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Report from the Hand Osteoarthritis Working Group at OMERACT 2018: update on core instrument set development

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Report from the Hand Osteoarthritis Working Group at OMERACT 2018: update on core instrument set development

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ABSTRACT

Objective. Evaluate hand osteoarthritis tools for core instrument set development.

Methods. For OMERACT2018, a systematic literature review and advances in instrument validation were presented.

Results. Visual analogue and numeric rating scales were considered valuable for pain and patient global assessment, despite heterogeneous phrasing and missing psychometric evidence for some aspects. Modified Intermittent and Constant Osteoarthritis Pain was lacking evidence. Michigan Hand Outcomes Questionnaire had advantages above other pain/function questionnaires. Hand Mobility in Scleroderma was valid, although responsiveness was questioned. Potential joint activity instruments were evaluated.

Conclusion. The core instrument set development is progressing, and a research agenda was also developed.

INTRODUCTION

Hand osteoarthritis (OA) is a highly prevalent disorder, causing a considerable burden of disease(1). Simultaneous involvement of multiple hand joints and presence of different subsets (e.g., nodal, thumb base and erosive OA) make it difficult to study. To advance our understanding, high-quality studies with optimal outcome measurement are essential.

The Outcome Measures in Rheumatology (OMERACT) Hand OA Working Group (WG), assembled in 2010, endorsed a core domain set for clinical trials of symptom and structure modification and observational studies at OMERACT 2014(2), which was included in the Osteoarthritis Research Society International (OARSI) recommendations for design and conduct of clinical trials in hand OA(3). The core domain set includes six domains for all settings (pain, physical function, patient global assessment (PGA), health-related quality of life (HRQoL), joint activity, and hand strength), and two additional domains for trials of structure modification and observational studies (hand mobility and structural damage). HRQoL and hand mobility are not mandatory domains.

A preliminary core instrument set was also proposed including visual analogue (VAS) or numeric rating scale (NRS) pain, Functional Index for Hand OA (FIHOA), tender joint count and pinch/grip strength(2). Subsequent goals of the WG were to (1) evaluate relevant instruments according to OMERACT Handbook (4), and (2) update the research agenda on final core instrument set selection(5). Progress was discussed at OMERACT 2018.

METHODS

Review of instruments measuring pain and patient global assessment (PGA)

A systematic literature review (SLR) was performed (RW, BK, AA) including studies reporting on hand pain and PGA measured on VAS or NRS in patients with hand OA. A previous SLR on measurement properties of pain and function instruments in hand OA until January 2014 was used as a basis(6). Relevant manuscripts from that SLR were extracted. Additionally, medical literature databases (Pubmed, Embase, Web of Science, COCHRANE, CINAHL, Academic Search Premier, ScienceDirect) were searched from January 2014 to January 2018 applying similar methodology (see supplementary file). Psychometric features of the scales such as reliability, responsiveness, construct validity and clinical trial discrimination were extracted and evaluated according to OMERACT Handbook (4). These features were discussed at OMERACT 2018. Special attention was given to the phrasing and other details of the VAS/NRS question.

Construct validity of the modified Intermittent and Constant OA Pain (ICOAP) (IKH,(7-9)) was studied in the Nor-Hand study to investigate whether constant and intermittent pain were separate constructs in hand OA.

Investigation of other potential core instruments

Recent work was conducted by WG members on the relevant validity and psychometric properties of other tools: (1) Properties of the Michigan Hand Outcomes Questionnaire (MHQ) (FK,(10, 11)) were compared to more commonly used hand OA questionnaires, specifically Australian/Canadian Hand OA Index (AUSCAN) and FIHOA(12, 13); (2) Performance of Hand Mobility in Scleroderma (HAMIS) and its responsiveness was compared to other mobility instruments (FK,(14)); (3) Assessment of tender joint count to measure joint activity (FK, (15, 16)).

Research agenda

Guided by discussions at OMERACT 2018, a research agenda was developed.

RESULTS

Domain pain and PGA: progress in instrument validation

From the previous SLR, 32 relevant manuscript were selected providing data on VAS/NRS pain and/or PGA(6). Since January 2014, 18 relevant manuscripts were published and could be added (S1-S50, see reference list in supplements). Details of all included manuscripts can be found in supplementary table 1. Summary results of the search (supplementary figure 1) and psychometric features of both scales within these domains were discussed by the WG (table 1). VAS range 0-100 mm was the most studied scale (in 26/46 studies for pain and 10/15 studies for PGA). No study reported test-retest reliability data on the use of either scale in these domains. For pain, good construct validity of VAS was shown(S3, S24, S50), while only limited data were available for NRS(S41). Twenty-three(S1, S2, S4, S6-S13, S15-S18, S21, S22, S26, S37, S38, S42, S46) and eight studies(S15, S25, S28, S33, S34, S41, S45, S47) showed evidence for responsiveness of VAS and NRS, and 13(S7-S12, S17, S21, S22, S26, S37, S38, S46) and six studies(S14, S28, S33, S34, S41, S47) for clinical trial discrimination.

For PGA, construct validity was not studied. Evidence to support responsiveness for VAS was available in ten(S3, S6, S12, S13, S15, S18, S22, S29, S38, S40), and three studies for NRS(S14, S28, S45) . The capacity to discriminate in clinical trials was shown for VAS PGA in agreement with the primary outcome in five studies(S12, S22, S29, S38, S40), while for NRS only one study supported this(S28).

