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Validation, Intrarater and Interrater Reliability Study of the Lateral-Anterior Drawer Test for Detecting Posterior Cruciate Ligament Ruptures: Study Protocol of a Prospective Controlled Single-Blinded Cross-Sectional Study

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ABSTRACT

Introduction Commonly used clinical tests for posterior cruciate ligament (PCL) rupture detection exhibit several limitations, thus requiring more precise clinical PCL tests. The lateral-anterior drawer (LAD) test has been proposed as a manually applied testing alternative but not yet been evaluated in vivo.

Methods and analysis Fifteen patients presenting with an MRI-confirmed acute or chronic unilateral PCL rupture and 15 subjects with no prior knee injury in their medical history will be included in this prospective single-blinded cross-sectional cohort study. Three examiners with different lengths of working experience (range 1–30 years), blinded to MRI outcomes and patient history, will use the LAD test on both knees of each participant to test for PCL integrity. Examiners will independently document the PCL status of each knee on a blank case report form. Fleiss-Kappa values will be calculated to investigate whether the LAD test shows clinically significant interrater and intrarater reliability. Furthermore, LAD test outcomes will be compared with MRI which serves as reference standard to check for concurrent validity. Moreover, LAD test accuracy with respect to tester experience will be evaluated.

Ethics and dissemination The study will be conducted in agreement with the World Medical Association Declaration of Helsinki (2013). Ethical permission (EK16-081-0616) to conduct this study was obtained from the review board of the city of Vienna on 1 September 2016. All personal and research data will be used in accordance with the Austrian Federal Data Protection Act and will be anonymised before publication in relevant international peer-reviewed journals.

Trial registrationnumber DRKS00013268; Pre-results.

Strengths and limitations of this study

- ► Timely and accurate clinical posterior cruciate ligament (PCL) rupture detection is of paramount importance in order to protect affected patients from long-term afflictions such as premature cartilage or meniscal degeneration.
- ► The lateral-anterior drawer (LAD) test could be a useful clinical PCL test that overcomes the limitations of commonly used PCL tests such as the posterior sag sign and posterior drawer test.
- ► The present study is adequately powered to detect clinically significant levels of LAD test interrater and intrarater reliability.
- ► This is the first study to provide sensitivity and specificity data as well as positive and negative likelihood ratios of the LAD test.
- ► This is the first study to provide preliminary data on whether experience with the LAD test influences concurrent validity.
- ► The study design takes account of measurement bias and ascertainment bias.
- ► The possibility of spectrum bias cannot be entirely ruled out.
- ► Correlations with other clinical PCL tests are missing from this study.

INTRODUCTION

Compared with anterior cruciate ligament (ACL) ruptures, injuries of the posterior cruciate ligament (PCL) have not received the same diagnostic and scientific attention for a long time.[1] Most likely, this was due to poor understanding of the ligaments' complexity, its definite role[2] and an underestimation of PCL rupture prevalence and incidence. The PCL is nowadays considered an essential knee stabiliser, thus, the importance of sufficient diagnostic testing comes to the fore.[2 3] However, clinical PCL rupture detection can be delayed or even missed, often due to mild symptoms in the acute stage.[4] In the clinical setting, three tests are commonly used for examining PCL integrity: (1) the posterior sag sign (or gravity sign), (2) the posterior drawer test and (3) the quadriceps

