Meta Analysis and Cost-effectiveness of Yangxin Dingji Capsule in the Treatment of Tachyarrhythmia

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Abstract [**Objectives**] To compare the clinical efficacy and cost-effectiveness of Yangxin Dingji capsule in conjunction with conventional Western medicine therapy against the use of conventional Western medicine therapy alone in the treatment of tachyarrhythmia. [**Methods**] A meta-analysis was conducted to evaluate the efficacy of Yangxin Dingji capsule in conjunction with conventional Western medicine therapy for the treatment of tachyarrhythmia, compared to conventional Western medicine therapy alone. A decision tree model was developed to conduct a cost-effectiveness analysis from the perspective of the healthcare system. The effect parameter was the clinical effectiveness rate obtained from a meta-analysis of clinical literature. The cost parameter was represented by the drug treatment cost. The incremental cost-effectiveness ratio (ICER) was subsequently calculated, and the robustness of the primary analysis results was assessed through one-way sensitivity analysis. [**Results**] The results of the meta-analysis indicated that, over an 8-week treatment period, the clinical efficacy of Yangxin Dingji capsule in conjunction with conventional Western medicine for the treatment of tachyarrhythmia was superior to that of conventional Western medicine therapy alone, and the difference was found to be statistically significant [$OR = 3.32$, 95% CI (2.22 - 4.96), $P < 0.000\ 01$]. The clinical efficacy of Yangxin Dingji capsule in conjunction with conventional Western medicine for the treatment of tachyarrhythmia was found to be superior when the treatment duration was 4 weeks, and the difference was found to be statistically significant [$OR = 2.39$, 95% CI (1.45 - 3.96), $P = 0.000\ 7$]. The cost-effectiveness analysis indicated that with an 8-week treatment regimen, each 1% increase in the clinical effectiveness rate of Yangxin Dingji capsule in conjunction with conventional Western medical therapy for the treatment of arrhythmia, as compared to conventional Western medical therapy alone, resulted in an increase in cost of 91.78 yuan. Conversely, when the treatment duration was 4 weeks, each 1% increase in the clinical effectiveness rate of the Yangxin Dingji capsule combined with conventional Western medical therapy led to a cost increase of 70.84 yuan. [**Conclusions**] In the management of tachyarrhythmia, the clinical efficacy of Yangxin Dingji capsule in conjunction with conventional Western medicine therapy is superior to that of conventional Western medicine therapy alone. When the willingness-to-pay value exceeds the corresponding ICER, the combination of Yangxin Dingji capsule with conventional Western medicine therapy is deemed more cost-effective than the use of conventional Western medicine therapy alone.

Key words Yangxin Dingji capsule, Arrhythmia, Meta analysis, Cost-effectiveness analysis

1 Introduction

Arrhythmia is defined as a series of clinical syndromes that result from the abnormal excitation of the sinoatrial node, or alternatively, the generation of excitation outside the sinoatrial node. This can result in the slow or blocked conduction of excitation, or the conduction of excitation through abnormal channels. In other words, the origin and/or conduction disorders of cardiac impulses result in abnormal frequencies and/or rhythms of heartbeats.

The *2021 China Cardiovascular Disease Medical Quality Report*[1] shows that the prevalence of cardiovascular diseases in China is experiencing a continuous upward trend. Currently, approximately 330 million individuals in China are affected by these conditions. Specifically, the report estimates that there are about 11.39 million cases of coronary atherosclerotic heart disease, 8.9 million cases of heart failure, 5 million cases of pulmonary heart disease, 4.87 million cases of atrial fibrillation, 2.5 million cases of rheumatic heart disease, and 2 million cases of congenital heart disease. The increasing pressures of modern life have resulted in a growing prevalence of arrhythmia among younger patients. While Western medicine remains the predominant approach to treating arrhythmia, the available pharmacological options are limited, and many patients exhibit a poor tolerance to these treatments. Traditional Chinese medicine frequently employs a dual approach that addresses both symptoms and underlying causes. This methodology has been shown to effectively alleviate clinical symptoms and enhance the quality of life for patients. Additionally, it is associated with fewer adverse reactions and improved patient compliance. In the spectrum of prescriptions for the treatment of various arrhythmias presented in the *Treatise on Cold Pathogenic and Miscellaneous Diseases*, Zhigancao decoction is the most frequently utilized remedy documented in the medical records[2]. Yangxin Dingji capsule is a Chinese patent medicine derived from the Zhigancao decoction, offering enhanced convenience for transportation and administration.

