
Article:
Steel, D.A., Codina, C.J. and Arblaster, G.E. orcid.org/0000-0002-3656-3740 (2019) Amblyopia treatment and quality of life: the child's perspective on atropine versus patching. Strabismus, 27 (3). pp. 156-164. ISSN 0927-3972

https://doi.org/10.1080/09273972.2019.1643894

Amblyopia treatment and quality of life: The child's perspective on atropine versus patching

This research was completed as part of Deborah Steel's MMedSci Vision and Strabismus degree at the University of Sheffield, which was funded by the NHS Yorkshire and the Humber LBR funding programme for Postgraduate Professional Development.

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Study conducted at: Academic Unit of Ophthalmology and Orthoptics, University of Sheffield, UK and Bradford Teaching Hospitals NHS Foundation Trust, Bradford, UK.

This research has not been presented at any national or international meetings.

Word count (text and abstract): 3905

Word count abstract: 304

ABSTRACT

Background

The impact on children of patching versus atropine treatment for amblyopia was assessed using children's perspective Health Related Quality of Life (HRQoL) scores in 5 to 7 year olds.

Methods

Forty-six children on the threshold of commencing either patching or atropine treatment for amblyopia were recruited. Treatment was prescribed for uniocular amblyopia of visual acuity (VA) 0.2 logMAR or worse. After four weeks of their chosen treatment, each child completed the Child Amblyopia Treatment Quality-of-Life Questionnaire (CAT-QoL). The Pediatric Quality of Life Inventory (PedsQL™), Young Child (5-7) Self-Report version, was completed before and after four weeks of treatment. Quality of life scores were compared between the two treatment groups.

Results

Sixty-one percent (n=28) of participants were male and 56.5% (n=26) were white British. The CAT-QoL has a range of 0-16, with 16 being the worst quality of life. No significant difference was found between the patching group (n=30, mean age 69.7 months) and the atropine group (n=16, mean age 69.3 months) for CAT-QoL quality of life scores (Patch median = 6.3, Atropine median = 5.6, U = 199, p = .341, 95% CI of the median difference -2.3 to 0.9). The Young Child (5-7) Self-Report version of the PedsQL™ has a 'total score' range of 0-100, with 0 being the worst quality of life. There was also no significant difference in PedsQL™ quality of life total scores (Patch median = 80, Atropine median = 83.33, U =239.5, p = .991, 95% CI of the median difference -13.33 to 10) after four weeks of

treatment.

Conclusion

Amblyopic children reported that patching and atropine treatments did not have a significant impact on their quality of life. Patching and atropine should continue to be offered as first line treatments for amblyopia, as children appear to tolerate both well and do not favour one over the other.

KEY WORDS; Amblyopia, Quality of Life, CAT-QoL

INTRODUCTION

Amblyopia is the most common disorder to affect childhood vision, with prevalence estimated between 1% and 5.3%.[1,2,3] By definition, amblyopia is a neurodevelopmental visual system condition caused by anomalous visual experience during the development of vision.[4] It is characterised by diminished visual functions that usually, though not always, affect just one eye.[5] Treatment for amblyopia is typically initiated before the end of the critical period of visual development; typically by the age of eight years, to gain the best chance of visual improvement; however treatment can improve visual acuity (VA) in the short term, in some patients up to age 17 years.[6] The aim of amblyopia treatment is to achieve the best possible level of VA in the amblyopic eye by promoting its use. This is most commonly achieved either by wearing an occlusive eye patch (patching) over the non-amblyopic eye for a number of hours per day,[7,8,9,10] or by instilling the cycloplegic agent atropine sulphate 1% (atropine) into the non-amblyopic eye for a number of days per week.[11,12,13,14] Both have been shown to be equally effective in the treatment of amblyopia and both are recommended as a first line treatment option.[15,16] Despite this, the choice of first line amblyopia treatment is variable around the UK, with some areas offering patching as the first and then atropine as the second line treatment, whilst others offer parents and children the choice of treatment.[17]

