

ICON PART-T

ICON 2019--International Scientific Tendinopathy Symposium Consensus: Recommended standards for reporting participant characteristics in Tendinopathy research (PART-T):

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Abstract

Objectives: To establish consensus for reporting recommendations relating to participant characteristics in tendon research.

Methods: A scoping literature review of tendinopathy studies (Achilles, patellar, hamstring, gluteal, and elbow) was followed by an on-line survey, and face to face consensus meeting with expert health care professionals (HCP) at the International Scientific Tendon Symposium, Groningen 2018.

Results: We reviewed 263 papers to form statements for consensus and invited thirty HCP from different disciplines and geographical locations; 28 completed the survey and 15 attended the meeting. There was consensus that the following data should be reported for cases and controls: sex, age, standing height, body mass, history of tendinopathy, whether imaging was used to confirm pathology, loading tests, pain location, symptom duration and severity, level of disability, co-morbidities, physical activity level, recruitment source and strategies, and medication use history.

Conclusion: Standardised reporting of participant characteristics aims to benefit patients and clinicians by guiding researchers in the conduct of their studies. We provide free resources to facilitate researchers adopting our recommendations

INTRODUCTION

Poor reporting of participant characteristics leads to the waste of valuable research resources.(1) Frequently, findings from research on tendinopathy cannot be applied in clinical practice because the reported research lacks sufficient information pertaining to the study characteristics of the participants. Clinicians need to consider how research applies to people seeking help with tendon related conditions, for example, the presence of co-morbidities that may influence treatment outcomes. Fundamentally, how researchers diagnose the tendon related condition and the detail by which they describe participants in their research facilitates translation to the intended end-user (patient).

If all relevant data on participants are not collected and reported, heterogeneous clinical presentations may be included in the research study and this may impact findings. Moreover, adequately describing all participant characteristics improves the ability to reproduce studies, draw comparisons clinically and conduct meta-analyses of data in systematic reviews. Fortunately, poor reporting is a “correctable weakness”(2) that can be addressed through adequate and standardised reporting of participant characteristics.

Our aim was to establish a consensus-derived list of recommended participant characteristics to be reported in clinical studies on tendinopathy. While established checklists are already available for different study designs to ensure methodological rigor, this expert driven list was intended to capture the essential participant features specific to tendinopathy research. Our consensus encourages researchers to consistently report key attributes of cases and controls, as well as acknowledge where such features were not collected. It is not intended to mandate selection criteria or to restrict data collection to these items.

METHODS

This was a three-stage process: (1) scoping literature review of tendinopathy, which informed items to be included in an online survey, (2) online survey of expert health care professionals (HCP) in the field of tendinopathy, and (3) a consensus meeting held at the 5th International

Scientific Tendinopathy Symposium (ISTS) in Groningen, the Netherlands (27-29 September, 2018).

Literature scoping

A scoping literature search was conducted by IK & ER to identify currently reported participant characteristics (for cases and controls) and potential gaps in descriptors. The most recent papers (from 2018) were reviewed first, before consulting in reverse chronological order to include papers published up to 1997. Scoping of the literature ensured that there was research representation by key tendon research groups around the world. This process was completed for the patellar tendon, Achilles, hamstring, gluteus medius and elbow tendons (Appendix A), as these were agreed as the most common presentations of tendinopathy (shoulder was not included given the complexity and disagreement around symptom source). Study designs included: randomised and non-randomised parallel group trials, prospective cohort studies, case series, retrospective studies where an intervention was applied and intervention studies. Case studies and letters to editors were not included. Systematic reviews and narrative reviews were used to identify original data papers (Appendix B).

Development of consensus statements for baseline reporting

The steering committee (SM, ER, AS, BV, AW, JZ) met by teleconference in March 2018 to define the scope and procedures of the Groningen Delphi and consensus process. Statements were drafted by ER with assistance from SM and feedback was provided by the steering committee. Consideration was given around burden to HCP and the number of statements overall to be voted on. Thirty-seven statements (Appendix C) were edited into 20 (e.g. by removing duplication of separate questions for cases and controls), for circulation to HCP.

