

Protocol

Psychometric properties of quantitative sensory testing focusing on healthy and patients with shoulder pain: a systematic review protocol

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ABSTRACT

Background: Quantitative sensory testing (QST) is a battery of non-invasive psychophysical methods to assess the function of somatosensory system. Although the use of QST is widespread and several studies in patients with chronic shoulder pain have used it, the level of evidence for the psychometric properties has not been established. The aim of this protocol is to investigate, through a systematic review, the level of evidence for the psychometric properties of QST in the shoulder.

Methods: For conducting and reporting this review the preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines and the consensus-based standards for the selection of health measurement instruments (COSMIN) guidelines will be used. Nine databases including PubMed, Medline, AMED (via EBSCO), PEDRO, Embase, Web of Science, Scopus, SportDiscus, Google Scholar and Cochrane Library will be searched for the period from their inception until September 2021. Two reviewers (BP and SK) will independently evaluate the retrieved articles (titles and abstracts) and the psychometric characteristics checklist based on the standards from the COSMIN. The modified grading of recommendations assessment, development, and evaluation (GRADE) approach will be used to assess the overall quality of the evidence.

Conclusions: Evaluation of the level of evidence for the psychometric properties of QST in the shoulder is an essential step for evidence-based assessment in clinical practice.

Trial registration: PROSPERO registration number is CRD42021232778.

Keywords: Quantitative sensory testing, Shoulder, Psychometric properties

INTRODUCTION

Shoulder pain (SP) is one of the most common musculoskeletal disorders and increases with age.¹ Shoulder includes a variety of structures, and it has a wide range of motion, thus its dysfunction causes serious consequences for patients, and it is a challenge for health professionals.² A recent study shows that the severity of

shoulder pain is a risk factor for poor physical quality of life in middle-aged and elderly people.³ The high levels of recurrence and chronicity of shoulder pain drove scientists away from the structural model of pain. It is now accepted that the extent of structural damage is often unrelated to the experience of pain.^{4,5} Over the past decade, a neurophysiological mechanism-based approach has been proposed for the diagnosis and management of chronic

pain.⁶ The clinical features of patients can provide important information about the underlying pathophysiological mechanisms.^{7,8} However, clinical evaluation seems to lag in detecting the mechanisms that contribute to the perception of pain.⁹ Thus, it is recommended to use objective measurements that will help strengthen the diagnosis and the direction of treatment.

Quantitative sensory testing (QST) is a battery of non-invasive psychophysical methods to assess the function of somatosensory system.¹⁰ QST evaluates subjective responses to a controlled quantitative stimulus. The procedure may involve evaluating the minimum perceived pain threshold, locating the stimulus, the threshold at which the stimulus becomes painful, the tolerance or differentiation of different sensory stimuli and is carried out with the use of simple tools for assessing perception of touch, vibration, proprioception, pinprick/blunt pressure sensitivity or sensitivity to cold or heat stimuli.¹¹ Table 1 presents different parameters of QST, the type of stimuli applied and the type of fibers stimulated.^{10,12,13} The diversity of QST provides the advantage of estimating sensory processing by large (A α and A β) and small (A δ and C) afferent nerve fibers and can provide important information about pain mechanisms.¹² It has been observed that a subset of patients with shoulder pain develop central sensitization signs such as generalized hyperalgesia, diffuse pain, and other centrally maintained symptoms.¹⁴⁻¹⁶ QST may provide: indications of peripheral or central sensitization (different response in affected or non-affected area); information on changing pain sensitivity in patients (compared to healthy individuals) but also between patients, possibly reflecting the mechanisms of pain, (i.e. sensitivity following the course of a nerve or diffuse, extensive pain without neuroanatomical logical); prediction of treatment outcomes; and results on response to treatment.^{12,17-21}

