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COVERAGE

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"Asthma definitely increases the risk of severe pneumococcal infections," said Dr. Sandra Fryhofer, acting liaison from the ACP.

Asthmatic Adults Merit Vaccination

BY MIRIAM E. TUCKER
Senior Writer

ATLANTA — All adults with asthma should now receive pneumococcal immunization, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention voted at its summer meeting.

The vote adds adults aged 18-64 with asthma to the list of individuals considered at increased risk for invasive pneumococcal disease (IPD).

Current Advisory Committee on Immunization Practices (ACIP) recommendations call for use of the 23-valent polysaccharide pneumococcal vaccine (PPSV23) in all adults aged 65 years and older and in high-risk individuals aged 2-64 years. Among the latter group are those with chronic pulmonary conditions including chronic obstructive pulmonary disease (COPD) and emphysema (MMWR 1997; 46[RR-8]:1-24).

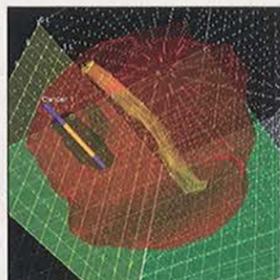
Asthma was not included at the time that recommendation was made because not enough data were available about the risk of IPD among individuals with asthma, except for those with long-term use of systemic corticosteroids. Such data have since become available, and were reviewed for the committee by Dr.

Pekka Nuorti of the CDC's National Center for Immunization and Respiratory Diseases.

In a nested case-control study of persons aged 2-49 years enrolled in Tennessee's Medicaid program (TennCare) for at least 1 year during 1995-2002, each case of IPD was matched with 10 controls of the same age without IPD. A total of 635 persons with IPD and 6,350 controls was identified, of whom 114 (18%) and 516 (8%), respectively, had asthma. The adjusted odds ratio for IPD among those with asthma, compared with controls, was 2.4,

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INSIDE



Better Biopsy

A 3-D mapping system improves prostate cancer detection and management.

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Cancer and CVD

Survivors of childhood cancers have an increased risk of heart disease.

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Dysplasia Drop

Many Barrett's esophagus patients experience complete response after ablation.

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FDA Panel Urges Review of CV Risks Of Diabetes Drugs

Long-term safety studies recommended.

BY ELIZABETH MECHCATIE
Senior Writer

SILVER SPRING, MD. — A Food and Drug Administration advisory panel agreed in a 14-2 vote that developers of new drugs or biologics for type 2 diabetes should be required to conduct a long-term study of cardiovascular safety or to provide "equivalent evidence" to rule out an unacceptable cardiovascular risk associated with the therapy—even in the absence of a worrisome cardiovascular safety signal in preapproval studies.

The FDA had previously decided that a long-term study assessing cardiovascular risks

should be required when a drug or biologic is associated with a cardiovascular safety signal during phase II and III studies.

But the FDA's Endocrinologic and Metabolic Drugs Advisory Committee was asked whether such a study should be required in the absence of such a signal. Several panel members advocated starting the study before approval and continuing it in the postmarketing period. Most panelists recommended that the studies last for at least 5 years and include patients with preexisting cardiovascular disease. They also said that the benefits of a glucose-lowering drug need to be considered when evaluating its risks.

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Magnetic Stimulation May Quell Migraine With Aura

BY DIANA MAHONEY
New England Bureau

BOSTON — Transcranial magnetic stimulation may be a promising new weapon in the pain relief arsenal of patients with chronic migraine with aura, according to the findings of a clinical trial.

Brain stimulation with magnetic pulses, delivered via a portable stimulation device held to the back of the head, eliminated migraine pain in approximately 39% of patients who were randomized to its use, according to data presented by Dr. Richard Lipton, professor of neurology and epi-

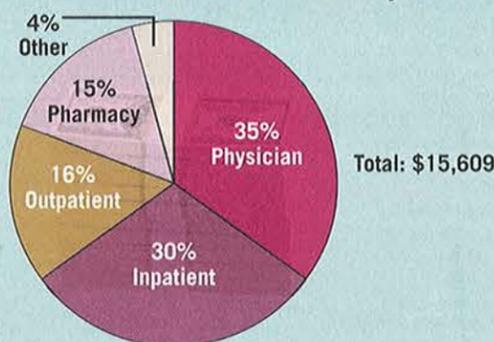
demiology at the Albert Einstein College of Medicine, New York.

