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Review Article

A meta-analysis of the clinical efficacy of rhBNP in treating patients with acute myocardial infarction and heart failure

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Abstract: Objective: To explore the clinical efficacy of rhBNP in patients with acute myocardial infarction (AMI) and heart failure (HF). Methods: A systematic review and a meta-analysis were performed using the *Preferred Reporting Items for Systematic Reviews and Meta-analyses* (PRISMA) guidelines. On May 30, 2020, we consulted the electronic databases PubMed, EBSCO, Elsevier, Springer, Wiley, and Cochrane using the keywords "acute coronary syndrome (ACS)", "brain natriuretic peptide (BNP)", and "acute myocardial infarction (AMI)". The quality of the data included in the study was assessed according to the *Cochrane Handbook for Systematic Reviews of Interventions*. The results of the clinical randomized controlled study reports were analyzed using Review Manager 5.1.0. Results: A total of nine, clinical, randomized, controlled studies were included. The effective rate in the rhBNP group was significantly higher than it was in the control group ($Z = 9.50$, $P < 0.00001$). The patients in the rhBNP group showed remarkably shorter hospital stays ($Z = 24.43$, $P < 0.00001$) and markedly increased left ventricular ejection fractions (LVEF) ($Z = 245.53$, $P < 0.00001$). Compared with the LVEF in the control group, the LVEF in the rhBNP group was significantly increased ($Z = 3.55$, $P = 0.0004$), but the rate of cardiac hypotension ($Z = 3.55$, $P = 0.0004$) and the headache incidence rate in the rhBNP group ($Z = 2.3$, $P = 0.04$) were not elevated. The rhBNP group showed no increase in either the low heart rate ($Z = 1.22$, $P = 0.22$) or the rate of renal insufficiency ($Z = 0.35$, $P = 0.73$). Conclusion: The meta-analysis suggests that, compared with the conventional treatment of patients with AMI and HF, rhBNP can markedly improve the clinical efficacy and myocardial functions and shorten the hospital stays, without elevating the rate of adverse reactions, such as hypotension, headaches, low heart rate, and renal insufficiency.

Keywords: Acute myocardial infarction, heart failure, meta-analysis, rhBNP

Introduction

Persistent myocardial ischemia is the main cause of acute myocardial infarction (AMI) [1]. Heart failure (HF), the most common serious complication of AMI, is an acute syndrome caused by decreased cardiac output and the insufficient perfusion of tissues and organs [2]. Empirical studies show that the mortality of patients with myocardial infarction (MI) and HF rises exponentially [3]. According to an epidemiological survey, approximately 32.4% of AMI patients die every year globally [4], so it is substantially urgent to further explore the treatment methods for patients with AMI and HF. Brain natriuretic peptide (BNP) is a neurohormone [5]. When a patient's volume load and hemodynamic pressure changes, endothelial disorders and vascular remodeling occur, and the BNP increases before the clinical symptoms appear [6]. The release of BNP into the blood leads to vasodilation, diuresis, and sodium excretions and inhibits the inflammation of the myocardium and blood vessels and the activation of neuroendocrine, thus protecting the cardiovascular system [7]. Recombinant human brain natriuretic peptide (rhBNP) is a novel synthetic drug widely used in the clinical treatment of patients with acute decompensated heart failure (ADHF), which can decrease anterior and posterior cardiac load, increase the cardiac output, improve cardiac functions, and thus reduce patient mortality and readmission rates.

In this study, to further compare and analyze the efficacy of BNP in AMI, recent comparative studies of BNP and nitroglycerin at home and

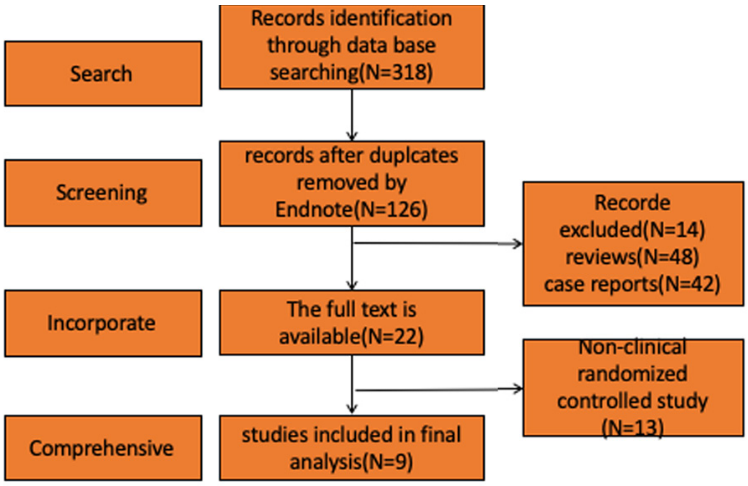

Figure 1. A total of 318 potentially related articles were retrieved from the initial search strategy. A total of 126 studies obtained after excluding the duplicate articles, then 22 studies were obtained after excluding the non-clinical, randomized controlled studies, such as reviews and case reports, and the 22 articles were read through. According to the aforementioned inclusion and exclusion criteria, a total of 9 references were finally obtained.

abroad were summarized, and a meta-analysis was performed using Review Manager to quantitatively compare and analyze BNP and the comparative factors, such as the cure rate, the treatment course, the left ventricular ejection fraction (LVEF), and the incidences of complications (hypotension, headache, nausea, low heart rate, renal insufficiency), so as to evaluate the clinical efficacy of BNP in MI patients, thereby providing a scientific and reliable basis for clinical practice.

Materials and methods

In this study, a systematic review and meta-analysis was performed using the *Preferred Reporting Items for Systematic Reviews and Meta-analyses* (PRISMA) guidelines [8]. On May 30, 2020, we consulted the electronic databases PubMed, EBSCO, Elsevier, Springer, Wiley, and Cochrane using the keywords "acute coronary syndrome (ACS)", "brain natriuretic peptide (BNP)", and "acute myocardial infarction (AMI)". There was no language restriction during this consultancy. If the following conditions were met, a retrieved study would be included: a. randomized controlled trial; b. trials conducted in humans; c. patients with AMI and HF; d. adult patients included. The exclusion criteria were as follows: a. duplicate references; b. systematic reviews and meta-analyses; c. the results and complete study details were not obtained after contacting the author.

