

*La historia nos enseña mucho, pero la experiencia
liberada para ser de otros mundos y otros tiempos.*

Appropriateness explicit criteria for carotid revascularization

**Fernández de Larrea N, Blasco JA, Masjuan J,
Santos E, Castro E, Andradas E.**

**Health Technology Assessment Unit, UETS
Madrid. Spain.**



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

 **Comunidad de Madrid**



Cerebrovascular disease

- **3rd cause of Disability Adjusted Life Years (DALY) in the world.**

- **2nd main cause of death in the world.**

Projections for 2030 (WHO): 10.6% of all deaths

- **Low-income countries: 8.2%**
- **Middle-income countries: 14.4%**
- **High-income countries: 9%**

- **Types: { 80% ischemic - 20-30% carotid origin
20% hemorrhagic**



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

 **Comunidad de Madrid**

Carotid stenosis

- **Risk of stroke (in 1 year):**
 - **Symptomatic patients (NASCET): 11% for stenosis 70%-79% and 35% for $\geq 90\%$.**
 - **Asymptomatics (ACST): $< 1\%$ for stenoses $< 60\%$ and 1-2.4% for $> 60\%$.**
- **Prevalence: 7% in women and 9% in men.**
 - **With underlying cardiac disease: 18%**
 - **Those presenting with stroke: 60%**
- **Main cause: atherosclerosis**
- **Main mechanism of cerebrovascular disease: embolization**
- **Clinical management:**
 - **Medical: cardiovascular risk factors control +/- drugs**
 - **Revascularization:**

}	Endarterectomy
	Endovascular treatment



6TH ANNUAL MEETING
HTAI
SINGAPORE 2009

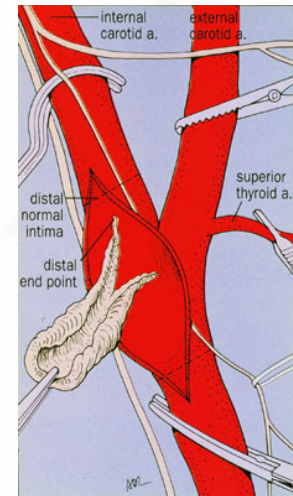


Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

Comunidad de Madrid

Carotid endarterectomy

- **First successful carotid endarterectomy: 1953**
- **Extraction of the atheromatous plaque through neck incision.**
- **Type of anesthesia:**
 - **Anesthesia General or Local**
- **Potential complications:**



Cardiovascular

- Hypertension (20%)
- Hypotension (5%)
- Myocardial infarction (1%)

Wound

- Infection (1%)
- Hematoma (5%)

Neurological

- Hyperperfusion syndrome
- Intracerebral hemorrhage
- Cranial nerve injury (7%)
- Seizures
- Stroke (2%–6%)

Carotid artery

- Carotid artery thrombosis
- Carotid artery dissection
- Restenosis (5%–10%)
- Death (1%)

Endovascular treatment

- **First balloon angioplasty for carotid stenosis: 1979**
- **Carotid lumen enlargement by angioplasty + stent.**
- **Technical aspects:**
 - **Femoral vascular access**
 - **Balloon angioplasty**
 - **Stent (balloon / self expandable, Nitinol / stainless steel, length)**
 - **Cerebral protection device**
- **Potential complications:**



Cardiovascular

- Vasovagal reaction (5%–10%)
- Vasodepressor reaction (5%–10%)
- Myocardial infarction (1%)

Carotid artery

- Dissection (<1%)
- Thrombosis (<1%)
- Perforation (<1%)
- ECA stenosis or occlusion (5%–10%)
- Transient vasospasm (10%–15%)
- Restenosis (3%–5%)

Neurological

- TIA (1%–2%)
- Stroke (2%–3%)
- Intracranial hemorrhage (<1%)
- Hyperperfusion syndrome (<1%)
- Seizures (<1%)

General

- Access site injury (5%)
- Blood transfusion (2%–3%)
- Contrast nephropathy (2%)
- Contrast reactions (1%)
- Death (1%)



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

Comunidad de Madrid

Objectives

1 - To develop explicit criteria for the appropriate indication of:

- **Carotid endarterectomy**
- **Carotid endovascular revascularization**

2 - To design manageable tools for decision making in clinical practice.



