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Discriminative Ability of Functional Measures in Knee Osteoarthritis Patients Classified Based on Radiographic Severity

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SUMMARY

Background. Determining the discriminative ability of functional outcome measures among patients of knee osteoarthritis (OA) with different severity degrees of radiographic signs can be valuable for clinicians and researchers to classify the functional limitations in these patients before starting their rehabilitation.

Objective. To determine the discriminative ability of patient-reported outcome measures (PROMs) and performance-based ones in knee OA patients classified based on radiographic severity.

Methods. Based-on the Kellgren-Lawrence (KL) grading scale, 130 knee OA patients were classified into 65 patients with mild (a KL grade ≤ 2) and 65 patients with moderate-to-severe (a KL grade ≥ 3) radiographic sign. PROMs and performance-based outcome measures in knee OA patients were assessed by Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire as well as Timed-up and go test (TUG), Functional Reach Test (FRT), and step test, respectively. The discriminative ability of these measures was determined by calculation of sensitivity, specificity, area under the Receiver Operating Characteristic curve, likelihood ratios, and predictive values.

Results. Our results showed that all subscales of the KOOS except for the sport/recreation and all performance-based outcome measures have good ability to discriminate between the two groups of knee OA. Also, the ADL subscale of KOOS and step test have good ability in accurate identification of mild grade of knee OA patients. The symptoms subscale of KOOS and TUG test have the best ability in correctly identifying moderate-to-severe grade of knee OA.

Conclusions. Our findings provide evidence for the good discriminative ability of functional measures in patients of knee OA classified based on radiographic severity.

KEY WORDS

Knee osteoarthritis; KOOS; performance-based outcome measures; sensitivity; specificity.

INTRODUCTION

Knee osteoarthritis (OA) is one of the most common causes of functional limitations and disability in older adults. It has been reported that knee pain and progressive disability in performing daily tasks are two primary concerns in patients with knee OA (1, 2). OA severity are often defined and graded based on degenerative changes seen in radiographic findings. The Kellgren and Lawrence (KL) classification of OA is a widely used radiographic classification system, wherein standard anterior-posterior radiographs are defined, ranging from mild (grade I) to severe (grade IV) radiographic OA (3, 4). Accordingly, knee OA patients with a KL grade ≤ 2 are considered as mild, and patients with a KL grade ≥ 3 as moderate-to-severe (5).

Assessment of functional limitations in patients with knee OA is frequently done using patient-reported outcome

measures (PROMs) and performance-based outcome measures. PROMs can assess an individual's perception of his/her functional ability, while performance-based outcome measures can measure the actual ability of an individual in performing daily activities (6, 7). These performance-based tests which are usually assessed by timing, counting, or distance methods, are complementary to PROMs. The Knee Injury and Osteoarthritis Outcome Score (KOOS) is a widely used disease-specific outcome measure which is valid and reliable for assessment of patients with knee OA. The KOOS is an expansion of Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire in which in addition to assessing pain and other symptoms, activities of daily living (ADL), quality of life, and sport/recreational activities are assessed (8). On the other hand, there are a number of performance-based outcome measures which assess aspects of balance and mobility of patients with knee OA. These tests are relatively simple, inexpensive and easy to administer in clinical settings (9). Timed up and go test (TUG) is recommended by Osteoarthritis Research Society International (OARSI) as simple test for evaluating mobility in knee OA patients and Functional Reach Test (FRT) and step test are also the most widely used tests for to quantify standing balance in people with knee OA (9-11). However, it is unknown which of these outcome measures is sensitive for discriminating between patients with mild and moderate-to-severe knee OA. The outcome measure that best discriminates between mild and moderate-to-severe knee OA patients could be used as a screening assessment tool to identify the functional limitations in patients of knee OA before starting their rehabilitation and could be valuable for clinicians and researchers to prevent future functional limitations by planning proper rehabilitation treatments (12).

Given the wide spectrum of severity of functional limitations in patients with knee OA (13), determining the discriminative ability of functional outcome measures among patients of knee OA with different severity of radiographic signs can provide a framework for the classification scheme of functional limitations in these patients. As a result, it can help to identify patients who are at risk of developing functional limitations and thus can help to reduce disability and increase independency of knee OA patients in carrying out their normal daily activates by planning proper rehabilitation treatments.

