DOI: https://doi.org/10.30795/jfootankle.2020.v14.1213

Special Article

Computed tomography with stress maneuvers for diagnosing syndesmotic instability: a summarized research protocol for a new examination

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Abstract

Syndesmotic instability is a fundamental question that guides treatment; despite the currently available diagnostic imaging tests, its determination is still challenging. Knowledge of the instability degree assists the physician in the decision-making process regarding surgical or nonsurgical treatments. The authors are currently conducting a prospective diagnostic accuracy study by consecutively selecting individuals aged 18 years and older with an orthopaedic clinical examination indicating suspected acute syndesmotic injury. Magnetic resonance imaging is the reference standard used for evaluating the diagnostic accuracy of 3 computed tomography index tests. These tests include the neutral position and 2 ankle stress maneuvers: external rotation and dorsiflexion. Comparative measurements between the injured syndesmosis and the uninjured contralateral side of the same individual evaluate the tibiofibular relationship and investigate syndesmotic instability. This study aims to describe a summarized research protocol for a new technique using computed tomography with stress maneuvers and to show a didactic example of syndesmotic instability diagnosis.

Level of Evidence V; Diagnostic Studies; Expert Opinion.

Keywords: Tomography, X-Ray Computed/methods; Ankle joint/diagnostic imaging; Magnetic resonance imaging.

Introduction

Ligament damage to the distal tibiofibular syndesmosis is a specific type of sprain commonly recognized as a high ankle sprain. Persistent disability and chronic pain are the leading causes of unfavorable outcomes concerning syndesmotic lesions, which frequently demand a significantly more intense treatment and longer recovery times than low lateral ankle sprains[1,2].

In case of syndesmotic disruption, the degree of instability guides decision-making on whether to operate or treat conservatively[3]. The diagnostic tools available to define the correct treatment option include clinical examinations, routine radiographs, stress radiographs, computed tomography in the neutral position (CTNP), weight-bearing computed tomography (WB-CT), and magnetic resonance imaging (MRI). The best current practice considers that clinical diagnosis is supported by limited evidence and that few clinical tests have any validity in recognizing syndesmotic disruption[4]. Identifying the wider articular space on the injured side relative to the contralateral unaffected side may immediately allow the diagnosis of severe syndesmotic instability (SI) on mortise or anteroposterior radiographic views. However, routine radiography may underdiagnose SI when this test demonstrates a normal tibiofibular relationship and it cannot reliably estimate syndesmotic injuries[5]. Stress radiographs are inaccurate for evaluating syndesmotic injuries, as shown in a cadaveric model[6]. Recently, the use of WB-CT (a new imaging test mo-

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How to cite this article: Rodrigues JC, Godoy-Santos AL, Prado MP, Alloza JFM, Amaral e Castro A, Masagão RA, Barros DCS, Nery CAS, Rosemberg LA. Computed tomography with stress maneuvers for diagnosing syndesmotic instability: a summarized research protocol for a new examination. J Foot Ankle. 2020;14(3):243-8.

dality) has emerged in syndesmosis examination; however, a study showed that WB-CT was not superior to CTNP[7], and axial loading did not improve the diagnosis of instability[8]. Although MRI tests have a high accuracy in visualizing and diagnosing syndesmotic injuries[9], they are expensive and not widely accessible. CTNP is more sensitive than radiography for identifying syndesmotic widening[10]; even so, the anterior tibiofibular distance obtained using CTNP has an undesirable area under the receiver operating characteristic (ROC) curve (AUC) performance of 0.56 for diagnosing SI[11].

Despite the utility of all these tests, the correct diagnosis of SI is still difficult to achieve, and syndesmotic disruption and real SI should be differentiated.

Comparative ankle CT with stress maneuvers (CTSM) is an alternative test that might advance SI diagnosis, and to the best of our knowledge, its implementation has not yet been reported. This study is currently in progress, recruiting participants, and for transparency purposes, the authors registered the complete research protocol on *ClinicalTrials.gov* (NCT04095598, pre-results). The authors have also published the complete research protocol, without results, in another medical journal[12]. This article is a summarized version of the entire research protocol, emphasizing the description of the examination technique and adding a didactic example.

