

Development and validation of a questionnaire to measure the severity of functional limitations and reduction of sports ability in German-speaking patients with exercise-induced leg pain

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ABSTRACT

Background Currently, there is no generally agreed measure available to quantify a subject's perceived severity of exercise-induced leg pain symptoms. The aim of this study was to develop and validate a questionnaire that measures the severity of symptoms that impact on function and sports ability in patients with exercise-induced leg pain.

Methods The exercise-induced leg pain questionnaire for German-speaking patients (EILP-G) was developed in five steps: (1) initial item generation, (2) item reduction, (3) pretesting, (4) expert meeting and (5) validation. The resulting EILP-G was tested for reliability, validity and internal consistency in 20 patients with exercise-induced leg pain, 20 asymptomatic track and field athletes serving as a population at risk and 33 asymptomatic sport students.

Results The patient group scored the EILP-G questionnaire significantly lower than both control groups (each $p < 0.001$). Test-retest demonstrates an excellent reliability in all tested groups (Intraclass Correlation Coefficient, ICC=0.861–0.987). Concurrent validity of the EILP-G questionnaire showed a substantial agreement when correlated with the chronic exertional compartment syndrome classification system of Schepis ($r = -0.743$; $p < 0.001$). Internal consistency for the EILP-G questionnaire was 0.924.

Conclusions EILP-G questionnaire is a valid and reliable self-administered and disease-related outcome tool to measure the severity of symptoms that impact on function and sports ability in patients with exercise-induced leg pain. It can be recommended as a robust tool for measuring the subjectively perceived severity in German-speaking patients with exercise-induced leg pain.

BACKGROUND

Exercise-induced leg pain is a well-recognised problem in athletes including a wide range of different aetiologies. Chronic exertional compartment syndrome, medial tibial stress syndrome, stress fractures, nerve entrapment syndrome (local and regional) and popliteal artery entrapment syndrome are the most common differential diagnoses.^{1–3} From current literature, the proportion of the syndromes which constitute exercise-induced leg pain is unclear. In a retrospective study involving 150 patients with chronic leg pain, chronic exertional compartment syndrome was the most prevalent condition with an incidence of 33%.⁴ In contrast, other studies suggest that medial tibial stress

syndrome is one of the most prevalent diagnoses in patients with exercise-induced leg pain.^{5–6}

Pain caused by exercise-induced leg pain occurs predominately in lower legs and affects both recreational and elite athletes.⁷ Besides pain, patients may complain of a wide variety of symptoms including burning, cramp, aching pain, muscle weakness, swelling, paraesthesia, numbness and tightness that adversely affect their physical performance. Athletes can usually predict at which intensity and/or distance the symptoms will appear. The complaints typically disappear within minutes to hours when the provocative activity is stopped.^{2–8–9} The symptoms usually become more severe over time.^{10–11}

Despite the fact that numerous symptoms often overlap, further differentiation of this umbrella term may be difficult.

The differential diagnoses were made using an algorithmic approach including the patient's history, physical examination and if necessary radiographs, compartmental pressure measurements, arteriograms, angiography, bone scans and MRI.²

On the basis of the exercise-induced leg pain aetiology, specific therapy options (conservative and operative) are proposed.

For evaluation of the patient's initial severity of complaint and the efficacy of treatment, disease-related questionnaires are demanded.^{12–13}

A rigorously designed and validated tool to measure the severity of symptoms affecting function and sports ability in patients with exercise-induced leg pain does not exist.

To quantify the severity in patients with chronic exertional compartment syndrome, a few investigators used visual analogue scales.^{11–14–18} An ordinal scaled chronic exertional compartment syndrome-specific measure has been introduced to grade the functional limitations resulting from chronic exertional compartment syndrome-induced pain.¹⁵

The aim of the study was therefore to develop and validate a questionnaire to quantitatively measure the impact of symptoms on function and sports ability in German-speaking patients with exercise-induced leg pain.

MATERIAL AND METHODS

The construction and validation of a questionnaire to assess the severity of functional impairment and limitations in sports ability in patients with exercise-induced leg pain were performed in five steps.

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Step I (item generation): Items that seem potentially suitable to measure the impact of symptoms on function and sports ability in patients with exercise-induced leg pain were generated from a literature review and sport restrictions as documented in our medical records. These items were then subsequently discussed in an expert consensus meeting. The expert committee comprised an orthopaedic surgeon who is specialised in leg, foot and ankle disorders, and a sport scientist who is specialised in medical research studies.

