

Diagnostic performance of the Strength and Pain Assessment (SPA) score for non-contact muscle injury screening in male soccer players

Original

Diagnostic performance of the Strength and Pain Assessment (SPA) score for non-contact muscle injury screening in male soccer players / Semperboni, L.; Vignati, C.; Ballatore, M. G.; Tabacco, A.; Busso, C.; Minetto, M. A.. - In: THE PHYSICIAN AND SPORTSMEDICINE. - ISSN 0091-3847. - (2020), pp. 1-7-7. [10.1080/00913847.2020.1824986]

Availability:

This version is available at: 11583/2869495 since: 2021-02-01T17:49:30Z

Publisher:

Taylor and Francis Ltd.

Published

DOI:10.1080/00913847.2020.1824986

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(Article begins on next page)



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Journal:	<i>The Physician and Sportsmedicine</i>
Manuscript ID	TPSM-ST-2020-0226.R1
Manuscript Type:	Original Research Article
Sub-Manuscript Type:	Not applicable
Therapeutic Area:	Muscle injury
Keywords – Click here to find your MeSH keywords.:	COSMIN, muscle injury, muscle pain, muscle strength, muscle tear, ultrasonography, STARD

SCHOLARONE™
Manuscripts

Submitted to The Physician and Sportsmedicine

September 2nd, 2020

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**Diagnostic performance of the
Strength and Pain Assessment (SPA) score
for non-contact muscle injury screening
in male soccer players**

Running title: SPA score for muscle injury screening

Manuscript word count: 2698 words

ABSTRACT

Objectives: The aims of this study were to develop a clinical-feature based scoring system for muscle injury screening and to assess its diagnostic accuracy when large number of injuries are suspected.

Methods: A prospective diagnostic accuracy study was performed according to the Standards for Reporting of Diagnostic Accuracy (STARD) criteria. The diagnostic accuracy of the Strength and Pain Assessment (SPA) score (index test) was assessed in relation to muscle ultrasonography (reference standard). A large (n=175) number of male soccer players met the inclusion/exclusion criteria: clinical assessment (i.e., evaluation of pain onset modality, location, distribution, impact on performance, and manual muscle strength testing) and ultrasonography were performed in all players after 48 hours from the sudden or progressive onset of muscle pain during or after a soccer competition.

Results: 91 of 175 cases (52%) were classified as functional muscle disorders, while signs of muscle tear were observed in the remaining 84 of 175 (48%) cases that were classified as structural muscle injuries. The median (1st – 3rd quartile) value of the SPA score was significantly ($P<0.001$) lower in the functional disorder group [9 (9-10)] compared to the structural injury group [12 (12-13)]. The area under the Receiver Operating Characteristic curve for different cut-off points of the SPA score was 0.977 (95% confidence intervals: 0.957 – 0.998) and the optimal cut-off value of the SPA score providing the greatest sensitivity and specificity (respectively, 99% and 89%) was 11.

Conclusion: This study found that the SPA score has high diagnostic accuracy for structural muscle injuries and could be used as a valid screening tool in soccer players presenting with sudden or progressive onset of muscle pain during or after a competition.

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3 **Abstract word count:** 276 words
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6 **KEYWORDS:** COSMIN, muscle injury, muscle pain, muscle strength, muscle tear,
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8 ultrasonography, STARD, sensitivity.
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For Review Only

INTRODUCTION

Muscle injuries are common in sports and account for 10 to 55% of all acute sports injuries [1-3]. Given their epidemiological relevance, injury prevention programs based on warm-up and flexibility strategies [4,5] as well as nutritional and conditioning approaches [6-8] are highly recommended to prepare athletes for training and competition. Most of the injuries in soccer occur in non-contact situations (hence they are classified as indirect muscle injuries) and affect lower limb muscle groups [1-3, 9,10], while direct muscle injuries (i.e., contusions and lacerations) are more frequently encountered in other sports such as American football, basketball, and rugby [11-15]. Previous studies performed in soccer players showed that the indirect injuries can also be re-injuries [16], the latter being associated with 30% of longer absence from competition than the original injury [1]. These findings highlighted the critical importance of correct diagnosis of this disorder [3] that in daily clinical practice relies on the combination of imaging findings and clinical examination [3,9,10]. The most commonly adopted imaging techniques are ultrasonography and magnetic resonance. The former technique has high (93%) sensitivity for structural injuries, while the latter technique has high (>90%) sensitivity for both non-structural and structural injuries and provides features (eg., injury volume and craniocaudal length) grading the injury severity and predicting injury recovery time [9,10]. The most commonly searched clinical findings include well-defined localized pain, stretch- and/or movement- and/or palpation-induced pain aggravation, ecchymosis or hematoma, loss of function [3,9,10]. The evaluation of resting and movement pain intensity is useful not only for diagnostic assessment but also for prognosis and follow-up of muscle injuries: for example, the Functional Assessment Scale for Acute Hamstrings Injuries (FASH) investigates the severity of pain in resting and different movement conditions and provides a valid,

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3 reproducible and responsive outcome measure for the prognostic assessment and
4 monitoring of patients with hamstrings injuries [17]. Besides the pain intensity, other
5 anamnestic and clinical data could also be collected to improve the diagnostic accuracy:
6 however, clinicians' omissions in gathering further critical information may hinder the
7 appropriate disease diagnosis and management [18,19]. For example, the assessment of
8 pain distribution and onset modality (sudden onset vs progressive or delayed onset)
9 could provide useful insights to distinguish between functional disorders (such as
10 fatigue-induced muscle disorder or delayed onset muscle soreness) and structural
11 injuries. In fact, the progressive (during activity) or delayed (after activity) onset of
12 poorly localized muscle soreness is suggestive for a functional disorder, while the
13 sudden onset during activity of a well-localized and sharp pain is suggestive for a
14 structural injury [3,9,10]. To our knowledge, no clinical-feature based scoring system is
15 currently available for muscle injury screening that may identify subjects having high
16 probability of structural injury, therefore suggesting the need for further investigation.
17 Thus, the aims of this study were to develop a clinical-feature based scoring system for
18 muscle injury screening and to assess its diagnostic accuracy when large number of
19 injuries are suspected.

