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RESEARCH ARTICLE
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DRY NEEDLING V/S SHAM ACUPUNCTURE [PLACEBO EFFECT] ALONG WITH CONVENTIONAL PHYSIOTHERAPY IN POST-STROKE SURVIVORS WITH SPASTICITY IN THE UPPER EXTREMITY – A COMPARATIVE STUDY

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ABSTRACT

Background-

Stroke, a cerebrovascular accident resulting from vascular injury within the central nervous system, ranks as the second leading cause of global mortality and disability. In India, stroke incidence has surged over recent decades, with varying rates. Hemorrhagic and ischemic strokes are the two main types, characterised by intra-cerebral haemorrhage and thrombi formation, respectively.

Spasticity, a motor disorder marked by increased muscle tone and resistance to stretch, is prevalent in upper motor neuron disorders. It manifests as non-reflex or reflex-mediated spasticity, the latter resulting from damage to upper motor neurons. Dry needling, an invasive therapeutic technique, targets myofascial trigger points within muscles to alleviate musculoskeletal pain and dysfunction. Mechanisms include inducing stretch within spastic tissue, altering sarcomere structure, and modulating afferent pathways.

Sham acupuncture, serving as a placebo control, involves inserting needles into non-points to evaluate the true effects of needling interventions.

Aim:

To identify the effectiveness of dry needling for the management of spasticity and identify the connection and contrast between dry needling and Sham acupuncture (placebo effect) for the treatment of spasticity.

Methodology: Convenient sampling was done for 30 individuals. The participants were taken in the age range of 35-65 years as per inclusion criteria. Participants were randomly assigned in two groups. The group A participants were given Dry Needling and Conventional Therapy and group B received Sham Acupuncture and Conventional Physiotherapy. Pre-intervention assessment was taken for spasticity, and both groups received two sessions per week over a span of five weeks. Pre-intervention and post-intervention assessment was analyzed by paired and unpaired t test using Instat software.

Outcome Measure:

Spasticity was assessed using Modified Ashworth Scale (MAS)

Results:
Both groups demonstrated significant difference in decreasing the muscle tone in 5 weeks of intervention when compared within group. Unpaired t test was done between the groups and the results showed dry needling was extremely significant, whereas Sham Acupuncture was considered moderately significant when compared between groups.
Conclusion:
The study concluded that while both the interventions showed significant differences, dry needling appears to be a promising technique for post-stroke spasticity management, its comparative efficacy with Sham acupuncture showed comparatively lesser significance.

Keywords: Stroke, Spasticity, Dry Needling, Sham Acupuncture

INTRODUCTION

Stroke:

Stroke, also known as a cerebrovascular accident (CVA), stands as a critical neurological event characterized by the sudden disruption of blood flow to the brain. This interruption deprives brain tissue of oxygen and essential nutrients, leading to cellular injury and neurological dysfunction. Stroke is a leading cause of chronic impairment and disability globally, with an estimated 13.7 million new cases reported each year. In India, the incidence of stroke has witnessed a significant rise over recent decades, driven by demographic shifts, urbanization, and lifestyle changes. The impact of stroke extends beyond individual health, imposing substantial economic and social burdens on families and communities.

Spasticity:

Spasticity emerges as a common consequence of stroke, presenting a complex array of motor impairments characterized by increased muscle tone, exaggerated reflexes, and involuntary muscle contractions. This motor dysfunction can significantly impede movement, impair functional independence, and hinder activities of daily living. Spasticity often manifests as a continuum of symptoms, ranging from mild stiffness to severe contractures, impacting mobility, gait, and overall quality of life for stroke survivors. Understanding the underlying mechanisms and manifestations of spasticity is essential for developing targeted interventions to address its multifaceted nature and improve patient outcomes.

Dry Needling (DN):

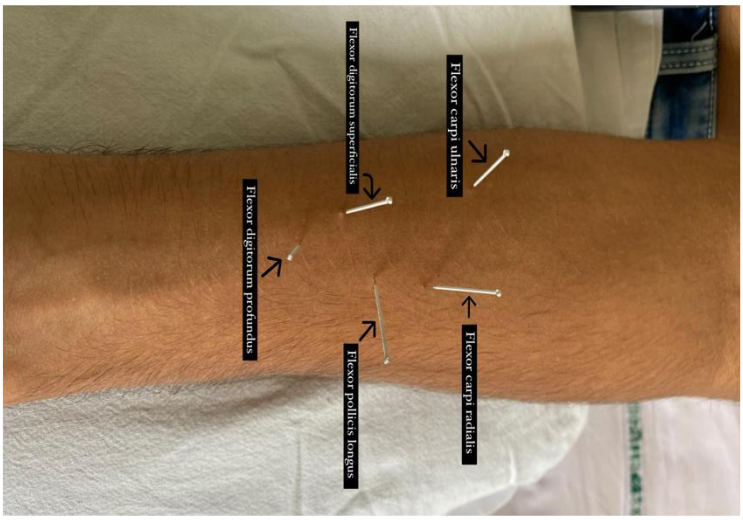
Dry needling has emerged as a promising therapeutic approach for managing musculoskeletal pain and dysfunction, including spasticity in post-stroke individuals. This minimally invasive technique involves the precise insertion of fine needles into myofascial trigger points within skeletal muscles, aiming to alleviate pain, reduce muscle tension, and improve functional mobility. The therapeutic effects of dry needling are thought to result from various mechanisms, including the mechanical disruption of trigger points, modulation of neural pathways, and release of endogenous pain-relieving substances. Despite its growing popularity and widespread use in clinical practice, the evidence supporting the efficacy of dry needling for spasticity management in stroke survivors remains limited and warrants further investigation through rigorous clinical trials and mechanistic studies.

