International Urogynecology Journal (2019) 30:1203–1209
https://doi.org/10.1007/s00192-019-03951-8

ORIGINAL ARTICLE

Validation of the Turkish version of the International Consultation on Incontinence Questionnaire-vaginal symptoms (ICIQ-VS)

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Received: 5 December 2018 / Accepted: 8 April 2019 / Published online: 29 April 2019

Abstract

Introduction and hypothesis The International Consultation on Incontinence Questionnaire–Vaginal Symptoms (ICIQ-VS) was developed and validated in 2006 to evaluate vaginal symptoms, sexual matters, and quality of life of patients. This study aimed to validate the Turkish version of ICIQ-VS.

Methods The English version of the questionnaire was translated into Turkish. On the basis of the pelvic organ prolapse quantification (POP-Q) system, symptomatic women with ≥ 2 grade pelvic organ prolapse (POP) were included in the symptomatic (patient) group and asymptomatic women with ≤ 1 grade POP in the asymptomatic (control) group. The questionnaire was administered three times: after the first examination of the women (T1), 3 weeks after T1 (T2), and 3 months after the POP surgery (T3).

Results A total of 111 women were included in the study (symptomatic group, $n = 53$; asymptomatic group, $n = 58$). The missing data were < 2%; the test-retest reliability was between 0.807 and 0.963, and the differences between the symptomatic and asymptomatic women were significant ($p < 0.001$). A significant positive correlation existed between POP-Q and the vaginal symptom score, sexual matter score, and quality-of-life score ($r_s = 0.844$, 0.393, and 0.698, respectively; $p < 0.001$). The Cronbach's alpha was 0.72 for the vaginal symptom score and 0.73 for the sexual matter score. The sensitivity to change was significant ($p < 0.05$). The effect size values of the vaginal symptom score, sexual matter score, and quality-of-life score were 2.55, 2.33, and 1.56, respectively.

Conclusion The Turkish version of ICIQ-VS was successfully validated in this study, and a newer version of the questionnaire was made available for assessing vaginal symptoms, sexual matters, and quality of life of patients with POP.

Keywords ICIQ-VS · Pelvic organ prolapse · Quality of life · Sexual matters · Turkish validation · Vaginal symptoms

Introduction

Pelvic floor disorders (PFDs) include pelvic organ prolapse (POP), urinary incontinence, fecal incontinence, sexual dysfunction, and urogenital symptoms. About 25% of women are affected with at least one PFD [1]. The incidence of PFDs increases with the increase in the number of elderly women in the population [2]. PFDs lead to vaginal symptoms in women, hence negatively affecting their sex life and overall quality of life. However, patients may be ashamed or embarrassed to share their sexual problems. Questionnaires that can evaluate complaints of patients and reveal the severity of complaints on a scale are useful for both patients and health care professionals. A questionnaire can provide subjective data to be used in the follow-up of patients, reveal the efficacy of treatments applied, and compare the effectiveness of treatments.

The International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS) was developed and validated in 2006 by Price et al. as a module of the International Consultation on Incontinence Questionnaire (ICIQ) project [3]. Subsequently, the ICIQ-VS was translated into several languages (German, Portuguese, Sinhala, Tamil, Greek, and Danish) and validated successfully [4–8]. The ICIQ-VS comprises three scales: (1) vaginal symptom score, (2) sexual matter score, and (3) quality-of-life score.

The commonly used questionnaires that were validated for assessing vaginal symptoms, sexual dysfunction, and quality of life as a result of PFDs were Pelvic Floor Distress Inventory-20 (PFDI-20), Pelvic Floor Impact

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Questionnaire 7 (PFIQ-7), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire 12, ICIQ short form, and Prolapse Quality-of-Life Questionnaire [9–11]. Zuchelo et al. investigated the pelvic floor dysfunction in the postpartum period and found that the most commonly used questionnaires were PFDI-20, PFIQ-7, and ICIQ-VS [12]. Also, ICI recommended the use of the ICIQ-VS questionnaire, particularly for evaluating patients with POP, but the Turkish version of ICIQ-VS has not been validated so far.

This study aimed to put into practice the Turkish version of ICIQ-VS for evaluating vaginal symptoms, sexual matters, and quality of life of patients with POP and also validate the performance and reliability of this version of questionnaire.

