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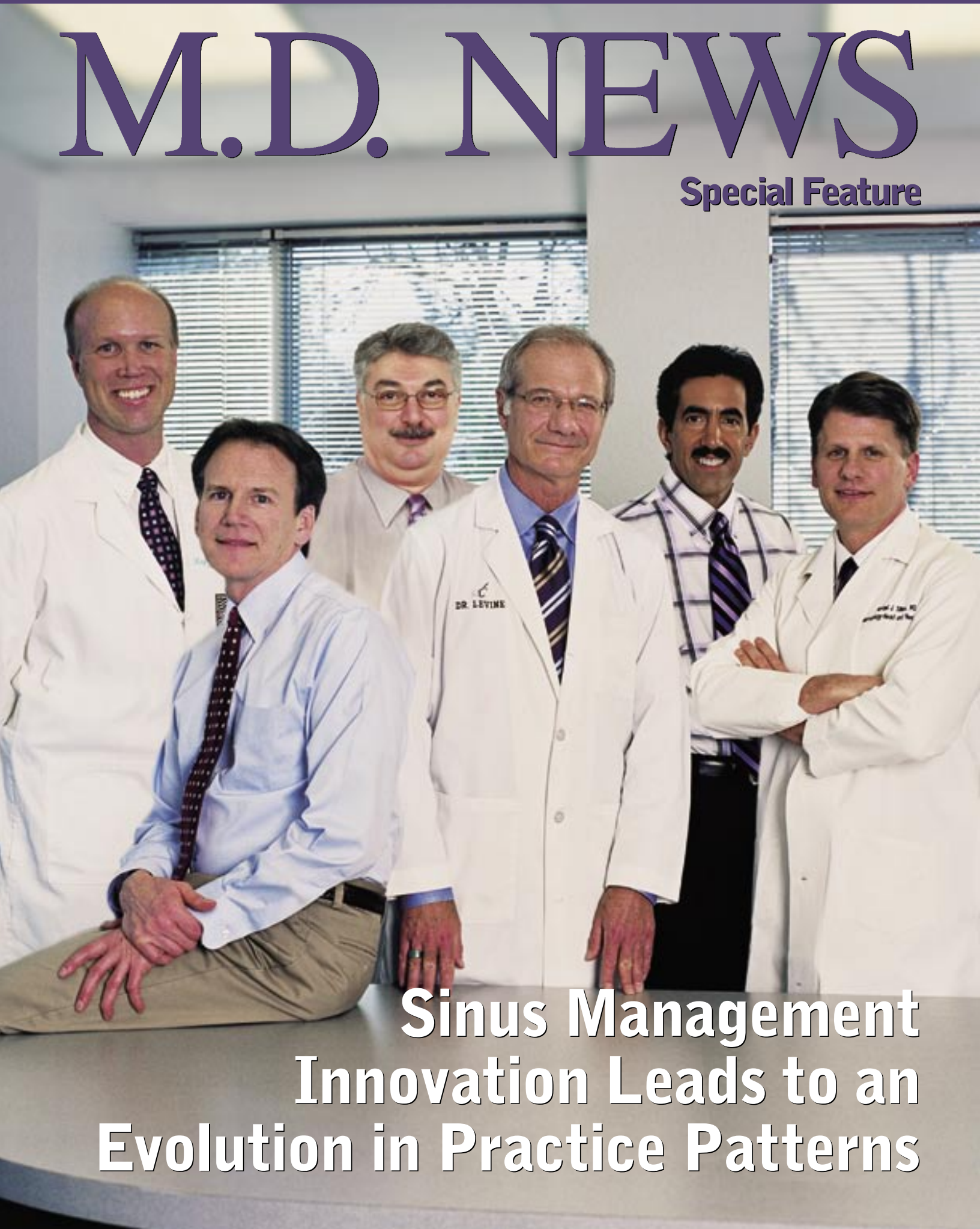
Special Feature

