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Deep Brain Stimulation

New Hope for Patients with
Obsessive-Compulsive Disorder

Insights

IN THIS ISSUE:

INNOVATION

- 2 Deep Brain Stimulation: Promising Therapy for Severe Obsessive-Compulsive Disorder

PATIENT CARE MODEL

- 4 Group Pharmacotherapy for Adults with ADHD

INTEGRATED RESOURCES

- 5 A Regional Approach to Behavioral Healthcare

BEST PRACTICE

- 6 Applying the Knowledge Program[®] to Improve Patient Care

DIAGNOSTICS

- 8 Preventing Misdiagnosis of Mood Disorders

SYMPTOMOLOGY

- 10 Psychiatric Issues in Parkinson's Disease Require Multidisciplinary Approach

COPING

- 12 Understanding the Spiritual Aspects of Cancer Patients' Experience

ALSO INSIDE

- 14 Publications
- 17 Presentations
- 19 Upcoming Symposia
- 19 Select Clinical Trials
- 20 Referrals
- 20 Services for Physicians and Patients

Dear Colleagues

Cleveland Clinic's Neurological Institute is a multidisciplinary institute that combines all physicians and other healthcare providers in neurology, neurosurgery, neuroradiology, the behavioral sciences and nursing who treat adult and pediatric patients with neurological disorders. This structure promotes a disease-specific, patient-focused approach to care. Our unique, fully integrated model is beneficial to our current standard of care, allows us to measure quality and outcomes on a continual basis, and enhances our ability to conduct clinical research.

I am pleased to present the 2009 issue of *Insights*, with a representative selection of clinical, research and organizational developments within Cleveland Clinic's Department of Psychiatry and Psychology.

Cleveland Clinic's Neurological Institute subsumes five departments (Psychiatry and Psychology, Neurology, Neurosurgery, Neuroradiology, and Physical Medicine and Rehabilitation) and a variety of centers. While the departments continue their tradition of professional training, academic advancement and governance, the centers embrace a patient-centric focus on optimal healthcare delivery.

In this issue, Dr. Donald Malone introduces us to the new Center for Behavioral Health, with the primary objective of convenient patient access to a regional network of high-quality mental health and chemical dependency services. Dr. Steven Krause and I introduce an intriguing institute-wide initiative, the Knowledge Program[®], designed to facilitate clinically relevant data collection that supports each center's primary mission; namely, the continual improvement of healthcare outcomes.

Dr. Malone also reports on results of the multicenter trial of deep brain stimulation for treatment-resistant obsessive-compulsive disorder. This groundbreaking work, performed by an international consortium that includes Cleveland Clinic, aims to improve the quality of life for an otherwise desperate group of patients. Dr. Karen Broer provides an update on our department's participation in a multicenter study of prayer in cancer patients; Dr. David Muzina enlightens the reader on misdiagnosis of mood disorders; Dr. Mayur Pandya highlights the importance of treating cognitive-behavioral impairments in patients with Parkinson's disease; and Clinical Nurse Specialist Stephanie Musto and I discuss an approach to pharmacologic management of adults with attention deficit hyperactivity disorder that is patterned after an innovative model of healthcare delivery, the Drop-In Group Medical Assessment (DIGMA).

We hope you find value in this information, and we welcome your comments.

Sincerely,



George E. Tesar, MD
Chairman, Department of Psychiatry and Psychology
Cleveland Clinic Neurological Institute

Deep Brain Stimulation: Promising Therapy for Severe Obsessive-Compulsive Disorder

By Donald A. Malone Jr., MD

For patients who fail to gain relief from severe and highly treatment-resistant obsessive-compulsive disorder (OCD), despite years of conventional therapies, innovative technological approaches such as deep brain stimulation (DBS) hold significant therapeutic promise.

Data from almost a decade of small-scale studies suggest that DBS, now an accepted alternative to ablative procedures for treatment of movement disorders, can be implemented safely and successfully for OCD by dedicated interdisciplinary teams.

A Multicenter Investigation

Relatively few institutions have the breadth or depth of requisite resources for this collaborative approach, which combines neurosurgeons, neurologists, psychiatrists, neuropsychologists and basic science researchers. Cleveland Clinic is among four centers where psychiatric neurosurgery teams have worked together for more than eight years, investigating the safety and efficacy of DBS of the ventral portion of the anterior limb of the internal capsule and adjacent ventral striatum for refractory and disabling OCD. Others in the collaborative group are the Catholic University of Leuven (Belgium), where B. Nuttin and colleagues originated stimulation at this target for OCD; Butler Hospital/Brown University; and the University of Florida, Gainesville.

Twenty-six patients with disease duration of at least five years participated in these studies, results of which have been published.^{1,2} All patients were treatment refractory, with a Yale-Brown Obsessive Compulsive Scale (YBOCS) score ≥ 28 . OCD was judged to cause marked functional impairment in all participants. In no case had sustained efforts at exposure response prevention therapy plus pharmacotherapy reduced symptoms to a tolerable level on a long-term basis.

Patients underwent implantation of bilateral DBS leads that allowed stimulation along the dorsal-ventral extent of the anterior capsule, extending into the ventral striatum. The stimulating leads had four cylindrical electrode contacts, which could be independently programmed. As DBS lead implantation continued

during the study, the implantation site was refined to become progressively more posterior, resulting in the current target just below the junction of the anterior capsule and anterior commissure.

The final stage of surgery was implantation of programmable implantable neurostimulators in the pectoral or abdominal region, usually on the same day as surgery.