Materials and methods

The ICIQ group (www.iciq.net) was contacted via e-mail to validate the Turkish version of ICIQ-VS. The license and study protocol for the Turkish version were obtained.

Translation

The ICIQ-VS was translated into Turkish as recommended by Guillemin et al. [13]. A bilingual native speaker translated the ICIQ-VS into Turkish, two urogynecologists reviewed the Turkish version, and another bilingual native speaker translated it back into English. The English version was evaluated by the ICIQ-VS development group (IDG). The final version of the questionnaire was prepared with IDG recommendations. The full Turkish version of ICIQ-VS is available from the authors and the ICIQ office (www.iciq.net) upon request.

The Inonu University Ethics Committee approved the questionnaire (approval no. 2018/9–12).

The questionnaire was administered to ten patients by two urogynecologists as a pretest twice at 3-day intervals and evaluated as to whether it made sense to the patients with pelvic organ prolapse. Unclear questions were discussed with the participants in the pretest group. The final version of the questionnaire was developed.

Study population

The numbers of symptomatic and asymptomatic patients were determined after statistical power analysis was conducted. The analysis revealed that each group had 30 patients with 95% confidence and 99.9% test power when the average values of vaginal symptom scores were considered; 30 patients with 95% confidence and 99.1% test power when the average values of sexual matter scores were considered; 30 patients with 95% confidence and 99.9% test power when the average values of quality-of-life scores were considered [7].

The study was conducted at the Derince Training and Research Hospital and Inonu University Turgut Ozal Medical Center in the Department of Obstetrics and Gynecology. Patients admitted to the urogynecology outpatient clinic between June and August 2018 were evaluated in the supine position by an experienced urogynecologist using the POP quantification (POP-Q) system. The symptomatic group consisted of 53 patients with the POP of grade 2 and higher. The asymptomatic group consisted of 58 patients admitted to the gynecology outpatient clinic on the same date, who had menstrual irregularity, adnexal mass, and uterine myoma; who came for the cervical screening test (smear); or who were not detected with POP in the pelvic examination.

The participants in the symptomatic and asymptomatic groups filled out the ICIQ-VS (T1). After 3 weeks, the participants completed the questionnaire again (T2). Patients aged < 18 years, those who were mentally incapable of completing the questionnaire, those who have vaginitis or pelvic inflammatory disease, puerperants, pregnant women, and those who did not agree to come to the hospital after 3 weeks to fill out the questionnaire were excluded from the study. Illiterate patients completed the questionnaire with the help of health personnel. Most of the patients who were admitted to the hospital for POP had not undergone a smear test before. They underwent a smear test and came to the hospital again 3 weeks later to collect their smear test results. Therefore, the questionnaire was repeated twice in 3 weeks. A total of 30 patients in the symptomatic group underwent surgery. Three months after the surgery, the patients were called again for postoperative control (T3). Age, body mass index (BMI), parity, and menopause statuses of patients were recorded.

Questionnaire

The ICIQ-VS is a questionnaire that includes14 items and 3 parts (vaginal symptom score, sexual matter score, and quality-of-life score). The questions except 10, 13, and 14 contain “a” and “b” parts. While “a” evaluates the symptoms, “b” evaluates the severity of these symptoms. Furthermore, “b” consists of 11 points ranging from 0 to 10. For evaluating the vaginal symptom score, the answers given to part “a” of the first eight questions are considered; the scores range from 0 (minimum) to 53 (maximum). For evaluating the sexual matter score, the answers given to part “a” of questions 11, 12, and 13 are considered; the scores range from 0 (minimum) to 53 (maximum). The ninth question is about the complaint of postoperative vaginal stenosis. For evaluating the quality-of-life score, the answer given to question 14 is considered; the score ranges from 0 (minimum) to 10 (maximum) (Table 1). The vaginal symptom scores, sexual matter scores, and quality-of-life scores increase as the severity of complaints increases.

