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EFFECTIVENESS OF EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) IN THE MANAGEMENT OF SPASTICITY POST-STROKE: A CLINICAL EVALUATION

Dr. Pawan Sharma[1*], Dr. Sonu Singh[2], Dr. Maan Singh[3], Dr. Dwit Vora[4]

[1*]Junior Resident, Dept. of Physical Medicine & Rehabilitation, Mahatma Gandhi Medical College, Jaipur
[2]Professor, Dept. of Physical Medicine & Rehabilitation, Mahatma Gandhi Medical College, Jaipur
[3]Assistant Professor, Dept. of Physical Medicine & Rehabilitation, Lady Hardinge Medical College, Delhi
[4]Junior Resident, Dept. of Pharmacology, Mahatma Gandhi Medical College, Jaipur

***Corresponding Author:** Dr. Dwit Vora
*Junior Resident, Dept. of Pharmacology, Mahatma Gandhi Medical College, Jaipur

Abstract
Spasticity following stroke significantly impairs motor function and impacts quality of life. Current interventions, including pharmacological treatments, physical therapy, and surgical options, have demonstrated limited effectiveness and potential side effects. Extracorporeal shock wave therapy (ESWT) is gaining attention as a non-invasive option for spasticity management. This study assessed the efficacy of ESWT in reducing spasticity and enhancing motor function and quality of life in stroke survivors through a randomized controlled trial. Eighty participants were randomly assigned to receive either ESWT or standard care, with spasticity and motor function assessed using the Modified Ashworth Scale (MAS) and Fugl-Meyer Assessment (FMA), while quality of life was evaluated with the Stroke-Specific Quality of Life Scale (SSQOL). Post-treatment results showed significant spasticity reduction in the ESWT group, alongside notable improvements in motor function and quality of life. The findings suggest that ESWT is a viable, non-invasive option for enhancing spasticity management in stroke rehabilitation.

Introduction

Stroke is one of the leading causes of long-term disability, and **spasticity** affects approximately 30% of stroke survivors within three months of the event [1]. **Spasticity** refers to a velocity-dependent increase in muscle tone due to hyperexcitability of the stretch reflex, resulting in muscle stiffness, pain, and restricted movement [2,3]. These symptoms can significantly hinder rehabilitation and reduce the quality of life for stroke survivors [4].

The **current treatments** for spasticity include:

- Pharmacological interventions, such as **botulinum toxin** and **oral antispasmodics** [5,6].
- Physical therapies, including **stretching** and **muscle strengthening exercises** [7,8].
- Surgical options, such as **tendon release** and **rhizotomy** [9].

However, these treatments have limitations, such as limited efficacy, high costs, and invasiveness [10]. In recent years, **Extracorporeal Shock Wave Therapy (ESWT)** has emerged as a non-invasive alternative for treating musculoskeletal conditions like **tendinopathies** and **calcific shoulder** [11,12]. Preliminary studies have indicated that **ESWT** can reduce muscle tone and improve functional

outcomes in stroke survivors by modulating neuromuscular junctions, reducing inflammation, and increasing blood flow [13,14,15].

The **primary aim** of this study is to evaluate the clinical effectiveness of **ESWT** in managing spasticity in stroke survivors. This study also aims to assess the impact of ESWT on **quality of life** and **motor function**.

Materials and Methods

Study Design

This study was a **randomized controlled trial (RCT)** with two parallel groups: an **ESWT intervention group** and a **control group** receiving standard care. The study was conducted with a **double-blind design**, ensuring that both participants and the clinical staff responsible for the outcome assessments were blinded to the group allocation.

Participant Selection

Participants were recruited from a **specialized stroke rehabilitation center**. Inclusion and exclusion criteria were as follows:

- **Inclusion criteria**:
  - Adults aged 18 years or older.
  - A confirmed diagnosis of ischemic or hemorrhagic stroke.
  - Spasticity in the upper or lower limbs, with a **Modified Ashworth Scale (MAS) score** ≥ 2.
  - Stroke onset between 6 months and 3 years prior to recruitment.
  - The ability to provide informed consent [16,17].

- **Exclusion criteria**:
  - Severe cognitive impairment affecting consent or reliable reporting.
  - Previous use of ESWT for spasticity.
  - Coexisting neurological or musculoskeletal disorders affecting motor function.
  - Current use of **antispasmodic medications** or **botulinum toxin injections** within three months of the study [18,19].

Randomization and Blinding

Participants were randomized into the **ESWT group** or **control group** using computer-generated random numbers. Allocation concealment was achieved through sealed opaque envelopes. Both the **participants** and the **clinical assessors** were blinded to the treatment assignments.

Treatment Protocol

The **ESWT group** received radial ESWT applied to the spastic muscles over three weekly sessions. Each session lasted 20 minutes and was delivered at an **energy flux density** of 0.09 mJ/mm², a **frequency** of 5 Hz, and **1500 pulses per muscle group** [20]. The **control group** received standard physical therapy but no ESWT.

Assessment Tools

- **Primary Outcome Measure**: Muscle tone and spasticity were evaluated using the **Modified Ashworth Scale (MAS)** [21].
- **Secondary Outcome Measures**:
  - Quality of life was assessed using the **Stroke-Specific Quality of Life Scale (SSQOL)** [22].
  - Motor function was measured using the **Fugl-Meyer Assessment (FMA)** [23].

Assessments were conducted at **baseline**, **immediately after treatment**, and at the **4-week follow-up**.

Flowchart of Study Methodology

Below is the flow chart illustrating the study methodology.

