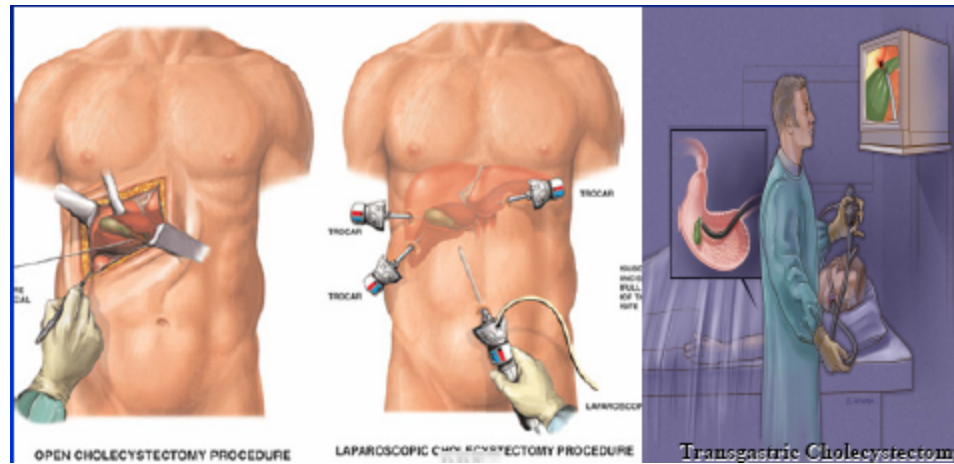


NOTES – From Dream to Reality



R Sim

TTS Hospital

- What?
- Why?
- How?
- Who?



- N - Natural
- O - Orifice
- T - Transluminal
- E - Endoscopic
- S - Surgery



Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR)

Home

White Paper

2006 Conference

General Presentations

Summary Presentations

Corporate Sponsors

ASGE Web Site

SAGES Web Site

Email: info@noscar.org

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ASGE

1520 Kensington Road

Suite 202

Oak Brook, IL 60523

SAGES

11200 W. Olympic Blvd

Welcome to NOSCAR.ORG

A joint initiative supported by the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

It is unique in one's career in medicine to see a true paradigm shift that significantly changes patient management. This generation experienced such a paradigm shift with the introduction and development of laparoscopic surgery. It is possible that we are on the verge of another paradigm shift - **Natural Orifice Transluminal Endoscopic Surgery (NOTES)**.

To address this emerging technology, a working group consisting of expert laparoscopic surgeons from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and a group of expert interventional endoscopists representing the American Society for Gastrointestinal Endoscopy (ASGE) came together for a meeting in New York City in July 2005. This group identified itself as the Working Group on Natural Orifice Transluminal Endoscopic Surgery. The overriding goal of the meeting was to produce a

About NOSCAR :

