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Original article

Diagnostic value of the GNRB® in relation to pressure load for complete ACL tears: A prospective case-control study of 118 subjects

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ABSTRACT

Introduction: The GNRB® is a reliable, validated arthrometer. A pressure pad exerts 0 to 250 Newtons of pressure on the upper calf. The goal of this study was to compare the diagnostic value of the different pressure loads that are usually applied for the diagnosis of complete anterior cruciate ligament (ACL) tears. Our hypothesis was that a load of 200 N would be sufficient to diagnose these tears.
Patients and methods: A prospective comparative case-control study was performed in 2012. One group included all the male athletes aged 15 to 21 who presented with a complete ACL tear confirmed by arthroscopy (the study group). The control group included male soccer players in a training center aged 15 to 19 with no history of knee injuries (the control group). Anterior laxity was measured in both knees by the same experienced operator using the GNRB® system. The main judgment criteria were the diagnostic values of each pressure load evaluated by the area under the curve (AUC), from "Null" (AUC < 0.5) to "Perfect" (AUC = 1).
Results: This study included 118 men: 64 in the study group, mean age 18.1 ± 2.3-years-old, who were mainly soccer players (39/64) or rugby men (16/64) and 54 control subjects, mean age 17.3 ± 1.5-years-old. Three hyperalgesic patients could not receive a pressure load of 250 N. The mean differential laxity was significantly higher in the control group, whatever the pressure load ($P < 10^{-5}$). The test was "highly informative" for all loads ($0.9 \leq AUC < 1$). Analysis of the AUC revealed a diagnostic value in descending order of: 200 N(0.97[0.94–1]) > 134 N(0.97[0.93–0.99]) > 250 N(0.96[0.93–0.99]) > 89 N(0.95[0.90–0.99]).
Conclusion: The GNRB® at 200 N was shown to be sufficient to diagnose complete ACL tears. Applying a pressure load of 250 N does not appear to be useful.
Level of evidence: III-case-control study.

1. Introduction

Quantification of anterior tibial translation is a decisional aid both for initial management and follow-up of anterior cruciate ligament (ACL) tears of the knee.

Several arthrometers are available on the market [1]. The KT-1000™ (MEDmetric®, San Diego, USA) device is the most frequently used because it is simple to use. The Rolimeter™ (Aircast, Summit, USA) is as reliable as the KT-1000™ [2], but both are operator-dependent [3,4]. The radiological Telos™ stress device (Gmbh Hungen/Obbornhafen, Germany) seems to be more precise than the KT-1000™ [5], however it is expensive and exposes the patient to radiation.

The GNRB® (Genourob, Laval, France) is a simple, non-invasive arthrometer with no radiation exposure. It provides comparative bilateral measurement of knee laxity with 0.1 mm accuracy. Different studies have shown that measurements obtained with this system are reliable and reproducible [6,7]. A pressure pad exerts 67 to 250 Newtons of pressure on the upper part of the calf. Recording of anterior translation of the anterior tibial tubercle in relation to the femur at each pressure load determines the drawer shift/pressure curve whose slope defines ligamentary laxity. Data analysis is digital.

The pressure load to be applied by the pressure pad is decided by the operator. Different published studies show that there is no consensus on the pressure load that should be applied. The manufacturers used 134 N to validate the GNRB® like the KT1000™

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and felt that a pressure load of 200 N was necessary to obtain good reproducibility of measurements in knees with ACL tears [6]. A maximum pressure load of 250 N was used in the clinical study of ACL tears and 200 N of pressure load was considered to be the threshold necessary to obtain good reproducibility of measurements in injured knees [6]. Di Iorio et al. [8], Lorbach et al. [9], and Morice et al. [10] applied a maximum pressure load of 134 N while Vauhnik et al. [11,12], Beldame et al. [13], Jenny and Arndt [14] and Pierrat et al. [15] applied a maximum pressure load of 250 N.

Daily clinical practice shows that applying 250 N of pressure can be impossible in hyperalgesic patients, or even be harmful during postoperative follow-up. Beldame et al. [13] could only exert 250 N of pressure in 133/157 patients because of the pain caused by the test. Vauhnik et al. [12] were unable to reach 250 N in 2/15 healthy subjects for the same reason. The goal of this study was to determine the optimal pressure load necessary for the diagnosis of complete ACL tears by analyzing the diagnostic value of the different loads that are usually applied during this test. Our hypothesis was that 200 N of pressure load would be sufficient.

2. Patients and methods

A comparative prospective case-control study was performed in 2012. This study was approved by an ethics committee (Comité de Protection des Personnes IDF VI) as a non-interventional study.

