Videofluoroscopic Swallowing Studies

A web-based continuing education course prepared by:

Contrast Agents for Videofluoroscopy

LENGTH: 30 minutes

OVERVIEW:

This module will discuss the contrast media that are used in videofluoroscopy. The majority of this module will focus on barium sulfate, which is the most commonly used contrast agent for gastrointestinal imaging in North America. It will explore issues of intended use and contraindications. Next will follow a discussion of off-label use and custom recipes for barium for videofluoroscopy, including barium concentration and the need to understand how concentration influences the flow and coating properties of barium. The module will wrap up with discussion of non-barium contrast agents and special considerations regarding contrast media in pediatric populations.

Learning Objectives:

At the end of this module, the clinician learner will be able to:

1) Understand the difference between high and low concentration barium
2) Understand the impact of barium concentration on mucosal coating
3) Understand the indications and contraindications for use of barium in children and individuals who aspirate
4) Describe the difference between manufacturer instructed use and off label use of barium
5) Understand the links between aspiration of contrast media and pneumonitis
6) Understand contraindications for use of xanthan-gum based thickeners in infants

Overview: Contrast Agents

- Barium Sulfate
  - Intended use, contraindications and warnings
  - Off-label use
  - Concentration/Density
  - Similarity in flow properties to non-barium
  - Coating properties
  - Recipes and food safety considerations
- Alternatives to barium
- Considerations in pediatric videofluoroscopy

Contrast Media

- X-ray contrast media are radiopaque, i.e., they attenuate X-rays.
- Two elements are in common use as x-ray contrast media:
  - barium, in the form of insoluble barium sulfate; and
  - iodine, the main component of all other X-ray contrast media.

Barium Sulfate ($BaSO_4$)

- Barium comes from the mineral "barite", which is mined in many places around the world, including Ontario and Nova Scotia.
- Barium Sulfate is water insoluble and is available either as a powder or as a liquid suspension.
- Commercial Barium Sulfate suspensions usually include other ingredients such as gum arabic, pectin, xanthan gum and/or methylcarboxycellulose
  - These additional ingredients influence characteristics such as flow, mucosal adhesion (coating), particle suspension, and foaming.

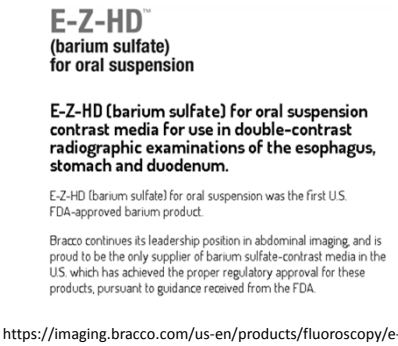
Barium Sulfate ($BaSO_4$)

- In some jurisdictions, including the United States, Barium Sulfate is considered to be a pharmaceutical product and falls under the regulations that apply to medication:
  - These regulations may include instructions regarding product storage, product tracking and restrictions on the professionals who are allowed to mix or reconstitute barium for use in medical examinations.
- In Canada, Barium Sulfate is classified as a "natural health product" rather than a drug.

Barium Sulfate ($BaSO_4$)

- Barium Sulfate has been used for many years for imaging of the gastrointestinal tract.
- When drug regulation was launched in the USA, the long history of use led to grandfathering of Barium Sulfate.
  - Consequently, many historical Barium Sulfate products have not undergone specific safety trials.
  - Recent changes in Food and Drug Act regulations in the United States mean that safety trials will be required for Barium Sulfate products.

Barium Sulfate Labelling



https://imaging.bracco.com/us-en/products/fluoroscopy/e-z-hd

Barium Sulfate Labelling

E-Z-HD™ (BARIUM SULFATE) FOR ORAL SUSPENSION, 98% w/w

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use E-Z-HD safely and effectively. See full prescribing information for E-Z-HD.

