Comparison of 2 Dosages of Stretching Treatment in Infants with Congenital Muscular Torticollis

A Randomized Trial

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Objective: To compare the short-term efficacy of 2 dosages of stretching treatment on the clinical outcomes in infants with congenital muscular torticollis.

Design: This was a prospective randomized controlled study. Fifty infants with congenital muscular torticollis who were randomly assigned to 100-times stretching group and 50-times stretching group received stretching treatment for the affected sternocleidomastoid muscle. The outcomes including the head tilt, the cervical passive range of motion, and the muscle function of cervical lateral flexors determined by the muscle function scale were assessed at baseline and at 4 and 8 weeks after treatment. The sternocleidomastoid muscle growth analyzed by the thickness ratio of sternocleidomastoid muscles was measured using ultrasonography at baseline and 8 weeks after treatment.

Results: Except the ratio of muscle function scale scores, the postintervention outcomes were all significantly improved in both groups compared with baseline ($P < 0.05$). The 100-times stretching group showed greater improvement compared with 50-times stretching group in head tilt and cervical passive range of motion at 4 and 8 weeks after treatment ($P < 0.05$).

Conclusions: Stretching treatment of 2 dosages may effectively improve head tilt, cervical passive range of motion, and sternocleidomastoid muscle growth in infants with congenital muscular torticollis. The stretching treatment of 100 times per day is likely to associate with greater improvement in head tilt and cervical passive range of motion.

Key Words: Congenital Muscular Torticollis, Dosage, Infant, Sternocleidomastoid Muscle, Stretching Treatment

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Congenital muscular torticollis (CMT) is known as a lateral head tilt or neck flexion toward the affected side and rotation toward the opposite side due to the shortening or excessive contracture of the sternocleidomastoid muscle.[1] Congenital muscular torticollis is typically categorized into 3 subtypes: mass CMT, muscular CMT, and postural CMT. It is the third most common congenital musculoskeletal deformation in neonates and infants with an incidence rate of 0.3% to 2.0%.[2,3] The disease may lead to secondary skull and facial asymmetry or plagiocephaly[4] and may even be associated with early developmental delay.

During the diagnosis of infantile CMT, physical therapy examination was performed to assess cervical passive and active rotation and lateral flexion, craniofacial asymmetries, and head/skull shape.[5] The range of motion is currently the most common physiotherapy assessment for CMT.[6] Recently, some studies have introduced the muscle function scale as a new evaluation tool for CMT that can be used to estimate the muscle function of the lateral flexors of the neck.[6] In addition, ultrasonography has been used as an evaluation tool because of its accuracy in detecting the morphological changes or muscular pathology.[7] The assessments of clinical outcomes of CMT vary across studies.

There are several types of therapeutic interventions for infantile CMT, such as massage or electrical stimulation (audioelectric stimulation or microcurrent therapy) of the affected sternocleidomastoid muscle, manual passive stretching, strengthening exercise or transcutaneous electrical nerve stimulation therapy of the unaffected sternocleidomastoid muscle, application of orthosis, vigorous manual myotomy, and various surgical procedures.

Stretching treatment is the most typical physiotherapy for infants with CMT, which aims to improve the extensibility of the involved sternocleidomastoid muscle. Petronic et al.[8] suggested that stretching treatment with proper application should be the main therapy that could decrease the risk of surgical operation. It has been shown that controlled stretching treatment is safe and effective for infants with CMT as indicated by the assessment using special scoring scale that includes residual band and head tilt.[4] Lee et al.[9] reported a treatment success rate

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of 98% based on the improvement of passive neck rotation deficit. Numerous studies showed satisfactory outcomes of stretching treatment.[10–13] The cervical range of motion has been improved in up to 99% of cases treated by stretching treatment.[14] However, the standard for minimal dosage remains to be clarified because of the variability in the intervention intensity and the outcome measures. Identifying the appropriate level of intervention dosage is an essential factor "to remediate the limitations that are present and to prevent secondary impairments."[5] Appropriate dosage of stretching can reach the highest ratio of energy and efficiency, shorten the treatment duration, and improve the compliance of the families. Nevertheless, there are no consistent formulas so far to determine the dosage of stretching treatment for satisfactory clinical outcomes in infants with CMT.[5] No studies have been previously performed to compare the effectiveness of various stretching treatment dosages in CMT.[15] On the other hand, the outcome measures in physical therapy management of CMT should be standardized in order to provide a reliable basis for improved therapeutic effect of stretching treatment and increase global comparability among the research community.

