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Effects of dry needling on function, hypertonia and quality of life in chronic stroke: a randomized clinical trial

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Abstract

Background: Persons with stroke commonly have impairments associated with a reduction in functionality. Motor impairments are the most prevalent, causing an impact on activities of daily life.

Objective: The aim of this study was to evaluate the effect of a session of dry needling (DN) applied to the upper extremity muscles on the sensorimotor function, hypertonia, and quality of life of persons with chronic stroke.

Methods: A randomized, sham-controlled clinical trial was performed. Participants were randomly assigned into an intervention group that received a single session DN in the biceps brachii, brachialis, flexor digitorum superficialis and profundus, extensor digitorum, adductor pollicis and triceps brachii muscles, or into a control group that received the same treatment but with a sham DN intervention. Treatment outcomes included the Fugl–Meyer Assessment Scale for the upper extremity, the Modified Modified Ashworth Scale, and the EuroQol-5D questionnaire. Measurements were carried out before, immediately after, and 14 days after intervention.

Results: Twenty-three persons participated in the study. Significant differences between groups were observed after the intervention in the total wrist–hand motor score ($p = 0.023$) and sensorimotor score ($p = 0.022$), for hypertonia in the elbow extensors both after treatment ($p = 0.002$) and at follow-up ($p = 0.018$), and in quality of life at follow-up ($p = 0.030$).

Conclusions: A single session of DN improved total wrist–hand motor function and total sensorimotor function in persons with chronic stroke immediately after treatment, as well as quality of life 2 weeks after treatment.

Trial registration number: NCT03546517 (ClinicalTrials.gov)

Keywords

chronic stroke, dry needling, hypertonia, quality of life, upper extremity function

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Introduction

Stroke represents one of the most common causes of disability with regard to its impact on functional limitations.[1] In addition, because of the aging population, the absolute number of strokes is expected to increase in the coming years.[2] Upper motor neuron lesions may result in positive symptoms like spasticity and negative symptoms like weakness or loss of dexterity.[3] Both result in some degree of functional limitation affecting the individual's quality of life (QoL),[4] as well as somatosensory impairments, also related to activity limitations.[5]

Currently, upper extremity rehabilitation protocols for functional improvement usually combine different physiotherapy

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approaches with medical treatments, such as oral antispastic drugs or botulinum toxin type A (BTX-A) infiltration,[6] or other pharmacological interventions. With respect to non-pharmacological treatments, dry needling (DN) is increasingly used to treat neurologic conditions like cerebral palsy,[7] spinal cord injury,[8] and stroke.[9–12] A single session of DN has shown to be effective at decreasing spasticity, improving balance, increasing range of motion (ROM)[10] and decreasing hemiparetic shoulder pain[9] in persons with stroke. Furthermore, the addition of three to six sessions of a specific DN treatment to a standard physiotherapy treatment appeared to lead to a reduction in spasticity,[11,12] increase in passive[11] and active[13] ROM and improvements in gait speed, functional mobility and independence.[11] It is known that DN acts on the dysfunctional motor endplate,[14] like BTX-A, although DN provokes a mechanical disruption, while BTX-A provokes a chemical denervation. Besides, although DN may induce side effects common to any minimally invasive procedure (e.g. hematoma), it does not have the other adverse effects that are characteristic of BTX-A, such as undesirable weakness in the short term, or anatomic denervation, muscle atrophy and immune resistance in the long term.[15]

However, current scientific evidence related to the effectiveness of DN is limited and, in some cases, controversial, which may partly be due to the fact that blinding in needling studies is an ongoing challenge, but of key importance for the accuracy of the outcomes.[16] To our knowledge, there has been no sham-controlled randomized clinical trial (RCT) to date that has investigated the effectiveness of DN in terms of upper extremity function in persons with chronic stroke.[16] Therefore, the main aim of this study was to evaluate the therapeutic effect of DN on upper extremity motor function (primary endpoint), QoL and hypertonia in individuals with chronic stroke after DN and 2 weeks after intervention.

Methods

Design

A randomized sham-controlled clinical trial was designed to analyze the therapeutic effect of DN. This study followed the CONSORT guidelines. All participants signed an informed consent form before their participation. The study was approved by the Ethics Committee of Aragon (reference no. PI16/0160) and followed the clinical practice principles of the Declaration of Helsinki. The trial was prospectively registered at http://www.clinicaltrials.gov (registration no. NCT03546517) on 6 June 2018.

