Infantile postural asymmetry and osteopathic treatment: a randomized therapeutic trial

Heike Philippi* MD, Department of Paediatric Neurology, University Children's Hospital, Heidelberg;
Andreas Faldum PhD, Institute for Medical Biostatistics, Epidemiology and Informatics, Johannes Gutenberg-University;
Angela Schleupen DO;
Bianka Pabst DO, Center of Osteopathy;
Tatjana Jung;
Holger Bergmann;
Imke Bieber MD;
Christine Kaemmerer MD, University Children's Hospital, Johannes Gutenberg-University;
Piet Dijs DO, Center of Osteopathy;
Bernd Reitter MD, University Children's Hospital, Johannes Gutenberg-University, Mainz, Germany.

**Correspondence to first author at* Department of Paediatric Neurology, University Children's Hospital, Im Neuenheimer Feld 150, 69120 Heidelberg, Germany.
E-mail: Heike.Philippi@med.uni-heidelberg.de

The aim of this study was to assess the therapeutic efficacy of osteopathic treatment in infants with postural asymmetry. A randomized clinical trial of efficacy with blinded videoscoring was performed. Sixty-one infants with postural asymmetry aged 6 to 12 weeks (mean 9wks) were recruited. Thirty-two infants (18 males, 14 females) with a gestational age of at least 36 weeks were found to be eligible and randomly assigned to the intervention groups, 16 receiving osteopathic treatment and 16 sham therapy. After a treatment period of 4 weeks the outcome was measured using a standardized scale (4–24 points). With sham therapy, five infants improved (at least 3 points), eight infants were unchanged (within 3 points), and three infants deteriorated (not more than –3 points); the mean improvement was 1.2 points (SD 3.5). In the osteopathic group, 13 infants improved and three remained unchanged; the mean improvement was 5.9 points (SD 3.8). The difference was significant (p=0.001). We conclude that osteopathic treatment in the first months of life improves the degree of asymmetry in infants with postural asymmetry.

In infancy, persistent asymmetry of spontaneous movements, muscle tone, automatic responses, and reflexes may be a clue to hemiplegia, cervical plexus injury, disturbances of spine segmentation, or other neuromuscular disorders (Brett 1991, Cioni et al. 2000, Vojta 2000). However, the cause is unknown in most patients and these cases are termed idiopathic (James 1975, Canale 1982). Depending on the most pronounced feature of this disease, terms like congenital torticollis, idiopathic infantile scoliosis, or deformational plagiocephaly have been used (Lloyds-Roberts and Pilcher 1965, James 1975, Mau 1979, Binder et al. 1987, Rosegger and Steinwendner 1992, Cheng and Au 1994, Walsh and Morrissy 1998). Addressing the entire symptom complex, terms such as positional preference (Boere-Boonekamp and van der Linden-Kuiper 2001, Cheng and Au 1994), moulded baby syndrome (Lloyds-Roberts and Pilcher 1965), seventh syndrome (Mau 1979), or turned head-adducted hip-truncal curvature syndrome (Hamanishi and Tanaka 1994) have been proposed. Focussing on the functional restrictions of this symptom complex we introduce the term infantile postural asymmetry, which is defined as the coincidence of cervical rotation deficit and trunk convexity for which a measurement scale was devised (Philippi et al. 2004).

Endogenous and exogenous factors are thought to cause the asymmetry complex. Exogenous factors are intrauterine and/or postnatal constraint and birth injuries (Lloyds-Roberts and Pilcher 1965, Wynne-Davies 1975, Rosegger and Steinwendner 1992, Cheng and Au 1994). Genetic disposition, as shown by a family history of scoliosis, rapid growth, reduced muscle tone, and reduced motor activity, contributes to the development of postural asymmetry (Wynne-Davies 1975, Mau 1979, McMaster 1983). Contractures, followed by asymmetric structural growth and weight-bearing deformities, are secondary morphological abnormalities that may produce a vicious circle (Wynne-Davies 1975, Mau 1979).

