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Published in:
Osteoarthritis and Cartilage

DOI:
10.1016/j.joca.2019.09.003

Publication date:
2020

Document version
Accepted manuscript

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Citation for published version (APA):

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Download date: 11. May. 2021
Comparison of three sets of clinical classification criteria for knee osteoarthritis: A cross-sectional study of 13,459 patients treated in primary care

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Brief report for Osteoarthritis and Cartilage

Manuscript (max. 2,000 words): currently 1,993 words
Abstract (max. 250 words): currently 236 words
Short title: Clinical classification criteria in knee osteoarthritis

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ABSTRACT

Objective. To determine and compare the proportion of patients treated in a primary care setting that have knee osteoarthritis (OA) according to the European League Against Rheumatism (EULAR), the American College of Rheumatology (ACR), and the National Institute for Health and Care Excellence (NICE) clinical classification criteria.

Design. A cross-sectional analysis of baseline data from 13,459 patients with knee symptoms or functional limitations associated with OA participating in the Good Life with osteoArthritis in Denmark (GLA:D®) treatment program. The prevalence of knee OA according to the EULAR, ACR and NICE criteria were calculated in all participants and in the subgroup of patients with self-reported radiographic changes associated with knee OA (n=10,651 or 79%).

Results. Mean age (SD) was 65.3 (9.8) years, median (IQR) duration of symptoms 12 (6-36) months and mean pain intensity (0-100; SD) 46.5 (22.1) mm. 39% fulfilled all three sets of criteria. 48%, 52% and 89% fulfilled the EULAR, ACR, and NICE criteria for having knee OA, respectively. In the subgroup with self-reported radiographic changes, the corresponding numbers were 49%, 54% and 90%.

Conclusions. While the EULAR and ACR criteria only identified around half of those, with or without self-reported radiographic knee OA, that were treated because of symptoms or functional limitations associated with knee OA, the NICE criteria identified most patients. The results indicate that the NICE criteria are relevant and appropriate to identify individuals treated for knee OA in primary care.

Keywords. Diagnosis, Primary Health Care, Knee, Osteoarthritis
INTRODUCTION

In recent years the possibility to diagnose knee osteoarthritis (OA) clinically without imaging\(^1,2\) has increased the likelihood of earlier diagnosis and treatment, as requested by patients.\(^3\) It also has the potential to reduce the use of imaging in patients with typical OA presentations, where radiographs are not recommended\(^4\) due to time required for structural changes to occur and only modest agreement with symptoms.\(^5,6\) However, this transition increases the demand for criteria applicable in primary care.

The most commonly applied criteria for knee OA are those described by the European League Against Rheumatism (EULAR),\(^1\) the American College of Rheumatology (ACR),\(^7\) and the National Institute for Health and Care Excellence (NICE).\(^2\) However, previous studies have argued that the criteria were primarily developed using data from patients in secondary care for late-stage OA with more severe radiographic OA changes,\(^8,9\) thus questioning their ability to classify knee OA in primary care and in patients with earlier stages of OA.\(^8\)

As most patients with knee OA are managed in primary care,\(^2\) knowledge of the performance of the classification criteria for knee OA in this setting is important. Previous studies with samples below 1,000 patients have found that between 30-81% of patients with knee symptoms presenting in primary care or from population-based studies fulfill the ACR criteria.\(^8-11\) We are unaware of any studies estimating the prevalence of patients fulfilling the EULAR and NICE criteria in primary care and large-scale studies comparing the performance of different classification criteria of patients treated in primary care.

