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Corresponding Author
Md Abdul Mokit,
Department of Physical Medicine and Rehabilitation, R.G.Kar Medical College and Hospital, Kolkata, West Bengal 700004, India
mokitcnmc@gmail.com

Author Designation
[1]Senor Resident
[2]Medical Officer

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A Study to Assess the Efficacy of Electrical Stimulation in the Management of Bell's Palsy

[1]Piu Dhua and [2]Md Abdul Mokit
[1,2]Department of Physical Medicine and Rehabilitation, R.G.Kar Medical College and Hospital, Kolkata, West Bengal 700004, India

ABSTRACT
Idiopathic facial palsy (Bell's palsy [BP]) is the most common peripheral lesion of the cranial nerves and the most common mononeuropathy. The clinical presentation of facial nerve palsy depends on the location, patho-physiology and severity of the lesion. To discuss the effectiveness of treating patients of Bell's palsy by electrical stimulation, to determine the improvement of clinical changes after electrical stimulation in patients with Bell's palsy by House-brackmann Score. This study was prospective observational analytical study. This study was conducted at Department of Physical medicine and rehabilitation in R.G. Kar Medical College and Hospital, Kolkata, West Bengal from 18 months. 30 patients were included in this study. In Group 0, 7 (46.7%) patients were Left side Involved and 8 (53.3%) patients were Right side Involved. In Group 1, 10 (66.7%) patients were Left side Involved and 5 (33.3%) patients were Right side Involved. Association of Involved side with Group was not statistically significant (p = 0.2690). The use of therapeutic ES in the early phase of BP should be encouraged. It seems worthy to continue with a large clinical trial on the use of ES in the management of BP to standardize the ES treatment intervention in this patient group.

INTRODUCTION

Idiopathic facial palsy (Bell's palsy [BP]) is the most common peripheral lesion of the cranial nerves and the most common mononeuropathy[1-3]. The clinical presentation of facial nerve palsy depends on the location, patho-physiology and severity of the lesion[4].

The aim of treatment in the acute phase of Bell's palsy includes strategies to speed recovery and to prevent corneal complications. Strategies to speed recovery include physical therapy, corticosteroids and antiviral agents. Prednisolone should be used in all patients with facial palsy of less than 72 hrs duration who do not have contraindications to steroid therapy. Eye care includes eye patching and lubrication, lubricating drops should be applied frequently during the day and a eye ointment should be used at night. Although two-thirds of patients progress to full recovery, residual symptoms may persist in about one-third of the patients and approximately 5% are seriously handicapped with permanent disfigurement or sequelae. These patients are usually associated with significant axonal loss and some permanent facial weakness may remain[5].

The long-term clinical presentation typically includes some combination of synkinesis, disuse atrophy, soft tissue adhesions and muscle lengthening of the affected side. Additional impairments may include muscle spasm, tearing, recurrent eye drying and infections. The studies on the effect of electrical stimulation in bell's palsy are few but some of them have shown satisfactory improvement. So a study has been formulated in which first we shall diagnose the patients clinically using meticulous history and examinations. Then on the basis of inclusion and exclusion criteria the patients will be divided into two groups in which one group will receive conventional therapy and the other will be given electrical stimulation for 14 days added to conventional therapy. Outcome of the study will be assessed by House-Brackmann score and Facial disability index score by comparing pre-stimulation and post-stimulation scores.

Facial paralysis, also known as Bell palsy (BP), is an acute facial nerve disease in which the 1st symptoms can be pain in the mastoid region and cause facial hemiparesis or paralysis. The annual incidence of BP is between 11.5 and 40.2 cases for 100,000 people. BP has a good prognosis[6]. Regression of BP was reported within 3 weeks in 85% of 2570 patients and in the remaining 15% after 3-5 months, normal mimic function was observed in 71% and mild to severe sequelae in the remaining 29% of patients, the contracture and associated movements were present in 17% and 16% of patients, respectively[7]. A survey showed that no treatment, including prednisone, could provide a better prognosis. The American Academy of Otolaryngology recommends 10 days of oral corticosteroids. No evidence supports only oral antiviral therapy for the management of BP[8]. Tuncay *et al*.[9] in a randomized controlled trial (RCT) with 60 patients, showed that the addition of 3 weeks of daily ES shortly after the start of facial paralysis (4 weeks) improved functional facial movements and electrophysiological outcome measures at 3 months of follow-up in patients with Bell palsy. Neuromuscular electrical stimulation (NMES) is a treatment that uses a small electrical current to activate nerves innervating muscles affected by paralysis neurologic disorders[10]. Choi[11] demonstrated that NMES is effective in muscle strengthening, in preventing muscular atrophy, in neuromuscular rehabilitation and improves facial muscle strength in stroke patients with facial paralysis.

