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Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium

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ABSTRACT

While research on chronic ankle instability (CAI) and awareness of its impact on society and health care systems has grown substantially in the last 2 decades, the inconsistency in participant/patient selection criteria across studies presents a potential obstacle to addressing the problem properly. This major gap within the literature limits the ability to generalise this evidence to the target patient population. Therefore, there is a need to provide standards for patient/participant selection criteria in research focused on CAI with justifications using the best available evidence. The International Ankle Consortium provides this position paper to present and discuss an endorsed set of selection criteria for patients with CAI based on the best available evidence to be used in future research and study designs. These recommendations will enhance the validity of research conducted in this clinical population with the end goal of bringing the research evidence to the clinician and patient.

EPIDEMIOLOGY AND IMPACT OF ANKLE INJURY

Injuries to the ankle joint account for 20% of the population that is afflicted with joint injury.¹ There are more than three million emergency room visits annually for ankle/foot injuries in the USA,² and the largest percentage of self-reported musculoskeletal injuries (> 10%) are to the ankle.³ More than 628 000 ankle injuries, including ankle sprains and fractures, per year are treated in USA emergency rooms, accounting for 20% of all injuries treated in emergency facilities.⁴ Ankle sprains account for an estimated 3–5% of emergency room visits in the UK,⁵ representing a significant amount of devoted healthcare resources. Additionally, it is estimated that as many as 55% of patients who sustain an ankle sprain do not seek evaluation or treatment from a healthcare professional.⁶ Subsequently, the reporting of traumatic ankle sprains may be grossly under-reported in healthcare statistics.

SHORT-TERM AND LONG-TERM SEQUELAE

Traumatic ankle injury represents a significant healthcare issue. Of further significance is that ankle sprains have a high rate of recurrence (as high as 80% in high-risk sports).^{7–9} Recent data indicate that ankle sprains are not just an innocuous injury primarily incurred by young athletes; rather, they also impact

approximately 8% of the general population who report persistent symptoms following an initial ankle sprain.¹⁰ Chronic joint injury and degeneration is associated with over US\$3 billion in annual healthcare costs in the USA.¹¹ Evidence for the relationship between acute and recurrent ankle joint trauma and the development of post-traumatic ankle joint osteoarthritis (OA) is growing.^{11 12} Saltzman *et al*¹³ have reported that as many as four in five cases of ankle joint OA are the result of previous musculoskeletal trauma, with these patients being on average a decade younger than patients with primary ankle joint OA. Additionally, self-reported disability using the SF-36 physical component score was significantly lower in patients with ankle OA from the USA¹³ as compared with the general population, and was also equal to or lower compared with patients with end-stage kidney disease,¹⁴ chronic heart failure¹⁵ or Parkinson's disease.¹⁶ Therefore, ankle joint sprains and its associated sequelae affect individuals across the lifespan and represent a large healthcare burden.

Advances in research

The prevalence and impact of ankle sprains on society and healthcare systems support the need for continued research related to the prevention, treatment and rehabilitation of ankle sprains and their associated sequelae. As aforementioned, an unfortunate and prominent consequence of acute ankle sprains is a very high recurrence rate. It has been reported that 32–74% of individuals with a history of ankle sprain have some type of residual and chronic symptoms, recurrent ankle sprains and/or perceived instability.^{17 18} Evidence from peer-reviewed literature suggests that the characteristics of patients with recurrent ankle injury are not homogeneous. Many categorical descriptions have been used to define this pathology, including chronic ankle instability (CAI), functional ankle instability, mechanical ankle instability (MAI) and recurrent ankle instability.^{19–21} CAI has been defined in a variety of ways, but is most predominantly described 'as an encompassing term used to classify a subject with both mechanical and functional instability of the ankle joint.'²⁰

International Ankle Consortium position statement

The International Ankle Consortium is an international community of researchers and clinicians

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whose primary scholastic purpose is to promote scholarship and dissemination of research informed knowledge related to pathologies of the ankle complex. The constituents of the International Ankle Consortium and other similar organisations have yet to properly define the clinical phenomenon known as CAI and its related characteristics for consistent patient recruitment and advancement of research in this area. While research on CAI and awareness of its impact on society and healthcare systems have grown substantially in the last two decades, the inconsistency in participant/patient selection criteria across studies presents a potential obstacle to addressing the problem properly. This major gap within the literature limits the ability to generalise this evidence to the target patient population. Therefore, there is a need to provide standards for patient/participant selection criteria in research focused on CAI with justifications using the best available evidence. The primary rationale for documenting such standards is to outline specific inclusion criteria that should be reported on as a minimum when conducting research in the area of CAI. This will be of particular importance as research into CAI continues to grow and become more sophisticated, especially to enable high-fidelity synthesis and meta-analyses of data through future systematic reviews.

