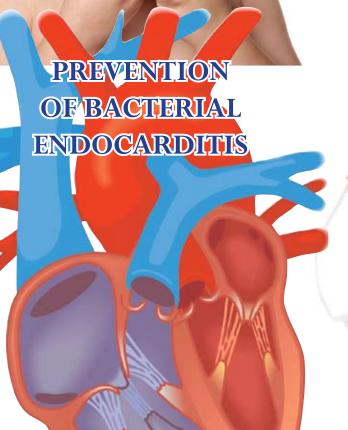
MEDICAL UPDATES



Issue No.:6 Jully 2011

Allergic Rhinitis ...
A Significant Burden
For Children



A Questionnaire To
Help Pediatricians
Track Kids' Asthma
Control

Egyphar Medical Updates



American Academy of Allergy, Asthma and Immunology (AAAAI) 2011 Annual Meeting

Allergic Rhinitis ...
A Significant Burden
For Children

Dr. Gross and Dr. Ogden have disclosed no relevant financial relationships.

March 30, 2011 (San Francisco, California) Allergic rhinitis continues to exact a high toll on the quality of life of Americans, according to a survey presented here at the American Academy of Allergy, Asthma and Immunology (AAAAI) 2011 Annual Meeting.

"The data are timely, as they were collected from patients who have allergies in surveys less than 1 year ago," study presenter Gary Gross, MD, from the Dallas Allergy and Asthma Center, Texas, told *Medscape Medical News*. "The results are more of a stimulus to try to improve the care for these patients whose lives are so dramatically influenced by allergies."

Reached for comment, Neeta Ogden, MD, an adult and pediatric allergist at Englewood Hospital and Medical Center in New Jersey, and member of the AAAAI, noted that "the quality-of-life impact can be overlooked in clinical practice."

"People may think allergies are not as 'lifethreatening' as other medical problems like diabetes or high blood pressure, etc. However, untreated allergies, especially during the peak pollen months, can lead to daily impairment that affects work/school and quality of life,"

Dr. Ogden said.



COMPARATIVE LOOK AT NASL 2010 AND AIA 2006

At the AAAAI's annual gathering, Dr. Gross presented results of the 2010 Nasal Allergy Survey Assessing Limitations (NASL) Survey, looking at the effect allergic rhinitis currently has on the quality of life of Americans.

As part of the survey, 400 people aged 18 years and older who had been diagnosed with allergic rhinitis and who had experienced nasal allergy symptoms or taken medication for their condition in the past 12 months were interviewed. The findings were compared with 2500 respondents from the 2006 Allergies in America Survey (AIA) to determine the degree to which allergic rhinitis still affects patient quality of life.

A look at the 2 data sets suggests no apparent easing of the emotional toll of allergic rhinitis, the researchers say.

Comparison Between NASL 2010 and **AIA 2006**

Measure	NASL 2010	AIA 2006
Feelings of depression	28%	30%
Irritability	67%	64%
Tiredness	85%	80%
Being embarrassed	15%	23%
Feeling miserable	60%	65%

«The survey reminds us all that these patients suffer far beyond the congestion, runny nose, and sneezing that are characteristic symptoms of allergic rhinitis, and that they need more effective treatment to be productive and to improve their quality of life,» Dr. Gross told Medscape Medical News.

He advised clinicians to "question patients who have allergic rhinitis more thoroughly regarding how allergic rhinitis impacts the quality of the patients' lives, and then try to determine the best approach to treatment."

The NASL 2010 survey also confirms that allergic rhinitis limits peoples' ability to participate in social activities (29%), to have or play with pets (34%), and to participate in outdoor (52%) and indoor (13%) activities.

Mirroring the AIA 2006 survey, 33% of respondents in NASL 2010 reported their symptoms affected them "a lot" or a "moderate" amount during the month when nasal symptoms were at their worst. In NASL 2010, work productivity was roughly 71% when nasal symptoms were at their worst; the figure was nearly the same (72%) among AIA 2006 respondents.