Step II (item reduction): Several of the predetermined items (step I) were found to match with the German version of the foot and ankle ability measure (FAAM-G).¹⁹ The FAAM-G was then reduced and modified to the predetermined items as stated in the expert consensus meeting. One item (running 30 min or longer) was added from our clinical experience resulting in a preliminary 'exercise induced leg pain questionnaire for German-speaking people' (EILP-G).

Step III (pretesting): The preliminary EILP-G questionnaire was completed by a cohort of five patients with exercise-induced leg pain. The participants were then interviewed to assess their individual understanding of the questionnaire's items.

Step IV (expert meeting): On the basis of the feedback from the patients and the investigators who were involved in the pretesting procedure, an expert meeting was conducted again to discuss the preliminary EILP-G questionnaire in terms of conceptual design, questionnaire construction and comprehensibility.

Step V (validation): The final EILP-G was then subjected to psychometric testing including an analysis of validity and reliability in 20 patients with exercise-induced leg pain, a first control group with 33 asymptomatic sport students, and a second control group with 20 asymptomatic persons at risk (track and field athletes). The internal consistency was evaluated in 20 patients with exercise-induced leg pain.

EILP-G questionnaire

The resulting EILP-G questionnaire comprises 10 items ranging from moderate sporting activities to more intensive and persistent ones. In common with the FAAM-G each item is scored on a five-point Likert scale from 4 (no difficulty) to 0 (unable to do), and there is also a 'non-applicable' category. Simple summation provides the total score (40 points). Items without a response or marked as not applicable are not counted. To get a percentage value, the individual's total score is divided by the highest potential score and multiplied by 100. A higher EILP-G questionnaire score represents a higher level of physical function (figure 1, see online supplementary appendix 1).

Subjects and diagnostic criteria

The study protocol was approved by the local ethics committee (Landesärztekammer Hessen) and informed consent was obtained from each participant included in the study. Age and the previous history of disease were noted for all study participants. The reliability and validity of the EILP-G questionnaire were examined in a patient group with exercise-induced leg pain (n=20), in a first-control group including university sport students without any previous leg complaints (n=33), and a second-control group (no previous leg complaints) representing a high-risk target population (track and field athletes, n=20). The patient group was selected from medical files in our institute for sports medicine. The sport students were directly contacted in the local university. The track and field athletes group were directly approached during their training sessions in the local track and field club.

Study subjects were classified as exercise-induced leg pain patients using our own institutional criteria: (1) history of exercise-induced lower leg pain increasing during their specific sport; (2) lower leg pain limiting running ability; (3) symptoms persisting longer than 3 months; (4) symptoms disappearing following a few minutes of rest; (5) diffuse pain, of one or both lower legs and (6) clinical examination, ultrasound investigation and/or radiography was inconspicuous.

Validity testing

For construct validity testing, all participants (n=73) completed the EILP-G questionnaire and the effect of pain on athletic performance was additionally rated by an orthopaedic surgeon (HL) using an established chronic exertional compartment syndrome outcome classification system:¹⁵ excellent—no pain during or after exercise, no limitation of duration and extent of exercise, patient considers himself or herself 'cured'; good—able to compete in sport at desired level of play, minimal discomfort or soreness during and after exercise, significantly improved, glad to have surgery; fair—pain with running/exercise or afterward, still has limitations, recurrence of symptoms, only slight improvement; poor—worse, complications. Even if the instrument is not formally validated, it has been used in studies investigating the outcome of chronic exertional compartment syndrome.²⁰

For face validity testing,²¹ the authors subjectively judged if the EILP-G questionnaire measures an individual's severity of exercise-induced leg pain-induced dysfunction. To improve the confidence of face validity, we assessed each of the EILP-G items for suitability, as compared with the following specific findings from the relevant history of clinical diagnosis of exercise-induced leg pain: (1) exercise-induced pain; (2) symptoms including burning, cramping, aching pain, muscle weakness, swelling and tightness; (3) symptoms disappearing with rest and (4) reduced sports ability.

Reliability testing

For intratester reliability, the patient group (n=20), the track and field athletes group (n=20), and the sport students group (n=33) completed the EILP-G questionnaire two times within 1 week. The intertester reliability was assessed by comparing the results when two authors (TN and HL) randomly administered the EILP-G questionnaire independently in a 1–7 day interval in eight patients with exercise-induced leg pain from the studied group.

