Study Protocol

Establishing return to play criteria after acute lateral ankle sprain injuries: A Delphi approach

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Background

Lateral ankle sprains are the most prevalent musculoskeletal injury sustained by individuals who participate in sports; they also account for the highest proportion of all musculoskeletal injuries presenting to US emergency departments[1-3]. Lateral ankle sprains have the highest recurrence rate of all musculoskeletal injuries; between 32%[4] to 74%[5] of individuals will experience a re-injury and/or report persistent injury-associated symptoms. The high prevalence (40%) of re-injury and persistent injury-associated symptoms experienced within the 1-year time period following first-time acute lateral ankle sprain injury suggests that current management practices may be insufficient[6,7]. A study of US high school athletes identified that 71% to 75% of athletes return to sport (RTS) within 3 days of incurring an acute lateral ankle sprain injury, whilst 95% of athletes RTS within 10 days of injury[8]. Based on these timeframes, it is not surprising that sensorimotor impairments associated with acute lateral ankle sprains are still present when athletes RTS. Specific impairments identified on RTS include: decreased self-reported activities of daily living and sport function, persistent swelling, ligamentous laxity, restricted dorsiflexion range of motion and compromised dynamic postural balance (as measured on the anterior reach direction of the Star Excursion Balance Test)[9]. Early, and symptomatic RTS after an acute lateral ankle sprain injury could heighten the risk of persistent injury-associated symptoms[4,5], future injury risk[10] and the development of secondary problems, such as ankle joint osteoarthritis[11]. For example, restricted ankle joint dorsiflexion range of motion, a commonly observed impairment at RTS following acute lateral ankle sprain injury, has been identified as a risk factor for sustaining other lower limb injuries, such as anterior cruciate ligament injuries[10].

There are a number of reasons as to why sportspersons RTS early, and with impairments, after incurring an acute lateral ankle sprain injury. First, lateral ankle sprains are often assumed to be minor injuries and consequently over half of individuals do not seek formal medical treatment[7,12,13]. Thus, in these individuals, injury-associated sensorimotor impairments are never addressed with specific targeted rehabilitation. Second, there are currently no criteria-based guidelines to guide RTS decision making for individuals with an acute lateral ankle sprain injury. A recent systematic review of literature failed to identify any studies that have prospectively utilized RTS criteria for individuals who have sustained an acute lateral ankle sprain injury (Tassignon et al; in preparation). A consensus statement suggests the consideration of a self-report questionnaire and functional performance testing (such as single leg hop tests and the SEBT with a cut-off of 80% that of the uninjured limb) when determining ability to RTS after acute lateral ankle sprain injury[14]. The problem is that there is no research to support these recommendations, which is a reason for proposing this study.

In light of the lack of evidence for RTS criteria following acute lateral ankle sprain injury, and lack of literature addressing this question, there is need to determine and collate expert opinion to inform RTS practice. The Delphi process is one method that can be used to collate and refine expert opinion. This approach has been undertaken to inform the development of RTS criteria for hamstring injuries[15,16]. Information gained by this process can be used to inform the development of RTS criteria for acute lateral ankle sprains and provide the basis for prospective cohort studies to test the use of the proposed criteria for successful RTS.

The aim of this study is to use a Delphi approach to develop consensus for RTS criteria for individuals who have sustained an acute lateral ankle sprain injury. Based on definitions of time loss injury from Fuller et al[17] and RTS from Ardern et al[18], RTS is defined as “sanctioned for unrestricted training and cleared/available for match play/competition selection”.

Methods

Study design

A 3-round Delphi approach will be used to establish consensus of opinion from a panel of experts on RTS criteria after an acute lateral ankle sprain injury. The process for each Delphi round will involve: data collection via an online survey (using the SurveyMonkey platform), analysis of responses, and provision of feedback to panelists. The goal of the Delphi process is to achieve

consensus, a priori defined as >70% agreement between panelists[19]. This study will be registered at The Australian New Zealand Clinical Trials Registry.

Participants

While there does not appear to be any clear recommendation for the ideal number of panelists in a Delphi process[20], it has been suggested that more participants is associated with greater reliability and judgement of data[21].

