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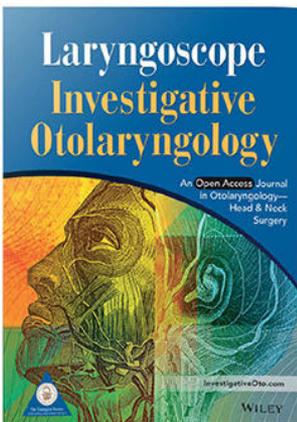


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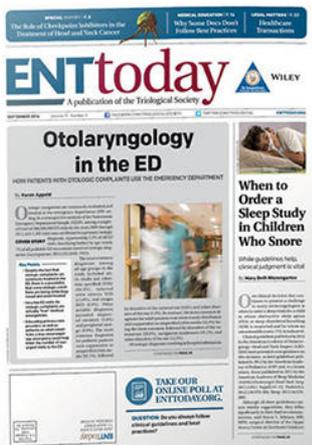
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Validation of the OMNI Vocal Effort Scale in the Treatment of Adductor Spasmodic Dysphonia

Hagit Shoffel-Havakuk, MD ; Katherine L. Marks, MS; Mariah Morton, BA; Michael M. Johns III MD; Edie R. Hapner, PhD

Objectives: To establish the validity of the OMNI Vocal Effort Scale (OMNI-VES) for resistance exercise, a single-question pictorial scale, in voice-related perceived exertion. Additionally, the study aimed to assess the role of the OMNI-VES as an outcome measurement in the treatment of adductor spasmodic dysphonia (ADSD).

Methods: A prospective validation study was conducted on 226 participants. The case group was comprised of 178 patients receiving botulinum toxin (BTX) injections for ADSD and 48 controls without a voice disorder. Prior to a planned injection, the participants were asked to complete the OMNI-VES and the Voice-Related Quality-of-Life (V-RQOL) questionnaires, and the clinician completed the Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V). A subgroup of 17 patients were administered a repeat assessment 1 month after injection.

Results: There was a weak correlation between the OMNI-VES and the V-RQOL score (Tau-b = -0.252, $P < 0.001$), and no significant correlation with the CAPE-V. Participants with ADSD had significantly higher OMNI-VES scores compared with normal controls, 5.07 ± 2.18 and 1.47 ± 2.28 , respectively (P value < 0.0001). The average OMNI-VES score significantly improved 1 month following a BTX injection, from 6 ± 2.4 to 3.4 ± 2.8 (P value = 0.0003). Eighty-eight percent of the patients demonstrated a decrease in the OMNI-VES score following injection, whereas only 47% demonstrated an improvement in the V-RQOL score.

Conclusion: The OMNI-VES is a validated tool for rating perceived voice-related exertion in people with ADSD and can be used for evaluating response to BTX injection treatment.

Key Words: Spasmodic dysphonia, adductor spasmodic dysphonia, botulinum toxin, vocal effort, OMNI Vocal Effort Scale.

Level of Evidence: 2b

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INTRODUCTION

Although the use of botulinum toxin (BTX) remains off-label, its safety and efficacy in the treatment of adductor spasmodic dysphonia (ADSD) has been established since the 1980s,¹ and it remains the standard of care for ADSD.^{2–4} Successful outcomes from these injections are associated with diagnostic accuracy, patient needs, patient expectations, physician injection skills, and dosing decisions.^{3,5–7} Dosing is variable between patients, and there often is a learning curve for both the physician and the patient until the optimal dosing for the specific patient is achieved. Therefore, there is an essential clinical requirement for

establishing tools to assess outcomes, which can inform dosing adjustments and treatment optimization.