For more information about NOSCAR, contact either ASGE



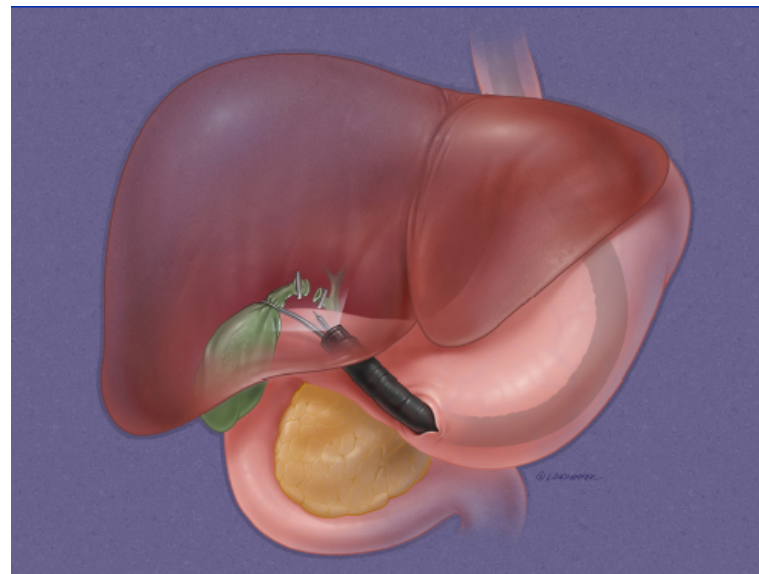
or SAGES



Digestive Disease Week® 2006

May 20-25, 2006 Los Angeles Convention Center

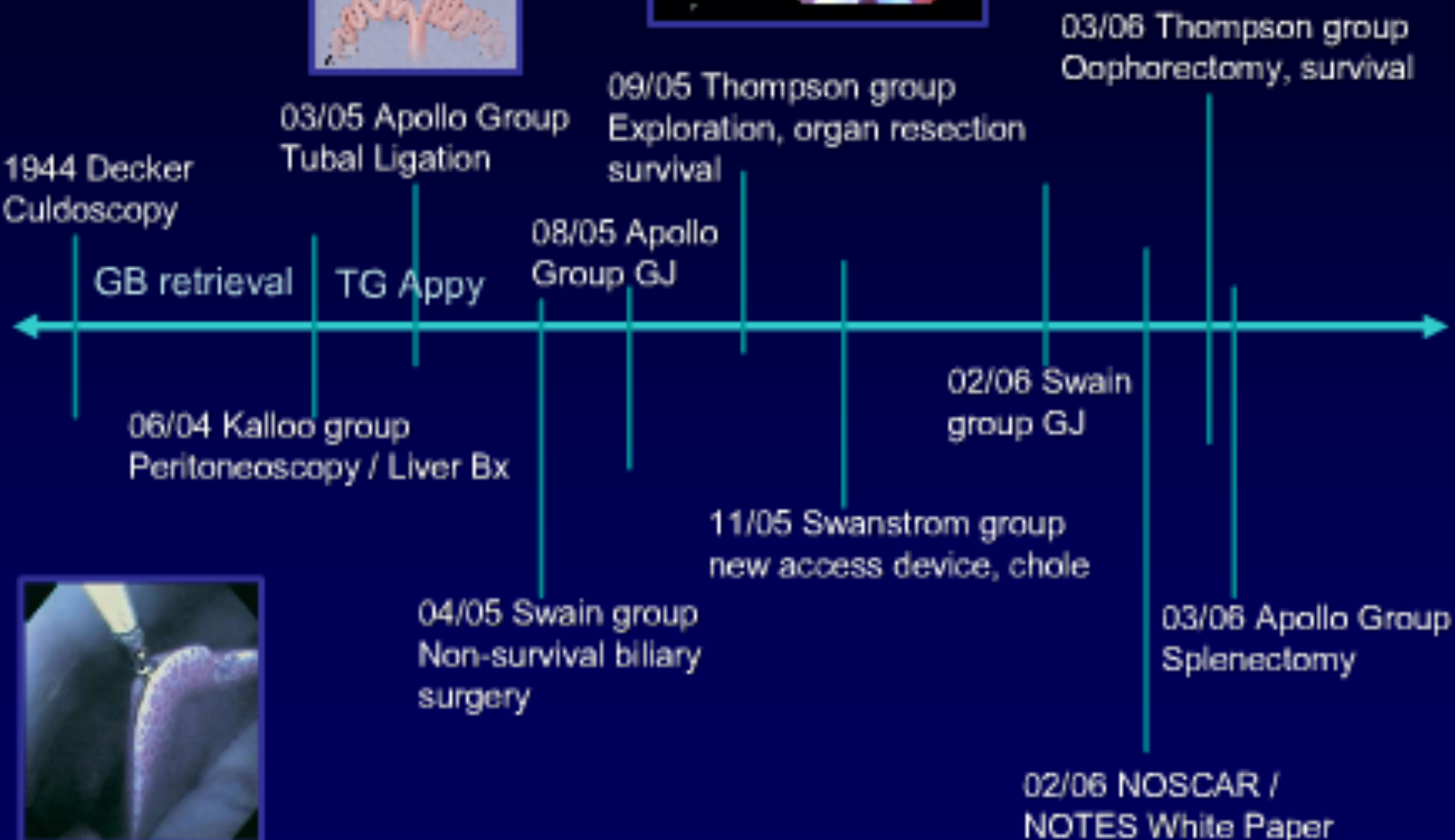
Turning Science into Medicine



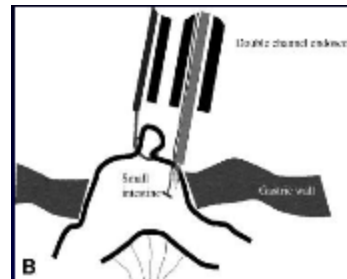
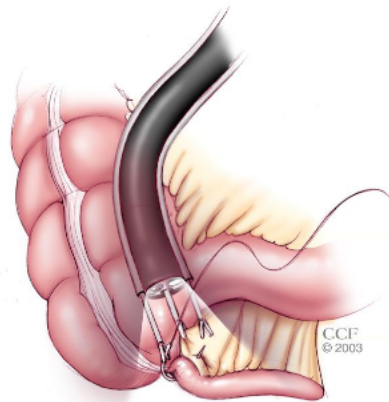
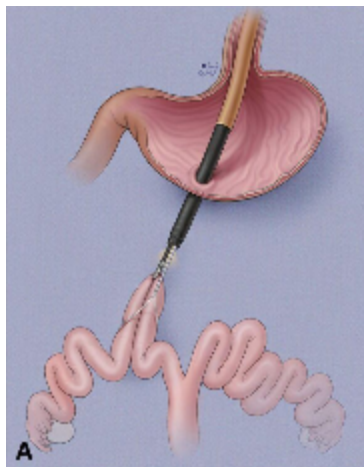
Transgastric appendicectomy- the first human case



(Rao 2003)



- Appendicectomy, liver biopsy, peritoneoscopy has been performed in humans
- Cholecystectomy, pyloroplasty, full thickness resection, anastomosis, Nissen fundoplication, lymphadenectomy, fallopian tube ligation, diaphragmatic suturing and pacing, bariatric procedures and have been performed in pigs and human cadavers
- Transanal cholecystectomy and transesophageal cardiac procedures have been performed



Why?

