

Análisis coste-utilidad del implante XEN vs. Trabeculectomía en cirugía de Glaucoma: Otro informe RedETS

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Introduction

RedETS is the Spanish Network of HTA Agencies

- 8 HTA agencies
- Common methodological framework
- Coordinated work
- Inform decision-making in HT adoption for the National Public Healthcare Services (SNS)
- Foster quality, efficiency and sustainability of the National Public Healthcare Services (SNS)

Introduction

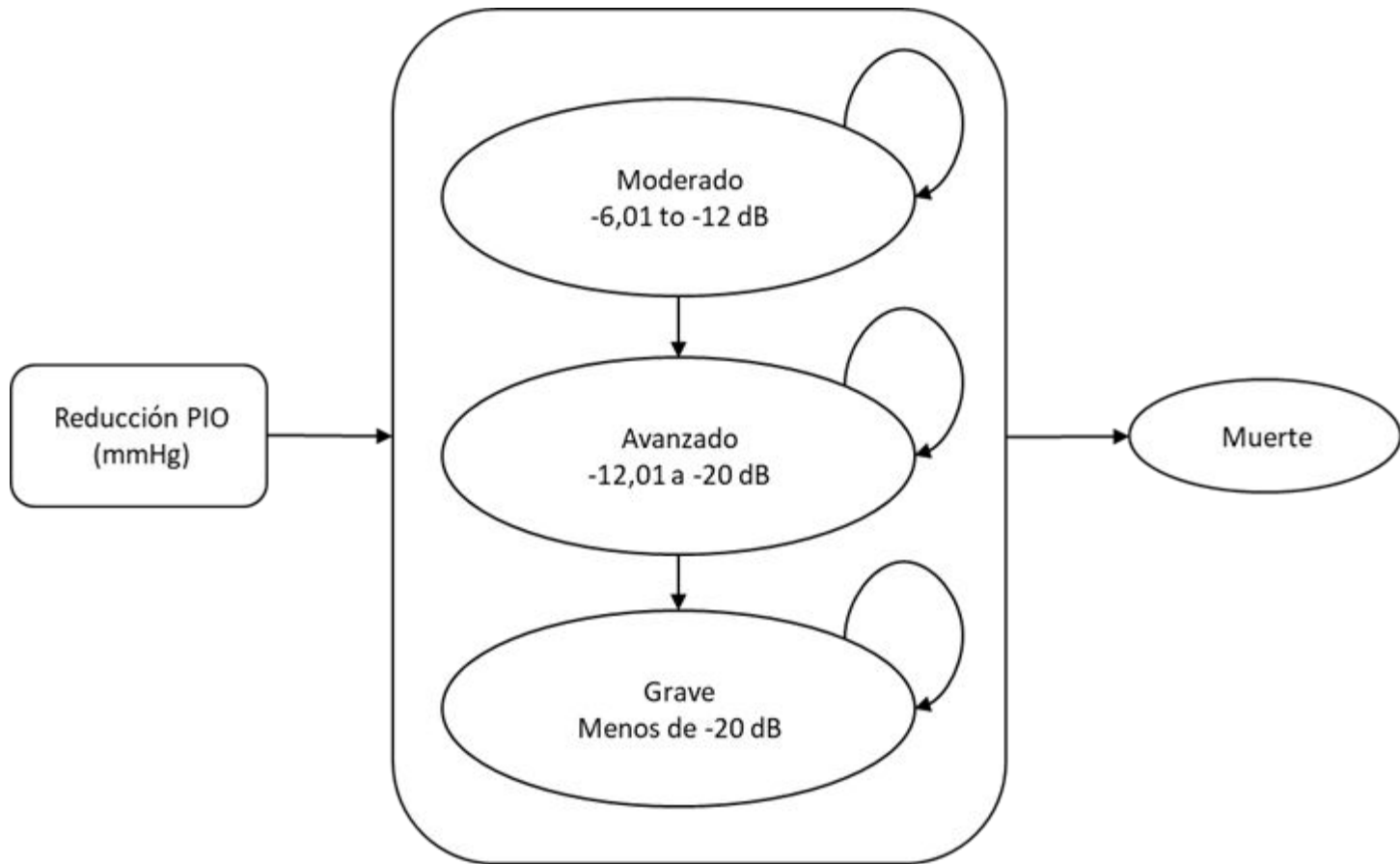
Primary Open Angle Glaucoma (POAG) is an optic neuropathy characterised by progressive degeneration of retinal ganglion cells. There are several therapeutic options for lowering intraocular pressure (IOP).