2.1. Patient inclusion and exclusion criteria

One group included all male athletes aged 15 to 21 who presented with a complete ACL tear confirmed by arthroscopy and with an indication for ligamentoplasty (the study group). The contralateral knee was healthy. Partial tears were excluded. The control group included male soccer players in a training center of the Fédération Française de Football (Paris Saint-Germain club), aged 15 to 19 with no history of knee injury (the control group).

2.2. Methods of measurement

Preoperative anterior laxity was measured in both knees in the "study group" and during the preseason evaluation in the "control group". Measurements were obtained with the GNRB® device by the same physical therapist who had 4 years experience with this arthrometer. The operator began with the healthy knee and applied 89, 134, 200 then 250 Newtons of pressure. The knee was flexed at 20° with 0° rotation. The test could be stopped at the patient's request in case of intense pain. Results were recorded on a separate computer. Three automatic measurements were taken for each level of pressure and the mean of the three was recorded.

2.3. Statistical analyses

Normal distributions were determined by the Shapiro-Wilk test. If the distribution was normal, the parametric Student *t*-test was used for quantitative variables. Otherwise, the non-parametric Mann-Whitney test was used. Optimal threshold values of differential laxity in relation to the GNRB® pressure load were determined by the receiver operating characteristic (ROC), with sensitivity on the x-axis and specificity (1-specificity) on the y-axis. This threshold value was chosen to obtain the greatest possible sensitivity (Se) and specificity (Sp) with the highest proportion of correctly classified subjects (P). The positive likelihood ratios (LR+) and the negative likelihood ratios (LR−) were calculated as the diagnostic value of a result increases as LR+ increases (> 10) and LR− decreases and approaches 0 (< 0.1) [16]. The diagnostic value of the tests was evaluated by the ROC area under the curve (AUC) with: null (AUC = 0.5), poorly informative (0.5 < AUC < 0.7), fairly informative (0.7 ≤ AUC < 0.9), highly informative (0.9 ≤ AUC < 1) and perfect (AUC = 1) [17]. $P < 0.05$ was considered to be statistically significant.

3. Results

One hundred eighteen subjects were included during the study period: 64 patients presenting with a complete ACL tear confirmed by arthroscopy (the study group) and 54 soccer players with no history of knee trauma or surgery (the control group). The mean age of control subjects was slightly younger than that in the study group: 17.3 ± 1.5 vs. 18.1 ± 2.3, $P = 0.04$. The mean delay between the accident and the measurements was 4.5 ± 3.8 months, range 15 days to 19.2 months. It was impossible to apply a load of 250 N to 3 hyperalgesic patients. The delay between the accident and the date of the tests in these patients was between 2 and 3 months (in 2 cases). One hyperalgesic patient presented with an intraoperative bucket handle tear of the medial and lateral menisci.

The differential laxity between the 2 groups was always statistically higher in the study group whatever the pressure load (Table 1, Fig. 1). Analysis of the AUC showed that the test was "highly informative" for all pressure loads (Table 2), allowing classification of the diagnostic value of the pressure loads in descending order: 200 N > 134 N > 250 N > 89 N (Fig. 2). The value of the tests was important for all pressure loads (LR+ >10 and LR− < 0.1). At 200 N, the differential laxity threshold value was 1.9 mm with a Se of 92.2%, a Sp of 98.1% and a percentage of correctly classified subjects of 94.9%.

4. Discussion

This case-control study showed that the efficacy of GNRB® at 200 N of pressure was sufficient for the diagnosis of complete ACL

Table 1
Differential laxity according to the GNRB® pressure.

Pressure applied (Newton)	Cases $n = 64$	Controls $n = 54$	P
89 N	2.8 ± 2.1	0.5 ± 0.4	$< 10^{-5}$
134 N	3.3 ± 1.6	0.6 ± 0.5	$< 10^{-5}$
200 N	3.9 ± 1.9	0.7 ± 0.5	$< 10^{-5}$
250 N	4.6 ± 2.4	0.7 ± 0.6	$< 10^{-5}$
Slope	10 ± 7.4	2.5 ± 2.1	$< 10^{-5}$

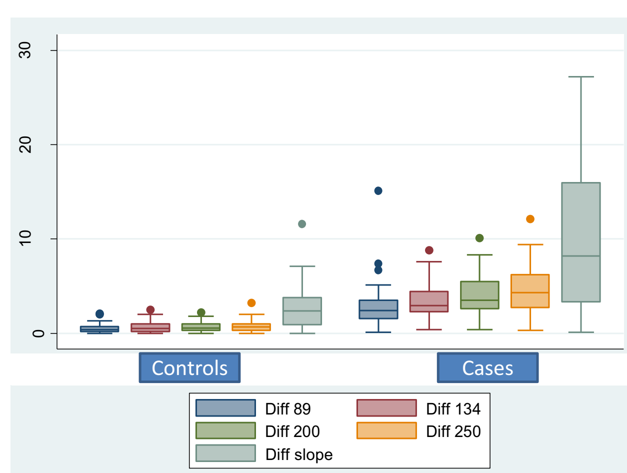

Fig. 1. Median and dispersion of differential laxities according to the GNRB® pressure load. Diff: differential value between the two knees.