Strikingly, phrasing of the question accompanying VAS/NRS in both domains was very heterogeneous, and details were often not reported. For pain, substantial variety existed in which aspect(s) of pain were assessed (e.g., pain at rest or upon exertion, average or worst pain), location and joint(s) referred to (e.g.,target joints, dominant hand, both hands) and time of recall (undefined or ranging from current to 2 weeks) (supplementary table 2). Likewise, for PGA, time of recall was undefined in most studies (3/15 studies did specify (all 48 hours)) (supplementary table 3). After

presentation of these findings at OMERACT 2018, the WG proposed that clear standardized phrasing accompanying these instruments should be defined for pain and PGA. It was proposed that PGA should assess the impact of the disease on the patient's general well-being. Review of results of previously held focus groups was suggested to explore what is most relevant to patients(17).

Results of the validation study of the modified ICOAP were discussed at OMERACT 2018. Detailed results are presented elsewhere(9). In short, in hand OA patients, constant and intermittent pain largely overlapped and were not separate constructs, in contrast to the situation in knee and hip OA (7, 8). The existence of separate constructs in hand OA seemed clinically plausible, but might be influenced by hand OA location (finger versus thumb base) and involvement of multiple hand joints at different disease stages. It was suggested to seek more patient input, since the development of ICOAP was based on focus group discussions with patients with knee and hip OA, but not hand OA. However, previous focus groups of hand OA patients have already identified a range of pain concepts, such as fluctuating pain and psychological consequences of pain, which are not represented in the commonly used instruments to assess hand OA (17).

Based on the available evidence, it was concluded that VAS and NRS are most likely the best instruments to measure pain and PGA. However, evidence about some essential psychometric properties is missing, in particular regarding reliability, construct validity for NRS pain/PGA, and clinical trial discrimination for NRS PGA.

Evaluation of other potential core instruments and research agenda

The results of comparison of MHQ with AUSCAN and FIHOA for measuring domains pain and function were discussed in light of OMERACT Filter 2.1(4) (table 2 and (11)). While displaying similar measurement properties, important advantages of MHQ above other instruments were that it can overcome issues of copyright (AUSCAN) and outdated questions (FIHOA). The possibility to propose more than one instrument for a core domain, with the accompanying risk of jeopardising standardisation, was discussed.

Assessment of performance of HAMIS in comparison to other mobility instruments was published previously(14). Though HAMIS appeared the most useful to measure hand mobility compared to other instruments, the WG debated that responsiveness data are weak. Over a two-year period, limited change over time was observed(14), either indicating that the domain itself does not change, or that the instrument cannot detect this change.

Progress in instrument development for joint activity is published in conference abstracts(15, 16). Lack of a well-accepted definition hampers instrument development for this domain. Potential instruments include inflammation on imaging (ultrasound, magnetic resonance imaging), pain upon palpation, self-reported painful joint count, soft tissue swelling, and pain while gripping. In the WG

discussion it was suggested that some instruments complement each other, and a combination may be useful. Prediction of radiological progression was proposed as an anchor to assess suitable instruments.

Following discussion of these results, a research agenda was developed to guide future research (table 3).

DISCUSSION

Results of progress of development of a core instrument set for hand OA through investigation of the psychometric properties of candidate instruments according to OMERACT Handbook (4), assessing construct validity, reliability, responsiveness and clinical trial discrimination, were presented, discussed, and serve as the basis of an updated research agenda.

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TABLES AND FIGURES

Table 1. Metric properties of VAS and NRS measuring pain and patient global assessment (PGA): construct validity, reliability, longitudinal construct validity (responsiveness) and clinical trial discrimination.

Table 2. Comparison of properties of Michigan Hand Outcomes Questionnaire (MHQ), Australian/Canadian Hand Osteoarthritis Index (AUSCAN), and Functional Index for Hand Osteoarthritis (FIHOA).

Table 3. Future research agenda to progress core instrument set selection for hand OA

Table 1. Metric properties of VAS and NRS measuring pain and patient global assessment (PGA): construct validity, reliability, longitudinal construct validity (responsiveness) and clinical trial discrimination.

Domain	Scale	Construct validity	Reliability	Longitudinal construct validity (responsiveness)			Clinical trial discrimination			
		Studies showing significant correlation with:	No of studies	No of studies showing change	No of studies showing no change, in disagreement with other outcomes	Percentage of studies that detected change	No of studies showing discrimination between arms in agreement with primary outcome	No of studies not showing discrimination between arms in agreement with primary outcome	No of studies showing discrimination between arms in disagreement with primary outcome	No of studies not showing discrimination between arms in disagreement with primary outcome
Pain	VAS	AUSCAN pain: r = 0.77 – 0.81 (S3, S24, S50)	0	23 (S1, S2, S4, S6-S13, S15-S18, S21, S22, S26, S37, S38, S42, S46)[#]	3 (S31, S39, S44)	88	13 (S7-S12, S17, S21, S22, S26, S37, S38, S46)	6 (S1, S5, S6, S23, S32, S44)	2 (S13, S42)	7 (S15, S19, S30, S39, S43, S48, S49)
	NRS	AUSCAN pain: R^2 = 0.606 (S41) AUSCAN function: R^2 = 0.471 (S41)	0	8 (S15, S25, S28, S33, S34, S41, S45, S47)	0	100	6 (S14, S28, S33, S34, S41, S47)	0	1 (S16)	1 (S25)
PGA	VAS	0	0	10 (S3, S6, S12, S13, S15, S18, S22, S29, S38, S40)[#]	0	100	5 (S12, S22, S29, S38, S40)	2 (S6, S40)	1 (S15)	0
	NRS	0	0	3 (S14, S28, S45)	0	100	1 [S28]	0	0	1 (S14)

[#]Saviola et al., 2017 (S38): no hard data shown, only described in full text; No: number; VAS: visual analogue scale; NRS: numeric rating scale; AUSCAN: Australian/Canadian Hand OA Index; r: coefficient of correlation; R^2: correlation. S(number): refers to the reference in the supplementary reference list.

