

AJCM Update

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Alternative Medicine

A Randomized trial of Acupuncture Compared with Sham Acupuncture in Fibromyalgia

Fibromyalgia is a common chronic pain condition of unknown cause that is characterized by chronic, diffuse pain and tenderness to palpation to specific musculoskeletal sites. It affects two to four percent of the U.S. population, and is the second most common rheumatologic condition in the U.S., after osteoarthritis. Many patients seek alternative medical care, such as acupuncture. This study was designed to look at the efficacy of acupuncture in the treatment of fibromyalgia.

Eligible participants were English-speaking adults 18 years of age or older, in whom fibromyalgia was diagnosed by a physician, and who had a pre-randomization pain score of four out of 10 on a visual analog scale. Participants were excluded if they reported another pain-related condition, potential contraindication to acupuncture treatment (bleeding disorders or needle phobia), were pregnant, breast feeding, had previously received acupuncture treatment, or were involved in litigation related to fibromyalgia. At baseline evaluation before randomization, a research coordinator trained in tender-point examination confirmed the diagnosis of fibromyalgia.

One hundred patients were randomized to receive acupuncture specifically designed for fibromyalgia, or one of three sham acupuncture groups: acupuncture for an unrelated condition, needle insertion at non acupoint locations or noninertive simulated acupuncture. Patients were asked to receive twice weekly treatments for 12 weeks (24 treatments), and were considered to have completed the therapy if they attended eighty percent (19) or more treatments. Patients were asked to keep the use of pharmacologic and non-pharmacologic fibromyalgia therapies constant throughout the trial. Participants had not received previous acupuncture treatment, so they would not be able to compare previous treatments. Participants were also blindfolded during treatments. Demographics of participants and their use of analgesics were similar in all four groups.

Eight U.S. trained and licensed acupuncturists, with a

median of 10 years experience (range 4 to 18 years) conducted the treatments in their private offices.

Out of 100 patients, 96 completed therapy. Outcome measures were recorded at 1, 4, 8 and 12 weeks of acupuncture treatment, and three and six months (24 and 36 weeks) following completion of treatments. Parameters measured were intensity of pain, intensity of fatigue, quality of sleep and overall well being. There was no significant difference in any of the outcomes. All groups showed the most rapid improvement during week 0 to 1, became attenuated during weeks 1 to 8, plateaued between weeks 8 and 12, and decreased slightly three and six months after treatment cessation.

The authors conclude that acupuncture was no better than sham acupuncture at relieving pain in fibromyalgia.

Assefi et al, *Annals of Internal Medicine*, July 5, 2005. *Ann Intern Med*, 2005;143:10-19

Editors note: This study was not blinded, due to the difficulty in blinding an acupuncturist who is administering therapy. However, if anything, any bias in administering therapy would be expected to favor acupuncture treatments. – MSB

Effect of Pomegranate Juice on Myocardial Perfusion in Patients With Coronary Artery Disease

Pomegranate juice is known to have antioxidants, and it has been speculated that it may have anti-atherosclerotic properties. The authors investigated the effects of pomegranate juice on patients with ischemic coronary heart disease (CHD).

This was a double blinded, randomized, controlled study. The investigators enrolled 45 patients with stable CHD. The CHD was confirmed by one or more reversible myocardial perfusion imaging defects, read by a blinded nuclear medicine physician, and confirmed by an independent observer. Patients were excluded if they had a history of debilitating stroke, TIA, myocardial infarction within the preceding six weeks, surgically untreated left main coronary artery lesion with >50% diameter narrowing, coronary revascularization during the preceding six months, current unstable angina, abnormal lung uptake on previous scan, class IV congestive heart failure or LVEF <30%

at time of study entry, significant co-morbidity, current use of tobacco products, alcohol or drug abuse.

Twenty-six patients were randomized to receive 240ml/day of pomegranate juice, 19 patients received 240ml/day of a placebo drink with similar caloric content, flavor and color. The demographics of the patients were similar. All patients were on lipid lowering agents, 23 (89%) of the study group were on anti-coagulants, 19 (100%) of the control group were on anticoagulants (not specified which anticoagulant).

Stress induced ischemia was measured as the summed difference score (SDS), which is the difference between the summed rest score and summed stress score. At baseline, the SDS was similar in both groups. Compliance was 97% in the experimental group and 96% in the placebo group.