E-Z-HD (barium sulfate) for oral suspension
Initial U.S. Approval: 2016

----------RECENT MAJOR CHANGES----------
Warnings and Precautions (5.6) 2/2017

----------INDICATIONS AND USAGE----------
E-Z-HD, a radiographic contrast agent, is indicated for use in double-contrast radiographic examinations of the esophagus, stomach and duodenum to visualize the gastrointestinal (GI) tract in patients 12 years and older (1)

----------DOSAGE AND ADMINISTRATION----------
- Recommended reconstituted oral dose for adults and pediatric patients 12 years and older is between 65 mL to 135 mL (155 to 321 grams of barium sulfate, respectively) (2.1)
- Must reconstitute supplied powder with water prior to use. See Full Prescribing Information for reconstitution instructions (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
For oral suspension: 334 grams of barium sulfate (98% w/w) in a single-dose bottle for reconstitution (3)

----------CONTRAINDICATIONS----------
- Known or suspected perforation of the GI tract (4)
- Conditions associated to high risk of aspiration (4)
- Conditions associated to high risk of GI perforation (4)
- Known hypersensitivity to barium sulfate or any of the excipients of E-Z-HD (4)

----------WARNINGS AND PRECAUTIONS----------
- Emergency equipment and trained personnel should be immediately available for treatment of a serious hypersensitivity reaction (5.1)
- Intra-abdominal leakage: Caution is recommended in patient conditions like GI fistula, ulcer, inflammatory bowel disease, appendicitis or diverticulitis, severe stenosis or obstructing lesions of the GI tract (5.2)
- Patients should maintain adequate hydration in days following a barium sulfate procedure to avoid obstruction or impaction caused by fecaliths (5.3)
- Aspiration: Caution is recommended in patients with history of food aspiration and in patients with known swallowing disorders (5.4)
- E-Z-HD is not intended for pediatric use from birth through 11 years of age (8.4)

----------ADVERSE REACTIONS----------
Common adverse reactions include nausea, vomiting, diarrhea and abdominal cramping (6)

To report SUSPECTED ADVERSE REACTIONS, contact Bracco Diagnostics Inc at 1-800-257-5181 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for PATIENT COUNSELING INFORMATION

Revised: 2/2017

https://imaging.bracco.com/us-en/products/fluoroscopy/e-z-hd

Cautious use of Barium Sulfate in patients at risk of aspiration:

"Ingestion of barium is not recommended in patients with a history of food aspiration. If barium swallow studies are required in these patients or in patients in whom integrity of the swallowing mechanism is unknown, proceed with caution. Administer initially *small amounts* such as a half-teaspoon of *low-density barium* and carefully observe swallowing under fluoroscopic control. If barium is aspirated into the larynx, further administration of barium should be immediately discontinued. If no aspiration is noted, additional barium may be given with continued fluoroscopic monitoring for aspiration."

Barium Sulfate Contraindications

- Adverse reactions to barium sulfate formulations are infrequent (~1 in 500,000)
- Barium Sulfate is contraindicated in cases of:
  - known or suspected perforation of the GI tract (e.g., patients with anastomoses from recent surgery or where there is a chance of perforation)
  - GI obstruction
  - Allergy to barium
  - hereditary fructose intolerance (due to addition of sorbitol as an ingredient)

Barium Sulfate Labelling

3 DOSAGE FORMS AND STRENGTHS
For oral suspension: 334 grams of barium sulfate supplied as a fine, white to lightly colored powder (98 % w/w) in a single-dose HDPE plastic bottle for reconstitution. The suspension is 238% w/v when reconstituted and should be homogeneous and white to lightly colored.

----------DOSAGE AND ADMINISTRATION-------
- Recommended reconstituted oral dose for adults and pediatric patients 12 years and older is between 65 mL to 135 mL (155 to 321 grams of barium sulfate, respectively) (2.1)
- Must reconstitute supplied powder with water prior to use. See Full Prescribing Information for reconstitution instructions (2.2)

https://imaging.bracco.com/us-en/products/fluoroscopy/e-z-hd

Barium Concentration

- The concentration (density) of the suspension varies with the type of examination.
  - Single-contrast barium enemas require low-density suspensions (15-20% w/v)
  - Double-contrast examinations of the stomach use medium or high-density suspensions (≥80% w/v)
  - For imaging of the oropharynx, "low density" concentrations are recommended (20 to 40% w/v)

An interesting emerging debate…

Dysphagia (2009) 24:285–289
DOI 10.1007/s00455-008-9203-y

Are We Testing a True Thin Liquid?

