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Original Article

Effectiveness of kinesiotape and sham kinesiotape application in children with cerebral palsy with dysphagia: A randomized controlled study

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ABSTRACT

Objectives: This study aimed to investigate the short- and long-term effects of kinesiotaping (KT) on dysphagia in children with cerebral palsy (CP).

Patients and methods: One hundred one CP patients (59 males, 42 females; mean age: 49.3±18.8 years; range, 2 to 6 years) with dysphagia referred between October 2017 and January 2020 were enrolled in the randomized controlled study. Children who met the study criteria were randomly assigned to the kinesiotape group (n=54) or the sham group (n=47). Specific swallowing evaluations were performed on all patients before the therapy. The KT or sham application protocole combined with conventional rehabilitaion therapy was conducted for six weeks. Evaluation parameters were repeated at 6 and 18 weeks. The evaluated parameters were compared within and between groups.

Results: Drooling, weak tongue movement, chewing difficulty, coughing/choking and retching/vomiting during/after feeding, functional oral intake score, and meal time were found to be significantly improved at six weeks in the kinesiotape group compared to the sham group, and the clinical improvements were present at 18 weeks ($p<0.05$). There was no statistically significant difference in any parameter in the sham group at 6 and 18 weeks compared to the pretreatment ($p>0.05$).

Conclusion: The addition of KT to a home exercise program is an effective method for dysphagia in CP.

Keywords: Cerebral palsy, dysphagia, kinesiotape, rehabilitation, swallowing.

Cerebral palsy (CP) is a permanent and nonprogressive disorder of the developing fetal brain due to damage in prenatal, natal, or postnatal periods.[1] Cerebral palsy patients, with an average life expectancy of 30 years, can have motor function disorders such as mobility, speech, and swallowing problems.[2,3] The difficulty in swallowing in CP is parallel to cognitive and motor functional abilities.[4,5] Although the overall incidence of dysphagia has been reported in the range of 30 to 80%, dysphagia is present in almost all children as the severity of motor involvement increases.[5,6]

There are conventional rehabilitation methods with a wide range of techniques, such as modifications, exercises, maneuvers, and stimulations, in the treatment of dysphagia in CP; however, there is no consensus on the preferred treatment method.[7,8] In recent years, kinesiotape has been used for various purposes in many diseases.[9] There are a few studies on the effectiveness of kinesiotape application in the treatment of dysphagia, and its effectiveness is controversial.[10-14] These studies have shown that kinesiotape application is effective and safe in reducing drooling. In another study, it was shown that adding

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kinesiotape to oromotor exercises was effective in reducing drooling.[13] However, there are no studies that have evaluated swallowing as a whole. Moreover, there is a need to carry out studies evaluating the efficacy of kinesiotape in dysphagia treatment with a high level of evidence and duration of effectiveness for a period longer than three months.[15] This study was designed to answer whether kinesiotape application is effective in the treatment of dysphagia in CP and, in the case that it is effective, whether the effect of kinesiotape therapy persists for more than three months.

PATIENTS AND METHODS

This study was planned and carried out as a prospective, randomized, double-blind, placebo-controlled investigation at the Gaziantep University Faculty of Medicine between October 2017 and January 2020. Patients with CP referred to the physical medicine and rehabilitation (PMR) clinics in two rehabilitation hospitals were enrolled in the study. One hundred and ten children who had oropharyngeal dysphagia symptoms or findings and were subsequently hospitalized and rehabilitated were included in this study. Patients with a history of maxillary, head, or neck surgery or botulinum toxin injection, structural oropharyngeal abnormality, known esophageal dysphagia or gastroesophageal reflux disease, who received medical or physical therapy for dysphagia in the last six months, those using drugs for seizures or spasticity, and tube-dependent patients with no oral intake were not included. Children who met the study criteria were randomly assigned to the kinesiotape group (n=54) or the sham group (n=47) after questioning in detail. Randomization was conducted by a clinical secretary who was not involved in the study by using the opaque envelope method. The randomization number of the envelope was only shared with the specialist who applied the kinesiotape. Patients and investigators were blinded to the study. While the study was continuing, one child from the kinesiotape group and eight from the sham group was excluded from the study because they did not come to the control evaluation. The study was completed with 101 children (59 males, 42 females; mean age: 49.3±18.8 years; range, 2 to 6 years) (Figure 1).

