UCLA Semel Institute

UCLA study to characterize severe mood dysregulation

Over the past 15 years, children and adolescents with severe irritability and aggressive outbursts have received increased attention from medical professionals as more and more of these youths have been diagnosed with pediatric bipolar disorder. In some cases, the pediatric patients clearly meet current diagnostic criteria for bipolar disorder, but in others, the diagnosis is unclear. Without validated biomarkers to diagnose bipolar disorder, this rising trend — with some data suggesting it may have increased by as much as 400 percent from 1994 to 2003 — has become one of the greatest controversies in child and adolescent psychiatry.

A growing number of researchers, however, believe that many of these pediatric patients may have a different disorder, which they have termed Severe Mood Dysregulation (SMD). With SMD a youth will exhibit outbursts that go far beyond a typical temper tantrum and require clinical intervention, but they will not experience other symptoms such as the manic and prolonged euphoria that often presents with bipolar disorder.

SMD is not an official diagnosis, but new research is under way to determine whether it should be considered a psychiatric disorder, which could ultimately affect how children with chronic and severe irritability are diagnosed and subsequently treated. A new UCLA research study at the Semel Institute for Neuroscience and Human Behavior seeks to develop a better characterization of SMD. The UCLA study is one of the first to be conducted outside of the National Institute of Mental Health.

A new diagnosis could lead to better treatment

Physicians are concerned that a growing number of children and adolescents currently being diagnosed with bipolar disorder could receive more appropriate care if Severe Mood Dysregulation (SMD) were an officially recognized diagnosis. With a separate diagnosis in the Diagnostic and Statistical Manual of Mental Disorders, these young patient could be treated with different medications than those used for bipolar disorder, sparing them the risk of side effects from the powerful drugs used to treat that condition. In addition, an SMD diagnosis could carry less social stigma than a diagnosis of bipolar disorder.

"We don't really know the population yet," says James J. McGough, MD, professor of clinical psychiatry in the UCLA Semel Institute Division of Child & Adolescent Psychiatry and lead investigator of the study. "But proper care always begins with an accurate diagnosis. The better we understand the underlying condition, the more precise we can be in our diagnosis and the better treatment we can offer these patients to help improve their ability to function in family, social and school settings."

The study, which is seeking 300 participants, aims to expand the understanding of SMD through careful phenotyping, including behavioral, neurocognitive and brain imaging measures that can be compared and contrasted with large existing controls. This work would help inform future decisions on the proper classification of youths with severe impulsivity and affective instability. It would also provide pilot data that could lead to both definitive medical trials and assessment of psychosocial interventions. Additionally, researchers will be looking at EEG (electroencephalography) findings to uncover any potential distinct "biosignatures" for SMD that could lead to a more biologically informed approach to early identification, diagnosis and personalized treatment.

Study components: a comprehensive assessment and medication trial

All patients are given a comprehensive evaluation by nationally recognized experts in the UCLA Division of Child and Adolescent Psychiatry. Assessments include extensive interviews, neuropsychological testing and brain testing with EEG. The study is closely affiliated with other programs in the division on attention deficit hyperactivity disorder (ADHD), depression and childhood bipolar disorder.

If a participant is found eligible, he or she will be asked to continue in the second phase of the study, which includes medical treatment. All eligible participants are treated for 12 weeks with lisdexamfetamine (Vyvanse), an approved medication for ADHD that also appears to be useful in controlling irritability, aggression and temper outbursts. Once an optimal dose of lisdexamfetamine is reached, participants are randomized to additional treatment with the antidepressant/anti-anxiety medication fluoxetine or a sugar pill placebo. The study is conducted as a double-blind to guard against bias and placebo effects, therefore neither the participants nor the physicians will know who receives the medication and who receives the placebo. However, all participants are followed with weekly clinic visits and study physicians and staff are available 24 hours a day to help manage emergencies.

Eligibility for screening

To qualify, participants must be between 7 and 17 years old. They must have significant and frequent problems with irritability or moodiness, over-activity, temper outbursts and over-reactions to emotional circumstances. Symptoms should be severe and be the cause of difficulties in at least one setting, such as home, school or with peers. To be eligible, participants should not be diagnosed with autism or Asperger's disorder. The study will require 12 visits over a 14-week period. All costs for visits, including parking, medical tests and medications, are covered by the study.

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