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# Compliance And Effectiveness Of Treatment Of Amblyopia Due To Uncorrected Refractive Errors In Children Aging Between 7 To 12 Years

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## Abstract

**Background**: Amblyopia is the most common cause of preventable visual disability in children. The successful outcome of treatment requires timely diagnosis as well as strict compliance. There is high percentage of children who fail to follow proper treatment protocol for amblyopia.

**Aim:** To study impact of age & various socio-economic factors on compliance in amblyopia treatment and to provide guidelines for the management amblyopia.

Material and Methods: This was a prospective, interventional study on 50 children aging between 7 to 12 years, newly diagnosed to have amblyopia in one eye due to uncorrected refractive error. Their visual acuity and compliance score was evaluated at 12 and 24 weeks.

Results: At the end of 12 weeks, (46%) children had improved visual acuity of at least one line which improved to (68%) at the end of 24 weeks. Age at which amblyopia treatment had started was found to be important prognostic factor (P=0.166888). Non-realization of long-term effects by parents and inability of parents to give time were found to be most influential factors (62%) in children where no improvement was observed even after 24 weeks.

**Conclusion**: The study showed that in an Indian population, socio-economic factors significantly influence the compliance of amblyopia treatment protocol. Amblyopia awareness programmes can improve compliance, making its treatment more effective.

Keywords: Amblyopia, Compliance, Refractive errors.

# INTRODUCTION

Amblyopia is defined as the reduction of best-corrected visual acuity of one or both eyes that can be attributed deprivation of visual stimuli. It's a functional loss of vision. The lack of stimulation of the primary visual cortex in causes diminution of visual acuity in amblyopia [1]. Amblyopia can cause visual disability in children, occurring in approximately two % to five % of the general population [2]. Causes of amblyopia include uncorrected refractive errors, strabismus, and visual axis obstruction. Management of amblyopia includes correction of underlying cause and penalization of the sound eye during the "critical period" of brain plasticity. Children in their first decade of life, who are not provided appropriate visual stimulation are vulnerable to amblyopia. Children should therefore be screened for vision problems and properly treated early in their life [3,4]. Although it is true that amblyopia can be treated more effectively in younger children, several studies have shown that older children and adults with amblyopia are also able to respond to amblyopia treatment [5,6,7,8]. The critical age for treatment of amblyopia was thought to be till seven years of age. But there have been studies concluding that treatment of older individuals may be successful as the plasticity of the visual system may extend into adulthood [9].

School going children having unilateral amblyopia due to refractive errors can be treated with minimal intervention i.e. correction of refractive error with patching of sound eye. We have also taken into consideration the factors which are affecting the compliance of this treatment. The efficiency of the treatment would ultimately depend on the compliance. Many studies have demonstrated that treatment compliance is the most critical factor for predicting a successful

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outcome in amblyopic children [10'11] .This is the reason why we focussed on various socioeconomical aspects which could affect the compliance.

The emphasis was on making parents realize the long term importance of this treatment as well as consequences of not treating amblyopia. We believed that the extra efforts taken for counselling on the first instance of diagnosis of amblyopia as well as during the course of treatment, would make positive impact on the outcome.

## MATERIAL AND METHODS

The present study was prospective , interventional study conducted in ophthalmology Out Patient Department (OPD) of a medical college. With average prevalence of amblyopia<sup>2</sup> taken as 3.5 % , sample size was calculated to be 50. All children aging between seven to twelve years ,newly diagnosed to have amblyopia in one eye were considered for this study. The study was started after obtaining institutional ethics committee approval . Detailed information about the diagnosis as well as management was given to parents and only after obtaining written consent ,they were included in the study.

## **Inclusion Criteria**

Children aging between seven to twelve years ,newly diagnosed to have amblyopia in one eye due to uncorrected refractive error.

