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A single cohort prospective trial of the immediate effects of spinal manipulation on visual acuity

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Introduction: *There is no high quality evidence on which to judge the generalizability of isolated reports of improvement in vision following manipulation. The current paucity of research results also precludes the thoughtful design of a controlled, prospective clinical study. Hence, the purpose of the current study was to test the feasibility of conducting a clinical trial of the acute effects of spinal manipulation on visual acuity.*

Methods: *New adult patients presenting to a community based chiropractic clinic were recruited into a single cohort prospective trial to determine the immediate effects of cervical spinal manipulation on visual acuity.*

Results: *The experimental protocol was well accepted by patients and caused minimal or no disruption of the clinic routine. By some measures, chiropractic treatment was accompanied by statistically significant improvements in visual acuity.*

Introduction : *Il n'y a pas de preuves de grande qualité permettant d'évaluer la généralisation de quelques rapports d'amélioration de la vision après la manipulation. La rareté actuelle des résultats de recherche empêche également la conception réfléchie d'une étude clinique éventuelle contrôlée. Par conséquent, l'objectif de la présente étude était de tester la faisabilité d'un essai clinique sur les effets aigus de la manipulation vertébrale sur l'acuité visuelle.*

Méthodologie : *De nouveaux patients adultes qui s'étaient adressés à une clinique chiropratique communautaire ont été recrutés dans une étude de cohorte prospective afin de déterminer les effets immédiats de la manipulation vertébrale cervicale sur l'acuité visuelle.*

Résultats : *Le protocole expérimental a été bien accepté par les patients et n'a pas du tout perturbé la routine de la clinique. Selon certaines mesures, le traitement chiropratique a été accompagné par une amélioration statistiquement significative de l'acuité visuelle.*

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Discussion: *The results of this study indicate that it is quite feasible to conduct a prospective, community based clinical study of the acute effects of spinal manipulation on visual acuity.*

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KEY WORDS: chiropractic; feasibility; pilot study; visual acuity; spinal manipulation

Discussion : *Les résultats de cette étude montrent qu'il est tout à fait possible de mener dans une communauté une étude clinique prospective des effets aigus de la manipulation vertébrale sur l'acuité visuelle.*

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MOTS CLÉS : chiropratique; faisabilité; étude pilote; acuité visuelle; manipulation vertébrale

Introduction

A number of intriguing case studies have reported instances of visual disorders which apparently commenced at the time of a spinal injury and/or were relieved following manual treatment of a spinal disorder. The particular disorders have been diverse and include glaucoma or otherwise restricted visual fields[1-8], scotoma[9,10], diminished visual acuity[6,11] and diplopia[12]. In some instances it is unclear whether recovery was promoted by or merely coincident with treatment. In other cases, the temporality of events strongly suggests that the treatment contributed to relief of the visual complaint.[1,2,5,8,12] Nonetheless, it is uncertain whether the lessons learned from these interesting cases are generalizable to the wider population. Are responders to spinal manipulation highly prevalent in the general population or are they quite rare?

The generalizability of treatment effects is best determined by prospective studies employing relatively large sample sizes.[13] To date, there has been only one prospective cohort study examining the effects of spinal manipulation on visual acuity.[14] While that study did report some improvement with spinal manipulation, the outcome measure which the authors used was novel and did not take into account the logarithmic scaling of the Snellen eye chart used to measure acuity. Additionally, there was no statistical correction for the multiple comparisons that the authors used, and there was no control cohort. Thus, to date, there is little clinical evidence on which to advocate the consideration of spinal manipulation as an intervention in patients with visual disorders.

The most convincing primary research design in support of a therapeutic intervention is, of course, a randomized controlled trial. Randomization to treatment and control cohorts substantially reduces the influence of bias, and corrects for non-specific effects and natural variability.[13,15] However, randomized controlled clinical trials are complex to manage and expensive to conduct. It would be challenging to justify this expense on the basis of the meager clinical evidence currently available, and without estimates of treatment effects it would be difficult to determine appropriate cohort sizes.[16]

Hence, the purpose of the current study was to test the feasibility of conducting a clinical trial of the acute effects of spinal manipulation on visual acuity, to obtain estimates of treatment effect size, and to determine the effects of small changes in methods of data analysis.