Three to four weeks after surgery, psychiatrists programmed the DBS in the outpatient setting. Patients were monitored at least monthly. Seventeen of the 26 patients had at least 24 months of follow-up and 12 reached 36 months. The majority of patients continue in follow-up with active stimulation.

Encouraging Outcomes

During the follow-up period, approximately two-thirds of patients experienced clinically significant symptom reduction and functional improvement. DBS was well tolerated overall, and adverse effects were largely transient. Results generally improved in patients implanted later in the study, when more posterior sites were investigated.

Mean YBOCS scores decreased after DBS, from average OCD severity at presurgical baseline of 34.0 ± 0.5 to 20.9 ± 2.4 at 36 months ($P = 0.002$). This degree of improvement was apparent by the third month of active stimulation. Categorically, the percentage of patients meeting the full response criterion (≥ 35 percent YBOCS decrease) increased from 28 percent at one month to 61 percent at last follow-up.

Global Assessment of Functioning scores improved significantly, from the presurgical baseline mean of 34.8 ± 1.1 to 59.0 ± 3.3 at last follow-up ($P = 0.006$).

Comorbid depressive symptoms also improved; improvement in affect and mood appeared to precede that in OCD itself. Similarly, improvement occurred in self-care;

Approximately two-thirds of patients experienced clinically significant symptom reduction and functional improvement. DBS was well tolerated overall, and adverse effects were overwhelmingly transient. Results generally improved in patients implanted later in the study, when more posterior sites were investigated.

ability to live independently; and work, school and social functioning.

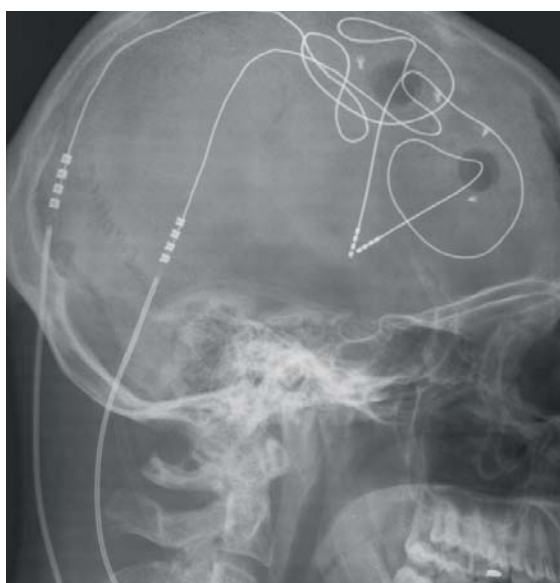
Based on the encouraging data from this long-term study, the U.S. Food and Drug Administration approved under a humanitarian exemption the first implantable device for DBS in OCD patients who have gained no benefit from intensive behavioral and drug therapies.

Reversible and adjustable, DBS appears to have a reasonable risk/benefit profile with long-term effectiveness in medically intractable OCD patients. Close collaboration of a multidisciplinary team of specialists is essential to a successful outcome.

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Postoperative X-ray shows placement of bilateral deep brain stimulation electrodes in the ventral capsule/ventral striatum of a patient with obsessive-compulsive disorder. Wires are tunneled under the skin and connect to batteries placed below the collarbone.

Group Pharmacotherapy for Adults with ADHD

By George E. Tesar, MD, and Stephanie Musto, CNS, CNP

Cleveland Clinic's Department of Psychiatry and Psychology is utilizing a group format to manage the pharmacologic treatment of adult patients with attention deficit hyperactivity disorder (ADHD).

The approach derives from Drop-In Group Medical Assessment (DIGMA), an innovative care model developed at Kaiser Permanente in California to improve access to general medical care. Since implementing it in 2006, we have found that this model works for many ADHD patients by creating efficiencies that enhance the therapeutic experience.

ADHD is a neuropsychiatric disorder associated with significant psychological, interpersonal and vocational disability and distress. Half of children diagnosed with ADHD will continue to have disabling symptoms and behaviors in adulthood. Common comorbidities, such as depressive, anxiety and substance use disorders, contribute to the pattern of disability.

Before joining the group, each patient undergoes a thorough psychiatric and medical (when indicated) evaluation. Some members have returned to individual treatment because one or more comorbid disorders have come to dominate the clinical picture. In our experience, sleep apnea, especially in males, has been more frequent than expected.

Pharmacologic intervention yields significant rewards for patients with ADHD. Conventional medications include amphetamine and methylphenidate compounds such as Adderall XR[®], Vyvanse[™], Ritalin LA[®] and Concerta[®]. Finding the optimal dose of the correct compound in any one patient — particularly in those with medical and/or psychiatric comorbidities — can be tricky, and much group time is devoted to this process. Patients value hearing about the treatment experiences of others and the many different types of treatment. An unexpected finding is that a core group of patients has returned regularly to the monthly group meeting for more than just medication monitoring. They seem to value the supportive aspect of being in a therapeutic group.

The DIGMA format permits us to see more patients per unit of time, and allows each patient more therapeutic exposure than received in a standard, 20-minute

individual visit. Monthly sessions are designed to accommodate eight to 12 patients; generally, eight to 10 show up. Vital signs as well as patient-rated depression and anxiety scales are obtained before each 90-minute session, which is led by the psychiatrist and psychiatric nurse practitioner. While the focus is on medication management, other common themes include time management, appropriate interaction with work personnel and self-esteem.

