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Current situation and influencing factors of surgical fear in patients with retinal detachment complicated with lung malignant tumor

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Abstract: Background: This study aims to understand the current situation of surgical fear in patients with retinal detachment combined with lung malignant tumor, explore the risk factors affecting its occurrence, and provide theoretical basis for clinical scientific implementation of psychological intervention. **Methods:** A total of 98 patients with lung cancer who underwent retinal detachment surgery in Affiliated Hospital of Jiangnan University from December 2021 to December 2024 were selected as the research objects. The general information questionnaire, Fear of Surgery Questionnaire (SFQ), Patient Health Questionnaire Depression Scale (PHQ-9) and Generalized Anxiety Disorder Scale (GAD-7) were used to investigate. The data were statistically analyzed with independent sample *t* test, rank sum test and multiple linear regression. **Results:** The median SFQ score of the patients was 16, and the quartile was (14, 19). There was a significant difference between the short-term fear (SFQ-S) and long-term fear (SFQ-L) ($p < 0.05$). There were statistically significant differences in the level of fear among patients with gender, education level, method of medical expenses settlement, experience of general anesthesia surgery, preoperative discomfort symptoms, lymph node metastasis, PHQ-9 and GAD-7 scores ($p < 0.05$). Multivariate analysis showed that female, self-financing, without obvious symptoms of discomfort before operation, with lymph node metastasis and anxiety were the independent risk factors of fear in patients ($p < 0.05$). The distribution of fear of surgery was positively correlated with anxiety ($r = 0.635, p < 0.05$) and depression ($r = 0.503, p < 0.05$). **Conclusion:** The incidence of preoperative fear in patients with retinal detachment and lung cancer is high. Medical staff can screen and assess people with moderate and severe fear of surgery according to its influencing factors, and take targeted interventions to reduce fear of surgery, anxiety and depression according to the source of fear.

Keywords: Retinal detachment; fear of surgery; anxiety; depression; the influencing factors

1. Introduction

Lung cancer remains one of the most commonly diagnosed cancers worldwide and a leading cause of cancer death [1]. In addition to clinical physical therapy, mental health problems of cancer patients, especially fear [2], anxiety, depression, etc. Previous studies have shown that anxiety and depression are closely related to fear of surgery. Preoperative anxiety and depression can lead to fear of surgery, and fear of surgery can also aggravate anxiety and depression symptoms of patients [3]. These emotions not only affect the mental health of patients, but also may affect their physical health and treatment cooperation, and therefore deserve the attention of clinical staff [4]. Retinal detachment (RD) is a relatively common eye disease [5]. Rhegmatogenous retinal detachment (RRD) is the most common form of retinal detachment where a retinal ‘break’ allows the ingress of fluid from the vitreous cavity to the subretinal space, resulting in retinal separation. RRD can occur at any age, but

prevalence peaks in people aged 60 to 70. It occurs in about 1 in 10,000 people each year [6]. If not treated in time, it will seriously affect the visual acuity of patients, even cause blindness, and bring a heavy burden to the mental and psychological pressure of patients. At present, vitrectomy retinal detachment reduction is often used in clinical treatment [7]. With the development of medical technology, the success rate of this operation is very high [8], but once the operation fails, most patients cannot bear the serious consequences psychologically. In addition, vitrectomy surgery is usually performed under local anesthesia, the operation time is too long, and patients are unfamiliar with the operating room environment, which will cause psychological burden to patients. Up to now, studies [9–12] have shown that preoperative bad emotions can lead to postoperative pain, complications, poor prognosis, low quality of life, low satisfaction, and even suicidal tendencies. Therefore, for patients with retinal detachment complicated with lung malignant tumor, they should not only bear the fear of tumor disease, but also face the fear of surgery, which is undoubtedly a double psychological pressure on patients and will directly affect the treatment effect and quality of life [13]. At present, the research on the influencing factors of patients' fear psychology is still unclear. Kuang et al. [14] found that blood type, monthly income and mood state were the factors affecting the progression of phobia in cancer patients, and the score of phobia progression was negatively correlated with the score of life quality. On the other hand, patients' fear often occurs before surgical operations, such as motor system operations [15], perinatal operations [16], and cataract operations [17]. A study by Boker et al. [18] found that patients who underwent various procedures after admission to the surgical ward experienced a significant increase in fear of surgery compared to assessments during pre-anesthetic outpatient visits. Understand surgery for patients with retinal detachment and tumor

