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STUDY LEVELS OF EVIDENCE (LOE)

From the Centre for Evidence-Based Medicine, Oxford. For the most up-to-date levels of evidence, see www.cebm.net/levels_of_evidence.asp)

Therapy/Prevention/Etiology/Harm:

- 1a: Systematic reviews of randomized controlled trials
- 1b: Individual randomized controlled trials
- 1c: All or none randomized controlled trials
- 2a: Systematic reviews of cohort studies
- 2b: Individual cohort study or low-quality randomized controlled
- 2c: "Outcomes" research, ecological studies

Diagnosis:

- 1a: Systematic review of level-1 diagnostic studies
- 1b: Independent blind comparison of an appropriate spectrum of consecutive patients, all of whom have undergone both the diagnostic test and the reference standard, or a clinical decision rule not validated on a second set of patients
- 1c: Absolute SpPins and SnNouts
- 2a: Systematic review of level >2
- 2b: Independent blind or objective comparison, study confined to a narrow spectrum of study individuals, or a diagnostic clinical rule not validated in a test set

Prognosis:

- 1a: Systematic review of inception cohort studies
- 1b: Individual inception cohort study with >80% follow-up, or a clinical rule not validated on a second set of patients
- 1c: All or none case series
- 2a: Systematic review of either retrospective cohort studies or untreated control groups in RCTs
- 2b: Retrospective cohort study or follow-up of untreated control patients in an RCT, or clinical rule not validated in a test set
- 2c: "Outcomes" research

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Prompt Tympanostomy Tube Insertion Doesn't Improve Nine-Year Outcomes

Clinical Question

Does the delayed insertion of tympanostomy tubes impair the long-term outcomes in children with persistent middle-ear effusion?

Bottom Line

Delayed tympanostomy tube insertion successfully helps many children avoid tubes and does not result in any developmental or other impairment. (LOE = 1b)

REFERENCE

Paradise JL, Feldman HM, Campbell TF, et al. Tympanostomy tubes and developmental outcomes at 9 to 11 years of age. *N Engl J Med.* 2007;356:248-261.

Study Design

Randomized controlled trial (single-blinded)

Funding

Government

Allocation

Concealed

Setting

Outpatient (any)

Synopsis

Many parents and clinicians still believe that there is a significant risk of permanent harm if tympanostomy tubes are not promptly inserted for children with persistent middle-ear effusion. In this study, which is a follow-up to a previously published POEM (*N Engl J Med.* 2005;353:576), 429 children between the ages of 2 months and 3 years with middle-ear effusion for ≥90 days (bilateral) or 135 days (unilateral) were randomized to receive

either prompt or delayed tympanostomy tube insertion. The delay was 6 months for bilateral effusion and 9 months for unilateral effusion. Allocation was concealed, groups were balanced at the start of the study, and analysis was by intention to treat. The researchers did an excellent job of following up: 195 of 216 in the early treatment group and 196 of 213 in the delayed treatment group underwent developmental testing between the ages of 9–11 years. At the time of this final evaluation, 86% in the early treatment group had received tympanostomy tubes, compared with only 49% in the delayed treatment group. There were no differences between groups in the results of a broad range of tests, including evaluation of hearing, reading, oral fluency, auditory processing, phonological processing, behavior or intelligence. There was also no difference between these groups and a group of children with ear problems that were not bad enough to qualify them for the study.

Montelukast + Salmeterol Inferior to Steroids + Salmeterol in Moderate Asthma

Clinical Question

Is montelukast plus salmeterol more effective than the combination of beclomethasone plus salmeterol in moderate asthma?

Bottom Line

Patients with moderate asthma have fewer treatment failures when treated with inhaled beclomethasone (Vanceryl®, Beclovent®) plus inhaled salmeterol (Serevent®) than those treated with oral montelukast

(Singular[®]) plus inhaled salmeterol. (LOE = 1b)

Study Design

Cross-over trial (randomized)

Funding

Industry + govt

Allocation

Uncertain

Setting

Outpatient (specialty)

