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## **Original article**

Validity of the lever sign test for the clinical diagnosis of anterior cruciate ligament tears:

#### assessments in ski resorts.

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## ABSTRACT

**Introduction**: The clinical diagnosis of an anterior cruciate ligament (ACL) tear is based on 3 tests: anterior drawer, pivot shift and Lachman. The latter is the most commonly used test. The "lever sign" is a new clinical test that was first described by Lelli et al. in 2014. The primary objective of this study was to determine the sensitivity of the lever sign test for the clinical diagnosis of ACL tears, in the primary care setting of patients with acute knee injuries. Primary care being the first point of contact between patients and the healthcare system (general practitioners in this study). The secondary objective was to calculate the positive predictive value (PPV) of the lever sign test, by comparing it to the PPV of the Lachman test and its sensitivity. The working hypothesis was that the sensitivity of the lever sign test was equal to or greater than 80%.

**Methods**: This prospective cohort study included patients with ski-related knee injuries which occurred in French ski resorts between December 1, 2019, and March 15, 2020. The Lachman test and the lever sign test were performed by 36 mountain physicians and were compared to the magnetic resonance imaging (MRI) findings. The lever sign test involved placing a closed fist under the patient's calf in the supine position and applying downward pressure over the quadriceps. Depending on whether the ACL was intact or not, the patient's heel would either rise off the examination table or remain still. This study included 258 patients: 190 women and 68 men.

**Results**: The MRIs found 219 ACL tears and 36 intact ACLs. Three MRIs were deemed uninterpretable. The sensitivity of the lever sign test was 61.2% and the PPV was 83.8%. The sensitivity of the Lachman test was 99.1% and the PPV was 86.5%.

**Conclusion**: This study determined the sensitivity of the lever sign test for the clinical diagnosis of ACL tears during real-life situations encountered by mountain physicians. This sensitivity was lower than expected. The Lachman test, on the other hand, showed a very high sensitivity. It remains the test of choice for the clinical diagnosis of ACL tears in patients with knee injuries. Therefore, the lever sign test can complement the Lachman test but is not a substitute for it.

#### Level of evidence: II

Keywords: anterior cruciate ligament; ACL; lever sign test; Lachman test.

#### **1. INTRODUCTION**

An anterior cruciate ligament (ACL) tear is a serious knee injury that is often sustained during accidents in ski resorts. The accident monitoring center of the *Association Médecins de Montagne* [French Mountain Physicians Association] tallied 110,791 ski-related injuries during the winter of 2019–2020, with 15% of these being ACL tears. The indication for

surgery has been constantly increasing over the years [1]. Early diagnosis is necessary to optimize the management strategy and avoid the risks associated with delayed diagnosis, especially chronic knee instability and its consequences: meniscal and chondral injuries and early onset osteoarthritis [2,3,4].

The diagnosis of a torn ACL is currently based on 3 clinical tests: Lachman, anterior drawer and pivot shift. However, several factors can interfere with these tests during the examination following acute trauma, specifically pain and apprehension. The anterior drawer has a sensitivity of 49% (95% confidence interval (CI); 0.43–0.55) and a specificity of 58% (95% CI; 0.39–0.76), the pivot shift has a sensitivity of 32% (95% CI; 0.25–0.38) and a specificity of 98% (95% CI; 0.96–0.99), and the Lachman test has a sensitivity of 85% (95% CI; 0.83–0.87) and a specificity of 94% (95% CI; 0.92–0.95) [5]. The pivot shift test is difficult to perform by a relatively inexperienced examiner, especially in the acute setting, and the Lachman test is impossible to perform when the examiner has small hands that cannot properly grasp the thigh or leg of muscular or obese patients.

The lever sign test was first described by Lelli et al. in 2014 [6] and seemed promising since the authors reported that it was easier to perform than previous tests and had a sensitivity and specificity of 100%. Since then, other authors have investigated this test [7–17] with variable outcomes despite the fact that these assessments were performed in specialized knee surgery centers. Two meta-analyses [18,19] reported some reservations about the validity of this test: it should be assessed in a primary care setting, a majority of women should be included (only 28% in previous studies), it should be performed without anesthesia to better mimic the conditions under which patients are usually treated, and biases should be minimized as much as possible (sample size, inclusion of patients whose ACL status is unknown, examiners blinded to arthroscopic or magnetic resonance imaging (MRI) results, etc.).