Aims

The aim of this study is to evaluate the **cost-utility of XEN[®]45 device compared to trabeculectomy** in patients with moderate POAG. This analysis is part of a Health Technology Assessment report developed in the Spanish HTA-Network.

Methods - Model

Simulation was carried out using a three-state Markov model (in addition to the death state) in which patients cycle monthly.



Methods - Model

In the Early Manifest Glaucoma Trial:

- Progression untreated patients -0.05 dB per month (converted to -0.6 dB per year).
- Treatment in this trial (i.e., laser therapy with medication) resulted in an IOP reduction of 5.1 mm Hg with a corresponding reduction in the rate of VF progression from -0.05 dB (baseline) to -0.03 dB per month.

Methods - Efficacy

Efficacy data were obtained from literature. A 12-month IOP reduction of 9.6 mmHg was reported in the XEN[®] group and 11 mmHg in the trabeculectomy group. With this, the annual progression of the visual field was calculated.

A time horizon of 15 years was adopted. A discount rate of 3% was applied.

Methods - Safety

	XEN®45	Trabeculectomía
Número de ojos	100	100
Hipotonía* (% pac)	30	16
Desprendimiento coroideo* (% pac)	14	9
Sangrado en cámara anterior** (% pac)	7	9
Reintervención (% pac)	16	30

*Durante el primer mes tras la cirugía, PIO <5mmHg

**Durante los 12 meses tras la cirugía

Methods - Utility values

Parameter	Value	Source
Disutility due to reintervention	-0,008	Assumption
<i>Utilities for POAG health states</i>		
Moderate	0,781	Van Gestel et al. 2012 ³⁴
Advanced	0,704	
Severe	0,594	

Methods - Costs

The perspective of the NHS in Spain was considered, so only direct costs (interventions, subsequent consultations and follow-up, medications and management of adverse effects) were taken into account.

Parameter	Cost (€ 2021)	Source
<i>Devices</i>		
XEN® 45	815,96	Martínez-de-la-Casa et al. 2019 ³⁵
<i>Interventions</i>		
Trabeculectomy	2562,24	Martínez-de-la-Casa et al. 2019 ³⁵
XEN® 45	847,72	Martínez-de-la-Casa et al. 2019 ³⁵
<i>Complications and reinterventions</i>		
Hypotony	78,36	Theilig et al. 2020, Boletín Oficial de la Comunidad de Madrid, Diari Oficial de la Generalitat de Catalunya ³⁶⁻³⁸
Choroidal detachment	2763,13	Theilig et al. 2020, Martínez-de-la-Casa et al. 2019 ^{35,36}
Bleeding in anterior chamber	2568,34	Theilig et al. 2020, Martínez-de-la-Casa et al. 2019 ^{35,36}
Needling	94,43	Theilig et al. 2020, Martínez-de-la-Casa et al. 2019 ^{35,36}
Reintervention Trabeculectomy	512,45	Assumption, 20% index intervention
Reintervention XEN® 45**	169,54	Assumption, 20% index intervention

	XEN®45	Dif.	Trabeculectomy	Dif.
Baseline	3,3		3,3	
12 months	0,800	2,500	0,600	2,700
24 months	0,600	2,700	0,500	2,800
36 months	0,870	2,430	0,780	2,520
48 months	1,113	2,187	1,032	2,268

	Bottle volume (ml)	Drops per ml	Drops per bottle	Dose/day (one eye)	Theoretical days per bottle	Bottles per month	Price (€ 2021)	Average monthly cost per patient (€)
Active ingredients (Market share)								
Fixed combinations (22,2%)								12,55
DORZOLAMIDA/TIMOLOL	5	25,9	129,5	2	64,75	0,46	12,11	5,61
LATANOPROST/TIMOLOL	2,5	25,9	64,75	2	32,375	0,93	8,93	8,27

Prostaglandinas (54,4%), Betabloqueantes (2,5%), INH Anhidrasa carbónica (7,2%), Alfa 2 antagonistas (13,7%)