DIGMA represents an opportunity to provide care more efficiently and cost-effectively. Although our data collection is not yet adequate to verify the benefits of group therapy for adult ADHD patients, anecdotal evidence indicates high patient satisfaction. These individuals tend to judge themselves harshly, and may be disheartened that they have not achieved what they hoped for or expected. In group, they find that they are not alone, and that difficulties reaching their goals can be overcome with effective treatment. To a great extent, our impressions reflect patient experience in a similar DIGMA group for pharmacologic management of depression.¹

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Stephanie Musto is a Clinical Nurse Specialist in adult psychiatric nursing and a Family Nurse Practitioner in the Department of Psychiatry and Psychology. She can be contacted at 216.444.0102 or mustos@ccf.org.

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A Regional Approach to Behavioral Healthcare

By Donald A. Malone Jr., MD

Cleveland Clinic has an abundance of high-quality behavioral health resources widely dispersed across the health system. Under the direction of our Neurological Institute, leaders throughout the system have collaborated on a plan to better integrate these multiple components, basing key services at designated regional locations best equipped to serve patients' needs.

This restructuring under a new Center for Behavioral Health will facilitate more effective patient management, ensure quality of care and drive operational improvements. In addition, we anticipate ongoing refinement of existing programs and development of innovative new behavioral healthcare models.

Improving Patient Outcomes

Consolidation presents a unique opportunity to leverage the strengths of the numerous behavioral health programs distributed among Cleveland Clinic's main campus, 10 community hospitals and 17 family health centers throughout northeast Ohio.

The pattern for this reorganization is Cleveland Clinic's institute model, a disease-specific, patient-focused, center-based approach that has encouraged collaboration among physicians and leaders systemwide. Applying this model to behavioral health, we expect to enhance our competitiveness and, most importantly, to reinforce our team's ability to deliver comprehensive therapeutic services that return patients to full functionality.

The Center for Behavioral Health will better position us to tailor treatment to individual patients, with more effective triage to the particular site where an appropriate concentration of skills and services can best meet their needs. This centralization of knowledge and expertise aims to produce better clinical outcomes and more enlightened research.

Moreover, outcomes data based on a broad regional population will be more relevant to referring physicians considering where to send their patients for specialized care. The collection of a large volume of information in the patient's electronic medical record aligns with the goals of the Neurological Institute's Knowledge Program[®], which is designed to facilitate systematic analysis of care and improve outcomes.

A Unified Network

Currently, our facilities are home to six separate inpatient adult psychiatric units, five geriatric psychiatric units, one child psychiatric unit, two chemical dependency detoxification units and myriad outpatient treatment programs.

While our multidisciplinary staff provides excellent care, a unified network will better serve patients and their physicians. We took a first step in this direction in 2005, when we relocated main campus adult psychiatric inpatient services to Lutheran Hospital, five miles to our west. Building on the success of that endeavor, we will further integrate related behavioral health resources by the end of 2009.

In addition to further consolidating adult psychiatric resources at Lutheran, we have designated other geographically dispersed community hospitals where we will combine child and adolescent and chemical dependency services.

The Center for Behavioral Health will encompass services at Cleveland Clinic's main campus as well. Clinical and administrative leadership will direct the center, bringing the regional vision that underpins this new healthcare model.

We expect the Center for Behavioral Health to offer maximum convenience to patients and their physicians, who will have one phone number to call for help around the clock. No matter where that call comes from or who makes it, streamlining the referral process is a critical first step toward restoring the patient to a productive, fulfilling life.

Donald A. Malone Jr., MD, is a Psychiatrist and Director of the Center for Behavioral Health at Cleveland Clinic. His specialty interests include psychopharmacology, mood disorders, anxiety disorders and neuromodulation. He can be contacted at 216.444.5817 or maloned@ccf.org.

Applying the Knowledge Program[®] to Improve Patient Care

By George E. Tesar, MD, and Steven Krause, PhD

In Cleveland Clinic's Department of Psychiatry and Psychology, we are accelerating our collection of electronic data through the Neurological Institute's Knowledge Program[®]. This initiative allows us to consistently measure each patient's illness severity over time and assess the efficacy of our treatment protocols. In the future, the project will greatly facilitate the conduct of clinical research.

Electronic Assessment

In the Department of Psychiatry and Psychology, an array of assessment tools helps quantify significant medical and psychological characteristics, including suicide risk, depression, anxiety, pain, alcohol and substance abuse risk, and overall functional ability. At the beginning of each clinical session, patients spend five to 10 minutes entering self-assessment data directly into their electronic medical record (EMR) — a novel approach that involves them more deeply in their care while saving clinicians' time. With this data, a care provider can identify an individual's risk for depression or substance abuse, for example. The clinician can then raise relevant concerns with the patient in the most appropriate and professional manner.

The electronic assessments that patients complete include:

- European Quality of Life Questionnaire
- Patient Health Questionnaire (PHQ-9)
- CAGE alcohol use questionnaire
- Mood Disorder Questionnaire
- Columbia Suicide Screen

Clinicians complete the Global Assessment of Functioning scale and Clinical Global Impression following each patient encounter. Departmental staff is being trained in the use of these tools to increase inter-rater reliability.

Patient-entered data are automatically stored in the Knowledge Program database and transferred into the EMR. The data can be reviewed immediately by those with access rights, providing updates on patient status and insight into clinically relevant issues that might

otherwise be overlooked. Flow sheets and graphs within the program allow physicians to track changes in response to treatment and to compare patients' progress with expected outcomes. This ongoing measurement of patient status reduces the risks of bias inherent in retrospective evaluation of patient progress.

