CLINICAL CAPSULES

Girls' Body Images Can Be Bolstered

Adolescent girls who reported peer and parental attitudes that encouraged healthy behavior and exercise, rather than weight loss, were significantly more likely to report high levels of body satisfaction, said Amy M. Kelly, M.D., and her colleagues at the University of Minnesota, Minneapolis.

Overall, 26.7% of 2,357 middle and high school students surveyed in 1998-1999 reported high body satisfaction (J. Adolesc. Health 2005;37:391-6).

The study population included 46% whites, 21% Asian Americans, 20% African Americans, and 5% Hispanics. Body satisfaction was significantly higher among African American girls (40%) and underweight girls (39%) after controlling for ethnicity, socioeconomic status, and age. Girls with high body satisfaction were more likely to report having mothers who exercised for fitness and who encouraged them to be active and eat healthfully.

In addition, girls who reported high body satisfaction were more likely to report that they cared about their health, being fit, and exercising.

Group CBT as Effective as Sertraline

Children and adolescents aged 9-17 years with obsessive-compulsive disorder demonstrated equally significant symptom reductions after being randomized to 12 weeks of sertraline (Zoloft) or 12 weeks of group cognitive-behavioral therapy, said Fernando Ramos Asbahr, M.D., of the University of São Paulo (Brazil), and his colleagues (J. Am. Acad. Child Adolesc. Psychiatry 2005;44:1128-36).

Although 10 of 18 patients (56%) who received sertraline required reintroduction of the drug during the 9-month follow-up, only 1 of 19 (5%) of the group therapy patients relapsed during follow-up.

The weekly 90-minute group therapy sessions, directed by cognitive-behavioral therapists, included education about OCD, cognitive training, and family therapy.

Smoking Stunts Girls' Growth

Persistent cigarette smoking retards physical growth in early adolescence, based on data from a 3-year follow-up study of 496 girls aged 11-15 years, said Eric Stice, Ph.D., and Erin E. Martinez, of the University of Texas at Austin.

Persistent smoking—defined as daily smoking between baseline and at 1-year follow-up or between 1-year and 2-year follow-up—was associated with a 34% reduction in height growth, 53% reduction in weight gain, and 71% reduction in BMI during a 1-year interval compared with nonsmokers (J. Adolesc. Health 2005;37:363-70). Smoking initiation in adolescence was associated with a 36% reduction in weight gain and a 68% reduction in BMI but not with significant changes in height growth, compared with nonsmokers.

Termination of smoking during adolescence was associated with barely significant increases in weight and BMI, but not with significant changes in height.

Academic Problems Beget Bullying

Elementary school students who suffer from psychosocial distress are more likely to be involved in bullying, and those with academic problems are more likely to be victims or bully-victims, according to a crosssectional study of 3,530 children, wrote Gwen M. Glew, M.D., of the University of Washington, Seattle, and her associates.

About 22% of third-, fourth-, and fifthgrade students reported involvement in bullying as either the bully, the victim, or both (bully-victims) in a cross-sectional study of data from a school-based survey. Overall, lower levels of school achievement, feeling unsafe at school, feelings of not belonging at school, and feeling sad were positively associated with being a victim rather than a bystander (Arch. Pediatr. Adolesc. Med. 2005;159:1026-31).

Students who reported feeling unsafe or feeling sad most days were 2.5 times and 1.5 times, respectively, more likely to be a bully than a bystander. In addition, feeling unsafe, feelings of not belonging at school, and lower school achievement were associated with increased odds of being a bully-victim rather than a bystander.

Drug Reduces Disruptive Behavior

Daily risperidone was significantly more effective than placebo at reducing disruptive behaviors in children aged 5-17 years with autism spectrum disorders, said Pieter W. Troost, M.D., of the University of Groningen (the Netherlands), and his associates.

After 24 weeks of treatment in an openlabel study, 18 of 26 children (69%) who received risperidone (Risperdal) were rated "much improved" or "very much improved" on the Clinical Global Impressions Scale of Symptom Change. During the discontinuation phase that followed the study phase, 8 of 12 children (67%) randomized to a placebo suffered relapses, compared with 3 of 12 (25%) who continued to take risperidone. The mean dose was 1.51 mg/kg at 8 weeks of treatment and increased to a mean of 1.81 mg/kg at 24 weeks to ensure treatment effects.

LAMICTAL® (lamotrigine) Tablets
LAMICTAL® (lamotrigine) Chewable Dispersible Tablets

adjustments may be necessary.

