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Can an intervention on clinical inertia have an impact on the perception of pain, functionality and quality of life in patients with hip and/or knee osteoarthritis? Results from a cluster randomised trial

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KEYWORDS

Osteoarthritis; Hip; Knee; Clinical inertia

Abstract

Objectives: Evaluate whether an intervention applied to general practitioners to prevent clinical inertia had an impact on pain, functionality, and health-related quality of life (HRQoL) of patients with hip and/or knee osteoarthritis.

Design: This was a cluster-based, multicentre, prospective, randomized, parallel-group study. Clusters of physicians working were assigned to one of two study groups. Physicians in Group 1 received a training session while those in Group 2 did not.

Setting: Primary Care Health centers representative of the entire Spanish territory.

Participants: 329 general practitioners of primary healthcare centre.

Interventions: The intervention consists of a motivational session to propose a proactive care, based on current recommendations.

Measurements: Visual analogue scale (VAS); functionality (WOMAC scale) and global perception of health by SF-12. Effects were measured in two visits six months apart.

Results: A total of 1361 physicians, and 4076 patients participated in the study. No significant differences were observed in the clinical benefit obtained between patients assigned to Group 1 and Group 2. Nevertheless, a significant improvement was observed in the combined population

Abbreviations: EULAR, European League Against Rheumatism; HRQoL, Health-related quality of life; MCS, Mental Component Summary; NSAIDs, Non-steroidal anti-inflammatory drugs; PCS, Physical Component Summary; SD, Standard deviation; SF-12v2, Short Form version 2 Health Survey; VAS, Visual Analogue Scale; WOMAC, Western Ontario and McMaster Universities Index.

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(Groups 1 + 2) in the VAS (p < 0.001), WOMAC (p < 0.0001) and SF-12v2 (p < 0.001) questionnaires in Visit 2 compared to Visit 1.

Conclusions: The results indicate that, although this specific intervention carried out on physicians did not provide an additional clinical benefit to patients with knee and/or hip osteoarthritis, an increased awareness of the patient's disease through the use of functionality indexes, as well as the mere fact of being observed, seem to improve patient-reported pain, functionality and HRQoL.

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PALABRAS CLAVE

Artrosis; Cadera; Rodilla; Inercia clínica

Estudio ARTRO-PRO: percepción del beneficio clínico y calidad de vida en pacientes con artrosis de cadera y rodilla

Resumen

Objetivos: Evaluar si una intervención aplicada a médicos de familia para evitar la inercia clínica tuvo un impacto en el dolor, funcionalidad y calidad de vida relacionada con la salud (CVRS) de los pacientes con artritis de cadera y/o rodilla.

Diseño: Estudio de grupos paralelos de *cluster*, multicéntrico, prospectivo, aleatorizado. Los médicos fueron asignados a 2 grupos, el grupo 1 recibieó una sesión de entrenamiento, el grupo 2. no.

Emplazamiento: Centros de salud representativos del territorio español.

Participantes: Médicos de familia de 329 centros de salud.

Intervenciones: Consistieron en una sesión motivadora para proponer una atención proactiva, basada en recomendaciones actualizadas.

Mediciones principales: Escala analógica visual (EVA); funcionalidad (escala WOMAC) y percepción global de salud mediante SF-12 en 2 visitas separadas por 6 meses.

Resultados: Participaron 1.361 médicos y 4.076 pacientes. No se observaron diferencias significativas en el beneficio clínico obtenido entre los pacientes asignados al grupo 1 y grupo 2. Sin embargo, se observó una mejora significativa en la población total (grupos 1+2) en la EVA (p < 0,001), WOMAC (p < 0,0001) y el SF-12V2 (p < 0,001) en la visita 2 en comparación con la visita 1.

Conclusiones: Esta intervención sobre médicos de familia no proporcionó un beneficio clínico adicional a los pacientes. Se observó en ambos grupos una mayor conciencia de la enfermedad del paciente por el uso novedoso de índices de funcionalidad y CVRS, que parece mejorar el dolor percibido, la funcionalidad y la calidad de vida relacionada con la salud.

