



weber®

**El valor de la investigación en salud**

# Antecedentes



**Alianza  
UCLM & IMW**

**Creación de  
WEYS  
(firma consultora)  
Con el apoyo de  
IMW & SIES.**

**WEBER  
Consolidación de  
marca  
Cambio de imagen  
Creación de la Fundación  
WEBER**

**weber / CONSULTORÍA  
ESTRATÉGICA**

**weber / PUBLICACIONES  
Y FORMACIÓN**

**weber / INVESTIGACIÓN  
APLICADA**

# Nuestros objetivos



- ✓ Apoyar a la toma de decisiones basada en criterios de eficiencia en el SNS
- ✓ Añadir valor a los proyectos de nuestros clientes
- ✓ Promover los conocimientos en economía de la salud y farmacoeconomía entre profesionales y decisores
- ✓ Ofrecer soporte en la evaluación de tecnologías sanitarias
- ✓ Ofrecer soluciones a medida del cliente
- ✓ Contribuir a la evaluación de tecnologías sanitarias basada en su valor económico y social, con el fin de apoyar a la toma de decisiones



# Nuestros valores



**Profesionalidad**

**Transparencia**

**Independencia**

**Trabajo en equipo**

**Practicidad**

**Adaptabilidad**

**Innovación**

**Proximidad al cliente**

**Rigor científico y técnico**

**Responsabilidad Social**

**Orientación al cliente**

# Socios



*Presidente, Fundación Weber*

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PhD in Economics (UCLM).  
Professor of Economics at UCLM.

*Socia-Gerente, Weber*

**Alexandra Ivanova**

Sc in Economic Evaluation of Health  
Technologies (UCLM). BA in Economics and  
Administration (U. Complutense).



# Equipo Weber



Álvaro Hidalgo  
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Consultora Senior



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Consultora Junior



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Directora



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Técnico de Formación



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Secretaría Técnica



Yulia Ivanova  
Asistente a la Dirección

# Áreas de trabajo



✓ Health Mapping

✓ Comunicaciones a congresos

✓ Modelos BI y CE: diseño y adaptación al SNS

✓ Política sanitaria y farmacéutica

✓ Advisory Boards

✓ Publicaciones científicas

✓ MCDA

✓ Estudios Delphi

✓ Formación *In-Company*

✓ Servicios de Acceso al Mercado: Dossier de Valor, precio&reembolso

✓ Monografías

✓ Calidad de Vida y Resultados en Salud

✓ SROI

✓ Estudios de carga de la enfermedad

✓ Revisión Sistemática y Meta-análisis

# Algunos ejemplos...

**SROI Psoriasis**  
**Best Ideas 2016 Award!**  
Diario Médico

**EL VALOR DEL  
MEDICAMENTO  
DESDE UNA  
PERSPECTIVA  
SOCIAL**

weber.

**Valor del medicamento**  
**Best Ideas 2018 Award!**  
Diario Médico

**1€**  
INVERTIDO  
en psoriasis

SE OBTIENE  
**5,04€**  
DE RETORNO SOCIAL



+ de **1.000**  
pacientes  
encuestados

## CÓMO NOS AFECTA LA PSORIASIS

ÁMBITO EMOCIONAL



**58,6%**

sienten más ansiedad desde el diagnóstico

**3 de cada 4** pacientes ven afectado este ámbito

ÁMBITO LABORAL



**14,0%**

de trabajadores declaran haber sufrido discriminación laboral

el **12,5%** considera que la psoriasis ha influido en la elección de su profesión

ÁMBITO DE LA SEXUALIDAD



**59,9%**

reconoce que se ve afectado este ámbito

**3 de cada 10** pacientes sin pareja considera que su enfermedad es la causa

Un **13,1%** de los separados/divorciados relaciona su situación con la enfermedad

RELACIONES SOCIALES



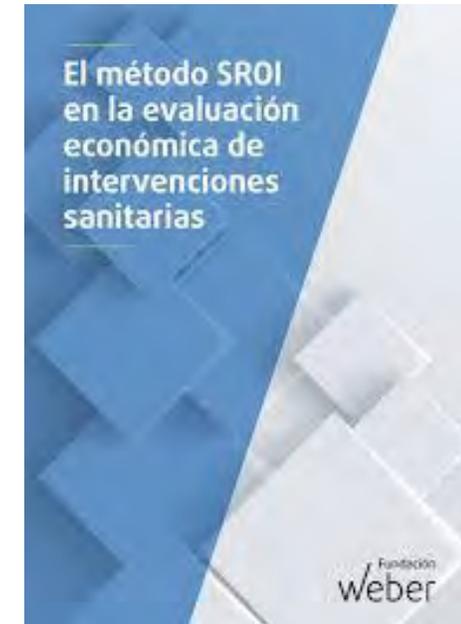
**46,1%**

de las personas con psoriasis reducen significativamente su vida social

**1 de cada 5** personas han empeorado gravemente sus relaciones sociales



# Algunos ejemplos...



# Algunas presentaciones relevantes a congresos ...



PDB33

## Costs of Type 1 Diabetes Mellitus in Pediatric Patients in Spain: CHRYSTAL Observational Study

Julio López-Bastida,<sup>1,2</sup> Juan Oliva,<sup>1,3</sup> Juan Pedro López-Siguero,<sup>4</sup> Luis Alberto Vázquez,<sup>5</sup> Dingfeng Jiang,<sup>6</sup> Renata Villoro,<sup>1</sup> Isaac Aranda,<sup>1,3</sup> María Merino,<sup>1</sup> Tatiana Dilla,<sup>5</sup> Jesús Reviriego,<sup>5</sup> Magaly Perez-Nieves<sup>6</sup>

<sup>1</sup> Instituto Max Weber, Madrid, Spain; <sup>2</sup> Nursing and Occupational and Speech Therapy Department, Universidad de Castilla-La Mancha, Spain; <sup>3</sup> Economics Department, Universidad de Castilla-La Mancha, Spain; <sup>4</sup> Pediatric Endocrinology Department, Hospital Universitario Carlos Haya, Málaga, Spain; <sup>5</sup> Eli Lilly and Company, Madrid, Spain; <sup>6</sup> Eli Lilly and Company, Indianapolis, IN, USA.

