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Meta-analysis of the clinical efficacy of various medications for treating pregnancy-induced hypertension

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Abstract: To analyse the literature on the efficacy and safety of medications for treating pregnancy-induced hypertension (PIH) and to provide evidence-based recommendations. PubMed, Embase and Web of Science databases were searched for studies published between January 2000 and October 2023. Studies comparing common PIH treatment drugs, either as the experimental group with an untreated control group or as a control group treated conventionally with magnesium sulphate alone or in combination with other drugs, were included in this analysis. The outcome measures assessed were overall treatment efficacy, adverse reactions and postpartum haemorrhage. The quality of the selected studies was evaluated using the Jadad scale and Cochrane risk-of-bias assessment tool. Medications significantly increased treatment efficacy (relative risk [RR] = 2.50, 95% CI = 1.85-3.37, $P < 0.00001$), reduced adverse reactions (RR = 0.52, 95% CI = 0.38-0.69, $P < 0.0001$) and decreased the risk of postpartum haemorrhage by 43% (95% CI = 0.35-0.69; $P < 0.0001$). Common treatment medications significantly increased the overall efficacy of PIH treatment and reduced the incidence of adverse reactions compared with the control treatments. Additionally, these medications reduced the risk of postpartum haemorrhage.

Keywords: Treatment; pregnancy-induced hypertension; meta-analysis

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INTRODUCTION

Pregnancy-induced hypertension (PIH) occurs during pregnancy. Severe cases may lead to cardiac and renal dysfunction, posing a threat to the lives of the foetus and the mother (Oarowski *et al*., 2018; Zhao *et al*., 2021). In addition, seizures or death can occur, with an incidence rate of 5%-12% (Vera and Bérard, 2012; Hayase *et al*., 2014). In China, the estimated incidence of PIH is approximately 9.4%-10.1%. The aetiology of this condition is complex and closely related to factors such as maternal age, multiple pregnancies or a history of pre-existing medical conditions. Currently, the primary treatment approach focuses on blood pressure control and symptomatic supportive care to manage the condition, extend the gestational period and ensure the safety of the mother and foetus (Sajith *et al*., 2014).

Pregnancy-induced hypertension typically occurs after 20 weeks of gestation, with an incidence rate as high as 6%-8%. The traditional treatment approach primarily employs magnesium sulphate, which has antispasmodic, sedative and blood pressure-lowering effects; it is the preferred medication in obstetrics for treating PIH. However, in some cases, this treatment exhibits limited effectiveness and carries the risk of drug toxicity (Patel *et al*., 2012). In addition, an excessive dosage of magnesium sulphate may lead to side effects. Recent studies have indicated that a combined treatment regimen of magnesium sulphate and low-dose aspirin significantly reduces adverse reactions and provides more pronounced blood pressure-lowering effects when managing PIH (Subhedar *et al*., 2013; Chen *et al*., 2021). Additionally, research has demonstrated the efficacy of ligustrazine in treating PIH (Han, 2022). However, many of these studies are based on small sample sizes, have inconsistent quality and lack robust support from multi-centred, large-scale clinical trials.

Therefore, this study utilises meta-analysis methods to comprehensively and quantitatively analyse the recent literature on danshen, aspirin, ligustrazine and sustained-release isosorbide mononitrate-based treatments for PIH. This analysis aims to provide evidence-based guidance for the clinical treatment of PIH.

MATERIALS AND METHODS

Literature search

The Preferred Reporting Items for Systematic Review and Meta-Analyses checklist was used to perform the meta-analysis and report the results.

Data sources and searches

The PubMed, Embase and Web of Science databases were searched for reports on PIH treatment published between January 2000 and October 2023, focusing on the use of danshen, aspirin, ligustrazine and magnesium sulphate, either alone or in combination with agents such as extended-release isosorbide mononitrate or phenytoin. The search terms used to retrieve relevant records included 'pregnancy-induced hypertension', 'PIH', 'antihypertensive medications', 'clinical efficacy' and 'treatment outcomes'.