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Introduction

Osteoarthritis is the most common type of arthritis in Western populations, and is a major cause of chronic musculoskeletal pain and mobility disability in elderly populations worldwide. The prevalence of osteoarthritis varies depending upon the diagnostic method used (clinical or radiological), the joint(s) studied, and the characteristics of the study population; nonetheless, it is considered one of the ten most disabling diseases in developed countries, affecting 10% of men and 18% of women over the age of 60.2 As with other chronic conditions, treatment of osteoarthritis is complex and involves a combination of pharmacological and non-pharmacological measures for its optimal management. 3,4

Failure to implement recommendations contained in the available guidelines of any chronic disease is one of several factors contributing to clinical inertia. Clinical inertia is a leading cause of potentially preventable adverse events. According to Phillips et al.⁵ factors that could contribute to clinical inertia include the overestimation of the quality of the care delivered by the physician or the underestimation

of the number of patients who need an intensification of pharmacotherapy. Additionally, other factors that could contribute are that some physicians lack the appropriate knowledge, tools and clinic facilities to deliver adequate care to patients with chronic diseases. As has been demonstrated in several randomised clinical trials and cohort studies, the deleterious consequences of clinical inertia for the patient can be significant, especially in certain chronic diseases such as diabetes mellitus or arterial hypertension. Unfortunately, information on the impact of clinical inertia on other diseases with low mortality but high morbidity, such as osteoarthritis, is limited or non-existent.

We carried out a cluster-based, multicentre, prospective, randomised, parallel-group study to evaluate whether patients with hip and/or knee osteoarthritis would benefit from a specific type of intervention received by their general practitioners, which was designed to reduce clinical inertia. Secondary objectives were to learn about the clinical characteristics of osteoarthritis patients attending primary care clinics, and to identify those factors related to clinical inertia that, when modified, may result in clinical benefit for the patient.

Materials and methods

Study design

A multicentre, prospective, randomised, parallel-group study of physician clusters (general practitioners) was performed to compare the effectiveness of two different healthcare approaches. The study protocol was approved by the Ethics Committee of the Hospital Universitario 12 de Octubre (Madrid, Spain) and by the Scientific Committee of the Spanish Family and Community Medicine Society (SemFYC).

Study populations

General practitioners (GP) working in the same primary healthcare centre for a period of at least six months after the start of the study were selected to participate in the study. Physicians involved in other studies related to healthcare improvement in osteoarthritis or similar were excluded. GP included in the study enrolled patients who attended their clinics with a diagnosis of hip and/or knee osteoarthritis according to the criteria of the American College of Rheumatology. Patients who had a prosthetic treatment of osteoarthritis, a prosthetic implantation planned within the next six months, osteoarthritis involving exclusively other joints besides the hip or knee, concomitant diagnosis of other rheumatic disorders, and/or inability to participate in the study were excluded.

With an anticipated effectiveness of 50% in group 2 and an estimated clinically relevant difference of at least 10%, a type I error of 5% and a study power of 90%, the estimated sample size for this study was 350 primary care centres with 5 general practitioners per site (1,750 GP). Assuming that 10% of physicians would probably drop out, the final sample size estimated for this study was 1,925 GP from the 350 primary care centres.

Study procedures

Clusters of physicians working at the same healthcare centre for more than six months were randomly assigned with a ratio 1:3 to one of two study groups. Group 1 (proactive intervention group) physicians received a specific scientific training session on the current management guidelines of osteoarthritis disease to avoid clinical inertia. Group 2 (control group) physicians did not receive any specific intervention and, hence, delivered usual healthcare to patients with hip and/or knee osteoarthritis.

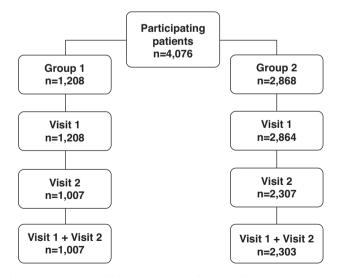
Each GP included the first three patients with hip and/or knee osteoarthritis who fulfilled selection criteria and agreed to participate in the study. Consequently, a total of 5,775 patients were expected to be included in the study.

