

In-Hospital Prevention Program Targets the Family

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COLORADO SPRINGS — A novel in-hospital lifestyle intervention aimed at family members visiting a relative hospitalized with cardiac disease pays dividends in terms of improved heart-healthy dietary habits.

Moreover, the members most likely to improve their diet in response to the hour-long counseling session tended to be those with baseline elevated cardiovascular risk factors

and lower self-perceived health status, Dr. Lori Mosca said at a conference sponsored by the American Heart Association.

“When a family member has someone hospitalized for heart disease it’s an opportune time to help them learn about their own risk for heart disease and [how] to lower it. It’s what we call the motivational moment,” Dr. Mosca, professor of medicine and director of preventive cardiology at New York–Presbyterian Hospital, said in an interview. “Interventions will be more ef-

fective when timed correctly and targeted to the right audience. The more threatened people feel by a condition, the more likely they are to adhere to preventive therapy.”

Dr. Mosca is principal investigator for the ongoing National Institutes of Health–funded Family Intervention Trial for Heart Health (F.I.T. Heart). In an interim analysis reported at the meeting, adherence to the National Cholesterol Education Program’s Therapeutic Lifestyle Change diet in 189 family members who went through the intervention rose from 53% at baseline to 79% at follow-up 6 weeks later. Of those who received the intervention 77% showed a significant improvement in their diet score at 6 weeks’ follow-up.

In the next phase, Dr. Mosca plans to document whether intervening with family members has a beneficial spillover effect on the cardiac patients. About half of the family members participating in the project are responsible for caring for the patient. “If we teach them about diet, there could potentially be a very important domino effect.”

Here’s how the F.I.T. Heart intervention

works: When patients enter the hospital with an MI or for a coronary revascularization procedure, they’re given a pamphlet explaining the program and inviting family members to attend. The prevention counselors, who are dietitians or health educators, go out onto the floors and invite family members to come by the counsel-

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DR. MOSCA

ing room on the cardiac floor for a cardiovascular risk factor assessment and risk-lowering suggestions. There is no charge for the program, which the hospital has been running for 5 years as a community

outreach project. “It’s a modest amount of resources, and the downstream effect is going to be very important,” she noted. The study has found that family members who care for a cardiac patient had higher levels of cardiovascular risk factors, higher psychosocial strain scores, less social support, and more depressive symptoms than did noncaregivers. The fact that caregivers may themselves be at increased risk of heart disease is not surprising, since they share lifestyle factors, and often genes, with the patient, Dr. Mosca noted. ■



LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION

(5% and 4%); Fatigue (5% and 2%). **Psychiatric Disorders:** Insomnia (9% and 4%); Somnolence (6% and 2%); Appetite Decreased (3% and 1%); Libido Decreased (3% and 1%). **Respiratory System Disorders:** Rhinitis (5% and 4%); Sinusitis (3% and 2%). **Urogenital:** Ejaculation Disorder¹ (3% and <1%); Impotence (3% and <1%); Anorgasmia (2% and <1%). ¹Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo > Lexapro: headache, upper respiratory tract infection, back pain, pharyngitis, inflicted injury, anxiety. ²Primarily ejaculatory delay. ³Denominator used was for males only (N=225 Lexapro; N=188 placebo). ⁴Denominator used was for females only (N=490 Lexapro; N=404 placebo). **Generalized Anxiety Disorder Table 3** enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia (see TABLE 3). **TABLE 3: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Generalized Anxiety Disorder* (Percentage of Patients Reporting Event) Body System/Adverse Event (Lexapro (N=429) and Placebo (N=427)).** **Autonomic Nervous System Disorders:** Dry Mouth (9% and 5%); Sweating Increased (4% and 1%). **Central & Peripheral Nervous System Disorders:** Headache (24% and 17%); Paresthesia (2% and 1%). **Gastrointestinal Disorders:** Nausea (18% and 8%); Diarrhea (8% and 6%); Constipation (5% and 4%); Indigestion (3% and 2%); Vomiting (3% and 1%); Abdominal Pain (2% and 1%); Flatulence (2% and 1%); Toothache (2% and 0%). **General:** Fatigue (8% and 2%); Influenza-like symptoms (5% and 4%). **Musculoskeletal:** Neck/Shoulder Pain (3% and 1%). **Psychiatric Disorders:** Somnolence (13% and 7%); Insomnia (12% and 6%); Libido Decreased (7% and 2%); Dreaming Abnormal (3% and 2%); Appetite Decreased (3% and 1%); Lethargy (3% and 1%); Yawning (2% and 1%). **Urogenital:** Ejaculation Disorder¹ (14% and 2%); Anorgasmia² (6% and <1%); Menstrual Disorder (2% and 1%). ³Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo > Lexapro: inflicted injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. ⁴Denominator used was for males only (N=182 Lexapro; N=195 placebo). ⁵Denominator used was for females only (N=247 Lexapro; N=232 placebo). **Dose Dependency of Adverse Events** The potential dose dependency of common adverse events (defined as an incidence rate of ≥ 5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). **Table 4** shows common adverse events that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group. **TABLE 4: Incidence of Common Adverse Events* in Patients with Major Depressive Disorder Receiving Placebo (N=311), 10 mg/day Lexapro (N=310), 20 mg/day Lexapro (N=125); Insomnia (4%, 7%, 14%); Diarrhea (5%, 6%, 14%); Dry Mouth (3%, 4%, 9%); Somnolence (1%, 4%, 9%); Dizziness (2%, 4%, 7%); Sweating Increased (<1%, 3%, 8%); Constipation (1%, 3%, 6%); Fatigue (2%, 2%, 6%); Indigestion (1%, 2%, 6%).** ⁶Adverse events with an incidence rate of at least 5% in either the Lexapro groups and with an incidence rate in the 20 mg/day Lexapro group that was approximately twice that of the 10 mg/day Lexapro group and the placebo group. **Male and Female Sexual Dysfunction with SSRIs** Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. **Table 5** shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-controlled trials. **TABLE 5: Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials (In Males Only: Adverse Event: Lexapro (N=407) and Placebo (N=383)); Ejaculation Disorder (primarily ejaculatory delay) (12% and 1%); Libido Decreased (6% and 2%); Impotence (2% and <1%). (In Females Only: Lexapro (N=373) and Placebo (N=356)); Libido Decreased (3% and 1%); Anorgasmia (3% and <1%).** There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. **Priligam** has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes** Patients treated with Lexapro in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes** Electrocardiograms from Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to an increase of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Events Observed During the Premarketing Evaluation of Lexapro** Following is a list of WHO terms that reflect treatment-emergent adverse events, as defined in the introduction to the ADVERSE REACTIONS section, reported by the 1428 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. All reported events are included except those already listed in Tables 2 & 3, those occurring in only one patient, event terms that are so general as to be uninformative, and those that are unlikely to be drug related. It is important to emphasize that, although the events reported occurred during treatment with Lexapro, they were not necessarily caused by it. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring on one or more occasions in at least 1/100 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1000 patients. **Cardiovascular - Frequent:** palpitation, hypertension. **Infrequent:** bradycardia, tachycardia, ECG abnormal, flushing, varicose vein. **Central and Peripheral Nervous System Disorders - Frequent:** light-headed feeling, migraine. **Infrequent:** tremor, vertigo, restless legs, shaking, twitching, dysequilibrium, tic, carpal tunnel syndrome, muscle contractions involuntary, sluggishness, coordination abnormal, faintness, hyperreflexia, muscular tone increased. **Gastrointestinal Disorders - Frequent:** heartburn, abdominal cramp, gastroenteritis. **Infrequent:** gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult. **General - Frequent:** allergy, pain in limb, fever, hot flushes, chest pain. **Infrequent:** edema of extremities, chills, tightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. **Hemic and Lymphatic Disorders - Infrequent:** bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical. **Metabolic and Nutritional Disorders - Frequent:** increased weight. **Infrequent:** decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. **Musculoskeletal System Disorders - Frequent:** arthralgia, myalgia. **Infrequent:** jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness. **Psychiatric Disorders - Frequent:** appetite increased, lethargy, irritability, concentration impaired. **Infrequent:** jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, anorexia, anxiety attack, bruxism, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. **Reproductive Disorders/Female - Frequent:** menstrual cramps, menstrual disorder. **Infrequent:** menorrhagia, breast neoplasm, pelvic inflammation, premenstrual syndrome, spotting between menses. *% based on female subjects only; N=905 Respiratory System Disorders - Frequent: bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. **Infrequent:** asthma, breath shortness, laryngitis, pneumonia, tracheitis. **Skin and Appendages Disorders - Frequent:** rash. **Infrequent:** pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodule. **Special Senses - Frequent:** vision blurred, tinnitus. **Infrequent:** taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste. **Urinary System Disorders - Frequent:** urinary frequency, urinary tract infection. **Infrequent:** urinary urgency, kidney stone, dysuria, blood in urine. **Events Reported Subsequent to the Marketing of Escitalopram** - Although no causal relationship to escitalopram treatment has been found, the following adverse events have been reported to have occurred in patients and to be temporally associated with escitalopram treatment during post marketing spontaneous and clinical trial experience and were not observed during the premarketing evaluation of escitalopram: Blood and Lymphatic System Disorders: hemolytic anemia, leukopenia, thrombocytopenia. **Cardiac Disorders:** atrial fibrillation, cardiac failure, myocardial infarction, torsade de pointes, ventricular arrhythmia, ventricular tachycardia. **Endocrine Disorders:** diabetes mellitus, hyperprolactinemia, SIADH. **Eye Disorders:** diplopia, glaucoma. **Gastrointestinal Disorders:** gastrointestinal hemorrhage, pancreatitis, rectal hemorrhage. **General Disorders and Administration Site Conditions:** abnormal gait. **Hepatobiliary Disorders:** fulminant hepatitis, hepatic failure, hepatic necrosis, hepatitis. **Immune System Disorders:** allergic reaction. **Investigations:** electrocardiogram QT prolongation, INR increased, prothrombin decreased. **Metabolism and Nutrition Disorders:** hypoglycemia, hypokalemia. **Musculoskeletal and Connective Tissue Disorders:** rhabdomyolysis. **Nervous System Disorders:** akathisia, choreoathetosis, dysarthria, dyskinesia, dystonia, extrapyramidal disorders, grand mal seizures (or convulsions), hypoaesthesia, myoclonus, neuroleptic malignant syndrome, nystagmus, seizures, serotonin syndrome, tardive dyskinesia. **Pregnancy, Puerperium and Perinatal Conditions:** spontaneous abortion. **Psychiatric Disorders:** acute psychosis, aggression, anger, delirium, delusion, nightmare, paranoia, visual hallucinations. **Renal and Urinary Disorders:** acute renal failure. **Reproductive System and Breast Disorders:** priapism. **Respiratory, Thoracic and Mediastinal Disorders:** pulmonary embolism. **Skin and Subcutaneous Tissue Disorders:** angioedema, ecchymosis, erythema multiforme, photosensitivity reaction, Stevens Johnson Syndrome, toxic epidermal necrolysis, urticaria. **Vascular Disorders:** deep vein thrombosis, hypotension, orthostatic hypotension, phlebitis thrombosis. 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Adherence to Process Measures Predicts Acute MI Mortality