The following information was gathered from the children: age (month), sex, height (cm), weight (kg), patient and family history, co-morbid conditions, motor functional state, and motor limb distribution (hemiplegia, diplegia, triplegia, and tetraplegia). The Gross Motor Function Classification System was used to determine the condition of motor function.[16]

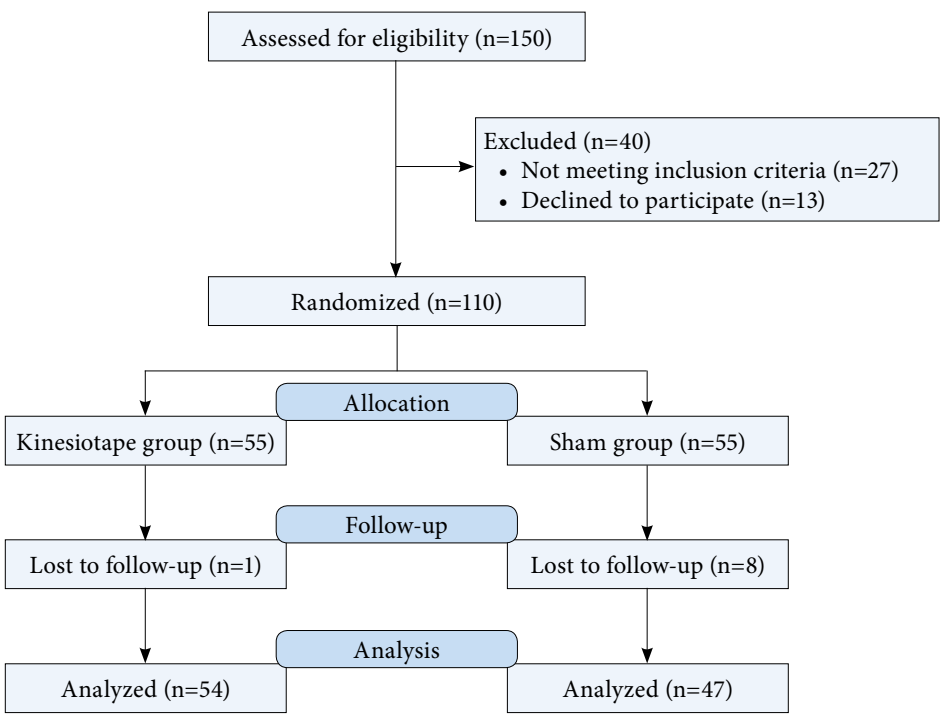

Figure 1. Flowchart of the study.

Two specialists videotaped and observed the lunchtime meal (the peak of attention) to study feeding. The primary caregivers administered three standardized textures: chewable meal (solid), food puree (semisolid), and water (fluid). Following this routine procedure, children were free to finish their snacks as usual. Additionally, using the second finger of the dominant hand, pulse oximetry was used to assess the arterial oxygen saturation during eating. Drooling, lip and tongue motions, eating, drinking, coughing, choking, and retching or vomiting were recorded after or during feeding. Meal time was defined as the time it takes in minutes to swallow the last bolus starting from the first bite. Each parameter was recorded as either "present" or "absent" at the end of the observation, and a single result was derived from the notes of the two observers.[8]

The functional oral intake scale (FOIS) evaluates the patient's safe and adequate functional oral intake and consists of seven levels.[17]

Children's primary caregivers were asked to evaluate the change in swallowing of children at 6 and 18 weeks with a 5-point Likert scale to evaluate the level of family satisfaction (1=much better, 5=much worse).

A short practical training was performed before the study. The study was performed by a group of independent specialists blinded to treatment allocation. On the day of hospital admission and at 6 and 18 weeks, video recordings of feeding were independently rated by two PMR specialists, and the results of the two observations were combined. Other specialists were assigned to score the FOIS scale throughout the study. These researchers were blinded to the kinesiotape or sham applications.