### BACKGROUND

The prevalence of Type 1 Diabetes Mellitus (T1DM) in Spain is 1.1-1.44 per 1,000 people under 15.<sup>1</sup> The social burden of the disease in the pediatric population was previously unknown.

The objective of the **CHRYSTAL** study (Costs and Health Related quality of life Study for Type 1 diabetes mellitus pediatric patients in Spain) was to shed light upon the social costs of T1DM amongst pediatric patients.

### METHODS

CHRYSTAL is an observational study conducted in 2014 on a representative sample of 275 patients aged 0-17 years diagnosed with T1DM, distributed across 12 randomly selected hospitals from a list of sites that treat diabetic children and adolescents in Spain.<sup>2</sup> The sites were distributed across 8 geographical regions grouping Autonomous Communities (Figure 1).

Figure 1. Sites' Distribution



1. H. U. 12 de Octubre, Madrid, 2. H. U. Fundación Alcorcón, Madrid, 3. H. U. Vall d'Hebron, Barcelona, 4. H. U. Sant Joan, Reus, 5. H. U. de Cruces, Barakaldo, 6. H. U. i Politècnic la Fe, Valencia, 7. H. General Nuestra Señora del Prado, Talavera de la Reina, 8. H. U. Virgen del Rocío, Sevilla, 9. H. Comarcal de la Axarquía, Vélez-Málaga, 10. H. Clínico U. San Cecilio, Granada, 11. C. H. U. Insular Materno Infantil, Las Palmas de Gran Canaria, 12. H. U. A Coruña, A Coruña.

**Inclusion criteria** were patients under 18 who had been diagnosed with T1DM for at least 12 months. Patients diagnosed with any other types of diabetes, patients

### RESULTS

A total of 249 patients were included for analysis (90.5% of all), 26 were excluded because of incomplete information for calculating all the resources identified. Patient characteristics are shown in Table 1.

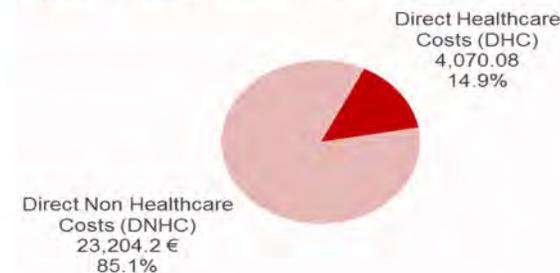
Table 1. Patient Characteristics (n=249)

Age (mean, SD)	11.04 (3.88)
Gender (% male)	53.0
Duration of diabetes (mean, SD)	5.02 (3.19)
Age at time of diagnosis (mean, SD)	5.58 (3.64)
Puberty status (% postpubertal)	57.7
HbA1c, % (mean, SD)	7.43 (0.97)
Patients using insulin pumps (%)	12.4
Patients using glucose sensors (%)	6.8
Number of hypoglycemic episodes in the last month (mean, SD)	11.58 (9.91)
Number of severe hypoglycemic episodes in the last month (mean, SD)	0.1 (0.41)
Primary caregiver's age (mean, SD)	42.72 (6.22)
Informal care hours/week* (mean, SD)	32.97 (29.18)

SD = Standard Deviation. \* Includes Primary caregiver and Other caregivers' time

The average annual cost for a T1DM patient was **€27,274**. 85.1% corresponds to DNHC (€23,204), and 14.9% to DHC (€4,070) (Figure 2).

Figure 2. Average Annual Costs per T1DM Patient



children without complications and/or comorbidities ( $p < 0.05$ ) (Figure 6). Both tests were calculated **controlling for age and gender**.<sup>12</sup>

Figure 5. Direct Healthcare Costs by HbA1c Level



Figure 6. Direct Healthcare Costs by Presence of T1DM Related Complications and/or Comorbidities



### DISCUSSION

This is the first study that estimates the social cost of T1DM in the population under 18 in Spain and, to our knowledge, the first study that estimates the informal cost of T1DM in the population under 18 in the world.

T1DM carries a considerable social economic burden, especially in terms of informal care. This suggests that any program on health promotion and care for T1DM children cannot overlook the importance of informal support networks.

### LIMITATIONS

There are two main limitations to our study. First, The 1-year prevalence approach impedes considering

# Algunas presentaciones relevantes a congresos ...



Poster Number: P3-700

## Health Related Quality of Life in Children and Adolescents with Type 1 Diabetes Mellitus in Spain: Results from the CRYSTAL Study

Luis Alberto Vázquez,<sup>1</sup> Juan Pedro López-Siguero,<sup>2</sup> Renata Villoro,<sup>3</sup> Dingfeng Jiang,<sup>4</sup> Maria Merino,<sup>3</sup> Jesus Reviriego,<sup>1</sup> Magaly Perez-Nieves<sup>4</sup>

<sup>1</sup>Eli Lilly and Company, Madrid, Spain; <sup>2</sup>Hospital Universitario Carlos Haya, Málaga, Spain; <sup>3</sup>Instituto Max Weber, Madrid, Spain; <sup>4</sup>Eli Lilly and Company, Indianapolis, IN USA

### ABSTRACT

**Background:** CRYSTAL (Costs and Health Related quality of life Study for Type 1 diabetes mellitus paediatric patients in Spain) is an observational study conducted in 2014 on a representative sample of 275 patients aged 0-17 years with Type 1 Diabetes Mellitus (T1DM) in Spain. The study collects diabetes specific health related quality of life (HRQoL) using the Diabetes Module of the Paediatric Quality of Life Inventory™ (PEDsQL). This scale has been identified to be one of the best scales to describe HRQoL in paediatric population.