In a cohort of 13,459 patients treated in primary care for knee symptoms and/or functional limitations, we determined and compared the proportion of patients having knee OA according to the EULAR, ACR, and NICE criteria, respectively, and report these proportions in all patients.
treated for knee OA. Results are also presented separately for those who self-reported to have radiographic knee OA.
METHOD

Design and setting

This was a cross-sectional, registry-based study using baseline data from 13,459 patients with symptoms and/or functional limitations of knee OA participating in Good Life with osteoArthritis in Denmark (GLA:D®). GLA:D® is an evidence-based treatment program of group-based patient education and supervised exercise offered to patients with knee and hip OA in private physiotherapy clinics and municipalities nationwide in Denmark. A more detailed description of GLA:D®, including patient characteristics, the treatment program and outcomes is published elsewhere.²

This report conforms to the STROBE statement for reporting observational studies. According to the ethics committee of the North Denmark Region, ethics approval of GLA:D® was not needed. GLA:D® has been approved by the Danish Data Protection Agency (SDU; 10.084) and all patients consented to report their data in the GLA:D® registry.

Participants

Patients with knee joint pain and/or functional limitations associated with knee OA (with and without radiographic OA) seeking health care are eligible for GLA:D® if they understand Danish and do not meet any of the exclusion criteria: 1) another reason for the specific knee joint symptoms than OA as evaluated by the physical therapist, e.g. inflammatory joint disease or patellar tendinopathy; 2) other symptoms that are more pronounced than the OA symptoms, e.g. chronic, generalized pain, or fibromyalgia.

For the current report, patients with the knee as their primary complaint and with available data on the classification criteria at baseline were included.
**Variables**

While classification criteria represent standardized definitions of relatively homogenous and comparable populations, require high specificity, diagnostic criteria are more broad and used in routine clinical care reflecting all possible features of a diseases and requiring both high specificity and sensitivity. For the purpose of consistency, we use the term ‘classification criteria’ to characterize the three set of criteria, although they have not all been defined as such in the literature.

The classification criteria are recorded by the physical therapist after clinical examination and by questioning the patient at baseline, before initiating the GLA:D® treatment program.

**EULAR criteria**

Proposition number 5 of the EULAR criteria was used. According to these criteria, patients older than 40 years of age with movement-related joint pain, morning knee stiffness of less than 30 min, and functional limitations have knee OA if they in addition have one or more of these examination findings: Crepitus, restricted range of motion, and bony enlargement.

**ACR criteria**

The decision tree version of the original ACR criteria for clinical knee OA was used. Although less commonly used than the “3 out of 6” version, the decision tree was originally recommended in the criteria paper, and it has previously been applied for the same purpose as in the current report. According to the decision tree, patients with knee pain have OA if they fulfill one of the following groups of criteria:

1) Crepitus, morning knee stiffness of 30 min or less, and age of 38 years or above

2) Crepitus, morning stiffness of longer than 30 min, and bony enlargement
3) No crepitus, but bony enlargement

In the current study, knee pain was defined as movement-related knee pain (yes/no) to be able to compare the performance of ACR with the two other set of criteria.

NICE criteria

According to the criteria from NICE, patients can be diagnosed with knee OA if they are 45 years or older, have movement-related joint pain and either no morning knee stiffness or stiffness of 30 min or less.²

Self-reported radiographic OA changes

At baseline, the physical therapist asked the patients whether they had radiographs of their knee joint, to which the patient answered either “no”, “yes, more than 6 months ago”, “yes, within the last 6 months” or “I do not know”. If the patients answered “yes” to the question, they were then asked whether the radiographs showed changes associated with OA with the response categories “yes”, “no”, and “I do not know”. Patients answering “yes” also to this question were categorized as having self-reported radiographic changes associated with knee OA.

Statistical analysis

The criteria were assessed from 7 February 2017 and the analyses included data until 31 December 2018.