Sham Acupuncture (Placebo Effect):

Sham acupuncture serves as a critical control intervention in research studies investigating the efficacy of acupuncture and dry needling therapies. It involves the superficial insertion of needles into non-acupoints or incorrect locations, mimicking genuine acupuncture procedures without eliciting specific physiological effects. While traditionally considered an inert control, sham acupuncture has been found to produce unexpected analgesic effects in some studies, challenging conventional notions of placebo interventions and highlighting the complex interplay between

psychosocial factors, patient expectations, and treatment outcomes. Understanding the mechanisms underlying the placebo effect and its implications for clinical practice is essential for interpreting research findings and optimizing rehabilitation strategies for stroke-related spasticity.

In conclusion, stroke-related spasticity represents a significant challenge in neurorehabilitation, requiring comprehensive and multidisciplinary approaches to address its diverse manifestations and underlying pathophysiology. Dry needling and sham acupuncture offer promising avenues for spasticity management, but their efficacy and mechanisms of action warrant further investigation. By advancing our understanding of these interventions and their impact on stroke recovery, we can enhance rehabilitation outcomes and improve the quality of life for individuals affected by stroke-related spasticity.



Dry needling for the biceps muscle

Dry needling for intrinsic muscles.

MATERIALS & METHODS

Study was approved by Institutional Ethical committee. All the subjects were acknowledged about the study and written inform consent form were signed by each one of them. All the participants were screened according to inclusion and exclusion criteria. All the participants will be divided in to 2 groups , Group ‘A’ received traditional dry needling along with conventional physiotherapy and Group ‘B’ received Sham acupuncture along with conventional Physiotherapy for the spasticity occurred in the upper limb. Before starting the intervention programme all exercises and procedure were explained and demonstrated to the patients. The study is conducted for 5 weeks.

- **METHODOLOGY:**
- **SOURCE OF DATA** – The Data is collected from Dr. Vitthalrao Vikhe Patil Rural Hospital , Loni, Rahata , Rahata Taluka , Ahmednagar , Maharashtra 413736
- **STUDY SETTING-** Dr. Vitthalrao Vikhe Patil Rural Hospital , Loni , Rahata , Rahata Taluka , Ahmednagar , Maharashtra 413736
- **STUDY TYPE-** Comparative study
- **STUDY DESIGN-** Comparison between the effectiveness of dry needling an sham acupuncture.
- **DURATION OF STUDY-** 6 months
- **METHOD OF COLLECTION OF DATA-** Data will be collected by Principle investigator.
- **TYPE OF DATA-** Quantitative Data
- **SAMPLE SIZE** – 30 samples to be collected out of which 15 will be treated with conventional dry needling and 15 will be treated with Sham acupuncture.
- **SAMPLING METHOD** – Convenient sampling
- **STUDY DURATION** – 6 months
- **STUDY POPULATION** – Post-stroke survivors

- **MATERIALS-**

➢ Consent forms
➢ Monofilament needles
➢ Laptop
➢ Pen/pencil

SELECTION CRITERIA:

Inclusion criteria-

- Clinically diagnosed stroke survivors with spasticity.
- Patients with upper limb spasticity.
- Agreed to the informed consent form and consented to participate in the experiment.
- Survivors that are cooperate with the evaluation and treatment.
- Patients who have reached Brunnstorm stage 3 or more than stage 3.

Exclusion criteria-

- Patients with other neurological disorders.
- Unconscious patients , aphasia or cognitive impairment.
- Patients with severe bleeding or infection of the treatment site.
- Phobia of needles leading to fainting.
- Refusal to fill out the consent form.

Outcome Measures:

Modified Ashworth scale.

Part A

Assessment of spasticity will be done pre and post the intervention with the help of Modified Ashworth Scale for spasticity.

- **Part B**

Includes the management of spasticity for post stroke survivors.

- Conventional physiotherapy:

I. Range of motion exercises

-shoulder
-elbow
-wrist

II.Stretching of the spastic muscles.
III.Strengthening of the antagonist muscles.
IV.Limb positioning.

- Dry needling:

Dry needling of the spastic group of muscles

- Shoulder –
  - Flexors - Deltoid
    - Coracobrachialis
    - Biceps Brachii
  - Extensors - Triceps
- Wrist –
  - Extensors - Extensor carpi radialis longus
    - Extensor carpi radialis brevis,
    - Extensor carpi ulnaris
    - Extensor digitorum
  - Flexors. - Flexor carpi radialis
    - Flexor carpi ulnaris
    - Flexor digitorum superficialis,
    - Flexor digitorum profundus
    - Flexor pollicis longus

- Sham acupuncture:

Superficial dry needling of the antagonist group of muscles.

- Shoulder –
  - Flexors - Deltoid
    - Coracobrachialis
    - Biceps Brachii
  - Extensors - Triceps
- Wrist –
  - Extensors - Extensor carpi radialis longus
    - Extensor carpi radialis brevis,
    - Extensor carpi ulnaris
    - Extensor digitorum
  - Flexors - Flexor carpi radialis
    - Flexor carpi ulnaris
    - Flexor digitorum superficialis,
    - Flexor digitorum profundus
    - Flexor pollicis longus

Statistical Analysis

The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using IBM SPSS (SPSS Inc., IBM Corporation, NY, USA) Statistics Version 25 for Windows software program. Descriptive statistics included computation of percentages, means and standard deviations. The data were checked for normality before statistical analysis using Kolmogorov Simonov test. The Mann–Whitney U-test (for quantitative data to compare two independent observations) was applied. The chi square test was used for qualitative data comparison of all clinical indicators. Level of significance was set at $P \leq 0.05$.

RESULT

Table 1: Gender distribution

There were 10 males and 5 females for Dry needling and Conventional therapy and there were 9 males and 6 females for Sham acupuncture and Conventional therapy. The duration of the treatment was for 2 days for 5 weeks.