Table 2. Comparison of properties of Michigan Hand Outcomes Questionnaire (MHQ), Australian/Canadian Hand Osteoarthritis Index (AUSCAN), and Functional Index for Hand Osteoarthritis (FIHOA).

	MHQ(10)	**AUSCAN(12)**	**FIHOA(13)**
Domain: Pain			
Number of items	5	5	-
Floor and ceiling effects*	No (1.8% with lowest score, 0% with highest score)	No (1.8% with lowest score, 1.3% with highest score)	-
Aspect of pain assessed	Frequency of experiencing pain in several situations (in general, during sleep or ADL) and whether it affects the respondent's happiness.	Pain severity during rest and several tasks (lifting, squeezing, turning, gripping)	-
Specific other comments	No	No	-
Domain: Function			
Number of items	Overall hand function scale: 10 ADL scale: 17	9	10
Floor and ceiling effects*	No (subscales overall hand function/ADL: 0%/0% with lowest score, 1.3%/3.1% with highest score)	No (1.8% with lowest score, 0.3% with highest score)	No (4.2% with lowest score, 0% with highest score)
Aspect of function assessed	Overall hand function scale: General questions of hand function, movement, strength and sensation. ADL scale: Ability to perform certain tasks (turning doorknob, picking up coin, holding glass of water, turning key in lock, holding heavy object with one hand, opening jar, buttoning shirt, using cutlery, carrying large and heavy objects, washing dishes, washing hair, tying shoelaces or knots); 4/12 grip strength tasks, 3/12 fine motor skills tasks.	Ability to perform certain tasks (turning doorknobs, holding heavy object with one hand, buttoning shirt, using cutlery, carrying large and heavy objects, turning taps, fastening jewelry, wringing cloth); 4/9 grip strength tasks, 2/9 fine motor skills tasks.	Ability to perform certain tasks (turning key in lock, holding heavy objects, buttoning shirt, using cutlery, tying shoelaces or knots, cutting with scissors, clenching fist, sewing (women) / using screwdriver (men), writing for a long time, accepting a handshake); 1/10 grip strength tasks, 4/10 fine motor skills tasks.
Specific other comments	Separate assessment of left and right hand.	No	Some items may be culturally challenging (accepting a handshake), or outdated (writing for more than 10 minutes; women sew and men use a screwdriver)
General aspects			

Recall period	1 week	48 hours	Not specified
Other available subscales (domain)	Work performance (N/A) Aesthetics (Structural damage) Satisfaction (N/A)	Stiffness (N/A)	N/A
Total number of items	58	15	10
Method of scoring	Includes normalizing to 0-100 scale, presented in user manual	Dependent on version used (Likert scale, VAS), presented in user manual	Simple addition of scores, user guide available online
Costs	Freely available for academic or non-profit institutions, permission needed before use (online application form)	Copyrighted, payment of fee and permission needed before use	No
Available in multiple languages	Yes	Yes	Yes
Interpretability comments	Pain scale has to be interpreted in opposite direction compared to other subscales	No	No

ADL, activities of daily living; N/A, not available; VAS, visual analogue scale.
*Data reviewed in HOSTAS cohort (N=383), LUMC, Leiden, The Netherlands

Table 3. Future research agenda to progress core instrument set selection for hand OA

• Definition of standardized phrasing for VAS and NRS pain and PGA
• Assessment of test-retest reliability of VAS and NRS pain and PGA
• Investigation of construct validity for NRS pain and PGA, and discriminative capacity in clinical trials for NRS PGA
• Investigation of validity of combinations of instruments to assess joint activity, including e.g., tender joints, self-reported painful joints, swollen joints, pain while gripping, and inflammatory signs on imaging
• Assessment of reliability of soft tissue joint swelling in hand OA
• Investigation of psychometric properties of grip and pinch strength to measure core domain hand strength
• Review of available instruments to assess health-related quality of life in hand OA, and development of a disease-specific instrument
• Investigation of the metric properties of ultrasound and magnetic resonance imaging
• Investigation of the value of computer tomography

VAS: visual analogue scale; NRS: numeric rating scale; PGA: patient global assessment; OA: osteoarthritis

SUPPLEMENTARY DATA

METHODS:

Systematic literature review (SLR) of VAS/NRS pain and patient global assessment (PGA)

Studies that did not include VAS or NRS to measure pain or PGA were excluded as well as studies only including thumb base OA. Relevant manuscripts were also extracted from the SLR by Visser *et al*. for the purpose of this work. All retrieved titles and selected abstracts were reviewed by one reviewer (BK). A random sample of 100 titles was reviewed by a second reader (RW) with perfect agreement. Data extraction from all selected full-text manuscripts was done by one reviewer (RW). Psychometric features of the scales such as reliability, responsiveness, construct validity and clinical trial discrimination were extracted. Special attention was given to the explicit phrasing and other details of the accompanying question. Because of the heterogeneity of the studies with respect to the instruments, only descriptive analyses were performed.