Methods

Patient recruitment

This study was approved by the Research Ethics Board of Canadian Memorial Chiropractic College. Between September 2012 and February 2013, consecutive new patients presenting to a community based chiropractic clinic in Toronto, Canada were recruited by the clinic receptionist into a single cohort prospective trial to determine the immediate effects of cervical spinal manipulation on visual acuity. Patients were required to be 18 years of age or older, and to have not received cervical spinal manipulation in the previous 3 months. Patients with frank eye disease, other than diminished visual acuity, were excluded. No other exclusion criteria were applied. Twenty-three patients who elected to participate in the study provided written informed consent.

Experimental procedure

Immediately prior to chiropractic examination and treatment, visual acuity was assessed by one of two investiga-

Table 1.
Visual acuity pre- and post-treatment.

	Outcome Measure	Pre-treatment Mean +(S.D.)	Post-treatment Mean +(S.D.)	p-value
1. Right eye	Snellen fraction	61 (63)	52 (56)	0.059 (t-test)
	Snellen line	5.6 (3.1)	6.2 (3.3)	0.006 (t-test)
	ETDRS	70 (20)	74 (20)	0.005 (t-test) 0.013 (Wilcoxon)
2. Left eye	Snellen fraction	52 (55)	54 (54)	0.075 (t-test)
	Snellen line	6.1 (3.2)	5.8 (3.2)	0.110 (t-test)
	ETDRS	74 (20)	72 (19)	0.085 (t-test) 0.075 (Wilcoxon)
3. Pooled results	ETDRS	62(16)	64(18)	0.024 (Wilcoxon)

Legend: *Segregated outcomes for the (1.) right and (2.) left eyes were Snellen fraction, Snellen line and Early Treatment Diabetes Retinopathy Study (ETDRS) score. P values were generated using paired, two-tailed t-tests and the Wilcoxon signed rank test. For the (3.) pooled results of right and left eyes with pre-treatment EDTRS score of 80 or less, data were analyzed only with the Wilcoxon signed rank test.*

tors, both chiropractic interns, using a Snellen eye chart. Patients were requested to remove eye glasses before testing, and to stand 20 feet away from a wall-mounted eye chart. With one eye covered, they were then instructed to read the letters on the Snellen chart beginning from the top and largest letter and proceeding to the smallest line they could read. This process was then repeated for the other eye. The visual acuity and Snellen line values for each eye were recorded as the smallest line for which more than half of the letters were read correctly.

Patients were then escorted to the treatment room where they received chiropractic treatment according to their individualized treatment plans and including, but not limited to, cervical spinal manipulation. The treating doctor was unaware of the results of the visual exam. Immediately following treatment, visual acuity was measured again and the patients were released.

Data analysis

Two analyses of the data were performed. First, visual acuity scores for the left and right eyes prior to and following treatment, were compared using the paired, two-tailed t-test and the Wilcoxon signed rank test, where a p-value of 0.05 or less was considered statistically significant. Subsequently, data for patients with an initial Snellen fraction of 20/20 or better were deleted, and the remaining pooled data for the two eyes were compared, pre- and post-treatment, with the Wilcoxon signed rank test. Cohen's d was calculated as a measure of treatment effect size.

Results

Within the recruitment period, 23 subjects were enrolled and completed the study. There were no drop-outs. The process of vision testing apparently caused minimal or no disruption of the normal clinic routine and was well accepted by patients. In this study, there was no attempt to record adverse events, and none were spontaneously reported by patients. The subjects consisted of 6 males and 17 females aged 22- to 71-years old (mean 43 years, S.D. 17 years). Thirteen subjects routinely wore eyeglasses which were removed prior to testing. One subject wore contact lenses which were not removed. Fifteen of the subjects were naïve to spinal manipulation.

Raw visual acuity data are attached as supplementary file #1. Table 1 shows the summary results for right and left eyes (mean ± standard deviation) in terms of Snellen visual acuity fractions, Snellen line scores and ETDRS

(Early Treatment Diabetic Retinopathy Study) scores. There were no statistically significant changes in any measure of visual acuity in the left eye using either the paired, two-tailed t-test or the Wilcoxon signed rank test (Cohen's d = -0.10). For the right eye, there were statistically significant changes in the Snellen line score and the ETDRS score (Cohen's d = 0.21), but not in the Snellen fraction score.

When data were removed for eyes with an initial Snellen fraction score of 20/20 or better, and the remaining data for the 2 eyes were pooled ('Pooled results,' Table 1), there was a significant improvement (p=0.018 per Wilcoxon signed rank test) in visual acuity for the ETDRS score (Cohen's d = 0.11). There were insufficient remaining data for separate statistical analyses of the left and right eyes.