Transcranial magnetic stimulation (TMS) is a method of focal brain stimulation based on the principle of electromagnetic induction, whereby a powerful, rapidly changing extracranial magnetic field generates small intracranial currents, Dr. Lipton explained. The technology has shown promise in the treatment of various neurologic and psychiatric diseases. It is thought to interrupt neuronal excitability in the motor cortex of the brain, which has been implicated as a

See *Migraine* page 7

VITAL SIGNS

Physician Costs Are Largest Portion Of Annual Medical Costs for a Family of Four



Note: Total costs based on the Milliman Medical Index estimates for a family of four covered by an employer-sponsored preferred provider organization program, using claims from millions of members.
Source: Milliman

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3-D Prostate Biopsy Improves Cancer Detection

ARTICLES BY DAMIAN
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Miami Bureau

ORLANDO — A systematic three-dimensional mapping biopsy of the prostate more precisely shows tumor volume and location, as well as true cancer stage, compared with a traditional transrectal ultrasound biopsy, according to a prospective study.

To determine if 3-D mapping biopsy software enhances prostate cancer detection and facilitates decisions about early management among men with low-risk disease, compared with traditional ultrasound, Dr. Al Baha Barqawi and his associates prospectively enrolled 125 men with low-risk disease beginning in January 2006.

They questioned whether patients should select an expectant management protocol based on transrectal ultrasound biopsy alone, Dr. Barqawi said.

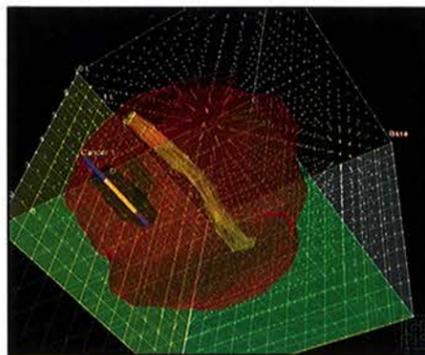
All participants were considering an expectant management or "watchful waiting" protocol for their prostate cancer based on a standard 12-core transrectal biopsy. The mean baseline Gleason

score was 6, and 98% had unilateral disease. Patients had localized or T1c- or T2a-stage prostate cancer and a low tumor burden, defined as one or two positive cores and fewer than 30% of cores positive for disease. The mean age was 61 years and mean prostate-specific antigen level was 5 ng/mL.

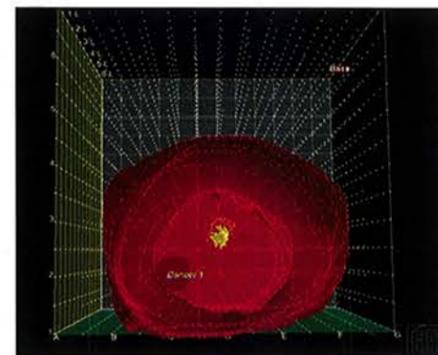
The large prostate sizes (average, 37 g) made 3-D mapping a challenge. "We got down to 53 [participants]. As you can appreciate, it is difficult to get to the anterior region in prostates of this size," Dr. Barqawi said at the annual meeting of the American Urologic Association.

The 3-D rendering of the prostate is done via a transperineal approach using a 5-mm grid. Patients are under intravenous sedation in the operating room during the procedure.

The 3-D technology yielded a mean of 62 biopsy cores assessed, compared with 11 cores with the traditional approach. Almost 70% of patients were upgraded or upstaged (for example, from unilateral to bilateral) based on the mapping results, said Dr. Barqawi, who is on the urology faculty in the urologic oncology section,



Lateral (left) and anterior-posterior (right) views in 3D reconstruction show one positive core on the right side of the prostate, and the reconstructed urethra (yellow).



PHOTOS COURTESY DR. AL BAHA BARQAWI

University of Colorado Health Science Center, Aurora. "These are very interesting results."

Almost 90% of the initial cohort of 125 patients had a Gleason score of 6 based on ultrasound examination. However, only 40% of the 53 who had 3-D mapping had a Gleason score of 6. Most were upgraded, including about 20% who ended up with a Gleason 8 or more.

In terms of complications associated with the 3-D mapping procedure, 10 patients developed transient orthostatic hypertension post sedation, 9 had clot retention and required reinsertion of a Foley catheter with bladder lavage, and 7 experienced urinary retention. There were no urinary tract infections.

Of the original cohort of 125 patients,

18 opted to continue on a watchful waiting protocol. Another 48 had targeted focal therapy for their prostate cancer, 30 patients underwent radical prostatectomy, 16 had primary cryotherapy, and 13 had radiation treatment.

"We believe that a 3-D mapping biopsy ... plays a pivotal role in carefully selected men with apparent low-risk disease. It allows better selection of patients who qualify for watchful waiting," Dr. Barqawi said. The technology is useful for improving detection of tumor volume, the true Gleason score, and the location within the prostate.