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The inclusion criteria were as follows: (1) research types included clinical cohort and randomised controlled studies published locally or internationally, limited to English-language publications; (2) research participants were patients diagnosed with gestational hypertension; (3) experimental groups received danshen, aspirin, ligustrazine or sustained-release isosorbide mononitrate, whereas control group treatments included magnesium sulphate alone or in combination with, for example, phenytoin sodium or no treatment; (4) outcome indicators included overall efficacy, adverse reactions and the occurrence of postpartum haemorrhage; (5) only studies that specified research objectives, study designs and statistical methods and provided data to calculate weighted mean differences with a 95% CI or odds ratios (ORs) with a 95% CI; studies had to specify the research period and publication date; and (6) when two studies from the same institution reported similar follow-up intervals and outcomes, the higher-quality or more comprehensive report was included, with the first author contacted to clarify any discrepancies.

The exclusion criteria were as follows: (1) non-original articles in Chinese or English; (2) animal or in vitro experiments; (3) duplicate publications; (4) publications that did not meet the previously mentioned inclusion criteria; (5) reports with incomplete data, such as the number of cases in each group; and (6) calls for papers, conference announcements and reviews.

The outcome measures were as follows: the effectiveness of blood pressure reduction, incidence of adverse reactions, clinical efficacy (cure, improvement, no improvement or deterioration), total effectiveness rate and incidence of postpartum haemorrhage.

Literature quality assessment

A literature quality assessment was performed independently by two researchers. In the case of disagreement, a third researcher participated in the literature quality assessment. In this study, two methods were used for the literature quality assessment. First, the quality of the randomised controlled trials was assessed using the Jadad scale, a relatively simple assessment method that focuses on reporting randomisation, blinding and withdrawals. This tool is commonly used to assess the quality and credibility of clinical trial studies, particularly randomised controlled trials. The Jadad scale scored from 0 to 5 points, and the score was positively correlated with article quality. Second, the literature was evaluated for risk of bias, again using the Cochrane risk-of-bias assessment tool. Articles were rated A when they fully m*et al*l the criteria, B when the potential for bias was moderate and C when none of the criteria were met.

STATISTICAL ANALYSIS

The Rev Man 5.3 software (Cochrane Collaboration, Copenhagen, Denmark) was used to perform the meta-analysis. Statistical heterogeneity was assessed using the I^2 statistic and the Chi-square test. An I^2 value greater than 50% or a *P*-value less than 0.10 was considered to indicate significant heterogeneity among the studies.

RESULTS

Search results

Initially, 219 relevant articles were identified. After manual deduplication and screening based on titles and abstracts, 54 articles were selected for inclusion. 30 articles were excluded due to duplication or poor quality. Subsequently, full-text screening was conducted on the remaining 24 articles, resulting in 10 articles that did not meet the inclusion criteria. After further assessment of the 14 included articles, 5 additional articles were excluded for incomplete or irrelevant content. Finally, 9 English-language articles were included. The flowchart of the literature selection is shown in fig. 1.

Quality assessment of the included studies

There were 550 and 525 patients in the experimental and control groups, respectively, in the 9 included publications. The quality assessment results of the included studies are presented in fig. 2. Detailed assessment criteria can be found in table 1. Each criterion was evaluated according to a low, high or unclear risk of bias. Studies were categorised into two evidence grades: A and B. Studies graded 'A' (El Sayed H [El Sayed H, 2020], Neri [Neri *et al*., 2006] and Shi [Shi, 2018]) were considered to have higher overall quality, whereas those graded 'B' (e.g. Babbar [Babbar *et al*., 2015], Lucas [Lucas *et al*., 2001] and Ren [Ren *et al*., 2018]) had lower quality, potentially due to more unclear risk factors.

Characteristics of the included studies

Nine studies were included, involving a total of 1075 participants. The control groups received conventional treatments, such as magnesium sulphate, a 25% magnesium sulphate solution, phenytoin plus magnesium sulphate or no treatment. By contrast, the intervention groups received ligustrazine, danshen, aspirin and sustained-release isosorbide mononitrate. The quality assessment of the included studies was repeated using the Jadad scale. The outcome measures included the total effective rate, postpartum haemorrhage, adverse reactions and clinical efficacy (table 2).

Meta-analysis results

Clinical efficacy

Clinical efficacy was divided into the total effectiveness (including cure, marked improvement or improvement) and the inefficacy rates. Among the studies included (Subhedar *et al*., 2013; Babbar *et al*., 2015; El Sayed, 2020; Lucas *et al*., 2001; Neri *et al*., 2006; Ren *et al*., 2018; Sastry *et al*., 2004; Shi, 2018; Vainio *et al*., 2002), five reported the total effective rate for patients in different drug groups compared with the control groups.