			Gender		Total
			Female	Male	
Groups	Dry needle	N	5	10	15
		%	33.3%	66.7%	100.0%
	Sham acupuncture	N	6	9	15
		%	40.0%	60.0%	100.0%
Total		N	11	19	30
		%	36.7%	63.3%	100.0%

P value=0.705

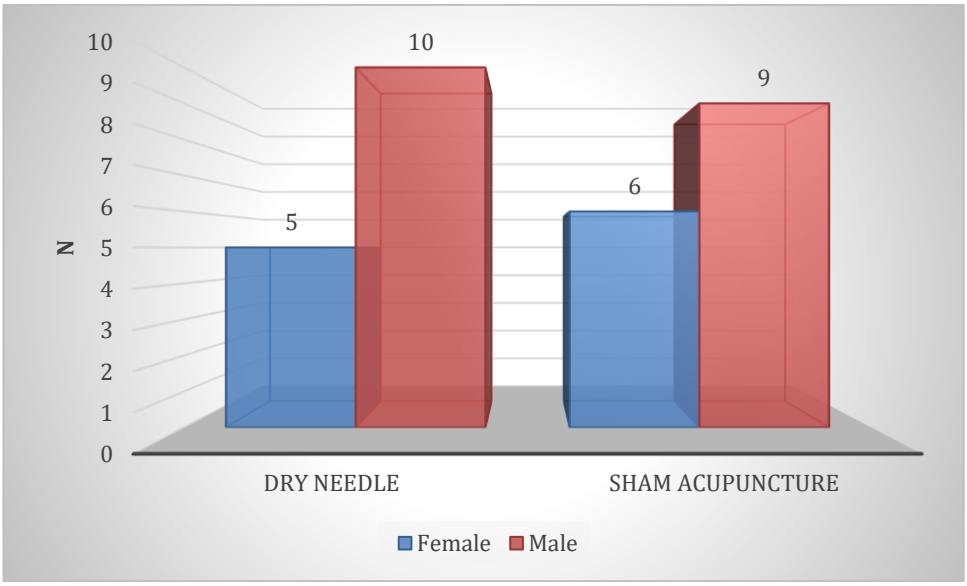


FIG [1] (GENDER DISTRIBUTION)

Table 2: Age distribution

	Mean	Std. Deviation	Minimum	Maximum	P value
Dry needle	59.33	9.890	43	77	0.007 (S)
Sham acupuncture	48.80	9.858	25	61	

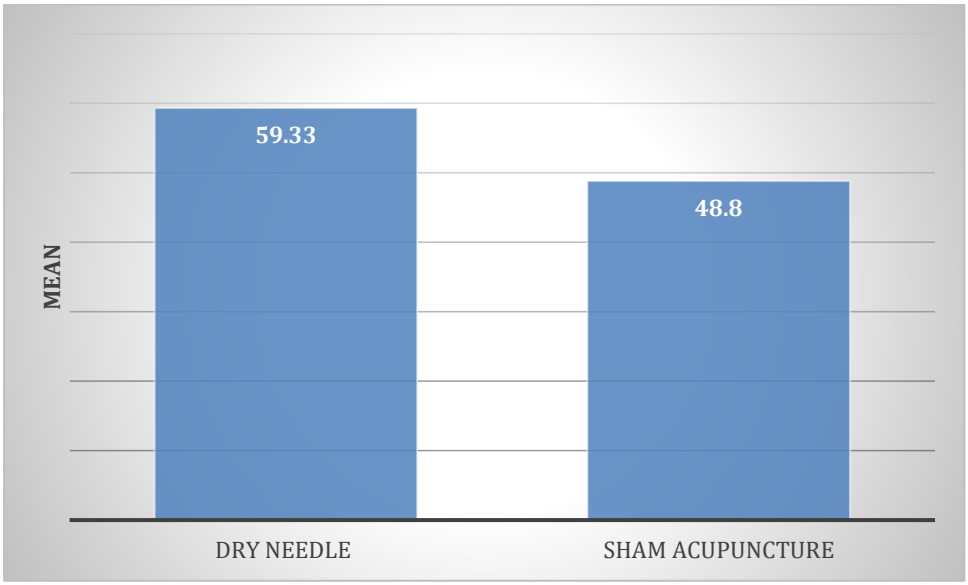


FIG [2] (AGE DISTRIBUTION)

Table 3: Affected muscle group

			Affected Muscle Group		Total
			Extensors	Flexors	
Groups	Dry needle	N	5	10	15
		%	33.3%	66.7%	100.0%
	Sham acupuncture	N	4	11	15
		%	26.7%	73.3%	100.0%
Total		N	9	21	30
		%	30.0%	70.0%	100.0%

P value=0.69

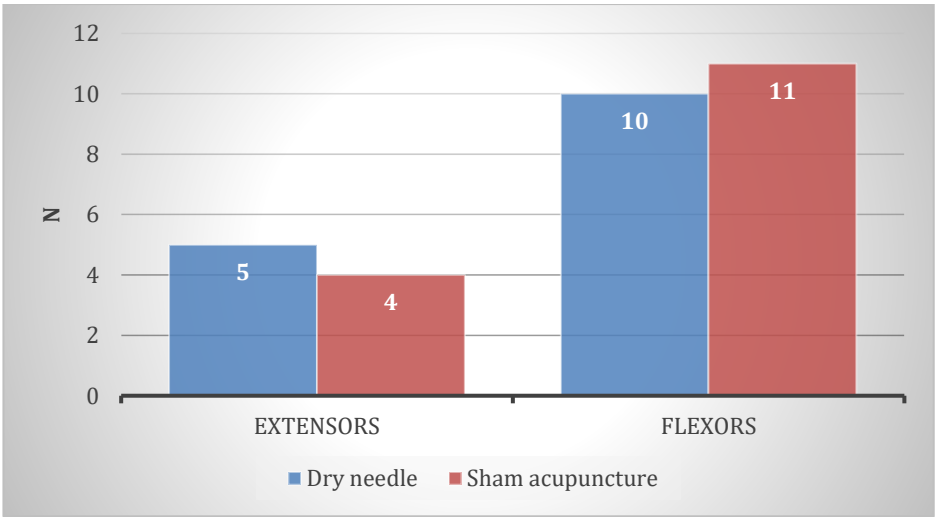


FIG [3] (AFFECTED MUSCLE GROUP)

Table 4: Side affected.

