Està justificat la utilització dels fàrmacs condroprotectors en l'artrosi?

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EAP Anglès

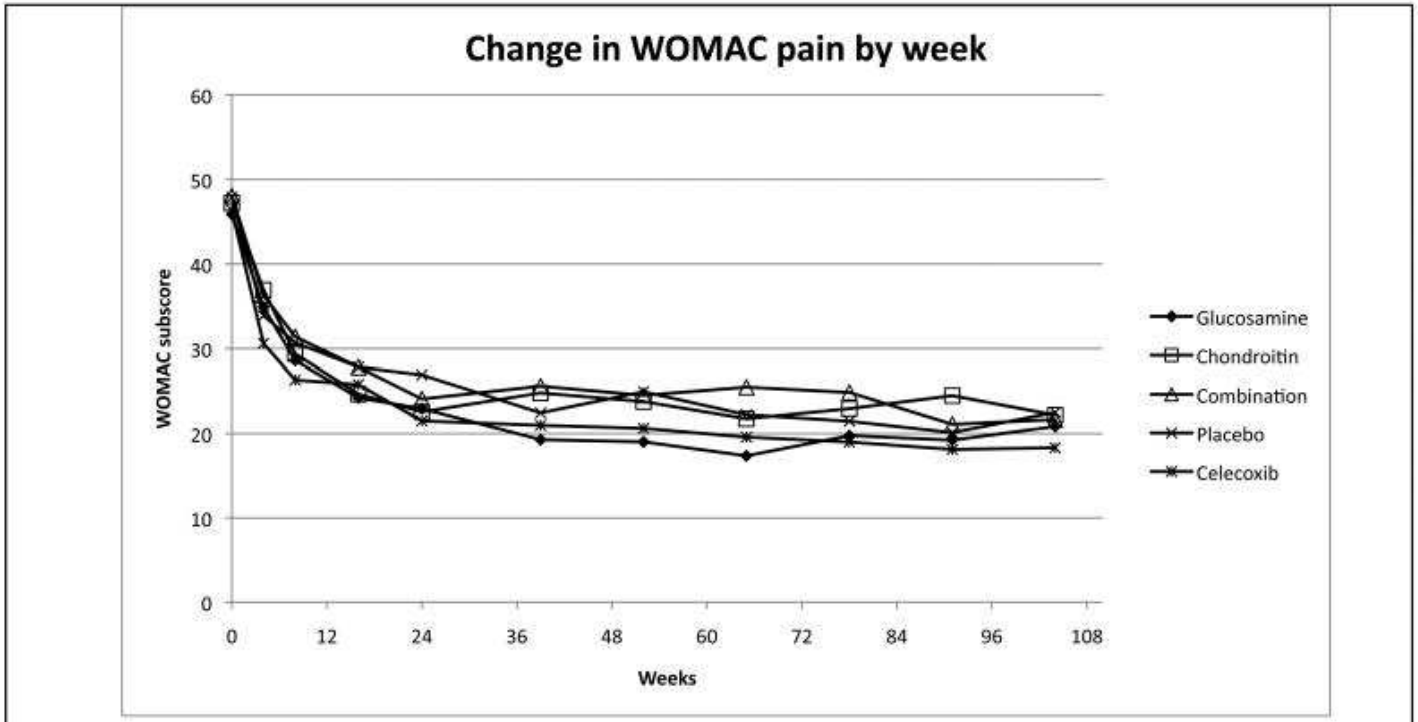
SYSADOA. Comunicado de la SER

- Desde la defensa de la libertad de prescripción por parte de los profesionales sanitarios, la Sociedad Española de Reumatología (SER) queremos manifestar lo siguiente:
  Los SYSADOA (condroitín sulfato y sulfato de glucosamina, entre otros) son fármacos aprobados por la Agencia Española del Medicamento (AEMPS) para el tratamiento sintomático de la artrosis. La excelente seguridad demostrada en toda la investigación clínica realizada con estos fármacos es también de especial interés en un tratamiento crónico como es el de la artrosis. Las recomendaciones terapéuticas de nuestra sociedad para el tratamiento de la artrosis, así lo avalan, concediendo el máximo nivel de evidencia científica (1A) y el grado de recomendación más elevado (A) para el condroitín sulfato y el sulfato de glucosamina en el tratamiento de dicha patología.
  Con este comunicado, la SER pretende seguir defendiendo la libertad de prescripción de los reumatólogos y asumir la necesaria concienciación de todos en el uso racional de los recursos, especialmente en la actual situación de recesión económica en la que nos encontramos inmersos.