Therefore, this study aimed to compare the short-term efficacy of 2 dosages of stretching treatment on the clinical outcomes in infants with CMT through a well-designed multilevel measurement procedure. The findings of this study will provide referral data on appropriate dosages of stretching treatment for infantile CMT.

METHODS

Study Design

This prospective, randomized controlled trial was conducted in the Department of Rehabilitation, Guangzhou Women and Children's Medical Center (trial registration: chictr.org ChiCTR-IPR-15007416). All infants with CMT were randomly divided into 100-times stretching group and 50-times stretching group with random-number table. Outcome measures consisted of 2 parts, a physical examination and an ultrasonography of the sternocleidomastoid muscle growth. Physical examination including the evaluation of the head tilt, the cervical passive range of motion, and the muscle function of lateral flexors of the neck was performed at baseline and at 4 and 8 weeks after treatment. Ultrasonography was performed at baseline and 8 weeks postintervention. Each infant was followed up on a weekly basis. Participants would be immediately withdrawn from this study if they failed to complete the specified stretching dosage. The overall study flowchart is shown in Figure 1. The study was approved by the ethical committee of the medical center. A consent form was signed by the parents of each participant.

Participants

The inclusion criteria were (1) diagnosis of CMT with the symptoms of head tilt and limited passive range of motion of the neck (lateral flexion and/or rotation); (2) younger than 3 months at the onset of treatment, because elder infants are mobile and it would become difficult to complete the necessary stretching treatment[15]; and (3) with parents who were able to comply with study instructions. The exclusion criteria were (1) postural CMT; (2) congenital abnormalities of the cervical spine, spasmodic torticollis, and other forms of organic, ocular, and neurogenic torticollis; or (3) any health problems that would prevent them from carrying out the intervention or assessment. The intervention might be discontinued in participants for administrative reasons, such as noncompliance or failure to meet visit schedule, or for treatment-related reasons that the subject cannot perform the stretching treatment properly or cannot finish the specified stretching dosage. Based on previous studies of CMT, we determined to have a power of 80% in statistical test and 2-sided $\alpha = 0.05$ to detect the difference in treatment effect. Assuming an estimated loss to follow-up of 15%, we calculated that we should enroll at least 55 infants. Except for 5 infants who were lost to follow-up, a total of 50 infants from 93 infants with CMT were selected for this study between February and July in 2015 including 24 boys and 26 girls, with a mean age of 44 ± 14 days (range, 21–76 days) at baseline. The excluded participants included 2 infants with ocular torticollis, 20 infants who were older than 3 months at their first diagnosis, and 16 infants whose parents refused to join their children in this study.

Intervention

Based on the recommendations of the guideline of the management in CMT,[5,15] low-intensity (10 manual stretches a session), sustained (10–15 seconds per stretching depending on the tolerance of the infant), frequent (10 sessions or 5 sessions per day), pain-free stretching treatment was performed in this study. All participants received a stretching treatment with the same intensity and duration of stretching but different stretching frequency. Participants in the 100- or 50-times stretching group, respectively, finished 10 or 5 sessions per day. Each session consisted of 10 manual stretches of the tight muscle and held for 10 to 15 seconds per stretch depending on the tolerance of the infant. There was a rest period of 10 seconds between any 2 stretches. The 2-person stretching technique was applied in this study. While one person stabilized the infant in supine around the shoulders with the head beyond the support surface, the other person stood above the head of the infant and held the head to guide it through the available range of cervical rotation and lateral flexion. The degree of rotation was less than 90 degrees because the infants might be at risk of decreased blood flow. The stretching treatment was performed every day at home by the parents who had learned the stretching treatment techniques in a course provided by the hospital. The course was 5 to 10 days depending on the level of family acceptance. The parents were not allowed to independently implement the stretching at home until their performance was approved by a physical therapist. Weekly telephone follow-up program was conducted to monitor the execution of home-based stretching treatment.