He added, however, that "long-term follow-up studies are needed" to confirm these results. He had no relevant financial disclosures.

Prostate Cancer Survival Longest After Surgery in Race Comparison Study

ORLANDO — Men who have surgery to remove prostate cancer experience better long-term survival, compared with patients who have radiation therapy or watchful waiting, according to a retrospective study of African American and white men.

Researchers assessed survival in a cohort of 23,811 men diagnosed with prostate cancer enrolled in the HMO Cancer Research Network. Twelve health maintenance organizations nationwide participate in this network.

This source of data has an advantage compared with previous, population-based studies that assessed potential racial differences in outcomes, Dr. Gerald Y. Tan said.

"Comparisons using HMO data may control for treatment selection biases across racial groups. Black men have equal access to care when you use an HMO database versus a population database," said Dr. Tan of the department of urology at New York Weill Cornell Medical Center, New York.

A total of 10,450 men chose watchful waiting for their prostate cancer management, another 6,804 chose to undergo radical prostatectomy, and 6,557 patients

chose to receive radiation therapy. The cohort comprised 3,613 African Americans, 17,345 whites, and 2,853 patients who reported their race as "other." The investigators decided to look for any differences between African American and white men.

A total of 44% of the African American and white men chose watchful waiting.

Among the remaining African American men, 30% chose surgery and 26% chose radiation.

Among white men, the percentages were slightly different—28% chose surgery and 28% chose radiation.

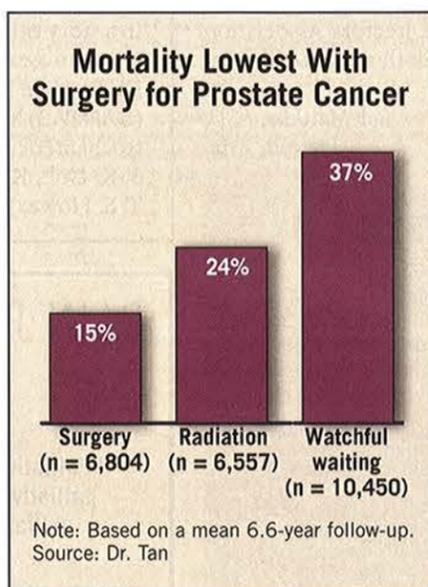
Men treated with surgery lived longer than did men in the other two groups, Dr. Tan said at the annual meeting of the American Urological Association.

After a mean follow-up of 6.6 years, 37% of the watchful waiting group, 15% of the surgery group, and 24% of the radiation group had died.

The prostate cancer-specific death rate was highest in the conservative treatment group, regardless of race.

This death rate was lower for African American men than for white men in both the radiation and surgery groups, said Dr. Tan, who presented the results on behalf of the principal investigator, Dr. Robert A. Leung, a urologist at the same institution.

The retrospective design and the unavailability of data regarding the patients' family history of prostate cancer were potential limitations of the study, Dr. Tan said at the meeting.



Cancer Found in One In Five Young Men With Elevated PSA

ORLANDO — Prostate cancer was detected in almost 20% of men 45 years or younger with elevated levels of prostate-specific antigen in an Austrian study, and a substantial number of the prostate cancers in this group were significant.

As part of the Tyrol Prostate-Specific Antigen Screening Project (J. Urol. 2001;165:1143-5), Dr. Wolfgang Horninger and his associates assessed 263 men aged 45 or younger enrolled in a PSA screening program in Tyrol, Austria. The men had a prostate-specific antigen (PSA) level of more than 1.25 ng/mL in combination with a free PSA of less than 18%. Cancer was detected in 52 men (19.8%), Dr. Horninger reported at the annual meeting of the American Urological Association.

Of the 48 men who opted for surgery, 31 had Gleason scores of 6 or less, and 17 had more advanced disease with Gleason scores of 7 or more, said Dr. Horninger, managing medical director of the department of urology, University of Innsbruck (Austria).

Of the 48 men who underwent surgery, 44 had a negative digital rectal examination; the 4 men with a positive result had a large variation in PSA levels: 9.7 ng/mL, 15.7 ng/mL, 17.0 ng/mL, and 40.5 ng/mL. The mean total PSA was 4.3 ng/mL and the mean free PSA was 13%. The mean age in the surgery patients was 43 years.

Pathology showed negative surgical margins in 42 of the men. "Of the six who had a positive surgical margin, or 12.5%, all had a negative digital rectal exam and unsuspecting intraoperative palpitation," Dr. Horninger said.

"The prostate cancer detection rate in young men with elevated PSA levels is as high as nearly 20%," he said. "There was a substantial percentage of significant prostate cancers, even in these young patients."