

Costs of the standard rheumatology care in active rheumatoid arthritis patients seen in a tertiary care center in Mexico City

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Objective: To assess the costs of standard care in patients with active rheumatoid arthritis (RA) seen in a tertiary care center in México City in the context of a clinical trial. To analyze the relationship between costs and utility units obtained by the patients in this scenario.

Patients and methods: This economic evaluation was performed during a clinical trial with a 48-week follow-up in a tertiary care center in México City. The trial compared the efficacy of omega-3 fatty acids versus placebo in patients with active RA who also received standard rheumatology care. The costs of medical consultations, complementary tests and drugs were assessed. Other direct costs were also measured.

Hypothetical scenarios with fewer medical consultations and complementary tests than those in the clinical trial were also analyzed. Utilities were assessed by the Health Utility Index. A cost-utility ratio was calculated using the baseline utilities score as comparator. A descriptive statistical analysis was performed.

Results: Ninety RA patients (83 women [92%], age [$X \pm SD$] 43.2 ± 14.2 years with disease duration of 3.3 ± 4.6 years) were included. Data from 88 patients were analyzed. The total direct costs were 152,704.11 US\$ 2005 divided into medical attention (78,386.43 US\$ 2005, 51.33%), drugs (39,339.5 US\$ 2005, 25.76%) and other direct costs (34,978.18 US\$ 2005, 22.91%). In scenarios with fewer medical consultations and complementary tests than those in the clinical trial, the total direct costs ranged from 39,507.4 to 103,880.6 US\$ 2005. Patients improved by a mean of 0.18 utility units on a 0-1 scale equivalent to 0.18 quality adjusted life-years (QALYs). The cost-utility ratios ranged from 2,494.1 to 9,640.38 US\$ 2005 per QALY in the scenarios analyzed.

Conclusions: The direct costs of the standard care of RA in the scenarios analyzed are substantial in the social and

economic context of Mexico. The cost per gained QALY is high.

Key words: Direct costs. Utilities. Rheumatoid arthritis.

Costes de la asistencia reumatólogica convencional en los pacientes con artritis reumatoide activa atendidos en un centro de nivel terciario en Ciudad de México

Objetivo: Determinar en el contexto de un ensayo clínico los costes de la asistencia sanitaria convencional en los pacientes con artritis reumatoide (AR) activa atendidos en un centro de nivel terciario de Ciudad de México. Analizar las relaciones existentes entre los costes económicos y las unidades de utilidad en los pacientes con las características señaladas.

Pacientes y métodos: Este análisis económico se realizó en el contexto de un ensayo clínico efectuado con un seguimiento de 48 semanas en un centro asistencial de nivel terciario en Ciudad de México. En el ensayo clínico se comparó la eficacia de los ácidos grasos omega-3 con la del placebo en pacientes con AR activa que también recibían asistencia reumatólogica convencional. Se determinaron los costes económicos de las consultas médicas, de las pruebas diagnósticas complementarias y de los tratamientos farmacológicos. También se determinaron otros costes directos. Además, se analizaron varios contextos hipotéticos en los que se hubieran realizado menos consultas médicas y menos pruebas diagnósticas complementarias que las que se llevaron a cabo en el ensayo clínico. La utilidad se evaluó a través del Health Utility Index. Se calculó un cociente coste-utilidad utilizando como factor de comparación la puntuación de utilidad inicial. Se realizó un análisis estadístico de tipo descriptivo.