Methods

This study was approved by the Institutional Review Board and registered on the Plataforma Brasil database under CAAE (Ethics Evaluation Submission Certificate) number: 62100016.5.1001.0071.

This prospective study of diagnostic test accuracy follows the Standards for Reporting of Diagnostic Accuracy Studies (STARD) guidelines[13]. The Radiology Department of a tertiary hospital is conducting this study in partnership with the Orthopaedics Department. A consecutive sample of participants with suspected syndesmotic disruption visiting the foot and ankle outpatient clinic is being referred to the Radiology Department of the same institution for CT and MRI examinations. Researchers are including participants aged 18 years and older with an episode of ankle sprain having occurred up to 3 weeks before imaging. Patients should also have a positive orthopaedic evaluation for unilateral syndesmotic injury determined as the presence of at least one of the following symptoms: pain during palpation of the distal tibiofibular syndesmosis, pain during manual compression of the tibia and fibula in the middle third of the leg (squeeze test), pain in the external rotation examination, and an inability to stand on the toes of the affected foot. Researchers are excluding participants with bilateral ankle sprains, previous ankle surgery, ankle fractures or dislocations, acquired or congenital ankle deformities, as well as infection, inflammatory, or neuropathic ankle arthropathies. Participants are required to sign an informed consent form, provide demographic data, and complete preexamination forms before undergoing imaging examinations.

Technical parameters for CT image acquisition

An Aquilion ONE CT scanner (Toshiba Medical Systems, Tochigi, Japan) with 320 channels uses the following technical parameters in the examinations: volumetric acquisition, 320-detector rows, medium or large field of view, a high-resolution bone filter, 120 kV, 150 mA, 0.5 s rotation time, 0.5mm slice thickness, and 0.25mm interpolation. The lowest possible irradiation dose produces images of diagnostic quality. The same field of view simultaneously examines the feet of the participants.

Existing index test: CTNP

In this test, one foot is parallel to the other in the neutral phase, and both feet are perpendicular to the long axis of the legs. The knees are in the extended position. Figure 1 (A and B) illustrates the position of the feet during CTNP.

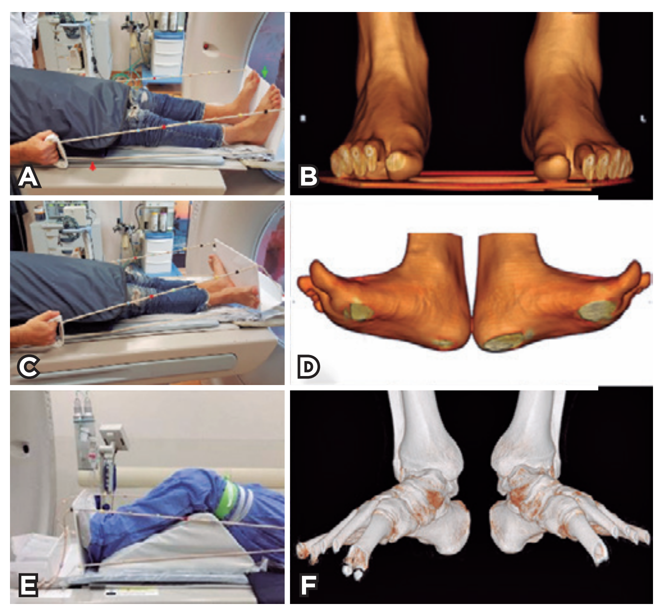

Figure 1. Position of feet during the CT examination. Photograph of a patient undergoing CT in the neutral position (A). A three-dimensional skin surface reconstruction CT image showing the feet in the neutral position (B). Photograph of a patient undergoing CT with ankle stress maneuvers and extended knees (C). A three-dimensional skin surface reconstruction CT image showing the feet with stress maneuvers and extended knees (D). Photograph of a patient undergoing CT with ankle stress maneuvers and semi-flexed knees (E). A three-dimensional bone reconstruction CT image showing the feet with stress maneuvers and semi-flexed knees (F).