Participants

Participants were recruited from the Aragon Association of Stroke in Zaragoza (Spain). Inclusion in the study was based on the following criteria: (1) age 40–90 years with hemiparesis resulting from stroke of more than 6 months evolution based on a diagnosis confirmed by a neurologist; (2) ability to follow instructions and reply to assessment questionnaires; and (3) presence of hypertonia $\geqslant 1$ in at least one of the muscles of the upper extremity evaluated according to a Modified Modified Ashworth Scale (MMAS) score. Individuals were excluded if they had: (1) grade 0 (no increase in muscle tone) or 4 (rigidity) hypertonia according to the MMAS; (2) previous treatment with BTX-A or other pharmacological agents for hypertonia at any time, or in the previous 6 months; (3) other concomitant neurodegenerative conditions; (4) fear of needles; (5) any contraindication to treatment with DN; or (6) cognitive decline (score $\leqslant 24$ points on mini-mental examination test). The withdrawal criteria consisted of the failure to attend assessments.

Treatment allocation

Participants were randomized into two groups: the intervention group (IG) and the sham group (SG). Simple randomization was performed with a 1:1 allocation ratio using an online research randomizer sequence generator (http://www.randomizer.org) by a therapist who was independent of the study. The allocation was concealed until interventions were assigned. The physiotherapist, who performed the interventions, opened each sealed envelope and applied the treatment following the random assignments.

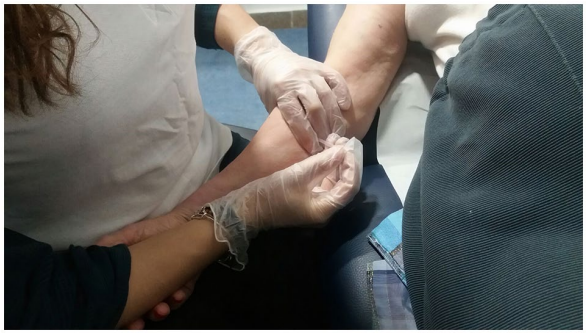
Evaluation

The physiotherapist performing the treatments palpated the muscles to assess myofascial trigger points (MTrPs) in the selected muscles for the study. The MTrPs for treatment were identified manually following the published diagnostic criteria for persons with neurological problems as follows[17]: (1) highest degree of tension (in muscles that are accessible); (2) nodular zone within the band or more sensitive area, if this exists; (3) assessment of movement and function of the patient; (4) restriction of ROM, increase in resistance to passive movement or triggering of a myotatic reflex (MR), or other reflexes.

DN treatment

Participants in the IG received a single-session treatment of DN on the upper extremity muscles using the DNHS® technique, following the application criteria for persons with neurological disorders. The DNHS® technique was applied on the most nodular area of the MTrP, with the muscle placed in a position of sub-maximal stretch[12,17] and sought to elicit a local twitch response (LTR), as this is widely considered to represent confirmation of having needled an MTrP. The application of the DN was performed with repeated needle insertions in the muscle at approximately 1 Hz, until all LTRs disappeared or substantially decreased. Treatment was discontinued if the participant asked to stop

Figure 1. Application of the DNHS® technique.



because of intolerable pain. The muscles were always treated in the same order: (1) biceps brachii and brachialis; (2) flexor digitorum superficialis and profundus; (3) extensor digitorum; (4) adductor pollicis; and (5) triceps brachii. These muscles were consistent with the typical hemiparetic pattern of persons with chronic stroke.

DN needles with a guide tube were used (APS®, Agupunt, Spain). These needles are similar to those used for acupuncture; they are filiform, solid, with a tapered tip and non-beveled. The caliber of the needles was 0.25 mm and the length was either 25 or 40 mm, depending on the muscle characteristics. The participants were treated in the supine position (Figure 1). There was only one insertion point per muscle. LTR achievement was key to confirm that MTrPs had been treated, especially in the case of deep muscles, as it was not possible to directly palpate them.

Sham DN treatment

The SG received the same treatments with sham DN (considered a non-active treatment for MTrPs, as they were neither reached nor needled).[18] Participants were blinded to the intervention using sham needles, which were only placed superficially at the level of the skin, enough for participants to perceive a needle prick but without going beyond the skin layer. Subsequently, the physiotherapist mimicked needle manipulation. The same protocol and temporalization were followed as in the IG. Apart from the needle blinding with a sham needle, the physiotherapist performing the interventions placed high importance on the entire intervention experience, as cognitive influences that extend beyond mimicking of tactile sensations are recommended to create a believable simulation.[19]

Both treatments and assessments were always performed at the same time and site to maximally standardize participant conditions. Each session lasted about 60 min. All participants were treated by a skilled physiotherapist (SC) trained in DN who was not blinded, and were evaluated by another physiotherapist (NB) who was blinded. None of the patients had previously received DN treatment.

