

Standardized Practice for the Administration of Rectal Lactulose in Hospitalized Patients with Hepatic Encephalopathy



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Problem and Significance

Lactulose, a non-absorbable disaccharide, is used as a first-line agent for the treatment of hepatic encephalopathy.¹ Oral lactulose may be administered; however, research has shown that the pH of the stool decreases more rapidly, and there is a significantly decreased time in lowering ammonia levels when administered rectally.² The manufacturer's recommendation for preparing lactulose for rectal administration is to mix 300 mL of lactulose solution in 700 mL of water or physiologic saline. This solution is then given via an enema and the patient is to retain this for 30 to 60 minutes.³ Many of these patients are in impending coma or coma as a result of their disease process and do not have the mental faculties required to hold this amount of fluid for the prescribed time. This often leads to fecal incontinence, bed soiling, and failure to absorb the medication effectively. Skin breakdown may result from frequent stooling, especially due to the acidity of the stool after lactulose administration. Even with oral or nasogastric administration, fecal incontinence, bed soiling, and potential for skin breakdown may occur.

Process Improvement

Historically at our hospital, the medication was administered via a standard enema bag, and then a large rigid urinary tube was inserted into the rectum to collect the stool. The use of this tube was off-label. Aware that this was not best practice, we collaborated with a colorectal surgeon, a hepatologist, and pharmacist to explore our options. We recently began using an indwelling bowel catheter system* to manage incontinent stool and we decided to explore the medication administration option available with this device. Over time, we discovered most of these patients were able to hold approximately 300 mL for 15 to 20 minutes at a time. We began to mix the lactulose solution in a smaller amount of normal saline in order to decrease the amount of volume the patient would have to retain, without decreasing the dose. Our multi-disciplinary team developed a nursing procedure and medication order set to standardize the administration of rectal lactulose for the encephalopathic patient in our hospital.

*ActiFlo Indwelling Bowel Catheter System

Pharmacy Req
Lactulose syrup enema - BLUE, FOUR

Order: Lactulose syrup enema Order ID: 001BCT627
Requested By: Schreiber, Matthew J Template Name: Lactulose syrup enema 200gm

Messages:

Conditional Order Max # of activations: [] [Clear]

Dose: 300 Unit: ml
Route: Rectal Frequency: q6h
PRN: PRN Reason: []

Duration/Number of doses: []

Special Instructions: Add to Normal Saline to total of 600 ml. Administer via ballooned rectal tube in increments of 300 ml; attempt to have pt retain medication at least 20 minutes for each incremental dose.

Additional Instructions: []

Start Date: [] Start Time: []
Prescribed Stop Date: [] Prescribed Stop Time: []
Pharmacy Stop Date: [] Pharmacy Stop Time: []
Rx Number: [] Reference #: []
Person giving order on behalf of MD: [] Signature Source Credential: []

Repeat Expert Dosing View Document OK Cancel

Screen print of standardized order

Results

At our liver transplant center, we care for acutely ill hepatic failure patients, many of whom suffer from hepatic encephalopathy prior to receiving their transplants. As a result of this multidisciplinary effort, we have been able to standardize our order set and protocol. This standardization has allowed us to consistently deliver the best care with regard to lactulose administration for this group of patients.

How Lactulose Works with Hepatic Encephalopathy

Lactulose is a synthetic disaccharide that acidifies the colon as it is degraded.⁴ This acidification process results in the retention of ammonia in the colon as the ammonium in $(\text{NH}_4)^+$. As this process occurs, the colon becomes more acidic than the blood, causing the migration of ammonia from the blood into the colon. The colonic contents convert the ammonia (NH_3) to the ammonium ion $(\text{NH}_4)^+$, trapping it and preventing its absorption. The trapped ammonium ion is then expelled in the stool.

Administration of Enema/Medications Using the ActiFlo Indwelling Bowel Catheter System*

CAUTION: Prior to using ActiFlo Indwelling Bowel Catheter System, be sure to read the entire ActiFlo Indwelling Bowel Catheter System Instructions for Use package insert supplied with the product.

