

## **Out come of oral Acyclovir& prednisolone therapy versus prednisolone alone for patients with Bell's palsy ; A randomized clinical trial**

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### **Abstract**

**Background:** *Bell's palsy* is a common disorder affecting all age groups and both genders, there are a lot of controversy in therapeutic lines. Although this syndrome was first described in 1821 by the Scottish anatomist and surgeon Sir Charles Bell, controversy still surrounds its etiology and management . The viral etiology have been mentioned in many reports and the use of Acyclovir therapy is controversial too.

**Objective :** To assess the out come of antiviral therapy in treatment of Bell's palsy among our patients.

**Design:** Randomized controlled clinical trial.

**Methods:** One hundred patients with Bell's palsy who had attended neurology out patient clinic and neurophysiology unit in Al Sadder Teaching Hospital in Najaf during the period from September 2005 to August 2007 . The cases were randomly assigned into two groups of therapy. which were age and sex matched. The first group; included patients who treated with prednisolone and Acyclovir (50 patients) . The second group was treated with prednisolone alone (50 patients). House BrackMann grading system was used to assess the therapeutic response after two weeks of treatment and two months of follow up period ..

**Results:** The bell's palsy was coming more from urban areas , and male affected more than females .The functional recovery among cases treated with prednisolone- Acyclovir and those treated with prednisolone alone was similar ( $P>0.05$ ) . . The only difference was that recovery time taken for the patients received oral Acyclovir was more rapid than the other group .

**conclusion :** Both treatments ended with same response but adding Acyclovir shortened the duration of therapy.

**Key words:** bell's palsy-treatment-antiviral therapy.

### **// الخلاصة //**

**مقدمة :** يعتبر مرض شلل العصب الوجهي من الأمراض الشائعة ولمختلف الفئات العمرية في المجتمع ولكلا الجنسين. بالرغم من وصف المرض لأول مرة عام 1821 من قبل جارس بيل فان الأسباب والتدبير السريري للمرض مازالت غير مؤكدة.

**الهدف:** اختبار تأثير المضاد الفيروسي اسايكلوفير ACYCOLOVIR في علاج شلل العصب الوجهي. تصميم الدراسة: تجربة سريرية عشوائية.

**الطريقة:** تم اختيار مئة مريض مصاب بشلل العصب الوجهي (العصب القحفي السابع) مكن مراجعي العيادة الخارجية لطب وفلسجة الجهاز العصبي في مستشفى الصدر التعليمي في النجف خلال الفترة من سبتمبر 2005 إلى آب 2007. وقد تم تقسيم المرضى عشوائياً الى مجموعتين لنوعين من العلاج (50 مريض لكل مجموعة): مجموعة الدراسة تمت معالجتها بأدوية سايكولوفار وبردنزولون ومجموعة المقارنة أعطيت علاج بردنزولون فقط. وكانت مدة العلاج لأسبوعين وإكمال مدة شهرين لمتابعة معدل الشفاء التام.

**النتائج:** إن شلل العصب الوجهي في محافظة النجف أكثر شيوعاً في المناطق الحضرية وبصيب مختلف الفئات العمرية من كلا الجنسين. إن معدل الشفاء الوظيفي للمرضى في المجموعتين متساوي في نهاية مدة المتابعة (وان الفرق بينهما فقط في إن الشفاء في مجموعة سايكولوفير أسرع من مجموعة العلاج الأخر).

**الاستنتاج:** أظهرت الدراسة إن الاستجابة للعلاجين متساوية وان إضافة عقار اسايكلوفير ACYCOLOVIR قد قصر فترة العلاج.

## **Introduction**

Bell's palsy is commonest lower motor facial weakness affecting all ages and both gender . The cause is unknown but many recent evidences and reports suggesting viral reactivation of latent herpes simplex -1(HSV-1) <sup>(1, 2)</sup>. Bell's palsy is so frightening for patients that they often fear of having a stroke or have a tumor and that the distortion of their facial appearance will be permanent <sup>(3-5)</sup>. Untreated Bell's palsy leave patient with major, permanent facial dysfunction & reduce quality of life <sup>(6)</sup>. The treatment is effective within 72 hr. and less effective after 7 days <sup>(7)</sup>. In the literature , there are only few studies world wide concern the use of Acyclovir, this limitations was partially due to a lack of an accepted facial recovery reporting system until American academy of head and neck surgery who adapted the house Brack Mann facial nerve grading scale in 1984 <sup>(8-12)</sup> . Acyclovir is a nucleotide analogue interferes with virus replication <sup>(6)</sup>. There is still controversy among neurologist about treatment of Bell's palsy. Many neurologists advise steroids and some would recommend acyclovir, the uncertainty regarding the treatment of Bell's palsy is still their <sup>13-14</sup>. This study is conducted to assess the out come of antiviral therapy in treatment of Bell's palsy. Of patients with Bell's palsy, 85% achieve complete recovery, 10% have some persistent asymmetry of facial muscles, and 5% experience severe sequel.