Although CAI is a multifaceted condition, there have been research developments to capture functional deficits associated with those who have recurrent issues. Freeman *et al*²² were among the first to recognise measurable differences in clinical outcomes in patients who had a history of ankle joint injury. Recognition of prolonged deficits in single-limb balance after ankle ligament sprains led to a theory of changes in neural signalling following trauma to the ankle joint and categorisation of these patients as having functional ankle instability. Several decades later, Hertel¹⁹ presented a model that recognised the contributions from functional and mechanical insufficiencies associated with an acute ankle sprain that may interact to precipitate the development of CAI. The development of this model was a seminal step in facilitating an understanding of why many patients incur repeated ankle joint dysfunction. The use of the term CAI according to the Hertel¹⁹ model represented the initial attempt to define and provide potential contributions from functional and mechanical insufficiencies, which helped develop a more comprehensive approach to researching and treating individuals with this pathology.

Research related to ankle joint instability evolved over the decade following the publication of the Hertel¹⁹ CAI model, with a primary aim of much of the research devoted to understanding exactly what combinations of functional and mechanical insufficiencies best define CAI. Many recent reviews and multifactorial studies have provided important information outlining that there are multiple potential contributing mechanical, neuromuscular, functional and/or perceived deficits that may persist long after physiological tissue healing times have elapsed and interventions have been completed following an acute ankle joint sprain.^{23–34} Consistently, these reviews and multifactorial studies support the proposition that CAI is a multifaceted and complex condition requiring a further in-depth interdisciplinary study.

Although the volume and quality of this research grew substantially, it became more evident that individuals with CAI are quite heterogeneous in their presentation of impairments, leading the research towards consideration of a possible conglomeration of subgroups. Recently, Hiller *et al*²¹ introduced an update of Hertel's¹⁹ CAI model that suggests that there may be as many as seven different subsets of patients who incur persistent symptoms following an initial ankle joint sprain,

which are dependent on the complex interaction of mechanical insufficiencies, perceived instability and frequency of recurrent sprains.

Rationale

When one examines the body of work related to repeated and recurrent ankle joint injury and instability, there is a spectrum of patient characteristics that have been used within the ankle instability (including CAI and functional ankle instability) research literature from the past two decades.^{20–21} Delahunt *et al*²⁰ systematically investigated these issues in the research relating to recurrent ankle joint sprain and the resulting inconsistent definitions and use of terms such as CAI, functional ankle instability, etc. They concluded that CAI was the most commonly used term to describe individuals who report ongoing symptoms after an initial ankle sprain; and the most commonly reported deficits associated with CAI were frequent/recurrent sprains and episodes of or the reporting of feelings of ankle joint 'giving way'. Subsequently, the authors advocated that research in this area could be improved if consistent terminology and a specific set of patient selection criteria could be established.

Statement objectives

It is the opinion of the International Ankle Consortium that some of the inconsistency in defining the factors and characteristics that best explain recurrent ankle sprains and instability may be attributed to inconsistent inclusion criteria among this literature. The International Ankle Consortium proposes the establishment of an accepted set of selection criteria, which should be used in this area of research, as it will provide consistency to the future data synthesis devoted to improving the understanding of CAI and enhancing the external validity of findings for this patient population. The purpose of this position statement is to present and discuss an endorsed set of selection criteria for patients with CAI based on the best available evidence to be used in future research and study designs. Our group wishes to advocate the pursuit of the strongest and most appropriate evidence that will improve the understanding and management of CAI.

CRITERIA RECOMMENDATIONS

The standard inclusion and exclusion criteria endorsed by the International Ankle Consortium, as a minimum, for enrolling patients who fall within the heterogeneous condition of CAI in controlled research are listed in boxes 1 and 2. Additionally, the International Ankle Consortium encourages the reporting of critical information found in table 1 for patients with CAI to provide a comprehensive description of the study participants who have been enrolled in controlled research studies.

DISCUSSION

The preceding endorsed criteria for selection of individuals with CAI in research are based on the best available evidence, and the International Ankle Consortium recommends adherence to produce consistent population characteristics for improved outcomes and external validity in future research of this clinical phenomenon. These recommendations will enhance the validity of research conducted in this clinical population with the end goal of bringing the research evidence to the clinician and patient. Additional rationale for the selection criteria will be provided below.