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PITTSBURGH — Hospitals with low adherence to acute MI process measures have higher 30-day mortality rates than do other U.S. hospitals, even after adjustment for differences in patient populations.

Recent studies have shown significant improvements in adherence to acute MI process measures—particularly aspirin and β-blockers and ACE inhibitors for left-ventricular systolic dysfunction—but little is known about the hospitals with consistently poor adherence and the relationship between poor adherence and outcomes.

Dr. Ioana Popescu of the department of internal medicine at the University of Iowa, Iowa City, and associates calculated a composite acute MI compliance score for 2,761 hospitals that reported acute MI process measures for at least 25 acute MI cases a year to the Centers for Medicare and Medicaid Services’ Hospital Quality Alliance database in 2004-2006. The number of hospitals—2,761—represents 63% of U.S. hospitals treating acute MI patients.

The hospitals were categorized as low-performing (lowest decile for every study year), high-performing (highest decile), and intermediate-performing (all other). Dr. Popescu reported at the annual meeting of the Society of General Internal Medicine.

Risk-adjusted mortality was calculated as the observed or predicted mortality multiplied by the mean overall population

mortality rate, using the records of 208,080 Medicare beneficiaries admitted with acute MI in 2005. The 30-day predicted mortality was estimated using models controlling for patient demographics, comorbidity, and patient clustering within hospitals.

Mean compliance for the five widely reported acute MI process measures was 68% for the 105 low-performing hospitals, 92% for the 2,493 intermediate performers, and 99% for the 163 high-performing hospitals.

Compared with high-performers, low performers were significantly less likely to be teaching hospitals or in an urban location. Low performers were more likely “safety net” hospitals and to be for-profit institutions. The proportion of uncompensated care was significantly greater at low-performing hospitals, whereas staffing ratio, acute MI volume, revascularization, and bed count rates were lower.

Patients at low-performing hospitals were slightly older (80 vs. 79 years), and more likely to be black (9% vs. 4%), female (56% vs. 48%), have lower incomes (\$33,739 vs. \$46,698), and more comorbidities than those at high-performing institutions.

Mean observed 30-day mortality after acute MI was 26% at the low-performers, 19% at intermediate hospitals, and 15% at the high performers. Even after controlling for differences in patient characteristics, the mean 30-day risk-adjusted mortality rate was significantly greater for low performers, at 19%, versus 16% for the intermediate and 15% for the high performers. ■