Reference screening and data extraction

The two researchers excluded the studies that had been subjected to rigorous preliminary review in accordance with the criteria, and independently screened and excluded the articles that did not meet the requirements. After carefully reading all possible materials, the two researchers fully discussed the different results in this study or invited another researcher to participate in the discussion.

The data related to the study were extracted into a pre-engineered table, including: (1) general data: title, first author, and date of publication; (2) study subjects, sample size; (3) outcome indexes, assessment of the patients' related conditions.

Quality assessment

The *Cochrane Handbook for Systematic Reviews of Interventions* (*Version* 5.1.0.) was adopted for our assessment of the quality of the references included and the risk of bias assessment, including the assessment of the randomized controlled trials (RCT) [9]. Specifically, it includes the following seven assessment criteria: (1) the generation of random sequences; (2) allocation concealment; (3) double-blinded implementers and participants; (4) blind method of result assessment; (5) integrity of the result data; (6) select report; and (7) other sources of bias.

Statistical analysis

All the data were analyzed using Review Manager Version 5.1.0 (The Cochrane Collaboration, Software Update, Oxford), and $P < 0.05$ was considered to be statistically significant. The analysis was carried out using the odds ratio (OR) of dichotomous variables with a 95% confidence interval (95% CI) and weighted mean difference (WMD), and the continuous variables had a 95% CI. The heterogeneity was assessed using χ^2 and I^2. Non-significant heterogeneous data ($P < 0.1$) were caculated

Table 1. General information

Study		Wang Y 2016	Peacock WF 4th 2004	Xing K 2016	Chow SL 2011	Gong Y 2019	Chen J 2019	Chen Y 2018	Wang X 2013	Chen J 2015
Study period		2014-2016	2002-2004	2014-2016	2009-2011	2018-2019	2016-2019	2016-2018	2011-2012	2014-2015
Country		China	China	America	America	China	China	China	China	China
Study design		RCT	RCT	RCT	RCT	RCT	RCT	RCT	RCT	RCT
Case		50	135	116	66	46	36	46	80	114
Control		50	135	107	66	46	36	46	80	114
Effective number (n)	Case	45	120	107	60	42	35	44	72	103
	Control	42	108	88	53	32	27	38	64	91
Hospital days (d)	Case	13.9±2.7	/	/	12.3±1.4	12.8±2.2	/	11.6±1.6	/	14.1±2.2
	Control	16.4±1.6	/	/	15.2±2.2	14.9±2.1	/	16.3±1.6	/	18.4±2.2
LVEF (%)	Case	55.2±1.3	47.3±1.2	48.1±1.2	51.6±2.4	44.3±2.1	52.1±1.2	48.3±2.1	48.1±1.1	51.3±1.6
	Control	38.2±1.6	40.1±2.2	38.1±2.2	35.5±1.2	37.8±1.9	35.6±1.6	37.2±1.4	36.4±2.2	33.9±2.7
Hypotension (n)	Case	2	2	/	4	3	/	4	2	2
	Control	6	6	/	6	8	/	8	6	4
Headache (n)	Case	2	/	/	3	/	/	1	1	2
	Control	4	/	/	2	/	/	3	4	7
Low heart rate	Case	/	/	/	/	1	/	2	3	/
	Control	/	/	/	/	4	/	2	5	/
Renal insufficiency	Case	3	/	/	/	2	/	2	/	/
	Control	5	/	/	/	1	/	2	/	/

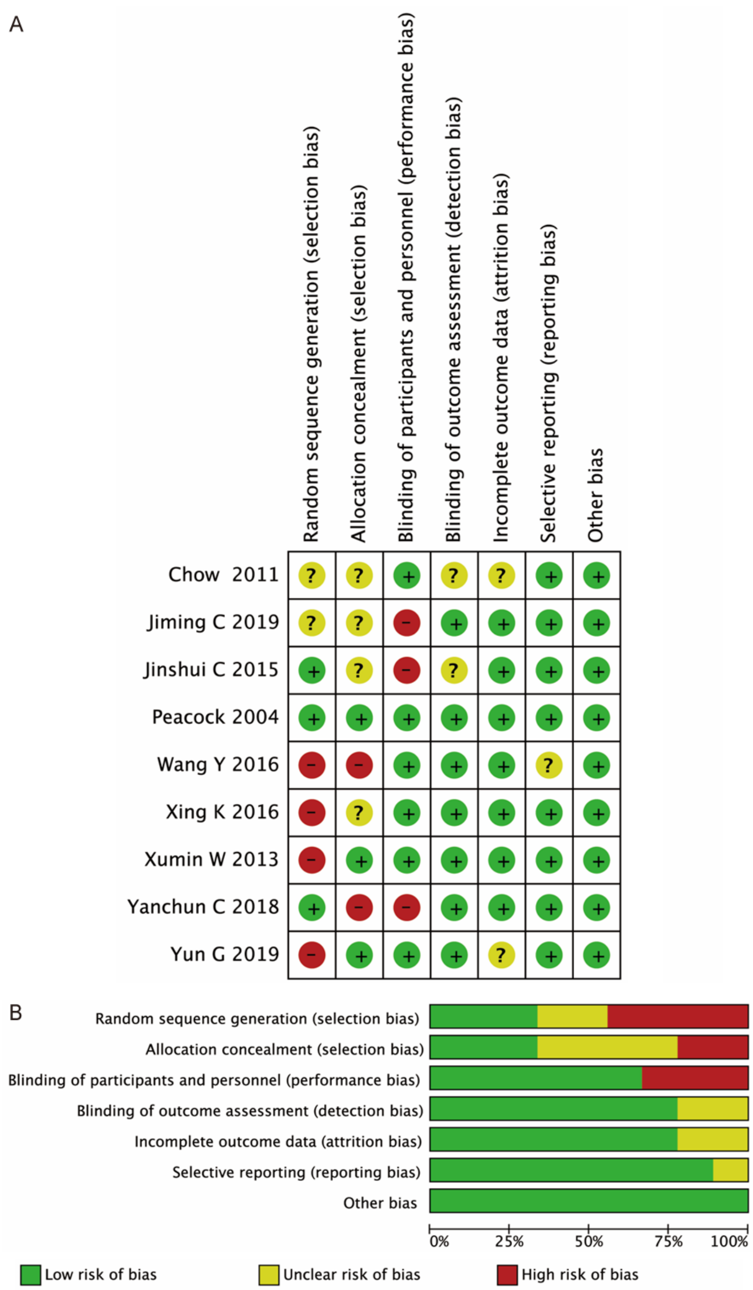

Figure 2. Risk of Bias Assessment Chart Included in the Literature. A. Risk of bias summary: a review of the authors' assessment of the risk of bias in the studies included. B. Risk of bias risk chart: a review of the authors' assessment of all the risks of bias, and a percentage is expressed in all the studies included.