Outcome Measurements

Outcome measure consisted of a physical examination and an ultrasonography of the sternocleidomastoid muscle growth. The examiners, a physical therapist and an ultrasonography doctor, were not aware of the treatment group of each participant. The head tilt and the cervical passive range of motion were measured by using an special large arthrodial protractor when the infant was lying in the supine position. Head tilt was recorded as

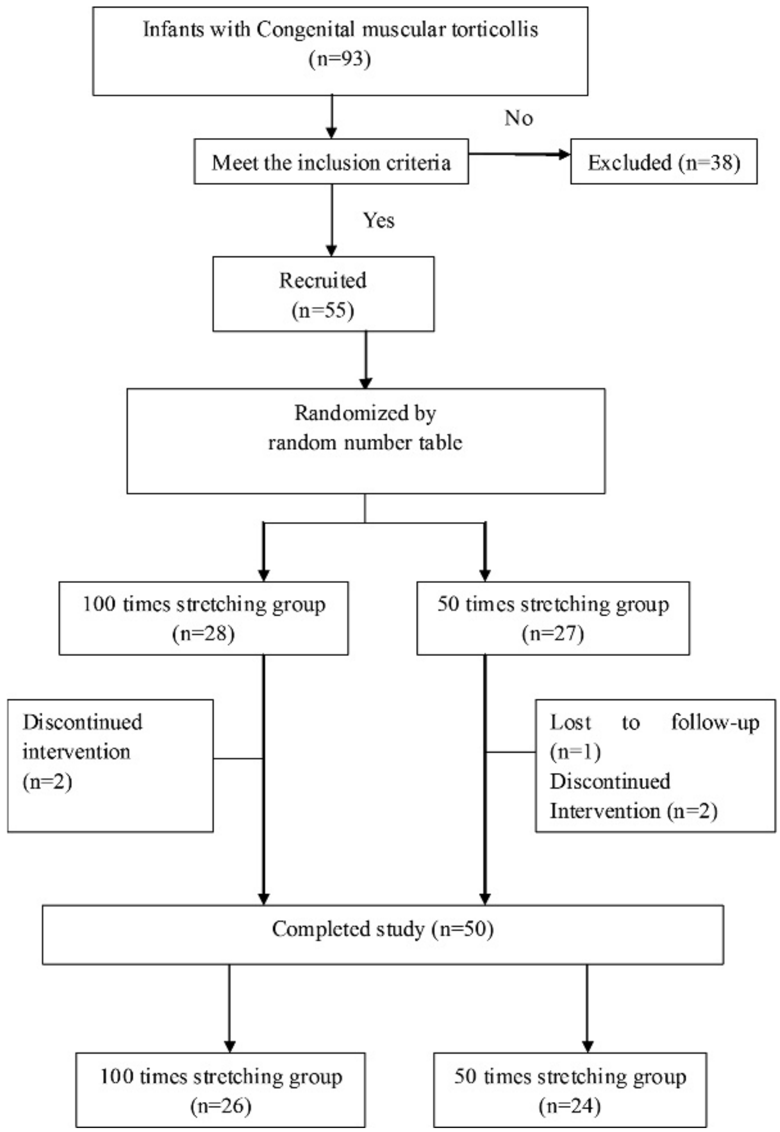

FIGURE 1. Flowchart of subject recruitment in the study.

the angle between the midline of the head and the midline of the body. The infant was stabilized by the shoulder when measuring the cervical passive range of motion in lateral flexion of the unaffected side and the rotation of the affected side. The head and neck were over the edge of the examination couch and supported by the examiner in neutral position, so that the neck could be moved freely in all directions, which allowed a detailed examination of the whole sternocleidomastoid muscle. The high interexaminer reliability of this method has been previously confirmed.[16]

Muscle function of the lateral flexors of the neck was evaluated using the muscle function scale yielding scores from 0 to 5. The validity of this scale was good, and the interrater and intrarater reliability was both high.[17] The examination produce of the muscle function scale was as follows: the infant was lowered from a vertical to a horizontal position in front of a mirror, and the head position in relation to the horizontal line was observed. When the head was held in the same position for 5 seconds, the infant could get the score at the corresponding level. The score of both sides was recorded. In this study, the muscle function scale scores were changed to 1, 2, 3, 4, 5, and 6 for subsequent statistical analyses. The ratio of muscle function scale scores was calculated (muscle function scale scores ratio = muscle function scale score of the affected side / muscle function scale score of the unaffected side).

