Amblyopic patient adherence under patching treatment

Adesão de pacientes amblíopes sob uso de oclusores

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ABSTRACT

Objective: To evaluate the effectiveness of text messaging in improving adherence to occlusion therapy for amblyopia. The secondary objective was to correlate the responses given in a self-reporting questionnaire with treatment outcome (improvement in visual acuity).

Methods: This is a prospective, randomized, blinded clinical trial. The patients' parents or legal guardians in the intervention group received text messages reminding them of the importance of patching. The control group received no text messages. At final evaluation, after a period of three to six months, the patients' parents or legal guardians answered a self-reporting questionnaire to evaluate adherence to treatment.

Results: The study included 34 patients with an average age of 5.35 years, 20 in the intervention group and 14 in the control group. According to the results of the self-reporting questionnaire, 50% of the study population was considered as having low adherence to treatment, 29% as having medium adherence, and 21% as having good adherence. There was no significant difference between trial groups. The comparison between an improvement in visual acuity and the mean value obtained in the self-reporting questionnaire showed a significant association between this improvement and adherence to treatment (p=0.03).

Conclusion: The present study did not find a correlation between text messaging and an improvement in adherence to occlusion therapy, as shown by previous studies for different treatments. A statistically significant association was identified between an improvement in visual acuity and a good therapeutic adherence, as measured by the self-reporting questionnaire. This finding allows us to recommend using a self-reporting questionnaire as a simple method to measure adherence to treatment and help decisions about therapeutic strategies to be adopted in the patient's continuing treatment.

RESUMO

Objetivo: Avaliar a eficácia do envio de mensagens de texto na melhora da adesão ao tratamento oclusivo da ambliopia. O objetivo secundário foi correlacionar as respostas dadas no questionário autorreportado e os resultados obtidos no tratamento (melhora da acuidade visual).

Métodos: Ensaio clínico prospectivo, mascarado e randomizado. Os pais ou responsáveis legais dos pacientes no grupo intervenção receberam mensagens de texto para lembrar a importância dos oclusores. O grupo controle não recebeu mensagens. Na avaliação geral após 3 a 6 meses, os responsáveis responderam a um questionário autorreportado para avaliar a aderência ao tratamento.

Resultados: Foram incluídos 34 pacientes com idade média de 5,35 anos; 20 eram do grupo intervenção. A população do estudo foi considerada 50% pouco aderente ao tratamento, 29% com aderência média e 21% com boa aderência, de acordo com resultado do questionário autorreportado. Não houve diferença significativa entre os grupos estudados. Quando comparada a relação entre a melhora da acuidade visual com o valor médio do questionário autorreportado, foi observada associação significativa da melhora com a adesão ao tratamento (p=0,03).

Conclusão: Este estudo não mostrou melhora da aderência ao tratamento oclusivo com o envio de mensagens de texto, como tinha sido observado em estudos anteriores para outros tratamentos. Foi identificada uma relação estatisticamente significativa entre a melhora na acuidade visual e boa aderência terapêutica medida pelo questionário autorreportado. Isso permite recomendar o uso do questionário autorreportado como uma forma simples de mensurar aderência ao tratamento e auxiliar nas decisões sobre estratégias a serem adotadas na continuidade do seguimento do paciente.

INTRODUCTION

Amblyopia is defined as a functional decrease in visual acuity (VA) in one or both eyes, without an apparent lesion or defined organic source and with best corrective refraction,[1] affecting from 1% to 5% of children.[2,3] The main causes are strabismus, anisometropia, and stimulus deprivation.[4]

Among the therapies adopted for improving amblyopia, the use of an eye patch over one of the eyes is the most common one. How to use and the number of hours the patch should be used per day depend on the physician's prescription and are usually associated with severeness of amblyopia and its etiology.[5] Despite the different treatment methods, one of the main prognostic factors for cure of amblyopia is adherence to prescribed therapy.[6]

Developing strategies to try to improve adherence to occlusion therapy of amblyopia is a constant effort among prescribing physicians. This study was designed to assess the effectiveness of a new proposed strategy: sending text messages to the patients' parents or legal guardians. The secondary objective was to correlate the responses given in a self-reporting questionnaire (SRQ) with treatment outcome (improvement in VA). And, therefore, try to evaluate therapeutic adherence.

