


SEPTEMBER 28, 2023

GEDP Breaking Barriers to Care through a Multidisciplinary Approach

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Objectives

- Describe pathophysiology of EoE
- Multidisciplinary care in the Gastrointestinal Eosinophilic Diseases Program (GEDP)
- Describe new and developing treatments in EoE



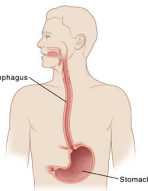
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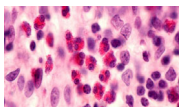
What is EoE?

Eosinophilic esophagitis is a chronic disease in which a type of white blood cell called an eosinophil builds up in the lining of the esophagus



Depending on the part of the gastrointestinal tract affected, these diseases can be called a variety of different names such as:

- Eosinophilic esophagitis (EoE)
- Eosinophilic gastritis
- Eosinophilic colitis



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Epidemiology of Eosinophilic Esophagitis (EoE)

- Prevalence is 1-4 in 10,000
- 75% of patients are male
- 75% of patients have associated atopic diseases
- **Most common cause for food impaction**
- Seen in 12-23% of patients undergoing endoscopy for difficulty swallowing



Waasdorp-Hurtado et al. JPGN 2011.
Dellon et al. Gastroenterology Clinics of North America 2014.
Furuta et al. Gastroenterology 2007.

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Symptoms of EoE can vary by age

Young children

- Feeding difficulties
- Gagging
- Vomiting
- Refusal of food
- Regurgitation/ Reflux
- Food or foreign body impaction
- Dysphagia
- Abdominal pain
- Coughing with eating

Older children & adults

- Dysphagia
- Food impaction
- Chest pain
- Regurgitation/ Reflux



Furuta et al. Gastroenterology 2007.

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How is EoE Diagnosed?

Diagnostic Criteria

- Combines clinical findings with microscopic findings
 - Clinically characterized by esophageal dysfunction
 - Pathologically 1 or more biopsies show eosinophil predominant inflammation (>15 Eos/high power field)



Furuta et al. Gastroenterology 2007

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Complications of EoE

- Esophageal stricture
- Esophageal food/foreign body impaction
- Feeding dysfunction



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What is the goal of EoE treatment?

- Improvement of symptoms
- Aim to maintain growth and development
- Prevention of complications
- Choose treatment that will maintain quality of life



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How is EoE Treated?

- Medications- Drugs
- Swallowed Topical Corticosteroids
 - PPI - Proton Pump Inhibitors
 - Biologics
- Dietary therapy
- Elimination Diets
 - Allergy Directed Diets
 - Elemental Diets
- Dilation



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Medications: What are swallowed topical steroids?

- A medication that decreases inflammation
- It is swallowed and coats the esophagus
- Taken twice daily
- Effectiveness of swallowed topical steroids 60-90%



Konikoff et al. Gastroenterology 2006.
 Acoves et al. Am J Gastroenterol 2007.
 Dohil et al. Gastroenterology 2010.
 Straumann et al. Gastroenterology 2010.
 Alexander et al. Clin Gastroenterol Hepatol 2012.
 Butz Gastroenterology 2014

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Topical Steroid Dosages Based On Age

Medication	Years of Age	Years of Age	Years of Age	Starting Dosage
	1-5	6-11	12 and older	All
Fluticasone (Flovent)	44 mcg	110 mcg	220 mcg	2 puffs swallowed twice a day. Order one inhaler per month.
Budesonide (Pulmicort)	0.25mg/2ml	0.5mg/2ml	1mg per dose (2 respules of 0.5mg, doubling Splenda or Nutra)	1 respule twice a day mixed with 5 packets Splenda or 1/2 teaspoon Nutra.
Ciclesonide (Alvesco)	80 mcg	80 mcg	160 mcg	2 puffs swallowed twice a day. Order two inhalers per month.
Beclomethasone Dipropionate (QVAR)	40 mcg	40 mcg	80 mcg	2 puffs swallowed twice a day. Order one inhaler per month.

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What are the side effects of swallowed topical steroids?



- Oral thrush
- Behavior changes
- Adrenal insufficiency - When the adrenal glands responsible for the production of cortisol don't produce enough hormones (cortisol)

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What are Proton Pump Inhibitors?