MATERIALS AND METHODS

Type of study: Prospective Observational Analytical Study.

Study area: This study was conducted in the Department of Physical medicine and rehabilitation in R.G. Kar Medical College and Hospital, Kolkata, West Bengal.

Study period: The study was conducted for 18 months.

Study population: All patients diagnosed clinically, fulfilling inclusion criteria and not having any of the features of exclusion criteria were counted in the study population.

Inclusion criteria:

- Age ≥18 years and ≤60 years
- History of (≥4 weeks) idiopathic unilateral facial palsy and who came within 6 weeks of onset[12]
- Cases of facial palsy who already took conventional treatment for 4 weeks and in which House-brackmann Score ≥3

Exclusion criteria:

- Stroke
- Diabetes
- Space occupying lesion in the CNS
- Ramsay Hunt syndrome
- Guillain-Barré syndrome
- Parotid tumor
- Recurrence of facial palsy
- Varicella zoster virus infection
- Facial palsy after traumatic injury
- Patients with cognitive impairment
- Patients, not willing to participate in this study

Statistical analysis: For statistical analysis, data were initially entered into a Microsoft Excel spreadsheet and then analyzed using SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism (version 5). Numerical variables were summarized using means and standard deviations, while categorical variables were described with counts and percentages. Two-sample t-tests, which compare the means of independent or unpaired samples, were used to assess differences between groups. Paired t-tests, which account for the correlation between paired observations, offer greater power than unpaired tests. Chi-square tests (χ^2 tests) were employed to evaluate hypotheses where the sampling distribution of the test statistic follows a chi-squared distribution under the null hypothesis, Pearson's chi-squared test is often referred to simply as the chi-squared test. For comparisons of unpaired proportions, either the chi-square test or Fisher's exact test was used, depending on the context. To perform t-tests, the relevant formulae for test statistics, which either exactly follow or closely approximate a t-distribution under the null hypothesis, were applied, with specific degrees of freedom indicated for each test. p-values were determined from Student's t-distribution tables. A $p \leq 0.05$ was considered statistically significant, leading to the rejection of the null hypothesis in favour of the alternative hypothesis.

RESULTS AND ANALYSIS

5 (33.3%) of the patients in the Conservative Group had HBS (0). There were 3, 5 (33.3%) HBS(0) patients. Three and 5 patients (33.3%) had HBS (0).5. Of the patients in the Conservative+Stimulation Group, 5 (33.3%) had HBS (0) There were 3, 5 (33.3%) HBS (0) patients. Three and five patients (33.3%) had HBS (0). 5. HBS (0) and Groups did not have a statistically significant association (p = 1.0000). 4 (26.7%) in the Conservative Group had HBS (3) Of the patients, 1, 9 (60.0%) had HBS(3). Two and two patients (13.3%) had HBS(3) 3. Of the patients in the Conservative+Stimulation Group, 12 (80.0%) had HBS (3) Three patients (20.0%) were HBS (3) 2. HBS(3) and Groups had a statistically significant association (p = 0.0111). The mean Conservative (Mean±S.D.) of the patients in FDI-PF(0) was 64.6667±10.7681. The mean Conservative (Mean±S.D.) of the patients in FDI-PF(3) was 81.3333±8.3381. A statistically significant distribution of mean Conservative was found with FDI-PF(0) and FDI-PF(3) (p<0.0001).64.6667±10.7681 was the mean Conservative+Stimulation (Mean±S.D.) of the patients in FDI-PF(0). The Conservative+ Stimulation mean (Mean±S.D.) of the patients in FDI-PF(3) was 95.6667±4.9522. A statistically significant distribution of mean Conservative+ Stimulation was found using FDI-PF(0) and FDI-PF(3) (p<0.0001) (Table 1-3 and Fig. 1).

DISCUSSION

It was a prospective observational analytical study. The patients were selected after careful deliberation of inclusion and exclusion criteria. One group (group 0) received conservative treatment for bell's palsy, another group (group 1) received electrical stimulation added to conservative treatment. Patients were selected from the Out-Patient Department using history, clinical examination.

