

Patient Views on Wireless Capsule Endoscopy in Italy: illuminating Safety and Acceptability

Marco Ratti, AGENAS

Marina Cerbo, Tom Jefferson, Alessandra Lo Scalzo

*Panel session: impact of including patient aspect in HTA
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Agenas and the Health Technology Assessment of WCE



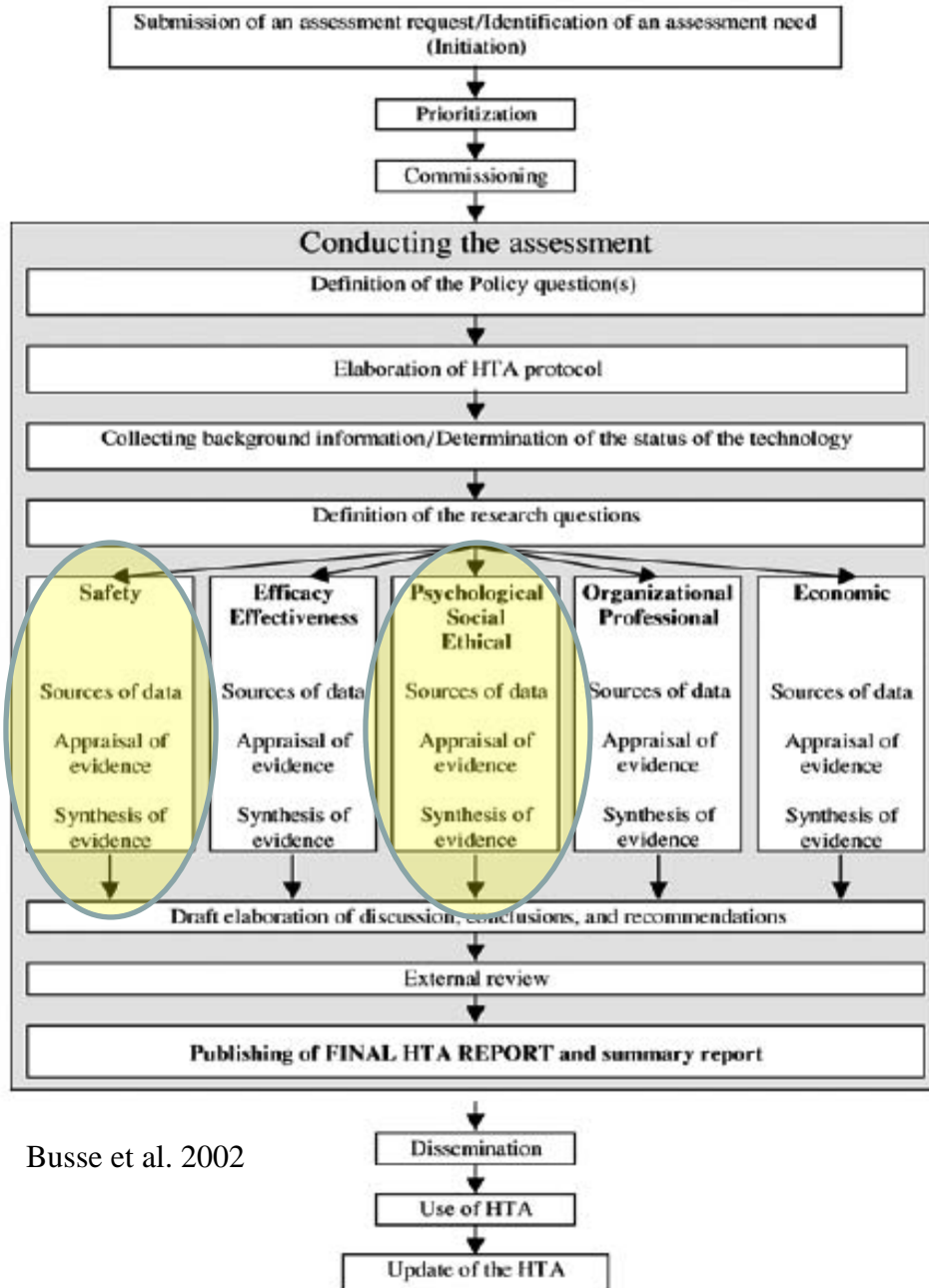
Committent: National Commission for Medical Devices - Italian Ministry of Health.

Is one of the first three Italian national HTA Reports

July 2007- Sept 2008

POLICY QUESTION OF HTA REPORT

What is the evidence of diagnostic accuracy underpinning the use of WCE and what are its use and cost in Italy?



Busse et al. 2002

Research question

What is the scientific evidence of WCE diagnostic accuracy, compared to other commonly used techniques?

What is the evidence of its safety and acceptability to patients in Italy?

Methods

➤ Systematic review of available evidence on:

- Effectiveness
- Safety



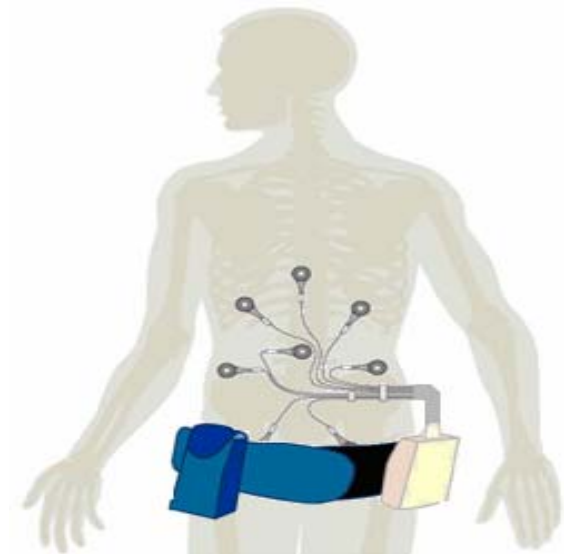
➤ National survey to collect context specific data:

- Use
- Efficacy
- Patients Views
- Real Safety
- Costs



WCE description

- WCE allows visualisation of small bowel.
- Main indication appears to be OGIB. Other indications: Crohn's disease (CD), Familial Polyposis (FAP), Coeliac disease (COD)
- The patient swallows a small capsule after fasting overnight (8-12 hours). The capsule contains a micro-imaging video technology, a light source and a wireless circuit for the acquisition and transmission of images. The system also includes software that provides localization of the device during its passage through the intestine. Patients is supposed to be able to move during registration. After the exam, the patient returns to the doctor's office and the recording device is removed.
- Comparators (literature): endoscopic procedures (e.g. Double Balloon Enteroscopy (DBE), Enteroclysis, Intraoperative Enteroscopy (IE), Push Enteroscopy (PE) and imaging procedures.