The level and characteristics of fear are of great significance. However, current studies on emotion of patients with retinal detachment complicated with tumor mostly focus on the postoperative situation but ignore the preoperative situation. The degree and dimension of fear of surgery have not been scientifically measured, and the characteristics of high-risk groups with adverse emotions before surgery have not been determined. Therefore, in order to improve the preoperative fear of patients with retinal detachment complicated with lung cancer, improve the therapeutic effect and improve the quality of life of patients. Based on the Surgical Fear Questionnaire (SFQ), subtle changes of related fears before surgery were detected, and the characteristics of high fear groups and fear dimensions were analyzed, so as to provide theoretical basis for clinical psychological intervention.

2. Materials and methods

A total of 98 patients who underwent retinal detachment vitrectomy in Affiliated Hospital of Jiangnan University from December 2021 to December 2024 combined with lung malignancy were included in this study. This study is a retrospective study. General and clinical data of patients were collected and investigated offline, and data were collected and sorted by questionnaire survey.

The inclusion criteria are as follows: (1) Age > 18 years old; (2) Patients with lung cancer diagnosed in accordance with the Chinese Medical Association Lung

Cancer Clinical Diagnosis and Treatment Guidelines (2023 edition); (3) Patients with confirmed retinal detachment and proposed vitrectomy; (4) Have communication skills and sign informed consent; (5) Complete medical records.

Exclusion criteria are as follows: (1) Severe cardiopulmonary insufficiency, or systemic multiple organ failure; (2) Patients with tumors in other sites; (3) Coagulation dysfunction (PT > 13s); (4) There are mental diseases; (5) Incomplete medical records.

This study is a retrospective study, aiming to study the current situation of surgical fear in patients with retinal detachment complicated with lung malignant tumor and related risk factors causing fear in patients, explore the psychology of fear in patients, and provide relevant suggestions and measures based on the research results. According to previous research and related literature reports, the incidence of fear in patients with retinal detachment combined with lung malignancy is about 85%. The allowable error is 3%, the confidence is $1 - \alpha = 0.95$, and the sample size $N = 62$ cases need to be investigated by using PASS 15 software. Assuming that the non-response rate of the subjects is 10%, the sample size $N = 62 \div 0.9 = 69$ cases is required. Assuming that the qualified rate of the questionnaire is 90%, the total sample size is $N = 69 \div 0.9 = 77$ cases. Therefore, this study reviewed all eligible patients from December 2021 to December 2024, a total of 98 cases, all of which were included in this study. The study was approved by Ethics Committee of Affiliated Hospital of Jiangnan University and informed consent was taken from all the patients.

3. General information questionnaire

The general information questionnaire included demographic data (such as age, gender, education level, marital status, place of residence, family per capita income, medical expense settlement method) and clinical data (pathological type of lung cancer, hypertension, diabetes, surgery experience under general anesthesia, obvious discomfort symptoms before surgery, lymph node metastasis, anxiety, depression and fear).