A meta-analysis of over 30 studies, published in 2002, evaluated outcomes following BTX injection for ADSD⁸ and found a moderately beneficial effect. Nevertheless, the authors of this meta-analysis cautioned about variations and inconsistency in measurement tools, along with methodological problems and lack of measurement standardization. Indeed, the literature describes a variety of methods to evaluate the success of BTX injections for ADSD. These include patient perception questionnaires for QOL or handicap,^{6,7,9–11} clinician's perception of quality of voice,^{1,3,7,12} acoustic or voice aerodynamic measures,^{3,13–17} and electroglottography (EGG).^{7,9,10,18–22} Nonetheless, the literature also demonstrates that in the case of measuring outcome of BTX injection for ADSD, these instruments do not necessarily correlate with each other,^{7,22,23} which raises the dilemma: which of the existing tools has the most clinical relevance? A comprehensive study of 199 patients found a weak correlation between the patient's and clinician's assessment of voice impairment following BTX injection for ADSD.⁷ Similarly, another study reported that whereas 91% of the patients who received BTX injections stated that their voice improved, the scores on the Voice-Related Quality of Life (V-RQOL) questionnaire were not associated with this effect.²² In a multi-institutional study of

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clinician's agreement on the differential diagnoses of ADS/D from abductor spasmodic dysphonia (ABSD), muscle tension dysphonia, and tremor, agreement was found between clinicians within institutions but not across institutions.²⁴ Thus, the major limitation in determining successful outcomes following BTX injection in ADS/D remains the lack of agreement between clinicians, clinicians and patients, the clinical relevance of QOL questionnaires, and the lack of a standard instrument in determining the severity of impairment.^{11,12,19,25-27}

Previous reports on the Consensus Auditory Perceptual Evaluation of Voice (CAPE-V) found that, in the case of ADS/D, the most reliable dimensions are the overall severity and strain.^{28,29} Because strain can be translated to the effort perceived by the clinician, it should be valuable to measure the vocal effort as perceived by the patient. However, the reliability of both patient perception of vocal strain and clinician and patient agreement of severity of vocal strain is moderate at best.³⁰

The concept of patient's perception of phonatory effort as an instrument to measure the severity of various voice conditions has been described by several authors in the past.³¹⁻³⁵ Few studies have examined the use of an adapted scale for rating perceived exertion (Borg scales) in determining vocal effort in a variety of voice disorders.³¹⁻³³ Specifically for persons with ADS/D, in an earlier work on patient satisfaction following BTX injections, the decreased vocal effort was among the features that defined a successful injection.³⁴ Interestingly, as early as 1993, when assessing outcome, Aronson et al. asked ADS/D patients to rate the change in their phonatory effort at several intervals after BTX injection.³⁵ Nevertheless, this tool is not routinely utilized in ADS/D patients and has not been reported again until recently.

The OMNI scales are series of validated scales used to determine rating of perceived exertion during a variety of exercises. These scales are easily understood, with a simple 0 to 10 equal interval rating accompanied by both pictures of "exertional meaning" and verbal descriptor.³⁶⁻⁴⁰ The term OMNI originates from *omnibus*, meaning that these scales have demonstrated acceptance in multiple physical exertion tasks.³⁷

The aims of this study are to present our methodology in the development of an OMNI Vocal Effort Scale (OMNI-VES) for use in measuring perceived vocal effort in voice disorders in general—and for ADS/D in particular—and to determine its validity. We also wished to assess the ability of the OMNI-VES to measure the success of BTX injection in patients with ADS/D.

MATERIALS AND METHODS

Scale Production: Development of an OMNI Vocal Effort Scale for ADS/D

Multiple attempts were made to develop an optimal disorder specific pictorial scale representing vocal effort, similarly to other OMNI scales for rating perceived exertion. A medical illustrator was employed to develop a pictorial description of the scale to accompany the 0 to 10 equal intervals of gradual increase in vocal effort. The medical illustrator was guided and instructed by the senior author, a speech-language pathologist with extensive experience working with patients with ADS/D (E.R.H.), and through interviews with patients who had received over five successive BTX injections for the treatment of ADS/D. Following institutional review board (IRB) approval, the newly designed pictorial vocal effort scale and the OMNI perceived exertion scale for resistance exercise (Fig. 1)⁴⁰ were presented to 40 ADS/D patients over a period of 4 weeks (9-11 patients each week). The participants were asked to choose between the newly designed pictorial vocal effort scale and the already validated OMNI perceived exertion scale for resistance exercise⁴⁰ to indicate which scale better described their voice-related effort prior to receiving a BTX injection when their effort should be the highest. The preferred scale was later used for all further validation and analysis of the OMNI-VES for ADS/D in this study.

