

Challenges in Gaining Approval for Devices in Pediatric Patients: An Obesity Perspective

Evan P. Nadler, MD
Co-Director, Obesity Institute
Attending Surgeon
Children's National Medical Center



Disclosures

- Co-investigator in an industry-sponsored trial of the Lap-Band® system in morbidly obese adolescents.
- Since leaving NYU, no longer part of this study.

Adolescent Obesity an Unmet Need?

- Recent figures suggest that greater than 25% of high school aged children are overweight.
- RAND study from CNMC revealed that at least 15% of high school students in DC were obese and another 15% were overweight.
- While diet and behavior modification can help a minority of adolescents the vast majority of these patients go on to become obese adults.

Devices to Treat Obesity

- Laparoscopic Adjustable Gastric Banding (2 approved devices for adults)
- BioEnterics Intragastic Balloon system
- TOGA™ System transoral gastroplasty
- Endoluminal sleeve (GI Dynamics)
- Medtronic Implantable Gastric Stimulator
- Others?



THE LAP-BAND® ADJUSTABLE GASTRIC BANDING
SYSTEM
SUMMARY OF SAFETY AND EFFECTIVENESS DATA

III CONTRAINDICATIONS

The **LAP-BAND System** is contraindicated in:

10. Non-adult patients (patients under 18 years of age).

Timeline

- Approved for use in adults in 2001.
- Used at NYU off-label until 2004.
- IDE obtained from FDA in 2005 to implant 50 devices.
- Philanthropy-supported safety and efficacy trial (ongoing).
- Industry sponsored trial beginning in 2007 (ongoing).

Questions Along the Way

- Why was the device labeled as contraindicated for patients less than 18?
- Where do investigators turn when industry is not interested in a pediatric trial?
- How can individual centers pool their data to provide the most useful information?
- How do we best monitor future use once a device gains approval?

Suggestions/Thoughts

- Work with FDA to ensure that lack of pediatric data is not construed as a contraindication.
- Publicize these consortia and the opportunities they provide.
- Create infrastructure for investigators who are trying to achieve the same goal.
- Infrastructure/funding for device registries for initial post-market surveillance.

Other GI Areas for Devices

- Gastro-esophageal Reflux (Stretta Device)
- Endoscopic pyloromyotomy (balloon, incision)
- Duodenal webs (excision)
- Achalasia (stents)
- Others?

Come to the GI Breakout!!

Thank You
Questions?