The objective of this study was to evaluate the clinical efficacy and cost-effectiveness of Yangxin Dingji capsule in conjunction with conventional Western medicine therapy, compared to conventional Western medicine therapy alone, in the treatment of tachyarrhythmia. This was achieved through a meta-analysis and an examination of relevant cost data, with the aim of providing guidance for the rational use of medications in clinical practice.

2 Materials and methods

2.1 Information retrieval The search was performed utilizing Chinese databases, including the China Academic Journal Full-text Database, Wanfang Data Knowledge Service Platform, and the Chinese Journal Full-text Database, as well as English databases such as PubMed, Embase, and the Cochrane Library. The

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temporal scope of the search extended from the inception of these databases up to December 2022.

In order to thoroughly compile all pertinent literature regarding Yangxin Dingji capsule, a comprehensive full-text search was conducted in Chinese using the characters "Yangxindingji Jiaonao" AND "arrhythmia", while another full-text search was performed in English employing the terms "Yang Xin Ding Ji Nang" OR "Yangxindingji Jiaonang" OR "Yangxindingji Capsule" AND "arrhythmia".

2.2 Inclusion and exclusion criteria According to the workbook of the *Cochrane Collaboration Network on Evidence-Based Medicine*[3], the inclusion criteria for the study were as follows: (i) all published randomized controlled trials concerning the treatment of tachyarrhythmias with Yangxin Dingji capsule, both domestically and internationally; (ii) the prescribed dosage of Yangxin Dingji capsule was 6 capsules per dose, administered twice daily; (iii) the treatment duration was either 4 or 8 weeks; (iv) the primary endpoints included the clinical efficacy rate; (v) the languages of the studies considered were Chinese and English; (vi) the diagnostic criteria for various types of tachyarrhythmias were established based on authoritative guidelines from both domestic and international sources.

The exclusion criteria for this study were as follows: (i) duplicated published literature; (ii) literature in which the combination of drugs influenced the assessment of therapeutic efficacy; (iii) descriptive studies; (iv) animal experiments; and (v) literature that presented contradictory data from prior and subsequent analyses and lacked the necessary statistical indicators.

2.3 Literature screening and data extraction The titles of the retrieved documents were imported into NoteExpress software for the purpose of conducting a literature screening to eliminate duplicate entries. The literature screening process was conducted independently by two researchers, who reviewed the full texts as needed. Upon completion of the literature screening, the results were compared, and any discrepancies or disagreements were addressed with the assistance of a third researcher. The data extraction form comprised the following components: (i) general information, including the authors' names and the year of publication; (ii) characteristics of the study sample, such as age, gender, interventions, and other baseline information; (iii) reported outcome indicators; and (iv) indicators for evaluating the risk of bias in the literature, *etc.*

2.4 Statistical analysis A meta-analysis was conducted utilizing RevMan 5.4 software, employing the odds ratio (*OR*) as the statistical measure for effect analysis of count data, along with the calculation of its 95% confidence interval (95% *CI*). In this study, the heterogeneity of the included studies was assessed using the *P*-value and I^2 statistic. A *P*-value greater than 0.1 and an I^2 value less than 50% indicated minimal heterogeneity among the studies, warranting the use of a fixed-effects model. Conversely, significant heterogeneity necessitated the application of a random-effects model.

2.5 Pharmacoeconomic evaluation

2.5.1 Model structure. In this study, Microsoft Excel 2019 was utilized to develop a decision tree model for the purpose of conducting a cost-effectiveness analysis. The duration of the study was either 4 or 8 weeks, with the primary endpoint being the classification of outcomes as either effective or ineffective. The structure of the model is illustrated in Fig. 1. It was assumed that the conventional Western medicine administered during the study intervention were identical for both groups; the sole distinction between the two groups was the coadministration of Yangxin Dingji capsule.

