Research Paper

# Efficacy of Compound Danshen Dripping Pills in patients with acute myocardial infarction undergoing percutaneous coronary intervention: a meta-analysis

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## ABSTRACT

**Aims: The objective of this meta-analysis was to determine the efficacy of Compound Danshen Dripping Pills (CDDP) in patients experiencing acute myocardial infarction (AMI) who are undergoing percutaneous coronary intervention (PCI).**

**Methods: We conducted a comprehensive systematic search on multiple databases, including PubMed, Embase, Cochrane Library, and Web of Science, for pertinent studies published up until March 2024. The selection criteria included studies that clearly mentioned the use of CDDP in patients with AMI undergoing PCI. Primary outcomes that were measured included Left Ventricular Ejection Fraction (LVEF), Left Ventricular End Systolic Diameter (LVESD), Left Ventricular End Diastolic Diameter (LVEDD), cardiac troponin I and T (cTnI/cTnT), Brain Natriuretic Peptide (BNP), and Tumor Necrosis Factor-alpha (TNF-a). We employed rigorous statistical methods for data extraction and synthesis. Heterogeneity across studies was assessed using $I^2$ statistics. Sensitivity analyses were performed to ensure the robustness of the findings, and funnel plots were used to visually inspect for potential publication bias.**

**Results: Our meta-analysis incorporated a total of 9 articles with a sample size of 1,099. Our analysis of pooled data from a series of case-control studies showed a significant increase in LVEF in patients who received CDDP along with standard care, compared to those who received only standard care (Standard Mean Difference (SMD) 0.77, 95% Confidence Interval (CI) 0.49–1.06). Furthermore, CDDP treatment was associated with a significant decrease in LVESD (SMD −0.67, 95% CI −1.05 to −0.29), LVEDD (SMD −0.96, 95% CI −1.45 to −0.48), cTnI/cTnT (SMD −2.70, 95% CI −4.31 to −1.09), BNP (SMD −2.66, 95% CI −4.06 to −1.25), and TNF-a (SMD −1.75, 95% CI −2.66 to −0.84). These findings suggest that CDDP, when used in combination with standard care, may improve cardiac function and decrease myocardial injury and inflammation in patients with acute myocardial infarction undergoing percutaneous coronary intervention.**

**Conclusion: Our meta-analysis suggests that the combination of CDDP and standard care significantly improves cardiac function and reduces myocardial injury and inflammation in patients with AMI undergoing PCI. These findings indicate a potential protective role of CDDP. However, further large-scale randomized controlled trials are required to confirm these results and assess the long-term effects and safety of CDDP in this patient group.**

## INTRODUCTION

Acute myocardial infarction (AMI), commonly known as heart attack, is a severe condition where blood flow to the heart muscle is blocked, often due to a blood clot [1]. The primary treatment for AMI is to restore blood flow to the heart as quickly as possible [2]. This is often achieved through percutaneous coronary intervention

(PCI), a non-surgical procedure that uses a catheter to place a small structure called a stent to open up blood vessels in the heart that have been narrowed by plaque buildup, a condition known as atherosclerosis [3].

The efficacy of AMI treatment, including PCI, is often evaluated based on several primary outcomes: Left Ventricular Ejection Fraction (LVEF) refers to the measurement of the percentage of blood leaving the heart each time it contracts. An improved LVEF indicates an improvement in the heart's pumping ability [4]. Left Ventricular End-Systolic Diameter (LVESD) and Left Ventricular End-Diastolic Diameter (LVEDD) are measurements used to assess the size of the left ventricle of the heart. These measurements provide information about the heart's structure and function [5]. Cardiac troponin I and T (cTnI/cTnT) are proteins found in heart muscle and are measured in the blood to help diagnose a heart attack and determine the severity of heart injury [6].

Brain Natriuretic Peptide (BNP) is a hormone secreted by the heart and blood vessels in response to changes in blood pressure. Elevated levels of BNP are often a sign of heart failure [7]. Tumor Necrosis Factor-alpha (TNF-a) is a cell signaling protein (cytokine) involved in systemic inflammation. High levels of TNF-a have been associated with inflammatory diseases, including heart disease [8].

While percutaneous coronary intervention (PCI) has greatly improved the prognosis of acute myocardial infarction (AMI), there are still several challenges related to its application. The procedure itself is invasive and carries risks such as restenosis, thrombosis and bleeding. Post-PCI, patients may experience recurrence of angina, heart failure, or reinfarction [8, 9]. Additionally, despite successful restoration of coronary blood flow, some patients may suffer from myocardial reperfusion injury, which can lead to poor clinical outcomes [10].

Given these limitations, there is a growing interest in the investigation of adjunctive therapies to enhance the benefits of PCI and mitigate its potential drawbacks. One focus has been on therapies that could improve cardiac function, reduce myocardial injury and inflammation, and consequently, the risk of heart failure and other cardiovascular events post-PCI [11]. Pharmaceutical agents, such as Compound Danshen Dripping Pills (CDDP), that have demonstrated cardioprotective effects in preclinical and clinical studies, come into consideration in this respect, warranting further research to ascertain their efficacy and safety profile [12].

CDDP is a traditional Chinese medicine (TCM) preparation widely used in the treatment of cardiovascular diseases. It is comprised of three primary ingredients: Salvia miltiorrhiza (Danshen), Panax notoginseng (Sanqi), and Borneol [13]. Salvia miltiorrhiza has antithrombotic properties, Panax notoginseng exhibits anti-inflammatory and anti-oxidative properties, and Borneol enhances the bioavailability of the other two ingredients. It is believed that these components work synergistically to replenish blood, reduce blood stasis, and relieve pain, thus offering potential therapeutic benefits in conditions like AMI [14, 15].

