

Adding connective tissue manipulation to physiotherapy for chronic low back pain improves pain, mobility, and well-being: a randomized controlled trial

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This study aimed to evaluate the effectiveness of connective tissue manipulation (CTM) for improving pain, mobility, and well-being in chronic low back pain (CLBP). Sixty-six patients with CLBP were randomized to three groups: CTM, sham massage (SM) and control groups. The groups got standardized physiotherapy and the related applications 5 days/wk, 3 weeks. Pain intensity, mobility, and well-being (Hospital Anxiety and Depression Scale [HADS], Oswestry Disability Index [ODI], and Short Form-36 [SF-36]) were assessed before and after the applications. Pain, mobility, and disability improved in all groups (P < 0.05). There were differences in resting pain, HADS, and SF-36 scores in CTM, resting pain in SM, and SF-36 scores in controls (P<0.05). Activity pain, HADS scores decreased, mobility and physical component of the SF-36 increased in CTM compared to SM (P<0.05). Pain, ODI, and HADS scores decreased, mobility and SF-36 increased in CTM, and ODI scores decreased in SM compared to controls (P<0.05). In conclusion, pain intensity during activity and at night and disability decreased, and spinal mobility increased in all groups. However, CTM showed superiority in improving pain, mobility, and well-being in patients with CLBP.

Keywords: Connective tissue manipulation, Low back pain, Physical therapy

INTRODUCTION

Non-specific low back pain (NSLBP) is defined as low back pain not attributable to a recognizable or known specific pathology (tumor, infection, fracture, osteoporosis, radicular symptoms, etc.). NSLBP has become one of the biggest problems for public health and it has been expanding worldwide (Balagué et al., 2012). About 70%-85% of the population experience NSLBP in their lifetime, and approximately 10% of them develop chronic low back pain (CLBP) (Furlan et al., 2012). The chronic state represents the greatest challenge. If it is not treated properly, it may cause progressive and recurrent problems. It requires more time and resources, and causes a great burden on the economy (Furlan et al., 2012; Kumar et al., 2013).

Efficient and cost-effective treatment methods are of utmost

importance for CLBP. A wide range of interventions are available. Educating patients, providing advice to stay active, nonsteroidal anti-inflammatory drugs, analgesics, exercise therapy, manual therapy techniques, and cognitive behavioral therapy are recommended in most guidelines for the conservative treatment (Balagué et al., 2012; Dagenais et al., 2010; Moseley, 2002).

Standardized physiotherapy programs include heat and electrotherapy applications, exercise programs, and preventive advice. In addition, manual therapy methods have recently gained popularity in physiotherapy programs to further enhance tissue healing and overall well-being (Ghildayal et al., 2016; Kumar et al., 2013). Clinically, many different manual therapy methods are available (Aure et al., 2003; Rubinstein et al., 2013). Connective tissue manipulation (CTM) is one of the specific manual therapy techniques. Unlike the other techniques, it stimulates autonomic responses

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via cutaneous-visceral reflexes (Holey and Dixon, 2014). CTM produces local mechanical effects on connective tissue and causes reflex mechanisms that reduce sympathetic activity to produce vasodilation. The general effects of the CTM also result in the rebalancing of the autonomic nervous system, usually moving in a parasympathetic direction, and generating endocrine responses. These effects may improve the release of endorphins (Kaada and Torsteinbø, 1989), resulting in increased feeling of relaxation and giving a raise of mood, improve sleep pattern, and help achieve normalized energy levels (Holey and Dixon, 2014; Holey et al., 2011; Langevin and Sherman, 2007). Therefore, CTM has been used for the management of a broad range of health conditions (Celenay et al., 2016; Celenay et al., 2017; Demirtürk et al., 2016; Gürsen et al., 2015; Kavlak et al., 2014; Yagci et al., 2004). CTM applications may also be important for connective tissue remodeling in response to varying levels of mechanical stress in CLBP. However, to our knowledge, no clinical trial for the effectiveness of CTM for the treatment of CLBP has been reported.

Therefore, the aim of this study was to investigate the efficacy of CTM on pain, spinal mobility, and overall well-being in patients with CLBP. The following hypothesis was investigated: Incorporation of CTM into standardized physiotherapy would be more effective for the treatment of CLBP in comparison to only standard physiotherapy or sham massage application.