Eligibility criteria for participants (experts) are: i) health professional (e.g. physiotherapist, athletic trainer/therapist, sports medicine physician); ii) currently working with athletes competing in nationally selected representative teams or teams in Tier/Division 1 national competitions (e.g. English Premier League, NCAA Division 1, Suncorp Super Netball); iii) currently working in field or court sports in which the primary gross motor skills are running and jumping/landing or changing direction and there is a high prevalence of lateral ankle sprain injuries; iv) involved in making RTS decisions for individuals with an acute lateral ankle sprain injury; v) proficiency in the English language. The sports to be targeted for this study include: basketball[22], volleyball[23], netball[24], handball[25], korfball[26], soccer[27], rugby[28], American/Canadian football[29], Australian rules football[24], Gaelic football[24], lacrosse[30], field hockey[24], hurling[24], camogie[24], tennis[31], badminton[31] and squash[24,31]. Individuals who are working with Paralympic, Invictus Games or other groups of disabled athletes, or athletes from selective populations (such as military or World Maccabiah Games athletes) are not eligible for inclusion.

It is recommended that Delphi panels be heterogeneous with individuals of different personalities, perspectives and backgrounds, and that members include those with clinical and scientific expertise in the area of study[32]. For a heterogeneous panel recruitment, we will target individuals from different geographical locations, health professions and types of sports. The investigators on this study are from a range of global geographical regions (including Australia, New Zealand, Ireland, United Kingdom, USA, Canada, Netherlands, Belgium, Denmark, Norway, Switzerland, France, Italy, Brazil, Japan, South Korea, China and Qatar) and will be responsible for identifying panelists from their geographic region. Individuals who meet the eligibility criteria and are known to the investigators will be approached directly and invited to participate. National sporting institutes (e.g. the Australian Institute of Sport), national teams and teams competing in Tier/Division 1 national competitions will also be contacted to identify health professionals that make RTS decisions for athletes.

Identified experts who meet eligibility criteria will be invited to be a panelist for the Delphi process. Individuals will be given two weeks to accept or decline the invitation to participate and will be reminded via email after one week.

This study has been approved by The University of Queensland Human Research Ethics Committee (#2018001434) and all panelists will provide electronic informed consent prior to participation.

Data collection

For each Delphi round, expert panelists will be sent an email invitation with a link to an online survey. Participants will be given four weeks to complete the survey, with reminders sent after one and three weeks.

The first round of the Delphi survey will include a combination of structured and open response questions[19]. Structured questions will be informed by a review of the literature (Tassignon et al; in preparation). Based on previous Delphi research, questions will ask participants to indicate their level of agreement with a statement such as, *"*Do you feel the assessment of swelling should be a criterion to support the RTS decision after an acute lateral ankle sprain?"[33,34]. Likert scale answers will include: *"Yes"*, *"No"* or *"Unsure/I do not know"*. Participants will be asked to provide reasons for their responses. To increase richness of the data collected[21], the first Delphi round will also include open response questions (e.g. *"*Is there anything else you feel should be a criterion to support the RTS decision after an acute lateral ankle sprain?*"*).

Prior to sending the first-round survey to all panelists, the survey will be piloted on Specialist Sports

Physiotherapists involved in making RTS decisions for individuals recovering from an acute lateral ankle sprain injury. This step will be undertaken to improve clarity of questions and identify any ambiguities[35].

The second and third Delphi rounds will use structured questions with Likert rating responses (as described in Round 1). These rounds aim to form a consensus among participants.

Content analysis will be used to identify themes from open response questions[36]. Responses will initially be read for familiarisation and then re-read for identification of themes. Once themes are identified, data will be categorised. Analyses will be discussed between the researchers to achieve agreement, and any items for which agreement is not achieved will be discussed with a third party. This will culminate in a list of RTS criteria from the open responses that will be developed into structured questions for the subsequent Delphi round.

