Revista Argentina de Clínica Psicológica
2020, Vol. XXIX, N°4, 941-951
DOI: 10.24205/03276716.2020.1505

Efficacy Of Chinese Herbal Medicine Fufang Banmao Capsule Combined With Chemotherapy For Non-Small Cell Lung Carcinoma: A Meta-Analysis Of Randomized Controlled Trials

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Abstract

Objective: To conduct a meta-analysis on the efficacy and safety of Fufang Banmao Capsule combined with chemotherapy for non-small-cell lung carcinoma (NSCLC).

Methods: Eight databases will be searched for Fufang Banmao Capsule combined with chemotherapy in the treatment of NSCLC with retrieval time up to October 2020, including Web of science, The Cochrane Library, Pubmed, Embase, CNKI, VIP, CBM and Wangfang Data databases. Manual retrieval of references included in the study and supplementary retrieval of unpublished academic papers was performed. Two researchers selected literature, extracted data and evaluated the included studies independently, and we conduct data analysis with RevMan5.3 software and Stata15 software.

Results: 10 studies involving 826 patients were included. Results showed that the disease control rate of Fufang Banmao Capsule combined with chemotherapy was better than that of chemotherapy alone [*RR*=1.14,95%CI(1.05,1.25),*P*=0.002], the adverse reaction rates of digestive tract reaction, abnormal liver function, abnormal liver and kidney function, anemia and leukopenia were all lower than that of chemotherapy alone, and quality of life improvement rate was better than that of chemotherapy alone [*MD*=1.56,95%CI(1.24,1.98), I^2=0%, *P*=0.0002].

Conclusion: Based on the existing evidence, Fufang Banmao Capsule combined with chemotherapy has a positive effect on NSCLC compared with chemotherapy alone, with lower adverse reaction rate and better improvement rate of life quality than chemotherapy alone. However, because of the small number of included studies and generally low quality, the findings need to be treated with caution.

Keywords: Non-small cell lung carcinoma; Fufang Banmao Capsule; Meta-analysis

1. Introduction

Lung cancer is known as primary bronchial cancer or primary bronchial lung cancer, refers to the malignant tumor originating from respiratory epithelial cells, one of the most common malignant tumor and the is the main cause of cancer death at present and cause by many environmental and chemical factors by improving the industies (Chen et al., 2020; (Feng et al., 2020; Liu et al., 2018; Su et al., 2020; Su et al., 2019; Duan et al., 2020; Zhong et al., 2020; Zuo et al., 2015; Zuo et al., 2017; Chen and Xu, 2020). And NSCLC is the most common with accounting for about 85% of the total incidence of lung cancer. However, due to the stealthiness of early clinical symptoms and insufficient early diagnosis, the disease has progressed to the middle and late stage at the time of diagnosis, thus missing the best opportunity for surgery and resulting in poor prognosis (Maomao and Wanqing, 2019). The systemic chemotherapy and radiation and radioactive particles implantation are major means of clinical commonly used treatment of locally advanced NSCLC, but they also produce a series of adverse reactions at the same time, and even destroy the patient's immune system to a certain extent (Wang and Feng, 2017; Xie et al., 2011), thus finding a appropriate treatment and improving the level of treatment are particularly important for the quality of life and the lifecycle of the patients. As a Chinese patent medicine, Fufang Banmao Capsule

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has been shown to have significant efficacy in improving the quality of life and cellular immune function of patients with advanced cancer, and it can cooperate with radiotherapy and chemotherapy to treat anti-tumor, so that it has become a variety of malignant tumor adjuvant therapy (Yi, 2012). In recent years, there have been more and more clinical reports on the treatment of NSCLC with Fufang Banmao Capsule. Many studies have reported that Fufang Banmao Capsule can inhibit the proliferation of NSCLC, improve the clinical symptoms and prognosis of patients, and stabilize the disease (Shao and Chen, 2014). However, there has been no systematic evaluation of its efficacy and safety. Therefore, this study conducted a meta-analysis by retrieving RCT studies in which Fufang Banmao Capsule was the main intervention method, and systematically evaluated the efficacy and safety of Fufang Banmao Capsule and its combination therapy for NSCLC, hoping to provide evidence-based evidence for clinical medication (Huang et al., 2019; Gao et al., 2019; Zhou et al., 2019).

