



**QUALITY IN ENDOSCOPY**

**UPPER GI ENDOSCOPY  
& NEOPLASIA**

# Is sedation necessary?

## - Con

**Name: Pedro Amaro**

**Institution: Coimbra University Hospital**

**Country: Portugal**



# Is sedation necessary?

- Does it increase quality in upper GI endoscopy?
- Is it safe?
- Is it cost-effective?
- Is it feasible?

# Is sedation necessary?

- Does it increase quality in upper GI endoscopy?

**QUALITY IN ENDOSCOPY**

# Is sedation necessary?

- Does it increase quality in upper GI endoscopy?

**QUALITY IN ENDOSCOPY**

**UPPER GI ENDOSCOPY & NEOPLASIA**

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better upper GI endoscopy?**
    - Higher completion rate?
    - Better endoscopic evaluation?
    - More patient tolerance and acceptance?
    - More endoscopist/nurse satisfaction?

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better neoplasia evaluation?**
    - Improved neoplasia detection?
    - (Improved neoplasia characterization)
    - (Improved neoplasia endoscopic treatment)

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better upper GI endoscopy?**
    - More technically adequate and satisfactory
    - Better tolerance
    - Less unpleasant memories
    - More willingness to repeat

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better upper GI endoscopy?**
  - **Assessing clinical generalizability in sedation studies of upper GI endoscopy**

Abraham NS, Wieczorek P, Huang J, Mayrand S, Fallone CA, Barkun AN.  
*Gastrointest Endosc* 2004;60(1):28-33



# Is sedation necessary?

- Does it increase quality in upper GI endoscopy?
  - Better upper GI endoscopy?
  - Sedation studies of upper GI endoscopy
    - ***Inclusion bias***
      - underestimating the benefit of non-sedated UGIE

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better upper GI endoscopy?**
  - **Sedation studies of upper GI endoscopy**
    - Significant number of refusals to participate in the RCT
    - Most common reason: request for no sedation!
    - Predictor of refusal: UGIE experience

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better upper GI endoscopy?**
  - **Sedation studies of upper GI endoscopy**
    - Outcomes?
    - Similar between non-sedated patients by option and sedated patients (opting or randomized)

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better upper GI endoscopy?**
  - **Sedation studies of upper GI endoscopy**
    - Outcome?
    - UGIE more adequate and better tolerated in those refusing sedation than in those having placebo

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better upper GI endoscopy?**
  - **Sedation studies of upper GI endoscopy**
  - Inadequate methodology
    - Lack of blinding
    - Study hypothesis not well defined
    - No sample size estimation; Inadequate sample size
    - Lack of external validation

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better neoplasia evaluation?**
    - Very few (if any) data from the literature
    - Improved quality of global endoscopic assessment
      - Propofol better than midazolam (randomized trial)
        - No control (non-sedated) group

Meining *et al.* *Endoscopy* 2007

# Is sedation necessary?

- **Does it increase quality in upper GI endoscopy?**
  - **Better neoplasia evaluation?**
    - In what setting?
      - Screening? (opportunistic? high-risk groups?)
      - Surveillance? (Barrett's? Chronic atrophic gastritis?)
      - Characterization?

# Is sedation necessary?

- **Is it safe?**

- Safety has been reasonably well demonstrated
- Conscious sedation (BZD±opioids) USA
  - n= 324 737
    - Unplanned events 1,4%
      - Cardiopulmonary unplanned events
        - 0,6% UGI endoscopy (0,9% global)
      - Cardiopulmonary deaths (8 per 100 000)



# Is sedation necessary?

- **Is it safe?**

- Safety has been reasonably well demonstrated
- Endoscopist-directed admin. propofol worldwide
  - n= 646 080
    - Endotracheal intubations 11
    - Neurological injuries 0
    - Deaths 4
  - Mask ventilation 0,1% (++) UGIE)

# Is sedation necessary?

- **Is it safe?**
  - Safety has been reasonably well demonstrated
- **Uncertainties**
  - Causality of unplanned cardiopulmonary events
    - Sedation or procedure related?
      - Equivocal effects of sedation on cardiac stress...

