Original Article

Are Foraminal Stenosis Severity and Herniation Level Associated with the Treatment Success of Cervical Interlaminar Epidural Steroid Injection?

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Background: Foraminal stenosis, defined as a narrowing of the cervical neural foramen, is one of the most common causes of upper extremity radicular pain.

Objectives: The aim of our study was to determine the effects of the severity of neural foraminal stenosis and spinal herniation level on treatment success in patients treated with interlaminar epidural steroid injections (ILESI) due to cervical disc herniation-related radiculopathy and their possible predictive roles.

Study Design: A retrospective assessment.

Setting: A university hospital interventional pain management center.

Methods: We performed our study between August 2017 and February 2019, retrospectively. All patients' demographic characteristics, clinical and demographic data, including pain scores before and after cervical ILESI in the first hour, third week, and third month follow-ups, presence of motor deficits, symptom side, symptom duration before cervical ILESI, and whether there was progression to surgery in the 3-month period after injection, were collected.

Results: We evaluated 61 patients in the final analysis. When the spinal herniation levels and foraminal stenosis grades were compared, there was a significant difference between the groups ($P = 0.003$, $P = 0.005$). We reported significant correlations between foraminal stenosis grade (odds ratio [OR], –0.425, $P = 0.038$) and spinal herniation level (OR, –0.925, $P = 0.001$) and treatment success.

Limitations: Our study's design was retrospective.

Conclusions: Cervical ILESI is a reliable treatment option that provides a significant reduction in pain of patients with cervical radiculopathy. However, the success of ILESI treatment may be negatively affected in these patients in the presence of high spinal level cervical disc herniation and severe foraminal stenosis. Therefore considering these 2 parameters in predicting the patient population who will benefit from cervical ILESI is of importance in terms of decreasing potential complications.

Key words: Interlaminar epidural steroid injections, foraminal stenosis, spinal level, cervical disc herniation, radicular pain

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Foraminal stenosis, defined as a narrowing of the cervical neural foramen, is one of the most common causes of upper extremity radicular pain (1). Degenerative bone spurs, facet and ligament hypertrophy, or lateral disc herniations may result in this narrowing. These anatomic changes that lead to a

progressive narrowing of the foramen result in cervical radiculopathy, causing compression, inflammation or both in the nerve root (2). Although the first-line treatment for cervical radiculopathy is conservative treatment methods, epidural steroid injections (ESIs) are frequently used in cases of unresponsiveness to treatment or insufficient response to treatment (3).

Currently, the question of what the possible predictive factors are for these injections in terms of treatment outcomes is increasingly gaining importance because of the increase in the frequency of administering cervical ESI, increasing treatment costs, and controversies on its efficacy (4). The results of a limited number of studies regarding the effect of cervical neural foraminal stenosis (NFS) on ESI treatment outcomes, which is considered as one of the possible predictive factors because of its role in the etiology, are controversial (5,6). When the data of 53 patients treated with transforaminal ESI for radiculopathy due to cervical NFS were retrospectively evaluated in one of these studies, Kim et al (5,7) reported that the severity of NFS determined according to the foraminal grading system had no effect on treatment outcomes. In another study evaluating NFS by measuring the maximum foramen diameter in the oblique sagittal plane of cervical magnetic resonance imaging (MRI), it was reported that among patients treated with cervical nerve block, those with severe NFS responded positively, whereas mild to moderate NFS was less predictive (6). However, to the best of our knowledge, there is no study regarding the effect of NFS severity on treatment outcomes in patients receiving cervical interlaminar epidural steroid injection (ILESI) due to cervical radiculopathy.

As a standard, cervical ESI is administered at either the C7-T1 or C6-7 level, where the diameter of the cervical spinal canal is the largest. Because of the narrowing epidural space as it is ascended to the higher levels, the risk of spinal cord injury that may occur because of the advancement of needle increases (8). Therefore although the administration from the lower cervical region provides an important advantage in terms of safety, it brings up the question of whether the efficacy of the injection will be reduced in the case of higher spinal level in which herniation and/or stenosis is present. McCormick et al (9) report that a catheter introduced through the C7-T1 or a lower level (a soft-tipped flexible plastic catheter) may provide an approach directly to the pathology level present at the upper level, and an approach to the lateral side in the presence of unilateral radicular symptoms, and that the pain and functional outcomes are better compared with the standard approach. However, it was found that this study did not have sufficient power in terms of determining a significant difference (9).