Nasal symptoms of allergic rhinitis also contribute to "substantial" sleep disturbances, including trouble falling to sleep and staying

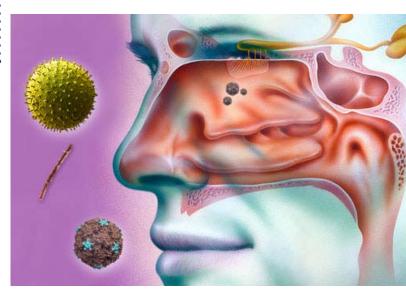
asleep, according to other data from the NASL 2010 Survey reported separately at the meeting.

NEW DATA "NOT SURPRISING"

In Dr. Ogden's view, the NASL 2010 findings are "not surprising, especially since allergy symptoms seem to be more intense than ever and people are experiencing new-onset allergies and worsening of existing allergies in the last few years."

"In terms of seasonal allergies," she said, "this has been attributed to global warming leading to more intense, longer seasons. People seem to have worse symptoms and often express breakthrough allergy symptoms even on doses of medications that used to help them before."

Following up with patients is key, Dr. Ogden said, "because there are a number of therapies out there that can be added if the first medication doesn't work. In addition, getting patients on your and their own radar in terms of allergy so they can start ? medications 2 to 3 weeks before the peak season is also important."



American Academy of Allergy, Asthma and Immunology 2011 Annual Meeting: Abstract 838. Presented March 20, 2011.

BMJ. 2010;340:b5463. Abstract

Daily Calcium Plus Vitamin D Supplements May Reduce Vertebrae Fracture Risk In Osteoporotic Patients

Dr. Sahota has disclosed no relevant financial relationships.

January 22, 2010 Daily supplements of calcium plus vitamin D, but not of vitamin D alone, are associated with significantly reduced fracture risk, according to the results of a patient level-pooled analysis reported in the January 12 issue of the BMJ.

"A large randomised controlled trial in women in French nursing homes or apartments for older people showed that calcium and vitamin D supplementation increased serum 25-hydroxyvitamin D, decreased parathyroid hormone, improved bone density, and decreased hip fractures and other non-vertebral fractures,"

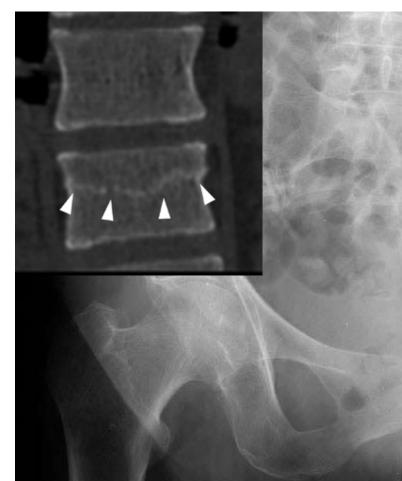
write B. Abrahamsen, from Copenhagen University Hospital Gentofte, in Copenhagen, Denmark, and colleagues from the DIPART (vitamin D Individual Patient Analysis of Randomized Trials) Group.

"Subsequent randomised trials examining the effect of vitamin D supplementation with or without calcium on the incidence of fractures have produced conflicting results.... We used individual patient data methods to do a meta-analysis of randomised controlled trials of vitamin D with or without calcium in preventing fractures and investigated if treatment effects are influenced by patients' characteristics."

The goals of the study were to identify characteristics affecting the antifracture efficacy of vitamin D or vitamin D plus calcium regarding any fracture, hip fracture, and clinical vertebral fracture and to

evaluate the effects of dosing regimens and coadministration of calcium.

Selection criteria were randomized trials with at least 1 intervention group in which vitamin D was given, in which there were at least 1000 participants, and in which fracture was an outcome. The investigators identified 7 major randomized trials of supplementation with vitamin D plus calcium or with vitamin D alone, enrolling a total of 68,517 participants. Mean age was 69.9 years (range, 47 - 107 years), and 14.7% of participants were men. Significant interaction terms were identified with logistic regression analysis, followed by Cox's proportional hazards models incorporating age, sex, fracture history, and



use of hormone therapy and bisphosphonates.

