Effect of Osteopathic Manipulative Therapy in the Attentive Performance of Children With Attention-Deficit/Hyperactivity Disorder

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Context: Attention-deficit/hyperactivity disorder (ADHD) is a neurobehavioral disorder most commonly affecting children and teenagers. It is characterized by the coexistence of attention problems and impulsivity and hyperactivity. Although several studies have been conducted on the efficacy of conventional and alternative therapies in children with ADHD, few studies have specifically investigated the efficacy of osteopathic manipulative therapy (OMTh).

Objective: To evaluate the efficacy of OMTh in the treatment of children with ADHD.

Methods: Children aged 5 to 15 years with a primary diagnosis of ADHD who were admitted to a single neuropsychiatry unit from November 2008 to September 2009 were randomly assigned to an intervention group (OMTh + conventional care) or a control group (conventional care only). Biancardi-Stroppa Modified Bell Cancellation Test accuracy and rapidity scores were recorded for both groups at baseline and after 10 weeks. Statistical analyses included univariate tests and multivariate linear regressions.

Results: A total of 28 participants were included in the study: 14 in the OMTh group and 14 in the control group. Univariate statistical analysis showed no statistically significant differences between the intervention and control groups in terms of characteristics measured at baseline, except for psychosocial intervention ($P=.05$). Multivariate linear regression showed that OMTh was positively associated with changes in the Biancardi-Stroppa Test accuracy ($\beta=7.948$ points; $P=.04$) and rapidity ($\beta=9.089$ points; $P=.03$) scores.

Conclusion: Participants who received OMTh had greater improvement in Biancardi-Stroppa Test scores than participants who received conventional care only, suggesting that OMTh can potentially increase performances of selective and sustained attention in children with ADHD. To confirm these findings, studies of larger and more diverse populations are warranted.

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Attention-deficit/hyperactivity disorder (ADHD) is a neurobehavioral disorder most commonly affecting children and teenagers that is characterized by deficit of attention associated with impulsivity and hyperactivity.[1] Attention-deficit/hyperactivity disorder is typically diagnosed in children before age 7 years, with symptoms being present for at least 6 months before diagnosis.[1-3] In 2007, a systematic review reported that the worldwide prevalence of children affected by ADHD was 5%.[4] Another multicenter study showed that the prevalence of ADHD is 3 times higher in males than in females.[5] Current advances in neurobiology have led to research on the multifactoral etiologic processes of ADHD; the evidence concludes that genetic, traumatic, neurologic, and environmental components are the most likely causes of the disorder.[6-10] Although pharmacokinetic drugs targeted at the central nervous system and behavioral therapy are standard treatments for patients with ADHD, results are discordant in terms of long-term efficacy and effectiveness.[11] Furthermore, adverse effects have been associated with long-term use of pharmacokinetic drugs.[12]

The use of complementary and alternative medicine for the management of ADHD in children has been investigated.[13-15] This area of research, however, still lacks robust evidence. Similarly, few studies have been conducted on the use of osteopathic manipulative treatment (OMT) for ADHD. Frymann and colleagues have investigated the application of osteopathic care for children with learning problems,[16] psychological deficiencies,[17] and seizure disorders.[18] This research highlighted the clinical association between newborns' traumas, somatic dysfunction, and physiologic development of the central nervous system.[16-18] Lassovetskaia[19] carried out a study on children with language and learning problems. Among 96 children with delayed academic performance, children who received OMT scored significantly higher in almost all categories of academic performance after 6 to 12 weeks compared with children who did not receive OMT.

Several tools have been widely used to evaluate attention performance in children with ADHD. However, differences in applicability, interrater reliability, ease of use, and validity exist. Among those clinical tests, the Biancardi-Stroppa Modified Bell Cancellation Test was introduced in late 1989 to evaluate the performance of sustained and selective attention in visual neglect,[20] incident stroke,[21] and children with ADHD.[22]

The primary objective of the present study was to determine the effect of osteopathic manipulative therapy (OMTh) on attention tasks in children with ADHD. Specifically, we aimed to detect differences in Biancardi-Stroppa Test scores between children who received OMTh plus conventional care and children who received conventional care only.

