COMPARING THE EFFECTIVENESS OF ULTRASOUND PLUS TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION THERAPY WITH LOCAL INJECTION OF STEROID IN THE CARPAL TUNNEL SYNDROME

KARPAL TÜNEL SENDROMUNDA TENS'LE BİRLİKTE ULTRASON TEDAVİSİNİN ETKİNLİĞİNİN LOKAL STEROİD ENJEKSİYONU İLE KARŞILAŞTIRILMASI

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ABSTRACT

Background: The aim of this study was to compare the effectiveness of ultrasound plus transcutaneous electrical nerve stimulation therapy with local injection of steroid in the carpal tunnel syndrome.

Method: This study was prospective, randomized, single blinded clinical trial with follow-up at 1, 4 and 12 wks. Thirty-five hands of 22 female patients with clinical and electrophysiological evidence of carpal tunnel syndrome were included in this study. All patients were randomly assigned to one of the two groups; group 1 (11 patients, 16 hands) received ultrasound plus transcutaneous electrical nerve stimulation therapy and group 2 (11 patients, 19 hands) received 6 mg of betamethasone asetate locally into the carpal tunnel. Clinical examinations (Tinel test, Phalen test, paraesthesia, visual analog scale score) and electrophysiological studies were performed before and after the treatments.

Results: Clinical and electrphysiological parameters were similar at baseline in both groups ($p>0.05$). There was a statistically significant improvement on the clinical and electrophysiological parameters of both groups after the treatments ($p<0.05$). Improvement was also similar when both groups were compared at 1, 4 and 12 wks ($p>0.05$).

Conclusion: Ultrasound plus transcutaneous electrical nerve stimulation therapy has good effectiveness in the carpal tunnel syndrome. It may be an alternative treatment to the local injection of steroid.

Key Words: Carpal tunnel syndrome, ultrasound therapy, transcutaneous electrical nerve stimulation therapy, steroid injection.

ÖZET

Amaç: Bu çalışmanın amacı karpal tünel sendromunda transkutanöz elektriksel sinir stimülasyonu tedavisi ile birlikte ultrason tedavisinin etkinliğinin lokal steroid enjeksiyonu ile karşılaştırmaktı.

Metod: Bu çalışma, 1, 4 ve 12 hafta takip süreli prospektif, randomize ve tek kör klinik bir çalışmadır. Çalışmaya klinik ve elektrofizyolojik olarak karpal tünel sendromu tanısı alan, 22 bayan hastanın 35 eli dahil edildi. Hastalar rastgele 2 gruba ayrıldı ve 1.gruba (11 hasta, 16 el) ultrasonla birlikte transkutanöz elektriksel sinir stimülasyonu tedavisi ve 2. gruba (11 hasta, 19 el) 6 mg betametason asetat lokal olarak karpal tünele uygulandı. Klinik muayeneler (tinel testi, falen testi, parestezi, vizüel analog skala) tedaviden önce, tedaviden sonra 1, 4 ve 12.haftalarda, elektrofizyolojik ölçümler ise tedaviden önce ve tedaviden 12 hafta sonra yapıldı.

Bulgular: Her iki grupta başlangıçta klinik ve elektrofizyolojik özellikler benzerdi ($p>0.05$). Tedavi sonrası iki grupta klinik ve elektrofizyolojik parametrelerde anlamlı düzelme vardı ($p<0.05$). Tedavi sonrası 1, 4 ve 12.haftalarda her iki grup karşılaştırıldığında iyileşme benzerdi ($p>0.05$).

Sonuç: Transkutanöz elektriksel sinir stimülasyonu ile birlikte ultrason tedavisi karpal tünel sendromunda iyi etkilidir ve lokal steroid tedavisine alternatif olabilir.

Anahtar Kelimeler: Karpal tünel sendromu, ultrason tedavisi, transkutanöz elektriksel sinir stimülasyonu tedavisi, steroid enjeksiyonu.

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INTRODUCTION

The carpal tunnel syndrome (CTS), caused by compression of the median nerve at the wrist, is considered to be the most common entrapment neuropathy and a frequent cause of disability, particularly among women. (1). Signs and symptoms associated with CTS include paraesthesia, numbness and tingling in the sensory distribution of the median nerve, positive Tinel sign, positive Phalen sign, hypoesthesia, nocturnal awakening, pain, and weakness (2).

