META-ANALYSIS

A Meta-analysis Assessing the Efficacy of Balloon Pulmonary Angioplasty in Resolving Chronic Thromboembolic Pulmonary Hypertension

Qingxu Guo, MM; Long Lu, MM; Baocheng Jia, BM; Yunlong Liu, BM

ABSTRACT

Background and Purpose • Chronic thromboembolic pulmonary hypertension (CTEPH) is the fourth most common form of pulmonary hypertension (PH), representing a pre-capillary manifestation of the disorder. This meta-analysis aims to evaluate the role of balloon pulmonary angioplasty (BPA) in the treatment of CTEPH.

Methods • Our investigation was conducted using PubMed, Embase, Cochrane Library, and Web of Science platforms.

Results • This meta-analysis includes the analysis of seven studies. BPA demonstrated a significant reduction in pulmonary arterial pressure in CTEPH patients (Mean difference (MD) = -9.80, 95% CI: -1.10 to -8.59, $P < .00001$). BPA also resulted in a decrease in pulmonary vascular resistance in CTEPH patients (MD = -4.70, 95% CI: -7.17 to -2.22, $P = .0002$). Moreover, BPA was associated with improved 6-minute walk distance of CTEPH patients (MD = 43.86, 95% CI: 26.19 to 61.53, $P < .00001$). Additionally, BPA led to a reduction in NT-proBNP levels in CTEPH patients (MD = -3.46, 95% CI: -10.63 to 3.71, p-value = 0.34). BPA also resulted in an improvement in the WHO functional class of CTEPH patients, with an increase in class I-II (MD = 0.28, 95% CI: 0.22 to 0.35, $P < .00001$) and a decrease in class III-IV (MD = 0.16, 95% CI: 0.10 to 0.26, $P < .00001$).

Conclusion • These findings support the effectiveness of BPA as an alternative treatment option for CTEPH patients, leading to improvements in prognostic factors such as hemodynamics, functional ability, and biomarkers. BPA may offer enhanced therapeutic benefits and potentially serve as an alternative treatment for select CTEPH patients. (*Altern Ther Health Med.* 2023;29(6):444-448).

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INTRODUCTION

The fourth most common form of pulmonary hypertension is chronic thromboembolic pulmonary hypertension (CTEPH), characterized by the persistent presence of chronic undissolved thrombus within the pulmonary artery.[1] This condition leads to remodeling and blockage of the small pulmonary arteries, resulting in increased pulmonary artery pressure and pulmonary vascular resistance, eventually leading to pre-capillary pulmonary hypertension.[2]

CTEPH is a relatively rare disease, often missed or misdiagnosed in clinical practice due to limited awareness among clinicians.[3] The prevalence of CTEPH in the general population cannot be accurately determined due to limitations in screening methods, and often misdiagnosed.[4] However, based on the analysis of registered studies in various countries, the estimated annual prevalence rate of CTEPH ranges from 3.2 to 50 cases per 100 000 individuals, with slight variations among different countries and races. Approximately 20% of all pulmonary hypertension patients in major PH clinics are diagnosed with CTEPH.[5,6]

Treatment options for CTEPH include pulmonary endarterectomy (PEA), balloon pulmonary angioplasty (BPA), and medication. Lifelong anticoagulation therapy is recommended for CTEPH patients to prevent the progression of pulmonary embolism and reduce the incidence of venous thromboembolism.[7,8]

In recent years, there has been growing interest in detecting CTEPH as early as possible following pulmonary thromboembolism (PTE), leading to the concept of post-pulmonary embolism syndrome (PPES).[9] Studies have shown that despite adequate anticoagulation, 25% to 50% of PTE patients still have unresolved thrombus, with PPES accounting for 40% to 60% of all PTE cases. Furthermore,

patients with PPES have a higher incidence of CTEPH compared to the general population.[10,11]

With advancements in interventional materials and endovascular technology, peripheral artery stenosis and occlusive disorders are now predominantly managed through endovascular interventions. Notably, drug-coated balloon (DCB) technology has made significant progress in recent years.[12,13] Clinical evidence has demonstrated the safety and efficacy of DCB in treating peripheral arterial stenosis/occlusive lesions. However, most research has focused on the superficial femoral artery and proximal femoral artery, while the anatomical and hemodynamic characteristics of the superficial femoral artery differ significantly from those of the superficial femoral artery, often considered a relatively non-scaffold area.[14-17] Therefore, the concept of "leaving nothing behind" is more applicable to the arterial region, emphasizing the importance of specific intervention or treatment without any residual obstructions or issues.[14] In this study, we aim to elucidate the role of balloon pulmonary angioplasty in the treatment of CTEPH through a meta-analysis.