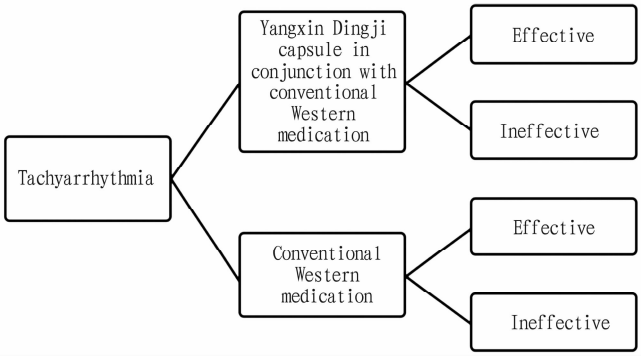

Fig. 1 Model structure

2.5.2 Effectiveness rate. The clinical effectiveness rates of the various treatment regimens utilized in the model were obtained from the findings of the meta-analysis. These rates were calculated by weighting the effectiveness rates reported in the studies included in the meta-analysis in accordance with their respective sample sizes.

2.5.3 Cost. The study adopted a healthcare system perspective, focusing exclusively on direct medical costs. It was assumed that all costs were equivalent between the two groups, with the exception of medication expenses. Therefore, only the costs associated with medication were included in this analysis. According to the most recent online pricing data from Yaozhi Network (https://www.yaozh.com/), Hebei Yongfeng Pharmaceutical Co., Ltd. offers the Yangxin Dingji capsule, which has a specification of 0.5 g/capsule and is packaged with 24 capsules per box, at a price of 55.00 yuan. The total treatment cost for a 4-week regimen, based on the recommended dosage of 6 capsules per administration, taken twice daily, amounts to 770.00 yuan. For an 8-week treatment course, the total cost is 1 540.00 yuan. According to the treatment protocols for conventional antiarrhythmic drugs outlined in the relevant literature and the recommended pharmacological interventions in clinical guidelines, mexiletine hydrochloride tablets were identified as the conventional Western medicine for this study. Mexiletine hydrochloride tablets, produced by Yunpeng Pharmaceutical Group Co., Ltd., are available in a specification of 50 mg/tablet, with each box containing 36 tablets, and are priced at 98.00 yuan per box. The recommended dosage of mexiletine hydrochloride tablets is approximately 600 mg per day, which equates to 12 tablets, administered in 2 to 3 doses. Consequently, the total cost for a 4-week treatment regimen amounts to 914.67 yuan, while an 8-week treatment course totals 1 829.33 yuan (Table 1).

Table 1 Price of therapeutic drugs

Generic name of drugs	Dosage form	Specification	Price yuan	Cost of 4-week treatment course // yuan	Cost of 8-week treatment course // yuan	Manufacturer
Yangxin Dingji capsule	Capsule	0.5 g×24 capsules/box	55.00	770.00	1 540.00	Hebei Yongfeng Pharmaceutical Co., Ltd.
Mexiletine hydrochloride tablets	Tablet	50 mg×36 tablets/box	98.00	914.67	1 829.33	Yunpeng Pharmaceutical Group Co., Ltd.

2.5.4 Cost-effectiveness analysis. A fundamental analysis was conducted to evaluate the difference in clinical effectiveness rates and treatment costs associated with the use of Yangxin Dingji capsule in conjunction with conventional Western medical therapy, compared to conventional Western medical therapy alone. These differences were utilized to calculate the incremental cost-effectiveness ratio (ICER), which serves as an important economic indicator.

A one-way sensitivity analysis was conducted to assess the robustness of the results obtained from the fundamental analysis. The parameters included in this sensitivity analysis comprised the price of Yangxin Dingji capsule, the price of mexiletine hydrochloride tablets, the clinical efficacy of Yangxin Dingji capsule in conjunction with conventional Western medical therapy, and the clinical efficacy of conventional Western medical therapy alone. These parameters were varied within a range of ±10% fluctuations from the original data.

3 Results and analysis

3.1 Meta analysis results

3.1.1 Literature screening results and fundamental characteristics. A total of 44 studies were initially reviewed, resulting in the inclusion of 13 randomized controlled trials[4-16], all of which were published in Chinese. The studies collectively involved 1 315 patients, with 660 receiving treatment with Yangxin Dingji capsule in conjunction with conventional Western medical therapy, while 655 patients were treated solely with conventional Western medical therapy. The primary endpoints assessed included the clinical effectiveness rate over either a 4-week or 8-week treatment course. The fundamental characteristics of the studies included in this analysis are presented in Table 2.