## **Materials & methods**

This is a randomized clinical trial , conducted in al-sadder teaching hospital in Najaf city, including 100 cases of Bell's palsy attended to neurology out patient clinic and physiotherapy department in period between september2005 to august 2007. Diagnosis of bell's palsy was made on basis of history and clinical features after excluding the other causes like otitis media, cerebello-pontine angle mass ,multiple sclerosis ,vasculitis -----etc ,this was supported on base of clinical examination and use of CT-scan or MRI specially if C-P angle mass is suspected.

The patients were randomly assigned into two groups ,fifty patients in each.

Group1: Acyclovir-prednisolone (AP) group: including 50 patients who presented early (within 72 hours), They received antiviral therapy; Acyclovir in a dose of 10mg/kg /dose Three times daily and prednisolone given was 40 to 60 mg of prednisolone daily for 7 days with rapid tapering.

Group 2: Comparison group or prednisolone group(P group) are including 50 patient who nearly have age and sex matching to study group and they received prednisolone alone(same dose).

All patients in the two groups ( 100 patients) were followed for 8-10 weeks including the two weeks of drug therapy , and assessed at 2 weeks intervals by direct questionnaires and examinations which was done blindly .The functional recovery then assessed according to house brake Mann grading system which was including 5 grades.

- Grade 1 & 2: complete recovery and akinesia.
- Grade 3: incomplete recovery (mild deficit).
- Grade4 &5: poor recovery (obvious deficit).

The data are collected and analyzed by applying chi-square test and correlation coefficient to differentiate between the two groups of therapy at level of significance of 0.05 . The SPSS program version 15 was used in statistical analysis.

## **Results**

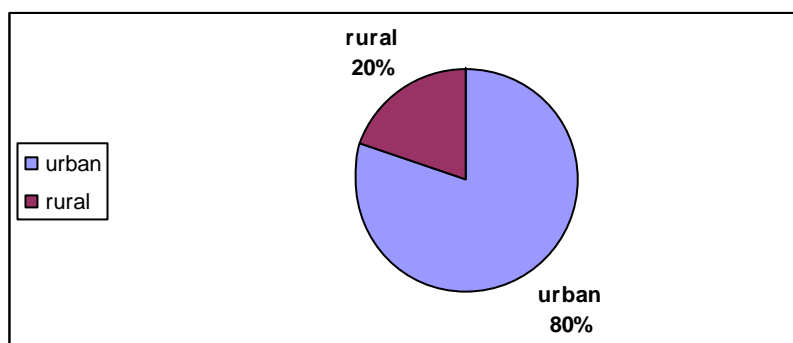
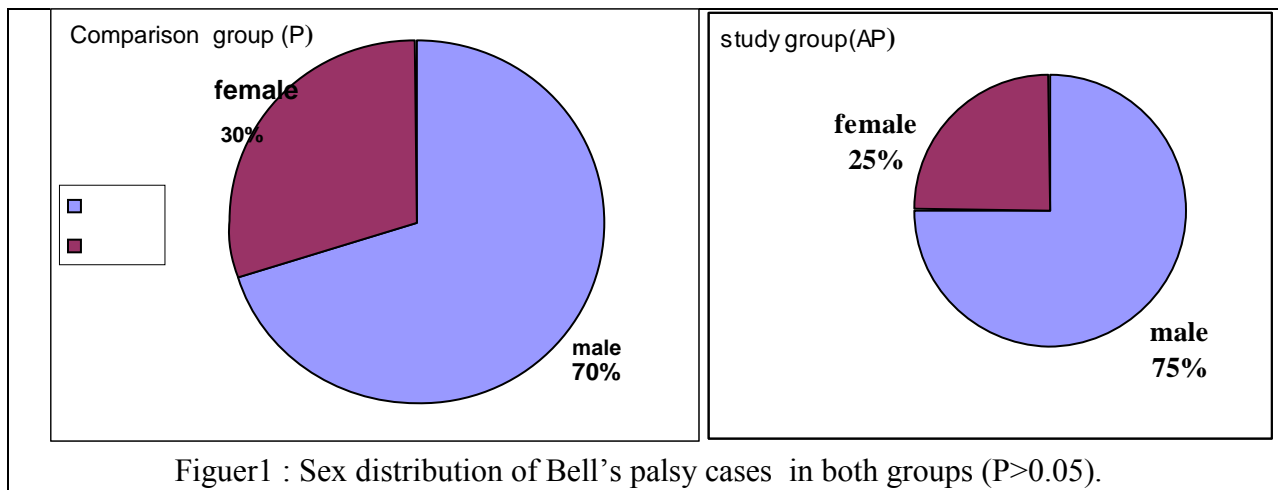
It was found that male affected more than female in both study group(AP group) ;75% male versus 25% female and for comparison group (P group) 70% male versus 30% female ; as shown in figure 1.