# Is sedation necessary?

- **Is it safe?**

- Safety has been reasonably well demonstrated

- **Limitations**

- Studies not prospective
- Heterogeneous levels of sedation
- Under reporting (ex. Clinical Outcomes Research Initiative)
- Limited time-scale of observation
  - 30 days for surgical procedures...

# Is sedation necessary?

- **Is it safe?**

- Safety has been reasonably well demonstrated

- **Limitations**

Prospective analysis of complications 30 days after outpatient colonoscopy  
Zubarik R, *et al. Gastrointest Endosc* 1999

- Phone interview after 30 days
- Higher number of reported complications (+ first 48 h)
- Unknown admissions to emergency dpts., physician consultations
- Unexpected time lost from work in 10%

# Is sedation necessary?

- **Is it safe?**

- Safety has been reasonably well demonstrated
- Endoscopist-directed admin. propofol ± midazolam (47,5%)
  - n= 7 893; German multicenter study, inquiry at 24 h

• Nausea, dizziness or vomiting	3%
• Cough	7,8%
• With fever	0,24%
• With shortness of breath	1,1%

# Is sedation necessary?

- **Is it safe?**
  - Safety has been reasonably well demonstrated
  - Non-sedated UGIE is...
    - ... **“sedation-risk free endoscopy”**

# Is sedation necessary?

- **Is it cost-effective?**
  - Costs
    - Direct cost of the endoscopic procedure
      - Anesthetic consultation and routines
      - Dedicated personnel
      - Drugs, gases
      - Venous access, lines, fluids
      - Monitoring
      - Facilities
      - Time

# Is sedation necessary?

- **Is it cost-effective?**
  - Costs
    - Indirect costs for the staff
      - Formation, training, certification, recertification
      - Distress (medical responsibility; legal issues)



# Is sedation necessary?

- **Is it cost-effective?**
  - Costs
    - Indirect costs for patient and others
      - Time lost from work (patient and escort)
      - Cost of care of childs and other dependents

# Is sedation necessary?

- **Is it feasible?**

- National differences

- Data and circumstances are not interchangeable among countries

- <25% UGIE with sedation in 47% of ESGE countries

*Ladas S, et al. Digestion 2006*

- Great variability

- Spain 17% (2004) vs Switzerland 77% (2003)

*Campo R, et al. Gastroenterol Hepatol 2004; Heuss LT et al. Endoscopy 2005*

# Is sedation necessary?

- **Is it feasible?**

- National differences

- Data and circumstances are not interchangeable among countries

- Different trends

- UK (1990>1998; 70>32%) *versus*

Switzerland (2003>2010; 77>83%)

Mulcahy HE *et al. Aliment Pharmacol Ther* 2001

Heuss *et al. Endoscopy* 2012

# Is sedation necessary?

- **Is it feasible?**
  - National differences
  - Regulatory issues
    - Health authorities
      - Restriction of moderate to deep sedation to anesthesiologists or intensive-care specialists

# Is sedation necessary?

- **Is it feasible?**
  - National differences
  - Regulatory issues
  - Economic factors
    - Continuing pressure to improve efficiency and reduce costs

# Is sedation necessary?

- **Is it feasible?**
  - National differences
  - Regulatory issues
  - Economic factors
  - Cultural and socio-economic status
    - Variable patients wishes and experiences

# Is sedation necessary?

- **Is it feasible?**
  - National differences
  - Regulatory issues
  - Economic factors
  - Cultural and socio-economic status
  - Diverging endoscopist/nurse attitude

# Is sedation necessary?

- **Conclusions**
- Quality of UGIE is probably improved
  - At best, global accuracy is increased
    - Neoplasia? Only by extrapolation...
  - Higher completion rate and patient satisfaction
    - In spite of inclusion bias



# Is sedation necessary?

- **Conclusions**
- Safety data seem reassuring
  - Better studies are welcome
  - Non-anesthesiologist sedation needs formal structured training programs and accreditation

# Is sedation necessary?

- **Conclusions**
- Cost-effectiveness is clearly not demonstrated
- Feasibility
  - Higher levels of endoscopic unit organization and availability of more differentiated personnel resources