In this context, it became apparent that a large-scale study needed to be carried out to investigate the validity of the lever sign test in a population consulting in the primary care setting.

The primary objective of this study was to determine the sensitivity of the lever sign test for the clinical diagnosis of ACL tears, in the primary care setting of patients with acute knee injuries. The secondary objective was to calculate the positive predictive value (PPV) of the lever sign test, by comparing it to the PPV of the Lachman test and its sensitivity.

The working hypothesis was that the sensitivity of the lever sign test was equal to or greater than 80%.

#### 2. MATERIALS AND METHODS

#### **2.1. Study population**

The data collection of this prospective cohort study began on December 1, 2019, but had to be prematurely stopped on March 15, 2020, because of the COVID-19 pandemic and the lockdown imposed by the French government as of March 16, 2020. Thirty-six ski resort physicians were involved in populating the database. The inclusion criteria were patients aged 18 and over who were living in France, recent unilateral knee injury (less than 7 days) with clinical suspicion of ACL injury (cracking, instability, apprehension, effusion) and a normal X-ray. Exclusion criteria were a history of ACL tear or previous ACL graft in the studied knee, associated fracture, polytrauma, life-threatening emergency, peripheral knee ligament tears, and MRI contraindications.

The number of subjects to enroll in the study was calculated at 816 patients, taking into account an expected sensitivity for the lever sign test of 80% and an estimated 50% of patients lost to follow-up.

During this period, 373 patients were assessed, 8 were excluded, and 107 were lost to followup. In the end, 258 patients had a complete record, which included an initial physical examination and an MRI (Figure 1).

Following the guidelines for good clinical practice, all enrolled patients were informed of the study design. This was given to them in writing in the patient information leaflet during the inclusion. Patients could withdraw from the study, at any time and for any reason, by directly contacting the coordinating investigator. All personal data collected by the examining physicians were anonymized. The study was approved by a French institutional review board (*Comité de Protection des Personnes Est 1*) on July 3, 2019, under the number SI 19.05.27.59248 – ID RCB 2019-A01467-50.

#### 2.2 Methods

The recruitment of examining physicians was made possible thanks to the support of the Association Médecins de Montagne. Each physician interested in participating in the study underwent practical training. Their experience using the lever sign test before the start of the study and the estimated number of ACL tears seen during a single winter season were very heterogeneous (Tables 1 and 2). The screening visit took place during the first consultation at a mountain medicine practice. The examining physician conducted the physical assessment by first performing the lever sign test and then the Lachman test. The data collected during this visit were: name of the examining physician, date of the consultation, name and family name of the patient, date of birth, telephone number, sex, side of the knee injury, whether or not the lever sign test was positive, and whether or not the Lachman test was positive. The data entered in the online LimeSurvey (Limesurvey GmbH, LimeSurvey: An open source survey Hamburg, Germany. URL http://www.limesurvey.org) tool. LimeSurvey GmbH, questionnaire by the examining physicians were then anonymized by the principal

investigator. The patients were given a prescription for an MRI at the end of the screening visit which could be performed at the radiology clinic of their choice.

MRI was considered the reference test. Indeed, it is often performed during the management of any suspected ACL tear. Previous research has shown that MRI has a sensitivity of 86.5%, a specificity of 95.2%, a PPV of 82.9%, and a negative predictive value (NPV) of 96.4% [20]. Once the MRI was performed, the patient sent a copy of the imaging results to the principal investigator who compared them with the data from the physical examination. Patients were then classified into 4 groups: true positives, false positives, true negatives and false negatives. Four groups were also established for the Lachman tests using the same classification scheme. The lever sign test was performed with the patient placed in the supine position on a hard surface like the X-ray table. The examining physician stood on the side of the injured knee and placed a closed fist under the proximal third of the leg (Figure 2). Downward pressure was then applied with the other hand on the distal third of the thigh. The lever sign test was said to be negative if the heel lifted off the table surface, which was indicative of an intact ACL. The vertical downward pressure applied to the femur was transmitted to the tibia by the ACL which caused the heel to rise due to the lever mechanism created by the fist. The test was said to be positive if the heel remained on the table despite the pressure applied to the thigh, which was indicative of an ACL tear.

