Disclosures

Financial Disclosure:
Clinical Sales Specialist for Dysphagia
Receive Salary from Bracco Diagnostics, Inc.
No Non-financial Disclosures

*Presentation will include product discussion.
Learner Outcomes

Participants will understand:

1. The intended use of traditional bariums used in GI radiology.

2. How viscosity is measured.

3. The difference between viscosity and density.

4. How to read a barium label.

5. Current issues with using traditional GI bariums for video-flouroscopic swallow studies (VFSS).

6. Goals of the Varibar line for the VFSS.
Our Mission

To provide a contrast agent that helps standardize the assessment of swallowing disorders in dysphagia patients, assisting SLPs to partner with radiologists to ensure a consistent and reliable diagnostic approach.
In the beginning…

• When we started to perform systematic imaging tests of the swallowing mechanism
  – We knew we needed
    • Thin liquid
    • Nectar
    • Honey
    • Solid (cookie or cracker)
  – We knew we had to use barium to see what we needed to see
Barium contrast choices at that time...

We used what was available to create the desired viscosities

*Available choices in the 1980's
*See important indication & safety information on slide 34
What we later considered...

• Inter-user and Intra-user reliability
  – Variability of barium preparations selected
  – Variability of recipes used to make each viscosity for testing
  – Subjectivity and perception
  – Evidence-based practice

• Unique Properties of Barium Preparations
  – Density (w/v)
  – Coating

• Intended Purpose of Traditional Barium Preparations
  – Designed to fill and/or coat
  – Designed for specific procedures
What is Barium?

• A rock:
What is Barium?^1,^2

- Barium is a chemical element, atomic number 56, atomic weight 137.34, symbol Ba
- Barium sulfate (BaSO$_4$), a common barium compound, is used as a filler for rubber, plastics and resins
- BaSO$_4$, when swallowed, can be used to visualize the GI tract because of the ability of the barium atoms to block X-rays

References: 1 Saunders Comprehensive Veterinary Dictionary, 3 ed. © 2007 Elsevier, Inc. 2 The Periodic Table of Elements, Jefferson Labs, Science Education
Other Barium Compounds

- Barium carbonate ($\text{BaCO}_3$) is used in the manufacture of ceramics and some types of glass
- Barium nitrate ($\text{Ba(NO}_3\text{)}_2$) burns with a bright green color and is used in signal flares and fireworks
- Barium chloride ($\text{BaCl}_2$) is used as a water softener
- Barium oxide ($\text{BaO}$) easily absorbs moisture and is used as a desiccant
- Barium peroxide ($\text{BaO}_2$) forms hydrogen peroxide ($\text{H}_2\text{O}_2$) when it is mixed with water and is used as a bleaching agent that activates when wet
- Barium titanate ($\text{BaTiO}_3$) is used as a dielectric material in capacitors
- Barium ferrite ($\text{BaO} \cdot \text{6Fe}_2\text{O}_3$) is used to make magnets

Reference 2 The Periodic Table of Elements, Jefferson Labs, Science Education
Traditional GI Barium Preparations

• Developed to fill or coat
• Formulated to image a specific section of the GI tract
• Used for Single or Double Contrast imaging
• Varying densities
E-Z-Paque®*: Challenges

• Attempt to mirror thin liquid
  – Cannot obtain the true viscosity of water and maintain adequate opacification/visualization

• Used as nectar
  – Wide manufacturing range for viscosity

• Sometimes mixed with pre-thickened liquids
  – Not a true viscosity match
  – Much waste of expensive pre-thickened beverage

*See Indication and Important Safety Information on slide 34
E-Z-Paste® BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w)*

E-Z-Paste®

- Designed specifically to coat the esophagus
- Very adhesive/sticky properties

Typical uses in MBS

- Used as puree or pudding consistency
- Sometimes mixed with puree or pudding food products
- Sometimes used to thicken a barium mixture to a desired honey viscosity
- Used to opacify cookie or cracker

*See Indication and Important Safety Information on slide 34
E-Z-Paste®*: Challenges

- Designed specifically to coat the esophagus
- Very adhesive/sticky properties
  - Does not mimic natural food
  - Can leave residual coating that can affect diagnostic accuracy and make data interpretation more difficult
  - Must apply clinical judgment whether residual barium is due to patient impairment or barium adhesiveness
  - Can be unpleasant for the patient

*See Indication and Important Safety Information on slide 34
E-Z-HD™

BARIUM SULFATE FOR SUSPENSION (98% w/w)*

E-Z-HD™

- For double contrast upper GI imaging
- Sold as a powder

Typical Uses in MBS

- Sometimes used as nectar; sometimes used as honey
- Sometimes mixed with pre-thickened liquids

*See Indication and Important Safety Information on slide 34
E-Z-HD™*: Challenges

• For double contrast upper GI imaging
  – Very dense and heavy coating properties.
  – Proprioceptive properties are very different than thickened liquids (grainy)
  – Flow characteristics are very different than lower density barium preparations