Table 1: Association of HBS (0) in groups

	Groups		
HBS(0)	Conservative	Conservative+stimulation	Total
3	5.0	5.0	10.0
Row (%)	50.0	50.0	100.0
Col (%)	33.3	33.3	33.3
4	5.0	5.0	10.0
Row (%)	50.0	50.0	100.0
Col (%)	33.3	33.3	33.3
5	5.0	5.0	10.0
Row (%)	50.0	50.0	100.0
Col (%)	33.3	33.3	33.3
Total	15.0	15.0	30.0
Row (%)	50.0	50.0	100.0
Col (%)	100.0	100.0	100.0

Chi-square value: 0.0000, p-value: 1.0000

Table 2: Association of HBS (3) in groups

	Groups		
HBS(3)	Conservative	Conservative+stimulation	Total
1	4.0	12.0	16.0
Row (%)	25.0	75.0	100.0
Col (%)	26.7	80.0	53.3
2	9.0	3.0	12.0
Row (%)	75.0	25.0	100.0
Col (%)	60.0	20.0	40.0
3	2.0	0.0	2.0
Row (%)	100.0	0.0	100.0
Col (%)	13.3	0.0	6.7
Total	15.0	15.0	30.0
Row (%)	50.0	50.0	100.0
Col (%)	100.0	100.0	100.0

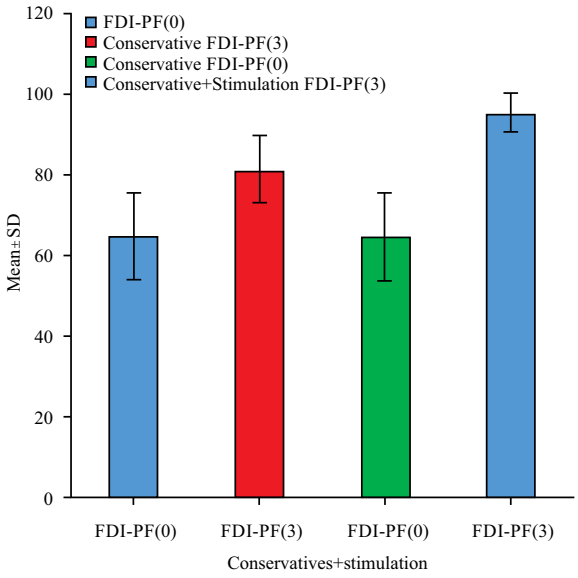

Fig. 1: Conservative+Stimulation

Table 3: Distribution of mean FDI-PF (0) and FDI-PF (3)

Conservative	No.	Mean	SD	Minimum	Maximum	Median	p-value
FDI-PF(0)	15	64.6667	10.7681	45.0000	75.0000	70.0000	<0.0001
FDI-PF(3)	15	81.3333	8.3381	65.0000	90.0000	80.0000	
Conservative+Stimulation							
FDI-PF(0)	15	64.6667	10.7681	45.0000	75.0000	70.0000	<0.0001
FDI-PF(3)	15	95.6667	4.9522	85.0000	100.0000	95.0000	

The total number of participants in this study was initially 51. 9 participants were excluded as they did not meet the inclusion criteria. 20 participants were in group 0 and 22 participants were in group 1. 5 and 7 participants dropped out of the study from group 0 and group 1 respectively and did not appear for timely follow-ups.

Only 30 patients completed the study. Baseline and incomplete follow up data collected from the drop-out participants were not included in statistical analysis.

In Group 0, 8 (53.3%) patients were ≤30 years old, 6 (40.0%) patients were 31-40 years old and 1 (6.7%) patient was >41 years old. In Group 1, 6 (40.0%) patients were ≤30 years old, 7 (46.7%) patients were 31-40 years old and 2 (13.3%) patients were >41 years old. Association of Age in group 0 with Group 1 showed no statistically significant difference (p = 0.7061).

Gender Distribution clearly showed a male predominance. Out of the total 30 participants, there were 20 males (66.66%) and 10 females (33.33%). Group 0 showed a male predominance of 60% and Group 1 showed a male predominance of 73.33%. Association of Sex in group 0 with Group 1 showed no statistically significant difference (p = 0.4385).

In Group 0, the mean BMI (Mean±S.D.) of patients was 22.8560±1.8766. In Group1, the mean BMI (Mean±S.D.) of patients was 23.6920±1.7374. Distribution of mean BMI with Group was not statistically significant (p = 0.2159).

Regarding the per capita monthly income (in rupees), the patients were classified according to the modified BG Prasad socioeconomic classification scale, January 2014. There were 5 categories viz. 5357 and above (Upper class), 2652-5356 (Upper middle class), 1570-2651 (Middle class), 812-1569 (lower middle class) and <811 (lower class). Out of these maximum was in the category of lower middle class .Though the per capita monthly income has no effect on bell's pa;sy, patients with higher economic status tend to adhere more to the rehabilitation program and lifestyle modification.

In Group 0, 7 (46.7%) patients were Left side Involved and 8 (53.3%) patients were Right side Involved. In Group 1, 10 (66.7%) patients were Left side Involved and 5 (33.3%) patients were Right side Involved. Association of Involved side with Group was not statistically significant (p=0.2690).

