Effectiveness of Osteopathic Manipulative Therapy in Nonsynostotic Plagiocephaly. Protocol of randomized controlled trial.

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Osteopathic manipulative therapy in NonSynostotic Plagiocephaly. A randomised Controlled Trial.

Nonsynostotic Plagiocephaly (NSP) is a non-synostotic deformation of the head that results from external forces that mould the skull in the 1st year of the life. (1) NSP may be detected in up to one of five infants during the first two months of life. (2) Risk factors associated with NSP include prematurity, prolonged labour, unusual birth position, assisted delivery, twins, first-born child, limited neck rotation or preference in head position, maternal age (older) and male gender.(3)(4) The prevalence of NSP is related to the age of infants, and changed over time after the educational "Back to Sleep" 1994 campaign, for reducing the incidence of sudden infant death syndrome (SIDS) (5). Prior to 1992, the incidence of NSP was estimated at 1 in 300 infants. (1). After the recommendation was estimated an increase of incidence of NSP that varies with different definitions and measuring methods. Ballardini et al. (6) reported on 283 infants examined with Argenta's assessment tool, 37,8% with DP at 8-12 weeks. Mawji et al. (7)estimated the incidence of NSP in infants at 7 to 12 weeks of age to be 46,6% using the Argenta's tool. Van Vlimmerer et al. evidenced on 380 infants an increased from 6,1% at birth to 22,1% at 7 weeks, with the plagiocephalometry assessment tool.(8). By two years of age, the point prevalence of positional plagiocephaly may be as low as 3.3% (3). Of note, four months seems to be the critical age for the development of NSP. (8)

Previously, NSP was considered merely a cosmetic problem (9)(10), but it causes parental worried and can require costly and lengthy management (11). Moreover, evidence has increased for a possible association, between developmental delay and deformational plagiocephaly. (12) Speltz et al. (11) found a clinically significant differences in gross motor development, infants with DP scored lower on items such as sitting up, rolling back to side, and crawling. Cabrera -Martos et al. (13) reported in children aged 3-5 years with history of non-synostotic plagiocephaly present significant differences in thoracic mobility and a muscle shortening of trunk and lower limb muscles.

In the first instance, assessment and diagnosis of NSP is based on a clinical examination from the anterior, posterior and vertex positions, look for symmetry of cheeks, eyes, and ear.(1) Visual assessment proposed by Argenta is an excellent way of communicating and explaining to parents the shape of a baby's head(13). In addition, accurate and consistent measurements of some transcranial diameters, head circumference, cranial width and length. DP is generally defined as including the presence of one or more of the following: a cranial vault asymmetry (CVA), of 3 mm or more, a Trans-cranial Vault Asymmetry (TCVA) (14) (15) of 4mm or more and an Oblique Diameter Difference Index (ODDI) score of 104% or more (16). Many tools are available for the clinical diagnosis and management of DP, including anthropometric calipers, plagiocephalometry, moulding device, digital devices with software analysis, and 3D scanning device (1)(17) (18).

Plagiocephalometry has been identified as an accurate, cost-effective, non-invasive method with a good intraclass correlation. The ODDI score being the most clinically relevant measure. (19)

Intervention strategies are depending on degree of NSP, age of infant and compliance to the therapy (1) Evidence reports that timing of treatment is generally consistent in suggesting that earlier treatment is more effective than later treatment. Common management's include repositioning and physical therapies that have a high rate of reducing NSP (9). For moderate persistent or severe NSP that are not responsive to conservative management strategies, helmet therapy can be used by the age of 5-6 months (1)(20).

Others option for the treatment of NSP are the CAM therapy. Osteopathic manipulative medicine is a form of manual therapy used to diagnose and treat somatic dysfunction, normalize the structure-function relationship and promote the body's own self-healing mechanism (21). Osteopathic manipulative medicine is commonly used as an adjunctive medical approach in the treatment of patients, including paediatric patients in different age categories, for a variety of conditions (22). The treatment component of osteopathic manipulative medicine is osteopathic manipulative therapy (OMTh) manipulative care provided by foreign-trained osteopaths), an array of many types of manipulative technique (23), considered safe and effective, used for many paediatric disorders, such as torticollis, neck pain, scoliosis, asthma, constipation and otitis. (24) (25) In NSP, the only pilot study shows an average reduction of 50% asymmetry in 12 infants who have undergone four osteopathic treatments. (16).

Therefore, the potential benefit of OMT in NSP requires studies with a larger population and, for the first time, in a randomized controlled trial. In the current study will test the hypothesis that a course of six osteopathic manipulative therapy will reduce the cranial asymmetries compared to Light Touch Therapy (LTT).

The objective of this study will be to assess the effectiveness of OMTh in reducing cranial asymmetries in neonates with Nonsynostotic plagiocephaly from 1 to 6 months of age in addition to repositioning therapy, compared to LTT.

Methods

Study design and setting

A randomized (1:1 ratio) placebo-controlled, parallel group study will be performed at the Department of Neonatology of Sant'Anna Hospital in Turin from September 2016 to February 2020. The trial was approved by the ethical commitee of *Città della Salute e della Scienza* of Turin (0074260) and registered on www.ClinicalTrials.gov (identifier: NTC NCT03970395).