Systematic review - Safety

21 out of 27 identified studies describe events related to the safety for the patient

We clustered adverse events into two groups depending on the type of risk:

- **Adverse Events:** directly related to the patient's safety
 - **Technical Problems:** that can cause repetition of the procedure
-

Systematic review: safety

Complications with WCE in OGIB patients

	N° of patients	%
Technical problems	80	9%
Adverse events	23	3%
TOT OGIB patients	863	

Complications with WCE in CD patients

	N° of patients	%
Technical problems	2	1%
Adverse events	6	2%
N° patients not eligible for strictures detected before WCE	29	10%
TOT eligible CD patients	281	

Safety of systematic review

Complications with WCE in FP patients

	N° of patients	%
Technical problems	1	1%
Adverse events	8	9%
TOT OGIB patients	92	

Complications with WCE in all patients

	N° of patients	%
Technical problems	82	7%
Adverse events	37	3%
TOT patients	1236	

Safety of systematic review

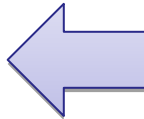
The principal producer (Given Imaging Ltd and Olympus Corporation) says that the capsule is:

➤ “the **least invasive** and most direct way for doctor’s to see the entire small intestine..”(Given).

➤ “this examination method is expected to make life easier for patients because the endoscopes take the form of easy-to-swallow capsules that do not require topical anesthesia in the throat” (Olympus)

But our preliminary safety analysis in the literature indicates:

- 3% Adverse Events
- 7% Technical Problems



Are patients (and physicians) advised of this data?

Collection of context specific data

Objectives	Methods (survey via questionnaires)	Materials
Actual diffusion of WCE in Italy (appropriateness of use, safety and cost)	Questionnaire to all centres providing WCE in Italy in 2007	116 centers - 2457 procedures in 2007
Patient views	Questionnaire to patients	In 5 selected centres - 127 recruited patients January-may 2008

Italian clinical practice: safety

Adverse Events

1%

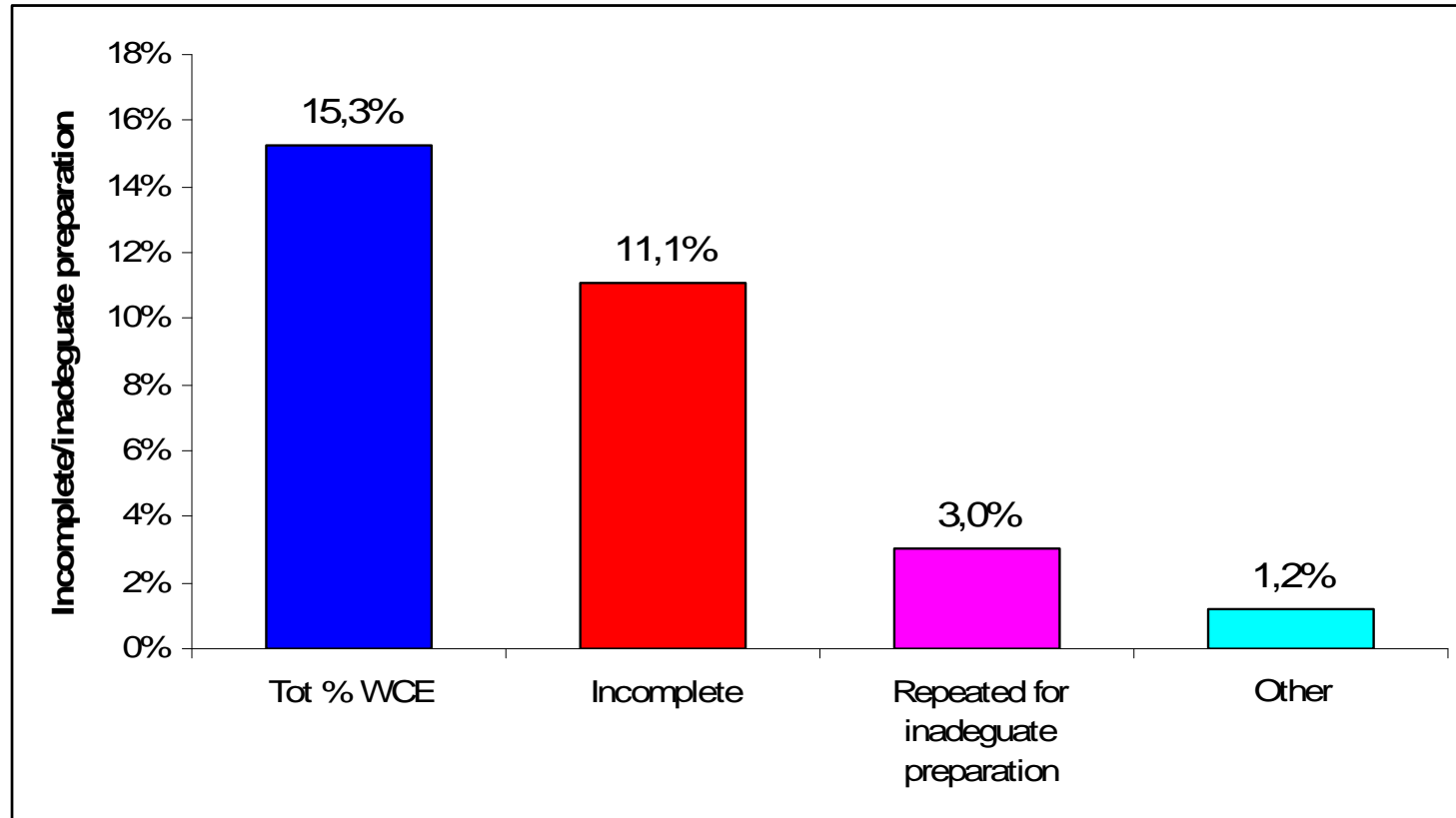
WCE RETENTION: 9/17

INTESTINAL OCCLUSION: 6/17

OTHERS 2/17



Incomplete/inadequate preparation with WCE (n=375)



Source: Age.na.s survey, 2008

Patient Views

Objective

Our objective was to collect information on the acceptability of the WCE by patients compared to other endoscopic interventions (Colonoscopy, EGDS) which are supposed to be more “invasive” and thus less acceptable

Methodology

Five centres amongst the ones that completed our questionnaire were selected on the basis of the highest number of WCE procedures performed per year: from a minimum 80 to a maximum of 190 WCE per year.