FIGURE LEGENDS

Figure 1. Overview of manuscript selection for NRS/VAS pain/PGA

OA: osteoarthritis; VAS: visual analogue scale; NRS: numeric rating scale; PGA: patient global assessment

Table 1: Details of included studies

Table 2: Details of phrasing of question accompanying VAS or NRS pain

Table 3: Details of phrasing of question accompanying VAS or NRS PGA

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Supplementary Table 1: Details of included studies

Studies	Source Population, **No. Patients (% women)**, Mean Age, Yrs	Definition of Hand OA and Inclusion criteria	Study Design (Outcome) Duration	Pain (VAS or NRS) (range)	PGA (VAS or NRS) (range)
Aitken, *et al.* 2018 (1)	Secondary care, **43 (77)**, 61	ACR criteria	RCT, cross over study (intervention = control)[§], 12 weeks	VAS (0-100mm)	-
Baltzer, *et al.* 2016 (2)	Secondary care, **34 (94)**, 61	Bony nodes, symptoms and radiographic	Interventional study, 8 weeks	VAS (0-10cm)	-
Barthel, *et al.* 2010 (3)	Secondary care, **783 (80)**, 64	ACR criteria, KL ≥ 1, symptoms ≥ 1 yr	RCT (intervention > control)[*], 8 weeks	VAS (0-100mm)	VAS (0-100mm)
Bjurehed, *et al*. 2017 (4)	Primary care, **49 (88)**, 69	Radiographic and symtoms, physician's diagnosis	Interventional study, 3 months	VAS (0-100mm)	-
Brosseau, *et al*. 2005 (5)	Secondary care, **88 (78)**, 65	ACR criteria, radiographic OA	RCT (intervention = control), 6 weeks	VAS (0-100mm)	-
Chevalier, *et al*. 2015 (6)	Secondary care, **85 (86)**, 63	ACR criteria, KL ≥ 2, VAS pain ≥ 40, ≥ 3 symptomatic joints > 3 months	RCT (intervention = control), 6 months	VAS (0-100mm)	VAS (0-100mm)
Dilek, *et al*. 2013 (7)	Secondary care, **56 (89)**, 59	ACR criteria	RCT (intervention > control), 3 weeks	VAS (0-10cm)	-
Dreiser, *et al.* 1993 (8)	Secondary care, **60 (85)**, 59	Radiographic OA	RCT (intervention > control), 2 weeks	VAS (0-100mm)	-
Fioravanti, *et al*. 2014 (9)	Primary care, **60 (87)**, 71	ACR criteria, symptomatic	RCT (intervention > control), 2 weeks, FU 12 months	VAS (0-100mm)	-
Gabay, *et al.* 2011 (10)	Secondary care, **162 (74)**, 63	ACR criteria, radiographic OA ≥ 2 joints ≥ 2 flares finger OA	RCT (intervention > control), 6 months	VAS (0-100mm)	-
Garfinkel, *et al.* 1994 (11)	Not specified, **25 (56)**, range 52-79	ACR criteria	RCT (intervention > control), 10 weeks	VAS	-
Grifka, *et al.* 2004 (12)	Secondary care, **594 (83)**, 62	ACR criteria, symptomatic > 3 months	RCT (intervention > control), 4 weeks	VAS (0-100mm)	VAS (0-100mm)
Gyarmati, *et al*. 2017 (13)	Secondary care, **47 (96)**, 64	ACR criteria, OA pain hands > 3 months	RCT (intervention 1 = intervention 2), 3 weeks	VAS (0-100mm)	VAS (0-100mm)
Hennig, *et al.* 2015 (14)	Secondary care, **80 (100)**, 61	ACR criteria, physician's diagnosis	RCT (intervention 1 > intervention 2), 3 months	NRS (0-10)	NRS (0-10)
Horvath, *et al.* 2011 (15)	Secondary care, **63 (81)**, 63	ACR criteria, radiographic OA, pain ≥ 3 months	RCT (intervention > control), 3 weeks	VAS (0-100mm)	VAS (0-100mm)
Kanat, *et al.* 2013 (16)	Not specified, **50 (100)**, 63	ACR criteria	RCT (intervention > control), 10 days	NRS (1-10)	-
Kasapoglu, *et al.* 2017	Secondary care,	Radiographic OA, KL >2, VAS ≥ 4/10	RCT (intervention 1 > intervention 2),	VAS (0-10cm)	-