Outcome measures

The study lasted 3 weeks. All measurements were assessed before, immediately after and 2 weeks after the intervention (follow-up test), except for the three-level version of the EuroQol five-dimension questionnaire (EQ-5D-3L), which was administered before and 2 weeks after treatment only.

The primary outcome measurement in this study was the Fugl–Meyer Assessment Scale, used to assess sensorimotor function in the upper extremity (FMA-UE). This scale assesses reflexes; synergistic movement patterns; wrist, hand, and grasp function; coordination; passive joint motion; and sensation. The FMA-UE is highly recommended as a clinical and research tool to evaluate changes in motor impairment following stroke, and it has a high interrater reliability (intraclass correlation coefficient (ICC) 0.98 to 0.99) for the total score and subscale levels.[20,21] The FMA-UE assessments are scored on a three-point ordinal scale (0–2), in which a higher score indicates superior results. The motor assessment (33 items; range of scores: 0–66) measures voluntary upper extremity movement. The sensory assessment (6 items; range of scores: 0–12) measures upper extremity sensation.[20] The global assessment (39 items; range of scores: 0–78) measures the sensorimotor score.

Secondary outcomes included the MMAS and the EQ-5D-3L. MMAS was employed for the assessment of hypertonia and was noted to have been widely used in the literature reviewed, despite its subjective component.[22] It is scored on an ordinal scale from 0 to 4 as follows: 0 = no increase in muscle tone; 1 = slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the ROM when the affected part(s) is moved in flexion/extension; 2 = marked increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of ROM, but affected part(s) easily moved; 3 = considerable increase in muscle tone, passive movement difficult; and 4 = affected part(s) rigid in flexion or extension.[10] The MMAS has exhibited good intra- and interrater reliability for assessing spasticity in persons who have experienced stroke.[23] Flexor and extensor muscles of the elbow and wrist were evaluated by assessing the resistance when the affected muscle group was passively stretched.[24]

The EQ-5D-3L was introduced in 1990 by the EuroQol Group and consists of two subscales: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system comprises five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each dimension has three levels: no problems, some problems, and extreme problems (labeled 1–3). The respondent is asked to indicate her or his health state according to the most appropriate statement. The digits for the five dimensions can be combined into a five-digit number that describes the patient's health state. The EQ

VAS records the patient's self-rated health on a numerical vertical health subscale (VAS) of 100 points, which evaluates health from 0 (worst health imaginable) to 100 (best health imaginable). The EQ VAS can be used as a quantitative measure of health outcome that reflects the patient's own assessment.[25,26]

Sample size

The sample size calculation was performed with G*Power 3.1 (Heinrich-Heine University Düsseldorf, Germany). The calculations were based on a standard deviation (SD) of 5.1 points, a between-group difference of 7.25 points (representing the minimal detectable change (MDC) of the FMA-UE),[27] an alpha level of 0.05, a β level of 20%, and a desired power of 80%. The estimated sample size was at least nine participants per group. Considering a drop-out rate of 20%, a total sample of 22 participants was estimated to be required.

Statistical analysis

Data were analyzed with the Statistical Package for the Social Sciences (SPSS) version 25.0 (IBM Corporation, Armonk, NY, USA). Data are presented as mean ± SD. Median with interquartile range and 95% confidence intervals (CIs) were calculated for each variable. The Shapiro–Wilk test was performed to determine normal data distribution. Independent Student's t-tests for parametric data, Mann–Whitney U tests for nonparametric data and Chi-square tests for categorical variables were performed to compare the baseline measurements between the two groups. Differences between the data of "post-test"/"follow-up" minus "pre-test" of both groups were compared using the independent Student's t-test or Mann–Whitney U test when appropriate. Student's t-tests for paired samples or Wilcoxon tests were applied to highlight within-group differences. $p < 0.05$ was considered as statistically significant.

Between-group and within-group effect sizes, depending on parametric or nonparametric data, were calculated as the difference between the data of "post-test"/"follow-up" minus "pre-test." An effect size of less than 0.2 was considered to reflect a negligible mean difference; between 0.2 and 0.5, a small difference; between 0.5 and 0.8, a moderate mean difference; and 0.8 or greater, a large difference.[28]

Results

A total of 27 participants with chronic stroke were screened for eligibility between June and September 2018. A flow diagram of participants recruited to the study is presented in Figure 2. Twenty-three participants aged 60.87 ± 15.16 years (mean ± SD; 61% male) satisfied the eligibility criteria and agreed to participate. The reasons for ineligibility can be found in the flow diagram (Figure 2). While 11 participants were randomly allocated to the IG, 12 were allocated to the SG. Table 1 shows the baseline participant characteristics, with no statistically significant differences between groups. All participants completed the treatment intervention. No participant reported any adverse effects after the interventions.