METHODS

This study was approved by the Research Ethics Committee of the *Fundação de Ensino e Pesquisa em Ciências da Saúde* (Fepecs) Health Sciences Education and Research Foundation under number CAAE 23374119.6.0000.5553. The data were collected in clinics of ophthalmologists dedicated to treatment of strabismus and pediatric ophthalmology in Brasília, Brazil, between November 2019 and November 2020.

The intervention was explained to the patients' parents or legal guardians both verbally and in writing, as it was clearly stated in the Informed Consent Form (ICF). Informed consent was obtained prior to participation in the study.

This is a prospective, randomized, blinded clinical trial. One of the authors (who did not take part in patient care or data collection) selected the participants randomly – each time a patient was added to the study, they were randomly placed in either intervention or control group. Since we have had different patients that failed to attend the follow-up visit due to the coronavirus disease 2019 (COVID-19) pandemic, control and intervention group are not even. The patients' parents or legal guardians included in the intervention group received a text message every three days (e.g.: "Remember to use occlusion as often as indicated") with the aim of reminding them of the importance of patching. Participants assigned to the control group did not receive text messages. Patients who had never worn eye patches were separated from those who were undergoing or had undergone that treatment in the past.

Seven ophthalmologists participated in the study by seeing patients and collecting data in their practices, both in private and public facilities. An ophthalmic examination measuring best-corrected VA, static refraction, ocular motility, biomicroscopy, and fundoscopy was conducted on the day of inclusion and during a follow-up visit, which took place between three and six months after the initial visit. Visual acuity was recorded using logMAR notation. Amblyopia was considered improved when there was a >1 line improvement in VA, or if there was an evolution from monocular fixation into alternating fixation (in patients with strabismus), among those patients who did not inform their VA. How patches should be worn (alternating days and hours of use) was different for each patient and determined by their physician, but all patients were recommended to wear adhesive patches.

During a follow-up visit to the doctor, the patients' parents or legal guardians answered an SRQ (Table 1) to evaluate the patients' adherence to treatment. The SRQ used was the one proposed by Morisky,[7] translated into Portuguese and validated by de Oliveira Filho.[8] This method was chosen to evaluate the patients' adherence because it is simple, cheap, and scientifically validated.[9] The questionnaire is composed of eight questions, formulated in such a way that prevents the responder from answering "yes" to all the questions regardless of their content. In items one through seven, the answers are either "yes" or "no," whereas in item eight there are five options, following the Likert scale. Each answer "no" was assigned a "1" value and each "yes" received a "0" value, except for item five, in which each answer "yes" was assigned a "1" value and each "no" a "0" value. In item eight, the answer "never" was assigned a "1" value and "always" a "0" value. The answers "almost never," "sometimes," and "often" were assigned "0.75," "0.50," and "0.25" values, respectively. Patients whose result was lower than six were considered as having low therapeutic adherence; those with results between six and eight were considered as having medium adherence; and patients whose result was eight were considered as having high adherence.

The study included patients up to 12 years of age,[10] with a diagnosis of amblyopia (strabismic, anisometropic,

Table 1. Self-reporting questionnaire (SRQ)

1. Você às vezes esquece de colocar o tampão?	( ) Sim	( ) Não
2. Nas duas últimas semanas, houve algum dia em que você não usou o tampão?	( ) Sim	( ) Não
3. Você já parou de colocar o tampão ou diminuiu a quantidade de horas sem avisar seu médico porque se sentia pior quando o fazia?	( ) Sim	( ) Não
4. Quando você viaja ou sai de casa, às vezes esquece de levar seus tampões?	( ) Sim	( ) Não
5. Você usou o tampão corretamente ontem?	( ) Sim	( ) Não
6. Quando sente que o paciente está com a visão melhor, você às vezes para de usar o tampão?	( ) Sim	( ) Não
7. Você já se sentiu incomodado por seguir corretamente seu tratamento para ambliopia?	( ) Sim	( ) Não
8. Com que frequência você tem dificuldades para se lembrar de colocar corretamente o tampão?		
( ) Nunca ( ) Quase ( ) Às Vezes ( ) Frequentemente ( ) Sempre		

Source: de Oliveira-Filho AD, Morisky DE, Neves SJ, Costa FA, Lyra DP Júnior. The 8-item Morisky Medication Adherence Scale: validation of a Brazilian-Portuguese version in hypertensive adults. Res Social Adm Pharm. 2014;10(3):554-61.

or mixed), with a >2 line difference in corrected VA, with literate parents or legal guardians, who had not undergone previous eye surgeries, and who had a working cell phone.

