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Improving the referral pattern of patients with knee osteoarthritis to the orthopaedic surgeon: Development and evaluation of a new screening algorithm based on patient-reported data and radiographs

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ABSTRACT

Introduction: Many patients with knee osteoarthritis referred to orthopaedic surgeons are not eligible for surgery and might benefit from being examined by other healthcare professionals. The objective of this study was to develop and test a screening algorithm to define relevant referral to the OS.

Methods: Prior to clinical examination, 173 consecutive patients referred to the orthopaedic outpatient clinic completed questionnaires, and radiographic osteoarthritis severity was graded. The gold standard for relevant referral to an orthopaedic surgeon was based on actual treatment. The performance of the algorithm in predicting relevant referrals and total knee replacement (TKR) was assessed using sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV).

Results: Referral to an orthopaedic surgeon was considered relevant in 65% (113/173) of patients. Sensitivity, specificity, PPV and NPV for predicting relevant referral to an orthopaedic surgeon were 0.70, 0.56, 0.76 and 0.48, respectively. The corresponding estimates for predicting TKR surgery were 0.92, 0.56, 0.55 and 0.92.

Conclusions: The algorithm was able to identify most patients relevant for referral to an orthopaedic surgeon, but less suitable for identifying those not relevant. The algorithm demonstrated excellent performance in predicting TKR surgery. With further development, this screening algorithm might contribute to improvement of the referral pattern in the orthopaedic outpatient clinic.

1. Introduction

Knee osteoarthritis is a significant contributor to global disability (Cross et al., 2014). As the prevalence of knee osteoarthritis is expected to increase rapidly in the future due to the aging population (Cross et al., 2014), treatment strategies and referral patterns need to be as optimal as possible. Before considering referral to surgery, it is recommended that the patient undergo non-surgical treatment of sufficient dose and length (Fernandes et al., 2013; McAlindon et al., 2014). Non-surgical treatments, such as supervised exercises, are effective in relieving pain and improving function in patients with knee osteoarthritis referred to outpatient orthopaedic clinics (Skou et al., 2015a; Skou et al., 2015b).

Despite agreement on the recommendation of non-surgical treatment among international guidelines (Nelson et al., 2014), current clinical care of patients with knee osteoarthritis is suboptimal (Basedow et al., 2015; Hagen et al., 2016). Furthermore, many patients referred to outpatient orthopaedic clinics are not eligible for surgery (Desmeules et al., 2013). The explanation for this is probably multifactorial, but it has been suggested that an underevaluation of the proven benefit of exercise, as well as the complexity and burden of adhering to conservative treatment modalities might be part of the reason (Basedow et al., 2015; Hagen et al., 2016). By optimizing and targeting patient referral to orthopaedic clinics, there is a potential for improving the rate of patients referred to the orthopaedic surgeon that are eligible for surgery. There is also potential for improving patient care, as patients

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relevant for non-surgical treatment could be referred to other healthcare professionals such as specialist nurses and physiotherapists and, thereby, initiate appropriate non-surgical treatment earlier. Among primary care physicians, there is large variability and uncertainty concerning who to refer to the orthopaedic surgeon when patients present with knee or hip osteoarthritis, so support tools to help identifying those who need referral are greatly needed (Waugh et al., 2016).

Previous studies attempting to define appropriateness of recommending TKR have included patient-reported outcomes and radiographic severity as well as clinical examination of knee mobility/stability by the orthopaedic surgeon (Escobar et al., 2003; Quintana et al., 2006; Riddle et al., 2014). However, to improve the rate of relevant referrals to the orthopaedic surgeon, the clinical algorithm should, preferably, be based on patient-reported outcomes and radiographic findings only, thereby making it useful prior to the clinical examination by the orthopaedic surgeon. Such an algorithm could either be used in primary care to guide the physician or, for example, a specialist nurse handling referrals, or it could serve as part of a "gatekeeper function" in the outpatient orthopaedic clinic.

In the present study we aimed to develop and evaluate a screening algorithm to define relevant referral to the orthopaedic surgeon based on patient-reported outcomes and radiographic findings and, subsequently, evaluate its ability to predict TKR surgery.