Pregnancy Exposure Registry: To facilitate monitoring fetal outcomes of pregnant women exposed to lamotrigine, physicians are encouraged to register patients, before fetal outcome (e.g., ultrasound, results of amniocentesis, birth, etc.) is known, and can obtain information by calling the Lamotrigine Pregnancy Registry at (800) 336-2176 (toll-free). Patients can enroll themselves in the North American Antipelieptic Drug Pregnancy Registry by calling (888) 233-2334 (toll-free).

Labor and Delivery: The effect of LAMICTAL on labor and delivery in humans is unknown.

Use in Nursing Mothers: Preliminary data indicate that lamotrigine passes into human milk. Because the effects on the infant exposed to LAMICTAL by this route are unknown, breast-feeding while taking LAMICTAL is not recommended.

Pediatric Use: JAMICTAL, is indicated as adjunctive therapy for partial seizures in patients above 2 years of age and for the generalized seizures of Lennox-Gastaut syndrome. Safety and effectiveness for other uses in patients with epilepsy below the age of 16 years have not been established (see BOX WARNING). Safety and effectiveness in patients below the age of 16 years have not been established (see BOX WARNING).

To years have not been established (see BOX WARNING). Safety and effectiveness in patients below the age of 18 years with Bipolar Disorder has not been established.

Gerlatric User, Clinical studies of LAMICTAL for epilepsy and in Bipolar Disorder did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, susually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS: (see BOX WARNING regarding the incidence of serious rash).

Epilepsy: Most Common Adverse Events in all Clinical Studies: Adjunctive Therapy in Adults With Epilepsy: The most commonly observed (≥5%) adverse experiences seen in association with LAMICTAL during adjunctive therapy in adults and not seen at an equivalent frequency among blacebo-treated patients were: dizziness, ataxia, somnolence, headache, diplopia, blurred vision, nausea, and vorniting were dose related. Dizziness, diplopia, ataxia, and blurred vision occurred more commonly in patients receiving Other AEDs with LAMICTAL clinical data suggest a higher incidence of rash, including serious rash, in patients receiving other AEDs with LAMICTAL therapy in pramareting clinical trial sidiscontinuous rash, in patients receiving other AEDs with LAMICTAL therapy in pramareting clinical trial sidiscontinuous rash, including serious rash, in patients who received LAMICTAL adult patients who received LAMICTAL adults, the rate of discontinuation of LAMICTAL for dizziness, ataxia, diplopia, blurred vision, nausea, and vorniting was dose realed. Monotherapy in Adults With Epilepsy: The most commonly observed (≥5%) adverse experiences seen in association with the use of LAMICTAL during the monotherapy dad-only priend, of seen at an equivalent frequency among low-dose valproatel-treated patients, were dizziness, headac

and asheria (2.4%).

Adjunctive Therapy in Pediatric Patients With Epilepsy: The most commonly observed (≥5%) adverse experiences seen in association with the use of LAMICTAL as adjunctive treatment in pediatric patients and not seen at an equivalent rate in the control group were infection, vomiting, rash, fever, somnolence, accidental injury, dizziness, diarrhea, abdominal pain, nausea, ataxia, tremor, astheria, bronchis, fit usyndrome, and diplopia, in 339 patients age 2 to 16 years, 42% of patients to LAMICTAL and Association of patients on placebo discontinued due to adverse experiences. The most commonly reported adverse experiences that led to discontinuation were ash for patients treated with placebo. Approximately very the 1,081 pediatric patients who received LAMICTAL as adjunctive therapy in premarketing clinical trials discontinued treatment because of an adverse experience. The adverse events most commonly associated with discontinuation were rash (4.4%), reaction approximatel of 1.7% and ataxia (6.6%).

11.5% of the 1,081 pediatric patients who received LAMICTAL as adjunctive therapy in premarketing clinical trials discontinued reatment because of an adverse experience. The adverse events most commonly associated with discontinuation were rash (4.4%), reaction aggravated (1.7%), and ataxia (0.6%), reaction aggravated (1.7%), and ataxia (0.6%).

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adverse expenence for which the reports on LAMICTAL were greater than 10% more requent in hemales furn males (without a corresponding difference between females and males in the rates of discontinuation of LAMICTAL for individual adverse experiences.