Nonsurgical treatment of CTS is frequently offered to those with mild to moderate symptoms. Conservative treatment options include adjusting the work environment, tendon and nerve gliding exercises, splinting the wrist in a neutral position, oral intake or local injection of corticosteroids, nonsteroidal anti-inflammatory drugs, diuretics and physical therapy. The benefit of conservative treatment seems to be limited if symptoms are refractory to conservative treatment or nerve conduction studies show severe entrapment. In this condition, open or endoscopic carpal tunnel release may be necessary (3,4).

Despite the importance of CTS, there is no universally accepted therapy. There is a need for new conservative treatments in CTS, which could be applied in the early stages of this disorder to prevent the disability, and to reduce the need for surgery. Although various physical therapy agents had been used, ultrasound (US) plus transcutaneous electrical nerve stimulation (TENS) therapy was not reported previously.

US is a physical therapy agent commonly used to increase temperature in deep tissue. (5) It is believed that US increases blood flow, clears the pain mediator, and changes the permeability of the biologic membrane, nerve conduction, and pain threshold (6,7). Experiments on the stimulation of nerve regeneretion and on nerve conduction by US treatment and findings of an anti-inflammatory effect of such treatment support the concept that US treatment might facilitate recovery from nerve compression (8,9,10).

Also, TENS is a physical therapy agent currently used to manage a range of both acute and chronic pain conditions, including postoperative, arthritic, labor, and low back pains (11,12,13). However, few studies reported benefit of US or TENS treatments in the CTS under clinical conditions, but the results were contradictory. (14,15,16,17). The aim of this study was to compare on the clinical and electrophysiological parameters of the effectiveness of US plus TENS therapy with local injection of steroid in idiopathic CTS. This is the first clinical trial comparing these two treatments in CTS.

MATERIAL and METHOD

This study was prospective, randomized, single blinded clinical trial with follow-up at 1, 4 and 12 wks. Thirty-five hands of 22 women with CTS were included in this study. All our patients had complaints of paraesthesia and/or pain for at least 1 month in all or part of the hand territory innervated by the median nerve, mainly at night or on waking and/or triggered by certain postures or repetitive forced movements of the fingers or wrist.

The patient excluded from the study if:

(1) There were other predisposing etiologic factors (such as diabetes mellitus, rheumatic diseases, acute trauma, pregnancy).

(2) The patient had physical or medical therapy in the previous month.

(3) The patient had a corticosteroid injection in the previous 3 months.

(4) The patient had serious medical problems that might have interfered with electrophysiologic testing during the study.

(5) The patient had medical problems that would have been contraindicated for US and TENS treatments.

(6) There was muscle atrophy, anesthesia, or intractable pain due to CTS.

(7) Electromyographic examination of the abductor pollicis brevis muscle was found spontaneous activity.

Clinical examinations were performed at the beginning and repeated at the first, fourth and twelfth weeks after treatment. Tinel and Phalen test were carried out in the standard manner (18). Pain was evaluated by a visual analog scale (VAS 0-100mm). Paraesthesia was assessed by four point scale (0: no, 1: mild, 2: moderate, 3: severe).

Electrophysiological studies were performed in median and ulnar nerve according to the American Association of Electrodiagnostic Medicine's guidlines before treatment and at the twelfth week after treatment. All electrodiagnostic tests were performed by the same physician (MA) with a Medelec (UK) Synergy, version 2.0, electromyography apparatus. (19). Subjects were studied in the supine position and the room temperature was kept at 22ª to 24ªC.

Motor or sensory nerve conduction studies were performed using standard tecniques of supramaximal percutaneous stimulation. The ring electrodes for sensory distal latencies of the median nerve were placed around the proximal and distal interphalangeal joints of the second and fourth digit. The stimulating electrode was placed proximal at the wrist at a distance of 14-15cm of the ring electrode of the second and fourth digit. The same was done for the ulnar nerve. To record the distal motor latency (DML) of the median nerve, surface recording electrodes were placed on the m.abductor pollicis brevis at 6-7cm distance of the proximal stimulating electrode at the wrist.