2. Methods

2.1. Study design

The study was a cross-sectional observational study with consecutive, unselected patient inclusion. Patients attending the orthopaedic outpatient knee clinic at the Elective Surgery Centre, Silkeborg Regional Hospital in Denmark in the period August to October 2015 were included in the study.

2.2. Participants

Inclusion criteria were adult patients (> 18 years) with a first-time referral to the orthopaedic outpatient knee clinic. Exclusion criteria were cognitive or language problems that precluded answering the questionnaires, unwillingness to participate, prior TKR in the index knee or one or more of the following co-morbidities: rheumatoid arthritis, neurological diseases or cancer.

2.3. Variables and data sources

The gold standard for the outcome "relevant" or "not relevant" for referral to an orthopaedic surgeon was based on actual treatment given in the outpatient clinic or referral for other treatments or to medical specialists after the clinical examination by the orthopaedic surgeon, e.g. referral to rheumatologist or further paraclinical investigations (magnetic resonance imaging (MRI), scintigraphy etc.) (Table 1). In Denmark, the primary care practitioner would usually refer for MRI of the knee on suspicion of a tendon or meniscal injury and to a rheumatologist if they thought the symptoms were due to another type of arthritis such as rheumatoid arthritis. In patients with osteoarthritis they would typically refer to the orthopaedic surgeon, who would then handle any further referral, if indicated. The gold standard for eligibility for TKR was actual referral and consent to undergo TKR surgery after the examination in the clinic. The variables used to categorize patients according to the gold standard were registered by the orthopaedic surgeon and nurse during the patient examination at the outpatient clinic.

The predictive variables were knee pain and function measured by the Knee injury and Osteoarthritis Outcome Score (KOOS), Pain and Activities of Daily Living (ADL) subscales, knee mobility/stiffness measured by two questions from the KOOS symptoms subscale (question S4 *Can you straighten your knee fully?* and S5 *Can you bend your knee fully?*) (Roos et al., 1998; Roos and Toksvig-Larsen, 2003) and radiographic osteoarthritis severity measured by the Kellgren-Lawrence (KL) scale (Schiphof et al., 2011). Although radiographs are less relevant when diagnosing osteoarthritis clinically, it is important when evaluating indication for TKA surgery; therefore we found it necessary to include it in the algorithm. (Carr et al., 2012; Gademan et al., 2016; Gossec et al., 2011; Riis et al., 2014). The KOOS questionnaire was completed by the patients prior to the clinical examination in order to avoid a dialogue with the orthopaedic surgeon that could influence the answers. The KL scale was evaluated by one of four participating surgeons before meeting the patient. This order was to prevent the clinical findings from affecting the radiographic evaluation and, thereby, ensure that the algorithm would be feasible to use without a clinical examination. The KL scale defines osteoarthritis in 5 grades ranging from 0 (no sign of osteoarthritis) to 4 (severe osteoarthritis). The inter-rater agreement of the KL classification was tested on 50 radiographs without patient identification by three of the participating surgeons. The three raters were two experienced, senior knee surgeons (rater 1: 12 years of experience, rater 2: 10 years of experience) and one junior knee surgeon (< 1 year of experience). During rating of the radiographs each individual rater was blinded to the others' ratings.

2.4. Screening algorithm

The algorithm was based on previously published algorithms to determine appropriateness of TKR surgery (Escobar et al., 2003; Quintana et al., 2006; Riddle et al., 2014). The algorithm was modified in the present study to be based only on patient-reported variables and radiographs (no clinical findings); see variable definitions in Table 2. In the present study, the judgement "appropriate for TKR" and "inconclusive" from the published algorithms were defined as "relevant referral to orthopaedic surgeon", whereas the category "inappropriate for TKR" was defined as "not relevant for referral to orthopaedic surgeon".

Table 1
Definitions of gold standard outcomes based on data from the orthopaedic outpatient clinic.

Gold standard for referral to OS	Classification criteria
Relevant referral	Referral for surgery Treated with intra-articular corticosteroid injection Referral to other medical specialist (e.g. rheumatologist) Referral for further diagnostics A new appointment at the orthopaedic outpatient clinic
Not relevant referral	Referral to or recommended non-surgical treatment
Gold standard for referral to TKR	**Criteria**
Eligible for TKR	Referred to TKR and consent to undergo surgery
Not eligible for TKR	Not referred to TKR

OS: Orthopaedic surgeon, TKR: total knee replacement.

