Original Article

A Randomized Control Trial to Review the Effectiveness of Combination Therapy versus Steroids Alone, for the Treatment of Bells Palsy

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ABSTRACT

Objective: To compare the effectiveness of combined programme including steroids, electrical stimulation with facial exercises as compared to steroids alone for treatment of Bells Palsy.

Study Design: Randomized Control trial study.

Place and Duration: At Holy Family Hospital Rawalpindi and in Private setting at Islamabad from August 2012 to August 2013.

Materials and Methods: A total of 113 male and female patients having been diagnosed with Bell's palsy were randomly assigned to two groups. The experimental group received a combined steroids, electrical stimulation and facial exercise programme. The control group was given steroids alone. House–Brackmann facial nerve grading system was used to assess the recovery in patients.

Results: Bell's palsy was graded according to House–Brackmann facial nerve grading system. Mean values for grades of experimental group were 2.95 (before treatment) and 0.98 (after treatment) showing a significant improvement in condition after receiving treatment (p=.000 for all). These findings were statistically supported by applying paired t-test which showed significant improvement regarding House–Brackmann facial grading and other symptoms of facial palsy (p < 0.05 for all).

Conclusion: The signs and symptoms improved in both groups. However, steroids, electrical stimulation with exercise has shown to be more effective in improving the outcome measure. This study supported the effectiveness of combined approach in the treatment of Bell's palsy.

Keywords: Bell's palsy, Medications, Electrical Stimulation, Facial Exercises.

Introduction

Various scales are available for grading the severity of Bell's palsy but a widely used one is House–Brackmann facial nerve grading system. Though recovery in Bell's palsy is expected to be spontaneous but is often delayed and incomplete.

Bell's palsy is a sudden one sided paresis or paralysis of the face in a manner similar to other peripheral nerve impairments. It is a lower motor type of lesion with an unknown cause having shown rare recurrences.[1] Different factors have been associated with its occurrence including; autoimmune inflammatory disorders, viral infections, inheritance and vascular ischemia but still the cause has been a mystery. The widely established pathophysiology of its occurrence is inflammation of facial nerve during its path through labyrinthine of facial canal causing its compression resulting in demyelination of axons and disruption of the blood supply to the nerve. It is most frequently found mono neuropathy affecting facial muscles, facial expression muscles, parasympathetic fibers to salivary

and lacrimal glands, as well as sensory fibers supplying taste sensation to anterior two third of tongue[2]. Additional symptoms may include; excessive tearing or dry eyes, drooling of saliva, pain in or behind the ear, numbness, hyperacusis, increased sensitivity to sound and disturbed taste sensations on the anterior part of tongue. Its incidence is almost equal on right and left side of face.

Bell's palsy was initially identified as a separate pathology by Sir Charles Bell (1893), and has been named after him. It has been found that Bell's palsy accounts for around 72% of all cases of facial palsies.[3] It affects both male and female equally at any part of their life, but its incidence have been reported more in third and fourth decade of life. The incidence is about 20 per year in a population of 100,000, while some studies reported it to be 10 to 40 cases in population of 100,000 although some geographical variations are there. [4]

The paralysis causes significant disturbance among patients not only in social activities, life style and psychological aspects but functional activities are also hindered like the ability to eat, drink and express oneself, either verbal or non verbal communication. [5] So far, many options of treatment exist including medications in the form of steroids, antiviral and neural multivitamins and surgery etc. [6] Physiotherapy is a conservative treatment intervention for this condition and considered to be an effective form of treatment although its effects have been found debatable according to different studies. The objective of study was to evaluate the efficacy of a combined treatment plan consisting of steroids, electrical stimulation and facial exercises against steroids alone.

Materials and Methods

Patients having Bells palsy seen at Holy Family Hospital Rawalpindi and in a Private setting at Islamabad; diagnosis and referral was made by neurologist.

Inclusion criteria: A total of 113 diagnosed patients of Bell's palsy were selected including male and female, age group of study population was 20 to 60 years.

Exclusion criteria: Bells' palsy because of any tumor or space occupying lesion, diabetic patients and pregnant females.