using the fixed effect model and heterogeneous data ($P < 0.1$) were caculated using the random effect model. The publication bias was visually assessed using the funnel chart, and the standard error analysis was carried out according to the log OR. If the analysis result suggested a statistical heterogeneity, a correlation analysis of the sources of heterogeneity was carried out.

Results

Study characteristics

A total of 318 potentially relevant articles were retrieved from the initial search strategy. A total of 126 articles were obtained after excluding the duplicates, and 22 articles were obtained after excluding the non-clinical, randomized controlled studies, such as reviews and case reports, and eventually a total of 9 articles remained according to the aforementioned inclusion and exclusion criteria [10-18] (**Figure 1**). A total of 1,369 patients were involved. **Table 1** summarizes the characteristics of these nine studies and assessments (**Table 1**).

According to the assessment tool referred to in the *Cochrane Handbook for Systematic Reviews of Interventions* (*Version* 5.1.0.), there were bias risks in the study, and these risks were assessed using 7 criteria. The results suggested that the research design methods were described in most trials, but the allocation concealment methods were rarely described. Some trials reported a detailed, double-blinded design (**Figure 2**).

Analysis of efficacy

Based on the nine articles [10-18], the researchers studied the efficacy of rhBNP in patients with AMI and HF, but the trial results revealed no heterogeneity in the efficacy (Chi-squared = 2.75, $P = 0.95$, $I^2 = 0\%$), so the fixed effect model was adopted. Compared with the effective rate in the control group, the effective rate in the rhBNP group was significantly higher ($Z = 9.50$, $P < 0.00001$), indicating that rhBNP can significantly improve the treatment efficacy in patients with AMI and HF. The funnel plot showed no publication bias (**Figure 3**).

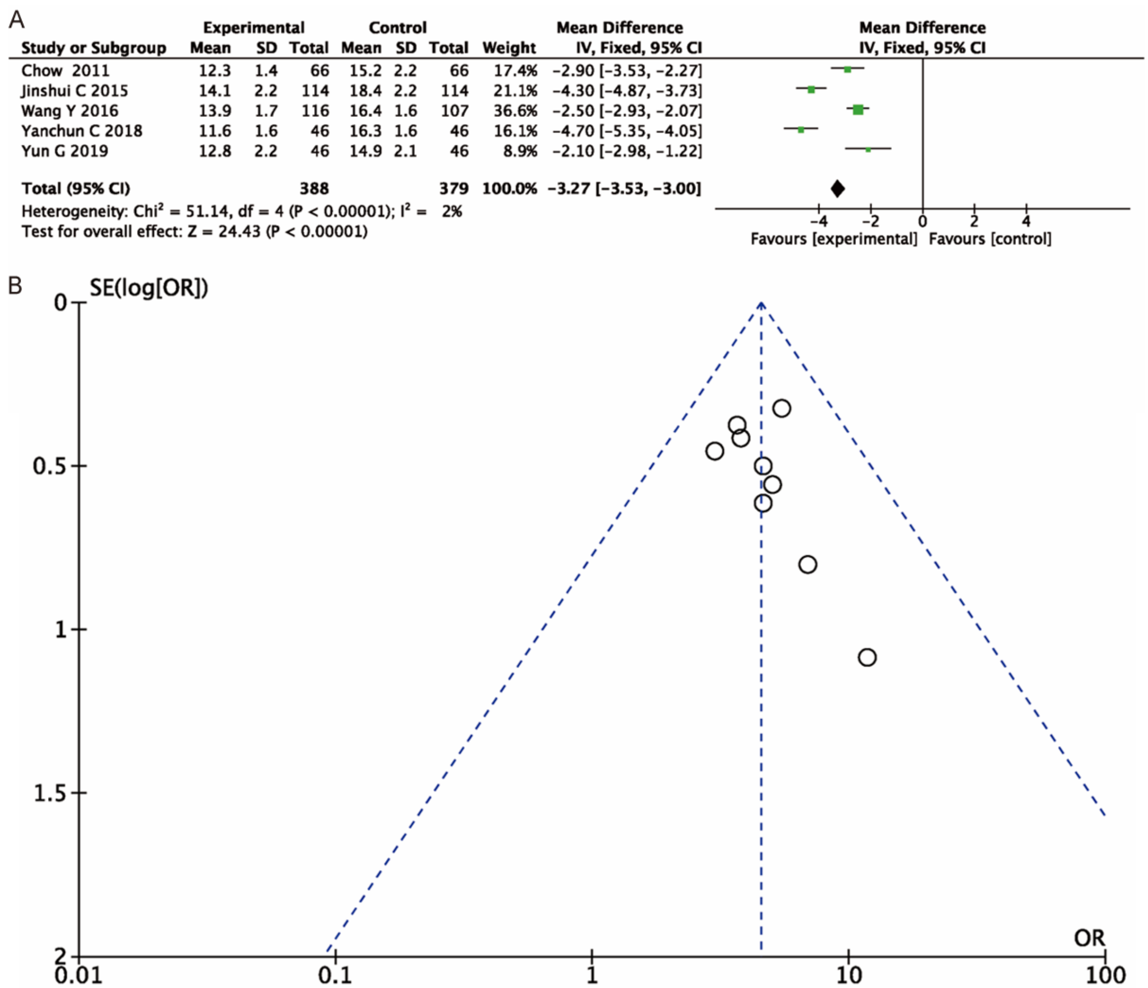

Figure 3. The Effects of rhBNP on the Treatment of Patients with AMI and HF. A. Forest plot; B. Funnel plot.