Population

Eligible participants will be infants between one and six months of age at first assessment, with Nonsynostotic plagiocephaly assessed using the Oblique Diameter Difference Index (ODDI) score of 104% or more, at term corrected age if born prematurely. Infants with synostotic plagiocephaly, infants who undergo an osteopathic manipulation before the enrolment, congenital muscular torticollis, dysmorphism, syndromes or cerebral palsy will be excluded. Written informed consent from parents or guardians will be obtain prior to the study enrolment of infants.

Randomization and blinding

Infants will be randomly assigned to either OMT group or Light Touch Therapy (LTT) groups using simple randomization procedures (computerized random number generator www.random.org) with a 1:1 allocation, that will be prepared in advance by an independent biostatistician. The allocation sequence will be concealed from paediatrician enrolling and assessing participants in sequentially numbered, opaque, sealed envelopes. Whereas parents or guardians' infants will be unaware of the allocated arm for the entire duration of the study. Outcome assessors, physical therapist, neonatology's staff will be kept blinded to the allocation. Two osteopaths in charge of osteopathic manipulative therapy and light touch therapy will be unaware of the outcome and clinical assessment but will not blinded to group assignment. The statistical analysis will be performed by a biostatistician who is not involved in the clinical allocation and management of patients.

Measures

During the first assessment, will be collected data about the obstetrical, perinatal and postnatal information: gender, age, age for preterm: term equivalent age (TEA), gestational age, birthweight, head circumference, presentation at birth, delivery, mother's first pregnancy, multiple birth, feeding, sleeping, daytime position, mother's age and father's age. Data will be retrieved by a paediatrician who will be blinded to group assignment.

The primary outcome will be an improvement in cranial asymmetries from baseline at 3 months and at 1 year of age, defined as a reduction of ODDI score < 104%. (9) The category of DP is defined by reference to the following score: ≥104 <108 mild NSP, ≥ 108<112 moderate NSP, ≥ 112 severe NSP.(19)

The ODDI score will be carried out by plagiocephalometry a strip of thermoplastic material that is located at the widest transverse circumference around the head of the infant. The score will be calculated as the longest oblique diameter divided by the shortest oblique diameter multiplied by 100%. Assessments will be performed by an osteopath blinded to group allocation and to clinical information.

Adverse events

Symptoms such as irritability that may occur after the osteopathic manipulative therapy or light touch therapy will be reported from first treatment up to the end of the course of care, at 3 months.

Arms and Interventions

Both groups will receive repositioning therapy that will be administered to the parents or guardians during the first visit. In addiction the two groups, OMTh and LTT will receive six interventions, first at baseline, second at 1 week, the third at 3 weeks, and then three more at 3 weeks.

OMTh

Osteopathic manipulative therapy requires an assessment phase to identify the area in which somatic dysfunctions are present in order to be treated with a specific osteopathic approach and technique. The assessment includes the pelvic girdle and lower limb, thorax abdominal area, pectoral girdle and upper limbs, cervical and upper thoracic area, cranial vault, cranial base and visceral cranium. The treatment consists of balanced ligamentous tension technique, myofascial release, visceral manipulation, and balanced membranous tension technique. The OMTh will last 45 minutes, including 15 minutes of assessment and 30 minutes of treatment.

OMTh and LTT will be performed by two registered osteopaths with a specific background in paediatric field.

Light Touch Therapy

The LTT is consistent with the OMTh during the phase of assessment. Treatment retains the same areas used for osteopathic manipulation, but avoids prolonged touch in any area of the body, moving the hands every few seconds, flattens and softens the surface of the hands to minimize focal areas of force.(26)

Repositioning Therapy

The repositioning therapy will be performed by a paediatric physical therapist, with specific neonatal experience. The repositioning therapy consists of strategies that guide parents or guardians to position the neonate “back to sleep”, by alternating head position, the use of tummy time while supervised, and infants will spend limited time in car seats or other devices that facilitate supine positions. In active counter-positioning the parents or guardians will be encouraged to put some toys on the side of the head where neck rotation is limited.(1)

Statistical analysis plan

This trial represents the first study involving only infants with ODDI score ≥ 104%. We considered that Osteopathic Manipulative Therapy reduced, NSP by at least 30% compared to the control group - Light Touch Therapy at the end of three-month intervention. We needed 45 infants, for each group, to give 80% power to detect a significant difference between the two groups, corresponding to a 30% of reduction of absolute risk, at the end of the intervention, with a type 1 error of 5%.

We conducted the analysis of baseline clinical characteristics according to intention-to-treat (ITT) using last observation carried forward (LOCF) imputation technique and, by per-protocol (PP) analysis of infants receiving 100% of three-month intervention. Continuous variables were analysed with means and standard deviation and discrete variables with counts and percentages. Intervention effect was presented as change in prevalence of mild NSP in the intervention and control group, defines as ODDI score <104% from baseline to three-month and at one year of age. Relative Risk (RRs) and 95% confidence intervals (CI), absolute risk reductions were calculated.

Thereafter to study the independent effect of OMTh on primary outcome we carried out a multiple regression model considering age start and end of intervention, sex, delivery and presentation at birth. Data were analysed using the software STATA/IC version 15.1 for Mac (Stata Corp LLC, USA).

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