The Lachman test was also performed in the supine position with the examiner standing on the side of the injured knee. Holding the distal end of the femur with one hand while the other grasped the proximal end of the tibia, the examiner pulled the tibia anteriorly from the femur with the knee flexed at 20°. The test was considered positive if the anterior translation of the tibia in relation to the femur had a soft or delayed endpoint when compared with the uninjured leg. The statistical analysis consisted in assessing the sensitivity and the PPV of the lever sign and Lachman tests. The sensitivity was calculated by dividing the number of true positives by the sum of true positives and false negatives. The PPV was calculated by dividing the number of true positives by the sum of true positives and false positives. As for the NPV and specificity, they were deliberately not calculated because the study design did not allow it. Indeed, these 2 diagnostic properties cannot be interpreted when no true negatives are included. A t test was used to compare the quantitative data and a chi-square test to compare the qualitative data. Statistical analyses were performed with Jamovi 1.0.7.0 software.

#### **3. RESULTS**

#### **3.1. Study population**

Among the 258 patients who had sent in their MRI results, there were 190 women (73.6%) and 68 men (26.4%). The mean age was  $42.2 \pm 13.4$  years (18–72). The "lost to follow-up" group was not statistically different from the study group (Table 3).

#### **3.2. MRI results**

The MRIs revealed 219 ACL tears (84.9%): 72 partial (32.9%), 107 complete (48.9%), and 40 undetermined (18.2%). The MRIs of 36 patients (13.9%) showed intact ACLs and for 3 others (1.2%) they were inconclusive.

#### **3.3.** Lever sign test

Among the population with usable MRIs: 160 patients (62.7%) had a positive lever sign test and 134 of these (83.8%) had an MRI confirmed ACL injury. Of the 95 patients (37.3%) with a negative lever sign test, 10 (10.5%) had an intact ACL on the MRI (Table 4). The sensitivity of the lever sign test was 61.2% and the PPV was 83.8%.

#### 3.4. Lachman test

Among the population with usable MRIs: 251 patients (98.4%) had a positive Lachman test and 217 of these (85.1%) had an MRI confirmed ACL injury. Of the 4 patients (1.6%) with a negative Lachman test, 2 (50%) had an intact ACL on the MRI (Table 4). The sensitivity of the Lachman test was 99.1% and the PPV was 86.5%.

#### 4. DISCUSSION

The working hypothesis could not be confirmed by this study because the reported sensitivity of the lever sign test was 61.2%.

The sensitivity of the lever sign test was lower than the Lachman test (61.2% vs. 99.1%), but higher than the anterior drawer (49%) and the pivot shift (32%) tests. The PPV results for the 2 tests were comparable (83.8% for the lever sign test and 86.5% for the Lachman test).

Our results regarding sensitivity were similar to those of Jarbo et al. [11] who reported a sensitivity of 63% in their series of 102 patients. The meta-analysis by Reiman et al. [18] considered this to be a high-quality study. Most of the other publications reported a higher sensitivity, ranging from 80% to 100%. This may be due to the fact that the series were collected in orthopedic surgery centers and were therefore not performed in an acute trauma setting as was the case in our study. The lever sign test had a better sensitivity for subacute and chronic injuries, especially since it was performed by orthopedic surgeons specialized in ACL reconstruction. This may also be explained by the appearance of capsular stretching over time, which facilitates clinical diagnosis.

Our PPV results for the lever sign test (83.8%) were similar to 4 other published series [11,13,17,21] that reported rates of 92%, 100%, 82.2% and 88.8%, respectively.

Regarding the performance of this test, all examining physicians received basic training and the median experience in mountain medicine was 5 years, which explained the high sensitivity of the Lachman test performed by these practitioners. They all reported that the test was unpleasant and even painful for the patients, which was contrary to the initial claim that the test was less painful than the Lachman test. They also reported that the positioning of the fist under the leg - more or less near the popliteal space - could influence its positivity.

The study had many strengths. To our knowledge, this was the first study to assess the lever sign test in an emergency setting without general anesthesia. Despite its premature termination because of the COVID-19 pandemic, this study is the largest published on the subject to date. This was the only study to include a majority of women (73.6%), to not put an upper age limit, and to focus on a single sport. The examining physicians who performed the lever sign test were blinded to the MRI results. Finally, the patient response rate was higher than expected (69.2% versus the 50% that was initially expected).