Prescripción de SYSADOA en diferentes países

- **Australia**, la glucosamina está disponible en formulaciones de sulfato o clorhidrato y se clasifica en la categoría de "hierbas medicinales y complementarias"
- **EEUU** también considera a la glucosamina un suplemento nutricional.
- **En Países Bajos el sulfato de glucosamina se comercializa como suplemento dietético**
- **Reino Unido 2008**, el Midlands Therapeutics Review and Advisory Committee (MTRAC) publicó un boletín de evaluación de medicamentos sobre la **glucosamina**. La evaluación concluye que **no se recomienda la utilización de medicamentos que contienen glucosamina por falta de evidencia sobre su efectividad**.
- La guía NICE de osteoartritis, en su recomendación nº 19, recoge que "el uso de glucosamina o productos con condroitina no se recomienda para el tratamiento de la osteoartrosis".
- **Suecia 2010,** la TLV (Agencia de Beneficios Farmacéuticos y Dentales), determina que **se excluyen del reembolso todos los medicamentos que contienen glucosamina, los estudios no han sido capaces de demostrar un beneficio claro.**
- **Dinamarca 2011,** el Comité de reembolso y la Agencia Danesa de Medicamentos, decidir que a partir del 28 de noviembre del 2011 **la glucosamina queda excluida de dicha financiación**.
- **Baleares 2012,** recomienda su utilización.

Clinical efficacy and safety of glucosamine, chondroitin sulphate, their combination, celecoxib or placebo taken to treat osteoarthritis of the knee: 2-year results from GAIT.



Placebo	131	130	120	115	115	89	78	73	68	61	66
Glucosamine	134	129	127	117	110	86	86	82	75	71	79
Condroitin	126	123	120	112	103	83	80	71	66	64	69
Combination	129	126	124	111	103	82	72	63	63	59	59
Celecoxib	142	141	136	129	123	97	90	83	78	71	76

Ann Rheum Dis. 2010;69:1459-1464.

ARTICLE | Annals of Internal Medicine

Effect of Glucosamine Sulfate on Hip Osteoarthritis

A Randomized Trial

Rianne M. Rozendaal, MSc; Bart W. Koes, PhD; Gerjo J.V.M. van Osch, PhD; Elian J. Uitterlinden, MD, PhD; Eric H. Garling, PhD; Sten P. Willemsen, MSc; Abida Z. Ginai, MD; Jan A.N. Verhaar, MD, PhD; Harrie Weinans, PhD; and Sita M.A. Bierma-Zeinstra, PhD

Background: The effectiveness of glucosamine sulfate as a symptom and disease modifier for osteoarthritis is still under debate.

Objective: To assess whether glucosamine sulfate has an effect on the symptoms and structural progression of hip osteoarthritis during 2 years of treatment.

Design: Randomized, controlled trial.

Setting: Primary care in the Netherlands.

Patients: 222 patients with hip osteoarthritis who were recruited by their general practitioner. Patients were eligible if they met the American College of Rheumatology clinical criteria for hip osteoarthritis.

Intervention: 2 years of treatment with 1500 mg of oral glucosamine sulfate or placebo once daily.

Measurements: Primary outcome measures were Western Ontario and McMaster Universities (WOMAC) pain and function subscales over 24 months and joint space narrowing after 24 months. The main secondary outcome measures were WOMAC pain, function, and stiffness after 3, 12, and 24 months.

Results: At baseline, both groups were similar in demographic and clinical variables. Overall, WOMAC pain did not differ (mean difference [glucosamine sulfate minus placebo], −1.54 [95% CI, −5.43 to 2.36]), nor did WOMAC function (mean difference, −2.01 [CI, −5.38 to 1.36]). Joint space narrowing also did not differ after 24 months (mean difference, −0.029 [CI, −0.122 to 0.064]). Only 1 of the sensitivity analyses, based on extreme assumptions regarding missing assessments due to total hip replacement, provided results consistent with a glucosamine effect.

Limitations: Twenty patients had total hip replacement during the trial. Half of the patients had a Kellgren and Lawrence score of 1.