20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 **MATERIALS AND METHODS**

46 47 ***Study design and subjects***

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49 A prospective diagnostic accuracy study was performed according to the Standards for
50 Reporting of Diagnostic Accuracy (STARD) criteria [20] (supplementary Table 1).

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52 All subjects gave their consent after receiving a detailed explanation of the protocol. The
53 study conformed to the guidelines of the Declaration of Helsinki and was approved by
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60 the local ethics committee.

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3 The study setting was a sports medicine and rehabilitation center where a total of 201
4 potentially eligible participants were consecutively recruited to participate in the study.
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6 One hundred seventy five male soccer players [median (min - max) age: 16.6 (14.0 -
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8 21.3) years] met the inclusion/exclusion criteria. Inclusion criteria were: i) age \geq 14
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11 21.3) years] met the inclusion/exclusion criteria. Inclusion criteria were: i) age \geq 14
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13 years, ii) competitive level of play, iii) sudden or progressive onset of muscle pain
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15 during or after a soccer competition. Exclusion criteria were: direct muscle injuries,
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17 chronic exertional compartment syndrome, joint disorders, bone stress injuries and
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19 fractures.
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21 22 23 24 **Procedures**

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26 Assessments were performed in all players after 48 hours from the pain onset. The
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28 same sports medicine physician (LS) recorded the anamnestic data relative to pain
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30 history and performed the clinical assessment (reported in Table 1) to obtain the
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32 Strength and Pain Assessment (SPA) score. Briefly, the pain onset modality, location,
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34 distribution, impact on performance were evaluated and a semi-quantitative
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36 assessment of muscle strength through manual muscle testing (see below) was
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38 performed: each item was rated between 1 and 3 on a 3-point Likert-based scale, for a
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40 maximum score of 15 points and a minimum of 5.
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46 Thereafter, muscle ultrasonography was performed in all players by the same
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48 experienced sonographer, blinded for the clinical assessment results. Muscle
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50 ultrasonography was adopted as reference standard because of previous studies
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52 showing its high sensitivity (93%) for structural muscle injuries [9,21]. The clinical
53
54 assessment and muscle ultrasonography were performed after 48 hours from the pain
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56 onset because of previous studies recommending to perform the ultrasound assessment
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58 between 1 and 3 days after suspected injury [21-24].
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Muscle strength assessment

The maximal isometric voluntary strength was assessed for both sides through manual muscle testing [25]. Subjects were instructed to perform a maximal voluntary isometric contraction by contracting their muscles as forcefully as possible for 4-5 s against a fixed resistance provided by the examiner.

Gluteal region was assessed with the subjects prone, with the knee of the tested side at 90° flexion. The subjects performed a hip extension against the examiner's resistance that was applied to the posterior part of the thigh.

Groin was assessed with the subjects supine, with the hip and knee of the tested side at 90° flexion: the subjects performed a hip flexion against the resistance (applied by the examiner to the anterior part of the thigh).

Anterior thigh was assessed with the subjects seated, with the legs perpendicular to the floor and both hips and knees at 90° flexion: the subjects performed a knee extension against resistance (applied to the anterior part of the leg).

Medial thigh was assessed with the subjects supine. The subjects performed a thigh adduction against resistance (applied to the medial aspect of the knees) in the following different conditions: both hips and knees extended, hips at 45° and knees at 90° flexion, hips and knees at 90° flexion.

Posterior thigh was assessed with the subjects prone, with the knee of non-tested leg extended and the contralateral knee at 45° flexion: the subjects performed a knee flexion against resistance (applied to the posterior part of the leg).

Posterior leg was assessed with the subjects prone, with both knees extended and feet hanging over the edge of the examination table: the subjects performed an ankle plantar flexion against resistance (applied to the foot plantar surface).

Ultrasound device and assessment

Ultrasound B-mode images were acquired using an Edge ultrasound device (Fujifilm Sonosite Inc., Amsterdam, The Netherlands) equipped by a linear-array transducer with variable frequency band (6-13 MHz).

The following ultrasound findings were considered for muscle injury assessment: fascicle disruption, hyper- or hypoechoic area, intramuscular haematoma or fascial injury with intermuscular haematoma [21-27]. Furthermore, since it has been previously recommended to recognize the tendon component of a muscle injury [10], the intramuscular tendon involvement was also systematically investigated. Based on these ultrasound findings, injuries were classified, according to the Munich consensus [3], as follows: i) functional muscle disorders (i.e., indirect muscle disorders without ultrasound evidence of muscular tear), ii) structural muscle injuries (i.e., indirect muscle disorders with ultrasound evidence of muscular tear). The latter injuries were further distinguished among the following three classes: i) type 3A: minor partial muscle tear, ii) type 3B: moderate partial muscle tear, iii) type 4: (sub)total tear.

Statistical analysis

The Shapiro–Wilk test for normal distribution of the data failed: the non-parametric Mann-Whitney U test was therefore used to assess the differences between the functional disorder group and the structural injury group.

According to Bujang and Adnan [28], a minimum sample size of 122 subjects is required to achieve a minimum power of 80% for detecting a change in the percentage value of sensitivity of a screening test from 0.50 to 0.70, based on a target significant level of 0.05 and an estimated disease prevalence of 40% [1]. The diagnostic accuracy of the SPA score (index test) was assessed in relation to muscle ultrasonography (reference

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3 standard) through a Receiver Operating Characteristic (ROC) curve for different cut-off
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5 points [29]: the area under the curve (and 95% confidence intervals) was calculated.
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7 The optimal cut-off value of the ROC curve was determined by using the Youden's index
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9 [30].
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12 Content validity (i.e., the degree to which the content of an instrument is an adequate
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14 reflection of the construct to be measured) of the SPA score was assessed as an expert
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16 opinion (the authors' expert view) according to the COSMIN guidelines (box D of
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18 recommendations) [31,32].
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21 Floor and ceiling effects were assessed (as markers of responsiveness) for the SPA score
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23 and were considered to be present if the lowest (5) or the highest (15) score was
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25 achieved by more than 15% of the cases.
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29 Data were expressed as median and 1st – 3rd quartile. The threshold for statistical
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31 significance was set to $P = 0.05$. All statistical tests were performed with SPSS 20.0
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33 (SPSS Inc., Chicago, IL, USA) software package.
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36 37 38 **RESULTS**