Although some studies have reported that the presence and severity of knee OA is associated with functional limitation (14-21), the ability of these functional outcome measures in differentiating knee OA patients with various degrees of radiographic severity has not been investigated. Thus, the aim of this study was to determine the discriminative ability of these patient-reported outcome measures and performance-based ones in knee OA patients classified based on radiographic severity. To analyze the discriminative ability of these measures, sensitivity and specificity, positive and negative likelihood ratios (PLR and NLR), positive and negative predictive value (PPV and NPV), area under the receiver curve (ROC), and best cutoff score for discriminating between knee OA patients with different severity were calculated (12, 22-24).

METHODS

Study population

A total of 130 patients were diagnosed with knee OA by an orthopedist, based on the classification criteria of the American College of Rheumatology (25). These patients were recruited from outpatient physiotherapy and orthopedic clinics in Ahvaz, Iran were invited to participate after receiving the explanation of the study, and signed written consent. Research is conducted according to international standards and as required by the journal as described in Padulo *et al.* (26). The patients included both male and female Persian native speakers aged between 40-70 years with knee pain and radiological signs of knee OA (unilateral or bilateral) who were able to do daily activity independently. Patients diagnosed with secondary knee OA, rheumatoid arthritis or any concurrent systemic inflammatory disease, hip or knee surgery history, total knee replacement, or hip disorder, were excluded (27, 28). Antero-posterior view of knee radiograph taken in position standing with knee 7-10° flexion (29), was considered as reference standard in this study. The radiological severity of knee OA was determined using KL grading on standard anterior-posterior radiographs by an experienced radiologist who was blinded for test results (3). Based on the KL score (range 1-4), severity of knee OA was categorized into two groups: 65 patients with mild (a KL grade ≤ 2) and 65 patients with moderate-to-severe (a KL grade ≥ 3) radiographic signs. The Ethics Committee at Ahvaz Jundishapur University of Medical Sciences approved the study.

Procedure

Anthropometric information of subjects including age, sex, weight, height, body mass index (BMI) was collected. In this study, measures of functional limitations in knee OA patients which were considered as index tests, were assessed by the KOOS questionnaire as a representative of PROM and TUG, FRT and step test as performance-based outcome measures. In bilateral involvement of knee OA, the side with more severe radiographic sign as the target knee was evaluated.

KOOS questionnaire

The KOOS is a 42-items specific patients-reported outcome measure that assesses five domains: Pain, Symptoms, Function in Activities of Daily Living, Function in Sport and Recreation, and knee-related quality of life. All items are scored by a five-point Likert scale from zero (no problems) to four (extreme problems). The scores of each subscale are calculated separately and transformed to a 0-100 scale, where zero indicates severe knee problem and 100 demonstrates no knee problem (30). The KOOS has good reliability and validity in Persian patients of knee OA (28).

Time up and go test

The functional mobility was determined by TUG test. Based on the standard manner, after the verbal command to begin, patients were asked to stand up from a 46-cm- high chair, walk forward 3 m in a straight line at their habitual walking speed, turn 180°, walk back to the chair and sit down again. Time needed for performing these tasks was recorded in seconds using a chronometer. Prior to its commencement, the test was explained to the patients. This test was repeated 3 times and their average was calculated (27).

Functional reach test

FRT is a single-item test developed as a quick screening test for identifying balance problems in older adults. A yard stick was attached to wall at about shoulder height. Patients stood adjacent to, but not touching, the wall with feet placed shoulder width apart and positioned the arm that is closer to the wall at 90 degrees of shoulder flexion with a closed fist. At this time, an initial reading at the 3rd metacarpal head on the yard stick can be taken. Patients were instructed to reach forward along the yardstick as far as possible without stepping or losing their balance. The practitioner talked a reading on the yardstick of the farthest reach attained by the patient without taking a step. The 3rd metacarpal phalangeal joint was used as marker. The initial reading was subtracted from the final to obtain the functional reach score in cm. The average of three trials was noted (9, 31).