New index test: CTSM and extended knees (CTSM-EK)

In the first stress phase, the researchers control external rotation by placing the feet at 45 degrees using an angle meter and a vertical line as reference. Voice commands instruct the participant to maintain maximum dorsiflexion to the limit of tolerable pain during image acquisition. The knees are maintained in the extended position. Figure 1 (C and D) shows the position of the feet during CTSM-EK.

New index test: CTSM and semi-flexed knees (CTSM-FK)

In the second stress phase, the researchers control external rotation by placing the feet at 45 degrees using an angle meter and a vertical line as reference. Voice commands instruct the participant to maintain maximum dorsiflexion to the limit of tolerable pain during image acquisition. A support pad maintains the knees in a flexed position at 45 degrees. Figure 1 (E and F) shows the position of the feet during CTSM-FK.

Acrylic board

Investigators perform the CTNP, CTSM-EK, and CTSM-FK tests in a standardized manner. All participants are placed in the supine position, and an acrylic board (Medintec, Mogi das Cruzes, Brazil) connected to a pair of side strings of adjustable length supports the feet during examinations. The researchers ask the participants to hold the proximal ends of the strings and provide verbal instructions to pull strings and perform dorsiflexion at proper times through the room's speakers.

Feasibility assessment of stress maneuvers

Technicians guide participants to train dorsiflexion by simulating the movement of the feet, pulling strings just before image acquisition. Difficulties in performing stress maneuvers, including pain exacerbation, motion artifacts, image repetition, total examination duration, and dropouts are used to assess the feasibility of the new index test.

CTNP, CTSM-EK, and CTSM-FK reading parameters

Syndesmotic injury is a multiplanar instability, and reading parameters should examine the rotational, anteroposterior, and lateral translation of the fibula to the tibia. Measurements comprising 6 distances, 2 ratios, and 2 angles as proposed by Nault et al[14] are a complete evaluation of the multiplanar tibiofibular relationship. A reference line placed 1 cm above the tibial plafond establishes the correct plane for all measurements except for the second angle, which is measured in the plane of the tibial plafond. All measurements are performed in a standardized manner for the CTNP, CTSM-EK, and CTSM-FK examinations.

MRI technical parameters

A 1.5-T magnet HDX (GE Healthcare, Milwaukee, USA) with a dedicated phased-array coil is being used in all examinations with the following sequence parameters: sagittal T2-weighted fat-suppressed (repetition time/echo time [TR/TE] = 3000/39; number of excitations [NEX] = 2; matrix = 384 x 224; thickness = 4mm; field of view [FOV] = 10cm); sagittal T1-weighted (TR/TE = 542/9; NEX = 1; matrix = 320 x 256; thickness = 4mm; FOV = 10cm); and axial T2-weighted fat-suppressed (TR/TE = 3483/48; NEX = 2; matrix = 384 x 224; thickness = 4mm; FOV = 10 cm). Two optimized sequences with a 3-mm slice thickness are also being performed: coronal T2-weighted fat-suppressed (TR/TE = 3000/39; NEX = 2; matrix = 384 x 224; thickness = 3 mm; FOV = 10cm) and coronal oblique PD-weighted (TR/TE = 2840/35; NEX = 2; matrix = 384 x 224; thickness = 3; FOV = 10cm).

Reference test (MRI)

The standard protocol acquires MRIs of all participants' ankles suspected to have a syndesmotic injury. Participants are scanned with their ankles in the neutral position and their knees in extension. Two studies compared the accuracy of MRI to that of arthroscopy and showed that MRI is highly sensitive and specific for evaluating syndesmotic injury[9,15]. The best reference standard for syndesmotic injuries is the arthroscopic examination, which enables correct diagnosis and treatment[16]. However, in this study, the inclusion criteria are based on the ankle sprain context and physical examination, which have limited accuracy[4]. A significant proportion of uninjured syndesmosis is selected with the alternative diagnosis of lateral collateral ligament injury. The use of arthroscopy would have been difficult to justify ethically because patients with alternative diagnoses would presumably show negative results in the index and reference tests. Although the arthroscopic examination is a minimally invasive procedure, it may lead to complications and is not risk-free[17,18].