Table 2 Fundamental characteristics of the studies included

Included literature	Type of arrhythmia	Underlying diseases/Comorbidities	Intervention		Number of cases (experimental group/control group)	Course of treatment week	Dosage of Yangxin Dingji capsule
			T	C			
Han Haili *et al.* [4]	Ventricular premature contraction	Perimenopausal period		ade	52/52	8	6 capsules per time, twice per day
Ying Lianghong *et al.* [5]	Atrial fibrillation	High blood pressure		bde	63/63	8*	6 capsules per time, twice per day
Hang Yanwen[6]	Atrial premature contraction, ventricular premature contraction, supraventricular tachycardia, paroxysmal atrial fibrillation	DCHD		acde	43/43	8	6 capsules per time, twice per day
Li Zhen *et al.* [7]	Ventricular premature contraction	Post-PCI		abd	57/57	8	6 capsules per time, twice per day
Liu Dongsheng *et al.* [8]	Ventricular premature contraction	ACS		be	61/61	8	6 capsules per time, twice per day
Qin Huan *et al.* [9]	Ventricular premature contraction	CHF		ad	30/30	8	6 capsules per time, twice per day
Bai Long *et al.* [10]	Atrial premature contraction, Ventricular premature contraction, sinus tachycardia	Coronary atherosclerotic heart disease	YXDJ+C	ad	43/43	8*	6 capsules per time, twice per day
Zhang Guorui *et al.* [11]	Ventricular premature contraction	Coronary atherosclerotic heart disease		ab	43/43	4	6 capsules per time, once per day
Zhang Baotian *et al.* [12]	Atrial premature contraction, ventricular premature contraction, supraventricular tachycardia, atrial fibrillation	–		a	43/43	4*	6 capsules per time, twice per day
Xie Xiao *et al.* [13]	Ventricular premature contraction	Post-PCI		b	49/49	4	6 capsules per time, twice per day
Wang Chunliang *et al.* [14]	Ventricular premature contraction	–		a	56/51	4*	6 capsules per time, twice per day
Lu Wei *et al.* [15]	Ventricular premature contraction	ACS		abe	70/70	4	6 capsules per time, twice per day
Tian Xiaochao *et al.* [16]	Ventricular premature contraction	CHF		a	50/50	8	6 capsules per time, twice per day

NOTE ACS. Acute coronary syndrome; CHF. Chronic heart failure; DCHD. Diabetic coronary heart disease; PCI. Percutaneous coronary intervention; T. Test group; C. Control group; YXDJ. Yangxin Dingji capsule; the expression *4 weeks/8 weeks represents a conversion for the original terms 1 month/2 months; a. Conventional antiarrhythmic medications, such as β-blockers (*e.g.*, metoprolol), amiodarone, and sodium channel blockers (*e.g.*, mexiletine, propafenone); b. Fundamental interventions aimed at enhancing cardiac function, which may include antiplatelet therapy, management of coronary artery ectasia, cardiotonic agents, blood pressure reduction, anticoagulation, and lipid modulation; c. Supportive care measures, encompassing patient monitoring, bed rest, and supplemental oxygen administration; d. Standard treatment protocols for primary conditions or co-morbidities; e. Guidance on health and dietary practices.

3.1.2 Clinical effectiveness rate. A total of 13 articles were included in the literature review concerning the treatment of tachyarrhythmia with Yangxin Dingji capsule in comparison to control medications. The analysis was conducted based on varying treatment duration (4 and 8 weeks). Notably, the heterogeneity among the studies was lower for the 8-week treatment course ($I^2=0\%$, $P=0.80$). Utilizing a fixed-effect model, the clinical effectiveness rate of Yangxin Dingji capsule in conjunction with conventional Western medical therapy for the treatment of tachyarrhythmia was found to be superior to that of conventional Western medicine alone, with a statistically significant difference observed [$OR=3.32$, 95% CI (2.22 – 4.96), $P<0.000\ 01$] (Fig. 2). The heterogeneity among the studies was low when the treatment duration was 4 weeks ($I^2=0\%$, $P=0.83$). Utilizing a fixed-effects model, the clinical effectiveness rate of Yangxin Dingji capsule in conjunction with conventional Western medical therapy for the treatment of tachyarrhythmia was found to be significantly superior to that of conventional Western medical therapy alone, with a statistically significant difference [$OR=2.39$, 95% CI (1.45 – 3.96), $P=0.000\ 7$] (Fig. 3).