The intervention delivered to Group 1 was a single clinical session of 45-60 minutes, in which a family physician, who had been previously trained, explained the assessment methods which would be used during the study: visual analogue scale (VAS) (range 0-100 mm), ¹⁰ Western Ontario and McMaster Universities (WOMAC) ¹¹ and the Short Form-12 version 2 (SF-12v2) Health Survey ¹² questionnaires. Motivational techniques were used and the latest EULAR evidence-based recommendations for the management of

osteoarthritis disease were delivered.^{3,4} The session was addressed to family physicians with daily clinical practice, who are supposed to have enough knowledge level to make decisions on the patients; thus, the aim of meeting was to motivate, break the weight that inertia supposes and generate proactive behaviour to lead physicians to search and update their knowledge of osteoarthritic disease and its treatment.

Additionally, GP from both study groups received a brief summary of the study protocol, the case report forms, and the questionnaires which would be used (VAS, WOMAC and SF-12v2). Scores were estimated for four of the health concepts (physical functioning, physical role, emotional role and mental health) using two items each, while the remaining four (pain, general health, vitality and social functioning) were represented by a single item. All 12 items are used to calculate the Physical and Mental Component Summary scores, which yield a mean of 50 and a standard deviation (SD) of 10.13 Thus, patients are classified as above or below average. If a patient's physical health difference score was negative but close to zero, he or she was considered in 'average' health. However, if a patient's score was around -20, he or she was considered 'below average', or in poor health. 14

Patients selected by GP were scheduled for at least two visits with a six months interval. During Visit 1, age, weight, height, medical history, time elapsed since diagnosis, presence of concomitant diseases, and pharmacological treatment(s) received were recorded. In addition, patient's global health perception, general health status, pain and functionality were assessed using the SF-12v2, WOMAC and VAS questionnaires. During Visit 2, patients underwent a physical examination, information about current pharmacological and non-pharmacological treatments and the presence of additional relevant events was recorded, and SF-12v2, WOMAC and VAS tests were administered.



General scheme of the study: Distribution of patients according to study groups and visits. Group 1, General Practioners who received a training session and Group 2 which did not receive one. Visit 1, first visit to the Family Doactor clinic, and Visit 2 six months later.

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Characteristic	Group 1	Group 2	Р
Age (years)	n = 1205	n = 2852	
Mean (± SD)	68.7 (±9.67)	68.6 (±9.66)	0.794
Gender, n (%)	n = 1205	n = 2848	
Male	876 (73)	1986 (70)	
Female	329 (27)	862 (30)	0.058
Weight (kg)	n = 1206	n = 2855	
Weight (kg)	76.3 ± 12.42	77.1 ± 12.79	0.102
Haight (m)			51.152
Height (m)	n = 1204 1.60 ± 8.28	n = 2854 1.61 ± 8.43	0.011
			0.01
Body mass index (kg/m²)	n = 1204	n = 2854	
	$\textbf{29.71} \pm \textbf{4.49}$	29.73 ± 4.62	0.693
Disease progression (years)	n = 1199	n = 2837	
Mean (±SD)	9.0 (±6.92)	9.3 (±6.93)	0.197
Type of osteoarthritis, n (%) ^b	n = 1208	n = 2861	
Knee	895 (74)	2029 (71)	0.039
Hip	501 (41)	1286 (45)	0.04
Hand	136 (11)	316 (11)	0.84
Spine	274 (23)	648 (23)	0.98
Generalized	101 (8)	234 (8)	0.84
Concomitant diseases n (%) ^b			
Arterial hypertension	707 (73)	1715(76)	0.010
Diabetes mellitus	222 (33)	568 (37)	0.03
Hiatal hernia/GE reflux	209 (33)	485 (36)	0.36
Dyspepsia/Peptic ulcer	167 (27)	431 (32)	0.02
Ischaemic cardiomyopathy	80 (14)	203 (17)	0.17
Chronic pulmonary disease	68 (12)	200 (16)	0.01
Treatments received n (%) ^c			
Non-pharmacological treatments			
Weight reduction recommendations	600 (75)	1405 (79)	0.01
Exercise	658 (77)	1443 (80)	0.20
Electrotherapy	71 (12)	184 (15)	0.09
Hydrotherapy	82 (14)	177 (15)	0.73
Therapeutic massage	136 (23)	309 (25)	0.39
Joint sparing/joint protection	96 (17)	186 (15)	0.45
Pharmacological treatment n (%)			
Oral analgesics	965 (93)	2252 (92)	0.45
Oral NSAIDs	743 (79)	1877 (82)	0.10
Opioids	80 (12)	243 (16)	0.02
Topical analgesics	240 (32)	622 (36)	0.40
Topical NSAIDs	403 (52)	1002 (55)	0.02
SYSADOA	346 (43)	729 (41)	0.39
Intra-articular treatment	67 (10)	176 (11)	0.28