On-line process

Tendinopathy HCP were invited to participate via an e-mail invitation, and were selected with consideration to expertise (defined as HCPs who have published original research on tendinopathy), representation from relevant disciplines (physician, physiotherapists,

epidemiologist, clinician, surgeon, radiologist) and attempt to obtain broad geographic representation. The invitation letter explained the process and the rules for participation, including an option to participate in both the online survey plus the in-person meeting, or just the online survey (Appendix D). The steering committee also submitted responses to the survey. In total, 30 HCPs were invited, of whom 28 agreed to participate (36% female, mean age 53, full demographic characteristics are listed in accompanying consensus paper Vicenzino et al). HCP were sent a link to an anonymized survey (Survey Monkey, San Mateo, CA). For each statement, HCP had three choices (Agree, Disagree, or Don't Know/ Not Sure) and space for comments. One author (BV) compiled the results of the survey and distributed the results back to the steering committee for analysis (Appendix D). Statements that already achieved consensus (70% or higher agreed or disagreed; Appendix E) were not discussed further during the in-person meeting.

ISTS Meeting

Fifteen of the 28 HCP who completed the survey participated in the preconference consensus meeting in Groningen in September 2018 . A summary from the on-line process was circulated prior to attendance. At the face-to-face meeting, statements that had already reached consensus during the online process were not discussed, but the results were presented to the group. Statements that had not reached consensus during the online process were discussed at the face-to-face meeting (facilitated by lead author ER). These statements were then rated yes or no in a blinded voting process, with the results announced after each statement (We did not have an option for 'don't know' at the meeting, in order to determine final resolution on statements). The summary of this information was presented by the four first authors (ER, AS, BV, JZ) at ISTS. Several other papers emanated from this consensus meeting.

RESULTS

A total of 263 studies were used to develop the 20 final statements for HCP consideration (85 elbow, 8 hamstring, 56 patellar tendon, 23 lateral hip and 91 Achilles, (Appendix B OR Supp file)). Thirteen statements achieved the pre-determined threshold for consensus of >70% agreement or disagreement following the online process, while seven statements which did not reach consensus online were further discussed at the in-person meeting. At the end of the process consensus was achieved for 18 statements (Figure 1, Table 1). Percentage agreement and the full statements are provided (Appendix D). Infographics and data collection sheets have been developed to assist with implementation.

Table 1. Consensus checklist for researchers

Item	Description
Sex	Report sex of all participants
Age	Report in years/months (and whether part of inclusion/exclusion into study)
Standing height	Report unit of measure* and whether it was measured or self-reported
Body mass	Report unit of measure* and whether it was measured or self-reported
Symptom duration	Length of current episode, and whether first episode
History of tendon pain	Description of whether any prior history at any tendon site
Level of disability	Report what was used, for example VISA, or other valid scale
Severity of symptoms	Report what was used as a measure for symptom severity for example - pain intensity rated on a visual analogue scale or numerical rating scale Record context and instructions given to participant (e.g., recall pain or pain during a load test)
Loading tests	Report whether loading tests were used, and detail appropriate methodology of utilised tests (e.g., joint angles, repetitions)
Location of symptoms	Describe location of patient reported pain, and whether this was a selection criterion and whether the pain was recorded during a pain provocative load test
Imaging	State whether imaging was used
Recruitment	Detail recruitment source and strategy, including number excluded from participation. Consider reporting geographical location, duration and target audience, whether participants were paid, and if they were currently seeking care
Comorbidities	Report whether any significant comorbidities for tendon conditions were included/excluded – use comorbidities infographic LINK
Medication use	Report whether any medication use was included/excluded – use medication guide LINK
Other characteristics	Consider previous interventions, other pain locations, nicotine use or sleep/well-being factors, psychological factors
Physical activity level	Report physical activity measure appropriate to the population
Cases and Controls - all items listed apply to both cases and controls	

Note: Two items did not reach consensus: primary aggravating activity and pain maps and are discussed in text, * NB: Body mass and standing height allow the calculation of body mass index

Two items (primary aggravating activity and pain maps) did not reach consensus (13% agreement and 27% agreement during online survey and at meeting, respectively). A brief outline of some of the comments provided by expert participants at the consensus meeting regarding the 7 statements discussed (including the 2 that did not reach consensus) is provided (Appendix E).

DISCUSSION

A consensus of essential participant characteristics that we recommend should be reported in tendinopathy studies was developed. Consensus was achieved on 18/20 items originally identified in the literature and considered in the process. Good quality reporting will allow better translation and implementation of research findings for both clinical practice and researchers. This will improve the care for patients and reduce research waste.(3)

The four key areas for reporting characteristics are of fundamental importance to clinical practice and researchers. Demographic information is a vital contributing factor to tendinopathy, particular in areas such as gluteal and Achilles tendinopathy, where factors such as sex and age are often associated with symptoms. Similarly, descriptors of tendinopathy such as symptom duration or severity may be associated with differences in clinical effects or demonstrate different subgroups of patients within a certain type of tendinopathy. This information also helps clinicians appraise how generalisable and relevant research findings may be to the patient in front of them.