- Reduce stomach and acid production
- Common Proton Pump Inhibitors
 - Omeprazole / Prilosec
 - Lansoprazole / Prevacid
 - Esomeprazole / Nexium

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Proton Pump Inhibitors



- Previous guidelines recommend PPI trial or normal PH impedance probe to "rule out" GERD as a cause of esophageal eosinophilia
- Clinical example:
 - Patient presents with esophageal dysfunction
 - Start high dose PPI to rule out GERD
 - If still symptomatic after this trial, recommend endoscopy to rule out Eosinophilic Esophagitis



Molina-Infante et al. Gut 2016.
Lucendo et al. Clinical Gastroenterology and Hepatology

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Proton Pump Inhibitors

- Evidence now suggests that PPI's are better classified as treatment for EoE rather than as a diagnostic criteria
- Data on PPI effectiveness varies, 50-60%



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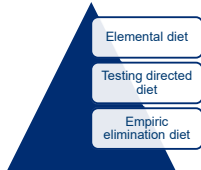
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Long Term Side Effects of PPI

Side Effect	Strength of Association
Bone fractures	Weak
GI infections	Moderate
Pneumonia	Weak
Kidney events	Weak
Dementia	Weak
Hypomagnesemia	Weak
Rebound acid hypersecretion	Moderate
Iron & B12 absorption	Weak
Liver Disease	Weak

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How do you treat EoE with dietary elimination?



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What is an elemental diet?

- All food is taken out of the diet and an allergy-free formula is used.
- 90.8 % effective

Kelly et al. Gastroenterology 1995.
 Arias et al. Expert Rev Clin Immunol 2014.

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What is a 1 food Empiric Elimination Diet ?

Elimination of -

- Milk : all types
Butter, margarine spread, yoghurt
Cream, ice cream



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What is a 2 Food Empiric Elimination Diet?

Elimination of -

- Milk and Milk products (buffalo, goats ewe milk)
- Wheat and wheat containing foods



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What is a 4 Food Empiric Elimination Diet ?

Elimination of -

- Milk and milk products
- Egg and egg containing products
- Wheat and wheat containing products
- Soy and soy containing products

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What is an 6 Food Empiric Elimination Diet ?

Elimination of -

- Milk and Milk products
- Egg and Egg containing foods
- Wheat and Wheat containing foods
- Soy and soy containing foods
- Fish/shellfish
- Peanuts and tree nuts
- 72% effective



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What Is Testing Directed Diet ?

Allergy testing to child's allergen's

- Overall Effectiveness: 45.5%
- Select studies in children around 65%
- Only 2 studies in adults with 26.6% & 35% effective



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Arias et al 2014

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Rank et al. Technical Review on the Management of Eosinophilic Esophagitis: a report from the AGA Institute and the joint task force on allergy-immunology practice parameters. Ann Allergy Asthma Immunol 2020

Dietary Approach	# of Studies	Achievement of histopathologic remission	Quality of Evidence
Elemental Diet	6 observational studies	93.6%	Moderate
6FED	10 single arm studies	67.9%	Low
4FED	3 single arm studies	56.9%	Low
2FED	2 single arm studies	42.1%	Very Low
1FED	2 single arm studies	54.1%	Very Low
Testing directed	12 single arm studies	50.8%	Very low

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Table 3. Pros and cons of specific elimination diets.

	Pros	Cons
Elemental diet	<ul style="list-style-type: none"> Highly effective Useful in patients with preexisting multiple food eliminations 	<ul style="list-style-type: none"> May require tube feeding May contribute to sensory and oral motor delays in young children Difficult to adhere to in adults Carries risk of social isolation Can be costly for some patients May require numerous endoscopies to identify food triggers
Test-directed elimination diet	<ul style="list-style-type: none"> Allows more foods to be consumed than an elemental diet 	<ul style="list-style-type: none"> Requires extensive testing, most not yet standardized or validated Has higher likelihood of creating set-up for <i>de novo</i> acute allergic reactions to food
Empiric elimination diet	<ul style="list-style-type: none"> Allows more foods to be consumed than an elemental diet Does not require any testing For some patients, can be less costly than the elemental diet 	<ul style="list-style-type: none"> Some empiric diets are quite restrictive Multiple endoscopies may be needed to identify food triggers

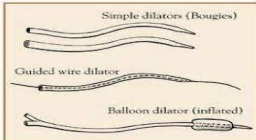
Children's Hospital Colorado  School of Medicine Chehade et al. 2020 25


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Procedure: What is esophageal dilation?