Although the prognosis of the infantile asymmetry complex is thought to be good in most cases, retrospective studies have shown persistent or progressive scoliosis in 10–50% of all patients (Lloyds-Roberts and Pilcher 1965, Ferreira et al. 1972, James 1975, Wynne-Davies 1975, Thompson 1980, Canale et al. 1982, McMaster 1983, Binder et al. 1987). A recent 2-year prospective study showed that in 25% of asymmetric infants asymmetric features will persist (Boere-Boonekamp and van der Linden-Kuiper 2001). This may be the reason for a growing number of therapeutic attempts including physiotherapy, manual therapy, and osteopathy. None of these interventions has been evaluated in controlled studies.

Based on a positive episodic clinical experience we decided to evaluate osteopathic treatment in a blinded, randomized trial. Osteopathy is less invasive than other interventions, safe and, being performed by the osteopath, independent of the parents' compliance (Sutherland 1990, Magoun 2001). Fine manipulative palpation techniques, which are individually adapted to tissue quality, are the hallmark of this alternative form of therapy. It is believed to 'maintain or restore the circulation of body fluids'. The manipulation is nearly invisible from the outside and allows for blinding the intervention in the presence of the parents. The outcome was measured using a standardized video-based asymmetry scale (Philippi et al. 2004). Results are reported following the recommendations of the revised Consolidated Standards of Reporting Trials (CONSORT) statement (Altman et al. 2001).

Method

SETTING AND PATIENTS

The trial was conducted at the outpatient clinic of the University Children's Hospital and the treatment was administered at the Center of Osteopathy, Mainz, Germany. The enrolment period was from March 2002 to December 2002; the last follow-up was in January 2003.

Infants aged 6 to 12 weeks (postterm age) with a diagnosis of postural asymmetry were referred from 19 paediatric practices in Mainz. A baseline full medical history was obtained, and the infants were neurologically and physically examined by a paediatric neurologist and a physiotherapist to establish the degree of asymmetry (see Objectives, observation techniques, and outcomes). Exclusion criteria were: (1) asymmetry score below 12 points; (2) significant underlying disease; (3) gestational age below 36 weeks; (4) parents not familiar with the German language; (5) any other treatment for asymmetry in the past or at present except for handling; (6) predominant oblique body position masking the trunk curvature; and (7) lack of parental informed consent.

The trial was approved by the ethics board of the Johannes Gutenberg-University, Mainz, and all parents provided written informed consent.

TREATMENT

Infants with asymmetry were randomized to receive either osteopathic treatment or sham therapy. Infants in both groups were treated once a week for 45–60 minutes over 1 month. After each intervention the parents of all infants were instructed in handling their infant, based on the Bobath concept (Lommel-Kleinert 1999, von Aufschnaiter 1999).

For the osteopathic treatment the infants were placed on a table, with the parents sitting beside them. At each visit the osteopathic technique, and the area it was applied to, was adapted depending on the diagnostic palpation of the osteopath who assessed and treated position, tissue quality, mobility, and relation to the environment of the skull, sacrum, iliac and coccygeal bones, thorax, sternum, diaphragm, and abdomen. The specific procedures were recorded by the osteopath. For instance, so-called primary respiration and the cranial rhythmic impulse, thought to be very fine autonomous rhythmic changes of tissue quality, were used to disengage fixations of adjoining structures (Sutherland 1990, Magoun 2001). The osteopathic treatment was administered by osteopaths who were experienced in the treatment of young infants.

For the sham treatment, the osteopaths placed their hands on the infants in comparable positions without treating them. For the parents the difference between sham therapy and osteopathic treatment was unrecognizable.