• Sometimes used as nectar; sometimes used as honey
  – User judgment vs. science

• Sometimes mixed with pre-thickened liquids
  – Not a true viscosity match
  – Considerable waste of expensive pre-thickened beverage

*See Indication and Important Safety Information on slide 34
LIQUID POLIBAR PLUS®
BARIUM SULFATE SUSPENSION (105% w/v, 58% w/w)

Polibar & Polibar Plus®

- For double contrast lower GI imaging
- Very dense and heavy coating
- Viscosity pattern seen in thixotropic liquids like paint

Produces an initial high viscosity followed by a sudden decrease to near-thin liquid values

Typical Uses in MBS

- Sometimes used as nectar; sometimes used as honey
- Sometimes mixed with pre-thickened liquids


*See important indication & safety information on slide 34
Liquid Polibar & Polibar Plus®*: Challenges

* See Indication and Important Safety Information on slide 34

• For double contrast lower GI imaging
  – Very dense and heavy coating properties
  – Proprioceptive properties are very different than thickened liquids
  – Flow characteristics are very different than lower density bariums

• Thixotropic
  – Which viscosity are we really testing?

• Sometimes used as nectar; sometimes used as honey
  – User judgment vs. science

• Sometimes mixed with pre-thickened liquids
  – Not a true viscosity match
  – Much waste of expensive pre-thickened beverage
Review of the problems

- Lack of standardization, increased variability
- Inconsistent study results
- Undesirable coating
- Non-uniform opacification
- Varying flow characteristics
- Prep time
- Waste

Varibar® Barium Sulfate Contrast Agent (40% w/v)* was developed to address these issues

*See Indication and Important Safety Information on slide 33
The need for standardization

• Developing standards for materials in MBS studies is a key concern throughout the SLP community

• 1999 National Institute of Health (NIH) grant: Protocol 201 Study (Robbins & Logemann)
  – Assess the efficacy of chin tuck & thickened liquids as treatment strategies
  – NIH mandated system controls required that diagnostic materials must be standardized for accurate comparisons
  – Approached E-Z-EM for assistance that would fit specific research needs

4 Components for Standardization and Differentiation

- Single, defined values for thin, nectar, honey & pudding viscosities, measured at a constant shear rate
- Contrast agent must not leave residue on oropharyngeal structures when swallowed normally
- Barium sulfate concentration had to be standardized at 40% w/v
- Each viscosity had to be formulated to provide flavors & textures to help elicit salivation and a natural swallowing action in patients

Reference 5: Data on File
The need for standardization

Viscosity was selected for initial standardization since the ultimate goal in dysphagia treatment is to slow the rate of liquid flow through the oropharynx.

*Viscosity, measured in centipoise (cps), describes frictional resistance to flow.*
The Solution

• **Varibar®** is the only premeasured, premixed barium preparation for modified barium swallow (MBS) studies, removing the uncertainty that comes with measuring and mixing prior to testing.
  
  Varibar Thin Liquid* is supplied as a powder and constituted to a standard volume with water.

• **Varibar®** was created with full input from the SLP community when developing the viscosity targets, concentration percentage and other product features.

*See Indication and Important Safety Information on slide 33
Development Considerations

• Thin Liquid’s viscosity value needed to be as close to that of water as possible (0 cps)

• Thin Liquid, Nectar, Honey, and Pudding viscosity values must be far enough apart to avoid any overlap between each categorical thickness

• The centipoise (cps) value of each viscosity level had to fall within a certain average range so that the suspension is neither too thin nor too thick

Reference 5: Data on file
Varibar®* Today

Five consistent, standardized viscosity ranges—at 40% w/v ratio of barium sulfate concentration across the product line—that correlate with thickened fluids and foods:

- Thin Liquid
- Nectar
- Thin Honey†
- Honey (original honey)
- Pudding

† Thin honey was developed in response to clinicians’ request for a closer match to pre-thickened liquids

*See Indication and Important Safety Information on slide 33
Varibar® Thin*

- Simulates water viscosity
- Target viscosity: 4 cps†
- Viscosity range: <15 cps†
- Apple Flavor
- Powder reconstitutes with water
- In-use stability: 72 hours under refrigeration
- Viscosity is essentially unaffected by temperature

† When measured at a shear rate of 30 sec⁻¹ at 25 degrees C. This shear rate value is well within the range associated with chewing and swallowing (10-100 sec⁻¹)

*See Indication and Important Safety Information on slide 33
Varibar® Nectar*

- Nectar consistency
- Target viscosity: 300 cps†
- Viscosity range: 150-450 cps†
- Apple Flavor
- In-use stability: 21 days at room temperature
- Viscosity is affected by temperature

† When measured at a shear rate of 30 sec⁻¹ at 25 degrees C. This shear rate value is well within the range associated with chewing and swallowing (10-100 sec⁻¹)

*See Indication and Important Safety Information on slide 33
Varibar® Thin Honey*