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40 As shown in Figure 1, the SPA score was obtained in 175 players and muscle
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42 ultrasonography was subsequently performed to distinguish between functional muscle
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44 disorders and structural muscle injuries. No adverse effects were observed from
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46 performing the clinical and ultrasound assessments. No signs of muscle tear were
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48 observed by ultrasonography in 91 of 175 cases (52%) that were classified as functional
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50 disorders, while signs of muscle tear were observed in the remaining 84 of 175 (48%)
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52 cases that were classified as structural injuries. The four sites most affected by
53
54 structural injuries were the following lower limb muscle groups: hamstrings (24 of 84
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56 cases: 28%), rectus femoris (20 of 84 cases: 24%), adductors (13 of 84 cases: 15%),
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3 triceps surae (12 of 84 cases: 14%). Structural injuries were further classified as type
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5 3A in 66 cases and type 3B in 18 cases: the anatomical distribution for each of the two
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7 classes of structural injuries is reported in Figure 1. None of the injuries (0/84) showed
8
9 an involvement of the intramuscular tendon.
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15 ***Discriminative power***

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17 The median (1st – 3rd quartile) value of the SPA score was 9 (9-10) in the functional
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19 disorder group and 12 (12-13) in the structural injury group (Figure 2A). A statistically
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21 significant difference ($P < 0.001$) was observed between the SPA scores of the two
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23 groups, indicating that the SPA score discriminates between functional disorders and
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25 structural injuries.
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31 ***Diagnostic accuracy***

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33 Figure 2B shows the ROC curve generated for different cut-off points of the SPA score:
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35 the area under the curve was 0.977 (95% confidence intervals: 0.957 – 0.998) and the
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37 optimal cut-off value providing the greatest sensitivity and specificity (respectively,
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39 99% and 89%) was 11.
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45 ***Content validity***

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47 COSMIN recommendations [31,32] about content validity were applied. The SPA score
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49 items (pain onset modality, location, distribution, impact on performance, and muscle
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51 strength) were relevant for the construct to be measured (D1), study population of
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53 patients with muscle pain (D2) and evaluative purpose of the test (D3). For the
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55 comprehensiveness of the items (D4), we think that all the relevant aspects of the
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57 construct were covered by the items. For the last requirement (D5), we think that the
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3 design and methods of the study have no important flaws. We conclude that the SPA
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5 score has good content validity.
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10 ***Floor and ceiling effects***

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12 No floor or ceiling effects were identified in the two groups, with less than 15% of
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14 players scoring the minimum (1 player in the functional disorder group) or maximum
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16 (1 player in the structural injury group) SPA score values.
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21 **DISCUSSION**

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23 The aims of this study were to develop a scoring system for muscle injury screening and
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25 to assess its diagnostic accuracy in a large population of soccer players. We found that
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27 the SPA score presents high diagnostic accuracy for structural muscle injuries,
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29 discriminates between functional disorders and structural injuries, has good content
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31 validity and no floor or ceiling effects.
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36 The observed very high sensitivity (99%) of the optimal cut-off value (11 points of the
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38 score) indicates that the SPA score can be considered a screening test with a negligible
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40 false negative rate [29]. From a clinical perspective, this finding has the relevant
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42 implication that soccer players with suspected injury and presenting with a SPA score
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44 ≥ 11 should be systematically investigated through an imaging technique for an early
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46 detection and proper evaluation of the injury. On the other hand, the use of an imaging
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48 technique could be avoided in soccer players presenting with a SPA score ≤ 10 who
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50 could therefore be suspected for functional disorders.
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55 A strength of this study is represented by its external validity [33]: the results were
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57 obtained in a large sample of soccer players presenting a distribution of structural
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59 injuries comparable to previous studies [1-3]. Similarly to our data, Ekstrand et al. [1]
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3 found in professional soccer players that the four muscle groups most affected by
4 injuries were the hamstrings (37%), adductors (23%), quadriceps (19%), and calf
5 muscles (13%). Therefore, the results obtained in the present sample of players can be
6 generalized to the target population of soccer players with lower limb injuries.
7
8 However, a limitation of the study is that we investigated only male players of one
9 sports discipline. Moreover, we did not investigate the possible mechanism underlying
10 the indirect injury (contraction-induced vs stretching-induced injury) [10,34]. Future
11 studies are therefore needed to investigate the SPA score diagnostic accuracy also in
12 athletes of both genders and other disciplines as well as to assess whether the
13 measurement properties are sensitive to the mechanism of muscle injuries.
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17 Another study limitation is represented by the lack of assessment of the intra- and
18 inter-rater reliability of the SPA score: this measurement property should be addressed
19 in future studies, especially because one of the items could present poor reliability. In
20 fact, the SPA score incorporates the semi-quantitative assessment of strength that may
21 have poor reliability due to the inaccuracy of the subjective ratings [25]. However, we
22 adopted in our scoring system the manual muscle testing that is the most commonly
23 used mode in routine clinical examinations because it is simple, quick, inexpensive.
24 Consistently, the manual testing-based Medical Research Council (MRC) scale is widely
25 adopted (both on the classic 0 to 5-point scale and on the expanded 0 to 12-point scale)
26 in daily clinical practice [35-37]. Differently for the MRC scale, our strength assessments
27 were performed both on the affected and on the contralateral unaffected side. The
28 bilateral strength assessment, that is usually recommended in injured athletes [38], did
29 not imply a relevant increase of the assessment duration and complexity. In fact, the
30 proposed clinical assessment can be completed in a few minutes and can be used as on-
31 field (or bed-side) tool.
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3 Another assessment that would not imply relevant increases of the assessment duration
4 and complexity, but could be useful to improve the SPA score reliability and/or
5 accuracy is represented by the active range of motion assessment. Consistently, several
6 previous studies showed that flexibility is an important physical characteristic in
7 athletes in terms of performance and injury prevention [39] and that active range of
8 motion deficit is an accurate measurement grading the injury severity and predicting
9 injury recovery time [40]. Moreover, normative values of range of motion are available and
10 may assist in better evaluating players presenting with muscle injuries [39]. Future studies
11 are therefore required to assess the accuracy and reliability of a modified version of the
12 SPA score incorporating the range of motion assessment.
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29 **CONCLUSION**