Accessible Data

Before initiation of the Knowledge Program, those wishing to conduct research on Neurological Institute patients were required to code clinical data on paper and submit the evaluations to a staffer who would key in the data — or the originators keyed it in themselves. Later, they needed to submit paper requests for information to a programming team. The programmers would then write information extractor software to search the medical record database, with results returned to the clinicians for analysis. This process could take weeks.

Now, with the development of a desktop query tool, clinicians will have direct access to the Knowledge Program database to retrieve aggregate data for a particular patient population or a specific disease state.

Once the Knowledge Program contains enough data points, it will become much easier to analyze information on individual patients and treatment protocols, and to conduct trials. Retrospective analyses will be significantly easier and less expensive to perform. The data from ongoing relationships between physicians and patients will be readily available for inclusion in large trials.

These data will also be useful to demonstrate the efficacy of treatments to payors, government agencies and the public. This application is expected to become increasingly important as government programs and private insurers move toward value-based reimbursement.

Patient-entered data are automatically stored in the Knowledge Program® database and transferred into the electronic medical record. The data can be reviewed immediately by those with access rights, providing updates on patient status and insight into clinically relevant issues that might otherwise be overlooked.

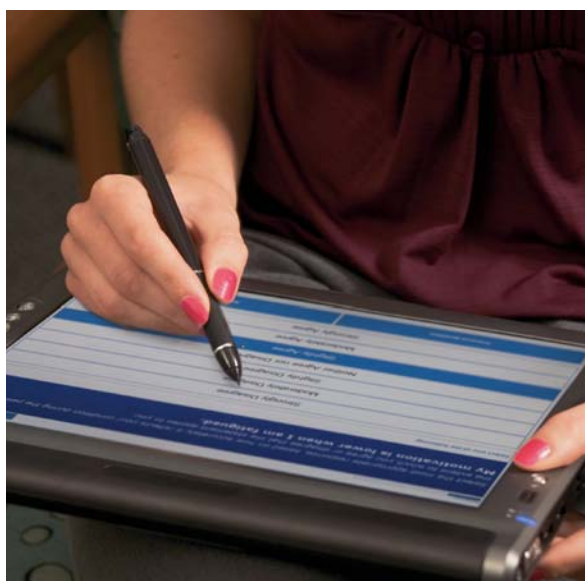
A Work in Progress

Following completion of the query tool for clinical data retrieval, the next phase in development of the Knowledge Program will be standardization of clinical record templates, allowing systematic searches not only of assessment data, but of individual clinical histories as well.

The Knowledge Program represents an institute-wide effort to change the method of data collection so that information can be harvested at the point of care and used to facilitate clinical decision-making, demonstrate the efficacy of clinical treatment approaches and conduct research. By facilitating immediate examination of data at both the individual and aggregate levels, we can evaluate clinical treatment over time and systematically improve the quality of patient care.

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A patient enters self-assessment data directly into her electronic medical record before meeting with her clinician. The process saves time and engages patients in their care.

Preventing Misdiagnosis of Mood Disorders

By David J. Muzina, MD

Increasing emphasis is appropriately being placed on the importance of evidence-based medicine in psychiatric practice. The majority of this emphasis has been placed on treatment interventions for specific diagnoses; however, evidence-based treatment first must be informed by accurate diagnosis.

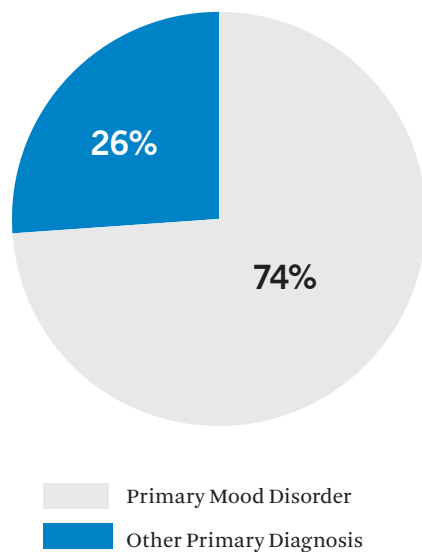
Little is known about the prevalence and characteristics of misdiagnosis among psychiatric patients. The bulk of the available literature on this topic addresses misdiagnosis of bipolar disorder and relies on retrospective chart reviews or subjective patient reporting.

Misdiagnosis of mood disorders has been linked to higher rates of psychiatric hospitalization and medical utilization as well as greater costs. Methodical investigation of misdiagnosis is warranted as a first step in the process of evidence-based psychiatric practice.

In January 2008, Cleveland Clinic's Center for Mood Disorders Treatment and Research opened a 10-bed adult inpatient unit at Lutheran Hospital, a Cleveland Clinic hospital, devoted to the diagnosis and treatment of major mood disorders. The first 100 adults admitted to the

| Changes in Admission Diagnosis Based on MINI-Plus and Clinician Interview | | | |
|---|------------------|---------------------|------------|
| Primary Diagnosis | On Admission (N) | Final Diagnosis (N) | Change (%) |
| Unipolar Major Depression | 70 | 56 | -20% |
| Bipolar Disorder | 30 | 18 | -40% |
| Anxiety Disorder | -- | 10 | +10% |
| Thought Disorder | -- | 5 | +5% |
| Other | -- | 11 | +11% |

