

A comparative study of the efficacy of part time occlusion and full time occlusion therapy in moderate and severe Amblyopia in children and factors influencing the outcome

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Abstract

Aims: A comparative study of the efficacy of full time occlusion and part time occlusion therapy in moderate and severe Amblyopia, to establish the dose-response relationship between occlusion therapy and improvement in visual acuity, and how this is modified by patient characteristics.

Methods: This is a prospective study including 44 amblyopic patients aged 5-10 years, who were initially given one month of spectacle correction. Four patients lost to follow up and remaining 24 patients were prescribed part time occlusion while 16 patients were given full time occlusion. Subsequently they were followed at 1 week, 2 week, 4 week, 8 week and 12 week intervals.

Result: The mean age of study population was 7.2 ± 1.8 years with 60% male and 40% of female. In part occlusion therapy average line of improvement was 1.08 ± 0.51 lines while in full time occlusion therapy improvement was 1.25 ± 0.70 lines and the difference among these groups was not statistically significant (p value 0.53).

Conclusion: Part time occlusion is comparable to full-time occlusion in effectiveness of treatment in moderate and severe Amblyopia. Prescribing fewer hours of daily patching may ease the implementation of patching therapy and monitoring of compliance for parents.

Key words: Amblyopia, Occlusion therapy, Full-time occlusion, Part-time occlusion

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Introduction

Amblyopia is defined as a unilateral or bilateral decrease of visual acuity for which no organic cause can be detected by the physical examination of the eye and in appropriate cases is reversible by therapeutic measures. It is caused by refractive error, strabismus, deprivation of the clear image. This reduced visual acuity persists after optimal correction of any refractive error. It is the most common cause of monocular visual impairment in both children and young adults. It affects 3-4% of adult population and 1-5% of childhood. It is caused by inhibition of neurologic signals in visual pathway of the amblyopic eye by the fellow eye during visual development. The basic strategy for treating amblyopia is to first provide a clear retinal image, and then correct ocular dominance. Treatment of amblyopia is a therapeutic challenge. Vastness and variety of treatment modalities tried and the research done in this field Occlusion therapy with patching of the non-amblyopic eye has long been the mainstay of amblyopia treatment. The low degree of compliance -

i.e. the degree to which a patient follows or completes a prescribed treatment has been reported as the major contributor to the failure of occlusion treatment. It is commonly seen with full time occlusion; hence part time occlusion was tried and promoted treatment of amblyopia and had promising results. Recently, various amblyopia treatment groups have started to look into the efficacy of part-time occlusion. Studies that prescribed occlusion for as less as one to two hours per day to a maximum of 24 h per day have been reported.

Accurate knowledge of the amount of occlusion a child actually receives is a prerequisite for determining a dose-response relation. Hence this study was done to evaluate the effect of full time of occlusion and part time occlusion and various factor as age of the patient, age at which inhibition become operative, type and depth of amblyopia, influencing final visual outcome.

Aims

The aim of this study is to establish the dose-response relationship between occlusion treatment and improvement in visual acuity, and to understand how this relationship is modified by patient characteristics.

Objectives

The purpose of this study is to determine efficacy of full time occlusion therapy and part occlusion therapy in moderate and severe amblyopia.

To evaluate the various factors influencing the visual outcome in moderate and severe amblyopia as:

- Age of the patient at presentation
- Cause of amblyopia
- Depth of amblyopia.
- Refractive status of amblyopic eye

Material and Methodology

This prospective comparative study was conducted in patients with amblyopia presenting in outpatient department, squint and orthoptic clinic at Regional Institute of Ophthalmology, after taking permission from institutional ethical committee

Total 44 amblyopic patients, 5 to 10 years of age were enrolled in the study. Written informed consent were taken from each candidate's parents.

Inclusion criteria were, Patients up to the age of 10 years with best corrected visual acuity in amblyopic eye in between 6/60 -6/12, Inter eye acuity difference of 2 or more lines, history of or presence of amblyogenic factors strabismus, anisometropia or both. Refractive correction prescribed and worn for at least four weeks prior to enrollment in study.