In an attempt to detect prognostic factors for the recognition of central sensitization, the systematic review of Clark et al showed that there is moderate evidence of a higher risk of developing central sensitization when there were higher levels of sensory sensitivity in the patient's history.²² A recent systematic review revealed a link between pain sensitivity, using QST, and disability. Also, QST may predict other factors such as depression in patients with musculoskeletal pain.²³ Although the use of QST is widespread and several studies in patients with chronic shoulder pain have used it, there is inconsistency in the results due to different protocols and other factors that may affect measurements (stimulation parameters, detection of stimuli, order of testing procedures, raters training, participants' familiarization, medication usage etc.).²⁴⁻²⁶ However, the use of reliable and valid assessment tools is vital whether they are used for research or clinical purposes. Over the last years, systematic reviews have been published that have examined the psychometric properties (PMPs) of different components of QST in different populations. It seems that there is great variability

in the reliability of specific sensory tests (thermal stimuli) as opposed to other tests (such as conditioning pain modulation-CPM).^{25,27} There is also, great heterogeneity in the protocols and population of studies.²⁸ It is worth mentioning that, in order to use a sensory test, its PMPs should be evaluated at a specific site for the target population. QST is used in adjunct with clinical decision making and therefore must be accurate when applied. A systematic review evaluated the level of studies focusing on the PMPs of the sensory abnormalities' assessment in individuals with pain in the joints of the upper and lower extremities until 2016. There is a lack of research on PMPs of QST test procedures in shoulder, elbow, hip, and ankle joint pain. The authors concluded that improvements in the quality of primary studies are needed as risks of bias are identified that threaten the validity of the results.²⁴

Table 1: Parameters of QST.

QST parameter	Type of stimulus	Nerve fiber
Pressure pain threshold	Mechanical	A δ and C
Mechanical detection threshold	Mechanical	A β
Temporal pain summation	Mechanical	A δ and C
Sharp pain threshold	Mechanical	A δ
Conditioned pain modulation	2 stimuli (mechanical+isc hemic/thermal)	A β and C
Vibration threshold	Mechanical	A β
Light touch threshold	Mechanical	A β
Warm pain threshold	Thermal	A δ and C
Warm detection threshold	Thermal	C
Cold detection threshold	Thermal	A δ
Heat pain threshold	Thermal	A δ and C
Cold pain threshold	Thermal	A δ and C
Electrical perception/pain threshold	Electrical	A δ
Flexor withdrawal reflex threshold	Electrical	A δ

At present, there are no recent systematic reviews (or meta-analyses) investigating the PMPs of QST specifically targeting the shoulder. Therefore, it is advisable to create a systematic review and meta-analysis to investigate the PMPs of QST in shoulder. The current protocol presents the methods and process for estimating the levels of evidence of the QSTs psychometric studies in shoulder.

METHODS

This systematic review and meta-analysis will follow the preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines and the consensus-based standards for the selection of health measurement instruments (COSMIN) guidelines (<https://www.cosmin.nl/tools/checklists-assessing-methodological-study-qualities/>) for conducting and reporting the review, international prospective register of ongoing systematic reviews (PROSPERO) registration, <http://www.crd.york.ac.uk/prospero>.^{29,30}

Eligibility criteria

This systematic review will focus on studies evaluating the psychometric parameters of QST in the shoulder. Therefore, due to the nature of the studies that will be included in this work, the eligibility criteria are determined by the parameters: population, construct, outcome measures, study type. Any studies excluded, will be reported on the PRISMA flow diagram.

Inclusion criteria

Population

Adults (≥ 18 years old), asymptomatic participants or with musculoskeletal shoulder pain. There will be no restrictions in terms of gender and/or ethnicity.

Construct

Studies involving one or more QST components (chemical, electrical, mechanical, and/or thermal stimuli applied to the skin, muscles, or joints) in the shoulder area.

Outcome measures

Quantitative studies considering any of the following psychometric properties (PMPs) of QST (total protocol or part of this) in the shoulder—reliability (absolute reliability (agreement) and relative reliability of test–retest, intra-rater and/or inter-rater designs), validity (criterion (concurrent or predictive), construct (hypothesis testing—known-groups or comparison with other outcome measurements), responsiveness, specificity and sensitivity.