OBJECTIVES, OBSERVATION TECHNIQUES, AND OUTCOMES

The primary objective of the current trial was to test the hypothesis that osteopathic treatment does not improve the degree of asymmetry in infants with infantile postural asymmetry (null hypothesis). The degree of asymmetry was assessed using standardized video-based measurements, as reported elsewhere (Philippi et al. 2004). In brief, trunk convexity and cervical rotation deficit as reactive movements to an orienting head turn in the prone and supine positions were assessed by three independent, trained, and blinded observers using a 6-point scale for each item. A total score of 4 points represents no symmetry and a score of 24 points maximal asymmetry. Statistical analysis indicated good reliability and consistency of the testing method, with an intraclass correlation coefficient of 91.5% (Cronbach alpha 0.84). Video tracings obtained at baseline and one week after the last intervention were compared.

Secondary objectives were factors that may affect treatment outcome. They included growth, age, and sex, which were derived from charts. Infantile position awake and asleep, time for carrying or 'kangarooing', and putting the infant in a car seat were recorded by the parents on a standardized questionnaire using a 4-point scale (less than 1h a week; 2–6h a week; 1–4h a day; more than 5h a day). At each visit the parents were asked to report any illness of the infant on a free questionnaire.

A further secondary objective was the evaluation of the effects of osteopathic treatment on vegetative parameters of the infants. At baseline and after each intervention the parents were asked to complete a standardized questionnaire quantifying changes in vomiting, sleeping, drinking, mood, excitability, stool frequency, and crying on a 3-point scale (more/better, same, less/worse, or don't know). To identify excessive crying, which is supposed to be more prevalent in asymmetric infants, the parents had to complete the standardized questionnaire according to Wurmser et al. (2001).

RANDOMIZATION AND BLINDING

At the baseline visit, the trial was explained in detail and written informed consent was obtained from the parents within the next three days. Eligible infants were randomly assigned to the treatment groups. Block randomization was used to achieve a balanced parallel group design stratified for two age groups (6–8 wks and 9–12 wks). The assignments were presented in sealed, sequentially numbered envelopes to the study coordinator who scheduled the intervention appointments by telephone and informed the osteopath about the infant's group assignment.

Parents, video scorers, and the physiotherapists and physicians performing the baseline and final examinations were blinded to the treatment assignment for the duration of the trial. Osteopaths, statistician, and study coordinator were unblinded.

STATISTICAL ANALYSIS AND STOPPING RULES

For testing the null hypothesis the mean of the total score of a patient rated by three independent observers given at the outcome recording was subtracted from the respective mean total score at the baseline recording. This averaged total score difference (TSC) was the assessment criterion for the primary objective of the trial. The interobserver reliability of TSC was assessed using intraclass correlation.

The one-sided null hypothesis that the TSC is not larger after osteopathic therapy than after sham therapy was checked on a significance level of $\alpha = 0.025$ by using an adaptive design with two stages and independent-samples *t*-tests. The significance limit for the *p* value of the first stage was 0.016 to reject the null hypothesis and 0.15 to stop the trial for lack of benefit. The adaptive design was chosen according to a design of Bauer and Köhne (1994), which was modified by a slope parameter. The principle of modification by slope parameters will be given in a forthcoming paper by the authors. Consequently, the null hypothesis had to be rejected after the second stage if the *p* value of the second stage was smaller than or equal to 1.366

divided by the sum of the p value of the first stage and 20.985.

The primary outcome was evaluated by intention-to-treat analysis. Rules for the analysis of the primary outcome were established before starting the study and documented in the proposal submitted to the ethical board.

Possible confounders on TSC were regarded as explorative, and the p values of the corresponding tests are presented for descriptive reasons only. The impact of growth and age on TSC was evaluated by Pearson's rank correlation coefficient. The influence of sex, infantile position, parental carrying, car seat sitting, and infection on TSC, as well as the correlation between TCS and vegetative parameters, were examined by independent-samples t-tests.