Step test

Step test is evaluated dynamic standing balance which has known reliability and validity. Patients were instructed to stand bare feet on the involved leg and maintain balance on the same leg, while stepping the contralateral leg on a 15-cm step and return it to the floor as quickly as possible in 15 seconds without any hand support. For patients with bilateral knee OA, the knee with more severe radiographic signs was deemed as the involved knee. The test was performed only once. Before starting the test, the patients performed two to three practice steps for familiarization with the test. In cases of balance loss during testing, the number of completed steps until this point was recorded and the test was terminated (11, 32).

Statistical analysis

All data were analyzed using SPSS version 21.0. The level of statistical significance was set at $p < 0.05$. Independent t-test and chi-square test were used for comparison of demographic characteristics between the two groups with differing severity of radiographic signs. Kolmogorov-Smirnov test was used to assess the normality of data distribution. Based on the results of this test, independent t-test was used for comparison of mean values of functional measures between the groups of mild and moderate-to-severe. The ability of each functional measure in distinguishing between the two groups with differing severity of knee OA was examined by determination of sensitivity, specificity, area under the ROC curve (AUC), PLR, NLR, PPV, NPV, and their 95% confidence intervals (22-24). Receiver operating characteristic (ROC) curves were constructed for the analysis of sensitivity and specificity (23). The sensitivity of a test describes its ability in correctly identifying subjects with a condition of interest, whereas specificity is concerned with the ability of a test to recognize the absence of a condition of interest (22, 24).

In this method, the discriminative ability of outcome measures to distinguish between groups was shown using Area under the curve (AUC) for ROC. ROC curve plots sensitivity (true-positive rate) *versus* 1-speficity (false-positive rate) of the entire range of values of functional measures, which is used to determine AUC and the best cutoff score for discriminating between the two groups (23). Values of AUC range from 0 to 1, where 1 indicates excellent discriminative ability of a measure between two groups and 0 indicates failure of a measure in discrimination between groups. A traditional academic point scale was used to classify the accuracy of the AUC: 0.9 to 1 indicating excellent; 0.8 to 0.89 good; 0.70 to 0.79 acceptable; 0.60 to 0.69 poor; and 0.00 to 0.59 indicating failure. The score with the combination of highest sensitivity and lowest 1-specificity was determined as the best cutoff point which was located in the most "northwest" point on the ROC curve (12).

To determine the clinical meaningfulness of tests and the predictive ability of measures in correctly identifying subjects with a condition of interest, PLR and NLR, PPV and NPV, and their 95% CI were calculated at the best

cutoff score determined using the ROC curve, respectively. PLR and NLR are the best indicators for ruling in and ruling out the diagnosis, respectively. PLR more than 10 and NLR less than 0.1 have a significant contribution of the test to the diagnosis for ruling in and ruling out subjects having the disease, respectively (22, 23).

RESULTS

Demographic information of subjects in the two groups of knee OA is provided in **table I**. The two groups were matched with each other in this regard.

Table II reports mean ± SD and P values for each functional measure. The moderate-to-severe group had greater scores than the mild group for all subscales of KOOS and TUG test, but had less values for FRT and step test. As shown, all functional measures were statistically different between the two groups ($p < 0.05$).

The sensitivity, specificity, AUC values, asymptotic significance, best cutoff score, LRs and PVs and their 95% confidence intervals for each measure are represented in **table II**. The results of ROC curve analysis showed that, except for sport/recreation subscale, all KOOS subscales had good ability for discrimination between the two groups of knee OA and also three functional tests had good to excellent accuracy in discrimination between them.

Also, the results of other indicators related to the discriminative ability of these measures showed that among the KOOS subscales, the highest specificity (0.92 (95% CI: 0.82-0.97)) and the greatest PLR (7.8 (95% CI: 3.28-18.5)) and PPV (0.88 (95%CI: 0.74-0.95)) were related to the symptoms subscale while the highest sensitivity (0.89 (95% CI: 0.78-0.95)) and the lowest amount of NLR (0.17 (95% CI: 0.08-0.35)) and NPV (0.85 (95% CI: 0.71-0.93)) were related to ADL subscale. In addition, among the functional tests, TUG test had the highest specificity (0.90 (95% CI: 0.80-0.96)) and the greatest PLR (8.66 (95% CI: 4-18.75)) and PPV (0.89 (95% CI: 0.78-0.95)), and step test had the highest sensitivity (0.93 (95% CI: 0.84-0.98)) and the lowest amount of NLR (0.09 (95% CI: 0.03-0.24)) and NPV (0.91 (95% CI: 0.78-0.97)).

