

Efficacy of part-time occlusion in amblyopia in Indian children

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Purpose: To study the effectiveness of part-time occlusion (PTO) in different types of amblyopia in Indian population. **Methods:** Prospective case series of consecutive cases of amblyopia from a tertiary care center were subjected to PTO of the better eye and monitored periodically for 6 months. Those who failed to improve by 6 months were shifted to full-time occlusion of the better eye and followed for a further 3 months. **Results:** 175 eyes of 175 patients with amblyopia underwent PTO for 6 months. The mean age of the patients was 10.47 ± 4.69 years (range: 3–26 years). Major subgroups included 94 eyes with strabismic amblyopia and 70 with anisometropic amblyopia. Overall, 168 (96%) children benefited from PTO (improvement being defined as a gain of at least one line of Snellen's visual acuity). The improvement rates for strabismic amblyopes (97.9%) was significantly more than anisometropia (94.3%); $P = 0.027$. Of the seven patients not responding to PTO, six did not benefit even after full-time patching. **Conclusion:** PTO is a viable and effective modality of management of amblyopia in Indian patients. Strabismic amblyopia was the commonest and responded best to the occlusion therapy in our cohort.

Key words: Amblyopia, Indian, part time, patching

Amblyopia is defined as unilateral or less commonly, bilateral reduction of best-corrected visual acuity (BCVA) that cannot be attributed directly to the effect of any structural abnormality of the eye or the posterior visual pathway. Amblyopia is a leading cause of monocular visual loss.^[1-3] Although the search for newer treatments for amblyopia is still on, patching remains the gold standard therapy.^[4-7] For a long time, the standard practice was to occlude the better eye for the entire duration of wakefulness for as many days as is the age of the child, followed by one day of occlusion of the amblyopic eye. The cycle then repeated itself.^[8] The pediatric eye disease investigator group has devised a treatment algorithm for part-time patching hours which is based on visual acuity (VA) and severity of amblyopia.^[5,6] This offers the advantage of binocular interaction between the two eyes and is devoid of the risk of occlusion amblyopia.

Part-time occlusion (PTO) has become the standard of care in the management of amblyopia in the western world. Compliance to PTO is a major issue in developing countries,^[9-12] where illiteracy and unfounded beliefs affect the number of hours that the seeing eye can be possibly occluded. There have been very few studies systematically evaluating the efficacy of PTO from developing countries.^[9] Furthermore, literature on the response of different types of amblyopia with patching is lacking.

The purpose of our study was to analyze the efficacy of PTO as a therapy for amblyopia in its different forms. We believe that this study will generate data on the efficacy of PTO in the developing world and will help us in deciding whether we need to tailor patching therapy in our setting or not.

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Methods

The study is a consecutive case series of children enrolled prospectively and treated for amblyopia in Squint and Pediatric Ophthalmology clinic at a tertiary care center over the 2 years. BCVA equal to or less than 20/30 or a difference of at least 2 lines between the two eyes that could not be explained by any organic cause was considered as the working definition of amblyopia.^[13] Newly diagnosed treatment naïve amblyopes presenting at all ages were recruited. Mild amblyopia was defined as VA of 6/9 to 6/12 (or 0.2 to 0.3 logMAR), moderate amblyopia as VA worse than 6/12 to 6/36 (0.3 to 0.8 log MAR), and severe amblyopia as a VA worse than 6/36 (or 0.8 logMAR).^[13] We included all types of amblyopias and subdivided them into three major groups: strabismic, anisometropic, and ametropic. The other types of amblyopia were marked as miscellaneous (deprivation amblyopia, functional, etc.). For the study, amblyopia was divided into the following groups:

1. Strabismic amblyopia: Constant degree esotropia or exotropia of the amblyopic eye, with no significant refractive error in either eye
2. Anisometropic amblyopia: A difference between the spherical equivalents of the two eyes exceeding 1.5DSph, irrespective of the presence or absence of strabismus
3. Isometropic amblyopia: Large refractive error in both eyes, with subnormal vision in both. In such cases, the subject was

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enrolled only if the vision in the two eyes was unequal by one or more line.