MATERIALS AND METHODS

Study Design

The study employed a systematic review and meta-analysis design. We conducted a comprehensive search of multiple databases, including Web of Science, PubMed, and Embase, using specific search terms and combinations. We also reviewed the reference lists of relevant articles.

Search Strategy

The study was conducted by searching the Web of Science, PubMed, and Embase databases, with the latest search performed in March 2023. The search utilized a combination of MeSH terms and free keywords, including "Balloon Pulmonary Angioplasty," "Chronic Thromboembolic Pulmonary Hypertension," and various combinations of these terms. In order to identify additional relevant papers, the reference lists of previously published reviews were systematically examined. Only articles written in English were included in the study.

Inclusion and Exclusion Criteria

The study employed specific inclusion criteria to determine the eligibility of publications: (1) Pathological evidence supporting the severity assessment in emergency cases, and (2) Selection of the most comprehensive article when multiple articles were available for the same patient cohort. Exclusion criteria included: (1) Abstracts, reviews, case studies, or comment letters; (2) Animal research studies; (3) Duplicate articles; and (4) Articles published in languages other than English.

Data Extraction and Quality Assessment

The abstracts of the identified articles were initially screened, and then the full texts were carefully reviewed independently by two researchers. Any discrepancies or disagreements were resolved through discussion or consultation with a third researcher, if necessary until a consensus was reached.[18] The extracted information included basic literature details, study type, study population, sample size, intervention details, outcome measures, and other relevant data.

Statistical Analysis

For this meta-analysis, we utilized the Review Manager (RevMan) software.[18] First, the pooled effects were determined for outcome measures, which consisted of various types of measured data and utilized different evaluation tools. The standardized mean difference (SMD) with a 95% confidence interval (CI) was calculated as an effect indicator to account for the differences in scores. Secondly, heterogeneity testing was conducted using the chi-square test to assess the presence of heterogeneity among the included studies. A fixed-effects model was applied for the meta-analysis if the $P > .1$ and $I^2 < 50\%$, indicating low heterogeneity.

Conversely, if $P < .1$ and $I^2 > 50\%$, indicating significant heterogeneity, potential sources of heterogeneity were investigated. If no clinical heterogeneity was identified, a random-effects model was used for the meta-analysis. Additionally, subgroup analyses were performed to explore potential differences in qualitative factors.

RESULTS

Summary of Study Selection and Risk Assessment

A total of 342 articles were initially identified for inclusion in this meta-analysis (Figure 1). Table 1 presents the key characteristics of the 7 selected studies (19-25). The risk of bias in the included studies was assessed using The Cochrane Collaboration's methodology (Figure 2A). Several studies demonstrated proper randomization, allocation concealment techniques, publication of partial outcome information, and double-blinding (Figure 2B).

Figure 1. PRISMA Flow Diagram

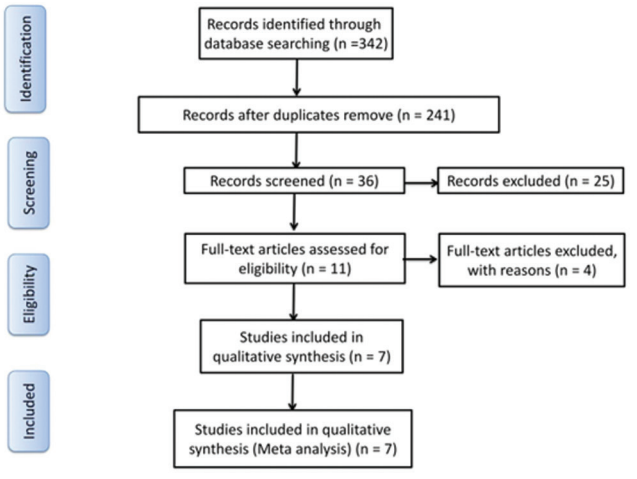


Table 1. Basic Characteristics of Included Studies

Study	Country	Cases	Group	Treatment	Control
Kawakami 2022	Japan	57	31/26	BPA accepted	BPA not accepted
Jaïs 2022	France	105	52/53	BPA accepted	BPA not accepted
Andreassen 2015	Norway	36	18/18	BPA accepted	BPA not accepted
Tatebe 2015	Japan	70	35/35	BPA accepted	BPA not accepted
Aoki 2016	Japan	48	24/24	BPA accepted	BPA not accepted
Fukui 2016	Japan	41	17/24	BPA accepted	BPA not accepted
Brenot 2018	France	308	154/154	BPA accepted	BPA not accepted

Note: Table 1 provides an overview of the basic characteristics of the included studies in the meta-analysis.

