**Ablation Benefits Remain at 5 Years in Barrett’s**

**BY MICHELE Q. SULLIVAN**

*From the annual Digestive Disease Week*

New Orleans — In a prospective, multicenter trial of Barrett’s esophagus patients, radiofrequency ablation achieved complete eradication of intestinal metaplasia, which was maintained for at least 5 years in 92% of 50 patients.

The findings may have implications for future Barrett’s surveillance recommendations, said Dr. David E. Fleischer.

Since annual rates of progression to esophageal carcinoma are low—less than 1% according to most studies—watchful waiting is the usual approach for patients with intestinal metaplasia. Although national guidelines recommend surveillance only, ablation offers an alternative for some patients.

“When I explain [that] this could be an alternative to surveillance to my patients, they almost always prefer to have the procedure done,” said Dr. Fleischer of the Mayo Clinic, Scottsdale, Ariz.

He presented 5-year follow-up data on patients enrolled in the Ablation for Intestinal Metaplasia (AIM-II) Trial. The 70 patients originally enrolled in this study had Barrett’s esophagus and histologic evidence of intestinal metaplasia without dysplasia. All received circumferential radiofrequency ablation of the affected area.

The treatment was repeated in 4 months of a follow-up endoscopy showed residual disease.

A prior study reported 2.5-year outcomes in this group (GastroIntest. Endosc. 2008;68:867-76). For the 5-year follow-up, 50 patients who had complete eradication of intestinal metaplasia at 2.5 years (37 men, mean age 59 years) underwent a repeat endoscopy at 5 years, with a mean of 31 biopsy specimens obtained.

None of the patients had esophageal stricture or mucosal lesions. In 46 patients (92%), there was complete eradication of intestinal metaplasia. The other four patients (8%) had levels of residual disease and underwent a single session of radiofrequency ablation.

A repeat endoscopy and biopsy 2 months later showed no evidence of disease in all four patients.

“Radiofrequency ablation represents a durable, long-term approach to treating Barrett’s esophagus and restoring cells to normal,” Dr. Fleischer said.

“We’ve shown that by treating patients with early Barrett’s, we were able to eliminate the disease in most instances, and we hope that will lead to a reduction in the cancer associated with [Barrett’s esophagus],” he said.

He pointed out that only additional long-term follow-up with many more patients would be able to determine if radiofrequency ablation offers a complete cure for Barrett’s.

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**LIDOCLONE® (Lidocaine Patch 5%)**

**Brief Summary**

For full prescribing information refer to package insert.

**INDICATIONS AND USAGE**

LIDOCLONE is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin.

**CONTRAINdications**

LIDOCLONE should not be applied to skin with known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

**Warnings**

**Accidental Exposure in Children**

Even small amounts of LIDOCLONE can contain a large amount of lidocaine (at least 65 mg). The potential exists for a small child or pet to suffer serious adverse effects if accidentally ingesting a new or used LIDOCLONE patch. Although this risk is minimal, it is important for caregivers to Monitor LIDOCLONE for the safety of children, pets, and others. (See HANDLING AND DISPOSAL)

**Excessive Dosing**

Excessive dosing by applying LIDOCLONE to larger areas or for longer than the recommended wearing time could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects (see ADVERSE REACTIONS). LIDOCLONE toxicity can also result from mixing, i.e., using with another patch.

**Drug Interactions**

When LIDOCLONE is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

**Allergic Reactions**

A minor metabolite, 2, 6-xylidine, has been found to be of doubtful value.

**Systemic (Dose-Related) Reactions**

Systemic adverse reactions following appropriate use of LIDOCLONE are unlikely, due to the small dose absorbed (see CLINICAL PHARMACOLOGY, Pharmacokinetics). Systemic adverse effects of lidocaine are similar in nature regardless of the route of administration (epidural, intravenous, etc) and include the following:

- CNS: Excitatory reactions may be brief or not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness. Cardiovascular manifestations include bradycardia, hypotension, and cardiovascular collapse leading to arrest. Cardiovascular collapse often occurs within 1-2 min.

**Diaphoresis**

Lidoanalgesia from cutaneous irritation is rare, but could occur.

**Eye Exposure**

When lidocaine is applied to the eye, there is a potential for severe eye irritation with the use of lidocaine levels.

**External Heat Sources**

Application to broken or inflamed skin, although not recommended, may all contribute to increasing the blood concentration of lidocaine. It should be applied only to intact skin.

**Hepatic Impairment**

Due to the nature and limitation of spontaneous reports in postmarketing surveillance recommendations, said Dr. Fleischer.

**Impairment of Fertility**

LIDOCLONE has not been studied in nursing mothers. Lidocaine is excreted in human milk, and the milk:plasma ratio of lidocaine is 0.4. Caution should be exercised when LIDOCLONE is administered to a nursing woman.

**Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

**ADVERSE REACTIONS**

**Application Site Reactions**

- **Acute Overdose**: Management of overdose includes close monitoring, supportive care, and symptomatic treatment. The patient may require resuscitation, intubation, and ventilation. Toxic effects are additive and potentially synergistic.

**Excessive Dosing**

- **External Heat Sources**: Application to broken or inflamed skin, although not recommended, may all contribute to increasing the blood concentration of lidocaine.

**General**

- **Impairment of Fertility**: Impairment of fertility in animals and humans has not been studied.

**LIDOCLONE**

(Lidocaine Patch 5%)

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