Table 1: Assessment of Quality Indicators for Included Studies

References	Randomization	Allocation Concealment	Blinding of Participants and Personnel	Blinding of Outcome Assessors	Completeness of Outcome Data	Selective Reporting of Study Results	Other Bias	Evidence Grade
Babbar K	Unclear	Low bias	Unclear	Unclear	Low bias	NO	Low bias	B
El Sayed H	Unclear	Unclear	Unclear	Unclear	Low bias	NO	Low bias	A
Lucas M J	Random number table	Unclear	Unclear	Low bias	Low bias	NO	Low bias	B
Neri I	Random number table	Low bias	Unclear	Unclear	Low bias	NO	Low bias	A
Ren L Q	Random number table	Unclear	Unclear	Unclear	Low bias	NO	Low bias	B
Sastry B K S	Unclear	Unclear	Unclear	Unclear	Low bias	NO	Low bias	B
Shi D D	Random number table	Unclear	Unclear	Unclear	Low bias	NO	Low bias	A
Subhedar V	Unclear	Low bias	Unclear	Unclear	Low bias	NO	Low bias	B
Vainio M	Unclear	Unclear	Unclear	Unclear	Low bias	NO	Low bias	B

Table 2: characteristics of included studies

References	year	location	Sample size (experiment vs. control)	Age (experiment vs. Control, year)	Intervention methods (experiment vs. Control)	Intervention Period ,day	Outcome	Value of Jadad
Babbar K	2015	India	74/74	30.4±1.3/27.14±4.02	2,3/1,4,5	4	①②③④⑤	3
El Sayed H	2020	Egypt	97/86	30.2±5.4/NO	2/1	4	③④⑤	3
Lucas M J	2001	Spanish	66/63	27.2±2.1/28.1±6.2	3/1,4	3	①②③	3
Neri I	2006	Italy	40/41	27.72±5.34/30.5±1.5	2,3/1,4	3	①③④⑤	2
Ren L Q	2018	China	33/36	28.6±3.9/28.37±6.24	2/1,4,5	2	①②③④⑤	3
Sastry B K S	2004	India	82/64	28.23±3.26/29.04±3.87	2,3/4,5	5	②③	2
Shi D D	2018	China	55/60	28.4±1.1/30.74±5.62	2,3/1,4,5	4	①②③	3
Subhedar V	2013	India	35/35	29.12±1.43/31.4±4.5	2,3/5	3	③④⑤	2
Vainio M	2002	Finland	68/66	NO/28.3±1.7	2,3/1,4,5	4	②③④⑤	2

Note: Treatment measures: 1: 25% magnesium sulfate solution; 2: Ligustrazine; 3: Aspirin; 4: Sustained-release nifedipine; 5: Phenylephrine with magnesium sulfate.

Outcome measures: ① Total effective rate; ② Postpartum hemorrhage; ④Adverse reactions; ⑤Clinical efficacy.

