Randomized Trial

Comparison Between Corticosteroid Injection Into Coracohumeral Ligament and Inferior Glenohumeral Capsule and Corticosteroid Injection Into Posterior Glenohumeral Recess in Adhesive Capsulitis: A Prospective Randomized Trial

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Background: For managing symptoms of adhesive capsulitis (AC), corticosteroid injection is typically conducted under the guidance of ultrasound via posterior glenohumeral recess (PGHR). It has been reported that pathologies such as inflammation and edema are most commonly observed in the coracohumeral ligament (CHL) and anterior and inferior joint capsules. We compared the therapeutic effects of corticosteroid injection into the CHL and inferior glenohumeral capsule (IGHC) with those of corticosteroid injection into PGHR in patients with AC.

Methods: One hundred twenty consecutive patients with AC were included in this study and randomly allocated to either the CHL + IGHC group (n = 60) or the PGHR group (n = 60). Patients in both groups received 3 injections at 2 week intervals. After the first injection, if the patient's shoulder pain showed satisfactory improvement, further injections were not administered. The therapeutic effect was measured at 2 and 4 months after the first injection. Pain intensity was evaluated using the visual analog scale (VAS). Additionally, the passive range of motion (ROM) of the shoulder joint (abduction, external rotation, and internal rotation) was measured.

Results: VAS scores and ROM of abduction, external rotation, and internal rotation improved at follow-up evaluation in both groups ($P < 0.05$) (CHL and IGHC: VAS, pre-treatment = 6.5 ± 0.5, 2 months = 2.1 ± 0.8, 4 months = 1.4 ± 0.6; ROM-abduction, pre-treatment = 131.3° ± 16.4°, 2 months = 162.4° ± 8.2°, 4 months = 176.2° ± 5.6°; ROM-external rotation, pre-treatment = 31.6° ± 16.9°, 2 months = 67.2° ± 11.1°, 4 months = 81.3° ± 12.1°, ROM-internal rotation, pre-treatment = 6.2 ± 2.2, 2 months = 4.0 ± 2.2, 4 months = 2.7 ± 1.2; PGHR: VAS, pre-treatment = 6.5 ± 0.5°, 2 months = 3.9 ± 1.1, 4 months = 2.1 ± 1.1; ROM-abduction, pre-treatment = 132.1° ± 9.5°, 2 months = 145.5° ± 11.7°, 4 months = 167.4° ± 11.2°; ROM-external rotation, pre-treatment = 32.4° ± 13.4°, 2 months = 49.3° ± 13.2°, 4 months = 72.7° ± 18.0°, ROM-internal rotation, pre-treatment = 6.3 ± 1.4, 2 months = 5.4 ± 0.8, 4 months = 3.6 ± 1.0). However, the improvements were greater in patients who received corticosteroid injection into the CHL and IGHC compared to that into the PGHR at 2 and 4 months after the initiation of the treatment ($P < 0.05$).

Limitations: Long-term therapeutic outcomes were not investigated, and the therapeutic effect of corticosteroid injection into the CHL and IGHC was not compared with placebo injection.

Conclusion: Corticosteroid injection into the CHL and IGHC might be a better treatment alternative for patients with AC.

Key words: Adhesive capsulitis, shoulder, pain, injection, corticosteroid

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Adhesive capsulitis (AC) of the shoulder is a common musculoskeletal disorder. Its incidence in the general population is 2-5% and increases to 10-38% in patients with diabetes and thyroid disease (1,2). AC is characterized by progressive and insidious pain and loss of range of motion (ROM) in the glenohumeral (GH) joint (3). Inflamed synovium and thickening of the shoulder capsule were observed in patients with AC during arthroscopic capsular release (4). Although the mechanism of AC development has not been demonstrated, a minor insult is thought to initiate an inflammatory healing process on the shoulder capsule (1). This may result in excessive accumulation and propagation of fibroblasts releasing type I and III collagen, which leads to an imbalance between the loss of normal collagenous remodeling and fibrosis (1,5,6). This imbalance results in loss of motion of the shoulder joint.