The exclusion criteria were: patients with any cognitive disorder that made measuring VA difficult or a neurological impairment that could be the cause of low vision and also a different response to treatment (such as Down syndrome, significant intellectual disability, among others), previous eye surgery, and a failure to attend a follow-up visit.

Qualitative variables were expressed as frequencies and percentage. The mean values obtained by the SRQ were compared between intervention and control groups and between improvement or not in VA by employing the Mann-Whitney nonparametric test. The association between VA and trial group was assessed using a Chi-squared test, where $p < 0.05$ was considered to be significant. Analyses were performed using Statistical Analysis System (SAS) software, version 9.4.

RESULTS

Of 49 patients who met the inclusion criteria, 34 concluded the study. Sixteen patients (47%) were females. The patients' average age was 5.35±2.42 years, ranging from 2 to 10 years, with no significant difference between the groups (p=0.99).

From those participants who completed the study, 20 (59%) were in the intervention group. Sixteen (47%) had never been treated, and 18 (53%) were either undergoing occlusion therapy or had undergone treatment at some point.

Fifty percent of the population in study was considered as having low adherence to treatment, 29% had medium adherence, and 21% had good adherence. Average

adherence measured by the SRQ was 5.78±1.87, ranging from 1.5 to 8, for the control group was 5.54±1.77, and for the intervention group was 5.95±1.97. There was no significant difference in adherence between the group that received text messages and the one that did not.

There was no association between improvement or no improvement in VA and the trial group (intervention/control) (p=0.56).

The comparison between an improvement in VA and the mean value obtained in the SRQ showed a significant association between this improvement and adherence to treatment (p=0.03) (Table 2).

Table 2. Mean values obtained in the self-reporting questionnaire. Total compared to improvement or not in visual acuity

	Visual acuity improved		
Variable*	No (n=15)	Yes (n=19)	p-value#
SRQ, total	5.05±2.01	6.36±1.58	0.0347

* Values expressed as mean ± standard deviation; †p-value calculated by the Mann-Whitney test.
SRQ: self-reporting questionnaire.

DISCUSSION

Previous studies showed an association between text messaging and an improvement in the treatment prescribed.[11,12] That was not the case when the therapy proposed was the use of eye patches. Sending text messages did not improve treatment adherence. This may be due to several factors, such as: an insufficient number of text messages (1 every 3 days); caretakers who overlooked the messages amidst so many others they receive regularly; the family member who received the message not being the one who effectively takes care of the patient during the day.

An average adherence close to 50%, i.e., similar to the one found in our study, has been reported in other studies. However, the method for determining this adherence was more subjective in those other studies than the one we employed.[6,13,14]

The present study had several positive points. It was randomized, blinded, and included patients from both private and public health systems. It also innovated by using the SRQ to assess adherence to treatment with eye patches.

A few limitations were the dropping out of those patients who could not attend follow-up visits due to restrictions imposed by the COVID-19 pandemic, which occurred in the middle of the data collection period, and the different number of hours during which patients were supposed to wear their patches, as per determined by the physicians.

CONCLUSION

One of the key therapeutic points is deciding whether the patient did not experience an improvement in visual

acuity due to a bad adherence to therapy or because the maximum potential improvement had been reached. This study has shown a statistically significant association between an improvement in visual acuity and good adherence to treatment, as measured by the self-reporting questionnaire. This allows us to recommend the use of an SRQ as a simple method to measure adherence to treatment and to assist in making decisions about therapeutic strategies to be adopted in the patient's continuing treatment, improving the information provided to families or considering other strategies, such as atropine penalization.

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