Changes in upper extremity function

There were statistically significant differences between groups for the total wrist–hand motor score after the intervention ($p = 0.023$; mean difference (MD) 2.12, 95% CI 0.39 to 3.85), with a moderate effect size ($d = 0.476$). At follow-up, these improvements showed a tendency toward a statistically significant difference ($p = 0.057$; MD 2.56, 95% CI −0.09 to 5.19), with a greater effect size ($d = 0.893$), although they did not reach formal statistical significance ($p < 0.05$). With respect to the total sensorimotor score, which is the global score after analyzing the effect on the total motor score and the total sensory score, there were also statistically significant differences between groups after the intervention ($p = 0.022$; MD 2.98, 95% CI 0.81 to 5.14), with a moderate effect size ($d = 0.477$), but these improvements were not maintained 2 weeks after the treatment (Table 2).

Changes in hypertonia

Regarding hypertonia, there were statistically significant differences between groups only for the elbow extensors after the intervention with a moderate effect size ($p = 0.002$; MD −0.74; 95% CI −1.16 to −0.31; $d = 0.644$), and at follow-up with a small effect size ($p = 0.018$; MD −0.65; 95% CI −1.16 to −0.14; $d = 0.492$) (Table 3).

Changes in QoL

Regarding the QoL, there were statistically significant differences between groups 2 weeks after the intervention ($p = 0.03$; MD 0.09; 95% CI −0.03 to 0.21) with a small effect size ($d = 0.449$). The IG exhibited statistically significant differences 2 weeks after DN treatment ($p = 0.012$; MD 0.09; 95% CI −0.02 to 0.19) with a moderate effect size ($d = 0.760$). The EQ VAS did not reveal differences in either the inter- or intragroup analysis (Table 4).

Discussion

This study analyzed the effects of a single session of DN on upper extremity function and hypertonia, as well as on QoL, in a group of persons with chronic stroke, immediately after and 2 weeks after the treatment. To our knowledge, this study is the first to evaluate the effect of DN on upper extremity function in persons with chronic stroke using a sham needling group as the control. Recent studies have analyzed the effects of DN on upper extremity

Figure 2. Flow chart of study participants.