MRI reading parameters

During MRI reading, investigators are classifying the syndesmotic ligaments (anterior inferior tibiofibular, posterior inferior tibiofibular, and interosseous), lateral collateral ligaments (anterior talofibular, calcaneofibular, and posterior talofibular), and deltoid ligaments (deep and superficial layer) as grade 0 (normal ligament), grade I (ligament sprain with soft tissue edema around the ligament, which is still intact), grade II (partial tear with high signal intensity and thickening), and grade III (complete ligament tear with avulsion or discontinuity)[19].

Statistical analysis

Descriptive analyses

Absolute frequencies and percentages describe categorical variables. Means, standard deviations, and minimum and maximum values describe numerical variables.

Inference analyses of diagnostic accuracy

The ROC curve and the AUC indicate the diagnostic accuracy of the 3 index tests. The absolute difference in AUC compares the performance of the tests. The CTSM-EK or CTSM-FK tests will have superior diagnostic accuracy if the ROC curves shift to the left when compared to the CTNP test. The CTSM-EK or

CTSM-FK tests will have the best diagnostic accuracy if their AUC values are greater than that of the CTNP test.

Analysis of variability

A subgroup analysis assesses sources of variability in the accuracy of the index tests. The reference standard test determines the degree of severity of the ankle sprain by prespecifying 3 subgroups based on the number of damaged syndesmotic ligaments. Isolated tears of the anterior inferior tibiofibular ligament define a mild sprain. Injuries involving the anterior inferior tibiofibular and interosseous ligaments define a moderate sprain. Lesions involving the anterior inferior tibiofibular, interosseous, and posterior inferior tibiofibular ligaments indicate a severe sprain. Higher degrees of ankle sprain produce higher degrees of instability that may be easier to diagnose, and lower sprain degrees act in the opposite direction. The index test is expected to be more accurate in higher than in lower sprain degrees. Another source of variability is the control of dorsiflexion by the participants during the stress maneuver. The current acrylic board setting does not enable researchers to control dorsiflexion, but they do register this measurement and investigate its influence on result accuracy. The pain reported by the participant may be another source of variability. Pain aggravation defines a subgroup, while no aggravation characterizes the other subgroup. The pain aggravation subgroup may have difficulties during dorsiflexion, and lower accuracy results are expected in comparison to the subgroup with no pain aggravation. The ROC curve and the AUC will compare the subgroups' diagnostic accuracy for all variability sources.

Inter-rater analysis

Two observers will independently read the index tests and, after a 3-month washout interval, the reference standard test. The intraclass correlation coefficient will verify the agreement between observers regarding the data extracted from the index test, and the Kappa coefficient will confirm the agreement concerning reference standard data. A second consensus reading will solve discordant cases.

Sample size calculation

A previous study found an AUC performance of 0.56 regarding CTNP[11]. Considering the null hypothesis that the existing CTNP test has an AUC of 0.56, researchers propose the alternative hypothesis that the new CTSM test will display superior accuracy with an AUC of 0.80. The full sample size needed to observe a difference between these outcomes is estimated as 39, considering a 1:2 proportion between the groups (13 and 26 participants per group, respectively).

Software and thresholds

The MedCalc Statistical Software (MedCalc Software Ltd, Ostend, Belgium), version 19.4.0, will be used for the analyses, considering a power of 80% for finding differences between groups, a significance level of 5%, and 95% confidence intervals.