(17)	**55 (93)**, 60		1 month		
Keen, *et al*. 2010 (18)	Secondary care, **36 (86)**, 58	ACR criteria, radiographic OA	Interventional study, 4 weeks	VAS (0-10cm)	VAS (0-10cm)
Kjeken, *et al.* 2011 (19)	Secondary care, **70 (97)**, 61	ACR criteria	RCT (intervention = control), 3 months	VAS (0-100mm)	-
Kortekaas, *et al*. 2014 (20)	Secondary care, **25 (76)**, 60	ACR criteria	Observational, FU 3 months	VAS (0-100mm)	-
Kovács, *et al.* 2012 (21)	Secondary care, **45 (93)**, 59	ACR criteria, KL ≥ 2 in ≥ 2 joints, VAS pain ≥ 30	RCT (intervention > control), 3 weeks	VAS (0-100mm)	-
Kvien, *et al.* 2008 (22)	Secondary care, **83 (93)**, 60	ACR criteria, KL ≥ 2, ≥ 1 swollen/tender joint, VAS pain ≥ 30	RCT (intervention > control), 42 days	VAS (0-100mm)	VAS (0-100mm)
Lee, *et al.* 2017 (23)	Secondary care, **196 (86)**, 58	ACR criteria, KL ≥ 2	RCT (intervention = control), 24 weeks	VAS (0-100mm)	-
Moe, *et al.* 2010 (24)	Secondary care, **128 (91)**, 69	ACR criteria	Observational, cross sectional	VAS (0-100mm)	-
Moe et al. 2016 (25)	Secondary care, **391 (86)**, 61	ACR criteria	RCT (intervention > control), 1 yr	NRS (0-10)	-
Myrer, *et al.* 2011 (26)	Volunteers, **35 (77)**, 64	ACR criteria, FIHOA > 5	RCT (intervention > control), 4 weeks	VAS (0-100mm)	-
Neuprez, *et al*. 2015 (27)	Tertiary care, **203 (90)**, 69	ACR criteria	Observational, cross-sectional	VAS (0-100mm)	-
Osteras, *et al.* 2014 (28)	Population based, **130 (90)**, 66	ACR criteria	RCT (intervention > control), 12 weeks	NRS (0-10)	NRS (0-10)
Park, *et al.* 2016 (29)	Secondary care, **130 (90)**, 66	ACR criteria	RCT (intervention > control), 12 weeks	-	VAS (0-100mm)
Pastinen, *et al.* 1988 (30)	Secondary care, **29 (79)**, 58	Clinical/ radiographic finger OA	RCT (intervention > control), 14 weeks	VAS (0-10cm)	-
Poiraudeau, *et al.* 2001 (31)	Secondary care, **89 (91)**, 63	ACR criteria	Observational, FU 6 months	VAS (0-100mm)	-
Romero-Cerecero, *et al.* 2013 (32)	Not specified, **113 (95)**, 62	ACR criteria, radiographic OA ≥ 2 IP joints, VAS ≥40, FIHOA ≥ 5	RCT (intervention = control), 6 weeks	VAS (0-10cm)	-
Rothacker, *et al*. 1994 (33)	Not specified, **49 (84)**, 66	Physician diagnosed/radiographic OA, symptoms	RCT (intervention > control), FU 15-120 min (after cream)	NRS (1-5)	-
Rothacker, *et al*. 1998 (34)	Secondary care, **81 (74)**, 61	Physician diagnosed OA, symptoms	RCT (intervention > control), FU 30-120 min (after cream)	NRS (1-5)	-
Sautner, *et al.* 2004 (35)	Secondary care, **60 (73)**, 62	ACR criteria	Observational, cross-sectional	-	VAS (0-100mm)
Sautner, *et al.* 2009 (36)	Secondary care, **66 (77)**, 58	ACR criteria	Observational, cross-sectional	-	VAS (0-100mm)
Saviola, *et al.* 2012 (37)	Secondary care,	Radiographic erosive OA ≥ 2 joints,	RCT (intervention 1 > intervention 2),	VAS (0-10cm)	-

	38 (95), 61	VAS ≥40	1 and 2 yr		
Saviola, *et al.* 2017 (38)	Secondary care, **40 (93)**, 70	Radiographic erosive OA > 1 IP joints, VAS ≥ 4/10	RCT (intervention 1 > intervention 2), 6 months	VAS (0-10cm)	VAS (0-10cm)
Schnitzer, *et al.* 1994 (39)	Not specified, **59 (68)**, 68	Radiographic/ physical OA findings	RCT (intervention > control), 9 weeks	VAS (0-100mm)	-
Shin, *et al.* 2013 (40)	Secondary care, **86 (97)**, 58	ACR criteria	RCT (intervention = control), 12 weeks	-	VAS (0-100mm)
Sofat, *et al*. 2017 (41)	Secondary care, **65 (80)**, 63	ACR criteria	RCT (intervention 1 > intervention 2 > control), 12 weeks	NRS (0-10)	-
Spolidoro Pashoal, *et al.* 2015 (42)	Secondary care, **60 (97)**, 61	ACR criteria	RCT (intervention 1 > intevention 2), 12 weeks	VAS (0-10cm)	-
Stamm, *et al.* 2002 (43)	Secondary care, **40 (88)**, 60	ACR criteria	RCT (intervention > control), 3 months	VAS (0-100mm)	-
Stange-Rezende, *et al.* 2006 (44)	Secondary care, **45 (93)**, 60	ACR criteria	RCT (intervention = control), 3 weeks	VAS (0-100mm)	-
Tubach, *et al.* 2012 (45)	Secondary care, **249 (88)**, 64	ACR criteria	Interventional, FU 4 weeks	NRS (0-10)	NRS (0-10)
Van Velden, *et al.* 2015 (46)	Primary care, **100 (not specified)**, 65	ACR criteria	RCT, cross over study (intervention > control), 56 days	VAS (0-10cm)	-
Watt, *et al.* 2014 (47)	Secondary care, **26 (88)**, 63	ACR criteria, NRS pain ≥ 2, radiograhic deformity	CT (intervention > control), 3 months	NRS (0-10)	-
Wenham, *et al*. 2012 (48)	Not specified, **70 (81)**, 61	ACR criteria	RCT (intervention = control), 4 weeks	VAS (0-100mm)	-
Widrig, *et al*. 2007 (49)	Primary and secundary care, **204 (74)**, 64	ACR criteria, radiographic OA ≥ 2 joints, VAS ≥ 40, FIHOA ≥ 5	RCT (intervention = control), 3 weeks	VAS (0-100mm)	-
Wittoek, *et al.* 2009 (50)	Secundary care, **72 (89)**, 62	ACR criteria	Observational, cross-sectional	VAS (0-100mm)	-