Incidence in a Controlled Monotherapy Trial in Adults With Partial Seizures: Listed below are treatment-emergent signs and symptoms that occurred in at least 5% of patients with epilepsy treated with monotherapy with LAMICTAL. In a double-blind trial following discontinuation of either concomitant carbamazepine or phenyloin not seen at an equivalent frequency in the control group. 43 patients received monotherapy with LAMICTAL up to 500 mg/day. 47 eceived low-dose VPA monotherapy at 1,000 mg/day. Patients in these studies were converted to LAMICTAL or VPA monotherapy from adjunctive therapy with CBZ or PHT. Patients may have reported multiple adverse experiences during the study; thus, patients may be included in more than one category. Treatment-Emergent Adverse Event Incidence in Adults With Partial Seizures in a Controlled Monotherapy Trial (Events in at least 5% of patients treated with LAMICTAL and numerically more frequent than in the valproate group are listed by body system with the incidence for LAMICTAL followed by valproate). Body as a whole. Pain (5,0), infection (52,2) chest pain (52,1) Elegistrive Vorniting (9,0), dyspepsia (7,2), aussea (7,2); Metabolic and nutritional: Weight decrease (5,2); Nervous: Coordination abnormality (7,0), dizaness (7,0), anxiety (5,0), insomnia (5,2); Respiratory: Rhinitis (7,2); Urogenia (female patients only): Dysmenorrhae (5,0). Adverse events that occurred with a frequency of less than 5% and greater than 2% of patients receiving LAMICTAL and numerically more frequent than placebo were: Body as a Whole: Asthenia, fever. Digestive: Anorexia, dry mouth, rectal hemornhage, epolic ulacer. Metabolic and Alpurtitional: Peripheral edema. Nervous System: Annesia, ataxia, depression, hypesthesia, libido increase, decreased ref

e (2,1), visual abnormality (2,0); **Urogenita**l: Urinary tract infection (male and female patients) (3,0), penis disorder (2,0).

Bipolar Disorder:
During the monotherapy phase of the double-blind, placebo-controlled trials of 18 months' duration, 13% of 227 patients who received LAMICTAL (100 to 400 mg/day), 16% of 190 patients who received placebo, and 23% of 166 patients who received discontinued therapy because of an adverse experience. The adverse events which most commonly led to discontinuation of the LAMICTAL were rash (3%) and mania/hypomania/mixed mood adverse events (2%). Approximately 16% of 2,401 patients who received LAMICTAL (50 to 500 mg/day) for Bipolar Disorder in premarketing trials discontinued therapy because of an adverse experience. The adverse events (2%). Approximately 16% of 2,401 patients who received LAMICTAL (50 to 500 mg/day) for Bipolar Disorder in premarketing trials discontinued therapy because of an adverse experience, most commonly led us to rash (5%) and maniaryhypomania/mixed mood adverse events (2%). Approximately 16% of 2,401 patients who received LAMICTAL (100 to 400 mg/day), following the discontinuation of other psychotropic drugs, in 2 double-blind, placebo-controlled trials of 18 months' duration and were numerically more frequent than in the placebo group. LAMICTAL was administered as monotherapy to 227 patients; 190 patients received placebo. Patients in these studies were converted to LAMICTAL (100 to 400 mg/day) or placebo monotherapy from add-on therapy with other psychotropic medications. Patients may have reported multiple adverse experiences during the study; thus, patients may be included in more than one category. Treatment—Emergent Adverse Event Incidence in 2 Placebo-Controlled Trials in Adults With Bipolar I Disorder (Events in at least 5% of patients treated with LAMICTAL monotherapy and numerically more frequent than in the placebo group are listed by body system with the incidence for LAMICTAL followed by placebo.) General: Back pain (8,6); fatigue (

Lawrite That in these trials (when patients may trave obert receiving Outcomman in Systoniupic microactions) compared to the monotherapy phase were headche (25%), nash (11%), dizziness (10%), diarrhea (8%), dream abnormality (6%), and pruntus (6%). Other events that occurred with phase pain, accidental injury, darmhea, and dyspepsia. Adversee events that occurred with headcache, infection, influenze, pain, accidental injury, darmhea, and dyspepsia. Adversee events that occurred with sequency of less than 5% and greater than 1% of patients receiving LAMICTAL and numerically more frequent than placebo were: *General:* Fever, neck pain. *Cardiovascular:* Migraine. *Digestive:* Flatulence. *Metabolic and *Nutritional.* Weight jagin, edema. *Musculoskeltal:* Arthraligia, myalgia. *Nervous *System: *Annesia, depression, aglation, emotional lability, dyspraxia, abnormal thoughts, dream abnormality, thypoesthesia. *Respiratory: Sinusitis. *Urogenital:* Urinary frequency. *Adverse Events Following Abrupt *Discordinaution:* In the 2 maintenance trials, there was no increase in the incidence, severity or type of adverse events in Bipolar Disorder patients after abruptly terminating LAMICTAL therapy. In clinical trials in patients with Bipolar Disorder, 2 patients experienced seizures shortly after abrupt withdrawal of LAMICTAL. However, there were confluential factors that may have contributed to the occurrence of seizures in these bipolar patients (see DOSAGE. AND ADMINISTRATION) section of full prescribing information.

