OUTCOMES FROM MAGNETIC RESONANCE IMAGING–CONFIRMED SYMPTOMATIC CERVICAL DISK HERNIATION PATIENTS TREATED WITH HIGH-VELOCITY, LOW-AMPLITUDE SPINAL MANIPULATIVE THERAPY: A PROSPECTIVE COHORT STUDY WITH 3-MONTH FOLLOW-UP

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ABSTRACT

Objective: The purpose of this study was to investigate outcomes of patients with cervical radiculopathy from cervical disk herniation (CDH) who are treated with spinal manipulative therapy.

Methods: Adult Swiss patients with neck pain and dermatomal arm pain; sensory, motor, or reflex changes corresponding to the involved nerve root; and at least 1 positive orthopaedic test for cervical radiculopathy were included. Magnetic resonance imaging–confirmed CDH linked with symptoms was required.

Baseline data included 2 pain numeric rating scales (NRSs), for neck and arm, and the Neck Disability Index (NDI). At 2 weeks, 1 month, and 3 months after initial consultation, patients were contacted by telephone, and the NDI, NRSs, and patient's global impression of change data were collected. High-velocity, low-amplitude spinal manipulations were administered by experienced doctors of chiropractic. The proportion of patients responding "better" or "much better" on the patient's global impression of change scale was calculated. Pretreatment and posttreatment NRSs and NDIs were compared using the Wilcoxon test. Acute vs subacute/chronic patients' NRSs and NDIs were compared using the Mann-Whitney *U* test.

Results: Fifty patients were included. At 2 weeks, 55.3% were "improved," 68.9% at 1 month and 85.7% at 3 months. Statistically significant decreases in neck pain, arm pain, and NDI scores were noted at 1 and 3 months compared with baseline scores ($P < .0001$). Of the subacute/chronic patients, 76.2% were improved at 3 months.

Conclusions: Most patients in this study, including subacute/chronic patients, with symptomatic magnetic resonance imaging–confirmed CDH treated with spinal manipulative therapy, reported significant improvement with no adverse events. (J Manipulative Physiol Ther 2013;36:461-467)

Key Indexing Terms: *Spine; Neck Pain; Manipulation; Chiropractic; Intervertebral Disk Displacement*

Symptomatic compression of a cervical nerve root occurs in approximately 83.2 of every 100 000 persons and is caused by disk herniations, degenerative spondylosis, or a combination of the 2. Degenerative stenosis leading to narrowing of the intervertebral foramen is reported to be the most common cause of nerve root compression.[1] The C6 and C7 nerve roots are most frequently involved, often resulting in severe pain and

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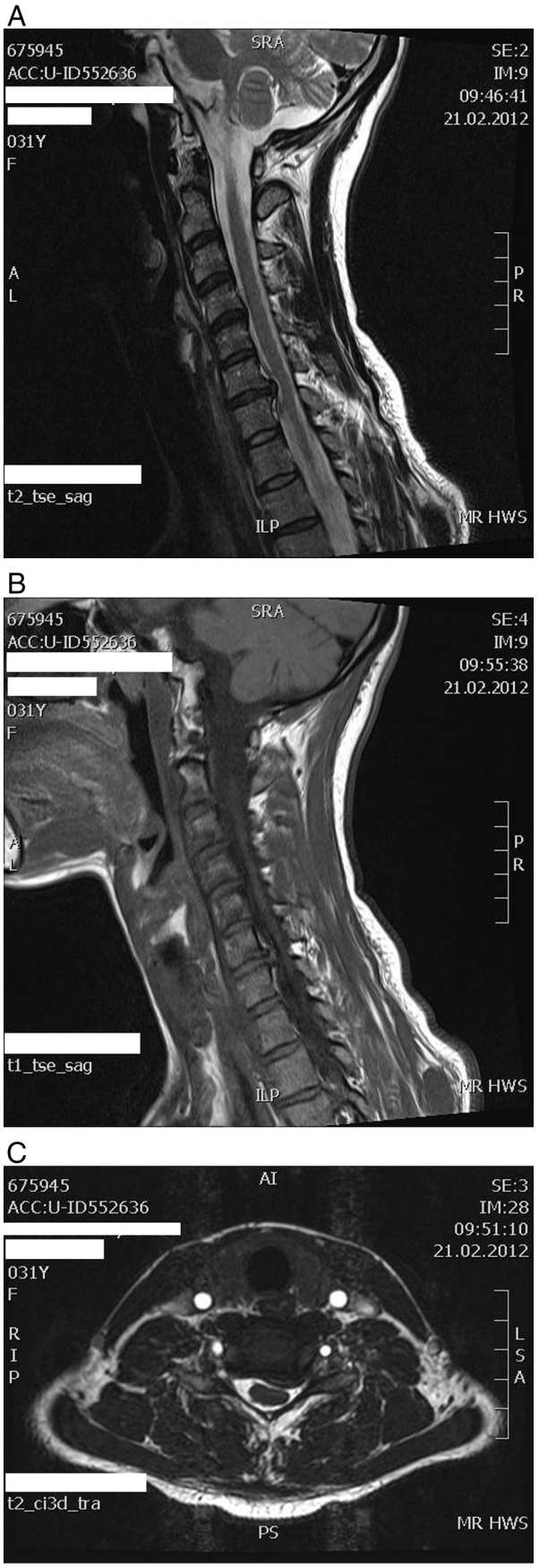
Paper submitted May 31, 2013; in revised form June 24, 2013; accepted June 27, 2013.
0161-4754/$36.00

