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INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/11361
DOI URL: http://dx.doi.org/10.21474/IJAR01/11361

RESEARCH ARTICLE

FAMCICLOVIR PLUS PREDNISOLONE IN COMPARISON WITH PREDNISOLONE ALONEIN THE TREATMENT OF BELLS PALSY

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Manuscript Info

Manuscript History
Received: 20 May 2020
Final Accepted: 24 June 2020
Published: July 2020

Key words:-
Bells Palsy, Prednisolone, Famciclovir

Abstract

Bell's palsy is the most common cause of acute onset unilateral peripheral facial weakness Bell's palsy treatment Comparison of Famciclovir plus Prednisolone with Prednisolone Alone was the aim of the current study. The present study was a time bound prospective study conducted in the department of otorhinolaryngology,Govt Medical College Srinagar during the period from March 2018 to March 2020 for 24 month. Total 60 eligible patients presenting with clinical featurescompatible with Bell's palsy were included in the study. Informed consent was taken from all patients. The patients were divided into two groups of 30 patients in each. Group I received Famciclovir 500 mg thrice a day for seven days plus prednisolone in a tapering dosage schedule (60 mg daily for initial 5 days, tapered by 10 mg daily over next 5 days). Group II received 10 days of oralprednisolone of similar schedule. Outcome was assessed at 3 months with House–Brackman scale and the patients were followed up to a period of three months.

Results: In this study, the total number of patients was 60 patients. The 37(61.67%) patient were females and 23 (38.33%) patient were males showing clearly a predominance of females .The peak incidence in the group 21-40 years accounting for 23 (38.33%) of the patients. The incidence of Bell's palsy shows a decline below the age of 20 years 13 (21.67%) patients, and above the age of 61years, 6 (10%) patients. From the total number of patients the study 36 (60%) patients were affected on the right side of the face and 24 (40%) on the left side of the face. The rate of complete recovery in our study was 21(70%) patients who received Famciclovir plus prednisolone and in those who received prednisolone alone it was18 (60%)patients.

Conclusion: Intreatment of Bell's palsy, combination therapy like famciclovir and prednisolone is more effective than prednisolone alone and can result inmore complete recovery of facial weakness.

Introduction:-

Facial nerve palsy (FNP) is a common problem in the emergency department that has a serious impact on patients' quality of life. It is estimated that 15–40 per 100 000 adults are affected annually by FNP.[1]Bell'spalsy(BP) is the

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most common cause of acute onset unilateral peripheralfacial weakness. The incidence of Bell's palsy is 20-30 cases for 100,000[2] and this constitutes 60-70% of all cases of unilateral peripheral facial palsy [3]. Bell's palsy (BP) representsmore than 70%of peripheral acuteidiopathic facial paresis, widespread all over theworld.[4]. Although generally unilateral, it is described insome rare cases involving both facial nerves [5]. The causesof the paresis still remain unknown even if the viral etiologyhas been discussed by several authors, and herpes virusesseemed to be the most plausible infective agent determininginflammation and swelling of the nerve with subsequentblockage of the neural activity [6, 7]. The natural history ofBP is encouraging for the patients since a total recovery offacial function is expected in 70–85% of the patients, anda higher percentage of recovery is achieved if corticosteroidtherapy is administered [8,9] andearlyphysical rehabilitationis performed in severe grades of paresis [10].

The facial nerve (FN) is mainly a motor nerve and provides innervation to the mimic muscles of the ipsilateral half of the face; it also innervates the posterior belly of the digastric muscle, the stapedius muscle, and the stylohyoid muscle. The sensory and parasympathetic functions of FNare carried by fibers that constitute the nervus intermedius (NI). The NI, also known as Wrisberg nerve or intermediate nerve, is commonly described as a root of the FN containing sensory and parasympathetic fibers, although for some authors it is considered, since the first anatomical studies in the 18th century, as an independent nerve .[11-14]

Many treatment options have been tried with varying results. About pathogenesis it is contemplated that Bell's palsy occurs as an inflammatory reaction to viral infection. Though expected to respond to antiviral, their role isstilcontroversial[15-18]. Corticosteroids, is most widely used and time tested treatment option [18 19],Prednisone and acyclovir are also widely used, famciclovir in combination with steroids also tried.