Antidromic sensory distal latencies (SDL) of the median and unlar nerve were recorded using ring electrodes around the proximal and distal interphalangeal joints of the second and fourth digit. The difference of the SDL of the median and the ulnar nerve (M-U) was calculated. The amplitude of sensory nerve action potential (SNAP) was determined from baseline to negative peak. The sensory and motor conduction velocities of the median nerve (SNCV, MNCV) to the second digit were calculated as well. The amplitude of the compound muscle action potential (CMAP) in the m.abductor pollicis brevis was determined from baseline to the major negative peak.

In our study a M-U above or equal to 0.6ms was considered abnormal. Secondary criteria were the DML to the m. abductor pollicis brevis (normal value ? 4.0ms) or the SNCV (normal value ? 42m/s).

Needle electromyography of the m.abductor pollicis brevis was only performed at the inclusion date. Special attention was given to the presence of spontaneous activity at rest.

The study was performed in accordance with the principles of the Declaration of Helsinki. The aim and methods of the study were explained to all patients before their informed consent was obtained.. When bilateral CTS was present, measures were taken for each hand.

Treatment

Patients were randomly assigned to one of the two groups; 16 hands of 11 patients in the first group (group 1) received physical therapy (US and TENS) and 19 hands of 11 patients in the second group (group 2) received 6 mg betamethasone asetate (1ml) injected locally by the same investigator (MS). The local corticosteroid injection was given using a 23 Gauge needle at the proximal of the carpal tunnel to the wrist crease just medial to the tendons of the flexor radial muscle involving a single 1ml betamathasone asetate (Diprospan, Firma, İstanbul, Turkey) injection without local anesthetic. The needle was introduced slowly, if a patient reported paraesthesia with insertion, the needle was immediately withdrawn and repositioned.

The recommended therapeutic dosage of US is generally 0.1 to 2 W/cm² (11,12). In this study, US therapy in circular fashion was administered to the area over the carpal tunnel at an intensity of 1.0W/cm² and a frequency of 1MHz, continuous mode, with a transducer of 5cm² and with aquasonic gel as couplant. Transmission gel and ultrasound soundhead were at room temperature before treatments. This therapy lasted 5 minutes per session, 5 days a week, for 3 weeks, and patients were aware of the treatment groups.

TENS therapy was applied at a frequency of 80Hz, a pulse width of 150?s, square waveform and conventional stimulation mode. The circular electrode (4cm diameter) for the milliamps TENS device was applied to the skin and located at the center of the wrist crease, and the grounding pad was applied to the skin and located on the dorsum of the wrist. After these were taped into place, the device was turned on. As the power intensity was gradually increased, the patient was asked if she felt any stimulation or tingling at either electrode site. Immediately after the patient reported sensation, the intensity level was applied. This therapy lasted 20 minutes per session, 5 days a week, for 3 weeks and patients aware of the treatment groups.

Statistical Analysis

SPSS 10.07 program (SPSS, Inc., Chicago, IL, USA) was used for statistical analysis. Fisher's exact and ?²

Tablo-I

The demographic and baseline characteristics of patients

	Group 1 N:16 hands	Group 2 N:19 hands	P value (between groups)
Mean age,yr ± SD	49.5 ± 10.1	45.7 ± 14.0	0.3
Duration of symptoms, months ± SD	26.4 ± 24.1	16.0 ± 16.1	0.1
VAS score, mm ± SD	35.8 ± 9.3	43.1 ± 9.7	0.5
Tinel test, n (%)	13 (81.3 %)	11 (57.9 %)	0.13
Phalen test, n (%)	16 (100 %)	16 (84.2 %)	0.09
Paraesthesia, n (%)	16 (100 %)	19 (100 %)	0.6
DML (ms)	5.13 ± 0.7	5.25 ± 1.5	0.7
MNCV (m/s)	55.9 ± 5.7	55.4 ± 7.4	0.8
CMAP (mV)	5.9 ± 2.0	6.3 ± 1.8	0.4
SDL (ms)	3.9 ± 0.4	3.7 ± 0.5	0.4
SNCV (m/s)	43.9 ± 5.9	43.9 ± 5.4	0.9
SNAP (i V)	13.5 ± 7.9	14.0 ± 5.6	0.8
M-U (ms)	1.0 ± 0.3	1.0 ± 0.5	0.8