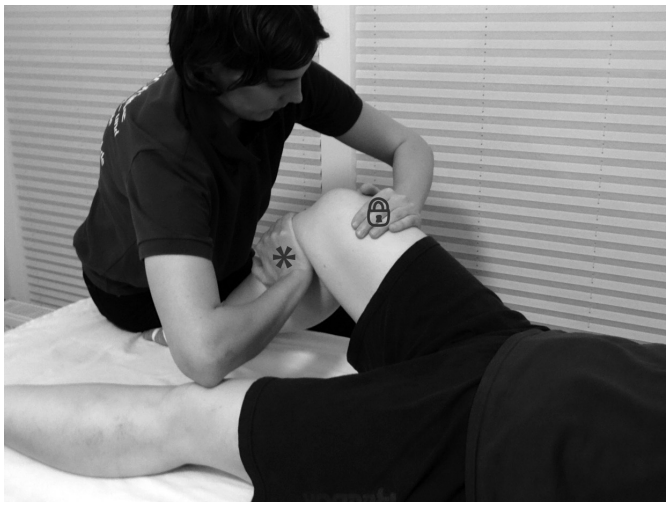

Figure 1 LAD test performance in the clinical setting; *Medial arm pushing proximal tibia in lateral-anterior direction towards Gerdy's tubercle; Lateral hand stabilising the femur in a medial-posterior direction (image taken with journal permission from Seeber *et al*).[7] LAD, lateral-anterior drawer test.

active test.[2] However, these tests are often unable to sufficiently detect PCL ruptures[4–6] necessitating more precise clinical PCL tests.[6]

The lateral-anterior drawer (LAD) test is an adaptation of the lateral-shear test, which was developed by Dr James Cyriax.[7] The LAD test has been introduced as a manually applied testing alternative[7 8] which attempts to resolve the weaknesses of the above mentioned clinical testing procedures. This test examines the knee while positioned in 90° of flexion, with the patient lying supine, so the PCL is aligned nearly perpendicular to the tibial plateau.[9] In this knee position, the PCL is enabled to restrict lateral movement of the tibia versus the femur.[9–12] With respect to the intercondylar eminence, the LAD testing force is applied from medial and slightly posterior (also recognised as medial-posterior) to lateral and slightly anterior (also recognised as lateral-anterior) in the direction of Gerdy's tubercle[7] (figure 1).

Both construct and concurrent validity of the LAD test as a valid measure for identifying PCL integrity have recently been established in a cadaveric study.[7] However, whether the LAD test indeed sufficiently detects PCL ruptures in vivo, and whether it shows clinically significant levels of intrarater and interrater reliability remains to be examined. Furthermore, concurrent validity of the LAD test compared with MRI has not yet been evaluated. Therefore, the main objective of the present study is to investigate if the LAD test reveals a clinically significant level of intrarater and interrater reliability when applied in vivo. Additionally, this study aims to evaluate the concurrent validity of the LAD test. Therefore, test outcomes will be compared with MRI, which is considered the current reference standard in PCL rupture diagnostics, because it shows high correlation with arthroscopic findings.[13–18] Moreover, this study aims to investigate whether differences in LAD test accuracy are subject to the investigator's experience with the LAD test.

METHODS AND ANALYSIS

Study design

This evaluation of validity and intrarater/interrater reliability is a prospective, single-blinded cross-sectional diagnostic phase II study.

Patient and public involvement

Patients and/or public were neither involved in the design of this study protocol nor in the development of the research question. Patients and/or public will not be involved in the recruitment process. Patient participation during data collection is described in detail in sections Preparation procedure and Testing procedure of this study protocol. Participating patients will be asked if they want to be informed about the study results. Those who indicate interest will be sent a result exposé edited in lay language.

Sample size calculation

Donner and Rotondi[19] supply the sample size requirements that achieve a prespecified expected lower limit for the 95% CI about the intraclass kappa statistic κ for the case of multiple raters and a binary outcome variable. Current epidemiological data on PCL rupture suggest a prevalence of 4%–40%.[20] Thus, an adequate estimated prevalence of ruptured PCL in a diagnostic phase II study sample was expected to be 25%. Based on this estimation and on a hypothesised lower limit for the 95% CI of a kappa value of 0.6, at least 55 knees need to be included in order to determine the presence of a clinically significant inter-rater agreement. Therefore, 15 PCL-deficient knees and 45 healthy knees will be included for testing, resulting in a total sample size of 30 subjects. Correspondingly, 15 patients presenting with an MRI-confirmed acute or chronic unilateral PCL rupture and 15 subjects with no prior knee injury in their medical history will be included in the study.