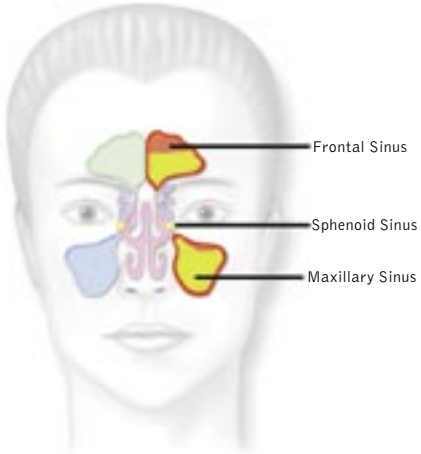


Sinus Management Innovation Leads to an Evolution in Practice Patterns

Sinus Management Innovation Leads to an Evolution in Practice Patterns

By Carol Sorgen

Approximately 37 million Americans suffer with sinusitis symptoms annually, making it one of the most common reasons for visits to primary care physicians. "Sinusitis considerably reduces a patient's quality of life," says Ray Weiss, M.D., Sinus Center of the South. In addition, sinusitis is the fifth most common condition for which antibiotics are prescribed in the United States and is responsible for total health care-related expenditures exceeding $8.1 billion per year. With such a large patient population and the societal implications, *M.D. News* assembled a panel of leading ENT physicians to shed some light on this complex disease, its care continuum and recent advancements in treatment.



Sinusitis patient with infected left frontal and left maxillary sinuses

A WIDE SPECTRUM OF OVERLAPPING SIGNS AND SYMPTOMS

Sinusitis refers to an inflammation of the sinus lining that can be associated with bacterial or viral infections and structural issues, like sinus ostia blockages. If the sinus ostium is closed, normal mucus drainage may not occur, predisposing the sinuses to infection and inflammation. The condition is considered acute when symptoms last less than four weeks and chronic when they persist for more than 12 weeks.

MATCHING PATIENTS' SYMPTOMS TO THEIR CONDITION

Experts don't necessarily agree, however, on the definition and pathophysiology of sinusitis. Some feel that rhinitis and sinusitis are linked conditions and have introduced the term *rhinosinusitis*, while others feel rhinitis and sinusitis are distinct

An Overview of Sinusitis

How prevalent is sinusitis?

- Sinusitis affects approximately 37 million people in the U.S. each year.[1]
- Sinusitis affects 21% of women and 16% of men each year.[2]
- Chronic sinusitis is more common than arthritis or high blood pressure.[3]

How does sinusitis affect one's quality of life?

- Sinusitis takes a greater toll on quality of life than even diabetes or congestive heart failure.[4]
- Total restricted activity days due to sinusitis are well over 73 million per year.[5]

What is the economic burden?

- Direct healthcare expenditures due to sinusitis cost over $8.1 billion each year.[6]
- Chronic sinusitis (not including acute sinusitis) results annually in an estimated 18-22 million physician office visits.[7]
- 645,000 people visit emergency rooms annually as a result of sinusitis.[8]
- Patients with chronic sinusitis have twice as many visits to primary care doctors and five times as many pharmacy fills as patients who do not have it.[9]

Sources:

1. National Institute of Allergy and Infectious Diseases
2. Anand, V., Ann Otol Rhinol Laryngol Suppl 113:2004
3. National Academy on an Aging Society
4. Benninger, M., Otolaryngol Head Neck Surg 2003; 129S: S1-S32
5. Anand, V., Ann Otol Rhinol Laryngol Suppl 113:2004
6. Anand, V., Ann Otol Rhinol Laryngol Suppl 113:2004
7. Benninger, M., Otolaryngol Head Neck Surg 2003; 129S: S1-S32
8. American Academy of Otolaryngology – Head and Neck Surgery
9. Anand, V., Ann Otol Rhinol Laryngol Suppl 113:2004

Many patients expect complete disease resolution after prolonged medical therapy and/or surgery, only to be disappointed when symptoms recur or persist, even if to a lesser degree than before treatment.