Traci A. Fink · Jill B. Ross

- Fink and Ross diluted Varibar Thin by 50% with water
- Revealed patients who aspirated on the diluted "ultra-thin" but not on the non-diluted contrast

http://steeleswallowinglab.ca/srrl/best-practice/barium-recipes/

If you are preparing barium stimuli in an off-label fashion, we would still strongly recommend that you use water as the liquid to which barium is added. Many barium sulfate powders include non barium ingredients… These ingredients may include gums or starches… interactions may occur… [with the] thickening agents in pre-thickened liquids, or… [with] proteins or other components of liquids such as milk or nutritional supplements. These interactions may include further thickening or thinning, …, and therefore introduce a risk that the flow properties of the barium that is used in an assessment may not match the flow properties of the liquids provided to patients on their diets.

Other Good Barium Practice

- Infection and food safety procedures
- Note dates barium is opened and dispose leftover product before expiry date
- Do not wash barium down the drain

Other contrast agents you may encounter…

Diatrizoate (Hypaque®; Gastrografin®)

- A water-soluble *iodinated* radiopaque contrast agent.
- Particularly useful when barium sulfate is not feasible, such as:
  - Threatening perforation
  - Suspected partial or complete stenosis
  - Cases of acute hemorrhage
  - Observation of foreign bodies before endoscopy
  - Observation of gastrointestinal fistula
- Aspiration into the trachea and airways may result in serious pulmonary complications including, pulmonary edema, pneumonitis or death.

Dysphagia (2013) 28:520–527
DOI 10.1007/s00455-013-9462-0

ORIGINAL ARTICLE

The Use of Low-Osmolar Water-Soluble Contrast in Videofluoroscopic Swallowing Exams

Julie A. Harris · Detlef Bartelt · Molly Campion · Bob W. Gayler · Bronwyn Jones · Andrea Hayes · Judith Haynos · Seanne Herbick · Therese Kling · Arpana Lingaraj · Michele Singer · Heather Starmer · Christine Smith · Kim Webster

Received: 8 June 2012 / Accepted: 19 February 2013 / Published online: 26 March 2013

Abstract The selection of the contrast agent used during fluoroscopic exams is an important clinical decision. The purpose of this article is to document the usage of a non-ionic, water-soluble contrast (iohexol) and barium contrast in adult patients undergoing fluoroscopic exams of the pharynx and/or esophagus and provide clinical indications for the use of each. For 1 year, data were collected on the use of iohexol and barium during fluoroscopic exams. The contrast agent used was selected by the speech language pathologist (SLP) or the radiologist based on the exam's indications. A total of 1,978 fluoroscopic exams were seen with the use of iohexol. When barium was used in cases of aspiration and extraluminal leakage, the amount of aspirated barium was small and the extraluminal barium in the instances of leakage was small. Iohexol is a useful screening contrast agent and can safely provide information, and its use reduces the risk of aspiration and the chance of leakage of large amounts of barium.

Keywords Iodine-containing contrast · Omnipaque · Iohexol · Fluoroscopic exams · Deglutition · Deglutition disorders

Dysphagia
DOI 10.1007/s00455-016-9726-6

ORIGINAL ARTICLE

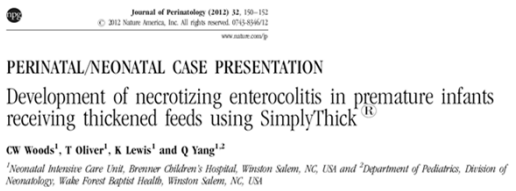
Understanding the Viscosity of Liquids used in Infant Dysphagia Management

Jacqueline Frazier[1] · Amanda H. Chestnut[1] · Arwen Jackson[1] · Carly E. A. Barbon[2,3] · Catriona M. Steele[2,3] · Laura Pickler[1]

Recommendation for videofluoroscopy with infants:

- Prepare a low-concentration barium liquid or use a low-osmolar contrast agent
- If thickening is needed, test consistency using the IDDSI Flow Test to confirm similarity to the non-barium liquids of interest

Thickeners for infants



Journal of Perinatology (2012) 32, 150–152

www.nature.com/jp

PERINATAL/NEONATAL CASE PRESENTATION

Development of necrotizing enterocolitis in premature infants receiving thickened feeds using SimplyThick®

CW Woods[1], T Oliver[1], K Lewis[1] and Q Yang[1,2]

[1]Neonatal Intensive Care Unit, Brenner Children's Hospital, Winston Salem, NC, USA and [2]Department of Pediatrics, Division of Neonatology, Wake Forest Baptist Health, Winston Salem, NC, USA

Key Messages

- In Canada, barium sulfate is classified as a "natural health product" rather than a drug, and many products may not have undergone specific safety trials.
- Commercial barium sulfate suspensions typically include other ingredients which influence characteristics such as flow, mucosal adhesion, particle suspension, and foaming.
- Use of barium sulfate for evaluation of oropharyngeal swallowing is considered "off-label".

Key Messages

- Barium sulfate product labels suggest caution is needed when using it with patients who have a history of aspiration and known dysphagia.
- Barium is not absorbed by the body. If large amounts are aspirated, they can consolidate in the lungs and can cause both pneumonitis and hypoxia.
- Barium sulfate is contraindicated in cases of:
  - known, suspected, or risk of perforation of the GI tract or GI obstruction
  - allergy to barium
  - hereditary fructose intolerance

Key Messages

- The weight-to-volume ratio describes how concentrated the barium is.
- Research shows that several aspects of swallowing physiology differ between high and low concentration barium suspensions.
- In imaging the oropharynx, 20% - 40% w/v concentrations achieve a balance of being concentrated enough for adequate x-ray viewing, but low enough to not leave a coating behind.

Key Messages

- Adding more barium to achieve a higher concentration is likely to alter other properties of the liquid.
- When combining barium with liquids other than water, interactions between the barium product ingredients and thickening agents/proteins may introduce a risk that the flow properties of the barium used in assessment may not match those of the liquids in the patient's diet.

Key Messages

- Bottles of barium should be marked with the date of opening and required date for disposal.
- Any unused barium suspension should be disposed of according to methods identified by pharmacy on site for safe and suitable disposal.
- New generation water-soluble low-osmolar agents may be an alternative to barium sulfate.

Key Messages

- Barium differs in density, viscosity, and taste from breastmilk and infant formulas.
- The interactions that can occur between the proteins in infant formula and barium can lead to changes in viscosity.
- The current best recommendation in pediatrics is to prepare low-concentration barium stimuli or use low-osmolar agents, thickening until they match the desired non-barium liquid of interest.

Key Messages

- Recipes are available online for combining barium sulfate products with water and different thickeners to achieve specific barium concentrations and consistencies.

http://steeleswallowinglab.ca/srrl/best-practice/barium-recipes/

KNOWLEDGE CHECK

1. **Which of the following statements is true?**

   A Barium sulfate suspensions are approved for oral administration to patients of all ages

   B Manufacturer labels for barium sulfate commonly include warnings about use in children

   C Barium is classified as a pharmaceutical drug in Canada

2. **Which of the following features of higher concentration bariums can lead to inaccurate impressions of oropharyngeal swallowing efficiency?**

   A Greater opacity (i.e. darkness on image)

   B Lower viscosity

   C Coating properties

   D Cohesiveness

3. **True or false? Mixing barium powder with products other than water, including thickened liquids or foods, constitutes "off-label" use.**

   A True

   B False

4. **True or false? The use of iodinated contrast media such as Hypaque or Gastrografin involves a risk of pneumonitis if aspirated.**

   A True

   B False

Answer key found on the following page.

KNOWLEDGE CHECK ANSWER KEY

1. B Manufacturer labels for barium sulfate commonly include warnings about use in children

2. C Coating properties

3. A True

4. A True

EXPAND YOUR KNOWLEDGE

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