2. Materials and Methods

2.1. Literature retrieval

We will use the computer to search Web of science, The Cochrane Library, Pubmed, Embase, CNKI, VIP, CBM and Wangfang Data contain 8 databases. A combination of medical subject headings terms and free words will be used to search the articles. Subject words include “Non-Small-Cell Lung Carcinoma” “Fufang Banmao Capsule”, free words such as “Non-Small Cell Lung Carcinoma” “Non Small Cell Lung Carcinoma” “Non-Small Cell Lung Cancer” “ Non-Small-Cell Lung Cancer” “Nonsmall Cell Lung Cancer” “ NSCLC”. And manual retrieval of references contained in the literature, unpublished dissertations and other supplementary retrieval. The retrieval time was from the time of building the repository to October 2020.

2.2. Inclusion criteria

2.2.1. Research type

Clinical Randomized Controlled Trials (RCTs)

2.2.2. Research object

The patients who were diagnosed as non-small cell lung carcinoma Ⅲ ~ Ⅳ period by Cell or histopathology, except other types of lung cancer or with unspecified types of lung cancer or with secondary lung cancer or concurrent tumors in other sites .The diagnostic criteria of western medicine are in line with the Standard of Diagnosis and Treatment of Common Malignant Tumors and the TNM stage criteria of lung cancer established by the International Union against Cancer (UICC), and the diagnostic criteria of Chinese medicine are in line with the Guiding Principles of Clinical Research on New Chinese Medicines.

2.2.3. Interventions

The control group was treated with chemotherapy drugs alone, while the treatment group were treated with Fufang Banmao Capsule alone or combined Fufang Banmao Capsule with chemotherapy drugs.

2.2.4. Outcome indicators

The main outcome measures contained the disease control rate and adverse reaction rate. The quality of life improvement was regarded as the secondary outcome measure. The disease control rate was divided into 4 degrees including complete response (CR), partial response (PR), disease stability (SD) and disease progression (PD) according to the solid tumor efficacy evaluation criteria of national Cancer Institute (RECIST). To be sure, CR refers to complete disappearance of tumor lesions and significant recovery of symptoms and signs; PR refers to a reduction in tumor target lesion diameter of ≥30% and improvement in symptoms and signs; SD refers to the reduction of tumor target lesion diameter <30%, the absence of new lesions, and the absence of significant improvement in symptoms and signs; PD refers to the increase of the maximum diameter of the tumor target lesion ≥20%, the emergence of new lesions, and significant deterioration of symptoms and signs. And the disease control rate = (CR number +PR number +SD number)/ total number ×100% .The Karnofsky score (KPS) was used as the criterion for quality of life improvement rate, the higher the score, the better the quality of life (Yan et al., 2019; Loya-Rivera et al., 2019).

2.3. Exclusion criteria

(1)Repeatedly checked out or repeatedly published literature;(2)Inconsistent intervention or disease;(3) Outcome indicators inconsistent with or incomplete data;(4)Unable to access the full text.

2.4. Literature screening, data extraction and quality evaluation

The literature checked out was screened step by step through removing duplicates, reading the title, abstract, and the full text. The content of data extraction mainly includes the followings:(1)literature title, first author,

publication time, etc.(2)key elements of quality evaluation;(3)sample size, gender, age, intervention measures, treatment course, etc. of experimental group and control group;(4)outcome index. The random-sequence generation, allocation and concealment, implementation bias, measurement bias, follow-up bias, reporting bias and other bias in the included literature were assessed as low risk, high risk or uncertain bias according to Cochrane Risk Assessment Form. The above work was done independently by two researchers, and any disagreement is discussed or decided by a third party (Feng et al., 2020; Liu et al., 2018; Su et al., 2020; Su et al., 2019; Duan et al., 2020).