The treatment of amblyopia in childhood is justified by the reduced risk of incapacitating vision loss in later life.[18,19] However, the treatment of amblyopia has the potential to affect a child's psychosocial well-being,[20,21] and one study has shown that parents consider atropine has a lesser impact on the child's quality of life compared to patching.[22] The impact of amblyopia treatment on a child's quality of life, as well as the condition itself, are increasingly recognised as important considerations. Quality of life assessments are widely available but amblyopia specific Health Related Quality of Life (HRQoL) instruments are

limited, especially those which capture the child's persepective.[23] Many studies have used the Pediatric Quality of Life Inventory (PedsQL™) to assess the impact of a variety of ocular conditions on general HRQoL.[24,25,26] Each concluded that the PedsQL™ results should be interpreted with caution, as it may not be the most suitable or sensitive tool for assessing the impact of milder ocular conditions on HRQoL. A child version of the Amblyopia Treatment Index is available and has been used to evaluate the burden of amblyopia treatment from the parent and child's perspective.[27] The child version of the ATI is suitable for completion by children aged 7+ and therefore not the younger age groups that are more commonly treated for amblyopia. The Child Amblyopia Treatment quality-of-life questionnaire (CAT-QoL) has been developed to allow the younger child's (aged 4 to 7 years) perspective of amblyopia treatment to be captured and considered.[28,29,30] Therefore this study was designed to measure the impact of amblyopia treatment, patching and atropine, on HRQoL from the child's perspective using this newly developed, treatment specific CAT-QoL.

MATERIALS AND METHODS

Participants

The study was conducted in the Orthoptic Department at Bradford Royal Infirmary, UK. Recruitment began in January and concluded in July. Children aged 5 to 7 years, on the threshold of commencing either patching or atropine treatment for amblyopia, were identified from their clinical notes on the day of their orthoptic appointment and invited to participate during their consultation. All children had previously had a normal fundus and media examination, refraction under cycloplegia and at least three months of refractive adaptation if glasses were required.[5] Amblyopia treatment was offered when amblyopic eye VA was 0.2 logMAR or worse. VA was measured with a crowded VA test appropriate for each child's age and ability, either Keeler crowded LogMAR or LogMAR crowded Kay pictures.

Children with strabismic, anisometropic or strabismic and anisometropic (mixed) amblyopia were included. Previous treatment for amblyopia was not cause for exclusion from this study, providing no treatment had been done in the month prior to recruitment. Families were offered either patching or atropine and could choose the therapy they preferred for the child's amblyopia treatment. 'Patching' was prescribed between 1 to 4 hours per day at the discretion of the Orthoptist.[8,9,31,32] 'Atropine' was 1% atropine drops prescribed for weekend instillation (i.e. instillation on Saturday and Sunday).[11,12]

Excluded from the study were patients with ocular pathology causing reduced VA; children unable to complete the CAT-QoL or PedsQL™ questionnaire; children who had received amblyopia treatment during the previous month; and children who had not undertaken any treatment at the four-week follow-up visit. The study was given ethical and NHS approval and adhered to the tenets of the Declaration of Helsinki. Written informed consent from the parent or legal guardian and written assent from the child were obtained prior to enrolment in the study.

Procedure

Following the clinical decision to start amblyopia treatment, the parents and the child were offered the choice of patching or atropine. Participants were not allocated or randomised to a treatment group.

Child participants completed the PedsQL™ questionnaire (Young Child (5-7) Self-Report version) at clinic on the day that treatment was selected. A higher 'total score' (out of a maximum score of 100) indicates a better quality of life. At the four-week follow-up visit, adherence to the treatment prescribed was confirmed by asking the parents what regime had been done. For the patching group the amount of patching prescribed versus the actual amount of time worn was recorded.

The child then completed the CAT-QoL treatment specific questionnaire and the PedsQL™ questionnaire (Young Child (5-7) Self-Report version) again.