Table 2
Classification criteria for the algorithm to determine relevant referral to the orthopaedic surgeon.

Predictive variable	Definition and scale	Cut-off value	Argument/reference
Symptoms	Raw scores on KOOS ADL scale and P5–P9 on the Pain scale (22 questions, scale 0–4, lower is better)	Divided into groups with cut off levels as in Riddle et al., 2014[a] 0-11: Mild 12-22: Moderate 23-33: Intense > 33: Severe	Riddle et al. (2014)
Knee mobility/stability	KOOS symptoms question: S4 + S5 Scale 0–4, lower is better	= 4 in either S4 or S5, defined as mobility limitations	Gossec et al., (2011)
Radiographic severity	KL scale 0-4, lower is less severe OA	0-2: Mild OA 3: Moderate OA 4, Severe OA	Gossec et al., (2011)

KOOS: Knee injury and Osteoarthritis Outcome Score, ADL: Activities of Daily Living KL: Kellgren-Lawrence, OA: Osteoarthritis, a: corresponding to up to half of the answers marked as mild/moderate/severe/extreme.

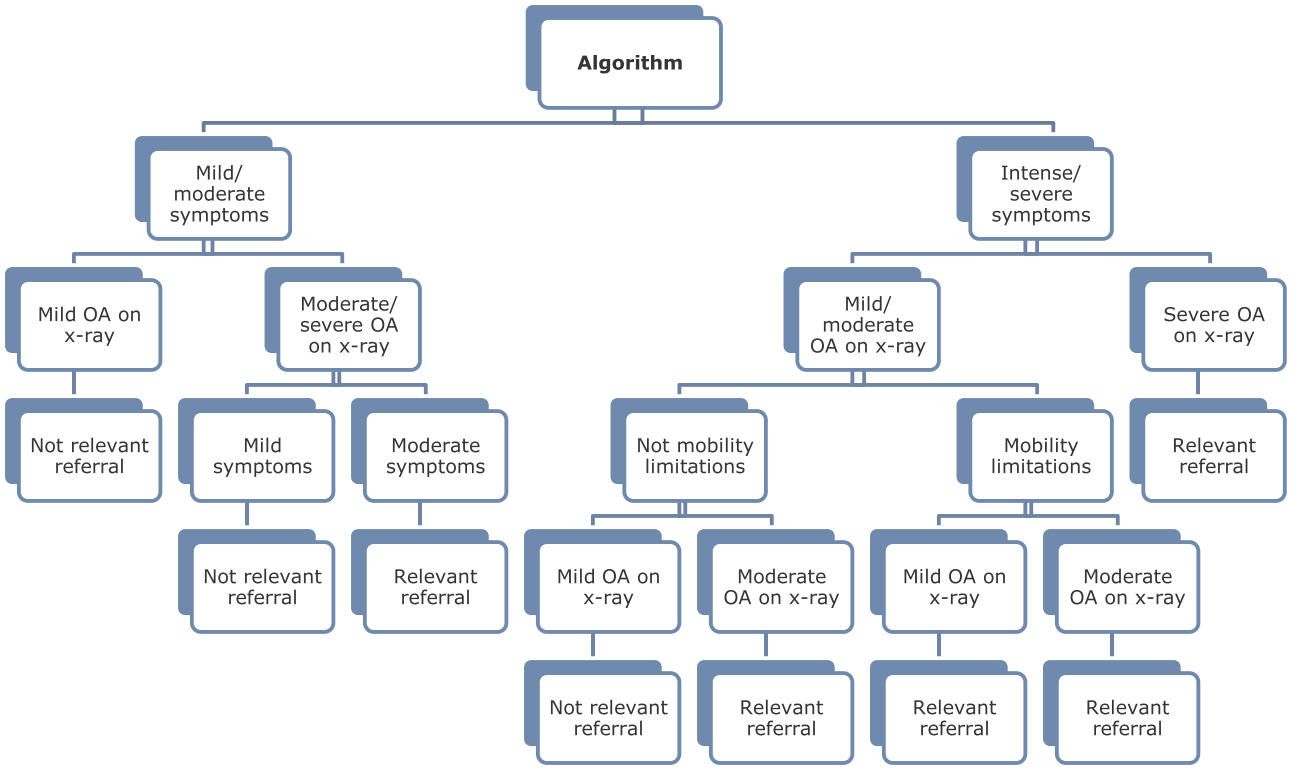

Fig. 1. Illustration of the algorithm categorizing patients as relevant or not relevant to refer for examination by an orthopaedic surgeon. The algorithm is modified from Riddle et al., (2014) to exclude clinical findings. OA: Osteoarthritis.