**Objective and hypotheses:** The objective was to describe the HRQoL for paediatric patients with T1DM in Spain and to compare results by HbA1c level.

**Method:** PEDsQL is modular instrument composed of 28 items comprising 5 dimensions (diabetes, treatment I, treatment II, worry, and communication) graded on a scale from 0 to 4. Scores were converted from 0 to 100, where higher scores indicate higher HRQoL. The questionnaire was self-administrated on patients 8-17 and proxy completed by the caregiver for children 2-7. The overall and itemized mean scores by age ranges were calculated. Results by HbA1c level (HbA1c <7.5% vs HbA1c ≥ 7.5%) were analyzed by Mann-Whitney U test.

**Results:** Valid results were obtained for 268 patients. The proxy results indicated an overall HRQoL of 65.5 for patients with HbA1c < 7.5% and 70.6 for those with HbA1c ≥ 7.5% in patients aged 2-7. For patients 8-17, the self-report indicated an overall HRQoL of 72.0 for patients with HbA1c < 7.5% and 73.2 for those with HbA1c ≥ 7.5%. Results by age range were consistently lower among patients with HbA1c ≥ 7.5%, although differences by HbA1c level were not statistically significant. The "Worry" dimension had the highest negative score on QoL across all age ranges.

**Conclusion:** CRYSTAL is the first study to evaluate HRQoL in a representative sample of children and adolescents with T1DM in Spain. Interventions are needed to include HRQoL measures as part of the regular practice while managing diabetes for better assessment of diabetes care.

### INTRODUCTION

- Recent incidence rates for type 1 diabetes in the Spanish paediatric population are considered high or very high depending on the regions and they are even increasing in some areas.<sup>1</sup>
- Assessing quality of life in clinical practice in chronic illnesses, including diabetes, has been recognized as an important way to improve diabetes care in paediatric population.
- Previous research has demonstrated that better glycemic control (lower HbA1c) is associated with higher quality of life.<sup>2</sup>
- Routine HRQoL assessment is likely to facilitate detection and discussion of psychological issues related to diabetes.
- Sharing the information regarding HRQoL as part of ongoing clinical care is crucial and may help to tailor care to the needs of the children and adolescents with diabetes.
- Structured and current information about quality of life in paediatric population with type 1 diabetes in Spain is very limited.<sup>3</sup>

### Costs and Health Related quality of Life Study for Type 1 Diabetes Mellitus in Paediatric Patients in Spain (CRYSTAL)

- This is a non-interventional, cross sectional observational study conducted in 2014 on a representative sample of 275 paediatric patients aged 0-17 years with Type 1 Diabetes Mellitus (T1DM) in Spain.
- The study was designed to estimate total annual costs (direct and indirect) and describe health related quality of life and adherence behaviors in paediatric patients with T1DM in Spain.

### Objective

- The objective of this investigation was to describe the HRQoL for paediatric patients with T1DM in Spain and to compare results by HbA1c level.

### METHODOLOGY

#### Patient Population

- Inclusion Criteria:**
  - Include patients with T1DM (World Health Organization [WHO] classification).
  - Include patients less than 18 years of age.
  - Have been diagnosed with T1DM for at least 12 months.
  - Have given informed consent to release information from caregivers and assent from patients to participate in the study in accordance with local regulations.
- Exclusion Criteria:**
  - Patients diagnosed with any other type of diabetes (i.e. latent autoimmune diabetes in adults "LADA", monogenic forms of DM, gestational diabetes, Type 2 diabetes, etc.).
  - Are considered to be "inpatient."
  - Patient or caregiver has a limitation (i.e. not able to understand local language or any cognitive impairment) that in opinion of the investigator, could affect the reliability of the responses or will not be able to complete the questionnaires.
  - Patient is participating in any clinical trial.

Figure 1. Sites Distribution

### RESULTS

Table 2. Patient Characteristics

Variable*	N**	% or Mean (95% CI)
Age (years)	268	11.02 (10.57 - 11.48)
<b>Gender</b>		
Female	127	47.4%
Male	141	52.6%
Time from Diagnosis (Years)	268	4.98 (4.59 - 5.36)
<b>Puberty status</b> *		
No (Pre-pubertal)	113	42.3%
Yes (Post-pubertal)	154	57.7%
Pump Usage (%)*	28 (out of 267)	10.5%
CGMS Usage (%)*	27 (out of 262)	10.3%
<b>HbA1c level</b>		
<7.5%	156	58.2%
≥7.5 - <9%	93	34.7%
≥9%	19	7.1%
HbA1c (%)	268	7.43 (7.31 - 7.54)
<b>Center size</b> †		
Small size	36	13.4%
Medium size	71	26.5%
Large size	161	60.1%

Abbreviations: BCa = bias-corrected and accelerated bootstrap; CI = confidence interval; Max = maximum; Min = minimum; N = number of patients; SD = standard deviation; T1DM = Type 1 Diabetes Mellitus.

\* Total sample for this variable is affected by missing values. \*\* Total sample analyzed for PEDsQL was 268 (out of 275 total participants); missing cases include 5 patients with more than 50% of the items in the scale missing and 2 children that were less than 2 years old (no scale was available for this age group). † Size categories were: <50 patients per year, small; 50-149, medium; ≥150, large.