#### **Exclusion Criteria**

- 1. Amblyopia due to structural abnormality of eye such as microcornea, subluxated / dislocated lens, chorioretinal coloboma, congenital optic atrophy.
- 2. Amblyopia due to media opacities such as corneal opacity, congenital cataract.
- 3. Strabismic Amblyopia.
- 4. Bilateral ametropic amblyopia

Every child was evaluated for unaided as well as Best corrected Visual acuity (BCVA) followed by slit-lamp examination and fundoscopy. Snellen's visual acuity chart was used for noting visual acuity. Both cover –uncover and alternate cover tests were carried out to exclude strabismic amblyopia. Slit-lamp examination was done to rule out any structural abnormality in anterior segment of an eye. Fundoscopy with 90 D lens was carried out to rule out any structural abnormality like optic atrophy or media opacity like vitreous haemorrhage .

Cycloplegic refraction was carried out for every child. Once all causes for diminution of vision other than refractive errors have been ruled out, only then these children were included in our study. Parents were advised to get the spectacles made and come for the visit to OPD.

Parents were then counselled with respect to importance of the treatment of amblyopia and shown the technique of patching. Counselling part also included any doubts or clarification required regarding probability or efficacy of successful outcome. Parents were advised to make their children use spectacles for maximum time.

We had selected patching of better eye as mainstay of our treatment protocol due to its cost effectiveness as well as simplicity of technique. Standard orthoptic eye patch available in the market @ 3M Opticlude Orthoptic Junior eye patch (5 cm x 6 cm) was used for patching. The duration of patching was decided as per the degree of Amblyopia. There have been many studies on the number of hours of patching per day[12,13]. As previous studies shown, we have selected patching regimen with near and far visual activities from two to six hours in these children who are older than seven years[14]. Amblyopia was classified according to Best Corrected Visual Acuity (BCVA) as severe (BCVA 6/30 to 6/120), moderate (BCVA 6/12 to 6/24) and residual (6/9 to 6/6p). Duration of patching was given as six hours for severe amblyopia, four hours for moderate amblyopia and two hours for residual amblyopia. The parents were advised to make their children get involved in near visual activities like reading, drawing playing with cards for half of the patching time. First follow-up was after 12 weeks where BCVA was evaluated and compliance factors were taken as social stigma, false beliefs, economic burden, non-realization of long term effects by parents and inability of parents to give time. This visit was also used to encourage as well as recounsel parents as per visual acuity findings and treatment compliance score.

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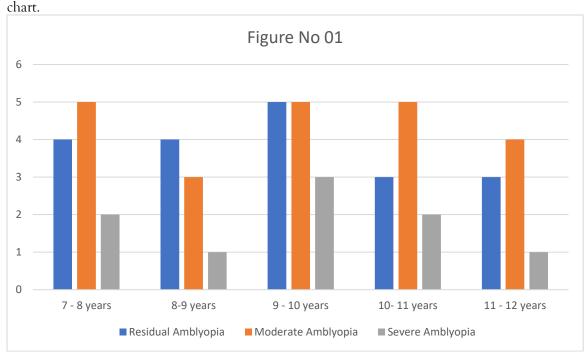
Treatment compliance score was calculated as two points (one each for spectacle wearing and patching for given time) per week, making total of 24 points for full compliance at the end of 12 weeks. Spectacle wearing of atleast eight hours was considered for satisfactory compliance. Eye patching was considered satisfactory only if it was done for given time. The next and final follow-up was after another 12 weeks when compliance score was calculated.

#### Statistical Analysis

Descriptive statistics and Paired-t test were used for statistical analysis. The obtained data was recorded in SPSS 20.0 (Statistical Package for the Social Sciences). The evaluations are to be made within the 95% confidence interval. P value less than 0.05 was considered statistically significant. Paired -t test was used to compare groups before and after the treatment.