We also founded that Urban areas were predominantly affected (80% urban versus 20% rural in area) among both study and comparison group ( figure2).

The study showed that there was higher proportion of cases of Bell's palsy among patients with age group of 20-50 years old in groups ; (figure 3).

The first medical contact among our patients was studied as shown in table1. It was found that; patients from rural areas most likely contact faith healers firstly in comparison to Urbana's, with statistically significant difference ( $p < 0.05$ ).

The interesting finding in this study that the facial functional recovery among study group (treated with oral acyclovir and prednisolone) and comparison group (treated with prednisolone alone) showed no significant difference ( $P > 0.05$ ); that 84% versus 80 % of patients recovered with grades 1 and 2 respectively (complete and /or akinesia) and 16% versus 20% (with grade 4 and 5 (poor recovery and obvious deficit) as shown in table 2. The only difference between the two groups was the mean duration of recovery ( figure 4). The study group with acyclovir treatment completely recovered in a period of ( $6 \pm 0.8$ ) weeks; while the comparison group took ( $8 \pm 1.2$ ) weeks for complete recovery which was the important advantage of Acyclovir treatment for Bell's palsy ..



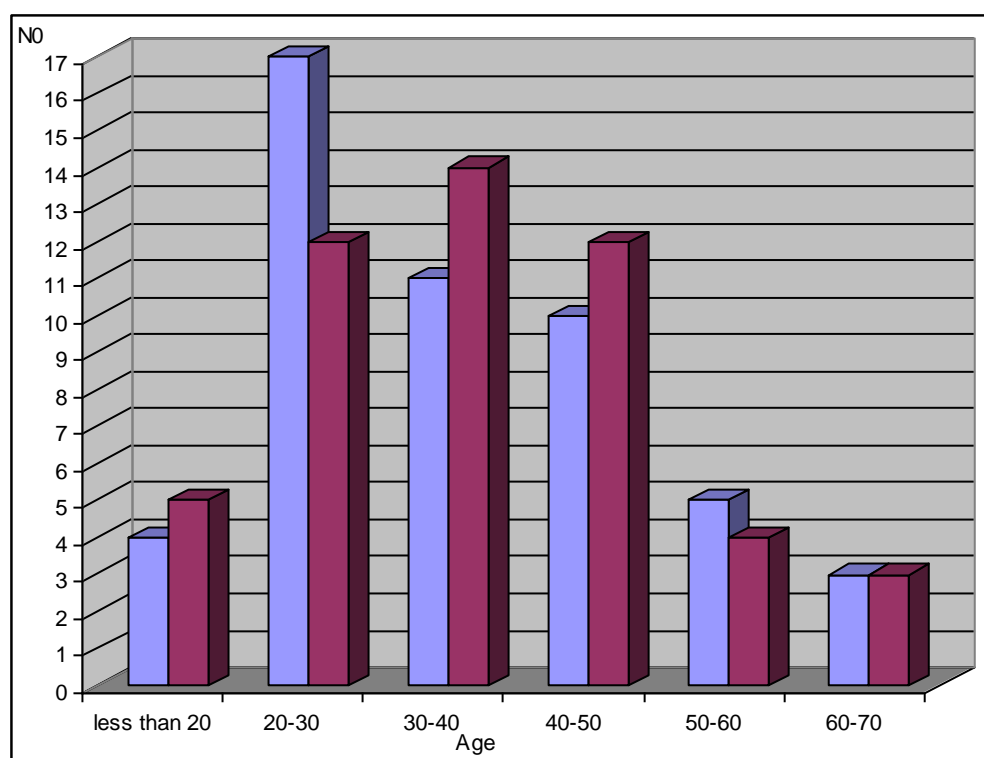


Figure3: Distribution of cases of Bell's palsy by age group

Table 1: The patients first approach to faith healer.