All patients underwent a complete ocular evaluation and orthoptic work-up at the first visit. BCVA was noted using a Snellen's visual acuity chart at a fixed distance of 6 m and was then converted to LogMAR scale using standardized conversion tables. The same observer recorded visual acuities for all patients. All patients received an age-appropriate refractive correction after cycloplegic refraction with cyclopentolate (1%) (>5 years)/atropine (1%) (<5 years). The patients were given a refractive adaptation period of 6 weeks before prescribing patching.

All patients were advised PTO of the dominant eye with an adhesive patch; 2 h/day for mild amblyopia and 6 h/day for moderate-to-severe amblyopia. These were followed up at 6 weekly intervals for 6 months for documentation and ensuring compliance. On each follow-up, the BCVA was recorded by the same observer as before using the same VA chart. Specific questions were asked from each parent and patient (if possible) separately to monitor compliance with occlusion [Table 1]. At least 50% compliance was considered acceptable. To reduce observer bias, the observer who recorded VA on each visit was kept in the dark about the patient's compliance assessment. A patient was judged to be compliant to occlusion only if respondents to this questionnaire confirmed that the patient had applied the patch every day since the last visit, for the prescribed duration of patching. Patients who were thus judged to be compliant to occlusion and failed to improve in 6 months went on to receive augmented occlusion [6 h/day for mild to moderate and full-time occlusion (FTO-80% of the awake time) in cases of severe amblyopia/nonimproving mild-moderate amblyopia] for next 3 months. Repeat cycloplegic refraction was carried out at 3 monthly intervals. The patients were examined at the end of 1 year. Patients who did not complete the required follow-up (6 months for PTO, and an additional 3 months if shifted to FTO) were excluded from the study.

Statistical analysis

Statistical tests were done on the SPSS software version 19.0. Parametric tests including t-test and multiple analysis of variance were used to compare means in subgroups of amblyopia. Correlations were performed using Pearson's coefficient. Results were considered significant at $P < 0.05$.

Results

At the end of the study period, we had recruited 183 consecutive patients. After ensuring acceptable compliance of patients, 175 fulfilled the inclusion criteria. There were 108 males (61.7%) and 67 females (38.3%). Three patients were lost to follow-up after diagnosis, hence were not included for analysis.

Table 1: Compliance assessment questionnaire

Are you/your child compliant with the recommended duration of patching?
Did you/your child apply the patch yesterday? If yes, for how many hours?
How many days in the last one week did you/your child miss the recommended duration of patching?
How many days since the last visit did you/your child miss the recommended duration of patching?

The mean age of the recruited 172 patients ranged from: 3–26 years (10.47 ± 4.69 years, median age 11.2 years). Table 2 depicts the age wise distribution of different types of amblyopia and their stratification according to refractive errors. The three groups of amblyopia did not significantly differ in their distribution in terms of age, gender, or the VA at presentation. As VA is a single best indicator of efficacy of therapy, our primary outcome measure was BCVA. Overall, 168 (96%) patients benefited from occlusion therapy (improvement being defined as gain of at least one line of Snellen's VA).

Type of amblyopia

The mean visual acuities at presentation for the strabismic, anisometropic, and isometropic amblyopia groups were 1, 0.93, and 0.63 LogMAR units, respectively. The final visual acuities for the three groups at the conclusion of the study were 0.61, 0.55, and 0.36, respectively, on the LogMAR scale. The improvement seen in each of the three groups of amblyopia from baseline was found to be statistically significant ($P < 0.001$, $P < 0.001$, $P = 0.041$ for each of the three groups, by paired t-test).