3.1. Surgical fear questionnaire (SFQ)

SFQ was first developed by Dutch scholars to measure the fear level of surgery in patients undergoing elective surgery [19]. The SFQ scale translated by Yang [9] was selected for this study. SFQ consists of four short-term fear (SFQ-S) dimension entries and four long-term fear (SFQ-L) dimension entries. SFQ-S dimension entries include fear of surgery (SFQ-S1), fear of anesthesia (SFQ-S2), fear of postoperative pain (SFQ-S3), and fear of postoperative side effects (SFQ-S4). SFQ-L dimension entries include fear of deteriorating health (SFQ-L1), fear of surgical failure (SFQ-L2), fear of not fully recovering from surgery (SFQ-L3), and fear of taking too long to recover (SFQ-L4). SFQ uses an 11-level scoring method, each entry from “not afraid at all” to “very afraid” respectively assigned 0 to 10 points, the total score of 80 points, the score value represents the degree of fear the higher the score value, the higher the degree of fear. Cronbach’s α value in this survey is: SFQ-S is 0.865, SFQL is 0.918, and SFQ is 0.904.

3.2. Patient health questionnaire-9 (PHQ-9)

PHQ-9, which was revised based on the diagnostic criteria of diagnostic and Statistical Manual of Mental Disorders DSM-I, was used for self-assessment of depression [20]. A total of 9 items were scored at levels 0 to 3. The total score >4 was classified as positive, 5 to 9 as mild depression, 10 to 14 as moderate depression, 15 to 19 as severe depression, and 20 to 27 as extremely severe depression. Cronbach's α is 0.89, and the retest reliability is 0.85.

3.3. Generalized anxiety disorder-7 (GAD-7)

GAD-7 was included in the self-rating Anxiety Scale compiled by Spitzer in 2006 [21]. GAD-7 has 7 items, using a four-point scale of 0-3, the total score >4 points as positive, 5–9 points as mild anxiety, 10-14 points as moderate anxiety, 15–21 points as severe anxiety. Cronbach's α was 0.93.

3.4. Statistical analysis

SPSS 26 (IBM SPSS, USA) was used for statistical analysis. The counting data were represented by n (%) and chi-square or rank sum tests were performed. Measurement data were represented by $\bar{x} \pm s$, and row independent sample T -test or rank sum test between the two groups. The risk factors of surgical fear in patients with retinal detachment complicated with lung cancer were analyzed by linear regression model. Spearman correlation analysis was used to explore the correlation between fear of surgery and anxiety and depression, and Wayne chart was drawn to analyze the overlap of severe fear of surgery with anxiety and depression. A two-side $P < 0.05$ was considered statistically significant.

4. Results

4.1. Baseline data

Baseline data included demographic and clinical data. A total of 98 patients were enrolled in the study, including 55 males (56.1%) and 43 females (43.9%). There were 41 cases (41.8%) aged < 60 years and 57 cases (58.2%) aged ≥ 60 years. The average PHQ-9 score was 10.7 ± 4.8 ; the average score of GAD-7 was 15.1 ± 7.1 . The median score for PHQ-9 was 3 with a quartile of (0,5) and the median score for GAD-7 was 2 with a quartile of (0,4). The remaining general information is shown in **Table 1**.

Table 1. Baseline data.

Variables	N (%) / Mean $\pm$ SD
Age (years)	
<60	41 (41.8)
≥ 60	57 (58.2)
Gender	
male	55 (56.1)
female	43 (43.9)
Education level	

Table 1. (Continued).

Variables	N (%) / Mean $\pm$ SD
High School and below	49 (50.0)
High School or above	49 (50.0)
Monthly household income (yuan)	
<6000	44 (44.9)
≥ 6000	54 (55.1)
Address	
Countryside	60 (61.2)
City	38 (38.8)
Marriage	
Unmarried	5 (5.1)
Married	82 (83.7)
Divorced or widowed	11 (11.2)
Fee payment method	
Medical insurance	89 (90.8)
Self-financing	9 (9.2)
With hypertension	
Yes	39 (39.8)
No	59 (60.2)
With diabetes	
Yes	17 (17.3)
No	81 (82.7)
With experience in general anesthesia surgeries	
Yes	26 (26.5)
No	72 (73.5)
With obvious symptoms of discomfort before operation	
Yes	31 (31.6)
No	67 (68.4)
With lymph node metastasis	
Yes	29 (29.6)
No	69 (70.4)
PHQ-9	10.7 $\pm$ 4.8
GAD-7	15.1 $\pm$ 7.1

PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7.