VAS:Visual analog scale, DML:Distal motor latency, MNCV:Motor nerve conduction velocity, CMAP: Compound action potential, SDL:Sensory distal latency, SNCV:Sensory nerve conduction velocity, SNAP:Sensory nerve action potential, M-U: Difference median to 1nlar nerve sensory distal latency

Tablo-II

Comparison of the clinical parameters in two groups before and after treatment

Clinical Parameters	Group 1 N:16 hands	Group 2 N:19 hands	P value (between groups)
Tinel test, n (%) Baseline	13 (81.3 %)	11 (57.9 %)	
1st wk	9 (56.3 %) p:0.06	6 (31.6 %) p:0.05	P >0.05
4th wk	5 (31.3 %) p:0.004	4 (21.1 %) p:0.013	P>0.05
12th wk	3 (18.8 %) p:0.0007	3 (15.8 %) p:0.005	P>0.05
Phalen test, n (%) Baseline	16 (100 %)	16 (84.2 %)	
1st wk	8 (50 %) p:0.001	10 (52.6 %) p:0.02	P>0.05
4th wk	6 (37.5 %) p:0.0003	3 (15.8 %) p:0.0001	P>0.05
14th wk	3 (18.8 %) p:0.00001	2 (10.5 %) p:0.00001	P>0.05
Paraesthesia, n (%) Baseline	16 (100 %)	19 (100 %)	
1st wk	13 (81 %) p:0.001	14 (74 %) p:0.0001	P>0.05
4th wk	10 (62 %) p:0.0001	9 (47 %) p:0.0001	P>0.05
12th wk	11 (69 %) p:0.0001	10 (62 %) p:0.0001	P>0.05
VAS score, mm ± SD Baseline	35.8 ± 9.3	43.1 ± 9.7	
1st wk	18.4 ± 25.4 p:0.003	18.1 ± 30.7 p:0.01	P>0.05
4th wk	8.0 ± 19.7 p:0.003	8.5 ± 16.5 p:0.008	P>0.05
12th wk	2.3 ± 6.7 p:0.003	6.0 ± 13.5 p:0.008	P>0.05

VAS:Visual analog scale

tests were used to compare the differences between groups for the clinical and electrophysiological assessments, before treatment. Pearson chi-square test for Tinel, Phalen, paraesthesia measures and Wilcoxon signed ranks test for VAS scores and electrophysiological values were used to compare the differences between before and after treatment in both groups. A $p< 0.05$ was considered statistically significant.

RESULTS

A total of 22 female patients were enrolled in this study. Carpal tunnel syndrome was bilateral in 13 patients (59%), on the right hand in 7 patients, and on the left side in 2 cases. The demographic and baseline characteristics of patients in two groups are shown in table 1.

At the beginning of the study, there was no statistically significant difference between group 1 and group 2 with respect to the clinical and electrophysiological findings ($p>0.05$). During the study, none of the patients reported progressive worsenning in symptoms or reluctance for the therapy. When the clinical parameters (Tinel and Phalen test, VAS score and paraesthesia) were compared before with after treatment, there was statistically significant improvement in all clinical parameters in both groups ($p<0.05$). The difference between groups was not statistically significant ($p>0.05$, table 2)

Tablo-III

Comparison of the electrophysiologic values in two groups before and after treatment

	Group 1 N:16 hands	Group 2 N:19 hands	P value (between groups)
DML (ms)			
BT	5.13 ± 0.7	5.25 ±1.55	0.7
AT	4.7 ± 0.8	4.9 ± 1.0	0.9
	p:0.01	p:0.01	
MNCV (m/s)			
BT	55.9 ± 5.7	55.4 ± 7.4	0.8
AT	53.7 ± 6.6	57.4 ± 5.5	0.06
	p:0.9	p:0.9	
CMAP (mV)			
BT	5.9 ± 2.0	6.3 ± 1.8	0.4
AT	6.2 ± 2.4	5.9 ± 1.9	0.2
	p:0.8	p:0.8	
SDL (ms)			
BT	3.9 ± 0.4	3.7 ± 0.5	0.4
AT	3.7 ± 0.6	3.3 ± 0.5	0.4
	p:0.008	p:0.008	
SNCV (m/s)			
BT	43.9 ± 5.9	44.4 ± 5.3	0.9
AT	46.3 ± 8.3	49.8 ± 8.8	0.2
	p:0.009	p:0.009	
SNAP (i V)			
BT	13.5 ± 7.9	14.0 ± 5.6	0.8
AT	17.9 ± 12.2	16.0 ± 6.4	0.2
	p:0.007	p:0.007	
M-U (ms)			
BT	1.0 ± 0.3	1.0 ± 0.5	0.8
AT	0.7 ± 0.4	0.7 ± 0.5	0.3
	p:0.03	p:0.01	