Esophageal dilation is used to stretch open a narrowed area (stricture) in the esophagus or another part of the gastrointestinal (GI) tract.

- Does not treat the underlying inflammation




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Radiology images -

Normal Esophagus



Esophagus with stricture

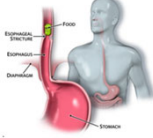


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What are Symptoms of Food Impaction?

- Food feels like is stuck and has not passed
- Not able to swallow other things (foods, other liquids)
- Drooling not able to swallow saliva
- When is it an emergency?
 - It is an emergency if the food impaction does not pass
 - Patient will need to go to the ED
 - Can try warm water or carbonated liquids- coke, carbonated water, other sodas
- When is it not an emergency ?
 - If they have been able to drink liquids or eat a meal, the food impaction has passed
 - Some people still feel pain or sensation there, but if they have been able to drink liquids or eat other foods, it is unlikely and impaction



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Our Mission

- Our mission is to improve the quality of life for patients and families affected by Eosinophilic Gastrointestinal Disease.
- We offer a thorough evaluation for pediatric patients with an established diagnosis.

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Gastrointestinal Eosinophilic Diseases Program (GEDP)

A Multidisciplinary Collaboration

- 1 Gastroenterologists (3 MDs)
- 2 Allergists (3 MDs)
- 3 Registered Dietician (3)
- 4 Feeding Therapist (5 SLP/ OT)
- 5 Allergy/ GI RNs, MAs
- research



Outside of Clinic:

- Psychologists
- Radiologists
- Pathologists

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What is the role of the Allergist in treatment of EoE?

- Management of other Atopic (asthma, eczema) conditions
- Fine tuning dietary therapy
- Assessment of seasonal allergies and role it plays with EoE
- Aid in decision for timing of next endoscopy
- Reintroduction of foods



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What is the role of the Dietitian in EoE?

- Registered Dietitian-**
- Registered Dietitians are food and nutrition experts. The dietitian plays a large role with the management of your child's diet intake and nutritional needs. They will assess if any adjustments need to be made with regards to diet and or supplements
 - They are experts in food and nutrition
 - Play an essential role in food elimination diets



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What is the role of the Feeding Specialist in EoE?

- Feeding Specialist -**
- Skilled at working with children with specific feeding behaviors
 - Help's lower stress and fear about eating
 - Step's to successful eating.
 - Setting goals to help improve mealtimes
 - Pill swallowing



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What is the role of research

- Our Research Program continues to engage in collaborative research studies dedicated to addressing immediate and long term needs of our patients with Eosinophilic Diseases.

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What is the role of the GI/ Allergy Nurse, MA, Administration

Our goal is to optimize patient care

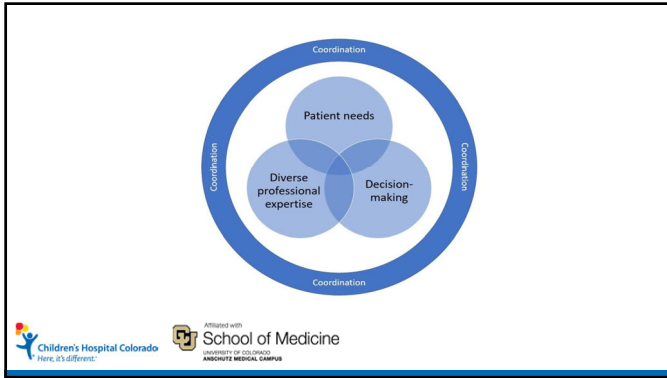
- Patient education pre and post multidisciplinary visit
 - Expectations of appointment
 - Procedure, radiology education
 - Medication education
- Care Coordination
 - Local and out of state
 - Provided point of contact and ongoing follow up care and recommendations

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What is the role of psychologist?

- Help's assess if there are psychosocial stressors associated with the diagnosis of eosinophilic diseases.
 - Childhood chronic illnesses can often give rise to a host of challenges for families
- Help manage anxiety, communication with care takers, managing symptoms and medication compliance, school issues, pill swallowing.
- Provides developmental screening to help families understand the impact of chronic illnesses on child development

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Breaking Barriers to Care

- Dupilumab / Dupixent
 - Education across state lines
- Barrium Pill Esophagram
- Endoflip
- Transnasal Endoscopy
- Esophageal String Test

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What biologics can be used to treat EoE?