Structured questions that reach consensus (>70% of panelists agreed on the inclusion or exclusion of the RTS criteria for use in sportspersons after a lateral ankle sprain) will be removed from the survey for the following round. A participant's opinion to include a RTS criteria is defined as selection of the *"Yes"* Likert option, and an opinion to exclude a RTS criteria is defined a selection of the *"No"* option.

Feedback on the previous round will be provided to participants. Data from structured questions will be presented back to participants as the percentage of panelists who selected each answer category. Data from open response questions will be summarised as new RTS criteria/themes that have come out of participant responses. A thematic summary of explanation of responses will be included after each structured question that did not reach consensus in the previous round[15].

Data analysis

Data from the online Delphi rounds will exported from SurveyMonkey into Excel for calculation of achievement of consensus (yes/no) and level (%) of agreement.

References

1. Gaulrapp H, Becker A, Walther M, Hess H. Injuries in women's soccer: a 1-year all players prospective field study of the women's Bundesliga (German premier league). *Clin J Sport Med.* 2010;20(4):264-271.
2. Lambers K, Ootes D, Ring D. Incidence of patients with lower extremity injuries presenting to US emergency departments by anatomic region, disease category, and age. *Clin Orthop.* 2012;470(1):284-290.
3. Waterman BR, Owens BD, Davey S, Zacchilli MA, Belmont PJ, Jr. The epidemiology of ankle sprains in the United States. *J Bone Joint Surg Am.* 2010;92(13):2279-2284.
4. Konradsen L, Bech L, Ehrenbjerg M, Nickelsen T. Seven years follow-up after ankle inversion trauma. *Scandinavian journal of medicine & science in sports.* 2002;12(3):129-135.
5. Anandacoomarasamy A, Barnsley L. Long term outcomes of inversion ankle injuries. *Br J Sports Med.* 2005;39(3):e14.
6. Gribble PA, Bleakley CM, Caulfield BM, et al. Evidence review for the 2016 International Ankle Consortium consensus statement on the prevalence, impact and long-term consequences of lateral ankle sprains. *Br J Sports Med.* 2016;50(24):1496-1505.
7. Gribble PA, Bleakley CM, Caulfield BM, et al. 2016 consensus statement of the International Ankle Consortium: prevalence, impact and long-term consequences of lateral ankle sprains. *Br J Sports Med.* 2016;50(24):1493-1495.
8. Medina McKeon JM, Bush HM, Reed A, Whittington A, Uhl TL, McKeon PO. Return-to-play probabilities following new versus recurrent ankle sprains in high school athletes. *J Sci Med Sport.* 2014;17(1):23-28.
9. McCann R, Kosik K, Terada M, Gribble P. Residual Impairments and Activity Limitations at Return to Play from a Lateral Ankle Sprain. *International Journal of Athletic Therapy & Training.* 2018;32:83-88.