— Michael J. Sillers, M.D., FACS

clinical conditions. "Understanding is confounded because symptoms, physical findings, radiologic signs and histologic correlates overlap. Due to the number of factors that weigh into sinusitis, medical treatment is complex and may present a challenge for physicians in the primary-care setting," says William E. Bolger, M.D., FACS, of the Maryland Sinus Center. "By sharing information and evaluating emerging technologies, we have the opportunity to refine our practices, ultimately leading to improved patient care."

EMERGING RESEARCH INDICATES THAT THERE IS MORE TO LEARN

There is still much to be learned about the causes of sinusitis and the spectrum of treatment options that are available, according to Howard Levine M.D., FACS, Director of the Cleveland Nasal-Sinus and Sleep Center. "There are still many areas we don't completely understand." Current research is exploring the role of fungus, biofilms, superantigens and osteitis, says Levine. Researchers at the Mayo Clinic are investigating whether sinusitis is an immune reaction to fungus, in which the body's immune system sends eosinophils to attack fungi, irritating the nasal membranes in the process. As long as fungi remain, so will the irritation. Biofilms, Levine explains, are organized groups of bacteria that can adhere to either a living or inert surface. This slimy coating can alter immunity and cause bacterial resistance. Bacterial proteins, known as superantigens, may also be a factor in sinusitis, says Levine, explaining that superantigens activate T-cells of the immune system, which can cause systemic inflammation. Researchers are also studying the relationship between sinusitis and osteitis, an infection in the bone that may stubbornly persist despite long-term antibiotic treatment. "These are the four key areas in which physiologic research is going on," says Levine, with treatments being developed — "some by trial and error, others with evidence-based medicine. But we still don't know as much as we should."

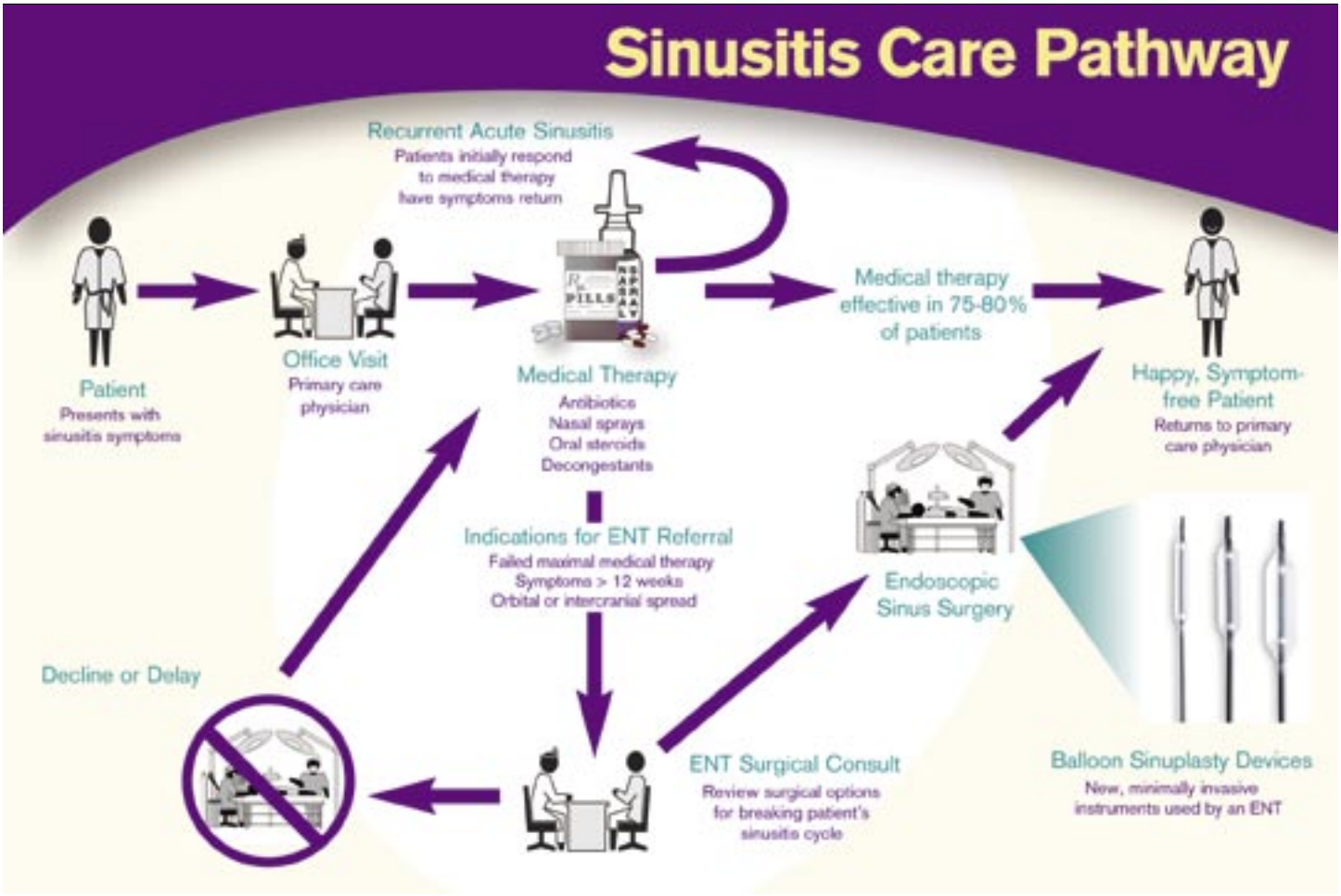
Matching Patients' Symptoms to Their Condition

