



W-F Professional Associates, Inc. 400 Lake Cook Rd., Suite 207 Deerfield, IL 60015 847-945-8050

March 2007 "Review of GERD" 707-000-07-003-H01



THIS MONTH--
"Review of GERD"

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HAVE YOU RECENTLY MOVED? PLEASE NOTIFY US.

In this lesson we review GERD. Specifically we concentrate upon antacids, and OTC H2RAs. Our goal is consideration of therapeutic options. In a future lesson we will discuss the prescription PPIs. This lesson provides 1.25 hours (0.125 CEUs) of credit, and is intended for pharmacists in all practice settings.

The program ID # for this lesson is 707-000-07-003-H01.

Pharmacists completing this lesson by March 31, 2010 may receive full credit.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

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The objectives of this lesson are such that upon completion the participant will be able to:

1. Define GERD.
 2. Describe the defensive mechanism that protects the stomach & esophagus.
 3. Discuss signs & symptoms of GERD.
 4. List the major complications associated with GERD.
 5. Relate the role of lifestyle modification in managing GERD.
 6. Differentiate between the various antacids utilized in the treatment of GERD.
 7. Comment upon the mechanisms of action & side effects of the H2RAs.
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BACKGROUND

Gastric distress, such as heartburn (a condition that does not affect the heart, but triggers a burning sensation in the middle to lower chest along with a sour or bitter taste in the throat and mouth) is a common occurrence. These symptoms may appear following the intake of a large meal or while lying down. Heartburn affects about 20% of Americans at least once a week. Approximately 25% of people in the Western countries experience heartburn at least once a month. About 10% to 20% of the population in the US requires medications to treat the condition. Between 50% and 80% of pregnant women experience heartburn daily. The main cause of heartburn is gastroesophageal reflux disease (GERD), which is a backward movement of gastric contents from the stomach to the esophagus. Gastric reflux, for the most part, does not cause damage to the esophageal mucosa. However, if mucosal damage does occur, then the disorder is referred to as GERD. In the absence of esophageal damage, the gastric reflux is defined as nonerosive reflux disease (NERD).

ETIOLOGY AND PREDISPOSING FACTORS

GERD occurs when the lower esophageal sphincter (LES) fails to close. As a result, acidic stomach contents enter the esophagus. This can cause inflammation and injury to the esophageal mucosa. Mild acidic reflux is a benign physiologic process and often occurs following meals. The incidence is usually short lived and has no after effect. The increase in frequency, severity and length of exposure to acid can potentially cause damage to the tissue. Frequent occurrences of reflux, strongly acidic gastric contents, and slower than normal clearance of stomach contents that entered the esophagus can lead to esophageal mucosal damage. The following are the main predisposing factors for GERD: excess weight, pregnancy and hiatal hernia.

Overweight: Being overweight may contribute to retrograde movement of gastric contents due to increased intraabdominal pressure, thereby affecting the tonicity of the LES. Likewise, wearing tight clothing around the waist may cause gastric reflux.

Pregnancy: One of the most common complaints during pregnancy is heartburn. It has been estimated that between 50% to 80% of pregnant women experience GERD, especially after the fourth month. It has been postulated that such symptoms occur as a result of increased pressure on the stomach. Other reports indicate that hormones play a role.

Hiatal Hernia: Herniation of the upper portion of the stomach through the diaphragm and into the thoracic cavity may inhibit closure of the LES allowing gastric contents to seep into the esophagus, especially when the patient is in a supine position.

PATHOGENESIS

In a normal healthy patient a balance exists between aggressive and defensive forces within the stomach and esophagus. The stomach is provided with normal defensive mechanisms to counter the acidic environment. Such mechanisms are referred to as gastric mucosal barriers. The gastric mucosa is protected by mucus and bicarbonate liberated from the gastric epithelial cells. Such secretions prevent or reduce the penetration of the gastric mucosa by the hydrogen ions. Moreover, blood flow through the gastric mucosa results in the removal of the hydrogen ion as well as in promotion of healing in the event that damage has taken place. In the presence of reduced blood flow, the risk for damage to the mucosa is increased. However, the epithelial cells are capable of repairing damage through reconstruction (fast cell turnover). This repair process is enhanced by

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the oxygen and nutrients provided by blood flowing through the mucosa.