Conclusion: Glucosamine sulfate was no better than placebo in reducing symptoms and progression of hip osteoarthritis.

Ann Intern Med. 2008;148:268-277. www.annals.org
For author affiliations, see end of text.
International Standard Randomised Controlled Trial Number: ISRCTN54513166.

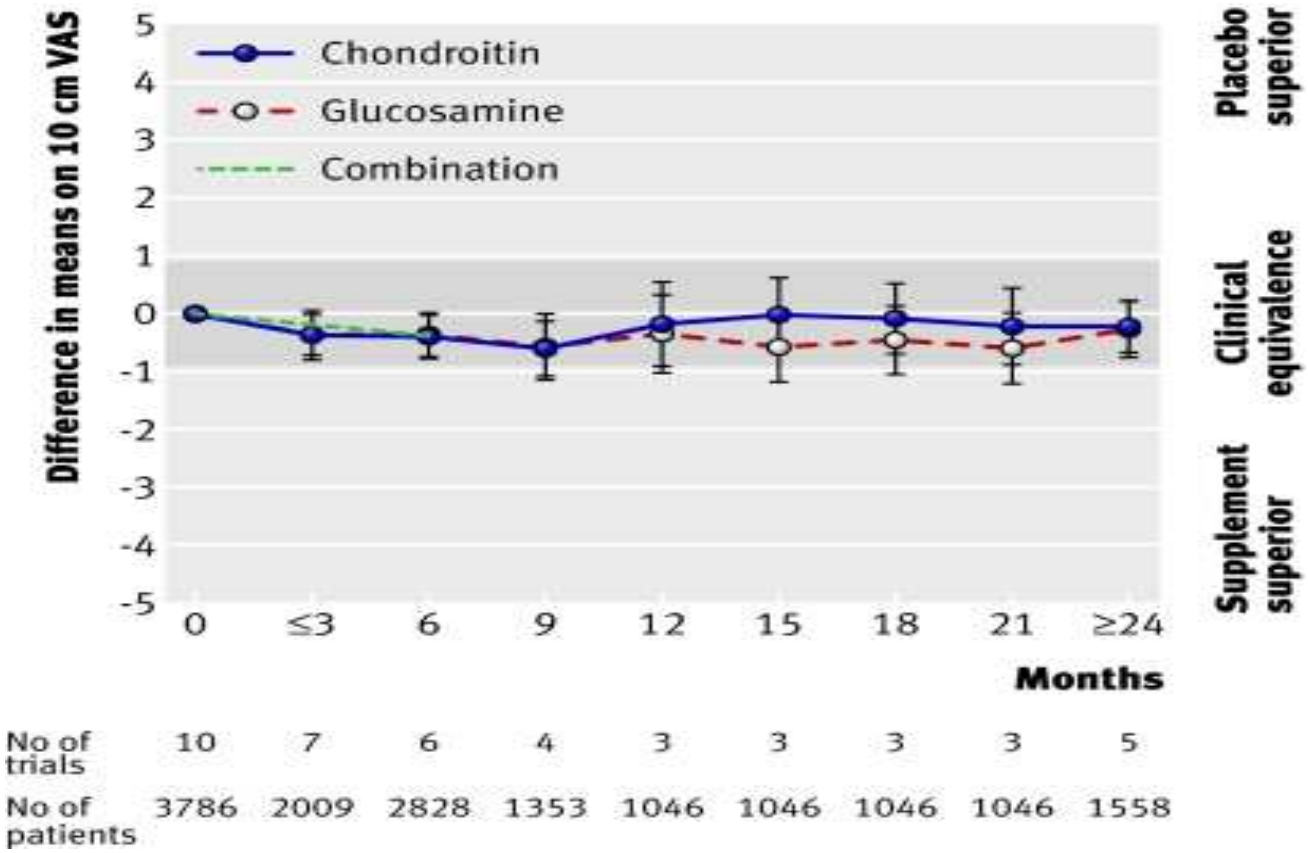
The effectiveness of glucosamine sulfate for treating os- osteoarthritis, with the exception of 3 early trials that in-

NIHR Health Technology Assessment programme: Executive Summaries. The clinical effectiveness of glucosamine and chondroitin supplements