- : not included; [*]Intervention group performed better than control group, according to the primary outcome measure. [§]Intervention group did not perform better than control group, according to the primary outcome measure. OA: osteoarthritis; Yr(s): year(s); VAS: visual analogue score; NRS: numeric rating scale; PtGA: patient global assessment; ACR: American College of Rheumatology; RCT: randomized controlled trial; KL: Kellgren and Lawrence; IP: interphalangeal; FU: follow up; CT: clinical trial; FIHOA: Functional Index for Hand OA

Supplementary Table 2: Details of phrasing of question accompanying VAS or NRS pain

Reference	Scale	Explicite phrasing[§]	Time of recall	Other details
RCT/Interventional studies				
Aitken, *et al.* 2018 (1)	VAS (0-100mm)	Yes	1 week	
Baltzer, *et al.* 2016 (2)	VAS (0-10)	No	ND	
Barthel, *et al.* 2010 (3)	VAS (0-100mm)	No	24 hours	Dominant hand
Bjurehed, *et al.* 2017 (4)	VAS (0-100mm)	No	current	At rest
Brosseau, *et al.* 2005 (5)	VAS (0-100mm)	No	ND	Pain intensity
Chevalier, *et al.* 2015 (6)	VAS (0-100mm)	Yes	24 hours	Global pain
Dilek, *et al*. 2013 (7)	VAS (0-10 cm)	No	48 hours	Pain at rest and during daily activity, both hands and hands separately
Dreiser, *et al.* 1993 (8)	VAS (0-100mm)	No	ND	Overall spontaneous pain
Fioravanti, *et al.* 2014 (9)	VAS (0-100mm)	No	ND	
Gabay, *et al.* 2011 (10)	VAS (0-100mm)	No	ND	Global spontaneous hand pain
Garfinkel, *et al.* 1994 (11)	VAS	No	ND	Hand pain at rest and during activity
Grifka, *et al*. 2004 (12)	VAS (0-100mm)	Yes	24 hours	Pain intensity In target hand
Gyarmati, *et al.* 2017 (13)	VAS (0-100mm)	No	ND	At rest and on exertion
Hennig, *et al.* 2015 (14)	NRS (0-10)	No	ND	
Horváth, *et al.* 2011 (15)	VAS (0-100mm)	No	ND	Severity of pain at rest and upon exertion; in small hand joints of the hands
Kanat, *et al.* 2013 (16)	NRS (1-10)	No	ND	Hand pain at rest and on use
Kasapoglu, *et al.* 2017 (17)	VAS (0-10cm)	No	ND	
Keen, *et al.* 2010 (18)	VAS (0-10cm)	No	ND	Most painful joint, all joints of both hands
Kjeken, *et al.* 2011 (19)	VAS (0-100mm)	No	ND	
Kovács, *et al*. 2012 (21)	VAS (0-100mm)	No	ND	
Kvien, *et al*. 2008 (22)	VAS (0-100mm)	Yes	48 hours	Pain intensity
Lee, *et al.* 2017 (23)	VAS (0-100mm)	No	24 hours	
Moe, *et al.* 2016 (25)	NRS (0-10)	No	ND	
Myrer, *et al.* 2011 (26)	VAS (0-100mm)	Yes	1 week, current	Pain at rest, pain upon movement, current pain
Osteras, *et al.* 2014 (28)	NRS (0-10)	No	ND	
Pastinen, *et al*. 1988 (30)	VAS (0-10cm)	No	ND	Pain provoked by grip and pinch strength tests
Romero-Cerecero, *et al.* 2013 (32)	VAS (0-10cm)	No	ND	Pain intensity
Rothacker, *et al*. 1994 (33)	NRS (1-5)	No	Immediately	
Rothacker, *et al*. 1998 (34)	NRS (1-5)	No	ND	
Saviola, *et al.* 2012 (37)	VAS (0-10cm)	No	ND	
Saviola, *et al*. 2017 (38)	VAS (0-10cm)	No	ND	
Schnitzer, *et al.* 1994 (39)	VAS (0-100mm)	No	ND	Level of pain
Sofat, *et al.* 2017 (41)	NRS (0-10)	No	ND	

Spolidoro Pashoal, *et al.* 2015 (42)	VAS (0-10cm)	No	ND	Pain at rest, on movement
Stamm, *et al*. 2002 (43)	VAS (0-100mm)	No	ND	
Stange-Rezende, *et al.* 2006 (44)	VAS (0-100mm)	No	ND	General level of pain
Tubach, *et al.* 2012 (45)	NRS (0-10)	Yes	48hours	
Van Velden, *et al.* 2015 (46)	VAS (0-10)	No	ND	
Watt, *et al.* 2014 (47)	NRS (0-10)	No	1 week	Average pain, worst pain
Wenham, *et al*. 2012 (48)	VAS (0-100mm)	Yes	48 hours, 2 weeks	Average pain both hands, in the most painful joints, at 1st CMC
Widrig, *et al.* 2007 (49)	VAS (0-100mm)	Yes	24 hours	Finger level
Observational studies				
Kortekaas, *et al*. 2014 (20)	VAS (0-100mm)	No	ND	
Moe, *et al.* 2010 (24)	VAS (0-100mm)	No	ND	
Neuprez, *et al.* 2015 (27)	VAS (0-100mm)	No	ND	Global assessment of pain
Poiraudeau, *et al*. 2001 (31)	VAS (0-100mm)	No	ND	Pain intensity
Wittoek, *et al*. 2009 (50)	VAS (0-100mm)	No	1 week	Global pain, both hands