Symptom	Cold	Flu	Allergic Rhinitis	Sinusitis
Congestion	Yes		Yes	Yes
Cough	Yes	Yes		Yes
Dizziness	Yes	Yes		Occasional
Sore throat	Early	Mild	Yes	Yes
Runny nose	Yes		Yes	Yes
Stuffy nose	Yes		Yes	Yes
Sneezing	Yes		Yes	
Nasal discharge	May be thick & yellow	Cloudy	Thin & clear	Thick, yellow-green
Duration	5-7 days	2-3 weeks	Episodic	Perpetual if not treated
Generalized aches and pains		Yes, often severe		Mild
Sweating		Yes		
Extreme exhaustion		Early and prominent		
Fatigue/weakness	Mild	Pronounced	Mild	Mild
Fever		High (>102), lasts 3-4 days		Low grade
Headache	Rare	Yes		Yes
Itchy nose/eyes/throat			Yes	
Seasonal pattern	Yes	Yes (Winter)	Yes	Yes
Hoarseness	Yes			Yes
Facial pain				Yes
Bad breath				Yes

EFFECTIVE MEDICAL MANAGEMENT IS COMPLEX AND FRUSTRATING

Medical management of sinusitis is aimed at reducing inflammation that affects the nasal cavity and paranasal sinuses, says Michael J. Sillers, M.D., FACS, Director of the Alabama Nasal and Sinus Center. In the majority of patients with acute viral illnesses, symptoms will resolve spontaneously without antibiotic therapy. Since bacteria are rarely the cause of acute uncomplicated viral sinusitis, overprescription of antibiotics needs to be monitored and is a current hot topic, particularly as it relates to drug-resistant bacteria. In a recent study published in the *Archives of Otolaryngology*, Donald A. Leopold, M.D., found that "antibiotics and inhaled nasal corticosteroids are being used more often than their published efficacies would encourage."

Antibiotics are the mainstay of acute bacterial and chronic sinusitis therapy. Antibiotic therapy may be chosen from any of several classes of antimicrobials,



including penicillin, cephalosporin, macrolide, tetracycline, sulfonamide and quinolone. Steroids, often used in conjunction with antibiotics, have potent anti-inflammatory properties and may be administered systemically or topically.