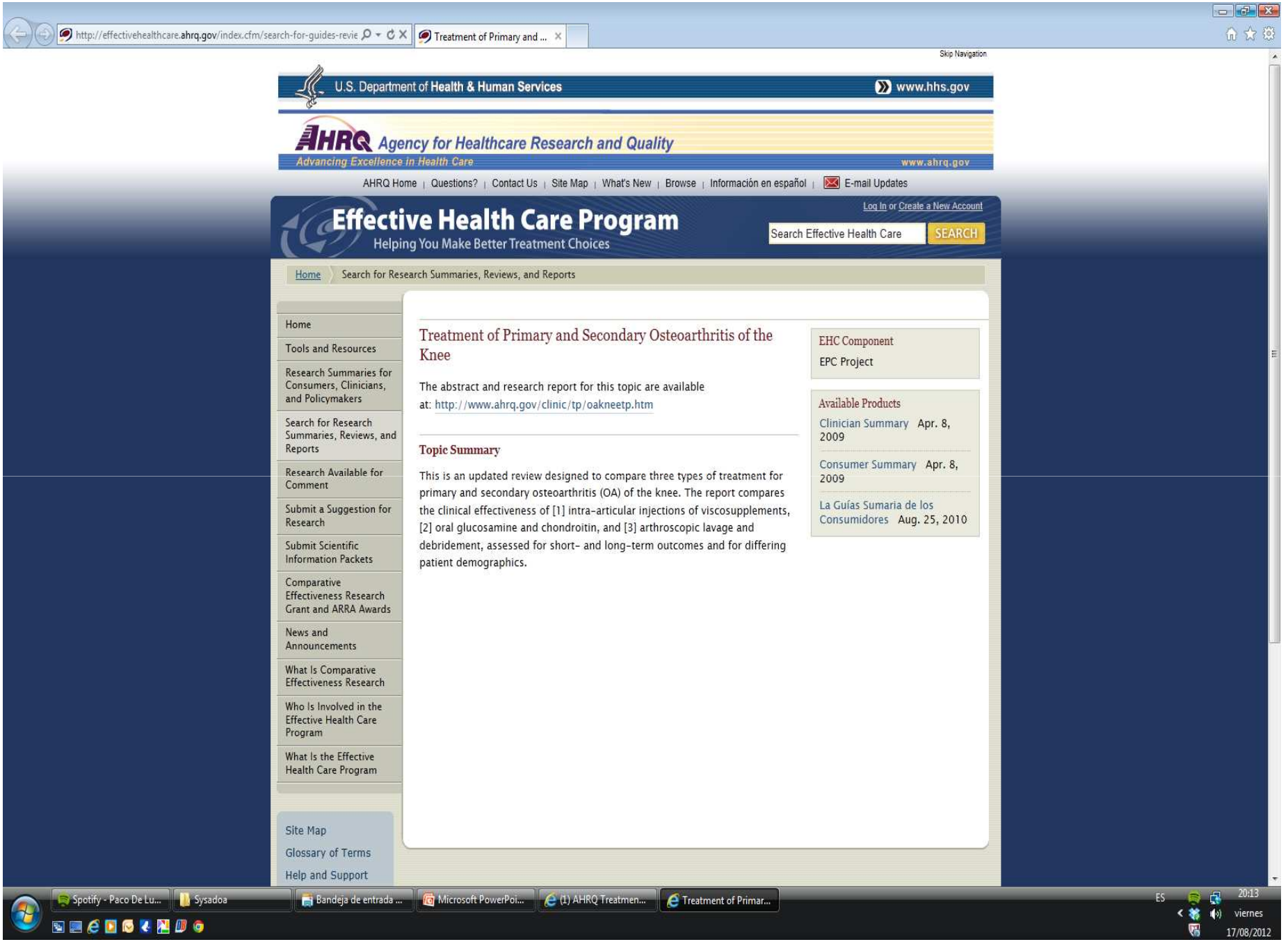
- Conclusions (2009)

  There was evidence that glucosamine sulphate shows some clinical effectiveness in the treatment of OA of the knee. No trial data came from the UK, and in the absence of good UK data about the current referral practice, management and surgical rate, caution should be exercised in generalising these data to the UK health-care setting. Cost-effectiveness was not conclusively demonstrated, with substantial uncertainty related to the magnitude and duration of QoL gain following treatment. There was evidence from biological studies to support the potential clinical impact of glucosamine sulphate. For other preparations, the evidence base was less consistent (chondroitin) or absent (glucosamine hydrochloride).