Mania/Hypomania/Mixed Episodes: During the double-blind, placebo-controlled clinical trials in Bipolar I Disorder in which patients were converted to LAMICTAL. monotherapy (100 to 400 mg/day) from other psychotropic medications and followed for durations up to 18 months, the rate of manic or hypomania or mixed mood episodes reported as adverse experiences was 5% for patients treated with LAMICTAL (16–180), in all bipolar controlled trials combined, adverse events of mania (including hypomania and mixed

The overall adverse event profile for LAMICTAL was similar between females and males, between elderly and nonelderly patients

The overall adverse event profile for LAMICTAL was similar between females and males, between elderly and nonelderly patients, and among racial groups.

Other Adverse Events Observed During All Claircal Trials For Pediatric and Adult Patients With Epilepsy or Bipolar Disorder and Other Mood Disorders: LAMICTAL has been administered to 6,694 individuals for whom complete adverse event data were captured during all clinical trials, only some of which were placebo controlled. All reported events are included except those already listed above, those too general to be informative, and those not reasonably associated with the use of the drug. Frequent events occurred in ≥1/100 patients; intrequent. Placing reaction, chilis, halitosis, and malaise. Pare: Abdomen enlarged, abscess, and suicided sucide attempt. Cardiovascular System: Infrequent: Flushing, hoft fashes, hypertension, patientions, postural properties, patients. Place and properties and patients and properties and patients. Place and properties and patients and properties and patients. Place and properties and patients and properties and patients. Place and properties and patients and patients. Place and properties and patients and properties and patients. Place and properties and patients and patients. Place and properties and patients. Place and properties and patients and patients and patients. Place and properties and patients and patients and patients. Place and patients and patients and patients and patients and patients and patients. Place and patients and patients and patients and patients and patients and patients. Place and patients an

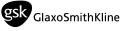
strabismus, taste loss, uveins, and visual netu celect. *uniquenua system. Imagene a lastic* and strabismus, taste loss, uveins, and visual netu celect. *uniquenua system. Imagene* Acute kidney failure, anorgasmia, breast abscess, breast neoplasm, creatinne increase, cystitis, dysuria, epididymitis, female lactation, kidney failure, kidney pain, nocturia, urinary retention, urinary urgency, and vaginal moniliasis.

Postmarketing and Other Experience: In addition to the adverse experiences reported during clinical testing of LAMICTAL, the following adverse experiences have been reported in patients receiving marketed LAMICTAL and from worldwide noncontrolled investigational use. These adverse experiences have not been listed above, and data are insufficient to support an estimate of their incidence or to establish causation. *Blood and Lymphatic: Agranulocytosis*, aplastic anemia, disseminated intravascular coagulation, hemolytic anemia, neutropenia, pancytopenia, red cell aplasia. *Gastrointestinal:* Esophagitis. *Hepatobiliary Tract and Pancreas:* Pancreatitis: *Immunologic:* Lupus-like reaction, vascullis. *Lower Respiratory:* Apnea. *Musculoskeletal:* Phabdomyolysis has been observed in patients experiencing hypersensitivity reactions. *Neurology:* Exacerbation of parkinsonian symptoms in patients with pre-existing Parkinsons's disease, its. *Non-site Specific:* Hypersensitivity reaction, multiorgan fallure, progressive immosuppression.

DRUG ABUSE AND DEPENDENCE: The abuse and dependence potential of LAMICTAL have not been evaluated in human studies.

OVERDOSAGE: Human Overdose Experience: Overdoses involving quantities up to 15 g have been reported for LAMICTAL, some of which have been fatal. Overdose has resulted in ataxia, nystagmus, increased seizures, decreased level of consciousness, coma, and intraventricular conduction delay.

Management of Overdose: There are no specific antidotes for LAMICTAL. Following a suspected overdose, hospitalization of the patient; is included to report in indirect thin



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—Heidi Splete