Table I. Demographic information of the study population.

Variable	Mild group (n = 65) Mean (SD)	Moderate to Severe group (n = 65) Mean (SD)	P value
Age (y)	56.2 (6.8)	58.3 (7.1)	0.08
Height (cm)	160.6 (8.2)	159.2 (7.3)	0.27
Weight (kg)	80.3 (12.7)	80.3 (11.1)	1.00
BMI (kg/m²)	31.2 (5.1)	31.8 (4.4)	0.46
Sex	17 (M), 48 (F)	13 (M), 52 (F)	0.40

M: male; F: female.

DISCUSSION

Our results showed that although all subscales of the KOOS except sport/recreation subscale, have good accuracy in discrimination between the two groups of knee OA, the symptoms subscale show the highest specificity and the greatest PLR and PPV, thus it can be useful for confirming the diagnosis of moderate-to-severe grade of knee OA patients. In addition, ADL subscale has the highest sensitivity and the least NLR and NPV and as a result has the best ability for screening for ruling-out moderate-to-severe grade of knee OA patients.

The results also demonstrated that all the performance-based outcome measures have good ability to discriminate between

Table II. Descriptive statistic of functional measures for each group of mild and moderate-to-severe radiographic grades of knee OA.

Outcome measures	Mild group of Knee OA Mean (SD)	Moderate to Severe group of knee OA Mean (SD)	P value
KOOS pain	60.26 (16.53)	42.52 (14.17)	0.00
KOOS symptoms	79.43 (15.02)	56.89 (17.37)	0.00
KOOS ADL	64.75 (19.28)	41.06 (15.60)	0.00
KOOS sport/rec	23.38 (16.39)	13.92 (11.67)	0.00
KOOS QOL	39.07 (21.32)	15.96 (14.69)	0.00
TUG test	9.48 (1.29)	13.21 (2.58)	0.00
FRT test	32.41 (4.23)	27.21 (4.18)	0.00
Step test	13.55 (2.25)	9.47 (2.19)	0.00

Table III. Sensitivity, specificity, area under the curve, P values, cutoff scores, LRs, PVs and 95% CIs for included measures.

Outcome measures	Sensitivity (95% CI)	Specificity (95% CI)	Area under the curve (95% CI)	P value	Cutoff score	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
KOOS pain	0.81 (0.69-0.89)	0.67 (0.54-0.78)	0.80 (0.72-0.88)	0.03	54.5	2.52 (1.74-3.65)	0.27 (0.16-0.46)	0.71 (0.59-0.81)	0.78 (0.65-0.87)
KOOS symptoms	0.60 (0.47-0.71)	0.92 (0.82-0.97)	0.83 (0.76-0.90)	0. 03	59	7.8 (3.28-18.5)	0.43 (0.32-0.58)	0.88 (0.74-0.95)	0.69 (0.58-0.78)
KOOS ADL	0.89 (0.78-0.95)	0.61 (0.48-0.73)	0.82 (0.75-0.89)	0.03	61.5	2.32 (1.68-3.19)	0.17 (0.08-0.35)	0.69 (0.58-0.79)	0.85 (0.71-0.93)
KOOS sport/rec	0.88 (0.76-0.93)	0.44 (0.32-0.57)	0.66 (0.57-0.76)	0.04	27.5	1.61 (1.27-2.03)	0.24 (0.11-0.50)	0.61 (0.51-0.71)	0.80 (0.63-0.91)
KOOS QOL	0.69 (0.56-0.79)	0.76 (0.64-0.86)	0.80 (0.73-0.88)	0.03	22	3 (1.78-4.81)	0.4 (0.27-0.58)	0.75 (0.61-0.84)	0.71 (0.59-0.81)
TUG test	0.80 (0.67-0.88)	0.90 (0.80-0.96)	0.90 (0.85-0.95)	0.00	11.16	8.66 (4-18.75)	0.22 (0.13-0.35)	0.89 (0.78-0.95)	0.81 (0.70-0.89)
FRT test	0.64 (0.51-0.75)	0.78 (0.66-0.87)	0.80 (0.73-0.87)	0.03	29.5	3 (1.82-4.93)	0.45 (0.32-0.63)	0.75 (0.61-0.85)	0.68 (0.56-0.78)
Step test	0.93 (0.84-0.98)	0.66 (0.53-0.77)	0.89 (0.84-0.94)	0.02	12.5	2.77 (1.96-3.91)	0.09 (0.03-0.24)	0.73 (0.62-0.82)	0.91 (0.78-0.97)