NOTE: The CLEAR connector (IRRIG/Rx) should be flushed with 20 mL of water before and after the administration of enema/medications. Viscous enema/medications may require dilution to facilitate administration through the irrigation lumen.

1. Inflate the intraluminal balloon with 25 mL of air via the RED connector (STOP FLOW 25 mL AIR). Disconnect the syringe.

2. Open the CLEAR connector (IRRIG/Rx) and flush the irrigation lumen with 20 mL lukewarm water (26°-38° C, 80°-100° F), then disconnect the syringe and close the connector.

3. Connect the medication syringe or medication bag to the CLEAR connector (IRRIG/Rx) and slowly inject the solution or allow it to flow in by gravity.

WARNING: Do not connect mechanical pumping devices to CLEAR connector (IRRIG/Rx).

4. Flush the CLEAR connector (IRRIG/Rx) with 20 mL lukewarm water (26°-38° C, 80°-100° F), then disconnect the syringe and close the connector.

5. Allow the enema/medication to dwell for the desired retention time as prescribed by the physician.

6. Using the syringe, completely aspirate the air from the intraluminal balloon via the RED connector (STOP FLOW 25 mL AIR). Disconnect the syringe and confirm that the pilot balloon is fully collapsed.

WARNING: Do not leave intraluminal balloon inflated in an unattended patient.

References

- 1 Marrero J, Martinez FJ, Hyzy R. Update in nonpulmonary critical care: Advances in critical care hepatology. *Am. J. Respiratory and Critical Care Medicine*. Dec 2003; 168: 1421–1426.
- 2 Healthline Drug Notebook: Lactulose (2009). June 15, 2009. www.healthline.com/ahfscontent/lactulose/3.
- 3 Raza M A, Bhatti R S, Akram J. Effect of rectal lactulose administration with oral therapy on time to recovery from hepatic encephalopathy: A randomized study. *Annals of Saudi Medicine*. 2004; 24(5): 374-377.
- 4 Lactulose Drug Information. 6/30/2009. <http://www.merck.com/mmpe/lexicomp/lactulose.html>.

Note: Use of Lactulose as described in this article is one option used by a particular hospital. No determination is made in the article as to the effectiveness of using Lactulose per the dilution and time intervals described by the hospital. Clinicians and hospitals should make an independent decision as to whether the hospital's approach is appropriate for them and their patients.

ActiFlo Indwelling Bowel Catheter System Product Information

NON STERILE:

Single patient use only. Latex-free

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. Refer to the complete ActiFlo Indwelling Bowel Catheter System Instructions for Use supplied by the manufacturer for directions on how to properly use this product.

INTENDED USE

The ActiFlo Indwelling Bowel Catheter System is intended for diversion of fecal matter to minimize contact with the patient's skin, to facilitate the collection of fecal matter for patients requiring bowel management, to provide access for colonic irrigation, and to administer enema/medications.

CONTRAINDICATIONS

- Do not use in patients having known sensitivities or allergies to the materials used in this device.
- Do not use if the patient's distal rectum cannot accommodate the inflated volume of the retention cuff or if the distal rectum/anal canal is severely strictured (e.g., secondary to tumor, inflammatory condition, radiation injury, scarring).
- Do not use on patients having impacted stool.
- Do not use on patients with a recent (less than 6 weeks old) rectal anastomosis, or a recent (less than 6 weeks old) anal or sphincter reconstruction.
- Do not use on patients with compromised rectal wall integrity (e.g., ischemic proctitis).