Overall risk for fracture was decreased in trials using vitamin D with calcium (hazard ratio [HR], 0.92; 95% confidence interval [CI], 0.86 - 0.99; P = .025), and risk for hip fracture was also decreased (HR for all studies, 0.84; 95% CI, 0.70 - 1.01; P = .07; HR for studies using 10 of vitamin D given with calcium, 0.74; 95% CI, 0.60 - 0.91; P = .005). There were no significant effects for vitamin D alone in daily doses of 10 or 20, nor was there any apparent interaction between fracture history and treatment response. No interaction was noted for age, sex, or use of hormone replacement

"This individual patient data analysis indicates that vitamin D given alone in doses of 10-20 is not effective in preventing fractures," the study authors write. "By contrast, calcium and vitamin D given together reduce hip fractures and total fractures, and probably vertebral fractures, irrespective of age, sex, or previous fractures."

Limitations of this study include lack of data for 4 of the 11 identified studies meeting

inclusion criteria, and insufficient information about compliance to do a per protocol analysis. In addition, only a single study provided data for vitamin D given alone at the lower dose.

"We must emphasise that this analysis does not allow for a direct comparison of vitamin D against vitamin D given with calcium, but only comparisons between each intervention and no treatment," the study authors conclude. "Whether intermittent doses of vitamin D given without calcium supplements can reduce the risk of fractures remains unresolved from the studies in this analysis. Additional studies of vitamin D are also needed, especially trials of vitamin D given daily at higher doses without calcium."

In an accompanying editorial, Dr. Opinder Sahota, from Queen's Medical Centre in Nottingham, United Kingdom, notes that these findings are important because they show that vitamin D alone, irrespective of dose, does not reduce the risk for fracture.

"Although the evidence is still confusing, there is growing consensus that combined calcium and vitamin D is more effective than vitamin D alone in reducing nonvertebral fractures," Dr.Sahota writes. "Higher doses are probably necessary in people who are more deficient in vitamin D, and treatment is probably more effective in those who maintain long term compliance.

Further studies are needed to define the optimal dose, duration, route of administration, and dose of the calcium combination."

The National Heart, Lung, and Blood Institute, National Institutes of Health, supported this study. Some of the study authors have disclosed various financial relationships with Novartis, Amgen, Nycomed, Eli Lilly, Procter & Gamble, Merck, Roche, Shire, ProStrakan, Servier, Celltech, ProStrakan, Alliance for Better Bone Health, GlaxoSmithKline, Pfizer, Sanofi-Aventis, and/or Osteologix.

Pediatrics. Published online February 21, 2011. Abstract

A Questionnaire To Help Pediatricians Track Kids' Asthma Control

March 4, 2011 A short questionnaire, originally developed for use by asthma specialists, has shown for the first time it can also help pediatricians monitor control of respiratory and asthma symptoms in children younger than 5 years.

The study was published online February 21 and will appear in the March print issue of Pediatrics.

The pediatrics-based, longitudinal study "extends the validity and reliability of the Test for Respiratory and Asthma Control in Kids (TRACK) by demonstrating its responsiveness to change in respiratory-control status over time in preschool-aged children with symptoms consistent with asthma," according to Bradley Chipps, MD, from Capital Allergy and Respiratory Disease Center, in Sacramento, California, and colleagues.

THE QUESTIONNAIRE

The TRACK questionnaire is based on impairment and risk domains that are part of guidelines published by the National Asthma Education and Prevention Program.

The multiple-choice questionnaire is completed by the child's caregiver and contains only 5 questions:

 During the past 4 weeks, how often was your child Dr. Teague has disclosed no relevant financial relationships.

bothered by breathing problems, such as wheezing, coughing, or shortness of breath?