MATERIALS AND METHODS

Design

A prospective randomized controlled trial design was used. This study was approved by the Ethics Committee of the University (approval number: 11/33). The study was conducted in accordance with the rules of the Declaration of Helsinki and registered at www. clinicaltrials.gov with the registration number NCT02714803.

Participants

Voluntary patients with CLBP who were diagnosed by their physicians and referred to the Physiotherapy and Rehabilitation clinic to get a treatment were included. The inclusion criteria were: age < 65 years, and having nonspecific CLBP without any relevant ongoing pathologies (e.g., disc prolapse, spondylolisthesis, fractures, tumor, osteoporosis, or infection). Exclusion criteria included: having other pain syndromes, a history of spinal surgery or invasive examinations in the past 6 months, a neurological disease, or a psychiatric disease, and being pregnant. Written informed consent was obtained from all participants before being allocated

to a group and before their baseline assessment.

Randomization

Block randomization, created by an individual not involved in the recruitment and treat-ment of patients, was carried out by a random number list generated by computer. The patients were randomly assigned to one of the following three groups: (a) standardized physiotherapy program with CTM (CTM group); (b) standardized physiotherapy program with SM (SM group); and (c) only standardized physiotherapy program (Control group).

Intervention

Treatment programs were applied on alternate days for a total of 15 sessions for 3 weeks by physiotherapists (STC, SGU). The standardized physiotherapy program included the application of superficial thermal heat, transcutaneous electrical nerve stimulation (TENS), advice, and an exercise program. Topical moist heat treatment at 40°C applied directly on the skin for 20 min to increase both tissue temperature and blood flow. After superficial thermal therapy, TENS (Sonopuls 492, Enraf Nonius, The Netherlands) at a frequency of 100 Hz (250-µsec pulses) was applied for 20 min using two 4- to 6-cm electrodes placed bilaterally on each side of the spinous process of the L4 to S1 vertebrae (Gozani, 2016). Then, the exercise program was provided to the patients. It was composed of 10-min warm-stretching exercises including low back and lower limb extremity muscles. Briefly, low-load activation of the core stabilizing muscles was initially administered, with no movement (isometrically) and in minimally loading positions (supine lying, 4-point kneeling, sitting, and standing). Progressively, the holding time and then the number of contractions were increased in those positions up to 10 contraction repetitions with 10-sec duration each (first week). The clinical measure used to ensure the correct activation of the transversus abdominis muscle was to observe a slight drawing-in maneuver of the lower part of the anterior abdominal wall below the umbilical level, consistent with the action of this muscle. Furthermore, a bulging action of the multifidus muscle should be felt under the physical therapist's fingers when they were placed on either side of the spinous processes of the L4 and L5 vertebral levels, directly over the belly of this muscle. Integration with dynamic function (activities that required spinal or limb movements) through the incorporation of the stabilizing muscles' cocontraction into light functional tasks was administered (Grenier and McGill, 2007; Koumantakis et al., 2005). Moreover, strengthening exercises activating the extensor (paraspinals), flexor (abdominals), and gluteal muscle groups were



performed (Koumantakis et al., 2005).

The CTM was applied by an experienced physical therapist (STC). Each treatment section took around 10 to 15 min. The treatment started with a series of short strokes over the sacrum, then lumbar spine, and posterolateral pelvis. Longer paravertebral and subcostal strokes were added. During the CTM, patient was in a sitting position. The back was unclothed and straight for optimal tension of the connective tissue. For creating traction between cutaneous tissues, the middle fingers of both hands were used. The pressure was high. It was felt like an uncomfortable scratching or slitting (Holey and Dixon, 2014).

The SM was performed by another physical therapist (SGU). The patient was in a sitting position and his/her low back was unclothed. General slow and slight strokes and effleurage on low back area were applied using no specific technique and specific muscles. The whole session took 10 to 15 min (Furlan et al., 2009).

Outcome measures

Demographic characteristics, age, gender, weight, height, body mass index, smoking, exercise habit, and history were recorded. Before and after the treatment programs, evaluations related to low back pain intensity, spinal mobility, disability, quality of life, anxiety, and depression were carried out. All evaluations were conducted by the same physical therapist (DOK), who was blinded to the group interventions.