Preadmission Misdiagnosis of Mood Disorder



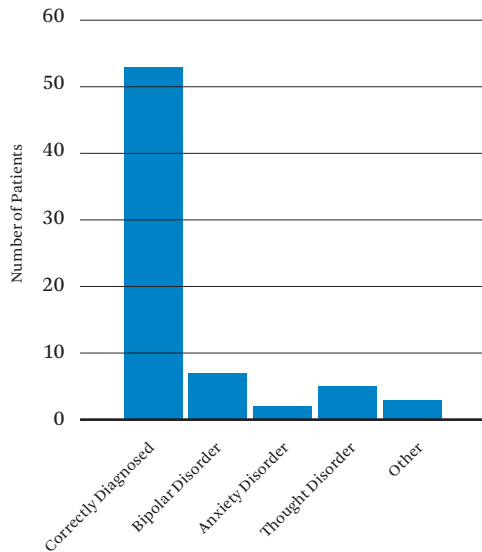
Cleveland Clinic Mood Disorders Unit (MDU) underwent structured research diagnostics with the Mini-International Neuropsychiatric Interview (MINI-Plus) after a research assistant obtained consent. Results of the MINI-Plus were then compared with the clinical diagnosis on admission to the MDU.

Among these patients admitted to the MDU, 26 percent carried a primary psychiatric diagnosis that was inconsistent with the diagnostic results obtained from the MINI-Plus interview as conducted by a blinded research assistant and verified by a clinician. A primary anxiety disorder was missed in 10 percent of admitted patients previously thought to have a primary mood disorder. Sixteen percent of admitted patients subsequently received other primary diagnoses (schizoaffective disorder, personality disorder).

In this initial small sample of 100 patients, about one in four had been incorrectly diagnosed prior to entering the MDU. Misdiagnosis is unfortunately common among adult patients admitted to the hospital with a suspected primary mood disorder. Anxiety disorders, thought

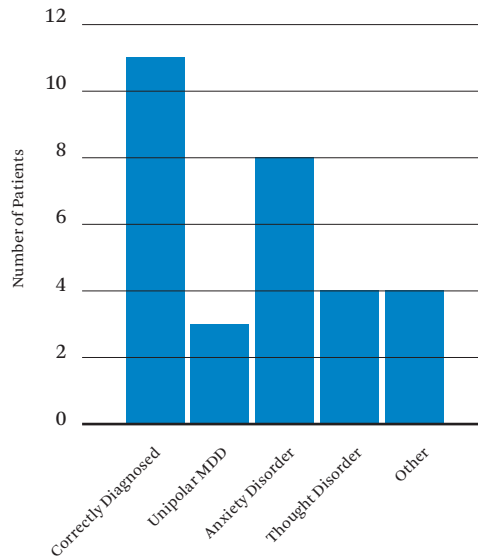
Final Diagnosis for Patients Admitted with Unipolar Major Depression

(N = 70)



Final Diagnosis for Patients Admitted with Bipolar Disorder

(N = 30)



disorders and other mental health problems are commonly misdiagnosed as mood disorders. In addition, correct classification of type of mood disorder — major depression vs. bipolar disorder — is often an immense challenge. Safe and effective treatment to full functional recovery relies first on establishing the correct diagnosis.

Further study is necessary to better understand the factors that place patients at risk for misdiagnosis and the associated potential negative treatment implications. Cleveland Clinic Center for Mood Disorders Treatment and Research, in partnership with the Mood Disorders Psychopharmacology Unit at the University of Toronto, is actively committed to this important work. Between these two academic sites, data from more than 800 patients have been collected in this internationally based collaborative research.

David J. Muzina, MD, is Director of Cleveland Clinic's Center for Mood Disorders Treatment and Research at Lutheran Hospital. His specialty interests include neuropsychiatric illness, depression, bipolar disorder, neuroimaging and behavioral health, and clinical research. The Center for Mood Disorders Treatment and Research can be contacted at 216.363.2122.

SUGGESTED READING

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Psychiatric Issues in Parkinson's Disease Require Multidisciplinary Approach

By Mayur Pandya, DO

Nonmotor symptoms are common in Parkinson's disease and may significantly impair both the health and quality of life of patients and their families. With up to 60 percent of patients suffering from more than one such indicator, identification and proper management are essential.

Cognitive-behavioral impairments occur to some degree in almost every patient with Parkinson's disease, and can distress patients more than the classic motor symptoms. In fact, depression or anxiety may foreshadow the onset of motor symptoms. Other cognitive-behavioral symptoms, including psychosis, confusion and impulsiveness, are often triggered by medications used to treat Parkinson's disease.

Although nonmotor symptoms are more widely recognized today than a decade ago, they are often overlooked and underdiagnosed. Correcting this problem demands a multidisciplinary team approach.

Depression: Difficult to Diagnose

Depression is among the most prevalent neuropsychiatric symptoms of Parkinson's disease; 50 to 70 percent of patients develop depression independent of their level of physical function. Depression may be difficult to recognize because many of its physical manifestations — fatigue, psychomotor slowing, constricted affect, sleep difficulties — mimic physical features of Parkinson's disease. The Beck Depression Inventory is sensitive for depression in patients with Parkinson's disease and, thus, may be a reasonable screening tool.

For patients who cannot tolerate antidepressant drugs, psychotherapy may be a first-line treatment. Relaxation techniques, a sleep hygiene regimen, engagement in meaningful activities and caregiver education facilitate functional improvement.

Medication Management Is Critical

Anxiety disorders often accompany depression in Parkinson's disease, though they can occur independently. Anxiety disorders in these patients often have atypical presentations and occur in the setting of medication-associated wearing-off or on-off fluctuations. Generalized anxiety and social phobias are common as well. Patients appear to respond as well as non-Parkinson's patients to selective serotonin reuptake inhibitors and benzodiazepines.