## **RESULTS**

Total of 50 children aging between seven to twelve years were given treatment in this study. Out of 50 children included in the study , 22 were male and 28 were female of which 19 has residual , 22 had moderate and nine had severe amblyopia [Figure No 01]. At the end of the study, out of 22 male children, 16 (72 %) showed improvement of visual acuity on Snellen's chart while out of 28 female , 18 ( 64 % ) showed improvement of visual acuity on Snellen's

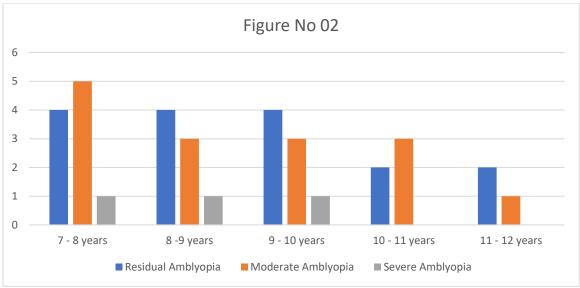


At the end of 12 weeks, 23 (46%) children had improved visual acuity of at least one line on Snellen's chart. After the end of 24 weeks which was the end point of our study, 34 (68 %) children had improved visual acuity of at least one line on Snellen's chart [Figure 02]. This confirmed that the efforts taken during treatment for understanding parents' difficulties with respect to various socio-economic factors have made significant positive difference towards outcome. This was supported by their higher (>70 %) compliance scores [Table 01].

TABLE 01

| Age ( Total patients | Residual Amblyopia | Moderate Amblyopia | Severe Amblyopia |
|----------------------|--------------------|--------------------|------------------|
| )                    |                    |                    |                  |
| 7 - 8 yrs (10)       | 04 ( 39/48 )       | 05 ( 38/48 )       | 01 ( 40/48 )     |
| 8 -9 yrs (8)         | 04 ( 38/48 )       | 03 ( 40/48 )       | 01 ( 37/48 )     |
| 9 - 10 yrs (8)       | 04 ( 36/48 )       | 03 (41/48)         | 01 ( 39 / 48 )   |
| 10 - 11 yrs (5)      | 02 ( 42/ 48 )      | 03 ( 42 /48 )      | 00               |
| 11 - 12 yrs(3)       | 02 ( 37/48 )       | 01 ( 37 / 48 )     | 00               |

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Compliance was one of the key determinants in our study. Children with non-improvement had low compliance score varying from 20 to 32 out of 48 [Table 02]. In all these children compliance score was less than 70 % which reflected importance of compliance as well as long term consistency in treatment protocol of amblyopia.

TABLE 02

| Age ( Total patients | Residual Amblyopia | Moderate Amblyopia | Severe Amblyopia |
|----------------------|--------------------|--------------------|------------------|
| )                    |                    |                    |                  |
| 7 - 8 yrs (1 )       | 00                 | 00                 | 01 ( 28/48 )     |
| 8 -9 yrs (0)         | 00                 | 00                 | 00               |
| 9 - 10 yrs(5)        | 01 ( 29/48 )       | 02 ( 32/48 )       | 02 ( 30 / 48 )   |
| 10 - 11yrs (5)       | 01 ( 26/ 48 )      | 02 ( 24 /48 )      | 02 ( 24/48 )     |
| 11 - 12 yrs (5)      | 01 ( 32/48 )       | 03 ( 32 / 48 )     | 01 ( 20 /48 )    |

Non-realization of long-term effects by parents and inability of parents to give time were found to be most influential factors in 10 out of 16 children (62 %) where no improvement was observed after 24 weeks [ Table 03 & 04].

TABLE 03

| IDED 03         |        |         |          |                |                 |
|-----------------|--------|---------|----------|----------------|-----------------|
| Age ( Total     | Social | False   | Economic | Non-           | Inability of    |
| patients)       | stigma | beliefs | burden   | realization of | parents to give |
|                 |        |         |          | long term      | time            |
|                 |        |         |          | effects by     |                 |
|                 |        |         |          | parents        |                 |
| 7 - 8 yrs (1)   | 01     | 01      | 00       | 01             | 01              |
| 8-9 yrs (0)     | 00     | 00      | 00       | 00             | 00              |
| 9 - 10 yrs (5)  | 03     | 02      | 02       | 02             | 04              |
| 10 - 11yrs (5)  | 02     | 03      | 02       | 04             | 04              |
| 11 - 12 yrs (5) | 02     | 02      | 01       | 03             | 01              |
| Total ( 16 )    | 08     | 08      | 05       | 10             | 10              |