Resultados: Participaron en el estudio 90 pacientes con AR (83 mujeres [92%], con una edad [$X \pm DE$] de $43,2 \pm 14,2$ años y con una duración de la enfermedad de $3,3 \pm 4,6$ meses). En los análisis se utilizaron los datos correspondientes a 88 pacientes. Los costes directos

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Manuscrito recibido el 29-9-2005 y aceptado el 7-2-2006.

totales fueron de 152.704,11 dólares estadounidenses de 2005, correspondientes a la asistencia médica (78.386,43 dólares estadounidenses de 2005, 51,33%), al tratamiento medicamentoso (39.339,05 dólares estadounidenses de 2005, 25,76%) y a otros costes directos (24.978,18 dólares estadounidenses de 2005, 22,91%). En los contextos hipotéticos en los que se consideró un número menor de consultas médicas y de pruebas diagnósticas complementarias, en comparación con el que tuvo lugar el ensayo clínico, los costes directos totales oscilaron entre 39.507,4 y 103.880,06 dólares estadounidenses de 2005. La mejora de los pacientes tuvo un valor medio de 0,18 unidades de utilidad en una escala de 0-1, equivalente a 0,18 años de vida con ajuste de la calidad (QALY, *quality adjusted life-years*). Los cocientes coste-utilidad oscilaron entre 2.494,1 y 9.640,38 dólares estadounidenses de 2005 por QALY en los contextos analizados.

Conclusiones: Los costes directos de la asistencia convencional realizada en México sobre los pacientes con AR en los contextos analizados son sustanciales tanto desde el punto de vista social como económico. El coste por QALY ganado es elevado.

Palabras clave: Costes directos. Utilidad. Artritis reumatoide.

Introduction

Rheumatoid arthritis (RA) is a systemic disease that causes pain, stiffness, functional disability and irreversible joint damage¹. It is associated with morbidity, impairment of quality of life and increased mortality^{2,3}. The economic impact of RA on society is high, mainly due to increased use of outpatient medical services, increased hospitalization rates and frequent work disability⁴. In addition, populations with RA generate an excess of costs (incremental costs) when compared with non-arthritis controls⁵⁻⁷ or populations with osteoarthritis⁶⁻⁸. Several works in the last decades^{4,5-10}, and more recent studies¹¹⁻¹⁹ have focused on direct and indirect cost generated by RA. All of them are done in developed countries. However, the RA costs studies are scarce in Mexico²⁰.

Utilities have been proposed to evaluate individual health status. These measurements provide a numerical value that shows patient's preference for a particular health state or health change and they differ from quality of life measures, which express a stated value of health state. Utilities can be combined with life expectancy into quality adjusted life years (QALYs)²¹ which are used in cost-utility analysis. This type of economic evaluation incorporates the preferences or values that individual have for particular health states to compare be-

nfits and costs from health care interventions²². Cost-utility or cost-QALY ratios of different interventions may be calculated and then comparisons between interventions can be made²³.

The purposes of our study were to assess the direct costs of RA in Mexico in the context of a clinical trial and, secondly, to analyze the cost per QALY obtained by Mexican RA patients in this scenario.

Patients and methods

Design

A cost descriptive study nested in a 48-weeks randomized clinical trial.

Setting

Outpatients attending the Rheumatology Department at the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, a tertiary care center in Mexico City.

Patients

Consecutive patients attending our outpatient clinic were selected to participate in a randomized, placebo-controlled clinical trial assessing the efficacy of omega-3 fatty acids versus placebo in the treatment of active RA patients besides their standard rheumatology care²⁴. Entry criteria were:

- Age between 18 and 80 years older.
- RA according to the 1987 criteria of the American College of Rheumatology (formerly, American Rheumatism Association²⁵).
- Steinbroker modified functional class I-III²⁶.
- Active disease (three or more of: morning stiffness \geq 60 minutes, \geq 9 tender joints, \geq 6 swollen joints, ESR \geq 30 mm/h).
- All patients gave their consent to participate in the study, and the protocol was approved by the Local Ethics committee.

Methods

The same rheumatologist (BHC) evaluated all patients at baseline and at 4, 8, 12, 16, 24, 32, 40, and 48 weeks. In all the visits disease-related variables were collected including patient and physician global assessments on visual analogue scales (VAS) from 0 = very well to 10 cm = very bad; patient pain assessment VAS from 0 =

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