4.2. Distribution of SFQ dimension scores

The violin plot of SFQ-S and SFQ-L scores (**Figure 1**) shows that SFQ-S scores 7 (5, 10) are lower than SFQ-L scores 9 (7, 10.25), SFQ-S scores are mainly concentrated in the lower scores, and SFQ-L scores are more than SFQ-S scores. The difference between SFQ-S and SFQ-L scores was statistically significant ($z = -2.796$, $p < 0.01$). The scores of each item of SFQ (**Figure 2**) showed that patients were most afraid of “postoperative pain” in SFQ-S (SFQ-S3), and the M (Q25, Q75) was 3 (1,

4). In SFQ-L, patients were most afraid of “not fully recovering after surgery” (SFQ-L3), M (Q25, Q75) was 3 (1, 5), shown as **Table 2**.

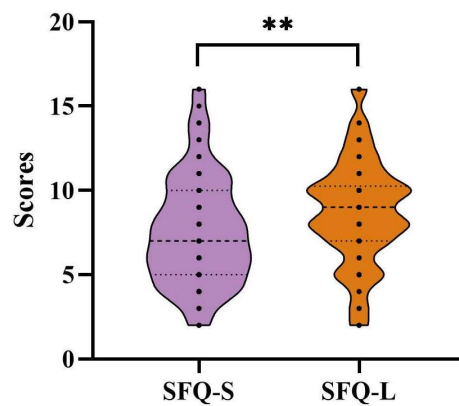


Figure 1. Violin plot of SFQ-S versus SFQ-L scores (SFQ, Surgical Fear Questionnaire).

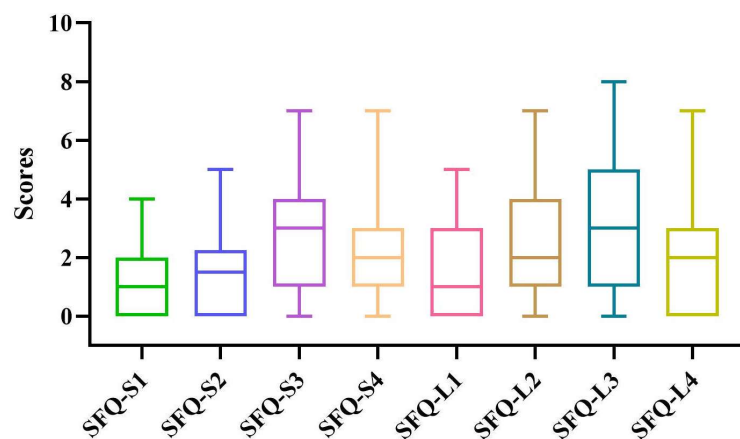


Figure 2. Box plot of SFQ item scores (SFQ, surgical fear questionnaire).

Table 2. SFQ projects specific score comparison.

Item	SFQ-S1	SFQ-S2	SFQ-S3	SFQ-S4	SFQ-S
M (Q25, Q75)	1.00 (0, 2.00)	1.50 (0, 2.25)	3.00 (1.00, 4.00)	2.00 (1.00, 3.00)	7.00 (5.00, 10.00)
	SFQ-L1	SFQ-L2	SFQ-L3	SFQ-L4	SFQ-L
	1.00 (0, 3.00)	2.00 (1.00, 4.00)	3.00 (1.00, 5.00)	2.00 (0.00, 3.00)	9.00 (7.00, 10.00)
Z	-				-2.796
p	-				0.005

SFQ, Surgical Fear Questionnaire; -: Blank item.

4.3. Single factor analysis of surgical fear level

The rank sum test results showed that the general information, PHQ-9 and GAD-7 scores of patients were compared. The results showed that there were statistical differences in patients' fear level among gender, education level, medical expense settlement method, experience of general anesthesia, obvious discomfort before surgery, lymph node metastasis, PHQ-9 and GAD-7 scores ($p < 0.05$) (**Table 3**), and no statistical differences were found in other variables.