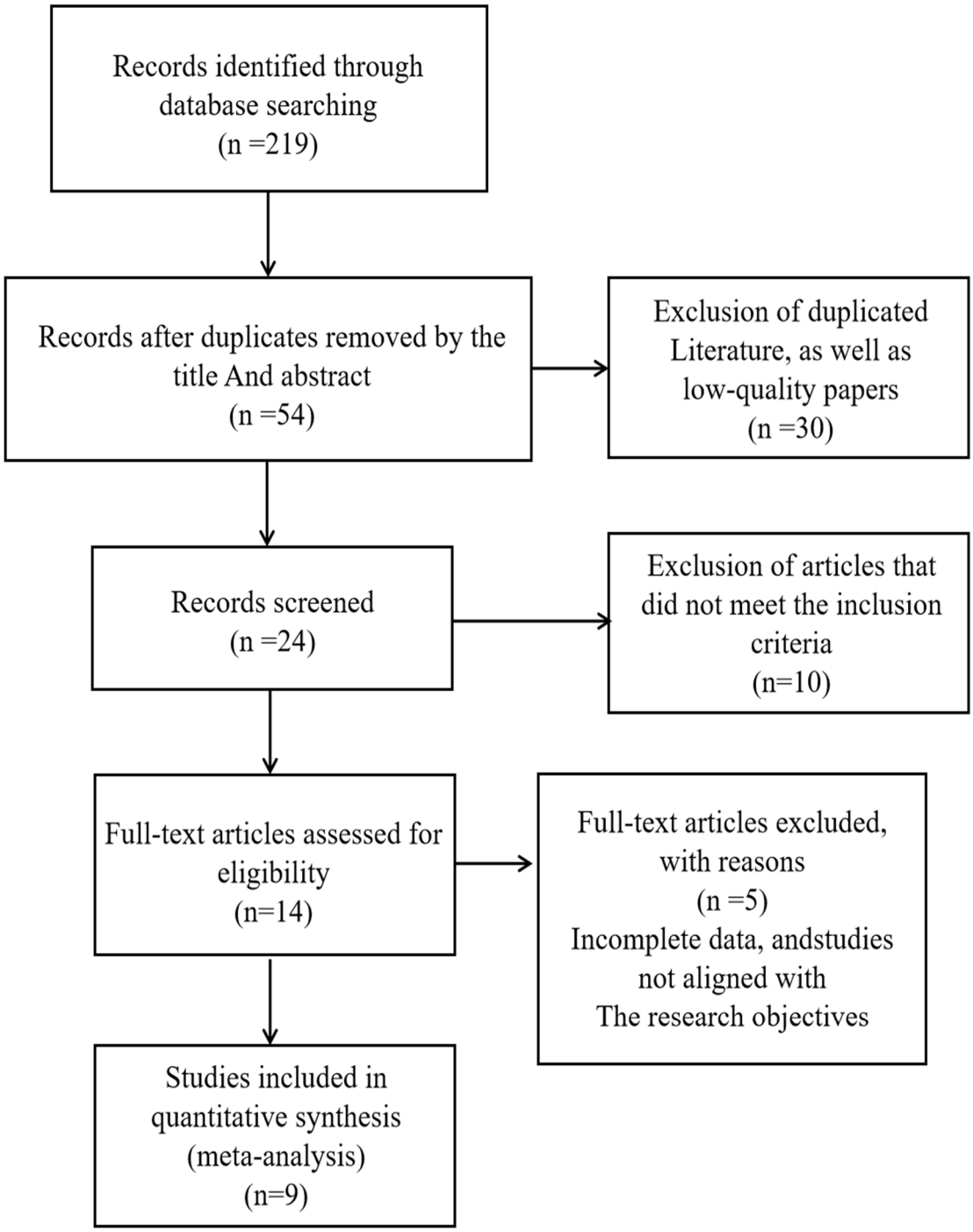

Fig. 1: Literature Selection Flowchart

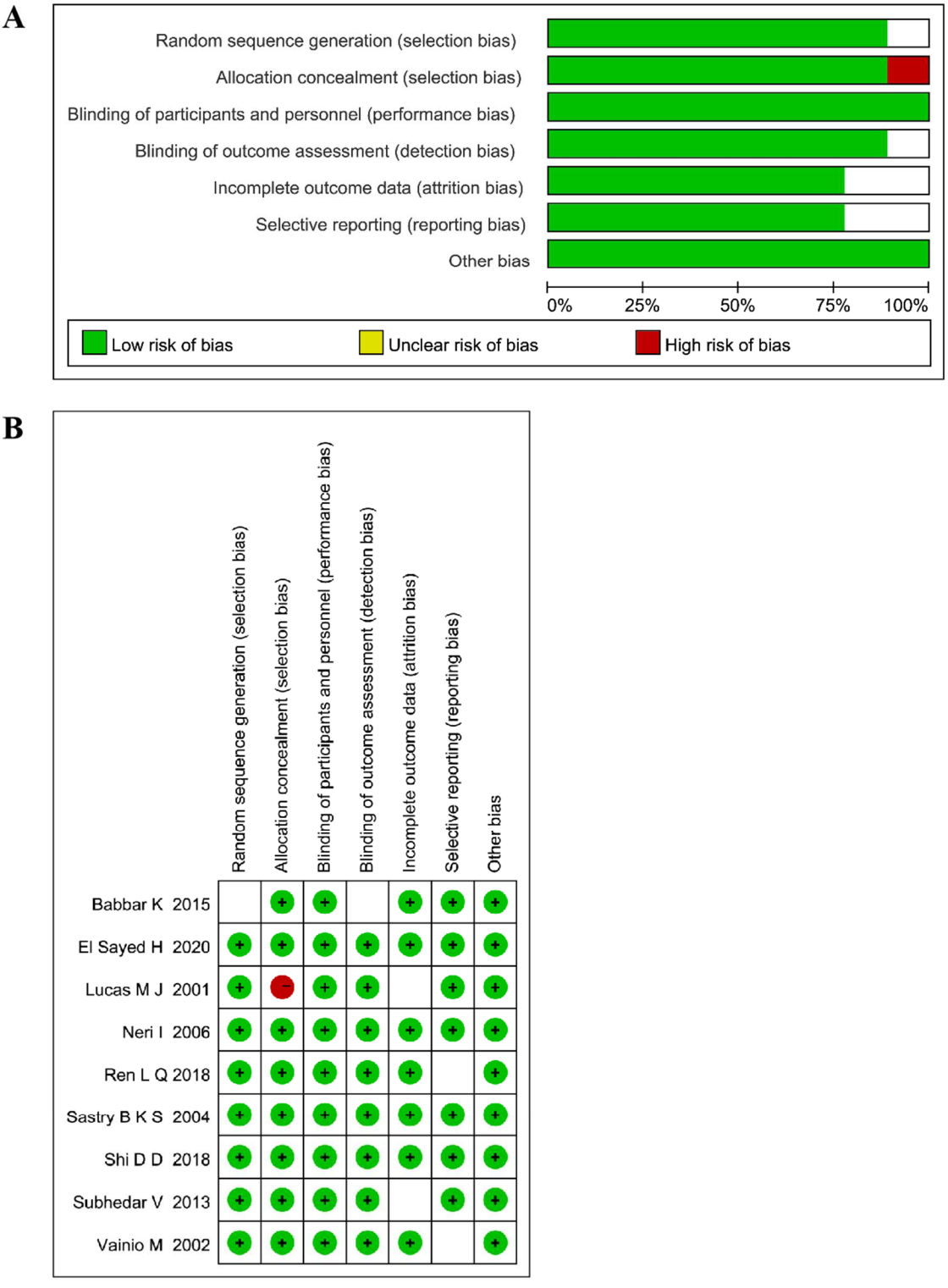