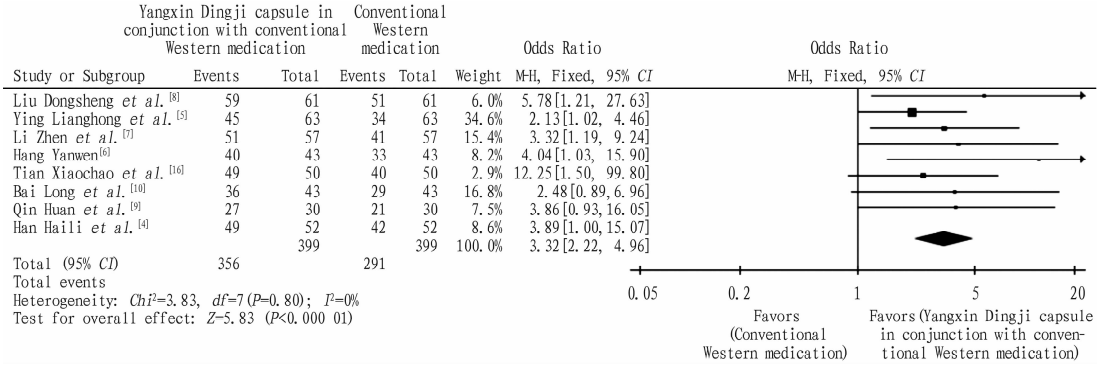

Fig. 2 Clinical effectiveness rate—Forest map of 8-week treatment course

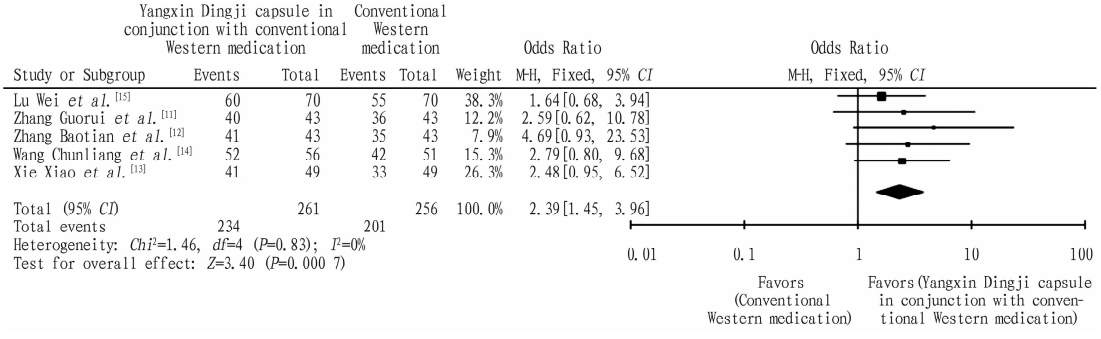

Fig. 3 Clinical effectiveness rate—Forest map of 4-week treatment course

3.1.3 Publication bias. A funnel plot was constructed to assess the publication bias of the studies included in this analysis. The results indicated the possibility of publication bias, as the distribution was not entirely symmetrical (Fig. 4).

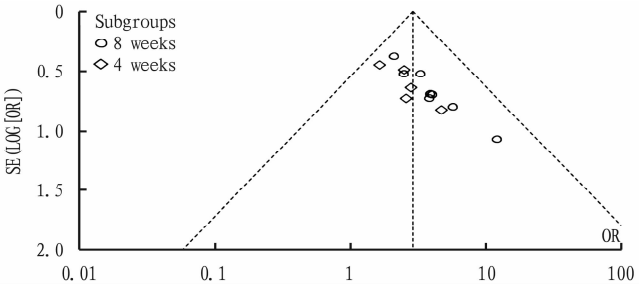

Fig. 4 Funnel plot of the effectiveness data of Yangxin Dingji capsule in the treatment of tachyarrhythmia