Impulse control difficulties, frequently manifested as unrestrained gambling, hypersexuality and food cravings, presumably reflect dopamine dysregulation caused by the dopamine agonists used for Parkinson's disease. Young males in particular are at risk for developing impulse control problems, although all ages and both genders are at risk. Overzealous medication usage by younger patients, whose goals are to maintain optimal marital, parental, social and/or occupational functioning, may contribute. Patient education and family therapy are critical, as is appropriate adjustment of dopaminergic agents.

Other Cognitive and Perceptual Side Effects

Visual hallucinations are another common adverse effect of dopaminergic drugs. Patients typically retain awareness that they are hallucinating but, as the disease progresses, they may lose insight. Embarrassment may prevent patients from disclosing this and other behavioral disturbances. Other potential causes of hallucination that the clinician should consider are systemic illness and dementia.

| Cognitive-Behavioral Symptoms in Parkinson's Disease: Management Strategies | |
|---|---|
| Symptom | Management |
| Depression | Supportive psychotherapy, selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), mirtazapine (Remeron®), electroconvulsive therapy |
| Apathy | Methylphenidate (Ritalin®), bupropion (Wellbutrin®) |
| Anxiety | SSRIs, SNRIs, benzodiazepines |
| Impulsive Behavior | Assess contribution of dopaminergic agents |
| Psychosis | Search for systemic illness, reduce medications active in the central nervous system (CNS), assess contribution of antiparkinsonian or other CNS-active medications, give quetiapine (Seroquel®) or clozapine (Clozaril®) |
| Dementia | Cholinesterase inhibitors |

Dementia in Parkinson's disease occurs in 20 to 30 percent of patients. Parkinson's dementia is a subcortical dementia characterized by slow thinking, impaired working memory and executive dysfunction due to disruption of frontal-subcortical circuits. Anti-Parkinson's drugs, especially anticholinergics, can exacerbate cognitive impairment in these patients. Anticholinesterase inhibitors such as rivastigmine (Exelon®) are indicated in patients with Parkinson's dementia, but typically provide only modest benefit.

Patients with Parkinson's disease face multiple physical and psychological challenges. At Cleveland Clinic, a multidisciplinary collaboration among neurology, psychiatry and neuropsychology has been effective in comprehensively addressing patient needs.

Mayur Pandya, DO, is a Staff Psychiatrist in the Center for Neurological Restoration at Cleveland Clinic. His specialty interests include neurobehavioral disorders in Parkinson's disease and other movement disorders. He can be contacted at 216.445.5585.

Understanding the Spiritual Aspects of Cancer Patients' Experience

By Karen Broer, PhD

Spiritual well-being often emerges as a critical quality-of-life variable for patients facing severe illness, signifying a need for more systematic investigation of religious variables and spiritually focused interventions for this population.

Though an increasingly comprehensive body of literature supports the efficacy of holistic approaches to cancer treatment, there is scant research designed to gather meaningful empirical data regarding patient experience of severe illness in relation to spiritual well-being. Such concerns as the role of spiritually oriented coping during post-diagnostic psychological adjustment and relationships between the integration of spirituality and a range of health status outcomes have been only nominally investigated. In the interest of remedying this gap in the research literature, an ongoing study is successfully adapting findings regarding the potentially positive impact of regularly practiced forms of meditation to a spiritually focused protocol with newly diagnosed leukemia patients.

Cleveland Clinic is participating in the multisite study that originated at the Hillman Cancer Center of the University of Pittsburgh Medical Center (UPMC). An earlier edition of *Insights* provided an overview of the study,¹ designed to assess the comparative impact of two meditation protocols — spiritually focused (SpM) and secularly focused (SM) — and a usual care/control condition (UCC) on treatment experience and long-term health outcomes for newly diagnosed acute leukemia patients. Data gathering occurs pre-intervention, post-intervention and at subsequent intervals of two, four and six months. Since its inception at UPMC in 2006, the

study has been funded by the Metanexus Institute on Religion and Science, with support from the John Templeton Foundation.

Broadly, the study is designed to enhance participant coping strategies and improve quality of life throughout both hospitalization and outpatient treatment. Participants in the SpM and SM conditions take part in five manualized therapy sessions utilizing a psycho-educational format. These sessions address emotional aspects of receiving the cancer diagnosis, emphasizing emotional well-being and a meaningful life in the face of severe illness.

Administered on a one-to-one basis, each session includes therapeutic techniques of established efficacy for cancer patients,² followed by brief (15- to 20-minute) meditation or relaxation exercises. First and final sessions focus primarily on issues related to therapy initiation and termination, with sessions two through four covering themes highly relevant to coping with cancer: loss of control, management of treatment side effects, and separation from friends and family. The SpM meditation format integrates overt spiritual content, while the SM format includes meditations representative of standard relaxation protocols (referred to as “relaxation exercises” to avoid any prompting of spiritually oriented associations) with physiological focal points.

An ongoing study is successfully adapting findings regarding the potentially positive impact of regularly practiced forms of meditation to a spiritually focused protocol with newly diagnosed leukemia patients.

First and final sessions focus primarily on issues related to therapy initiation and termination, with sessions two through four covering themes highly relevant to coping with cancer: loss of control, management of treatment side effects, and separation from friends and family.