Corticosteroid injection into the GH joint is widely applied for the treatment of AC (7-9). The anti-inflammatory action of corticosteroids decreases inflammation in the glenohumeral joint and improves the symptoms of patients with AC (10). In general, the corticosteroid injection into the GH joint is conducted with an approach through the posterior glenohumeral recess (PGHR) (7-9). However, recent studies have reported that pathologies such as inflammation and edema were most commonly observed in the coracohumeral ligament (CHL) and anterior and inferior joint capsules (11-13). In addition, in patients with AC, CHL hypertrophy is associated with limited ROM (11). Therefore, we believe that the injection of corticosteroids into the coracohumeral ligament (CHL) and inferior glenohumeral capsule (IGHC) can have a superior therapeutic effect in AC than that in PGR.

In the current study, we compared the effect of corticosteroid injection into CHL and IGHC with that into PGHR on pain and ROM in patients with AC.

Patients

A total of 120 consecutive patients with AC who visited an outpatient pain clinic were included based on the following inclusion criteria: (1) shoulder pain with limitation of passive motion of > 30° in 2 or more planes at the time of presentation and (2) a visual analog scale (VAS) score for pain ≥ 5, despite oral pain medication (meloxicam and/or acetaminophen/tramadol hydrochloride). The exclusion criteria were as follows: (1) bilateral AC of the shoulder; (2) previous corticosteroid injection into the shoulder joint within 6 months; (3) history of shoulder joint dislocation or previous shoulder surgery; (4) osteoarthritis in the shoulder joint; (5) contraindications to the injection procedure such as local cellulitis, septic arthritis, and acute fracture; and (6) poor cognitive function. The Institutional Review Board of a university hospital approved the study, and all patients signed an informed consent form.

We calculated the sample size based on a previous study (14), in which the mean differences between pretreatment and 4 months in the VAS score for the CHL + IGHC group and PGHR group were 4.7 and 6.0, respectively. Therefore, the mean difference in the change in the VAS score after the 2 treatments was 1.3. When we used a type I error of 0.05, a power of 80%, and a 2-sided test, 54 patients per group were required for our study. Using a dropout rate of 10%, we recruited 60 patients in each group. One hundred and twenty patients with AC were randomly assigned to one of the 2 study groups. Randomization was performed using a random-number table. Sixty patients were included in the CHL + IGHC group and 60 in the PGHR group.

Procedure

All procedures were performed by a single specialist (SHL) with over 20 years of experience in the field. In the CHL + IGHC group, for injection of CHL, the patient was placed in the supine position. The shoulder was slightly extended, and the arm was rotated externally. The elbow was fully extended. For the ultrasound (US)-guided injection, a 12 MHz linear probe (Venue 40 unit: GE Healthcare, Milwaukee, WI, USA) and a 23-gauge, 6 cm needle were used. Initially, a long-axis US image of the coracoacromial ligament was obtained. Then, with the medial edge of the probe fixed on the distal medial portion of the coracoid process, the lateral edge of the probe was pivoted until the CHL was revealed overlying the subscapularis musculotendinous complex (Fig. 1) (15). The 1 mL dexamethasone palmitate (3.5 mg dexamethasone) was injected in-plane with a lateral to medial direction on the CHL within 1 cm of its origin at the coracoid process. After the CHL injection, injection into the IGHC was performed (Fig. 2). The patient was placed in a supine position with the shoulder abducted at 40°, and the elbow flexed at 90°. The shoulder was externally rotated maximally within the ROM. The probe was placed around the anterior axillary line to visualize the humerus cortex. The probe was placed over the IGHC (axillary pouch near the anatomic neck of the humerus), and 0.5 mL (20 mg) triamcinolone