The prevalence of symptoms, clinical examination findings and risk factors for knee OA and the prevalence of knee OA according to the EULAR, ACR, and NICE criteria were calculated. The analyses were repeated in the subgroup of patients with self-reported radiographic knee OA.
Movement-related joint pain was assessed as yes/no to pain with joint movement. “Stiffness lasting longer than 30 min” is a typical feature of rheumatoid arthritis (RA), and duration of morning stiffness is part of all three classification criteria to help differentiate OA from RA. Presence of morning stiffness is however registered as a binary variable in the GLA:D® registry with no information on the duration and was considered to be lasting less than 30 minutes. This meant that item 2) and 3) of the ACR criteria was reduced to only include the presence of bony enlargement and that the variable could not be included in the analyses of the NICE criteria. A sensitivity analysis excluding patients self-reporting to have RA was conducted to evaluate whether that affected the results.

All analyses were performed in SAS Enterprise Guide 7.1 (SAS Institute Inc., Cary, NC).
RESULTS

13,459 patients from GLA:D with the knee as their primary complaint were included in the analyses, while 2 patients did not have available data on the classification criteria. 10,651 (79%) had self-reported OA changes on x-ray and 441 (4%) had RA (Table 1).

Table 2 presents the prevalence of symptoms, examination findings and risk factors of knee OA, and the prevalence of knee OA according to the three different classification criteria. 48%, 52% and 89% fulfilled the EULAR, ACR, and NICE criteria for having knee OA, respectively, while the corresponding numbers were 49%, 54% and 90% in the great majority (79%) with self-reported radiographic OA changes. There was some overlap between patients fulfilling different sets of criteria. 39% (n=5,192) fulfilled all three criteria, 12% (n=1,620) fulfilled both the ACR and NICE criteria, 8% (n=1,135) fulfilled both the EULAR and NICE criteria, and 0.5% (n=70) fulfilled both the ACR and EULAR criteria. A Venn-diagram illustrating the overlap is presented in Appendix 1.

10% (1,392) and 9% (988) of all patients and patients with self-reported radiographic OA changes, respectively, did not fulfill any of the criteria. No movement-related joint pain was the main reason for not fulfilling any of the criteria.

In the sensitivity analysis excluding patients with RA (n=441), 47%, 51% and 89% fulfilled the EULAR, ACR, and NICE criteria, respectively, while the corresponding numbers were 49%, 54% and 90% in those with radiographic OA changes (excluding 360 patients with RA).
DISCUSSION

In a population of patients treated in primary care because of symptoms and/or functional limitations associated with knee OA, only every other fulfilled the EULAR and ACR classification criteria, respectively, for knee OA, while 9 out of 10 fulfilled the NICE criteria. Only 4 out of 10 patients fulfilled all sets of criteria while 1 out of 10 did not fulfill any of the criteria. The results from our Danish population suggest that the NICE criteria can identify patients diagnosed and treated for knee OA in primary care.

This is the first large-scale comparison of the three most commonly applied classification criteria for knee OA. As the great majority of patients with knee OA are managed in primary care,\(^2\) it is important that classification criteria for knee OA adequately reflect patients diagnosed and treated in a primary care setting. Our finding that 52\% of patients fulfilled the ACR criteria is within the middle of the range found in previous studies demonstrating that 30-81\% of patients with knee symptoms presenting to primary care, or in population-based studies, fulfill the ACR criteria.\(^8\)-\(^11\)

Furthermore, we found that a similar proportion fulfilled the EULAR criteria. Our results thereby substantiate and extend some of the criticism raised on the relevance of the ACR and EULAR criteria and question their relevance in patients treated in primary care.\(^8\),\(^9\)

The NICE criteria identified 89\% of patients in our Danish cohort of patients seeking primary care as having knee OA, suggesting that it is suitable for use in primary care to allow more symptomatic people to have access to primary OA care and in clinical research of non-pharmacological treatment. A possible and notable limitation of the three sets of classification criteria in primary care is the lower age limit (although not mandatory in the “3 out of 6” version of the ACR criteria), since OA is increasingly common also in younger patients. In people aged between 15 and 49 years, OA accounts for 2.4 million years lived with disability worldwide thereby posing a substantial burden on the person and society\(^14\) and highlighting an important limitation of strictly applying the NICE
criteria for knee OA in primary care. Ongoing work to establish classification criteria for early knee OA\textsuperscript{15} may help overcome this limitation in the future and ensure that younger patients with OA also receive treatment according to clinical guidelines.