Statistical analysis

Statistics were performed using descriptive data analysis as mean, SD and 95% CI. A factor analysis was conducted to test the structure of the EILP-G questionnaire. Reliability testing was performed by Spearman's rank correlation test (ρ) and Intraclass Correlation Coefficients (ICC), type 2.1. Concurrent validity was calculated by Spearman's rank correlation coefficient between the EILP-G score and the Schepsis *et al* grading scale.¹⁵ In addition, SE of measurement ($SEM=SD \times \sqrt{1-\text{test-retest reliability coefficient}}$) and minimal detectable change ($MDC_{95}=1.96 \times \sqrt{2} \times SEM$)² were calculated. Internal consistency for the total score was calculated using Cronbach's α . ICC values >0.75 are considered as excellent, 0.75–0.40 as fair to poor and <0.40 as poor.²² Spearman correlation coefficients were interpreted according to the Koch and Landis terminology:²³ 0.0–0.20=slight, 0.21–0.40=fair, 0.41–0.60=moderate, 0.61–0.80=substantial and 0.81–1.0=almost perfect agreement. Significance level was set at $p<0.05$. All statistical analyses were carried out using SPSS V.15.0 (SPSS GmbH, München, Germany).

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EILP-G (Excercise induced leg pain Questionnaire - German version) Fragebogen zur Bestimmung des Schweregrades bei Sport induzierten, chronischen Beschwerden am Unterschenkel

Liebe Patientin/lieber Patient

Bitte beantworten Sie jede Frage mit einer Antwort (ankreuzen), die ihren Zustand während der vergangenen Woche am besten beschreibt. Bei beidseitiger Symptomatik ist die schlimmere Seite entscheidend für Ihre Antwort. Wenn die angegebene Aktivität durch etwas anderes als durch ihre Beschwerden an der *Knochenhaut/ Unterschenkelmuskulatur* limitiert ist, kreuzen Sie bitte „nicht zutreffend“ an.

Wie starke Probleme haben Sie aufgrund der Reizung Ihrer Knochenhaut/Unterschenkelmuskulatur mit

	Keine Schwierigk.	Leichte Schwierigk.	Mäßige Schwierigk.	Extreme Schwierigk.	Nicht ausführbar	Nicht zutreffend
Laufbelastungsbeginn (Rennen, Joggen)						
Nach ca. 10 min. Rennen, Joggen						
Nach ca. 15 min. Rennen, Joggen						
Nach ca. 30 min. oder länger Rennen, Joggen						
Absprungvorgang (Sprung)						
Landungsvorgang (Sprung)						
Schnelle Start und Stopp Manöver						
Richtungsänderungen, Seitwärtsbewegungen						
Aktivitäten mit niedriger Stoßbelastung (z.B. Gehen)						
Fähigkeit, Sport zeitlich unbegrenzt auszuüben						

Figure 1 Final version of the EILP-G questionnaire.

RESULTS

Unidimensionality of the EILP-G questionnaire

In the principal factor analysis, the Kaiser–Meyer–Olkin measure was 0.877 indicating good sampling adequacy. The Bartlett's test of sphericity ($p < 0.0001$) made it possible to accept the identity of the matrix correlations for the EILP-G score, thus indicating the suitability of the factor analysis. Examination of the screeplot indicates a one-factor solution (figure 2). Principal factor analysis using the total set of 10 items yielded one factor that explained 71.4% of the total variance. The communalities after factor extraction are 0.590–0.942. The correlations between the scores of the 10 items ranged from $r = 0.39$ to 0.88; each $p < 0.001$.

EILP-G study subjects

The tested groups were not homogeneous for age. The exercise-induced leg pain patient group (29.5 ± 11.4 years) was

significantly older than the subjects in the track and field athletes group (21.0 ± 2.6 years), and the sport students group (22.1 ± 2.2 years) (each $p < 0.001$, table 1). There was no significant difference between the track and field athletes group and the sport students group ($p = 0.106$). Exercise-induced leg pain symptom severity as measured with the Schepsis classification system for chronic exertional compartment syndrome¹⁵ shows differences between the patients, the track and field athletes group, and the sport students group (each $p = 0.001$). There was no difference between the track and field athletes group and the sport students group ($p = 0.957$).