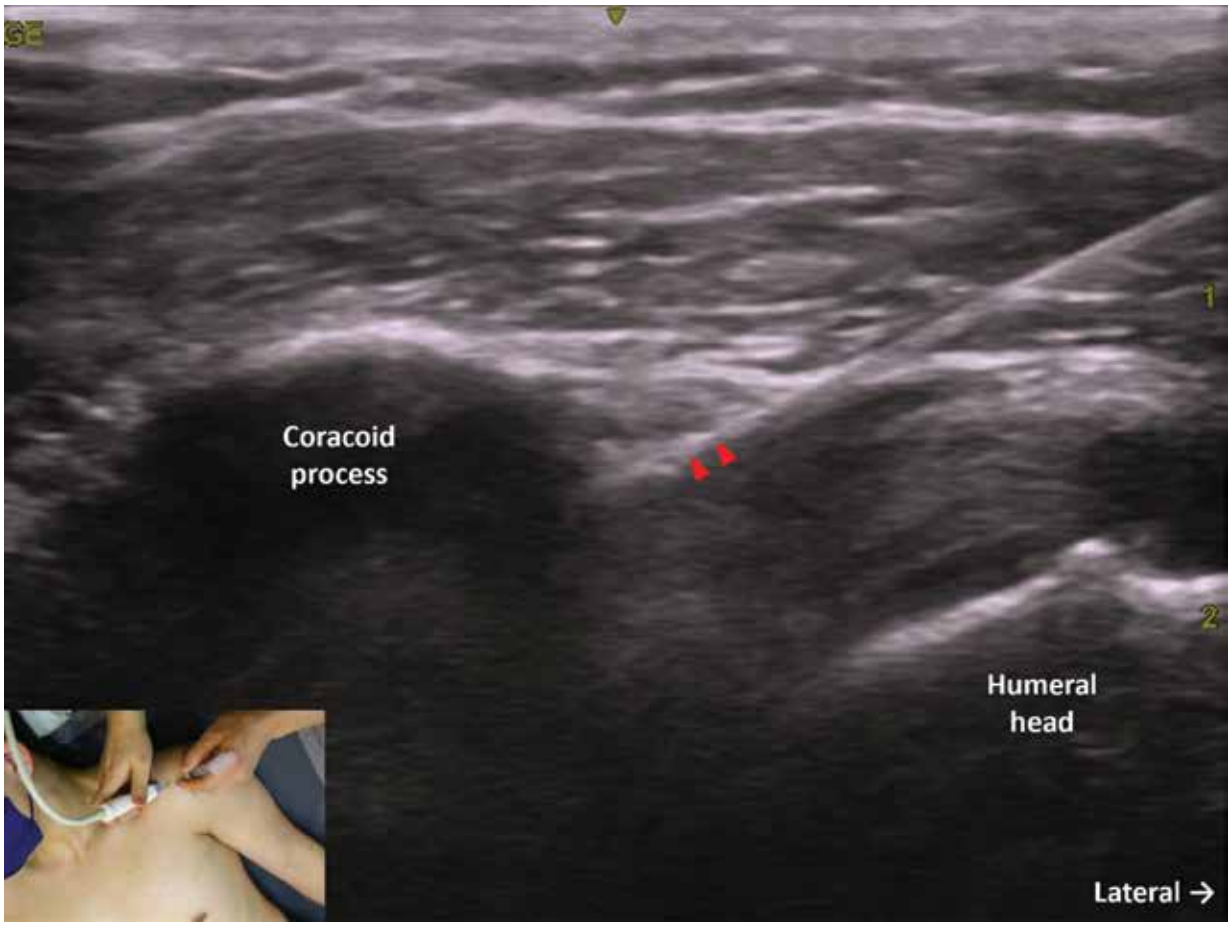

Fig. 1. *Ultrasound-guided corticosteroid injection into the coracohumeral ligament. Arrowhead: needle*

acetonide was injected within the IHC in a distal to proximal direction. In the PGR injection group, the patient was placed in the semi-lateral decubitus position on the unaffected side and 45° anterior tilting of the affected side. In the US group, the needle was advanced laterally to medially with visualization of its shaft and reaching the glenohumeral joint space between the posterior aspect of the humeral head and the glenoid labrum. A mixed solution of 1 mL dexamethasone palmitate (3.5 mg dexamethasone) and 0.5 mL (20 mg) of triamcinolone acetonide was injected.

Patients in both groups received 3 injections at 2 week intervals. After the first injection, if the patient's shoulder pain demonstrated satisfactory improvement, further injections were not administered.

All patients were instructed to perform home-based exercise consisting of gentle ROM and isometric exercise to increase ROM (10 min/time, 3 times/day).