			Side		Total
			Bilateral	Unilateral	
Groups	Dry needle	N	4	11	15
		%	26.7%	73.3%	100.0%
	Sham acupuncture	N	3	12	15
		%	20.0%	80.0%	100.0%
Total		N	7	23	30
		%	23.3%	76.7%	100.0%

P value=0.66

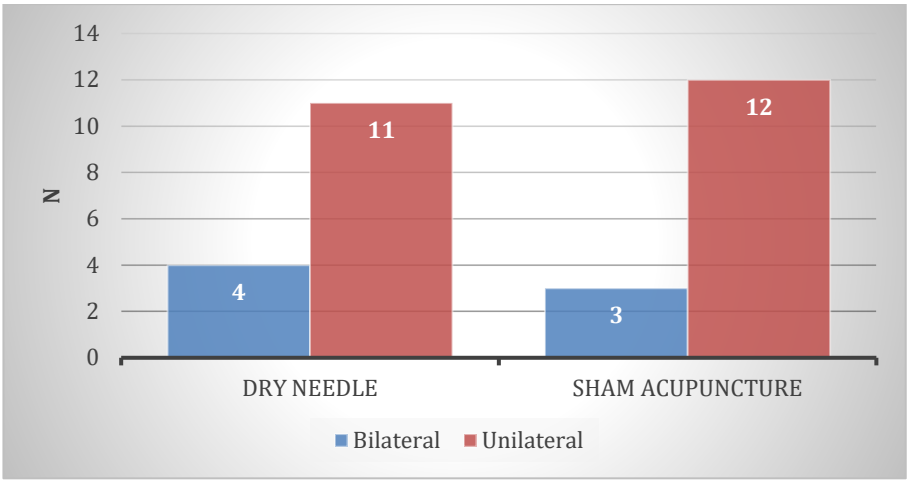


FIG [4] (QUANTITY OF THE SIDE AFFECTED)

Table 5: Affected side

FIG [5] (AFFECTED SIDE)

			Affected side			Total
			Left	Left/Right	Right	
Groups	Dry needle	N	5	4	6	15
		%	33.3%	26.7%	40.0%	100.0%
	Sham acupuncture	N	3	3	9	15
		%	20.0%	20.0%	60.0%	100.0%
Total		N	8	7	15	30
		%	26.7%	23.3%	50.0%	100.0%

P value=0.53

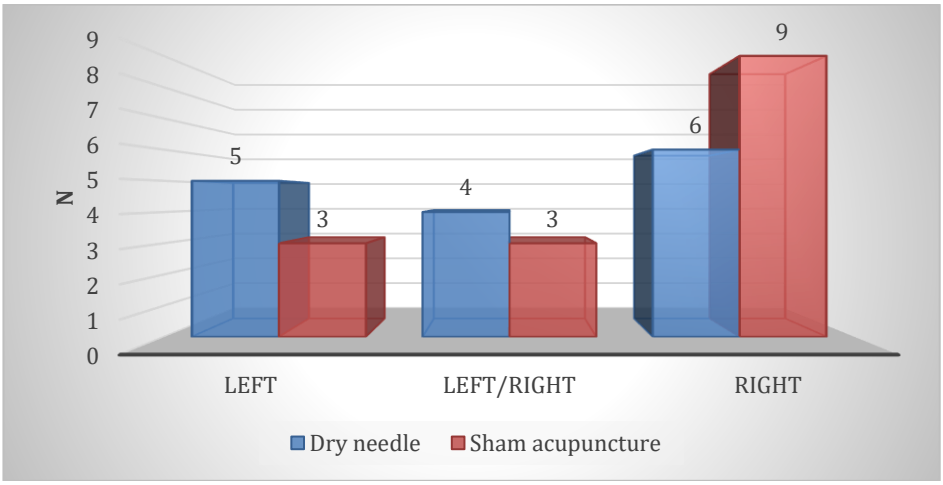


FIG [5] (AFFECTED SIDE)

Table 6: Pre-assessment of spasticity [left side]

			Pre (left)					Total
				1	1+	2	3	
Groups	Dry needle	N	6	3	4	1	1	15
		%	40.0%	20.0%	26.7%	6.7%	6.7%	100.0%
	Sham acupuncture	N	9	2	0	4	0	15
		%	60.0%	13.3%	0.0%	26.7%	0.0%	100.0%
Total		N	15	5	4	5	1	30
		%	50.0%	16.7%	13.3%	16.7%	3.3%	100.0%