2.5. Evidence quality evaluation

GRADE Profile3.6 will be used to evaluate the quality of evidence for disease control rates in primary outcome measures. The evidence was degraded in terms of bias risk, inconsistencies, inconsistencies, accuracy, and publication bias, and the evidence was degraded in terms of confounding factors and dose-effect relationships with large effect values that may reduce efficacy. According to the result of promotion and downgrade, the evidence body was rated as high, medium, low or very low (Irshad et al., 2019; Bhatti et al., 2019).

2.6. Statistical method

We will apply RevMan5.3 software and Stata15 software for statistical processing. When $P>0.1$, $I^2<50\%$, we will adopt the fixed effect model; On the contrary, the random effects model was selected. While the heterogeneity was large, we will choose subgroup analysis or sensitivity analysis to reduce the influence. Dichotomous variables will be expressed by relative risk (*RR*) and its 95%CI, while continuous variables will be expressed by mean difference (*MD*) or standardized mean difference (*SMD*) and its 95%CI.

3. Result

3.1. Literature search results

83 papers were initially checked in each database, including 25 from Wanfang Data, 20 from CNKI, 21 from CBM, 16 from VIP and 1 from Cochrane Library. No relevant papers were found in other databases .After stage by stage screening, there were 10 literatures included for the meta-analysis. The literature screening process follows the process shown in Figure 1.

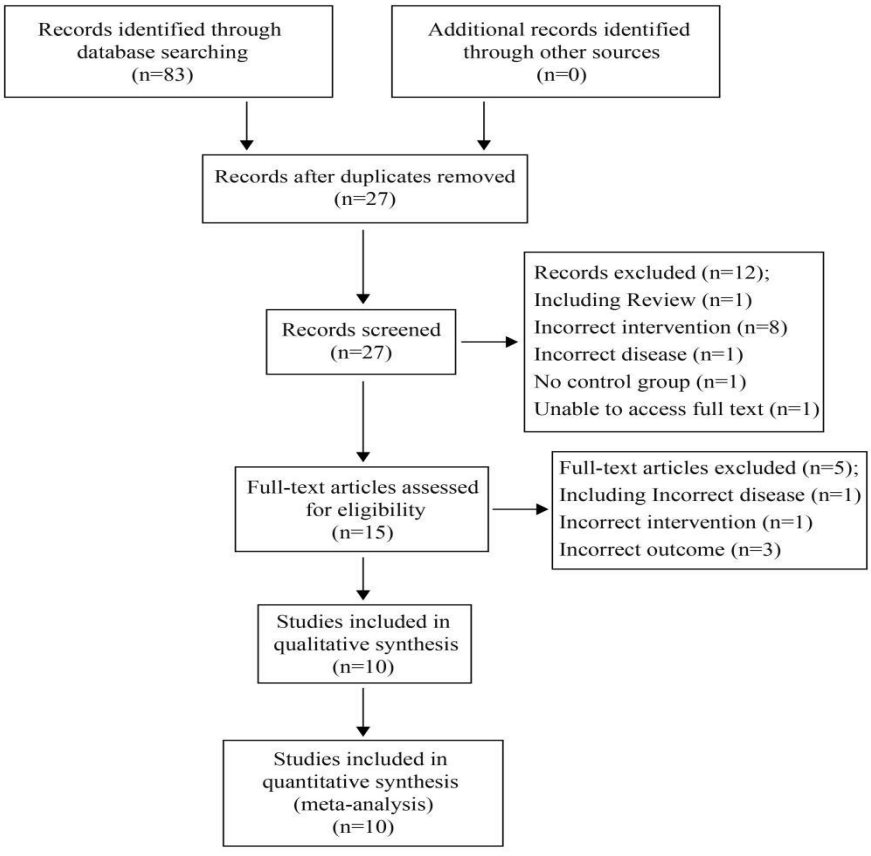

Figure 1. **Literature screening process**

3.2. Basic information of literature

There were 826 patients with 418 patients included in the treatment group and 408 patients in the control group. There were 501 male patients and 325 female patients. Oxaliplatin, Gefitinib, Paclitaxel, Docetaxel, Cisplatin,Guitar xibin, Carboplatin and other chemotherapy drugs were used in the control group, while Fufang Banmao Capsule was used in the treatment group combined with corresponding chemotherapy drugs in the control group. The detail was shown in Table 1.