GE: gastroesophageal reflux; NSAIDs: non-steroidal anti-inflammatory drugs; SD: standard deviation; SYSADOA: symptomatic slow acting drugs for osteoarthritis.

Statistical analysis

Qualitative variables were expressed as percentages. Continuous variables were described using mean, median, SD, range, and 95% confidence intervals (CI). Frequency

distributions of qualitative variables were compared by Pearson X^2 or Fisher exact tests. Health centre and physician were considered random effects, and perception of patient changes was considered as fixed effect. All analyses were carried out using SAS version 9.1 (SAS Institute, Cary, NC).

^a Statistically significant.

^b Patients may have more than one type of osteoarthritis, and more than one disease.

^c Patients may be receiving more than one treatment.

Table 2 Global differences between Group 1 an	nd Group 2 in Visit 2 compared with Visit 1
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Instrument	Visit 2 – Visit 1		Р
	Group 1 (mean \pm SD)	Group 2 (mean \pm SD)	
SF-12			
Physical Functioning	1.2 ± 14.3	1.3 ± 13.00	0.956
Role Physical	1.4 \pm 11.8	1.7 ± 11.5	0.525
Bodily Pain	4.8 ± 27.6	6.1 ± 26.4	0.205
General Health	$\textbf{1.8} \pm \textbf{23.6}$	1.6 ± 21.3	0.801
Vitality	-0.9 \pm 29.3	1.4 ± 27.6	0.049 ^a
Social Functioning	$\textbf{3.3} \pm \textbf{28.8}$	2.0 ± 25.1	0.233
Role Emotional	1.5 \pm 12.6	1.3 ± 11.9	0.617
Mental Health	$\textbf{3.8} \pm \textbf{23.0}$	3.5 ± 21.7	0.736
Physical Component Summary	$\textbf{0.6} \pm \textbf{6.4}$	1.0 ± 5.8	0.169
Mental Component Summary	1.1 ± 8.8	$\textbf{0.9}\pm\textbf{8.5}$	0.624
WOMAC			
Pain	-5.1 \pm 16.0	-5.3 ± 16.0	0.736
Stiffness	-4.6 ± 20.4	-4.1 ± 21.0	0.585
Physical Function	-4.3 ± 15.2	-3.9 ± 15.8	0.518
VAS	-10.4 ± 19.5	-9.9 ± 18.7	0.516

SF-12v2: Short Form 12-item version 2 Health Survey; VAS: Visual Analogue Scale; WOMAC: Western Ontario and McMaster Universities Index

Results

Between September and October 2007, a total of 1361 GP were selected: 403 (30%) were assigned to Group 1 and 958 (70%) to Group 2. No significant differences were observed between groups regarding the number of years practicing, scientific and academic activity, age and gender.

A total of 4076 patients with hip and/or knee osteoarthritis were included in the study, 1208 (30%) attended by GP assigned to Group 1 and 2868 (70%) attended by GP belonging to Group 2. Overall, 1007 (83%) group 1 patients and 2303 (80%) group 2 patients attended both study visits. Discontinuation rate was a slightly higher in the control group (20% vs 17%).

Baseline characteristics of the study groups are described in Table 1. There were small significant differences regarding the type of osteoarthritis (in Group 1, knee osteoarthritis was more frequently observed: 74% vs. 71%, *P*=.039; and hip osteoarthritis less frequently observed: 41% vs 45%, *P*=.041).