Study Design

A prospective validation pilot study was conducted at an interprofessional voice center within a large tertiary care medical center. After securing IRB approval, 178 patients were prospectively recruited from all patients receiving BTX injections for ADS/D between 2012 and 2013. Diagnosis of ADS/D was confirmed or determined by a board-certified fellowship-trained laryngologist with over 10 years of experience in the diagnosis and treatment of movement disorders impacting voice and a certified

Based on the scale below, **CIRCLE** the number (0-10) that indicates how much effort, strain, discomfort and/or fatigue you perceive when using your voice **TODAY**?

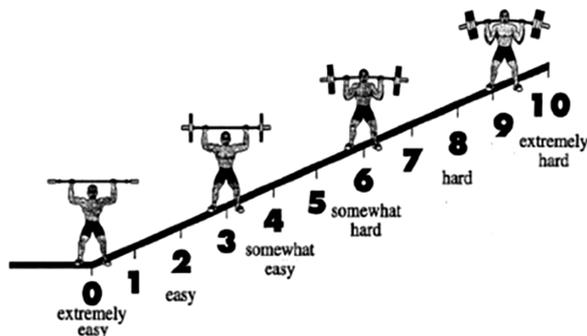


Fig. 1. The OMNI Vocal Effort Scale (the OMNI perceived exertion scale for resistance exercise modified for vocal effort). Reprinting permission of the OMNI Resistance Exercise Scale of Perceived Exertion was granted by the author Robertson RJ.⁴⁰

and licensed speech–language pathologist with over 30 years of experience in working with the same population. Further inclusion criteria were: patients aged 18 years or older receiving at least five injections and who had been receiving a stable injection dose of BTX over the last three injections. Participants diagnosed with both ADSD and tremor were eliminated from the study.

Data collection for each participant included age, gender, diagnosis, indication for BTX injection, previous BTX injection history, and comorbidities—as well as participant-reported OMNI-VES and V-RQOL scores and clinician-reported CAPE-V scores, which will be further described in detail.

Participants were scheduled to come in for a 30-minute appointment prior to their scheduled BTX injection (Botox [onabotulinumtoxinA], Allergan Inc., Irvine, CA). Measures were collected in the following order: V-RQOL,⁴¹ OMNI-VES, CAPE-V.⁴²

The V-RQOL and the OMNI-VES were submitted as a paper survey; the OMNI-VES used was the OMNI-perceived exertion scale for resistance exercise with written instructions to use the scale to describe vocal effort,⁴⁰ as depicted in Figure 1. For CAPE-V determination, a standardized voice recording was performed during that visit prior to the injection. The voice recording protocol included reading of a standardized passage, sustained phonation of the vowels /a/ and /i/, reading of the CAPE-V sentences, loud phonation of the word “Hey,” and a glissando from low to a high and high to low. A team of two speech–language pathologists exclusively treating voice disorders and blinded to the patient’s identity, characteristics, and timing of recording, rated each voice sample according to the guidelines for CAPE-V assessment (www.asha.org). Furthermore, 20% of the samples were scrambled and randomly repeated to ensure intrarater reliability.

A small sampling of the participants (N = 17, 10%) were scheduled for an additional 30-minute appointment 1 month after the injection to determine content validity (ensuring the test corresponds with the symptoms) and any changes in scores postinjection. The timing of the follow-up appointment corresponded to the timing in which optimal outcome from the BTX injection was anticipated. During the 1-month follow-up visit, the following data were collected using an equivalent methodology, as listed above: participant-completed OMNI-VES and V-RQOL, and clinician assessment using the CAPE-V.

Control Group

Participants for the control group were recruited by flyer on the campus of a large private university and self-identified as without any voice complaints at the time of rating. For each control group participant, data collection included age, gender, previous history of voice condition or vocal cord surgery/intervention, and whether they feel any voice problems the day of the assessment. Control participants were also asked to complete the OMNI-VES.