Subject recruitment and inclusion and exclusion criteria

Patients will be recruited from the trauma hospital Unfallkrankenhaus Klagenfurt (Austria) by one of the participating medical doctors according to predefined inclusion and exclusion criteria. Eligible patients need to present with an acute or chronic unilateral PCL rupture as confirmed by MRI scan interpreted by an independent radiologist prior to inclusion. The healthy age-matched and gender-matched control group will be recruited from the staff of the Speising Orthopaedic Hospital (Vienna, Austria). The complete study procedure is depicted in figure 2 and will be discussed in detail in the subsequent sections. In order to take part in this study, participants must fulfil the following inclusion criteria:

1. Age >18 years.

2. Acute* or chronic* unilateral complete PCL rupture (Grade II (complete isolated) or grade III (complete PCL tear combined with other capsular ligamentous lesions) as defined by Raj and Gossmann[21] and confirmed by MRI scan prior to study).
3. Males and females.
4. Signed written informed consent.
5. First-time PCL rupture.

*In this context, acute means <3 months since the initial injury/traumatic incidence; chronic means >3 months must have passed since the injury/traumatic incidence.

Subjects who fulfil at least one of the following criteria are not allowed to participate in this study:

1. Persons not capable of understanding spoken and/or written German.
2. Presence of a total knee arthroplasty.
3. Previous ACL and/or PCL operations at one or both knees.
4. Stroke or other neurological conditions that impair lower extremity function (eg, spasticity).
5. Any other surgery of knee-related structures.
6. Any restrictions in the lower extremity joints limiting the possibility to achieve the LAD testing position of 90° flexion and neutral rotation.
7. Patients not able to lie supine.
8. Pregnancy.

Since the PCL is often torn with concomitant injuries, for example the posterolateral capsule (PLC) and/or the medial collateral ligament (MCL),[2] patients presenting with such injuries will not be excluded. Instead, the radiologist will document any concomitant knee injuries or degenerative changes observed on the MRI, where special focus will be placed on coexistent PLC and MCL injuries.