Fig. 2: Quality Assessment of the Literature

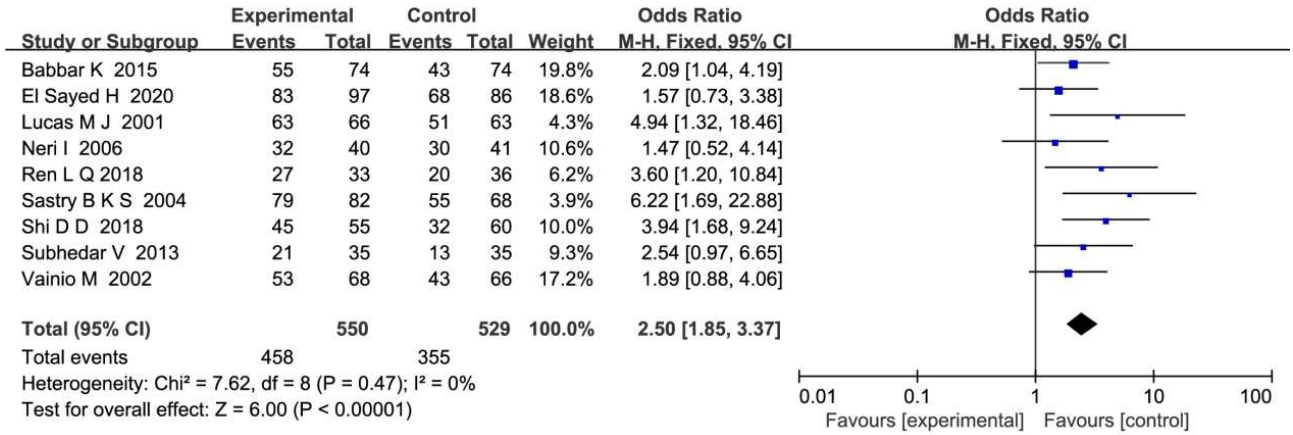

Fig. 3: Forest plot analysis results for overall clinical efficacy