Statistical Analysis

To determine convergent and discriminant validity (ensuring measures that are supposed to be related are related and measures that are not supposed to be related are unrelated), the OMNI-VES scores were correlated with the CAPE-V and V-RQOL using Kendall rank correlation coefficient (Tau) for non-parametric analysis. To determine construct validity (ensuring that the test measures what it claims to be measuring), OMNI-VES scores of ADSD patients were compared with those of the control group using unpaired Student *t* test. A paired samples *t* test was used to determine the difference in OMNI-VES, V-RQOL, and CAPE-V before and 1 month following BTX injection in the intervention group. The Mann-Whitney U test was

used to compare nonparametric variables between ADSD participants and the control group. For all statistic tests performed, an alpha of 5% or less was considered statistically significant. Statistical analyses were accomplished using SPSS Statistics 20.0 (IBM Corp., Armonk, NY).

RESULTS

Development of the OMNI Vocal Effort Scale for ADSD

Face validity (a subjective assessment ensuring the measure covers the concept that it is supposed to be measuring) was satisfied by both clinicians’ and patient participant assessments. The previously available OMNI perceived exertion scale for resistance exercises and the newly designed pictorial vocal effort scale were evaluated by a speech–language pathologist with extensive experience with ADSD patients. Two serial pictorial scales were then chosen and presented to 40 ADSD patients for preference. Patient participant preference was defined as better descriptor of their voice-related effort. Eighty percent (32 of 40) preferred the OMNI perceived exertion scale for resistance exercise (Fig. 1) over the newly designed pictorial vocal effort scale. Table I summarizes the responses and preference regarding the use of the two scales. Therefore, agreement was reached on the OMNI perceived exertion scale for resistance exercise, with the instructions modified to measure vocal effort (Fig. 1), and this was used for all further validation and analyses in this current study.

Association Between the OMNI-VES and V-RQOL and CAPE-V

One hundred and seventy-eight participants meeting the study inclusion criteria were recruited to the study group. There were 132 (74%) female and 46 (26%) male participants, comparable to incidence in the general population for ADSD and gender. Age range was 26 to 96 years, with a mean age of 63.6 ± 13.4 years. The average number of years for receiving injections was 8.56 years.

With respect to convergent and discriminant validity, the associations between the OMNI-VES and the other measured instruments, V-RQOL and CAPE-V, were tested. In general, the associations between these three instruments were weak or nonsignificant, suggesting that they all measure different aspects of ADSD (Table II).

TABLE I.
ADSD Patients Preference for Better Description of Their Voice-Related Effort

| Week | Number of Participants | Prefer the Newly Designed Pictorial Vocal Effort Scale | Prefer the OMNI Perceived Exertion Scale for Resistance Exercise |
|-------|------------------------|--|--|
| 1 | 10 | 2 | 8 |
| 2 | 11 | 3 | 8 |
| 3 | 9 | 2 | 7 |
| 4 | 10 | 1 | 9 |
| Total | 40 | 8 | 32 |

ADSD = adductor spasmodic dysphonia.

TABLE II.
Correlation Between the OMNI Perceived Exertion Scale, CAPE-V, and V-RQOL Scores

| | | | CAPE-V | V-RQOL | OMNI-PES |
|---------------|-------------------------|-------------------------|---------------------|---------|---------------------|
| Kendall tau-b | CAPE-V | Correlation coefficient | 1.000 | -0.104* | 0.077 |
| | | significance (2-tailed) | - | 0.045 | 0.152 |
| | | N | 178 | 178 | 178 |
| | V-RQOL | Correlation coefficient | -0.104* | 1.000 | -0.252 [†] |
| | | significance (2-tailed) | 0.045 | - | <0.001 |
| | | N | 178 | 178 | 178 |
| OMNI-PES | Correlation coefficient | 0.077 | -0.252 [†] | 1.000 | |
| | significance (2-tailed) | 0.152 | <0.001 | - | |
| | N | 178 | 178 | 178 | |

*Correlation is significant at the 0.05 level (2-tailed).

[†]Correlation is significant at the 0.01 level (2-tailed).

CAPE-V = the Consensus Auditory-Perceptual Evaluation of Voice; OMNI-PES = OMNI Perceived Exertion Scale; V-RQOL = Voice-Related Quality of Life.

There was a weak correlation between the OMNI-VES and the V-RQOL score ($\text{Tau}_{-b} = -0.252, P < 0.001$). There was no significant association found between the OMNI-VES and the CAPE-V. The study population also demonstrated a weak correlation between the V-RQOL score and the CAPE-V ($\text{Tau}_{-b} = -0.104, P = 0.045$).