- 2. During the past 4 weeks, how often did your child's breathing problems wake him or her up at night?
- 3. During the past 4 weeks, to what extent did your child's breathing problems interfere with his or her ability to play, go



- to school, or engage in usual activities that a child should be doing at his or her age?
- 4. During the past 3 months, how often did you need to treat your child's breathing problems with quick-relief medications?
- 5. During the past 12 months, how often did your child need to take oral corticosteroids for breathing problems not controlled by other medications?

Each response is scored from 0 to 20 points on the basis of a 5-point Likert-type scale for a total score of 0 to 100. A cutoff point score of 80 is thought to accurately identify children whose symptoms are controlled from those whose symptoms are not.

The 5 questions were culled from a 33-item draft questionnaire that was assessed in a developmental study. That study involved 486 caregivers of preschool children being cared for by asthma specialists.

The study authors point out that assessing control in young children can be challenging because of a lack of objective measures of pulmonary function. Besides that, symptoms of asthma may mimic those of other common childhood illnesses, they say.

Also, tracking symptoms are of special concern in preschoolers because they tend to make more visits to their clinician and to the emergency department more often than older children, and their illnesses may be associated with more morbidity.

QUESTIONNAIRE VALIDATION

In the current study, Chipps and colleagues sought to validate the use of the TRACK questionnaire in 20 general pediatrician practices in the United States. The study was carried out January to May 2009.

"Caregivers of children younger than 5 years with symptoms consistent with asthma within the past

- 1. During the past 4 weeks, how often was your child bothered by breathing problems, such as wheezing, coughing, or shortness of breath?
- 2. During the past 4 weeks, how often did your child's breathing problems wake him or her up at night?
- 3. During the past 4 weeks, to what extent did your child's breathing problems interfere with his or her ability to play, go to school, or engage in usual activities that a child should be doing at his or her age?
- 4. During the past 3 months, how often did you need to treat your child's breathing problems with quick-relief medications?
- 5. During the past 12 months, how often did your child need to take oral corticosteroids for breathing problems not controlled by other medications?

year (N = 438) completed TRACK at 2 clinic visits separated by 4 to 6 weeks," they write.

The pediatricians were blinded to the caregivers' assessments and completed guidelines-based respiratory-control surveys at both visits. They were also asked whether the patient visit resulted in a change in therapy. The researchers used the data to evaluate the responsiveness of TRACK to changes in respiratory control status with time and to assess reliability and discriminant validity.

The study authors report, "Mean changes in TRACK scores from the initial to follow-up visits differed in the expected direction in subsets of children whose clinical status improved, remained



unchanged, or worsened, based on physicians' and caregivers' assessments (P < .001)."

Mean TRACK scores also differed significantly across patient subsets with lower scores indicating poorer control in children who were classified as having very poorly controlled asthma; in those who needed a step-up in therapy; and in those who had 4 or more episodes of wheezing, coughing, or shortness of breath per week during the previous 3 months.

The authors conclude that the study shows the TRACK questionnaire can be useful in evaluating children not just in asthma specialty practices but also in general pediatric settings.

STUDY FINDINGS MERITED

When asked by Medscape Medical News to comment on the study, Gerald Teague, MD, said the findings are significant.

"Assessment of respiratory control status is difficult in pre-school children, and is based primarily on the reporting of symptoms by caregivers, which are often incomplete, and subject to recall bias," he noted.

Dr. Teague is professor of pediatrics and director from the Division of Respiratory Medicine at the University of Virginia School of Medicine, in Charlottesville.

He said the TRACK questionnaire has merit as a "validated, objective assessment of changes in respiratory control that is more complete and less subject to misinformation than the openended method of simply asking the parents to describe their child's symptoms."

Dr. Teague said the findings warrant changes in management. "Pediatricians should consider more objective means for assessing asthma control using validated questionnaires and spirometry."

As to the limitations of the study, Dr. Teague said the only significant one he saw was that the study is based on the assumption that the symptoms of asthma correlate with the degree of airways inflammation and thus should be used to guide treatment. However, he said that may not be true.