Patients with any history of previous treatment, Stimulus deprivation amblyopia Amblyopia with eccentric fixation. Presence of Nystagmus were excluded.

A detailed history was taken from each patient at the time of presentation including family history. A complete ocular examination were done, which included baseline visual acuity at 6meters with snellen chart, refraction under cycloplegia, best corrected visual acuity, ocular motility and alignment evaluation, anterior segment examination by slitlamp, fundus examination and assessment of fixation pattern, binocular function by Worth Four Dot Test, Stereopsis by TNO test, synaptophore examination as required.

Patients were given spectacle correction for one month and then divided into two groups according to the severity of amblyopia on the basis of snellen visual acuity in the amblyopic eye:

Group A: Included 24 patients having severe amblyopia with best corrected visual acuity $\leq 6/36$ in amblyopic eye. Out of which 14 patients received full time occlusion therapy and 10 patients received six hours occlusion therapy with 1 hour of near exercises.

Group B: Included 16 patients having moderate amblyopia with best corrected visual acuity between 6/18 -6/24 in amblyopic eye. Out of which 10 patients received full time occlusion therapy and 6 patients received 2-4 hours occlusion therapy with 1 hour of near exercises.

Occlusion was done by conventional occluders and opticlude. Occlusion schedule described by von Noorden was followed for prescribing full time patching.

Age	Dominant eye	Amblyopic eye
0-1yrs	3	1
2-3 yrs	4	1
4-6yrs	5	1
>6yrs	6	1

Follow up was done at one week, two weeks, one month, two months and three months. The frequency and composition of successive follow up evaluation was depend upon age of the patient and severity of amblyopia. At every follow up, each patient was assessed for visual acuity, line of improvement, fixation pattern, side effects of occlusion including occlusion amblyopia, and level of compliance.

Finally a meticulous counseling was performed for Regular maintenance of a diary by patients/ parents and its regular check-up. All efforts were done to build up confidence towards occlusion method of therapy thus making good compliance and acceptance to achieve a much higher level of success.

Results

Total 44 patients were enrolled in the study. Out of which 4 patients excluded from the study due to irregular follow up or poor compliance to patching. We assessed them and made our observation on the following parameters: Age, Sex, Laterality of eye, Presenting complaint, Type of amblyopia, Depth of amblyopia, Refractive error, Visual acuity improvement in each group

The mean age of study population was 7.2 ± 1.8 years (5-10yrs.), with 60% males and 40% females. Right eye was affected more as seen in 70% cases. Most common presenting complains was diminution of vision seen in 85% of cases followed by deviation of eye seen in 15% of cases. Most common type of refractive error was hypermetropia as seen in 70% of patients. In our study anisometropic amblyopia was more common as seen in 80% of patients.

60% patients were belong to Group A and 40% patients were belong to Group B.

Best corrected visual acuity was FC -6/60 in 32%, 6/60- 6/36 in 28%, 6/36-6/24 in 23% and 6/24-6/18 in 17% of total patients in study population.

Table 1: Best corrected visual acuity in various study groups

Best corrected visual acuity	No of patient
FC-6/60	13(32%)
6/60-6/36	11(28%)
6/36-6/24	9(23%)
6/24-6/18	7(17%)

After giving the amblyopia therapy final improvement in visual acuity were measured at 3 months. 36 patients(90%) were responded to amblyopia therapy.

1 line improvement seen in 65% of patients and 2 line improvement seen in 25% of patients. 10% patients were not responded.

Table 2: Visual improvement in each group

Line of Improvement	Group A	Group B
0	4(16.6%)	0
1	14 (58.3%)	12 (75%)
2	6 (25.1%)	4(25%)

In Group A (severe amblyopia), out of 24 patients, 14(58%) patients were given the part time occlusion (6 hour) and 10(42%) patients were given full time occlusion.

Table 3: Visual improvement and type of occlusion in group A (severe amblyopia)

Line of Improvement	Part time occlusion (6 hrs) (n=14)	Full time occlusion (n=10)
0	2(14.3%)	2(20%)
1	10(71.4%)	4(40%)
2	2(14.3%)	4(40%)

86% patients of 6 hour patching group and 80% patients of full time occlusion therapy were responded to therapy. 14% patients of part time occlusion and 20% patients of full time occlusion group were not responded to therapy.