In both groups, the application was performed twice a week for six weeks. After three days of application, the kinesiotape was removed for one day of resting, then again applied for three days. The application was performed by the same specialist. The Y-type kinesiotape (Kinesio Tex, Gold; Kinesio UK, Newcastle upon Tyne, UK) was applied to all kinesiotape groups by the muscle technique, and the tail part of the Y strip was adhered with 10 to 15% stretching under the mandibular line to the origins of the mylohyoid muscle 2.5 to 3.5 cm in width according to the age of the child. The strip, which was brought as a whole to the imaginary line passing through the posterior corners of the mandible, was adhered to the hyoid bone just over the top to prevent direct taping of the hyoid bone. The arms of the band were glued up to the level of the manubrium sterni as a paper-off tension to prevent the facilitation of the sternohyoid muscle (Figure 2). In the sham group, kinesiotape was applied without stretching to the suprahyoid region and not including the origins of mylohyoid and digastric muscles (Figure 3).

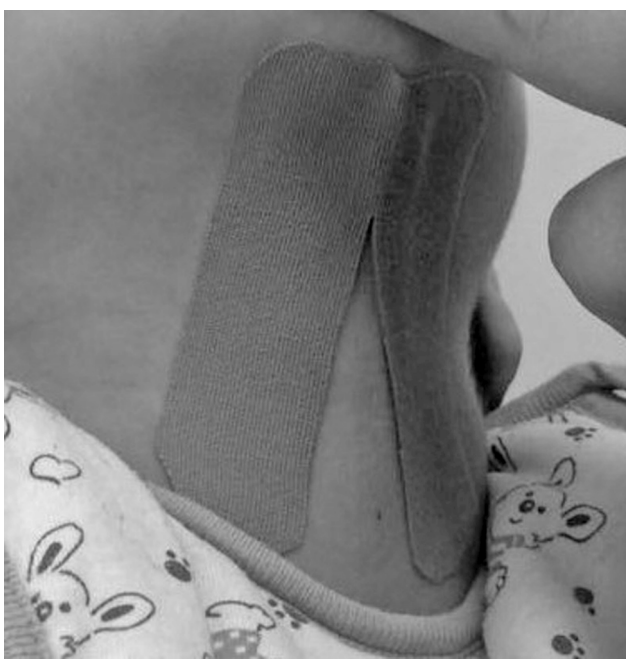

Figure 2. Kinesiotape application in the kinesiotape group.

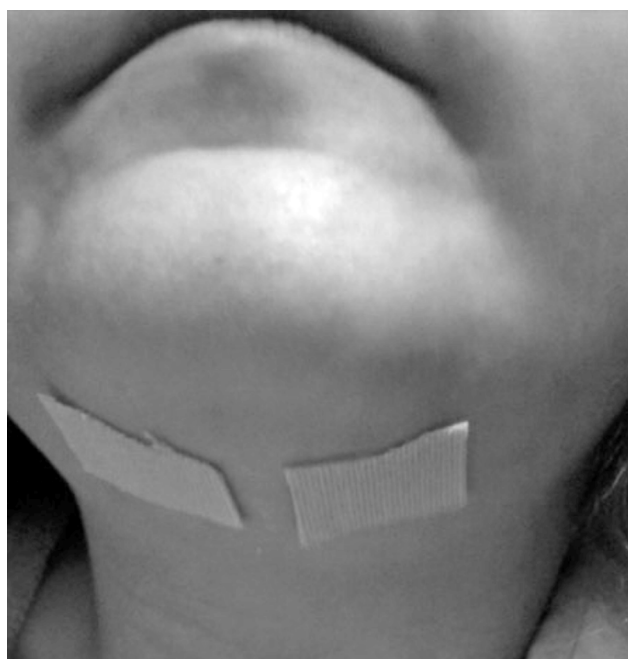

Figure 3. Kinesiotape application in the sham group.

All participants were also informed about oral hygiene. Both groups were taught cold stimulation, head and trunk positioning, and daily care for diet change according to the swallowing characteristics of the children.[8] Home programs were reminded and encouraged in the days the patient presented for taping.