Treatment for acute rhinosinusitis is typically supportive in nature, aimed at reducing the severity and duration of symptoms, says Sillers. Most episodes begin as viral illnesses, which do not require antibiotic therapy. When a viral illness is prolonged or worsens, it has often progressed to a bacterial infection and antimicrobials may be necessary. When prescribing for acute rhinosinusitis, Sillers says, general antimicrobial therapy should continue for 10-14 days and include coverage for *H. influenzae* and *S. pneumoniae*. Adjuvant treatment options include nasal saline spray, decongestants and mucolytics.

"There are several challenges in treating patients with chronic rhinosinusitis," says Sillers. First, is the misperception of the extent to which chronic rhinosinusitis impacts a patient's life. "It has been shown that in several areas, patients with chronic rhinosinusitis score lower in quality of life assessments than patients with diabetes, heart disease and chronic low back pain," Sillers says. Another challenge is the lack of understanding of the chronic nature of this disease process. "Many patients expect complete disease resolution after prolonged medical therapy and/or surgery, only to be disappointed when symptoms recur or persist, even if to a lesser degree than before treatment," Sillers says. Physicians need to effectively communicate the chronic, persistent nature of this disease process. There can be significant loss in productivity in many areas and the patient disappointment is clearly realized in their inability to live their life to its fullest.

INNOVATIVE, LESS INVASIVE SURGICAL TECHNOLOGIES ARE SAFE AND EFFECTIVE

When medical management is not effective, patients with sinusitis are often referred to ENT specialists for surgical consultation. Indications for referrals may include chronic headache, weather-sensitive headache, facial pressure under or over the eyes, suspected orbital or intercranial spread, symptoms recurring after three or four medical therapy trials, chronic symptoms after eight weeks of sustained medical therapy and disease confirmed on CT scan to involve the frontal and/or sphenoid sinuses.

Surgical treatment of sinusitis is aimed to break the patient's cycle of recurring symptoms and improve quality of life. The overarching goals of surgery are to clear blocked sinuses, restore normal sinus drainage and function, and preserve

Pediatric Patients Require a Different Approach

Rhinosinusitis in children is often compared to rhinosinusitis in adults. However, there are significant differences between rhinosinusitis in children and adults, says Hassan H. Ramadan, M.D., M.Sc., FACS, professor and vice chair of the Department Of Otolaryngology - Head and Neck Surgery, and professor of the Department of Pediatrics of West Virginia University.

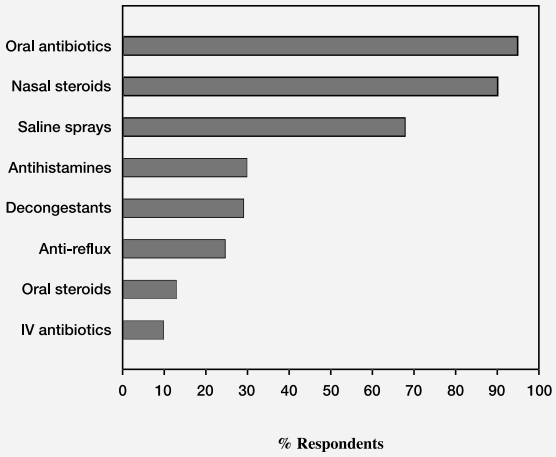
Where adult sinuses are fully developed, Ramadan explains, a child's sinuses are still developing. The frontal and sphenoid sinuses usually are not present in young children and are not a problem for them. The ethmoid and maxillary sinuses are present at birth and are the affected sinuses in most rhinosinusitis children.

Presenting symptoms in children are typically different from those in adults, says Ramadan. The most common adult symptoms include facial pressure, nasal obstruction and postnasal drip. While a child may present with these, the main symptom leading to the diagnosis of rhinosinusitis in children is cough.

Performing an examination on kids is difficult and usually not helpful, says Ramadan. While endoscopic exam is routine in adults, diagnosis of chronic rhinosinusitis in children is mainly based on symptoms reported and on X-rays.

Once diagnosis is made, initial medical treatment is similar to adults. In children, however, the use of quinolones is not advisable, Ramadan cautions, limiting the choice of antibiotics.