Differences in pain intensity measured on visual analogue scale (VAS) between experimental interventions and placebo over time



Wandel et al. BMJ.2010 Sep 16;341:c4675.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Submit a Suggestion for Research
Submit Scientific Information Packets
Comparative Effectiveness Research Grant and ARRA Awards
News and Announcements
What Is Comparative Effectiveness Research
Who Is Involved in the Effective Health Care Program
What Is the Effective Health Care Program
Site Map
Glossary of Terms
Help and Support
Treatment of Primary and Secondary Osteoarthritis of the Knee
The abstract and research report for this topic are available at: http://www.ahrq.gov/clinic/tp/oakneetp.htm
Topic Summary
This is an updated review designed to compare three types of treatment for primary and secondary osteoarthritis (OA) of the knee. The report compares the clinical effectiveness of [1] intra-articular injections of viscosupplements, [2] oral glucosamine and chondroitin, and [3] arthroscopic lavage and debridement, assessed for short- and long-term outcomes and for differing patient demographics.
EHC Component
EPC Project
Available Products
Clinician Summary Apr. 8, 2009
Consumer Summary Apr. 8, 2009
La Guías Sumaria de los Consumidores Aug. 25, 2010
Spotify - Paco De Lu...
Sysadoa
Bandeja de entrada ...
Microsoft PowerPoi...
(1) AHRQ Treatmen...
Treatment of Primar...
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17/08/2012

AHRQ Treatment of Primary and Secondary Osteoarthritis of the Knee

- **Objectives:** Systematic review of outcomes of three treatments for osteoarthritis (OA) of the knee:
  - Intra-articular viscosupplementation.
  - Oral glucosamine, chondroitin or the combination.
  - Arthroscopic lavage or debridement.

- **Data Sources:** We abstracted data from: 42 randomized, controlled trials (RCTs) of viscosupplementation, all but one synthesized among six meta-analyses; 21 RCTs of glucosamine/chondroitin, 16 synthesized among 6 meta-analyses; and 23 articles on arthroscopy. The search included foreign-language studies and relevant conference proceedings.

- **Conclusions:** Osteoarthritis of the knee is a common condition. The three interventions reviewed in this report are widely used in the treatment of OA of the knee, yet the best available evidence does not clearly demonstrate clinical benefit. Uncertainty regarding clinical benefit can be resolved only by rigorous, multicenter RCTs. In addition, given the public health impact of OA of the knee, research on new approaches to prevention and treatment should be given high priority.

Economics analysis conducted by the National Institute for Health and Clinical Excellence (NICE)

- **Evidence to support the efficacy of glucosamine for osteoarthritis is mixed, and any benefits are small. A Cochrane systematic review performed a meta-analysis of data from 20 RCTs: 17 trials compared glucosamine with placebo, and four trials compared glucosamine with a nonsteroidal anti-inflammatory drug (NSAID; ibuprofen in three trials and piroxicam in one trial). Sixteen RCTs evaluated the knee exclusively, two evaluated osteoarthritis at multiple sites, and two did not specify the location. When data from all studies were pooled, glucosamine was found to be more effective than placebo with respect to pain and function. However, subgroup analyses of the 10 RCTs in which allocation was adequately concealed, found that glucosamine was not more effective than placebo for relieving pain, stiffness, or function. Another subgroup analysis found that the glucosamine sulfate product made by the Rotta Pharmaceutical Company was more effective than placebo, while other glucosamine preparations (glucosamine sulfate and glucosamine hydrochloride) failed to show a benefit.**

Economics analysis conducted by the National Institute for Health and Clinical Excellence (NICE)

- **The reasons for the differences in results are unknown, but may include differences in the products (there is no common standard for their manufacture), differences in the trial methods (e.g. different outcome measures), and differences in the methodological quality of the studies, including susceptibility to bias (most of the positive, and few of the negative, trials were funded by manufacturers of glucosamine). The health economics analysis conducted by the National Institute for Health and Clinical Excellence (NICE) concluded that glucosamine is not currently cost-effective for the NHS.**

Posición de la FDA sobre los SYSADOAs

I. Introduction

- The human clinical studies in the petitions reported benefits from consumption of glucosamine sulfate, glucosamine hydrochloride (HCl) and/or chondroitin sulfate on indices of pain, swelling, joint tenderness, joint swelling, joint degeneration and cartilage deterioration associated with osteoarthritis (OA). FDA is focusing its review on reduced risk of OA, joint degeneration and cartilage deterioration since these are the subject of pending claims. FDA has performed an initial review of the petitions and has reached the following tentative conclusions.