The sternocleidomastoid muscle growth was measured with a computer-based ultrasound system (Siemens Acuson S2000, Siemens Medical Solutions USA, Inc, Malvern, PA) equipped with a broadband linear transducer set at 7- to 14-MHz. In order for a thorough check of the sternocleidomastoid muscles, the infant was placed in supine position, with neck extended and rotated to the opposite side. Both longitudinal and transverse-sectional views of the sternocleidomastoid muscles were measured. The muscular thickness of sternocleidomastoid muscle was defined as the anteroposterior diameter at the largest cross section of the sternocleidomastoid muscle. The thickness ratio of sternocleidomastoid muscles was calculated (sternocleidomastoid thickness ratio = affected sternocleidomastoid thickness / unaffected sternocleidomastoid thickness).

Statistical Analysis

Statistical analysis was performed using SPSS 16.0 (SPSS Inc., Chicago, Illinois). Independent-samples t test and χ^2 test were used to compare the differences of age, sex, affected sides, subtype of CMT, head tilt, cervical passive range of motion of the neck, muscle function scale scores ratio, and the sternocleidomastoid thickness ratio between 2 groups at baseline. Repeated-measures analysis of variance was applied to compare the differences of physical examinations before treatment and at 4 and 8 weeks after treatment within each group. The t test was used to compare the differences of physical examinations between the 2 groups at 4 and 8 weeks after treatment and the intragroup and intergroup differences of the thickness ratio of sternocleidomastoid muscles. $P < 0.05$ was considered statistically significant.

RESULTS

At baseline, no significant differences ($P > 0.05$, Table 1) were found in age, sex, affected side, and subtype of CMT between the 2 groups or in head tilt, cervical passive range of motion of the neck, muscle function scale scores ratio, and the sternocleidomastoid thickness ratio between the 2 groups obtained with independent-samples t test.

Improvement in Head Tilt and Cervical Passive Range of Motion

Compared with the results before the treatment, significant improvement in the degree of head tilt and the cervical passive range of motion including both the lateral flexion and the rotation were observed for all infants at 4 and 8 weeks, respectively, obtained with repeated-measures analyses of variance ($P < 0.05$; Figs. 2 and 3 and Table 2). The 100-times stretching group showed greater improvement compared with 50-times stretching group in head tilt and cervical passive range of motion at 4 and 8 weeks after treatment as indicated by independent-samples t test ($P < 0.05$; Table 2).

Changes in Muscle Function of Neck

No significant postintervention differences were found in the ratio of muscle function scale scores compared with baseline in each group at 4 and 8 weeks after treatment ($P > 0.05$; Fig. 4 and Table 2), obtained with repeated-measures analyses of variance. And no significant differences in the ratio of muscle function scale scores were detected between 2 groups at each follow-up session, obtained with independent-samples t test ($P > 0.05$, Table 2).

Growth in Sternocleidomastoid Muscle

After 8 weeks of treatment, the postintervention sternocleidomastoid muscle thickness ratios were significantly decreased in all infants compared with baseline as indicated by paired t test ($P < 0.05$; Fig. 5 and Table 2). However, there were no significant differences in the sternocleidomastoid muscle thickness ratios between the 2 groups at 8 weeks after treatment ($P > 0.05$; Table 2).

Adverse Events

No adverse events such as the sternocleidomastoid muscle snapping and skin irritation were reported.

DISCUSSION

This prospective, randomized controlled study demonstrated that stretching treatment of 2 dosages may effectively improve the head tilt and the cervical passive range of motion including both the lateral flexion and rotation of the neck and the bilateral sternocleidomastoid muscle growth in infants with CMT. The 100-times stretching treatment per day resulted in more improvement in the head tilt and the cervical passive range of motion compared with the 50-times stretching treatment per day.

Congenital muscular torticollis is a common pediatric musculoskeletal condition of idiopathic postural deformity due to unilateral tightness or fibrosis of the sternocleidomastoid muscle. Stretching treatment has been well known as the primary therapy to elongate the shortened sternocleidomastoid muscle in infants with CMT,[6,15] which was consistent with the results in this study. The sternocleidomastoid muscle on the affected side was shortened compared with the unaffected side. During stretching treatment, the specific muscle or tendon (or muscle group) is deliberately extended in order to directly improve the muscle flexibility and range of motion by increasing the elasticity of tissue and muscle tone. On the other hand, controlled stretching treatment might stimulate the myoblasts to produce

TABLE 1. Demographic and baseline data: mean (SD) or n (%)