Discussion

This study measured immediate changes in visual acuity following chiropractic treatment which included cervical manipulation. Perhaps due to the convenience of the testing process and the fact that pre- and post-treatment measures were taken in a single visit, there were no dropouts and no incomplete data sets. By some measures, with the caveats discussed below, there were immediate improvements in visual acuity following treatment.

A number of previous studies of spinal manipulation and visual acuity have employed eye charts as evaluation tools.[6,11,14] However, caution must be exercised when interpreting the data.[17] The Snellen fraction represents acuity based on the distance at which the subject can resolve a symbol. On the other hand, the physiological basis for acuity is the ability to resolve two points within the visual field (or more precisely on the spherically shaped retina) and hence could more properly be described in terms of angles rather than distance. Thus, Snellen fractions and line scores are logarithmic and cannot be directly interpreted using conventional statistical methods, so that our apparent finding of an improvement in Snellen line score for the right eye (Table 1) is in fact spurious. The same considerations would affect the conclusions of the previous study by Kessinger and Boneva[14] and those case studies which reported raw eye chart data.

In order to apply conventional statistical analyses, such as a t-test or Wilcoxon signed rank test, Snellen data must first be converted to values on a scale which reflects the arc subtended by a line joining two points in the visual field. One such scale is the Early Treatment Diabetic Retinopathy Study (ETDRS) scale.[18] In the current study, when Snellen data were converted to ETDRS scores, there remained a convincing improvement in visual acuity in the right eye according to the paired, two-tailed t-test (p=0.005) or the Wilcoxon signed rank test (p=0.013). Based on a Cohen's d = 0.21, this would be considered a small effect. Given the small number of subjects in this pilot study, it is not possible to determine whether or not the data were truly normally distributed, and so the Wilcoxon test, which is more parsimonious, provides a more rigorous test of statistical significance. Analyzing the data from the two eyes separately is also appealing in terms of statistical rigour, as it allows for a laterality to the clinical phenomena. This would occur in the unlikely event that all left eyes were, on average, inherently different in some regard from right eyes. Analyzing the eyes separately also allows for the less unlikely possibility that eyes respond differently to contralateral versus ipsilateral adjustment and the clinician had a bias (in the scientific sense) for adjusting on one side versus the other.

In our second statistical analysis, we pooled data for the two eyes as if the response of one eye would be independent of the response of its contralateral mate. This may or may not be true in any given patient depending in part upon the cause of their visual deficit. It may, nonetheless, be the preferred practical approach since in everyday life functional visual acuity is essentially determined by the acuity of the 'best' eye.[19] In the second analysis, we used only ETDRS values, and we removed data for eyes with an initial Snellen fraction of 20/20 or better. This step was taken in order to minimize any 'ceiling effect' – if visual acuity was already very good, then there would not be much room for it to improve following any treatment. This selective removal of data necessarily creates a non-Gaussian distribution which requires non-parametric analysis – the Wilcoxon signed rank test. The analysis was based on 30 eyes with pre-treatment ETDRS scores (mean $\pm$ S.D.) of 62 $\pm$ 16 and post-treatment scores of 64 $\pm$ 18. Thus in our second analysis, which we believe to be both more rigorous and realistic, treatment was associated with a statistically significant improvement in visual acuity (p=0.024) which was quite small in terms of treatment effect size (Cohen's d =0.11).

Conclusions

In summary, this study suggests that it is feasible to measure acute responses to chiropractic treatment in a community-based clinic. Furthermore, a small but statistically significant treatment effect may be achieved with a relatively small number of subjects. In this instance, the treatment effect was quite small, and is of uncertain clinical significance. These results do not speak to long term effects. Additionally, there was no control group in this study and so it is not possible to determine the contribution of a non-specific treatment effect. Overall, however, given the promising pilot data, it would appear reasonable to conduct a larger controlled study of the effects of spinal manipulation on visual acuity and to anticipate convincing acute results, either negative or positive, with a manageable number of subjects. The outcome measure should be a linear measure of visual acuity, such as the ETDRS score, and consideration should be given to the influence of a ceiling effect and to the appropriateness of a non-parametric statistical analysis.

Competing interests:

All authors declare that they have no competing interests.

Authors' contributions:

MA, CR and BB all contributed to the design of this study. MA and CR conducted data collection. BB conducted data analysis. MA, CR and BB all contributed to and approved the final manuscript.

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