In fact, one important question that still remains to be answered, Dr. Teague said, is whether, in fact, changes in treatment on the basis of symptoms is the best way to adjust therapy in children with asthma. "In the future, we may use biomarkers of inflammation or metabolic tests to better guide us in the treatment of asthma."

Some of the study authors have disclosed various financial relationships with Alcon, Aventis, Genentech, AstraZeneca, GlaxoSmithKline, Novartis, Schering-Plough, Sepracor, Merck, MedPoint, Boehringer, Pfizer, Aerocrine, DBV Technologies, Genentech, MedImmune, and/or Dey.

How We Can Improve Patients Comfort After Milligan-Morgan Open Haemorrhoidectomy

Ba-bai-ke-re MM, Huang HG, Re WN, Fan K, Chu H, Ai EH, Li-Mu MM, Wang YR, Wen H.

SOURCE

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ABSTRACT

AIM:

To demonstrate the value of Diosmin (flavonidic fraction) in the management of post-haemorhoidectomic symptoms.

METHODS:

Eighty-six consecutive patients with grades III and IV acute mixed hemorrhoids admitted to the Anorectal Surgical Department of First Affiliated Hospital, Xinjiang Medical University from April 2009 to April 2010, were enrolled in this study. An observer-blinded, randomized trial was conducted to compare post-haemorhoidectomic symptoms with use of Diosmin flavonidic fraction vs placebo. Eighty-six patients were randomly allocated to receive Diosmin flavonidic fraction 500 mg for 1 wk (n = 43) or placebo (n = 43). The Milligan-Morgan open haemorrhoidectomy was performed by a standardized diathermy excision method. Pain, bleeding, heaviness, pruritus, wound edema and mucosal discharge were observed after surgery. The postoperative symptoms and hospitalization time were recorded.

RESULTS:

The mean age of the Diosmin group and controls was 53.2 and 51.3 years, respectively. In Diosmin

group, haemorrhoid piles were of the third degree in 33 patients and the fourth degree in 10; and in the control group, 29 were of the third degree and 14 were of the fourth degree. There was no statistically significance in age, gender distribution, degree and number of excised haemorrhoid piles, and the mean duration of haemorrhoidal disease between the two groups. There was a statistically significant improvement in pain, heaviness, bleeding, pruritus from baseline to the 8th week after operation (P < 0.05). Patients taking Diosmin had a shorter hospitalization stay after surgery (P < 0.05). There was also a significant improvement on the proctoscopic appearance (P < 0.001). However, there was no statistical difference between the two groups in terms of wound mucosal discharge. Two patients experienced minor bleeding at the 8th week in Diosmin group, and underwent surgery.

CONCLUSION:

Diosmin is effective in alleviating postoperational symptoms of haemorrhoids. Therefore, it should be considered for the initial treatment after haemorrhoid surgery. However, further prospective randomized trials are needed to confirm the findings of this study.

PREVENTION OF BACTERIAL ENDOCARDITIS



American Heart Association Association

Learn and Live a



The American Heart Association's Endocarditis
Committee together with national and international
experts on Infective Endocarditis (IE) extensively
reviewed published studies in order to determine
whether dental, gastrointestinal (GI), or genitourinary
(GU) tract procedures are possible causes of IE. These
experts determined that there is no conclusive evidence

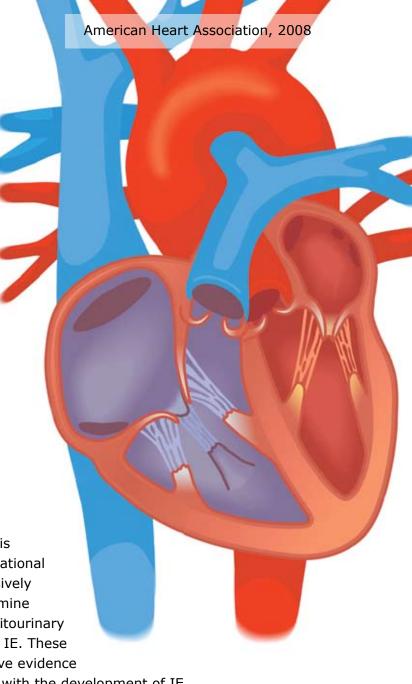
that links dental, GI, or GU tract procedures with the development of IE.