1. Patient Recruitment
|
2. Randomization
|
├──> ESWT Group
│ (Radial ESWT for 3 sessions, 1 per week)
|
└──> Control Group
(Standard Physical Therapy)
|
3. Assessment (MAS, SSQOL, FMA)
|
4. 4-Week Follow-up
(MAS, SSQOL, FMA)

Statistical Analysis
Data were analyzed using **paired t-tests** for within-group comparisons and **analysis of variance (ANOVA)** for between-group comparisons. Statistical significance was set at **$p < 0.05$**. An intention-to-treat approach was employed to preserve data integrity.

Results

Baseline Characteristics

A total of 80 participants were recruited and randomized (40 in the **ESWT group** and 40 in the **control group**). Baseline characteristics, including **age**, **MAS**, **SSQOL**, and **FMA scores**, were similar across both groups, ensuring balanced randomization.

Table 1. Baseline Characteristics of Participants

Characteristic	ESWT Group (n = 40)	Control Group (n = 40)	p-value
Mean Age (years)	63.8 ± 7.2	64.3 ± 6.7	0.62
MAS Score	3.2 ± 0.3	3.1 ± 0.4	0.47
SSQOL Score	54 ± 9	56 ± 8	0.35
FMA Upper Limb Score	19 ± 6	21 ± 7	0.49

Primary Outcome: Modified Ashworth Scale (MAS)

There was a **statistically significant reduction** in spasticity in the **ESWT group**, as measured by MAS scores. The ESWT group demonstrated reduction in MAS scores, from 3.2 ± 0.3 at baseline to 1.9 ± 0.4 at the 4-week follow-up ($p < 0.01$). In contrast, the control group showed minimal change, from 3.1 ± 0.4 to 3.0 ± 0.5 ($p = 0.46$), indicating the limited effect of standard care on spasticity.

Table 2. Change in MAS Scores from Baseline to 4-Week Follow-up

Group	Baseline MAS Score	Post-Treatment MAS Score	p-value
ESWT Group	3.2 ± 0.3	1.9 ± 0.4	< 0.01
Control Group	3.1 ± 0.4	3.0 ± 0.5	0.46

Secondary Outcomes

Quality of Life (SSQOL)

Participants in the **ESWT group** demonstrated **significant improvements** in quality of life (SSQOL scores) compared to the control group. SSQOL scores increased from 54 ± 9 at baseline to 70 ± 8

post-treatment ($p < 0.05$). The control group displayed a smaller, non-significant increase from 56 ± 8 to 58 ± 9 ($p = 0.38$).

Table 3. Change in SSQOL Scores

Group	Baseline SSQOL	Post-Treatment SSQOL	p-value
ESWT Group	54 ± 9	70 ± 8	< 0.05
Control Group	56 ± 8	58 ± 9	0.38

Motor Function (FMA)

Moderate improvements in **motor function** were observed in the **ESWT group**, as shown in the Fugl-Meyer Assessment scores. The ESWT group exhibited improvement in FMA scores, rising from 19 ± 6 to 28 ± 5 ($p = 0.03$), compared to a slight increase from 21 ± 7 to 23 ± 6 in the control group ($p = 0.09$).

Table 4. Change in Fugl-Meyer Assessment Scores (Upper Limb)

Group	Baseline FMA	Post-Treatment FMA	p-value
ESWT Group	19 ± 6	28 ± 5	0.03
Control Group	21 ± 7	23 ± 6	0.09

Discussion

This study provides robust evidence supporting the effectiveness of **ESWT** in reducing spasticity among stroke survivors. The significant reduction in **MAS scores** in the ESWT group is consistent with previous studies suggesting that ESWT has **neuro-modulatory** and **anti-inflammatory effects**, which contribute to reduced muscle tone [5,6,13,20].

Similar outcomes were observed in recent studies by Guo et al. (2022) and Yildirim et al. (2021), with both moderate and high-energy ESWT settings showing benefit, albeit with varying comfort levels. While our short-term results align with those of Oh et al. (2023), who reported significant motor function gains, longer-term studies like Zhang et al. (2021) indicate sustained improvements.

Additionally, the **improvements in SSQOL scores** suggest that the benefits of ESWT go beyond spasticity reduction, potentially improving overall participation in rehabilitation and enhancing quality of life [25]. These findings are in line with previous research highlighting ESWT's positive effects on **musculoskeletal** and **neurological rehabilitation** [11,14,23].

Limitations

This study has a few notable limitations that affect its scope and depth. First, the **small sample size** restricts the generalizability of our findings, making it challenging to apply these results to broader populations. Additionally, the **short follow-up period** of just 4 weeks may not adequately reflect the long-term effects of ESWT on spasticity, as potential sustained benefits remain unobserved. Finally, the **absence of detailed physiological measures** of neuromuscular changes limits our understanding of the mechanisms behind ESWT's effects, hindering insights into its precise impact on spasticity reduction.[2,6] Future studies should address these factors to strengthen evidence for ESWT.

Future Directions

Future research should focus on conducting larger trials with longer follow-up periods to investigate the **long-term effects** of ESWT. Additionally, studies should explore the **mechanisms of action** of ESWT in reducing spasticity, including its effects on **neuroplasticity** and **muscle reinnervation** [15,27].

Conclusion

This study demonstrates that **Extracorporeal Shock Wave Therapy (ESWT)** is an effective and non-invasive treatment for reducing spasticity in stroke survivors. The therapy significantly improved **muscle tone**, **motor function**, and **quality of life**. As a promising alternative to conventional

treatments, ESWT offers a feasible solution for spasticity management in stroke rehabilitation. **Future research** should investigate the **long-term outcomes** of ESWT and explore its integration into comprehensive rehabilitation protocols.

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