SAMPLE SIZE

Following the adaptive design described above, 16 patients had to be recruited for each group to achieve a power of 80% at the first stage if the TSC after osteopathic treatment was 4 points larger than the TSC after sham therapy and the SD was 3.7 in both groups. The underlying assumptions for the power calculation were chosen in accordance with the experience of a pilot study of 12 asymmetric infants aged 7–12 weeks (mean 10wks), who were scored before and after an interval of 4 weeks without any treatment. Asymmetry in these infants showed a mean deterioration of 1 point (SD 3.7). Using an adaptive design the number of patients for the second stage had not to be fixed beforehand. The power calculation for the stage had to be performed before starting the second stage if the p value of the first stage was between 0.016 and 0.15. All results of the first stage could have been used for these calculations.

Results

Sixty-one infants were referred and assessed for eligibility. Of those, 29 infants were rejected. Thirty-two infants were randomized and 16 infants were allocated to each study group for the first-stage evaluation. There was no protocol violation. The osteopathic-treatment group and the sham-treatment group were similar for demographic and clinical variables (Table I). All infants of the treatment group and all but one infant of the control group attended the four interventions. One infant of the control group received only three interventions, which was still in accordance with the study protocol. Final video documentation 4 weeks after the last intervention was obtained for all infants, and all their videos were subsequently analyzed.

Mean changes in the asymmetry score from baseline to the final visit are shown in Figures 1 and 2. In the control group the mean improvement was 1.2 points (SD 3.5) from 14.2 points (SD 2.0) to 13 points (SD 2.8), and in the treatment group 5.9 points (SD 3.8) from 15.4 (SD 2.7) to 9.5 (SD 3.1). The mean TSC between both groups was 4.7 points (95% confidence interval [CI] 2.0 to 7.3) with $p=0.001$ (significance limit $p<0.017$), implying that the trial was finished after the first-stage evaluation. The intraclass correlation coefficient was 81% (95% CI 71 to 91%), reflecting a good interobserver reliability. In the control group, five infants improved (at least 3 points), eight infants were unchanged (within 3 points), and three infants deteriorated (not more than –3 points). In the treatment group 13 infants improved and three remained unchanged.

To explain spontaneous improvement in the control group and non-responders in the treatment group we tried to identify predictive outcome factors. Growth, age, sex, car seat sitting,

Table I: Baseline demographic and clinical characteristics

Characteristics	*Treatment group (n=16)*	*Control group (n=16)*	*Relation to outcome*
Mean (SD) age, wks	9 (2)	9 (2)	No ($r=0.05$)[a]
Sex, male/female, *n*	9/7	9/7	No ($p=0.64$)[b]
Mean (SD) growth, cm	3.9 (1.7)	3.2 (1.2)	No ($r=0.06$)[a]
Posture awake, *n*			No ($p=0.35$)[b]
All positions	7	5	
No prone position	9	11	
Posture asleep, *n*			Not tested[c]
Supine	11	12	
Supine, side	4	4	
Prone	1	0	
Parental carrying, *n*			Not tested[c]
<1h/week	1	0	
2–6h/week	1	1	
1–4h/day	11	14	
>5h/day	3	1	
Car seat sitting, *n*			No ($p=0.23$)[b]
<1h/week	7	2	
2–6 h/week	9	12	
>1h/day	0	2	
Mode of birth, *n*			Not tested[c]
Spontaneous delivery	12	6	
Caesarean section	3	7	
Vacuum delivery	0	3	
Forceps delivery	1	0	
Fetal position at birth, *n*			Not tested[c]
Cephalic presentation	14	12	
Face presentation	1	1	
Breech presentation	1	3	
Mean time of final fetal birth position, wks	13	12	Not tested[c]
(Range)	(1–28)	(15–28)	
Mean first fetal movements, gest. wks	21	21	Not tested[c]
(Range)	(16–28)	(15–28)	
Fetal movement amount[d], *n*			Not tested[c]
Little	2	2	
Moderate	4	4	
Much	10	10	
Oxytocin infusion during birth, *n*	10	8	Not tested[c]
Peridural anaesthesia, *n*	5	6	Not tested[c]
Parity, *n*			Not tested[c]
1	9	12	
2	6	3	
3	0	1	
4	1	0	
Twin birth, *n*	2	1	Not tested[c]
Mean birthweight, g	3390	3330	Not tested[c]
(range)	(2415–4300)	(2720–4250)	
Excessive crying[e], *n*	4	6	Not tested[c]
Illnesses, *n*			No ($p=0.57$)[b]
Common cold	5	5	
Diarrhoea	0	2	
Mean asymmetry score points (SD)	15 (3)	14 (3)	Not tested