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31 This study provides a new tool that can be used as a valid screening instrument in
32 soccer players presenting with sudden or progressive onset of muscle pain during or
33 after a competition. The SPA score has high diagnostic accuracy for structural muscle
34 injuries. We propose that its optimal cut-off value (11 points) should be adopted to
35 distinguish between patients suspected for structural muscle injury (who require
36 further evaluations for an early diagnosis and proper severity assessment and
37 prognosis) and those suspected for functional disorders. Moreover, we suggest that the
38 critical evaluation of pain history, that is part of any diagnostic approach in pain
39 medicine, has priority ahead of other diagnostic procedures also in the evaluation of
40 muscle injuries in soccer players.
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3 **DECLARATION OF INTEREST**
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5 The authors report no conflict of interest.
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10 **ETHICAL STATEMENT**
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12 All subjects gave their consent after receiving a detailed explanation of the protocol. The
13 study conformed to the guidelines of the Declaration of Helsinki and was approved by
14 the local ethics committee.
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FIGURE CAPTIONS**Figure 1.**

Standards for Reporting of Diagnostic Accuracy (STARD) flow diagram of the study.

Figure 2.

Panel A. Box plots showing the 1st - 3rd quartile values and min-max range of the SPA score in the two groups of functional muscle disorders (n=91 players) and structural muscle injuries (n= 84 players).

* Between group comparison: $P < 0.0001$

Panel B. Receiver Operating Characteristic curve for different cut-off points of the SPA score, with an area under the curve equal to 0.977.

Submitted to *The Physician and Sportsmedicine*

September 2nd, 2020

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**Diagnostic performance of the
Strength and Pain Assessment (SPA) score
for non-contact muscle injury screening
in male soccer players:
~~development and validation of a new tool~~**

Running title: SPA score for muscle injury screening

Manuscript word count: ~~1978-2698~~ words

ABSTRACT

Objectives: The aims of this study were to develop a clinical-feature based scoring system for muscle injury screening and to assess its diagnostic accuracy when large number of injuries are suspected.

Methods: A prospective diagnostic accuracy study was performed according to the Standards for Reporting of Diagnostic Accuracy (STARD) criteria. The diagnostic accuracy of the Strength and Pain Assessment (SPA) score (index test) was assessed in relation to muscle ultrasonography (reference standard). A large (n=175) number of male soccer players met the inclusion/exclusion criteria: clinical assessment (i.e., evaluation of pain onset modality, location, distribution, impact on performance, and manual muscle strength testing) and ultrasonography were performed in all players after 48 hours from the sudden or progressive onset of muscle pain during or after a soccer competition.

Results: 91 of 175 cases (52%) were classified as functional muscle disorders, while signs of muscle tear were observed in the remaining 84 of 175 (48%) cases that were classified as structural muscle injuries. The median (1st – 3rd quartile) value of the SPA score was significantly ($P<0.001$) lower in the functional disorder group [9 (9-10)] compared to the structural injury group [12 (12-13)]. The area under the Receiver Operating Characteristic curve for different cut-off points of the SPA score was 0.977 (95% confidence intervals: 0.957 – 0.998) and the optimal cut-off value of the SPA score providing the greatest sensitivity and specificity (respectively, 99% and 89%) was 11.

Conclusion: This study found that the SPA score has high diagnostic accuracy for structural muscle injuries and could be used as a valid screening tool in soccer players presenting with sudden or progressive onset of muscle pain during or after a competition.

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3 **Abstract word count:** 276 words
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6 **KEYWORDS:** COSMIN, muscle injury, muscle pain, muscle strength, muscle tear,
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8 ultrasonography, STARD, sensitivity.
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For Review Only

INTRODUCTION

Muscle injuries are common in sports and account for 10 to 55% of all acute sports injuries [1-3]. Given their epidemiological relevance, injury prevention programs based on warm-up and flexibility strategies [4,5] as well as nutritional and conditioning approaches [6-8] are highly recommended to prepare athletes for training and competition. Most of the injuries in soccer occur in non-contact situations (hence they are classified as indirect muscle injuries) and affect lower limb muscle groups [4-41-3, 9,10], while direct muscle injuries (i.e., contusions and lacerations) are more frequently encountered in other sports such as American football, basketball, and rugby [5-911-15]. Previous studies performed in soccer players showed that the indirect injuries can also be re-injuries [1016], the latter being associated with 30% of longer absence from competition than the original injury [1]. These findings highlighted the critical importance of correct diagnosis of this disorder [3] that in daily clinical practice relies on the combination of imaging findings and clinical examination and imaging findings [3,49,10]. The most commonly adopted imaging techniques are ultrasonography and magnetic resonance. The former technique has high (93%) sensitivity for structural injuries, while the latter technique has high (>90%) sensitivity for both non-structural and structural injuries and provides features (eg, injury volume and craniocaudal length) grading the injury severity and predicting injury recovery time [9,10]. The most commonly searched clinical findings include well-defined localized pain, stretch- and/or movement- and/or palpation-induced pain aggravation, ecchymosis or hematoma, loss of function [3,49,10]. The evaluation of resting and movement pain intensity is useful not only for diagnostic assessment but also for prognosis and follow-up of muscle injuries: for example, the Functional Assessment Scale for Acute Hamstrings Injuries (FASH) investigates the severity of pain in resting and different movement conditions

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3 and provides a valid, reproducible and responsive outcome measure for the prognostic
4 assessment and monitoring of patients with hamstrings injuries [17].