This study also had a few limitations. The examining physicians were instructed to always perform the lever sign test before the Lachman test so as not to be influenced by the result of the latter. If the study had been randomized, the order of the tests would have been randomly assigned. The examining physicians only recently started using the lever sign test, even though it is easier to perform than the Lachman test and has a quick learning curve. Finally, because of its noninvasive nature we chose the MRI as the reference test to diagnose ACL tears. Although this choice is debatable, we found that its specificity and its routine use were sufficient to carry out this study. Laxity measurement devices could be another comparison test but was not included in this study because of its limited use in the primary care setting.

Finally, to determine the exact place of the lever sign test among all the other tests used in diagnosing ACL tears, it would be interesting to compare it to the Lachman test in patients with a high body mass index (BMI) as the circumference of the thigh often makes it difficult to adequately perform the Lachman test.

#### **5. CONCLUSION**

This study determined the sensitivity of the lever sign test for the clinical diagnosis of ACL tears. It used MRI as the reference test and the lever sign test was performed in the primary care setting by mountain physicians. The sensitivity of the lever sign test, calculated at 61.2%, was lower than the expected 80%. The Lachman test, on the other hand, showed a very high sensitivity of 99.1%. Therefore, the lever sign test seems to complement the Lachman test but does not replace it. Further studies are needed to clarify the exact place of this test in the emergency setting, especially in patients with a high BMI where the Lachman test is often difficult to perform adequately.

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#### **Conflicts of interest:**

The authors have declared having no conflicts of interests regarding this article.

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#### Author contributions:

- CB: data collection and analysis of results.
- DL: study conception, design and supervision.
- GD: revision of the article.
- PR: literature review and revision of the article.
- DS: formatting and drafting of the article.

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## Figure and table captions

Figure 1: flowchart

Figure 2: performing the lever sign test.

- On the left: starting position.
- On the right: pressure applied on the thigh and the heel rises.

Table 1: physician experience with the lever sign test.

- Table 2: estimated number of ACL tears seen in one winter season.
- Table 3: demographics of the 2 populations.

Table 4: true positives, true negatives, false positives, false negatives, sensitivity and PPV for the lever sign and Lachman tests.

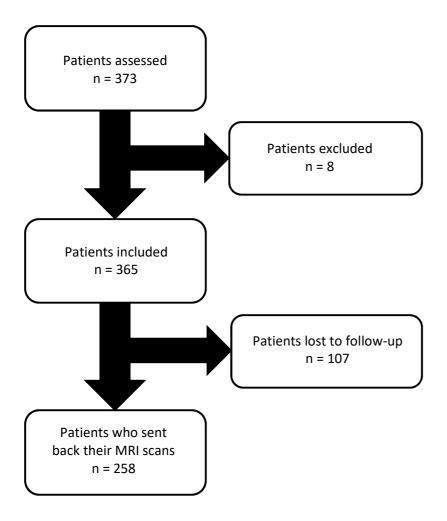




Figure 1

Experience in practicing the lever sign test (in years)	Number of physicians
0	20 (55.6%)
1	9 (25.0%)
2 to 5	7 (19.4%)

Table 1

Estimated number of ACL tears seen in one winter season	Number of physicians
<50	8 (22.2%)
51–100	14 (38.9%)
101–200	8 (22.2%)
>201	6 (16.7%)

Table 2

Variables of interest	Study population	Lost to follow-up	Significance of the difference
Mean age	42.2 years	39.2 years	p = 0.054
Men	26.4% (n = 68)	27.1% (n = 29)	p = 0.956
Women	73.6% (n = 190)	72.9% (n = 78)	p = 0.956
Right side	49.2% (n = 127)	41.1% (n = 44)	p = 0.135
Left side	50.8% (n = 131)	58.9% (n = 63)	p = 0.135

Table 3

	Lever [sign]	Lachman	
True positives	134 (52.6%)	217 (85.1%)	
True negatives	10 (3.9%)	2 (0.8%)	
False positives	26 (10.2%)	34 (13.3%)	
False negatives	85 (33.3%)	2 (0.8%)	
Sensitivity	61.2%	99.1%	
PPV	83.8%	86.5%	
Table 4			

T	a	bl	le	4