http://dx.doi.org/10.1016/j.jmpt.2013.07.002



disability.[1,2] Symptoms can arise from the nerve root compression, inflammation, or both and include pain in a radicular distribution, paresthesias in a dermatomal pattern, decreased relevant reflex, and weakness of the muscles innervated by the nerve root.[3]

Patients with radiculopathy from cervical disk herniations (CDHs), the second most common cause of cervical nerve root compression, typically have acute neck pain with associated arm pain following the distribution of the involved nerve root, although the arm pain may be the predominant symptom.[3,4] However, it is important to recognize that disk protrusions are also a common finding on magnetic resonance imaging (MRI) scans of asymptomatic people.[5–7] One study found that 63% of asymptomatic athletic males older than 40 years had protruding disks in the cervical spine.[5] In another study, disk protrusion with demonstrable spinal cord compression was noted in 7.6% of asymptomatic subjects over the age of 50 years.[6] However, extruded disk herniations and cord compression are unusual findings in asymptomatic individuals.[7]

The treatment of patients with cervical radiculopathy is often surgical if conservative therapies fail.[2–4,8] Conservative treatments of patients with CDH are not well described or studied but may include lifestyle changes, pain medications, physiotherapy, epidural steroid injections, or spinal manipulative therapy (SMT).[2,3,8–12] Like most of the conservative treatments other than epidural steroid injections, the research evidence supporting SMT as a treatment for CDHs is lacking. Three systematic reviews on manipulation for various neck disorders found insufficient evidence to support this therapy for patients with neck pain and radiculopathy.[9–11] However, it is known that some doctors of chiropractic (DCs) and other manual therapists treat CDH patients with SMT in spite of the lack of supporting evidence.[11,13] Therefore, the purpose of this study is to investigate the clinical outcomes of patients with cervical radiculopathy from MRI-confirmed CDH who are treated with high-velocity, low-amplitude SMT in an outpatient chiropractic practice.

Methods

Ethics approval was obtained from the Orthopaedic University Hospital of Balgrist and Canton of Zürich ethics committees before the start of the study.

Fig 1. *Left parasagittal T2-weighted and T1-weighted as well as T2-weighted axial MRI slices showing C6-7 left posterolateral disk herniation with posterior displacement of the spinal cord and left C7 nerve root.*

Inclusion Criteria

Consecutive German-speaking patients from a single chiropractic practice in Switzerland were recruited from (January 2010) to (April 2013). Subjects were between 18 and 65 years of age with no contraindications to cervical SMT and with neck pain and moderate to severe arm pain in a dermatomal pattern, sensory, motor, or reflex changes corresponding to the involved nerve root. In addition, at least one of the following positive orthopaedic tests for cervical radiculopathy was required: (*a*) positive upper limb tension test, (*b*) positive cervical distraction test, (*c*) positive Spurling test, (*d*) cervical rotation less than 60° (3). Magnetic resonance imaging–proven CDH at the corresponding spinal segment was also required (Fig 1). The neurologic examination was repeated at each follow-up visit by 1 of the 3 DCs practicing at this site. The inclusion criteria remained constant throughout the study. All patients provided consent to participate in this study.