The lack of information on duration of morning stiffness in the GLA:D\textsuperscript{®}-registry made it impossible to adhere completely to the classification criteria, which is an important limitation of the study. On the other hand, the primary reason that the duration of morning stiffness is part of the classification criteria is to rule out RA\textsuperscript{2,7} and our sensitivity analysis excluding the approximately 4\% of patients with self-reported RA demonstrated similar results as the main analysis.

Furthermore, the physical therapists in GLA:D\textsuperscript{®} are trained in identifying and including patients with symptoms associated with knee OA and excluding those with other diagnoses with a similar clinical presentation, such as generalized pain or fibromyalgia. Finally, the fact that radiographic OA changes were self-reported represent a limitation of the study.

In conclusion, the EULAR and ACR criteria seem less appropriate to identify knee OA in primary care, as they only identified approximately half of treated patients, with no difference in those with or without self-reported radiographic knee OA. Conversely, the NICE criteria identified 9 out of 10 treated patients and seem to be appropriate classification criteria for use in primary care.
The initiation of GLA:D® was partly funded by the Danish Physiotherapy Association’s fund for research, education and practice development; the Danish Rheumatism Association; and the Physiotherapy Practice Foundation. Dr. Skou is currently funded by a grant from the European Research Council (ERC) under the European Union’s Horizon 2020 research and innovation program (grant agreement No 801790). The funders did not have any role in this study other than to provide funding.

FINANCIAL DISCLOSURES AND CONFLICTS OF INTEREST

Dr. Roos is deputy editor of Osteoarthritis and Cartilage, the developer of the Knee injury and Osteoarthritis Outcome Score (KOOS) and several other freely available patient-reported outcome measures and co-founder of Good Life with Osteoarthritis in Denmark (GLA:D®), a not-for profit initiative hosted at University of Southern Denmark aimed at implementing clinical guidelines for osteoarthritis in clinical practice.

Dr. Skou is associate editor of the Journal of Orthopaedic & Sports Physical Therapy, has received grants from The Lundbeck Foundation, personal fees from Munksgaard, all of which are outside the submitted work. He is co-founder of GLA:D®.

The authors affirm that they have no financial affiliation (including research funding) or involvement with any commercial organization that has a direct financial interest in any matter included in this manuscript, except as disclosed in an attachment and cited in the manuscript.

Dr. Young has received PhD funding support from the Danish Foundation for Chiropractic Research and Post-graduate Education, the Ontario Chiropractic Association, the Canadian Memorial Chiropractic College, the National Chiropractic Mutual Insurance Company Foundation, and a faculty scholarship from the University of Southern Denmark.
ACKNOWLEDGEMENTS

The authors would like to thank the clinicians and patients involved in collecting data for GLA:D®.

AUTHOR CONTRIBUTIONS

Study conception and design. Skou, Koes, Young, Grønne, Roos

Recruitment of patients: Skou, Roos

Acquisition of data. Skou, Grønne, Roos

Analysis and interpretation of data. Skou, Koes, Young, Grønne, Roos

Drafting the article or revising it critically for important intellectual content. Skou, Koes, Young, Grønne, Roos

Final approval of the article. Skou, Koes, Young, Grønne, Roos

All authors had full access to all the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
REFERENCES