Table 1 Scoring of ICIQ-VS

Vaginal symptom score = (Q1X2) + (Q2X2) + (Q3X1) + (Q4X2) + (Q5X2) + (Q6X2) + (Q7X2) + (Q8X1)
Q1. Are you aware of dragging pain in your lower abdomen?
Q2. Are you aware of soreness in your vagina?
Q3. Do you feel that you have reduced sensation or feeling in or around your vagina?
Q4 Do you feel that your vagina is too loose or lax?
Q5. Are you aware of a lump or bulge coming down in your vagina?
Q6. Do you feel a lump or bulge come out of your vagina, so that you can feel it on the outside, or see it on the outside?
Q7. Do you feel that your vagina is too dry?
Q8. Do you have to insert a finger into your vagina to help empty your bowels?
Q9. Do you feel that your vagina is too tight?
Sexual matter score = (Q11X8) + (Q12X8) + (Q13X1)
Q10. Do you have a sex life at present?
Q11. Do worries about your vagina interfere with your sex life?
Q12. Do you feel that your relationship with your partner is affected by vaginal symptoms?
Q13. How much do you feel that your sex life has been spoiled by vaginal symptoms?
Quality-of-life score = Q14X1
14. Overall, how much do vaginal symptoms interfere with your everyday life?

Statistical analysis

The data were analyzed using SPSS version 23.0 (IBM Corp., Armonk, NY). Compliance with normal distribution was examined using the Kolmogorov-Smirnov test. Kruskal-Wallis, Mann-Whitney *U*, and Wilcoxon tests were used to compare the non-normal distribution of data. The relationship between the pretest and posttest results was analyzed using intraclass correlation analysis. The sensitivity to change was also examined using the effect size or standardized effect size. Cohen's d classification was used to interpret effect size values: <0.2, trivial; ≥0.2 and < 0.5, small; ≥0.5 and < 0.8, moderate; and ≥ 0.8, large [14]. The data that did not show normal distribution were presented as median (min–max). The significance level was taken as $p < 0.05$.

Results

In this multicenter cross-sectional observational study, 111 patients were enrolled [symptomatic (patient) group, 53 participants; asymptomatic (control) group, 58 participants]. In the symptomatic group, 35 patients had an active sex life and answered the questions on sexual matters. The median age was 56 years (range 30–78 years), median BMI was 28.9 kg/m^2 (range 18.9–40.4 kg/m^2), and the median parity was 4 (range 2–12). Of the 53 participants, 29 (54.7%) had grade 2, 11 (20.7%) had grade 3, and 13 (24.5%) had grade 4 of POP. In the asymptomatic group, the median age was 46 years (range 26–52 years), median BMI was 27.5 kg/m^2 (range 18.3–43.2 kg/m^2), and the median parity was 2 (range 1–4); all of the 58 participants had grade ≤ 1 POP (100%) (Table 2). The mean time between T1 (test) and T2 (retest) was 22.5 days (range 21–27 days). In the symptomatic group, 6 patients underwent laparoscopic pectopexy, 14 underwent vaginal hysterectomy and sacrospinous fixation (VH + SSF), and 10 underwent anterior and posterior colporrhaphy (CA + CP). Laparoscopic pectopexy is a new technique for apical prolapse repair. The apex is suspended to the iliopectineal ligament on both sides by mesh [15]. Of the 15 patients who came for the postoperative 3rd-month control, 3 underwent laparoscopic pectopexy, 8 underwent VH-SSF, and 4 underwent CA + CP. Eight patients answered the questions on sexual matters in both T2 and T3.

Table 2 Basic characteristics of participants

	Patients ($n = 53$) median (min–max)	Controls ($n = 58$) median (min–max)
Age	56 (30–78)	46 (26–52)
BMI (kg/m^2)	28.9 (18.9–40.4)	27.5 (18.3–43.2)
Parity	4 (2–12)	2 (1–4)

BMI, body mass index; max, maximum; min, minimum

Validity

Content/face validity

The questionnaire was administered to patients in the pretest group ($n = 10$). These patients were interviewed by two urogynecologists to investigate whether they had difficulty understanding or responding to the questionnaire and whether they had any suggestions to improve the questionnaire. According to all the participants, the questionnaire was clear, and the questions were easy to understand and answer. They did not provide any suggestions regarding the questionnaire.

The rate of missing data was ≤ 2% in the test group: one participant did not answer question 4a, and one did not answer question 10 in the symptomatic group.