There were small differences in some concomitant diseases: arterial hypertension, diabetes mellitus, hiatal hernia or gastroesophageal reflux, and dyspepsia or peptic ulcer. A large proportion of patients were being treated with non-pharmacological measures. Most of those who were treated with pharmacotherapy took: analgesics (>90%), oral and topical non-steroidal anti-inflammatory drugs (NSAIDs) (>70% and >50%, respectively), and SYSADOAS (Symptomatic Slow Acting Drugs for Osteoarthritis) (>40%). The only differences observed were patients receiving topical NSAIDs (P=.021) and opioids (P=.021).

No significant differences were observed in any of the items evaluated by the SF-12v2, the WOMAC or the VAS questionnaires in visits 1 and 2 (Table 2), except the vitality evaluated by SF-12v2 (P=.049). In the comparison of the incidence of relevant events occurring during the six-month study period (Table 3), Group 1 showed significantly more induced medical evaluations (P=.011) and less referrals to other specialties.

Event	Group 1 %	Group 2 %	P G1 vs G2
Induced medical evaluations	78	73	0.011 ^a
Referral to other specialists	30	35	0.005 ^a
Additional X-ray requests	25	28	0.055
Treatment modifications	23	22	0.208
Surgical treatment	3	4	0.238

^a Statistically significant.

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Instrument	Visit 2 – Visit 1 (mean \pm SD)	Р
SF-12		
Physical Functioning	1.2 ± 13.4	<0.001a
Role Physical	1.6 ± 11.6	<0.001a
Bodily Pain	$\textbf{5.7} \pm \textbf{26.7}$	<0.001a
General Health	1.6 ± 22.0	<0.001a
Vitality	0.7 ± 28.1	0.168
Social Functioning	$\textbf{2.4} \pm \textbf{26.3}$	<0.001a
Role Emotional	1.4 \pm 12.1	<0.001a
Mental Health	3.6 ± 22.1	<0.001a
Physical Component Summary	0.8 ± 6.0	<0.001 ^a
Mental Component Summary	1.0 ± 8.6	<0.001a
WOMAC		
Pain	-5.2 ± 16.0	<0.0001 ^a
Stiffness	$\textbf{-4.3} \pm \textbf{20.5}$	<0.0001 ^a
Physical Function	-4.0 ± 15.6	<0.0001
VAS	-10.0 ± 19.0	<0.001a

SF-12 v: Short Form 12-item version 2 Health Survey; VAS: Visual Analogue Scale; WOMAC: Western Ontario and McMaster Universities Index.

Comparing the results of the two visits for the whole study population, significant differences were observed in most of the items evaluated (Table 4).

Discussion

The results of our study can be grouped into three major observations: (1) patients with osteoarthritis have a high degree of comorbidity and a low health-related quality of life (HRQoL), as reflected by the SF-12v2, WOMAC and VAS scores; (2) patients did not seem to obtain a clinical benefit from the intervention studied, as there were no significant differences between visit 2 and visit 1; and (3) patient-reported pain, functionality and HRQoL significantly improved in the overall study population.

Study patients seem to have a higher degree of impairment and a worse health status in relation to the general Spanish population. This was tested by Vilagut et al., ¹² who observed that the mean SF-12v2 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of a representative sample of the Spanish population were 45.05 (SD: 10.17) and 47.81 (SD: 9.20), respectively, indicating a somewhat better quality of life than our study group.

One limitation of the study is the discontinuation rate, around 20%, higher than the 10% used to calculate the sample size, despite the motivation strategy, follow-up, phone and e-mail reminders. It was not possible to do a systematic analysis of discontinued patients, as many were due to job changes of GP, but were similar in number in both groups. The high prevalence of some diseases, like diabetes mellitus (33% and 37% in the control and intervention group) are consistent with the average age of the sample (68 years) and the existence of high rates of comorbidity.

As regards the clinical benefit obtained by patients treated by the GP who had received the specific

intervention, our findings call for careful interpretation, and several aspects must be taken into consideration. Therefore, despite the efforts to modify clinical inertia in GP, it is likely that these were insufficient, probably, among other reasons, because they focus on a single factor.