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

 **Comunidad de Madrid**

Methodology



- ***RAND Appropriateness Method combines scientific evidence with expert criteria***
- ***Objective: Create appropriateness criteria or indications for medical/surgical/diagnosis procedures***
- ***Appropriateness procedure: the expected health benefit exceeds the expected harms***

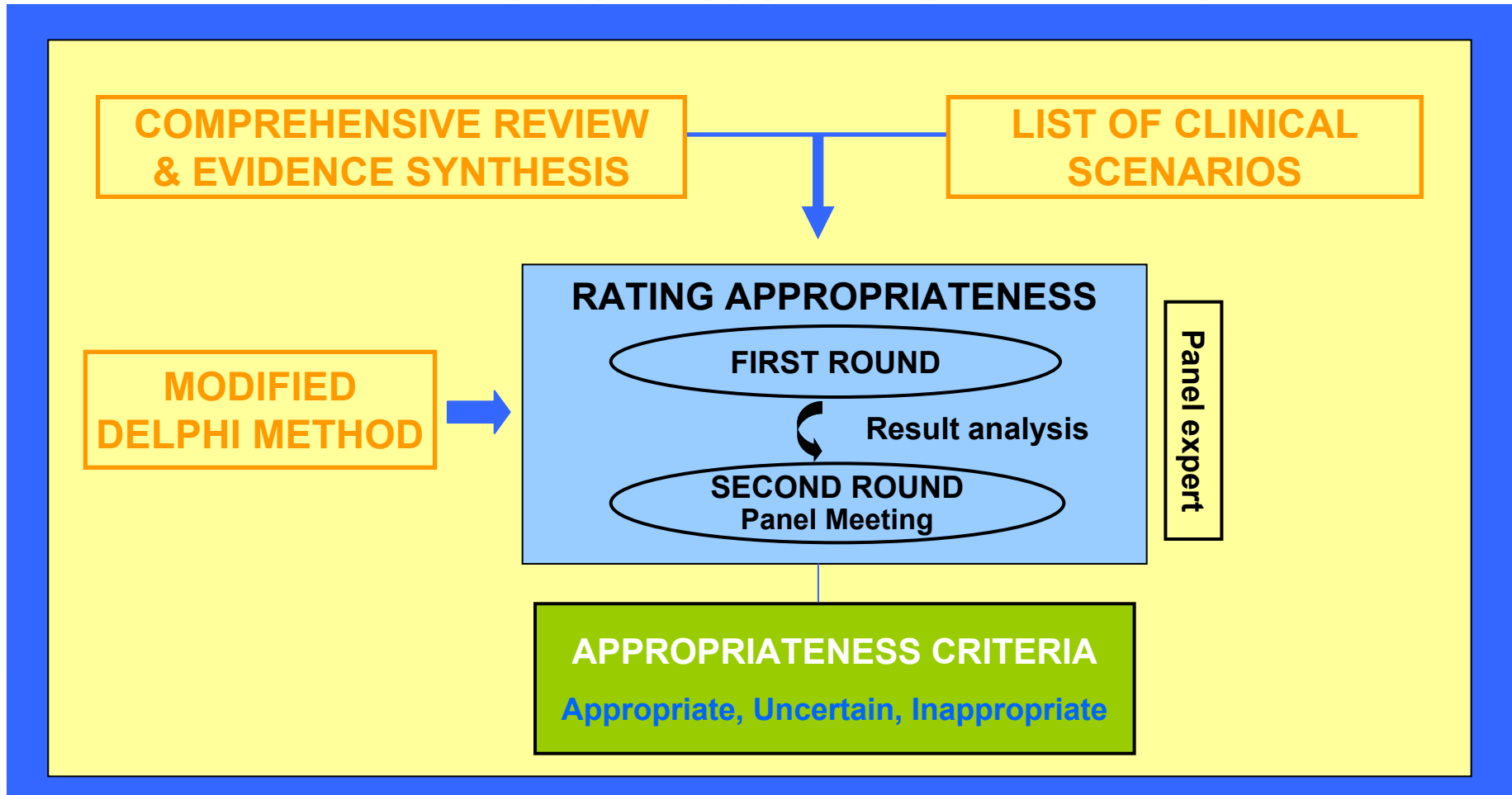


Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

Comunidad de Madrid

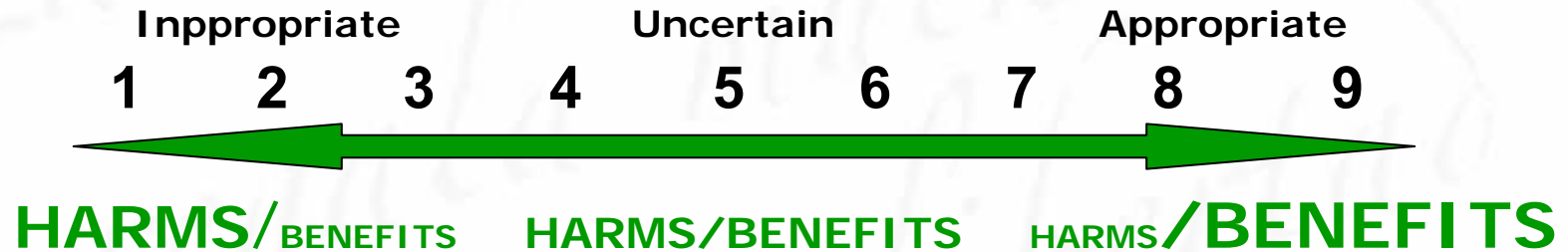
Methodology

RAND Appropriateness Method



Adapted from Fitch K, et al. RAND monograph report. The RAND/UCLA Appropriateness Method User's Manual, 2001

Rating Appropriateness



- *Rate using scientific evidence, whenever possible, and own best clinical judgement*
- *Assess balance negative consequences/benefits of each procedure*
- *Consider the procedure is performed in an average hospital/care-proving facility*
- *NOT to consider cost implications*

Methodology

1.- Literature review:

- **Efficacy, effectiveness and safety.**
- **Pubmed, Embase, Cochrane library, Pascal Biomed, Cinahl and Lilacs.**
- **Included studies:** $\left\{ \begin{array}{l} \text{RCT (efficacy)} \\ \text{Other designs (safety)} \end{array} \right.$
- **Data extraction and summary of evidence.**



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