Considering these data, the aim of our study was to determine the effects of the severity of NFS and spinal herniation level on treatment success in patients who received ILESIs due to cervical disc herniation-related radiculopathy and their possible predictive roles.

Methods

After obtaining approval for our study from the Ethics Committee of Marmara University (approval no: 09.2019.379) and informed patient consent form, the data of patients who were diagnosed with unilateral radiculopathy due to cervical disc herniation after clinical, physical, and MRI examinations in the pain medicine clinic, and who were treated with cervical ILESI between August 2017 and February 2019, were retrospectively reviewed. The patient data were evaluated based on the study inclusion and exclusion criteria. The inclusion criteria were as follows: age 18 to 65 years, presence of neck pain and unilateral arm pain unresponsive to conservative treatment for at least 3 months, having cervical MRI taken a maximum of 6 months before the procedure, and presence of single-root and single-level herniation on MRI with or without concomitant unilateral foraminal stenosis. The exclusion criteria were determined as follows: repetition of cervical ILESI within the last 3 months, history of cervical operation, presence of central spinal stenosis, history of a known psychiatric disease, and absence of posttreatment follow-up data.

All patients' demographic characteristics, clinical and demographic data were collected, including pain scores (Numeric Rating Scale [NRS-11]) before and after cervical ILESI at the first hour, third week, and third month follow-ups, presence of motor deficits, symptom side, durations of symptoms before ILESI, and whether there was progression to surgery in the 3-month period after injection. The success of treatment was determined as 50% or more decrease in NRS-11 scores in the third month compared with the preprocedure period. Treatment failure was a decrease of less than 50% in NRS-11 scores in the third month and progression to surgery during the follow-up period.

MRI Evaluation

In MRI evaluation, the MRI examinations of all patients were evaluated by 2 neuroradiologists blinded

to each other to determine the level of disc herniation and the grade of foraminal stenosis in accordance with clinical and physical examination findings, and the outcomes of the patients' treatment. After this evaluation, there was no difference in the evaluation results of both neuroradiologists in terms of herniation level, whereas there were differences only in the results of 2 patients in terms of foraminal stenosis grading. The MRI examinations of these 2 patients were evaluated by a neuroradiologist blinded to both neuroradiologists and the grade of foraminal stenosis was decided.

Foraminal Stenosis Grading

The grading system for cervical foraminal stenosis developed by Kim et al (7) in 2011 was used in the study. This grading system allows making the diagnosis of NFS, as well as evaluating the severity of stenosis. According to this, the severity of stenosis is evaluated in 3 grades: grade 0, "absence of foraminal stenosis"; grade I, "the width of the narrowest portion of the foramen the same or less than the width of the nerve root, but less than 50% stenosis"; and grade II, "the width of the narrowest portion of the foramen is less than the width of the nerve root, but this decrease is more than 50%." NFS was evaluated from the level of symptomatic radiculopathy (Fig. 1).

Procedures

All cervical ILESIs were performed under sterile conditions using C-arm fluoroscopy by a single pain physician (SS) and followed by other investigators. The patients were taken to the operating room and placed in the prone position on the fluoroscopy table and monitored. The injection site was sterilized and draped. After confirmation of the level (C7-T1) and interlaminar space with fluoroscopy, a local anaesthetic (3 mL 2% prilocaine) was injected at the entry site of the needle. Using contralateral oblique fluoroscopic imaging, an 18-gauge Tuohy needle was advanced into the posterior epidural space at the C7/T1 level with a paramidline approach matched on the symptomatic side. The epidural space was entered with the loss of resistance, and 2 mL iohexol was injected for confirmation. A final image was obtained to document contrast medium in epidural space, needle position, and the absence of intravascular or intrathecal contrast medium. Next a mixture of 80 mg triamcinolone acetate, 1 mL 2% lidocaine, and 3 mL 0.9% physiological saline solution was injected. The patient was kept under observation for 1 hour in terms of side effects. The patient, who was observed to have