Total N=100	Rural area N=20	Urban area N=80
First contact to faith healer	16 80%	10 12.5%

$$X^2 = 37.9$$

$$P = 0.0001$$

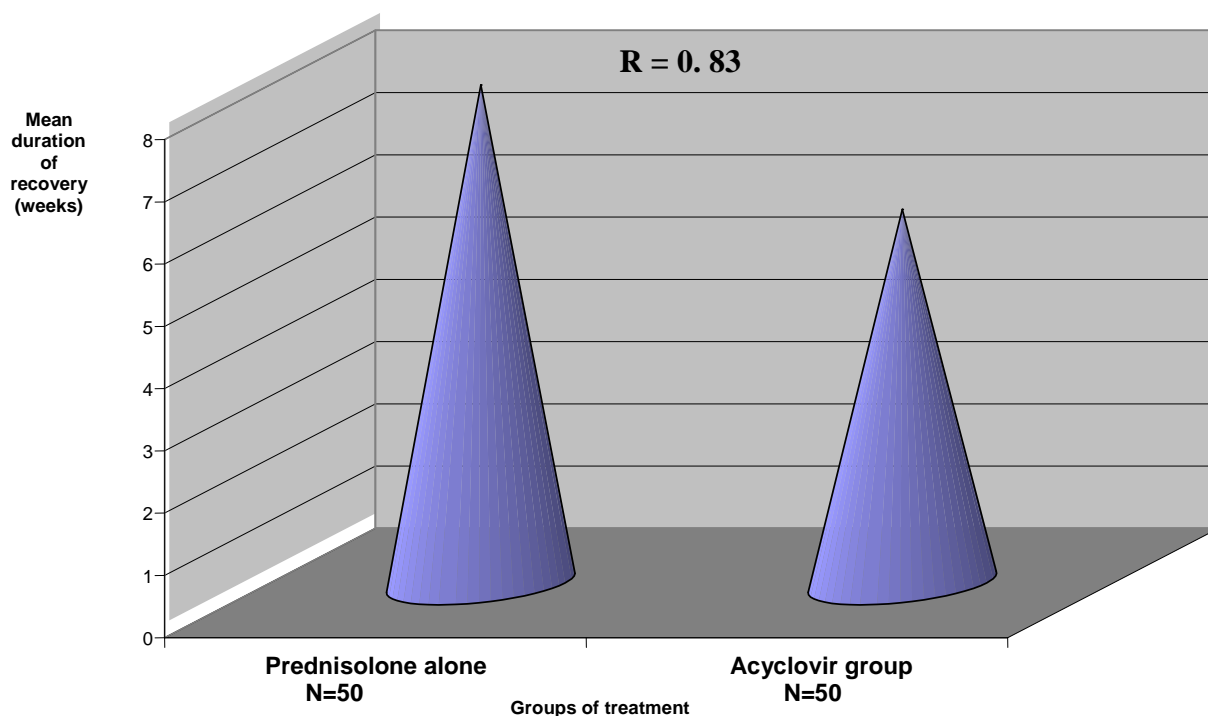
Table 2: The rate of functional recovery among both groups after two months of follow up.

Groups	Functional recovery		Total number
	Recovered patients (Grade1-3)	Un-recovered patients (Grade4&5)	
Study group (Acyclovir + Prednisolone)	42 (84%)	8 (16%)	50 (100%)
Comparison group (prednisolone alone)	40 (80%)	10 (20%)	50 (100%)

$$X^2 = 0.27$$

$$df = 1$$

$$P = 0.60$$



**Figure 4 : The mean recovery speed among the two groups of therapy**

## **Discussion**

The bell's palsy is common neurological problem we face every daily in our neurology practice , unfortunately there is no study conducted in our country concerning this problem .There is neither epidemiological nor therapeutic aspects of study had been done for the disease.