EILP-G questionnaire results

Compared to both control groups (track and field athletes group and sport students group), the EILP-G scores for the patient group were significantly lower (each $p = 0.001$). The EILP-G questionnaire outcome showed no difference between the track

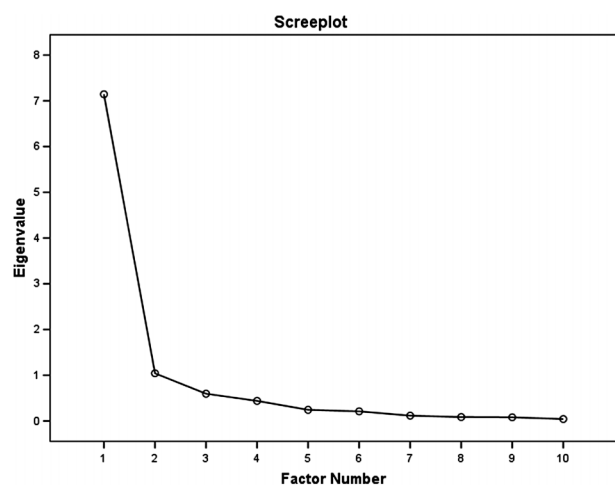


Figure 2 Scree plot of eigenvalues from the 10-item EILP-G questionnaire.

and field athletes group and the sport students group ($p=0.905$, table 1; figure 3).

Validity testing

Face validity

The EILP-G questionnaire was judged as good by the expert committee consensus meeting as all items relating to sport restrictions as documented in our medical records were included in the questionnaire.

Construct validity

The EILP-G questionnaire demonstrates a substantial agreement, when compared with the non-validated chronic exertional compartment syndrome classification system from Schepsis¹⁵ ($r=-0.743$; $p=0.001$).

Reliability testing

Test-retest analysis revealed no significant differences when the participants of the study were evaluated by the EILP-G questionnaire two times within 1 week ($ICC=0.859-0.987$; table 2).

This was also true for the reliability analysis of the individual test items from 1 to 10 ($ICC=0.842-0.976$; $p=0.001$; table 3); The intertester estimation also demonstrates excellent results ($n=8$; $ICC=0.820$, $p=0.001$). SEM was 1.50 for the patients group, 0.88 for the track and field athletes group and 1.59 for the sport students group. The calculated minimal detectable change for the test-retest identified higher differences in the sport students group (4.41 ± 8.67) than in the patients group (4.16 ± 5.54) and the track and field athletes group (2.43 ± 3.97 ; table 2).

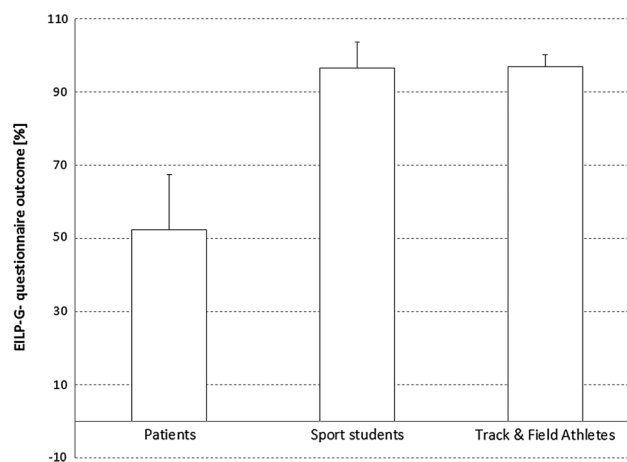


Figure 3 Bar chart demonstrating the distribution of the EILP-G score results in relation to the tested groups.

DISCUSSION

We have demonstrated that the EILP-G questionnaire is an effective clinical measure for exercise-induced leg pain and functional limitations. As a unidimensional patient administered tool it is easy to handle and addresses patient relevant symptoms. It has demonstrated its validity in measuring the severity of exercise-induced leg pain-related impairment. It also shows excellent reliability in all tested groups.

Objectively quantifying the loss of function associated with exercise-induced leg pain is essential for both clinical practice and research. Without such a measure it is impossible to scientifically assess the outcome of any given treatment.¹³ The evaluation of a specific treatment seems to be more effective when both subjective patient assessment and disability-related outcome measures are compared.²⁴ Without such a structured questionnaire different perceived levels of pain related to physical activity are difficult to identify. In terms of exercise-induced leg pain, there are few patient-related and disability-specific assessment tools available to determine the outcome of treatment.^{11 14-18} All previously available patient-assessed exercise-induced leg pain measures have not demonstrated reliability and validity in measuring the impact of pain on function and sports ability. Because clinical trials measure change over time, the adequacy of a patient-related and disability-specific instrument for use in a clinical trial depend on its reliability.²⁵ In addition to reliability, validity is an important criterion for the quality of a given test. A test with high validity will be correlated closely with the test's intended focus. A measurement with a poor validity does not measure the related content.²⁶ Our results demonstrated a substantial agreement between the EILP-G questionnaire and the classification system of Schepsis which was chosen as standard¹⁵ ($\rho=-0.754$; $p<0.001$). This classification system, however, is based on an ordinal scaled

