

INPATIENT PRACTICE

Tools Assess Patients' Potential for Violence

Violent acts by psychiatric inpatients are distressingly common. In one survey of 330 people working in the department of psychiatry at Odense (Denmark) University Hospital, 90% of physicians, nurses, and nursing aides reported having been subjected to violence at least once during their careers.

In addition, 17% of medical residents reported experiencing violence directed toward themselves during a year, and one-

third of the nurses and nursing aides said they had considered changing fields because they felt so threatened by the potential of being a victim of violence (Ugeskr. Laeger 1997;159:1768-73).

In response to this problem, several checklists and tools have been developed for assessing a patient's potential to be violent, for use in outpatient, inpatient, and hospital discharge situations.

Dr. John C. Kennedy, director of the University Institute for Psychiatry and Law at the University of Cincinnati, has reviewed three of these tools: the Bröset Violence Checklist, the Classification of Violence Risk (COVR), and the Historical Clinical Risk-20. After his review, Dr. Kennedy determined that the use of such instruments should be integrated into inpatient practice.

The Bröset Violence Checklist is the one of the most interesting instruments for inpatient practice. It is a simple test in which six behaviors or emotional states are assessed to predict the likelihood that an inpatient will become violent within the next 24 hours. It was developed by Phil Woods, Ph.D., of the college of nursing at the University of Saskatchewan, Saskatoon, and Roger Almvik, Ph.D., of St. Olav's University Hospital, Trondheim, Norway.

The checklist, developed with data from a large inpatient study, assesses whether confusion, irritability, boisterousness, verbal threats, physical threats, and attacking objects are present. If two or more factors are present, the patient is considered to be potentially violent. (More information is available at <http://home.no.net/bvc2>.)

In one Swiss study of 219 consecutive patients assessed upon admission to a unit and at various points afterward, the checklist was found to have a sensitivity of 64%, a specificity of 94%, and a positive predictive value of 11% (J. Psychiatr. Ment. Health Nurs. 2004;11:422-7). However, the researchers noted that those values could be underestimates, because many patients deemed to be at risk had intense interventions imposed because of their checklist results.

The COVR is an actuarial tool designed to assess whether a psychiatric patient is a risk at discharge; it takes about 10 minutes of chart review and 10 minutes of patient interview to complete. The Historical Clinical Risk-20, the most complex instrument, is designed for use in many different settings.

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DR. KENNEDY

assessment tools are available. What made you focus on those three?

Dr. Kennedy: I wanted to give an example of a well-respected instrument for a variety of circumstances. None of the three really fully overlap. They target slightly different populations. The HCR-20 is a longer-term instrument that requires much more data gathering. You could use it in an acute civil hospital, but the data that you need for it might not be readily available, so it might not be as practical. It is better suited for a long-term civil or a forensic hospital.

The COVR is more nicely applied to acute civil hospital settings. And the Bröset targets violence while in the hospital.

CPN: Do you know how often hospitals use these types of tools now?

Dr. Kennedy: It has been my experience in speaking with clinicians that they are rarely used, actually, despite their having been available for awhile. I think that forensic and state hospitals are probably more ahead of the curve than [are] acute civil hospitals, in part because their patients stay longer, and they have more access to data. And the issue of dangerousness to others is a common issue for their patients, particularly in regard to releasing them to the community.

CPN: You have said that the use of these tools should become more common. What exactly is their advantage over clinical experience?

Dr. Kennedy: I think when researchers have, in a variety of experiments, compared

man to machine, so to speak, the predictive accuracy of the tools has always come out on top. So, it is very hard in the face of the data to argue that we should continue to use unstructured clinical judgment. And, I think the thought leaders in the field are in virtually unanimous agreement.

CPN: Are there other instruments that might rival the Bröset?

Dr. Kennedy: Yes; there are a couple of competing models. One is the Dynamic Appraisal of Situational Aggression (DASA). It is very close to the Bröset. It has seven items, and you score each. Many of the items are identical to those on the Bröset. Another is called the Short-Term Assessment of Risk and Treatability (START), which is similar to the other two.

CPN: Are there any specific directions for what staff should do if a test predicts violence potential?

Dr. Kennedy: Interestingly, part of the value of these instruments is in formally requiring that the assessments be done. Doing them is half the battle. I think that the level of attention they require makes the clinicians focus on issues of violence. Much of why we have violence on inpatient units is because attention is not paid, and situations get out of hand. The theory is that use of these tools will lead to early, and earlier, interventions.