P value=0.107

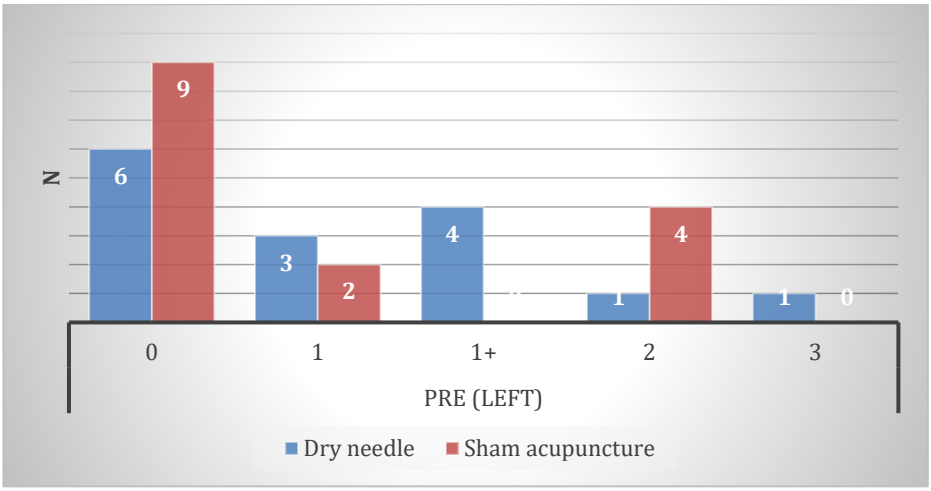


FIG [6] (PRE-ASSESSMENT OF SPASTICITY [LEFT SIDE])

Table 7: Pre-assessment of spasticity [Right side]

			Pre (right)					Total
				1	1+	2	3	
Groups	Dry needle	N	5	1	4	3	2	15
		%	33.3%	6.7%	26.7%	20.0%	13.3%	100.0%
	Sham acupuncture	N	3	2	2	6	2	15
		%	20.0%	13.3%	13.3%	40.0%	13.3%	100.0%
Total		N	8	3	6	9	4	30
		%	26.7%	10.0%	20.0%	30.0%	13.3%	100.0%

P value=0.64

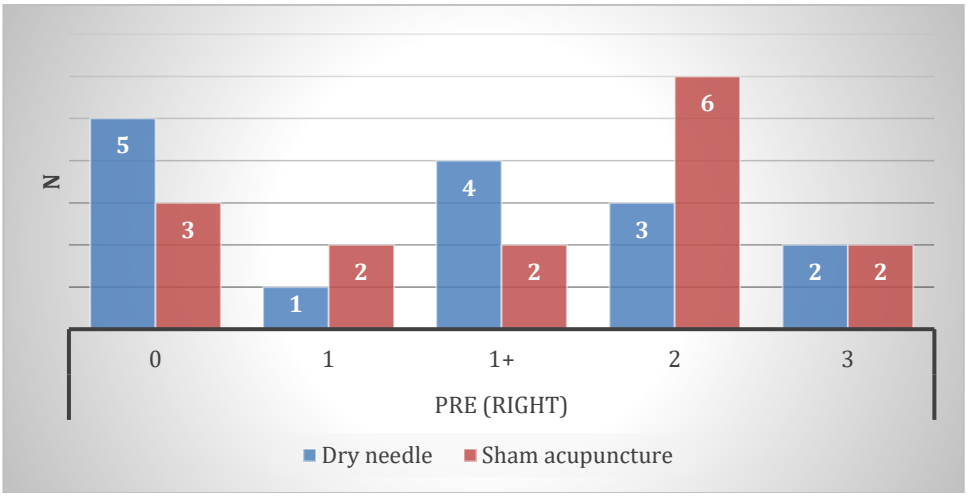


FIG [7] (PRE-ASSESSMENT OF SPASTICITY [RIGHT SIDE])

Table 8: Post-assessment of spasticity [left side]

			Post (left)					Total
			0	1	1+	2	4	
Groups	Dry needle	N	7	7	0	0	1	15
		%	46.7%	46.7%	0.0%	0.0%	6.7%	100.0%
	Sham acupuncture	N	10	1	2	2	0	15
		%	66.7%	6.7%	13.3%	13.3%	0.0%	100.0%

Total	N	17	8	2	2	1	30
	%	56.7%	26.7%	6.7%	6.7%	3.3%	100.0%

P value=0.04 (S)

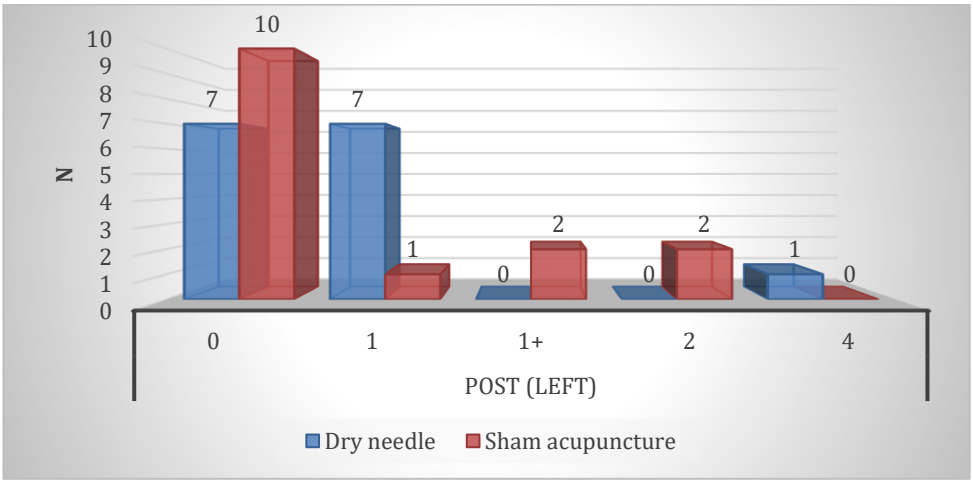


FIG [8] (POST-ASSESSMENT OF SPASTICITY [LEFT SIDE])

Table 9: Post-assessment of spasticity [Right side]

			Post (right)					Total
			0	1	1+	2	3	
Groups	Dry needle	N	5	4	4	2	0	15
		%	33.3%	26.7%	26.7%	13.3%	0.0%	100.0%
	Sham acupuncture	N	3	3	7	1	1	15
		%	20.0%	20.0%	46.7%	6.7%	6.7%	100.0%
Total		N	8	7	11	3	1	30
		%	26.7%	23.3%	36.7%	10.0%	3.3%	100.0%