Most of our patient consulting faith healer for this problem, this why most of our patients presented late to our outpatient neurology unit, this make initial therapeutic approach whether conservative medical therapy or surgical decompression beyond therapeutic window leaving the benefit of rehabilitation and plastic surgery is the main hop to help some patient who left with dreaded facial neurological deficit; we carry this study to direct our physician and general practitioner for this problem.

### **Bell's palsy and gender distribution:**

It was found that ; male patients is more affected than female in both study and comparison group which was about 75% male versus 25% female as shown in figure 1 , this is not consistent with more or less equal affection incidence in many reports<sup>(1-7)</sup> . This result may be due to small numbers of patient taken in this study which not represent the actual relationship between the gender and bells palsy cases in Najaf city, we think that other explanation is related to religious concept where female patients in rural area have tendency to consult faith healer (the master).

### **Bell's palsy and residency:**

we observed that the patients from urban areas are predominantly affected in this study (75% urban versus 25% rural area in both study and comparison group), this is most likely due to the tendency of patients in rural areas to consult faith healer rather than doctor in urban areas due to their religious belief, unfortunately there is no statistical study on relation between residence and bells palsy in Iraq or in the world to compare our result.

Bell's palsy and age

**Bell's palsy and age :**

Bells palsy account for almost three quarters of all acute facial palsy with high incidence of cases between age of 20 years and 50 years<sup>1,9</sup> . Our finding is consistent with result above with high incidence of cases of bell's palsy between 20-50 years old age among both study and comparison group as shown in figure 3.

**1<sup>st</sup> therapeutic attachment :**

In this study we highlights an interesting view on the concept about patients 1st therapeutic contact, we know that the traditional medical practice is present over all the world ,faith healer is one of therapeutic approach in some surrounding countries especially in bell's palsy ,they did special type of maneuver like strong massage on affected side in upwards direction while the patient is lying in lateral decubitus position ; this done by faith healer together with a talk about things related to the patient religious background which may give big psychological support , the maneuver is repeated 5 times over 5 days (one session/day),some patients are improving probably as a matter of spontaneous recovery which seen usually in large number of patients , further studies is needed to test it's ways and efficacy ,we thought that such approach may support the patient psychologically and it may be of help as a way of massager like that done as physiotherapy .we found that significant number of patient have their 1<sup>st</sup> therapeutic attachment to faith healer ,this why many of our patient came with late presentation with significant neurological deficit. We found that the patients from rural areas most likely seeking faith healers firstly (20% in study group and 28% in comparison group) and this significantly different from that among urban areas (12% among comparison group and 8% among study group) as shown in table 1, we think that this is because of the religious concept of society as well as the socioeconomic factor plays a role in the first attachment of the patients affected by bell's palsy in Najaf city.

**Functional recovery :**

The percentage of facial functional recovery cases among study group (treated with oral acyclovir & prednisolone) and comparison group (treated with prednisolone alone) was same .It was 84 % who recovered with grades (Grade 1 and 2: complete and akinesia), and (16%) with grade (4and 5; poor recovery and obvious deficit). This means there is no difference in outcome in both groups. The only difference between tow groups is the speed of recovery. The study group recovers in a period less then (6 weeks) while the comparison group takes about (8-10 weeks); the results is consistent with all other studies about treatment of Bell's palsy<sup>15-18</sup> , this will help to decrease the incidence of eye complication. We advise to Administer acyclovir (Zovirax) 800 mg PO 5 times/day for 10 days ; 20 mg/kg in patients younger than 2 years especially recent evidence supports HSV as a major cause of Bell's palsy<sup>19,20</sup> .

**Conclusion and recommendations :**

The data from this study suggested that the use of oral acyclovir in combination with prednisolone increase the speed of facial functional recovery rate in patient with Bell's palsy in a degree more than the use of steroid alone in the 1<sup>st</sup> 2 weeks; this will help to decrease the risk of eye complication, more study is needed to explore the effectiveness of other oral antiviral for example use of pro-drug of acyclovir (i.e. Valacyclovir) to overcome the relatively narrow bioavailability of acyclovir . The other interesting finding which needs to be clarified more and more; it is the use of traditional medicine by means of faith healer in treatment of Bell's palsy.

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