In light of the relative absence of successful empirical research in this area, the SpM intervention was developed carefully around the specific conceptualization of spirituality as one's experience of or relationship with the sacred (defined as the source of ultimate meaning in a person's life). This intervention can be individually tailored to incorporate language and imagery specific to each participant's unique conceptualization of the sacred. Meditations provide opportunities for patients to develop and practice an experience of connection with the sacred, deriving predicted benefits such as increased comfort, support, meaning, strength and relationship. Intervention components are consistent with practices reported in the research literature.^{3,4}

With more than 70 participants thus far, recruitment continues at UPMC and Cleveland Clinic through September 2009. Quantitative data analysis is preliminary, but investigators hypothesize that the SpM intervention will have a more positive influence on health status outcomes than the SM or UCC conditions. Daily meditation practice rates of the SpM and SM groups will be evaluated as predictors of physical, psychological and spiritual well-being. Qualitative data analysis of session recordings is also being conducted to identify thematic content derived from the experience of SpM participants.

It is the hope of investigators that this rigorous multi-method study will reveal findings of significant benefit to patients and families experiencing the difficult adjustment to the reality of a cancer diagnosis.

Investigators for this study are Karen Broer, PhD, and Mikkael Sekeres, MD, MS (Cleveland Clinic); Brenda Cole, PhD, and Michael Boyiadzis, MD, MHSc (University of Pittsburgh Cancer Institute); Clare Hopkins, PhD, RN (Carlow University); and John Tisak, PhD (Bowling Green State University).

Karen Broer, PhD, is a Psychologist at Cleveland Clinic. Her specialty interests include women's issues, stress management, life span development issues and spiritually based interventions. She can be contacted at 216.444.0480 or broerk@ccf.org.

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2008 – 2009

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2008 – 2009

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Psychiatry and Psychology

- Bea S. Resilience in the face of adversity. Presented at: National Alliance on Mental Illness and BRIDGES; May 21, 2009; Mentor, Ohio.
- Chapin JS. Cognition in older adults with epilepsy. Presented at: Cleveland Clinic Epilepsy Grand Rounds; August 1, 2008; Cleveland, Ohio.
- Chapin JS. Memory and epilepsy. Presented at: Cleveland Clinic “Clinical Neurophysiology with Focus in Epilepsy and EEG” course; August 29 and November 12, 2008; Cleveland, Ohio.
- Chapin JS. Introduction to neuropsychology. Presented at: Cleveland State University, “Introduction to Clinical Psychology”; November 2008; Cleveland, Ohio.
- Chapin JS. The role of ApoE4 in cognition in patients with medically intractable epilepsy. Presented at: Cleveland Clinic Epilepsy Grand Rounds; December 2008; Cleveland, Ohio.
- Chapin JS. Predicting risk of postoperative cognitive decline. Presented at: 18th International Cleveland Clinic Epilepsy Symposium; June 23, 2009; Cleveland, Ohio.
- Chapin JS. Using neuropsychiatric measures in counseling patients about postoperative memory outcome. Panelist at: 18th International Cleveland Clinic Epilepsy Symposium; June 23, 2009; Cleveland, Ohio.
- Falcone T. Schizophrenia and immunology. Presented at: Colombian Neuropsychiatric Meeting; February 2009; Bogotá, Colombia.
- Falcone T. Psychiatric comorbidities in children with epilepsy. Presented at: Colombian Neuropsychiatric Meeting; February 2009; Bogotá, Colombia.
- Falcone T, Janigro D, Franco K. Inflammation psychosis and the brain. What do we really know. Presented at: 14th Biennial Schizophrenia winter workshop; February 2008; Montreux, Switzerland.
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- Ferguson L, Scheman J. Patient Global Impression of Change scores within the context of a Chronic Pain Rehabilitation Program. Poster presented at: the 28th Annual Scientific Meeting of the American Pain Society; May 2009; San Diego, California.
- Franco K. What I've learned since leaving MCO – a tale of two schools. Presented at: University of Toledo (AOA Visiting Professor); February 19, 2008; Toledo, Ohio.
- Franco K. Delirium in cardiac patients: dimensions in cardiac care. Presented at: Cleveland Clinic Continuing Medical Education Program; March 10, 2008; Cleveland, Ohio.
- Franco K. Anxiety disorders in primary care. Presented at: Immunology and Schizophrenia Internal Medicine Grand Rounds Forum Health; March 13, 2008; Youngstown, Ohio.
- Franco K. Psychiatric disparities. Presented at: Cleveland Clinic Lerner College of Medicine; April 15, 2008; Cleveland, Ohio.
- Franco K. Immunology and schizophrenia. Presented at: American Psychiatric Association 2008; May 8, 2008; Washington, D.C.
- Franco K. Communication: understanding among different generations. Presented at: Cleveland Clinic Department of Psychiatry and Psychology Grand Rounds; February 5, 2009; Cleveland, Ohio.
- Franco K. Millennials: what they think and why. Presented at: Cleveland Clinic Department of Psychiatry and Psychology Grand Rounds; February 5, 2009; Cleveland, Ohio.
- Franco K. Teaching millennial students the Cleveland Clinic culture. Presented at: Cleveland Clinic Lerner College of Medicine Basic Science Education Committee; February 13, 2009; Cleveland, Ohio.
- Franco K. Suicide in professionals. Presented at: Cleveland Clinic Department of Psychiatry and Psychology Residency Training Program; February 18, 2009; Cleveland, Ohio.
- Franco K. Generations working together. Presented at: Case Western Reserve University; February 19, 2009; Cleveland, Ohio.
- Franco K. Exploring generational differences in the healthcare area. Presented at: Cleveland Clinic Academy; May 28, 2009; Cleveland, Ohio.
- Franco K, Haynes C, Lewis K, Olges J, Oriol N, Padrez R, Richards P. The millennial becomes a physician. Presented at: plenary session of the Association of American Medical Colleges; October 31, 2008; San Antonio, Texas.
- Haynes C, Franco K, Mellman L. Millennial students, medical education and mental health – an oxymoron? Presented at: the Annual Meeting of the Association of American Medical Colleges; November 6, 2008; San Antonio, Texas.
- Janesz JW. Substance-induced mood disorder or dual diagnosis? Presented at: Substance Use and Mood Disorders; March 11, 2009; Cleveland, Ohio.