P value=0.59

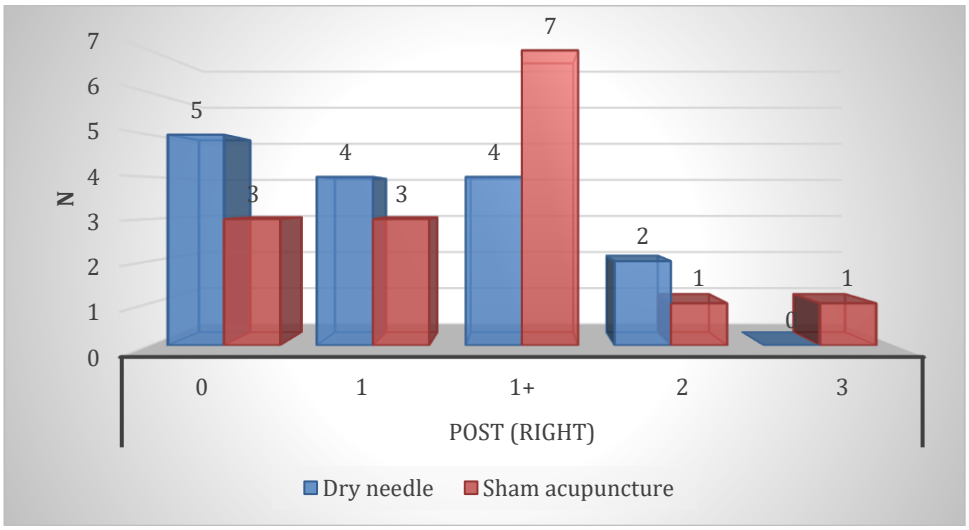


FIG [9] (POST-ASSESSMENT OF SPASTICITY [RIGHT SIDE])

Table 10: Group dry needling (Left side)

			Grade Of Spasticity						Total
				1	1+	2	3	4	
Left	Pre	N	6	3	4	1	1	0	15
		%	40.0%	20.0%	26.7%	6.7%	6.7%	0.0%	100.0%
	Post	N	7	7	0	0	0	1	15
		%	46.7%	46.7%	0.0%	0.0%	0.0%	6.7%	100.0%
Total		N	13	10	4	1	1	1	30

	%	43.3%	33.3%	13.3%	3.3%	3.3%	3.3%	100.0%

P value=0.12

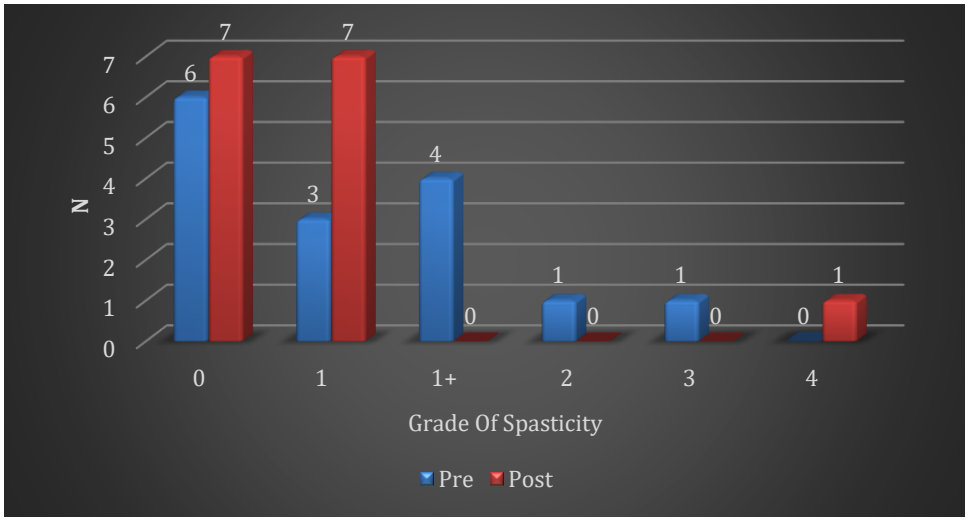


FIG [10] (GROUP DRY NEEDLING [LEFT SIDE])

Table 11: Group dry needling (right side)

			Grade Of Spasticity					Total
				1	1+	2	3	
Right	Pre	N	5	1	4	3	2	15
		%	33.3%	6.7%	26.7%	20.0%	13.3%	100.0%
	Post	N	5	4	4	2	0	15
		%	33.3%	26.7%	26.7%	13.3%	0.0%	100.0%
Total		N	10	5	8	5	2	30
		%	33.3%	16.7%	26.7%	16.7%	6.7%	100.0%

P value=0.406

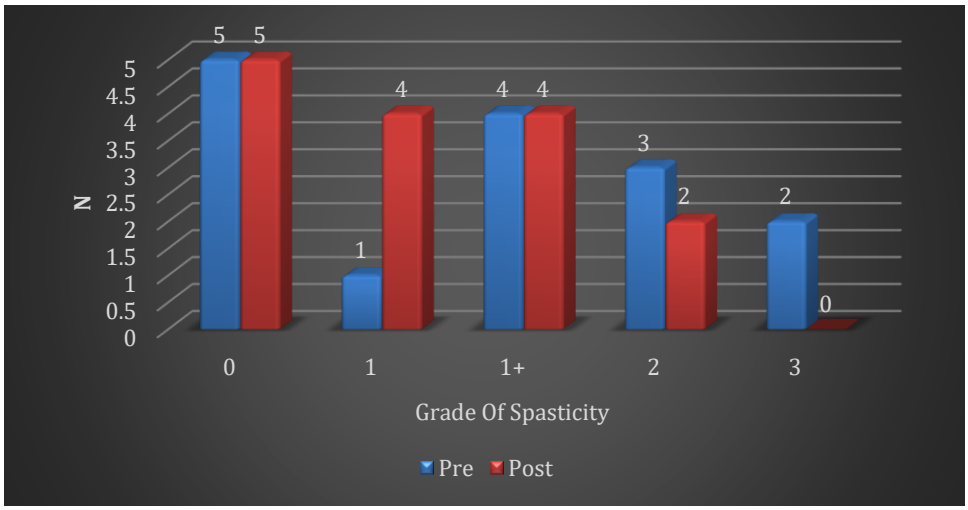


FIG [11] (GROUP DRY NEEDLING [RIGHT SIDE])