Exclusion Criteria

Patients with specific pathologies of the cervical spine that are contraindications to chiropractic manipulative treatment, such as tumors, infections, inflammatory spondylarthropathies, acute fractures, Paget disease, and severe osteoporosis, were excluded. Also excluded were patients with previous spinal surgery, a history of strokes, signs of cervical spondylotic myelopathy, spinal stenosis, and pregnancy.

Baseline Data and Outcome Measures

Before the first treatment, the treating DC completed a questionnaire consisting of demographic information on the patient (age, sex, chronicity of complaint, specific nerve root level involved). The patients completed a baseline questionnaire consisting of numeric rating scales (NRS) for pain where 0 is no pain and 10 is the worst pain imaginable for both the neck and the arm pain separately. In addition, they completed the Neck Disability Index (NDI).[14] At 2 weeks, 1 month, and 3 months after the initial consultation, a trained research assistant from the university hospital who was unknown to the patient and independent from the treating practice contacted the patients via telephone and the NDI, both NRSs and patient's own global impression of change (PGIC) data were collected. The PGIC scale is a 7-point verbal scale, including the responses much worse, worse, slightly worse, no change, slightly better, better, and much better.[15] Only the responses "much better" and "better" were considered clinically relevant "improvement," as determined by previous studies and used in other cohort research.[13,16–18] This was considered the primary outcome.

Treatment Procedure

The treatment procedure was a standardized, single, high-velocity, low-amplitude cervical manipulation with rotation to the opposite side and lateral flexion to the same side of the affected arm. The DC stood on the affected side of the supine patient's neck, with an index contact on the articular pillar of the most symptomatic vertebral motion segment on the side of the patient's complaint and at the spinal level clinically assessed to correspond with the MRI findings. The assisting hand stabilized the head of the patient. Rotation to the opposite and lateral flexion to the ipsilateral side was used to take out skin and joint slack (Fig 2). Once the patient was positioned, a high-velocity, low-amplitude thrust was applied, with the goal of moving the affected segment and producing an audible release. Because an audible release was achieved in most cases, the presence or absence of an audible release was not recorded. In the rare case where an audible release did not occur during the procedure, the DC might repeat the manipulation up to 2 additional times. When a patient reported bilateral neck and/or arm pain (extremely rare), the procedure could be reproduced on the opposite side as well. Treatments were repeated 3 to 5 times per week for the first 2 to 4 weeks and carried on 1 to 3 times per week thereafter until the patient was asymptomatic. All patients were treated by 1 of the 3 DCs who work together in the same clinic. All 3 of these

Fig 2. *Doctor and patient position for high-velocity, low-amplitude SMT in a patient with symptomatic MRI-confirmed CDH. (Color version of figure is available online.)*

Table 1. *Baseline and outcome data for all patients at the various time points*

	Baseline data (50 pts)	2 wk (39 pts)	1 m (45 pts)	3 mo (50 pts)
PGIC		55.3%, much better or better 0%, worse	68.9%, much better or better 2.2%, slightly worse	85.7%, much better or better 0%, worse
NRS neck, mean (SD)	5.71 (2.98)	3.54 [a] (2.17)	2.58 [a] (1.97)	1.68 [a] (1.72)
NRS arm, mean (SD)	6.43 (2.77)	4.12 [a] (2.58)	2.71 [a] (2.19)	1.64 [a] (1.84)
NDI, mean (SD)	18.17 (8.71)	14.12 [a] (8.52)	9.15 [a] (5.15)	4.95 [a] (4.29)

NDI, neck disability index; *NRS*, numeric rating scale; *PGIC*, patient's global impression of change.
[a] $P < .0001$ compared with baseline score using the Mann-Whitney *U* test.