Percent improvement in each of the individual groups was: Strabismic: 86.17%; Anisometropic: 75.71%; and Isometropic: 62.5%. Since the numbers were small in the isometropic group, it was excluded from further comparisons. Intergroup comparison by ANOVA test showed a significant difference in the improvement seen in strabismic group as compared to anisometropic group ($P = 0.027$). In other words, the strabismic patients benefited more from the occlusion therapy than the patients with anisometropia.

Effect of age: We analyzed the magnitude of improvement in each group according to their age at presentation by Analysis of Variance. Table 3 shows the age wise stratification of patients in the three groups. We found that the improvement seen in the age wise subgroups did not significantly differ from each other in the same amblyopia group ($P = 0.7$ and $P = 0.61$, respectively, for strabismic and anisometropic amblyopia). There was a positive correlation between age and VA in all types of amblyopia. On evaluating the data of the outliers, i.e., patients more than 17 years of age, one patient showed four-line improvement, three showed two-line improvement, one patient showed one-line improvement, and one did not improve at all. Incidentally, all five patients who improved had anisometropia.

Severity of amblyopia

Severity of amblyopia: We divided each of the three amblyopia type groups into those with mild-to-moderate amblyopia (VA at presentation $\geq 20/100$) and those with severe amblyopia, to compare the efficacy of occlusion in these subgroups. According to unpaired t-test, the subgroups with VA at presentation $< 20/100$ improved more in both strabismic and anisometropic groups ($P < 0.001$ and $P = 0.011$). However, the numbers were too small to draw any meaningful conclusions from the isometropic group which was thus excluded from the analysis.

We found that for the strabismic and anisometropic groups, worse the VA at presentation, more was the improvement in VA (by Pearson's correlation $P < 0.001$; $r = 0.8$ for strabismic groups and $P = 0.011$; $r = 0.74$ for anisometropic subgroups). This data could not be assessed for the isometropic group due to small numbers. Seven patients who did not respond to PTO therapy

Table 2: Distribution of various types of amblyopia stratified according to the age and refractive errors

Type of amblyopia	No of eyes	Mean age \pm SD	Mean BCVA of the amblyopic eye at presentation	Amblyopic eye: Mean cycloplegic refraction in D	Refractive error (n)
Strabismic	94 (53.71)	10.5 \pm 5.3 years	1 \pm 0.2	2.25 (Hyperopia) 2.75 (Myopia)	81 (Hyperopia) 13 (Myopia)
Anisometropic	70 (40%)	11 \pm 3.97 years	1 \pm 0.21	4.75 (Hyperopia) 7 (Myopia)	60 (Hyperopia) 10 (Myopia)
Isometropic*	8 (4.57%)	7.1 \pm 3.14 years	0.6 \pm 0.15	5.5 (Hyperopia) -5 (Myopia)	7 (Hyperopia) 1 (Myopia)

Table 3: Age wise distribution of cases in each group

	3-7 years	8-12 years	12-17 years	>17 years
Strabismic (1)	32	35	24	3
Anisometropic (2)	14	33	20	3
Isometropic (3)	5	3	0	0

were shifted to FTO. Out of these, one was lost to follow-up. Five out of six cases showed no improvement in VA even after full-time patching. Due to the small numbers involved in FTO, tests of statistical significance were not done.

Discussion

The present study evaluated the effectiveness of PTO in different types of amblyopia. We also analyzed other factors that affect the improvement in amblyopia and how does the type of amblyopia affect it. The most common type of amblyopia in our cohort was the strabismic type. After 1 year of therapy, all groups showed an improvement in the VA; this improvement being more marked in the strabismic type of amblyopia. Severe amblyopes showed better improvement regardless of the type of amblyopia.