II. Evaluation of the Evidence

A. **Treatment Studies vs. Risk Reduction Studies**
B. **B. Modifiable Risk Factors/Surrogate Endpoints for OA**
C. **C. Animal studies and in vitro studies**

III. Summary

- In summary, FDA has tentatively concluded that a relationship between glucosamine and chondroitin sulfate and a reduced risk of OA is not established. The reasons for this tentative conclusion includes the lack of relevance of animal and in vitro models of OA to human OA, the lack of valid modifiable risk factors for OA, and the lack of relevance of the OA treatment studies to OA risk reduction in the general healthy population.

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DOI 10.1002/acr.21596

SPECIAL ARTICLE

American College of Rheumatology 2012 Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee

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Guidelines and recommendations developed and/or endorsed by the American College of Rheumatology (ACR) are intended to provide guidance for particular patterns of practice and not to dictate the care of a particular patient. The ACR considers adherence to these guidelines and recommendations to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances. Guidelines and recommendations are intended to promote beneficial or desirable outcomes but cannot guarantee any specific outcome. Guidelines and recommendations developed or endorsed by the ACR are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

The American College of Rheumatology is an independent, professional, medical and scientific society which does not guarantee, warrant, or endorse any commercial product or service.

Objective. To update the American College of Rheumatology (ACR) 2000 recommendations for hip and knee osteoarthritis (OA) and develop new recommendations for hand OA.

Methods. A list of pharmacologic and nonpharmacologic modalities commonly used to manage knee, hip, and hand OA as well as clinical scenarios representing patients with symptomatic hand, hip, and knee OA were generated. Systematic evidence-based literature reviews were conducted by a working group at the Institute of Population Health, University of Ottawa, and updated by ACR staff to include additions to bibliographic databases through December 31, 2010. The Grading of Recommendations Assessment, Development and Evaluation approach, a formal process to rate scientific evidence and to develop recommendations that are as evidence based as possible, was used by a Technical Expert Panel comprised of various stakeholders to formulate the recommendations for the use of nonpharmacologic and pharmacologic modalities for OA of the hand, hip, and knee.

Results. Both "strong" and "conditional" recommendations were made for OA management. Modalities conditionally recommended for the management of hand OA include instruction in joint protection techniques, provision of assistive devices, use of thermal modalities and trapeziometacarpal joint splints, and use of oral and topical nonsteroidal antiinflammatory drugs (NSAIDs), tramadol, and topical capsaicin. Nonpharmacologic modalities strongly recommended for the management of knee OA were aerobic, aquatic, and/or resistance exercises as well as weight loss for overweight patients. Nonpharmacologic

Table 4. Pharmacologic recommendations for the initial management of knee OA

- We conditionally recommend that patients with knee OA should use one of the following:
  - Acetaminophen
  - Oral NSAIDs
  - Topical NSAIDs
  - Tramadol
  - Intraarticular corticosteroid injections
- We conditionally recommend that patients with knee OA should not use the following:
  - Chondroitin sulfate
  - Glucosamine
  - Topical capsaicin
- We have no recommendations regarding the use of intraarticular hyaluronates, duloxetine, and opioid analgesics

Arthritis Care & Research Vol. 64, No. 4, April 2012, pp 465–474

Table 6. Pharmacologic recommendations for the initial management of hip OA

- We conditionally recommend that patients with hip OA should use one of the following:
  - Acetaminophen
  - Oral NSAIDs
  - Tramadol
  - Intraarticular corticosteroid injections
- We conditionally recommend that patients with hip OA should not use the following:
  - Chondroitin sulfate
  - Glucosamine
- We have no recommendation regarding the use of the following:
  - Topical NSAIDs
  - Intraarticular hyaluronate injections
  - Duloxetine
  - Opioid analgesics

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Conclusions

- La evidència actual disponible no demostra clarament el benefici clínic dels SYSADOA
- La incertesa pel que fa al benefici clínic dels SYSADOA pot ser resolta només per rigorosos ECA multicèntrics
- Es recomana no fer servir els SYSADOA en el tractament de l'artrosi