
Efficacy of Phonophoresis with Corticosteroids on Bell's Palsy Patients: A Randomized Controlled Trial

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ABSTRACT

Background: Bell's palsy is an acute, generally unilateral paralysis or weakness of facial musculature consistent with peripheral facial nerve dysfunction, of no detectable cause, Additional symptoms frequently include pain around or behind the ear on the affected side, sometimes extending into the occipital or cervical regions. **The purpose** of this study was to investigate the effect of phonophoresis with hydrocortisone on patients with acute bell's palsy. **Methodology:** thirty patients with acute bell's palsy both sexes, their ages were ranged from (15-45) years were assigned into three equal groups (group a and b): group (A) This group consists of 15 patients received oral systemic steroids and a placebo effect of Phonophoresis (sham effect) while group (B) This group consists of 15 patients received the same oral drugs and hydrocortisone Phonophoresis.. Subjects were assessed using Electrodiagnostic testing (nerve conduction velocity). **Results:** Considering the effect of the tested group (first independent variable) on NCV, "unpaired t test" revealed that the mean values of the "pre" test between both groups showed there was no significant differences ($p > 0.05$). But, the mean values of the "post" test between both groups showed there was significant differences ($p < 0.05$) and this significant increase in favor of group B in compared to group A. **Conclusion:** It was suggested that phonophoresis with hydrocortisone is beneficial for patients with acute bell's palsy.

Keywords: Bell's palsy, Phonophoresis, Hydrocortisone

Introduction

Bell's palsy is a disorder in which a nerve that controls the facial muscles becomes dysfunctional, resulting in weakness or paralysis of one side, or more rarely, both sides of the face. It often manifests rapidly, such that those affected may rise from bed in the morning with inexplicable one-sided facial weakness or paralysis and fear that they have experienced a stroke (Baugh and Basura, 2013).

Bell's palsy is an acute, generally unilateral paralysis or weakness of facial musculature consistent with peripheral facial nerve dysfunction, of no detectable cause, Additional symptoms frequently include pain around or behind the ear on the affected side, sometimes extending into the occipital or cervical regions. Impaired tolerance to ordinary levels of noise and disturbed sense of taste on the affected side may also be present (Martyn and Hughes 1997; Morales *et al.*, 2013).

The most common acute mono-neuropathy or disorder affecting a single nerve, and is the most common diagnosis associated with facial nerve weakness/ paralysis. Bell's palsy is a rapid unilateral facial nerve paresis (weakness) or paralysis (complete loss of movement) of unknown cause. The condition leads to the partial or complete inability to voluntarily move facial muscles on the affected side of the face, the facial paresis/paralysis that occurs in Bell's palsy may cause significant temporary oral incompetence and an inability to close the eyelid, leading to potential eye injury. Additional long-term poor outcomes do occur and can be devastating to the patient (Song *et al.*, 2008).

Risk factors for Bell's palsy include the following (Holland and Weiner, 2004).

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- Pregnancy
- Severe preeclampsia
- Obesity
- Hypertension and chronic hypertension
- Diabetes
- Upper respiratory ailment

Bell's palsy is acute palsy of the facial nerve that results in muscle weakness usually on one side of the face. The clinical picture may differ, depending on the location of the lesion of the facial nerve along its course to the muscles. Symptoms and signs may also differ because of the fact that the facial nerve carries not only motor fibers including fibers to the stapedius muscle but also supplies autonomic innervation of the lacrimal gland, submandibular gland, sensation to part of the ear and taste to the anterior two thirds of the tongue via chorda tympani (Finsterer, 2008).

Bell's palsy is a clinical diagnosis based on symptoms as well as history and physical exam findings. The physician may ask the patient to "show me your teeth" (for palsy of lower facial muscles) and "close your eyes" (for assessing upper facial muscles). The timing of onset of symptoms is also important, as Bell's palsy typically has a sudden onset and progression as opposed to other causes of facial palsy such as tumors, which typically cause a gradual progression of muscle weakness over the course of weeks (Baugh and Basura *et al.*, 2013).