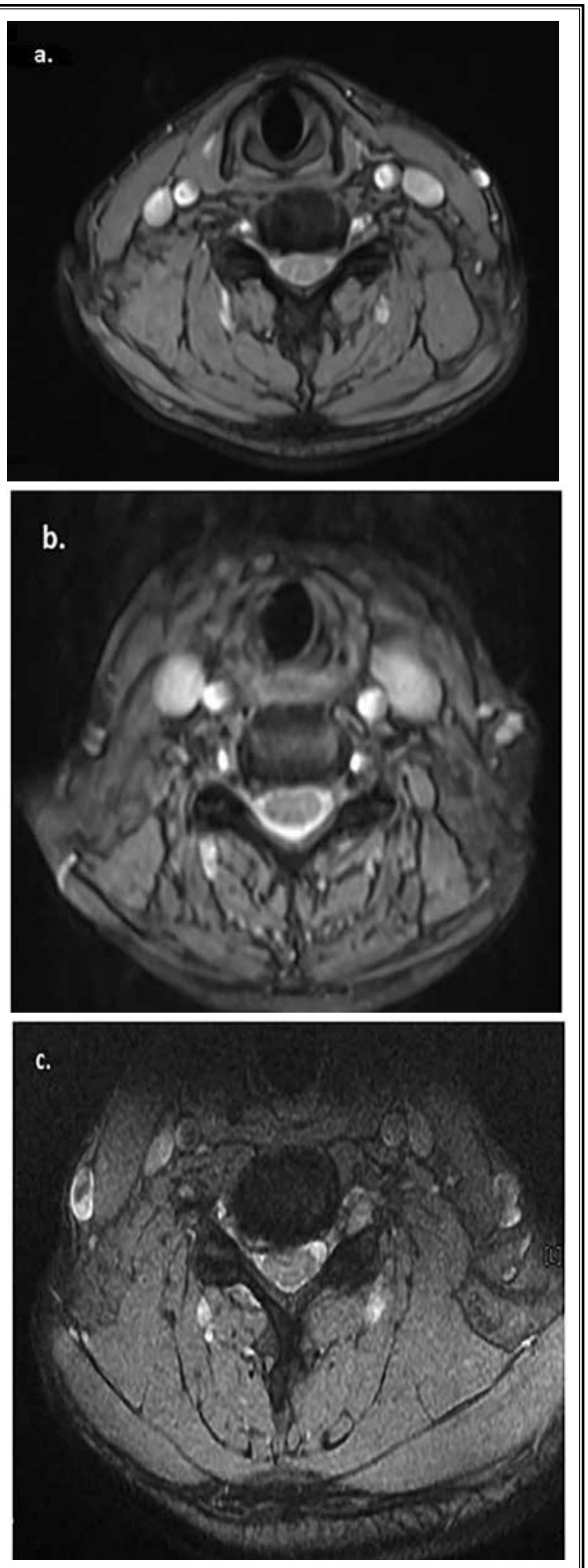

Fig. 1. *Grade 0 (a) no foraminal stenosis. Grade I (b) foraminal stenosis. Grade II (c) foraminal stenosis.*

a good general condition, was discharged, recommending follow-up after 3 weeks.

Statistical Analyses

The SPSS Version 21.0 software (IBM Corporation, Armonk, NY) was used for the statistical analyses. When evaluating the study data, the descriptive statistical methods (mean, standard deviation, frequency, and percentage) along with the Mann–Whitney U test were used in the comparisons of nonnormally distributed quantitative data between the groups, and the Student t-test and analysis of variance were used in the comparison of qualitative data. The Bonferroni test was used for multiple comparisons within the groups. The correlation between treatment success and foraminal stenosis grade and spinal herniation level was evaluated by linear logistic regression analysis. Statistical significance was set at $P < 0.05$. Power and Sample Size Program (P.S. version 3.1.2) (IBM Corporation, Armonk, NY) was used for the analysis of sample size. When we predict that the change in Visual Analog Scale is 50%, a minimum of 58 patients are required for $\alpha = 0.05$ and power = 0.80 in the final analysis. The possible drop-out rate was calculated as 10%, and it was calculated that a total of 63 patients were required in the data evaluation for the first study.