Analysis of the lengths of the hospital stays

Based on Wang et al. (2016) [10], Chow et al. (2011) [13], Gong and Zhang (2019) [14], Chen (2018) [16], and Chen et al. (2015) [18], the researchers studied the effects of rhBNP on the lengths of the hospital stays of the patients with AMI and HF. The heterogeneity test result was (Chi-squared = 51.15, $P < 0.001$, $I^2 = 2\%$), so the fixed effect model was adopted. Compared with the lengths of the hospital stays in the control group, the lengths of the hospital stays in the rhBNP group were significantly reduced (Z = 24.43, $P < 0.00001$). The funnel plot showed no publication bias (**Figure 4**).

Analysis of left ventricular ejection fractions (LVEF)

Based on the nine articles [10-18], the researchers studied the effects of rhBNP on the LVEF of patients with AMI and HF. The heterogeneity test result was (Chi-squared = 204.62, $P < 0.0001$, $I^2 = 6\%$), so the fixed effect model was adopted. Compared with the LVEF in the control group, the LVEF of the patients in the rhBNP group increased significantly (Z = 245.53, $P < 0.00001$). The funnel plot showed no publication bias (**Figure 5**).

Analysis of the hypotension

Based on the nine studies [10-18], the researchers studied the effects of rhBNP on the hypotension of the patients with AMI and HF. The heterogeneity test result was (Chi-squared = 3.17, $P = 0.92$, $I^2 = 0\%$), so the fixed effect model was adopted. Compared with the cardiac hypotension incidence rate in the control group, the cardiac hypotension incidence rate in the rhBNP group was not elevated (Z = 3.55,

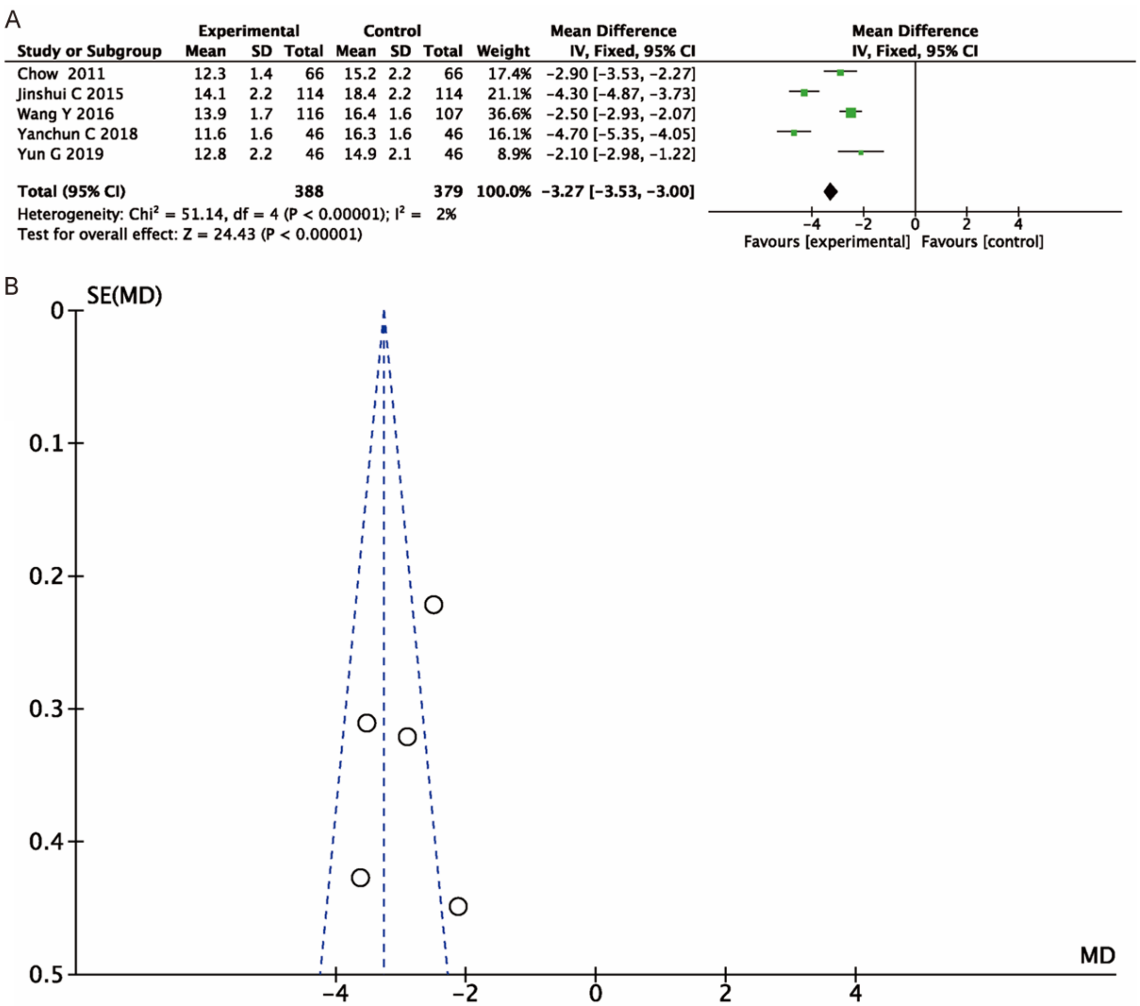

Figure 4. The effects of rhBNP on the lengths of the hospital stays among patients with AMI and HF. A. Forest plot; B. Funnel plot.

P = 0.0004). The funnel plot showed no publication bias (**Figure 6**).

Analysis of the headaches

Based on Wang et al. (2016) [10], Chow et al. (2011) [13], Chen (2018) [16], Wang (2013) [17] and Chen et al. (2015) [18], the researchers studied the effects of rhBNP on the occurrence of headaches in patients with AMI and HF. The heterogeneity test result was (Chi-squared = 2.5, P = 0.64, I^2 = 0%), so the fixed effect model was adopted. The results showed that compared with the headache incidence rate in the control group, the headache incidence rate in the rhBNP group did not increase (Z = 2.3, P = 0.04). The funnel plot showed no publication bias (**Figure 7**).