Famciclovir is a guanine analogue antiviral drug used for the treatment of various herpes virus infections; it is a prodrug form of penciclovir with improved oral bioavailability. However, their effectiveness has been controversial.

Materials & Methods:-

The present study was a time bound prospective study conducted in the department of otorhinolaryngology,Govt Medical College Srinagar during the period from March 2018 to March 2020 for 24 months. Total 60eligible patients presenting withclinical featurescompatible with Bell's palsy were included in the study. Informed consent was taken from all patients and prior permission from local ethical committee was also attained.

Inclusion criteria:

Patients with unilateral facial nerve weakness of no identifiable cause(eg, a diagnosis of Bell's palsy). Theywere recruited mostly through their family doctors (75%) but also through emergency rooms and dental doctors, and were referred to otolaryngologists at hospitals within 72 hours.The degree of initial facial paralysis was moderate to severe, based on the House Brackmann scale, a widely used system for grading recovery from facial nerve paralysis.

Exclusion criteria:

Exclusion criteria included pregnancy, breastfeeding, uncontrolled diabetes (Hb A1c >8.0%), peptic ulcer disease,suppurative otitis media, multiple sclerosis, systemic infection,sarcoid or other rare disorder, and inability to give informed consent.

The patients were divided into two groups of 30 patients in each. Group I received Famciclovir 500 mg thrice a day for seven days plus prednisolone in a tapering dosage schedule (60 mg daily for initial 5 days, tapered by 10 mg daily over next 5 days). Group II received 10 days of oral prednisolone of similar schedule. Outcome was assessed at 3 months with House–Brackman scale and the patients were followed up to a period of three months.

The House Brackman classification of facial nerve function

Grade	Description	Clinical signs
I.	Normal	Normal symmetrical function
II.	Mild dysfunction	Slight weakness noticeable only onclose inspection. Complete eye closure with minimal effort. Slightasymmetry of smile with maximal effort. Synkinesis barelynoticeable; contracture or spasm is absent

III.	Moderate dysfunction	Obvious weakness, but not disfiguring. May not be able to lift eyebrow. Complete eye closure and asymmetric mouth movement with maximal effort; obvious but not disfiguring synkinesis
IV.	Moderate severe dysfunction	Obvious disfiguring weakness; inability to lift brow; incomplete eye closure and asymmetry of mouth with maximal effort; severe synkinesis
V.	Severe dysfunction	Motion barely perceptible; incomplete eye closure, slight movement of corner of mouth; synkinesis
VI.	Total paralysis	No movement; loss of tone; nosynkinesis, contracture or spasm

The primary outcome was assessed usingthe House–Brackmann grading system for facialnerve function, which assigns patients to 1 of 6categories.

Based on the HouseBrackmann criteria, theresponse to treatment were graded as complete recovery (grade 1), partial recovery (grade 2–5), and no response (grade 6)at 3 months.

Results:-

In this study, the total number of patients was 60 patients. The 37(61.67%) patient were females and 23 (38.33%) patient were males showing clearly a predominance of females(Table 1), The peak incidence in the group 21-40 years accounting for 23 (38.33%) of the patients. The incidence of Bell's palsy shows a decline below the age of 20 years 13 (21.67%) patients, and above the age of 61years,6 (10%) patients

Table-1:- Distribution of Bell's palsy according to Gender distribution.

Gender	Number of patients	Percent of total patients
Female	37	61.67
Male	23	38.33
Total	60	100

This study demonstrated convincingly the influence of age on the incidence of Bell's palsy (Table 2).

Age at presentation	Number of patients	Percent of total patients
0-20	13	21.67
21-40	23	38.33
41-60	18	30.00
61-80	6	10.00
Total	60	100

Table 2:- Distribution of Bell's palsy according to age group.

From the total number of patients the study 36 (60%) patients were affected on the right side of the face and 24 (40%) on the left side of the face. The study showed that the right side is predominantly affected,) which was illustrated in (Table 3).

Table 3.:- Distribution of Bell's palsy according to site.

Site	Number of patients	Percent of total patients
Right	36	60.00
Left	24	40.OO
Total	60	100

.The rate of complete recovery in our study was 21 (70%) patients who received Famciclovir plus prednisolone and in those who received prednisolone alone it was18(60%) patients (Table 4)

Table-4:- Treatment results. Recovery pattern at 3 month.