At three months, myocardial perfusion scans were repeated. The investigators found that at three months, stress induced ischemia (SDS) increased from baseline in the control group, but decreased from baseline in the experimental group. There was no significant change from baseline in plasma lipids, blood glucose, hemoglobin A1c, body weight or blood pressure during the study for either group. Angina episodes decreased by 50% in the experimental group and increased by 38% in the control group, but the difference was not statistically significant.

The authors conclude that daily consumption of pomegranate juice may improve stress induced myocardial ischemia in patients who have CHD.

Sumner et al, American Journal of Cardiology, September 15, 2005. Am J Cardiology 2005;96:810-14

Editors note: A well designed study. Both longer term and corroborating studies are needed. I applaud the effort to corroborate alternative medicine claims with scientific studies – MSB

Cardiology

Colchicine as First-Choice Therapy for Recurrent Pericarditis

This was a prospective, randomized, open label, parallel group study which looked at Colchicine as an adjunct to conventional therapy for the first episode of recurrent pericarditis.

Eighty-four patients with recurrent pericarditis were enrolled in the study. All patients received aspirin 800mg every six or eight hours for seven to 10 days, with gradual tapering over the next three to four weeks. In addition, the colchicine group received 1 to 2 mg colchicine for the first day, then a maintenance dose of 0.5 to 1mg daily for six months. The lower dose was given to patients weighing less than 70kg, or who were intolerant of the higher dose. At 18 months,

recurrence rates were 50.6% in the aspirin group and 24% in the aspirin plus colchicine group.

Persistence of symptoms at 72 hours was 31% in the aspirin group and 10% in the aspirin plus colchicine group.

The authors conclude that colchicine therapy led to a clinically important and statistically significant benefit over conventional treatment, decreasing the recurrence rate in patients with a first episode of recurrent pericarditis

Imazio et al, Archives of Internal Medicine, September 26, 2005. Arch Intern Med. 2005;165:1987-91

Editors note: While these are promising results, I have to wonder why the authors did not do a double blinded, placebo controlled study. – MSB

Emergency Medicine

The Emergency Department Utility of Simplify D-dimer to Exclude Pulmonary Embolism in Patients With Pleuritic Chest Pain

This study was designed to evaluate the sensitivity and specificity of simplify D-dimer to rule out pulmonary embolism in patients presenting to the emergency department with pleuritic chest pain. Simplify D-dimer is a rapid, bedside d-dimer test.

This was a prospective diagnostic study. Seven hundred ninety-nine patients were assessed for inclusion into the study. Of these, 277 were excluded and 97 declined to participate. A total of 425 patients participated in the study.

A total of 120 patients tested positive on the simplify D-dimer, and of those 18 were positive for pulmonary embolism. A total of 297 patients tested negative on the simplify D-dimer and of those, 4 had pulmonary embolism. The sensitivity was 81.8%, and the specificity was 74.2%. The positive predictive value was 15%, The negative predictive value was 98.6%. When the simplify D-dimer was combined with pre-test probability scoring, the sensitivity of the combined test was 90.9%, and the specificity of the combined test was 68.9%.

The authors conclude that the Simplify D-dimer is not sufficiently accurate to exclude the diagnosis of pulmonary embolism in all patients presenting to the ED with pleuritic chest pain.

Hogg et al, Annals of Emergency Medicine, October, 2005. Ann Emerg Med 2005;46:305-10

Editors note – It should be re-emphasized that this is for the one bedside d-dimer test. – MSB

Infectious Disease

Amoxicillin-Clavulanate vs Ciprofloxacin for the treatment of Uncomplicated Cystitis in Women

This was a randomized, single-blind study which compared the efficacy of a three-day regimen of amoxicillin-clavulanate to that of a three-day regimen of ciprofloxacin for the treatment of uncomplicated cystitis in women. The study was undertaken because of the high prevalence of resistance to trimethoprim-sulfamethoxazole and other antimicrobials among *Escherichia Coli*, leading to an increased use of alternative antibiotics in the treatment of acute cystitis.

The study was conducted at the University of Washington Student Health Center and at Group Health Cooperative from July 1998 to May 2002. Women were eligible if they were healthy, between 18 and 45 years of age, had frequency, dysuria and/or urgency. Women were ineligible if they were pregnant, had symptoms of pyelonephritis, allergy to a fluoroquinolone or penicillin, a chronic medical illness, a known anatomic or functional abnormality of the urinary tract, or had received systemic or vaginal topical antimicrobials in the previous 14 days.