Nerve conduction studies showing prolonged distal latency and reduced compound muscle action potential may provide useful information on the severity and nature of the lesion; although more prospective studies are required to assess the validity of nerve conduction studies for the prognosis of facial nerve lesions. Assessment of the ear should include pneumatic otoscopy, tuning fork tests, otomicroscopy, and audiometry. Additional tests may include electronystagmography, video nystagmography, and video oculoscopy. The stapedius reflex may be reduced or absent (Teixeira *et al.*, 2011).

Conventional treatment for Bell's palsy hinges on corticosteroids. Corticosteroids are used to reduce inflammation and help increase the likelihood of recovery of facial muscle function. A 10-day course of corticosteroids, such as 10 days of 50 mg of prednisolone or 60 mg prednisone for 5 days with a 5-day tapered dose, initiated within 72 hours of the onset of symptoms, is often used (Baugh and Basura *et al.*, 2013).

Corticosteroids alone improve rate of recovery and the proportion of people who make a full recovery, and reduce cosmetically- disabling squeal, motor silkiness, and autonomic dysfunction compared with placebo or no treatment. Treatment is likely to be more effective when started within 72 hours of onset and less effective after seven days (Finsterer, 2008).

Physical therapy can also help people with Bell's palsy to recover the muscle function. It appears that facial exercises, such as practicing emotional expressions may help improve the muscle function and reduce involuntary facial movements in people with Bell's palsy (Teixeira *et al.*, 2011).

Physical therapy, in the context of Bell's palsy, mainly uses methods which increase muscle and nerve function either through exercise or electrotherapy. Thermal methods, massage and phonophoresis work by decreasing swelling and increasing blood flow to the affected tissues, increasing the amount of oxygen available to damaged, hypoxic tissues with the aim of promoting recovery (Lockhart *et al.*, 2011).

Phonophoresis, also known as sonophoresis, has been claimed to enhance the percutaneous absorption of certain pharmacological agents such as anti-inflammatory steroids and local anesthetics from intact skin into the underlying subcutaneous structures by ultrasound, therefore improving their effectiveness. This procedure is commonly used in physical therapy practices. The procedure generally utilizes an ultrasound apparatus that generates frequencies of 0.7 to 1.1 MHz. The ultrasound intensities employed usually range from 0.0 to 3.0 Watts per cm². Both continuous-mode as well as pulse-mode applications were utilized, and most treatments lasted from 5 to 8 mins, with the exception of treatments of larger areas (greater than 36 cm²) requiring more than 8 mins (Machet and Boucaud, 2002).

The aim of the present study is to determine the effect of the effect of phonophoresis with hydrocortisone on patients with acute bell's palsy.

Subjects

Thirty Egyptian patients from both genders were recruited from the Out-Patient physical therapy clinic in Delingat Central Hospital. Patients were chosen according to the following criteria :

Inclusive criteria:

- 1) Age ranges from 15 to 45 years.
- 2) Cases from both genders.
- 3) All patients suffered from acute Bell's palsy not more than one 72 Hours from the onset.
- 4) Normal and stable vital signs (heart rate, blood pressure, temperature and respiratory rate).

Exclusive criteria:

1. Patients who suffer from bilateral Bell's palsy.
2. Patients who suffer from UMN Facial palsy.
3. Patients who suffer from mental or psychological problems.
4. Patients who dropped out through the study more than three sessions.
5. Patients who suffer from any systemic disease (hypertension, diabetes, etc..) or smokers.
6. Chronic infectious diseases ex: T.B, chronic HBV.
7. Malignancies
8. Patients with decreased liver functions (Compensated liver Disease).
9. Kidney diseases.

Design of the study

Cross sectional study "assessment study". Patients were assigned to three equal groups randomly :

Group (A)

This group consists of 15 patients received oral systemic steroids and a placebo effect of Phonophoresis (sham effect): applying ultrasound waves with the gel only) for three weeks duration 6 times per week along with the routine physical therapy treatment sessions.

Group (B)

This group consists of 15 patients received the same oral drugs and Dexamethasone Phonophoresis for three weeks duration 3 times per week along with the routine physical therapy treatment sessions .