Prostaglandins, especially prostaglandin E2, that are produced by the gastric mucosa provide added protection to the mucosa by inhibiting gastric secretion, and assist in keeping regular blood flow within the gastric mucosa.

Other defensive factors include the LES, esophageal clearance, saliva, and tissue resistance. The function of the LES, which consists of smooth muscles, is to prevent stomach contents from entering the esophagus. In healthy individuals, the sphincter's tone is capable of preventing regurgitation. However, such tone may vary from one individual to another. As a result the LES may not relax, thereby allowing backward movement of the gastric fluid into the esophagus.

The length of exposure of the esophageal epithelium to the gastric contents depends on the speed at which the refluxate (refluxed gastric fluid) is returned to the stomach. The longer the time of exposure of the esophageal mucosa to refluxate, the higher the risk of causing inflammation and injury. This process, which is referred to as esophageal clearance, is assisted by gravity and should take only a few minutes.

The bicarbonate contained in saliva assists in keeping the acidity of the uncleared esophageal contents low, thereby preventing inflammation and irritation that may be caused by the originally strongly acidic environment. Normal esophageal epithelium is capable of resisting the harmful effect of refluxate due to the presence of mucus that coats the surface of the tissue. This layer of mucus provides protection against physical and chemical injury. In addition, the esophageal epithelium has the capability for regeneration of injured tissue.

Gastric emptying is a physiologic process that occurs regularly. Factors such as fat-rich meals, and when a patient is in the supine position can cause a delay in gastric emptying rate. The slower the emptying rate, the higher the risk of reflux. Regardless of the cause, the damage done by refluxate depends on the duration of exposure of the esophageal mucosa to the gastric contents. The longer the contact, the higher the risk of producing mucosal damage, such as inflammation, hyperplasia, esophageal erosion, or ulcerations.

SIGNS AND SYMPTOMS

The most common symptom of GERD is heartburn or pyrosis. Patients describe such symptoms as a burning or gripping pain in the lower part of the chest that may radiate to the left arm, shoulder or neck. Heartburn often occurs after consuming a large or a fatty meal, or after lying down. The pain may interfere with sleep, as the patient may experience the "water-brash" phenomenon (fluids rush into the mouth due to hypersalivation caused by acid refluxate). Heartburn may occur when the patients stoops over or during exercise after meals. There may be complaints of dysphasia (difficulty in swallowing), odynophagia (pain upon swallowing) and regurgitation. Problems experienced during swallowing are due to injuries to the esophageal muscle and mucosa. Esophageal ulceration may cause bleeding. Esophageal damage may result in experiencing a sensation of an object in the throat (globus sensation). Other symptoms include tightness in the throat, pharyngitis, laryngitis, choking episodes, bitter taste in the mouth, bloating and nausea. Even though symptoms of GERD may cause sharp or dull chest pain that may radiate to the back and neck, such symptoms usually are transient. Another symptom that may be experienced by patients with GERD is aspiration of refluxate into airways and lungs. This can result in coughing and asthma-like symptoms caused by chemical irritation to the bronchi and bronchioles. Furthermore, aspiration pneumonia, chronic dilatation of the bronchi, laryngospasm, coughing of blood and pulmonary collapse may occur.

COMPLICATIONS OF GERD

Failure to treat GERD may lead to serious health problems. Complications such as esophageal ulcerations, esophageal stricture (narrowing of esophageal lumen), and dysphasia may indicate serious mucosal damage. Erosive esophagitis may lead to Barrett's esophagus, which is characterized by midesophageal stricture, esophageal ulceration and changes in the lower esophageal mucosa. Individuals with Barrett's esophagus are at risk of developing cancer of the esophagus. There are reports that indicate an association between the presence of GERD and esophageal cancer even in the absence of Barrett's esophagus.