A total of 370 women, aged 18 to 45 years were randomized to receive treatment. Forty-eight women were excluded from the analysis, 39 due to less than 10 CFU/ml at enrollment and nine had no follow-up. The remaining 322 women were eligible for analysis. Compliance with at least five of six doses of study drug was 99% in both groups. Women taking less than six doses of study drug were included in the data.

The women received either amoxicillin-clavulanate 500mg/125mg or ciprofloxacin 250mg twice daily for three days. They were asked to return to the clinic every two weeks for four months, or until they were retreated for symptomatic or recurrent UTI.

Clinical cure was observed in 95 (58%) of 160 women treated with amoxicillin-clavulanate and 124 (77%) of 162 women treated with ciprofloxacin. The difference in clinical cure rates was almost entirely in the first two weeks. Microbiological cure at two weeks was observed in 118 (76%) of 156 women treated with amoxicillin-clavulanate and 153 (95%) of 162 women treated with ciprofloxacin.

The authors conclude that a three-day regimen of amoxicillin-clavulanate is not as effective as ciprofloxacin for the treatment of acute uncomplicated cystitis, even in women infected with susceptible strains. This difference may be due to the inferior ability of amoxicillin-clavulanate to eradicate vaginal *E. coli*, facilitating early re-infection. – MSB

Hooton et al, *Journal of the American Medical Association*, February 23, 2005. JAMA 2005;293:949-955

A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults

Herpes Zoster is characterized by a vesicular rash generally limited to one dermatome. It results from reactivation of latent varicella-zoster virus (VZV) within the sensory ganglia. The incidence and severity increases with age, with more than 50% of the cases developing in patients older than 60 years. Complication rate in older patients is almost 50%. The most frequent debilitating complication is post-herpetic neuralgia, a neuropathic pain syndrome that persists or develops after the dermatomal rash has healed.

This study was designed to test whether a vaccine against VZV would reduce the incidence and/or severity of herpes zoster and postherpetic neuralgia. The study was a randomized, double blinded, placebo controlled, multicenter (22 sites) trial in which adults 60 years of age or older received either VZV vaccine or placebo. Eligible patients had a history of varicella, or had resided in the continental United States for more than 30 years. Immunocompromised patients were excluded from the study. Patients received one 0.5ml injection of investigational live, attenuated VZV vaccine or placebo. Patients were followed monthly by an automated telephone-response system, and if any symptoms suggested a possible case of Herpes zoster infection (eg. new rash, unilateral pain), they were urged to contact their study site for further evaluation. Subjects with clinically diagnosed zoster were offered, without cost, famciclovir, and standard of care pain treatment. Subjects with a new rash or unilateral pain were classified as "suspected cases of herpes zoster." Prior to unblinding, the suspected cases were classified as either confirmed or as not a confirmed case by an algorithm that incorporated the results of the polymerase-chain-reaction (PCR) assay, and a clinical evaluation consisting of a panel of five physicians with expertise in herpes zoster.

There were 38,546 subjects enrolled in the study between November 1998 and September 2001. Follow-up was completed in April 2004. More than 95% of patients continued in the study to its completion, with a median time of 3.12 years of surveillance. Demographics were similar in both groups. There were a total of 957 confirmed cases of herpes zoster, of which 315 were among vaccine recipients and 642 were among the placebo recipients. There were 107 cases of postherpetic neuralgia, 27 among the vaccine group, 80 among the placebo group.

The most frequent adverse event was pain, tenderness or swelling at the injection site, which was significantly higher in the vaccine group. The study was sponsored, in part, by a grant from Merck. Merck also manufactured and supplied the vaccine and placebo.

The authors conclude that the zoster vaccine markedly reduced morbidity from herpes zoster and postherpetic neuralgia among older adults. – MSB

Oxman et al, New England Journal of Medicine, June 2, 2005. NEJM 2005;352:2271-84

Oncology

Levofloxacin to Prevent Bacterial Infections in Patients with Cancer and Neutropenia

The prophylactic use of fluoroquinolones in patients with cancer and neutropenia is controversial and currently not recommended.