Construct validity

The patients were divided into symptomatic and asymptomatic groups on the basis of the answers they gave to question 5a (Are you aware of a lump or bulge coming down in your vagina?). When the answer was 0, they were included in the asymptomatic group; when it was > 0, they were included in the symptomatic group. The women's POP-Q grade was ≤ 1 in the asymptomatic group and ≥ 2 in the symptomatic group. The median value of vaginal symptom scores differed according to the groups ($p < 0.001$): 29 in the symptomatic group and 3 in the asymptomatic group. The median values of quality-of-life scores also differed according to the groups ($p < 0.001$): 7 in the symptomatic group and 0 in the asymptomatic group. The median value of sexual matters scores also differed according to the groups ($p < 0.001$): 16 in the symptomatic group and 0 in the asymptomatic group (Table 3).

Criterion validity

A strong significant positive correlation existed between the POP-Q scores and vaginal symptom scores ($r_s = 0.844$, $p < 0.001$) and quality-of-life scores ($r_s = 0.698$, $p < 0.001$). There was also a significant positive correlation between the POP-Q scores and sexual matter scores ($r_s = 0.393$, $p < 0.001$). Despite this positive correlation, no statistically significant difference was found between the median scores of all three parameters in patients with grades 2, 3, and 4 POP (Table 4).

Reliability

Internal consistency

Internal consistency (reliability) was calculated by eliminating the score of one group from the total score at a time. The Cronbach's alpha value was 0.72 for the vaginal symptom score and 0.73 for the sexual matter score. It could not be calculated for the quality-of-life score, as the latter included only one question.

Stability (test-retest reliability)

The relationship between the pretest and posttest values of the vaginal symptom score, sexual matter score, and quality-of-life score were evaluated using the intraclass correlation coefficient (ICC). The ICC values in the symptomatic group were 0.963, 0.807, and 0.950, respectively; they were 0.907, 0.941, and 0.926, respectively, in the asymptomatic group (Table 5; Fig. 1).

Sensitivity to change

The difference among the preoperative (T1) vaginal symptom score medians, quality-of-life score medians, and postoperative (T3) medians was significant ($p = 0.001$, $p = 0.008$, and $p = 0.018$, respectively). The number of the patients who responded to questions on sexual matters preoperatively (T1) and came for the postoperative 3rd-month (T3) control was low ($n = 8$) (Table 6).

Table 3 Construct validity of the questionnaire

	Patients ($n = 53$)* median (min–max)	Controls ($n = 58$) median (min–max)	*P*
VSS T1	29 (8–48)	3 (0–14)	< 0.001
SMS T1	16 (0–58)	0 (0–16)	< 0.001
QoLS T1	7 (0–10)	0 (0–10)	< 0.001
VSS T2	25 (8–47)	2.5 (0–19)	< 0.001
SMS T2	16 (0–58)	0 (0–54)	< 0.001
QoLS T2	6 (0–15)	0 (0–10)	< 0.001

Max, maximum; min, minimum, *QoLS*, quality-of-life score; SMS, sexual matter score; VSS, vaginal symptom score. T1 test; T2 retest. * SMS, $n = 35$

Table 4 Criterion validity

	POPQ ≤ 1 median (min–max)	POPQ 2 median (min–max)	POPQ 3 median (min–max)	POPQ 4 median (min–max)	P^*
VSS	3 (0–14)	26 (8–36)	24 (10–38)	35 (15–48)	< 0.001
SMS	0 (0–10)	19 (0–58)	32 (0–58)	28 (0–58)	< 0.001
QoLS	0 (0–10)	5 (0–10)	8 (0–10)	10 (0–10)	< 0.001

POP-Q, pelvic organ prolapse quantification; QoLS, quality-of-life score; SMS, sexual matter score; VSS, vaginal symptom score. * Kruskal-Wallis test; the median value of the first stage for each measurement was different from the remaining values, and no difference was found between the remaining values

The effect size values or standardized effect size values for the vaginal symptom score, sexual matter score, and quality-of-life score were 2.55, 2.33, and 1.56, respectively. The effect size (Cohen's d values) indicated that all parts of the questionnaire had a large effect size [14].