The International Ankle Consortium acknowledges the work of Delahunt *et al*²⁰ that has provided the framework for this

Box 1 Standard inclusion criteria endorsed, as a minimum, by the International Ankle Consortium for enrolling patients who fall within the heterogeneous condition of chronic ankle instability in controlled research.

Inclusion criteria

1. A history of at least one significant ankle sprain
 - ▶ The initial sprain must have occurred at least 12 months prior to the study enrolment
 - ▶ Was associated with inflammatory symptoms (pain, swelling, etc)
 - ▶ Created at least one interrupted day of desired physical activity

The most recent injury must have occurred more than 3 months prior to the study enrolment.

We endorse the *definition of an ankle sprain* as "An acute traumatic injury to the lateral ligament complex of the ankle joint as a result of excessive inversion of the rear foot or a combined plantar flexion and adduction of the foot. This usually results in some initial deficits of function and disability".²⁰

2. A history of the previously injured ankle joint 'giving way', and/or recurrent sprain and/or 'feelings of instability'. We endorse the *definition of 'giving way* as "The regular occurrence of uncontrolled and unpredictable episodes of excessive inversion of the rear foot (usually experienced during initial contact during walking or running), which do not result in an acute lateral ankle sprain".²⁰

Specifically, participants should report at least 2 episodes of 'giving way' in the 6 months prior to the study enrolment.

We endorse the *definition of 'recurrent sprain'* as "Two or more sprains to the same ankle".²⁰

We endorse the *definition of feeling of ankle joint instability* as "The situation whereby during activities of daily living (ADL) and sporting activities the subject feels that the ankle joint is unstable and is usually associated with the fear of sustaining an acute ligament sprain".²⁰

Specifically, self-reported ankle instability should be confirmed with a validated ankle instability-specific questionnaire using the associated cut-off score. Currently recommended questionnaires:

- A. Ankle Instability Instrument (AII)⁴⁰: answer 'yes' to at least five yes/no questions (This should include question 1, plus four others)
 - B. Cumberland Ankle Instability Tool (CAIT)⁴¹: score of <24
 - C. Identification of functional ankle instability (IdFAI)³⁷: score of >11
- 3 A general self-reported foot and ankle function questionnaire is recommended to describe the level of disability of the cohort, but should only be an inclusion criterion if the level of self-reported function is important to the research question. Currently endorsed questionnaires:
 - A. Foot and Ankle Ability Measure (FAAM)⁴²: ADL scale <90%; Sport scale <80%
 - B. Foot and Ankle Outcome Score (FAOS)⁴³: score of <75% in three or more categories

position statement and recommends consultation of and familiarisation with that work by all researchers with an interest in CAI. The aims of the systematic investigation by Delahunt *et al*²⁰ were to: (1) identify the definition of ankle instability used by authors publishing research papers pertaining to ankle joint

Box 2 Standard exclusion criteria endorsed, as a minimum, by the International Ankle Consortium for enrolling patients who fall within the heterogeneous condition of chronic ankle instability in controlled research.

Exclusion criteria

1. A history of previous surgeries to the musculoskeletal structures (ie, bones, joint structures and nerves) in either lower extremity.

It is understood and accepted in clinical and research practice that surgery to repair insufficient joint structures is designed to restore structural integrity, but creates residual changes in the central and peripheral portions of the nervous system. Even with appropriate rehabilitation and follow-up management, there are concomitant neuromuscular and structural alterations after surgery that would confound the ability to isolate the effects of chronic ankle instability.

2. A history of a fracture in either lower extremity requiring realignment.

Similar to the first exclusion criterion, significant compromise to skeletal tissue will threaten the internal validity of the selection of study populations with isolated chronic ankle instability.

3. Acute injury to the musculoskeletal structures of other joints of the lower extremity in the previous 3 months, which impacted joint integrity and function (ie, sprains, fractures) resulting in at least 1 interrupted day of desired physical activity.

sprain and its subsequent sequelae; (2) identify the terminology used by authors to classify patients with CAI (eg, CAI, functional ankle instability, MAI or others) and (3) to identify the specific inclusion criteria used by authors publishing research papers pertaining to ankle joint sprain and subsequent sequelae. This was the first published paper to systematically investigate the aforementioned issues which may lead to inconsistencies in research results relating to ankle joint sprain and its subsequent sequelae. The results of this systematic investigation indicated that CAI was the most commonly used term to describe patients who report ongoing symptoms after an initial ankle sprain. Furthermore, the most commonly used descriptors relating to CAI were frequent/recurrent sprains and episodes of or the reporting of feelings of ankle joint 'giving way'. Based on their findings, Delahunt *et al*²⁰ recommended that consistent terminology and a specific minimum set of criteria be reported as this would improve research endeavour pertaining to CAI. As such, Delahunt *et al*²⁰ devised a set of operational definitions related to ankle joint sprain and its subsequent sequelae, as well as a specific set of criteria that should be reported when undertaking research on individuals with CAI. These definitions and criteria set formed the basis of discussion at the International Ankle Symposium, from which the International Ankle Consortium formed a consensus statement relating to the operational definitions pertaining to ankle joint sprain and its subsequent sequelae and a minimum set of criteria to be reported when conducting CAI research.

