Title: Should Deep Brain Stimulation be Used in Psychiatry?

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Abstract: Deep brain stimulation (DBS) is an accepted neurosurgical intervention for movement disorders. More recently, DBS has been postulated for treating psychiatric conditions. This needs serious ethical consideration due to the extraordinary vulnerability of patients in psychiatry. This research demonstrates that modern science cannot justify the application of psychiatric DBS, the history of lobotomy is instructive to the use of DBS, and the mental health legislation does not reflect present knowledge of psychosurgery in this country. An additional examination reveals that introducing DBS to psychiatry contests its unique ethics, therapeutic alliance, and may expose patients to exploitation.
Introduction

DBS is an established treatment of last resort for neurological disorders such as Parkinson’s disease and essential tremor. Successes of DBS, recent insights of psychiatric disorder through computed imaging, and observations of psychological manifestations after the use of DBS, have motivated the idea to extend DBS to the field of psychiatry. Case reports have shown promising results of DBS for various psychiatric indications especially in obsessive-compulsive disorder (OCD) and treatment resistant depression.

In New Zealand (NZ), the Ministry of Health (MOH) funded up to six patients annually to receive DBS surgery for movement disorders (MD) in Australia from 1999. In 2008, Auckland District Health Board (ADHB) proposed a national DBS programme for MD at a lower cost while benefiting more patients. Since 2009, the procedure has been performed at Auckland City Hospital (ACH). (1, 2) In ADHB’s proposal, it was declared that there were no significant ethical, social, political or legal issues of DBS for MD. (1) After this business case was considered by the National Service & Technology Review Advisory Committee, approval was given by the MOH in the context that DBS may well have additional applications for treating psychiatric disorders. (1) This change of clinical setting from neurology to psychiatry provokes a question for ethical debate “Should DBS be used in psychiatry?” The writer is inclined to say no. This research illustrates the use of DBS can be challenging from medico-scientific, historical and legal perspectives, and DBS may also be a misfit in the contemporary ethics and values of psychiatry.

DBS in Modern Psychiatry

DBS is a stereotactic procedure involving the implantation of electrodes into the brain, which are then wired to a battery-powered pulse generator placed subcutaneously in the chest. Simply, DBS sends electrical impulses to a specific subcortical region such as the subthalamic nucleus, which disrupts neuronal circuitry that contributes to motor impairment. (1) It evolved from lesion therapies, such as thalamotomy and pallidotomy, which used surgical severance to achieve a similar interruption. The most infamous lesion therapy in the history of psychiatry is prefrontal lobotomy. (3) After decades of psychoactive pharmacotherapy, it has become clear that a proportion of patients are treatment refractory. Although indiscriminate use of lobotomy more than five decades ago has given psychosurgery a bad name, surgical procedures, such as cingulotomy and capsulotomy, are still cautiously performed for severe and refractory
psychiatric disorders under stringent protocols. (3, 4) DBS has also been investigated for the same purpose, and proven to be superior due to its less invasive nature. This has prompted excitement in psychiatry.

Many people hold a liberal view that medicine is ever evolving, and the current environment is conducive to safely investigate DBS for psychiatric disorders. For example, great precision in surgery can be achieved by modern stereotactic and computed imaging. Interference with erroneous neuronal circuitry in DBS is reversible. More importantly, people believe that ethics and research infrastructure of medicine today is infinitely improved from the days of lobotomy. (5) There is the Health and Disability Ethics Committees safeguarding patients’ rights, health and wellbeing. The Code of Ethics (6) forbids exploiting the patient in any manner. The patient’s informed consent is sought before undertaking any procedure or treatment. The writer agrees that science is advancing, and the growth of societal expectation has shaped more strictly regulated scopes of practice and required qualifications in medical professions.