Table 1. **Basic features of the included study**

Included studies	(M/F)/ Example	Age/Year	Intervention	Duration	Outcome
Song2019 (Song et al., 2019)	T:22/22 C:20/16	T:62.48±11.44 C:62.62±11.50	T:Fufang Banmao Capsule+Oxaliplatin C:Oxaliplatin	18w	②
Zhao2019 (Zhao, 2019)	T:30/23 C:29/22	T:59.32±4.31 C:58.78±4.53	T:Fufang Banmao Capsule+Gefitinib C:Gefitinib	8w	①②
Zhao2018 (Zhao et al., 2018)	T:28/12 C:24/16	T:60.23±8.75 C:62.42±9.84	T:Fufang Banmao Capsule+Gefitinib C:Gefitinib	9w	①②
Fan2019 (Fan, 2019)	T:22/15 C:23/14	T:59.84±6.97 C:59.64±6.82	T:Fufang Banmao Capsule+Gefitinib C:Gefitinib	8w	①②
Hu2019 (Hu et al., 2019)	T:23/16 C:24/15	T:57.84±9.97 C:57.64±9.82	T:Fufang Banmao Capsule+Gefitinib C:Gefitinib	2m	①②
Yan2020 (Yan and Ye, 2020)	T:17/13 C:19/11	T:63.85±9.94 C:64.05±8.27	T:Fufang Banmao Capsule+Paclitaxel+Cis-platinum C:Paclitaxel+Cis-platinum	42d	①②
Cai2019 (Cai, 2019)	T:25/25 C:27/23	T:57.31±2.64 C:55.82±1.94	T:Fufang Banmao Capsule+Paclitaxel+Docetaxel C:Paclitaxel+Docetaxel	12w	②
Wang2018(Wang, 2018)	T:32/13 C:31/14	T:56.94±13.63 C:55.74±11.54	T:Fufang Banmao Capsule+Gemcitabine+Cis-platinum C:Gemcitabine+Cis-platinum	84d	②
Duan2016 (Duan, 2016)	T:30/10 C:31/9	T:65.50±4.50 C:64.50±3.80	T:Fufang Banmao Capsule++Gemcitabine+Carboplatin C:Placebo+Gemcitabine+Carboplatin	9w	②
Wu2019(Wu, 2019)	T:23/17 C:21/19	T:66.75 C:65.14	T:Fufang Banmao Capsule++Gemcitabine+Carboplatin C:Placebo+Gemcitabine+Carboplatin	9w	②

T: treatment group C: control group NR: not reported Outcome. ①disease control rate ②adverse reaction rate

3.3. Literature quality evaluation

Among the 10 RCTs included, 1(Cai, 2019) adopted the ball-touching method, 4 (Zhao, 2019; Hu et al., 2019; Yan and Ye, 2020; Duan, 2016) adopted the random number table method, and the rest were randomly grouped but not specifically described. Two (Duan, 2016; Wu, 2019) of the control interventions in the study used placebo that was identical in appearance to Fufang Banmao Capsule, so the corresponding implementation bias was assessed as low risk. Only 2 cases of bias follow-up (Duan, 2016; Wu, 2019) reported long-term follow-up efficacy and their corresponding follow-up bias was assessed as low risk ， which was not mentioned in the rest of the literature. Allocation concealment, measurement bias, reporting bias and other bias were all not mentioned, the corresponding bias evaluation evaluates as unknown risk. The specific results were shown in Figure 2.