Figure 2. Characteristics of Included Studies and Risk of Bias Assessment; **A.** Risk of Bias Summary; **B.** The risk of bias of randomized trials included in the meta-analysis.

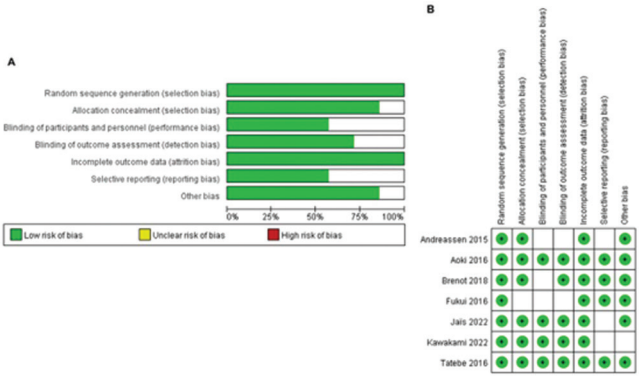


Figure 3. Effects of BPA on Pulmonary Arterial Pressure and Pulmonary Vascular Resistance in CTEPH. **A**. Pulmonary Arterial Pressure; **B.** Pulmonary Vascular Resistance

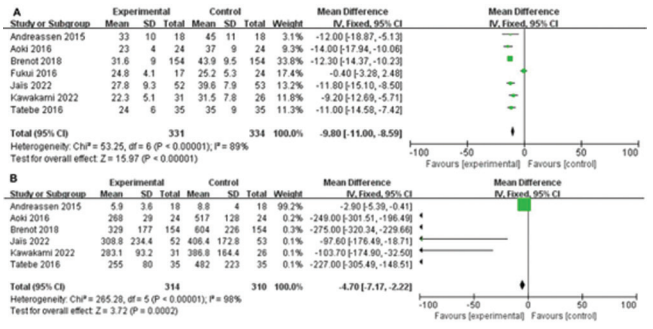


Figure 4. Publication Bias of BPA on Pulmonary Arterial Pressure and Pulmonary Vascular Resistance in CTEPH. **A.** Publication Bias – Pulmonary Arterial Pressure; Figure **B.** Publication Bias - Pulmonary Vascular Resistance.

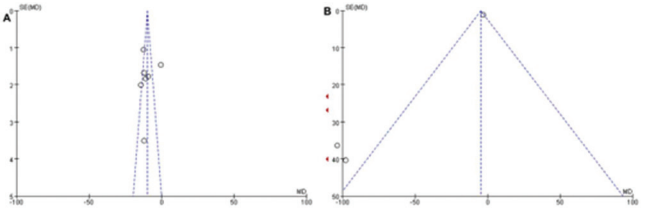


Figure 5. Effects of BPA on 6-Min Walk Distance and NT-proBNP in CTEPH. **A**. Effects on 6-Min Walk Distance; **B**. Effects on NT-proBNP.

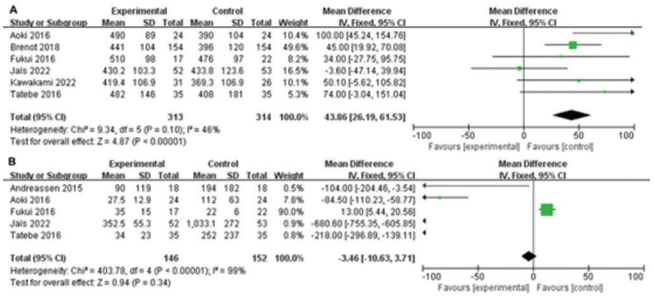


Figure 6. Effects of BPA on WHO Functional Class in CTEPH; **A.** Effects on WHO Functional Class (I-II); **B.** Effects on WHO Functional Class (III-IV).