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7 ~~Furthermore~~ Besides the pain intensity, other anamnestic and clinical data could also be
8 collected to improve the diagnostic accuracy: however, clinicians' omissions in
9 gathering further critical information may hinder the appropriate disease diagnosis and
10 management [11,12,18,19]. For example, the assessment of pain distribution and onset
11 modality (sudden onset vs progressive or delayed onset) could provide useful insights
12 to distinguish between functional disorders (such as fatigue-induced muscle disorder or
13 delayed onset muscle soreness) and structural injuries. In fact, the progressive (during
14 activity) or delayed (after activity) onset of poorly localized muscle soreness is
15 suggestive for a functional disorder, while the sudden onset during activity of a well-
16 localized and sharp pain is suggestive for a structural injury [3,4,9,10]. To our
17 knowledge, no clinical-feature based scoring system is currently available for muscle
18 injury screening that may identify subjects having high probability of structural injury,
19 therefore suggesting the need for further investigation. Thus, the aims of this study
20 were to develop a clinical-feature based scoring system for muscle injury screening and
21 to assess its diagnostic accuracy when large number of injuries are suspected.
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45 **MATERIALS AND METHODS**

46 ***Study design and subjects***

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50 A prospective diagnostic accuracy study was performed according to the Standards for
51 Reporting of Diagnostic Accuracy (STARD) criteria [13,20] (supplementary Table 1).

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53 All subjects gave their consent after receiving a detailed explanation of the protocol. The
54 study conformed to the guidelines of the Declaration of Helsinki and was approved by
55 the local ethics committee.
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3 The study setting was a sports medicine and rehabilitation center where a total of 201
4 potentially eligible participants were consecutively recruited to participate in the study.
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6 One hundred seventy five male soccer players [median (min - max) age: 16.6 (14.0 -
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8 21.3) years] met the inclusion/exclusion criteria. Inclusion criteria were: i) age \geq 14
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12 21.3) years] met the inclusion/exclusion criteria. Inclusion criteria were: i) age \geq 14
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14 years, ii) competitive level of play, iii) sudden or progressive onset of muscle pain
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16 during or after a soccer competition. Exclusion criteria were: direct muscle injuries,
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18 chronic exertional compartment syndrome, joint disorders, bone stress injuries and
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20 fractures.

21 22 23 24 **Procedures**

25
26 Assessments were performed in all players after 48 hours from the pain onset. The
27
28 same sports medicine physician (LS) recorded the anamnestic data relative to pain
29
30 history and performed the clinical assessment (reported in Table 1) to obtain the
31
32 Strength and Pain Assessment (SPA) score. Briefly, the pain onset modality, location,
33
34 Strength and Pain Assessment (SPA) score. Briefly, the pain onset modality, location,
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36 distribution, impact on performance were evaluated and a semi-quantitative
37
38 assessment of muscle strength through manual muscle testing ([see below](#)) was
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40 performed: each item was rated between 1 and 3 on a 3-point Likert-based scale, for a
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42 maximum score of 15 points and a minimum of 5.

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44 Thereafter, muscle ultrasonography was performed in all players by the same
45
46 experienced sonographer, blinded for the clinical assessment results. Muscle
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48 ultrasonography was adopted as reference standard because of previous studies
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50 showing its high sensitivity (93%) for structural muscle injuries [[4,149,21](#)]. The clinical
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52 assessment and muscle ultrasonography were performed after 48 hours from the pain
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54 onset because of previous studies recommending to perform the ultrasound assessment
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56 between 1 and 3 days after suspected injury [[14-17,21-24](#)].
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Muscle strength assessment

The maximal isometric voluntary strength was assessed for both sides through manual muscle testing [25]. Subjects were instructed to perform a maximal voluntary isometric contraction by contracting their muscles as forcefully as possible for 4-5 s against a fixed resistance provided by the examiner.

Gluteal region was assessed with the subjects prone, with the knee of the tested side at 90° flexion. The subjects performed a hip extension against the examiner's resistance that was applied to the posterior part of the thigh.

Groin was assessed with the subjects supine, with the hip and knee of the tested side at 90° flexion: the subjects performed a hip flexion against the resistance (applied by the examiner to the anterior part of the thigh).

Anterior thigh was assessed with the subjects seated, with the legs perpendicular to the floor and both hips and knees at 90° flexion: the subjects performed a knee extension against resistance (applied to the anterior part of the leg).

Medial thigh was assessed with the subjects supine. The subjects performed a thigh adduction against resistance (applied to the medial aspect of the knees) in the following different conditions: both hips and knees extended, hips at 45° and knees at 90° flexion, hips and knees at 90° flexion.

Posterior thigh was assessed with the subjects prone, with the knee of non-tested leg extended and the contralateral knee at 45° flexion: the subjects performed a knee flexion against resistance (applied to the posterior part of the leg).

Posterior leg was assessed with the subjects prone, with both knees extended and feet hanging over the edge of the examination table: the subjects performed an ankle plantar flexion against resistance (applied to the foot plantar surface).

Ultrasound device and assessment

Ultrasound B-mode images were acquired using an Edge ultrasound device (Fujifilm Sonosite Inc., Amsterdam, The Netherlands) equipped by a linear-array transducer with variable frequency band (6-13 MHz).

The following ultrasound findings were considered for muscle injury assessment: fascicle disruption, hyper- or hypoechoic area, intramuscular haematoma or fascial injury with intermuscular haematoma [21-27]. Furthermore, since it has been previously recommended to recognize the tendon component of a muscle injury [10], the intramuscular tendon involvement was also systematically investigated. Ultrasound findings (i.e., fascicle disruption, hyper- or hypoechoic area, intramuscular haematoma or fascial injury with intermuscular haematoma) [16-20] were adopted to classify
theBased on these ultrasound findings, injuries were classified, according to the Munich consensus [3], as follows: i) functional muscle disorders (i.e., indirect muscle disorders without ultrasound evidence of muscular tear), ii) structural muscle injuries (i.e., indirect muscle disorders with ultrasound evidence of muscular tear). The latter injuries were further distinguished among the following three classes: i) type 3A: minor partial muscle tear, ii) type 3B: moderate partial muscle tear, iii) type 4: (sub)total tear.