Study design

Studies including PMPs of QST (total protocol or part of this) in the shoulder as one of the (primary) aims or the sole aim of their study; studies that have valued reliability, validity, specificity, sensitivity and/or responsiveness as secondary or addable findings, (in this case, the full text will be considered and accepted only if quality/bias risk assessment information is available); peer-reviewed

observational studies, cross-sectional studies, randomized controlled trials, controlled clinical trials will be included if they have at least one PMP of QST (at least one component of QST); studies in English and Greek will be accepted to ensure time and cost. The full text of the studies to be included should also be available.

Exclusion criteria

Studies with experimental pain or symptoms; duplicate publication of data (follow-up analysis of already published data); studies including participants with neurological disorders including cerebral, spinal cord, basal ganglia, brainstem, cerebellar and peripheral nerve injuries and/or diseases; and data and results from abstracts of conference presentations, systematic reviews and meta-analyses, narrative reviews, book reviews, book chapters, doctoral dissertations, other dissertations theses, case series/reports, commentaries, editorials, letters to the editor, patient education handouts, consensus statements, clinical practice guidelines, or unpublished literature were excluded from the study.

Information sources

Searches will include the following databases: PubMed, Medline, AMED (via EBSCO), PEDRO, Embase, Web of Science, Scopus, SportDiscus, Google Scholar and Cochrane Library for the period from their inception until September 2021. Up-to-date and comprehensive search strategies will be developed, based on database suggestions to ensure search effectiveness.

Search strategy

To ensure the maximum possible search results, the initial search of the databases will be performed without the restrictions (filters) on language or date of publication. A professor in the field of physiotherapy from the University of Thessaly and experience with previous systematic reviews will contribute to the search. The search strategy will include topic headings and keywords, combining MeSH terms related to psychometric attributes (reliability, validity, responsiveness, specificity, sensitivity), quantitative sensory testing (PPT, CMP, etc.) and shoulder. We also checked the reference lists from relevant articles to contribute to the completeness of the search.^{23,24} The article selection procedure will be presented in the PRISMA flowchart. A complete electronic search strategy for the PubMed database is presented in Table 2. This search strategy will be adapted to the rest of the databases.

Study selection

Initially, the examiners will evaluate a few articles separately (pilot study), using the examination questionnaire, to test their effectiveness. The two reviewers (BP and SK) will then independently evaluate the retrieved articles using a screening questionnaire. In case of uncertainty regarding the incorporation of the

article (after checking the title and the abstract), the full version of the text will be retrieved and checked. A third examiner (PA) will intervene only in cases of doubt. Recovered publications will be imported into the Endnote software package.

Data extraction process

An appropriate form will be configured to collect the data of the selected articles. Specific study information will be collected by the first examiner (BP). The second examiner (SK) will check the accuracy of the procedure. Some studies may have incomplete data, so we will encourage communication with their authors. Given the rigorous curriculum, the authors will have 2 weeks to answer our questions. Otherwise, the study will be described as "vague". The elements that we will gather from the selected studies, include the construct, population, type of measurement instrument, measurement properties of interest and the statistics (the model used, the result and its 95% confidence interval).

Risk of bias assessment

Assessing the quality of primary studies is an important part of a systematic review to assess the risk of bias. Understanding the quality of the studies and the measuring instrument used is a difficult task. To this end, the COSMIN checklist was developed, a standard tool for assessing the risk of bias in studies.³¹ The COSMIN checklist was originally developed for self-reported

evaluation tools, but now its revised format has been extended to other tools, too.³² In this review, two reviewers (BP and SK) will independently evaluate the psychometric characteristics (reliability, validity and measurement error, criterion validity, hypotheses testing for construct validity and responsiveness) (Table 3) checklist in a four-point scoring system (very good, adequate, doubtful and inadequate) of each study, based on the standards from COSMIN.