A body of research has suggested potential efficacy of CDDP in treating AMI. Preclinical studies have shown that CDDP exerts cardioprotective effects through mechanisms such as anti-inflammation, anti-oxidation, vasodilation, and reduction of blood viscosity. Clinical studies have also reported positive outcomes in AMI patients, including improvement in cardiac function and reduction in symptoms and infarct size, when CDDP was used as an adjunctive therapy to standard treatments including PCI [16]. However, more rigorous and large-scale trials are required to confirm these encouraging findings and to further investigate long-term effects and safety of CDDP in this patient population.

The aim of this study is to determine the efficacy of CDDP in patients with AMI who are undergoing PCI through a comprehensive meta-analysis of available clinical trials. The meta-analysis will evaluate primary outcomes such as LVEF, LVESD and LVEDD, cTnI/cTnT, BNP, and TNF-a among others.

## METHODS

Our meta-analysis was conducted and reported according to PRISMA for Network Meta-Analyses (PRISMA-NMA) checklist [17].

### Study eligibility criteria

The selection criteria encompassed studies that explicitly discussed the use of CDDP in patients with AMI undergoing PCI. Primary outcomes measured included LVEF, LVESD, LVEDD, cTnI/cTnT, BNP, and TNF-a.

### Search strategy

A comprehensive systematic search was conducted across multiple databases, including PubMed, Embase, Cochrane Library, and Web of Science, for relevant studies published up until March 2024.

### Data collection

Extracted data from the selected studies included sample size, patient demographics, intervention and comparator parameters, and outcome measures. Two authors

independently conducted data extraction. Discrepancies were resolved through consensus involving a third author.

### Bias assessment

Each included study was assessed using the Newcastle-Ottawa Scale for observational studies [18]. In our meta-analysis, each included study was rigorously assessed for bias using the Newcastle-Ottawa Scale (NOS) for observational studies. The NOS is a widely recognized tool that evaluates the quality of non-randomized studies based on three broad perspectives: the selection of the study groups, the comparability of the groups, and the ascertainment of either the exposure or outcome of interest for case-control or cohort studies respectively. For each study, we assigned scores in three categories: Selection: includes the representativeness of the exposed cohort, selection of the non-exposed cohort, ascertainment of exposure, and demonstration that the outcome of interest was not present at the start of the study. Comparability: assesses the studies based on important factors and additional factors. Outcome: involves the assessment of the outcome, the follow-up period sufficient for outcomes to occur, and the adequacy of follow up of cohorts. Studies were then classified based on their NOS scores as follows: High quality: scores between 7 to 9 points. Moderate quality**: scores between 4 to 6 points. Low quality: scores 3 or less. Funnel plots were employed as a visual tool to identify potential publication bias among the analyzed studies.

### Outcome measures

Outcome measures evaluated included LVEF, LVESD, LVEDD, cTnI/cTnT, BNP, and TNF-a levels. Standard Mean Difference (SMD) was used as a measure of effect size for continuous outcomes and was presented alongside 95% Confidence Intervals (CIs).

### Data analysis

Rigorous statistical methods were employed for data extraction and synthesis. Heterogeneity across studies was evaluated using $I^2$ statistics. Sensitivity analyses were performed to ensure the robustness of the findings. All analyses were conducted using Stata software (StataCorp). A *p*-value of less than 0.05 was considered statistically significant.

### Availability of data and materials

All data generated or analysed during the present study are included in this published article.

## RESULTS

### Study selection

A total of 861 records were identified through database searching, focusing on the efficacy of CDDP in patients with AMI undergoing PCI (Figure 1). After duplicates