Table 1. *The demographic and clinical data of all patients.*

Descriptive Parameters	Mean ± SD (n = 61)
Age (years)	51.25 ± 11.72
Body mass index	27.36 ± 4.18
Duration (months)	7.96 ± 5.85
Preprocedure NRS-11	7.87 ± 1.46
Level	
C3-4	6 (9.83%)
C4-5	14 (22.95%)
C5-6	24 (39.34%)
C6-7	17 (27.86%)
Motor deficit	
Yes	3 (4.92%)
No	58 (95.08%)
Gender	
Female	34 (55.73%)
Male	27 (44.27%)
Foraminal stenosis grade	
0	24 (39.34%)
1	20 (32.78%)
2	17 (27.86%)
Side	
Right	25 (40.99%)
Left	36 (59.01%)
Treatment success	
Yes	37 (60.7%)
No	24 (39.3%)
Surgical intervention	
Yes	2 (3.7%)
No	59 (96.2%)

Results

When the data of 82 patients treated with cervical ILESI were reviewed, of these patients 7 were excluded from the study owing to absence of follow-up data after the treatment, 9 patients owing to absence of cervical MRI scans, 2 patients owing to having operated cervical discopathy, and 3 patients because of the diagnosis of central cervical spinal diagnosis. The study was completed with a total of 61 patients, 34 women and 27 men, who met the inclusion criteria. The demographic and clinical data including all patients are given in Table 1. There was a significant decrease in the NRS-11 scores of all controls compared with the pretreatment period (Table 2). After cervical ILESI, no major complication was observed, except 2 patients who developed vasovagal reaction. Of the patients, 60.7% (n = 37) achieved treatment success, whereas 39.3% (n = 24) failed to achieve success at the third month follow-up after the injection. Two patients who did not have a decrease in pain at the third week follow-up and progressed to surgery in the later period were included in the patient group who failed to achieve treatment success.

When the data of the patients with and without treatment success were compared, there was no significant difference in terms of age, gender, body mass index, symptom duration, presence of motor deficit, baseline pain level, and symptom side. However, when the spinal herniation levels and foraminal stenosis grades were compared, there was a significant difference between the groups ($P = 0.003$, $P = 0.005$, respectively) (Table 3). As a result of the pairwise comparisons to determine from which foraminal stenosis grade the significance originates, the decrease between grade 0

Table 2. *Temporal variation of NRS-11 scores.*

NRS-11	Mean Difference ± SD	*P* Value
Preprocedure first hour	7.19 ± 1.91	0.0001
Preprocedure third week	4.52 ± 2.98	0.001
Preprocedure third month	3.78 ± 2.88	0.001
First hour to third week	−2.67 ± 2.89	0.001
Third week to third month	−0.73 ± 2.01	0.006

A P value of < 0.05 was considered statistically significant.

and grade 2 (P = 0.003) and grade 1 and grade 2 (P = 0.044) were found to be significant. As a result of the pairwise comparisons to determine from which spinal herniation levels the significance originates, there was a significant decrease between C5-6 and C3-4 (P = 0.043), C6-7 and C3-4 (P = 0.007), and C6-7 and C4-5 (P = 0.010) (Table 4).

When we evaluated the correlations of our treatment success data using regression analysis, there were significant correlations between foraminal stenosis grade (odds ratio [OR], –0.425; P = 0.038) and spinal herniation level (OR, –0.925; P = 0.001) and treatment success. As the foraminal stenosis grade increases, the treatment success decreases. Moreover, the treatment success decreases as the spinal herniation level increases.

Discussion

The aim of our study was to determine the effects of the severity of NFS and spinal herniation level on treatment success in patients treated with ILESI due to cervical radiculopathy and their possible predictive roles. It was found that there was a significant decrease in the pain scores of 61 patients treated with cervical ILESI at all follow-ups compared with the pretreatment period, and a treatment success rate of 60.7% could be achieved. Among the patients with and without treatment success, there was no significant difference in terms of age, gender, symptom duration, presence of motor deficit, baseline pain level, and symptom side. However, it was found that as the severity of foraminal stenosis increased and the spinal herniation level ascended, the treatment success decreased. After the linear regression analysis, it was determined that these 2 parameters, particularly spinal herniation level, were important predictive factors in terms of treatment success.