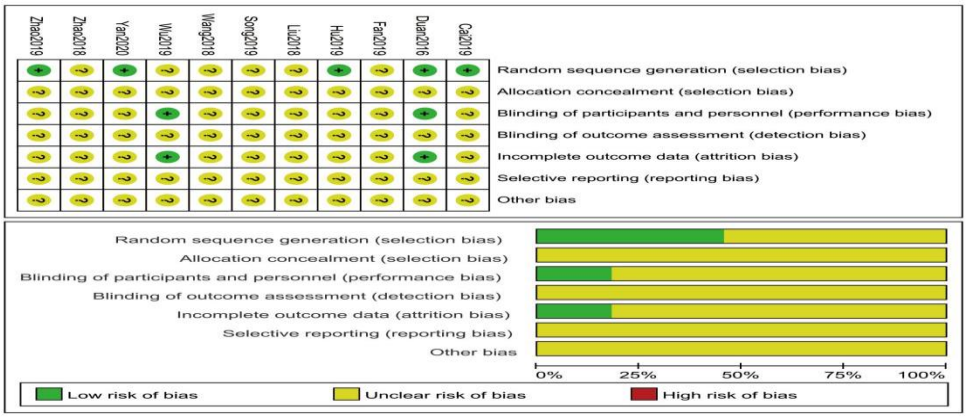

Figure 2. **Literature bias risk graph**

3.4. Meta-analysis

3.4.1. Disease control rate

5 studies (Zhao, 2019; Zhao et al., 2018; Fan, 2019; Hu et al., 2019; Yan and Ye, 2020) reported the disease control rate of Fufang Banmao Capsule combined with chemotherapy compared with single chemotherapy, and the results showed there was no heterogeneous difference. Result showed that the efficacy of using Fufang Banmao Capsule combined with chemotherapy was better than that of using chemotherapy alone for NSCLC [*RR*=1.14,95%CI(1.05,1.25),*P*=0.002, I^2=0]. According to the funnel of publication bias Figure 4, all the included studies were within the confidence interval, but the images were asymmetrical, which may be related to the small number of included studies and the publication bias such as unpublished studies with some negative results. Because the number of included studies is small, using Stata15 software Egger's test was used to detect publication bias is more precise. And the result Was *P*>0.1 shown in Figure 5 Egger's publication bias plot, suggesting that there was no obvious evidence to support the existence of publication bias.