CPN: What about the false positives? Does this mean that in the end, assessment still comes down to clinical judgement?

Dr. Kennedy: The issue of false positives becomes important when something bad might happen to an individual because they are identified as positive.

If they are going to get sent to jail because of their score, then we want to be really sure we don't have any false positives. But if the response to a positive score is for a staff member to sit down and talk with a patient, a false positive is not a bad thing, the way it might be for something like a false positive on an HIV test. That would cause all kinds of undue emotional toll—to think you have HIV when you really don't.

By Timothy F. Kirn, Sacramento Bureau.
Share your thoughts and suggestions at cpnews@elsevier.com.

LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION

(3% and <1%); Anorgasmia (2% and <1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo \geq Lexapro: headache, upper respiratory tract infection, back pain, pharyngitis, inflicted injury, anxiety. †Primarily ejaculatory delay. ‡Denominator used was for males only (N=225 Lexapro; N=188 placebo). §Denominator 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* (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 (16% 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 1%). †General: Fatigue (8% and 2%); Influenza-like symptoms (6% 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 Disorder^{1,2} (14% and 2%); Anorgasmia³ (6% and <1%); Menstrual Disorder (2% and 1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo \geq Lexapro: inflicted injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. †Primarily ejaculatory delay. ‡Denominator used was for males only (N=182 Lexapro; N=195 placebo). §Denominator 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 $\geq 5\%$ 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 Events¹ 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%). †Adverse events with an incidence rate of at least 5% in either of 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: 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=137) and Placebo (N=636); Libido Decreased (3% and 1%); Anorgasmia (3% and <1%) There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Priapism 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 parameters 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=327) 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, shakiness, twitching, dysequilibrium, tics, 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, amnesia, 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, linitus, 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 experience and were not observed during the premarketing evaluation of escitalopram: abnormal gall, acute renal failure, aggression, akathisia, allergic reaction, anger, angioedema, atrial fibrillation, chorea, choreoathetosis, delirium, delusion, diplopia, dysarthria, dyskinesia, dystonia, ecchymosis, erythema multiforme, extrapyramidal disorders, fulminant hepatitis, hepatic failure, hypoesthesia, hypoglycemia, hypokalemia, INR increased, gastrointestinal hemorrhage, glaucoma, grand mal seizures (or convulsions), hemolytic anemia, hepatic necrosis, hepatitis, hypotension, leucopenia, myocardial infarction, myoclonus, neuroleptic malignant syndrome, nightmare, nystagmus, orthostatic hypotension, pancreatitis, paranoia, photosensitivity reaction, priapism, prolactinemia, prothrombin decreased, pulmonary embolism, QT prolongation, rhabdomyolysis, seizures, serotonin syndrome, SIADH, spontaneous abortion, Stevens-Johnson Syndrome, tardive dyskinesia, thrombocytopenia, thrombosis, torsade de pointes, toxic epidermal necrolysis, ventricular arrhythmia, ventricular tachycardia and visual hallucinations.

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Informed Consent Important With Lamotrigine

MIAMI BEACH — Inadequate informed consent places physicians prescribing lamotrigine at increased risk of malpractice liability, Dr. Neelam Varshney suggested.

Given that, it is important to inform patients about the risk of a rare but life-threatening rash that can develop with lamotrigine, Dr. Varshney said in a poster presented at the annual meeting of the American Academy of Psychiatry and the Law.

In an interview, Dr. Varshney pointed out that although such cases are rare, these rashes can progress to Stevens-Johnson syndrome or to toxic epidermal necrolysis.

Severe rashes can result in hospitalization, permanent disability, or even death. "That is why it is so important to give adequate informed consent," said Dr. Varshney, a resident in the department of psychiatry at Elmhurst (N.Y.) Hospital.

It is a good idea to have solid therapeutic rapport for explaining everything to the patient, including risks and benefits. Also, it is important to remind patients of the risk throughout treatment. "Informed consent is not just given on the first visit," she said.

Some physicians have suggested showing pictures of the rash to patients, but Dr. Varshney said she thinks doing this is unnecessary.

When prescribed as adjunctive therapy for epilepsy, the incidence of severe rash is about 0.8% among patients younger than 16 years and 0.3% among adults, according to a black box warning on the product's label. In clinical trials of adults with bipolar and other mood disorders, the rate of serious rash was 0.08% with monotherapy and 0.13% when used as adjunctive therapy.

—Damian McNamara