Discussion

This study showed that the Turkish version of the self-administered ICIQ-VS is a reliable and valid questionnaire for evaluating vaginal symptoms, sexual matters, and quality of life of patients due to its low rate of missing data, adequate internal consistency, good stability, excellent construct validity, and good correlation with the POP-Q classification in patients with POP.

The POP-Q system classifies prolapse into five grades: grades 0, 1, 2, 3, and 4. The prolapse of patients can be evaluated objectively using the POP-Q grading system [16]. Each patient with POP was evaluated using POP-Q in the clinic, which was easier than filling out a form. Hence, the POP-Q classification system was preferred instead of a questionnaire as a reference test in this study. The correlation of ICIQ-VS with the POP-Q grades was satisfactory. A statistically significant difference was found between the medians of the vaginal symptom score, sexual matter score, and quality-of-life score, especially for grade ≤ 1 and ≥ 2 POP ($p < 0.001$). In the Portuguese validation study, patients with grade 0 and ≥ 3 POP were able to be discriminated using vaginal symptom scores and quality-of-life scores [5]. In the Danish, Sinhala, and Tamil validation studies, a significant correlation was observed between POP-Q grades and all three parameters [6, 8].

Table 5 ICC analysis results in patient and control groups

	Patients ($n = 53$)*	Controls ($n = 58$)
VSS	0.963	0.907
SMS	0.807	0.941
QoLS	0.950	0.918

QoLS, quality-of-life score; SMS, sexual matter score; VSS, vaginal symptom score. * SMS, $n = 35$

The ICIQ-VS was excellent at discriminating symptomatic and asymptomatic patients. In the previous Danish, Portuguese, Sinhala, and Tamil validation studies, the questionnaire was successfully validated [5, 6, 8]. The asymptomatic group consisted of patients who were admitted to the gynecology outpatient clinic and did not have POP, vaginitis, or pelvic inflammatory disease. However, other gynecological pathologies (cyst, myoma, and so forth) could affect the questionnaire score. This was minimized by including patients who underwent the smear screening test and showed no gynecological pathology in the asymptomatic group (30/58). The differentiation between symptomatic and asymptomatic patients was quite successful.

The pretest of the Turkish version of ICIQ-VS in ten patients did not pose any problem. The self-administered questionnaire was also easy for health care professionals. Two patients hesitated to answer the questions on their sex life until they were assured that their information would not be shared. The same problem occurred with three patients in the symptomatic group. They did not share their sex life issues even with the physicians. This was the reason why questionnaires evaluating the effects of POP on sex life were important. In the symptomatic group, 17 of 53 patients stated that they had no sex life. Among these patients, 61% noted that this resulted from their vaginal symptoms, and 39% stated that this was due to other reasons. The asymptomatic group included no such patients.

One limitation of this study was that the number of patients with menopause was higher in the symptomatic group (34/53) than in the asymptomatic group (1/58). Their sex life might have been affected by the menopausal status [17, 18]. Another limitation was that the mean age of the patients was higher in the symptomatic group than in the asymptomatic group (56/46). The age might also have influenced the sex life of patients [18].

The Cronbach's alpha value > 0.7 indicated adequate internal consistency in the symptomatic and asymptomatic groups. In this study, the Cronbach's alpha value was good for the vaginal symptom score and sexual matter score (0.7 and 0.73, respectively).