3.2 Results of cost-effectiveness analysis

3.2.1 Cost-effectiveness analysis using clinical effectiveness rate as an effect parameter. Data regarding the effects of various medication regimens were obtained by calculating the weighted average effectiveness rates of the studies included in the analysis. The weights assigned to these studies were derived from the results of the meta-analysis (Figs. 2 – 3). Following the analysis, it was determined that the clinical effectiveness rate of Yangxin Dingji capsule in conjunction with conventional Western medical therapy was 83.69% over a 8-week treatment course, compared to a clinical effectiveness rate of 66.91% for conventional Western medical therapy alone. In a 4-week treatment course, the clinical effectiveness rate for the combination of Yangxin Dingji capsule and conventional Western medical therapy increased to 87.92%, while the rate for conventional Western medical therapy alone was 77.05%. Based on the effect data and the costs associated with various treatment courses for pharmacoeconomic evaluation, the findings indicated that when the treatment duration was 8 weeks, each 1% increase in the clinical effectiveness rate of Yangxin Dingji capsule in conjunction with conventional Western medical therapy for the treatment of arrhythmia, as compared to conventional Western medical therapy alone, resulted in an increase in cost of 91.78

yuan. Conversely, when the treatment duration was 4 weeks, each 1% increase in the clinical effectiveness rate of Yangxin Dingji capsule combined with conventional Western medical therapy led to a cost increase of 70.84 yuan (Table 3). The willingness-to-pay values exceeded the corresponding ICER values, indicating that the combination of Yangxin Dingji capsule with conventional Western medical therapy is more cost-effective than conventional Western medical therapy alone.

Table 3 Cost-effectiveness analysis using clinical effectiveness rate as an effect parameter

Intervention	Course of treatment week	Treatment cost//yuan	Effectiveness rate//%	CEA		
				ΔC//yuan	ΔE//%	ICER//yuan
Yangxin Dingji capsule in conjunction with conventional Western medical therapy	8	3 369.33	83.69	1 540.00	16.78	91.78
Conventional Western medical therapy		1 829.33	66.91			
Yangxin Dingji capsule in conjunction with conventional Western medical therapy	4	1 684.67	87.92	770.00	10.87	70.84
Conventional Western medical therapy		914.67	77.05			

NOTE ΔC represents the outcome of Yangxin Dingji capsule in conjunction with conventional Western medical therapy; ΔE denotes the effectiveness of Yangxin Dingji capsule in conjunction with conventional Western medical therapy; the effectiveness rate is derived from the pooled results of a meta-analysis.

3.2.2 Results of one-way sensitivity analysis. When the treatment duration was set at 8 weeks, the three parameters that exerted the most significant influence on the outcomes were, in order of impact, the treatment effectiveness rate of Yangxin Dingji capsule in conjunction with conventional Western medical therapy, the treatment effectiveness rate of conventional Western medical therapy alone, and the cost associated with Yangxin Dingji capsule (Fig. 5). The three parameters that exerted the most significant influence on the outcomes of the 4-week treatment regimen were, in order of impact, the effectiveness rate of Yangxin Dingji capsule in conjunction with conventional Western medical therapy, the effectiveness rate of conventional Western medical therapy alone, and the cost associated with Yangxin Dingji capsule (Fig. 6).

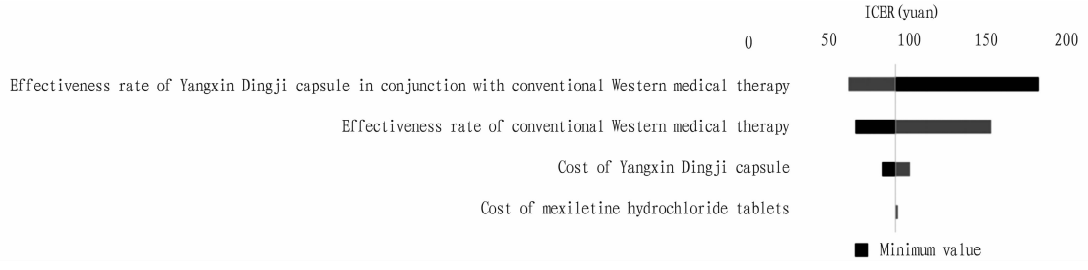

Fig. 5 One-way sensitivity analysis (8-week course, ICER)