A 10-cm visual analogue scale (VAS) was used to determine the low back pain intensity at rest (VAS rest), during activity (VAS activity), and at night (VAS_night). The VAS has been shown to be a valid and reliable tool for measuring experimental and clinical pain (Clark et al., 2003). The VAS is scored on a 10-cm horizontal line with 0 indicating 'no pain' and 10 'worst imaginable pain'. The patients were asked to mark their low back pain on the horizontal line.

Spinal mobility was assessed with a modified version of the Schober test (Rezvani et al., 2012). While the patient was in standing erect position, a mark was made on the back in the midpoint on the imaginary line joining posterior superior iliac spine. Another mark was made 10 cm above and 5 cm below of this mark. The patient was asked to maximally bend forward keeping the knees fully extended. The distance between these marks was measured. Mobility was calculated by examining the difference between upright and maximum flexion end positions.

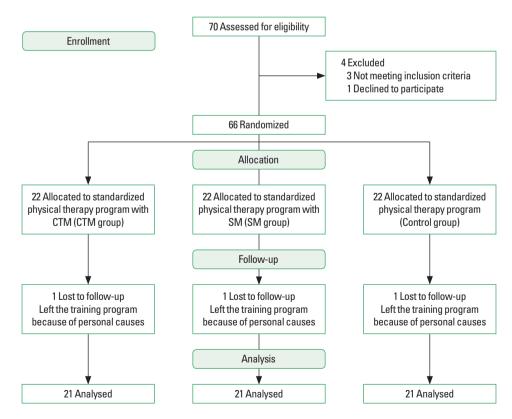


Fig. 1. Study process. CTM, connective tissue massage; SM, sham massage.



The Turkish version of Oswestry Disability Index (ODI) was used to evaluate the functional status or disability of the patients (Yakut et al., 2004). The index has 10 items (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, travelling), which are scored on a scale of 0-5 points based on functional performance, with higher scores indicating more severe disabilities.

The quality of life was evaluated with the Medical Outcome Study 36-Item Short Form Health Survey (SF-36) (Ware, 2000). The Turkish version, whose reliability and validity study was established by Kocyigit et al. (1999), was used. It includes eight different fields: general health, bodily pain, physical function, physical and mental role limitations, mental health, vitality, and social function. The eight fields can be join mainly the physical component summary (PCS) and the mental component summary that reflects physical and mental health. While '100' is the best score the '0' is the worst and higher scores indicate better functioning.

The Turkish version of the Hospital Anxiety and Depression Scale (HADS), whose reliability and validity study was conducted by Aydemir et al. (1997), was used for evaluating cognitive-emotional aspects of anxiety (HADS-A) and cognitive-emotional aspects of depression (HADS-D). Each question is scored on a 4-point Likert scale, ranging from 0 to 3, where a higher score represents more severe anxiety or depression.

Statistical analysis

G*Power package software program (Version 3.1.9.2, Franz Faul, Universitat Kiel, Germany) was used to determine the required sample size for this study. It was calculated using analysis of variance (ANOVA): repeated measures, within-between interaction menus of the program. Post hoc power was determined as

Table 1. Demographic characteristics of patients

Characteristic	CTM group (n=21)	SM group (n=21)	Control group (n=21)	Test	<i>P</i> -value
Age (yr)	53 (40-65)	48 (39–63)	55 (24-65)	5.174	0.075
Gender					
Female	19 (90.5)	17 (81.0)	15 (71.4)	2.565	0.277
Male	2 (9.5)	4 (19.0)	6 (28.6)		
Body mass index (kg/m²)	31.06 ± 4.10	28.93 ± 3.82	31.43±3.16	2.779	0.070
Smoking	2 (9.5)	8 (38.1)	5 (23.8)	4.725	0.094
Exercise habit	5 (23.8)	1 (4.8)	3 (14.3)	3.356	0.187

Values are presented as median (range), number (%), or mean ± standard deviation. CTM, connective tissue massage; SM, sham massage.