The surgical management of refractory chronic rhinosinusitis in children usually takes a different path. Adenoidectomy followed by sinus wash/lavage and management based on culture result is the first surgical step in most children, says Ramadan. If those initial surgical measures fail, only then is FESS considered.



Medical therapy recommended for chronic sinusitis (percent of respondents). IV = intravenous

Source: Sobol, et al. Trends in the Management of Pediatric Chronic Sinusitis: Survey of the American Society of Pediatric Otolaryngology. The Laryngoscope 2006; 115:78-80.

Prevalence of Sinusitis in Children

- Average child have 6-8 upper respiratory infections per year during the first decade of life
- 5-10% of these infections will be complicated by sinusitis
- 6-13% of all children develop sinusitis by age 3 years.

Source: Zacharisen, et al. Pediatric Sinusitis. Immunol Allergy Clin N Am 25(2005) 313-332.

Treatment Options for Pediatric Rhinosinusitis

Medical

First-line treatment: amoxicillin
- 45 mg/kg [day if no risk factors are present]
- 90 mg/kg/day if risk factors are present (with clavulanic acid)

Second-line treatment: amoxicillin with clavulanic acid
- Cephalosporins (cefprozil, cefuroxime)
- Macrolides (clarithromycin, azithrornycin)

Adjunctive therapy

Nasal saline irrigation

Decongestants (topical and oral)

Topical steroids

Mucolytics

Surgical

Antral lavage

Adenoidectomy

Nasal antral window (limited efficacy)

Functional endoscopic sinus surgery

Polypectomy

Maxillary antrostomy

Ethmoidectomy

[a] Risk factors include age less than 2 years, recent antibiotics (within 3 months), and day care.

Source: Zacharisen, et al. Pediatric Sinusitis. Immunol Allergy Clin N Am 25(2005) 313-332.

These are the four key areas in which physiologic research is going on. With treatments being developed — some by trial and error, others with evidence-based medicine. But we still don't know as much as we should.

natural anatomy. As with medical therapy, there are a number of different options. The most common procedure today, at more than 330,000 per year, is functional endoscopic sinus surgery (FESS).

Since its introduction in the mid-1980s, FESS has become the standard surgical intervention for patients who don't respond to medical therapy, says Peter J. Catalano, M.D., FACS, Chairman of the Department of Otolaryngology - Head and Neck Surgery at the Lahey Clinic, and associate professor of otolaryngology at Boston University. Much less invasive than prior surgical options, FESS revolutionized sinus surgery with the introduction of nasal endoscopes to enhance visualization within the nasal cavity. FESS patients generally achieve relief from their symptoms and are able to return to their general primary care physician.

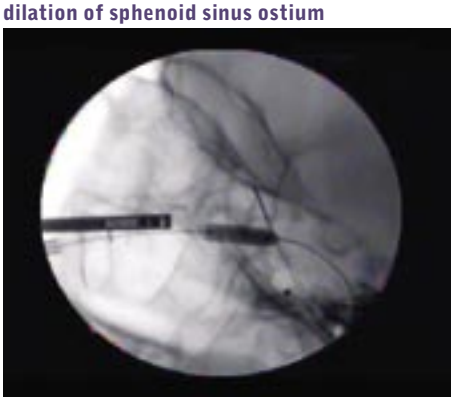
FESS is performed through the nasal cavities using specialized instruments designed to remove thin bony partitions and tissue from the sinus drainage pathways to enhance their function. Postoperative visits to remove debris from the surgical site are often needed. Revision surgery is often required for more advanced cases of refractory polyposis.

Chronic sinusitis patient with nasal polyps.
Pre-endoscopic sinus surgery CT scan and post-endoscopic sinus surgery CT scan.