Didactic Case Example

A 47-year-old male patient suffered a high ankle sprain. He complained of persistent pain and swelling in the left ankle since the sprain episode 3 weeks earlier. The orthopaedic clinical examination was positive for syndesmotic injury. A painful syndesmosis on palpation inspection and difficulty to stand on the toes of the affected foot were the main positive clinical signs. Anteroposterior, mortise, and lateral radiographic views of the ankle were unremarkable. The patient was referred to the Radiology Department for CT and MRI. In the first phase of the examination (CTNP), the left anterior, central, and posterior tibiofibular distances were similar to those of the unaffected contralateral side, representing a false-negative result (Figure 2A). In the second phase, where external

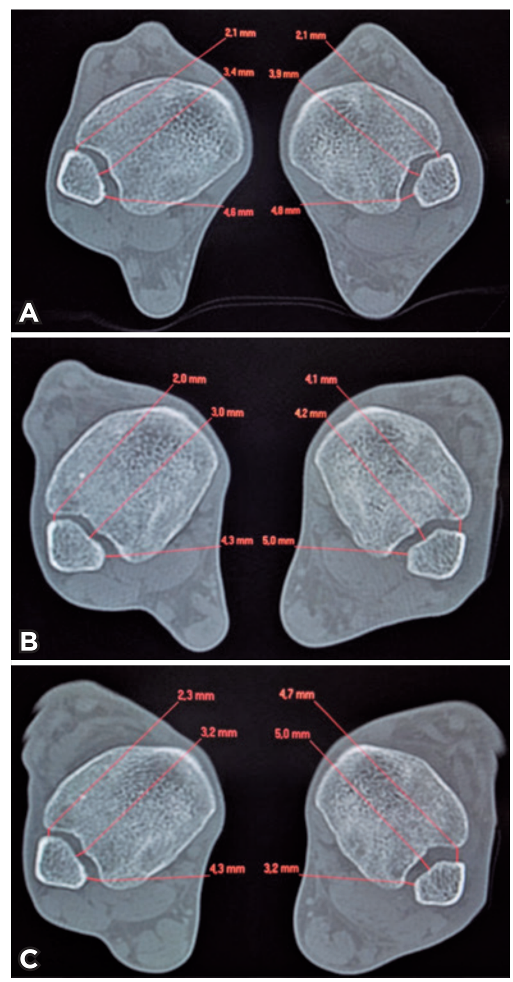

Figure 2. CT images in the axial plane 1 cm above the tibial plafond during the three phases of the examination. CT in the neutral position (A). CT with ankle stress maneuvers and extended knees (B). CT with ankle stress maneuvers and semi-flexed knees (C).

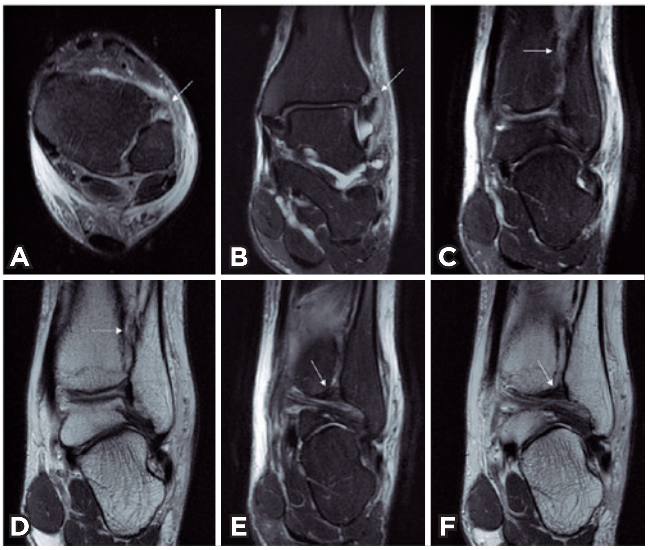

Figure 3. MRI of the left ankle. An axial T2-weighted fat-suppressed image shows complete tear of the anterior inferior tibiofibular ligament (A – white arrow). A coronal T2-weighted fat-suppressed image shows complete tear of the anterior inferior tibiofibular ligament (B – white arrow). A coronal T2-weighted fat-suppressed image shows complete tear of the interosseous ligament (C – white arrow). A coronal DP-weighted image shows complete tear of the interosseous ligament (D – white arrow). A coronal T2-weighted fat-suppressed image shows an intact posterior inferior tibiofibular ligament (E – white arrow). A coronal DP-weighted image shows an intact posterior inferior tibiofibular ligament (F – white arrow).