Analysis of the heart rate decreases

Based on Gong and Zhang (2019) [14], Chen (2018) [16], and Wang (2013) [17], the researchers studied the effects of rhBNP on the low heart rates of patients with and HF. The heterogeneity test result was (Chi-squared = 0.92, P = 0.63, I^2 = 0%), so the fixed effect model was adopted. Compared with the incidences of low heart rate in the control group, the incidences of low heart rate in the rhBNP group were not elevated (Z = 1.22, P = 0.22). The funnel plot showed no publication bias (**Figure 8**).

Analysis of the renal insufficiency

Based on Xing et al. (2016) [12], Gong and Zhang (2019) [14], and Chen (2018) [16], the

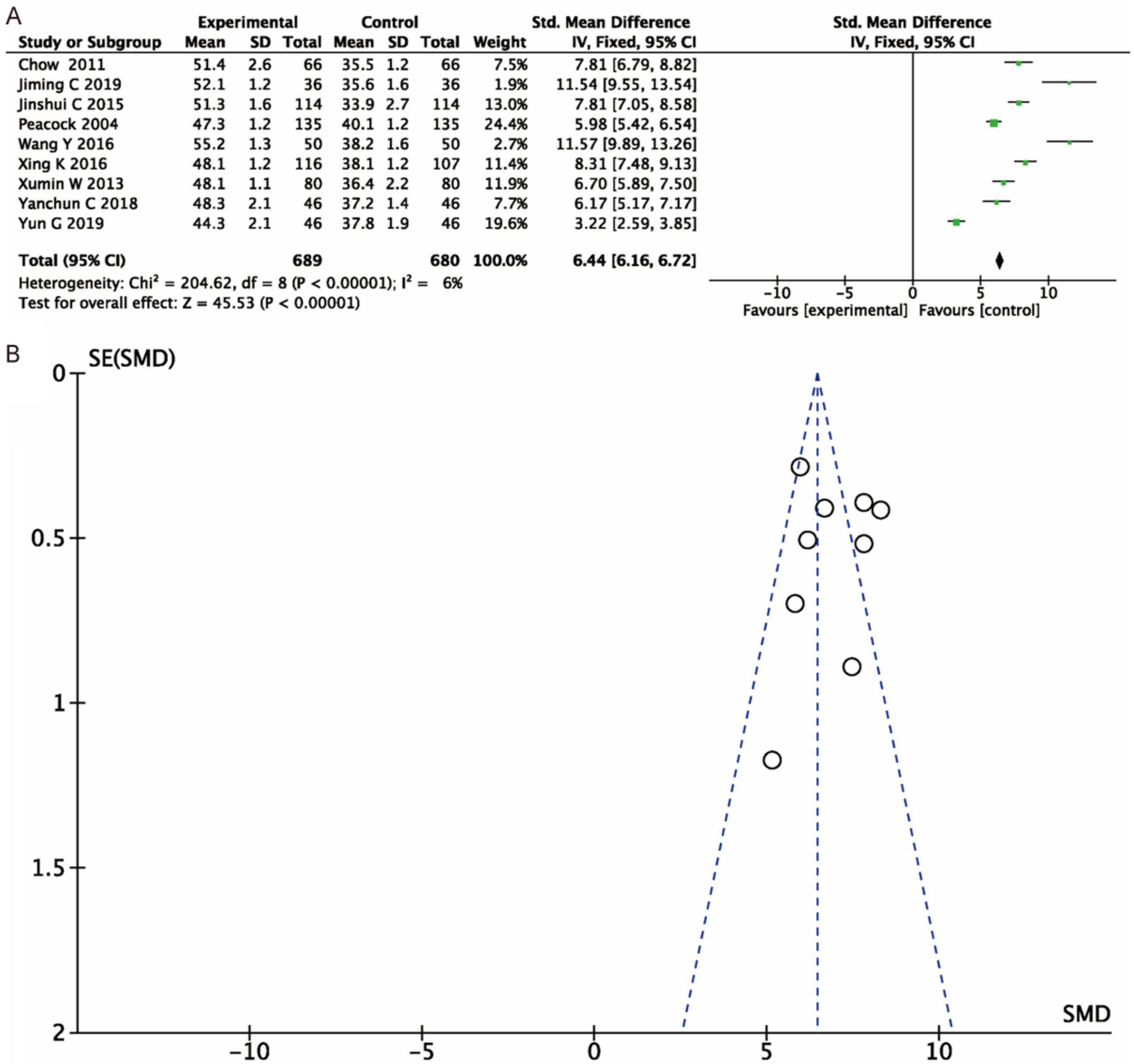

Figure 5. The effects of rhBNP on the LVEF in patients with AMI and HF. A. Forest plot; B. Funnel plot.

researchers studied the effects of rhBNP on the renal insufficiency in patients with AMI and HF. The heterogeneity test result was (Chi-squared = 0.89, $P = 0.64$, $I^2 = 0\%$), so the fixed effect model was adopted. Compared with the incidences of renal insufficiency in the control group, the incidences of renal insufficiency in the rhBNP group did not increase ($Z = 0.35$, $P = 0.73$). The funnel plot showed no publication bias (**Figure 9**).

Discussion

In this study, articles on the clinical efficacy of rhBNP in patients with AMI and HF were meta-analyzed, and the benefits of rhBNP in treating patients with AMI and HF were analyzed. A total of nine RCT-related studies were included, involving 1,369 patients in all. Through the meta-analysis, we found that rhBNP can significantly improve the clinical efficacy, reduce the lengths of the hospital stays, and increase patients' LVEF. Compared with the conventional efficacy, the efficacy of rhBNP did not lead to an increased incidence of the adverse reactions, such as hypotension, headache, low heart rate, or renal insufficiency. No potential publication bias was observed in our study, suggesting the stability of the results.