Synopsis

In this study, 192 patients aged 12–65 years with moderate asthma completed a four-week run-in period during which they received inhaled beclomethasone and oral montelukast. To be eligible, the patients had to have ≥ 1 of the following: 1-second forced expiratory volume (FEV1) of $\geq 40\%$ of predicted; demonstrated hyperresponsiveness to methacholine; or a $\geq 12\%$ improvement in FEV1 after a beta-agonist (if FEV1 was $< 55\%$ of predicted). Those who passed the run-in period (i.e., had the capacity to attain reasonable asthma control) were enrolled into a cross-over trial. These patients were randomly assigned to 14 weeks of inhaled beclomethasone (80 mcg twice daily) plus inhaled salmeterol (50 mcg twice daily) plus oral placebo or inhaled placebo plus salmeterol plus oral montelukast (10 mg at bedtime). After this, the patients went through an additional four-week period identical to the initial run-in period, then crossed over for 14 weeks of the alternate therapy. The main outcome, assessed via intention to treat, was treatment failure, defined primarily by a variety of spirometric measures, increased use of rescue albuterol, symptoms resulting in emergency department treatment, or use of nonstudy medications for worsening symptoms. A total of 98 of the 192 patients did not complete the study; 75 of those 98 were dropped when the data monitoring and safety committee terminated the study. There were no differences in the numbers

or reasons for withdrawal between the treatment arms. Ten patients (9%) failed therapy while taking the beclomethasone-based regimen compared with 29 (26%) of those taking the montelukast-based therapy (number needed to treat = 6; 95% CI: 4–13). Finally, this study was stopped by the data safety and monitoring board because of convincing evidence of the superiority of inhaled corticosteroids.

REFERENCE

Deykin A, Wechsler ME, Boushey HA, et al, for the National Heart, Lung and Blood Institute's Asthma Clinical Research Network. Combination therapy with a long-acting beta-agonist and a leukotriene antagonist in moderate asthma. *Am J Respir Crit Care Med.* 2007;175:228-234.

Fetal Pulse Oximetry Not Beneficial

Clinical Question

Does knowledge of fetal oxygen saturation in conjunction with electronic fetal monitoring lead to fewer cesarean deliveries or improved neonatal outcomes?

Bottom Line

Fetal pulse oximetry as an adjunct to continuous electronic fetal monitoring does not decrease the cesarean delivery rate or improve neonatal outcomes. (LOE = 1b)

Study Design

Randomized controlled trial (single-blinded)

Funding

Government

Allocation

Uncertain

Setting

Inpatient (ward only)

Synopsis

In May 2000, the Food and Drug Administration granted conditional approval for a device to monitor fetal oxygen saturation (OxiFirst Fetal Oxygen Saturation Monitoring System). They required further studies

to ascertain whether use of the device results in fewer cesarean deliveries and/or improved neonatal outcomes. This study of 5,431 women in labor was conducted to address this need. Nulliparous women with singleton pregnancies at term, in cephalic presentation, and 2–6-cm cervical dilations were recruited on admission to participating labor and delivery units. Women were excluded if they had a plan for cesarean delivery, fever, HIV, hepatitis, renal or cardiac disease, diabetes, or a failed attempt to insert the sensor device. All women in the study had the pulse oximetry sensor devices inserted and were randomized to 1 of 2 groups: one with clinician access to the fetal oxygen saturation data, and one without access. There were no differences in the overall cesarean rate between open and masked groups (26.3% vs. 27.5%) or for the indication of nonreassuring fetal heart rate (7.1% vs. 7.9%). Fetal heart rate patterns were recorded before randomization and were categorized into reassuring and nonreassuring according to well-defined criteria used in previous studies. The subgroup of women with nonreassuring heart rate patterns prior to randomization had similar results (31.1% vs. 30.5% cesarean deliveries). There were no differences between groups in neonatal outcomes. A composite outcome of a 5-minute Apgar score of < 4 , umbilical artery pH < 7.0 , seizures, intubation in the delivery room, stillbirth, neonatal death and intensive care admission for > 48 hours was 3.2% vs. 3.4%.

REFERENCE

Bloom S, Spong CY, Thom E, et al, for the National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. Fetal pulse oximetry and cesarean delivery. *N Eng J Med.* 2006;355:2195-2202.

Alendronate Therapy Unnecessary for Most Women after Five Years

Clinical Question

What is the optimal duration of therapy with alendronate for women with postmenopausal osteoporosis?

Bottom Line

This study found little, if any, benefit to continuing therapy with alendronate (Fosamax®) for >5 years in women with postmenopausal osteoporosis. Unfortunately, in the real world, only one in five women continues prescribed osteoporosis therapy for >1 year (Downey TW, et al. *S Med J*. 2006;99:570-575.) (LOE = 1b-)

Study Design

Randomized controlled trial (double-blinded)

Funding

Industry

Allocation

Uncertain

Setting

Outpatient (specialty)

Synopsis

The optimal duration of therapy with bisphosphonates for women with

postmenopausal osteoporosis is uncertain. These investigators enrolled women aged 55–81 years previously enrolled in another experimental trial who received alendronate (Fosamax) and completed ≥ 3 years of treatment during the follow-up period. This population is likely to include individuals highly compliant with prescribed medications, unlike the “real world” where as many as 80% of women stop their bisphosphonate prescription within five years. Thus, reported results may overestimate the “true” benefit of treatment. Subjects randomly received (uncertain allocation assignment) alendronate, 5 mg/day, alendronate, 10 mg/day, or placebo. Individuals also received 500 mg of supplemental calcium and 250 IU of vitamin D. Unfortunately, this dose of vitamin D is significantly less than the dose (800 IU/day) previously shown to be effective in reducing fractures, thus unnecessarily again accentuating the difference between the treatment and placebo groups and the “real world”.