### Health Related Quality of Life

Figure 2. PEDsQL (All Ages) – Per Dimension and Overall

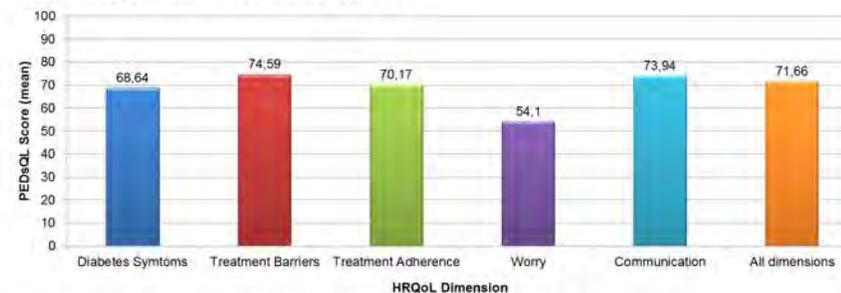


Figure 3. PEDsQL per HbA1c by Age Groups – Per Dimension and Overall (Proxy by Caregivers)

Ages 2-4

Ages 5-7

# Algunas presentaciones relevantes a congresos ...



## ECONOMIC IMPACT OF IMPROVING THE ACCURACY OF BLOOD GLUCOSE SELF-MONITORING ON THE SPANISH HEALTH SERVICE

Borja Rodríguez, M.D., Víctor M. González, M.D., PhD, et al.

**OBJECTIVE:** To estimate the economic impact of improving the accuracy of blood glucose self-monitoring on the Spanish Health Service.

**DESIGN:** A retrospective cohort study. The study included 100,000 patients with type 2 diabetes mellitus (T2DM) who were treated with oral hypoglycemic agents (OHA) and insulin. The study was conducted in the Spanish Health Service (Sistema Nacional de Salud, SNS) from 2010 to 2014.

**SETTING:** The study was conducted in the SNS, which is the largest and most complex health system in the world.

**MEASUREMENTS AND MAIN RESULTS:** The study found that improving the accuracy of blood glucose self-monitoring led to a significant reduction in the number of hospitalizations and emergency department visits. This resulted in a total savings of 1.2 million euros for the SNS.

**CONCLUSIONS:** Improving the accuracy of blood glucose self-monitoring is a cost-effective strategy for the Spanish Health Service.

**KEY WORDS:** Blood glucose self-monitoring, economic impact, Spanish Health Service, type 2 diabetes mellitus.

**INTRODUCTION:** The Spanish Health Service (SNS) is the largest and most complex health system in the world. It is responsible for the health care of over 45 million people. The SNS is facing a significant challenge due to the increasing prevalence of chronic diseases, such as type 2 diabetes mellitus (T2DM). T2DM is a major public health problem in Spain, with a prevalence of 12.5% in the adult population. The SNS spends a significant amount of money on the treatment of T2DM, including hospitalizations, emergency department visits, and medications. Improving the accuracy of blood glucose self-monitoring is a key strategy to improve the management of T2DM and reduce the economic burden on the SNS.

**OBJECTIVES:** The objective of this study was to estimate the economic impact of improving the accuracy of blood glucose self-monitoring on the Spanish Health Service.

**DESIGN:** A retrospective cohort study. The study included 100,000 patients with T2DM who were treated with OHA and insulin. The study was conducted in the SNS from 2010 to 2014.

**SETTING:** The study was conducted in the SNS, which is the largest and most complex health system in the world.

**MEASUREMENTS AND MAIN RESULTS:** The study found that improving the accuracy of blood glucose self-monitoring led to a significant reduction in the number of hospitalizations and emergency department visits. This resulted in a total savings of 1.2 million euros for the SNS.

**CONCLUSIONS:** Improving the accuracy of blood glucose self-monitoring is a cost-effective strategy for the Spanish Health Service.

**KEY WORDS:** Blood glucose self-monitoring, economic impact, Spanish Health Service, type 2 diabetes mellitus.

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**OBJECTIVES:** The objective of this study was to estimate the economic impact of improving the accuracy of blood glucose self-monitoring on the Spanish Health Service.

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**KEY WORDS:** Blood glucose self-monitoring, economic impact, Spanish Health Service, type 2 diabetes mellitus.

## REDUCTION OF COSTS ASSOCIATED WITH A NEW DRY-POWDER INHALER FORMULATION WITH BECLOMETHASONE DIPROPIONATE AND FORMOTEROL COMBINATION FOR THE TREATMENT OF ASTHMA

Rodrigo Rodríguez, M.D., PhD, et al.

**OBJECTIVE:** To evaluate the economic impact of a new dry-powder inhaler formulation for the treatment of asthma.

**DESIGN:** A retrospective cohort study. The study included 100,000 patients with asthma who were treated with the new dry-powder inhaler formulation.

**SETTING:** The study was conducted in the Spanish Health Service (SNS).

**MEASUREMENTS AND MAIN RESULTS:** The study found that the new dry-powder inhaler formulation led to a significant reduction in the number of hospitalizations and emergency department visits. This resulted in a total savings of 1.5 million euros for the SNS.

**CONCLUSIONS:** The new dry-powder inhaler formulation is a cost-effective strategy for the treatment of asthma.

**KEY WORDS:** Asthma, dry-powder inhaler, economic impact, Spanish Health Service.

**INTRODUCTION:** Asthma is a chronic respiratory disease that affects millions of people worldwide. The Spanish Health Service (SNS) spends a significant amount of money on the treatment of asthma, including hospitalizations, emergency department visits, and medications. The use of a new dry-powder inhaler formulation for the treatment of asthma is a key strategy to improve the management of asthma and reduce the economic burden on the SNS.

**OBJECTIVES:** The objective of this study was to evaluate the economic impact of a new dry-powder inhaler formulation for the treatment of asthma.

**DESIGN:** A retrospective cohort study. The study included 100,000 patients with asthma who were treated with the new dry-powder inhaler formulation.

**SETTING:** The study was conducted in the SNS.

**MEASUREMENTS AND MAIN RESULTS:** The study found that the new dry-powder inhaler formulation led to a significant reduction in the number of hospitalizations and emergency department visits. This resulted in a total savings of 1.5 million euros for the SNS.