Comparison With Normal Controls

Forty-eight patients were recruited to the control group. Of these, 38 (79%) were female and 10 (21%) were male. The mean age was 35.6 ± 10.7 years. All participants had a negative history for previous voice condition or vocal fold surgery/intervention, and they stated their voice felt good/nonhoarse the day of completing the rating scales. With respect to construct validity, the OMNI-VES score for the ADSD patients group ($n = 178$) was significantly higher than the score for persons without a voice problem (control group, $n = 48$), 5.07 ± 2.18 , compared with 1.47 ± 2.28 , respectively (P value < 0.0001).

Pre- Versus Postinjection Analysis

A subgroup of 17 study participants took part in further investigation of pre- versus post-BTX injection scales' comparison. This subgroup was comprised of 10 (59%) female and seven (41%) male participants, and the mean age was 56.2 ± 12.7 years. Results indicated there were significant differences in QOL scores using the V-RQOL and the OMNI-VES scores 1 month following a BTX injection. The average V-RQOL score improved from 46.97 ± 29.21 to 62.21 ± 31 (P value = 0.033), and the average OMNI-VES score improved from 6 ± 2.4 to 3.4 ± 2.8 (P value = 0.0003). Fifteen (88%) of the 17 patients demonstrated a decrease in the OMNI-VES score following injection, whereas only eight patients (47%) demonstrated an improvement in the V-RQOL score.

DISCUSSION

One of the major challenges in the treatment of ADSD is optimization of BTX injection treatment. It is therefore essential to utilize feedback instruments for

adjustments. Hereby, we originally present a new tool to measure the success of BTX injection for ADSD: the OMNI-VES. Having only one question, the OMNI-VES is easily applied and can be considered an instrument with very low burden and high responsiveness. In this study, the OMNI-VES for ADSD accomplished the various requirements of scales' validity and reliability. The OMNI-VES was able to distinguish patients with ADSD from those without (by significantly higher scores). Furthermore, it demonstrated a significant improvement after BTX injections even when another patient perception validated tool failed to (the V-RQOL). Remarkably, The OMNI-VES associations with the V-RQOL and CAPE-V were weak or nonsignificant, suggesting that it measures a distinct aspect of ADSD. Overall, these properties of the OMNI-VES make it a reliable and useful instrument in evaluating ADSD patients' perception on the success of BTX injection.

Numerous attempts have been made by multiple authors and institutions to find an objective instrument that reliably measures the success of BTX injections for ADSD. Aerodynamic measures, more specifically laryngeal resistance, have been studied with variable results. A study of 15 patients found that laryngeal resistance consistently decreases after successful BTX injections in patients with focal laryngeal dystonia.¹⁴ Another study on 13 patients with laryngeal dystonia found that laryngeal resistance and subglottal pressures were able to differentiate between ADSD and ABSD.¹⁵ On the other hand, in an earlier work by Plant and Hillel that examined indirect and direct methods of measuring laryngeal resistance in normal and ADSD subjects, the indirect method of measuring laryngeal resistance, as used in most clinical studies of spasmodic dysphonia, underestimated laryngeal resistance as compared to the direct cricothyroid puncture method.¹³

Another attempt to find an objective instrument to measure the success of BTX injections for ADSD studied EGG. The EGG parameters of 12 ADSD patients were compared with normal speakers by analyzing continuous speech and were able to distinguish strained syllables from unstrained syllables. Acknowledging the importance of strain and effort in ADSD response to treatment, the

authors of this study postulated that EGG parameters may be able to measure vocal strain and serve as a marker for treatment response in subjects with ADSD.¹⁹ Additional methodologies for measuring strain and effort in individuals with ADSD were described using acoustic analyses; nevertheless, none of the acoustic measures was found to be superior to others for this purpose. An example for acoustic measure is demonstrated in a study on 19 ADSD patients: the standard deviation of the fundamental frequency during sustained phonation moderately correlated with clinician's perception of "strain-strangled quality."¹⁷ Another study investigated relative fundamental frequency (RFF) measures and their correlation with perceived vocal effort in ADSD patients. They found that onset RFF values were negatively correlated with listeners' ratings of vocal effort and overall severity and suggested it may be utilized as an outcome measurement in the future when measurement of RFF became less clinically burdensome.¹⁶