Methods

Setting and Participants

The present randomized controlled trial was approved by the Accademia Italiana Osteopatia Tradizionale institutional review board and was conducted at the Center for Pediatric Neuropsychiatry at the Macerata Public Hospital in Italy from November 2008 to September 2009. Male and female children aged 5 to 15 years with a primary diagnosis of ADHD who presented to the Center for Pediatric Neuropsychiatry during the study period were recruited to participate in the study. Participants were excluded if they had a secondary diagnosis of ADHD or a diagnosis of mental retardation, anxiety disorder, pervasive development disorder, diphasic disorder, childhood schizophrenia, manic episode, underdevelopment of a special learning skill, overactive symptoms caused by organic disorders, or adverse drug reactions. All participants needed informed consent from their parent or legal guardian to be included in the study. Parents and participants were given information regarding the study design and protocols.

At enrollment, participants were examined by a neuropsychiatrist (M.P.), who confirmed the ADHD diagnosis according to criteria in the 4th edition of *Diagnostic and Statistical Manual of Mental Disorders*.[1] The neuropsychiatrist (M.P.) and the psychologist (F.F.) entered the following clinical data for each participant into a computer-based spreadsheet at enrollment: age, sex, date of birth, duration of labor, route of delivery, gestational age at birth, body mass index, psychomotor development (ie, time to crawling, walking, and verbalization), drug therapy, psychosocial intervention, and history of sleep disorder, physical or psychological trauma, physical activity, menarche, gastrointestinal disorders, and visual, dental, and otolaryngologic disorders. Moreover, data on adverse effects and adverse events were collected at each session by the neuropsychiatrist (M.P.).

At entry, participants were randomly assigned to either an intervention group (OMTh + conventional care) or a control group (conventional care only). The randomization was based on permuted-block process (ratio 1:1) and was generated using R statistical program (v.2.12.0, R Foundation for Statistical Computing). Both the neuropsychiatrist and the psychologist were blinded to the allocation of participants. The participants and their parents were not blinded to group placement, but they did not receive information about the outcomes of the study.

Conventional Care

Participants in both groups were receiving drug therapy and psychosocial intervention before enrollment in the study, if indicated, and continued to receive these therapies for the duration of the study. First-line drug therapy involved the use of psychostimulants (methylphenidate or atomoxetine), with posology following national guidelines defined by the Italian Ministry of Health.[23] The psychosocial intervention was part of a cognitive-behavioral program that was led by a specialized psychologist (F.F.). Participants in the program underwent weekly group and individual sessions aimed at promoting and strengthening the use of self-control strategies (cognitive-behavioral program).[24] The psychosocial therapy was performed weekly by the same psychologist and in different days with respect to OMTh.

Osteopathic Manipulative Therapy

In addition to conventional care, children from the intervention group received OMTh for the entire period of the study. The OMTh techniques were chosen according to each participant's needs, as well as the physical condition and age of the participant. Manipulative techniques used included myofascial release, craniosacral, balanced ligamentous tension, and balanced membranous tension.[25-27] At enrollment, each participant was randomly assigned to 1 of 4 osteopaths (A.A., C.L., L.D.M., or C.G.) certified by the Registro Osteopati d'Italia. Osteopaths included in the study obtained the same osteopathic education at Accademia Italiana Osteopatia Tradizionale and underwent 8 hours of prestudy training that defined a standardized evaluation procedure on the basis of Johnston's functional tests.[28] Osteopaths remained with their assigned participants for the duration of the study.

The sequence and dose of OMTh techniques were left to the discretion of the osteopaths and not based on a predetermined protocol. Participants allocated to the intervention group received six 40-minute OMTh sessions. The first 2 sessions occurred weekly and the last 4 sessions biweekly, for a total of 10 weeks. Sessions occurred on the same day of the week to reduce performance bias, increase adherence rates, and reduce the risk of overlapping treatments. For each session, the treating osteopath collected data on somatic dysfunction found.