In the prospective study by Hashemi et al (10) administering ILESI to 26 patients with unilateral radiculopathy due to cervical disc herniation, it was reported that decrease in pain and improvement in functional disability were achieved at the first month follow-up. In this study, including 2 groups treated with paramedian and midline ILESI, it was found that the treatment outcomes of the paramedian group were better. It was emphasized that this result might be associated with more distribution to the anterior epidural space using the paramedian approach. Likewise in our study, there was a significant decrease in the pain scores at the first month follow-up after

Table 3. *Comparison of the demographic and clinical data between the groups with and without treatment success.*

Descriptive Parameters	With Treatment Success (n = 37)	Without Treatment Success (n = 24)	*P* Value
Age (years)	50.24 ± 11.71	52.79 ± 11.82	0.412
Body mass index	26.96 ± 3.71	27.98 ± 4.84	0.353
Duration (months)	7.18 ± 5.22	9.16 ± 6.65	0.225
Preprocedure NRS-11	8.11 ± 1.31	7.63 ± 1.63	0.207
Herniation level C3-4 C4-5 C5-6 C6-7	 1 (2.70%) 5 (13.51%) 16 (43.24%) 15 (40.54%)	 5 (20.83%) 9 (37.5%) 8 (33.33%) 2 (8.83%)	0.003*
Motor deficit Yes No	 1 (2.71%) 36 (97.29%)	 2 (4.54%) 22 (95.45%)	0.556
Gender Female Male	 23 (62.16%) 14 (37.83%)	 11 (45.83%) 13 (54.16%)	0.292
Grade 0 1 2	 19 (51.35%) 13 (35.13%) 5 (13.51%)	 5 (20.83%) 7 (29.17%) 12 (50%)	0.005*
Side Right Left	 19 (36.06%) 18 (59.01%)	 6 (25%) 18 (75%)	0.075

* There was a significant difference herniation levels and foraminal stenosis grades between the groups. A P value of < 0.05 was considered statistically significant.

Table 4. *Comparisons of herniation levels and foraminal stenosis grades within the groups.*

	Mean Difference ± Standard Error	Sig.	95% Confidence Interval	
			Lower Bound	Upper Bound
Lesion level				
C3-4 vs. C4-5	0.19 ± 0.21	1.000	–0.399	0.780
C5-6 vs. C3-4	–0.69 ± 0.24	0.043*	–1.369	–0.014
C5-6 vs. C4-5	–0.27 ± 0.16	0.251	–0.715	0.164
C6-7 vs. C3-4	–0.71 ± 0.20	0.007*	–1.430	–0.042
C6-7 vs. C4-5	–0.52 ± 0.15	0.010*	–0.961	–0.089
C6-7 vs. C5-6	–0.21 ± 0.14	0.777	–0.598	0.167
Foraminal stenosis grade				
Grade 0 vs. Grade 1	–0.14 ± 0.13	0.926	–0.4817	0.1984
Grade 0 vs. Grade 2	–0.49 ± 0.14	0.003*	–0.8536	–0.1415
Grade 1 vs. Grade 2	–0.35 ± 0.15	0.044*	–0.7264	0.0146

*There was a significant decrease in number of patient with treatment success between herniation levels and foraminal stenosis grades. A P value of < 0.05 was considered statistically significant. Sig, significance.

cervical ILESI compared with the pretreatment period, and the pain scores continued to decrease at the third month follow-up. Our preference for using the paramedian approach in ILESI may have contributed to the reduction in long-term pain. Moreover, because we determined a 50% or more decrease in pain scores in the third month compared with the pretreatment period as treatment success, 60.7% of our patients had achieved treatment success. When the data of the patients with and without treatment success were compared, there was no significant difference in terms of age, gender, symptom duration, presence of motor deficit, baseline pain level, and symptom side. These results were consistent with the results of the studies in the literature reporting that these parameters were not predictive in terms of treatment outcomes (5,11,12).

Intervertebral foramina are one of the major anatomic sites affected by many pathological processes, especially degenerative processes and disc herniation (13). In patients with cervical radiculopathy, posterolateral disc herniation and osteophytes come to the fore as the most common causes of foraminal stenosis (14). Although MRI is the most commonly used method for spinal evaluation in patients with cervical radiculopathy, there is still no standardized method (15). In the majority of patients with persisting complaints after surgical treatment, the cause has been reported as inadequacies in determining the level of radiculopathy, and in line with this requirement, new grading systems are developed to evaluate nerve injury, including foraminal stenosis (16).