Some studies have suggested that rhBNP exerts a good protective effect on the myocar-

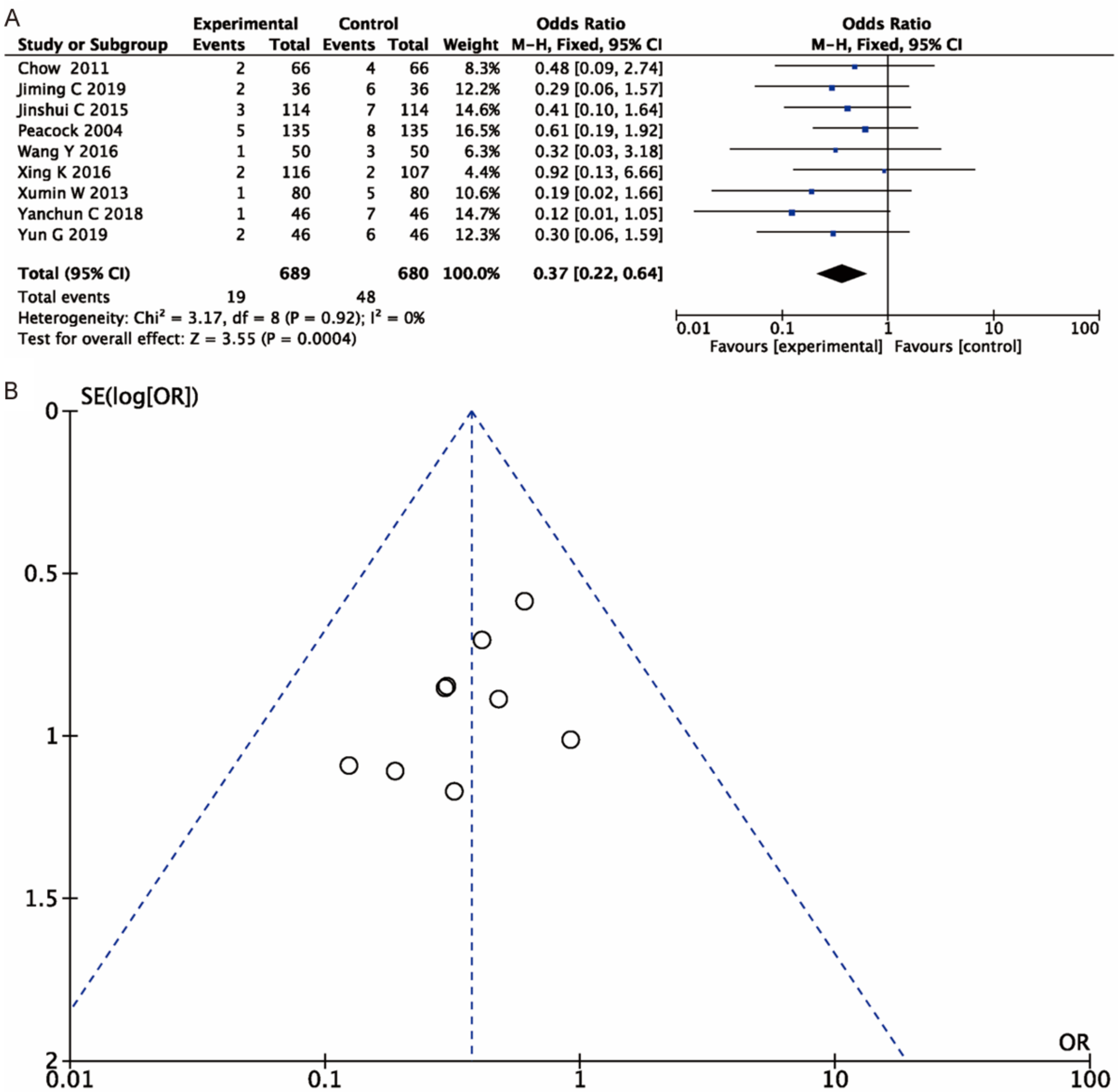

Figure 6. The Effects of rhBNP on the Hypotension in Patients with AMI and HF. A. Forest plot; B. Funnel plot.

dium [19]. According to relevant clinical studies, a good clinical efficacy is achieved when patients with AMI and HF receive rhBNP treatment [20]. Other related studies revealed that AMI patients receiving the rhBNP treatment during the prophase could effectively improve their cure rates [21]. In this study, the results of the meta-analysis showed that rhBNP can effectively improve the treatment efficacy in patients with AMI and HF, which is consistent with the aforementioned study results. rhBNP is an endogenous polypeptide substance and is conducive to vasodilation, diuresis and sodium excretion, and delayed cardiac remodeling. When AMI occurs, there is insufficient BNP secreted in the body. Therefore, the early administration of rhBNP can help secrete sufficient BNP in the body, thereby preventing further myocardial injuries and improving the treatment effective rate.

The timely administration of rhBNP can shorten the hospital stays of AMI patients [22]. However, according to some articles, rhBNP has no marked effect on the treatment courses of AMI patients [23]. In this study, through a meta-analysis, it was found that the early administration of rhBNP significantly shorten-