Biancardi-Stroppa Modified Bell Cancellation Test

All participants took the Biancardi-Stroppa Modified Bell Cancellation Test (*Figure*)[22] at enrollment and after 10 weeks; participants in the intervention group took the test the day after their last OMTh session. The Biancardi-

Stroppa Test, used to measure visual-spatial attention, is a modified version of the traditional paper-and-pencil test called the Bell Cancellation Test.[21] The test consists of 4 different sheets, each of which contains 35 bells among other confounding stimuli (such as icons of houses, trees, fish, and horses) of the same size and orientation in space. Participants are asked to find and tick only the bells within a fixed time (2 minutes) for each sheet. The examiner (F.F.) recorded the total number of bells found on all 4 sheets after 8 minutes (ie, the accuracy score) and the total number of bells identified in the first 30 seconds per sheet (ie, the rapidity score) for each participant. Four rapidity scores were recorded for each participant (ie, 1 per sheet), and the mean score was used for analysis.

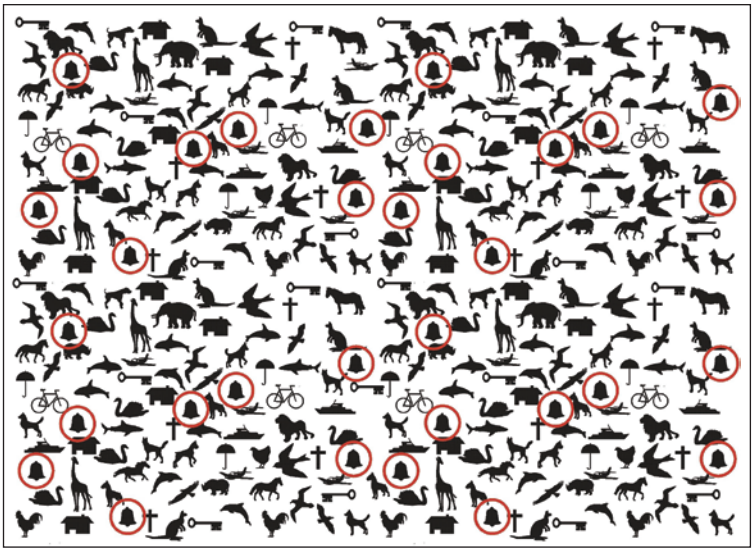

Figure.
Biancardi-Stroppa Modified Bell Cancellation Test.[22]
Red circles highlight all bells in the chart. Reprinted with permission from Andrea Biancardi.

Statistical Analyses

Descriptive analysis was performed on continuous data using arithmetic mean, median, and standard deviation (SD) and on categorical data using frequency and percentage. The Shapiro-Wilk test was used to assess the normality of the sample. Univariate statistical tests (student t and χ^2) were performed to explore the differences in Biancardi-Stroppa Test scores between intervention and control groups at baseline and at the end of the study period. Multivariate linear regression was used to evaluate differences in Biancardi-Stroppa Test accuracy and rapidity scores and independent variables including age, sex, drug therapy, psychosocial intervention, OMTh, and the other Biancardi-Stroppa Test score (ie, the rapidity score for the accuracy score and vice versa). Results were expressed in point estimates (β) and 95% confidence intervals (CIs).

Period prevalence was used as an epidemiologic measure to detect the proportion of the population with a given SD over the entire study period. Alpha values less than .05 were considered statistically significant. To compute post hoc power analysis, regression model values were used. The following parameters were taken into account: numerator degree of freedom equal to 6, denominator degree of freedom equal to 27, and effect size equal to 2.44. The effect size was calculated using the following formula: $R^2/1\text{-}R^2$, where R^2 is the population squared multiple correlation. All analyses were performed using R statistical program (v.2.12.0, R Foundation for Statistical Computing). The R package used for post hoc power calculation was "pwr."