### Table 1. Characteristics of patients with knee osteoarthritis (OA) in primary care

<table>
<thead>
<tr>
<th></th>
<th>All (n: 13,459)</th>
<th>Self-reported OA changes on x-ray* (n: 10,651)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>65.3 (9.8)</td>
<td>65.5 (9.7)</td>
</tr>
<tr>
<td>Gender female, n (%)</td>
<td>9,380 (69.7)</td>
<td>7,339 (68.9)</td>
</tr>
<tr>
<td>Educational level**, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>2,072 (18.5)</td>
<td>1,674 (18.8)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>1,215 (10.8)</td>
<td>966 (10.9)</td>
</tr>
<tr>
<td>Short-term education</td>
<td>2,285 (20.4)</td>
<td>1,796 (20.2)</td>
</tr>
<tr>
<td>Middle-term education</td>
<td>4,383 (39.0)</td>
<td>3,500 (39.3)</td>
</tr>
<tr>
<td>Long-term education</td>
<td>1,275 (11.4)</td>
<td>968 (10.9)</td>
</tr>
<tr>
<td>Body mass index (kg/m²), mean (SD)</td>
<td>29.1 (5.5)</td>
<td>29.2 (5.5)</td>
</tr>
<tr>
<td>Duration of symptoms from joint (months), median (IQR)</td>
<td>12 (6-36)</td>
<td>12 (6-40)</td>
</tr>
<tr>
<td>Baseline pain (VAS 0-100 mm best to worst), mean (SD)</td>
<td>46.5 (22.1)</td>
<td>47.0 (22.1)</td>
</tr>
<tr>
<td>Bilateral knee symptoms, n (%)</td>
<td>4,872 (43.4)</td>
<td>3,920 (44.0)</td>
</tr>
<tr>
<td>Rheumatoid Arthritis, n (%)</td>
<td>441 (3.9)</td>
<td>360 (4.1)</td>
</tr>
<tr>
<td>Did have x-rays of the joint taken, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1,754 (13.0)</td>
<td></td>
</tr>
<tr>
<td>Yes, more than 6 mo ago</td>
<td>3,519 (26.2)</td>
<td></td>
</tr>
<tr>
<td>Yes, within the last 6 mo</td>
<td>8,089 (60.1)</td>
<td></td>
</tr>
<tr>
<td>Do not know</td>
<td>97 (0.7)</td>
<td></td>
</tr>
<tr>
<td>Did X-ray show OA changes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10,651 (91.8)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>479 (4.1)</td>
<td></td>
</tr>
<tr>
<td>Do not know</td>
<td>478 (4.1)</td>
<td></td>
</tr>
<tr>
<td>Use of pain killers***, n (%)</td>
<td>8,899 (66.1)</td>
<td>7,216 (67.8)</td>
</tr>
</tbody>
</table>

*11,608 had x-rays taken and of those 478 did not know if the x-ray showed radiographic signs of OA.

**Short-term education: under 3 years after secondary school; Middle-term education: 3-4 years after secondary school; Long-term education: at least 5 years after secondary school.

***Pain killers: Use of at least one of the following medications during last 3 months: Paracetamol, NSAID (oral or topical), Morphine or other opioids.

Missing values for all patients: Educational level 2,229; BMI 80; Duration of symptoms 4; Baseline pain VAS 2,230; Bilateral knee symptoms 2,234; Rheumatoid Arthritis 2,224.
Table 2. Prevalence of symptoms, examination findings, risk factors and knee osteoarthritis (OA) according to clinical classification criteria for all patients and for patients with x-ray showing OA changes.