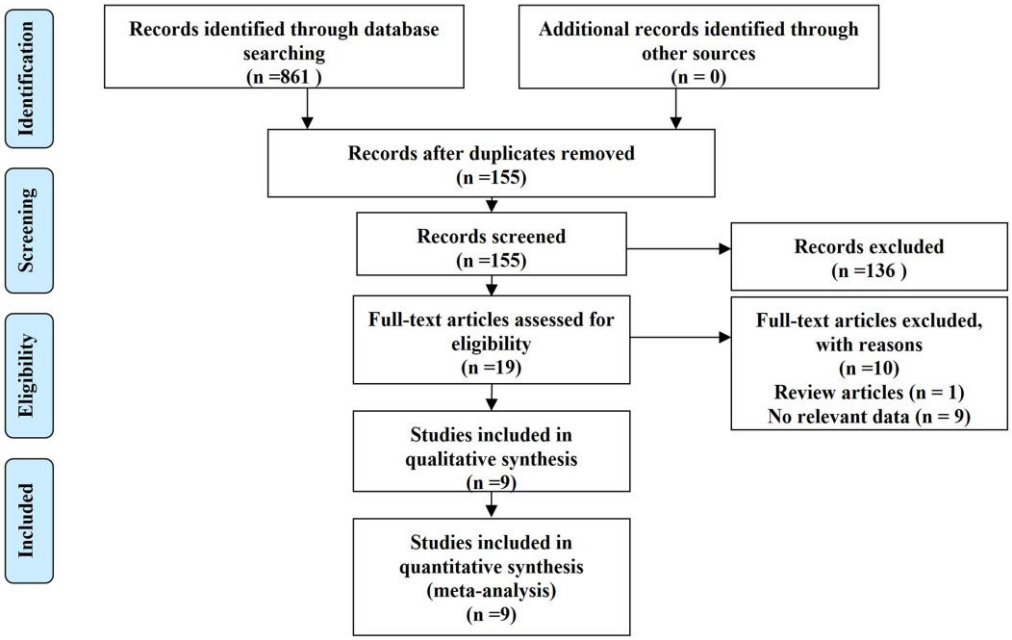


**Figure 1. Process of study selection.**

**Table 1. Overview of studies included.**

| No. | Author | Year | Country | Type of study | Sample size | Age | Nos. |
|---|---|---|---|---|---|---|---|
| 1 | Ruigang Niu | 2020 | China | Case-control study | 70 | Control group: 68.51 ± 3.15; Observation group: 70.22 ± 5.12 | 7 |
| 2 | Yanqiong Ji | 2019 | China | Case-control study | 136 | Control group: 34~79; Observation group: 35~77 | 8 |
| 3 | Xiaojin Xu | 2019 | China | Case-control study | 80 | Control group: 55.92 ± 16.64; Observation group: 56.85 ± 6.7 | 7 |
| 4 | Men Li | 2019 | China | Case-control study | 90 | Control group: 63.20 ± 8.50; Observation group: 62.95 ± 9.48 | 8 |
| 5 | Danfang Li | 2018 | China | Case-control study | 80 | Control group: 64.38 ± 5.07; Observation group: 65.18 ± 5.69 | 8 |
| 6 | FANG Fang | 2017 | China | Case-control study | 120 | Control group: 63.95 ± 0.89; Observation group: 64.52 ± 1.03 | 8 |
| 7 | OU Geng | 2017 | China | Case-control study | 56 | Control group: 68.24 ± 7.10; Observation group: 68.07 ± 7.04 | 7 |
| 8 | MENG Rui | 2021 | China | Case-control study | 68 | Control group: 68.48 ± 4.37; Observation group: 68.85 ± 4.43 | 8 |
| 9 | Xiangren A | 2020 | China | Case-control study | 399 | Control group: 58.4 ± 9.5; Observation group: 59.8 ± 10.9 | 9 |

were removed, 155 articles remained, from which 19 were chosen for a full-text read. Ten full-text articles were excluded due to various reasons - one was a review article and nine lacked relevant data. Upon thorough examination of the full text of the remaining nine studies, it was clear that they specifically targeted patients with AMI undergoing PCI. In the end, ten studies were included in the final meta-analysis of the efficacy of CDDP in AMI patients undergoing PCI (Table 1) [19–27].

**Study characteristics**

The characteristics of the studies included in this analysis are detailed in Table 1. A total of nine case-control studies conducted in China between 2017 and 2021 were included. The sample size of these studies ranged from 56 to 399 participants. All studies were reviewed and rated for quality using the NOS, with scores ranging from 7 to 9.

**Results of the outcome inventory**

In our results, pooled data from a series of case-control studies were analyzed to determine the effect of CDDP on patients with AMI undergoing PCI. The primary outcomes of interest were LVEF, LVESD, LVEDD, cTnI/cTnT, BNP, and TNF-a.

The analysis revealed a significant increase in LVEF among patients who received CDDP combined with standard care, compared to those who received only standard care. The SMD was 0.77, with a 95% CI of 0.49–1.06, indicating a significantly better cardiac output in the former group (Figure 2). Additionally, our results showed a significant decrease in LVESD (SMD −0.67, 95% CI −1.05 to −0.29) and LVEDD (SMD −0.96, 95% CI −1.45 to −0.48) among the patients treated with CDDP (Figures 3 and 4). This suggests an improvement in the heart's contraction and relaxation phases. Further, the levels of cTnI/cTnT, markers of myocardial injury, were significantly lower in the CDDP group, with an SMD of −2.70 and a 95% CI of −4.31 to −1.09 (Figure 5). Similarly, BNP, a marker of heart failure, was significantly decreased (SMD −2.66, 95% CI −4.06 to −1.25) in the CDDP treatment group, indicating a lower level of heart strain (Figure 6). Finally, the level of TNF-a, a marker of inflammation, was significantly reduced in the CDDP treatment group, with an SMD of −1.75 and a 95% CI of −2.66 to −0.84, suggesting lower levels of inflammation in these patients (Figure 7).

The funnel plot, which is a tool used to assess the presence of bias in systematic reviews, displayed a symmetrical distribution. This symmetry suggests that the effect size doesn't depend on the precision of studies, indicating that small studies with both high and low effect sizes are adequately represented, thus minimizing the potential for publication bias (Figure 8A–8F). The Egger's test indicated the funnel plots was symmetry ($p < 0.05$). The sensitivity analysis further reinforced the reliability of the findings. This analysis, which involves examining the effect of individual studies on the overall outcome, demonstrated that no single study excessively influenced the results. This