Table 3. Single factor analysis of influencing patients' fear level.

Variables	Median (25%, 75%)	Z	p
Gender			
male	15 (13, 18)	-3.137	0.002
female	17 (15, 21)		
Education level			
High School and below	16 (12, 17)	-3.242	0.001
High School or above	17 (15, 20)		
Fee payment method			
Medical insurance	16 (14, 19)	-2.618	0.009
Self-financing	21 (16.5, 23)		
With experience in general anesthesia surgeries			
Yes	15 (13, 17.75)	-3.259	0.001
No	19 (16.75, 19.5)		
With obvious symptoms of discomfort before operation			
Yes	15 (13, 18)	2.699	0.007
No	18 (16, 19)		
With lymph node metastasis			
Yes	17 (16, 19.5)	-2.192	0.028
No	15 (12.5, 19)		
PHQ-9 (scores)			
<10	15 (12, 18)	2.397	0.017
≥10	17 (15, 19)		
GAD-7 (scores)			
<15	15 (12, 19)	-2.484	0.013
≥15	17 (15, 19)		

PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7.

4.4. Multivariate factor analysis of surgical fear level

The variables with differences in univariate analysis were included in multivariate linear regression analysis and collinearity was diagnosed. The results are shown in **Table 4**. Women were more fearful than men ($p = 0.017$). Compared with the patients with medical insurance settlement, the patients who paid their own medical expenses were more fearful ($p = 0.022$). Compared with patients without obvious discomfort before surgery, patients with obvious discomfort before surgery had more fear ($p = 0.012$). Compared with patients without lymph node metastasis, patients with lymph node metastasis had more fear ($p = 0.002$). Compared with non-anxious patients, anxious patients had more fear ($p = 0.034$). To sum up, female, self-financing, with obvious symptoms of discomfort before operation, with lymph node metastasis and anxiety were the independent risk factors of fear in patients ($p < 0.05$).

Table 4. Risk factors of intraoperative bleeding analyzed by multiple linear regression models.

Item	B	SE	t	p	VIF
Female	10.126	3.153	2.633	0.017	1.859
High school or above	0.657	0.316	2.373	0.060	1.428
Self-financing	9.583	4.336	2.592	0.022	1.623
With experience in general anesthesia surgeries	3.637	3.145	1.375	0.231	1.542
Without obvious symptoms of discomfort before operation	0.341	0.105	2.135	0.012	2.463
With lymph node metastasis	10.703	5.352	4.205	0.002	1.439
PHQ-9	1.387	1.853	1.653	0.350	1.542
GAD-7	0.464	0.204	2.129	0.034	2.183

SE, standard error; VIF, variance inflation factor; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7.

4.5. Correlation and population overlap analysis of surgical fear, anxiety and depression

Spearman correlation analysis showed that fear distribution was moderately positively correlated with anxiety ($r = 0.635$, $p < 0.05$) and depression ($r = 0.503$, $p < 0.05$). Among the 22 patients with severe fear of surgery, 6 patients were combined with severe anxiety and depression, with an overlap rate of 27.27%. Among them, 10 patients had severe fear of surgery combined with severe anxiety, and 8 patients had severe fear of surgery combined with severe depression, accounting for 45.45% and 36.36% of the 22 patients with severe fear of surgery, respectively (**Figure 3**).

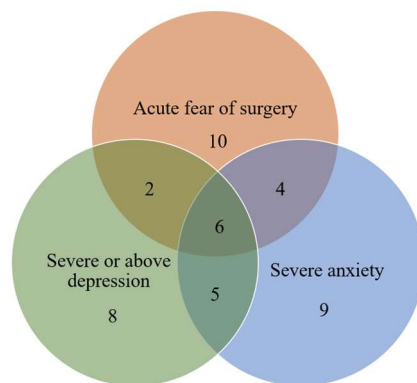


Figure 3. Venn diagram of patients with severe fear of surgery, anxiety and depression.