Dupilumab/Dupixent

FDA Approves First Treatment for Eosinophilic Esophagitis, a Chronic Immune Disorder

"It is the first and only FDA treatment that treats the underlying cause of EoE"

"Today's approval will fulfill an important unmet need for the increasing number of patients with eosinophilic esophagitis."

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How does Dupilumab/Dupixent work?

- Dupilumab targets an underlying source of inflammation which is the cause of EoE
 - Target specific proteins that can contribute to the disease



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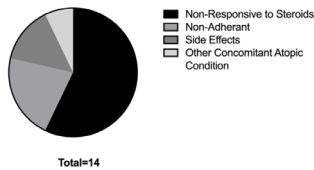
Who can get Dupilumab/Dupixent for their EoE?

- Patients that have been diagnosed with EoE
- Ages 12+ Years
- Weight at least 88lb (40kg)



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Who should we consider Dupilumab in for EoE?



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How often do you take Dupilumab/Dupixent?

▪ Dose for EoE - commonly prescribed as 300 mg injected in areas below...subcutaneously in pen or prefilled syringe once per week



The diagram shows a human silhouette with green circles indicating injection sites on the Outer Upper Arms, Abdomen, and Thighs. A legend below indicates that yellow circles represent 'Injection sites for subcutaneous therapy' and green circles represent 'Injection sites for intravenous therapy'. To the right, a cross-section of the skin shows a needle inserted at a 45-degree angle into the subcutaneous tissue layer.


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Dupilumab

Prefilled pen Prefilled syringe



The image shows two forms of Dupilumab: a prefilled pen and a prefilled syringe. The pen is white with green and yellow accents, and the syringe is blue and white.

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What are the side effects of dupilumab/dupixent?

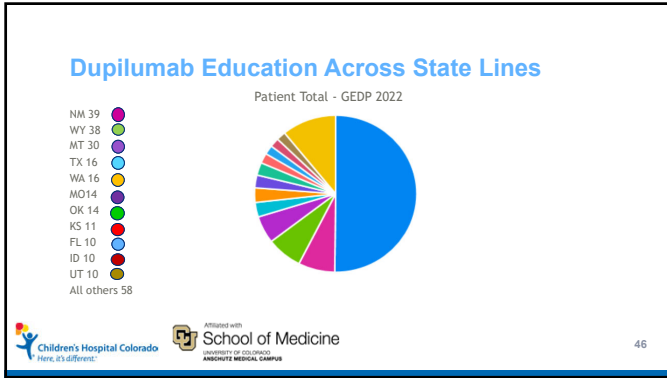
The most common side effects include:

- Injection site reaction (redness, swelling, etc.)
- Upper respiratory tract infection
- Cold sores in your mouth or on your lips
- Joint pain (arthralgia)
- Eye irritation

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Project Development

Meeting patient and family needs

- Optimizing the use of Telehealth and Nurse Licensure Compacts for Out of State care for EoE patients receiving dupilumab
- Developing standard of care practiced for patients and families for the use of a new medication
 - Utilizing telehealth nursing educational visits during the first year of Dupilumab use for EoE

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Dupilumab Nursing Program for patients and families during in person and telehealth visits

Table 1: Dupilumab Nursing Program for Patients and Families during in person and telehealth visits

- Review dose and frequency of giving dupilumab
- Review optimal sites for injection
- Review proper use of the pen or prefilled syringe
- Instruct on proper technique of giving the subcutaneous injection
- Observe patient or family member giving injection
- Identify most common side effects
 - Injection site reaction
 - Upper respiratory tract infections
 - Arthralgia
 - Conjunctivitis
- Inform about treatments to alleviate injection site pain
 - Allow medication reach room temperature 24 hours prior to the injection
 - Apply cool compress to site prior to injection
 - Use "Buzzy Bee" at injection site
 - Provide diphenhydramine or hydrocortisone cream after injection

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In State GEDP Patient Education on Dupilumab

- Patient and family is appointed a Nursing visit for education on Dupilumab this can be in person or telehealth
 - The injection will be given at that time of the visit
 - The injection will be given by patient or family member
 - Patient will remain in the visit for 20 minutes to observe for any reaction