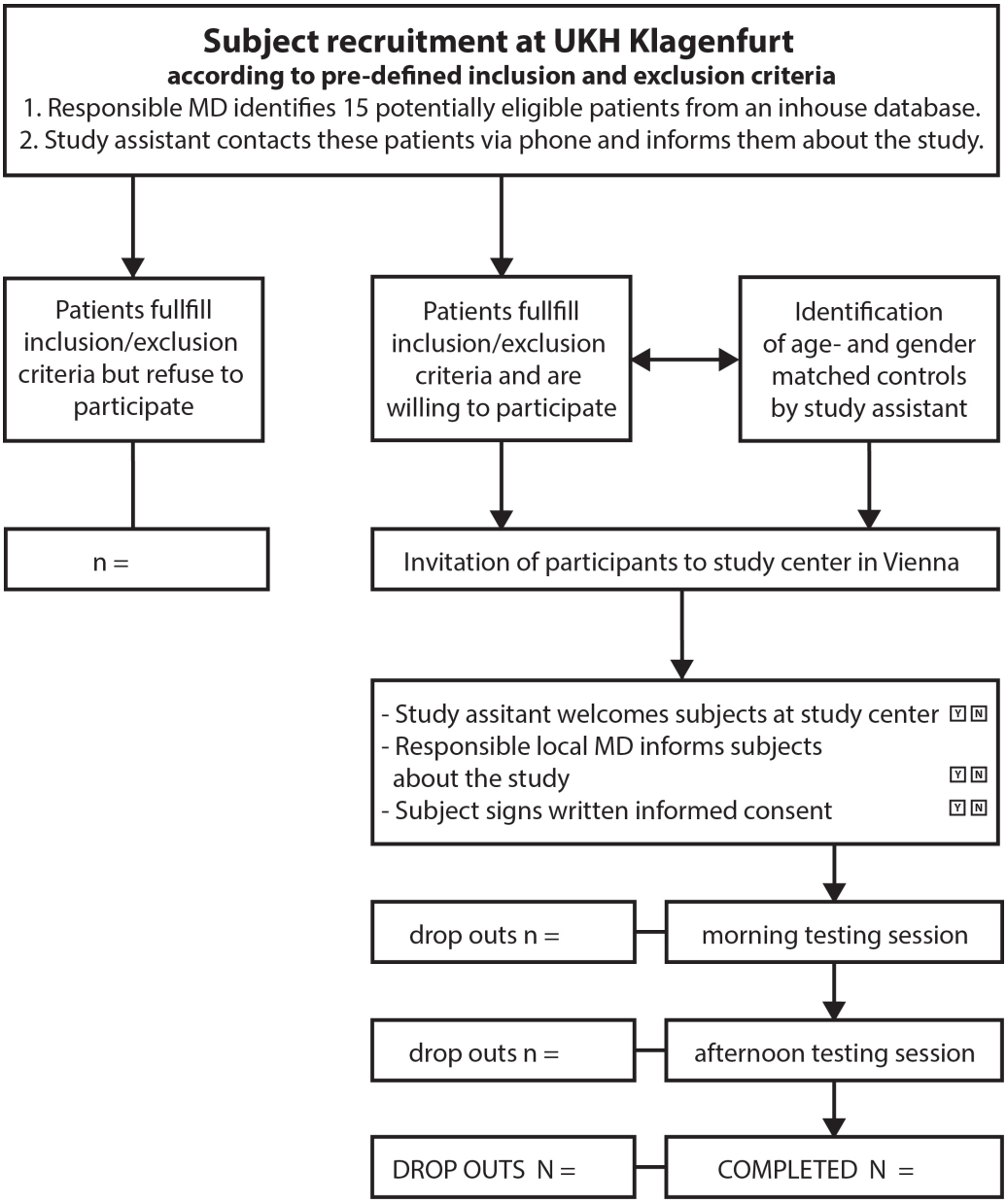

Figure 2 Flow of participants through the study.

Preparation procedure

The names of eligible patients will be recorded on a recruiting list at the study centre at Unfallkrankenhaus Klagenfurt. Subsequently, those patients will be called by an independent study assistant who will inform them about the study and ask if they are interested to participate. Those interested will be marked on the list. At the end of patient recruiting, the study assistant will enrol gender-matched and age-matched healthy subjects from the staff of the Speising Orthopaedic Hospital in Vienna. The study assistant will schedule patients and healthy subjects for examination on an extended weekend. At the time of appointment, the patient will be (1) received by the independent study assistant, who (2) informs the patient about relevant details of the process (eg, not to talk to the examiner at any time) and (3) guides the patient to the examination rooms after having him/her sign the written informed consent form. The patient will then be placed on the treatment table as follows:

1. Supine position.
2. Lower extremities undressed to the skin (all patients are asked to wear shorts).
3. Lower extremities prepositioned by the study assistant as required for LAD testing.

For LAD testing, the knee is required to be aligned in 90° of flexion. This will be measured using a standard goniometer. In order to achieve neutral tibial rotation, the second metatarsal will be aligned in the parasagittal plane. In order to avoid any personal contact between the examiner and the patient/subject, the participants will be hidden behind a curtain. Only the participants' feet will be visible to the examiner. The study assistant will not play any role in the judgement of either the index test or the reference test, nor in data analysis.