We included the variables pain, function, radiographic severity and knee mobility, as these have been identified as relevant variables when deciding on eligibility for TKR (Gossec et al., 2011; Skou et al., 2016). We defined a priori that a sensitivity of 0.80 would be considered acceptable performance of the algorithm. The algorithm is illustrated graphically in Fig. 1 and the classification criteria are presented in Table 2.

2.5. Additional descriptive data collection

Data relating to age, sex, height, weight, previous injury and treatment of the index knee (surgical and non-surgical) were collected for descriptive purposes.

2.6. Sample size estimation

With an expected sensitivity of 0.90 in predicting relevant referral to orthopaedic surgeon, a lowest acceptable limit of a 95% confidence interval of 0.80, a significance level of 0.05 and a power of 0.80, the required sample size was 86 patients categorized as "relevant referral to orthopaedic surgeon". Based on pilot data collection (not published) we expected the prevalence of relevant referrals to an orthopaedic surgeon to be 0.53, so the required sample size was estimated to be 163 (86/0.53).

2.7. Statistical analysis

The results from the algorithm were presented in 2x2 tables comparing the gold standard for referral to an orthopaedic surgeon and the gold standard for TKR. The performance of the algorithm was estimated by calculating the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). The corresponding 95% confidence intervals (CI) were estimated based on the Clopper-Pearson method for estimating confidence intervals for binomial proportions (Brown et al., 2001). Likewise, the performance of the algorithm in predicting TKR surgery was presented and similar performance

statistics were estimated. The inter-rater reliability between the three raters for 50 radiographs was calculated using weighted kappa comparing the raters two by two against each other. The common inter-rater reliability for all three raters was also calculated using a two-way mixed model which corresponds to a weighted kappa with quadratic weights for ordinal scales (Norman and Streiner, 2008). Statistical analyses were performed using STATA software version 13.

2.8. Ethics and registration

The regional ethical committee accepted initiation of the study and reviewed the study as non-notifiable (Inquiry 123/2015). The study was approved by the Danish Data Protection Agency (ref no: 1-16-02-292-15) and pre-registered at clinicalTrials.gov (Identifier: NCT02673801). Patients participating in the study received the standard treatment in the department and gave informed written consent to participate in the study. The only disadvantage for the participants was the time spent on completing questionnaires, which was performed in the waiting room. The staff adjusted their practice in order to make time for completion of questionnaires for all patients prior to clinical examination. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation (The Danish National Committee on Health Research Ethics) and with the Helsinki Declaration of 1975, as revised in 2008.

3. Results

3.1. Participants

In the inclusion period, 207 patients were identified as eligible, whereas 41 were excluded for various reasons (see flowchart in Fig. 2), thus there were data from 166 patients available for the statistical analysis. The patient characteristics are presented in Table 3.

3.2. Clinical examination

The actual treatment and referral decisions based on the clinical examination in the orthopaedic outpatient clinic are presented in Table 4. Of the 166 included patients, 61 (37%) were treated with a TKR and 64 (39%) were referred for or advised about non-surgical treatment.

3.3. Algorithm

In Table 5 the agreement of the results from the algorithms and the orthopaedic outpatient clinic are presented.

In Table 6 the performance of the algorithms on predicting relevant referral and TKR surgery is presented.

3.4. Inter-rater reliability

The results from the inter-rater reliability of the KL scale evaluation are presented in Table 7.

4. Discussion

To our knowledge, this is the first study to develop and evaluate a screening algorithm to identify relevant referrals to orthopaedic surgeon for patients with knee OA based on patient-reported data and radiographic evaluation only. The algorithm did not meet the pre-defined acceptable performance level. While it was able to identify most patients relevant for referral for the orthopaedic outpatient clinic, it was less suitable for identifying those who did not need to see an orthopaedic surgeon.