Table 1. Anterior, central, and posterior tibiofibular syndesmosis distances in both ankles.

	Distance (mm)					
	Anterior		Central		Posterior	
	Right	Left	Right	Left	Right	Left
CTNP*	2.1	2.1	3.4	3.9	4.6	4.8
CTSM-EK**	2.0	4.1	3.0	4.2	4.3	5.0
CTSM-FK***	2.3	4.7	3.2	5.0	4.3	3.2

*CTNP: CT in the neutral position. **CTSM-EK: CT with ankle stress maneuvers and extended knees. ***CTSM-FK: CT with ankle stress maneuvers and semi-flexed knees.

rotation and ankle dorsiflexion were performed (CTSM-EK), the left anterior and central tibiofibular distances were wider than those of the unaffected contralateral side (Figure 2B). In the third phase, using external rotation, ankle dorsiflexion, and semi-flexed knees (CTSM-FK), the left anterior and central tibiofibular distances were wider than those of the unaffected contralateral side, confirming syndesmotic instability (Figure 2C). Table 1 shows the anterior, central, and posterior tibiofibular syndesmosis distances in both ankles. The left ankle MRI depicted a complete tear of the anterior inferior tibiofibular (Figure 3, A and B) and interosseous (Figure 3, C and D) ligaments. The posterior inferior tibiofibular ligament was intact (Figure 3, E and F).

Discussion

Various imaging tests are available for the diagnostic of syndesmotic injuries; however, a fundamental question guiding treatment remains partially answered. Current imaging tests readily diagnose severe syndesmotic instability but have difficulty in confirming mild and moderate cases. Undoubtedly, the correct treatment is not being offered to a significant proportion of individuals. Undiagnosed and untreated mild and moderate cases of syndesmotic instability are the primary sources of inappropriate outcomes. If this study endorses CTSM as an accurate test for diagnosing syndesmotic instability, a novel approach for investigating demanding cases may become available and more individuals may benefit from correct treatment, thus reducing the burden of unfavorable outcomes. An algorithm matching clinical suspicion, MRI findings, and the CTSM protocol may be the most correct and precise method to diagnose SI. To the best of our knowledge, this is the first study to test the accuracy of CTSM in diagnosing syndesmotic instability and to evaluate the feasibility of stress maneuvers; this represents the main strength of our protocol. Our limitation is related to the use of MRI as the reference standard test, which, although not perfect, has a high estimated accuracy when compared to the gold-standard arthroscopy(15). Other potential limitations are the fact that the participants themselves control dorsiflexion, which introduces an inherent degree of imprecision and variability, and the absence of follow-up imaging for recording the evolution of the instability, producing long-term outcomes, and estimating the strength of the initial imaging data.

Authors' contributions: Each author contributed individually and significantly to the development of this article: JCR *(https://orcid.org/0000-0002-7107-2621) conceived and planned the activities that led to the study, wrote the paper, participated in the reviewing process, approved the final version; ALGS *(https://orcid.org/0000-0002-6672-1869) interpreted the results of the study, participated in the reviewing process, approved the final version; MPP *(https://orcid.org/0000-0003-0325-8050) interpreted the results of the study, participated in the reviewing process, approved the final version; JFMA *(https://orcid.org/0000-0002-7664-2064) interpreted the results of the study, participated in the reviewing process, approved the final version; AAC *(https://orcid.org/0000-0003-0649-3662) interpreted the results of the study, participated in the reviewing process, approved the final version; RAM *(https://orcid.org/0000-0002-7830-8318) interpreted the results of the study, participated in the reviewing process, approved the final version; DCSB *(https://orcid.org/0000-0002-5210-3605) interpreted the results of the study, participated in the reviewing process, approved the final version; CASN *(https://orcid.org/0000-0002-9286-1750) interpreted the results of the study, participated in the reviewing process, approved the final version; LAR *(https://orcid.org/0000-0003-4395-1159) interpreted the results of the study, participated in the reviewing process, approved the final version. *ORCID (Open Researcher and Contributor ID) iD.

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