<table>
<thead>
<tr>
<th>Symptoms, n (%)</th>
<th>All (n: 13,459)</th>
<th>Self-reported OA changes on x-ray* (n: 10,651)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Movement-related joint pain, n (%)</td>
<td>12,274 (91.2)</td>
<td>9,744 (91.5)</td>
</tr>
<tr>
<td>Functional limitation</td>
<td>10,979 (81.6)</td>
<td>8,758 (82.2)</td>
</tr>
<tr>
<td>Morning stiffness</td>
<td>8,672 (64.4)</td>
<td>6,945 (65.2)</td>
</tr>
<tr>
<td>Crepitus</td>
<td>8,440 (62.7)</td>
<td>6,744 (63.3)</td>
</tr>
<tr>
<td>Restricted knee range of motion</td>
<td>8,482 (63.0)</td>
<td>6,873 (64.5)</td>
</tr>
<tr>
<td>Bony enlargement</td>
<td>3,594 (26.7)</td>
<td>3,061 (28.7)</td>
</tr>
<tr>
<td>Risk factors, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (more than 40 years)</td>
<td>13,328 (99.0)</td>
<td>10,564 (99.2)</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>9,380 (69.7)</td>
<td>7,339 (68.9)</td>
</tr>
<tr>
<td>Overweight (BMI 25 or higher)</td>
<td>10,224 (76.4)</td>
<td>8,190 (77.3)</td>
</tr>
<tr>
<td>Prior joint injury</td>
<td>4,702 (34.9)</td>
<td>3,770 (35.4)</td>
</tr>
<tr>
<td>Hard physical labour or overuse in spare time</td>
<td>5,666 (42.1)</td>
<td>4,572 (42.9)</td>
</tr>
<tr>
<td>Family members with OA</td>
<td>6,394 (47.5)</td>
<td>5,094 (47.8)</td>
</tr>
<tr>
<td>Number of symptoms fulfilled, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>98 (0.7)</td>
<td>72 (0.7)</td>
</tr>
<tr>
<td>1</td>
<td>498 (3.7)</td>
<td>390 (3.7)</td>
</tr>
<tr>
<td>2</td>
<td>1,419 (10.5)</td>
<td>1,012 (9.5)</td>
</tr>
<tr>
<td>3</td>
<td>2,744 (20.4)</td>
<td>2,100 (19.7)</td>
</tr>
<tr>
<td>4</td>
<td>3,943 (29.3)</td>
<td>3,111 (29.2)</td>
</tr>
<tr>
<td>5</td>
<td>3,441 (25.6)</td>
<td>2,829 (26.6)</td>
</tr>
<tr>
<td>6</td>
<td>1,316 (9.8)</td>
<td>1,137 (10.7)</td>
</tr>
<tr>
<td>Fulfill criteria for OA, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EULAR**</td>
<td>6,411 (47.6)</td>
<td>5,246 (49.3)</td>
</tr>
<tr>
<td>ACR***</td>
<td>6,938 (51.6)</td>
<td>5,718 (53.7)</td>
</tr>
<tr>
<td>NICE****</td>
<td>12,007 (89.2)</td>
<td>9,557 (89.7)</td>
</tr>
<tr>
<td>Fulfill number of sets of criteria for OA (EULAR, ACR, NICE), n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1,312 (9.8)</td>
<td>988 (9.3)</td>
</tr>
<tr>
<td>1</td>
<td>4,130 (30.7)</td>
<td>3,091 (29.0)</td>
</tr>
<tr>
<td>2</td>
<td>2,825 (21.0)</td>
<td>2,286 (21.5)</td>
</tr>
<tr>
<td>3</td>
<td>5,192 (38.6)</td>
<td>4,286 (40.2)</td>
</tr>
</tbody>
</table>

* 11,546 had x-rays taken and of those 478 did not know if the x-ray showed radiographic signs of OA.
** The European League Against Rheumatism (EULAR): More than 40 years, movement-related joint pain, functional limitations, morning stiffness and at least one of the following: crepitus, restricted range of motion, and bony enlargement.
*** The American College of Rheumatology (ACR): Movement-related joint pain and either crepitus, morning knee stiffness of 30 min or less, and age of 38 years or above or bony enlargement.
**** The National Institute for Health and Care Excellence (NICE): 45 years or older and movement-related joint pain.

Missing values for all patients: Overweight 80; Previous joint injury 3; Family members with osteoarthritis 5.
Appendix 1.
The overlap between patients fulfilling the NICE, ACR and EULAR criteria respectively. The diagram includes the 90% of patients who fulfilled at least one of the criteria.

NICE: The National Institute for Health and Care Excellence
ACR: The American College of Rheumatology
EULAR: The European League Against Rheumatism