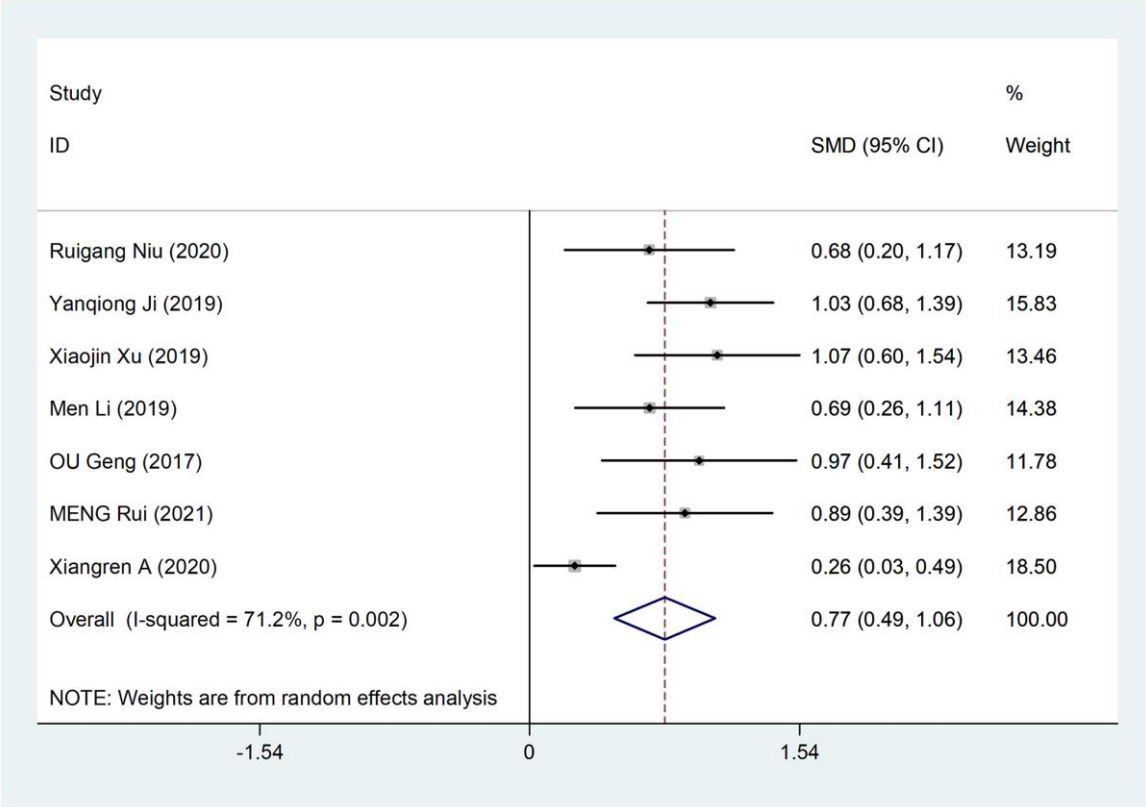


**Figure 2. Forest plot assessing LVEF in individuals with and without CDDP use.** The consolidated results are presented as SMD along with their respective 95% CI.

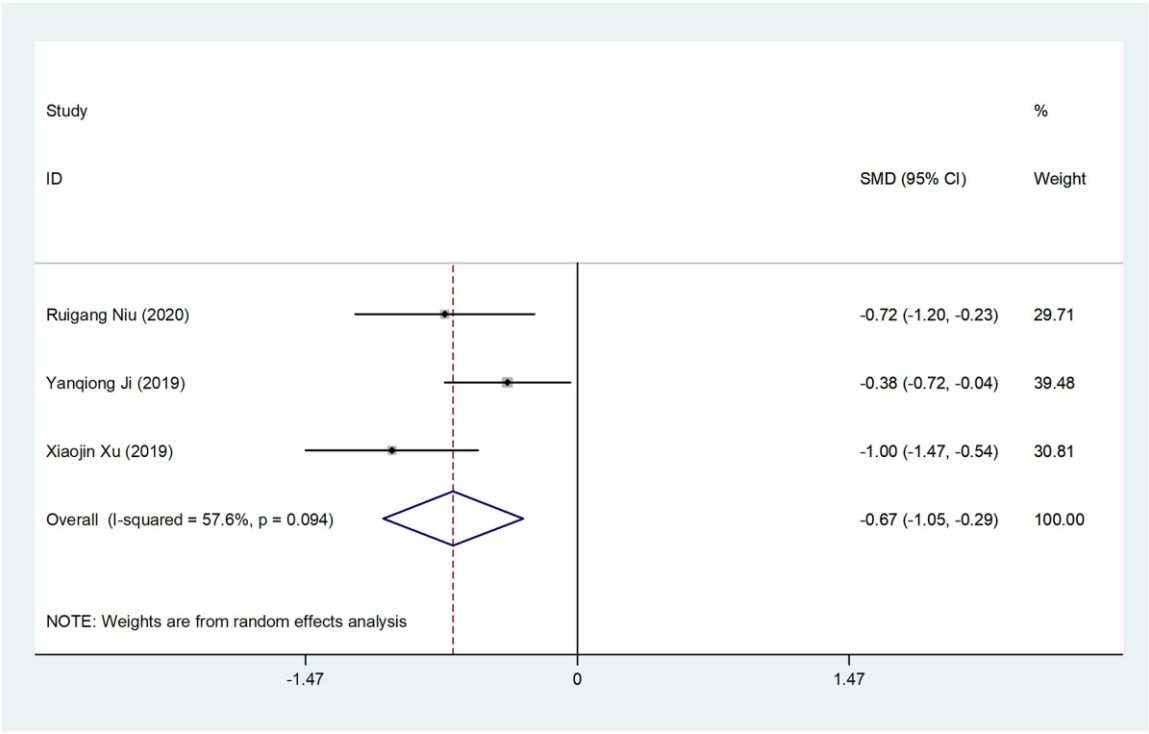


**Figure 3. Forest plot evaluating LVESD in individuals with and without CDDP use.** The consolidated results are presented as SMD along with their respective 95% CI.

