula "Threshold = Mean - Standard Deviation", and indicators above this threshold were selected. For the coefficient of variation, the threshold was calculated using the formula "Threshold = Mean + Standard Deviation", and indicators below this threshold were selected. This approach ensured that the selected indicators fell within a reasonable range, maintaining scientific rigor [12]. Additionally, to prevent key indicators from being inadvertently eliminated, indicators that did not fully meet all three criteria were discussed. They were then modified and refined based on rationality, systematic considerations, and clinical needs. (See Tables 2-6 and 2-7)

Table 2-5 First round evaluation results

	mean	standard deviation	dividing value
arithmetic mean value	5.4653	2.8548	2.6105
variable coefficient	0.5318	0.0946	0.6264
Perfect frequency	0.0373	0.0241	0.0132

Table 2-6 Second round evaluation results

	mean	standard deviation	dividing value
arithmetic mean value	8.0706	0.8735	7.1971
variable coefficient	0.0909	0.0242	0.1151
Perfect frequency	0.1262	0.1881	-0.0619

2.5 Summary of Expert Opinions

Based on the first round of the expert opinion questionnaire, the main content of the "Tumor Pathogenesis Identification and Evaluation Table" was determined, including 8 first-level items and 109 second-level items. However, the first-round expert questionnaire revealed that the experts' suggestions for the first-level indicators were relatively consistent, so a second-round survey for the first-level indicators was not conducted. In contrast, no consensus was reached on

the second-level indicators. After fully considering the experts' suggestions, we made the following modifications:

Indicators with an average score of ≥ 4.00 in the first round were classified as Grade A recommendations, while those with scores below 4.00 were classified as Grade B recommendations.

Based on expert recommendations, similar or closely related symptoms were refined to ensure comprehensiveness.

Six indicators with low relevance were deleted, including "impotence," "excessive salivation," "dry and bitter mouth," "nocturnal pain in masses," "fatigue," and "weak pulse."

After these modifications, the second-round questionnaire was developed and sent to the experts. The results of the second round showed good coordination and consensus, indicating that the majority of experts approved of the design. Additionally, some syndrome types were further refined and modified. Finally, all the results were summarized.

3. Discussion

3.1 Purpose and Significance

The advancement in the clinical diagnosis and treatment of malignant tumors is evident. Since 2016, the Chinese Society of Clinical Oncology (CSCO) has formulated and published multiple editions of the "Guidelines for the Diagnosis and Treatment of Common Malignant Tumors," which have become essential references for many clinicians in the field of oncology [13,14]. Although traditional Chinese medicine (TCM) has proven effective in treating malignant tumors, there is still no consensus-based guideline. The systematic and standardized clinical diagnosis and treatment plans for tumors remain an area yet to be fully developed. For many years, TCM clinical practice has largely relied on empirical judgment and some basic theories [15,16]. With the progress of technology and societal development, individual experiences are often insufficient to form a broad consensus, which, to some extent, hinders the advancement of TCM. Particularly for malignant tumors, which are characterized by complex pathogenesis and intricate diagnosis and treatment, it is necessary to establish a unified, standardized, and systematic clinical diagnostic approach [17]. Such an approach not only enables clinicians to quickly and accurately identify syndromes and prescribe appropriate treatments but also facilitates follow-up tracking of patients to evaluate treatment efficacy [18,19]. It is worth mentioning that a scientifically designed assessment scale can also track the suitability of specific formulas for certain patient groups, thereby contributing to the development of anti-cancer drugs. Based on the above reasons, we compiled the experiences of several renowned experts in TCM treatment of malignant tumors from relevant literature and developed the "Eight Methods of Tumor Pathogenesis

Questionnaire." Using the Delphi method, we collected expert opinions and ultimately formulated the "Tumor Pathogenesis Identification and Evaluation Table," which aims to fill the gap in TCM syndrome differentiation for malignant tumors.

3.2 Evaluation of the Delphi Method

The Delphi method is widely used, primarily due to its ability to prevent lateral influence among experts, avoid deference to authority, and allow experts to make judgments based entirely on their own experience and knowledge, resulting in relatively objective and accurate outcomes [20,21]. In this study, the threshold method was employed to screen relevant indicators. The threshold method distinguishes and filters different indicators by setting a threshold, quickly narrowing the scope and enabling the rapid identification of key or non-key indicators during the statistical process. Moreover, it minimizes subjectivity due to its simplicity and ease of integration. In terms of expert selection, a total of 45 experts were chosen. To ensure the questionnaire was completed on time and effectively, active participation from the experts was required. The response rate of the questionnaire was used to reflect the experts' enthusiasm, which was intuitive. In both rounds of the study, the expert response rate reached 100%, demonstrating that this research gained recognition from the experts and holds significant value.

During the process of summarizing and analyzing the questionnaire results, we calculated the experts' authority coefficient, concentration, and coordination level. Most experts have extensive clinical experience and are well-versed in the domestic and international developments in their field, which contributes to their high authority. Through the data analysis of the two rounds of surveys, significant differences were observed between the results of the first-level and second-level items in the first round. The coordination coefficient for the first-level indicators was 0.65, indicating relatively minor disagreements among experts regarding the first-level items. This suggests that the pathogenesis of malignant tumor patients is broadly covered. However, the coordination coefficient for the second-level indicators was 0.065, significantly lower than the ideal value, indicating poor coordination among experts, with some experts expressing disagreements. We analyzed two possible reasons for this: ① Some indicators might only reflect the conditions of a minority of patients and cannot be generalized to the majority, making them unsuitable as preferred recommendations; ② Some diagnostic items summarized by clinicians based on their personal experiences in the reviewed literature might lack consensus, leading to expert disagreements. In the second round of the survey, modifications were made to the first-round questionnaire, including prioritizing the indicators, which received positive feedback. Experts agreed that the revised items better aligned with clinical practices.

Reviewing previous literature on the Delphi method reveals that the threshold method can intuitively screen items that meet the criteria, and its calculations are relatively simple and less prone to errors. However, the use of the threshold method may inadvertently exclude some important items that fall outside the threshold. To address this issue, expert discussions can be

conducted based on the clinical significance of such items, thereby avoiding the unintended elimination of critical factors that could compromise the final results. Overall, the application of the Delphi method in this study yielded favorable outcomes.

3.3 Insights from the Application of the Delphi Method

Using the Delphi method to develop relevant assessment scales reduces time and labor costs, especially when combined with modern information technology, eliminating the need for traditional face-to-face meetings. Additionally, this method integrates the opinions of multiple experts to summarize consensus-based viewpoints, which hold significant value for clinical diagnosis and treatment [22,23]. The iterative process of the Delphi method is essentially a refinement process. Each round of the survey is generated based on feedback from the previous round, making the issues more prominent and the experts' consensus more evident, thereby facilitating the exploration and resolution of complex problems.

To date, there are still relatively few studies on the identification and evaluation of tumor pathogenesis. Although this study has certain value, it also has limitations. It is hoped that during its promotion, more expert opinions can be gathered to further refine and improve the proposed framework.

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