The Conventional Answer

- **Replace current laparoscopic techniques to improve outcomes**
 - **Less complications**
 - **Cosmetic**
 - **Other**
 - **Reduced adhesions**
 - **Improved motility: less ileus**
 - **Less pain**
 - **Improve access over laparoscopy**
 - **Obese patient**
 - **Improve costs and efficiency**

NOTES: back to the future?

Touted Advantages of Laparoscopic compared to Open Surgery

- **Shorter hospitalization**
- **Reduced postoperative pain**
- **Less pulmonary complications (atelectasis)**
- **Faster recovery**
- **Fewer wound complications (incisional hernias and infections)**

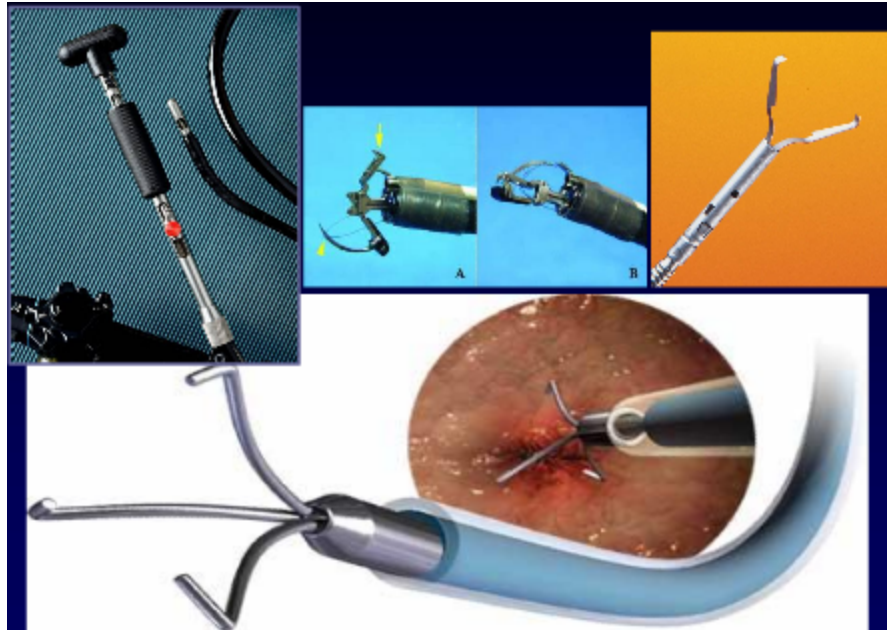
Phase I: Exploration Results

- 9/9 peritoneal cavity accessed uneventfully
- Successful evaluation
 - Parietal peritoneum, anterior stomach, small bowel, colon, urinary bladder, uterus, fallopian tubes and ovaries were easily identified in all cases
- Limitations
 - Gallbladder identified 5/9
 - Portions of liver and spleen could not be evaluated
 - Retroperitoneal organs could not be consistently evaluated



Table 2. Potential barriers to clinical practice

Access to peritoneal cavity
Gastric (intestinal) closure
Prevention of infection
Development of suturing device
Development of anastomotic (nonsuturing device)
Spatial orientation
Development of a multitasking platform to accomplish procedures
Control of intraperitoneal hemorrhage
Management of iatrogenic intraperitoneal complications
Physiologic untoward events
Compression syndromes
Training other providers



What We've Learned

- The peritoneal cavity can be safely accessed and explored using the transgastric and transcolonic approaches (with limitations)
- Aseptic technique is still important
- Closure of access site is very challenging and likely critical
- Platform stability and triangulation are necessary for more complex procedures