Statistical analysis

The sample size was carried out using G*Power version 3.1.9.2 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The smallest sample size required for a minimum change of 0.5 units in FOIS for each group was provided by the two-sample t-test as 41 participants with a power of 80%, significance

TABLE 1
Demographic and disease characteristics of the patients according to groups

	Kinesiotape group (n=54)			Sham group (n=47)			
Parameters	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (month)			50.4±17.4			47.9±18.6	0.098¶
Sex							0.163*
Males	34	63		25	53.2		
Females	20	37		22	46.8		
Height (cm)			94.6±15.8			91.3±17.9	0.372¶
Weight (kg)			15.0±5.0			14.5±8.4	0.809¶
History							0.447**
Prematurity	29	53.7		23	48.9		
Multiple pregnancy	12	22.2		10	21.3		
Birth trauma	3	5.6		4	8.6		
Infection	4	7.4		5	10.6		
Maternal predisposing factor (e.g age, comorbid disease)	6	11.1		5	10.6		
Consanguineous marriage	8	14.8		11	23.4		
Additional problems							
Mental retardation	33	61.1		27	57.5		0.764*
History of epilepsy	35	64.8		21	44.7		0.073*
Hearing disorder	5	9.3		8	17		0.251*
Vision disorder	22	40.7		18	38.3		0.599*
Speech disorder	32	59.3		29	61.7		0.572*
Bowel incontinence	44	81.5		38	80.9		0.968*
Dental disorder	43	79.6		34	72.3		0.965*
GMFCS (1-5)			4.1±1.1			3.9±1.1	0.102¶
Motor limb distribution							0.721*
Hemiplegia	7	13		9	19.1		
Diplegia	13	24		11	23.4		
Triplegia	24	44.5		21	44.7		
Tetraplegia	10	18.5		6	12.8		
Presence of symptoms/findings							
Drooling	41	75.9		34	72.3		0.858*
Poor lip movements	39	72.2		31	66.0		0.562*
Poor tongue movements	47	87.1		38	80.9		0.394*
Difficulty in biting	25	46.3		21	44.7		0.890*
Difficulty in chewing	48	88.9		39	83.0		0.721*
Difficulty in drinking	8	14.8		5	10.6		0.257*
Coughing/choking during/after feeding	28	51.9		19	40.2		0.634*
Retching/vomiting during/after feeding	18	33.3		12	25.5		0.639*
Reduced in pulse O_2 saturation	14	25.9		12	25.5		0.982*
FOIS (1-7)			5.1±1.2			5.4±0.9	0.078¶
Meal time (min)			47.0±11.3			44.1±13.3	0.347¶

SD: Standard deviation; GMFCS: Gross Motor Function Classification System; FOIS: Functional oral intake scale; * Chi-square test; ** Fischer's exact test; ¶ Independent simple t test.

Table 2
The distribution of results of kinesiotape group before treatment and at 6 and 18 weeks

	Pre-treatment			6th weeks			18th weeks			Pre-treatment-6th weeks	Pre-treatment-18th weeks	6th weeks-18th weeks
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p*	*p*	*p*
Drooling	41	75.9		27	50		29	53.7		**0.008***	**0.011***	0.282*
Poor lip movements	39	72.2		37	68.5		37	68.5		0.811*	0.811*	1.000*
Poor tongue movements	47	87.1		38	70.4		41	75.9		**0.014***	**0.012***	0.351*
Difficulty in biting	25	46.3		21	38.9		22	40.7		0.374*	0.257*	0.865*
Difficulty in chewing	48	88.9		36	66.7		38	70.4		**0.011***	**0.013***	0.764*
Difficulty in drinking	8	14.8		3	5.6		3	5.6		0.103^	0.103^	1.000**
Coughing/choking during/after feeding	28	51.9		11	20.4		16	29.6		**0.001***	**0.002***	0.218*
Retching/vomiting during/after feeding	18	33.3		7	13		8	14.8		**0.013***	**0.015***	0.689*
Reduced in pulse O_2 saturation	14	25.9		7	13		9	16.7		0.019*	0.065*	0.212*
FOIS† (1-7)			5.1±1.2			5.9±1.1			5.8±1.1	**0.011¶**	**0.013¶**	0.193¶
Meal time (min)			47.0±11.3			31.5±9.7			33.3±14.2	**0.001¶**	**0.007¶**	0.440¶
Satisfaction level												**0.008***
So much better				33	61.1		0	0				
Slightly better				11	20.4		1	1.9				
No change				8	14.8		46	85.1				
Slightly worse				2	3.7		7	13				
So much worse				0	0		0	0				