The CAT-QoL Questionnaire

The CAT-QoL questionnaire is available in seven different versions; patch, drops, glasses, patch and drops, patch and glasses, glasses and drops, glasses, patch and drops. Each version is almost identical just with slightly different wording to make it applicable to the type/combination of amblyopia treatment. Relevant to this study were the 'patch' version and the 'drops' version only, as such the child completed whichever CAT-QoL version matched their treatment type. The CAT-QoL has eight items (questions), which encompass physical, psychological and social aspects of daily life as follows;

1. Sad
2. Feeling of your patch/drops on your face
3. Hurt
4. Doing work at school
5. How other children have treated you
6. Doing things (like playing on the computer, colouring, playing games, watching TV)
7. Worried
8. Playing with my friends

Each question has three response levels, scored either 0, 1 or 2, (e.g question one 'Sad': My Patch has not made me feel sad = 0, My patch has made me feel a bit sad = 1, My patch has made me feel very sad = 2). These raw scores are then totalled to give a score between 0-16. In contrast to the PedsQL™ a lower score indicates better quality of life. The CAT-QoL comes with a Rasch scoring conversion chart (Table 1). The Rasch converted scores were used for this study (full details of the development and validation of the CAT-QoL and the

scoring system are available).[33,34,35, 36]

All questionnaires were completed by the child, with their parent present, following the user instructions. Licenses for the use of both the PedsQL™ and the CAT-QoL were obtained for the purposes and duration of this study prior to commencement.

The primary outcome measure was the CAT-QoL score after four weeks of treatment. The secondary outcome measure was the change in PedsQL™ total score from pre-treatment to after 4 weeks of treatment. Following completion of the questionnaires after 4 weeks of treatment, the orthoptic examination took place. Clinical information was recorded including age, ethnicity, gender, glasses wearer, aetiology of amblyopia, VA, treatment group, and previous treatment. Data was statistically analysed using SPSS (IBM SPSS software package version 21).

Statistics

Non-parametric analyses were performed, as the results were skewed and did not follow a normal distribution. The Mann-Whitney U test was used to compare the PedsQL™ total scores of the patch and atropine group pre-treatment to ensure no differences existed prior to treatment commencement. It was also used to compare the CAT-QoL scores of the patch and atropine group after 4 weeks of treatment and the PedsQL™ total scores of the patch and atropine group after 4 weeks of treatment. Within each treatment group, the Wilcoxon Signed Ranked test was used to compare PedsQL™ total scores pre-treatment to after 4 weeks of treatment.

RESULTS

Forty-six participants were recruited to the study between January and July. The demographics of the patching and atropine groups are shown in Table 2. Thirty-three percent of the patching group and 56% of the atropine group had previously received treatment for amblyopia, although none had received any amblyopia treatment in the two months prior to enrolment in the study. The atropine group also included more children with poorer vision in their amblyopic eye (Table 2).

Thirty (61%) opted for patching treatment and 16 (39%) opted for atropine eye drops. Sixty-one percent (n=28) were male and 56.5% (n=26) were white British. Sixty-one percent of the males (n=17) and 72% of the females (n=13) chose patching. The average age of the participants was 69.7 months in the patching group (range 60-92 months) and 69.3 months in the atropine group (range 61-85 months). All but two of the participants wore glasses (n=44), of the two without glasses, one chose patching and the other chose atropine. The design of the study, which allowed patients and their parents to choose their treatment option, resulted in the patching group being almost double the atropine group in participant number.

Reports of Problems with Treatment

Four children in the patching group reported problems including not liking the stickiness on the face, being unable to see properly when the patch was on and the patch causing redness and soreness around the eye (one of these children requested to swap to atropine at the four week follow up visit). These 4 children managed to wear the patch less than half the prescribed number of hours. Five children reportedly wore their patch for 50-75% of the number of hours prescribed, 19 children reportedly wore their patch for the prescribed

number of hours and 2 children reportedly wore their patch for an hour more than that prescribed.

Six children in the atropine group reported problems related to the anticipation and worry of having the drop instilled. Some parents reported having to physically restrain their child to instil atropine, causing distress and other parents reported instilling the atropine while the child was asleep. Two of these children requested to swap to patching at the four-week follow up visit. All children in the atropine group reportedly adhered to the weekend atropine instillation.

PedsQL™ Scores

The PedsQL™ pre-treatment total scores for both groups showed a negative skew towards better quality of life (Figure 1a). Importantly, using the Mann-Whitney U test, no significant difference in quality of life total scores between the two groups was evident prior to treatment (*U*= 232, p=.853, median for both patch and atropine groups = 80.0, 95% CI of the median difference = -10 – 6.67) as shown in Table 3.