Information on general health and comorbidities in relation to tendon symptoms is also often gathered as part of history taking in clinical practice, yet in research is under-reported. It is potentially a major confounder to treatment outcomes, and particularly influential on conditions such as Achilles tendinopathy. Recruitment sources may provide context regarding demographics, social context and potential differences of those presenting to clinics or hospitals (as opposed to study participants recruited via social media or online advertising).

Importantly, it is vital that all of these parameters are reported to ensure the clearest picture of the research participants, as many of these factors may intersect (for instance recruitment source, comorbidities, and physical activity level), aiding translation.

Impact for clinical practice and patients

Detailed information about study participants facilitates immediate and appropriate clinical translation. Certain tendinopathy treatments might be more effective in specific patient groups (athletic vs. non-athletic, older vs. younger, presence of co-morbidities, etc). For example, eccentric exercise has high level evidence for the treatment of recreational male runners with mid-portion Achilles tendinopathy(4) but this treatment has been shown to be less effective for tendons other than the Achilles(5), in-season athletes,(6) women,(7) sedentary patients and those high body mass index.(8) This example highlights the large number of relevant participant characteristics that may be associated with treatment response that should be available to clinicians and other researchers. It also highlights the challenges represented by heterogenous sample populations. Patients and clinicians benefit from having the participant characteristics clearly described in making management decisions.(9)

Impact for researchers – reporting and reviewing

Systematic reviews form the basis of clinical guidelines/recommendations in musculoskeletal research. Pooling data from studies to estimate the likely magnitude of benefits of treatments informs clinical practice. This pooling of data is impeded if individual studies report or do not report salient patient characteristics.(10) Substantial variation in the reporting of participant characteristics in tendinopathy has limited pooling of data in systematic reviews because of clinical heterogeneity (e.g. different metrics or outcomes, participant characteristics, different settings, etc.). The current consensus-derived list of participant characteristics for tendinopathy aims to address this issue by ensuring appropriate data is reported so that it can be compared between studies and enable appropriate pooling of tendinopathy trials when composing systematic reviews and meta-analysis.

Palpation and imaging

Palpation and imaging are commonly used clinically. The recommendation was to report if and which type of imaging was or was not used in both cases and control in a study. The use of imaging is hotly debated in tendinopathy circles and the greater musculoskeletal community, given the poor relationship between pain and structure on imaging, the cost of imaging and its relevance to diagnosis. Discussions of these are beyond the scope of this consensus, however reporting whether imaging was used on cases and controls helps clinicians and researchers understand the study population better. Palpation was also not a recommended reporting item, though this should not prevent it being reported and importantly, whether it was applied to cases and controls.

Impact for funding bodies

Funding bodies can consider using this list of participant characteristics to evaluate research proposals, ensuring adequate participant data collection and reporting, securing that the resources they invest will be put to the best possible use.

Limitations

Many authors from different countries, research areas and groups have contributed to the tendinopathy literature. Although we aimed to capture representation of clinical excellence in the field, we were limited in the number of experts who were included in this consensus. Also the characteristics of the experts may have been unequal (e.g. 36% women), and global geographic diversity may not have been fully represented.

Future directions

As this is the first consensus of its kind in tendinopathy research, regular review of the items will be needed as new information emerges. The inclusion of pain maps and primary aggravating activity did not reach consensus. Further research and clinical perspectives on these criteria may show them to be a useful metric to include in tendinopathy studies in the future.

As knowledge about tendon conditions improves, future consensus meetings should consider items such as psychological factors,(11-13) patient expectation and pain self-efficacy(14), in addition to reviewing the items raised in the current consensus.

CONCLUSION

Our consensus recommends reporting of eighteen baseline participant characteristics across four areas: individual population demographics, clinical characteristics, general health and co-morbidities and participant recruitment. These descriptors of participant features should be used in tendon research. Describing tendinopathy participants across these relevant characteristics will enable more detailed analyses, facilitating a better understanding of how and why people with tendinopathy recover. We provide infographics and a data collection sheet to assist with implementing this into new research.

FIGURE LEGEND

Figure 1. Summary of recommended participant characteristics to be reported*

**** “Other characteristics”:***

These items were suggested at the meeting for future work and not individually voted on:

- Other measures of obesity – adiposity, waist or hip circumference
- Bilateral/Unilateral presentations
- Previous interventions
- Other current pain sites
- Nicotine use
- Sleep

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