VAS: visual analogue scale; NRS: numeric rating scale; ND: not defined

§ Explicit phrasing of scales in domain pain:

- *On this line, where would you rate your pain, using the last 7 days as a timeframe*? (1)
- *What is the global level of pain in your hands in the past 24 hours*? (6)
- *Indicate the most pain from your OA in the target hand over the previous 24hours?* (12)
- *How would you describe the intensity of your joint pain during the last 2 days?* (22)
- *How would you estimate your perception of average 'pain at rest' and average 'pain with movement' over the week prior to the assessment? (26)*
- Circle the number that best describes *the pain you felt due to your hand osteoarthritis during the last 48 hours?* (45)
- *Indicate the level of pain in the hands during the last 48 hours/ last 2 weeks? (48)*
- *Indicate the level of pain in the most painful joint during the last 48 hours? (48)*
- *Indicate the level of pain at the 1st CMC joint during the last 48 hours? (48)*
- *Indicate the most intense pain in the previous 24 hours in the worst affected finger? (49)*

Supplementary Table 3: Details of phrasing of question accompanying VAS or NRS PGA

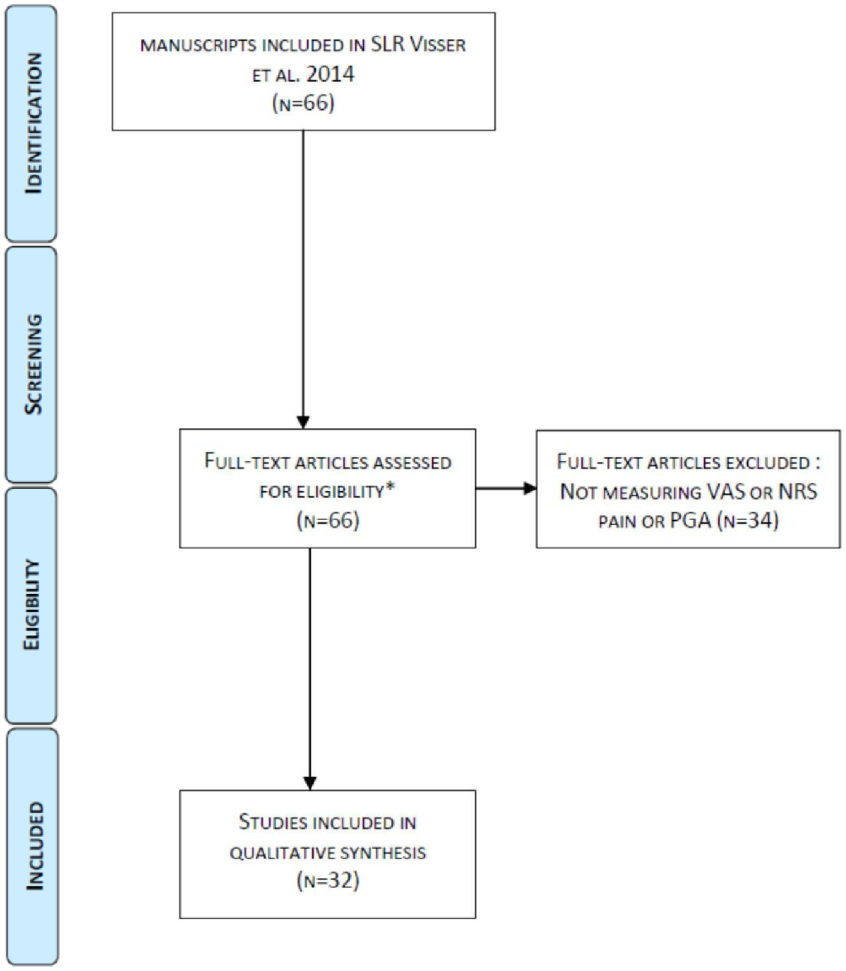
Reference	Scale	Exact phrasing[§]	Time of recall	Other comments
RCT/Interventional studies				
Barthel, *et al.* 2010 (3)	VAS (0-100mm)	Yes	ND	Global assessment of disease activity
Chevalier, *et al*. 2015 (6)	VAS (0-100mm)	No	ND	
Griftka, *et al.* 2004 (12)	VAS (0-100mm)	No	ND	Global assessment of disease activity
Gyermati, *et al*. 2017 (13)	VAS (0-100mm)	No	ND	
Hennig, *et al.* 2015 (14)	NRS (0-10)	No	ND	Global assessment of disease activity
Horváth, *et al*. 2011 (15)	VAS (0-100mm)	No	ND	
Keen, *et al.* 2010 (18)	VAS (0-10 cm)	No	ND	
Kvien, *et al.* 2008 (22)	VAS (0-100mm)	Yes	48 hours	
Osteras, *et al.* 2014 (28)	NRS (0-10)	No	ND	Global assessment of disease activity and disease activity affecting activities in daily life
Park, *et al.* 2016 (29)	VAS (0-100mm)	No	ND	General health
Saviola, *et al.* 2017 (38)	VAS (0-10 cm)	No	ND	Global assessment of disease activity
Shin, *et al.* 2013 (40)	VAS (0-100mm)	No	ND	
Observational studies				
Sautner, *et al.* 2004 (35)	VAS (0-100mm)	No	ND	
Sautner, *et al*. 2009 (36)	VAS (0-100mm)	Yes	48 hours	
Tubach, *et al*. 2012 (45)	NRS (0-10)	Yes	48 hours	