4.1. Relevant referral to the orthopaedic surgeon

We aimed to develop a screening algorithm based on patient-reported data and radiographs only that it would be possible to apply

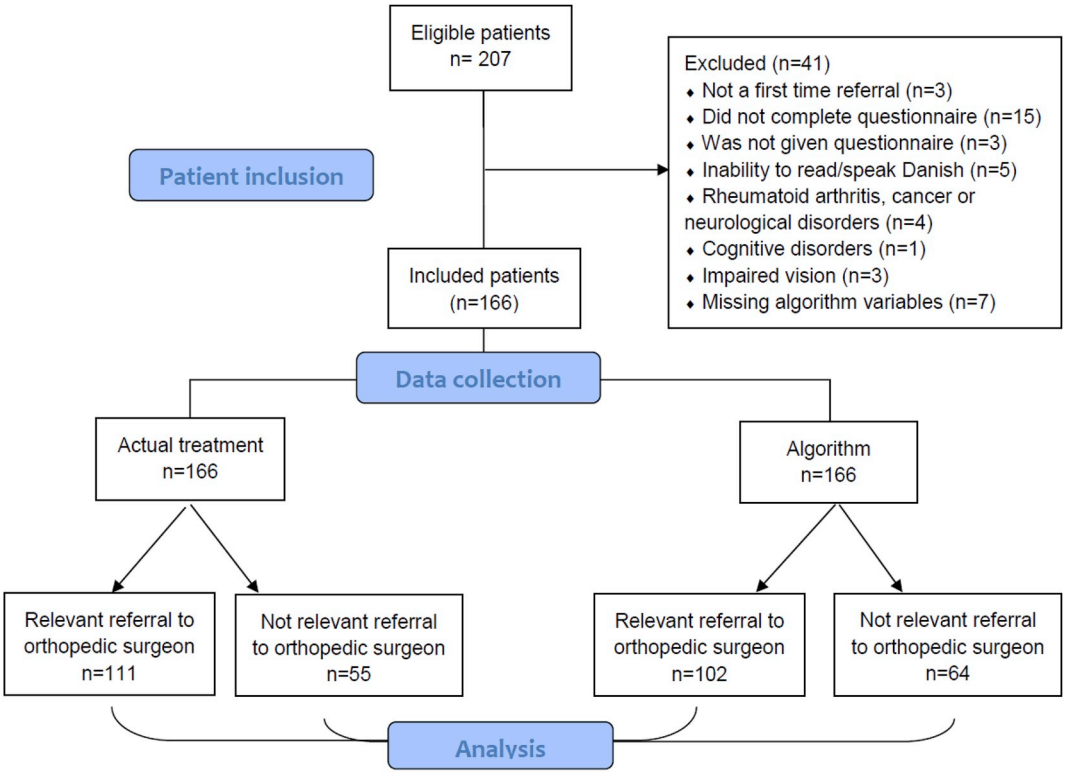

Fig. 2. Participant flow.

Table 3
Patient characteristics presented in number (%) unless otherwise stated.

Variable	n = 166	Eligible for TKR (n = 61)	Not eligible for TKR (n = 105)	Missing
Gender				0
Male	64 (39)	20 (33)	44 (42)	
Female	102 (61)	41 (67)	61 (58)	0
Age (years), mean (sd)	67.4 (9.5)	69.5 (9.8)	66.7 (8.8)	0
Range	38–99	44–99	44–87	
BMI (kg/m^2), mean (sd)	28.4 (4.6)	28.7 (5.4)	28.2 (4.0)	4
Diagnosis (defined after the clinical examination)				1
Knee osteoarthritits	134 (81)	61 (100)	73 (70)	
Meniscal related	22 (13)	0	22 (21)	
Other	9 (5)	0	9 (9)	
Radiographic severity (KL scale)				0
KL 0	11 (7)	1 (2)	10 (10)	
KL 1	34 (20)	1 (2)	33 (31)	
KL 2	27 (16)	4 (7)	23 (22)	
KL 3	54 (33)	28 (46)	26 (25)	
KL 4	40 (24)	27 (44)	13 (12)	
Prior injury/surgery				
Injury, same knee	92 (58)	37 (62)	55 (55)	7
Surgery, same knee	60 (36)	22 (37)	38 (37)	3
TKR, opposite knee	17 (10)	12 (20)	5 (5)	0
Symptoms				
Mild/moderate†	11 (7)	1 (2)	10 (10)	0
Intense/severe‡	155 (93)	60 (98)	95 (90)	0
KOOS ADL, mean (sd)	47.6 (18.2)	43.7 (17.1)	49.8 (18.5)	2
KOOS Pain, mean (sd)	44.2 (17.0)	40.2 (15.1)	46.5 (17.6)	1
Participated in supervised exercise				
GLA:D	24 (14)	12 (20)	12 (11)	12
Other physiotherapist	44 (27)	17 (28)	27 (26)	19
At least one of the above	55 (33)	23 (38)	32 (30)	N/A