Similarly in Group B (moderate Amblyopia) out of 16 patients, 10 (62.5%) patients were given part time occlusion (2 hour with one hour of near activity) and 6 (37.5%) patients were given full time occlusion

Table 4: Visual improvement and type of occlusion in group B(moderate amblyopia)

Line of Improvement	Part time occlusion (2hrs) (n=10)	Full time occlusion (n=6)
0	0	0
1	8(80%)	4(66.7%)
2	2(20%)	2(33.3%)

All the patients of Group B showed improvement in their visual acuity.

The age of the patient had no effect on line of improvement. 16 patients of 5-7 yrs and 20 patients of 7-10 yrs showed improvement in their visual acuity. The difference among these groups was not statistically significant (p value- 1.0 chi-square test).

In part time occlusion therapy average line of improvement was 1.08 ± 0.51 lines while in full time occlusion therapy improvement was 1.25 ± 0.70 lines. However, the difference among these groups was not statistically significant (p value- 0.53 t test).

Table 5: Average Line of Improvement in the study population

Group	Average line of improvement
Part time occlusion (n= 24)	1.08 ± 0.51
Full time occlusion (n=16)	1.25 ± 0.70
p value	0.53



Fig. 1



Fig. 2

Discussion

Treatment of amblyopia remains a therapeutic challenge to the ophthalmologists. The vastness and variety of treatment modalities tried and the research done in this field, none of the modality is full proof.

Occlusion remains the gold standard treatment modality of amblyopia. By means of removing the suppression effect of brain cells driven by the sound eye over the brain cells which are involved in processing vision in the amblyopic eye, patching helps improving the vision.

We compared the effectiveness of prescribing part time of daily patching to that of prescribing full-time patching for the treatment of amblyopia in 44 children. The mean age of our population was 7.2 ± 1.8 years in which 60% patients were male and 40% patients were females. Incidentally all patients in our study population are school going children. The age group of our study population was nearly similar with the study done by *Inderpreet Singhet et al.*

In the present study we could not find any relationship between age and degree of visual function

improvement. Compliance with treatment rather than the patient's age, appears to be a key factor.

Anisometropia was the most common cause of amblyopia in our study population. It was found to be the cause in 83.33% followed by strabismus (12.2%) and combined (8.33%). As found by *Attebo et al* and *Pediatric Eye Disease Investigator Group*.

In our study population 60% patients having severe amblyopia and 40% having moderate amblyopia. Patients of severe amblyopia are more may be because severe amblyopia comes in notice earlier than mild and moderate amblyopia. The treatment outcomes are influenced by the severity of the amblyopia as stated by *Stewart, Fielder et al*.

Most common type of refractive error found in our study population was hypermetropia (70% of patients) followed by myopia (17.14% of patients) and astigmatism (12.86%). These findings are consistent with finding of *McMullen* who stated that Amblyopia is more common and of a higher degree in patients with anisohypermetropia than in those with anisomyopia. Because when myopia is unequal, the more myopic eye can be used for near work and the less myopic eye for distance. Therefore, unless the myopia is of a high degree, both retinas receive adequate stimulation and amblyopia does not develop.

The traditional and most widely used method of amblyopia treatment is occlusion of the healthy eye. There have been many arguments about the duration (in terms of hours per day) of occlusion treatment. Some have suggested full-time occlusion treatment and others have suggested part-time occlusion treatment.