CI: confidence interval.

the two radiographic grades of knee OA (AUC: 0.80-0.90). Furthermore, due to having the highest specificity and the greatest PLR and PPV, TUG test has the best ability for correctly identifying and ruling in moderate-to-severe grade of knee OA. On the other hand, step test has the highest sensitivity and the least NLR and NPV; thus, it can help correctly identify mild grade of knee OA and rule out moderate-to-severe grade of knee OA patients.

These findings of the KOOS questionnaire could be explained by the fact that enrolled patients in this study were middle aged/old patients with knee OA which had a low level of sport activities. Given that items of the KOOS Sport/rec subscale involve high level activities which were not part of usual activities of the participants, doing these activities might be difficult for the two groups. Therefore, it could not discriminate between the two groups of knee OA.

In support of this explanation, it was observed that the two groups of knee OA patients showed lower scores in the KOOS Sport/Rec subscale compared with other KOOS subscales, which means that they had more difficulties in the KOOS Sport/Rec subscale compared with others. Therefore, it seems that this dimension of the KOOS does not have the ability to distinguish between different severities of knee OA.

On the other hand, the most common complaints of patients with knee OA are pain and activity limitation and subsequently, limitation in quality of life, and these limitations aggregate with increasing severity of knee OA (18-21, 34). As seen, our results demonstrated that these subscales of the KOOS had good accuracy in discrimination between the two groups of knee OA. Thus, good accuracy of these subscales of the KOOS in discrimination between the two groups of knee OA seems logical.

Although, there is no study on the accuracy of KOOS questionnaire in discrimination between patients with knee OA, the study of the initial validation of KOOS questionnaire by Roos *et al.* (30) showed that items related to sports/recreational subscales were not feasible for 71% of knee OA patients, and were therefore considered as missing data (30, 35). In addition, Peer *et al.* (35) reported that the Sport/Rec subscale had weak-to-moderate reliability and weak construct validity in patients following a total knee arthroplasty. Also, Salavati *et al.* (28) who assessed the validity of the Persian version of the KOOS questionnaire in Iranians with knee injuries, concluded that the test-retest reliability coefficients were high for all subscales except Sport/Rec subscale.

Furthermore, the results of this study showed that the symptoms subscale has the highest specificity and the greatest amount of PLR; thus it has the best ability to confirm

identification of knee OA with moderate-to-severe signs. This result may be justifiable through items within this subscale. Since effusion, morning stiffness, crepitation and limitation of motion are part of hallmarks of patients with knee OA, these symptoms are significantly more important in patients with moderate-to-severe radiographic signs (18). Therefore, the positive result of the symptoms subscale (the score of this subscale was below 59) can be useful for ruling in the moderate-to-severe group of knee OA. Also, the results of the PPV (88%) of the symptoms subscale indicate that if this test is positive, *i.e.*, the score of this subscale is lower than 59 (the optimal cutoff point), with a probability of 88%, the person has the moderate-to-severe grade of knee OA.

On the other hand, among the subscales of the KOOS questionnaire, the subscale of daily activities has the highest sensitivity and the least amount of NLR; as a result, it has the best screening ability in ruling out the moderate-to-severe group of patients with knee OA. Also, the large NPV of this subscale shows that if the test result is negative or the score of this subscale is higher than 61.5, there is an 85% probability that the person will have mild grade of knee OA. The same pattern of findings has also been reported by Collins *et al.* who conducted a systematic review with meta-analysis of the measurement characteristics of the KOOS in people with knee injuries and/or osteoarthritis, and concluded that the subscale of daily activities has better content validity for older patients (36). Also, Gandek *et al.* (37) did a comparative study of the validity and responsiveness of the KOOS questionnaire among total knee replacement patients, and reach the conclusion that the subscale of symptoms and quality of life had the best discriminant validity between comorbid condition groups.