IMAGES COURTESY OF DR. MICHAEL J. SILLERS

Centered in the goals of FESS, new surgical technologies have come to the forefront that aim to further minimize the invasiveness of sinus surgery while continuing to improve success and lower complication rates. One such technique is the minimally invasive sinus technique (MIST), a targeted endoscopic approach with minimal tissue trauma, says Catalano. MIST first introduced endoscopically guided powered instrumentation into sinus surgery. Powered instruments provide true cutting blades and real-time suction for improved precision. This technique markedly reduces nasal trauma, eliminates exposed sinus bone, decreases blood loss and postoperative discomfort.

Sinus Balloon catheter:
dilation of sphenoid sinus ostium



IMAGES COURTESY OF DR. RAY WEISS

Final result:
post-dilation of sphenoid sinus ostium

Just as new endoscopic techniques are impacting the care of the sinusitis patient, new catheter-based devices are further expanding treatment options. The latest advancement in minimally invasive technologies was the introduction of *Balloon Sinuplasty* devices. In 2005, these catheter-based devices were FDA approved as a less invasive approach for treating symptoms of chronic sinusitis. Using sinus balloon catheters to open the ostia is proving to be far less invasive for the patient and just as safe and effective as other surgical devices. "I suspect that we will see rapid innovation in this platform. Disposable instrumentation lends itself well to the incorporation of advanced concepts, as demonstrated in other specialties," says Catalano.

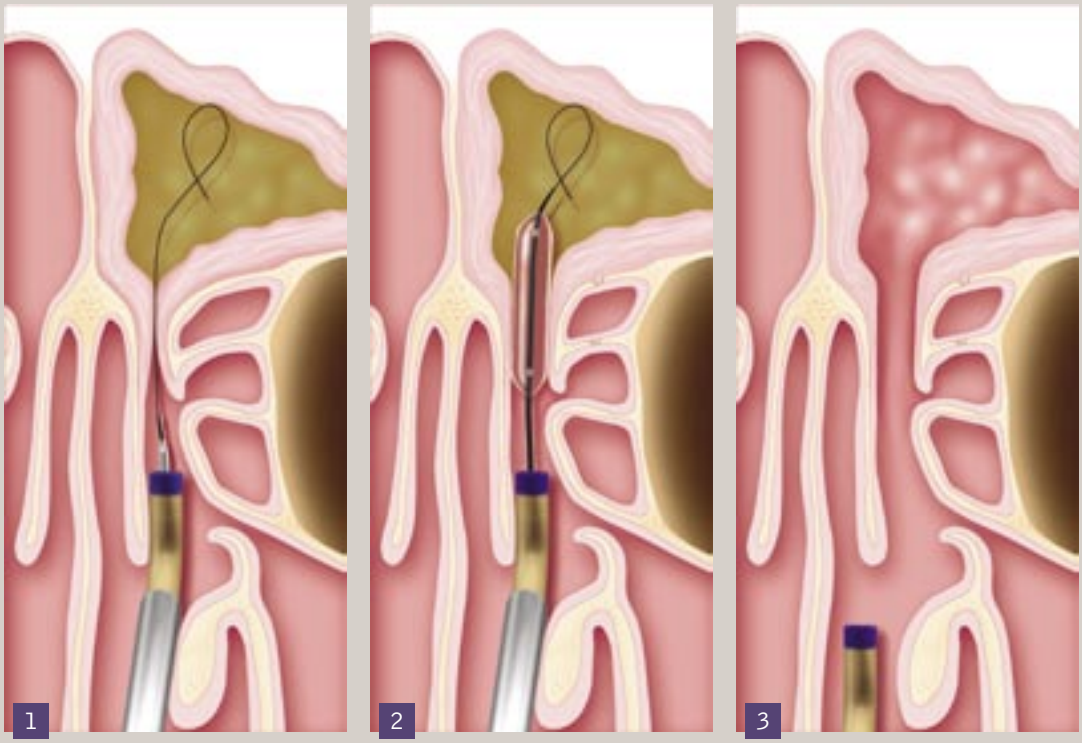
Relieva® Balloon Sinuplasty™ Devices

Innovation Leads to Improved Patient Satisfaction

One of the hot new developments in the ENT field and world of sinusitis treatment, Relieva Balloon Sinuplasty™ devices are novel medical products used in endoscopic sinus surgery that offer sinusitis patients a less invasive alternative to traditional sinus surgery instrumentation.