Questionnaire is aimed at gathering data on:

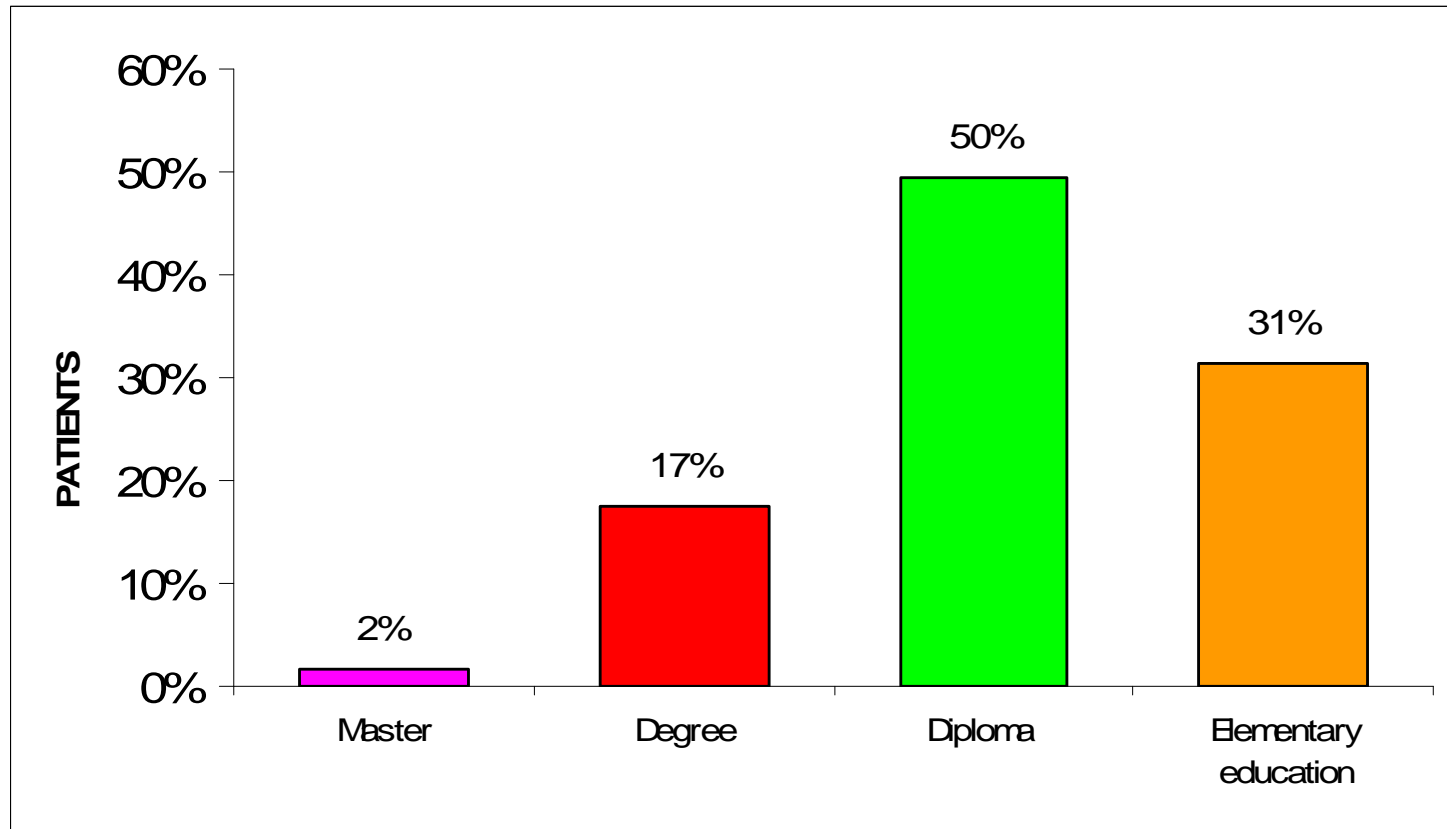
- ✓ Socio economical characteristics of patients
- ✓ Acceptability dimensions for the WCE and other more invasive endoscopies

Patient Views

Socio economical characteristics of patients:

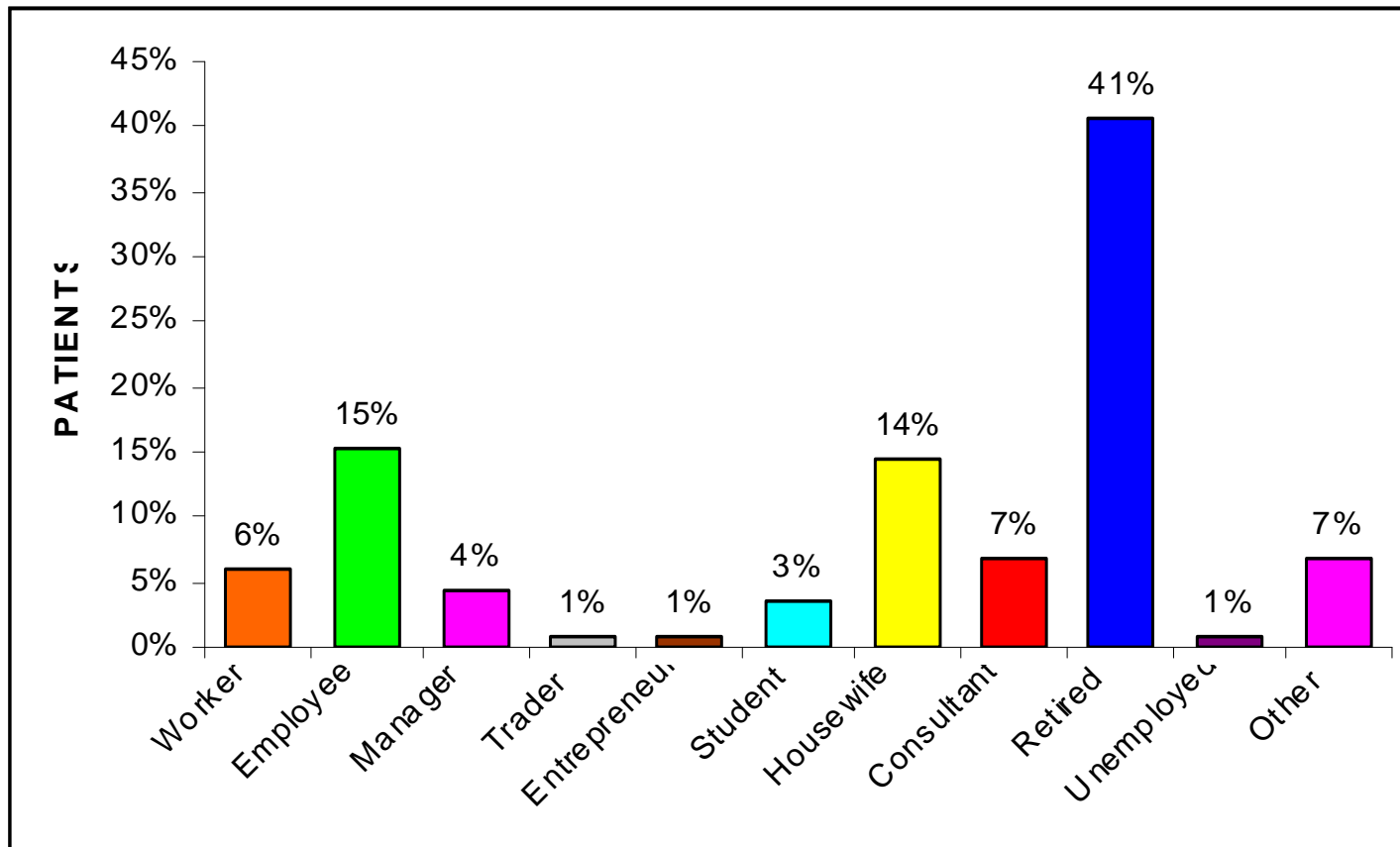
- Age;
- Gender;
- Status;
- Education;
- Occupation
- Loss of productivity

Educational qualification of patients (n=115)



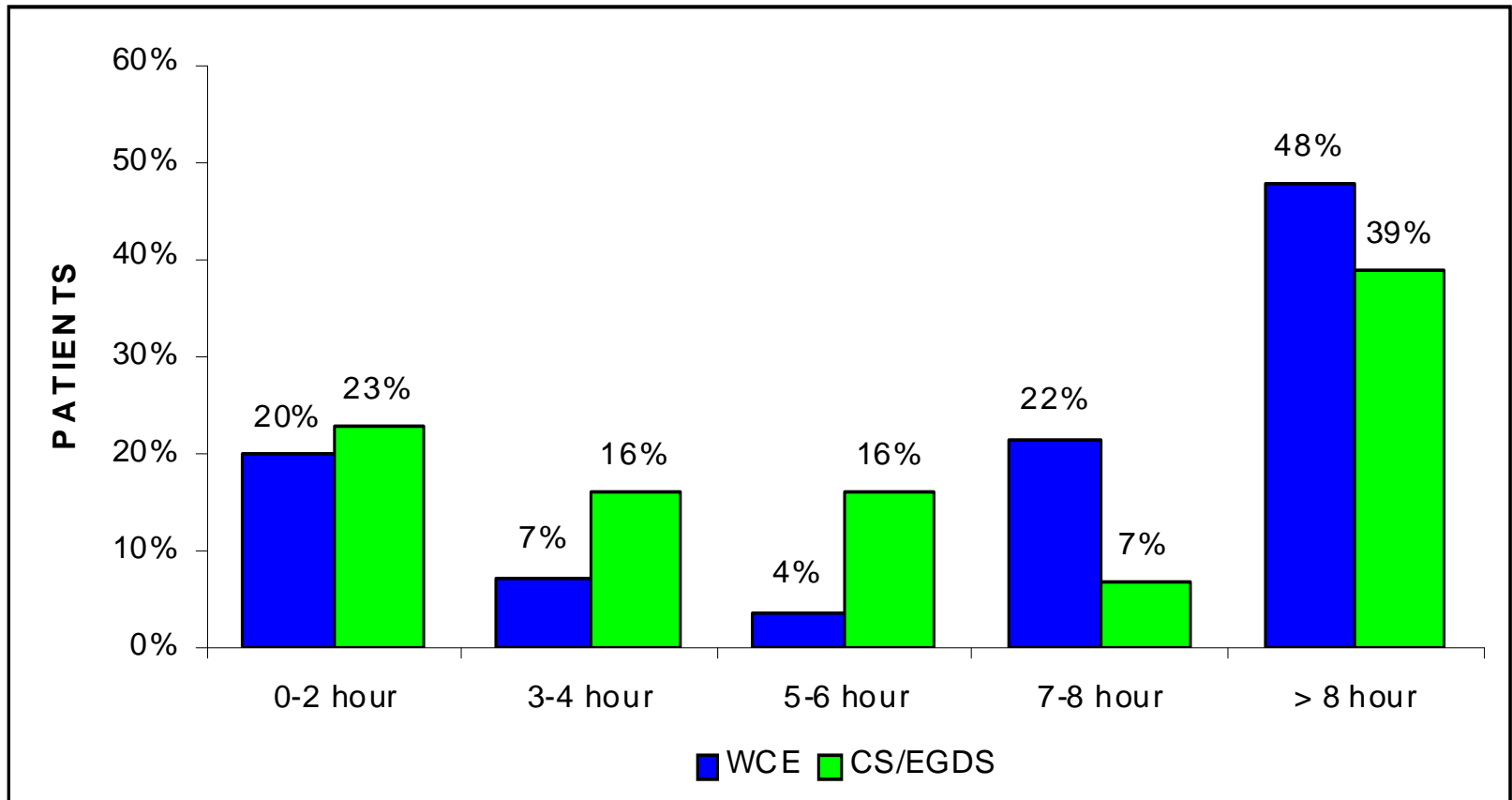
Source: Age.na.s survey, 2008

Occupation of patients (n=118)