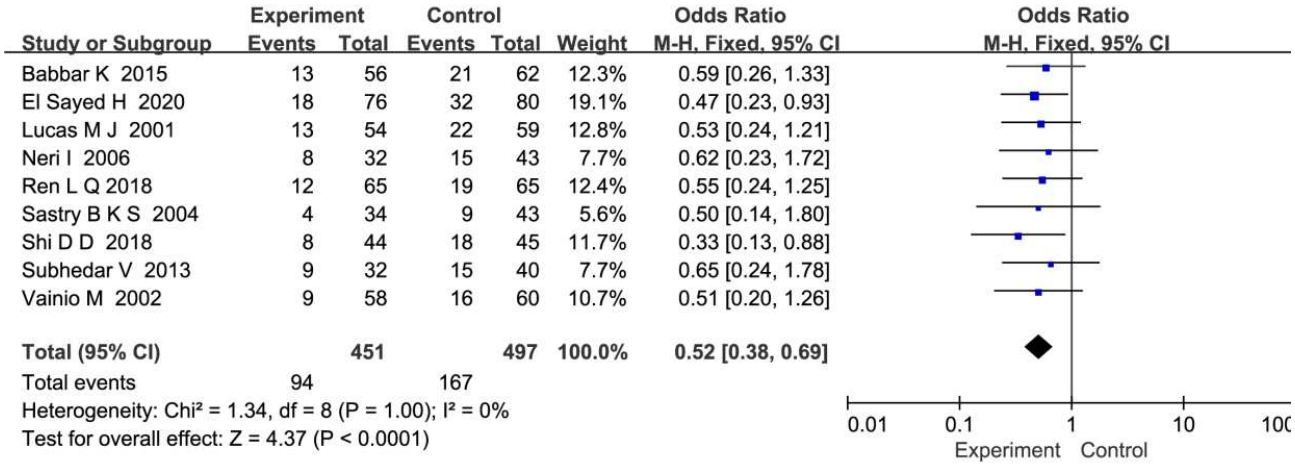

Fig. 4: Forest plot analysis results for the incidence of adverse reactions after treatment in both groups