Statistical analysis

The Shapiro-Wilk test for normal distribution of the data failed: the non-parametric Mann-Whitney U test was therefore used to assess the differences between the functional disorder group and the structural injury group.

According to Bujang and Adnan [2128], a minimum sample size of 122 subjects is required to achieve a minimum power of 80% for detecting a change in the percentage value of sensitivity of a screening test from 0.50 to 0.70, based on a target significant

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3 level of 0.05 and an estimated disease prevalence of 40% [1]. The diagnostic accuracy of
4 the SPA score (index test) was assessed in relation to muscle ultrasonography
5 (reference standard) through a Receiver Operating Characteristic (ROC) curve for
6 different cut-off points [2229]: the area under the curve (and 95% confidence intervals)
7 was calculated. The optimal cut-off value of the ROC curve was determined by using the
8 Youden's index [2330].
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Content validity (i.e., the degree to which the content of an instrument is an adequate reflection of the construct to be measured) of the SPA score was assessed as an expert opinion (the authors' expert view) according to the COSMIN guidelines (box D of recommendations) [24,2531,32].

Floor and ceiling effects were assessed (as markers of responsiveness) for the SPA score and were considered to be present if the lowest (5) or the highest (15) score was achieved by more than 15% of the cases.

Data were expressed as median and 1st – 3rd quartile. The threshold for statistical significance was set to $P = 0.05$. All statistical tests were performed with SPSS 20.0 (SPSS Inc., Chicago, IL, USA) software package.

RESULTS

As shown in Figure 1, the SPA score was obtained in 175 players and muscle ultrasonography was subsequently performed to distinguish between functional muscle disorders and structural muscle injuries. No adverse effects were observed from performing the clinical and ultrasound assessments. No signs of muscle tear were observed by ultrasonography in 91 of 175 cases (52%) that were classified as functional disorders, while signs of muscle tear were observed in the remaining 84 of 175 (48%) cases that were classified as structural injuries. The four sites most affected by

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3 structural injuries were the following lower limb muscle groups: hamstrings (24 of 84
4 cases: 28%), rectus femoris (20 of 84 cases: 24%), adductors (13 of 84 cases: 15%),
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7 triceps surae (12 of 84 cases: 14%). Structural injuries were further classified as type
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10 3A in 66 cases and type 3B in 18 cases: the anatomical distribution for each of the two
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12 classes of structural injuries is reported in Figure 1. None of the injuries (0/84) showed
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14 an involvement of the intramuscular tendon.
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20 ***Discriminative power***

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22 The median (1st – 3rd quartile) value of the SPA score was 9 (9-10) in the functional
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24 disorder group and 12 (12-13) in the structural injury group (Figure 2A). A statistically
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26 significant difference ($P < 0.001$) was observed between the SPA scores of the two
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28 groups, indicating that the SPA score discriminates between functional disorders and
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30 structural injuries.
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36 ***Diagnostic accuracy***

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38 Figure 2B shows the ROC curve generated for different cut-off points of the SPA score:
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40 the area under the curve was 0.977 (95% confidence intervals: 0.957 – 0.998) and the
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42 optimal cut-off value providing the greatest sensitivity and specificity (respectively,
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44 99% and 89%) was 11.
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50 ***Content validity***

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52 COSMIN recommendations [25,26,31,32] about content validity were applied. The SPA
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54 score items (pain onset modality, location, distribution, impact on performance, and
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56 muscle strength) were relevant for the construct to be measured (D1), study population
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58 of patients with muscle pain (D2) and evaluative purpose of the test (D3). For the
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3 comprehensiveness of the items (D4), we think that all the relevant aspects of the
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5 construct were covered by the items. For the last requirement (D5), we think that the
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7 design and methods of the study have no important flaws. We conclude that the SPA
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9 score has good content validity.
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15 ***Floor and ceiling effects***

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17 No floor or ceiling effects were identified in the two groups, with less than 15% of
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19 players scoring the minimum (1 player in the functional disorder group) or maximum
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21 (1 player in the structural injury group) SPA score values.
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26 **DISCUSSION**

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28 The aims of this study were to develop a scoring system for muscle injury screening and
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30 to assess its diagnostic accuracy in a large population of soccer players. We found that
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32 the SPA score presents high diagnostic accuracy for structural muscle injuries,
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34 discriminates between functional disorders and structural injuries, has good content
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36 validity and no floor or ceiling effects.
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41 The observed very high sensitivity (99%) of the optimal cut-off value (11 points of the
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43 score) indicates that the SPA score can be considered a screening test with a negligible
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45 false negative rate [2229]. From a clinical perspective, this finding has the relevant
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47 implication that soccer players with suspected injury and presenting with a SPA score
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49 ≥ 11 should be systematically investigated through an imaging technique for an early
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51 detection and proper evaluation of the injury. On the other hand, the use of an imaging
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53 technique could be avoided in soccer players presenting with a SPA score ≤ 10 who
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55 could therefore be suspected for functional disorders.
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3 A strength of this study is represented by its external validity [2633]: the results were
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5 obtained in a large sample of soccer players presenting a distribution of structural
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7 injuries comparable to previous studies [1-3]. Similarly to our data, Ekstrand et al. [1]
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9 found in professional soccer players that the four muscle groups most affected by
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11 injuries were the hamstrings (37%), adductors (23%), quadriceps (19%), and calf
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13 muscles (13%). Therefore, the results obtained in the present sample of players can be
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15 generalized to the target population of soccer players with lower limb injuries.
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17 However, a limitation of the study is that we investigated only male players of one
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19 sports discipline. Moreover, we did not investigate the possible mechanism underlying
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21 the indirect injury (contraction-induced vs stretching-induced injury) [10,34]. Future
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23 studies are therefore needed to investigate the SPA score diagnostic accuracy also in
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25 athletes of both genders and other disciplines as well as to assess whether the
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27 measurement properties are sensitive to the mechanism of muscle injuries.