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- Klaas P, Tuxhorn I. Timing is everything: the effects of age of onset and seizure duration on cognitive development in children with temporal lobe epilepsy. Presented at: International Neuropsychological Society; July 2009; Helsinki, Finland.
- Malone Jr D. DBS for psychiatric disorders: outcomes and quality of life. Presented at: Cleveland Clinic/U.S. Department of Health and Human Services conference; May 2008; Washington, D.C.
- Newey C, Khawam E, Coffman K. Two cases of serotonin syndrome with venlafaxine XR and calcineurin inhibitors. Presented at: the 31st Annual Meeting of the Cleveland Consultation Liaison Society; May 6, 2009; Cleveland, Ohio.
- Rothermundt M, Steiner J, Falcone T, Gonsalves C. The role of glia cells in psychiatric disorders. Presented at: Congress of the World Federation of Societies of Biological Psychiatry; June 2009; Paris, France.
- Scheman J. Outcome instruments: what to use and why? Presented at: Cleveland Clinic Spine Review Hands-On 2008; July 16, 2008; Cleveland, Ohio.
- Scheman J. The treatment of comorbid pain and addictive disorders. Presented at: Midwest Pain Society Meeting; September 2008; Chicago, Illinois.
- Scheman J. Ten years of Chronic Pain Rehabilitation Program outcome studies ... why bother? Presented at: Cleveland Clinic Department of Psychiatry and Psychology Grand Rounds; April, 16, 2009; Cleveland, Ohio.
- Schuermeier I. Living well with MDS. Presented at: the "Living with MDS" Conference of the Aplastic Anemia & MDS International Foundation; May 16, 2009; Cleveland, Ohio.
- Streem D. Chemical dependency. Presented at: Cleveland Clinic Lerner College of Medicine; June 13, 2008; Cleveland, Ohio.
- Streem D. Bipolar disorder. Presented at: Fairview Hospital Family Medicine Resident Lecture; August 6, 2008; Cleveland, Ohio.
- Streem D. Chemical dependency. Presented at: Cleveland Clinic Lerner College of Medicine; August 22, 2008; Cleveland, Ohio.
- Streem, D. Alternative medicine. Presented at: Cleveland Clinic Psychiatry Resident Didactic Series; September 10, 2008; Cleveland, Ohio.
- Streem D. Advanced ethics. Presented at: Cleveland Clinic Psychiatry Resident Didactic Series; September 17, 2008; Cleveland, Ohio.
- Streem D. Chemical dependency. Presented at: Cleveland Clinic Lerner College of Medicine; October 17, 2008; Cleveland, Ohio.
- Streem D. Neurophysiology of OCD. Presented at: Cleveland Clinic Lerner College of Medicine; November 3, 2008; Cleveland, Ohio.
- Streem D. Physicians and addiction. Presented at: Cleveland Clinic Lerner College of Medicine; November 4, 2008; Cleveland, Ohio.
- Streem D. Psychopharmacology of antipsychotics and lithium. Presented at: Cleveland Clinic Lerner College of Medicine; February 18, 2009; Cleveland, Ohio.
- Strober LB, Kalman CC, Chapin JS, Tesar G, Naugle R, Najm I, Busch R. Depression in epilepsy: seeing it through the eyes of the BDI-II. Presented at: the 62nd Annual Meeting of the American Epilepsy Society; December 5, 2008; Seattle, Washington.
- Tesar GE. The NI Knowledge Program[®], health status measures and development of inter-rater reliability. Presented at: Cleveland Clinic Department of Psychiatry and Psychology Grand Rounds; November 6, 2008; Cleveland, Ohio.
- Tesar GE. Don't let the blues ruin your holidays: focus on seasonal affective disorder. Presented at: Cleveland Clinic Wellness Grand Rounds; November 12, 2008; Cleveland, Ohio.
- Tesar GE. Clinical outcomes assessment: rationale and implementation. Presented at: Cleveland Clinic Department of Psychiatry and Psychology Grand Rounds; January 8, 2009; Cleveland, Ohio.
- Tesar GE. Communicating with the non-epileptic seizure patient. Presented at: Cleveland Clinic Epilepsy Grand Rounds; March 20, 2009; Cleveland, Ohio.
- Tesar GE, Franco E, Busch RM, Najm I. Recognition, characterization and treatment of depression in epilepsy surgery candidates. Presented at: the 55th Annual Meeting of the Academy of Psychosomatic Medicine; November 20, 2008; Miami, Florida.
- Tesar G, Glazer J, Falcone T, Hagen D, Humbel D, Kanner A, Koch-Stoeker S. Managing psychiatric issues following epilepsy surgery. Presented at: 18th International Cleveland Clinic Epilepsy Symposium; June 23, 2009; Cleveland, Ohio.

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Contact: Jenna Stump, CCRP, 216.444.2673, or
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Principal Investigator: Adele C. Viguera, MD, MPH
Contact: Judith Meinert, ACSW, LISW, CCRP, 216.445.7168

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Principal Investigator: David J. Muzina, MD
Contact: Judith Meinert, ACSW, LISW, CCRP, 216.445.7168

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