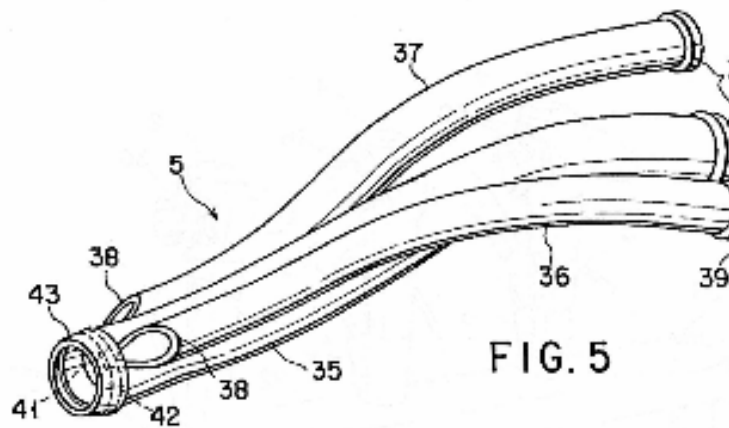
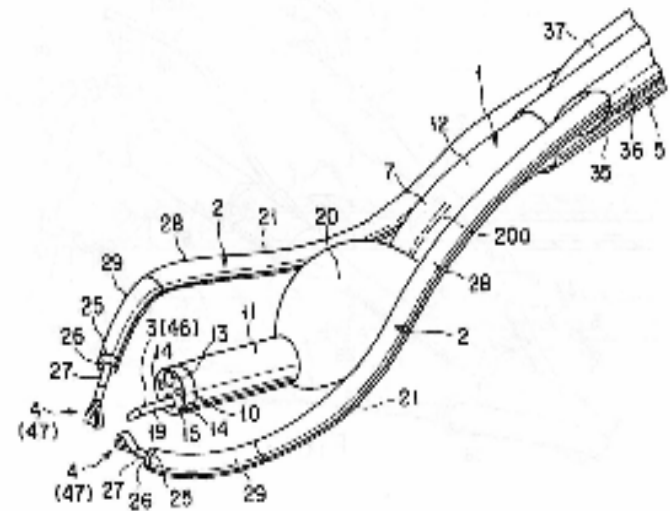
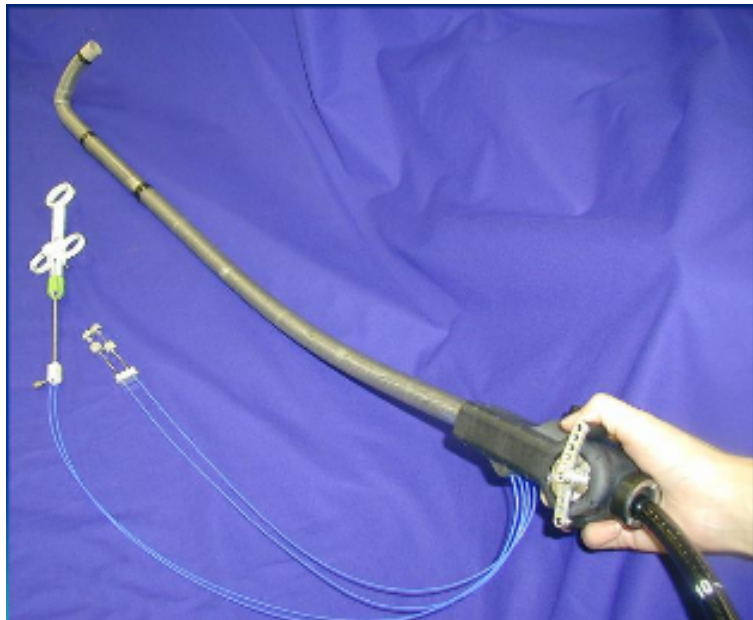