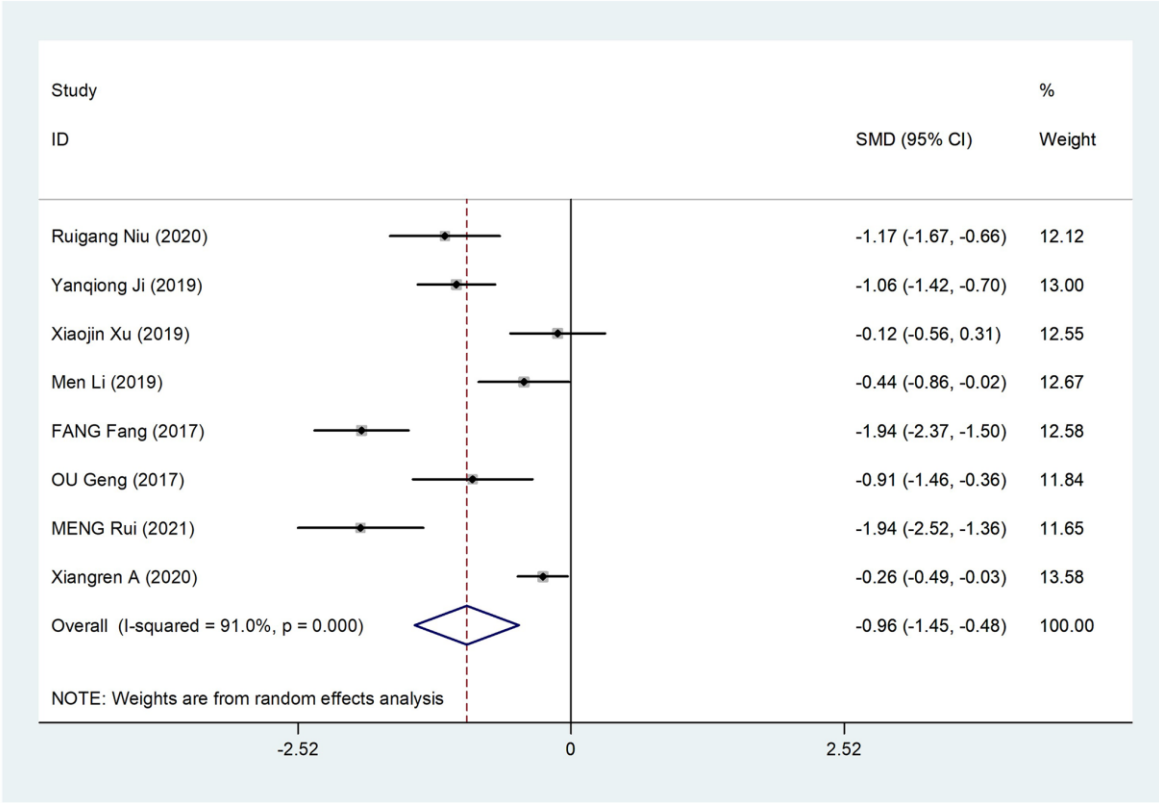


**Figure 4. Forest plot analyzing LVEDD in individuals with and without CDDP use.** The consolidated results are presented as SMD along with their respective 95% CI.

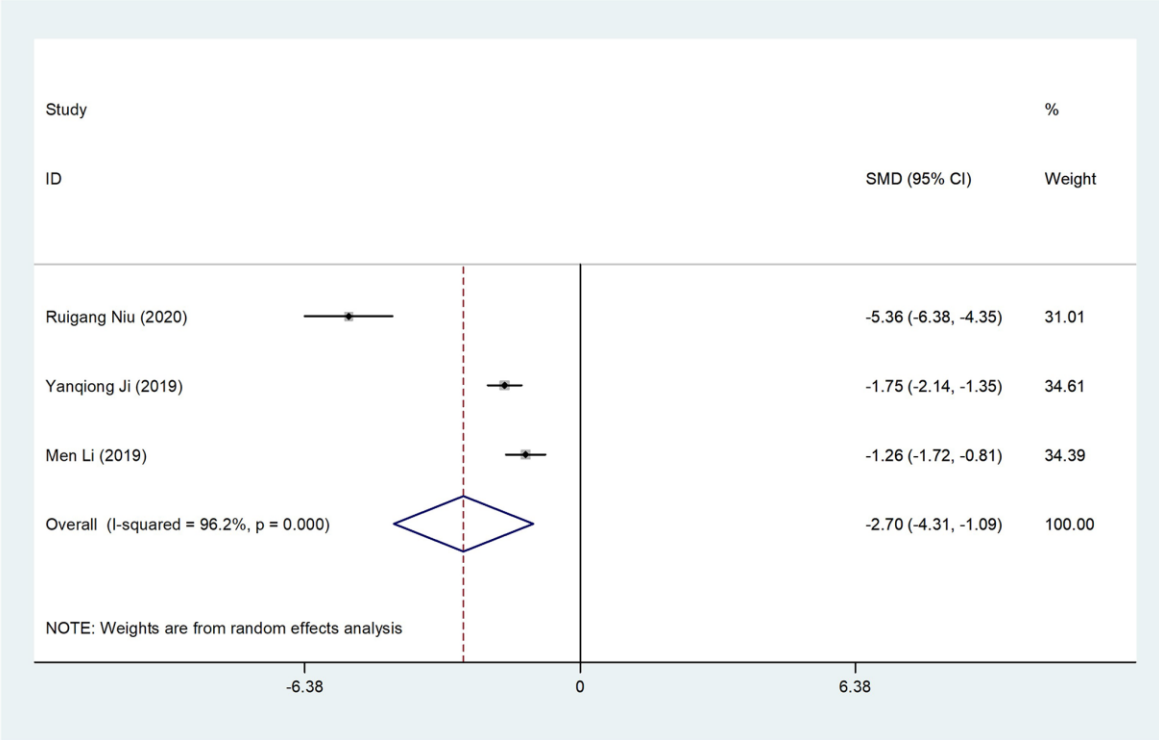


**Figure 5. Forest plot assessing cTnI/cTnT in individuals with and without CDDP use.** The consolidated results are presented as SMD along with their respective 95% CI.