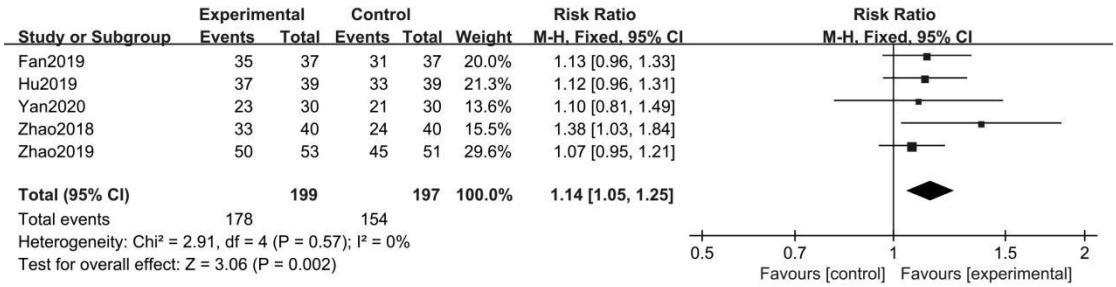

Figure 3. **Forest plot of the effective rate**

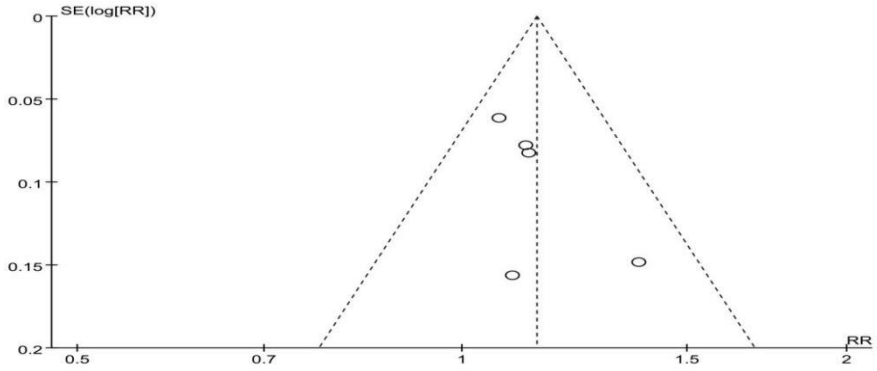

Figure 4. **Funnel plot of publication bias of the effective rate**

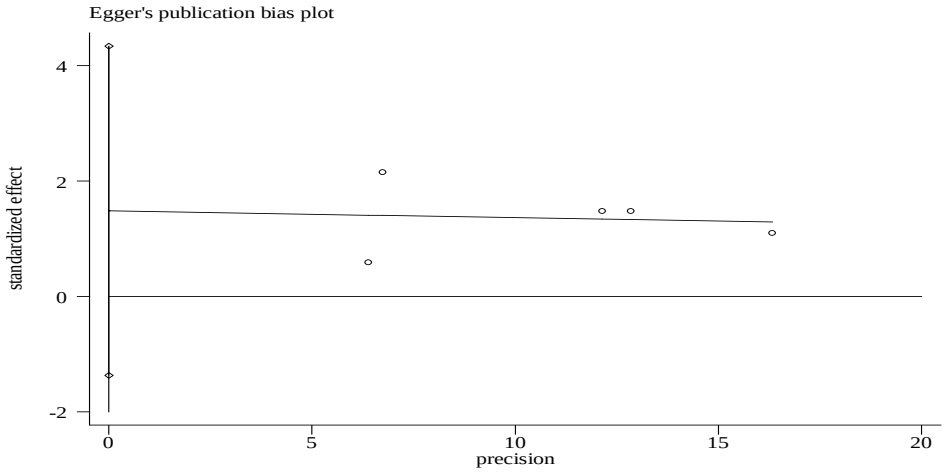

Figure 5. **Egger's publication bias plot**

3.4.2. Adverse reaction rate

Because patients in some studies had two or more adverse reactions at the same time, a subgroup analysis of adverse reaction rates was performed according to the type of adverse reaction. It was divided into 5 subgroups: alimentary reaction, abnormal liver function, abnormal liver and kidney function, anemia and leukopenia.

3.4.2.1. Alimentary reaction

Alimentary reaction symptoms include vomiting, nausea and abdominal distension, etc. A total of 6 studies (Zhao et al., 2018; Hu et al., 2019; Cai, 2019; Wang, 2018; Duan, 2016; Wu, 2019) reported that the results showed that the rate of adverse reactions in the combination chemotherapy with Fufang Banmao Capsule was lower than that with single chemotherapy [*RR*=0.30, 95%CI (0.18,0.50), I^2=0%,*P*<0.0001].

3.4.2.2. Abnormal liver function

A total of 3 studies (Zhao et al., 2018; Hu et al., 2019; Wang, 2018) reported that using the fixed-effect model, the adverse reaction rate of abnormal liver function of Fufang Banmao Capsule combined with chemotherapy was lower than that of single chemotherapy [*RR*=0.40, 95%CI (0.21,0.78), I^2=0%, *P*=0.007].

3.4.2.3. Abnormal liver and kidney function

A total of 3 studies (Song et al., 2019; Wang, 2018; (Duan, 2016) reported that the adverse reaction rate of Fufang Banmao Capsule combined with chemotherapy was lower than that of single chemotherapy [*RR*=0.46, 95%CI (0.33,0.63), I^2=0%, *P*<0.0001].

3.4.2.4. Anemia

A total of 3 studies (Wang, 2018; Duan, 2016; Wu, 2019) reported that there was no heterogeneous difference in the results. The anemia adverse reaction rate of Fufang Banmao Capsule combined with chemotherapy was lower than that of chemotherapy alone [*RR*=0.25, 95%CI (0.11, 0.59), I^2=0%, *P*=0.002].