The pre-treatment PedsQL™ total scores were compared to the PedsQL™ total scores after 4 weeks of treatment using the Wilcoxon signed-rank test. No significant difference between the total scores was found for the patching group (Z=-.817, p=.414, pre-treatment median = 80.0, after 4 weeks of treatment median = 80.0), or for the atropine group (Z=-.439, p=.6603, pre-treatment median = 80, after 4 weeks of treatment median = 83.33). This indicates that four weeks of amblyopia treatment with patching or atropine did not significantly affect quality of life, as measured by the PedsQL™.

The PedsQL™ total scores after 4 weeks of treatment showed a negative skew towards better quality of life in both groups (Figure 1b). Using the Mann-Whitney U test to compare the

PedsQL™ results between the patching and atropine group after 4 weeks of treatment, no significant difference in total scores was found (U = 239.5, p = .991, patch median = 80.0, atropine median= 83.3, 95% CI of the median difference = -13.33 - 10) as shown in Table 3. No difference was found in the scores from the different PedsQL™ (Young Child (5-7) Self-Report version) domains (physical functioning (U = 236, p = .925), emotional functioning (U = 268.5, p = .485), social functioning (U = 248, p = .844) and school functioning (U = 247.5, p = .853)) between the patching and atropine groups.

The PedsQL™ total scores after 4 weeks of treatment indicate that from the child's perspective amblyopia treatment overall did not negatively affect their quality of life, with an overall median score for all participants (n=46) of 78.2 (SD 18.4) out of a possible 100.

CAT-QoL Scores

Following four weeks of amblyopia treatment the CAT-QoL questionnaire was completed by all 46 participants which showed an overall mean converted score of 5.6 (SD 2.9) out of a possible 16. Although the CAT-QoL atropine median (5.6) was lower (towards better QoL) than the patching median (6.3) (figure 2), the Mann-Whitney U test found no significant difference between atropine and patching after treatment (U = 199, p = .341, 95% CI of the median difference = -2.3 – 0.9) as shown in Table 4.

The response to each individual question of the CAT-QoL was compared between the patch and the atropine group using the independent samples Mann-Whitney U test (Table 5).

Overall, the results from both the PedsQL™ and the CAT-QoL found no significant negative impact of either treatment option on the child. The HRQoL scores as reported by the child (aged 5-7 years) show no statistically significant difference after receiving 4 weeks of

amblyopia treatment with either patching or atropine. The 95% confidence intervals for the median PedsQL™ and CAT-QoL results, and the differences between the treatments, (shown in tables 3 and 4), demonstrate the similarity of the medians and lack of significant differences between treatments, however, the possibility of differences in a larger sample size cannot be ruled out.

DISCUSSION

This study aimed to measure, and compare, the impact of patching and atropine treatment, on the HRQoL of children with amblyopia, aged 5 to 7 years, using the CAT-QoL and the PedsQL™ HRQoL questionnaires. Children reported no significant difference between patching and atropine within the first four weeks of treatment and both treatments had little negative impact on their HRQoL. To date there have been no other studies which have explored and compared the effect of patching and atropine on HRQoL from the child's perspective in this age group. This may be because the availability of amblyopia specific HRQoL instruments for this age group is limited.[23] One study has used a child version of the Amblyopia Treatment Index (ATI) to compare HRQoL scores in older children (aged 7 to <13 years) treated with atropine and those treated with patching.[27] It was found that those treated with atropine had better overall QoL scores, and better scores on the subscales of compliance and social stigma. The adverse effects subscale was similar in both treatment groups. Interestingly, in contrast to this, our study showed a higher number of children in the atropine group reporting difficulties with carrying out the treatment and adverse effects. This could be due to the difference in age groups questioned. Our patching group may also have reported a lesser effect on QoL due to the relatively low number of hours per day that patching was prescribed in this study, giving the opportunity to carry out the treatment at

home away from peers. We also relied on the parents' reports of adherence to the treatment regime, whose accuracy may be questionable. These factors could have led to a reduced effect on reported quality of life in the patching group.