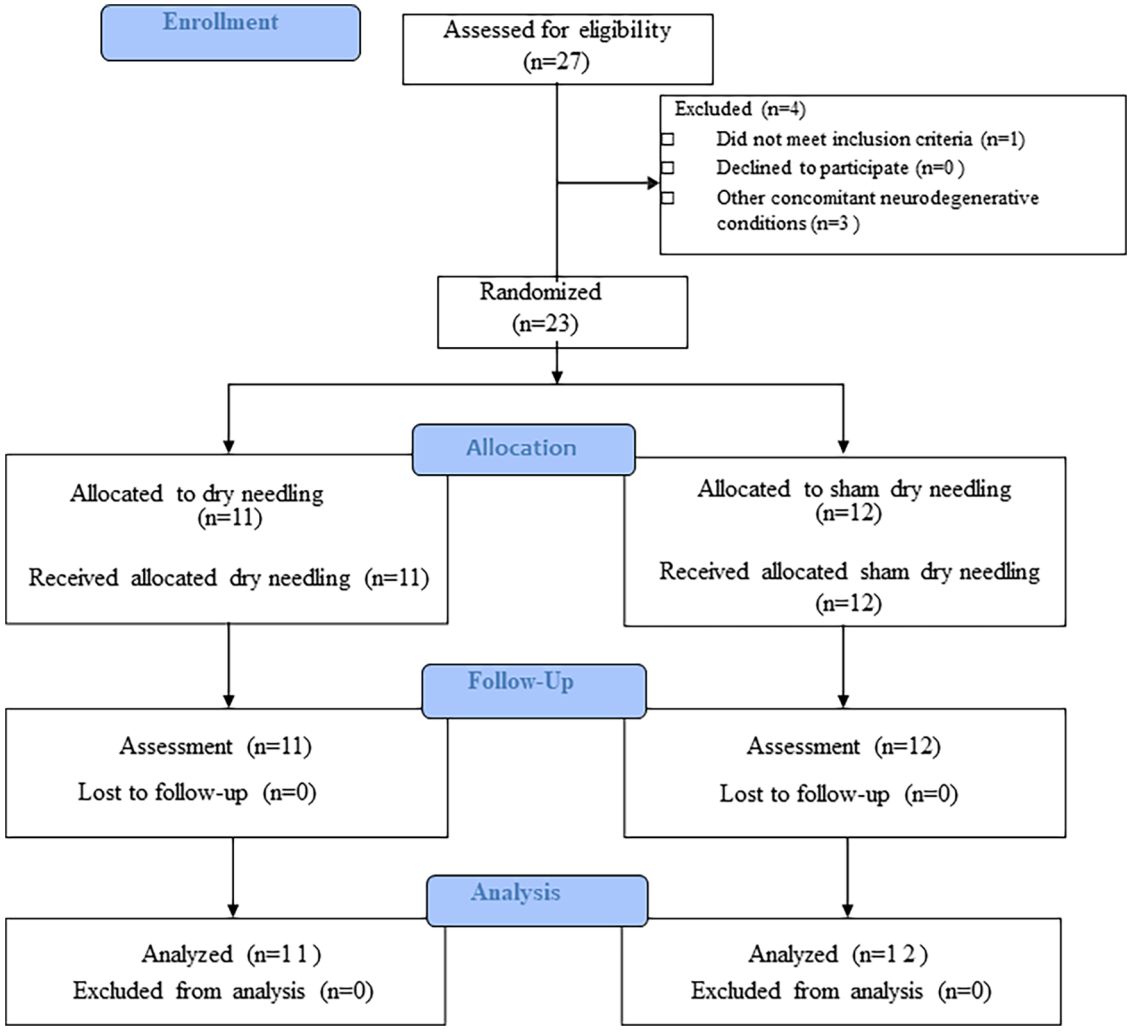


Table 1. Baseline characteristics.

Characteristics	Intervention group (n = 11)	Sham group (n = 12)	p value
Age (years)[a]	63.6 ± 9.0	58.3 ± 19.3	0.4
Gender (% male)	45%	75%	0.1
Affected side (right/left)[b]	7/4	6/6	0.5
Type of stroke (hemorrhagic/ischemic)	7/4	8/4	0.9
Years after stroke[a]	7.5 ± 5.9	4.6 ± 4.0	0.1
Height (m)[a]	167 ± 12.3	170.4 ± 8.7	0.4
Weight (kg)[a]	78.3 ± 12.5	73.7 ± 11.8	0.4
Body mass index (kg/m^2)[a]	28.0 ± 2.8	25.2 ± 2.6	0.1

[a]Values are presented as mean ± standard deviation.
[b]Only one side affected per patient.

Table 2. Within- and between-group comparisons of clinical observational measures of sensorimotor impairment using FMA-UE scores.