3.4.2.5. Leucopenia

A total of 2 studies (Wang, 2018; Duan, 2016) reported that Meta-analysis results showed that white cell reduction of Fufang Banmao Capsule combined with chemotherapy was lower than that of single chemotherapy [*RR*=0.11,95%CI(0.03,0.44), I^2=23%, *P*=0.002]

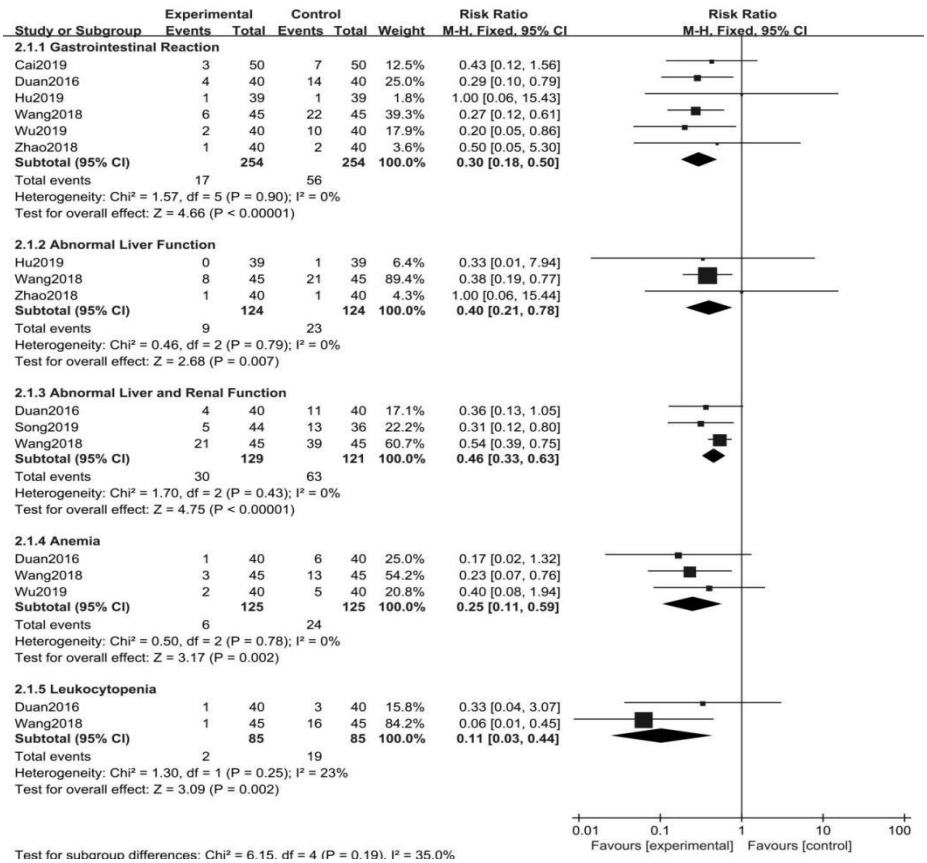

Figure 6. **Forest plot of adverse reaction rate**

3.4.3. Quality of life improvement rate

A total of 3 studies (Zhao, 2019; Fan, 2019; Duan, 2016) reported quality of life improvement rate using KPS score. Using the fixed-effect model, Fufang Banmao Capsule combined with chemotherapies had a better rate of improvement in quality of life than single chemotherapy [*MD*=1.56, 95%CI (1.24,1.98), I^2=0%, *P*=0.0002].

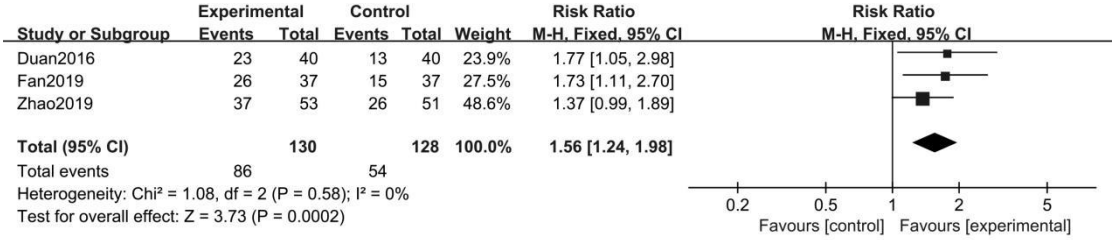

Figure 7. **Forest plot of quality-of-life improvement rate**

3.4.4. GRADE grading results

Disease control rates for major outcome measures were graded, and the quality of evidence for efficacy was low (Zhong et al., 2020; Zuo et al., 2015; Zuo et al., 2017; Chen and Xu, 2020).

