INPLASY

Efficacy and Safety of Extracorporeal Shockwave Therapy Combined with Botulinum Toxin A for Post-stroke Spasticity: A Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 3 March 2026 and was last updated on 3 March 2026.

INTRODUCTION

Review question / Objective The objective of this study is to systematically evaluate the clinical efficacy and safety of combining extracorporeal shockwave therapy (ESWT) with botulinum toxin type A (BTX-A) for the treatment of post-stroke spasticity. By synthesizing evidence from randomized controlled trials, this review aims to determine the impact of this combination therapy on muscle tone, motor recovery, and functional outcomes in stroke survivors.

Condition being studied Post-stroke spasticity (PSS) is a common and debilitating complication of stroke, characterized by a velocity-dependent increase in muscle tone and hyperreflexia. PSS often leads to chronic pain, joint contractures, and impaired motor function, significantly limiting activities of daily living and reducing the overall quality of life for stroke survivors.

METHODS

Participant or population The study population consists of adult patients (aged 18 years or older) with a confirmed clinical diagnosis of either ischemic or hemorrhagic stroke. Participants must present with post-stroke spasticity in the upper and/or lower limbs, typically characterized by a Modified Ashworth Scale (MAS) score of 1 or higher. There are no specific restrictions regarding gender, ethnicity, or the duration of time elapsed since the stroke onset (including acute, subacute, or chronic stages).

Intervention The intervention consists of extracorporeal shockwave therapy (ESWT), including focused or radial modalities, applied as an adjuvant treatment following botulinum toxin type A (BTX-A) injections. ESWT involves the application of acoustic waves to spastic muscles to potentially modulate muscle rheology and neurotransmission , while BTX-A reduces muscle

hyperactivity by inhibiting acetylcholine release at the neuromuscular junction.

Comparator The comparator groups consist of post-stroke patients receiving one of the following interventions:Botulinum toxin type A (BTX-A) injections alone;BTX-A injections combined with sham/placebo extracorporeal shockwave therapy (sham-ESWT);BTX-A injections combined with conventional rehabilitation programs (e.g., physical therapy, electrical stimulation);Conventional rehabilitation programs alone (without BTX-A injections).

Study designs to be included Randomized controlled trials (RCTs).

Eligibility criteria Inclusion criteria:Adult patients (aged 18 years or older) with a confirmed diagnosis of ischemic or hemorrhagic stroke; Clinical presence of limb spasticity with a Modified Ashworth Scale (MAS) score of 1 or more; Randomized controlled trials comparing the combination of BTX-A and ESWT against valid comparators (including BTX-A alone, sham-ESWT, or conventional rehabilitation).
Exclusion criteria:Spasticity caused by other neurological conditions (e.g., traumatic brain injury, cerebral palsy, or spinal cord injury); Non-randomized studies, case reports, animal experiments, or studies with missing primary outcome data (MAS); Studies where full-text versions are unavailable for data extraction.

Information sources We will systematically search the following electronic databases from their inception to March 2026: PubMed, Embase, Cochrane Library, and Web of Science. Additionally, major Chinese databases including China National Knowledge Infrastructure (CNKI), Wanfang Data, the VIP Database, and SinoMed (China Biology Medicine disc) will be searched to identify relevant randomized controlled trials. Reference lists of the included studies and relevant systematic reviews will also be manually searched for any additional eligible trials.

Main outcome(s) The primary outcome is the Modified Ashworth Scale (MAS) score, which is used to assess the level of muscle spasticity.

Quality assessment / Risk of bias analysis The risk of bias for each included randomized controlled trial will be independently assessed by two reviewers using the Cochrane Risk of Bias tool (RoB 2). The assessment will cover domains including bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result. Any discrepancies will be resolved through discussion or by consulting a third reviewer.

Strategy of data synthesis Statistical analysis will be performed using standard meta-analysis software (e.g., RevMan 5.4 or Stata). For continuous outcomes such as the Modified Ashworth Scale (MAS) scores, we will calculate the mean difference (MD) or standardized mean difference (SMD) with 95 percent confidence intervals. Statistical heterogeneity among the included studies will be assessed using the Chi-square test and the I-squared (I2) statistic. A fixed-effect model will be used if heterogeneity is low (I2 less than 50 percent); otherwise, a random-effects model will be applied to provide a more conservative estimate. We will also conduct subgroup analyses to explore potential sources of heterogeneity based on clinical variables such as shockwave parameters or treatment duration. Sensitivity analysis will be performed to test the robustness of the results by excluding individual studies. Publication bias will be assessed using funnel plots and Egger's test if a sufficient number of studies (usually 10 or more) are included.

Subgroup analysis Subgroup analyses will be performed to explore potential sources of clinical and methodological heterogeneity if sufficient data are available. Potential factors for subgroup analysis may include, but are not limited to, the type of extracorporeal shockwave therapy (e.g., focused vs. radial shock waves), the location of the treated limb (upper vs. lower limb), and different follow-up durations (e.g., short-term vs. long-term). Other relevant clinical characteristics or treatment parameters may also be considered for subgrouping as appropriate.

Sensitivity analysis Sensitivity analysis will be performed to evaluate the stability and robustness of the pooled results. We plan to use the leave-one-out method, which involves sequentially excluding each individual study and re-calculating the pooled effect size to determine whether any single study significantly influences the overall estimate. Additionally, if applicable, we will perform sensitivity analysis by excluding studies with a high risk of bias to assess whether the quality of primary studies affects the primary outcome (MAS scores).

Language restriction Chinese, English.

Country(ies) involved China.

Keywords Stroke; Muscle Spasticity; Extracorporeal Shockwave Therapy; Botulinum Toxins, Type A; Rehabilitation; Systematic Review; Meta-Analysis.

Contributions of each author

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