This was a prospective, multi-center, double blind, randomized, placebo controlled study designed to look at the effect of levofloxacin prophylaxis in neutropenic cancer patients in reducing bacterial infection.

A total of 760 patients with neutropenia due to chemotherapy were enrolled in the study. Subsequently, 384 were randomly assigned to receive oral levofloxacin, and 376 were randomized to receive placebo. Adult patients with leukemia, solid tumors or lymphomas at risk for chemotherapy induced neutropenia lasting more than 7 days were eligible for the study. Patients with fevers from bacterial infection, documented infection at the time of enrollment or antimicrobial therapy within the preceding 5 days were excluded.

Patients received 500mg levofloxacin or placebo daily. Randomized patients were examined daily for signs of infection. When axillary temperature was greater than 38.5 degrees centigrade once, or greater than 38 degrees centigrade at least twice within a 12 hour period, blood cultures were obtained and the patient started on empirical antibacterial therapy.

Among the 363 placebo patients 308 (85%) developed fever, and 18 (5%) died. Among the 375 levofloxacin patients, 243 (65%) developed fever, and 10 (3%) died. Among leukemia patients receiving levofloxacin 123/183 (67%) developed fever, 39/165 (24%) had microbiologically documented infection of the levofloxacin and 34/165 (21%) had bacteremia. Among leukemia patients who received placebo, 154/179 (86%) developed fever, 74/165 (45%) had microbiologically documented infection, and 64/165 (39%) had bacteremia.

Among lymphoma or solid tumor patients receiving levofloxacin, 120/192 (62%) had a febrile episode, 35/174 (20%) had a microbiologically documented infection, and 28/174 (16%) had bacteremia. Lymphoma or solid tumor patients receiving placebo 154/184 (84%) has a febrile episode, 57/171 (33%) had a microbiologically documented

infection and 57/171 (30%) had bacteremia.

The authors conclude that prophylactic treatment with levofloxacin is an effective and well-tolerated way of preventing febrile episodes and other relevant infection related outcomes in-patients with cancer and profound and protracted neutropenia. The long-term effect of this intervention on microbial resistance in the community is not known.

Bucaneve et al, New England Journal of Medicine, September 8, 2005. NEJM 2005;353:977-87

Editors note – The episodes of febrile episodes were definitely reduced, although there was still a high incidence in the treatment group. I would have preferred to see oral temperatures over axillary temperatures simply for the sake of accuracy. There was a predictably higher levofloxacin resistance (41/47 vs 32/68) in the levofloxacin group. The authors themselves point out that the long-term effect of levofloxacin prophylaxis on microbial resistance is not known. However, overall it seems reasonable to put susceptible patients on daily levofloxacin. - MSB

Pediatric Emergency Medicine

Clinical Efficacy of Racemic Albuterol Versus Levalbuterol for the Treatment of Acute Pediatric Asthma

Inhaled B-adrenergic agonists are the mainstay of therapy for acute asthma exacerbations. Albuterol is the most frequently administered B-adrenergic. Albuterol has 2 enantiomers, R & S. The R-enantiomer was thought to be responsible for the drugs bronchodilating activity and adverse effects, while the S-enantiomer was thought to be inert. Some studies have postulated that the S-enantiomer may cause increased airway disease. Additionally, the S-enantiomer has a slower clearance than the R-enantiomer, resulting in accumulation of the S-enantiomer with repeated racemic treatments. Levalbuterol is a formulation of the R-enantiomer and marketed as being more efficacious and with fewer side effects than the RS-albuterol. Studies in chronic asthma have suggested improved bronchodilation with R-albuterol compared with RS-albuterol.

This was a prospective, double blinded, randomized controlled study involving 129 children, ages 2 to 14years, presenting to a pediatric ED with an acute moderate or severe asthma exacerbation. The study compared racemic (RS) albuterol to R-albuterol in treating pediatric acute asthma.

There were 651 patients evaluated for the study, of which 512 were excluded (332 did not meet inclusion criteria, 33 refused, 112 were on prior medications, and 35 other). This left 139 patients, of which 68 were randomized to the racemic albuterol group, and 71 randomized to the levalbuterol group.

No differences were detected in the groups after the 1st, 3rd or 5th nebulizer treatment in the primary outcome of asthma score or percentage of FEV1. Additionally, no differences were detected in the number of nebulizer treatments, hospitalization rate, length of care or changes in pulse rate.