4. Discussion

According to Chinese medicine, the reason why people suffer from cancer is related to the deficiency of vital qi and the dysfunction of zang-fu organs. The main principle of Chinese medicine in the treatment of lung cancer is to maintain health and dispel evil (Liu, 2007; Liu et al., 2017; Jiang et al., 2020; Pan et al., 2020; Chen et al., 2020; Zuo et al., 2013; Li et al., 2020; Liu et al.,2020; Wang et al.,2019; Xu et al., 2019; Zhang et al., 2019; Zhang et al., 2019).

This is similar to the viewpoint of modern medicine that the occurrence and development of malignant tumors are related to the decline of the body's defense function, especially the low level of cellular immunity, and the correlation between the immune status and prognosis of patients (Liu et al., 2017; Jiang et al., 2020; Pan et al., 2020). Fufang Banmao Capsule is composed of blister beetle, ginseng,milkvetch root, root and vine of manyprickle acanthopanax, common buried rubber, barbated skullcup herb, zedoray rhizome, asiatic cornelian cherry fruit，glossy privet fruit, bear bile powder，liquorice root. Blister beetle, common buried rubber, barbated skullcup herb and zedoray rhizome can break blood to scatter stasis, challenge poison to erode sore; ginseng,milkvetch root, root and vine of many prickle acanthopanaxhave beneficial effect of invigorating the spleen; asiatic cornelian cherry fruit and glossy privet fruit are good at tonifying liver and kidney; licorice blends all medicines, widely used in the adjuvant therapy of malignant tumors, with the effect of enhancing efficacy and reducing toxicity (Wang, 2020).

Cantharidin in modern pharmacology found Fufang Banmao Capsule has obvious antitumor effect and animal experiments found that it could improve a tumor-burdened NK activity and LAK cells in mice, increased the IL-2 and TNF alpha level, improve the proportion of T cell subgroup, the role and improve the cellular immune function of tumor suppression, inducing tumor cell apoptosis related (Zhang, 2006; Xia et al., 2007; Liu et al., 2019; Gou et al., 2019; Xu et al., 2019; Zhu et al., 2019; Zhao et al., 2019).

Meta-analysis showed that the disease control rate of Fufang Banmao Capsule combined with chemotherapy was better than that of chemotherapy alone, the improvement rate of quality of life was better than that of chemotherapy alone, and the adverse reaction rate was lower than that of chemotherapy alone. The disease control rate in outcome indicators was graded, and the quality of evidence was found to be low, with the quality of evidence being downgraded mainly in terms of bias risk and publication bias. It is suggested that the quality of evidence is of great significance to clinical guidance, and relevant studies in the future should focus on the application of random allocation, allocation concealment, blind method and other methods, so as to reduce the risk of bias in the literature (Chen et al., 2020; Zuo et al., 2013; Li et al., 2020; Liu et al.,2020).

There are many limitations in this study. For example, all the included studies are in Chinese, and the quality of the literature is generally low, with a large risk of bias. Traditional Chinese medicine stresses treatment based on syndrome differentiation. Most of the included studies fail to point out the types of syndrome differentiation of traditional Chinese medicine, and fail to conduct further research on the efficacy of Fufang Banmao Capsule in different types of TCM syndromes. The

efficacy of specific cell typing in lung cancer has not been studied. Moreover, KPS score is subjective because it is the scale score, and the included studies that reported this outcome indicator did not mention the blind method of evaluators, so the results are not reliable. Most of the included studies did not report the long-term survival, and the long-term efficacy was not reported (Wang et al.,2019; Xu et al., 2019; Zhang et al., 2019; Zhang et al., 2019).

In the future, more large-sample, multicenter, random-distribution sequence generation, distribution-hiding, blind application and other measures should be included to carry out more complete and high-quality trials, so as to provide evidence-based reference for the efficacy and safety of Fufang Banmao Capsule combined with chemotherapy for NSCLC. It is also important that nothed the other caused of this kind of cancer (Xiao et al., 2019; Kamran et al., 2019; Li et al., 2019; Xu et al., 2019; Wan et al., 2019; Mou et al., 2019; Si et al., 2019; Zhou et al., 2019).

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