Table 2. Comparisons of pre and post pain intensity and spinal mobility of treatment groups

	CTM group	SM group	Control group	Test	<i>P</i> -value
VAS_rest (cm)					
Pretreatment	5.2 (2.0-10.0)*	2.5 (0.0-6.5)*	4.5 (0.0–10.0)	8.997	0.011
Posttreatment	3.0 (0.0-6.2)	0.0 (0.0-6.3)*	4.0 (0.0-10.0)*	8.159	0.017
<i>P</i> -value	< 0.001	< 0.001	0.192		
			Group×time interaction	6.104	0.005
VAS_activity (cm)					
Pretreatment	8.0 (4.0-10.0)	7.3 (2.5–10.0)	7.5 (4.5–10.0)	2.689	0.261
Posttreatment	5.3 (0.0-10.0)*	6.5 (1.6–9.0)	7.0 (3.7–10.0)*	6.045	0.049
<i>P</i> -value	< 0.001	< 0.001	< 0.001		
			Group×time interaction	10.616	< 0.001
VAS_night (cm)					
Pretreatment	5.0 (0.0–10.0) [†]	0.0 (0.0-8.0)*,†	6.0 (0.0–10.0)*	11.347	0.003
Posttreatment	3.0 (0.0-8.0)†	0.0 (0.0–8.0)*,†	5.0 (0.0-9.0)*	13.530	0.001
<i>P</i> -value	< 0.001	0.032	0.013		
			Group×time interaction	0.909	0.395
Schober score (cm)					
Pretreatment	5.0 (1.5-8.5)	5.0 (1.0-8.0)*	3.5 (1.0-6.5)*	6.242	0.044
Posttreatment	6.0 (2.5–9.5)*	6.0 (2.0-8.0) [†]	4.2 (1.5–6.5)* ^{,†}	11.351	0.003
<i>P</i> -value	< 0.001	< 0.001	< 0.001		
			Group×time interaction	10.171	< 0.001

VAS, visual analogue scale; CTM, connective tissue massage; SM, sham massage.

^{*,†}P<0.05, statistically significant difference.



100.0% for group×treatment interaction regarding VAS_activity values.

Statistical analysis was performed via IBM SPSS Statistics ver. 21.0 (IBM Co., Armonk, NY, USA) and "nparLD" package in R. The variables were investigated using visual (histograms, probability plots) and analytical methods (Shapiro–Wilk test) to determine whether or not they are normally distributed. Descriptive analyses were presented using mean and standard deviation for the normally distributed variables, median (range) for the nonnormally distributed variables, and count (%) for the categorical variables.

Treatment groups were compared by Kruskal–Wallis test and ANOVA, respectively, for age and BMI. Kruskal–Wallis test was also used in group comparisons for baseline and second measurements, separately. After Kruskal–Wallis test, Bonferroni adjusted Mann–Whitney *U*-test was performed to reveal different groups. Chi-square test was used for comparisons of treatment groups in

terms of gender, smoking, and exercise habit. Groups were compared by nonparametric F1-LD-F1 design to determine the differences in terms of changes in pain intensity, spinal mobility, disability, quality of life, and anxiety-depression due to the treatment. ANOVA-type statistics and P-values of interaction effect were included in tables. A P < 0.05 was accepted as statistical significance.

RESULTS

Sixty-six patients out of the 70 patients with CLBP were included in this study; however, 63 completed the study (Fig. 1). None of the 63 patients reported adverse effects of the treatment. Demographic characteristics among the groups were similar for all variables (P > 0.05) (Table 1).

There were no pretreatment differences between groups in terms of pain intensity during activity, ODI, HADS, and SF-36 scores

Table 3. Comparisons of pre and post disability, quality of life, anxiety, and depression levels of treatment groups