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29 Another study limitation is represented by the lack of assessment of the intra- and
30
31 inter-rater reliability of the SPA score: this measurement property should be addressed
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33 in future studies, especially because one of the items could present poor reliability. In
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35 fact, the SPA score incorporates the semi-quantitative assessment of strength that may
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37 have poor reliability due to the inaccuracy of the subjective ratings [2725]. However, we
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39 adopted in our scoring system the manual muscle testing that is the most commonly
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41 used mode in routine clinical examinations because it is simple, quick, inexpensive.
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43 Consistently, the manual testing-based Medical Research Council (MRC) scale is widely
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45 adopted (both on the classic 0 to 5-point scale and on the expanded 0 to 12-point scale)
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47 in daily clinical practice [28-3035-37]. Differently for the MRC scale, our strength
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49 assessments were performed both on the affected and on the contralateral unaffected
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51 side. The bilateral strength assessment, that is usually recommended in injured athletes
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3 [3138], did not imply a relevant increase of the assessment duration and complexity. In
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5 fact, the proposed clinical assessment can be completed in a few minutes and can be
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7 used as on-field (or bed-side) tool.
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10 Another assessment that would not imply relevant increases of the assessment duration
11 and complexity, but could be useful to improve the SPA score reliability and/or
12 accuracy is represented by the active range of motion assessment. Consistently, several
13 previous studies showed that flexibility is an important physical characteristic in
14 athletes in terms of performance and injury prevention [39] and that active range of
15 motion deficit is an accurate measurement grading the injury severity and predicting
16 injury recovery time [40]. Moreover, normative values of range of motion are available and
17 may assist in better evaluating players presenting with muscle injuries [39]. Future studies
18 are therefore required to assess the accuracy and reliability of a modified version of the
19 SPA score incorporating the range of motion assessment.
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36 CONCLUSION

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38 ~~This study found that the SPA score has high diagnostic accuracy for structural muscle~~
39 ~~injuries and could be used as a valid screening tool in soccer players presenting with~~
40 ~~sudden or progressive onset of muscle pain during or after a competition.~~
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45 This study provides a new tool that can be used as a valid screening instrument in
46 soccer players presenting with sudden or progressive onset of muscle pain during or
47 after a competition. The SPA score has high diagnostic accuracy for structural muscle
48 injuries. We propose that its optimal cut-off value (11 points) should be adopted to
49 distinguish between patients suspected for structural muscle injury (who require
50 further evaluations for an early diagnosis and proper severity assessment and
51 prognosis) and those suspected for functional disorders. On the basis of the observed
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3 **findings**Moreover, we suggest that the critical evaluation of pain history, that is part of
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6 any diagnostic approach in pain medicine, has priority ahead of other diagnostic
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8 procedures also in the evaluation of muscle injuries in soccer players.
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10 11 12 13 **DECLARATION OF INTEREST**

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16 The authors report no conflict of interest.
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20 21 **ETHICAL STATEMENT**

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23 All subjects gave their consent after receiving a detailed explanation of the protocol. The
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25 study conformed to the guidelines of the Declaration of Helsinki and was approved by
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27 the local ethics committee.
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FIGURE CAPTIONS**Figure 1.**

Standards for Reporting of Diagnostic Accuracy (STARD) flow diagram of the study.

Figure 2.

Panel A. Box plots showing the 1st - 3rd quartile values and min-max range of the SPA score in the two groups of functional muscle disorders (n=91 players) and structural muscle injuries (n= 84 players).

* Between group comparison: $P < 0.0001$

Panel B. Receiver Operating Characteristic curve for different cut-off points of the SPA score, with an area under the curve equal to 0.977.

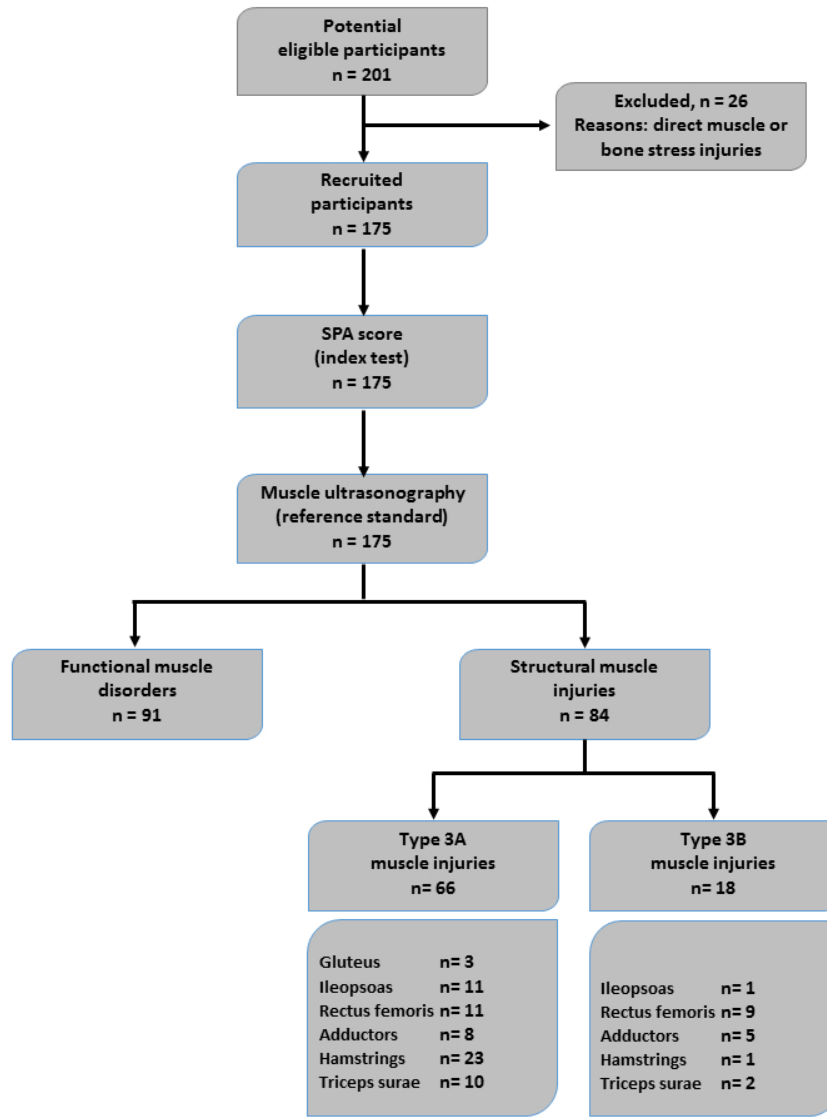


Figure 1.
Standards for Reporting of Diagnostic Accuracy (STARD) flow diagram of the study.