Table 12: Group Sham Acupuncture (Left side)

			Grade Of Spasticity				Total
				1	1+	2	
Left	Pre	N	9	2	0	4	15
		%	60.0%	13.3%	0.0%	26.7%	100.0%
	Post	N	10	1	2	2	15
		%	66.7%	6.7%	13.3%	13.3%	100.0%
Total		N	19	3	2	6	30
		%	63.3%	10.0%	6.7%	20.0%	100.0%

P value=0.38

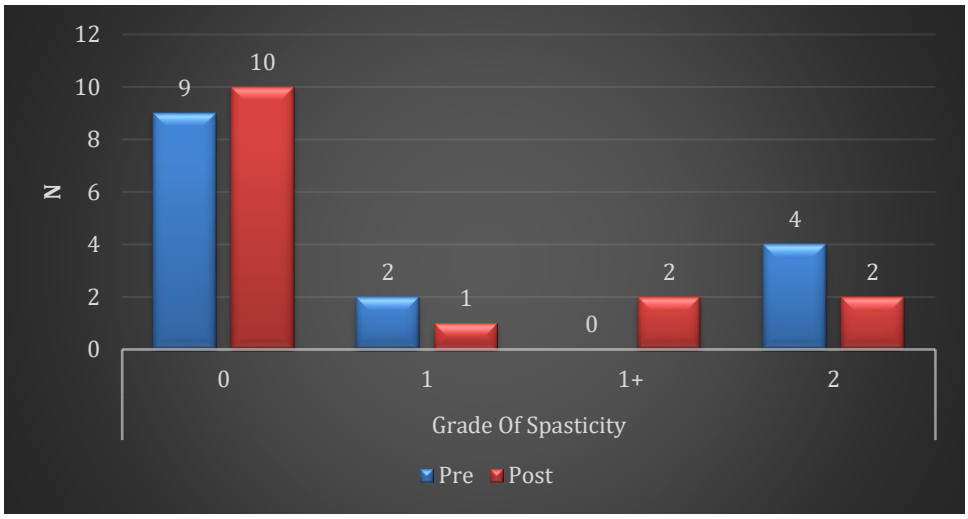


FIG [12] (GROUP SHAM ACUPUNCTURE [LEFT SIDE])

Table 13: Group sham acupuncture (right side)

			Grade Of Spasticity					Total
				1	1+	2	3	
Right	Pre	N	3	2	2	6	2	15
		%	20.0%	13.3%	13.3%	40.0%	13.3%	100.0%
	Post	N	3	3	7	1	1	15
		%	20.0%	20.0%	46.7%	6.7%	6.7%	100.0%
Total		N	6	5	9	7	3	30
		%	20.0%	16.7%	30.0%	23.3%	10.0%	100.0%

P value=0.14

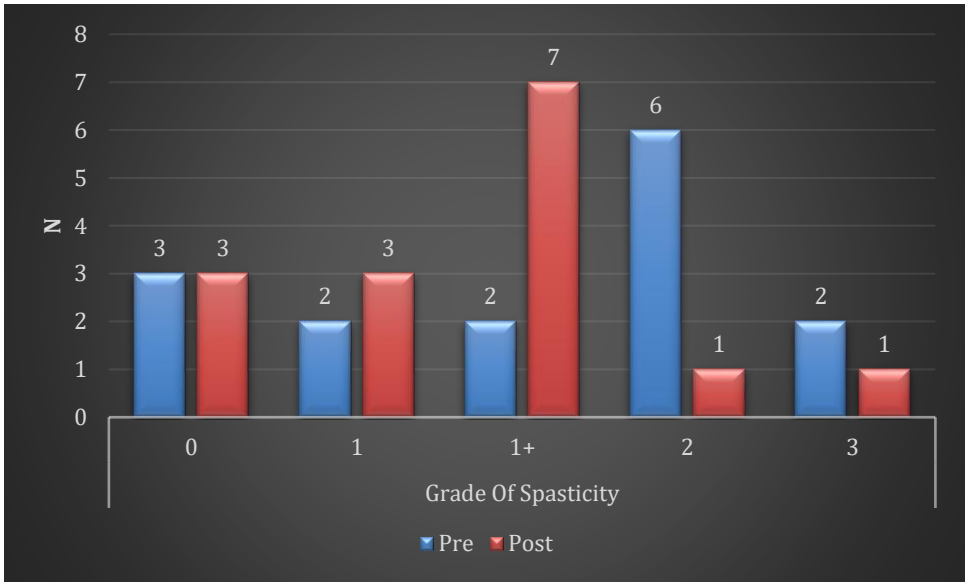


FIG [13] (GROUP SHAM ACUPUNCTURE [RIGHT SIDE])

DISCUSSION

The management of spasticity in post-stroke patients poses a challenging aspect of stroke rehabilitation due to its multifactorial nature and diverse clinical manifestations. This comparative study aimed to evaluate the effectiveness of dry needling versus sham acupuncture in addressing

spasticity, pain, and motor function in post-stroke survivors. The results of the study provide a valuable insight into the comparative effectiveness of dry needling versus sham acupuncture in the management of spasticity among post-stroke survivors. Our analysis revealed significant improvements in spasticity grades within both intervention groups over the course of the 5-week intervention period.