	CTM group	SM group	Control group	Test	<i>P</i> -value
Oswestry score					
Pretreatment	27 (10–40)	21 (9-45)	25 (14–39)	1.474	0.479
Posttreatment	21 (8–39)	18 (10-45)	23 (12–33)	0.634	0.728
<i>P</i> -value	< 0.001	0.040	< 0.001		
			Group×time interaction	3.679	0.028*
SF36-PCS					
Pretreatment	29.1 (20.5–40.0)	33.2 (17.3–47.5)	33.6 (19.8–49.6)	3.737	0.154
Posttreatment	33.5 (22.4–42.5)	33.5 (22.4-47.5)	34.6 (19.8–51.2)	1.091	0.580
<i>P</i> -value	< 0.001	0.311	0.002		
			Group × time interaction	9.162	< 0.001*
SF36-MCS					
Pretreatment	36.6 (20.5–48.6)	38.9 (22.6–58.9)	37.0 (9.3–64.3)	0.679	0.712
Posttreatment	42.0 (28.6–60.5)	36.4 (22.6–63.7)	39.7 (9.3–64.5)	2.431	0.297
<i>P</i> -value	< 0.001	0.237	0.021		
			Group×time interaction	8.715	< 0.001*
HADS-A					
Pretreatment	11 (0–18)	10 (0-20)	10 (2–27)	0.547	0.761
Posttreatment	8 (2–13)	10 (0-20)	10 (2–27)	5.062	0.080
<i>P</i> -value	< 0.001	0.493	0.714		
			Group×time interaction	5.602	0.004*
HADS-D					
Pretreatment	9 (0–13)	9 (0–18)	6 (0–19)	0.403	0.818
Posttreatment	5 (1–16)	9 (0–18)	7 (1–19)	3.287	0.193
<i>P</i> -value	< 0.001	0.534	0.292		
			Group×time interaction	6.086	0.002*

SF-36, Short Form-36; PCS, physical component summary; MCS, mental component summary; HADS-A, anxiety component of Hospital Anxiety and Depression Scale; HADS-D, depression component of Hospital Anxiety and Depression Scale; CTM, connective tissue massage; SM, sham massage.

^{*}P<0.05, statistically significant difference.



(P > 0.05), while there were differences in terms of pain intensity at rest and night and spinal mobility (P < 0.05) (Tables 2, 3). There were no posttreatment differences between groups for the ODI, HADS, and SF-36 scores (P > 0.05), while there were differences in terms of pain intensity at rest and night, during activity, and spinal mobility (P < 0.05) (Tables 2, 3).

After treatment, the VAS_rest, VAS_activity, VAS_night, ODI, and HADS scores decreased, and spinal mobility and SF-36 scores increased in the CTM group (P < 0.05) (Tables 2, 3). In the SM group, the VAS_rest, VAS_activity, VAS_night, and ODI scores reduced, and only spinal mobility increased (P < 0.05) (Tables 2, 3). However, no significant difference was detected in other parameters (P > 0.05) (Table 3). In the control group, the VAS_activity, VAS_night, and ODI scores decreased, spinal mobility and the SF-36 scores increased (P < 0.05) (Tables 2, 3); nevertheless, there were no significant differences in terms of the VAS rest and HADS scores (P > 0.05) (Tables 2, 3).

The intergroup comparison showed significant differences in the VAS_rest, VAS_activity, spinal mobility, ODI, HADS, and SF-36 scores among the groups (P < 0.05) (Tables 2, 3). The VAS activity and HADS scores decreased, and spinal mobility and the PCS of the SF-36 increased in the CTM group in comparison to the SM group (P < 0.05) (Tables 2, 3). The VAS_rest, VAS_activity, ODI, and HADS scores reduced, spinal mobility and SF-36 scores increased in the CTM group in comparison to the control group (P < 0.05) (Tables 2, 3). Moreover, ODI scores decreased in the SM group compared to the control group (P < 0.05) (Table 3). However, changes in ODI scores were similar between the CTM and SM groups (P > 0.05) (Table 3).

DISCUSSION

This study puts forward the following findings: (a) Pain intensity (during activity and at night) and disability decreased and spinal mobility increased for all groups; (b) Pain intensity at rest, anxiety, depression, and quality of life improved in the CTM group, pain intensity at rest decreased in the SM group, and quality of life increased in the control group; (c) Standardized physiotherapy with CTM was more effective in improving pain during activity, spinal mobility, anxiety, depression and physical health component of quality of life survey compared to standardized physiotherapy with SM, and in improving pain at rest and during activity, spinal mobility, disability, anxiety, depression and quality of life compared to only standardized physical therapy; and (d) Standardized physiotherapy with SM was superior in disability compared to only standardized physical therapy.