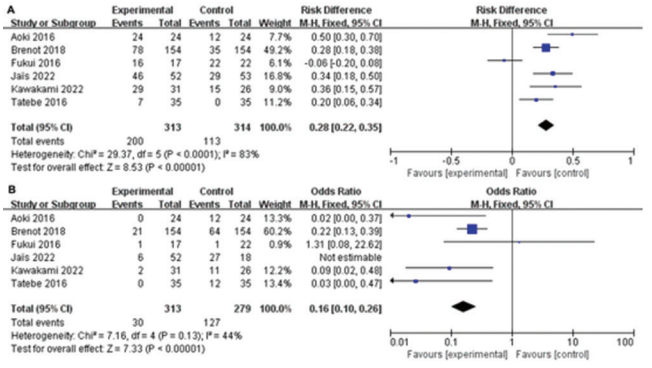
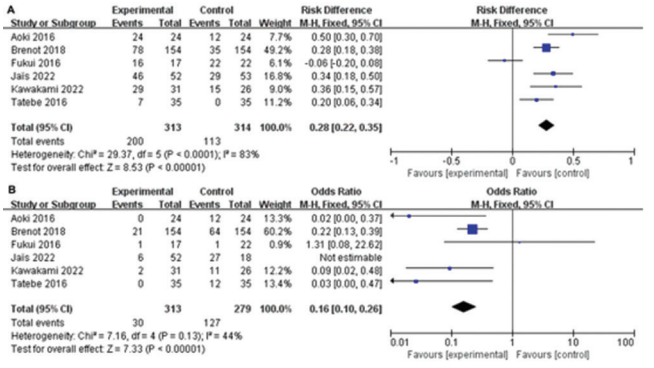


Figure 7. Publication Bias Assessment; **A.** Publication Bias for 6-Min Walk Distance; **B.** Publication Bias for NT-proBNP; **C.** Publication Bias for WHO Functional Class (I-II); **D.** Publication Bias for WHO Functional Class (III-IV).



BPA Effects on PAP and PVR in CTEPH

The study analyzed the impact of BPA on PAP and PVR in CTEPH. BPA demonstrated a significant reduction in PAP (mean difference (MD) = -9.80, 95% CI: -1.10 to -8.59, $P < .00001$, Figure 3A). Similarly, BPA was found to decrease PVR (MD = -4.70, 95% CI: -7.17 to -2.22, $P = .0002$, Figure 3B). Funnel plots (Figure 4A) assessing publication bias for PAP analysis showed no significant asymmetry, indicating no noticeable publication bias. However, for PVR analysis, noticeable publication bias was observed (Figure 4B), suggesting some deviation in the clinical data.

Effects of BPA on 6-Min Walk Distance and NT-proBNP in CTEPH

The study also investigated the impact of BPA on 6-min walk distance and NT-proBNP in CTEPH. BPA demonstrated a significant increase in 6-min walk distance (Figure 5A) (MD = 43.86, 95% CI: 26.19-61.53, $P < .00001$). However, regarding NT-proBNP, BPA showed a reduction (Figure 5B) (MD = -3.46, 95% CI: -10.63-3.71, $P = .34$), although this difference was not statistically significant.

The Impact of BPA on WHO Functional Class in CTEPH

The effects of BPA on the WHO functional class of CTEPH were also evaluated in this investigation. The results demonstrated that BPA led to an improvement in the I-II class of WHO functional class in CTEPH (Figure 6A) (MD = 0.28, 95% CI: 0.22-0.35, $P < .00001$). Additionally, BPA resulted in a decrease in the III-IV class of WHO functional class in CTEPH (Figure 6B) (MD = 0.16, 95% CI: 0.10-0.26, $P < .00001$).

Publication Bias

Funnel plots were used to assess publication bias in the meta-analysis of significant complications and hospital deaths in individuals with urgent serious illnesses (Figure 7). The funnel plots demonstrated no significant publication bias, as indicated by their symmetrical shape across all analyses.

DISCUSSION

Chronic thromboembolic pulmonary disease refers to the persistence of acute pulmonary thromboembolism with or without pulmonary hypertension, depending on the presence of residual and organized pulmonary arteries after at least three months of standard anticoagulation treatment.[26,27] CTEPD and CTEPH share similarities in terms of fibrous and organized thromboembolic obstructive pulmonary artery injury, placing them in the fourth category of pulmonary hypertension.[28] In this meta-analysis, we evaluated the key characteristics of seven studies to examine the topic.