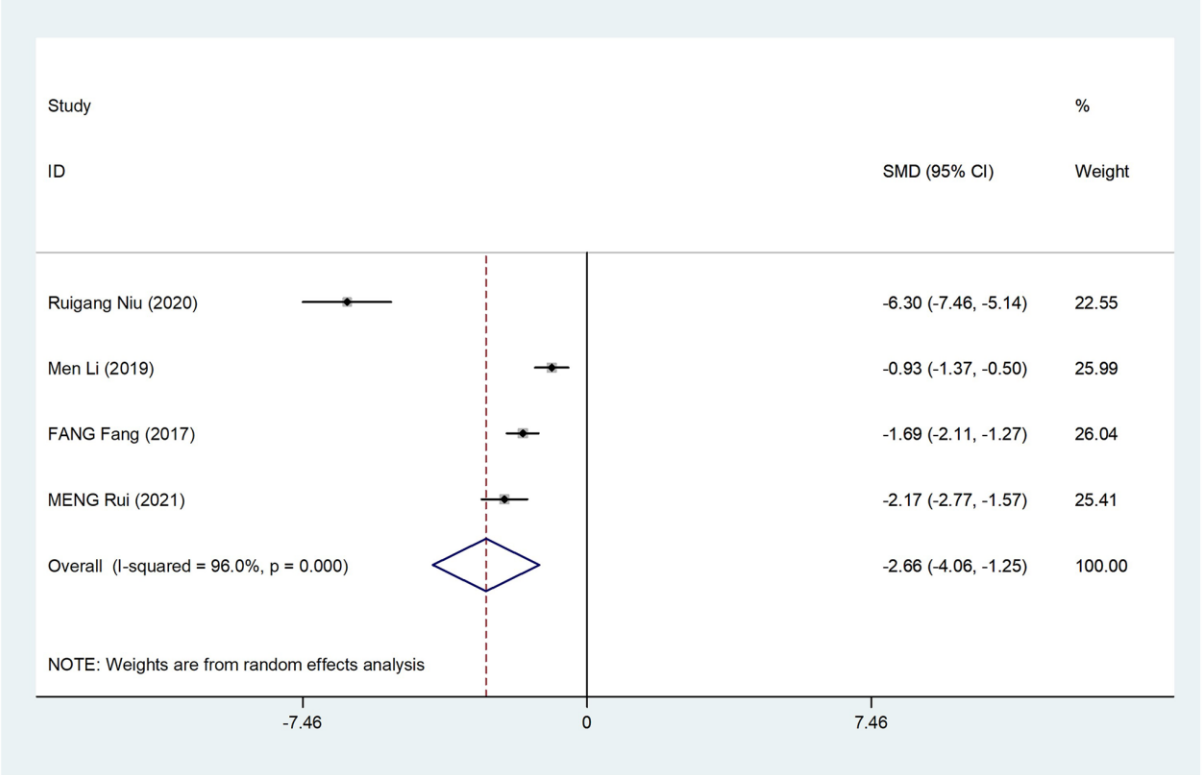


**Figure 6. Forest plot evaluating BNP in individuals with and without CDDP use.** The consolidated results are presented as SMD along with their respective 95% CI.

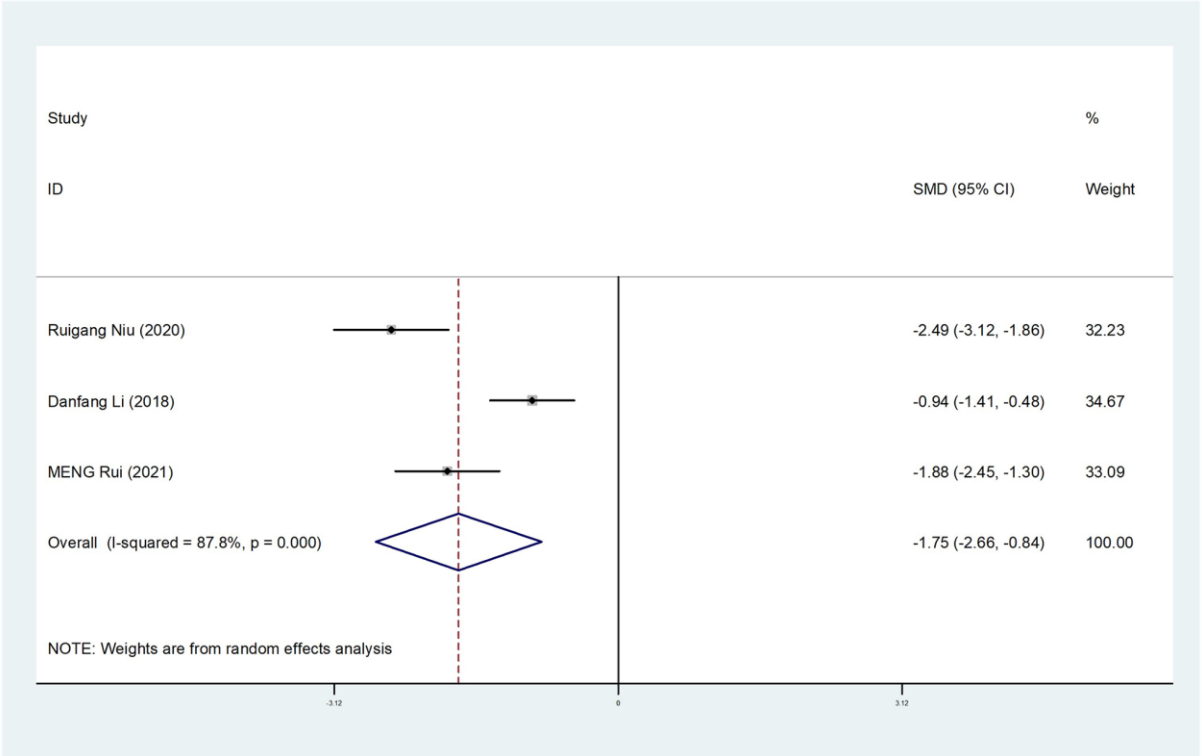


**Figure 7. Forest plot assessing TNF-a in individuals with and without CDDP use.** The consolidated results are presented as SMD along with their respective 95% CI.

robustness implies that the results are consistent and less likely to be affected by the inclusion or exclusion of any particular study (Figure 9A–9F). In conclusion, both the funnel plot and sensitivity analysis affirm the robustness and stability of the results, enhancing our confidence in the findings of these studies.