SD: Standard deviation; FOIS: Functional oral intake scale; ‡ Functional oral intake scale; * Chi-square test ** Fischer exact test, ¶ Wilcoxon signed-rank test.

Table 3
The distribution of results of sham group before treatment and at six weeks and 18 weeks

	Pre-treatment			6th weeks			18th weeks control			Pre-treatment-6th weeks	Pre-treatment-18th weeks control	6th weeks-18th weeks control
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p*	*p*	*p*
Drooling	34	72.3		31	66.0		32	68.1		0.827*	0.864*	0.911*
Poor lip movements	31	66.0		29	53.7		29	53.7		0.549*	0.549*	1.000*
Poor tongue movements	38	80.9		37	78.7		36	76.6		0.965*	0.878*	0.892*
Difficulty in biting	21	44.7		20	42.6		21	44.7		0.914*	1.000*	0.914*
Difficulty in chewing	39	83.0		37	78.7		35	74.5		0.438*	0.224*	0.317*
Difficulty in drinking	5	10.6		5	10.6		5	10.6		1.000*	1.000*	1.000*
Coughing/choking during/after feeding	19	40.2		18	38.3		17	36.2		0.962*	0.513*	0.879*
Retching/vomiting during/after feeding	12	25.5		11	23.4		12	25.5		0.846*	1.000*	0.846*
Reduced in pulse O_2 saturation	12	25.5		12	25.5		11	23.4		1.000*	0.846*	0.846*
FOIS† (1-7)			5.4±0.9			5.4±1.3			5.4±1.1	0.469¶	0.958¶	0.458¶
Meal time (min)			44.1±13.3			44.5±10.1			45.1±10.0	0.871¶	0.647¶	0.465¶
Satisfaction level												0.714*
So much better				0	0		0	0				
Slightly better				3	5.5		0	0				
No change				43	91.4		44	81.5				
Slightly worse				1	2.1		3	5.5				
So much worse				0	0		0	0				

SD: Standard deviation; FOIS: Functional oral intake scale; ‡ Functional oral intake scale; * Chi-square test ¶ Wilcoxon signed-rank test.

level of 5%, and an effect size of 0.631. Previous studies also reported that studies including more than 30 patients are sufficient.[18]

Data were analyzed using IBM SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). The Kolmogorov-Smirnov test was used to determine the normality of the continuous variables. The mean and standard deviation for numerical measurements and the number (%) for categorical variables were used as descriptive statistics. The Wilcoxon (continuous variables) test, Fisher exact, and the chi-square test (dichotomous variables) were used to assess statistically significant differences in repeated measurements among the groups. The Bonferroni correction was applied to account for potential

Table 4
Comparison of change with treatment between groups

	Pre-treatment-6th weeks				Pre-treatment-18th weeks			
	n	%	Mean±SD	*p*	n	%	Mean±SD	*p*
Drooling				0.036*				0.037*
Kinesiotape group	-14	25.9			-12	22.2		
Sham group	-3	5.5			-2	4.3		0.521*
Poor lip movements				0.521*				
Kinesiotape group	-2	3.7			-2	3.7		
Sham group	-2	4.3			-2	4.3		
Poor tongue movements				0.011*				0.076*
Kinesiotape group	-9	16.7			-6	11.1		
Sham group	-1	2.1			-2	4.3		
Difficulty in biting				0.281*				0.156*
Kinesiotape group	-4	7.4			-3	5.6		
Sham group	-1	2.1			0	0		
Difficulty in chewing				0.037*				0.108*
Kinesiotape group	-12	22.2			-10	18.5		
Sham group	-2	4.3			-4	8.6		
Difficulty in drinking				0.001*				0.001*
Kinesiotape group	-5	9.3			-5	9.3		
Sham group	0	0			0	0		
Coughing/choking				0.017*				0.037*
Kinesiotape group	-17	31.5			-12	22.2		
Sham group	-1	2.1			-2	4.3		
Retching/vomiting				0.024*				0.026*
Kinesiotape group	-11	20.4			-10	18.5		
Sham group	-1	2.1			0	0		
Reduced in pulse O_2 saturation				0.021*				0.117*
Kinesiotape group	-7	13.0			-5	9.3		
Sham group	0	0			-1	2.1		
FOIS (1-7)				0.001¶				0.001¶
Kinesiotape group	1.03	1.75			0.98	1.07		
Sham group	0.04	0.24			-0.01	0.27		
Meal time (min)				0.001¶				0.001¶
Kinesiotape group			-14.8±3.9				-13.7±2.7	
Sham group			0.4±1.7				0.4±1.8	