Variable		Descriptive data			Within-group effect				Between-group effect			
		Pre (test)	Post (test)	Follow-up (test)	Post-test minus pre-test		Follow up-test minus pre-test		Post-test minus pre-test		Follow up-test minus pre-test	
		Mean ± SD Median [range]	Mean ±SD Median [range]	Mean ± SD Median [range]	Mean difference (95% CI)	Effect size	Mean difference (95% CI)	Effect size	Mean difference (95% CI)	Effect size	Mean difference (95% CI)	Effect size
Total motor score	IG	33.91 ± 19.48 30.00 [25–66]	37.18 ± 19.17 34.00 [15–66]	41.09 ± 19.75 45.00 [13–66]	[a]**3.27** **(1.35 to 5.20)***	[b]**0.762**	[a]**7.18** **(2.62 to 11.75)***	[b]**0.364**	[c]**2.52** **(0.51 to 4.53)***	[b]0.457	[c]4.18 (−0.34 to 8.70)	[b]0.311
	SG	27.83 ± 18.51 25.00 [5–59]	28.58 ± 18.13 25.50 [6–59]	30.83 ± 16.75 27.00 [7–59]	[d]0.75 (−0.02 to 1.52)†	[e]0.041	[d]**3.00** **(1.01 to 4.99)***	[e]0.179				
Total sensory score	IG	8.82 ± 4.17 10.00 [0–12]	9.18 ± 3.57 11.00 [3–12]	9.45 ± 3.27 11.00 [4–12]	[a]0.36 (−1.23 to 0.50)	[b]0.236	[a]0.64 (−0.68 to 1.95)	[b]0.278	[c]0.14 (−1.47 to 1.19)	[b]0.000	[c]0.28 (−2.15 to 1.59)	[b]0.008
	SG	8.33 ± 4.74 11.00 [0–12]	8.83 ± 4.04 11.00 [0–12]	9.25 ± 4.69 12.00 [0–12]	[a]0.50 (−0.60 to 1.60)	[b]0.289	[a]0.92 (−0.55 to 2.39)	[b]0.463				
Total sensorimotor score	IG	42.73 ± 21.62 35.00 [18–78]	46.45 ± 21.17 40.00 [19–78]	50.82 ± 21.42 51.00 [22–78]	[d]**3.73** **(1.64 to 5.81)***	[e]0.176	[d]**8.09** **(2.94 to 13.24)***	[e]**0.378**	[c]**2.98** **(0.81 to 5.14)***	[b]**0.477**	[f]4.17 (−1.31 to 9.65)	[e]0.669
	SG	36.16 ± 22.50 37.00 [5–71]	36.92 ± 22.16 37.50 [6–71]	40.08 ± 20.05 39.00 [7–71]	[d]0.75 (−0.22 to 1.52)	[e]0.034	[d]3.92 (1.47 to 6.36)†	[e]0.034				
Total upper arm score	IG	19.18 ± 11.76 16.00 [4–36]	19.73 ± 11.32 18.00 [4–34]	22.73 ± 12.04 25.00 [2–36]	[d]0.55 (−0.74 to 1.83)	[e]0.048	[d]**3.55** **(0.58 to 6.51)***	[e]**0.294**	[c]0.13 (−1.12 to 1.38)	[b]0.083	[c]1.63 (−1.53 to 4.79)	[b]0.131
	SG	15.92 ± 10.54 13.50 [4–30]	16.33 ± 10.55 13.50 [4–31]	17.83 ± 10.00 14.50 [4–32]	[a]0.42 (−0.09 to 0.92)	[b]0.471	[a]**1.92** **(0.50 to 3.34)***	[b]**0.779**				
Total wrist–hand score	IG	14.73 ± 9.03 11.00 [6–30]	17.18 ± 8.04 16.00 [9–30]	18.36 ± 8.15 20.00 [8–30]	[a]**2.45** **(0.75 to 4.16)***	[b]**0.715**	[a]**3.64** **(1.12 to 6.16)***	[b]**0.761**	[c]**2.12** **(0.39 to 3.85)***	[b]**0.476**	[c]2.56 (−0.09 to 5.19)†	[b]**0.893**
	SG	11.92 ± 8.43 11.50 [0–29]	12.25 ± 8.08 12.00 [1–29]	13.00 ± 7.79 13.50 [0–29]	[d]0.33 (−0.08 to 0.75)	[b]0.041	[d]**1.08** **(0.02 to 2.15)***	[b]0.139				

Statistically significant differences and relevant effect sizes are in bold. FMA-UE: Fugl Meyer assessment-upper extremity; CI: confidence interval; IG: intervention group; SG: sham group.
Trend is identified by †.
*$p < .05$.
[a]Wilcoxon test.
[b]Effect size expressed as r.
[c]Mann–Whitney U test.
[d]Paired Student's t-test.
[e]Effect size expressed as Cohen's d.
[f]Independent Student's t-test.

Table 3. Within- and between-group comparisons of clinical observational measures of sensorimotor impairment using MMAS scores.