Comunidad de Madrid

Methodology

2.- List of clinical scenarios:

- **Select variables relevant for decision making:**
 - **Clinical presentation**
 - **Degree of stenosis**
 - **Age**
 - **Gender**
 - **Comorbidity**
 - **Life expectancy**
 - **Technical complexity**

Comprehensive, mutually exclusive, homogeneous and manageable.



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

 **Comunidad de Madrid**

Methodology

3.- Modified Delphi method (panel of experts):

- **12 participants:**

- 4 Neurologists (3 completed the 2nd round)
- 4 Vascular surgeons (3 completed the 2nd round)
- 4 Interventional radiologists/neuroradiologists (3 completed the 2nd round)

- **First round. Panelists rated each procedure in 512 scenarios on a 1-9 scale. No interaction among panelists.**



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

Comunidad de Madrid

Methodology

3.- Modified Delphi method (panel of experts):

▪ **Second round. Panel meeting.**

- **Discuss disagreements.**
- **Modify misunderstanding definitions**
- **Simplify redundant clinical scenarios.**
- **Panelists re-rated each procedure in 352 scenarios on the 1-9 scale.**



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

 **Comunidad de Madrid**

Methodology

4.- Analysis of data:

- **Classification of each scenario in appropriateness levels:**

What does disagreement mean?