FIG. 5

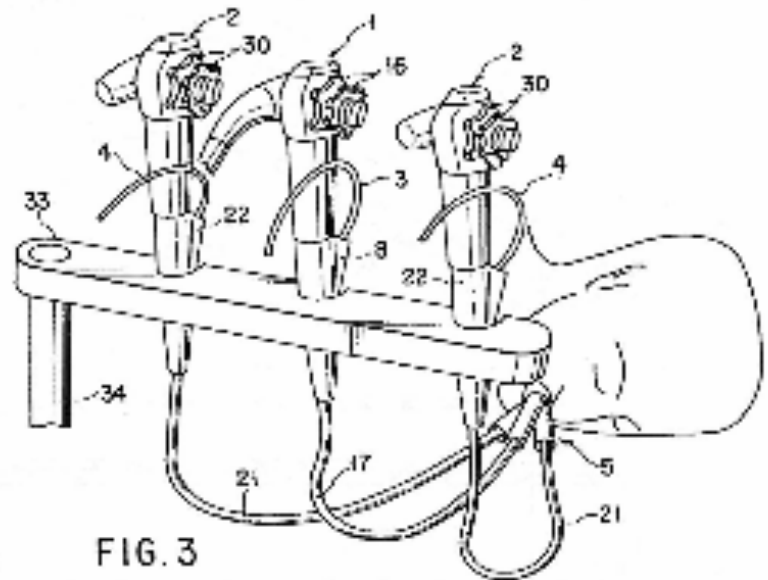


FIG. 3



The USGI Medical® TransPort™



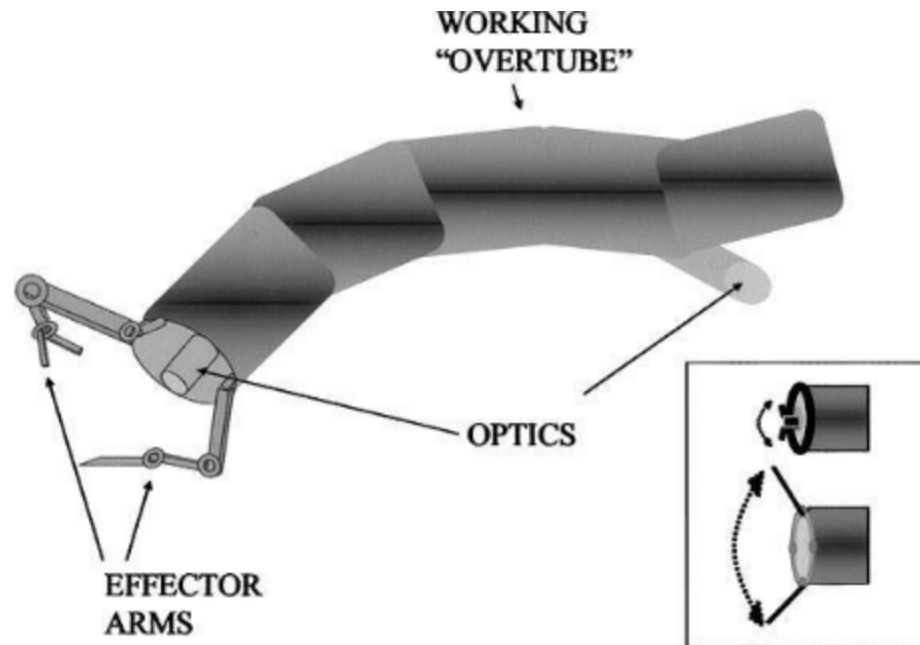
The device has 4 channels for instruments of different sizes, one of which will usually be used with a small diameter (5.2 mm) gastroscope



Shape-locked transport allow effective retraction of the cystic duct and artery



Forwards force causes flexible instruments to buckle and push gastroscope away from target tissue



Multi-functional "Hands"



Impact of Minimally Invasive Surgery:

Will NOTES have the same?

- + Challenged dogma on patient management
 - 🌐 bowel surgery
- + Changed/expanded indications for surgery
- + Halo effect on other disciplines
 - 🌐 endovascular repair of AAA
- + Accelerated consumer driven medicine
 - direct marketing to patients by industry

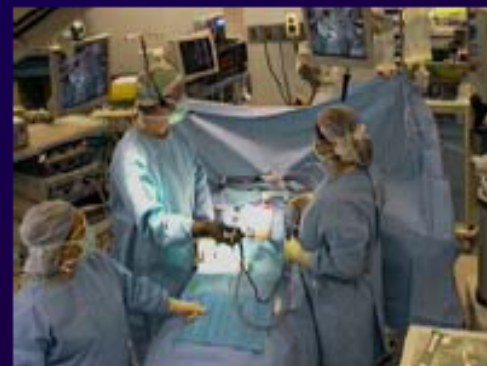
Can NOTES Compete for Common Surgical Procedures?

- **Less complications?**
 - Unknown
 - Unlikely to be significantly better
 - Learning curve problems will be significant
- **Eliminate Need for an anesthesiologist?**
 - No

Can NOTES Compete for Common Surgical Procedures?

Cheaper?

- **Professional fees will be higher**
 - More complex
 - More MD's involved
- **No change or higher facility fee**
 - Site of service likely to remain hospital based
 - Cost of new devices and equipment
- **Possible cost advantage:**
 - Decreased: ileus, analgesia, LOS
- **Possible cost disadvantage:**
 - Increased: duration, failure and redo rate



Better Cosmetics



“He took out my appendix and I haven’t
DDW a scar.”

Transluminal Approach: So where should we focus?

The promise of truly disruptive technology:

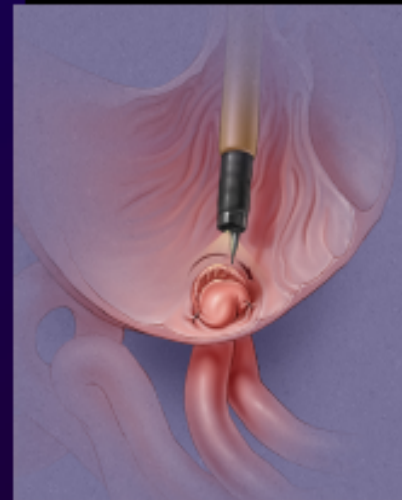
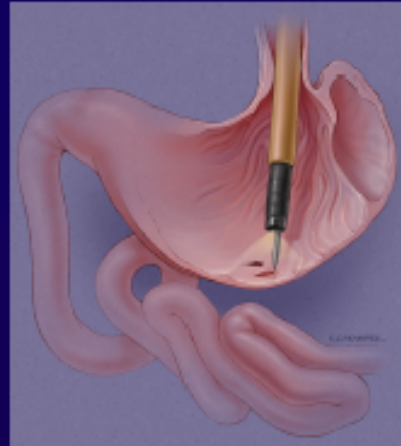
- Enables less skilled people do more complex procedures
- Simplifies complex procedures
- Provides solutions for unmet needs