DCs had completed the mandatory 2-year full-time postgraduate residency program in Switzerland and had between 6 and 30 years of chiropractic clinical experience. The senior DC had trained the 2 younger practitioners, which standardized the manipulative procedure.

Patients were allowed to take over-the-counter pain medications as needed, but no other treatments were administered to these patients in the practice. The type and quantity of pain medication were not monitored in this study. If a patient wished to have surgery or a nerve root infiltration, these options would have been discussed with the patient, and they would have been referred directly for these procedures, as Swiss DCs are legally allowed to make these direct referrals. The patient would then be deleted from the study. This did not occur in any of the patients however.

Statistical Analysis

Only patients responding better or much better on the PGIC scale were categorized as "improved," and this was the primary outcome measure. These 2 options have been shown to reflect clinically relevant improvement.[17,18] "Slightly better" was not considered to be improved, consistent with previous studies.[13,16] However, responses of "slightly worse," "worse," and "much worse" were all counted as worsening of the condition to error on the side of caution.[13,16] The proportion (%) of patients improved or worse was calculated. In addition to descriptive statistics, scores on the pretreatment and posttreatment NRSs and NDI were compared using the Wilcoxon test for matched pairs. Patients with symptoms 4 weeks or less (acute) were compared with patients with symptoms more than 4 weeks (subacute/chronic) using the Mann-Whitney *U* test to assess for differences. $P < .05$ was considered statistically significant.

Results

A total of 50 patients had baseline and 3-month data available. The mean patient age was 44.38 (SD, 7.6) years, and 34 (68%) of the patients were male. There was no significant age difference between the males and females nor were there significant differences in their baseline NRS neck pain, NRS arm pain, or NDI scores. Thirty-nine patients had 2-week data, and 45 patients had 1-month data available. The reason for the smaller patient numbers at the 2-week and 1-month data collection time points was due to the narrow windows in the study protocol in which these follow-up telephone calls could occur. If a patient was not reached within the allocated time frame, that telephone call was missed but the patient remained in the study unless the patient could not be reached for 3 consecutive phone calls. This only occurred for 1 patient. An additional 2 patients had baseline, 2-week, and 1-month data, but the 3-month telephone call was missed, and for 3 patients with baseline, 2-week, and 1-month data, the time for the 3-month telephone call had not yet arrived. Thus, 56 patients were enrolled in the study to obtain the 50 patients with both baseline and 3-month data.

By 2 weeks after the first treatment, 55.3% of all patients reported that they were significantly improved (Table 1), and none reported being worse. At 1 month, 68.9% were significantly improved (1 patient was slightly worse), and by 3 months, after the first treatment, this figure rose to 85.7% with no patients being worse. When comparing the follow-up NRS and NDI scores to the baseline scores, statistically significant reductions at all data collection time points were noted (Table 1).

When comparing acute patients (symptoms $\leq$4 weeks, n = 26) with patients whose symptoms were longer than 4 weeks (n = 24), a higher proportion of the acute patients reported clinically relevant improvement, and this improvement was faster compared with those patients who were subacute or chronic (Table 2). However, at 3 months after the first treatment, 76.2% of the subacute/chronic patients reported clinically relevant improvement with no patients reporting that they were worse. The mean duration of symptoms for the subacute/chronic patients was 298.73 days (SD, 766.45). The acute patients had statistically significant reductions in their NRS neck, NRS arm, and NDI scores compared with baseline at all data collection time points. The subacute/chronic patients also had statistically significant reductions in their NRS and NDI scores at all time points with 1 exception—the baseline to 2-week NRS arm pain score ($P = .052$) was not significantly reduced.