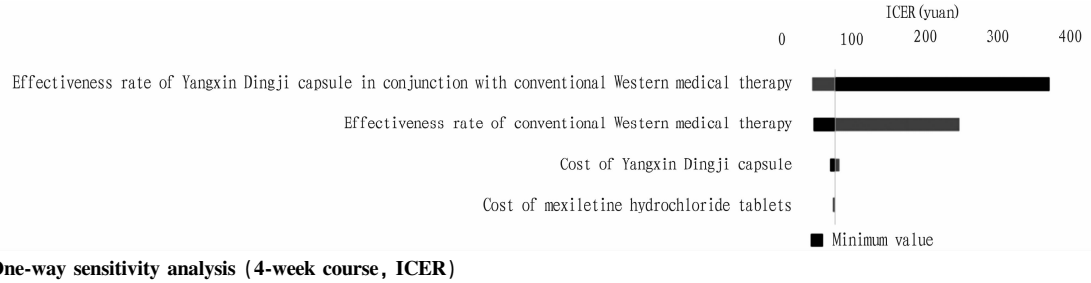

Fig. 6 One-way sensitivity analysis (4-week course, ICER)

4 Discussion

Yangxin Dingji capsule is the sole medication designated for the treatment of tachyarrhythmia within the category of qi and blood double tonics, as outlined in the *Drug Catalogue of National Basic Medical Insurance, Workers' Compensation Insurance, and Maternity Insurance (2021)*.

The meta-analysis conducted in this study was based on the existing published literature, incorporating a total of 13 papers. The findings indicated that the clinical efficacy of the Yangxin Dingji capsule, when used in conjunction with conventional Western medical therapy for the treatment of tachyarrhythmia, was significantly superior to that of conventional Western medical therapy alone. The differences observed were statistically significant at both the 4-week and 8-week treatment courses. The findings of the pharmacoeconomic evaluation indicated that, with a treatment duration of 8 weeks, each 1% increase in the clinical effectiveness rate of the Yangxin Dingji capsule, when used in conjunction with conventional Western medical therapy for the treatment of arrhythmia, was associated with an increase in cost of 91.78 yuan compared to conventional Western medical therapy alone. In contrast, with a treatment duration of 4 weeks, each 1% increase in the clinical effectiveness rate of Yangxin Dingji capsule combined with

conventional Western medical therapy resulted in a cost increase of 70.84 yuan. The economic viability of combining Yangxin Dingji capsule with conventional Western medical therapy is contingent upon the willingness-to-pay threshold of stakeholders. If the willingness-to-pay value exceeds the corresponding ICER, then the combination of Yangxin Dingji capsule and conventional Western medical therapy is deemed more cost-effective than conventional Western medical therapy alone.

This study has several limitations. (i) The efficacy data were primarily derived from a meta-analysis. However, the studies included were predominantly from Chinese literature and featured small sample sizes. Therefore, there is a need for more high-quality, large-sample clinical studies to validate these findings. (ii) The efficacy of Yangxin Dingji capsule in conjunction with conventional Western medical therapy is superior. However, this study solely accounted for the cost of medications in the cost analysis, which may have led to an underestimation of the advantages of Yangxin Dingji capsule when combined with conventional Western medical therapy. This underestimation pertains to direct non-medical costs, indirect costs, and other relevant expenses, which warrant further investigation in future research. (iii) The conventional treatment regimen for the control group encompassed a range of therapeutic options. This study primarily utilized the cost of mexiletine hydrochloride tablets to represent the expenses associated with the control group, without calculating the weighted average of all routine treatments. Consequently, this approach may not provide an accurate depiction of the overall treatment costs for the control group. However, it is important to note that the experimental group received coadministration of Yangxin Dingji capsule in addition to the standard treatment provided for the control group. As a result, the costs associated with the control group were effectively offset during the incremental analysis, thereby exerting no influence on the calculation of ICER. (iv) Tachyarrhythmia is a chronic condition that is more appropriately modeled through long-term simulations utilizing Markov modeling techniques. However, due to limitations in research time and resources, this study was restricted to short-term simulations. Consequently, additional related studies are anticipated in the future.

In conclusion, the clinical efficacy of Yangxin Dingji capsule in conjunction with conventional Western medical therapy for the treatment of tachyarrhythmia surpasses that of conventional Western medical therapy alone. Furthermore, when the willingness-to-pay value exceeds the corresponding ICER, the combination of Yangxin Dingji capsule and conventional Western medical therapy demonstrates greater economic viability compared to conventional Western medical therapy alone.

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