

EU meeting

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# Proton therapy: HTA assessments in Spain

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UNIVERSITAT DE  
BARCELONA

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# HTA reports in Spain: Proton therapy

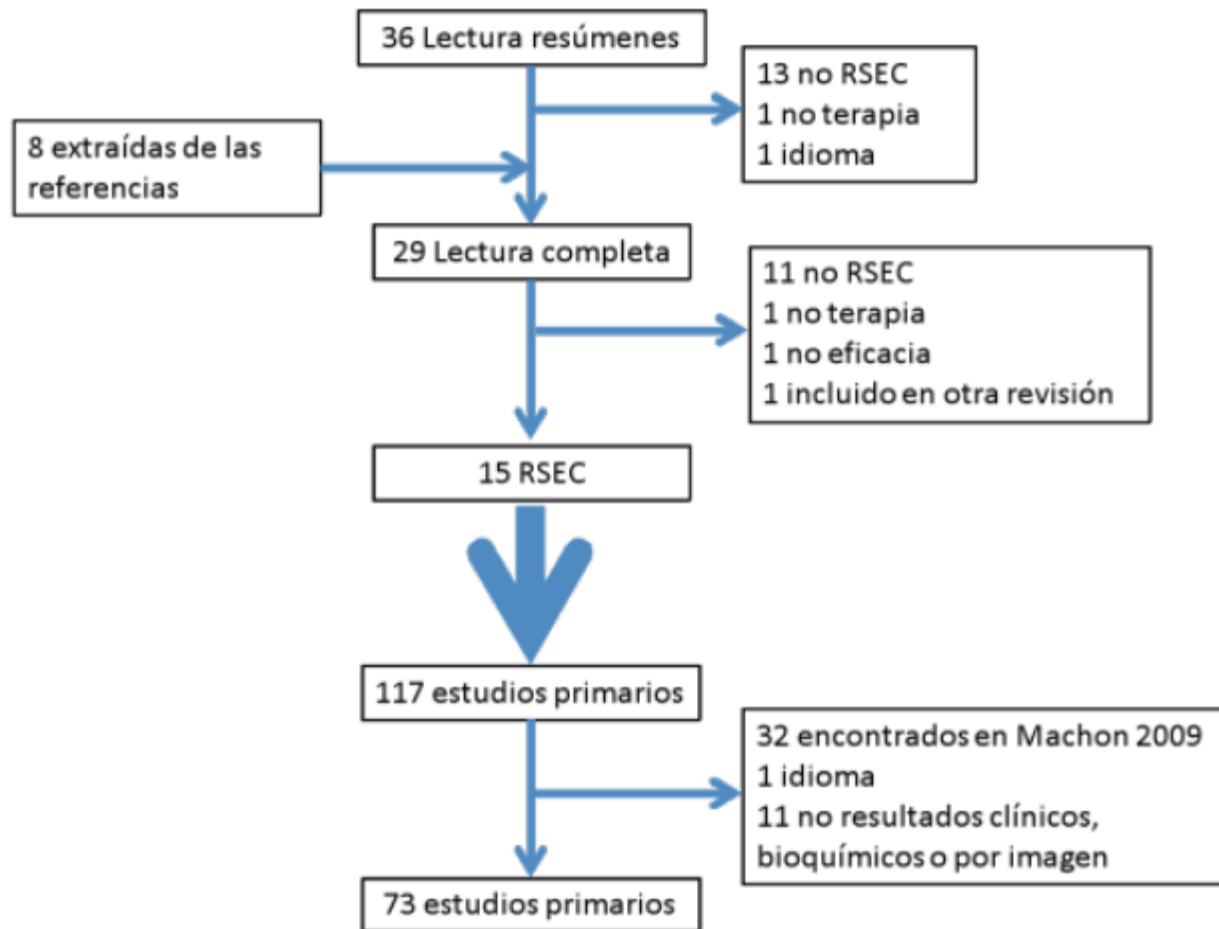
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- Three HTA reports have been published in Spain: 2009, 2014 and 2018 (an update of the previous one)
- All reports were requested by the Ministry of Health and Health Services of Autonomous regions
- Spanish Network of HTA agencies: report was carried out by AQUAS (Catalonian HTA agency)
- Objective: review of the international literature about evidence and analysis of the facilities planned or working in Europe (this only in the 2014 report)

# HTA reports in Spain. methodology (2014 report)

- Systematic review  
2008 and Dec

Figura 1. Procedimiento de selección de los estudios



La protonterapia  
en el tratamiento  
del cáncer

Informes de Evaluación de Tecnologías Sanitarias

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# HTA reports in Spain: number of studies and patients included

Localización anatómica o tipo de tumor	Núm. de estudios	Núm. de pacientes con PTR <sub>≤</sub>
Carcinoma hepatocelular	8	556
Melanoma de la úvea	13	3.802
Tumores de cabeza y cuello	8	305
Tumores de próstata	11	4.054
Tumores de pulmón de células no pequeñas	2	112
Tumores óseos de la base del cráneo	4	344
Tumores pediátricos	7	129
Otros tumores	20	953
TOTAL	73	10.255