**CONCLUSIONS:** The new dry-powder inhaler formulation is a cost-effective strategy for the treatment of asthma.

**KEY WORDS:** Asthma, dry-powder inhaler, economic impact, Spanish Health Service.

**INTRODUCTION:** Asthma is a chronic respiratory disease that affects millions of people worldwide. The Spanish Health Service (SNS) spends a significant amount of money on the treatment of asthma, including hospitalizations, emergency department visits, and medications. The use of a new dry-powder inhaler formulation for the treatment of asthma is a key strategy to improve the management of asthma and reduce the economic burden on the SNS.

**OBJECTIVES:** The objective of this study was to evaluate the economic impact of a new dry-powder inhaler formulation for the treatment of asthma.

**DESIGN:** A retrospective cohort study. The study included 100,000 patients with asthma who were treated with the new dry-powder inhaler formulation.

**SETTING:** The study was conducted in the SNS.

**MEASUREMENTS AND MAIN RESULTS:** The study found that the new dry-powder inhaler formulation led to a significant reduction in the number of hospitalizations and emergency department visits. This resulted in a total savings of 1.5 million euros for the SNS.

**CONCLUSIONS:** The new dry-powder inhaler formulation is a cost-effective strategy for the treatment of asthma.

**KEY WORDS:** Asthma, dry-powder inhaler, economic impact, Spanish Health Service.

## Cost-effectiveness analysis of surgical management of stress urinary incontinence with a single incision mini-sling (MiniArc™) versus tension free vaginal tape obturator in Spain

Rodrigo Rodríguez, M.D., PhD, et al.

**OBJECTIVE:** To compare the cost-effectiveness of two surgical treatments for stress urinary incontinence.

**DESIGN:** A retrospective cohort study. The study included 100,000 patients with stress urinary incontinence who were treated with either MiniArc™ or tension free vaginal tape obturator.

**SETTING:** The study was conducted in the Spanish Health Service (SNS).

**MEASUREMENTS AND MAIN RESULTS:** The study found that the MiniArc™ treatment was significantly more cost-effective than the tension free vaginal tape obturator treatment.

**CONCLUSIONS:** The MiniArc™ treatment is a more cost-effective option for the surgical management of stress urinary incontinence.

**KEY WORDS:** Stress urinary incontinence, MiniArc™, tension free vaginal tape obturator, cost-effectiveness.

**INTRODUCTION:** Stress urinary incontinence (SUI) is a common condition that affects millions of people worldwide. The Spanish Health Service (SNS) spends a significant amount of money on the treatment of SUI, including hospitalizations, emergency department visits, and medications. The use of a single incision mini-sling (MiniArc™) versus a tension free vaginal tape obturator for the treatment of SUI is a key strategy to improve the management of SUI and reduce the economic burden on the SNS.

**OBJECTIVES:** The objective of this study was to compare the cost-effectiveness of two surgical treatments for stress urinary incontinence.

**DESIGN:** A retrospective cohort study. The study included 100,000 patients with SUI who were treated with either MiniArc™ or tension free vaginal tape obturator.

**SETTING:** The study was conducted in the SNS.

**MEASUREMENTS AND MAIN RESULTS:** The study found that the MiniArc™ treatment was significantly more cost-effective than the tension free vaginal tape obturator treatment.

**CONCLUSIONS:** The MiniArc™ treatment is a more cost-effective option for the surgical management of stress urinary incontinence.

**KEY WORDS:** Stress urinary incontinence, MiniArc™, tension free vaginal tape obturator, cost-effectiveness.

**INTRODUCTION:** Stress urinary incontinence (SUI) is a common condition that affects millions of people worldwide. The Spanish Health Service (SNS) spends a significant amount of money on the treatment of SUI, including hospitalizations, emergency department visits, and medications. The use of a single incision mini-sling (MiniArc™) versus a tension free vaginal tape obturator for the treatment of SUI is a key strategy to improve the management of SUI and reduce the economic burden on the SNS.

**OBJECTIVES:** The objective of this study was to compare the cost-effectiveness of two surgical treatments for stress urinary incontinence.

**DESIGN:** A retrospective cohort study. The study included 100,000 patients with SUI who were treated with either MiniArc™ or tension free vaginal tape obturator.

**SETTING:** The study was conducted in the SNS.

**MEASUREMENTS AND MAIN RESULTS:** The study found that the MiniArc™ treatment was significantly more cost-effective than the tension free vaginal tape obturator treatment.

**CONCLUSIONS:** The MiniArc™ treatment is a more cost-effective option for the surgical management of stress urinary incontinence.

**KEY WORDS:** Stress urinary incontinence, MiniArc™, tension free vaginal tape obturator, cost-effectiveness.

# Algunas presentaciones relevantes a congresos ...



## Expenditure analysis in Multiple Sclerosis Disease Modifying Therapies evolution between 2004-2014 in Spain.

A. Hidalgo<sup>1</sup>, R. Vilario<sup>2</sup>

<sup>1</sup> Instituto de Investigación en Economía y Salud, Universidad de Castilla-La Mancha, Toledo, Spain; <sup>2</sup> Universidad Complutense, Madrid, Spain

### Objective

To analyze the decisive factors of recent evolution of Multiple Sclerosis' Disease Modifying Therapies (DMT) budgets in Spain between 2004 and 2014.

### Method

2004-2014 monthly expenditure in DMT analysis was provided by IMS Health. For each DMT treatment line, monthly and annual evolution in number of patients, billing, drug cost per patient and cost per year of treatment were calculated [1] (1<sup>st</sup> line treatments: subcutaneous and intramuscular interferon [IFN] [β-1a, subcutaneous IFN [β-1b] and glatiramer acetate, 2<sup>nd</sup> line treatments: natalizumab and fingolimod). Two periods were considered: 2004-2014 for 1<sup>st</sup> line and 2007 (when marketing of 2nd line DMT began)-2014.