According to the instructions we will use the lower score counts methods to come to an overall rating per study. The third examiner (PA) will intervene again in case of doubt.

Synthesis of results

The next step is to summarize the data. If at least three studies with relevant data are available for each QST component in the shoulder and with sufficient homogeneity, the attempt for meta-analysis using a random effects model will be encouraged. Otherwise, the quality of the evidence for each measurement tool and method will be separately evaluated. The criteria for each of the estimated measurement properties for each instrument and the measurement method will be marked as sufficient (+), unspecified (?) or insufficient (-) (Table 4). Finally, the modified grading of recommendations assessment, development, and evaluation (GRADE) approach will be used to assess the overall quality of the evidence as high, medium, low or very low, based on the risk of bias, inconsistency, imprecision, and indirectness.³²

Table 2: Search strategy for PubMed.

Search strategy	
#1	((("Psychometrics"[Mesh]) OR "Reproducibility of Results"[Mesh]) OR "Observer Variation"[Mesh]) OR "Bias"[Mesh]) OR "Discriminant Analysis"[Mesh] "psychometr*" [tw] OR "clinimetr*" [tw] OR "valid*" [tw] OR "content validity" [tw] OR "construct validity" [tw] OR "structural validity" [tw] OR "hypothesis -testing" [tw] OR "criterion validity" [tw] OR "predictive validity" [tw] OR "sensitivity" [tw] OR specificity [tw] OR "measurement error" [tw] OR "reliab*" [tw] OR "intratester reliability" [tw] OR "intertester reliability" [tw] OR responsiveness [tw] OR "standard error of measurement" [tw] OR "coefficient of variation" [tw] OR reproducibility [tw] OR "intratester reliability" [tw] OR "test-retest reliability" [tw] OR "absolute reliability" [tw] OR "relative reliability" [tw] OR agreement [tw] OR "generaliz*" [tw] OR "smallest real difference" [tw] OR "minimal detectable change" [tw] OR "minimal important difference" [tw] OR "clinically important difference" [tw] OR "meaningful change" [tw] OR "interpretab*" [tw] OR repeatability [tw] OR accuracy [tw] OR precision [tw] OR consistency [tw])
#2	((("Pain Measurement"[Mesh]) OR "Nociceptors"[Mesh]) OR "Central Nervous System Sensitization"[Mesh]) OR "Pain Threshold"[Mesh]) OR "Sensory Thresholds"[Mesh] OR "quantitative sensory test" [tw] OR "sensory test" [tw] OR qst [tw] OR threshold [tw] OR tolerance [tw] OR pressure [tw] OR electrical [tw] OR warm [tw] OR heat [tw] OR hot [tw] OR cool [tw] OR cold [tw] OR mechanical [tw] OR hyperalgesia [tw] OR hyperaesthesia [tw] OR allodynia [tw] OR "sensiti*" [tw] OR "pain threshold" [tw] OR "thermal detection" [tw] OR "electrical perception threshold" [tw] OR "peripheral sensitization" [tw] OR "central sensitization" [tw] OR "central nervous system" [tw] OR "conditioned pain" [tw] OR modulation [tw] OR "wind up" [tw] OR "pain*" [tw] OR "algo*" [tw] OR "sensory abnormalities" [tw] OR "pain*" [tw])
#3	("Shoulder"[Mesh] OR "Shoulder Pain"[Mesh]) OR "shoulder*"
#4	#1 AND #2 AND #3

Table 3: Definitions of measurement property adapted from COSMIN recommendation (except where indicated) (*definitions adapted from other sources).