SD: Standard deviation; FOIS: Functional oral intake scale; * Fischer exact test; ¶ Independent simple t test.

type 1 errors in within-group comparisons (p=0.017). Bonferroni correction was used to control for possible type 1 errors in between-group comparisons (p<0.017). Independent samples t-test and Fisher exact test were used to assess differences between groups. The results were considered significant for p<0.05.

RESULTS

There was no difference in demographic characteristics between the groups (p>0.05, Table 1).

The distribution of swallowing evaluation parameters before treatment according to the groups is shown in Table 1. Before treatment, the most common finding in both groups was the difficulty of chewing (48 in the kinesiotape group, 39 in the sham group), and there was no difference between groups (p>0.05).

Distribution and comparison of the swallowing evaluation in the pretreatment at 6 and 18 weeks according to the groups were presented in Tables 2 and 3.

Within-group comparisons revealed that drooling, weak tongue movement, chewing difficulty, coughing/choking, and retching/vomiting, as well as FOIS score and meal time, significantly improved in the kinesiotape group at 6 and 18 weeks compared to pretreatment scores (p<0.017). Although the 18th week values decreased slightly compared to the sixth week, there was no significant difference (p>0.017). In the sham group, there was no significant difference in any parameter at 6 and 18 weeks compared to pretreatment (p>0.017). None of the children in either group had any treatment-related side effects. In addition, the kinesiotape group's satisfaction level was significantly greater (p=0.008).

When comparing the change with treatment between the groups, significant improvement was found in the kinesiotape group at six weeks in all evaluation parameters, except for poor lip movement and difficulty in biting (Table 4). These improvements continued in the drooling, difficulty in drinking, coughing/choking and retching/vomiting during/after feeding, FOIS, and meal time in the kinesiotape group at 18 weeks (Table 4).

The patients were more likely to answer "much better" or "slightly better" in the kinesiotape group at six weeks compared to the sham group (p=0.003). In addition, it was determined that favor state continued in the 18th week in the kinesiotape group, but there was no significant difference between groups at 18 weeks (p=0.152).

DISCUSSION

The results show that drooling, weak tongue movement, chewing difficulty, coughing/choking and retching/vomiting during/after feeding, FOIS score, and meal time were found to be significantly improved at six weeks in the kinesiotape group and clinical improvements continued for 18 weeks. In addition, change with treatment in all evaluation parameters except poor lip movement and difficulty in biting was significantly better in kinesiotape group in the 6th weeks. Moreover, these improvements continued in the drooling, difficulty in drinking, coughing/choking and retching/vomiting during/after feeding, FOIS scale and mealtime in the 18th weeks.