Although an adult perspective may not truly represent the thoughts and feelings of the child, the view of the parent should not be disregarded, as their involvement in the treatment is paramount to success. Parents have reported that the use of a patch can cause problems with everyday life, schoolwork and can put a strain on the parent-child relationship.[38] Parents find that implementing the treatment is not easy and is commonly associated with some level of distress.[39] Parents have also identified significantly worse adverse effects to treatment, greater difficulty with treatment compliance and increased problems with social stigma when their child is patching compared to instilling atropine.[40] Some atropine users have reported concerns about the appearance of the dilated pupil,[41] but it is mostly patch users who feel that their treatment draws adverse attention to them with teasing and name calling frequently reported.[20,21] One study reported that patch users had a significantly worse social acceptance score than atropine users.[40] Our study found no statistically significant difference in the quality of life scores between the patching and atropine groups. In this study both patching and atropine were explained to the child and parent, which instigated a discussion about which treatment they would prefer to use. This gave the child the opportunity to voice any concerns about either treatment option prior to commencement. Some parents and children openly discussed the possibility of teasing if they were to choose the eye patch, and stated from the beginning that the patch could be worn only at home. This process of actively involving the child in their own treatment decisions has the potential to aid their understanding and tolerance of the treatment given, which may then have been reflected in the answers that they gave to the CAT-QoL at their four-week follow up visit. The lack of negative impact on a child's self-reported HRQoL during the first four weeks of amblyopia

treatment may have been positively influenced by involving children in the decision about their choice of treatment.

We included children in the study who had previously undergone some amblyopia treatment, either patching or atropine. We acknowledge this may have influenced their responses to the quality of life questionnaires, positively or negatively.

Despite children reporting amblyopia treatment causing little effect on their HRQoL, difficulties with adhering to the prescribed treatment were reported in both the patching and atropine group. Four children in the patching group reported problems including not liking the stickiness on the face, being unable to see properly when the patch was on and the patch causing redness and soreness around the eye. Six children in the atropine group reported problems related to the anticipation and worry of having the drop instilled, not to the after effects of the atropine (i.e. blurred VA or light sensitivity). Some parents reported having to physically restrain their child to instil atropine, causing distress and other parents reported instilling the atropine while the child was asleep. Difficulties with instilling weekend atropine may be worse than with daily atropine due to lack of routine,[12,22] therefore a daily routine for the patch group versus a weekend only routine for the atropine group in this study could have influenced the results. One child in the patching group (3%) requested to swap to atropine and two children in the atropine group (12.5%) requested to swap to patching at the four-week follow up visit.

Study Limitations

Nearly double the number of parents, after discussing treatment type with their child, chose patching over atropine. This is an interesting finding in itself in regard to treatment preference, but did result in unequal group sizes for our study. A future study comparing HRQoL measures in children who have had input into amblyopia treatment decisions to those

who have not is needed to understand how much this is a factor in their perceived HRQoL. It is also acknowledged that the CAT-QoL is a relatively new QoL instrument and therefore extensive validation results are not available. For this reason, the PedsQL was used as a secondary outcome measure, but it is recognised that this is not a disease/treatment specific HRQoL measure and its sensitivity when used in ocular conditions in younger age groups has been questioned.[24,26] Future studies of larger, equally sized and matched groups of patients receiving amblyopia treatment for the first time and during the entire course of their amblyopia treatment would help address some of the limitations of this study. However, the findings of this study are encouraging in that during a four week course of amblyopia treatment there was no significant negative impact of either atropine or patching to perceived quality of life and no difference between the two interventions.

Conclusions

There was no difference in the HRQoL of children receiving patching treatment compared to those receiving atropine treatment. Four weeks of either patching or atropine treatment has minimal effect on the HRQoL of amblyopic children, aged 5 to 7 years. This is in contrast to previous studies that reported parents think atropine affects the HRQoL of their children less than patching. Our results suggest that offering a choice of patching or atropine as the first line treatment for amblyopia is appropriate, as children tolerate both equally well.

ACKNOWLEDGEMENTS

This research was completed as part of the MMedSci Vision and Strabismus degree at the University of Sheffield, which was funded by the NHS Yorkshire and the Humber LBR funding programme for Postgraduate Professional Development.

We would like to thank the children who took part in the study, the staff at Bradford Royal Infirmary for their support during data collection, Kim Cocks and Dr David Buckley for statistical advice and Dr Alison Bruce for her support.

CONFLICTS OF INTEREST; None.

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