# HTA reports in Spain: results

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- Low quality of the evidence: most of the studies reviewed were retrospective case series.
- No RCT comparing directly proton and photon therapies
- Comparative studies were found with historical cohorts (3) and 4 trials assessing dose escalation

# HTA reports in Spain: potential number of patients

**Tabla 4. Estimación de la demanda de PTR en España según tasa de demanda de países europeos**

País europeo*	Escenario 1 Total casos estimados**	Escenario 2 Total casos estimados**
Bélgica	198,3	424,3
Holanda	691,7	19.830,2
Suecia	332,0-410,4	2.969,9-4.408,8
Italia	765,5	11.483,1
Gran Bretaña	691,7	

*Fuente:* Agence d'évaluation des technologies et des modes d'intervention en santé (AET-MIS). La protonthérapie. Note informative préparée par Jean-Marie R. Lance. AETMIS NI-2010-03:1-30.

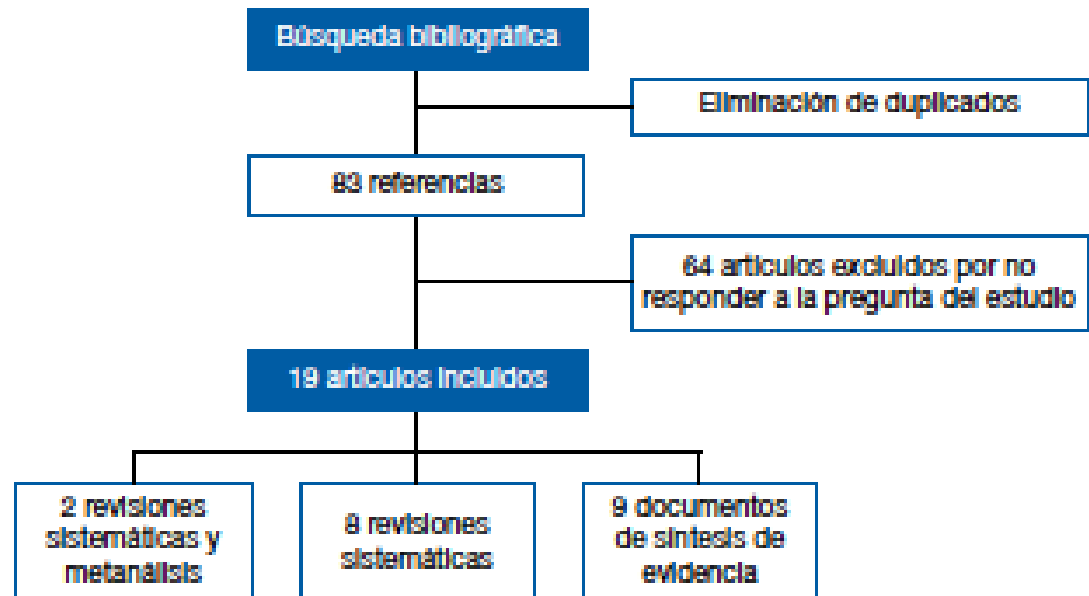
# **HTA reports in Spain: concluding comments**

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The low quality of the studies did not allow establishing definitive conclusions on the clinical superiority of this treatment. However, in the studies selected, potential clinical benefits were observed in certain types of tumors, such as in uveal melanoma, chordomas and chondrosarcomas of the skull base, or early-stage non-small cell lung cancers. Regarding pediatric tumors, the lack of studies with sufficiently long follow-up did not allow assessing the long-term toxicity of PTR in these patients. Finally, the quality of the studies published to date on the effectiveness of the PTR as part of treatment in other tumors, such as in hepatocellular carcinomas, head and neck tumors, or prostate tumors, make it difficult to define the therapeutic role of PTR.

# HTA reports in Spain: 2018 update

- Analysis restricted to systematic reviews from January 2012 to December 2016.



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Actualización

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# HTA reports in Spain: 2018 update

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- Proton therapy showed unequal results depending on the tumour site and the criteria used for evaluation
- Only global benefit for the treatment of medulloblastoma in any age group
- Benefits observed in some features of other paediatric cancers, uveal melanomas (efficacy, effectiveness and safety) and in skull base tumours (efficacy and effectiveness).
- More rigorous studies required.

# HTA reports in Spain: final comments

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Protontherapy did not show more efficacy, effectiveness, cost-effectiveness and safety than the photon or ion therapies in most cancer types. However, protontherapy showed better global results for meduloblastoma; whereas, for several pediatric tumors of the central nervous system, the skull base tumors, and the uveal melanoma, this therapy showed some benefit at least in one of the analyzed features.

It would be reasonable to choose to use the protontherapy in cases where there is enough evidence (particularly in children's tumors) along with the recording of clinical results to allow the completeness of evidence. It would also be reasonable to promote the gathering of new evidence from randomized controlled trials or by means of coverage with evidence development schemes.

# HTA reports in Spain: potential applications

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- The perspective of the Spanish Society of Radiation Oncologists has been always clearly favourable with no clear estimates of number of potential patients that could be candidates
- Decentralized Spanish health care system is an organizational feature to take into account
- Number of patients candidates is a key issue to assess any project from a public health care perspective