Oropharyngeal dysphagia in CP children is frequently seen, similar to adults with neurological diseases such as stroke.[19,20] In the oral phase dysphagia, symptoms and findings such as drooling, difficulty in chewing, and prolongation of meal time due to the abnormal coordination and weakness of the muscles and joints of oral phase under voluntary control can develop. Furthermore, in the pharyngeal phase dysphagia, which is one of the involuntary phases of swallowing, delay or absence in swallowing reflex and weakness of pharyngeal and supra-and infrahyoid muscles can occur. Consequently, aspiration and its complications, such as pneumonia and mortality, can arise.[19,20] Similar to the findings of previous studies, the current study has shown that the difficulty of chewing and weakness of the tongue movement, which are commonly seen in oral phase dysphagia, were the most frequent findings in cerebral palsy. Moreover, these studies have reported that as many as 90% of CP may show symptoms of oral motor dysfunction.[5,6] Therefore, the aim then of any swallowing treatment for CP is to increase the efficacy of the oral phase in the literature.[8,21,22]

In the literature, oral sensorimotor stimulation, modification, maneuvers, and exercises have been used for the treatment of dysphagia in children with cerebral palsy.[6-8] However, it has been stated that there is limited evidence on the effectiveness of conventional rehabilitation. In our study, the changes within the group were also not found to be significant in the sham group. Moreover, the change in evaluation parameters with the addition of kinesiotape to the treatment was significantly greater than the change in the sham group.

Kinesiotape is an application that has taken place in the treatment methods in cerebral palsy, and its popularity is increasing in recent years.[10-14] There are

conflicting results regarding the efficacy of kinesiotape in children with developmental disorders due to a lack of standardization, such as duration, technique, and place of application.[15,23,24] There are only a few studies on the treatment of dysphagia in cerebral palsy, and these studies remained limited to drooling therapies.[10-15] In these studies, the taping technique of the orbicularis oculi muscle, jaw stabilization, and suprahyoid muscle support techniques were used.[10,11,13,15] In a case report study, the stimulation and inhibition technique was applied to more than one muscle, including orbicularis oculi, the masseter, supra-and infrahyoid muscles, partially similar to our study.[14]

In a study including 11 children (three of them had CP) with one-month follow-up of the application of kinesiotape to the mylohyoid and suprahyoid muscles with maximum stretching for drooling, a decrease in drooling was found at one month but not at three months.[11] In another study, López Tello et al.[12] applied kinesiotape to the hyoid area in 10 children who had drooling with different etiologies and followed up to the seventh month. They evaluated families' satisfaction and reported that there was a change in the apron and smell, but they did not use an objective scale like the FOIS that we used in our study. In our study, despite the slight decrease in efficacy after six weeks of therapy, the effect of therapy continued without a significant difference until 18 weeks. A reason for this is that although the swallowing is evaluated separately in oral, pharyngeal, and esophageal phases, the event is coordinated and synergistically working as a combination of events that intertwine and interact with each other. We stimulated the mylohyoid muscle, which elevates the hyoid bone during swallowing, and inhibited the sternohyoid muscle, which works as an antagonist to the mylohyoid muscle. Thus, in a synergic state, we evaluated the event as a whole. According to us, as demonstrated in the studies evaluating the effect of kinesiotape on the brain with functional magnetic resonance imaging, this application may have increased proprioception and affected the brain's motor control, coordination, and motor learning regions with a positional stimulus.[25] In addition, some kinesiotape studies have reported that kinesiotape increases muscle strength and regulates muscle tone.[26,27] Motor dysfunction in CP is often associated with muscle weakness. Our application may have improved motor dysfunction by affecting muscle strength and tone.

This study has some limitations. The relatively small number of patients and the relatively short follow-up period were our limitations. In addition, the fact that we did not use an objective assessment method for dysphagia is another limitation. It includes mostly observation-based assessment. Nevertheless, we believe that large-scale studies using objective methods will provide a better understanding of our results.

In conclusion, kinesiotape application added to conventional rehabilitation methods may be an effective and safe treatment method for CP and dysphagia. It was also found that the effect of kinesiotape persisted at 18 weeks. Clinicians should consider kinesiotape applications as a treatment option. Large-scale studies with longer follow-up periods are needed to confirm our results.

Ethics Committee Approval: The study protocol was approved by the Gaziantep University Faculty of Medicine Ethics Committee (date: 23.09.2020, no: 2020/216). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Planned the study: M.S.A., E.U.; Supplied the data: M.S.A., E.U.; Conducted the data analysis: O.A., O.Z.K.; Wrote and revised the article's drafts: E.U., O.Z.K.; All co-authors read, approved, and took full responsibility for the final version after each one of them had critically evaluated the text.

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