The results of functional tests showed that all three tests have good ability for discrimination between mild and moderate-to-severe groups of knee OA. In addition, among these functional tests, the highest sensitivity, the least amount of NLR, and the greatest NPV were related to step test; as a result it has the best ability for ruling out the moderate-to-severe grade of knee OA. Also, due to the highest specificity and the greatest PLR and PPV, the TUG test, can be useful for confirming the diagnosis of moderate-to-severe grade of knee OA patients.

Since no study has examined the relationship between the severity of knee OA and clinical tests of standing balance, as noted in Hatfield *et al.*'s systematic review and meta-analysis of clinical tests of standing balance in knee OA patients in 2015, no comparison could be made between our results and results of other studies (9). However, it can be noted that the results of the present study are in agreement with previous studies that have examined these functional tests in the knee OA group compared with healthy subjects.

Based on the available literature, the most commonly used clinical test for assessing the standing balance in knee OA patients is the step test (9, 11, 32). According to comparative studies of knee OA patients with healthy older adults, due to the large standardized mean differences in assessing the between group differences, it has been reported that this clinical test may have sufficient sensitivity for detecting and monitoring standing balance deficits (9, 11, 32).

On the other hand, based on previous studies, TUG test is one of the simplest and quickest tests of functional mobility evaluation in knee OA patients, which demonstrates excellent reliability (intra-rater and inter-rater reliability were 97% and 96%, respectively) (27). Also, this test is a predictor of risk of falling in the elderly (38).

Based on the results of present study, the optimal cutoff point for TUG test was determined 11.16 with 80% sensitivity and 90% specificity. In agreement with our results, Shumway-cook *et al.* (38) showed that the TUG test was a sensitive (0.87) and specific (0.87) to identify elder people who are at risk of falling. They stated that the cutoff point of 14-seconds as the optimal cutoff point significantly discriminates between the faller and non-faller groups (38). In 2002, Rose *et al.* (39) identified cutoff point of 10-second with 71% sensitivity and 86% specificity as the optimal cutoff point for discrimination between non-faller and recurrent faller. Also, Barry *et al.* (40) demonstrated that this test with a cutoff point ≥ 13.5 seconds with a higher specificity (73%) than sensitivity could be useful for ruling in individuals at higher risk of falling. Thus, depending on the subjects' characteristics and walking speed, the cutoff score obtained from this test has been reported differently in different studies. Of course, in some of the previous studies, the diagnostic accuracy of this test in correctly classifying individuals as fallers has been reported poor to moderate (41). Since there was no study of discriminative ability of this test in patients with knee OA, we inevitably compared our study results with those of studies on the elderly. Therefore, we recommend future studies on the discriminative ability of functional measures to confirm our findings in patients of knee OA classified based on severity of OA.

Limitations

We only assessed patients with mild and moderate-to-severe grades of OA of tibiofemoral joint and did not investigate patients with other knee conditions (OA of patellofemoral) that may have functional limitations. Thus, future studies may examine the discriminative ability of these measures between patients with OA of tibiofemoral and other knee pathologies. Also, we only assessed the KOOS questionnaire and three functional tests. We recommend examining

the discriminative ability of WOMAC and other functional tests with good reliability and validity (6-min walk test and 30-s chair stand test) for discrimination between the two groups of knee OA patients.

CONCLUSIONS

In brief, all subscales of the KOOS except sport/recreation subscale and all of the performance-based outcome measures (TUG, FRT, Step test) have good ability to discriminate between mild and moderate-to-severe groups of knee OA. Thus, these functional measures could be recommended to be evaluated first for clarifying the severity of functional limitations in patients with knee OA. Based on the results obtained, clinical decisions could be made with the aim of appropriate intervention of these patients. Overall, our findings provide evidence-based information for clinicians and researchers about discriminative ability of functional measures in knee OA patients classified based on radiographic signs.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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