Median	Disagreement	Appropriateness
7-9	No	Appropriate
4-6	-	Uncertain
1-3	No	Inappropriate
-	Yes	Uncertain

≥ 3 experts 1 2 3 4 5 6 7 8 9 ≥ 3 experts



6TH ANNUAL MEETING
HTAI
SINGAPORE 2009



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

Comunidad de Madrid

Methodology

4.- Analysis of data:



- **Influence of variables on the final appropriateness score was assessed by multiple linear regression.**
- **Results were summarized by classification and regression tree analysis (CART).**



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

Comunidad de Madrid

Results

Literature review

Endarterectomy

9 Systematic reviews

1 HTAR

3 RCT

33 Observational studies (> case series)

Endovascular treatment

2 Systematic reviews

3 HTAR

1 RCT

22 Observational studies (> case series)

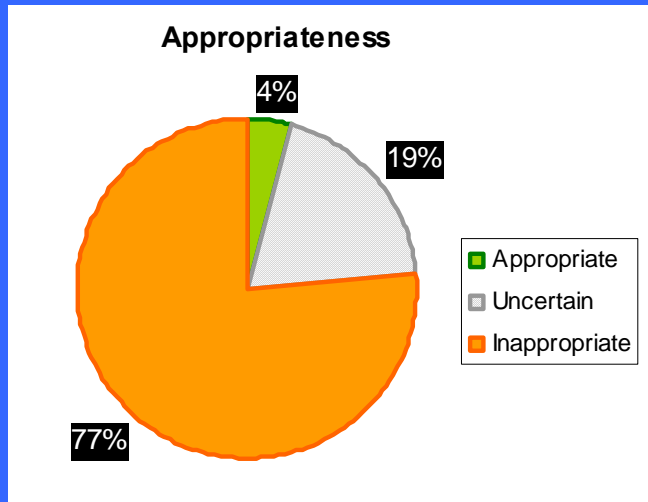
4 Consensus documents

1 HTAR

Results

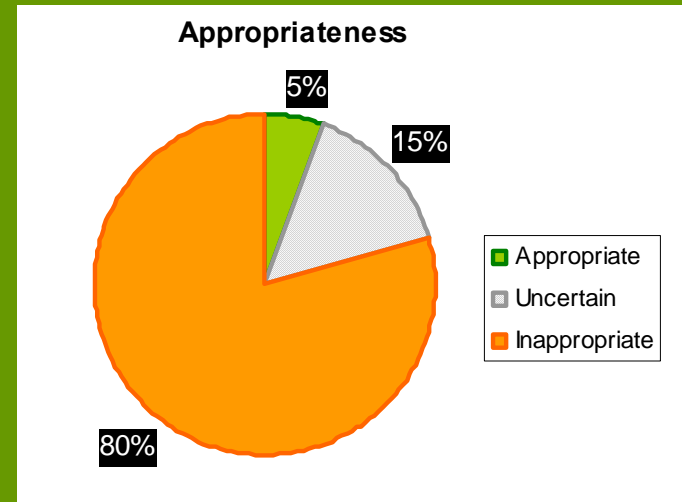
Appropriateness and Agreement levels

Endarterectomy



% of disagreement: 3%

Endovascular treatment

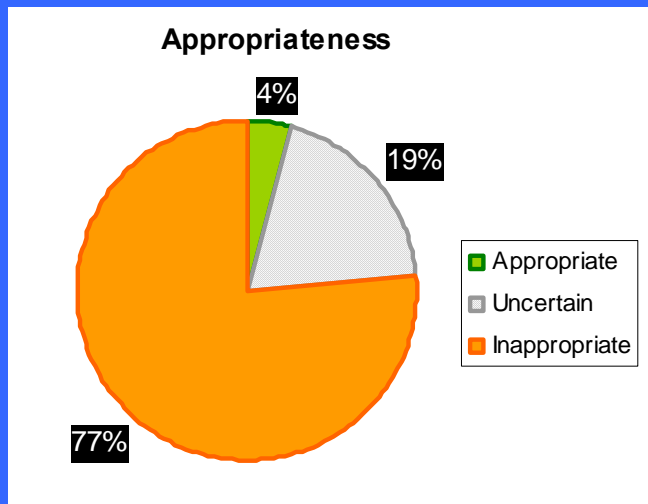


% of disagreement: 5%

Results

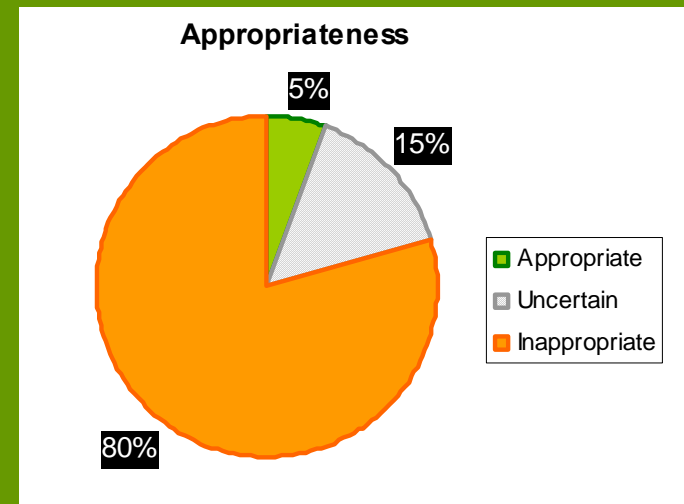
Contribution of each variable to the appropriateness score