5. Discussion

RD as a severe ocular disease has devastating visual consequences, with most RD patients initially presenting with acute onset flashes or floaters that progress to shadows in peripheral vision and eventually a decrease in central vision as RD affects the macula, the part of the retina responsible for central vision. Without intervention, it can lead to permanent vision loss [22]. Studies have found that the lifetime risk of RD is about 0.1%, which is higher in patients who are older, have high myopia (myopia greater than -6.0 diopters), have a history of ocular trauma or previous ophthalmic surgery, or have a family history of retinal detachment [23,24]. Patients

with RD and malignant tumors often need surgical treatment. The potential fears of surgical patients include: fear of surgical complications, worry about the time and degree of postoperative disability, worry about general anesthesia and its loss of control, fear of awakening and intraoperative or postoperative discomfort and pain [3,25].

In a meta-analysis published in 2020, which included data from more than 14,000 patients in 28 studies, the global pooled prevalence of preoperative anxiety in surgical patients was as high as 48% (95% confidence interval 39%–47%) [26]. In this study, 93.9% of RD patients with malignant tumors had fear of surgery, which suggests that the fear of surgery is common in RD patients with malignant tumors, and the fear of surgery needs to be paid attention to by clinicians and family members. In this study population, the total SFQ score of patients was low [16 (14,19)], indicating a low level of overall fear, which was consistent with the results of most studies related to surgical fear of other diseases [27–29]. Further exploration found that the SFQ-S score [7 (5, 10)] was lower than the SFQ-L score [9 (7, 10.25)], and the SFQ-S score was mainly concentrated in the low score, while the SFQ-L high score was more than the SFQ-S. This result indicates that patients' fear of long-term surgical injury is higher than that of short-term surgical injury, which is inconsistent with the research results of surgical fear of breast cancer, abdominal diseases and other diseases [30,31], but consistent with the surgical fear of brain tumor patients [32]. The reason may be that the incidence of breast cancer and abdominal diseases is much higher than that of retinal detachment and lung cancer. The surgical methods are mature and the relevant knowledge is publicized, and the public's awareness is high and easy to accept. On the one hand, patients with retinal detachment and lung cancer should be concerned about the occurrence and development of tumors or tumor recurrence in the body. On the other hand, the increase of intraocular pressure, metamorphopsia, decreased vision, cataract, blindness and other problems after retinal detachment will seriously affect the quality of life and social function of patients [33], which is difficult for patients to accept. Among the 8 items of SFQ, the highest fear of patients was "postoperative pain" and "postoperative can't fully recover". Therefore, special attention should be paid to pain management and postoperative rehabilitation knowledge in the clinical education of patients with retinal detachment and lung cancer. Preoperative pain fear can aggravate postoperative pain and cause adverse effects, so pain management should be started before surgery [34]. Health promotion manuals and videos are good media, which should focus on answering patients' concerns such as postoperative rehabilitation methods, rehabilitation process and rehabilitation outcome, which has a good effect on reducing patients' fear.

This study showed that patients who were female, paid for medical care out of their own pocket, had lymph node metastasis, had no obvious discomfort symptoms before surgery, and had higher preoperative anxiety were more likely to have fear of surgery. Patients with obvious preoperative discomfort symptoms are less likely to have fear of surgery. The reason may be that patients with obvious preoperative pain, ulceration, dysphagia and other symptoms may have a higher degree of psychological burden on the disease itself, and have a higher expectation of urgently improving the status quo, so they have a higher degree of acceptance of surgery and a lower fear of surgery itself. However, patients without obvious discomfort symptoms before surgery