### Results

**Table 1. Patients and expenditure annual evolution 2004-2014**

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
<b>1<sup>st</sup> Line</b>											
Patients (n)	151,676,886	154,677,238	164,881,248	164,799,461	164,282,124	153,827,218	152,076,178	150,966,894	151,387,494	151,215,891	150,892,884
Expenditure (€)	112,678,882	116,677,238	126,881,248	126,799,461	126,282,124	115,827,218	114,076,178	112,966,894	113,387,494	113,215,891	112,892,884
% of total	100.00%	100.00%	100.00%	99.12%	97.20%	75.32%	75.57%	75.50%	75.50%	75.50%	75.50%
2 <sup>nd</sup> Line											
Patients (n)	-	-	1,428,828	14,792,238	28,123,124	37,574,238	50,823,428	67,288,627	84,381,320	101,578,891	118,892,884
Expenditure (€)	-	-	1,428,828	14,792,238	28,123,124	37,574,238	50,823,428	67,288,627	84,381,320	101,578,891	118,892,884
% of total	-	-	1.27%	12.81%	18.07%	24.65%	33.82%	44.82%	59.82%	79.82%	94.50%
<b>Total</b>											
Patients (n)	151,676,886	154,677,238	166,310,076	165,591,700	164,404,248	153,401,436	148,062,812	147,055,771	145,768,814	145,431,782	145,005,768
Expenditure (€)	112,678,882	116,677,238	128,303,476	141,591,700	154,405,248	153,401,436	180,354,506	218,255,517	297,769,814	314,794,783	323,785,768
% of total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%
<b>Annually</b>											
Patients (n)	151,676,886	154,677,238	164,881,248	164,799,461	164,282,124	153,827,218	152,076,178	150,966,894	151,387,494	151,215,891	150,892,884
Expenditure (€)	112,678,882	116,677,238	126,881,248	126,799,461	126,282,124	115,827,218	114,076,178	112,966,894	113,387,494	113,215,891	112,892,884
% of total	100.00%	100.00%	100.00%	99.07%	97.09%	75.32%	75.57%	75.50%	75.50%	75.50%	75.50%
2 <sup>nd</sup> Line											
Patients (n)	-	-	1,428,828	14,792,238	28,123,124	37,574,238	50,823,428	67,288,627	84,381,320	101,578,891	118,892,884
Expenditure (€)	-	-	1,428,828	14,792,238	28,123,124	37,574,238	50,823,428	67,288,627	84,381,320	101,578,891	118,892,884
% of total	-	-	1.27%	12.81%	18.07%	24.65%	33.82%	44.82%	59.82%	79.82%	94.50%

### Treated patients distribution and annual expenditure evolution

### DMT expenditure distribution and total expenditure evolution

### Conclusions

The growing incorporation of new therapies and the appreciable rise in the number of treated patients (10.27% annual growth per year) are components to be considered in the pharmaceutical budget management.

- During 2004-2014 DMT expenditure increased from 115,5M€ to 353,8M€ due to:
  - A greater number of treated patients: 1.65% (10.27% annual growth per year).
  - A further growth of annual cost per patient: 13.82% (1.48% annual growth per year).
- ✓ In December 2014, 2<sup>nd</sup> line treatments represented 35.62% of total DMT expenditure.
- ✓ Annual cost per patient in 2<sup>nd</sup> line treatment represents:
  - 53% greater cost per treated patient.
  - 42% greater than 1<sup>st</sup> line DMT cost per year.
- ✓ If year 2007 is omitted from analysis (Only 68 2<sup>nd</sup> line treatments and 1.44M€ in associated expenses) and 2006-2014 period is analyzed, 2nd line DMT imply:
  - 41% of new treatments.
  - 78% increase in DMT expenditures.
  - 2<sup>nd</sup> line DMT participation in 2014:
    - Reaches 56% of new treatments.
    - Causes 91.23% increase of DMT expenditure.

## Comparative efficacy and costs of the treatment of moderate to severe persistent asthma with a new dry-powder inhaled beclomethasone dipropionate and formoterol combination

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### Introduction

Nowadays, moderate to severe asthma affects roughly two million adults in Spain. As a first choice it is treated with combinations of a long-acting beta2 agonist and a low-medium-dose of inhaled corticosteroids if it is not fully controlled with inhaled corticosteroids alone. The new pharmacologic approaches for moderate to severe persistent asthma treatment involve dry-powder inhaled corticosteroid plus long-acting beta2-agonist.

### Objective

To analyze the efficacy and total direct costs of an innovative extrafine formulation of beclomethasone dipropionate plus formoterol, Foster® Neohaler® (BCL/FOR) versus two therapeutic alternatives: fluticasone propionate plus salmeterol (FLU/SAL) and budesonide and formoterol fumarate (BUD/FOR), all of them as dry powders, delivered via a pressurized metered dose inhaler in patients suffering moderate-severe asthma whose symptoms were not controlled with inhaled corticosteroids alone.

### Methods

The efficacy data were extracted from two phase III randomized non-inferiority controlled trials between BCL/FOR (400/24 mcg/day) versus FLU/SAL (500/100 mcg/day) [1] and versus BUD/FOR (800/24 mcg/day) [2]. Patients of each group were homogeneous: adults aged 18-65 with moderate-severe persistent asthma with a forced expiratory volume in one second (FEV1) 50-80% of predicted normal values, and not adequately controlled with inhaled corticosteroids alone. They were followed-up for a 12-week period. The clinical primary outcome was the morning pre-dose peak expiratory flow (PEF) in the last 2 weeks of treatment.

A model was designed to estimate the direct costs of a cohort of 1,000 patients, with a 1-year time horizon, the Spanish National Health System perspective was adopted. The direct costs included diagnosis, pharmacological treatment, monitoring and complications (exacerbations) costs. The diagnosis one was related to the primary and specialist care. Monitoring is composed by the spirometries, blood tests, allergen tests and thorax Rx. The cost of exacerbations were estimated by the hospitalizations, unit care admissions and emergency hospital and primary care visits. Finally, the pharmacological treatment consisted in the administered drugs (corticosteroids and long-acting beta2-agonist).