Results

Forty consecutive outpatients entered the study, 28 of whom met the study criteria and were included in the study. Of those, 14 participants were randomly assigned to the intervention group and 14 to the control group. No dropouts were recorded throughout the study period. At enrollment, the study sample was normally distributed (Shapiro-Wilk normality test for age, W=0.97; P=.58) and univariate statistical analysis showed no significant

Table 1.
Baseline Characteristics and Outcome Measures of Children With Attention-Deficit/Hyperactivity Disorder (N=28)

Characteristic, No. (%)[a]	Study Group (n=14)	Control Group (n=14)	*P* Value[b]
Sex			>.99
Male	11	12	
Female	3	2	
Age, Mean (SD)	7.8	8.6	.24
Drug Therapy			>.99
Yes	4	5	
No	10	9	
Psychosocial Intervention			.05
Yes	6	12	
No	8	2	
Biancardi-Stroppa Modified Bell Cancellation Test Score, Mean (SD)			
Rapidity	44.1	42.9	.81
Accuracy	104.1	112.7	.24

[a] Data presented as No. (%) unless otherwise indicated.
[b] For data presented as No. (%), *P* value is from χ^2; for data presented as mean (standard deviation [SD]), *P* value is from *t* test.

differences between the 2 groups for any characteristic except for psychosocial intervention (*Table 1*). No statistically significant differences were found between groups for any clinical data.

At the end of the study period, there was a statistically significant difference between the intervention group and the control group on Biancardi-Stroppa Test scores for rapidity (mean [SD] score, 59.2 [17.6] vs 42.2 [7.4]; $P<.01$) but not for accuracy (mean [SD] score, 116.4 [24.3] vs 110.5 [10.5]; $P=.14$).

Multivariate linear regression showed that OMTh was positively associated with a change in the Biancardi-Stroppa Test accuracy score (β=7.948 points; 95% CI, 0.181-15.714; $P=.04$). Similarly, the Biancardi-Stroppa Test rapidity score was associated with a positive change for the Biancardi-Stroppa Test accuracy score (β=0.387 points; 95% CI, 0.006-0.769; $P=.04$) (*Table 2*). Multivariate linear regression also revealed that OMTh and the Biancardi-Stroppa Test accuracy score were positively associated with a change in the Biancardi-Stroppa Test rapidity score (β=9.090 points; 95% CI, 0.821-17.358; $P=.03$ and β=0.451 points; 95% CI, 0.007-0.896; $P=.05$; respectively) (*Table 3*).

Post hoc power analysis was computed and the final result was 0.99. No adverse effects were recorded in the study and control groups during the investigation.

In the intervention group, baseline prevalence of somatic dysfunction was as follows: L5-S1, 9; sphenobasilar synchondrosis, 7; left sacroiliac, 6; occipital condylar, 5; visceral fascia, 4; left ilium, 3; diaphragm, 2; and metopic

suture, 2. At the end of the study period, somatic dysfunction prevalence was as follows: L5-S1, 9; left sacroiliac, 3; diaphragm, 3; visceral fascia, 2; and sphenobasilar synchondrosis, 2 (*Table 4*).

During the study, the period prevalence for the following somatic dysfunctions were as follows: L5 through S1, 14; sphenobasilar synchondrosis, 11; left sacroiliac, 10; occiput-mastoid suture, 9; left ilium, 9; diaphragm, 9; interparietal suture, 7; viscera fascia, 6; occiput condyles left, 7, and right, 5; and T12 through L1, 6.

Discussion

The present study demonstrated beneficial effects of OMTh in children with ADHD. The use of OMTh as an adjunct to conventional care was associated with a statistically significant improvement of selective and sustained attentive performances, as measured using the Biancardi-Stroppa Test. On the basis of these results, it is possible to speculate that OMTh might have positive effects on short- and long-term attention in this patient population. These findings are particularly noteworthy considering that the number of participants who were undergoing psychosocial intervention was lower in the intervention group than in the control group, suggesting that the intervention group may have been in less favorable conditions than the control group at baseline. Drug therapy was not associated with changes in Biancardi-Stroppa Test scores.

Because the Biancardi-Stroppa Test was administered the day after the last OMTh session, OMTh could have more than just immediate effects on attentive performances. Limited ADHD research has been conducted in the field of osteopathic medicine; it is therefore difficult to interpret and compare our findings to those of other researchers.