Group Item	100-Times Group n = 26	50-Times Group n = 24	P (Between Groups)
Age, d	42.76 (12.13)	44.75 (15.17)	0.62
Male	13 (50%)	11 (46%)	0.79
Involved side (left)	13 (50%)	15 (63%)	0.41
Mass CMT	17 (65%)	18 (75%)	0.55
Muscular CMT	9 (35%)	6 (25%)	0.55
Head tilt, degrees	22.31 (10.51)	23.75 (8.24)	0.59
Cervical passive lateral flexion of the unaffected side, degrees	47.31 (11.07)	45.00 (10.11)	0.45
Cervical passive rotation of the affected side, degrees	57.31 (15.83)	53.13 (12.92)	0.31
Muscle function scale scores ratio (affected side/unaffected side)	1.80 (0.68)	1.56 (0.86)	0.38
Sternocleidomastoid thickness ratio (affected side/unaffected side)	2.38 (0.66)	2.21 (0.47)	0.11

TABLE 2. Changes of outcomes data at 4 and 8 weeks after treatment

Group Item	100-Times Group n = 26	50-Times Group n = 24	*P* (Between Groups)
Heal tilt, degrees			
Week 4–baseline	−11.15 (8.36)	−6.04 (5.00)	0.01[a]
Week 8–baseline	−17.88 (9.52)	−10.42 (5.57)	<0.001[a]
Cervical passive lateral flexion of the unaffected side, degrees			
Week 4–baseline	11.54 (9.88)	6.88 (5.29)	0.01[a]
Week 8–baseline	18.65 (10.24)	13.54 (6.74)	<0.05[a]
Cervical passive rotation of the affected neck, degrees			
Week 4–baseline	17.69 (12.27)	10.63 (9.63)	<0.05[a]
Week 8–baseline	34.42 (12.58)	18.96 (9.67)	<0.05[a]
Muscle function scale scores ratio (affected side/unaffected side)			
Week 4–baseline	−0.12 (0.53)	−0.03 (0.91)	0.45
Week 8–baseline	−0.24 (0.79)	−0.14 (0.76)	0.52
Sternocleidomastoid thickness ratio (affected side/unaffected side)			
Week 8 baseline	−1.32 (0.47)	−0.44 (0.50)	0.58

Values are presented as mean (SD).
[a]Significant changes between 100-times group and 50-times group ($P < 0.05$).

normal myofibrils, leading to regeneration and repair of the abnormal sternocleidomastoid muscle.[4]

In this study, the therapeutic effect of stretching treatment in infants with CMT was also confirmed by the better balance of sternocleidomastoid muscle thickness between the affected and unaffected side in ultrasonographic examination. The thickness ratio of sternocleidomastoid muscles in both groups was significantly decreased after intervention, suggesting a marked improvement of the condition. This finding is consistent with a previous study in which the outcome score has been shown to be negatively correlated with the thickness ratio of sternocleidomastoid muscles.[4] This result indicated that the stretching treatment might promote the growth of bilateral sternocleidomastoid muscles. The ultrasonography is a relatively inexpensive, safe, and comfortable technique in detecting the morphological changes or muscular pathology. Ultrasonography can be used as the qualitative method for the measurement of the involved sternocleidomastoid muscle in infants with CMT according to the echo texture of sternocleidomastoid muscle including brightness, uniformity, linearity, and alignment of the muscle fibers.[9,18] Meanwhile, it can be used as the quantitative assessment while measuring the involved area of the sternocleidomastoid muscle. Usually, the intervention outcome is evaluated by measuring the size of the mass and the thickness of the involved sternocleidomastoid muscle.[19] Stretching treatment might affect the proliferation of fibrous tissue. Therefore, the resolution of the thickened sternocleidomastoid muscle is generally considered a good indicator of clinical recovery. However, the sternocleidomastoid muscle in infants with CMT grows thicker physiologically because of the rapid growth of the body. The evaluation of treatment effect based on the thickness of the affected sternocleidomastoid muscle might be misleading.[20] Alternatively, the thickness ratio of the sternocleidomastoid muscles has been used to quantify the outcome of rehabilitation therapy in infants with CMT.[20–23] In this study, the thickness ratio of sternocleidomastoid muscles was also chosen as the parameter to assess the clinical outcome of the intervention. However, no significant differences in the thickness ratio of sternocleidomastoid muscles were observed between 2 groups after treatment, probably because of the limitation of single stretching treatment program in this study. Further study should be performed to clarify this issue.