### Results

The difference between the values of the primary outcome (pre-specified limit: -20 L/min) for BCL/FOR and FLU/SAL was 3.32 L/min (lower unilateral 97.5% CI: -17.82), and 0.49 L/min (lower unilateral CI: 97.5%: -11.97) vs BUD/FOR, showing non-inferiority of BCL/FOR. There was no difference between secondary health outcomes neither, mainly in the mean percentage of symptom-free days over the entire treatment period.

Primary outcomes	BCL-FOR	BUD-FOR	BCL-FOR	FLU/SAL
Morning pre-dose PEF (L/min)	358.3	371.4	362.6	373.8
Difference (L/min)	0.49	-	-3.32	-
95% confidence interval	-11.97; -12.95	-	-17.92; -11.28	-

### Conclusion

The analysis of data of the new dry-powder inhaled BCL/FOR shows that its effectiveness and security are not inferior to BUD/FOR or FLU/SAL but would result in yearly cost savings for the Spanish National Health Service of € 68,828 in comparison with FLU/SAL and €109,362, respect of BUD/FOR, for each 1,000 patient cohort.

Cost of resources	BCL/FOR	FLU/SAL	BUD/FOR
Medical visits (%)	7.24	6.95	6.75
Diagnosis test (%)	8.87	8.49	8.27
Exacerbation (%)	46.8	44.83	43.71

However, a significant difference in costs was observed. For a 1,000 patients cohort, a total cost of €1,913,208 (drug cost: € 560,228) was estimated with BCL/FOR, whereas were € 1,861,836 (drug cost: € 628,855) with FLU/SAL and €1,822,570 (drug cost: € 606,588) with BUD/FOR.

### Acknowledgement

We thank Chiesi Spain for the restrictive educational grant for the financial support of the study.

# Algunos artículos relevantes...



Hidalgo-Vega et al. *Cost Effectiveness and Resource Allocation* (2015) 13:11  
DOI 10.1186/s12962-015-0087-9



RESEARCH

Open Access



## Cost-utility analysis of certolizumab pegol versus alternative tumour necrosis factor inhibitors available for the treatment of moderate-to-severe active rheumatoid arthritis in Spain

Álvaro Hidalgo-Vega<sup>1\*</sup>, Renata Villoro<sup>2†</sup>, Juan Antonio Blasco<sup>3†</sup>, Pablo Talavera<sup>4†</sup>, Belén Ferro<sup>5†</sup> and Oana Purcaru<sup>6†</sup>

### Abstract

**Background:** Certolizumab pegol, a PEGylated tumour necrosis factor (TNF)-inhibitor, improves the clinical signs and symptoms of rheumatoid arthritis (RA) when used in combination with methotrexate or as monotherapy. This study evaluated the cost-utility of certolizumab pegol versus TNF-inhibitors plus methotrexate in the treatment of moderate-to-severe RA in Spain.

**Methods:** A Markov cohort health state transition model was developed to evaluate the cost-utility (costs and quality-adjusted life years [QALYs]) of certolizumab pegol versus other TNF-inhibitors licensed in Spain in 2009. Efficacy was measured using the American College of Rheumatology (ACR) responses at 6 months, based on adjusted indirect comparisons from published clinical trials. Utilities were derived from EQ-5D data from certolizumab pegol RA clinical trials. Clinical history and resource use data came from published literature. Unit costs were taken from Spanish databases or published data (cost year 2009). Base case analyses were conducted from the payer perspective, with a lifetime horizon, 3.5 % annual discounting rates for costs and outcomes, and 3 % inflation rate for 2009 onwards. One-way sensitivity analyses were conducted.

**Results:** The average lifetime costs for certolizumab pegol, etanercept, adalimumab (every 2 weeks and weekly) and infliximab (3 mg/kg and 5 mg/kg) in combination with methotrexate were €140,971, €141,197, €139,148, €164,741, €136,961 and €152,561, respectively. The QALYs gained were 6.578, 6.462, 6.430 (for both adalimumab doses), 6.430, and 6.318 (for both infliximab doses), respectively. At a €30,000/QALY willingness-to-pay threshold, certolizumab pegol plus methotrexate dominated adalimumab weekly, etanercept, and infliximab 5 mg/kg, and was cost-effective versus adalimumab every 2 weeks and infliximab 3 mg/kg (all with methotrexate), with estimated ICERs of €12,346/QALY and €15,414/QALY, respectively. Certolizumab pegol monotherapy was more cost-effective versus adalimumab, and less expensive with similar health gains versus etanercept (6.416 QALYs vs 6.492). Univariate analysis showed ICERs to be sensitive to changes in time horizon, ACR response time point, baseline Health Assessment Questionnaire (HAQ) score, and rate of HAQ-disability index deterioration after discontinuing treatment.

**Conclusions:** This analysis shows that certolizumab pegol is cost-effective compared with other TNF-inhibitors recommended in Spain for the treatment of RA.

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Pharmacoecón Span Res Artic (2014) 11:97–107  
DOI 10.1007/s40277-013-0019-2

ARTÍCULO DE INVESTIGACIÓN ORIGINAL

## Tratamiento biológico de la artritis reumatoide en España. Análisis de impacto presupuestario de la utilización de certolizumab pegol

Álvaro Hidalgo · Renata Villoro · Alexandra Ivanova · Alberto Morell · Pablo Talavera · Belén Ferro

Published online: 29 June 2013

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**Resumen** *Objetivo* Estimar el impacto presupuestario (IP) en España del uso combinado de certolizumab pegol (siguiendo un régimen fijo de dosis subcutáneas cada 2 semanas, tras una dosis de inducción en las semanas 0, 2 y 4) más metotrexato (MTX), como terapia para la artritis reumatoide (AR) de moderada a grave.