Source: Age.na.s survey, 2008

Time off work for WCE (n=111) and for CS/EGDS (n=106)



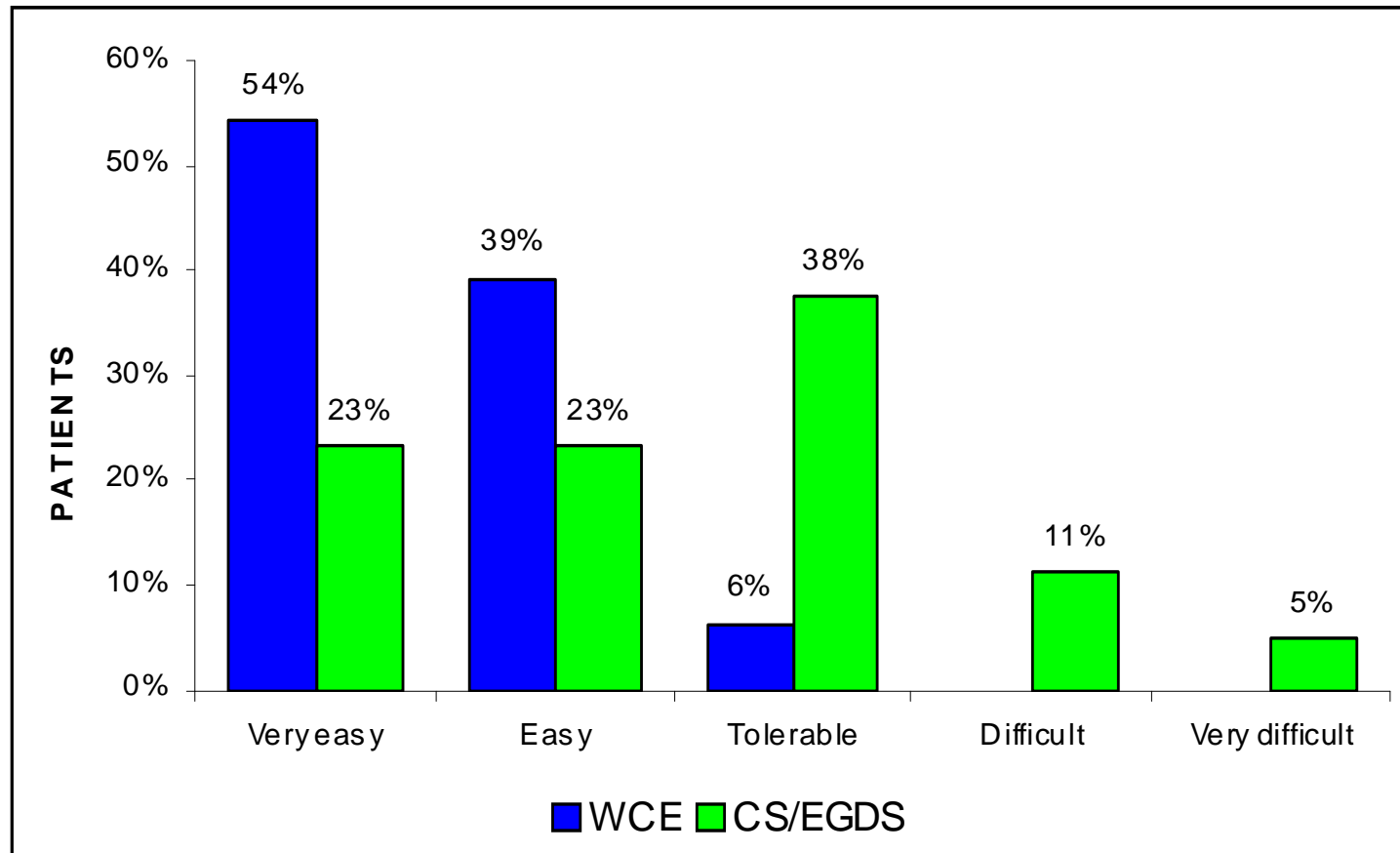
Source: Age.na.s survey, 2008

Patient Views

Acceptability dimensions for the WCE and other endoscopies:

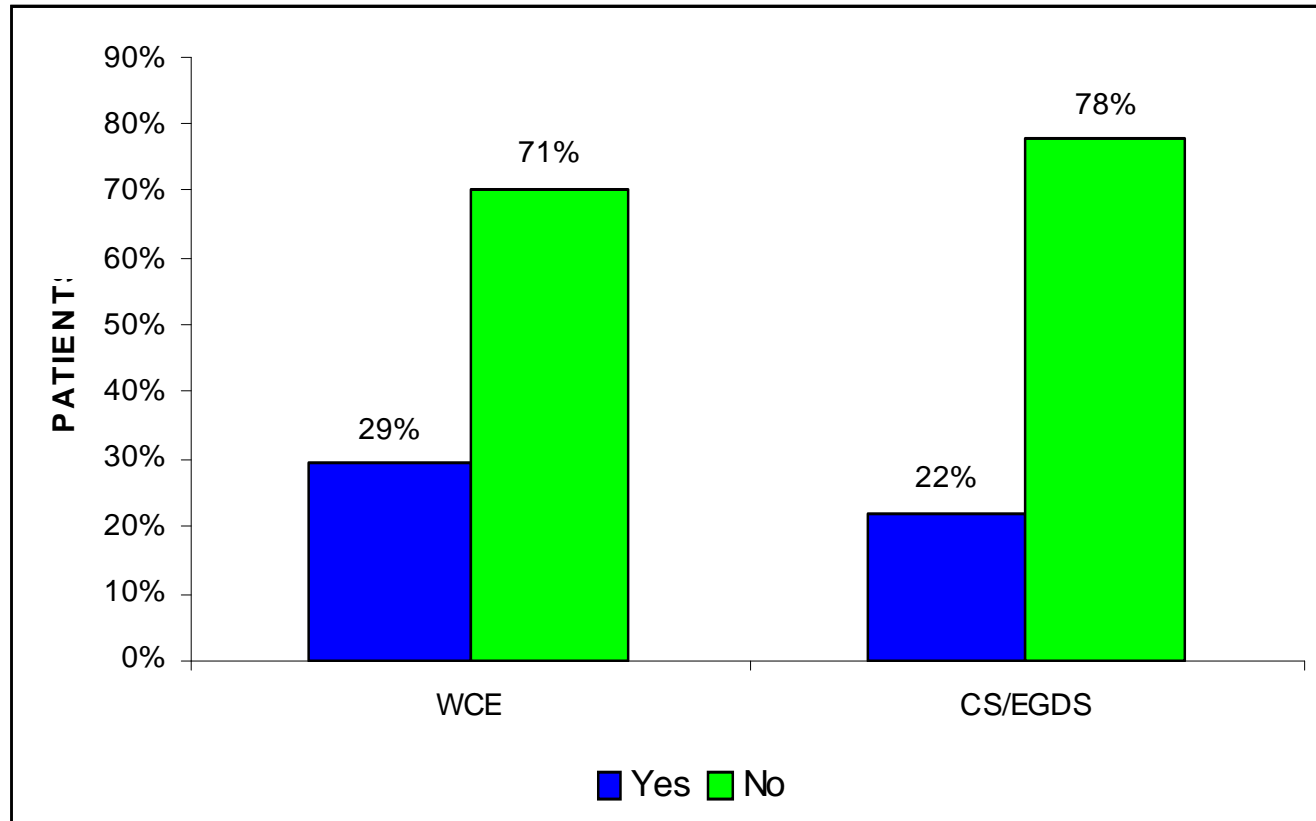
- Ease of execution of the procedure
- Difficulty of movement during the recording/procedure
- Pain during and after the procedure
- Anxiety in patients
- Total level of tolerability