Instrumentations:

1. H.M.S computerized Digisonic Ultrasound Device:

Advanced and trend setter ultrasound therapy from HMS R&D. Digisonic is devices with international standards , comes 1&3 Megahertz of frequency , with output power 0-3 W/cm and safety class type 1 (IEC 60601-1).

2. Hydrocortisone gel 10% concentration.

3. House Brackmann Grading scale:

The primary outcome measure was the House– Brackmann grading system for facial-nerve function is an easily administered, widely used clinical system for grading recovery from facial-nerve paralysis caused by damage to lower motor neurons.

The scoring system assigns patients to one of six categories on the basis of the degree of facial-nerve function, with grade 1 indicating normal function and 6 indicating complete paralysis (Peitersen, 2002).

Facial nerve dysfunction (facial paralysis) manifests in various symptom patterns. To objectively describe facial function, clinicians use a number of standardised scales - the most common being the House-Brackmann facial nerve grading system.

The patients signed a written consent form. The study protocol was approved by the ethical committee of Faculty of Physical Therapy, Cairo University, Egypt. All patients were subjected to a full clinical neurological assessment.

The patients were assigned into two equal groups control group (A) and study group (B). Both groups were matched in the general characteristics including age, height and weight, body mass index and duration of illness ($P > 0.05$). The control group (A) was treated by selected physical therapy program consisted of stretching exercises, facilitation of the weak muscles, strengthening exercises, proprioceptive neuromuscular facilitation, neuromuscular stimulation and, ultrasound without hydrocortisone (sham ultrasound) six sessions per for successive three weeks. Duration of each session ranged from 25-30 minutes according to the ability of each patient. The study group (GB) was treated by the same program in addition to phonophoresis with hydrocortisone the following parameters 1.5watts was applied, a current of 4 grams of hydrocortisone gel 10 % concentration was delivered using the ultrasound transducer, for 5 minutes. The treatment program was done with same treatment duration.

Statistical analysis:

Statistical analysis was conducted using SPSS for windows, version 23 (SPSS, Inc., Chicago, IL). The current study involved two independent variables. The first one was the tested group that had two levels (group A was treated by selected physical therapy program consisted of stretching exercises, facilitation of the weak muscles, strengthening exercises, proprioceptive neuromuscular facilitation ,neuromuscular stimulation and, ultrasound without hydrocortisone (sham ultrasound) six sessions per for successive three weeks. and group B receiving was treated by the same program in addition to phonophoresis with hydrocortisone the following parameters 1.5watts was applied, a current of 4 grams of hydrocortisone gel 10 % concentration was delivered using the ultrasound transducer, for 5 minutes.

The second one was the treatment periods, which had two levels (pre and post). In addition, this study involved one tested dependent variable (Nerve conduction velocity). Normality test of data using Shapiro-Wilk test was used, that reflect the data was normally distributed for NCV, so parametric statistical tests in the form of (paired t test) was used to compare between "pre" and "post" treatment for each group and "unpaired t test" was conducted to compare NCV between both groups in the "pre" and "post" treatment. The alpha level was set at 0.05.

Results

Baseline and demographic data

There were no statistically significant differences ($P > 0.05$) between subjects in both groups concerning age, weight, height and BMI (Table 1).

Table 1: Demographic characteristics of both groups:

	Group A	Group B	Comparison	
	Mean \pm SD	Mean \pm SD	t-value	P-value
Age (years)	33.8 \pm 6.15	29.73 \pm 10.58	1.286	0.209
Body mass (kg)	79.73 \pm 13.19	82 \pm 12.61	-0.481	0.634
Height (cm)	168.26 \pm 10.48	169.73 \pm 8.18	-0.427	0.673
BMI (kg/m ²)	27.78 \pm 2.01	28.6 \pm 4.2	-0.687	0.497

*SD: standard deviation, P: probability.

Nerve conduction velocity (NCV):

The mean \pm SD values of pain level in the "pre" and "post" tests are presented in table (2) for both groups. "Paired t test" revealed that there was a significant increase of NCV ($p < 0.05$) at post treatment in compared to pretreatment for both groups (A and B). Considering the effect of the tested group (first independent variable) on NCV, "unpaired t test" revealed that the mean values of the "pre" test between both groups showed there was no significant differences ($p > 0.05$). But, the mean values of the "post" test between both groups showed there was significant differences ($p < 0.05$) and this significant increase in favor of group B in compared to group A.