Recovery extent	Famciclovir plus prednisolone (Group I)		Prednisolone alone (Group II)	
	Number of patients	Percent of total patients	Number of patients	Percent of total patients
Complete	21	70	18	60.00
Partial	9	30	8	26.67
No response	0	0.00	4	13.33
Total	30	100	30	100

Discussion:-

In this study, the totalnumber of patients were 60 patients. The 37(61.67%) patient were females and 23 (38.33%) patient were males showing clearly a predominance of females. Similar figures were reported by Valenca*et al*.,fromPortugal[20]where the female gender comprised 66.7% of the cases. Our finding in this respect are also in agreement with thefigures shown by Goncalves*et al*., in Brazil [21], who reported a predominance of female mounting up to 77.71% ofthe cases.

Peak incidence in the group 21-40 years accounted for 23 (38.33%) of the patients. The incidence of Bell's palsy shows a decline below the age of 20 years 13 (21.67%) patients,and above the age of 61years,6 (10%)patients. This study demonstrated convincingly the influence of age on the incidence of Bell's palsy. Pietersen from Denmark[22] reported similar results, and found the incidence of Bell's palsy reaches a maximum between the ages of 15 and 45years. The author also found that Bell's palsy is significantly less below the age of 15 years as well as above the age of60 years. Goncalves*et al*., from Brazil [21] showed similar findings and that the incidence of Bell's palsy is high in theage group bracket 31-60 years and low above the age of 60 years.

From the total number of patients the study 36 (60%) patients were affected on the right side of the face and 24 (40%) on the left side of the face. The study showed that the right side is predominantly affected,) which was illustrated in Table 3. Because the sample size is small we can't assume this result representing the actual situation. Further investigation is needed to verify or negate this observation. Nevertheless, our findings are similar to those reported by Savettieri*et al*., from Italy[23] who found that the right side was affected in 63% of their cases.

Consensus is evolving on how to treat Bell's palsy. Rate of complete recovery in our study was 70% in in patients who received Famciclovir plus prednisolone and in those who received prednisolone alone it was 60%. Many studies have shown higher performance and greater improvement rate of combination therapy of prednisolone and acyclovir compared with prednisolone alone. One study alsodemonstrated that patients with Bell's palsy whowere treated with prednisolone and Famciclovirperformed better .[24]

Comparison of acyclovir and famciclovirin the treatment of Bell's palsy is not clear. Ho JooKing et al in 2016 compared recovery outcomes inpatients with Bell's palsy treated with acyclovir andfamciclovir. Patients were given prednisolone pluseither acyclovir (n = 457) or famciclovir (n = 245).House-Brackmann scale was used for assessment,according to initial severity of disease andunderlying disease. The overall recovery ratetended to be higher in the famciclovir than in theacyclovir group. The rate of recovery in patientswith initially severe facial palsy (grades V and VI)was significantly higher in the famciclovir than inthe acyclovir group (p = 0.01), whereas the rates ofrecovery in patients with initially moderate palsy(grade III–IV) were similar in the two groups.Treatment with steroid plus famciclovir was moreeffective than treatment with steroid plus acyclovirin patients with severe facial palsy. They suggestedthat famciclovir may be the antiviral agent ofchoice in the treatment of patients with severefacial palsy .[25]

Hato*et al*. reported that the recovery ratein patients treated with valacyclovir andprednisolone was higher than for patients treatedwith prednisolone alone [26]. Giving prednisoloneand famciclovir together was more effective thanprednisolone alone in the treatment of Bell's palsyin a study and a significant number of patientsimproved by adding famciclovir[27]. Adding anantivirus to the treatment of Bell's palsy looksprudent because of HSV involvement in facialnerve inflammation. Antiviruses can eradicate thevirus while corticosteroid reduced nerve swelling.Studies have shown that the effect ofcorticosteroids in the treatment of Bell's palsy isclear though role of antivirals is having only weakevidence .[28 29]

In some cases of Bell's palsy, probablycombination therapy with famciclovir is moreeffective than prednisolone alone and results inmore complete recovery of facial weakness

Conclusion:-

In treatment of Bell's palsy, combinationtherapy like famciclovir and prednisolone is moreeffective than prednisolone alone and can result inmore complete recovery of facial weakness. However larger randomized control trails are required for a better understanding of the disease and its treatment. Funding issues/confounding factors; none

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