Although the above tools aimed to report objective reliable measurements, their clinical usefulness and significance remain uncertain. Other commonly reported methods to estimate treatment outcomes for voice disorders use clinician or patient perception to measure voice impairment. Discrepancies between the clinician's and the patient's perceptions of the degree of impairment in voice disorders have been previously described in the literature and have been shown to be more prominent when an emotional component is considered.^{43,44} Although the CAPE-V is the only validated perceptual voice assessment tool with its parameter, overall severity, demonstrating the greatest accuracy and validity for the evaluation for quality of voice,⁴² it is widely agreed that patient's perception has a great clinical significance, especially when measuring response and satisfaction with treatment. This is particularly true for ADSD patients treated with BTX injection because both previous publications⁷ and our current study data demonstrate weak or no association between the clinician's and the patient's perceptions. For instance, our data showed a very weak correlation between the V-RQOL and the CAPE-V scores ($Tau_b = -0.104$, $P = 0.045$). Furthermore, in many cases the previously validated tools for voice-related QOL or handicap would not exhibit an improvement after treatment,^{7,22} as described by our data (V-RQOL improvement: $t = -1.985$, $P > 0.5$). We believe that the OMNI-VES focuses on a particular dimension, which is more relevant and specific to ADSD patients and their perception of their symptoms; hence, it may succeed where other patients' questionnaires failed and can demonstrate the improvement following a successful BTX injection.

We argue that, although the OMNI-VES is a simple single-question instrument, in the case of ADSD it may be more reliable than previously validated QOL or handicap questionnaires and can better reveal nuances of improvement as perceived by the patient. The OMNI-VES points out the one essential component for ADSD patients in defining a successful BTX injection: reduction in perceived effort.³⁴ The outcomes of our study showed that ADSD patients notice an improvement in their vocal perceived exertion that is demonstrated by the

OMNI-VES, even when other validated questionnaires such as the V-RQOL demonstrate no improvement.

Construct validity refers to how well a measurement conforms to theoretical concepts (constructs) concerning the entity under study. In this study, our theoretical construct that vocal effort by the OMNI-VES measures patients' perceived improvement following BTX injections was validated. *Criterion validity* is the degree to which the measurement correlates with an external criterion of the phenomenon under investigation. Although there is no accepted gold standard at this time to measure a change following BTX injection for ADSD, we referred to the CAPE-V as a reliable external criterion. Our study showed that when there was a significant improvement in CAPE-V scores, a comparable improvement was demonstrated by the OMNI-VES scores.

This study provides key insights regarding the role of patients' perceived effort in measuring the treatment outcome in ADSD patients. Nevertheless, our current study is limited by its relatively small sample size aimed to establish validation alone. Future studies using the OMNI-VES in ADSD patients will be able to verify our assumption that patient's perceived phonatory effort plays a significant role in ADSD symptoms, as well as in measuring response to treatment. Because the purpose of this study was an initial validation, it focuses on a homogenous study group; patients with ADSD or tremor were excluded from the study. Nevertheless, we believe the OMNI-VES can be useful in measuring treatment response for these patients as well, which should be investigated in future studies. Furthermore, future studies will be able to investigate other clinical applications of the OMNI-VES in voice patients.

Although it may provide some additional value, the use of aerodynamic measures was not applied in our current study because there has been a controversy in the literature regarding the use of aerodynamic assessment in ADSD. Plant and Hillel¹³ questioned the reliability of aerodynamic assessment in patients with ADSD, and Higgins et al. demonstrated no significant differences compared to patients with muscle tension dysphonia⁴⁵ as a result of large intersubject variation.^{45,46}

CONCLUSION

The OMNI-VES for ADSD is a single-question and easily understood scale with low burden and high responsiveness. The OMNI-VES is now a validated tool for rating of voice-related perceived exertion in patients with ADSD and can be used for evaluating response to BTX injection treatment. The OMNI-VES may detect patient's perceived improvement after BTX injection, even when other validated tools fail to do so. Further advantages and clinical applications of the OMNI-VES for ADSD should be investigated.

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