TKR: Total Knee Replacement, BMI: Body Mass Index, KL: Kellgren-Lawrence scale, KOOS: Knee injury and Osteoarthritis Outcome Score, ADL: Activities of daily living, GLA:D™: Good Life with osteoArthritis in Denmark (Skou et al., 2016), treatment consisting of 8 weeks of patient education and supervised neuromuscular exercise. As some patients had participated in both GLA:D™ and other physiotherapist-supervised exercise the third category was added. †Raw score = 0–22 on 22 questions from KOOS, ‡Raw score ≥ 23 on 22 questions from KOOS.

Table 4
Results from the clinical examination at the orthopaedic outpatient clinic.

Treatment/referral	N = 166	Defined as relevant referral to OS
Surgery	67 (40)	Yes
TKR	61 (37)	
Arthroscopy	6 (4)	
Steroid injection[a]	14 (8)	
Other medical treatments[b]	2 (1)	
New appointment in the outpatient clinic[c]	6 (4)	
Further referral (to other medical specialists or investigations such as MRI scan)	28 (17)	
Referral to other non-surgical treatment	23 (14)	No
Advise on treatment	41 (25)	

Patients can be represented in more than one category. OS: Orthopaedic surgeon, TKR: Total knee replacement, MRI: Magnetic resonance imaging. a: Of these, one was referred to physiotherapy, and six got new appointments in the outpatient clinic, b: Of these, one was referred to other specialist and one was referred to physical therapist, c: Of these, six had a steroid injection.

prior to clinical examination by an orthopaedic surgeon. The algorithm needed to be able to identify 70% (sensitivity) of the patients that were relevant to refer to the orthopaedic surgeon. However, the algorithm could only identify 56% of the patients not relevant to refer to orthopaedic surgeon (specificity), implying there would be many false positives if it is used to select patients to refer to an orthopaedic surgeon. Based on the definitions in this study, where all medical treatments and further referral to medical specialists were considered relevant referrals, we found that, if the algorithm predicts a patient to be relevant to refer to orthopaedic surgeon, it will be true in 76% of the cases (positive predictive value). If the algorithm predicts a patient to be not relevant to refer to orthopaedic surgeon, this will only be true in 48% of the cases (negative predictive value). However, some of the treatments and referrals included in the definition of relevant referral could potentially be handled by specialist nurses or physiotherapists or other health care professionals, e.g. the patients treated with steroid injections or those with new appointments or further referrals. The algorithm might be optimized by applying different cut-offs in the included variables or by including more variables such as age, previous treatment etc. An age criterion (≤55 years of age) has previously been applied to an algorithm to classify patients as inappropriate for TKR surgery (Escobar et al., 2003; Riddle et al., 2014). However, the age limit was arbitrarily set and there is no consensus on its use (Riddle et al., 2014), hence we did not include age in the present algorithm. Not responding to non-surgical treatment would be a relevant variable to include in the algorithm according to clinical guidelines and it has

Table 5
Prediction of relevant referral to OS and referral to TKR surgery.

a. Results from the algorithm concerning prediction of relevant referral to OS

Algorithm	Orthopaedic outpatient clinic		
	Relevant referral to OS		
Relevant referral to OS	Yes	No	Total
Yes	78	24	102
No	33	31	64
Total	111	55	166

b. Results from the algorithm concerning prediction of TKR surgery

Algorithm	Orthopaedic outpatient clinic		
	TKR surgery		
Relevant referral to OS	Yes	No	Total
Yes	56	46	102
No	5	59	64
Total	61	105	166

Table 6
Performance measures of the algorithm.