Parámetro	Uso de recursos			Fuente
	Moderado	Avanzado	Grave	
Consultas Oftalmología	3	4	4	Supuesto del grupo elaborador del informe
Gonioscopías	1	1	1	
Pruebas de campo visual	2	2	2	
Imagen de disco óptico	3	4	4	
Tomografía de coherencia óptica	2	3	3	

Parámetro	Valor (€ 2021)	Fuente
Consultas Oftalmología	78,36	Boletín Oficial de la Comunidad de Madrid, Diari Oficial de la Generalitat de Catalunya
Gonioscopías	6,97	Fea et al. 2021
Pruebas de campo visual	15,09	Fea et al. 2021
Imagen de disco óptico	80,91	Fea et al. 2021
Tomografía de coherencia óptica	118,12	Diari Oficial de la Generalitat de Catalunya

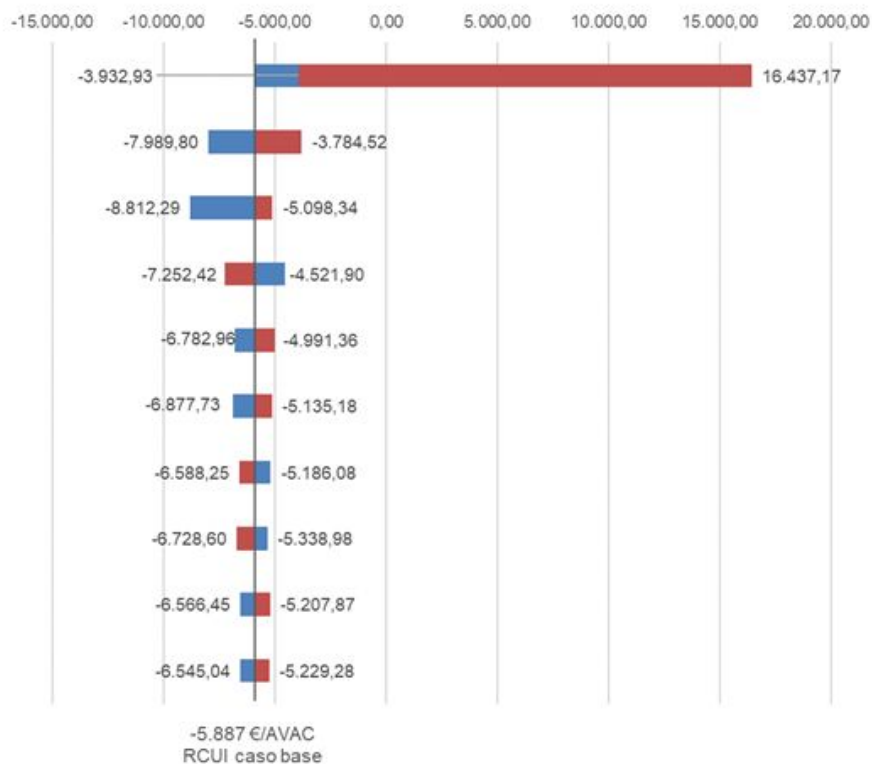
Methods - Sensitivity Analysis

The robustness of the model was tested by one way and probabilistic sensitivity analysis.

- Confidence intervals of estimators
- Professional consultation
- $\pm 20\%$
- Probabilities and utilities - Beta
- Resource use and costs - Gamma

Results

	Coste (€ 2021)	AVAC	Dif. Coste	Dif. AVAC	RCUI (€/AVAC)
Trabeculectomía	16.068,45	7,51			
XEN®45	14.633,65	7,75	-1.434,80 €	0,24	-5.887



■ Lim. Inferior

■ Lim. Superior

Defecto en campo visual de inicio en el grupo de Trabeculectomía

Coste de la intervención de trabeculectomía

Defecto en campo visual de inicio en el grupo de XEN®45

Coste de la intervención de XEN(45)