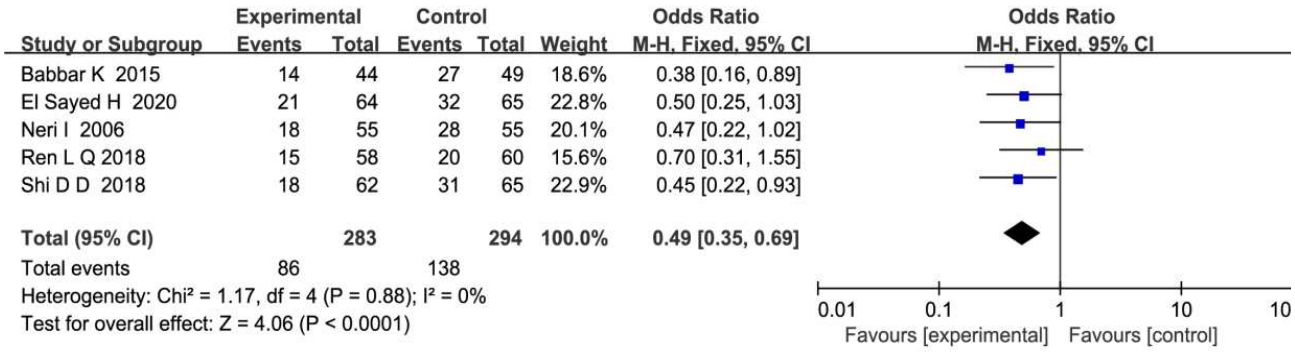

Fig. 5: Forest Plot Analysis of Postpartum Hemorrhage Incidence

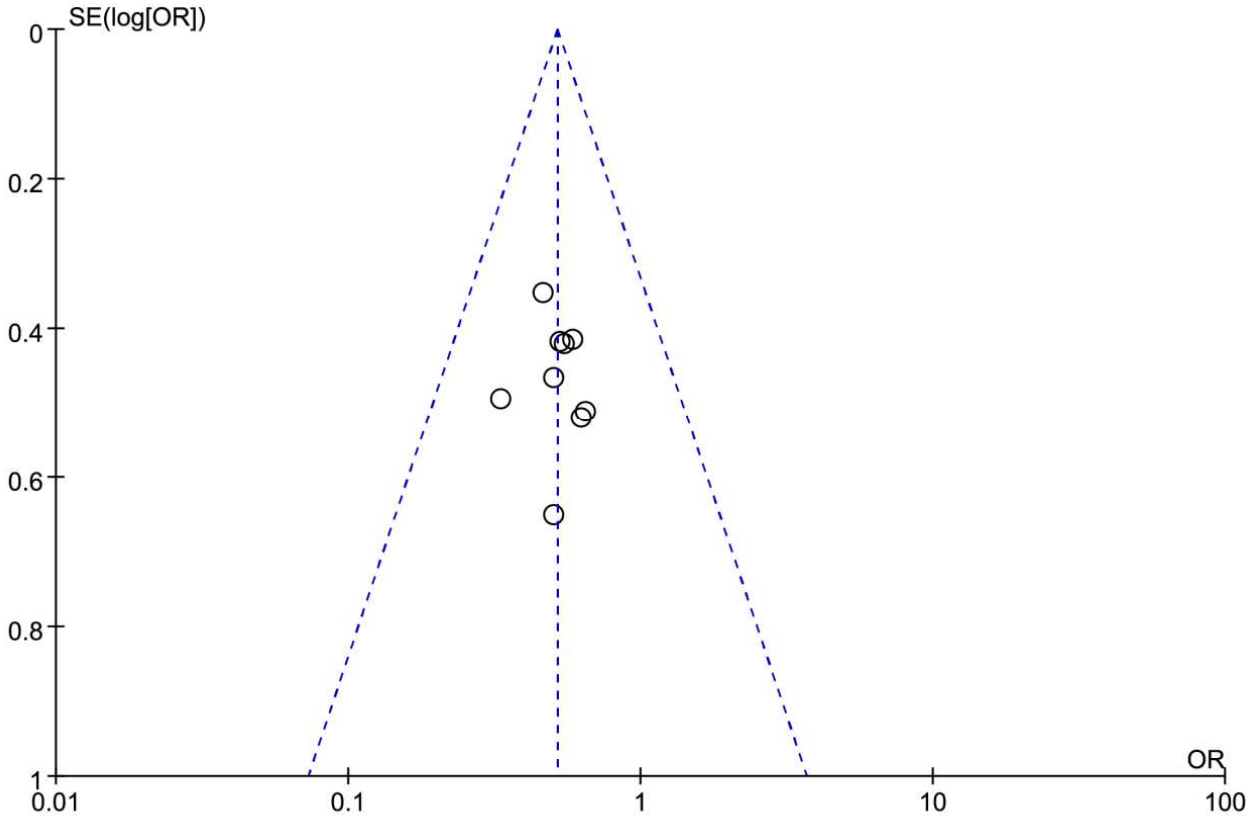

Fig. 6: Funnel Plot of the Efficacy of Different Drug Treatments for Pregnancy-Induced Hypertension

There was no heterogeneity among the various study samples ($P = 0.47$, $I^2 = 0\%$); therefore, a fixed-effect model was used. The meta-analysis results showed that compared with the control groups treated with drugs such as magnesium sulphate, drug treatment increased the total effective rate 2.45 times, with statistical significance (OR = 2.50, 95% CI = 1.85-3.37, $P < 0.00001$) (fig. 3).

Adverse reactions

Nine articles (Subhedar *et al*., 2013, Babbar *et al*., 2015, El Sayed, 2020, Lucas *et al*., 2001, Neri *et al*., 2006, Ren *et al*., 2018, Sastry *et al*., 2004, Shi, 2018, Vainio *et al*., 2002) were included for the outcome measures of adverse reactions, and there was statistical heterogeneity between the studies ($P = 1.00$, $I^2 = 0\%$). A random-effects model was used for the analysis. The meta-analysis results indicated that, compared with the control groups, the incidence of adverse reactions in the experimental groups was low, with statistically significant differences (OR = 0.52, 95% CI = 0.38-0.69, $P < 0.0001$), as shown in fig. 4.

Postpartum haemorrhage

Among the publications included in this study, five (Babbar *et al*., 2015; El Sayed, 2020; Neri *et al*., 2006; Ren *et al*., 2018; Shi, 2018) reported the incidence of postpartum haemorrhage in patients from the danshen and control groups. There was no heterogeneity observed between the various study samples ($P = 0.88$, $I^2 = 0\%$). The drug treatment group reduced the risk of postpartum haemorrhage by 43%, and the difference was statistically significant (OR = 0.49, 95% CI = 0.35-0.69; $P < 0.0001$) (see fig. 5).

Publication bias assessment

The assessment of publication bias in the articles included in this study (Subhedar *et al*., 2013; Babbar *et al*., 2015; El Sayed, 2020; Lucas *et al*., 2001; Neri *et al*., 2006; Ren *et al*., 2018; Sastry *et al*., 2004; Shi, 2018; Vainio *et al*., 2002) to evaluate the effectiveness of different drugs for PIH treatment is presented in Figure 6. The studies included in the funnel plot are generally symmetrically distributed, indicating relatively low publication bias.