In the last few years, it has been demonstrated that the endocannabinoid system is a key element in the neurophysiologic management of ADHD and that rebalancing the function of the endocannabinoid system should be the target of all therapeutic approaches.[29] McPartland et al[30] proposed that OMT produces a cannabinoid effect. Although McPartland et al studied the use of OMT in an adult population, their results raise the question of a possible cannabimimetic mechanism of the OMTh used in the current study's pediatric population. Additional research is needed to corroborate an endogenous action of OMTh.

Table 2.
Multivariate Linear Regression for Biancardi-Stroppa Modified Bell Cancellation Test—Accuracy

Characteristic	β	95% CI	*P* Value
Age	−0.714	−1.967 to 0.538	.25
Sex	2.689	−2.532 to 7.929	.30
Treatment			
Drug therapy	−0.861	−5.794 to 0.538	.72
Psychosocial intervention	−0.090	−5.860 to 5.680	.97
OMTh	7.948	0.181 to 15.714	.04
Biancardi-Stroppa Modified Bell Cancellation Test—Rapidity	0.387	0.006 to 0.769	.04

Abbreviations: CI, confidence interval; OMTh, osteopathic manipulative therapy.

Table 3.
Multivariate Linear Regression for Biancardi-Stroppa Modified Bell Cancellation Test—Rapidity

Characteristic	β	95% CI	*P* Value
Age	0.652	−0.712 to 2.017	.33
Sex	−0.495	−6.288 to 5.297	.86
Treatment			
Drug therapy	−0.176	−5.516 to 5.163	.95
Psychosocial intervention	−0.992	−7.202 to 5.218	.74
OMTh	9.090	0.821 to 17.358	.03
Biancardi-Stroppa Modified Bell Cancellation Test—Accuracy	0.452	0.007 to 0.896	.05

Abbreviations: CI, confidence interval; OMTh, osteopathic manipulative therapy.

Table 4.
Somatic Dysfunction Prevalence in Children With Attention-Deficit/Hyperactivity Disorder Before and After Osteopathic Manipulative Therapy (N=14)

Anatomic Region With Somatic Dysfunction	Positive Findings, No.	
	Baseline	End Point
Cranium		
Sphenobasilar synchondrosis	7	2
Occipitomastoid suture	1	1
Lambdoid suture	0	1
Sphenoparietal suture	1	1
Frontal suture	2	0
Left frontozygomatic suture	1	0
Left orbit	1	1
Intersquamous occiput	1	0
Left occipital condyle	3	0
Right occipital condyle	2	0
Ilium		
Left	3	1
Right	1	0
Sacrum		
S4-S5 region	0	1
Lumbosacral spine	9	9
Left sacroiliac joint	6	3
Cervical Region	1	0
Thoracic Region		
T1-T4	0	1
T5-T8	1	1
T9-T12	0	2
T12-L1	1	2
Rib/sternum	1	1
Lumbar Region	1	0
Diaphragm	2	3
Visceral Fascia	4	2

It is interesting to highlight that all participants were found to have L5-S1 dysfunction at least once during the study period. Moreover, sphenobasilar synchondrosis dysfunction was diagnosed in 79% of participants. Regarding the cranial region, the highest period prevalence was for the occiput mastoid suture (64%), the interparietal suture (50%), and occiput condyles (left, 46%; right, 29%). These results seem to confirm data from previous studies,[31] although the heterogeneity of the current study sample limits further comparisons.

Finally, the current study had several limitations. The sample size was small, and because of the lack of previous ADHD studies, we were unable to estimate a sample size based on expected effect before initiating the study. In addition, participants were not blinded and not controlled for other psychosocial and drug treatments. Thus, no detailed data on drug posology and psychosocial intervention were collected. Interexaminer reliability was not formally tested before the start of the investigation. Moreover, the lack of a predetermined treatment protocol reduces the generalizability of the results. Furthermore, the Biancardi-Stroppa Modified Bell Cancellation Test is only validated and used in children in Italy with ADHD; thus, results may not be reproducible in study populations outside of Italy.

Conclusion

Results from the present randomized controlled trial suggest that OMTh can improve selective and sustained attention performances in children with ADHD. Additional explanatory research is needed to confirm and clarify the role of OMTh in the management of ADHD.

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