TREATMENT

The major steps that should be taken in the treatment of GERD are: provide symptomatic relief, enhance healing of damaged tissue, prevent complications and recurrence of GERD. In order to alleviate symptoms or to accelerate healing of damaged mucosa, it is essential to reduce contact between the mucosa and the refluxate. This may be accomplished by increasing the pH of the stomach to above 4. **Lifestyle modifications**, along with the use of **antacids** and nonprescription **H2RAs** are useful in providing relief of mild to moderate GERD. In addition to their neutralizing effect on the acidic environment, antacids are capable of increasing LES pressure. Patients who fail to respond to this therapy may need to use prescription drugs (H2RAs and PPIs).

LIFESTYLE MODIFICATIONS

Lifestyle changes, such as dietary modifications, may reduce the intensity and occurrence of GERD. Since heartburn occurs mostly after overeating, when bending over or when lying down, one should avoid these factors. Gastric distension is increased intragastric pressure resulting in relaxation of the sphincter followed by movement of gastric contents into the esophagus. To reduce the possibility of gastric distension, patients with GERD should be counseled to eat several small meals a day. Since some GERD sufferers may experience nocturnal reflux, it is recommended that the last meal for such patients should be small, and taken a few hours before retiring in order to ensure completion of gastric emptying. Furthermore, patients should elevate the head of the bed by placing a foam wedge under their heads or other soft object.

Meal composition plays a role in triggering GERD. Fatty foods tend to interfere with the function of the esophageal sphincter and to decrease gastric emptying. Meals rich in protein are digested and evacuated at a faster rate than a meal rich in fat. Acidic foods or liquids such as citrus drinks, nonalcoholic beverages with or without caffeine, tomato juice or tomato containing products; spicy foods (chili, pizza, curry and hot pepper) should be avoided. Caffeine-containing drinks, such as regular or decaffeinated coffee and certain soft drinks are gastric irritants. Alcoholic beverages tend to increase gastric secretions and lower intra-gastric pressure. Depending on the alcohol contents, such products may directly irritate esophageal mucosa. Chocolate, which is fatty and contains caffeine, tends to impair sphincter function. Likewise, the intake of mint or spearmint has similar effects on the LES. Because of its nicotine contents, the use of tobacco, including smokeless, should be avoided. Nicotine can decrease the LES pressure and impairs esophageal clearance, thereby increasing the incidence of GERD.

There are a number of drugs that result in a significant decrease in pressure or have direct irritant effects. Aspirin, ibuprofen, caffeine, ethanol, theophylline, tricyclic antidepressants, progesterone, nitrates, morphine, meperidine, estrogen, calcium channel antagonists, and dopamine should be avoided by switching to other drugs with similar therapeutic effect and with lesser or no irritant effect.

PHARMACOLOGIC THERAPY

There are a number of therapeutic agents that may provide relief from symptoms of GERD. These medications include antacids, histamine 2-receptor antagonists (H2RAs) and Proton-Pump Inhibitors (PPIs).

ANTACIDS

Antacids play an important role in the management of GERD, especially in mild to moderate cases. Because of their chemical properties, antacids tend to decrease the pH of the gastric contents, thereby reducing the risk of damage caused by reflux, as well as by the frequency and the quality of refluxate. It has been reported that antacids may increase LES pressure. Even though the FDA recommends antacids to combat GERD, it allows manufacturers of nonprescription antacids to indicate that the product is to be used for heartburn, but will not permit the use of the word GERD on the label. Antacids should not be used in children less than 2 years old, and cannot be used for longer than 2 weeks of therapy unless advised by a physician. Patients

also should be advised as to the potential for drug interactions. Nonprescription antacids are usually used to treat minor gastric distress disorders such as heartburn, sour stomach and indigestion.

One or more of the following major ingredients are utilized in antacid products: sodium bicarbonate, calcium carbonate, aluminum hydroxide or phosphate and the magnesium salts such as hydroxide. These ingredients differ in potency, side effects, systemic absorption, and complications as a result of duration of action, drug interactions and dissolution rate.