# TABLE 04

| Compliance score | Social | False   | Economic | Non-           | Inability of    |
|------------------|--------|---------|----------|----------------|-----------------|
|                  | stigma | beliefs | burden   | realization of | parents to give |
|                  |        |         |          | long term      | time            |
|                  |        |         |          | effects by     |                 |
|                  |        |         |          | parents        |                 |
| 20 - 24 (01)     | 00     | 00      | 01       | 01             | 00              |
| 24 - 28 (06)     | 05     | 04      | 02       | 04             | 05              |

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| 28 - 32 (09 ) | 03 | 04 | 02 | 05 | 05 |
|---------------|----|----|----|----|----|
| Total ( 16 )  | 08 | 08 | 05 | 10 | 10 |

Paired-t test was applied for determining significance of age at which treatment was received. Two groups were considered for statistical analysis. First group aging less than nine years and second group aging more than nine years. The t-value is 1.816. The p-value is 0.0166. This infers that age is an important prognostic factor in outcome of amblyopia treatment.

## **DISCUSSION**

This study was designed in such a way that more focus was given on understanding difficulties of children and their parents while managing treatment protocol for amblyopia. Likewise, parents were counselled before and during follow-up and they were guided according to the problem they were facing. So, in this study we wanted to know which factors influence the compliance more. This would ultimately help ophthalmologists in counselling parents of amblyopia children. Age at which amblyopia treatment had started was found to be important prognostic factor. Eighteen out of 19 children (94 %) who were less than nine years of age showed improvement while the successful outcome was significantly less in children above nine years where only 15 out of 31 children (48 %) showed improvement. It suggests amblyopia treatment needs to be started as early as possible. This result is consistent with findings of study conducted by Holmes et al<sup>[15]</sup> where older age group was less responsive to amblyopia treatment. It highlights the importance of proper guidance at the very instance when amblyopia is detected so as to avoid delayed treatment. Our study suggests that there is lack of awareness in parents about importance of timely visual correction. This finding was consistent with the study conducted in Saudi Arabia by Mahadi Bashir et al<sup>[16]</sup> regarding awareness of amblyopia in parents. Non-realization of long term effects by parents can be overcome by providing them informative content about consequences of improper treatment of amblyopia. Social stigma and false beliefs were the second most influencing factors (50%) in these children. Notable false beliefs were fear of losing sight in better eye due to patching and the eye unnecessarily getting used to wear spectacle forever. These factors need to be addressed by reaching community on large scale especially in low economical society. Economic burden was the least contributing factor ( 31 %) for non-compliance. The grade of amblyopia was found to be equally important as far as prognosis is concerned. Thirteen out of sixteen children without improvement were having moderate to severe amblyopia. This reflects that it's difficult to achieve visual improvement once amblyopia progresses to higher grades. This finding was consistent with study conducted by Catherine E. Stewart et al<sup>[17]</sup>, where they found greater residual amblyopia in higher degrees of amblyopia. However this study also confirmed that the proportion of corrected deficit was not different. As higher degrees of amblyopia are expected to be consistent with higher age group, this finding once again reiterates the role of age at which amblyopia treatment is initiated.

# **CONCLUSION**

This study provided us information regarding contributing factors which play role in non-compliance of amblyopia treatment protocol. It highlighted various aspects of socio-economic factors which we have considered in general population. The results suggest that the counselling should be focussed upon parents to make them understand the importance of compliance and awareness about amblyopia treatment.

The limitations of this study were limited sample size as well as lack of long term follow-up. Type and degree of refractive errors were not considered in this study, which can also influence the prognosis in amblyopia.

## Recommendations

Multicentric studies are required which could include population of different socio-economical status and long-term follow-up would confirm the statistical significant of compliance. Ophthalmologist should play active part in managing amblyopic children by giving some time to

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parents regarding their doubts and difficulties in following amblyopia treatment protocol. The use of selective literature on amblyopia for home reading or sharing video content about it is highly recommended. Amblyopia awareness programmes targeting school going children and their parents can improve compliance, making it's treatment more effective. These programmes could include skits or role plays in their native language which have better impact at community level.

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