NOTES: Facilitating Aggressive Approaches to Luminal Endoscopy



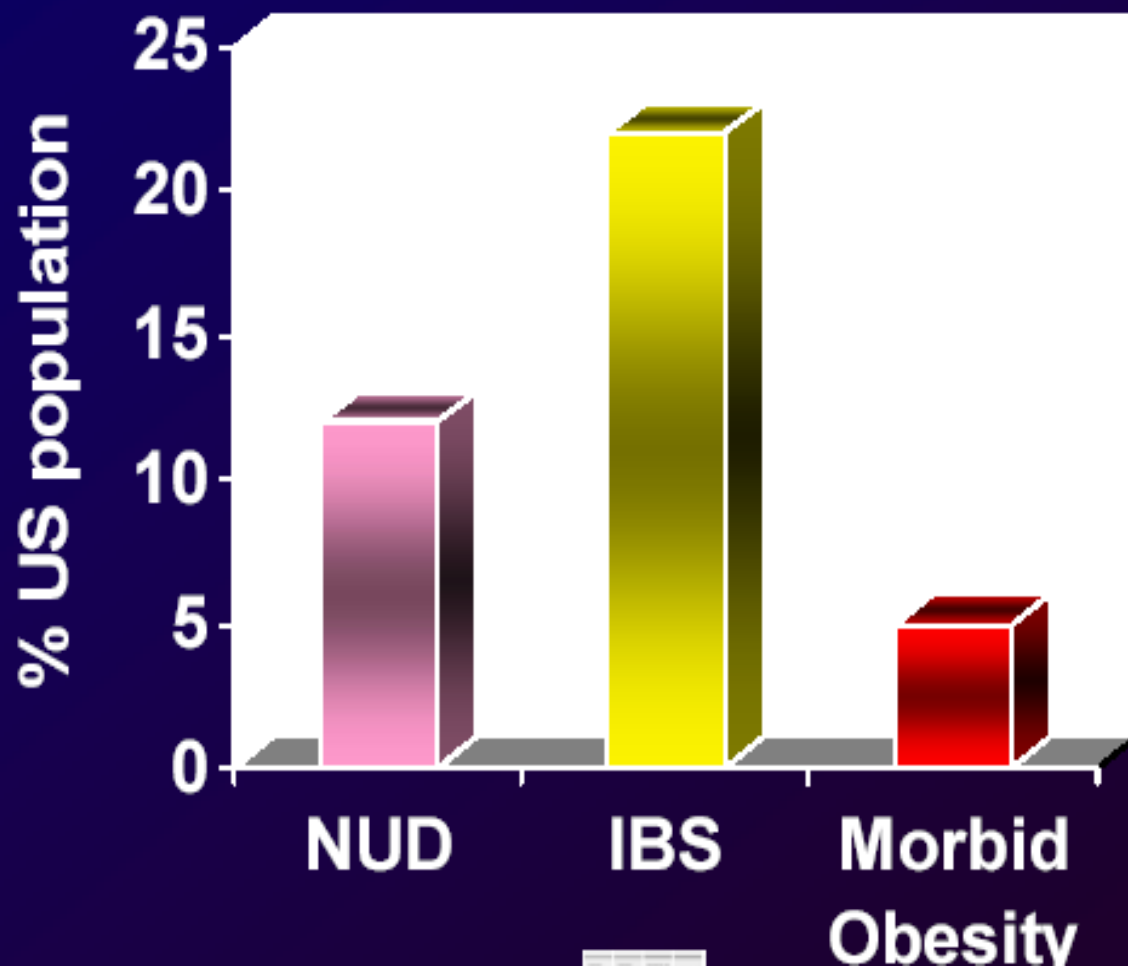
NOTES: Simplifying Complex Procedures

- Need for alternatives to complex procedures
 - Gastric bypass surgery

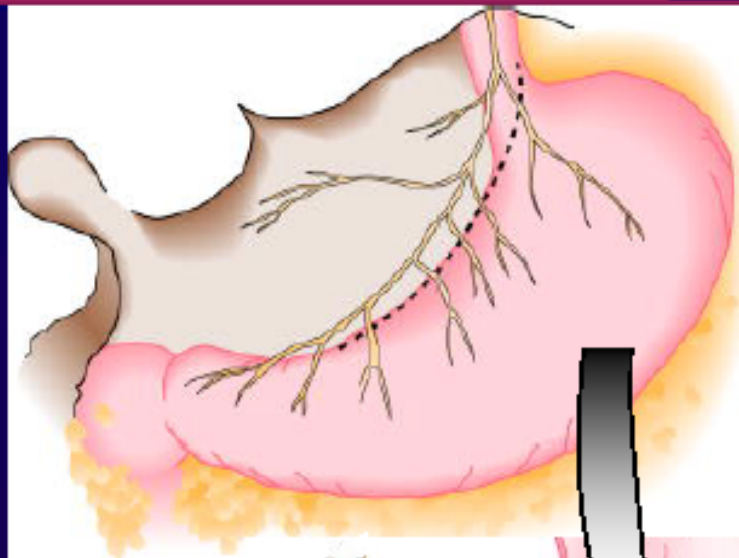
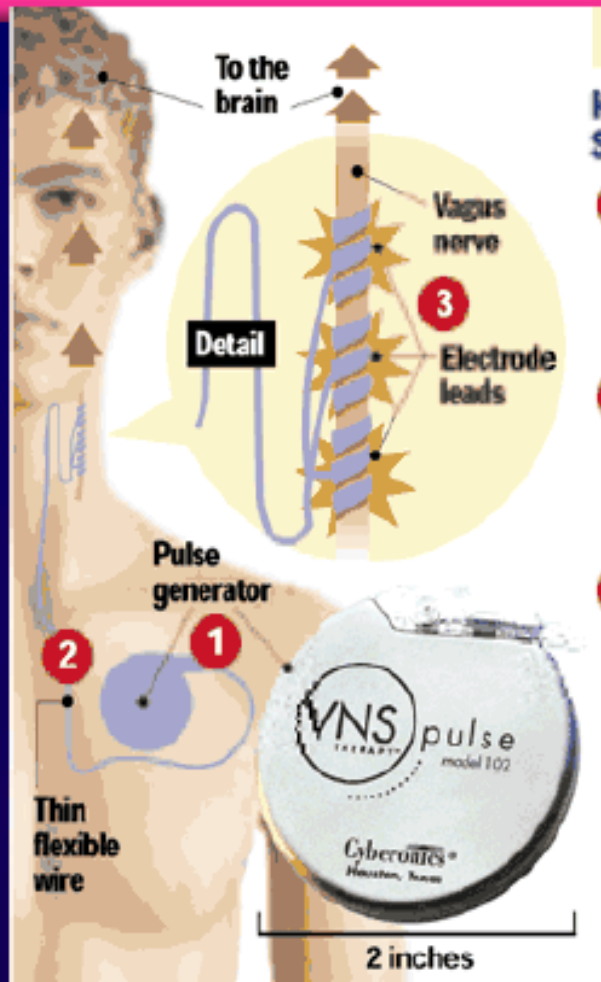


Target Diseases

Prevalence of common diseases



Transgastric Vagal Stimulation



Who- there's a little bit for everybody

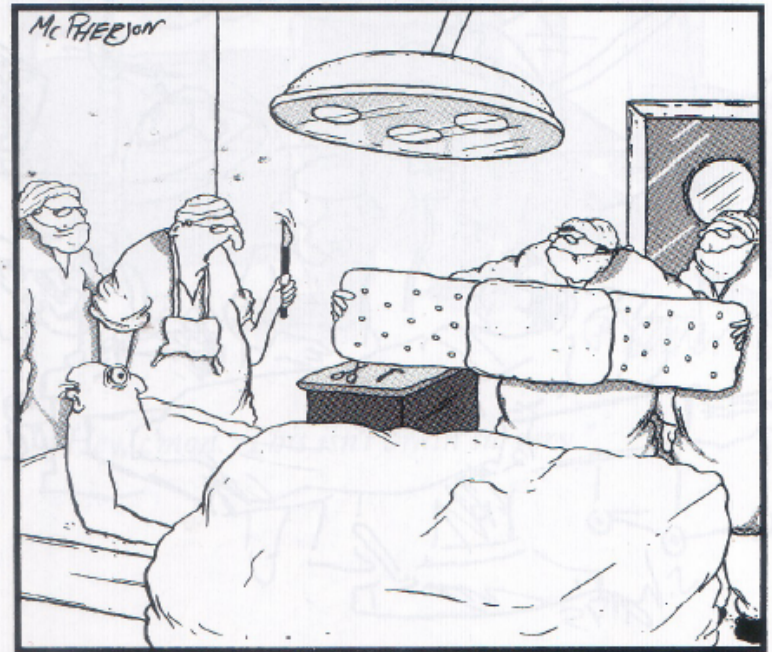
- **Replace current laparoscopic techniques to improve outcomes**
- **Enhance luminal procedures**