Because antacids are basic compounds, once in the stomach they react with hydrochloric acid to cause a reduction in the acidity of the gastric contents. However, antacids in the usual doses are incapable of neutralizing gastric fluid and cannot maintain gastric pH above 4 to 5. Antacids have no effect on the quantity of acid secreted. Elevation of gastric pH caused by antacids may have detrimental effect on the conversion of pepsinogen to pepsin, and the activity of pepsin which requires an environment having pH 1.8 to 3. A gastric pH of 4 and greater may inhibit the activity of pepsin.

The onset of action of antacids is dependent upon dissolution rate in acidic gastric fluid. Sodium bicarbonate and magnesium hydroxide have a quick dissolution rate. Consequently they provide fast symptomatic relief of heartburn. The opposite is true for aluminum hydroxide and calcium carbonate. Such compounds have a slow dissolution rate in acidic pH. While the antacid effects of sodium bicarbonate and magnesium hydroxide are almost instantaneous, those of aluminum hydroxide and calcium carbonate may begin 10 to 30 minutes after ingestion. To enhance their effects, aluminum hydroxide and calcium carbonate are preferred in suspension rather than in tablet forms. Duration of action of an antacid depends on the dosage form and on the gastric emptying rate. The antacid effect is shorter if the product is taken before meals because the stomach is emptied quicker, than if the antacid is taken after meals. Food tends to reduce the gastric emptying rate. Because of their fast solubility in acidic media and their absorbability from the GI tract, sodium bicarbonate and magnesium hydroxide have shorter durations of action than aluminum hydroxide and calcium carbonate.

As indicated earlier, the FDA has determined that antacids are safe and effective in the management of heartburn, sour stomach and acid indigestion. Furthermore, such products are approved for use to relieve symptoms that occur following overeating or over indulgence of alcohol. The label for antacids may indicate its use for heartburn, sour stomach, acid indigestion and upset stomach associated with these symptoms or associated with overindulgence of food and alcohol. The FDA endorsed the use of antacid/acetaminophen combinations for combating symptoms for hangover or overeating and indulgence of alcohol (category I). However, products that contain antacid/cafeine combinations are considered category II, meaning that they are not generally recognized as safe and effective. It is not clear whether antacids alone are effective in treating GERD. Depending on its severity, patients who use antacids for treating this disorder may find it necessary to ingest up to five doses during the day. Occasionally, antacid products may include simethicone to combat flatulence and bloating. Such symptoms may accompany indigestion.

SODIUM BICARBONATE

Sodium bicarbonate is available in some nonprescription combination antacids. It is a powerful antacid that is very soluble in the acidic gastric fluid. Once in contact with the gastric fluid, it instantly reacts with the hydrochloric acid to release sodium chloride, carbon dioxide and water. Due to its solubility, sodium bicarbonate is systemically absorbed. As a result, it may cause systemic alkalosis. This contributes to milk-alkali syndrome. Such a condition occurs when systemic alkalosis, high level of calcium and renal failure are present simultaneously. The intake of sodium bicarbonate, along with calcium, can result in the milk-alkali syndrome. It may be encountered in pregnant women who take milk as well as calcium containing products. Likewise, women who ingest large doses of supplemental calcium may become vulnerable. Symptoms of milk-alkali syndrome include hypocalcaemia, alkalosis, irritability, headache, vertigo, nausea, vomiting and weakness. Chronic intake of calcium may cause neurological disorders and renal impairment. When sodium bicarbonate is taken, it raises gastric acid pH rapidly. As a result the stomach responds by pumping more acid, thereby actually aggravat-

ing heartburn. This process is referred to as acid rebound. Regular sodium bicarbonate intake can result in an increase in patient's sodium load, causing fluid retention, edema, renal failure, and an increase in blood pressure. Due to its side effects, the use of sodium bicarbonate alone is almost obsolete. Sodium bicarbonate is not recommended to pregnant women and persons with high blood pressure due to the risk of systematic alkalosis, edema and weight gain.

