PILOT PROTOCOL PROPOSAL FOR OBSERVATION OF HEALTH TECHNOLOGIES AFTER INTRODUCTION INTO ROUTINE CLINICAL PRACTICE

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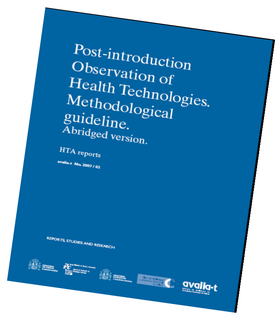
INTRODUCTION



- In the period 2008-2009, the Galician Health Technology Assessment Agency in collaboration with other 6 national HTA organizations developed a methodological document to guide the observation of health technologies after their introduction into routine clinical practice.

- The **AIM** of this work was to test the methodology with the *development of a protocol proposal* for the observation of a technology recently approved into the Galician Health Care Basket.

TECHNOLOGY SELECTED FOR ASSESSMENT: Sacral stimulation for the treatment of faecal incontinence

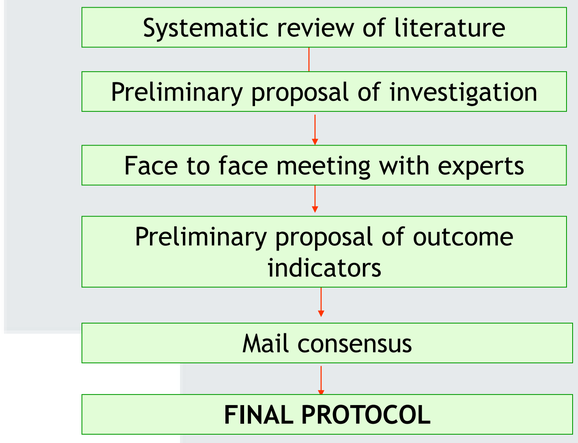
Approval conditions:

- Patients that present severe incontinence with duration greater than 6 months and are not candidates for more conventional treatment (Wexner Score > 15 points)
- Authorization subject to the creation of adequate mechanism to guarantee the remission of patients to the centres that are authorized to apply the technology to guarantee thesame effective access conditions for all patients within the Autonomous Community

METHODS

WORKING GROUPS

- **TECHNICAL GROUP** (3 avalia-t staff)
- **CONSULTANT GROUP** (3 specialists in General and Digestive Tract Surgery from the 2 centres that are authorized to carry out sacral stimulation in Galicia)



STEPS IN PROTOCOL DEVELOPMENT

- **Systematic review of literature to identify uncertainties**
- **Definition of the goals and outcome variables to be assessed**
- **Consensus on the subgroups to be separately evaluated**
- **Definition and consensus on follow up scheme**
- **Selection and elaboration of quality indicators**
- **Consensus on outcome indicators and reference standards**

RESULTS

MAIN OBJECTIVES

- **Establish the adequacy of diffusion and use of sacral stimulation.**
- **Establish if equity of access has been achieved.**
- **Investigate effectiveness and safety in real practice and establish if the benefit risk ratio is acceptable in all subgroups of patients**

SELECTED INDICATORS

Diffusion	Adoption in authorized centres
	Coverage
	Acceptability
Accessibility	Geographic accessibility
Adequacy of use	Adequacy of patient selection criteria
	Effectiveness of provisional stimulation
Effectiveness	Effectiveness of permanent implantation
	Effectiveness to alleviate chronic pain associated with incontinence
Safety	Infection after electrode implantation
	Severe adverse effects
	Adverse effects that result in withdrawal
	Moderate or mild adverse events

EXAMPLE OF AN INDICATOR WITH ALL RELEVANT INFORMATION FOR ASSESSMENT

Effectiveness to reduce incontinence	
Explanation	The rate of patients that obtain more than a 50% reduction of the incontinence is acceptable?
Justification	There is uncertainty that reduction of faecal incontinence can be generalized to different aetiologies, severe cases or if benefits are the same for different protocols or can be maintained in the medium term.
Formula	*Nº of patients that obtain more than a 50% reduction in the Wexner-Cleveland score* / *Total number of patients that have been implanted the definitive electrode*
Description of terms	*Wexner-Cleveland score*: the score is derived from the sum of a 5 item severity scale: 0 (perfect state); 20 (worse state=daily incontinence). The reduction is calculated against the baseline value
Study subgroups	Data will be analyzed according to the pathophysiology mechanism responsable for the faecal incontinence: altered stool consistency, abnormal rectal capacity or compliance, decreased anorectal sensation and pelvic floor or anal sphicter disfunction. The severity of the lesion will be also analyzed (less than 30º or more than 30º) If different protocols or different leads are used (for example, bilateral stimulation), these subgroups will be independently analyzed.
Scope of study	Authorized centres of the Galician Public Health System (2)
Standard	Global: 75%
Time frame	Assessment before the intervention, 6 months and 1 year
Data-sources	Register

CONCLUSIONS AND RECOMMENDATIONS

✓ This work presents the successful development of a pilot protocol for observation of sacral stimulation for treatment of faecal incontinence that can serve as a reference for future assessments in this field

✓ It is essential that the current protocol be refined so that it does not solely serve as an example but can be used by different centres that apply this technology in order to obtain a standardised registry with relevant results that can be assessed and compared.

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