DISCUSSION

Pregnancy-induced hypertension is a pregnancy-specific systemic condition that poses a severe threat to maternal and foetal safety (Masi *et al*., 2019). Its main symptoms include proteinuria, oedema and high blood pressure. Currently, Western medicine treatments primarily focus on symptomatic relief, including antispasmodics, antihypertensives, volume expansion, diuretics and the timely termination of pregnancy (Shopen *et al*., 2015).

However, the effective therapeutic concentration of the preferred drug for PIH treatment, magnesium sulphate, is

very close to the blood magnesium concentration, which can cause toxic side effects and result in a relatively high clinical risk (Cao *et al*., 2018). Magnesium sulphate is the first-line medication for treating PIH due to its beneficial effects, such as muscle relaxation, sedation and blood pressure reduction. However, the excessive use of magnesium sulphate can lead to side effects, such as reduced urine output, loss of knee reflexes, respiratory paralysis and impaired kidney and heart function (Shopen *et al*., 2015). Low-dose aspirin reduces the sensitivity of blood vessels to vasoconstrictive substances by regulating the ratio of prostaglandins to thromboxanes (Kintiraki *et al*., 2015).

This article reviews previous studies that provide data on PIH. For example, previous research has shown that the incidence of PIH is associated with factors such as age, parity, pre-pregnancy weight, family history, history of hypertension and diabetes (Manik, 2023; Dhillon *et al*., 2021). These data can assist clinical practitioners in identifying high-risk pregnant women and providing appropriate preventive and treatment measures. Additionally, previous studies have indicated that PIH can lead to adverse symptoms in pregnant women, such as headaches, blurred vision, abnormal liver function and kidney dysfunction and, in severe cases, cause complications such as preeclampsia, placental abruption and amniotic fluid embolism (Cullins *et al*., 2013; Aghamohammadi *et al*., 2011).

Regarding treatment, previous research has suggested that pharmacological and non-pharmacological approaches can be used to control blood pressure, including the use of medications such as methyldopa, nifedipine and labetalol (Guo *et al*., 2018; Kumar *et al*., 2023). Furthermore, earlier studies have explored alternative treatment methods, such as acupuncture, traditional Chinese medicine and nutritional supplementation (Hayase *et al*., 2014; Mantel *et al*., 2023). These data emphasise the need for a comprehensive approach when treating PIH.

Pregnancy-induced hypertension can have serious consequences for the mother and the foetus. Maternal complications may include preeclampsia, eclampsia and haemolysis, elevated liver enzymes, low platelet count syndrome and foetal complications (Subhedar *et al*., 2013; Zhong and Zhang, 2023). Antihypertensive medications, such as methyldopa, nifedipine and labetalol, can be used to control blood pressure. Non-pharmacological interventions, such as rest, salt restriction and increased protein intake, can also be effective. In addition, supportive care, such as monitoring maternal and foetal status, maintaining fluid and electrolyte balance and correcting anaemia, is important. In addition to traditional treatment methods, some studies have explored new treatment methods for PIH.

This study had the following limitations. First, there were multiple outcome indicators included in the literature, which resulted in a limited number of studies available for the meta-analysis. Second, the included literature exhibited methodological variations, leading to a degree of heterogeneity in the analysis of the results. Third, the number of included studies was relatively small, which may have reduced the statistical power and potentially introduced bias, affecting the feasibility and accuracy of the research results. Therefore, to further validate the efficacy and safety of relevant drug treatments for PIH, it is necessary to conduct more high-quality, scientifically designed, well-executed, multi-centred and large-sample randomised controlled trials to provide robust evidence.

CONCLUSION

Pregnancy-induced hypertension is a common complication of pregnancy that can have serious consequences for the mother and foetus. Identifying high-risk pregnant women and providing appropriate prenatal care is important to prevent and manage PIH. Treatment involves controlling blood pressure and providing supportive care. Traditional and new treatment methods have been studied, but further research is needed to confirm their efficacy and safety.

Declarations

Ethics approval and consent to participate

An ethics statement was not required for this study type, n o human or animal subjects or materials were used.

Conflict of interest

None of the authors have any personal, financial, commercial, or academic conflicts of interest.

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