CALCIUM CARBONATE

Calcium carbonate is a potent antacid that is soluble in gastric fluid, but at a slower dissolution rate and more prolonged action than sodium bicarbonate. Upon reaching the stomach, calcium carbonate reacts with the hydrochloric acid to produce calcium chloride, carbon dioxide and water. The vast majority of calcium chloride reaches the small intestine where it reacts with the bicarbonate to form an insoluble calcium salt. This is excreted in the feces, thereby causing non systemic effects. Unlike sodium bicarbonate, calcium carbonate is a non systemic antacid. Only a small portion of the calcium chloride does not react with the bicarbonate in the small intestine. Instead it is absorbed and enters general circulation. In cases where large doses of calcium carbonate are taken over a long period of time, enough calcium may be absorbed systemically to cause hypocalcaemia, a condition characterized by fatigue, muscle weakness, confusion, memory loss, and renal calculi. Patients with renal impairments are vulnerable to hypocalcaemia. Like sodium bicarbonate, calcium carbonate can cause acid rebound and milk-alkali syndrome.

MAGNESIUM SALTS

Magnesium hydroxide is the most commonly used magnesium salt as an antacid. However the oxide, carbonate, and trisilicate also have antacid properties, but are less potent. Compared to sodium bicarbonate and calcium carbonate, all magnesium salts are less potent. Following the intake of these salts, magnesium chloride is formed in the stomach, and most of it reacts with intestinal bicarbonate, thereby preventing the occurrence of systemic alkalosis. A small amount of magnesium chloride is absorbed, and eventually it is excreted by the kidney. Accumulation of magnesium ion may occur in patients with impaired kidney function. Symptoms may include: hypertension, nausea, vomiting, respiratory depression and muscle paralysis. Magnesium salts, especially the hydroxide form, are capable of causing osmotic diarrhea. In fact, magnesium salts at proper doses may be used as laxatives. Osmotic diarrhea is due to the small amount of magnesium hydroxide that failed to react with gastric acid. The incidence of diarrhea may occur in patients taking large doses of magnesium hydroxide. To prevent the occurrence of diarrhea, the magnesium salt is administered in combination with aluminum hydroxide, an antacid with astringent properties that combats diarrhea.

ALUMINUM HYDROXIDE

Aluminum hydroxide is the least potent of all antacids and dissolves slowly in the stomach. It reacts with gastric acid to form aluminum chloride. Like other antacids, the chloride salts react with the intestinal bicarbonate to produce poorly absorbed aluminum salts. Thus, the risk of developing systemic alkalosis following the intake of aluminum hydroxide is minimal. Up to about one-third of the aluminum chloride formed in the stomach is absorbed. Patients with renal impairment may experience hyperaluminemia. Other aluminum salts that are used as antacids are the phosphates and aminoacetates. The hydroxide salt is the most commonly used. The main side effect of aluminum salts is constipation. This is dose related. Chronic use of these compounds may result in intestinal obstruction, especially in elderly patients. Constipation can be relieved with mild laxatives, or may be prevented by taking a combination of aluminum-magnesium salts. The constipating effect of the aluminum hydroxide is relieved by the diarrheal effect caused by the magnesium chloride which is formed in the stomach after the intake of the magnesium hydroxide.

DRUG INTERACTIONS

There are a number of interactions that may occur with the concurrent intake of drugs and antacids. Even though the vast majority of these are clinically insignificant, in certain circumstances they may have potential for failure of treatment. Changing gastric acidity may increase absorption of salicylates, but also can cause early release of enteric-coated medications. Forming a complex with antacids may hinder the absorption of tetracycline. Aluminum hydroxide may slow gastric emptying rate. Labels for antacids must include the following statement: "drug interaction precaution: antacids may interact with certain prescription drugs. If you are presently taking prescription drugs, do not take this product without consulting with your physician or other health professional."

HISTAMINE 2- RECEPTOR ANTAGONISTS (H2RAs)

The H2RAs relieve GERD by binding to H2 receptors of parietal cells resulting in inhibition of gastric acid secretions thus reducing the risk of damage to the esophageal mucosa. It appears that such compounds have no effect on LES tone. H2RAs are well absorbed from the small intestine. The presence of food in the stomach appears to have no influence on absorption rate. However, the concurrent intake of antacids may reduce their bioavailability. All nonprescription H2RAs are indicated for heartburn, acid indigestion and sour stomach. While antacids provide symptomatic relief of these conditions, H2RAs tend to relieve discomfort in two hours after administration.