[a]Pearson's correlation; [b]t-test for independent variables; [c]Sample size did not allow statistical analysis; [d]Subjective judgement of the women; [e]At least 3 hours per day for at least 3 days per week, for at least 3 weeks (Wurmser et al. 2001). gest., gestation.

parental carrying, position awake and asleep, and infections were not predictive for outcome (Table I).

Changes in the vegetative parameters were similar in both groups: vomiting (p=0.06), sleeping (p=0.36), drinking (p=0.62), mood (p=0.58), excitability (p=0.47), stool frequency (p=0.2), and crying (p=0.42). Ten out of 32 infants, six from the control group and four from the treatment group, showed excessive crying as defined by Wurmser et al. (2001). All parents were satisfied with the study. At least two of the seven vegetative symptoms aggravated for 2 days after the interventions in six patients of the control group and in four patients of the treatment group. Otherwise no adverse effects were seen.

Discussion

The results of our therapeutic trial render first evidence that osteopathic treatment in the first months of life significantly improves the degree of asymmetry in infants with postural asymmetry. Blinding the intervention and using a standardized measuring scale asserted the objectivity of this result. Sample size calculation and an adaptive study design allowed early completion of the study with an overall size of 32 infants, suggesting a strong treatment effect. The study question was formulated as one-sided to avoid directional conflicts between both adaptive stages. Moreover, we planned to recommend osteopathic treatment only if there was clear superiority of this therapy. Therefore, and for ethical reasons, we did not plan the trial to be continued to demonstrate that osteopathic treatment may be harmful. However, additional studies with a larger sample are required to evaluate the consistency of the effect of osteopathic treatment on infantile postural asymmetry.

The relative short intervention period of 4 weeks was chosen because validation of the asymmetry scale was limited to this age group. The high variability of inter- and intraindividual maturation and self-regulating processes currently precludes evaluating the extent of spontaneous improvement. However, the results of a 2-year follow-up study of 623 infants with asymmetry demonstrated a persistence of asymmetric features in about 25% of the children (Boere-Boonekamp and van der Linden-Kuiper 2001). Our patients are currently followed up using a standardized protocol, although their analysis will be complicated by variable individual treatment regimes after the end of the study.

As the analysis of our data failed to identify any reliable predictor for outcome, the question of which asymmetric infant has to be treated cannot be answered. During the spontaneous course (pilot study for sample size calculation) we have seen both spontaneous improvement and deterioration. Consequently, the only way of avoiding over- or undertreatment is to watch closely the development of the asymmetric infant by using the asymmetry scale. During the observation period, handling recommendations may be beneficial as indicated by a mean improvement of 1.2 points in the control group versus a mean deterioration of 1 point in the preceding spontaneous course group. Admittedly, accepting a waiting period conflicts with empirical knowledge that with decreasing tissue smoothness, therapeutic efficacy may decrease.