The authors conclude that there was no difference in clinical improvement in children with acute moderate to severe asthma exacerbations treated with racemic albuterol or levalbuterol.

Qureshi et al, *Annals of Emergency Medicine*, July 2005. *Ann Emerg Med* . 2005;46:29-36

Pulmonary

Prevention of Exacerbations of Chronic Obstructive Pulmonary Disease with Tiotropium, a Once-Daily Inhaled Anticholinergic Bronchodilator.

Tiotropium is a new long-acting anticholinergic bronchodilator which has been shown to improve lung function in patients with COPD.

This was a prospective, randomized, double blind, placebo controlled study which evaluated the effectiveness of tiotropium in reducing COPD exacerbations and exacerbation related health care utilization.

The authors screened 2,498 patients for entry into the study. Patients were eligible if they were 40 years of age or older, had a minimum 10 pack year smoking history, a clinical diagnosis of COPD, FEV1 less than 60% of predicted and FVC of less than 70% of predicted. Patients were excluded if they had a previous diagnosis of asthma, myocardial infarction within the last six months, a serious cardiac arrhythmia or hospitalization for congestive heart failure within the previous year, moderate or severe renal impairment, moderate to severe prostatic hypertrophy or bladder neck obstruction, narrow angle glaucoma, current radiation or chemotherapy for a malignant condition, on unstable doses of prednisone, on more than 20mg per day of prednisone, or who had not recovered from an exacerbation within the previous 30 days of the first study visit. The study took place at Veteran Administration Facilities, and the participants were 99% men.

A total of 1,829 patients were randomized, of which 915 were randomized to receive placebo, and 914 were randomized to receive tiotropium for a six month period. Patients continued to take all other respiratory medications, with the exception of another anticholinergic bronchodilator. At six months, 296 (32.3%) patients in the placebo group and 255 (27.9%) patients in the tiotropium group had ≥ 1 COPD exacerbation, and 87 (9.5%) patients in the placebo group and 64 (7.0%) of patients in the tiotropium group had ≥ 1 hospital-

ization for COPD. While small, the differences were statistically significant.

The authors conclude that tiotropium reduces COPD exacerbations and may reduce health care utilization in patients with moderate to severe COPD. – MSB

Niewoehner et al, *Annals of Internal Medicine*, September 6, 2005. *Ann Intern Med* 2005;143:317-326

Psychiatry

Cognitive Therapy for the Prevention of Suicide Attempts

Suicide is a major cause of death in adults between the ages of 18 to 65 years old. In 2002, suicide was the fourth leading cause of death in this age group. Suicide attempts are a major risk factor for completed suicide.

This study looked at the effectiveness of 10 cognitive therapy sessions designed to prevent a repeat suicide attempt in adults who had recently attempted suicide. This was a randomized, non-blinded study.

Potential participants were identified in the emergency department following a suicide attempt or intentional self-injury. Inclusion criteria included a suicide attempt within 48 hours prior to evaluation at the emergency department, age 16 years or older, ability to speak English, ability to complete a baseline assessment, ability to provide at least two verifiable contacts to improve tracking for subsequent assessment, and the ability to understand and provide informed consent. Individuals were not asked to discontinue any other form of mental health or substance abuse treatment.

There were 350 patients assessed for eligibility. Of these, 164 did not meet inclusion criteria, and 66 refused participation. This left 120 patients who were randomly assigned to receive either cognitive therapy or usual care. Participants were between the ages of 18 and 66 years old. Of these, 61% were female, 60% were black, 35% white, and 5% Hispanic, Native American or unspecified. At baseline, 77% had a major depressive disorder and 68% had a substance abuse disorder. There was no significant demographic variability between the two groups.

Participants in the cognitive therapy group received 10 weekly or biweekly sessions as needed. The sessions were specifically developed for preventing suicide attempts. The subsequent in person assessments were conducted independently of study therapists at one, three, six, 12 and 18 months following the baseline interview.

The primary outcome measure was the occurrence of a suicide attempt within the follow-up period. There were 13 participants (24.1%) in the cognitive therapy group and

23 participants (41.6%) in the usual care group that made at least one suicide attempt during the follow-up period. There was no significant difference in suicide ideation between the two groups.