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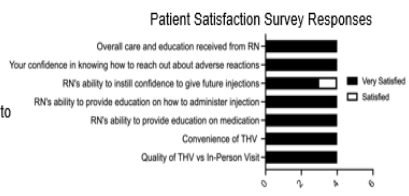
GEDP OOS Nurse Telehealth Visits

- Patient and family is appointed a telehealth nursing visit for education on Dupilumab
- The patient has to reside in a nursing compact state
 - The injection will be given at that time of the visit
 - The injection will be given by patient or family member
- Patient will remain in the visit for 20 minutes to observe for any reaction



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Figure 2: Patient Satisfaction Survey Responses- 4 of 10 patients responded to patient satisfaction survey after the telehealth visit



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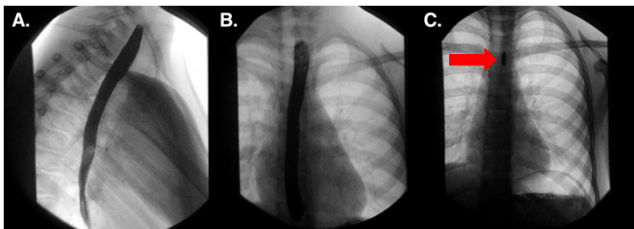
Barium Pill Esophagram

- Esophagram has been used to evaluate for esophageal stricture and long segment narrowing in Eosinophilic Esophagitis and other esophageal disorders
- Identifying patients that may benefit from esophageal dilation (stretching of the esophagus) can be challenging to identify very subtle narrowing
- Addition of barium pill esophagram allowed detection of the narrowing that may have been missed with esophagram alone



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Barium Pill Esophagram



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Endoflip

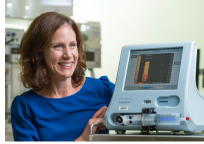
- Research started at Children's Hospital Colorado in 2014.
- Researching the use of Endoflip for Eosinophilic Esophagitis to see if this will be useful in detecting narrowing /stricture of esophagus



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What is Endoflip ?

- This can be done with Upper endoscopy procedure
- A catheter is gently passed through the mouth down into the esophagus . A flexible balloon is attached to a narrow catheter . The balloon is filled with saline and this measures esophageal pressure and diameter in real time.
- This can be done on patients with EoE or that have symptoms prior to their diagnosis.



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Transnasal Endoscopy



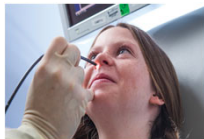
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What is a Transnasal Endoscopy?

Development from a multidisciplinary collaboration

- Aerodigestive Program: Working together with pulmonology and otolaryngology
- Led to the development of unsedated (child is awake) TNE in pediatrics at Children's Hospital Colorado in 2014



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What is a TNE?

- TNE is Un-sedated -child remains awake
- The provider uses soft bendable tube
- The tube is put into the nostril and gently passed down into the esophagus and stomach
- During the test the endoscopist will take small biopsies of the tissue from inside the esophagus and stomach
 - The tube is also used to look at the esophagus



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TNE – Average time in office

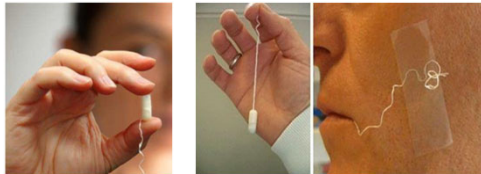
- Arrive 15 minutes prior to TNE
- When first started average time for TNE in office was 70 minutes from check in to check out
- Now takes 40 minutes
- Procedure takes 3-8 minutes



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What is Esophageal String Test ?

- First string test done at Children's Hospital Colorado August 2022



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Esophageal String Test

- EST was able to capture eosinophil-associated biomarkers
- Biomarkers (MBP and eotaxin-3) correlate with peak eosinophil count and endoscopic visual scoring

The 1-hour EST distinguishes active from inactive EoE in children and adults and can facilitate monitoring of disease activity in a safe and minimally invasive fashion



Furuta et al. Gut, 2013.
Ackerman et al. Am J Gastroenterol, 2019.