Table 1 Outcome of the EILP-G questionnaire for the study population

	Age (years)			Day 1			Day 2		
	Mean	SD	95% CI	Mean	SD	95% CI	Mean	SD	95% CI
Patients group (n=20)	29.5	11.4	24.1 to 34.8	52.3	15.1	45.2 to 59.4	53.8	15.4	46.6 to 60.9
Sport students group (n=33)	22.1	2.2	21.4 to 22.9	96.7	7.0	94.2 to 99.1	95.9	6.0	93.8 to 98.2
Track and field group (n=20)	21.0	2.6	19.7 to 22.3	96.9	3.3	95.3 to 98.4	97.3	3.0	95.8 to 98.7

Table 2 Results of reliability testing of the 10 EILP-G items

	Spearman's rho	p Value	ICC	p Value	Wilcoxon	Cronbach's α	MDC	SEM
Test-retest Patients group (n=20)	0.989	<0.001	0.987	0.000	0.367		4.16±5.54	1.50
Test-retest Sport students group (n=33)	0.836	<0.001	0.859	0.000	0.441		4.41±8.67	1.59
Test-retest Track and field group (n=20)	0.867	<0.001	0.861	0.000	0.197		2.43±3.97	0.88
Internal consistency Patients group (n=20)						0.924		

ICC, Intraclass Correlation Coefficient; MDC, minimal detectable change; SEM, SE of measurement.

classification system, which was originally constructed to measure the outcome of a given treatment and not as an overall measurement.

Our exercise-induced leg pain patient group was older than both control groups, which was simply a matter of patients' recruitment. We selected the patients from medical files in our institute for sports medicine as they presented. However, comparing other studies dealing with exercise-induced leg pain, the mean age was comparable.^{15 27 28}

The EILP-G questionnaire is not a 'diagnostic tool' nor does it actually play a role in decision-making in respect of treatment for patients. Therefore, before administering the EILP-G questionnaire to patients, the diagnosis has to be established.

A weakness of the study is the small numbers within the study groups, although the numbers within those groups allow for valid comparisons. Another limitation is the use of the Schepisis *et al*¹⁵ classification system for calculating the construct validity. That scale was actually constructed to measure the outcome of a specific treatment and has previously been used in clinical chronic exertional compartment syndrome research.^{20 29} However, its validity and reliability in patients with exercise-induced leg pain have not yet been proven. The responsiveness of the EILP-G questionnaire as a measurement over time has to be evaluated in future investigations. The EILP-G questionnaire should be validated for specific syndromes constituting exercise-induced leg pain like chronic exertional compartment syndrome or medial tibial stress syndrome. Also further cross-cultural adaptations and validations (especially an English version) are needed to promote well-designed internationally comparable clinical research on exercise-induced leg pain.

CONCLUSIONS

The EILP-G questionnaire is a patient-related tool to measure the severity of symptoms on function and athletic performance

Table 3 Results of reliability testing of the EILP-G questionnaire

	Spearman's r	p Value	ICC	p Value
Question 1	0.886	<0.001	0.944	0.000
Question 2	0.976	<0.001	0.976	0.000
Question 3	0.942	<0.001	0.952	0.000
Question 4	0.964	<0.001	0.967	0.000
Question 5	0.878	<0.001	0.932	0.000
Question 6	0.813	<0.001	0.842	0.000
Question 7	0.931	<0.001	0.947	0.000
Question 8	0.919	<0.001	0.951	0.000
Question 9	0.861	<0.001	0.890	0.000
Question 10	0.909	<0.001	0.963	0.000

ICC, Intraclass Correlation Coefficient.

What are the new findings

- ▶ The EILP-G questionnaire is a patient-related tool to measure the severity of symptoms on function and athletic performance in German-speaking patients suffering from exercise-induced leg pain.
- ▶ The questionnaire is clearly structured, easy to understand and quick to complete.

What is the impact on clinical practice in the near future

With the implementation of the EILP-G questionnaire in the clinical practice, objectively quantifying the loss of function associated with exercise-induced leg pain will be possible.

in German-speaking patients suffering from exercise-induced leg pain. To date it is not condition specific. The questionnaire is clearly structured, easy to understand and quick to complete. The validity and reliability analysis of the EILP-G questionnaire demonstrated good results.

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Contributors TN and HL conceived the study, participated in its design, performed data acquisition, analysed and interpreted the data, drafted the manuscript and revised it critically for important intellectual content. NP and JK conceived the study, participated in its design, interpreted the data, and revised it critically for important intellectual content and English grammar. All authors read and approved the final manuscript.

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Ethics approval Landesärztekammer Hessen.

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