Experimental group received steroids in the form of prednisolone. The dosage for first 5 days was 60 mg per day. It was then decreased by 10 mg per day (for a total treatment time of 10 days) and 50 mg per day in two divided doses for 10 days). Parameters for electrical stimulation were surged faradic current with pulse duration 0.1ms, pulse frequency 50 Hz, and surge duration: interval ratio was 5:5. Intensity was increased to produce mild contraction of facial muscles stimulated at nerve trunk branch. 30 contractions daily for 14 days were given. Facial exercises were also advised. Control group received steroids (prednisolone) alone for same duration and time as experimental group. Informed consent was obtained from patients. Duration of study was twelve months and a structured Questionnaire was developed. Data was analyzed using SPSS-16 and two tailed T-Test was used to confirm study hypothesis keeping level of significance at 5%.

Results

As per the requirement of study design, two groups were formed "experimental and non- experimental group"; 58 patients were assigned to experimental group receiving steroids, facial exercises along with stimulation while 55 patients were included in control group which received steroids alone. Incidence of age varied from 20 to 60 years in present study with 50% of patients was between 30 to 40 years. The patient condition was graded according to House–Brackmann facial nerve grading system. Grade I indicated no dysfunction while grade VI indicated complete paralysis. Initially, 40% patients were having Grade IV dysfunction, 24 % having Grade V while 5 % had complete paralysis in the experimental group. After receiving treatment in the form of combined program, almost 50 % of the patients progressed to having no dysfunction while 26% were left with mild dysfunction, and there was insignificant improvement among patients with complete paralysis. In the control group, results did not show marked progress as only 22 % patient were completely cured after receiving treatment, while 15 % were experiencing mild dysfunction, 33 % patient were still left with severe symptoms.

Other parameters which were tested included drooling, dry/ watery eyes, loss of taste ability, pain in ear, numbness on face and hyperacusis. Steroids along with electrical stimulation and exercise showed greater improvement than controlled group as 78 % patients were experiencing symptom of drooling before receiving treatment which was reduced to 24 % after receiving treatment, whereas drooling was still present in 36 % of patient after receiving treatment in control group. In case of dry / watery eyes, only 19 % patients in experimental group were left with this symptom after getting the treatment while 38% of the patients in control group were still experiencing it after treatment.

In case of intact taste ability, every second patient had complaints of reduced taste ability and pain in ear. These symptoms improved significantly and only 17% and 10% of the patients respectively were left with symptoms in the experimental group after receiving treatment. In the non-experimental group, steroids also helped in reducing the symptoms as 27% and 22% of the patient were left with reduced taste ability and pain in ear after the treatment.

Similar improvements with mild variations were found in both groups after treatment for hyperacusis and

Table I: Showing the P values of different variables

Variable	P Value
Drooling	p< 0.05
Dry/watery eyes	p< 0.05
Loss of Taste ability	p< 0.05
Pain ear	p< 0.05
Numbness in face	p< 0.05
Hyperacusuis	p< 0.05

numbness on face indicating the efficacy of both treatment interventions as shown in figure 1 and 2 for experimental and non-experimental group respectively. P value for all variables is listed in Table I.

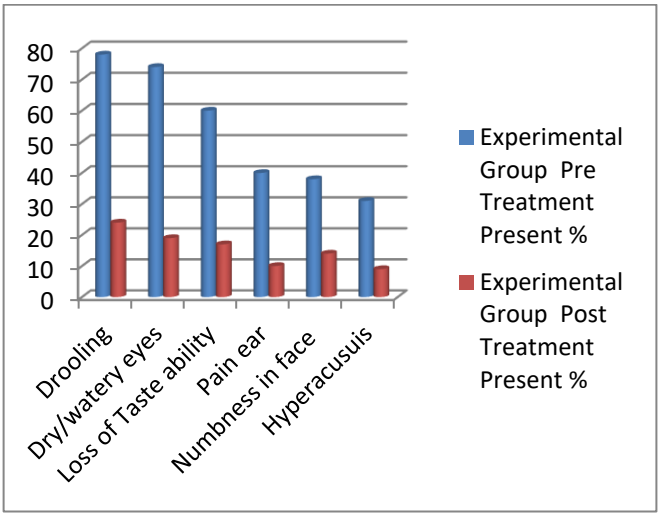

Figure 1: Showing percentage of other symptoms associated with Bell's palsy in experimental group