In our study we found that amblyopia improved with both patching regimens In part time occlusion therapy average line of improvement was 1.08 lines (SD 0.51) while in full time occlusion therapy improvement was 1.25 lines (SD 0.70). The difference among these groups was not statistically significant (p value- 0.53 t test). So there was no demonstrable advantage to prescribing a greater number of hours of patching in either the rate or the magnitude of improvement after 3 months of treatment. Our results are comparable with several studies done in the past. Some of them are like study done by *Pediatric Eye Disease Investigator Group* and *Catherine E Stewart et al*

Visual outcome was influenced by type of amblyopia. In our study 90% patients showed improvement in their vision. In group A (severe amblyopia) 83.3% patients are improved with the occlusion therapy while in group B (moderate amblyopia) all the patients showed improvement in their visual acuity. Which is comparable with the study done by *Melissa Anne M et al* who reported that Patients with mild to moderate amblyopia had a higher rate of treatment success as compared to severe amblyopia.

In our study among the hypermetropes line of improvement is more in patients with less amount of

refractive error but it is not statically significant. The results are consistent with finding of *C J Cobb et al*. It may be concluded that in certain cases role of duration of hours of patching cannot be underestimated especially in our surrounding where age of presentation is comparatively more.

One factor for good outcome in our study was near activities while patching. Although many doctors recommend children to do near activities that need hand-eye coordination while patching and they believe it is successful in improving visual acuity in most children, it was unclear whether near activities enhance the effect of occlusion treatment or not.

We did not include an untreated control group in the study. Therefore, our conclusion that both part time patching per day and full-time patching improved visual acuity is based on clinical experience indicating that substantial improvement of amblyopia rarely occurs without treatment.

The amount of improvement that occurred during the 3 months of the trial should not be considered to be the maximum amount of improvement that can occur with patching for amblyopia.

Eye patching can cause considerable distress for both the child and family therefore compliance remains the major challenge with occlusion therapy.

Regarding our first possibility, we recognize that our results relate to the prescription of a specific number of hours of patching rather than to the actual number of hours of occlusion that were performed. Despite of all efforts to maintain good level of compliance and acceptance. It is possible that the patients prescribed full-time patching may have actually worn the patch far less than full time, and that, as a group, their average wearing time might have been close to the 6-hour group's duration.

Preliminary data from *Gottlob's group* using an occlusion dose monitor, suggest that a longer duration of prescribed patching is associated with more variability in actual wearing time. *MJ, Stephens et al* objectively monitored occlusion found similar results.

Regarding the hypothesis of a maximal rate of improvement as a possible explanation of no difference between full-time and part-time patching, *Cleary* found no difference between full-time and part-time patching during the first 200 hours of cumulative patching. Further studies designed to address this issue should be done, and an occlusion dose monitor is required to quantify the amount of occlusion during the therapy.

In this study we did not found an age effect on success of amblyopia treatment; it is due to slightly older children in the study population (mean age 7.2 ± 1.8 years) similarly in *ATS 2A* moderate amblyopia age effect was not found. It is consistent with study done by *Epelbaum et al*.

The limitations of the study include its smaller sample size, Patients in each group are few in number and there may be a selection bias. And the duration of

our study is shorter than that of other studies. Moreover, it does not address the issue of maintenance therapy and the recurrence of treated amblyopia in this age group. Still, the present study suggests a beneficial effect of part-time occlusion therapy. Larger studies with longer follow-up are needed to address issues of recidivism and extent of improvement with part-time occlusion therapy.

Conclusions

Anisometropia was found to be most common cause of amblyopia in our study, age of presentation may be delayed to a great extent so meticulous screening of preschool, school going children is recommended for early detection and good result.

The prognosis for attaining and maintaining essentially normal vision in an amblyopic eye depends on many factors, including the age of the patient at detection, the cause and severity of amblyopia and compliance with treatment. In general, amblyopia is amenable to treatment in children under age 10 due to plasticity of the visual pathway; therefore, children even around 10 years of age must be essentially subjected under active amblyopia therapy. Patients of severe amblyopia and having significant refractive error also improved to a good extent so irrespective of severity of amblyopia especially if presentation is earlier must be subjected to active amblyopia therapy with proper enthusiasm.

Part time occlusion is comparable to full-time occlusion in effectiveness of treatment in moderate and severe amblyopia in children between 5-10 years of age. Even in severe amblyopia good result may be obtained by six hours occlusion. Prescribing fewer hours of daily patching may ease the implementation of patching therapy and monitoring of compliance for parents.

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