In the standardized physiotherapy program, heat application was preferred since it is low-cost and easy to use, and it prepares the tissue for the other treatments. The overall qualities of warmth and heat have long been associated with comfort and relaxation for many types of low back pain (French et al., 2006). TENS have long been used in the management of CLBP with heat therapy. However, the evidence does not support the use of TENS alone in the treatment of CLBP (Milne et al., 2001). In addition, it was declared in systematic reviews that exercise therapies consisting of individually designed programs, including stretching or strengthening, and delivered with supervision may improve pain and function in CLBP (Hayden et al., 2005). Similar to the literature, in our study, pain intensity (during activity and at night) and disability decreased, spinal mobility and quality of life increased in the control group (standardized physiotherapy).

The SM group, which served as placebo, also showed improvements for pain (at rest and night, during activity), spinal mobility, and disability in the present study. In addition, it was seen that the SM group was superior in disability compared to the control group. These results obtained from the SM group may be originated from the effects of touches on the skin. The therapeutic touch, with or without a specific technique, with standardized physiotherapy may have positive effects by decreasing stress hormones and muscle tension, and thus decreasing pain and disability (Brattberg, 1999). In addition, the effect of placebos in CLBP may involve decreased fear of pain with consequent increased physical activity and therefore improving disability.

There were a variety of studies investigating the effects of CTM on different populations. Kavlak et al. (2014) concluded that CTM could be used for minimizing depressive symptoms and improving quality of life in healthy young subjects. Yagci et al. (2004) presented that CTM with exercise intervention improved pain intensity, number of trigger points, and cervical range of motion in patients with cervical myofascial pain syndrome. Celenay et al. (2017) found that exercises with CTM might be superior in improving pain, sleep problem, fatigue, and role limitations due to physical health compared to exercise alone. In another study by Celenay et al. (2016) explained that in patients with chronic mechanical neck pain, stabilization exercises with CTM might be superior in improving pain intensity at night, pressure pain threshold, state anxiety, and mental health compared to stabilization exercise alone. Akbayrak et al. (2002) studied the effects of CTM on pain in patients with tension type headache. They found improvements in pain intensity, duration, and frequency at the 6-month



follow-up. However, in this study, the lack of a control group means that isolating the CTM effect from other effects, such as placebo, was difficult. We also carried out standardized physiotherapy with CTM (CTM group) in patient with CLBP and compared both placebo (standardized physiotherapy with SM) and control (standardized physical therapy) groups. After treatment, in the CTM group, all parameters improved. In addition, it was observed in our study that standard physiotherapy with CTM might be more effective in improving pain during activity, spinal mobility, anxiety, depression, and physical health component of quality of life survey compared to standard physiotherapy with SM, and in improving pain at rest and during activity, spinal mobility, disability, anxiety, depression, and quality of life compared to only standard physical therapy. A reduction of one point (between 0.9 and 1.1 cm) or a reduction of 15.0% in the numeric rating scale (at VAS) represented as the minimal clinically important difference. A change score of -2.0 and a percent change score of -33.0% were best associated with the concept of "much better" improvement (Ostelo et al., 2008; Salaffi et al., 2004). The improvements were not only statistically significant, but also clinically important for the CTM group. Our results obtained from the CTM group were in line with these studies in the literature. The improvements in the CTM group have been originated from the local mechanic, segmental, and general effects of this manipulation. Moreover, according to these results, the CTM especially might be an alternative method in case of anxiety, depression, and negative impacts of quality of life accompanied by chronic pain.

The current study had some limitations. First, we evaluated the clinical results using self-reported measures, not objective measurements, which may have some influences on the final result. Secondly, the results of a three-week program, which is a short term, were presented in this study. Future studies should investigate the long-term outcomes of the CTM applications with a follow-up for the management of CLBP.

In conclusion, pain intensity during activity and at night and disability decreased, and spinal mobility increased in all groups. In addition, pain intensity at rest, anxiety, depression, and quality of life improved in the CTM group, pain intensity at rest decreased in the SM group, and quality of life increased in the control group. Standardized physiotherapy including CTM was better in improving pain during activity, spinal mobility, anxiety, depression, and physical health component of quality of life survey compared to standardized physiotherapy with SM, and in improving pain at rest and during activity, spinal mobility, disability, anxiety, depression, and quality of life compared to only standard-

ized physical therapy; and also standardized physiotherapy with SM was superior in disability compared to only standardized physiotherapy.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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