are more likely to produce information overload when they are suddenly informed of surgical risks and possible complications, and it is difficult to cope with such information in a short time [35,36]. They are afraid of postoperative functional damage and serious decline in quality of life, etc. Therefore, they are more likely to produce psychological burden and fear of surgical treatment itself. Therefore, for patients without obvious symptoms before surgery, more attention should be paid to communication skills and patient explanation during preoperative communication to reduce unnecessary fear caused by information overload. In addition, in this study, women are more prone to high surgical fear, and the overall fear level is higher than that of men, which is consistent with the results of Akutay et al. [37]. Patients who pay for their care out of their own pocket may be concerned about the high cost of surgery and whether it will be proportional to the effectiveness of treatment. Therefore, for patients who pay for their own medical treatment, they should be helped to reduce part of their medical expenses and enhance their treatment confidence. Finally, in this study, the distribution of fear of surgery was moderately positively correlated with anxiety and depression, and the overlap rate of the three was 27.27%, which was similar to the results of previous studies. By analyzing the reasons, patients with anxiety and depression are in low mood, often pay too much attention to negative information and ignore objective content. This thinking deviation can enlarge the perception of fear of patients, and cause and aggravate the fear of surgery of patients. In addition, the autonomic nervous system is unbalanced and neurotransmitters are disordered in patients with anxiety and depression. The physiological reactions such as shortness of breath and elevation of blood increase and gradually form a vicious circle, which increases the physical discomfort and the fear of surgery. The surgical fear assessment not only has a certain screening effect on patients with severe emotional disorders, but also each item of SFQ can be regarded as a source of fear, which can be used as a supplement to the assessment of anxiety and depression to clarify the specific reasons for targeted intervention. The medical team can carry out psychological screening for high-risk groups with moderate and severe fear of surgery, and reasonably use psychotherapy or alternative therapy for positive psychological intervention to promote the good mood of patients.

Therefore, for patients with retinal detachment combined with malignant tumors, pain management should be carried out from the preoperative stage to reduce the fear of postoperative pain. At the same time, through the media such as health promotion manuals and videos, the postoperative rehabilitation methods, rehabilitation process and rehabilitation outcomes of patients' concerns were mainly answered to help patients understand the recovery process after surgery. In addition, for patients who already have anxiety or depression, they can be encouraged to talk about their thoughts and feelings, and they can choose to let out negative emotions in time by listening to music, painting, writing in a diary or exercising. Finally, we should pay attention to the psychological state of patients during hospitalization, and pay attention to psychological screening of high-risk groups with moderate and severe fear of surgery. By reconstructing the cognition of patients, some negative, deviant or unreasonable thinking of patients can be actively corrected, and the attitude of patients to face problems can be changed, so as to improve the belief of patients and overcome their fear. It can be seen that the rational use of psychotherapy or alternative therapy for

positive psychological intervention to help patients relieve negative emotions is also equally important in clinical treatment.

In conclusion, this study used psychometric tools to understand the surgical fear, preoperative anxiety and depression levels of patients with retinal detachment and lung cancer, revealed the current status of surgical fear in patients with retinal detachment and lung cancer and the risk factors affecting the patients' surgical fear, and analyzed the characteristics of people with high fear and the characteristics of fear dimensions. It provides a good theoretical basis for improving the prognosis of patients and scientific implementation of psychological intervention. However, this study also has some shortcomings. First, this study is a retrospective study, which lacks empirical evidence of causality compared with prospective study. Secondly, this study is a single-center study, and due to the limitation of manpower and material resources, the sample size is also small, which limits the generalization of this study. Therefore, our research group will focus on the above shortcomings and carry out a multi-center prospective study in the future to obtain more in-depth results.

6. Conclusion

The incidence of preoperative fear in patients with retinal detachment and lung cancer is high. Medical staff can screen and assess people with moderate and severe fear of surgery according to its influencing factors, and take targeted interventions to reduce fear of surgery, anxiety and depression according to the source of fear.

Author contributions: Designed the research study, CW, provision of study materials, HS and JZ, collected and analyzed the data, CW and HS; provided administrative support, JW; wrote manuscripts, CW, HS and JZ. All authors have read and agreed to the published version of the manuscript.

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Informed consent statement: Informed consent was obtained from all subjects involved in the study.

Conflict of interest: The authors declare no conflict of interest.

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