At the fifth International Ankle Symposium (Lexington, Kentucky, USA, 2012), the International Ankle Consortium executive committee discussed the concepts of this position paper based on the existing work and the new information being presented at the meeting.³⁵ Consistent with the work by

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Table 1 Information recommended by the International Ankle Consortium for patients with chronic ankle instability with the goal of providing a comprehensive description of the study participants who have been enrolled in controlled research studies

Topic	Suggested content
Quality of ankle injury history	<ol style="list-style-type: none"> 1. The number of previous ankle sprains 2. The presence and frequency of reported episodes of 'giving way' 3. The presence and frequency of reported episodes of feelings of instability 4. The scores on the validated self-reported ankle instability instruments utilised to establish inclusion criteria 5. Severity of injury (index and most recent incidents), including the number of days of immobilisation and/or non-weight bearing 6. If diagnosis was performed by a healthcare professional or self-diagnosed
Timing of ankle sprain injury	<ol style="list-style-type: none"> 7. The time since the most recent ankle sprain 8. The number of weeks of supervised rehabilitation by a healthcare professional 9. The number of weeks since supervised rehabilitation was completed
Potential confounding factors	<ol style="list-style-type: none"> 10. Any included mechanical instability ratings (ie, clinical laxity scales, arthrometry measures and stress radiography) 11. A rating of the current level of physical activity level using a validated scale (eg, Tegner scale, Godin Leisure Time Physical Activity, etc), and the minimum number of hours per week of participation in physical activity 12. Any concomitant, non-surgical injuries at the time of ankle sprain 13. The frequency of use of prophylactic ankle support 14. The results of any functional or range of motion assessments 15. Presence of pain during functional activities

Delahunt *et al*,²⁰ new papers presented at the International Ankle Symposium emphasised the strength of the reported episodes of 'giving way' and patient-reported instability in defining CAI. Snyder *et al*,³⁶ using the Delphi method to gather input from expert clinicians and researchers, reported that the 'recurrent sense of giving way' was the strongest characteristic in defining CAI. However, there are other characteristics such as feelings of instability and recovery from a 'rolling over' incident³⁷ that are important in identifying who has CAI and establishing the severity of the condition that is not obtained through the reporting of 'giving way' alone. A series of studies³⁸⁻³⁹ support the use of condition-specific self-report questionnaires to identify those with the minimal accepted criteria for ankle instability. It is critical to use condition-specific questionnaires that are both valid and reliable³⁷⁻⁴⁰⁻⁴¹ in the collection of this information. This recent work highlights the increasing evidence for the selected criteria we introduced in this position paper.

Additionally, measurement of self-reported instability should be differentiated from measurement of resulting change to physical function or quality of life. Changes to physical function may be a result of any or all mechanical insufficiencies, self-reported instability and recurrent sprains. Therefore, if investigators are interested in the deficits present in participants with CAI, such as strength, neuromuscular or proprioception deficits as examples, measures of self-reported function may not be a necessary inclusion criterion for this type of study. However, if functional impairment is relevant to the proposed project or intervention, then validated ankle-specific questionnaires that were designed to evaluate self-reported function should be used to create the necessary inclusion criterion.⁴²⁻⁴³

Our recommended inclusion criteria are based on assessments of injury history, function and disability, but we recognise the lack of a definitive selection criteria based on an assessment of joint integrity or laxity. While an initial ankle sprain often threatens the integrity of ligamentous structures and some authors have reported lingering ankle laxity, hypomobility and hypermobility, these outcomes do not appear to be observed consistently in patients with CAI. Previous authors have considered mechanical instability as an explanatory factor for lingering ankle instability, but there has not been a definitive association of ankle laxity with CAI.¹⁹⁻²¹⁻²³⁻²⁸⁻²⁹⁻³³⁻⁴⁴⁻⁴⁵