Ease of execution of the procedure WCE (n=125) and CS/EGDS (n=125)



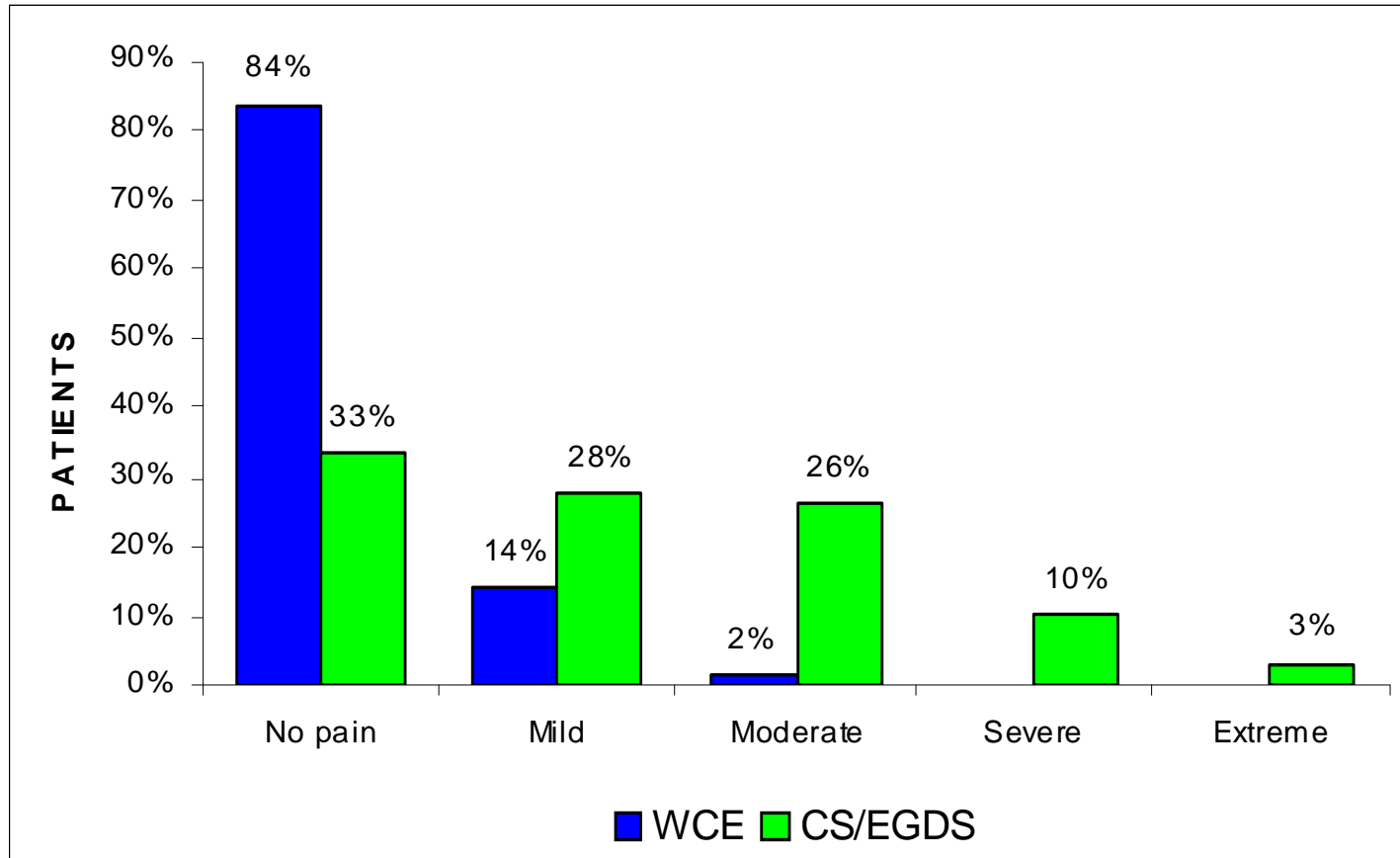
Source: Age.na.s survey, 2008

Difficulty of movement during the recording/procedure with WCE (n=126) and CS/EGDS (n=117)