Outcome Measurement

The same investigator (HHC) who is a researcher in the field of pain measured the treatment outcomes before treatment and at 2 and 4 weeks after the first injection. The investigator was blinded to the patient grouping and did not participate in any treatment. The pain was evaluated using a VAS, and the passive ROM of the shoulder joint (abduction, external rotation, and internal rotation) was measured using a hand-held goniometer in the supine position. Passive shoulder ROM was measured by moving the patient's arm until it was mechanically limited. The range of abduction was evaluated, including scapulohumeral motion. To measure the range of internal rotation, the scratch test was performed by recording the location reached with the tip of the thumb in the sitting position. This level was then converted into a serial number as follows: L2 to L5 into 1-4, respectively; posterior superior iliac spine

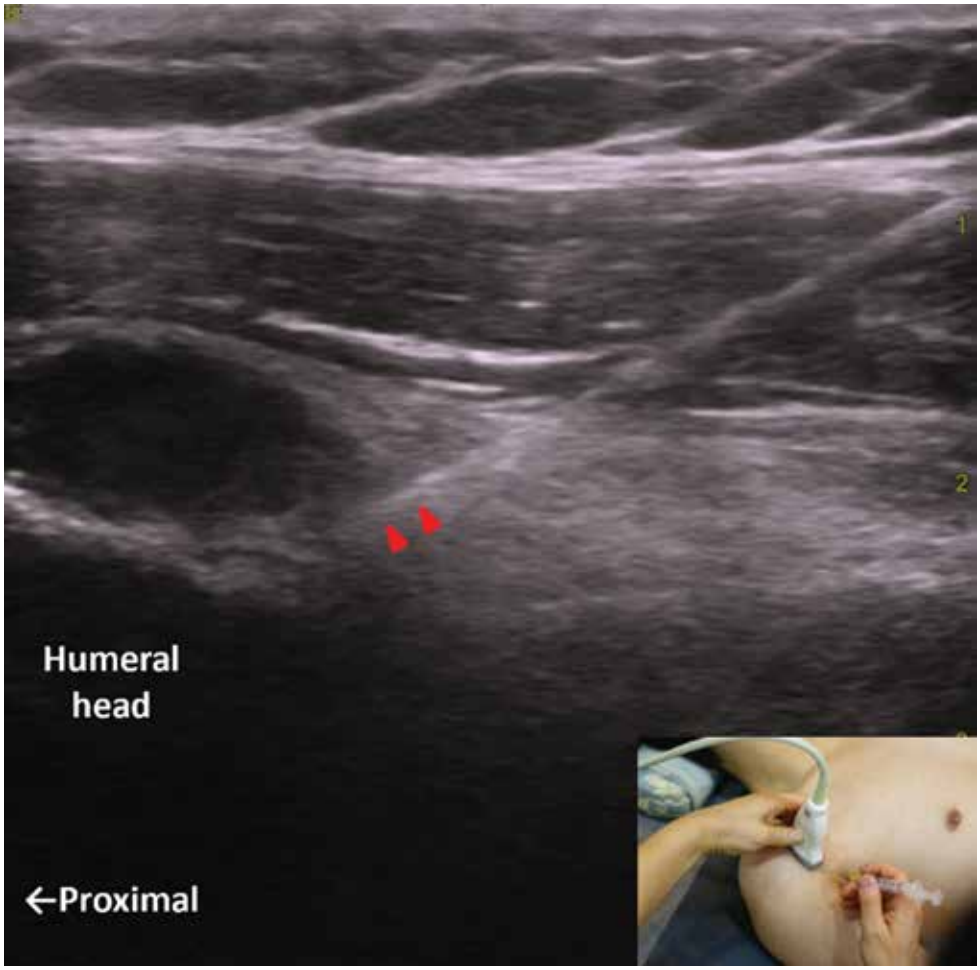

Fig. 2. *Ultrasound-guided corticosteroid injection into the inferior glenohumeral capsule. Arrowhead: needle*

(PSIS) into 5; PSIS to the ischial tuberosity (with equal division into 3 parts): 6-8; ischial tuberosity: 9; and greater tubercle: 10. The lower scores in the internal rotation test indicated a larger internal rotation angle. Additionally, we checked the number of injections.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Science (SPSS) version 31.0 (IBM Corp., Armonk, NY). The independent t-test and chi-square test were used to compare the demographic data, initial pre-treatment measurement, and the number of injections between the groups. Within each group, changes in the measured outcomes were evaluated using repeated-measure one-factor analysis. Repeated-measure 2-factor analysis was used to compare the clinical changes over time between the groups. Multiple comparison results were obtained by contrast following adjustment using the Bonferroni correction. All tests were performed using a 2-sided test, and the level of statistical significance was set at $P < 0.05$.