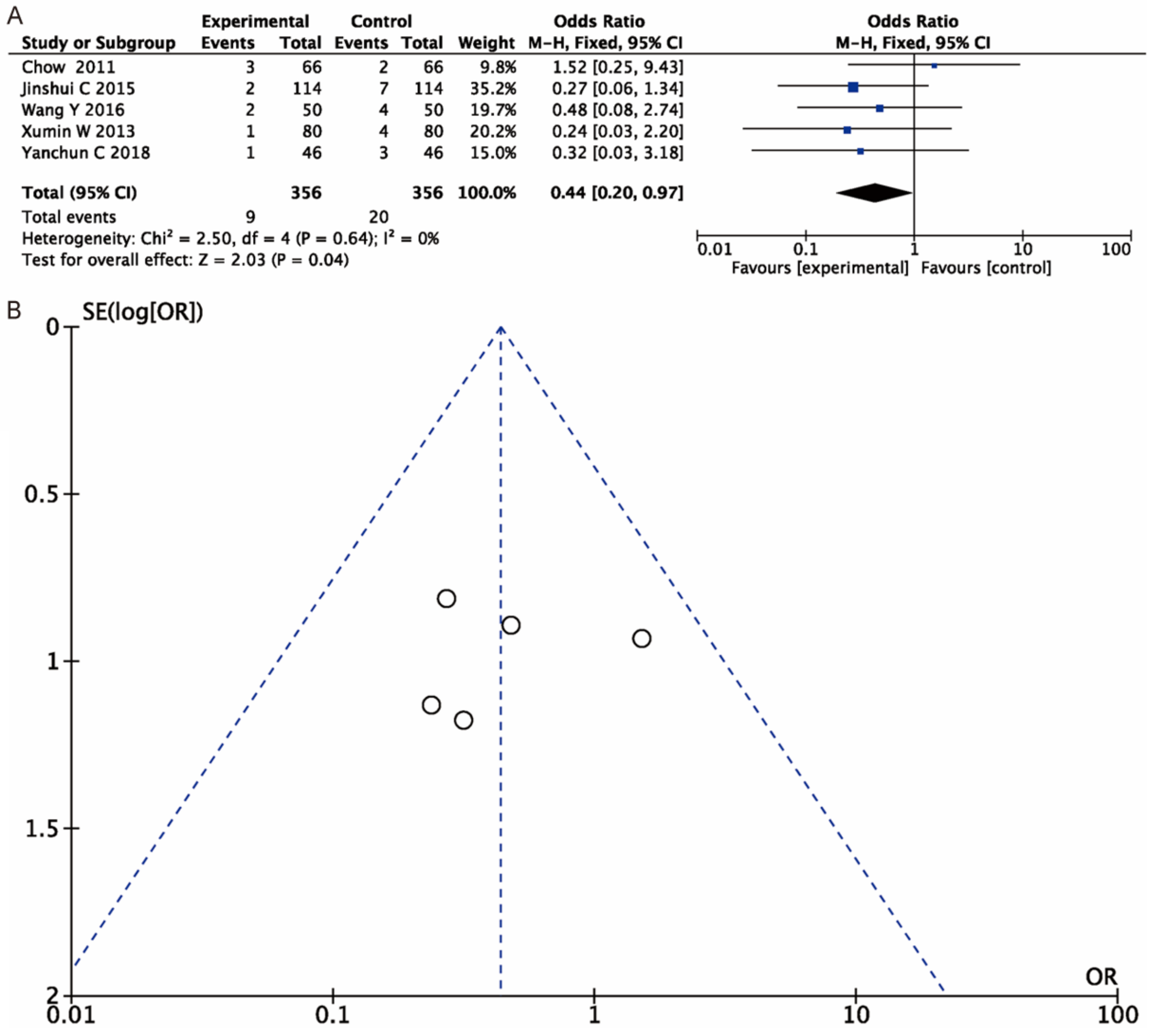

Figure 7. The Effects of rhBNP on the Incidences of Headaches in Patients with AMI and HF. A. Forest plot; B. Funnel plot.

ed the hospital stays of patients with AMI and HF, which may be due to the fact that the early administration of rhBNP can help promptly secrete sufficient BNP in AMI patients, thereby preventing the further aggravation of myocardial injury.

LVEF is an important index reflecting the contractility and quantity of functional cardiomyocytes [24]. A lower LVEF indicates a reduced number of functional cardiomyocytes, and a greater ratio of fibrosis and myocardial necrosis suggests poorer myocardial contraction and a poorer prognosis [25]. LVEF increases significantly after rhBNP treatment [26]. In our analysis, we found that the LVEF of patients with AMI and HF was increased significantly after rhBNP treatment, which is consistent with the results of the aforementioned studies. This shows that rhBNP can effectively improve cardiac dysfunction in patients with AMI and HF.

Additionally, the adverse events that often occur in patients with AMI and cardiac dysfunction include hypotension, headache, low heart rate, and renal insufficiency [27]. Some studies have shown that rhBNP treatment may elevate the risks of hypotension and renal dysfunction [28, 29]. Relevant studies have suggested that after treatment, rhBNP does not increase the incidence of adverse reactions, such as hypotension and headache [30]. The meta-analysis revealed that rhBNP does not increase the incidence of the aforementioned adverse reac-