Term			
Domain	Measurement property	Subsets of measurement property	Definition
Reliability (extended definition)			The degree to which the results for participants, are the similar for repeated measurements of QST (in the same group under several conditions) and free from measurement error.
	Test-retest		The extent of agreement in repeated measurements of QST over time.
	Intra-rater		The extent of agreement in repeated measurements of QST on the same participant by the same rater.
	Inter-rater		The extent of agreement between raters investigating sensory abnormalities scores with QST on the same individual.
	Measurement error		The systematic and random error of a participant's score that is not attributed to true changes in sensory to be measured.
Validity			The degree to which a component of QST measures the sensory abnormalities i.e., the construct which has designed to measure.
	Construct validity		The extent to which the scores of a specific sensory test of QST are consistent with hypotheses regarding the scores of other measurement methods or differences between known groups, given that QST validly measures the construct it is purported to measure.
		Discriminative/known groups validity	The degree to which the scores of a specific test of QST can discriminate between groups known to differ in sensibility (i.e. individuals with SIS versus healthy individuals).
		Convergent and discriminant (divergent) validity* ³³	The specific test of QST show conceptual convergence or divergence between them or with other outcome measures attributed to different constructs such as pain intensity, disability, depression etc.
	Criterion validity	Predictive validity	The degree of correlation to a reference standard (i.e. a PRO) measuring sensibility with a specific test of QST (i.e. PPT).
Responsive ness			The ability of a special test of QST to detect change in sensibility over time
Sensitivity* ³⁴			The proportion of individuals with shoulder pain (affected) identified with sensory abnormalities
Specificity* ³⁴			The proportion of healthy individuals (unaffected) identified without sensory abnormalities

QST=Quantitative sensory testing, SIS=shoulder impingement syndrome, PRO=patient-reported outcome, PPT=pressure pain threshold

Table 4: Criteria for evaluating the quality of the psychometric properties according to the COSMIN checklist.

Measurement property/rating	Criteria
Reliability	
Sufficient (+)	ICC or weighted kappa ≥ 0.70
Indeterminate (?)	ICC or weighted kappa not reported
Insufficient (-)	ICC or weighted kappa < 0.70
Measurement error	
Sufficient (+)	SDC or LoA $< \text{MIC}$
Indeterminate (?)	MIC not defined
Insufficient (-)	SDC or LoA $> \text{MIC}$
Criterion validity	
Sufficient (+)	Correlation with gold/reference standard ≥ 0.70 or AUC ≥ 0.70
Indeterminate (?)	Not all information for “+” reported
Insufficient (-)	Correlation with gold/reference standard < 0.70 or AUC < 0.70
Responsiveness	
Sufficient (+)	Agreement with the hypothesis or AUC ≥ 0.70

Continued.

Measurement property/rating	Criteria
Indeterminate (?)	Hypothesis is NOT defined (by the review committee)
Insufficient (-)	Not agreement with the hypothesis or AUC<0.70
Sensitivity and specificity	
Sufficient (+)	Sensitivity and specificity calculated
Indeterminate (?)	Not applicable
Insufficient (-)	Sensitivity and specificity NOT calculated

AUC=Area under the care, SDC= smallest detectable change, LoA=limits of agreement, MIC=minimal important change

DISCUSSION

To our knowledge, this is the first systematic review investigating the PMPs of QST specifically targeting the shoulder. Only one study assessed the level of evidence for PMP testing procedures in people with pain in peripheral joints, including the shoulder. However, the literature search in this study was conducted in seven databases from inception to March 2016. In this search, the gap from the previous review will be filled. The limitations of this protocol include the acceptance of original research articles published in English and Greek. Studies that have not been published in peer-reviewed journals (eg results from conference presentations, chapters and book reviews, doctoral and other dissertations) will be rejected. This protocol was written in accordance with the recommendations provided by Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) and Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN). The results will allow clinicians to make an informed evidence-based assessment and will inform further research into this topic.

CONCLUSION

To date, although the use of QST is common in assessment of patients with chronic shoulder pain, the level of evidence for psychometric properties has not been documented. Evaluation of the level of evidence for the psychometric properties of QST in the shoulder is an essential step for evidence-based assessment in clinical practice.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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