Table 2. *Comparison of CDH patients with symptoms 4 weeks or less with those having symptoms more than 4 weeks (acute and nonacute)*

	Baseline (mean + SD)	2 wk (mean + SD)	1 mo (mean + SD)	3 mo (mean + SD)
PGIC				
Sx ≤4 wk		61.9% (n = 20), much better or better (0% worse)	76.9% (n = 24), much better or better (0%worse)	92.9% (n = 26), much better or better (0% worse)
Sx >4 wk		47.1% (n = 19), much better or better (0% worse)	57.9% (n = 21), much better or better (5.3% slightly worse)	76.2% (n = 24), much better or better (0% worse)
NRS neck				
Sx ≤4 wk	6.15 (2.79) (n = 26)	3.50 [a] (2.43)	2.02 [a] (1.55)	1.37 [a] (1.45)
Sx >4 wk	5.00 (3.04) (n = 24)	3.47 [a] (1.81)	2.97 [a] (2.21)	2.07 [a] (1.97)
NRS arm				
Sx ≤4 wk	6.90 (2.36)	3.85 [a] (2.70)	2.60 [a] (2.26)	1.23 [a] (1.48)
Sx >4 wk	5.71 (2.99)	4.47 (2.50)	2.79 [a] (2.22)	2.00 [a] (2.18)
NDI				
Sx ≤4 wk	19.36 (8.01)	13.60 [a] (9.49)	9.20 [a] (4.66)	4.38 [a] (3.64)
Sx >4 wk	15.56 (8.95)	15.15 [a] (7.89)	9.10 [a] (6.07)	5.62 [a] (5.11)

NDI, neck disability index; *NRS*, numeric rating scale; *PGIC*, patient's global impression of change; *Sx*, symptoms.
[a] Statistically significant compared with the baseline figures at $P < .05$.

Although 1 patient reported being "slightly" worse at 1 month, at 3 months, no patients were worse, and there were no adverse events in this cohort of patients.

Discussion

Most patients in this study with MRI-proven symptomatic CDHs who were treated with high-velocity, low-amplitude spinal manipulation reported clinically significant improvement at all time points, particularly at 3 months. The PGIC responses of much better and better have previously been shown to indicate clinically relevant improvement, whereas slightly better is not clinically relevant.[16,17] In addition, the large reductions in NRS neck and arm pain scores as well as the NDI scores at 3 months of approximately between 66% and 75% far exceed the threshold of 30% to 35% pain reduction considered clinically relevant.[18] Because of the paucity of research into SMT for patients with CDHs, comparisons with other studies cannot be directly made. However, a recent large prospective outcomes study on Swiss neck pain patients undergoing chiropractic treatment found that the presence of radiculopathy was not a negative predictor of improvement.[13] In that study, however, the specific treatment method was not determined, and the diagnosis of radiculopathy was made by numerous different treating DCs and not necessarily linked to MRI findings.

It is important to point out that even the subacute/chronic patients in this study with symptoms lasting longer than 4 weeks (mean duration, 298.73 days) reported high levels of clinically significant improvement. This is clinically important as the chronic patients are the ones who are usually the most costly in terms of health care use and quality-of-life disruption.[19–21] Although the natural history of acute patients with radiculopathy from CDHs has been reported to be quite favorable, this only applies to patients with symptoms of less than 4 to 8 weeks.[22,23] The most recent review on the natural history of radiculopathy states that the clinical course of cervical radiculopathy is poorly documented.[24] Indeed, it is virtually impossible to extract reliable figures on the natural history of this condition from the few published studies for acute CDH patients with radiculopathy who have not had any type of treatment at all.[2,24] The results of this current study can, therefore, only be compared with those published, which involved another treatment for patients with CDH and radiculopathy. Kolstad et al[23] studied 21 chronic (symptoms >3 months) CDH patients with radiculopathy who received 2 cervical nerve root blocks consisting of a corticosteroid and anesthetic. They reported that 24% of these patients (5/21) had clinically relevant reduction in their symptoms, that is, a 25% reduction in their NRS score, at 6 weeks and 4 months after injection. The results of this current study using SMT for the subacute/chronic patients had substantially better results with more than 76% reporting clinically relevant improvement and a 65% reduction in arm pain as well as a 59% reduction in neck pain NRS scores at 3 months. However, the patients in this current study included those with symptoms between 4 and 12 weeks as well as those whose symptoms were longer than 3 months, and this may have favorably influenced the results.

The mean duration of the symptoms in this subacute/chronic cohort was over 298 days however.