Individuals assessing outcomes remained blind to treatment group assignments. Follow-up occurred for 87% of the 1,099 participants for five years. Using intention-to-treat analysis, no significant differences among the three treatment groups were reported in total clinically significant fracture rates (both vertebral and nonvertebral). In subgroup analysis, clinical vertebral fractures (based on individual pain report, not a difference in height loss) occurred less often in women receiving alendronate compared to placebo (2.4% vs. 5.3%, NNT=35, 18–174). Discontinuation rates due to adverse events occurred equally in all three groups; no cases of osteonecrosis of the jaw were reported.

REFERENCE

Black DM, Schwartz AV, Ensrud KE, et al. Effects of continuing or stopping alendronate after 5 years of treatment. The Fracture Intervention Trial Long-term Extension (FLEX): a randomized trial. *JAMA*. 2006;296:2927-2938.

C A R E E R O P P O R T U N I T I E S

General Internist. UAB School of Medicine Huntsville Regional Medical Campus seeks clinician educator to join an exciting hospitalist teaching service with a broad spectrum of patients and illnesses. Outpatient and geriatric service opportunities are available. This full-time, non-tenure earning faculty position requires board certified/eligible physician to train third/fourth year medical students and FM residents. Strong recommendations with licensure and credentialing in Alabama are required. UAB offers competitive salary, excellent benefits and relocation. Academic rank and salary will be commensurate with education and experience. Huntsville is a high-tech, family oriented, and culturally diverse community with excellent schools and numerous cultural and recreational opportunities. Huntsville Hospital operates a 901-bed regional referral and trauma center with a staff of over 600 physicians. Don't miss this opportunity! Send letters of application and CV to Lourdes C. Corman, MD, FACP, Professor & Director of Internal Medicine, 301 Governors Drive, SW, Huntsville, AL 35801 or fax to 256-551-4451. UAB is an Affirmative Action/Equal Opportunity Employer.

University of Alabama at Birmingham School of Medicine/ UAB Huntsville Regional Medical Campus

OB/GYN clinician educator needed. The Huntsville Campus has a fully accredited 12-12-12 unopposed Family Medicine Residency Program. We offer Fellowships in Obstetrics and Sports Medicine and clinical training for 60 junior and senior medical students. Huntsville is a high-tech, family-oriented, and culturally diverse community with excellent schools and numerous cultural and recreational opportunities. Huntsville Hospital's regional referral and trauma center has over 600 physicians. Candidate must be board certified/eligible and qualified for Alabama medical licensure and hospital privileges. UAB offers competitive salary, excellent benefits and relocation. Academic rank, tenure status, and salary will be commensurate with education and experience. Don't miss this opportunity! Reply to Paula Cothren, Suite 313, UAB Huntsville Campus, 301 Governors Drive, Huntsville, AL 35801. May email at pdcc@uab.edu or fax to 256-551-4451. UAB is an Affirmative Action/Equal Opportunity Employer.

FAMILY MEDICINE FACULTY MD or DO at the University of Alabama at Birmingham, School of Medicine. Huntsville Regional Medical Campus seeks a superior clinician educator with demonstrated administrative, interpersonal and leadership skills to join our Family Medicine Division. Our faculty supports a 12-12-12 unopposed FP residency program. Fellowships in Obstetrics and Sports Medicine and clinical training for 60 junior and senior medical students. Candidate must be board certified, have 2 years full-time family practice or residency teaching experience and must obtain Alabama medical licensure and hospital privileges. Interest in inpatient and/or nursing home care is required with OB optional. Huntsville is a high-tech, culturally diverse community with excellent schools and numerous cultural and recreational opportunities. Huntsville Hospital operates a 901-bed regional referral and trauma center with a staff of over 600 physicians. UAB offers competitive salary, excellent benefits and relocation. Academic rank, tenure status, and salary will be commensurate with education and experience. Reply to Paula Cothren, Suite 313, UAB Huntsville Campus, 301 Governors Drive, Huntsville, AL 35801. May email at pdcc@uab.edu or fax to 256-551-4451. UAB is an Affirmative Action/Equal Opportunity Employer.