- **Provide solutions to common but difficult conditions currently not considered as amenable to a procedural approach**
- **Surgeon**
- **Advanced endoscopist**
- **General gastroenterologist**

Who?

- **Both surgeons and gastroenterologists can benefit initially if they focus on what comes naturally**
- **Over time, evolution of a new specialty will make this irrelevant**

Conclusions

- Success of a device or procedure requires 2 of 3 of the following:
 - large felt need¹
 - simplicity/safety²
 - efficacy³

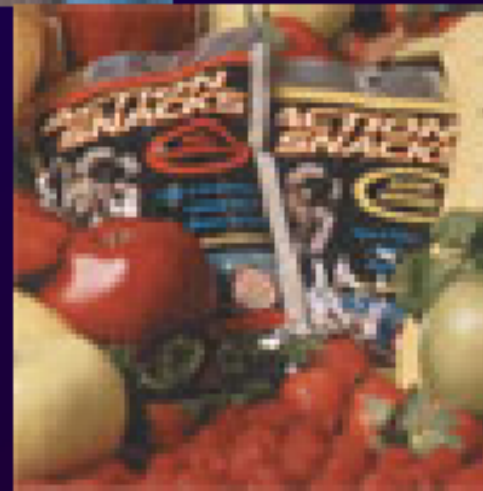
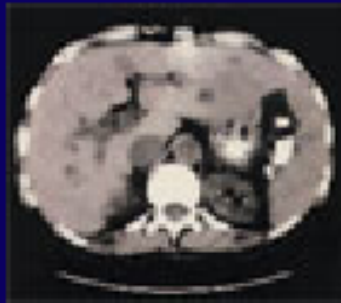