Endarterectomy



Variability explained by included variables: 64%

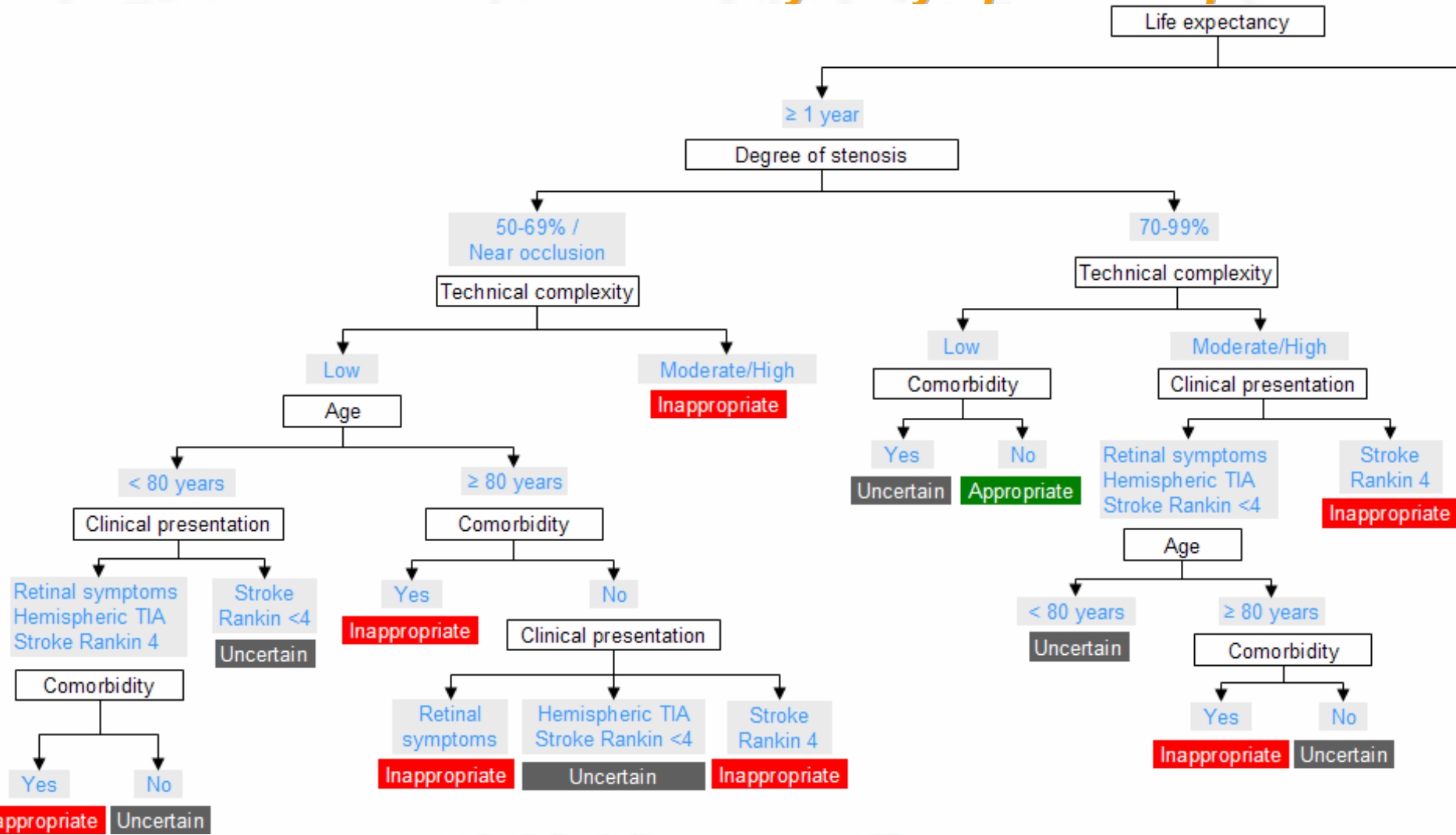
Endovascular treatment



Variability explained by included variables: 51%

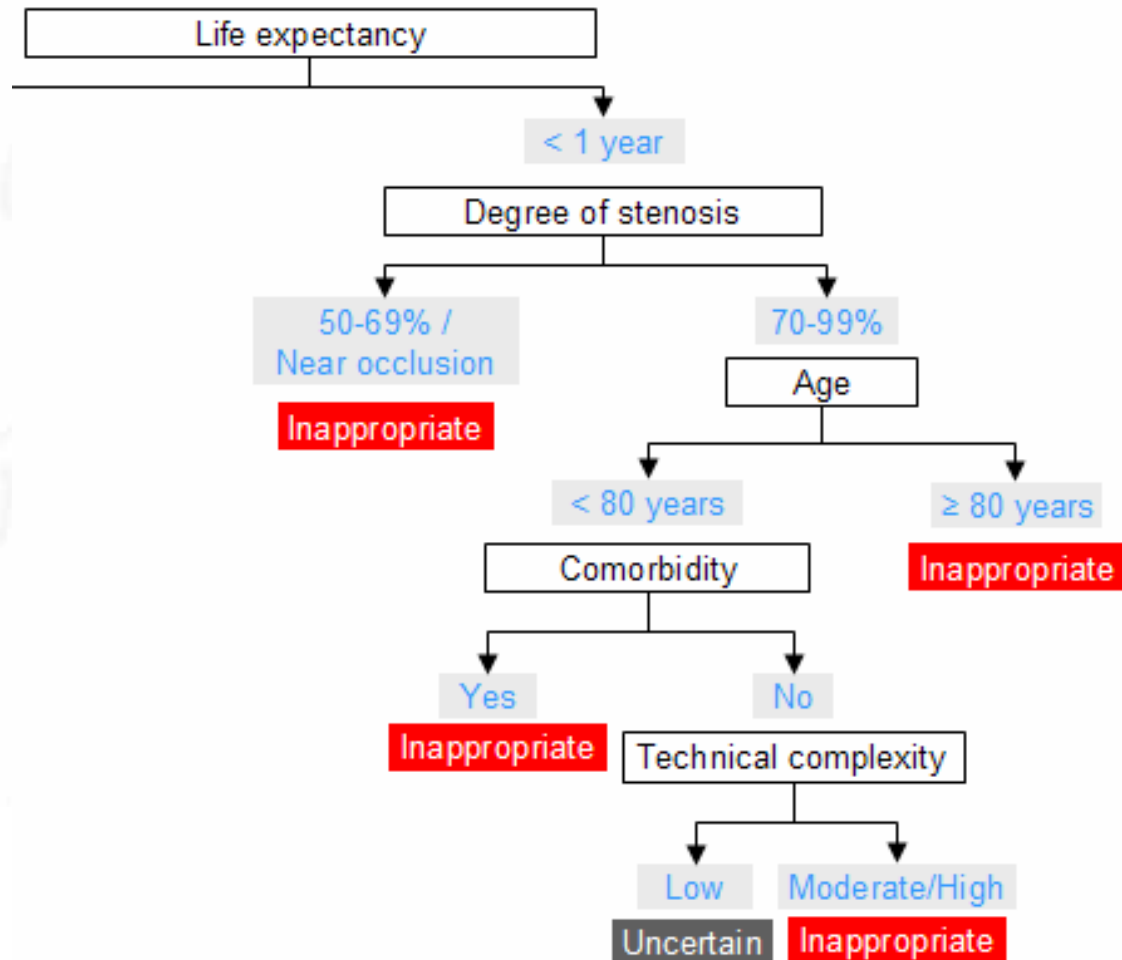
Results

Decision tree for endarterectomy in symptomatic patients



Results

Decision tree for endarterectomy in symptomatic patients



Applicability

■ **Clinical decision aids**

- **Algorithms**
- **Online**
- **Software packages**

■ **Health services research: measure underuse / overuse**

■ **Clinical practice guidelines development**

Carotid Revascularization

Start Main Glossary Understanding results RAND Appropriateness Method About

Clinical presentation

- Asymptomatic
- Retinal symptoms
- Hemispheric TIA
