

# Enemas Are Ineffective in Pediatric Constipation

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MILWAUKEE — Regular enemas did not reverse increased rectal compliance in children with intractable functional constipation, Dr. Marc Benninga reported at an international symposium sponsored by the International Foundation for Functional Gastrointestinal Disorders.

The prospective, longitudinal barostat study of 101 patients also found that in-

creased rectal compliance was not related to treatment failure.

Rectal compliance is an indirect measure of contraction and relaxation in the rectum. It is thought to be increased in children with constipation compared with healthy children, and to be reduced in those with irritable bowel syndrome with diarrhea.

Regarding the result that enemas did not reverse increased rectal compliance, Dr. Benninga said: "It is a provocative finding, because increased rectal compliance seems

not to be an important underlying mechanism of intractable functional constipation in childhood." Dr. Benninga works in the department of pediatric gastroenterology and nutrition at Emma Children's Hospital/Academic Medical Center, University of Amsterdam.

The study was enthusiastically received by audience members. "Your study required a lot of work and a lot of courage," said Dr. David R. Fleischer of the department of child health at the University of

Missouri in Columbia. "It deflates a lot of the pediatric folklore that has led to iatrogenic abuse of children."

The investigators randomized 101 children aged 8-18 years, with symptoms of functional constipation lasting for at least 2 years, to either conventional treatment with laxatives and toilet training or conventional treatment plus enemas. Patients in the latter group had three enemas per week for the first 3 months, with a reduction in the number of enemas by one per week every 3 months.

Among the 87 children who completed 12 months of treatment, there were no significant differences in clinical success between the two treatments or between children with and without abnormal rectal compliance at baseline.

Functional constipation was defined as the presence of two or more of the following criteria: defecation frequency less

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than three times a week, fecal incontinence at least twice a week, large-diameter stool, and fecal retention at physical examination.

The patients' mean age was 11 years, 65% were boys, 72% had large-diameter stools, and

47% had fecal impaction. Defecation frequency averaged 1.5 per week, and fecal incontinence occurred an average of seven times per week. Symptom duration averaged 7 years.

Assessment of rectal compliance was performed with an electronic barostat and polyethylene bag, which is thought to be more accurate than a latex balloon and manual inflations used in clinical settings, Dr. Benninga explained. The upper limit of the normal range was 20 mL/mm Hg.

Clinical success, defined as defecation at least three times per week and fecal incontinence less than once a week, was achieved in 33 children with normal rectal compliance, 34 with moderately increased compliance, and 20 with severely increased compliance, Dr. Benninga said at the meeting, which was cosponsored by the University of Wisconsin. ■

## AzaSITE™

(azithromycin ophthalmic solution) 1%

### Sterile topical ophthalmic drops

#### BRIEF SUMMARY

Before prescribing, please consult the full prescribing information.

#### INDICATIONS AND USAGE

AzaSite is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms:

CDC coryneform group G\*  
*Haemophilus influenzae*  
*Staphylococcus aureus*  
*Streptococcus mitis* group  
*Streptococcus pneumoniae*

\*Efficacy for this organism was studied in fewer than 10 infections.

#### DOSAGE AND ADMINISTRATION

The recommended dosage regimen for the treatment of bacterial conjunctivitis is:  
Instill 1 drop in the affected eye(s) twice daily, eight to twelve hours apart for the first two days, and then instill 1 drop in the affected eye(s) once daily for the next five days.

#### CONTRAINDICATIONS

None

#### WARNINGS AND PRECAUTIONS

##### Topical Ophthalmic Use Only

NOT FOR INJECTION. AzaSite is indicated for topical ophthalmic use only and should not be administered systemically, injected subconjunctivally, or introduced directly into the anterior chamber of the eye.

##### Anaphylaxis and Hypersensitivity With Systemic Use of Azithromycin

In patients receiving systemically administered azithromycin, serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens Johnson Syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy. Although rare, fatalities have been reported. While these reactions have not been observed with topical ophthalmic use of AzaSite, the potential for anaphylaxis or other hypersensitivity reactions should be considered, since patients with a known hypersensitivity to azithromycin or erythromycin were excluded from study.

##### Growth of Resistant Organisms With Prolonged Use

As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and where appropriate, fluorescein staining.

##### Avoidance of Contact Lenses

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

#### ADVERSE REACTIONS

The most frequently reported ocular adverse reaction in patients receiving AzaSite was eye irritation. This reaction occurred in approximately 1% to 2% of patients. Other adverse reactions associated with the use of AzaSite were reported in

less than 1% of patients and included burning, stinging and irritation upon instillation, contact dermatitis, corneal erosion, dry eye, dysgeusia, nasal congestion, ocular discharge, punctate keratitis, and sinusitis.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

**Pregnancy Category B.** Reproduction studies have been performed in rats and mice at doses up to 200 mg/kg/d. The highest dose was associated with moderate maternal toxicity. These doses are estimated to be approximately 5000 times the maximum human ocular daily dose of 2 mg. In the animal studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

##### Nursing Mothers

It is not known whether azithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when azithromycin is administered to a nursing woman.

##### Pediatric Use

The safety and effectiveness of AzaSite solution in pediatric patients below 1 year of age have not been established. The efficacy of AzaSite in treating bacterial conjunctivitis in pediatric patients one year or older has been demonstrated in controlled clinical trials.

##### Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

#### STORAGE AND HANDLING

Store unopened bottle under refrigeration at 2°C to 8°C (36°F to 46°F). Once the bottle is opened, store at 2°C to 25°C (36°F to 77°F) for up to 14 days. Discard after the 14 days.

#### PATIENT COUNSELING INFORMATION

Patients should be advised to avoid contaminating the applicator tip by allowing it to touch the eye, fingers, or other sources. Patients should be directed to discontinue use and contact a physician if any signs of an allergic reaction occur.

Patients should be told that although it is common to feel better early in the course of the therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by AzaSite or other antibacterial drugs in the future.

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis. Patients are advised to thoroughly wash hands before using AzaSite.

#### Rx only

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Manufactured by Cardinal Health  
U.S. PAT NO. 5,225,196; 5,192,535; 6,239,113; 6,569,443;  
6,861,411; 7,056,893; and Patents Pending  
AZA-0037

INSPIRE

## Hotline Launched for Colon Cancer Patients

The Patient Advocate Foundation is offering the Colorectal CareLine, a hotline designed to assist people who have been diagnosed with colorectal cancer and are seeking education and access to care. The CareLine is staffed by case managers with both nursing and social work backgrounds. Financial aid is available for those who need financial assistance. To contact the CareLine, which is sponsored by Amgen Inc., call 866-657-8634. ■