One patient reported being slightly worse at 1 month, but by 3 months, no patients were worse. No cases of serious adverse events occurred. Risks of SMT to the cervical spine in general include fainting/dizziness/light-headedness (at worse 16/1000 treatment consultations), headache (at worse 4/100 treatments), and numbness/tingling in upper limbs (at worse 15/1000 treatments).[25] Serious adverse events such as dissection of the vertebral artery or serious neurologic deficits are so rare that accurate estimations of the frequency cannot be calculated but are estimated at 1 of 200 000 to 1 of several million treatments.[25,26] The most common adverse events are transient local pain and stiffness.[27,28] Other uncommon adverse events include tiredness, dizziness, nausea, and ringing in the ears.[27,28]

An advantage to this study is that the treatment was standardized to a high-velocity, low-amplitude manipulative procedure, based on the location of the disk herniation as seen on the MRI scans and correlated with the clinical signs and symptoms. In addition, patients whose herniation had penetrated through the peripheral annular fibers, the posterior longitudinal ligament, or were sequestered were not excluded from being treated with SMT. However, no studies have been conducted to determine whether there is a difference in outcome based on the choice of the specific manipulative procedure or the type and location of disk herniation. Future studies should address these issues.

Limitations

There are several limitations to this study. As a cohort outcomes study and not a randomized controlled clinical trial, the outcomes reported here cannot be directly attributed to the SMT treatment. Additional research comparing SMT with other treatments, for example, therapeutic nerve root infiltrations using the randomized controlled clinical trial methodology, needs to be done. Furthermore, all patients in this study were examined and treated in a single chiropractic practice in Zürich, Switzerland, by any 1 of the 3 DCs working there using a standardized treatment approach. Thus, the results obtained may not be representative of other chiropractic practices or other practitioners using SMT. The relatively small sample size for the subgroup of CDH patients whose symptoms were "subacute/chronic" (24 patients) is another limitation.

Additional limitations include the fact that all outcomes were self-reported, consistent with many other research studies. No attempt was made to confirm the reality of the information given to the research assistants. However, the DCs themselves monitored and documented the patients' progress, including their neurologic evaluations as outlined in the methodology. Furthermore, the fact that the follow-up outcomes were obtained by telephone interviews, whereas the baseline data were completed by the patient in a written format, may also influence the results. However, all patients were handled in the same way, and there was no mixture of telephone and written questionnaire follow-up data collection.[29] In addition, the primary outcome measure of the PGIC can only be collected after treatment, and thus, there was no "baseline" data for this scale. By conducting the telephone interviews at the university hospital by research assistants unknown to the patients rather than collecting the data at the practice site itself, an attempt was made to avoid a positive bias.

Conclusions

A high proportion of acute and most importantly subacute/chronic patients with MRI-confirmed symptomatic CDHs treated with high-velocity, low-amplitude cervical spine manipulation reported clinically relevant improvement at 1 and 3 months after the first treatment. There were no adverse events reported for patients in this study.

Practical Applications

- Patients with symptomatic MRI-confirmed cervical disk herniations treated with SMT to the level of herniation reported high levels of clinically relevant improvement at 2 weeks, 1 month, and 3 months after the first treatment.
- A higher proportion of acute patients improve, and this improvement is faster than those patients who are subacute or chronic.
- Of the subacute/chronic patients, 76.2% reported clinically relevant improvement at 3 months.
- There were no adverse events.

Funding Sources and Potential Conflicts of Interest

The Uniscientia Foundation, the European Academy for Chiropractic, and the Balgrist Hospital Foundation provided funding support for this study. No conflicts of interest were reported for this study.

Contributorship Information

Concept development (provided idea for the research): SL, CS, BA
Design (planned the methods to generate the results): CP, BKH, SL, CS, BA
Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): CP, BKH

Data collection/processing (responsible for experiments, patient management, organization, or reporting data): SL, CS, BA, CP, BKH

Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): CP

Literature search (performed the literature search): CP

Writing (responsible for writing a substantive part of the manuscript): CP, SL, CS

Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): CP, BKH, SL, CS, BA

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