- Stroke with acceptable recovery
- Stroke with disabilities

Degree of stenosis

- 50 - 69 %
- 60 - 69 %
- 70 - 99 %
- Near occlusion

Gender

- Male
- Female

Age

- < 80 years
- >= 80 years

Comorbidity

- Present
- Absent

Life expectancy

- < 1 year
- >= 1 year
- < 5 years
- >= 5 years

Technical complexity

Endarterectomy

- Low
- Moderate / High

Endovascular

- Low
- Moderate / High

ENDARTERECTOMY

Assessment : - ? -

Median: - ? -

Level of agreement : - ? -

ENDOASCULAR TREATMENT

Assessment : - ? -

Median: - ? -

Level of agreement : - ? -

Calculate

Start

Conclusions

- *Low level of disagreement among experts.*
- *Application of appropriateness criteria to individual patients may be helpful in the decision making, but should always be made cautiously and never replace medical judgment.*
- *Other variables should be taken into account in some cases (variability explained by included variables is moderate).*
- *Software available in AUNETS -> <http://aunets.isciii.es>*
- *Future updates.*



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

Comunidad de Madrid

*La libertad es el estado natural de la humanidad
liberada para ser lo que es y no ser lo que no es.*

Thank you for your attention.

Juan Antonio Blasco: juan.blascoa@salud.madrid.org

Nerea Fdez. de Larrea: nerea.fernandez@salud.madrid.org

**Health Technology Assessment Unit, UETS
Madrid. Spain.**



Agencia Laín Entralgo
para la Formación, Investigación y Estudios Sanitarios

 **Comunidad de Madrid**