Table 2: Mean \pm SD, t and P values of Nerve conduction velocity pre and post treatment at both groups.

Nerve conduction velocity	Means \pm SD Pre test	Means \pm SD Post test	% of Change	t-value	P- value
Group A	46.2 \pm 1.37	51.33 \pm 1.17	11.1%	-56.503	0.0001*
Group B	46.33 \pm 1.39	54 \pm 1.41	16.55%	-15.818	0.0001*
t-value	-0.264	-5.617			
P- value	0.794	0.0001*			

*Significant level is set at alpha level <0.05.

Discussion

Thirty acute Bell's palsy patients from both genders their age ranged from 15-45 years were assigned randomly into two treatment protocols. Group (A) received oral steroids, routine physical therapy session and placebo effect of phonophoresis for 5 minutes, six times/ week for three weeks .Whereas group (B) received the same steroids and physical therapy sessions as group (A) with hydrocortisone gel 10% concentration phonophoresis with the same parameters as group (A). Evaluation was done using Nerve conduction velocity and House-Brackmann facial nerve grading system before and after the study for both groups.

The results of this study demonstrated that, there was no statistically significant difference in the mean values of age, height, weight and sex between group A and B. Additionally, there was no statistically significant difference in the mean values of affected sides between group A and group B before treatment. This indicates that the selection of patients in the both groups (group A and group B) was homogenous and this facilitated the comparison between them.

Regarding the Nerve conduction velocity and House-Brackmann facial nerve grading system scores, there was a statistically significant difference in the mean values of scores between group (A) and group (B) (P = 0.001) after treatment, with the highest value in group B.

Although there are limited studies about the phonophoresis in treatment of acute Bell's palsy, It has been shown to be in favor of dexamethasone phonophoresis in acute Bell's palsy that confirmed the results of our study on comparing group (B) and group (A).

Based on the findings of our study, group B that treated with hydrocortisone phonoophoresis showed significantly better prognosis than group A in both NCV and House Brackmann Grading Scale, with better facial symmetry , better facial expressions with ease of contracting facial muscles and faster healing rate .Consequently; the results suggested a rejection of our hypothesis which stated that there is no statistical significance in the effect of using hydrocortisone phonoophoresis in acute Bell's palsy.

It appears that phonophoresis has many advantages of its use, that it is Usually provides less chance of an overdose or underdose, Permit both local and systemic effects, Reduces dosing frequency, Noninvasive drug delivery system, Improve physiological and pharmacological responses, Reduction of dosing frequency and patient compliance and it takes much less time than iontiphoresis (Mitragotri, 2004).

A similar study was performed to test the efficacy of phonophoresis with hydrocortisone gel 1% concentration on 30 patients with carpel tunnel syndrome with similar parameters as our study within 10 days. they estimated the pain status and the grip strength with VAS and hand dynamometer , there were a significant improvement in grip strength and reduction of pain in study group than the control group , the improvement was attributed to the effect of hydrocortisone in decreasing the nerve inflammation. So this study supports our results that the facial nerve inflammation could be decreased by hydrocortisone phonophoresis (Chetry, 2010).

Also, there is evidence that hydrocortisone is the gold standard for phonoophoresis application as it is an anti-inflammatory drug and can be used to treat various acute and chronic inflammatory conditions (Sedghimehr and Bahrpeima, 2006).

Many studies demonstrated that hydrocortisone is transferred phonoophoretically into all tissue layers underlying the ultrasound transducer. So phonoophoresis is an effective mode of delivering ionized anti-inflammatory drugs into inflamed tissues. It is effective painless and safe and provides viable alternative treatment, Hence we can conclude that hydrocortisone may penetrate and

reach a sufficient depth to the facial nerve to give the better improvement which are in agreement with our findings. (Sreeraj *et al.*, 2015).

Conclusion

In the light of the present data supported by relevant study, it is possible to conclude that there was significant improvement in acute Bell's palsy after hydrocortisone phonophoresis.

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