Because there is an imbalance in muscle function around the neck for infants with CMT, the muscle function scale based

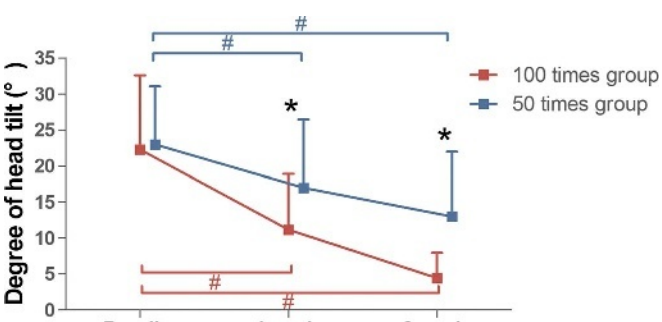

FIGURE 2. Improvement in posture of head tilt (degrees). Data are mean ± SD. #Significant changes between pretreatment and posttreatment ($P < 0.05$). *Significant changes between 100-times group and 50-times group ($P < 0.05$).

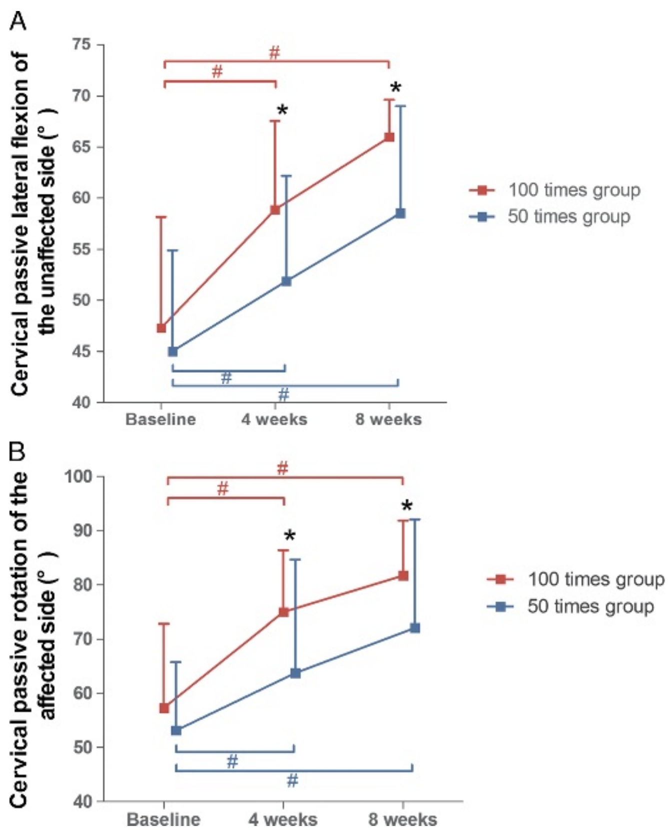

FIGURE 3. Improvement in cervical passive range of motion. Data are mean ± SD. A, Cervical passive lateral flexion of the unaffected side (degrees). B, Cervical passive rotation of the affected side (degrees). #Significant changes between pretreatment and posttreatment ($P < 0.05$). *Significant changes between 100-times group and 50-times group ($P < 0.05$).

on the lateral up-righting response has been used to examine the strength of the sternocleidomastoid muscles.[16] It has been proven as a valid tool to measure the muscle function of the lateral flexors of the neck in infants with CMT. The previous researches showed that symmetrical scores on muscle function scale were related to the symmetrical posture of the head.[6,16,24] Therefore, the ratio of the affected to the unaffected side on muscle function scale score was applied as measurement in this study in order to reflect the symmetrical posture of the neck. The balance of both sternocleidomastoid muscle strength seems to be positively influenced by the stretching treatment in this study, although this effect did not reach a statistical significance. The results of this study indicated that the muscle function scale might be more suitable for infants older than 3 months. We speculated that strength training or electrical stimulation of the unaffected sternocleidomastoid might have more effect on muscles' function in infants with CMT who already had good control of the head. More studies are needed.