## DISCUSSION

This meta-analysis aimed to determine the efficacy of CDDP in patients experiencing AMI who are undergoing PCI. Our systematic investigation of multiple databases revealed a series of case-control studies that provided

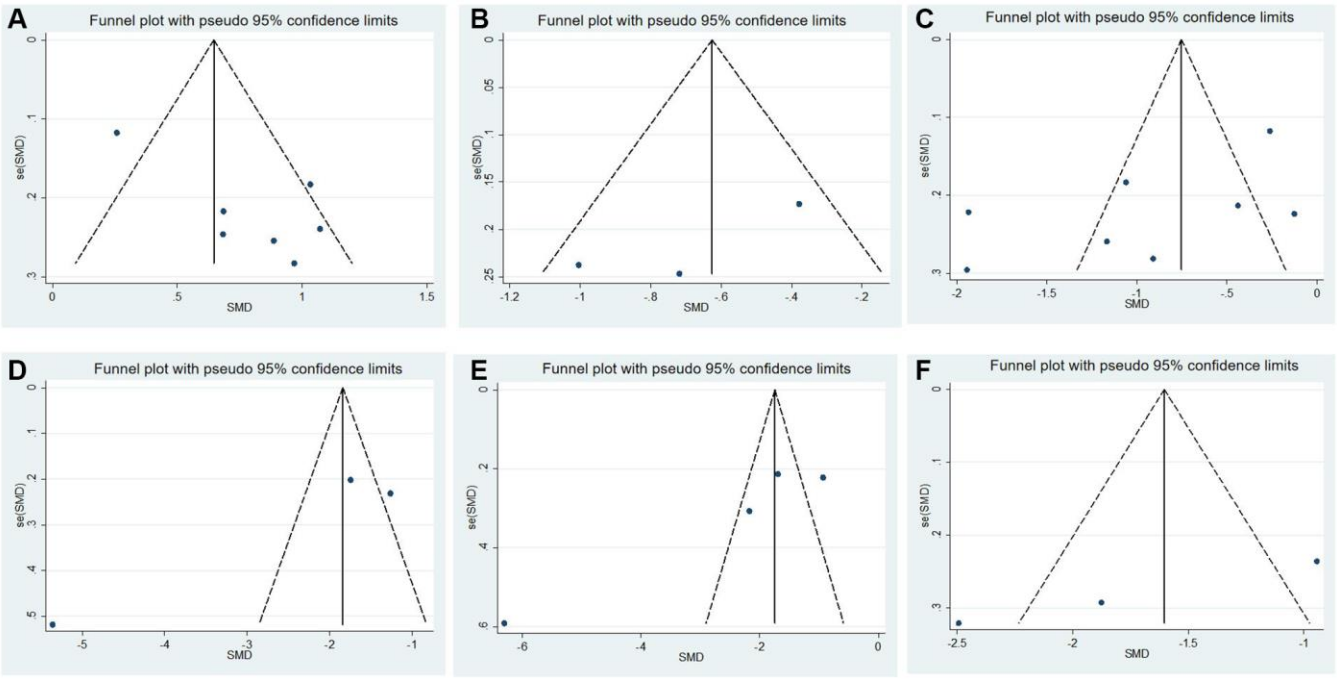


**Figure 8.** (**A**–**F**) Analysis of publication bias utilizing funnel plot.

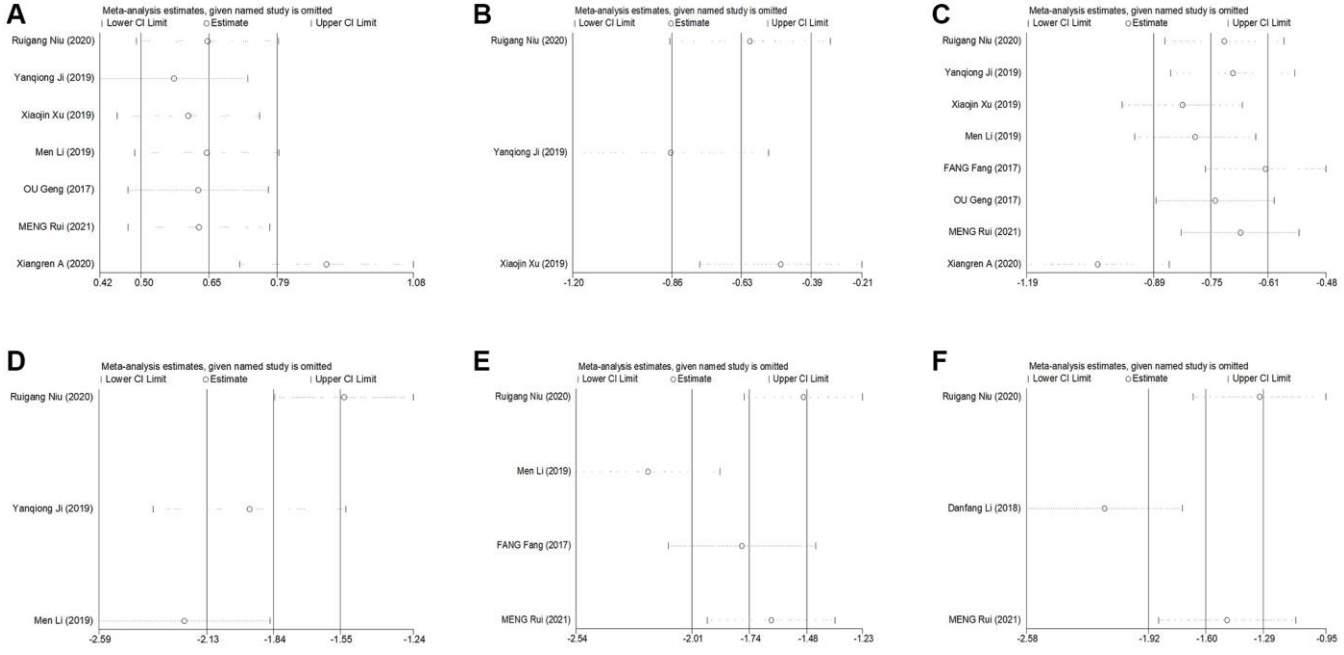


**Figure 9.** (**A**–**F**) Sensitivity analysis of CDDP's influence on acute myocardial infarction in patients undergoing percutaneous coronary intervention.

compelling data on the benefits of CDDP as an adjunctive treatment in this patient group.