Hertel's¹⁹ original model differentiated mechanical instability from functional instability. More recently, Hiller *et al*,²¹ refining the model of categorising CAI, suggests as many as seven

subgroups of individuals with CAI who most likely provide better homogeneity in describing the pathology. Of the three primary separation factors, the authors suggested that mechanical instability provided the weakest contribution. Additionally, hypomobility, rather than joint laxity, contributes more to the subgroup model creation. It appears that mechanical instability may be a factor in some patients that leads to recurrent ankle injury and measures of perceived ankle instability, but these are not necessarily dependent on the presence of ankle hypermobility. Data from other multifactorial studies that have included measures of mechanical instability in patients with CAI suggest that mechanical instability alone is not a consistent identifier of this pathology.²⁸⁻³³

A recent advancement in the CAI literature has been the stratification of individuals based on the structural and functional impairments associated with ankle instability. Multiple studies by Brown *et al*⁴⁴⁻⁴⁶ compared sensorimotor and biomechanical measures between patients classified as having MAI, functional ankle instability and copers (no measurable ankle instability or repeated injury). While the presence of mechanical laxity was associated with some proximal joint sensorimotor alterations and increases in ground reaction forces during landing tasks compared with the other groups, these differences were not observed consistently. It is also interesting to note that the MAI groups had more self-reported disability and no differences in the number of episodes of 'giving way' as compared with the functional ankle instability groups, suggesting that the MAI groups had similar, if not more, functional instability than the functional ankle instability groups did. The design of these studies to separate MAI and functional ankle instability represents the needed comparisons required to glean the factors that best define CAI. The information would seem to lend support to the strength of the contribution of functional instability measures, rather than mechanical instability, to defining CAI.

Future considerations

We have provided recommendations for the selection of patients with CAI to improve the quality of research on this pathology. The healthcare burden associated with ankle instability necessitates increased research and clinical outcomes that can be used to reduce the disability and recurrence rates associated with CAI. It is clear from the body of literature that there are many contributing factors to CAI that can create a host of impairments¹⁹⁻²⁰⁻²³⁻²⁶⁻²⁸⁻²⁹⁻³²⁻³³; however, this condition is more

heterogeneous than many realise.^{20 21} Therefore, researchers need to be cognisant of criteria that are best associated with CAI based on the current available evidence. Based on the collective expertise of the International Ankle Consortium, we feel that the specified selection criteria should be incorporated in all future research on CAI.

The selection criteria are based on a history of initial injury and of ongoing bouts of instability, as well as ratings of patient perceived function and disability gathered from validated survey instruments. In addition, to study CAI in patients, concomitant issues such as fracture and surgery and other significant lower extremity joint injury should be absent; also, an appropriate amount of time should have passed since suffering acute, inflammatory symptoms, all for the purpose of eliminating the confounding influence on the outcomes that researchers choose to employ.

We have provided our list of additional patient information that we feel should be reported, and we look forward to evaluating and using the evidence that continues to grow from this work to modify our recommendations moving forward. In the future, consistency among these suggested reported measures will only help to strengthen the description and understanding of CAI. In the mean time, researchers should strive to report as many of these data to create clearer descriptions of CAI, which may lead to more homogeneous subgroups being enrolled in studies. The rationale for this is to improve the understanding of the consequences of repetitive ankle injury and lingering instability, leading to the development of more effective interventions to decrease the acute and chronic ankle injury rates in physically active populations.

Statement and background of creation of the position statement

The International Ankle Consortium, formed in 2004, is an international community of researchers and clinicians whose primary scholastic purpose is to promote scholarship and dissemination of research informed knowledge related to pathologies of the ankle complex. We are a collegial network that strives to support the ongoing growth of scientific and clinical evidence to elucidate the mechanisms, characteristics and interventions related to ankle complex/joint pathologies. The International Ankle Symposium is the primary venue by which the International Ankle Consortium disseminates the work of its constituents in an effort to present and discuss the most contemporary theories and research related to ankle joint clinical phenomena and related interventions, with a primary focus on CAI.

Another focus of the International Ankle Consortium is to provide endorsement for standards of clinical research related to ankle joint pathologies. The International Ankle Consortium endorses the summary statements from past International Ankle Symposia that have presented the major findings and updates from the content of the meetings.^{35 47–49} Additionally, the International Ankle Consortium establishes position statements, such as this one, to endorse consistent standards for research and clinical management of ankle joint conditions among the physically active. This position statement will provide the background and discuss the existing evidence to support a set of specific selection criteria for patients with chronic/functional ankle instability with the goal of improving the quality of research and outcomes related to this specific ankle condition.

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