Testing procedure

Three different examiners (all of them licensed physical therapists) with varying professional experience (1 year vs 8 years vs 30 years) will independently examine both knees of each individual participant. Since we also report on intrarater reliability, all patients will be tested two times, once in a morning session and once in an afternoon session. All examiners will be blinded to the respective participant's MRI scan, which has been evaluated prior to study inclusion by an independent radiologist. As soon as the patient is placed properly, the first examiner enters the room. Order of tester appearance will be randomised for both testing sessions (morning and afternoon) using a random number table.[22] Additionally, the order of patient appearance will be randomised for the afternoon session in order to avoid testers recalling their first choices during the morning session. On entering the room, the first examiner picks a slip of paper. The words LEFT KNEE or RIGHT KNEE will be written on the backside of the paper. This guarantees that the knees of each patient will be examined randomly. The independent study assistant will monitor this procedure. Subsequently, the examiner will position himself in a sitting position on the patient's forefoot to gently fix it to the treatment table. In order to accurately perform the LAD test, the examiner will place his hands as follows: the lateral hand will be placed laterally onto the distal end of the femur being careful not to deform the iliotibial band. The heel of the fully pronated medial hand will be placed onto the posterior medial aspect of the proximal tibia. The forearm will be oriented towards Gerdy's tubercle. The examiner's fingers encompass the anterior tibial border. After correct hand positioning, the examiner pushes the tibia repeatedly in lateral-anterior direction and pulls it back again in medial-posterior direction in order to move through the entire range of motion. After doing so for 10 repetitions, the examiner notices the amount of lateral-anterior motion. Next, the examiner changes to the other side to perform the LAD test in the same way. Having the direct side-to-side comparison, the tester determines the knee presenting with a PCL rupture by marking one of the following categories on a standardised case report form: (1) right PCL intact or right PCL ruptured and (2) left PCL intact or left PCL ruptured. Subsequently, the examiner leaves the room. Prior to the arrival of the next tester, the study assistant repositions the patient correctly. Without getting in contact with the previous examiner, the second investigator enters the room and proceeds as described. Following that, the third examiner will assess the patient. A new blank case report form will be used for every tester and patient. Each tester will wait in a separate room to be picked up by the study assistant. Raters are not allowed to use cell phones and computers during data collection at any time. Any contact between testers is thus avoided.

Data analysis

Data analysis will be performed using SPSS (V.24; IBM Corporation, Armonk, NY). Descriptive statistics will be obtained for overall sample characterisations. Interval-scaled variables (eg, height, weight, age) will be shown as mean and SD. Nominal data (eg, sex) will be shown as per cent values. LAD test outcome criteria (positive vs negative) will also be shown as per cent agreement (yes vs no). In order to answer the main question of the present study, Fleiss' kappa values will be calculated. To sort out whether there is a significant clinical agreement of LAD test and MRI outcome, the sensitivity, specificity, positive and negative likelihood ratio will be calculated and displayed in a 2×2 table. To clarify whether there is a correlation between LAD test outcome and tester experience, sensitivity, specificity, positive and negative likelihood ratios will be calculated for each tester separately. Cases with either missing index test results or missing reference test results are not expected to occur within this study.

ETHICS AND DISSEMINATION

The study will be conducted in agreement with the 2013 World Medical Association Declaration of Helsinki.[23] In accordance with these ethical principles, the review board of the city of Vienna was informed about the study

and asked for a written approval. Additionally, this study was registered in the German Trials Register (DKRS) under DRKS00013268. Participation in the study will be voluntary. Signing a written informed consent prior to testing will be mandatory for all study participants. Regarding personal data and research data management, the Austrian Federal Data Protection Act will be respected. All data will be protected from unauthorised access. For the sake of pseudonymization, every participant will be assigned a consecutive number depending on time of testing. During study duration, all collected (personal) data will be transferred into a database and stored under this personal number. A master list with the names of the study participants will be used so to be able to associate each number with the matching patient. Unauthorised individuals will not have access to the master list and/or study data as access will be secured by the statistician (JH). The master list will be stored separately from study data and will be kept until data collection and data analysis are completed. Once data collection and statistical analysis are fully completed, the master list will be completely deleted to ensure that no post hoc links can be drawn to specific persons anymore. No other than the anonymised data will be used for publication of the study results in an international peer-reviewed journal.

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Contributors GHS, CT and OM designed the study. JH did the sample size calculation. GHS wrote the first draft of the manuscript. GHS, CT and OM created the final version of the manuscript. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient consent Not required.

Ethics approval Ethical permission (EK16-081-0616) to conduct this study was granted on 1 September 2016.

Provenance and peer review Not commissioned; externally peer reviewed.

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