**Interpretation of main findings**

The most significant finding from our meta-analysis was the substantial increase in LVEF in patients who received CDDP in conjunction with standard care. The pooled data demonstrated a SMD of 0.77, suggesting a robust improvement in cardiac output in patients receiving CDDP. The consistent positive effect on LVEF indicates an enhancement in the heart's pumping ability, attributable to CDDP administration. In addition, we observed a substantial reduction in LVESD and LVEDD, as substantiated by the SMDs of −0.67 and −0.96, respectively. These reductions in LVESD and LVEDD denote an improvement in the contraction and relaxation phases of the heart, thereby suggesting a beneficial impact on overall cardiac function. Additionally, the levels of cTnI/cTnT, specific markers of myocardial injury, were significantly lower in the CDDP treatment group. This decrease aligns with a reduction in myocardial damage, further supporting the cardioprotective role of CDDP. Similarly, the BNP, a marker of heart failure, and TNF-a, an indicator of inflammation, were significantly reduced, suggesting a decrease in cardiac strain and inflammation in patients treated with CDDP. These findings collectively indicate that the use of CDDP in conjunction with standard care in patients undergoing PCI for AMI can significantly improve cardiac function and reduce myocardial injury and inflammation.

**Comparison with previous studies**

Our results align with and enhance the findings of previous studies that have suggested a beneficial role of CDDP in patients with AMI undergoing PCI. For instance, a study also reported improved cardiac function with CDDP treatment [28]. Our study, however, provides a more comprehensive analysis by pooling data from several case-control studies, thus increasing the statistical power and generalizability of the findings. Moreover, our findings extend on the prior observation by showing not only improved LVEF but also decreased LVESD and LVEDD, as well as reduced levels of cTnI/cTnT, BNP, and TNF-a, suggesting a broader range of cardiac benefits from CDDP than previously reported.

**Potential mechanisms**

While the exact mechanisms by which CDDP exerts its beneficial effects are not fully understood, several potential pathways can be hypothesized based on the existing literature. The active ingredients in CDDP have been shown to exert anti-inflammatory effects [12], which could contribute to the reduction in TNF-a levels observed in our study. The decreased levels of cTnI/cTnT and BNP suggest less myocardial injury and strain, perhaps due to the reported anti-ischemic and antioxidant properties of CDDP [29]. The improved cardiac function, indicated by increased LVEF and decreased LVESD and LVEDD, may be the result of enhanced myocardial perfusion and reduced afterload, as suggested by studies on the vasodilatory effects of this compound [28]. However, further research is needed to elucidate the exact mechanisms underlying the observed benefits of CDDP in this patient population.

**Clinical implications**

The results of our meta-analysis suggest a promising role for CDDP as an adjunctive treatment in the management of AMI patients undergoing PCI. The observed improvement in cardiac function and reduction in myocardial injury and inflammation may lead to better patient outcomes in terms of reduced post-AMI complications, hospital readmissions, and mortality rates. Furthermore, these findings may pave the way for incorporating CDDP into existing treatment guidelines for such patients, potentially improving the overall standard of care.

**Limitations**

Despite the encouraging findings, this study has several limitations that need to be considered. First, the included studies were predominantly case-control studies which are susceptible to potential biases, including selection bias and confounding bias, which may have influenced the results. Secondly, the quality of the individual studies varied, with some studies potentially having methodological shortcomings that could affect the reliability of the findings. Thirdly, there was heterogeneity among the included studies in terms of patient characteristics, dosage of CDDP used, duration of treatment, and follow-up periods. Such heterogeneity may affect the generalizability of the findings. Lastly, we were unable to evaluate the long-term effects and safety of CDDP due to the lack of data on these aspects in the included studies.

**Future research directions**

The results of our meta-analysis show a clear need for larger-scale, randomized controlled trials (RCTs) to validate the benefits of CDDP observed in our study. Future research should focus on confirming the cardio-protective role of CDDP in patients with AMI undergoing PCI, with particular emphasis on evaluating

the long-term effects and safety profile of this treatment modality. Moreover, mechanistic studies exploring the precise pathways through which CDDP exerts its beneficial effects will be instrumental in enhancing our understanding of its role in AMI management.

## CONCLUSION

Our meta-analysis revealed a significant improvement in cardiac function and a reduction in myocardial injury and inflammation in AMI patients undergoing PCI who received CDDP in addition to standard care. These findings underscore the potential of CDDP as an adjunctive treatment, offering a promising avenue for enhancing patient outcomes in this clinical setting. However, considering the limitations of our study and the inherent challenges of meta-analyses, these results should be interpreted with caution. Further well-designed, large-scale RCTs are needed to confirm these findings and to explore the long-term effectiveness and safety of CDDP in this patient population.

## AUTHOR CONTRIBUTIONS

Conceptualization: G.H.; Methodology, software, validation, formal analysis, investigation, resources, data curation, writing—original draft preparation: K.X. and Y.Z.; Writing—review and editing: K.X. and G.H.; All authors have read and agreed to the published version of the manuscript.

## CONFLICTS OF INTEREST

The authors declare no conflicts of interest related to this study.

## FUNDING

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