*Métodos* Se diseñó un modelo desde la perspectiva del Sistema Nacional de Salud (SNS) con un horizonte temporal de 5 años (2013–2017). Se estimó la población candidata a esta terapia frente a otras terapias biológicas para la AR (abata-

*Resultados* Con las asunciones hechas en el modelo, la cifra de pacientes tratados con certolizumab pegol evolucionaría de 1.943 pacientes en 2013 a 6.234 en 2017. El modelo estima que durante el período 2013–2017 la utilización de certolizumab pegol en España generaría unos ahorros globales medios por valor de 10,26 millones de euros. Dichos ahorros serían debidos fundamentalmente a la reducción de los costes de administración y la ausencia de necesidad de intensificación de dosis o ajustes por peso del paciente.

*Conclusiones* El tratamiento de los pacientes con AR de mo-

# Algunos artículos relevantes...



Comin-Colet et al. *Health Qual Life Outcomes* (2020) 18:329  
<https://doi.org/10.1186/s12955-020-01566-y>

Health and Quality  
of Life Outcomes

REVIEW

Open Access

## Impact of non-cardiovascular comorbidities on the quality of life of patients with chronic heart failure: a scoping review

Josep Comin-Colet<sup>1,2</sup>, Teresa Martín Lorenzo<sup>3</sup>, Almudena González-Domínguez<sup>3\*</sup>, Juan Oliva<sup>4</sup> and Sílvia Jiménez Merino<sup>5</sup>

### Abstract

**Purpose:** To determine the impact of non-cardiovascular comorbidities on the health-related quality of life (HRQoL) of patients with chronic heart failure (CHF).

**Methods:** A scoping review of the scientific literature published between 2009 and 2019 was carried out. Observational studies which assessed the HRQoL of patients with CHF using validated questionnaires and its association with non-cardiovascular comorbidities were included.

**Results:** The search identified 1904 studies, of which 21 fulfilled the inclusion criteria to be included for analysis. HRQoL was measured through specific, generic, or both types of questionnaires in 72.2%, 16.7%, and 11.1% of the studies, respectively. The most common comorbidities studied were diabetes mellitus (12 studies), mental and behavioral disorders (8 studies), anemia and/or iron deficiency (7 studies), and respiratory diseases (6 studies). Across studies, 93 possible associations between non-cardiovascular comorbidities and HRQoL were tested, of which 21.5% regarded anemia or iron deficiency, 20.4% mental and behavioral disorders, 20.4% diabetes mellitus, and 14.0% respiratory diseases. Despite the large heterogeneity across studies, all 21 showed that the presence of a non-cardiovascular comorbidity had a negative impact on the HRQoL of patients with CHF. A statistically significant impact on worse HRQoL was found in 84.2% of associations between mental and behavioral disorders and HRQoL (patients with depression had up to 200% worse HRQoL than patients without depression); 73.7% of associations between diabetes mellitus and HRQoL (patients with diabetes mellitus had up to 21.8% worse HRQoL than patients without diabetes mellitus); 75% of associations between anemia and/or iron deficiency and HRQoL (patients with anemia and/or iron deficiency had up to 25.6% worse HRQoL than between patients without anemia and/or iron deficiency); and 61.5% of associations between respiratory diseases and HRQoL (patients with a respiratory disease had up to 21.3% worse HRQoL than patients without a respiratory disease).

**Conclusion:** The comprehensive management of patients with CHF should include the management of comorbidities which have been associated with a worse HRQoL, with special emphasis on anemia and iron deficiency, mental and behavioral disorders, diabetes mellitus, and respiratory diseases. An adequate control of these comorbidities may have a positive impact on the HRQoL of patients.

**Keywords:** Heart failure, Health-related quality of life, Comorbidity, Chronic disease

BioDrugs (2018) 32:281–291  
<https://doi.org/10.1007/s40259-018-0284-3>



ORIGINAL RESEARCH ARTICLE

## Determining the Value of Two Biologic Drugs for Chronic Inflammatory Skin Diseases: Results of a Multi-Criteria Decision Analysis

Néboa Zozaya<sup>1</sup>, Lucía Martínez-Galdeano<sup>1</sup>, Bleric Alcalá<sup>1</sup>, Jose Carlos Armario-Hita<sup>2</sup>, Concepción Carmona<sup>3</sup>, Jose Manuel Carrascosa<sup>4</sup>, Pedro Herranz<sup>5</sup>, María Jesús Lamas<sup>6</sup>, Marta Trapero-Bertran<sup>7</sup>, Álvaro Hidalgo-Vega<sup>8,9</sup>

Published online: 29 May 2018  
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### Abstract

**Background and Objective** Multi-criteria decision analysis (MCDA) is a tool that systematically considers multiple factors relevant to health decision-making. The aim of this study was to use an MCDA to assess the value of dupilumab for severe atopic dermatitis compared with secukinumab for moderate to severe plaque psoriasis in Spain. **Method** Following the EVIDEM (Evidence and Value: Impact on Decision Making) methodology, the estimated value of both interventions was obtained by means of an additive linear model that combined the individual

weighting (between 1 and 5) of each criterion with the individual scoring of each intervention in each criterion. Dupilumab was evaluated against placebo, while secukinumab was evaluated against placebo, etanercept and ustekinumab. A retest was performed to assess the reproducibility of weights, scores and value estimates.

**Results** The overall MCDA value estimate for dupilumab versus placebo was  $0.51 \pm 0.14$ . This value was higher than those obtained for secukinumab:  $0.48 \pm 0.15$  versus placebo,  $0.45 \pm 0.15$  versus etanercept and  $0.39 \pm 0.18$  versus ustekinumab. The highest-value contribution was reported by the patients' group, followed by the clinical

# Algunas Publicaciones ....



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