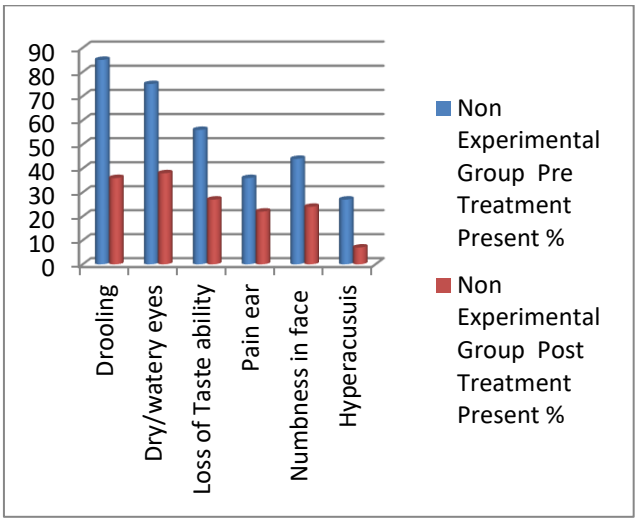

Figure 2: Showing percentage of other symptoms associated with Bell's palsy in non-experimental group

Discussion

Accurate evaluation, diagnosis and proper follow up combining a team approach is necessary for the successful management of patients suffering from Bell's palsy. Careful evaluation in the form of clinical and electrophysiological assessment should be done. Severity of paralysis and presence of complications should be graded first as it is first step before the start of treatment or rehabilitation. While treatment of Bell's palsy may be considered contentious, there is evidence supporting the use of physiotherapy interventions along with medications for its successful management.[7, 8]

In case of a complete or persistent paralysis of the facial nerve, surgical nerve decompression and steroid therapy are considered as treatment modalities of choice. [9] There is agreement amongst most authors that 75% cases of patients get complete recovery spontaneously. There is adequate recovery with a slightly detectable neurological deficit in approximately 15% of the cases while rest of the cases develops permanent paralysis. In children, Bell's palsy has good prognosis.[10]

One form of traditional treatment which has consistently been practiced is prescribing oral steroids for Bell's palsy. Prednisolone is typically the drug of choice in this case. But there is little evidence suggesting its benefits. When a Cochrane review and meta analyses of three randomized controls was conducted in 2004, they found insignificant improvements in patients having incomplete paralysis after six months. In these trials, steroids were compared against placebo.[11]

The use of antiviral drugs has also been advocated in Bell's palsy because there is possible involvement of herpes zoster virus in its etiology. A Cochrane review was done in 2004 to find its efficacy which found insufficient evidence in its favor as sole intervention.[12] Later on, two placebo controlled randomized controlled trials were conducted in which an antiviral drug was combined with steroid against corticosteroid alone. The results showed full recovery in higher number of patients treated with combined intervention (100 % vs. 91 % and 95 % vs. 90 %) [13, 14]

Physical therapy for patients with Bell's palsy traditionally has consisted of electrical stimulation or generic facial exercises.[15] In a study conducted in 2003, role of facial exercises was evaluated on 34 patients with Bell's palsy. Results showed greater improvement in exercise group than in control group.[16]

Secondary outcome measures tested in the study were complete recovery after one year. Although it was not achieved completely, but the group receiving exercises showed greater improvements on all grading scales.

Two studies done in 2004 showed contrasting results as one author found significant improvement in a group of individuals on medicines, conventional physiotherapy,

acupuncture and facial exercises. Secondary outcome parameters tested in the study were presence of hyperkinesias, motor synkinesis, contracture, facial spasm or crocodile tears six months after onset which were significantly reduced. But in other study, no statistical difference in improvement was found when facial exercises were compared against medicines.[17, 18]

Electrotherapy has been considered a major part of conservative treatment although its efficacy is controversial. A study in 1998 on Bell's palsy revealed insignificant improvement after six months of treatment with electrotherapy.[19] Outcome measure to be considered was 75% recovery. In case of secondary outcome parameters, formation of facial muscle contracture was evaluated which showed insignificant improvement. Later on, studies done in 2007 and 2008 showed somewhat good improvement with electrotherapy after three and six months respectively. In these studies, secondary outcome parameters also tested were presence of contracture, facial spasm, hyperkinesias, motor synkinesis, or crocodile tears six months after the onset and results were a mix making them debatable. One of the drawbacks was that sample size was small in both studies causing ambiguity in results.[20, 21]

Accupuncture has also been tried for the treatment of Bell's palsy. A study done in Pakistan supported its use although results are debatable because of small sample size. [22]

CONFLICT OF INTEREST: The authors declared no conflict of interest with regard to funding or affiliation

Conclusion

The signs and symptoms improved in both groups. However, steroids, electrical stimulation with exercise has shown to be more effective in improving the outcome measure. This study supported the effectiveness of combined approach in the treatment of Bell's palsy.

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