Designed to meet the ENT physicians' sinus surgery goals of clearing blocked sinuses, restoring normal sinus drainage and function, and preserving natural anatomy, Balloon Sinuplasty™ devices are FDA-cleared catheter-based products pioneered by Acclarent™. They are a system of minimally invasive devices designed to navigate the sinus anatomy and are comprised of small, soft, flexible instruments introduced entirely through the nostrils. The key component of the Balloon Sinuplasty™ system is a sinus balloon that is positioned to gently open blocked sinuses. Upon completion of dilation, the devices are removed, leaving behind an open ostium and intact sinus anatomy. After sinus balloon dilation, medical therapies or irrigation can be directed into the opened sinus. The benefits of being minimally invasive go beyond just anatomical preservation. In many cases, the Balloon Sinuplasty™ devices may provide a solution for patients where medical management has not achieved the desired result and the satisfaction that a patient's quality of life will be impacted by a reduction in the severity of their symptoms.

Balloon Sinuplasty Technology



Step 1: The ENT surgeon gains access to the target sinus with a flexible Sinus Guidewire. Then a Sinus Balloon Catheter is advanced over the Sinus Guidewire.

Step 2: The Sinus Balloon Catheter is positioned across the blocked ostium and gently inflated.

Step 3: The Relieva system is removed, leaving an open sinus ostium and restoring normal sinus drainage and function.

CLINICALLY PROVEN SAFE AND EFFECTIVE

Since the launch of these devices in the fall of 2005, physicians have demonstrated a strong adoption and use of this technology, to date treating more than 10,000 patients with the Balloon Sinuplasty™ devices. This adoption can be linked to a high safety profile and rigorous clinical testing program supporting the development of this technology, including a multi-center clinical trial, the CLEAR study (The **CL**inical **E**valuation to **C**onfirm **SA**f**e**ty and **E**fficacy of **S**inuplasty in the **PaR**anasal **S**inuses). In this study, the sinus balloon catheter devices successfully dilated the intended blocked sinus in nearly all cases without complications or adverse effects and patients reported improved outcomes when the balloon catheters were used in their overall treatment plan. The Academy of Otolaryngology – Head and Neck Surgery recently recognized "the value and potential of the technology."

MINIMALLY INVASIVE OPTION IMPORTANT TO PATIENTS

In addition to physician acceptance, a minimally invasive option is extremely important to patients. Many patients, when presented with sinus surgery using traditional instrumentation, decide to delay or forego surgery. Surgery with Balloon Sinuplasty™ devices now provides a minimally invasive option for these patients who want safe and effective, clinically proven relief from their symptoms and the ability to return to their normal activities.

Chicago ENT surgeon Robert C. Kern, M.D., who has used Balloon Sinuplasty™ devices in approximately a dozen procedures, recently chaired the TRILOGICAL Balloon Sinuplasty™ panel. "This technology is ideal for difficult frontal sinuses and useful in the other sinuses as well," says Kern, adding that he strongly believes that Balloon Sinuplasty™ devices hold significant potential for the future. "I believe that these devices will be particularly useful for the delivery of new medical therapies for sinusitis patients, possibly in an office setting, as we look for less invasive and more effective solutions for symptom management," he says.

Robert C. Kern, M.D.

Dr. Kern is a professor of otolaryngology at the Feinberg School of Medicine, and Chairman of the Department of Otolaryngology, Head and Neck Surgery at Northwestern Memorial Hospital in Chicago. Dr. Kern graduated from Jefferson Medical College in Philadelphia and completed his residencies in general surgery and otolaryngology at Wayne State Affiliated Hospitals in Detroit. He can be reached at (312) 503-0458.

For more information on Balloon Sinuplasty™ devices, please visit www.acclarent.com. Acclarent, Balloon Sinuplasty™, and Relieva are trademarks of Acclarent, Inc. All rights reserved. ■