Results

During the study period, none of the patients dropped out, and no patients reported adverse effects. Table 1 shows the demographic and initial clinical characteristics of the patients in both groups. No significant differences were found between the 2 groups for any demographic data or initial measurements (Table 1, $P > 0.05$). In both the CHL + IGHC injection group and the PGHR group, at the 2-month and 4-month follow-ups, VAS was significantly reduced compared with the scores before the treatments (Table 2, $P < 0.05$). In addition, at the 2-month and 4-month follow-ups, ROM of abduction and external rotation were significantly increased, and internal rotation scores were significantly decreased (internal rotation angle was increased) compared with those of pre-treatment (Table 2, $P < 0.05$).

In the intergroup comparison, VAS scores and internal rotation scores at the 2-month and 4-month follow-ups were significantly more reduced in the CHL + IGHC group than in the PGHR group (Table 2, $P < 0.05$). In addition, passive ROM of abduction and external rotation at the 2-month and 4-month follow-ups were significantly higher in the CHL + IGHC group than in the PGHR group (Table 2, $P < 0.05$).

The number of injections was significantly lower in the CHL + IGHC group (2.58 ± 0.59) than in the PGHR group (2.93 ± 0.25) (independent t-test, $P < 0.001$).

Discussion

In the current study, we evaluated the clinical effects of corticosteroid injection into CHL and IGHC and compared them with those of corticosteroid injection into PGHR. Our results showed that the degree of pain, which was measured using the VAS score, was significantly reduced, and passive ROM of abduction and external and internal rotations were significantly increased after both the corticosteroid injection into CHL and IGHC and that into PGHR. Furthermore, their clinical effects were sustained for at least 4 months after initiating each procedure. However, the reduction in the VAS scores and the increase in the ROM of abduction and external and internal rotations were greater in patients who received the corticosteroid injection into CHL and IGHC compared to that into PGHR at 2 and 4 months after the initiation of the treatment.

To date, several previous studies have demonstrated the short-term effect (up to approximately 12

Table 1. *Demographic and baseline clinical data in the CHL+IGHC and PGHR groups.*

Variables	CHL + IGHC group (n = 60)	PGHR group (n = 60)	*P* value
Age (years)	53.4 ± 6.3	52.3 ± 6.1	0.351†
Sex M:F (n)	21:39	20:40	0.847‡
Symptom duration (weeks)	16.5 ± 7.8	16.6 ± 6.2	0.897†
VAS (score)	6.5 ± 0.5	6.5 ± 0.5	0.483†
ROM			
Flexion (degree)	131.3 ± 16.4	132.1 ± 9.5	0.760†
External rotation (degree)	31.6 ± 16.9	32.4 ± 13.4	0.779†
Internal rotation (score)	6.2 ± 2.2	6.3 ± 1.4	0.845†

Values are presented as the mean ± standard deviation or frequency. †: Results of independent t-test. ‡ Results of the chi-square test. CHL, coracohumeral ligament; IGHC, inferior glenohumeral capsule; PGHR, posterior glenohumeral recess; VAS, visual analog scale; ROM, range of motion.