WARNINGS

(Failure to comply with the following warnings may result in patient injury)

- Do not use if package is open or damaged.
- Do not use improper amount or type of fluids for irrigation or cuff/balloon inflations. NEVER use hot liquids.
- Do not over inflate retention cuff or intraluminal balloon.
- Inflation of the intraluminal balloon causes complete catheter occlusion. Do not leave intraluminal balloon inflated in an unattended patient. To verify complete deflation of the intraluminal balloon, aspirate all air until RED connector (STOP FLOW 25 mL AIR) pilot balloon is collapsed when the syringe is removed from the connector.
- Use only gravity or slow manual irrigation. Do not connect manual pumping devices to catheter irrigation lumen. Do not irrigate patient with compromised intestinal wall integrity.
- Extreme caution should be exercised in patients at risk for the development of toxic megacolon. Occluding the tube by inflating the intraluminal balloon could aggravate this situation.
- Perform irrigations, and enema/medication administrations, via the CLEAR connector (IRRIG/Rx) AND NOT via the BLUE connector (CUFF 35-40 mL H₂O) or RED connector (STOP FLOW 25 mL AIR).
- Blood per rectum should be investigated to ensure no evidence of pressure necrosis from the device. Discontinue use of the device if evident.
- Abdominal distention that occurs while using the device should be investigated.
- The section of the catheter that crosses the anal canal (transsphincteric zone) is made of soft collapsible material designed to help avoid impact on the rectal sphincter. Excessive prolonged traction on the catheter, resulting in the retention cuff migrating into the anal canal, could result in temporary or permanent clinical sphincter dysfunction, or catheter expulsion.

PRECAUTIONS

- Do not sterilize.
- The ActiFlo Indwelling Bowel Catheter is not intended for use longer than 29 days.
- The ActiFlo Indwelling Bowel Catheter is not recommended for pediatric use.
- To avoid damage to retention cuff or intraluminal balloon, DO NOT contact either with ANY sharp edge including the enclosed lubricating jelly packets.
- The ActiFlo Indwelling Bowel Catheter may not be effective in individuals who have had their distal rectum significantly altered by surgical resection or reconstruction.
- Patients with very weak sphincter function may expel the catheter under normal use, or may have increased leakage of stool or irrigation fluids compared to patients with normal sphincter function.
- Caution should be observed in patients whose rectum may be altered by stricture due to radiation or affected with radiation proctitis.

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Covered under one or more of the following patents: US Patents 5,569,216, 7,147,627, Australian Patents 2003207608, 2000274575, 2007201015, Canadian Patent 2421405, Japanese Patent 4260107, and other patents pending.

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- Patients with severe tenesmus, or patients who experience tenesmus or severe pain after insertion of device, may not tolerate the catheter in place.
- Avoid inserting anything (e.g., thermometer, suppository, etc.) into the anal canal with the catheter in place to minimize patient injury or catheter damage.
- Care should be taken when disconnecting syringe from the CLEAR connector (IRRIG/Rx). Fluids that are retained in the rectum and colon may drain or splatter from the connector when it is disconnected.
- Use water only to inflate retention cuff. Do not use saline solution, which may adversely affect valve function.
- Use air only to inflate the intraluminal balloon. Do not use water or any other fluid.
- Do not use vigorous aspiration to remove fluid from the retention cuff or to remove air from the intraluminal balloon. Vigorous aspiration may collapse the inflation lumen and/or pilot balloon and prevent retention cuff or intraluminal balloon deflation.
- Do not allow ointments or lubricants having a petroleum base (e.g., Vaseline®, petroleum-based hand/body lotion) to contact the catheter. They may damage the silicone and may compromise the integrity of the device.
- Use only ActiFlo Collection Bags with the ActiFlo Indwelling Bowel Catheter.
- Feces contains infectious material. Protect caregiver and others from splatter which may occur when disconnecting or emptying the collection bags or during catheter removal.
- After use, this system is a biohazard. Handle and dispose of in accordance with institutional universal precautions for contaminated waste.

ADVERSE EVENTS

The following adverse events may be associated with the use of any rectal device:

- Perforation
- Pressure necrosis
- Loss of sphincter tone
- Obstruction
- Infection
- Excessive leakage of fecal contents

As Presented at American Journal of Nursing Conference

October 4-6, 2009

Chicago, IL

FINANCIAL ASSISTANCE/DISCLOSURE

The support of Hollister Incorporated for this clinical presentation is gratefully acknowledged.



Hollister

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