No adverse events such as sternocleidomastoid muscle snapping and skin irritation were reported, even though the mass CMT was the major subtype in this study. Cheng et al.[25] have reported a 9.2% incidence rate of sternocleidomastoid

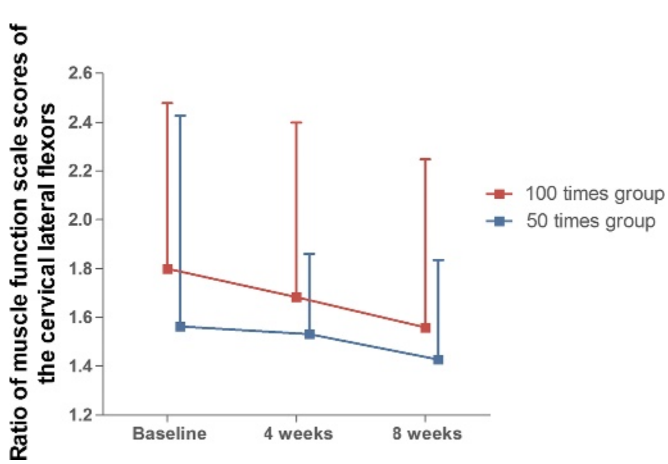

FIGURE 4. Changes in the ratio of muscle function scale scores of cervical lateral flexors (affected side/unaffected side) ($P > 0.05$). Data are mean ± SD.

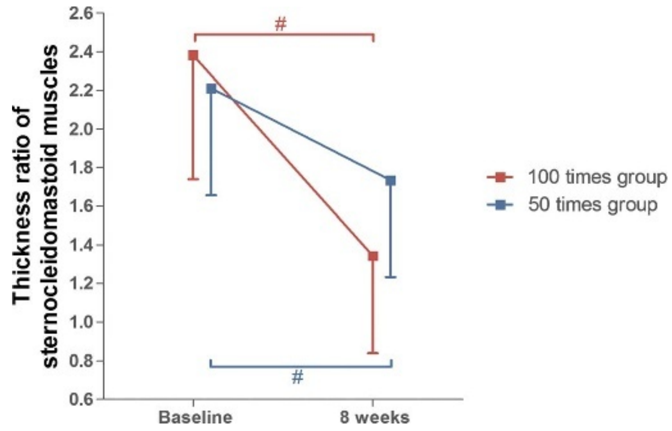

FIGURE 5. Changes in the thickness ratio of sternocleidomastoid muscles (affected side/unaffected side). Data are mean ± SD. #Significant changes between pretreatment and posttreatment ($P < 0.05$).

muscle snapping in mass CMT cases during the treatment. The 45 stretches per session in their study were much higher compared with those of this study, indicating that the 10 stretches per session might be more suitable for infants with CMT.[5,15]

In a previous study, the outcome in the stretching treatment performed by a physiotherapist was more satisfactory than that performed by parents.[24] However, the satisfactory therapeutic effect of home-based intervention was also achieved in this study. This study provided a course of stretching treatment technique to the families. Moreover, the study strictly followed a weekly telephone follow-up schedule to monitor the home-based stretching treatment. Home-based program is very convenient and costless for families with CMT.[5] A strict follow-up system is the key point to monitor the implementation of home-based stretching treatment.

This study has several limitations. For instance, only the assessor was blinded, but all parents knew which intervention was applied. Moreover, this study also may be limited by its short follow-up period. Finally, this study did not include the control group. Further research is needed to overcome these limitations.

To our best knowledge, this is the first study that compares the short-term effect of 2 stretching dosages in infants with CMT. It provides a reliable basis for the determination of standardized formulas of stretching treatment. The low-intensity (10 manual stretches per session), sustained (10–15 seconds per stretch depending on the tolerance of the infant), frequent (10 sessions 100 times per day, or 5 sessions 50 times per day) stretching treatment developed in this study is safe and efficient and shall be well accepted by infants with CMT and their families. Furthermore, this study states that the head tilt and cervical passive range of motion combined with the ultrasound thickness ratio of sternocleidomastoid muscles constitute a good way to measure the progress of treatment in these young infants with CMT.

In summary, stretching treatment of 2 dosages may effectively improve the head tilt, the cervical passive range of motion, and the bilateral sternocleidomastoid muscle growth in infants with CMT. Most families were able to comply with either dosage. The stretching treatment of 100 times per day is likely to associate with greater improvement in head tilt and cervical passive range of motion.

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SUPPLEMENTARY CHECKLIST

CONSORT Checklist: http://links.lww.com/PHM/A332; Trial Protocol: http://links.lww.com/PHM/A333

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