10. Wahlstedt C, Rasmussen-Barr E. Anterior cruciate ligament injury and ankle dorsiflexion. *Knee Surg Sports Traumatol Arthrosc.* 2015;23(11):3202-3207.
11. Valderrabano V, Horisberger M, Russell I, Dougall H, Hintermann B. Etiology of ankle osteoarthritis. *Clin Orthop.* 2009;467(7):1800-1806.
12. Delahunt E, Gribble PA. Structured clinical assessment: a brake to stop the ankle joint 'rolling'. *Br J Sports Med.* 2018.
13. McKay GD, Goldie PA, Payne WR, Oakes BW. Ankle injuries in basketball: injury rate and risk factors. *Br J Sports Med.* 2001;35(2):103-108.
14. Kaminski TW, Hertel J, Amendola N, et al. National Athletic Trainers' Association position statement: conservative management and prevention of ankle sprains in athletes. *J Athl Train.* 2013;48(4):528-545.
15. van der Horst N, Backx F, Goedhart EA, Huisstede BM, Group HI-D. Return to play after hamstring injuries in football (soccer): a worldwide Delphi procedure regarding definition, medical criteria and decision-making. *Br J Sports Med.* 2017;51(22):1583-1591.
16. Zambaldi M, Beasley I, Rushton A. Return to play criteria after hamstring muscle injury in professional football: a Delphi consensus study. *Br J Sports Med.* 2017;51(16):1221-1226.
17. Fuller CW, Ekstrand J, Junge A, et al. Consensus statement on injury definitions and data collection procedures in studies of football (soccer) injuries. *Br J Sports Med.* 2006;40(3):193-201.
18. Ardern CL, Glasgow P, Schneiders A, et al. 2016 Consensus statement on return to sport from the First World Congress in Sports Physical Therapy, Bern. *Br J Sports Med.* 2016;50(14):853-864.
19. Diamond IR, Grant RC, Feldman BM, et al. Defining consensus: a systematic review recommends methodologic criteria for reporting of Delphi studies. *J Clin Epidemiol.* 2014;67(4):401-409.
20. Hsu CC, Sandford BA. The Delphi Technique: Making Sense Of Consensus. *Practical Assessment, Research & Evaluation.* 2007;12(10):1-8.
21. Murphy MK, Black NA, Lamping DL, et al. Consensus development methods, and their use in clinical guideline development. *Health Technol Assess.* 1998;2(3):i-iv, 1-88.
22. McCarthy MM, Voos JE, Nguyen JT, Callahan L, Hannafin JA. Injury profile in elite female basketball athletes at the Women's National Basketball Association combine. *Am J Sports Med.* 2013;41(3):645-651.
23. Kilic O, Maas M, Verhagen E, Zwerver J, Gouttebarge V. Incidence, aetiology and prevention of musculoskeletal injuries in volleyball: A systematic review of the literature. *Eur J Sport Sci.* 2017;17(6):765-793.
24. Fong DT, Hong Y, Chan LK, Yung PS, Chan KM. A systematic review on ankle injury and ankle sprain in sports. *Sports Med.* 2007;37(1):73-94.
25. Bere T, Alonso JM, Wangensteen A, et al. Injury and illness surveillance during the 24th Men's Handball World Championship 2015 in Qatar. *Br J Sports Med.* 2015;49(17):1151-1156.
26. Backx FJ, Beijer HJ, Bol E, Erich WB. Injuries in high-risk persons and high-risk sports. A longitudinal study of 1818 school children. *Am J Sports Med.* 1991;19(2):124-130.
27. Shalaj I, Tishukaj F, Bachl N, Tschan H, Wessner B, Csapo R. Injuries in professional male football players in Kosovo: a descriptive epidemiological study. *BMC musculoskeletal disorders.* 2016;17:338.
28. Fuller CW, Taylor A, Raftery M. Eight-season epidemiological study of injuries in men's international Under-20 rugby tournaments. *J Sports Sci.* 2018;36(15):1776-1783.
29. Mulcahey MK, Bernhardson AS, Murphy CP, et al. The Epidemiology of Ankle Injuries Identified at the National Football League Combine, 2009-2015. *Orthop J Sports Med.* 2018;6(7):2325967118786227.
30. Putukian M, Lincoln AE, Crisco JJ. Sports-specific issues in men's and women's lacrosse. *Curr Sports Med Rep.* 2014;13(5):334-340.
31. Chevinsky JD, Newman JM, Shah NV, et al. Trends and Epidemiology of Tennis-Related Sprains/Strains in the United States, 2010 to 2016. *Surg Technol Int.* 2017;31:333-338.

32. Powell C. The Delphi technique: myths and realities. *J Adv Nurs.* 2003;41(4):376-382.
33. Bossard DS, Remus A, Doherty C, Gribble PA, Delahunt E. Developing consensus on clinical assessment of acute lateral ankle sprain injuries: protocol for an international and multidisciplinary modified Delphi process. *Br J Sports Med.* 2018.
34. Delahunt E, Bleakley CM, Bossard DS, et al. Clinical assessment of acute lateral ankle sprain injuries (ROAST): 2019 consensus statement and recommendations of the International Ankle Consortium. *Br J Sports Med.* 2018.
35. Jairath N, Weinstein J. The Delphi methodology (Part one): A useful administrative approach. *Can J Nurs Adm.* 1994;7(3):29-42.
36. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77-101.