The PEDIG group has published the results of their randomized controlled trial of PTO vs. FTO therapy.^[5,6] They found no statistical difference in the degree of improvement of VA in the two treatment groups. They also found no difference in compliance between FTO and PTO, as assessed by a standard tool. Other reports from Western literature have echoed this result.^[14,15] In developing countries, however, it has been argued that it may be better to recommend greater number of hours of patching (as in FTO), to ensure that a minimum required level is achieved. Advocates of this theory discourage advising PTO to patients at any point during therapy. The counterview is that if we prescribe a few number of hours of patching each day as opposed to entire day patching, patients are more likely to start and maintain the treatment.^[9] In addition, less number of hours of patching means fewer side effects on the skin from the patch, and less adjustment in work schedule needed on the part of the patients.

We conducted this study to assess the efficacy of PTO in the treatment of amblyopia in Indian children and young adults. We found almost 81% of patients started on PTO to gain 1 or more line of VA. This is in accordance with improvement rates reported from western literature. The mean VA improvement found in our study was also comparable to reported statistics.

Strabismic amblyopia was the most common type of amblyopia in our study like some others from the past.^[16-18] Strabismus as an evident pathology tends to present to us more in a tertiary hospital than the silent anisometropias. We found greater extent of improvement in strabismic amblyopes. This contrasts with the majority of published literature from the west^[19,20] and also from same geographic as ours^[21] where a similar level of visual impairment was found irrespective of the cause of amblyopia. Perhaps the subset of population that we see are different in distribution. Strabismus could be intermittent to begin with and consequently, the extent of visual suppression is less than anisometropia, and the likelihood of improvement is greater.

We found out that strabismic patients benefited most from occlusion therapy. The PEDIG group did not find any difference in the outcome in different types of amblyopia.^[3,4] Theoretically speaking the parents of children with strabismus are more likely to be compliant as strabismus is a social stigma. We were careful not to include patients with "anisometropia with strabismus" in the "strabismic subgroup" in our study. Due to conflicting definitions used in different studies, a mixed mechanism amblyopia is often disregarded; hence, our results seem to be different than literature. Our definitions were such that some of the patients in the anisometropic group had strabismus also, hence mixed mechanism and probably did not show much improvement.

In our study, mean VA improved with amblyopia therapy throughout the age range. Newer literature supporting amblyopia treatment to be effective in some older children questions the relationship between age and magnitude of treatment response.^[22,23] Perhaps type of amblyopia and its severity is also a factor that affects the outcome other than the age of the patient. Anisometropic amblyopes seem to do well at all ages. Hence, amblyopia therapy should be tried at all presenting age groups, especially when the patient has been previously untreated with patching.

The findings from our study dispel the notion that poor compliance in Indian patients affects the efficacy of PTO. The drawback is that we used self-reporting for calculating compliance which may not be reliable. The compliance rates and thus response to treatment in our study seem to match^[16] or exceed^[10] those reported for FTO from developing countries. These results suggest that PTO is highly effective in the context of developing nations. In terms of treatment efficacy, the success rates reported with PTO in our study were comparable to those reported from other parts of the world with any form of occlusion. Our study thus provides strong support for PTO

therapy in the management of amblyopia in Indian patients at all age points. Conversion to FTO in cases where PTO fails did not prove to be counterproductive in our cohort. The importance of adherence to treatment needs to be emphasized. We recommend restressing the need for adherence to occlusion on each follow-up, with positive and negative reinforcements to children as appropriate.

Our study suffers from lack of randomization between patients undergoing FTO and PTO. There is a pressing need for such studies in developing countries to establish a management protocol for amblyopia, and reduce the financial burden caused by this avoidable disorder. We also realize that compliance assessment in our study was entirely based on the responses of the patient and family, which can be untruthful. However, we found this to be the only feasible and cost-effective method of assessment in our study. Snellen's VA could be more practical in an Indian scenario, but we should have used logMAR annotations for better standardization.

Conclusion

In summary, following a period of refractive adaptation, PTO according to the guidelines by the PEDIG group works efficiently in India. Pediatric ophthalmologists in our country should advocate part-time patching. The present study is the first to establish the efficacy of PTO in a developing country.

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Conflicts of interest

There are no conflicts of interest.

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