CTEPH is recognized as a rare consequence of pulmonary thromboembolism (PTE), with higher incidence rates observed among individuals who have previously experienced PTE.[29] Previous studies have reported varying rates of CTEPH development following PTE, ranging from 0.4% to 9.1%, with the majority falling within the range of 0.1% to 4%.[30] It should be noted that these figures may underestimate the actual prevalence due to asymptomatic cases of pulmonary embolism.[31] A multi-center registry study conducted in Japan revealed that 15% of CTEPH patients had a prior diagnosis of PTE, suggesting potential population and ethnic heterogeneity in the occurrence and progression of CTEPH.[32]

However, it is important to note that not all patients who experience PTE will develop CTEPH. The prevalence of CTEPH in the population of PTE survivors with persistent dyspnea is estimated to be only 5% to 8%.[33] There is significant heterogeneity in the timeframe for the development of CTEPH following PTE.[30] Recent studies have shown that most individuals were diagnosed with CTEPH within 24 months after PTE, with a median diagnostic duration of 4.3 months.[34] These findings highlight the importance of regular follow-up in the first two years after a PTE diagnosis to enable early detection of potential CTEPH and timely intervention.[35]

Targeted drugs or BPA are recommended as alternative treatments for patients who are not eligible for pulmonary thromboendarterectomy. The use of BPA has shown promising potential in the management of pulmonary hypertension.[20] In the context of hemodialysis, intravenous fistula has become the preferred vascular access due to its advantages of low infection rate, reduced thrombotic complications, and longer durability.[36] However, stenosis of the internal fistula is a common clinical complication during the monitoring and treatment of arteriovenous fistula (AVF) patients. It poses a significant risk factor for internal fistula thrombosis and loss of functionality.[37] Percutaneous transluminal angioplasty (PTA) has long been the preferred method for treating AVF stenosis. Early detection and treatment of AVF stenosis hold significant importance in preventing vascular thrombosis and prolonging the patency of the AVF dialysis pathway.[38,39]

Our study observed significant effects of BPA on various parameters in CTEPH patients. BPA administration resulted in a reduction in PAP (MD = -9.80, 95% CI: -1.10 to -8.59, $P < .00001$) and PVR (MD = -4.70, 95% CI: -7.17 to -2.22, $P = .0002$) in CTEPH. Additionally, BPA demonstrated a positive impact on the 6-min walk distance (MD = 43.86, 95% CI: 26.19 to 61.53, $P < .00001$) and a decrease in NT-proBNP (MD = -3.46, 95% CI: -10.63 to 3.71, $P = .34$) in CTEPH patients. Furthermore, BPA influenced the WHO functional class of CTEPH, with an increase in the I-II class (MD = 0.28, 95% CI: 0.22 to 0.35, $P < .00001$) and a decrease in the III-IV class (MD = 0.16, 95% CI: 0.10 to 0.26, $P < .00001$).

Study Limitations

In this study, we acknowledge several limitations. Firstly, the inclusion of only 10 studies may restrict the generalizability of our findings, and further research is needed to fully understand the impact of BPA on CTEPH. Secondly, while our results suggest that BPA can improve the therapeutic effectiveness in CTEPH, additional high-quality, large-scale

studies with a diverse range of patients are essential to validate and strengthen our findings.

CONCLUSION

In conclusion, this study provides valuable insights into the effects of balloon pulmonary angioplasty on chronic thromboembolic pulmonary hypertension. Our findings demonstrate that BPA significantly affects pulmonary arterial pressure, pulmonary vascular resistance, 6-minute walk distance, NT-proBNP levels, and WHO functional class in CTEPH patients. These results suggest the potential of BPA as a promising treatment option for CTEPH, particularly for patients who are unable to undergo pulmonary thromboendarterectomy. However, it is important to acknowledge the limitations of this study, including the limited number of included studies and the need for further high-quality research. Future studies should aim to explore the long-term efficacy and safety of BPA and include larger and more diverse patient populations. Overall, our findings contribute to the growing body of evidence supporting the use of BPA in managing CTEPH, offering hope for improved outcomes and quality of life for affected individuals.

CONFLICT OF INTERESTS

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTIONS

All authors contributed equally; they read and approved the final manuscript.

FUNDING

This study did not receive any funding in any form.

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