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Letter to the editor

Deep brain stimulation for psychiatric disorders

There is increasing interest in the use of deep brain stimulation (DBS) as a treatment for patients with psychiatric conditions. For example, the preliminary results from the first trials, reported by Nuttin et al [1], have shown that DBS may have beneficial effects in patients with severe obsessive-compulsive disorder (OCD) that is refractory to treatment. These preliminary results suggest that DBS may have a role in the treatment of patients with intractable OCD. Treatment of psychiatric patients with DBS remains investigational, however, and is not considered standard therapy.

Concern regarding the use of neurosurgery for the treatment of patients with psychiatric illnesses is attributable largely to the indiscriminate and widespread application of extensive, destructive procedures before the stereotactic era. The tragic example of frontal lobotomy, which was performed many times before adequate long-term safety data were available, remains an enduring caution.

Given this history, it is incumbent on the scientific community to respect the dignity of patients who may be included in studies by ensuring adequate protection while providing access to potential therapeutic innovations. We recommend that all investigators adhere to comprehensive standards that protect this potentially vulnerable population while they pursue valuable clinical research. Toward that end, we urge that investigators who are engaged in this research establish multidisciplinary, multicenter teams to systematically investigate DBS in OCD. On the basis of our experience, we recommend that studies aimed at investigating the use of DBS to treat patients with psychiatric illnesses meet the following minimum requirements.

1. An ethics committee (eg, the Institutional Review Board in the United States) that will

- have ongoing oversight of the project should approve the investigational protocol.
- 2. A patient assessment committee should evaluate each patient as a possible candidate for inclusion in the protocol. The role of this committee is to ensure that potential candidates meet certain medical and psychiatric criteria and are appropriate for inclusion in the study and to monitor the adequacy of the consent process. Patient assessment committees should be constituted broadly to achieve an ethically valid consensus, and they should have the opportunity to obtain independent capacity assessments when indicated.
- 3. Candidates for DBS surgery should meet defined criteria for severity, chronicity, disability, and treatment refractoriness.
- 4. The use of DBS should be limited solely to those patients with decision-making capacity who are able to provide their own informed consent. Patient consent should be maintained and monitored throughout the process, and patients should be free to halt their participation voluntarily.
- 5. Patient selection, surgical treatment, device programming, and comprehensive, regular psychiatric follow-up should be conducted at or supervised by a clinical research center.
- 6. The investigative team should include specialists from the following disciplines, and they should work in close collaboration:
 - a. A functional neurosurgical team with established experience in DBS.
 - b. A team of psychiatrists with extensive experience in the psychiatric condition under investigation.
 - c. Preferably, both of the preceding groups should have some experience in neurosurgical treatment for psychiatric disorders. If not, close consultation with experienced centers is indicated.

- Investigators must disclose potential conflicts
 of interest to regulatory bodies such as ethics
 committees or institutional review boards and
 to potential enrollees during the informed
 consent process.
- 8. The surgery should be performed only to restore normal function and relieve patients' distress and suffering.
- The procedure should be performed to improve patients' lives and never for political, law enforcement, or social purposes.

In our experience, embarking on this type of research requires a major commitment of time, energy, and resources across disciplines before and after device implantation. DBS has the potential to offer hope for severely ill patients, but investigations in this area should proceed cautiously to maintain the public trust necessary for scientific progress.

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