In the mid 1990's, H2RAs became available as nonprescription drugs, with doses one-half that of prescription drugs except for Tagamet HV 200 in which a 200mg prescription strength of Tagamet is available. These drugs are contraindicated in children 12 years of age and younger and should not be taken for more than two weeks after onset of symptoms and with frequency up to twice daily. Currently, there are four nonprescription H2RAs available on the market: in the order of potency these are famotidine, nizatidine, ranitidine, and cimetidine. In addition to potency, they vary in the time of onset of action and when to be taken. Famotidine should be taken one hour before eating, nizatidine either immediately before meals or up to one hour prior to eating, and cimetidine right before meals or up to half an hour before eating.

Adverse effects of H2RAs are not considered serious. The most common side effects include: headache, drowsiness, constipation, nausea and vomiting.

PROTON PUMP INHIBITORS (PPIs)

There are five PPIs that are available: esomeprazole, omeprazole, lansoprazole, rabeprazole, pantoprazole. The PPIs are capable of reducing the production of acid. We will discuss the prescription PPIs in a later lesson.

SUMMARY

GERD and heartburn are common occurrences, especially in persons who indulge in food and alcohol. Excess weight, pregnancy, wearing tight clothing around the waist, and hiatal hernia are factors that may predispose GERD. The stomach and esophagus are provided with normal defensive mechanisms to counter the effect of the acidity of the stomach. Such mechanisms include secretion of mucus and bicarbonate, blood flow through gastric mucosa, prostaglandins, saliva and esophageal clearance. Symptoms of GERD include heartburn, water-brash, dysphasia, regurgitation and odynophagia (pain upon swallowing). GERD and heartburn may be treated by using antacids, H2RAs, and PPIs. Lifestyle modifications may be useful in the symptomatic relief of GERD symptoms.

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FOR 2007

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Please fill-out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

Define GERD	Yes	No
Describe the defensive mechanism that protects stomach & esophagus	Yes	No
Discuss signs & symptoms of GERD	Yes	No
List the major complications associated with GERD	Yes	No
Relate the role of lifestyle modification in managing GERD	Yes	No
Differentiate between the antacids utilized for treating GERD	Yes	No
Comment upon mechanisms of action & side effects of H2RAs	Yes	No
2. Was the program independent & non-commercial?	Yes	No

	Poor			Average			Excellent
3. Relevance of topic to your practice	1	2	3	4	5	6	7

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

Quiz—Please Select the Most Correct Answer

- | | |
|--|---|
| <p>1. Heartburn is encountered:
 A. In 50-80% of pregnant women
 B. Mostly in normal weight patients
 C. Far less in the elderly
 D. Mostly in patients who eat small frequent meals</p> <p>2. Which of these is not considered a gastric defense barrier?
 A. Mucus & bicarbonate liberated from gastric epithelial cells
 B. Blood flowing through gastric mucosa
 C. Prostaglandins
 D. Age of patient</p> <p>3. The function of the LES is to facilitate stomach contents from entry to the esophagus.
 A. True
 B. False</p> <p>4. Odynophagia means:
 A. Difficulty in digesting
 B. Pain upon swallowing
 C. Difficulty in swallowing
 D. Excessive salivary secretion</p> <p>5. Acidic foods or liquids tend to enhance healing of damaged esophageal mucosa.
 A. True B. False</p> | <p>6. The FDA recommends antacids to combat GERD, but will not permit use of the word GERD on labels.
 A. True B. False</p> <p>7. Sodium bicarbonate is the antacid of choice for pregnant women.
 A. True
 B. False</p> <p>8. A common side effect of aluminum hydroxide is:
 A. Fluid retention
 B. Vertigo
 C. Headache
 D. Constipation</p> <p>9. H2RAs:
 A. Lower production of gastric acid
 B. Poorly absorbed from stomach
 C. Should be taken with antacids
 D. Available as prescription drugs</p> <p>10. Magnesium hydroxide is:
 A. Constipating
 B. A less potent antacid than magnesium trisilicate
 C. Is capable of producing osmotic diarrhea
 D. None of these</p> |
|--|---|

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