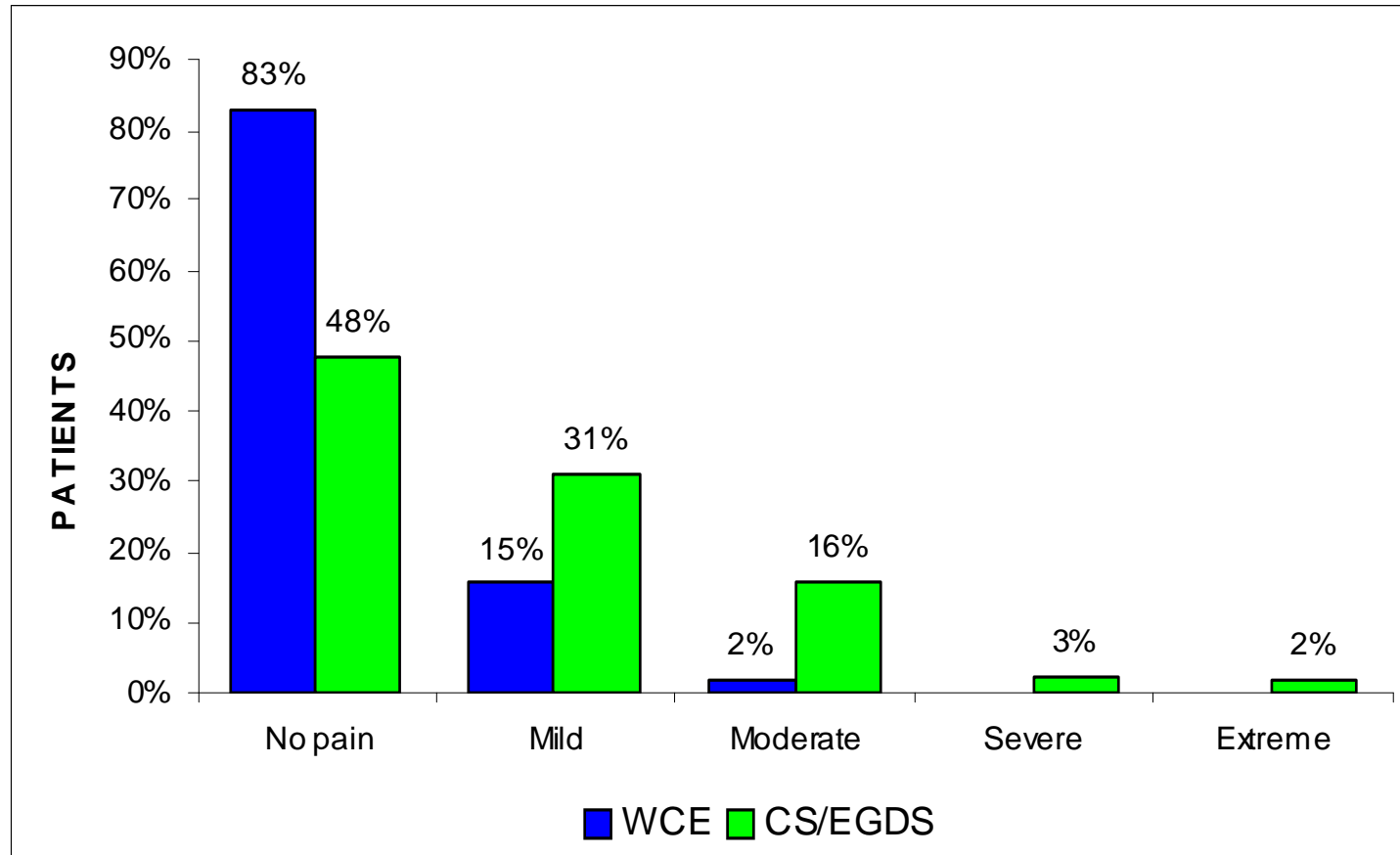
Source: Age.na.s survey, 2008

Pain during the procedure with WCE (n=123) and CS/EGDS (n=126)