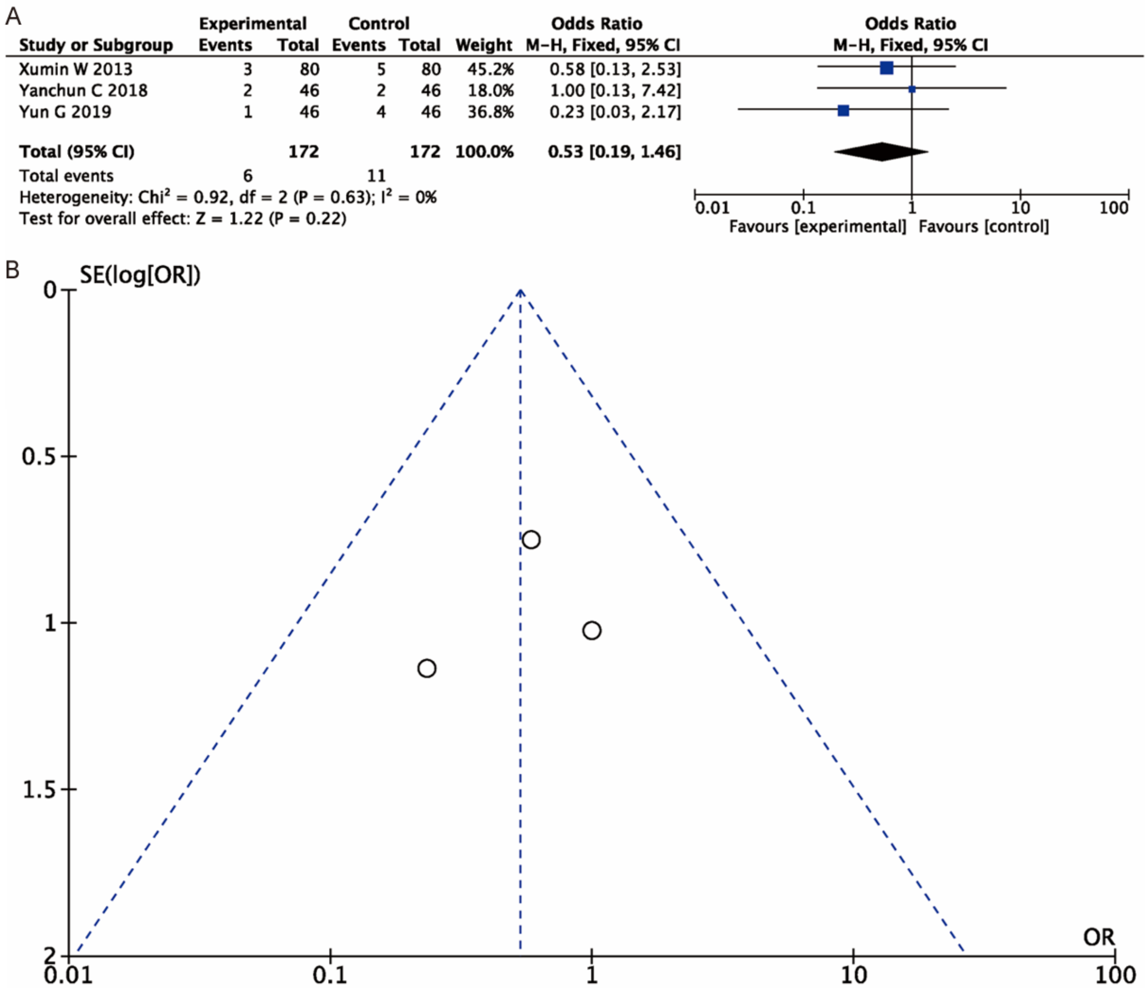

Figure 8. The Effects of rhBNP on the Low Heart Rates of Patients with AMI and HF. A. Forest plot; B. Funnel plot.

tions after the treatment. However, due to the small number of studies pertaining to hypotension, headache, low heart rate, and renal insufficiency, the conclusions need to be further verified by a large number of clinical studies.

There are some limitations to this study. First of all, although we consulted a large number of databases extensively, we only included Chinese and English language articles, which may lead to a biased selection in this study. Second, we only included nine high-quality RCTs, which may result in an insufficient total number of samples. For some items, only 3-5 studies were included for our analysis, so the conclusions need to be further verified using a large number of clinical studies. Finally, there were many Chinese articles included in the references, which may cause a regional bias in the final conclusion.

In summary, our study results show that rhBNP can markedly improve clinical efficacy and myocardial functions and shorten hospital stays without increasing the rate of adverse reactions, such as hypotension, headaches, low heart rate, and renal insufficiency. However, due to the aforementioned limitations, it is necessary to conduct large-scale prospective and randomized trials to verify our study results.

Disclosure of conflict of interest

None.

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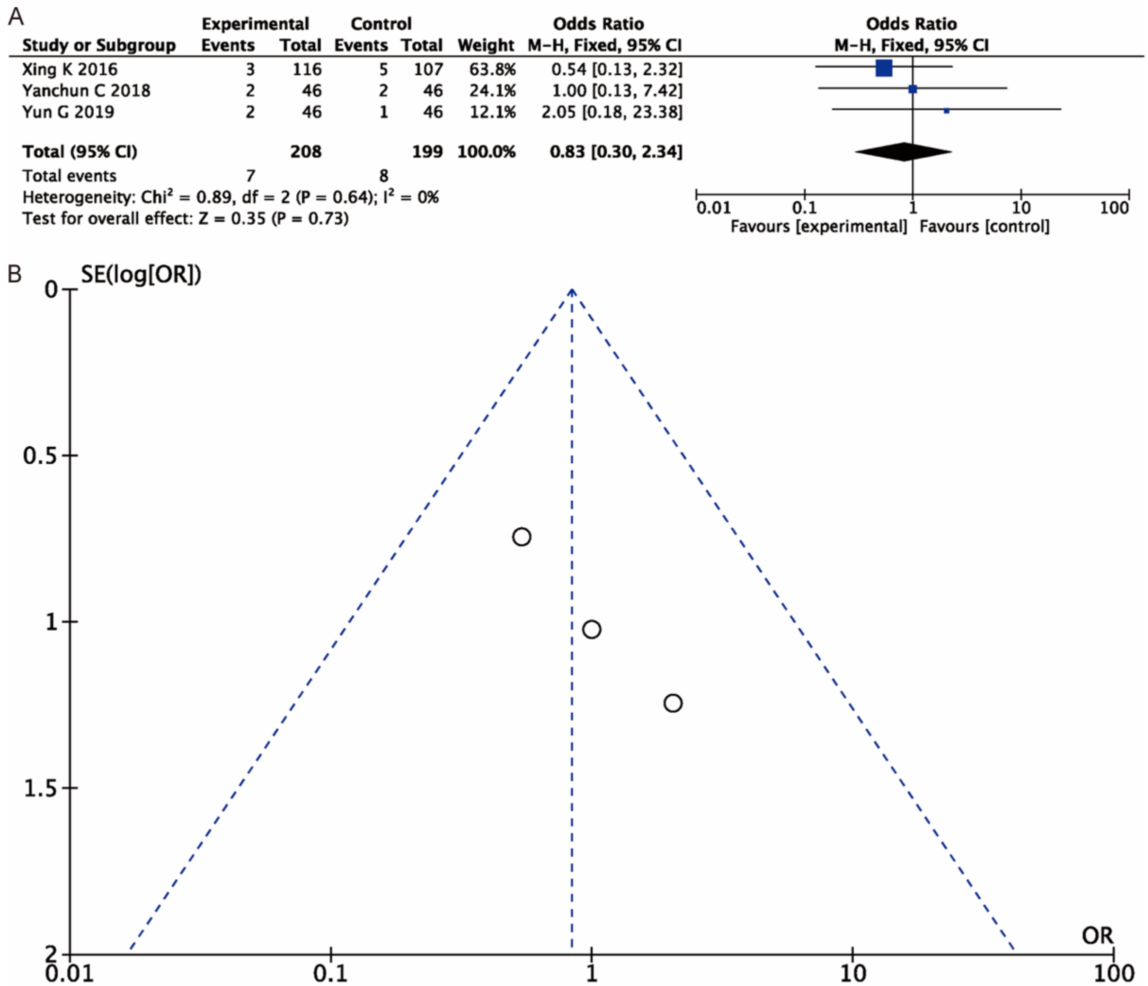

Figure 9. The Effects of rhBNP on the Renal Insufficiency in Patients with AMI and HF. A. Forest plot; B. Funnel plot.

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