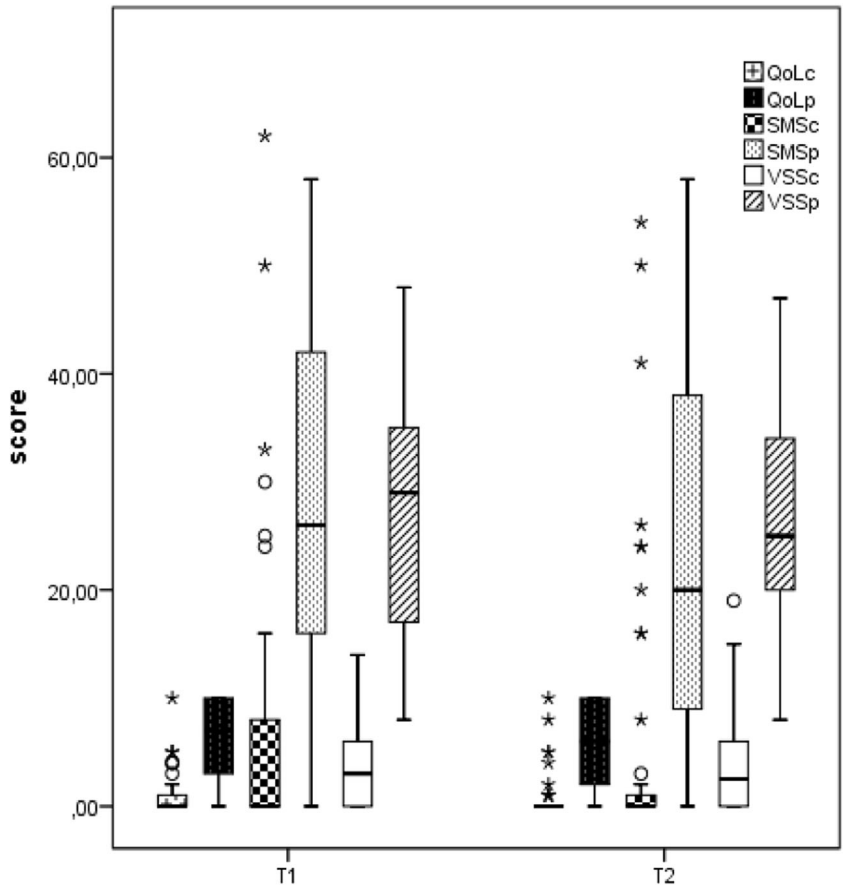

Fig. 1 Test-retest reability. *p* patient, *c* control, *T1* test, *T2* retest, *VSS* vaginal symptom score, *SMS* sexual matter score, *QoL* quality-of-life score

In the validation studies, the average time between the two tests was recommended to be between 2 and 6 weeks to evaluate the test-retest reliability of the questionnaire. In this study, this period was 22.5 days. The ICC indicated a strong significant positive correlation between test and retest values for the three parts of the questionnaire (vaginal symptom score, sexual matter score, and quality-of-life score) in the two groups (Table 5; Fig. 1).

Responsiveness was evaluated with sensitivity to change. The preoperative medians of the vaginal symptom score, sexual matter score, and quality-of-life score were significantly higher than the postoperative 3rd month medians. However, the number of the patients admitted for the postoperative control was only 15. In Portuguese and Tamil validation studies, the sensitivity to change was significantly higher for all three scores [5, 6]. In the Danish study, the sensitivity to change was significantly higher for the vaginal symptom score and quality-of-life score, but it was low for the sexual matter score [8]. In the Sinhala study, the sensitivity to change was enough for the vaginal symptom score and quality-of-life score, but it was not significant for the sexual matter score, and it was even lower in postoperative sexual matters [6]. The effect size of the vaginal symptom score, sexual matter score, and quality-of-life score was > 0.8. This value showed a large effect size

Table 6 Sensitivity to change assessed using the Wilcoxon signed-rank test and effect size (ES)

	n	Preoperative		Postoperative		*P*	ES (Cohen's d)
		Median (min–max)	Mean (SD)	Median (min–max)	Mean (SD)		
VSS	15	33.5 (17–45)	32.6 (9.9)	6 (2–30)	9.3 (9.7)	0.001	2.36
SMS	8	21 (0–42)	21.3 (13.7)	0 (0–9)	1.1 (3.18)	0.018	2.03
QoLS	15	9 (3–10)	7.6 (3.1)	4 (0–8)	3.8 (2.55)	0.008	1.31

QoLS, quality-of-life score; SD, standard deviation; SMS, sexual matter score; VSS, vaginal symptom score. Max, maximum; min, minimum

based on Cohen's classification [14]. The Portuguese validation study yielded similar results [5]. The validated Turkish version of ICIQ-VS could be used to evaluate the postoperative changes in the vaginal symptom score, sexual matter score, and quality-of-life score.

In conclusion, the Turkish version of ICIQ-VS was successfully validated in this study. As a self-administered questionnaire, ICIQ-VS can easily be used by health care professionals to evaluate vaginal symptoms, sexual matters, and quality of life of patients with POP. Also, the questionnaire can be used to measure treatment benefits in clinical practice and research.

Compliance with ethical standards

Conflicts of interest None.

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