	Prediction of relevant referral to OS (95% CI)	Prediction of TKR surgery (95% CI)
Sensitivity	0.70 (0.61; 0.79)	0.92 (0.82; 0.97)
Specificity	0.56 (0.42; 0.70)	0.56 (0.46; 0.66)
Positive predictive value	0.76 (0.67; 0.84)	0.55 (0.45; 0.65)
Negative predictive value	0.48 (0.36; 0.61)	0.92 (0.83; 0.97)

Table 7
Inter-rater reliability of KL scale.

	Weighted kappa (95% CI)
All three raters	0.83 (0.74; 0.89)
Rater 1 versus 2	0.70 (0,52; 0.88)
Rater 1 versus 3	0.64 (0.46; 0.82)
Rater 2 versus 3	0.60 (0.41; 0.78)

previously been suggested to be an important eligibility criterion for TKR surgery (Carr et al., 2012; Skou et al., 2016). In future studies it could be relevant to incorporate this factor in models for determinating relevant referrals to orthopaedic surgeon as well as eligibility for TKR. However, although it is considered important by most orthopaedic surgeon, the variable was not associated with eligibility in a previous study (Skou et al., 2016). The primary drivers for TKR surgery are radiographic severity and functional limitations, which supports the variables included in our algorithm.

4.2. Relevant referral to total knee replacement

Although preliminary in nature and requiring further development and validation, our algorithm demonstrated excellent performance in predicting TKR surgery as the algorithm identified 92% of the patients eligible for TKR, and ruled out TKR surgery with 92% certainty. However, the algorithm was only capable of identifying 56% of the patients not eligible for TKR surgery, meaning there would be many false positives if it is used to predict TKR. This underlines the importance of the consultation with the orthopaedic surgeon when deciding whether a patient should undergo surgery or not. It is well known that pain, function and radiographic severity alone poorly reflect the complexity of the decision to recommend TKR and total hip replacement (Carr et al., 2012; Gossec et al., 2011; Skou et al., 2016). TKR referral should always be based on a shared decision between surgeon and patient after thorough clinical and radiographic evaluation. Willingness to consider total joint replacement has previously been demonstrated to be the strongest predictor of the time to first total joint replacement (Hawker et al., 2006), highlighting that despite clinical and radiographic findings, patient preferences will always contribute significantly to the decision. If the algorithm in the current study defines a patient to be relevant to refer to orthopaedic surgeon it will only result in a referral for TKR in 55% of the cases. This corresponds to the “hit-rate” for TKR surgery in the orthopaedic outpatient clinic if the algorithm is implemented in practice. Comparing it to results from current practice where the “hit-rate” was 36%, some improvements can be achieved by applying this algorithm. This indicates a potential cost saving, since an improvement in “hit-rate” would result in fewer referrals of patients to the orthopaedic surgeon who should have been referred to non-surgical treatment instead. Research has shown that use of an algorithm to determine appropriateness of TKR can potentially improve the outcome after surgery, since patients classified as appropriate for TKR according to the algorithm achieve larger health gains than those classified as inappropriate or inconclusive (Quintana et al., 2006; Riddle et al., 2015). In the present study only 8% (5/61) of the patients referred for TKR surgery where classified as inappropriate according to the algorithm. We find this satisfactory since earlier studies classified larger proportions of TKR surgeries as inappropriate even though they included more variables in their algorithm than in ours (Quintana et al., 2006; Riddle et al., 2014). Riddle et al. found 34% and Quintana et al. 12% of the TKR surgeries inappropriate according to their algorithms, which opposite to our algorithm, required a clinical examination.

4.3. Current quality of care in clinical practice

Previous research has shown discrepancies between clinical practice and guideline recommendations, highlighting that sufficient non-surgical treatment should be carried out before considering surgery (Hagen et al., 2016). In the present study, only 33% (55/166) of the included patients had undergone supervised exercise prior to referral to orthopaedic surgeon. Hence, our results confirm previous findings and underline the need for continued focus on implementation of guideline recommendations concerning first line treatment of knee osteoarthritis in primary care. This discrepancy was also present in patients referred for TKR, since only 35% (23/61) of those had tried out supervised exercise before referral to surgery, further emphasizing the importance of implementing guideline recommendations, even in patients with more pronounced knee osteoarthritis.