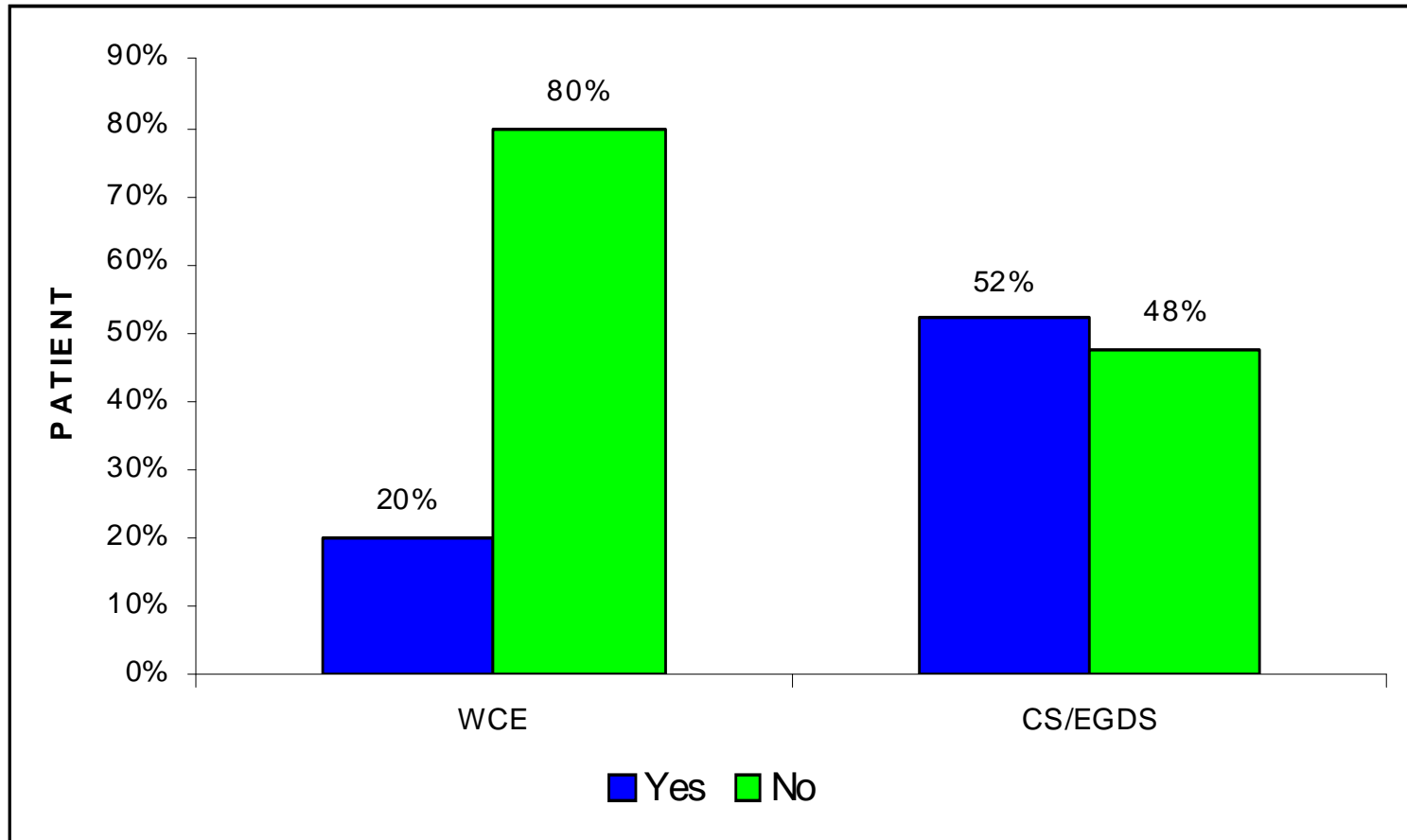
Source: Age.na.s survey, 2008

Pain after the procedure with WCE (n=110) and CS/EGDS (n=119)



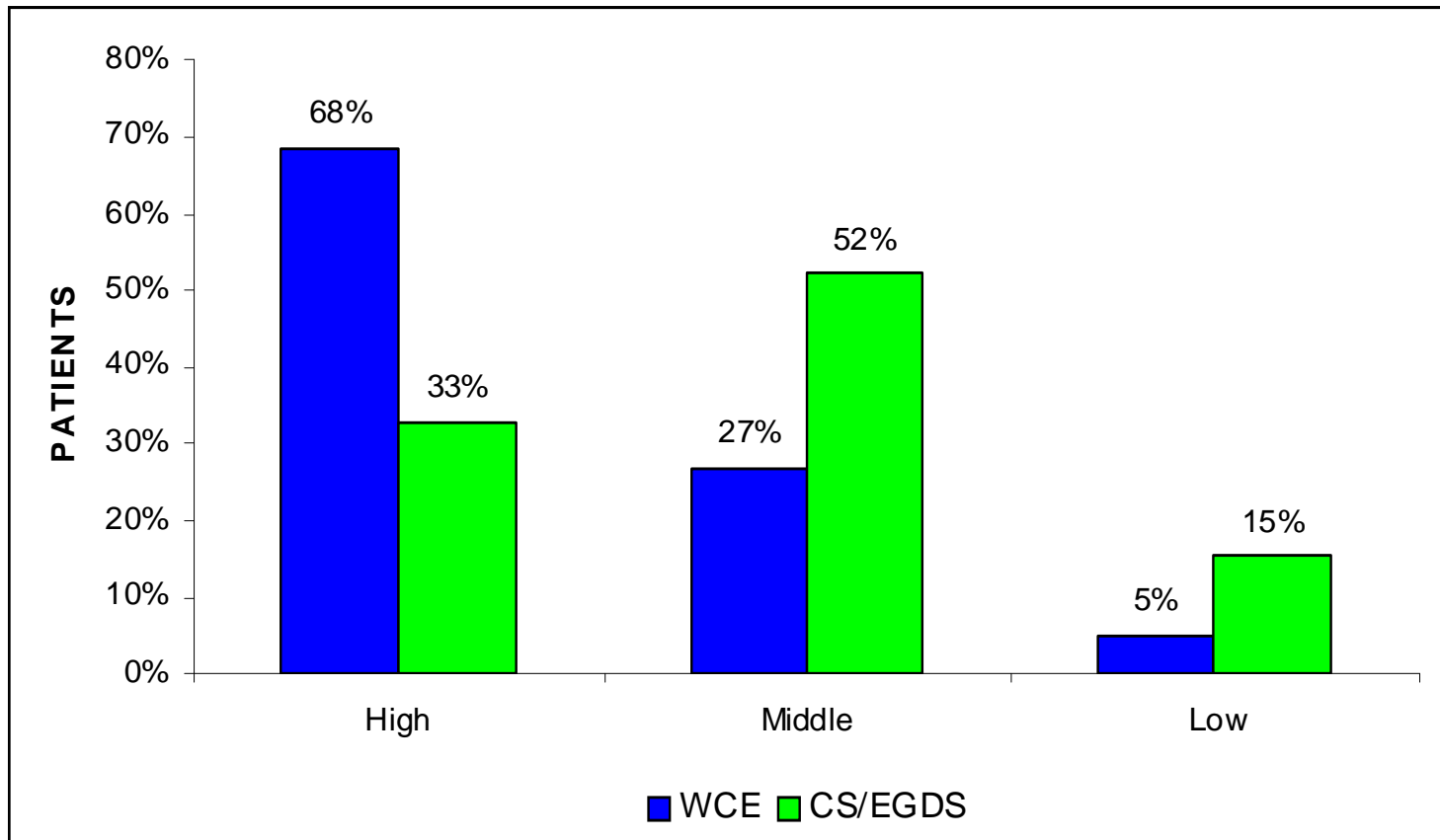
Source: Age.na.s survey, 2008

Anxiety in patients undergoing the WCE procedure (n=124) and CS/EGDS (n=115)



Source: Age.na.s survey, 2008

Total level of tolerability of WCE procedure (n=123) and CS/EGDS (n=119)



Source: Age.na.s survey, 2008

Conclusions

- ❑ **Better tolerability of WCE versus other endoscopic procedures (EGDS / CS) by patients, BUT:**

Our data on safety show a higher percentage of “adverse effects”, than the percentage taken from the literature and stated by the producer

Positive and negative impact of including patients

- The assessment of patient's dimension through generation of new data did not increase very much costs and time spent for the overall evaluation.
- We had the chance to verify some of the producer's statements.
- Doubts on the specific weight that an assessment on the patients' dimension can have on the final recommendation, when this is not pulled in a Cost Utility Analysis. This probably depends on the type of technology assessed (procedure/drug/medical device)

Thank you
ratti@agenas.it

The entire HTA report on WCE can be downloaded at:
http://www.ministerosalute.it/imgs/C_17_pagineAree_1202_listaFile_itemName_3_file.pdf