- Honey consistency
- Target viscosity: 1500 cps†
- Viscosity range: 800-1800 cps†
- Apple Flavor
- In-use stability: 21 days at room temperature
- Viscosity is affected by temperature

† When measured at a shear rate of 30 sec⁻¹ at 25 degrees C. This shear rate value is well within the range associated with chewing and swallowing (10-100 sec⁻¹)

*See Indication and Important Safety Information on slide 33
Varibar® Honey*

- Spoon thick consistency†
- Target viscosity: 3000 cps‡
- Viscosity range: 2500-3500 cps‡
- Apple Flavor
- In-use stability: 21 days at room temperature
- Viscosity is affected by temperature

† “Spoon thick” is a National Dysphagia diet viscosity guideline
‡ When measured at a shear rate of 30 sec⁻¹ at 25 degrees C. This shear rate value is well within the range associated with chewing and swallowing (10-100 sec⁻¹)

*See Indication and Important Safety Information on slide 33
Varibar® Pudding*

- Pudding/puree consistency
- Target viscosity: 5000 cps†
- Viscosity range: 4500-7000 cps†
- Vanilla Flavor
- In-use stability: 21 days at room temperature
- Viscosity is affected by temperature

† When measured at a shear rate of 30 sec$^{-1}$ at 25 degrees C. This shear rate value is well within the range associated with chewing and swallowing (10-100 sec$^{-1}$)

*See Indication and Important Safety Information on slide 33
## Comparison of other contrast agents used for MBS

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>VARIBAR*</th>
<th>OTHER CONTRAST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specifically designed and optimized for the MBS</td>
<td>✓</td>
<td>NO</td>
</tr>
<tr>
<td>Standard Density: 40% w/v ratio of barium sulfate concentration</td>
<td>✓</td>
<td>NO</td>
</tr>
<tr>
<td>- Uniform opacification for consistent visualization</td>
<td>✓</td>
<td>NO</td>
</tr>
<tr>
<td>Standardized viscosity ranges for reliable, reproducible results</td>
<td>✓</td>
<td>NO</td>
</tr>
<tr>
<td>Viscosity Measured at Ideal Shear Rates</td>
<td>✓</td>
<td>NO</td>
</tr>
<tr>
<td>Viscosity Measured at Standardized Temperature</td>
<td>✓</td>
<td>NO</td>
</tr>
<tr>
<td>Smooth non-gritty texture with a mild flavoring added to improve</td>
<td>✓</td>
<td>NO</td>
</tr>
<tr>
<td>patient acceptance and cooperation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimal coating and flow characteristics closely mimic regular</td>
<td>✓</td>
<td>NO</td>
</tr>
<tr>
<td>liquids and foods</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*See Indication and Important Safety Information on slide 33*
In today’s healthcare environment of evidence-based practice, Varibar® provides a clinical standard for diagnostic accuracy and reproducible results.

*See Indication and Important Safety Information on slide 33*
INDICATIONS AND USAGE:
The Varibar products are indicated for use in radiography of the esophagus, pharynx and hypopharynx. Varibar is indicated for Adult use only.

IMPORTANT SAFETY INFORMATION:
For oral use only. This product should not be used in patients with known or suspected gastrointestinal tract perforation, or hypersensitivity to barium sulfate or any component of this barium sulfate formulation. Rarely, severe allergic reactions of anaphylactoid nature have been reported following administration of barium sulfate agents.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please consult full Prescribing Information provided.

Manufactured by
Phone: 609-514-2200; Toll Free: 1-800-544-4624 (US only)
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**INDICATIONS AND USAGE**

- LIQUID E-Z-PAQUE® BARIUM SULFATE SUSPENSION (60% w/v, 41% w/w), 355 mL bottles
  - Indications: For radiographic visualization of the gastrointestinal tract.

- LIQUID E-Z-PAQUE® BARIUM SULFATE SUSPENSION (60% w/v, 41% w/w), 1900 mL jug
  - Indications: For use in single contrast radiography of the esophagus, stomach, duodenum and small bowel.

- E-Z-PAQUE® BARIUM SULFATE FOR SUSPENSION (96% w/w), 176 g bottles
  - Indications: For use in single contrast radiography of the esophagus, pharynx, hypopharynx and for cardiac series.

- E-Z-PASTE® BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w), 454 g tube
  - Indications: For use in single contrast radiography of the esophagus, stomach and duodenum.

- E-Z-HD™ BARIUM SULFATE FOR SUSPENSION (98% w/w), 340 g bottles
  - Indications: For use in double contrast radiography of the esophagus, stomach and duodenum.

- LIQUID POLIBAR PLUS® BARIUM SULFATE SUSPENSION (105% w/v, 58% w/w), 1900 mL jug

**IMPORTANT SAFETY INFORMATION:**

- Contraindications: These products should not be used in patients with known gastric or intestinal perforation or hypersensitivity to barium sulfate products.
- Warnings: Rarely, severe allergic reactions of anaphylactoid nature, have been reported following administration of barium sulfate contrast agents.

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