VAS: visual analogue scale; NRS: numeric rating scale; ND: not defined

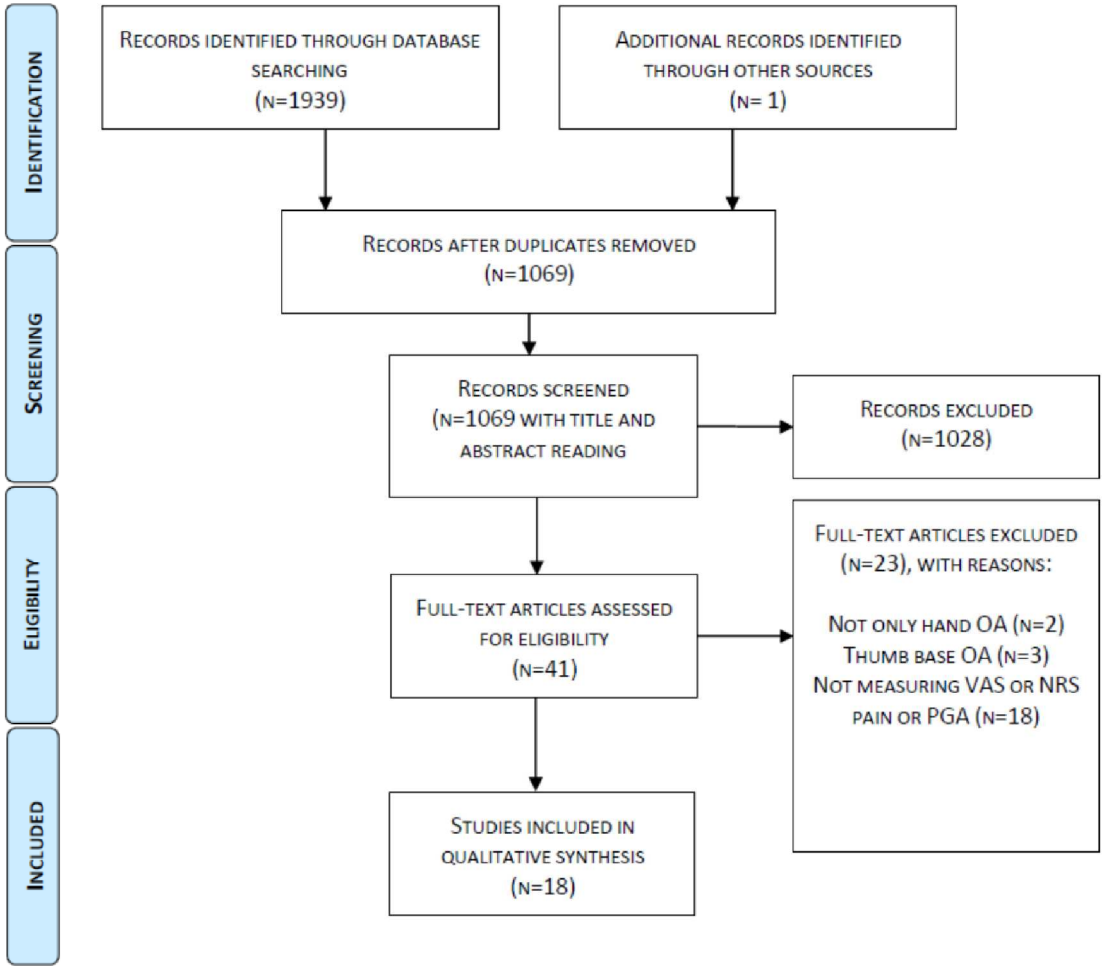
[§] Explicit phrasing of scales in domain PGA:

- *Considering all the ways osteoarthritis of your hands affects you, please indicate with an 'X' through the horizontal line how well are you doing?* (3)
- *We ask you to evaluate the activity of your osteoarthritis over the last 2 days? When you take all symptoms into consideration, how will you evaluate your condition?* (22)
- *Please indicate how severe you are compromised by your hand osteoarthritis during the last 48 hours?* (36)
- *Considering all the ways your hand osteoarthritis has affected you during the last 48 hours, circle the number that best describes how you have been doing? (45)*

FROM SLR VISSER ET AL. (UNTIL JANUARY 2014)



FROM SLR (FROM JANUARY 2014 – JANUARY 2018)



riginal SLR, all instruments for pain, PGA and function were included

STATEMENT OF CONTRIBUTION

We declare that this manuscript presents substantial new information that is evaluable by peer review.

Main findings: This report includes the results of a recent systematic literature review on instruments (visual analogue and numeric rating scale) in the domains pain and patient global assesments in hand osteoarthritis (OA). Also in other domains, progress in validation of certain instruments has been made. Michigan Hand Outcomes Questionnaire had advantages above other pain/function questionnaires. Hand Mobility in Scleroderma was valid, although responsiveness was questioned.

What is novel: This report gives an overview of new evidence contributing to instrument validation in certain domains in hand OA. The discussion and proposed research agenda of OMERACT 2018 is reported.

How it advances published research to date: A good overview is provided of where remaining gaps exist for further validation of several instruments before final core instrument set selection in hand OA. The discussions held at OMERACT 2018 serve as a basis for the future research agenda.

Status regarding prior publication/submission elsewhere: This work was not previously published or submitted elsewhere.