Table 2. *Changes in VAS and ROM of the shoulder joint.*

Variables	Group	Time, mean ± SD			*P* value†	*P* value‡		
		Pre-treatment (p)	2 months (2)	4 months (4)		T	G	T*G
VAS (score)	CHL + IGHC group	6.5 ± 0.5	2.1 ± 0.8	1.4 ± 0.6	< 0.001 $P > 2 > 4$ϕ	< 0.001 $P > 2 > 4$ϕ	< 0.001	< 0.001 $P > 2 > 4$ϕ
	PGHR group	6.5 ± 0.5	3.9 ± 1.1	2.1 ± 1.1	< 0.001 $P > 2 > 4$ϕ			
ROM-abduction (degree)	CHL + IGHC group	131.3 ± 16.4	162.4 ± 8.2	176.2 ± 5.6	< 0.001 $P < 2 < 4$ϕ	< 0.001 $P < 2 < 4$ϕ	< 0.001	< 0.001 $P < 2 < 4$ϕ
	PGHR group	132.1 ± 9.5	145.5 ± 11.7	167.4 ± 11.2	< 0.001 $P < 2 < 4$ϕ			
ROM-external rotation (degree)	CHL + IGHC group	31.6 ± 16.9	67.2 ± 11.1	81.3 ± 12.1	< 0.001 $P < 2 < 4$ϕ	< 0.001 $P < 2 < 4$ϕ	< 0.001	< 0.001 $P < 2 < 4$ϕ
	PGHR group	32.4 ± 13.4	49.3 ± 13.2	72.7 ± 18.0	< 0.001 P < 2 < 4ϕ			
ROM-internal rotation (score)	CHL + IGHC group	6.2 ± 2.2	4.0 ± 2.2	2.7 ± 1.2	< 0.001 $P > 2 > 4$ϕ	< 0.001 $P > 2 > 4$ϕ	< 0.001	< 0.001 $P > 2 > 4$ϕ
	PGHR group	6.3 ± 1.4	5.4 ± 0.8	3.6 ± 1.0	< 0.001 $P > 2 > 4$ϕ			

Values are presented as the mean ± standard deviation. †: Results of repeated measures one-factor analysis for each group. ‡ Result of repeated measure 2-factor analysis. ϕ: Multiple comparison results by contrast. CHL, coracohumeral ligament; IGHC, inferior glenohumeral capsule; PGHR, posterior glenohumeral recess; VAS, visual analog scale; ROM, range of motion; SD, standard deviation; T, time; G, group; NS, not significant.

weeks) of intra-articular steroid injection in AC (7-9). Because AC is an inflammatory and fibrotic disease, early corticosteroid injections would reduce synovitis and prevent the development of capsular fibrosis and restriction of shoulder ROM (7-9). Park et al investigated the findings of AC in 104 shoulder magnetic resonance fat-suppressed T2-weighted images and their association with clinical findings (13). Anterior extracapsular edema, joint capsule edema, and joint capsule thickening in the humeral portion of the axillary recess were associated with the degree of AC symptoms (pain and ROM of abduction and external rotation) (13). However, edema around the posterior shoulder capsule was not associated with the AC symptoms. These facts might be attributed to the superior effect of corticosteroid injection into the IGHC compared to the conventional corticosteroid injection method (approach via the PGHR).

In addition, several recent studies have confirmed that thickening or hypertrophy of the CHL is the key morphological change in AC (11-13). Changes in the CHL restrict external-internal rotation in patients with AC (11). CHL release in patients with AC has been reported to result in a dramatic increase in shoulder ROM (16,17). Arai et al reported that the CHL is composed of sparse and irregular fibers (18). Therefore, a corticosteroid injection into the CHL is possible without significant resistance. We believe that corticosteroid injection into the CHL may have contributed to the reduction of inflammation in the CHL and resulted in pain reduction and an increase in shoulder ROM.

Regarding the effect of corticosteroid injection in AC following injection sites, subacromial and glenohumeral corticosteroid injections demonstrated similar therapeutic effects in patients with AC (19). In addition, corticosteroid injection through the rotator cuff interval showed a better therapeutic effect in patients with AC than that through the PGHR (20). However, the effects of corticosteroid injection into the IGHC or CHL were not evaluated. Our study has some limitations. First, we did not evaluate the effect according to the disease stage. In addition, long-term therapeutic outcomes were not investigated. Second, the therapeutic effect of corticosteroid injection into the IGHC and CHL was not compared with placebo injection. Third, the therapeutic effect according to the number of injections was not analyzed. Lastly, an imaging evaluation was not performed. In the future, further studies that compensate for these limitations should be conducted. Also, studies on complications from repeated corticosteroid injection into the CHL are required.

Conclusion

In conclusion, we found that corticosteroid injection into the CHL and IGHC has a superior therapeutic effect on reducing shoulder pain and increasing passive ROM of the shoulder joint, compared with corticosteroid injection into PHGR. Therefore, a corticosteroid injection into the CHL and IGHC might be a better treatment alternative for patients with AC. To the best of our knowledge, our study is the first to evaluate the clinical efficacy of corticosteroid injection into the CHL and IGHC in patients with AC.

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