In 2011, Kim et al (7) developed a 3-step grading system in which the width of cervical neural foramen is evaluated according to the thickness of extraforaminal nerve root in T2-weighted axial slices. A high intra/interrater agreement rate has been reported with the current method (15). In 2012, Park et al (17) developed an alternative grading method in which T2-weighted oblique magnetic resonance slices are evaluated for grading cervical foraminal stenosis. However, its clinical use appears to be impractical because of the requirement for scan protocols in addition to routine cervical MRI scan and weakness of oblique slices to show the nerve root (18). Therefore in our study, we used the grading system of Kim et al (7) to evaluate the width of neural foramina on standard cervical MRI.

When the patients without foraminal stenosis were compared with those with nonsevere and severe foraminal stenosis in our study, we found that they achieved a higher rate of treatment success. We are of the opinion that more effective ESI in the absence of significant mechanical compression on the nerve root and prominent inflammation based on radicular pain may be explanatory for these outcomes (19). Moreover, the results of the study by Kwon et al (11) investigating whether the etiology of cervical radiculopathy could predict benefit after ESI, reported that patients with disc herniation responded better to treatment after interlaminar ESI compared with patients with central and foraminal stenosis support our study.

In the study by Kim et al (5) investigating the correlation between the severity of foraminal stenosis and treatment success in 53 patients with cervical radiculopathy treated with cervical transforaminal ESI, no correlation was found. Although in our study using the same grading system as Kim et al (5), it was found that as the severity of foraminal stenosis increases, treatment success decreases, and that the severity of foraminal stenosis was a predictive parameter in terms of ILESI treatment success. The main reason for this difference between the results of both studies may be related to the different methods of ESI administration. Because the injectant given in transforaminal ESI is directly delivered to the target area of pathology, we think that the achievability of treatment success may be higher compared with interlaminar ESI despite the negative effect of existing stenosis (20). However, because of the presence of severe life-threatening complications reported after transforaminal ESIs, ILESIs are preferred more widely in the treatment as a more reliable option (21).

We found that the success of treatment decreases as the spinal herniation level ascends in the patients to whom we administered ILESI at the standard C7-T1 level. This result may be related to the reduction in the rate of injectant that can reach the relevant spinal level after interlaminar injection administered at the standard C7-T1 level. Therefore unlike the standard approach, the use of an alternative injection technique that can provide access to the upper spinal levels with a soft flexible catheter (a soft-tipped flexible plastic catheter) suggests that the treatment success may increase, especially in high spinal level herniations. McCormick et al (9) found no significant difference between 67 patients treated with the standard approach and C7-T1 ILESI using a catheter, although the pain and functional outcomes were better in patients in whom catheter was used. In this study, which supports our study results, more significant results could be obtained, especially if these 2 techniques were compared

in higher number of patients with high spinal level herniation.

In cervical ILESI injections, the use of contralateral oblique imaging is recommended for procedure safety owing to inability to obtain optimal images in lateral imaging because the shoulder joint enters the imaging area, and the challenges in determining the actual needle depth in the paramedian approach (22). Therefore in our study, contralateral oblique imaging was used during our cervical ILESI injection procedures. No major complication was observed, except 2 patients who developed vasovagal reaction.

Although our study has some limitations due to the retrospective design and absence of functional evaluation, to the best of our knowledge, it is a valuable study in terms of being the first study investigating the effect of the severity of foraminal stenosis and spinal herniation level on treatment success in patients treated with cervical ILESI and its results. Another limitation for our study was small sample size. A higher number of patients could have increased the predictability of our results.

Conclusions

Cervical interlaminar ESI is a reliable treatment option that provides a significant reduction in pain in patients with cervical radiculopathy. However, the success of ILESI treatment may be negatively affected in these patients in the presence of high spinal level cervical disc herniation and severe foraminal stenosis. Therefore considering these 2 parameters in predicting the patient population who will benefit from cervical ILESI is of importance in terms of preventing the number of unnecessary procedures and reducing potential complications.

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