Table 2
Diagnostic value of GNRB® according to pressure load.

	89 N	134 N	200 N	250 N
AUC[a]	0.95 [0.90–0.99]	0.97 [0.93–0.99]	0.97 [0.94–1]	0.96 [0.93–0.99]
Threshold (mm)	1	1.5	1.9	2.1
Sensitivity	92.2%	92.2%	92.2%	90.6%
Specificity	88.9%	96.3%	98.1%	98.1%
Percentage correctly classified	90.7%	94.1%	94.9%	94.1%
LR+[b]	8.3	24.9	49.8	48.9
LR−[c]	0.1	0.1	0.1	0.1

[a] Area under the curve.
[b] Positive likelihood ration.
[c] Negative likelihood ratio.

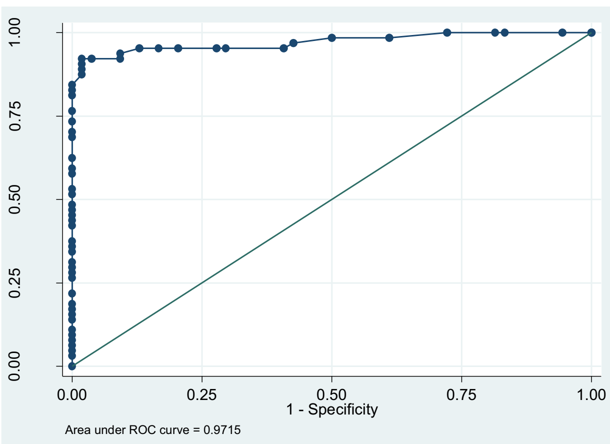

Fig. 2. Receiver operating characteristic (ROC) curve for GNRB® 200 Newtons.

tears. It is sometimes not possible to apply a pressure load of 250 N to hyperalgesic patients.

The reproducibility of the GNRB® system was shown to be better than that of KT-1000™ whatever the level of training of the operator [6,7]. Vauhnik et al. showed that the intraoperator reproducibility of GNRB® is good [12] while the interoperator reproducibility is poor [11]. Jenny and Arndt [14] showed that preoperative laxity measurements with GNRB® were as reliable as dynamic X-rays but significantly less reliable than intraoperative measurements obtained by the navigation system. According to Lefevre et al. [18], the diagnostic value of GNRB® is better than that of Telos™ for partial ACL tears. For Beldame et al. [13] both techniques are comparable for complete ACL tears. The lack of radiation exposure with the GNRB® was mentioned by all authors.

In the first validation study performed by Robert et al. [6] at 134 N the differential laxity threshold value for the diagnosis of partial tears was 1.5 mm (Se = 80%, Sp = 87%) and for complete tears was 3 mm (Se = 70%, Sp = 99%). Beldame et al. [13] found a lower threshold value of 1.5 mm (Se = 62.2%, Sp = 75.9%) for the diagnosis of complete tears with GNRB® 250 N. In our study, the optimal threshold value for the diagnosis of complete tears with GNRB® 134 N was 1.5 mm (Se = 92.2%, Sp = 96.3%) and 1.9 mm with GNRB® 200 N (Se = 92.2%, Sp = 98.1%). The sensitivities and specificities were high.

The manufacturers of GNRB® have emphasized the importance of analyzing the slope differentials to evaluate ligamentary stiffness [6]. Our study showed that the average differential in healthy subjects was low and significantly lower than that of patients presenting with a complete ACL tear.

The main limitation of this study was the lack of evaluation of the diagnostic value of GNRB® 200 N for partial ACL tears. To obtain comparable study cases and controls, we used two groups of young male athletes. In that category of patients, we had too few patients presenting with partial tears to perform an analysis.

5. Conclusion

A pressure load of 200 N was found to be sufficient for the diagnosis of complete ACL tears with GNRB®. It does not appear to be useful to apply a load of 250 N. The optimal differential laxity threshold value for the diagnosis of complete tears with GNRB® 200 N is 1.9 mm with a sensitivity of 92.2% and a specificity of 98.1%.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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