Regarding the duration of palsy, the patients having pain for less than 4 wks were excluded; In Group 0, the mean Duration (week) (Mean±S.D.) of patients was 4.8667±0.8338. In Group 1, the mean Duration (week) (Mean±S.D.) of patients was 5.2000± .8619.Distribution of mean Duration (week) with Group was not statistically significant (p = 0.2909).

Discussion regarding outcomes of the study: In Conservative Group, the mean of HBS (0) (Mean±S.D.) was 4.0000±0.8452. In Conservative+stimulation

Group, the mean of HBS (0) (Mean±S.D.) was 4.0000±0.8452. Distribution of mean HBS (0) with groups was statistically significant (p<0.0001).

In Conservative Group, the mean of HBS (3) (Mean±S.D.) was 1.8667±0.6399. In Conservative+ stimulation Group, the mean of HBS (3) (Mean±S.D.) was 1.2000±0.4140. Distribution of mean HBS (3) with groups was statistically significant (p = 0.0021).

In Conservative group the mean of HBS (0) (Mean±S.D.) was 4.0000±0.8452 and the mean of HBS (3) (Mean±S.D.) was 1.8667±0.6399.Distribution of mean in Conservative group with HBS (0) and HBS (3) was statistically significant (p<0.0001).

In Conservative+Stimulation group the mean of HBS (0) (Mean±S.D.) was 4.0000±0.8452 and the mean of HBS (3) (Mean±S.D.) was 1.2000±0.4140. Distribution of mean in Conservative+ Stimulation with HBS (0) and HBS(3) was statistically significant (p<0.0001).

In Conservative Group, the mean FDI-PF (0) (Mean±S.D.) was 64.6667±10.7681. In Conservative+ stimulation Group, the mean FDI-PF (0) (Mean±S.D.) was 66.3333±9.5369. Distribution of mean FDI-PF (0) with groups was not statistically significant (p = 0.6571).

In Conservative Group, the mean FDI-PF (3) (Mean±S.D.) was 81.3333±8.3381. In Conservative+ stimulation Group, the mean FDI-PF (3) (Mean±S.D.) was 95.6667±4.9522. Distribution of mean FDI-PF (3) with groups was statistically significant (p<0.0001).

In Conservative group the mean in FDI-PF (0) (Mean±S.D.) was 64.6667±10.7681. In FDI-PF (3), the mean (Mean±S.D.) was 81.3333±8.3381. Distribution of mean in Conservative group with FDI-PF (0) and FDI-PF (3) was statistically significant (p<0.0001).

In Conservative+Stimulation group the mean FDI-PF (0) (Mean±S.D.) was 64.6667±10.7681 and mean FDI-PF (3) (Mean±S.D.) was 95.6667±4.9522. Distribution of mean in Conservative+Stimulation group with FDI-PF (0) and FDI-PF (3) was statistically significant (p<0.0001).

In Conservative Group, the mean FDI-SF (0) (mean± s.d.) was 52.5333± 15.2590.In Conservative+ stimulation Group, the mean FDI-SF (0) (Mean±S.D.) was 55.2667±14.9498. Distribution of mean FDI-SF (0) with groups was not statistically significant (p = 0.6241).

In Conservative Group, the mean FDI-SF (3) (Mean±S.D.) was 61.0667± 9.4979.In Conservative+ stimulation Group, the mean FDI-SF (3) (Mean±S.D.) was 89.3333±5.5891. Distribution of mean FDI-SF (3) with groups was statistically significant (p<0.0001).

In Conservative group the mean FDI-SF (0) (Mean±S.D.) was 52.5333±15.2590 and mean FDI-SF (3) (Mean±S.D.) was 61.0667±9.4979. Distribution of mean in Conservative group with FDI-SF (0) and FDI-SF (3) was not statistically significant (p = 0.0766).

In Conservative+Stimulation group the mean FDI-SF (0) (Mean±S.D.) was 55.2667±14.9498 and mean FDI-SF (3) (Mean±S.D.) was 89.3333±5.5891. Distribution of mean in Conservative+Stimulation group with FDI-SF (0) and FDI-SF (3) was statistically significant (p<0.0001).

The null hypothesis (H0) was thus rejected as there was difference in House-Brackmann score and Facial Disability Index in between the two groups over the follow-up visits. The alternate hypothesis (HA) was thus accepted.

In 2015 a study conducted by Samim[12] produced similar result.

CONCLUSION

Within the limits of study design, it was demonstrated that the addition of ES to traditional conservative treatment during the early phase of recovery from BP was superior to not adding it. Continued research is needed to determine the correct dose, stimulation intensity, frequency, or the number of ES treatments required in BP patients to maximize recovery. The use of therapeutic ES in the early phase of BP should be encouraged. It seems worthy to continue with a large clinical trial on the use of ES in the management of BP to standardize the ES treatment intervention in this patient group.

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