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Esophageal String Test

- Used to evaluate the esophagus for eosinophilic inflammation consistent with active EoE
 - Can help with frequent monitoring of esophageal inflammation during drug treatment, elimination diets and food re-introductions
- Safe and minimally invasive
- String stays in esophagus for 1 hour
- Done in office
- Can help with management of EoE without doing a more invasive endoscopy



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Who Can Have an Esophageal String Test Done?

- Must be able to swallow a capsule/pill to do the string test
 - If the patient is unable to swallow capsules, they should work with their EoE team to learn how to swallow pills/capsules.
- Cannot have allergy to bovine /beef - (capsule is made of bovine)
- Cannot have esophageal stricture /narrowing



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What should the Patient know before the procedure

- No eating 2 hours prior to the procedure
- No drinking 1 hour prior to the procedure
- No MRI for 48 hours following procedure

What if the patient vomits ?
 Have the patient return on a different day to repeat procedure

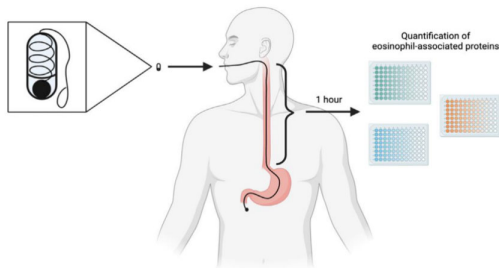
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Nurse visit for the Esophageal String

Before swallowing the String

- Explain the procedure to the patient and family
- Provide water
- Remove capsule from the pouch
- Unravel string from the outer portion of the capsule
- Hold the string while the patient swallows the capsule
- Instruct to swallow the capsule with water

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Nurse visit for the Esophageal String

After Swallowing the String




- The Patient swallows the capsule
- The string is secured to the patients check
- The collection string continuously unravels reaching the upper small intestine
- The string is marked where it lies on the corner of the patients mouth
 - This is the 0 mark (used once string is pulled out)
- The string will remain in the patients mouth x 1 hour
- Once the hour is completed the esophageal string is removed from the patients mouth

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Identification of esophageal section

- The string is then put on a measuring board with parafilm
 - measurement starts at 20 cm (for children)- PH stick is used to mark the string every 2 cm's to identify esophageal section







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If Unable to Identify the Esophageal Section

What if we are unable to identify the esophageal section?

- Use the Equation for Esophageal Length to identify where the GASTRIC region BEGINS
 - Children: $5 + 0.252 \times \text{height (cm)}$
 - Adults: $6.7 + 0.226 \times \text{height (cm)}$
 - Example: I am 5'4" tall
 - $5'4" = 64 \text{ inches} = 162.56 \text{ cm}$
 - $6.7 + 0.226 \times 162.56 = 43.44 \text{ cm}$
 - My gastric region begins at approximately 43.44 cm → mark here as the end of the esophageal region

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Prepare Sample

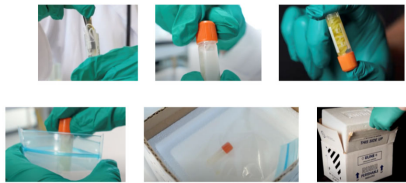
The esophageal string segment is then transferred into the sample buffer vial, mix, and taken to the lab on dry ice



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Collection of the sample

COLLECT SAMPLE



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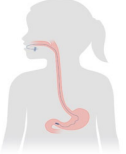
EoE Score

- The EoE Score represents the probability of a patient having the equivalent of >15 peak eosinophils per high power field (HPF) in biopsies of their esophageal epithelium.
- An EoE Score of >0.53 represents a high likelihood that the patient has active EoE, with sensitivity of 80% and specificity of 75%

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Esophageal String



Esophageal String (E-String) Test: 23A-054Y0002
 Status: Final result

0 Result Notes

Component	Ref Range & Units
<input checked="" type="checkbox"/> EoScore(TM)	<0.530 Probability 1.000

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Esophageal String

- 32 patients have successfully completed the esophageal string since 9/2022
- We are expanding the use of the esophageal string test to the Digestive Health Institute in January 2024

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Summary

- EoE is a chronic disease
- Treatment is guided by family's goals and priorities: PPI vs topical steroids vs diet elimination and there are new medication on the horizon
- Collaboration is key- we work together to improve quality of life with continued development of new treatments and methods of disease monitoring

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Questions



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