The current practice of giving patients antibiotics prior to a dental procedure is no longer recommended EXCEPT for patients with the highest risk of adverse outcomes resulting from IE. The Committee cannot exclude the possibility that an exceedingly small number of cases, if any, of IE may be prevented by antibiotic prophylaxis prior to a dental procedure. If such benefit from prophylaxis exists, it should be reserved ONLY for those patients listed below. The Committee recognizes the importance of good oral and dental health and regular visits to the dentist for patients at risk of IE.

The Committee no longer recommends administering antibiotics solely to prevent IE in patients who undergo a GI or GU tract procedure.

Changes in these guidelines do not change the fact that your cardiac condition puts you at increased risk for developing endocarditis.

Antibiotic prophylaxis with dental procedures is reasonable only for patients with cardiac



conditions associated with the highest risk of adverse outcomes from endocarditis, including:

- Prosthetic cardiac valve or prosthetic material used in valve repair
- Previous endocarditis
- Congenital heart disease only in the following categories:
 - Unrepaired cyanotic congenital heart disease, including those with palliative shunts and conduits
 - Completely repaired congenital heart disease with prosthetic material or device, whether placed by surgery or catheter intervention, during the first six months after the procedure*
 - Repaired congenital heart disease with residual defects at the site or adjacent to the site of a prosthetic patch or prosthetic device (which inhibit endothelialization)
- Cardiac transplantation recipients with cardiac valvular disease

*Prophylaxis is reasonable because endothelialization of prosthetic material occurs within six months after the procedure.

Dental procedures for which prophylaxis is reasonable in patients with cardiac conditions listed above.

All dental procedures that involve manipulation of gingival tissue or the periapical region of teeth, or perforation of the oral mucosa*

*Antibiotic prophylaxis is NOT recommended for the following dental procedures or events:

routine anesthetic injections through noninfected tissue; taking dental radiographs; placement of removable prosthodontic or orthodontic appliances; adjustment of orthodontic appliances; placement of orthodontic brackets; and shedding of deciduous teeth and bleeding from trauma to the lips or oral mucosa. **Gastrointestinal/** Genitourinary

Procedures: Antibiotic prophylaxis solely to prevent IE is no longer recommended for patients who undergo a GI or GU tract procedure, including patients with the highest risk of adverse outcomes due to IE.

Adapted from Prevention of

ANTIBIOTIC PROPHYLACTIC REGIMENS FOR DENTAL PROCEDURES

Situation	Agent	Regimen—Single Dose 30-60 minutes before procedure	
		Adults	Children
Oral	Amoxicillin	2 g	50 mg/kg
Unable to take oral medication	Ampicillin OR	2 g IM or IV*	50 mg/kg IM or IV
	Cefazolin or ceftriaxone	1 g IM or IV	50 mg/kg IM or IV
Allergic to penicillins or ampicillin— Oral regimen	Cephalexin**†	2 g	50 mg/kg
	OR		
	Clindamycin	600 mg	20 mg/kg
	OR		
	Azithromycin or clarithromycin	500 mg	15 mg/kg
Allergic to penicillins or ampicillin and unable to take oral medication	Cefazolin or ceftriaxone†	1 g IM or IV	50 mg/kg IM or IV
	OR Clindamycin	600 mg IM or IV	20 mg/kg IM or IV

^{*}IM-intramuscular; IV-intravenous

Infective Endocarditis: Guidelines From the American Heart Association, by the Committee on Rheumatic Fever, Endocarditis, and Kawasaki Disease. Circulation, 2007; 116: 1736-1754.

^{**} Or other first or second generation oral cephalosporin in equivalent adult or pediatric dosage.

†Cephalosporins should not be used in an individual with a history of anaphylaxis, angioedema or urticaria with penicillins or ampicillin.