BT: Before treatment, AT: After treatment, DML: Distal motor latency, MNCV:Motor nerve conduction velocity, CMAP: Compound action potential, SDL:Sensory distal latency, SNCV:Sensory nerve conduction velocity, SNAP:Sensory nerve action potential, M-U: Difference median to ulnar nerve sensory distal latency

Table 3 shows the mean values and standard deviations of electrophysiological measures in both groups. At twelfth week after treatment, both in group 1 and in group 2 significant improvement was observed on the electrophysiologic measures (SDL, DML, SNCV, SNAP and M-U) except MNCV and CMAP when compared with baseline values ($p>0.05$). The improvement in both groups was similar ($p>0.05$).

After treatment, we determined a slight decrease in MNCV (from 55.9 ± 5.7, to 53.7 ± 6.6) in group 1 and a slight increase in MNCV (from 55.4 ± 7.4 ,to 57.4 ± 5.5) in group 2, but the difference was not statistically significant ($p>0.05$). Also, we observed a nonsignificant slight increase in CMAP amplitude (from 5.9 ± 2.0, to 6.2 ± 2.4, $p>0.05$) in group 1, and a slight decrease in CMAP amplitude (from 6.3 ± 1.8, to 5.9 ± 1.9, $p>0.05$) in group 2.

DISCUSSION

Carpal tunnel syndrome occurs commonly in adults older than 30 years, paricularly among women, and involves compression of the median nerve at the wrist, affecting both sensory and motor branches (20). Chronic repetitive use of fingers creates shearing forces that may lead to localized hyperplasia and fibrosis of tenosynovium around the flexor tendons as well as the median nerve in the tunnel (21). Lifetime risk of developing this pathology is 10 % (22).

To date, no recognized, standardized, consistent conservative treatment programme has been documented for CTS management. Treatment approaches commonly used in CTS have remained essentially the same for years (3). The beneficial effects of steroid injections were reported in several studies of idiopathic CTS (23,24,25). The improvement in measured median nerve function indicates a favorable effect of steroids on median nerve physiology, as demonstrated in previous studies. The mechanism of improvement is currently unknown, but could occur due to the reduction in nerve or tendon inflammation, alteration in the mechanical properties of the carpal tunnel structures resulting in decreased intracarpal pressures, or via direct effects on the median nerve itself (26,27). Potential adverse effects on nerves and tendon with repeated injections have limited the value of this treatment (28). There are conflicting results in the literature about the long-term efficacy of steroid injections, and recurrence rates range between 8 % and 100 % (29).

Ultrasound is used to treat musculoskeletal disorders such as tendinitis, bursitis, arthritis, or fracture. It is assumed that ultrasound has thermal effects on the target tissue resulting in an increase in blood flow, local metabolism, and tissue regeneration, and also reducing inflammation, oedema and pain thereby facilitating the recovery of nerve compression (6,7). In this study, we investigated the therapeutic effectiveness of US therapy plus TENS therapy as

conservative treatment agent in idiopathic CTS. After 3 weeks of 5 minutes daily with 1W/cm² intensity, 1MHz frequency continuous US therapy plus 3 weeks of 20 minutes daily with 80Hz frequency, 150 ?s pulse width conventional TENS therapy significant improvement was observed in the clinical (Tinel and Phalen test, VAS score, paraesthesia) and electrophysiological parameters (SDL, DML, SNCV, SNAP and M-U) except MNCV and CMAP. However, this improvement was similar to those of injection groups.