190x254mm (96 x 96 DPI)

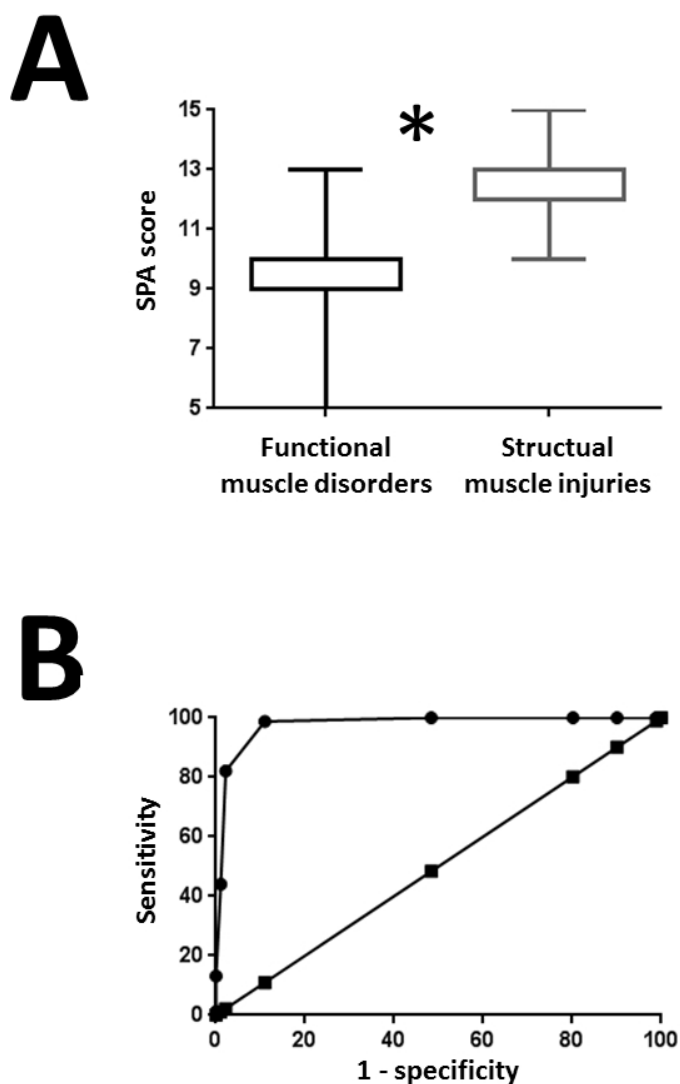


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190x254mm (96 x 96 DPI)

ITEM	SCORE
Pain onset modality	
Progressive (during activity) or delayed (after activity) onset of muscle soreness	1
Sudden onset of muscle cramp	2
Sudden onset of sharp pain preceded by a “pop” or “snap” feeling	3
Pain location	
Diffuse	1
Well-localized to the tendon	2
Well-localized to the muscle	3
Pain distribution	
Gluteal region	1
Groin, anterior thigh, medial thigh, posterior leg	2
Posterior thigh	3
Pain impact on performance	
None	1
Moderate functional impairment with delayed activity interruption	2
Severe functional impairment with immediate activity interruption	3
Muscle strength	
Muscle contracts normally against full manual resistance, without difference between the two sides	1
Muscle strength against manual resistance is moderately reduced with respect to the contralateral unaffected side	2
Muscle strength against manual resistance is severely reduced with respect to the contralateral unaffected side	3

Table 1. Items and scoring numbers of the Strength and Pain Assessment (SPA) score.

Section & Topic	No	Item	Reported on page #
TITLE OR ABSTRACT			
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	1-2
ABSTRACT			
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	2
INTRODUCTION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	4
	4	Study objectives and hypotheses	5
METHODS			
<i>Study design</i>	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	5
<i>Participants</i>	6	Eligibility criteria	5
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	6
	8	Where and when potentially eligible participants were identified (setting, location and dates)	6
	9	Whether participants formed a consecutive, random or convenience series	6
<i>Test methods</i>	10a	Index test, in sufficient detail to allow replication	6-7 and Table 1
	10b	Reference standard, in sufficient detail to allow replication	8
	11	Rationale for choosing the reference standard (if alternatives exist)	6
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	Not applicable
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	Not applicable
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	6-8
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	6-8
<i>Analysis</i>	14	Methods for estimating or comparing measures of diagnostic accuracy	8-9
	15	How indeterminate index test or reference standard results were handled	Not applicable
	16	How missing data on the index test and reference standard were handled	Not applicable
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	8-9
	18	Intended sample size and how it was determined	8
RESULTS			
<i>Participants</i>	19	Flow of participants, using a diagram	Figure 1
	20	Baseline demographic and clinical characteristics of participants	6
	21a	Distribution of severity of disease in those with the target condition	9-10
	21b	Distribution of alternative diagnoses in those without the target condition	9-10
	22	Time interval and any clinical interventions between index test and reference standard	6
<i>Test results</i>	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	Figure 2
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	10
	25	Any adverse events from performing the index test or the reference standard	9
DISCUSSION			
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	12
	27	Implications for practice, including the intended use and clinical role of the index test	11-12
OTHER INFORMATION			
	28	Registration number and name of registry	Not available
	29	Where the full study protocol can be accessed	Not available
	30	Sources of funding and other support; role of funders	Provided