Stroke is a complex neurological condition characterised by diverse aetiologies and clinical features [2]. Early onset of spasticity following stroke, as observed in prospective observational trials [6], highlights the critical need for prompt and targeted rehabilitation interventions to mitigate its detrimental impact on functional outcomes and quality of life in affected individuals.

The gender distribution and age demographics of our study population are consistent with previous research on stroke demographics [2, 5]. Stroke incidence tends to be higher in males, and age is a significant risk factor for stroke development. Our findings underscore the importance of considering demographic factors in stroke rehabilitation research to ensure the generalisability of study findings to diverse patient populations. The most commonly affected muscle group among participants in both intervention groups was the flexor group, which is consistent with the literature on post-stroke spasticity patterns [6]. This suggests that interventions targeting flexor spasticity may be particularly beneficial in improving functional outcomes and quality of life for post-stroke survivors. The unilateral distribution of spasticity in the majority of participants highlights the asymmetrical nature of stroke-related impairments, with a higher proportion of individuals experiencing spasticity on their dominant side. This aligns with previous research indicating that stroke often leads to unilateral motor deficits, affecting activities of daily living and functional independence [2, 7].

Intra-group analysis using paired t-tests demonstrated statistically significant improvements in spasticity grades for both the dry needling and sham acupuncture groups. Notably, the effect of dry needling, when combined with conventional physiotherapy, was found to be extremely significant, indicating robust improvements in spasticity, pain, and motor function among participants. Conversely, the effect of sham acupuncture, when combined with conventional physiotherapy, was comparatively less significant, suggesting a limited impact on spasticity reduction and functional outcomes.

The findings build upon existing evidence regarding the efficacy of dry needling in post-stroke rehabilitation. The findings corroborate existing evidence regarding the potential efficacy of dry needling in post-stroke rehabilitation with a systematic review and meta-analysis demonstrated by César Fernández-de-las-Peñas et Al which result in favourable outcomes in terms of spasticity reduction, pain alleviation, and improvements in motor function following dry needling interventions. These findings underscore the importance of considering dry needling as a valuable adjunctive therapy in comprehensive stroke rehabilitation programs as measured by standardised clinical assessment tools such as the Modified Ashworth Scale or the Modified Tardieu Scale. However, further research is warranted to explore the underlying mechanisms and long-term effects of these interventions, as well as to identify optimal treatment strategies for post-stroke spasticity management.

A similar study done by James Dunning et al , the results of which are consistent the study demonstrating the effectiveness of manual therapy interventions, such as dry needling, in reducing spasticity and improving motor function in stroke patients. Furthermore, our study observed improvements in pain intensity and motor function following both dry needling and sham acupuncture treatments. These improvements may be attributed to various mechanisms, including the release of endogenous opioids, modulation of neural pathways, and enhanced circulation to affected muscles.

While the potential benefits of dry needling are evident, the comparative efficacy of this intervention versus sham acupuncture warrants careful consideration, particularly in light of the ongoing debate surrounding placebo effects in acupuncture research. Mechanistic studies exploring biomarkers and neural pathways associated with sham acupuncture offer valuable insights into its potential therapeutic mechanisms.

Furthermore, our study sheds light on the distribution and severity of spasticity among post-stroke survivors. The most commonly affected muscle group among participants in both intervention groups was the flexor group, which is consistent with the literature on post-stroke spasticity patterns [Wissel J et Al]. This suggests that interventions targeting flexor spasticity may be particularly beneficial in improving functional outcomes and quality of life for post-stroke survivors.

Zacarías Sánchez-Mila Et al studies state that Sham acupuncture, despite lacking the physiological mechanisms of true acupuncture, has been found to elicit comparable therapeutic benefits in certain contexts. This raises important questions regarding the specificity of needling techniques and the potential role of non-specific effects, such as expectancy and therapeutic context, in influencing treatment outcomes. However, the translation of these mechanistic findings into clinical practice and the implications for patient care require further elucidation.

Shima Ghannadi et al also imply that importantly, the comparable efficacy of sham acupuncture suggests that non-specific effects, such as patient expectations and therapeutic context, may contribute significantly to treatment outcomes.

The comparative effectiveness of dry needling versus sham acupuncture raises important considerations for clinical practice. While dry needling may offer distinct physiological benefits, such as trigger point release and neuromuscular modulation, the therapeutic equivalence observed with sham acupuncture highlights the potential role of non-specific effects in influencing treatment outcomes. Therefore, clinicians should carefully weigh the relative benefits and risks of each intervention, taking into account patient preferences, clinical presentation, and treatment goals within the broader context of stroke rehabilitation.

All interventions significantly improved the grades of spasticity compared to baseline parameters. Furthermore, most of the studies presented with similar results where both the interventions show results, but dry needling showed considerable better results.Collaborative efforts between physiotherapists, rehabilitation specialists, and other healthcare professionals are essential for optimising treatment strategies and delivering holistic care tailored to the individual needs of post-stroke survivors.

CONCLUSION

In conclusion, our study provides valuable insights into the comparative effectiveness of dry needling versus sham acupuncture in managing spasticity in post-stroke survivors. While dry needling shows promise as an effective intervention for managing spasticity in post-stroke survivors, its comparative effectiveness against sham acupuncture raises important questions that warrant further investigation. While both interventions demonstrate efficacy in reducing spasticity, pain, and improving motor function, the therapeutic equivalence observed with sham acupuncture underscores the importance of considering non-specific effects in treatment outcomes.

Declaration by Authors

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