Previous studies have reported that the application of US of 0.5 to 2 W/cm² on a peripheral nerve may cause an increase of conduction velocity due to a thermal effect (30,31). Since the underlying pathology in CTS is focal demyelination caused by compression, the demyelinated part of the median nerve was probably more sensitive to the US treatment (15). In particular, studies performed on sensory nerves are more supportive of a parallel relationship between increased temperature and increased sensory NCV (30,31). Also, in our study, after US application we determined a significant increase of the sensory nerve conduction velocity (from 43.9 ± 5.9, to 46.3 ± 8.3, $p<0.05$).

Kramer reported that sensory and motor NCV respond to US treatment. It is suggested that US effects on motor NCV are intensity dependent and could be a result of both thermal and nonthermal effects of insonation. Motor NCV may increase or decrease, depending on US intensity, increase in tissue temperature, and duration (32). In our study, we determined a slight nonsignificant decrease in MNCV in the ultrasound treated groups and thought that decreased MNCV might be attributed to the mechanical effect of US rather than to the thermal effect. Zankel suggested that lowering motor NCV in clinical doses might be due to a change in the rate of exchange of transmembranal electrolytes in which the micromassage action (mechanical) plays a major role (33). In an experimental study by Hong, it was shown that lower doses of US therapy could facilitate recovery of compression neuropathy, but higher doses could induce an adverse effect. The authors suggested that increased local blood flow induced by lower-dose US treatment may contribute to nerve regeneration or recovery of nerve conduction in entrapment neuropathy. The inhibition of recovery of high-dose ultrasound treatment may be due to overheating or mechanical damage (8).

Most studies have been conducted in laboratory setting. The results of three clinical trial, in which US was applied to patients with CTS as a conservative treatment method, have recently been reported, but the results were contradictory. Ebenbichler et al. reported that subjective symptoms, hand grip, finger pinch strength and electrophysiological parameters (DML and SNCV) were improved when a dose of 1W/cm² US was applied to patients with CTS over a period of 6 weeks. In this study improvements persisted for at least 6 months in most patients (14). By contrast, Oztas et al. found no significant differences in clinical (pain, night pain/paraesthesia, frequency of awakening) and electrophysiological parameters (DML, MNCV, SDL, SNCV) between control and treatment groups, when 1.5 or 0.8 W/cm² of US was applied over a period of 2 weeks (for 5min, 5 day per week). The dosages and methods of US applications in these two studies were different. In addition, the clinical and electrophysiological evaluations were performed before treatment and on the fifth day after treatment in the later study, so the interval between evaluations was 20 days. This period may be short to indicate improvements in the clinical and electrophysiologic parameters (15).

Baktiary et al compared the efficacy of US (1MHz, 1.0w/cm², pulse 1:4, 15 min/session) with laser (9 joules, 830nm infrared laser at 5 points) treatment for mild to moderate idiopathic CTS. Improvement was significantly more pronounced in the US group than in laser therapy group for motor latency, motor action potential amplitude, finger pinch strength and pain relief (16).

A study on the effect of US therapy for the acute form of CTS in rabbits was reported by Paik et al. By contrast to our results, they suggested that the CMAP amplitudes showed significant improvement in group 1 (1.5W/cm²) compared to the other two groups (0.2W/cm²and 0.0W/cm²) following US application but the motor latency showed no statistically significant differences among either of the groups or at differences times (34). In this study, the subjects and duration of disease were different from ours. In addition, US was applied with a different technique (stroking technique) and a different dosage (1.5 W/cm², 3MHz).

Most standard TENS devices use milliamperes and the patient feels a tingling sensation from the surface electrodes. TENS is believed to reduce pain perception, in part, as described by gate control theory (35). To our knowledge, a study on the effect of TENS therapy for CTS has been reported by Naeser et al. They investigated whether real or sham low-level laser therapy plus microamperes TENS significantly reduces pain in CTS. They reported significant decreases in McGill Pain Questionnaire score, median nerve sensory latency, and Phalen and Tinel signs after the real treatment but not after the sham treatment (17).

In conclusion, our study results indicate that US plus TENS treatment has good short and medium term effectiveness in the clinical and electrophysiological measures in patients with idiopathic CTS. Moreover, the results of the study show that this application is a safe method and has no complications or side effects, and it may be an alternative treatment to the injection. Because follow-up was limited to 12 wks, we cannot comment on recurrence rates or long term results. Therefore, larger, double blind clinical trials to investigate long term effects of these methods are needed.

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