Submit your events and announcements no later than four months before the event to the calendar editor, Theresa G. Reed, MD, MPH; shaynes@nmanet.org. Include the following information: date, name of event, location; sponsoring group(s); topics to be presented; CME credit hours (if applicable); fees; event's web address (online brochure); and name, telephone number and e-mail of a contact person.

MAY



4-6
2007 Region-IV NMA Annual Meeting. "Health Care Advocacy: Priorities for the African-American Community." Cincinnati, OH. Deirdre Holloway, MD, region IV chair: dwat248@comcast.net



Region-VI NMA Annual Meeting. Morongo Casino Resort & Spa, Palm Springs, Cabazon, CA. Arthur W. Fleming, MD, regional chair: artflem@aol.com

7-12
Howard University Commencement Week. May 11: 9:30 AM: Annual Honors and Oath Day Ceremony. May 12: 10 AM: Commencement

10
62nd HUMA Reunion Dinner Dance 2007. 7/8 PM. The Fairmont Hotel, Washington, DC. 202-238-2586

15-19
Meharry Medical College National Alumni Reunion. Celebrating graduates of 2s and 7s. Nashville, TN. Frances Wright: fwright@mmc.edu. Commencement: May 19: 2:15 PM: Commencement. Gentry Center at Tennessee State University.

19
Commencement at Morehouse School of Medicine. King Chapel at Morehouse College. Karen Lewis: 404-752-1657

23
National Provider Identification (NPI) compliance date. 800-465-3203



24-28
Region-I NMA Annual Meeting (Memorial Day weekend). Half-Moon Resort in Montego Bay, Jamaica. Jay C. Cowan, MD, region-I chair. Register: www.halfmoon.com. Click on Group Rates & Reservations. Scroll down and enter group code 319444. For full information, visit www.NMAnet.org Region-I page.

JUNE

2
Commencement—Charles R. Drew University of Medicine and Science.



6-9
114th Annual Convention and Scientific Assembly of the Georgia State Medical Association. NMA affiliate. Hilton Oceanfront Resort, Hilton Head, SC. CME 20 hours of AMA PRA Cat. I. www.gastatemedicalassoc.org; Lisa Saleemi, executive director: 404-752-1564



15-17
Old Dominion Medical Society Annual Meeting. NMA affiliate. Sheraton Oceanfront, Virginia Beach, VA. Diane Munn: asscmgmtserv@msn.com

22-Jul. 2
National African-American Youth Initiative (NAAI) Scholars Program. Washington, DC. Sponsored by the Auxiliary to the National Medical Association. Mae Walton: 202-371-9008

24-Jul. 4

Association of Black Cardiologists 2007 Symposium in China. "The Emerging Pandemic of Heart Disease: Metabolic Syndrome, Diabetes, Hypertension, and Atherosclerosis." To Shanghai, Beijing and other points. Educational dinner symposia. Admiral Travel Gallery. Prices start at \$3,988. Julie Potranz: julie@admiraltravel.com; www.admiraltravel.com, 888-722-3401

JULY

29-Aug. 6
The National Professional Network's 15th Anniversary Leadership Summit at Sea and the 2007 National Medical Association (NMA) Preconvention Cruise Seminar to Hawaii. To Honolulu, Oahu; Hilo, HI; Kahului, Maui; Lanai, HI; Kona, HI; Nawiliwili, Kauai. CME available. www.npncruise.com, 877-416-3005, npncruise@aol.com
2007 Black Congress on Health, Law, and Economics (BCHLE). Meets every four years. Derrick A. Humphries, Esq.: 202-347-7000

AUGUST



4-9
The 112th Year of the National Medical Association and Its 105th Annual Convention and Scientific Assembly. "Health Professional Collaboration at the Point of Practice." Hawaii Convention Center, Honolulu, HI. www.NMAnet.org, 202-347-1895. Registration: \$475 by Feb. 1, \$550 Feb. 2-June 30, and \$650 July 1-Aug. 9



9-12
NMA Postconvention Seminar on Maui. CME available. 202-347-1895

SEPTEMBER

National Sickle Cell Month. www.sicklecelldisease.org

OCTOBER



19-20
NMA Board of Trustees. 202-347-1895

NOVEMBER

13
Roman Barnes Society of Ophthalmology Annual Meeting. World Trade Building, New Orleans, LA. Clifton Peay, MD, chairman. Catherine Miller: 804-559-7002

2008



WINTER
Interim Meeting of the National Medical Association's House of Delegates. Washington, DC area. 202-347-1895

JULY



26-31
The 113th Year of the National Medical Association and Its 106th Annual Convention and Scientific Assembly. Atlanta, GA. www.NMAnet.org, 202-347-1895