Conclusions

- Transluminal approaches will change the way we approach the treatment of GI diseases
- Its biggest contribution may be the demolition of psychological and conceptual barriers
- Gastroenterologists should not focus on replacing common surgical procedures but leapfrog their way to the future to diseases not currently being treated adequately



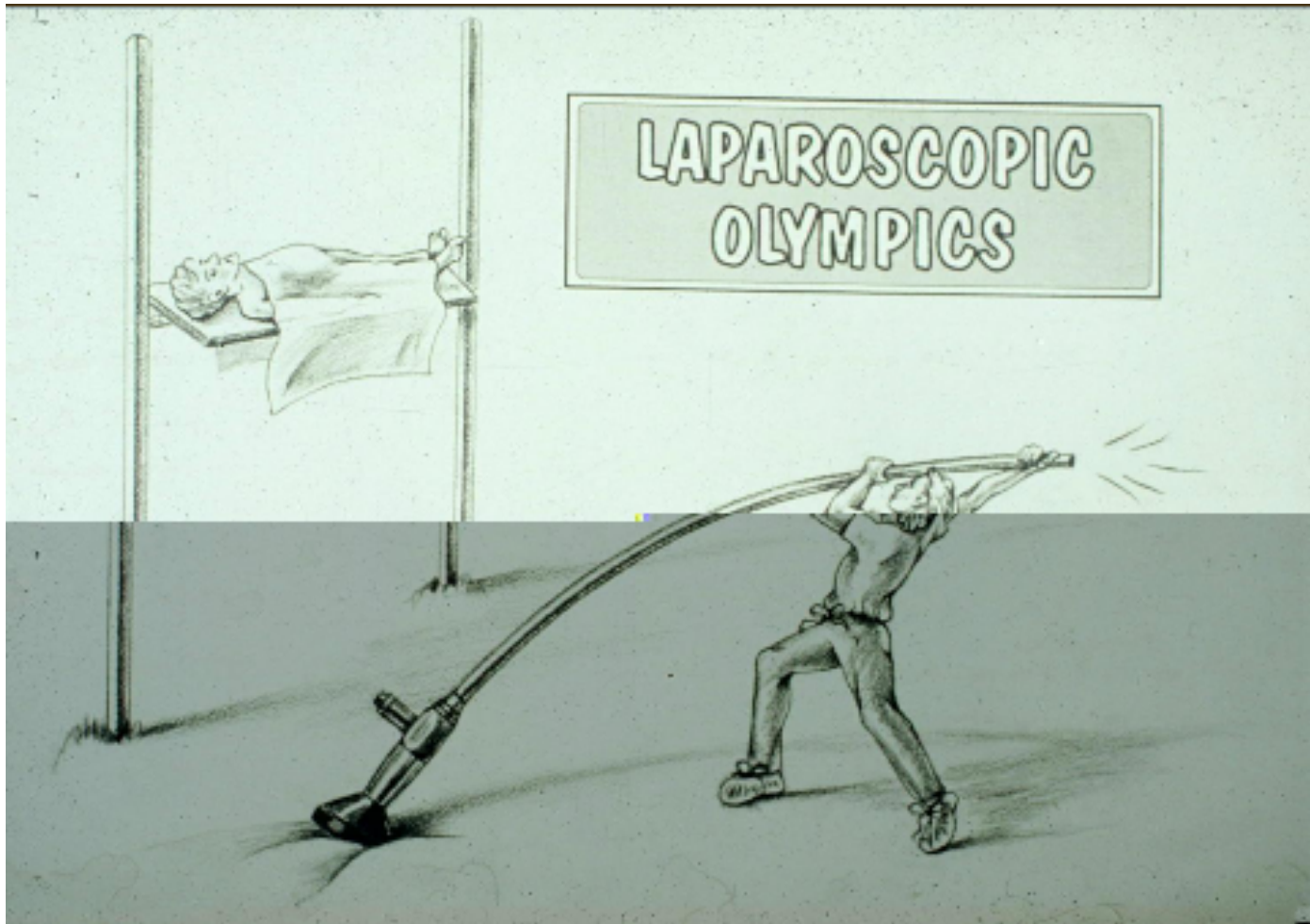
The promise of spin-offs



Epilogue

That's an amazing invention, but who would ever want to use one of them?

President Rutherford B Hayes, to Alexander Graham Bell, 1876 on viewing the telephone for the first time



We work harder so that patients heal better