Not until recently have asymmetric features in infancy been studied in a standardized and prospective way (Cioni et al. 2000, Boere-Boonekamp and van der Linden-Kuiper 2001, Philippi et al. 2004). However, different aspects have been considered and terminology is preliminary. This may be a potential source of confusion. Cioni's asymmetry scale

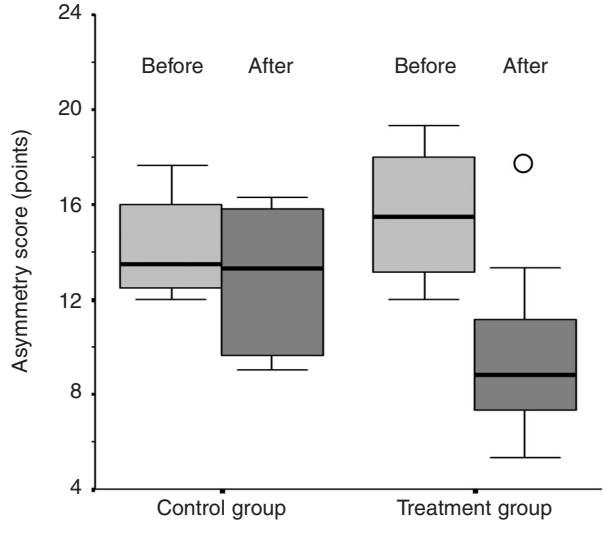

Figure 1: *Total score before and after intervention in treatment and control groups. Results are presented by box-and-whisker plots. Horizontal line in middle of a box shows mean. Edges of a box mark 25th and 75th centiles. Whiskers show range of values that fall within 1.5 box-lengths. Values more than 1.5 box-lengths from 25th or 75th centiles are marked by a circle.*

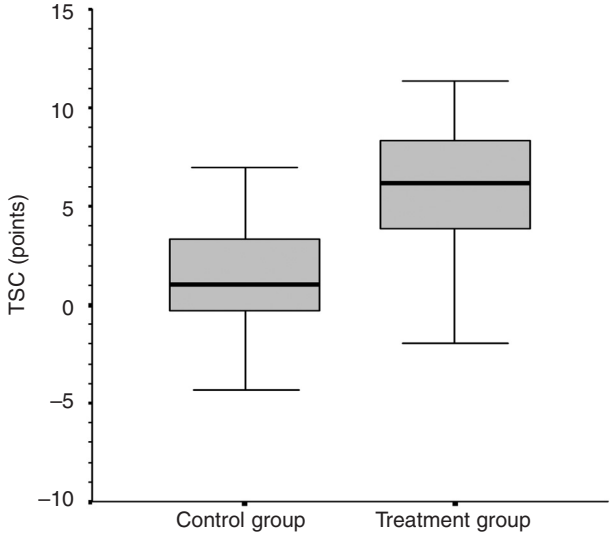

Figure 2: *Total score difference (TSC) in treatment and control groups presented as box-and-whisker plots. A positive TSC represents an improvement, a negative TSC a deterioration.*

evaluates asymmetric general movements and serves for early identification of hemiplegia. Boere-Boonekamp and our study group investigated the same condition: the entire infantile and idiopathic asymmetry complex (see Introduction) from different perspectives. The Boere-Boonkamp group studied the course in infants with positional preference, which was defined as a head rotation preference to one side and head rotation restriction to the contralateral side in the supine position. Our study group focused on head and spinal movement restrictions in the supine and prone positions. However, the data of both study groups highlight that for evaluation of the asymmetric infant and its sequels (persistent scoliosis, restricted head movements, asymmetric gait disturbances, facial scoliosis with temporomandibular joint displacement and/or functional lateralities), the broad clinical spectrum including functional aspects has to be considered rather than prematurely categorizing an infant as having torticollis, scoliosis, or plagiocephaly only.

Physiotherapy and manual intervention are used in many infants including those with postural asymmetry, but there have been few attempts to prove their effectiveness. Although research in this young age group is difficult because of maturation effects, the protocol of our asymmetry model opens the opportunity for similar studies of other therapeutic concepts.

Conclusions

Our data suggest that osteopathic treatment in the first months of life is beneficial for infants with idiopathic asymmetry, and that rehabilitation methods can be evaluated in this young age group.

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