Número de principios activos a los 24 meses tras trabeculectomía

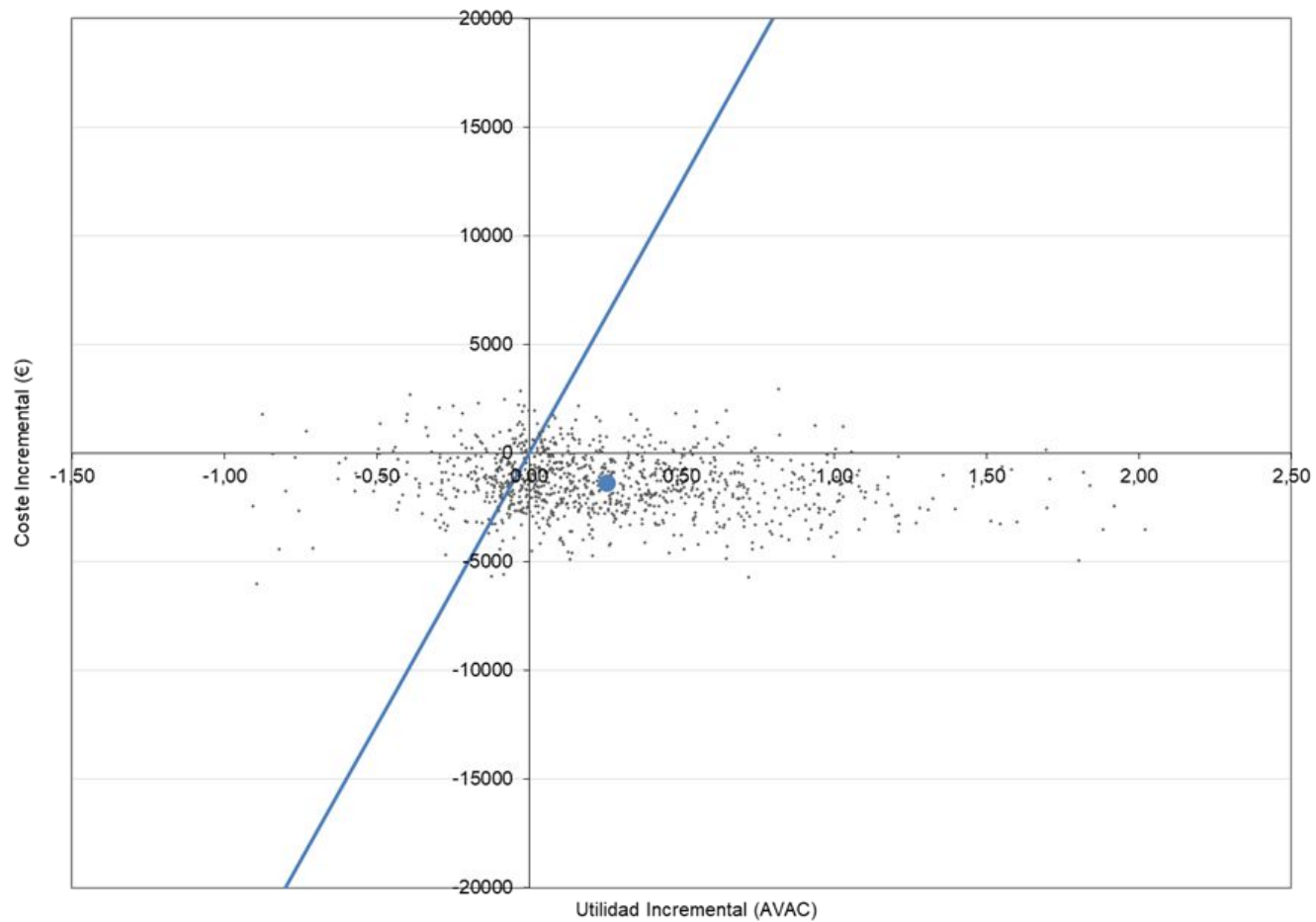
Presión Intraocular basal en el grupo de trabeculectomía

Número de principios activos a los 12 meses tras trabeculectomía

Presión Intraocular basal en el grupo de XEN

Número de Imágenes de disco óptico anuales en pacientes avanzados

Número de visitas a Oftalmología en pacientes avanzados



Conclusions

- According to the results obtained, XEN[®]45 could be a less costly strategy than the trabeculectomy approach and may be dominant from an NHS perspective over a 15-year time horizon.
- There is uncertainty regarding the HRQoL outcomes between the two techniques compared, and the improvements in quality of life obtained with XEN[®]45 may not be consistent if the baseline profile of the patients undergoing surgery varies.

Thank you!

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