The authors conclude that cognitive therapy was effective in preventing suicide attempts for adults who recently attempted suicide. – MSB

Brown et al, Journal of the American Medical Association, August 3, 2005. JAMA 2005;294:563-5,70

Surgery

Supplemental Perioperative Oxygen and the Risk of Surgical Wound Infection

This was a double blind, randomized controlled trial designed to evaluate the effect of perioperative oxygen supplementation and its effect on the rate of post-operative wound infection.

The authors randomized 300 patients undergoing elective colorectal surgery. Patients were randomized to receive either 30% (143 patients) or 80% (149 patients) oxygen during surgery. Nine patients were excluded after randomization. Patients undergoing polypectomy, laproscopic surgery, expected operative time of less than one hour, diabetes, HIV, existing signs of infection, serum albumin less than 30g/L, or a leukocyte count less than 2,500 were excluded.

Following induction, the anesthesiologist open randomized envelopes assigning the patient to their study group. The surgical team was blinded during the surgery and post-operatively. The wound evaluation team was also blinded to the study group. Demographics, lengths of surgery and surgical procedure were similar in both groups.

In the 30% FiO₂ group, 35 (24.4%) patients developed surgical site infections, 37 (25.9%) of patients had daily ASEP-SIS scores \geq 20 at any given time, and five (3.5%) patients required ICU admission. In the 80% FiO₂ group, 22 (14.9%) patients developed surgical site infection, 25 (16.9%) had daily ASEP-SIS scores \geq 20 at any given time, and four (2.7%) requires ICU admission. ASEP-SIS score is a scoring system – additional treatment, serous discharge, erythema, purulent exudate, separation of deep tissues, isolation of bacteria and duration of inpatient stay.

The authors conclude that patients receiving supplemental inspired oxygen had a significant reduction in the risk of wound infection. Supplemental oxygen appears to be an effective intervention to reduce surgical site infection in patients undergoing colon or rectal surgery.

Belda et al, Journal of the American Medical Association, October 25, 2005. JAMA 2005;294:2035-42

Editors note – A well done study and a simple intervention which can reduce postoperative wound infection. – MSB

Women's Health

Safety and Efficacy of a Testosterone Patch for the Treatment of Hypoactive Sexual Desire Disorder in Surgically Menopausal Women

Oophorectomy reduces serum testosterone levels. The authors studied the efficacy and safety of a testosterone patch in treating hypoactive sexual desire in surgically menopausal women.

This was a randomized, double blind, placebo controlled, parallel study. The authors screened 879 patients for enrollment. Women were excluded if they had received androgen therapy in recent months, moderate or severe hirsutism, hyperlipidemia, psychiatric illness, dyspareunia or other physical limitation to sexual function, history of breast or gynecological cancer, or were taking medications likely to interfere with sexual function. After screening, 447 women, 24 to 70 years old were enrolled. All women had undergone bilateral salpingo-oophorectomy and hysterectomy at least one year before entering the study, and had been receiving oral estrogen at a stable dose for at least 12 weeks. The dose and type of estrogen remained constant throughout the study.

The women were randomized to receive patches with testosterone or placebo, 150ug, 300ug, or 450ug of testosterone per day. Placebo and active patches were identical in appearance and participants applied the patches twice weekly.

At 24 weeks, all groups (including placebo) reported an increase in the subsets of female sexual function score (PFSS), including sexual desire, sexual arousal, orgasm, sexual pleasure, sexual concerns, sexual responsiveness and sexual self-image. Only the increase in sexual desire and sexual arousal showed a statistically significant increase over placebo. The other parameters did show numerical, but not statistically significant increases over placebo. There was no difference in the response of the 300ug and 450ug patches. The testosterone levels at week 24 showed a predictable dose/level response. The adverse side effect profile was the same for all groups.

The authors conclude that the 300-ug/d testosterone patch increased sexual desire and frequency of satisfying sexual activity and was well tolerated in women who developed hypoactive sexual desire disorder after surgical menopause.

Braunstein et al, Archives of Internal Medicine, July 25, 2005. Arch Intern Med 2005;165:1528-1589

Editors note – Further studies need to be done on this subject. As the authors themselves pointed out, there was a large response to placebo. This may well be due to the fact that hypoactive sexual disorder is a multidimensional problem. With all the changes in protocols for hormone replacement therapy over the past 20 years, I would wait for more studies before applying these results to clinical practice. - MSB

Section Editor: Matthew S. Berry, MD, FACP, FAAEP

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