Variable		Descriptive data			Within-group effect				Between-group effect			
		Pre-test	Post-test	Follow up-test	Post-test minus pre-test		Follow up-test minus pre-test		Post-test minus pre-test		Follow up-test minus pre-test	
		Mean ± SD Median [range]	Mean ± SD Median [range]	Mean ± SD Median [range]	Mean difference (95% CI)	Effect size	Mean difference (95% CI)	Effect size	Mean difference (95% CI)	Effect size	Mean difference (95% CI)	Effect size
Elbow flexors	IG	1.27 ± 1.42 1.00 [0–3]	1.00 ± 1.27 0.00 [0–3]	1.00 ± 1.27 0.00 [0–3]	[a]−0.27 (−0.59 to 0.04)†	[b]**0.522**	[a]−0.27 (−0.59 to 0.04)†	[b]**0.522**	[c]−0.06 (−0.36 to 0.48)	[b]0.064	[c]−0.06 (−0.36 to 0.48)	[b]0.064
	SG	2.17 ± 0.84 2.00 [1–3]	1.83 ± 0.84 2.00 [1–3]	1.83 ± 0.84 2.00 [1–3]	**[a]−0.33 (−0.65 to −0.02)***	[b]**0.577**	**[a]−0.33 (−0.65 to −0.02)***	[b]**0.577**				
Elbow extensors	IG	1.91 ± 1.04 2.00 [0–3]	1.09 ± 1.04 1.00 [0–3]	1.09 ± 1.04 1.00 [0–3]	**[d]−0.82 (−1.22 to −0.41)***	[e]**0.783**	**[d]−0.82 (−1.22 to −0.41)***	[e]**0.783**	**[c]−0.74 (−1.16 to −0.31)***	[b]**0.644**	**[c]−0.65 (−1.16 to −0.14)***	[b]**0.492**
	SG	1.50 ± 1.17 1.50 [0–3]	1.42 ± 1.16 1.00 [0–3]	1.33 ± 1.15 1.00 [0–3]	[d]−0.08 (−0.27 to 0.10)	[e]0.072	[a]−0.17 (−0.53 to 0.20)	[b]0.289				
Wrist–dorsal flexors	IG	1.73 ± 1.27 2.00 [0–3]	1.36 ± 1.21 2.00 [0–3]	1.27 ± 1.10 2.00 [0–3]	**[d]−0.36 (−0.70 to −0.03)***	[e]**0.603**	**[d]−0.45 (−0.80 to −0.10)***	[e]**0.674**	[c]−0.11 (−0.53 to 0.30)	[b]0.121	[c]−0.29 (−0.69 to 0.12)	[b]0.306
	SG	1.83 ± 0.94 1.50 [1–3]	1.58 ± 0.79 1.00 [1–3]	1.67 ± 0.89 1.00 [1–3]	[a]−0.25 (−0.54 to 0.37)	[b]0.522	[a]−0.17 (−0.41 to 0.08)	[b]0.408				
Wrist–palmar flexors	IG	0.73 ± 1.01 0,00 [0–3]	0.55 ± 0.93 0.00 [0–3]	0.45 ± 0.93 0.00 [0–3]	[a]−0.18 (−0.45 to 0.09)	[b]0.426	[a]−0.28 (−0.59 to 0.04)†	[b]**0.522**	[c]−0.01 (−0.36 to 0.33)	[b]0.020	[c]−0.11 (−0.48 to 0.26)	[b]0.126
	SG	0.67 ± 1.15 0.00 [0–3]	0.50 ± 0.80 0.00 [0–2]	0.50 ± 0.80 0.00 [0–2]	[a]−0.17 (−0.41 to 0.08)	[b]0.408	[a]−0.17 (−0.41 to 0.08)	[b]0.408				
Thumb adductor	IG	1.00 ± 0.94 1.00 [0–2]	0.60 ± 0.51 1.00 [0–1]	0.50 ± 0.71 0.00 [0–2]	**[a]−0.40 (−0.77 to −0.31)***	[b]**0.526**	[a]−0.50 (−1.10 to 0.10)†	[b]**0.492**	[c]−0.31 (−0.69 to 0.12)	[b]0.306	[c]−0.08 (−0.69 to 0.52)	[b]0.032
	SG	0.67 ± 0.65 1.00 [0–2]	0.58 ± 0.67 0.50 [0–2]	0.25 ± 0.45 0.00 [0–1]	[a]−0.09 (−0.27 to 0.10)	[b]0.289	**[a]−0.42 (−0.74 to −0.09)***	[b]**0.645**				

Statistically significant differences and relevant effect sizes are in bold. MMAS: modified modified Ashworth scale; CI: confidence interval; IG: intervention group; SG: sham group.
Trend is identified by †.
*$p < .05$.
[a]Wilcoxon test.
[b]Effect size expressed as r.
[c]Mann–Whitney U test.
[d]Paired Student's t-test.
[e]Effect size expressed as Cohen's d.

Table 4. Within- and between-group comparisons of health status using EQ-5D scale scores.

Variable		Descriptive data		Within-group effect		Between-group effect	
		Pre (test)	Follow up-test	Follow up-test minus pre test		Follow up-test minus Pre test	
		Mean ± SD median [range]	Mean ± SD median [range]	Mean difference (95% CI)	Effect size	Mean difference (95% CI)	Effect size
EQ-5D	IG	0.09 ± 0.43 −0.03 [−0.6–0.6]	0.18 ± 0.47 −0.02 [−0.6–0.7]	[a]**0.09 (0.01 to 0.19)***	[b]**0.760**	[c]**0.09 (0.03 to 0.20)***	[b]**0.449**
	SG	0.01 ± 0.16 −0.03 [−0.3–0.4]	0.005 ± 0.06 −0.03 [−0.1–0.2]	[a]−0.005 (−0.08 to 0.07)	[b]0.031		
EQ-VAS	IG	60.00 ± 16.88 55 [30–85]	61.82 ± 11.68 60 [50–85]	[a]1.81 (−3.65 to 7.29)	[b]0.182	[c]−9.02 (−22.05 to 4.02)	[b]0.173
	SG	53.25 ± 23.46 50 [10–90]	64.08 ± 19.89 60 [25–95]	[a]10.83 (−1.49 to 23.16)	[b]0.464		