4.4. Limitations and strengths

The study has some limitations. There is no perfect or true definition of the gold standard for relevant referral to an orthopaedic surgeon. We chose to define all surgical and medical treatments and further referral as relevant referral to an orthopaedic surgeon, but treatment and referral patterns could potentially be dependent on how the outpatient clinic is organized and the degree of experience, advanced skills and continued education of the employees. Furthermore, this is a preliminary algorithm that should be further improved and tested. For instance, the symptom variable (pain and function) in the current algorithm did not add much to the categorization of the patients. Only 7% of the sample was categorized as having mild or moderate symptoms, whereas 93% had intense or severe symptoms with the severe category accounting for 81% of the sample. In a future version of the algorithm we suggest to base the symptom variable on the subscale scores KOOS ADL and pain. However, there is no well-defined clinically relevant cut-off level for KOOS subscales so further research to define this is needed (Gossec et al., 2011).

The primary strength of the study is that the algorithm includes only patient-reported and radiographic variables, thus making it possible to implement prior to physical examination of patients. This has great potential if it is improved as a screening tool, either applied in primary care or as a gate-keeper function in the outpatient clinic, where the patients can potentially be referred to either an orthopaedic surgeon or other healthcare professionals such as specialist nurses or physical therapists based on the prediction from the algorithm. Nurses and physical therapists managing ambulatory functions traditionally performed by an orthopaedic surgeon is not a new innovation (often referred to as advanced practice nurses/physiotherapist); it is increasingly used in several countries (Desmeules et al., 2012; McCleery et al., 2011). However, a new perspective from this study is the ability to make an evidence-based categorization of which patients to refer to which health care professional. A practical challenge, if the algorithm is to be used in primary care, is the need for KL evaluation of the radiograph. Depending on how the referral system is used in the specific setting, it might be possible to apply the algorithm somewhere in between primary and secondary care. For instance, if the primary care physician deems a patient potentially eligible for surgery, the patient could be referred to radiographic evaluation and the orthopaedic surgeon could evaluate the radiograph without seeing the patient. At the same time, the patient could complete the relevant questionnaires, maybe as an online survey. Then the results of both the radiographic evaluation and the questionnaires can be combined and determine whether the patient is referred to the orthopaedic surgeon or another health care professional, e.g. specialist nurse or physiotherapist with the purpose of initiating conservative treatment. Applying the algorithm could thereby potentially save time and money for the patient and health care system, as the surgeons would primarily see patients who actually were eligible for surgery.

4.5. Generalizability

We consider the external validity of the present study to be fairly good since we used consecutive sampling with broad inclusion criteria. However, there were some exclusions and a few with missing variables, so 20% of the eligible patients were not included, thus leading to a risk of selection bias that could affect the external validity. However, we believe our results can be generalized to countries with a health care system with similarities to the Danish setting.

5. Conclusion

The algorithm was able to identify most patients relevant for referral to the orthopaedic surgeon, but was less suitable for identifying those who did not need to see an orthopaedic surgeon. The algorithm predicted almost all patients who underwent TKR surgery using only patient-reported data and radiographs. With further development, this screening algorithm might be able to improve the referral pattern and, thereby, improve patient care and efficiency in primary health care.

Conflicts of interest

All authors declare that they have no financial or personal relationships with other people or organizations that could inappropriately influence this work.

Sources of funding

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Ethical statement

The regional ethical committee accepted initiation of the study and reviewed the study as non-notifiable (Inquiry 123/2015). The study was approved by the Danish Data Protection Agency (ref no: 1-16-02-292-15) and pre-registered at clinicalTrials.gov (Identifier: NCT02673801). Patients participating in the present study received the standard treatment in the department and gave informed written consent to participate in the study. The only disadvantage for the participants was the time spent on completing questionnaires, which was performed in the waiting room. The staff adjusted their practice in order to make time for completion of questionnaires for all patients prior to clinical examination. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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