The observation that HRQoL perception improved significantly in overall population from Visit 1 to Visit 2, regardless of the study group, is important. Since the majority of patients had one or more concomitant diseases, osteoarthritis may have been unimportant until enrolment in this study. Thus, a small increase in GP attention may have represented a significant change to the patient in the quality of medical care received, which in turn, had an effect on the HRQoL. We are aware that the mere fact of having been included in a study, which produces a psychological effect of being observed, may have generated a positive response in the physicians, which in turn affected the quality of healthcare delivered to patients, irrespective of the group assigned to. This Hawthorne effect is expected in all types of studies in which the investigator or subject are aware of their participation. 15 Therefore, the long-term effects on HRQoL will need further evaluation.

The results of this study should be interpreted in the light of potential limitations. First, considering the chronic nature of osteoarthritis, the six months follow-up period might not have been long enough. Secondly, as discussed above, the type of intervention we designed in order to modify clinical inertia may have fallen short, or the factors we intended to modify were not the most appropriate. Nevertheless, since the actual recruitment was 1361 physicians and 4076 patients, we consider that the power of the study is enough to support the main conclusions. Also, although the fact that approximately 20% of patient data was lost on follow-up when an estimation of 10% was initially planned, does not invalidate our results. Moreover, it could be an additional factor contributing to clinical inertia due to

^a Statistically significant.

lack of an adequate follow-up of the disease.¹⁶ The search for factors that might contribute to clinical inertia through interventions on primary care physicians have been used in other cluster randomised trials,^{17,18} yielding positive results regarding the implementation of interventions carried out on physicians to reduce clinical inertia.¹⁸ Future educational interventions on practitioners could use the recent Clinical Practice Guidelines for Osteoarthritis of the Royal College of Physicians as a reference.¹⁹

In conclusion, the results suggest that minor interventions, such as an increased awareness of the patient's disease through the use of functionality indexes, as well as the mere fact of being observed, may be improving patient-reported pain, functionality and HRQoL. Nevertheless, because this specific intervention carried out on physicians to prevent clinical inertia did not provide an additional clinical benefit to our sample of patients with knee and/or hip osteoarthritis, efforts should be made to identify potentially modifiable factors that lead to clinical inertia other than physician-related factors.

Background

- Osteoarthritis (OA) is the most common type of arthritis in Western populations, and is a major cause of chronic musculoskeletal pain, mobility disability and health services use in populations worldwide.
- Clinical inertia, do not initiate or intensify therapy when clinically indicated is described in many chronic conditions and it also applies to OA.

Contributions of this study

- Patients with osteoarthritis have a high degree of comorbidity and a low HRQoL, as reflected by the scores obtained in the SF-12v2, WOMAC and VAS questionnaires;
- Patients did not seem to obtain a clinical benefit from the intervention we made on their treating general practitioners, given that inertia was not modified.
- Minor, in clinic, interventions, such as an increased awareness of the patient's disease through the use of functionality indexes, as well as the mere fact of being observed, may improve patient-reported pain, functionality and HRQoL.

Author's contributions

AGC, ATV and FLV developed the original idea for the paper. AGC, ATV and FLV contributed to the design of the study. AGC, ATV, FLV, DLP, APM, FVN and JHH participated in the execution of the study.

The Clinical Epidemiology Unit of the Hospital 12 de Octubre performed the analysis and interpretation of data. AGC, ATV, and FLV wrote the article, helped by Dr. Ximena Alvira from HealthCo SL (Madrid, Spain).

AGC, ATV, and FLV made the decision on submitting the manuscript for publication.

All authors approved the final version of the submitted article.

Researchers were independent from funders and sponsors, and they had access to all the study data.

Competing interests

The authors declare that they have no competing interests.

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COMMENTARY

Clinical Inertia in Osteoarthritis

Inercia clínica en la artrosis

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Osteoarthritis (OA), or degenerative joint disease, refers to a clinical syndrome of joint pain accompanied by varying degrees of functional limitation and reduced quality of life (QoL). Moreover OA is one of the leading causes of pain and disability worldwide. Any synovial joint can develop osteoarthritis but hips, knees, ankles and small hand joints are the peripheral sites most commonly affected. Risk factors include age older than 50, injury to a joint, obesity, competitive contact sports, and heredity. The number of

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