Statistically significant differences and relevant effect sizes are in bold. EQ-5D: EuroQol five-dimension questionnaire; CI: confidence interval; IG: intervention group; SG: sham group; EQ-VAS: EuroQol visual analogue scale.
*$p < .05$.
[a]Wilcoxon test.
[b]Effect size expressed as r.
[c]Mann–Whitney U test.

function in persons with stroke in the subacute[12] and chronic[29] phases, and have shown no changes in upper extremity function. Another study that analyzed the effect of DN on lower extremity function showed improvements in the sensory subdomain of the FMA-UE but not in the motor score,[10] whereas we found changes in both the motor and sensorimotor domains, with improvements in the total wrist–hand motor score and in the total sensorimotor score after treatment. In relation to other studies carried out on persons with stroke that have assessed function, we found a systematic review where only two studies showed significant improvements in upper extremity function compared with the control group after the application of BTX-A.[30] One of the studies included in the aforementioned review carried out by Devier et al.,[31] which used the FMA-UE to measure function after up to two injections of BTX-A plus a rehabilitation program, found changes in the upper arm motor score and pain subscale, but not in the wrist–hand total motor score or total sensorimotor score like in our study. Our results are similar to those achieved with BTX-A infiltration, although it seems that BTX-A has a more extended effect on the upper arm compared with the local effects found in our study. This could possibly be due to the spread effect[32] of the BTX-A or, because of the combination of BTX-A plus an exercise program, the fact that we only applied a single session of DN in our study.

Regarding the assessments carried out using the MMAS scale, we realized that individual studies using this scale have reported their results differently, using terms like spasticity, muscle tone,[4] or hypertonicity,[33] when this scale actually measures hypertonicity, defined clinically as resistance to passive movement.[34] Therefore, we used the term *hypertonia*, although our results are comparable to all studies using the MMAS scale independently of the terms used. We found that a single session of DN only decreased the hypertonia in the elbow extensors in favor of the IG, in contrast with a crossover RCT performed by Hernández-Ortiz et al.[29] that revealed no significant differences in MMAS after a DN session for any of the muscles treated, and a crossover study by Mendigutia-Gomez et al.[13] that did not find any differences between groups after three sessions of DN, except for the infraspinatus muscle. However, a recent study carried out by Cuenca Zaldívar et al.[12] found changes after six sessions of DN in persons with stroke in the subacute phase in shoulder abduction, elbow extension, forearm supination, wrist extension, and finger extension. Ansari et al.[35] also reported a decrease in the spasticity scores for the pronators, wrist, and finger flexors immediately and 15 min after a single session of DN, and a study by Ghaffari et al.[36] found improvements in the finger and wrist flexors after the application of a session of DN plus a session of 15 min of electrical stimulation in cases of hemiparesis of the upper extremity. Besides, other studies carried out in different populations have also shown changes after 10 sessions of DN, for example, Cruz-Montecinos et al.,[8] who showed an improvement in the elbow, wrist, and finger flexors immediately after DN in a person with an incomplete spinal cord injury. Although different studies show improvements after DN application,

more research has to be conducted to demonstrate whether DN has an effect on hypertonia and whether this effect is the same in all muscle groups and/or for both components of hypertonia (peripheral and/or central), as this would allow clinicians to use DN when there is evidence of its effectiveness according to a proper assessment of hypertonia.

Regarding QoL, we observed improvements in the EQ-5D in the IG but not in the SG, with a difference of 0.09 between groups, which is considered a clinically significant difference.[37] Cuenca Zaldívar et al.[12] also evaluated QoL but the participants were in the subacute phase, and they did not find changes when DN was added to the standard treatment. By contrast, changes in the EQ VAS were not found, possibly because the participants did not report pain at baseline.

Although our study has some strengths, like being an RCT and having measured both function and QoL, a few limitations should be considered. We only studied the effect of a single session of DN. Future research should evaluate a greater number of sessions to determine whether the effects are maintained across the sessions and whether they are cumulative. It would also be important to consider the cost-effectiveness of adding DN to standard rehabilitation treatments. Moreover, our follow-up was limited to 15 days, so future studies should include evaluation over longer follow-up periods.

Despite this, the current study found that a single session of DN improved total wrist–hand motor function and total sensorimotor function in persons with chronic stroke immediately after treatment and 2 weeks later. These results must be interpreted with caution, as the differences between groups found in the study on upper extremity function were below the MDC.

Contributors

SC and PH conceived and designed the study. SC and NB collected the data. EE and CJ analyzed and interpreted the data. EE, PH, and SC contributed to the literature review and interpretation of the data. PH and SC prepared and reviewed the manuscript. All authors revised the text for intellectual content and read and approved the final version of the manuscript accepted for publication.

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