However, the reality is far from ideal. Firstly, the writer wants to emphasize that despite sophisticated medical knowledge, complex techniques and advanced technology, complications and side-effects related to DBS remain unpredictable. One summary reported that the infection risk was 6.1%, lead migration or misplacement, and breakage happened in 5% of cases respectively, a death rate of 0.4%, and cognitive, behavioural, psychiatric and psychosocial disturbances reached 60%. (7) Curiously, ADHB’s proposal suggested less concerns. (1) While the target for stimulation is fundamental in DBS, there is no consensus of the DBS target in treating psychiatric illness. At least six hypothesized targets have been suggested for depression, and three for OCD. (7, 8) Secondly, DBS studies are vulnerable to selective-reporting. (9) Because there was no case registry for psychiatric DBS studies, several single-case studies were primarily published for attractive secondary findings, whereas the principle objectives had failed. Additionally, the mass media is over enthusiastic for positive results. (10) Misapprehension of excellent results could lead to unnecessary duplication of research efforts. Families and patients are at risk of receiving a distorted picture of the efficacy of DBS, and being given unjustified hopes. Therefore they remain naïve about risks associated with DBS, which compromises the validity of informed consent. Preventable damage might occur in patients through interventions that might not have been carried out if all data had been available. It is worth noting that when most lobotomies were performed in the isolation of private practices a registry
was never mandated. (3, 11) Thirdly, another potentially flawed area is post-approval surveillance. The British Medical Journal in 2010 exposed that adverse events, such as seizures and mortality, related to the vagus nerve stimulator device were not adequately investigated by the United States (US) Food and Drug Administration. The pharmaceutical company had control over the post-approval data. (12) Due to the invasive nature of device implantation, large trails are often impossible before product-approval. (12) The impracticality of conducting large scale clinical trials before approval for DBS devices will place the same burden on its post-approval surveillance.

Current knowledge of DBS is insufficient. Publications of DBS are biased. Setting up a DBS case registry is necessary. Pre-approval trials and post-approval surveillance are problematic for implantable devices. Medico-scientifically, DBS is invasive and potentially harmful, thus may not be suitable for clinical use in psychiatry, or suitable only under strict ethical constraints.

Collective Memory of Psychosurgery

From an historical point of view, the term psychosurgery has been heavily stigmatized by lobotomy. The sense of the destructive effects of lobotomy has been persistently sensationalized through films such as “One Flew Over the Cuckoo’s Nest”, and “Frances”. The writer is not confident that the public will be as exhilarated as the medical field about introducing DBS to psychiatry. It is beyond the scope of this study to redraw a family tree of DBS in medicine. The writer attempts to acknowledge history in a few words. Predecessors such as stereotaxis and electrocorticography are notable inventions shared by both psychosurgery and neurosurgery. (4) The progress from lesion techniques to DBS was then delayed by the introduction of medications such as chlorpromazine in the 50s, and L-dopa in the late 60s. In the 90s, the advances in brain imaging led to a resurgence of ablative surgery, which targeted individuals with a refractory neurological or psychiatric disorder. Advocates say that because language use shapes the public’s knowledge and attitudes, stressing DBS’s neurosurgical lineage is less likely to provoke an ethical struggle. (13) However, it is deceptive, and impedes truthfulness, not to acknowledge the full history of psychosurgery in discussions of implementing DBS in psychiatry.

Clearly, there were lessons to be learnt from past psychosurgery. Freeman alone tragically popularized transorbital frontal lobotomy although he was not a neurosurgeon in the late 1940s to early 1950s. (3)
During that time the US health system was deeply burdened by the increased demand to institutionalize the mentally ill. There was no regulator for the procedure of lobotomy. It brought disastrous experiences to thousands of patients. This tragic event was not Freeman’s personal glory or disgrace. Lobotomy’s use indiscriminately for psychiatric complaints was also a systemic failure of health care. As a result performing DBS as an interdisciplinary effort to avoid the errors of lobotomy has been a recurring theme in contemporary literature. The DBS programme at ACH appears to have met this requirement. The existing resource of personnel of the national DBS clinic consists of a neurosurgeon, neurologist, liaison psychiatrist, neuropsychologist and nurse. It should be emphasized that if we were to expand DBS to psychiatry in this country, the end focus for the health system to consider should be, and only be, the benefit of quality of life for patients and their families.

**DBS as a Form of Psychosurgery**

It is debated whether DBS is a form of psychosurgery or better referred to as “neuropsychosurgery”, “neurosurgery for psychiatric disorders”, or “psychiatric neurosurgery”, all of which describe the use of DBS for psychiatric conditions. “Limbic system surgery” for instance, was suggested to replace the term psychosurgery. (13) Sachdev (14) argued that DBS should not be categorized at all as a form of psychosurgery, because tissue damage that occurred in the surgery of DBS is for device implantation not for the purpose of ablation. It is understandable that renaming is a mere exercise to detach the negative connotation, and unload the burden of the sense of destruction associated with the term psychosurgery as mentioned in the above section. (13, 14)

The name does not change the nature of DBS, and may matter least on the operation table. It is significant when it comes to the public and political perception, which influences the actual implementation of DBS. The writer sought guidance in mental health legislation in the hope to clarify the association between DBS and psychosurgery. Disappointingly, the term psychosurgery does not appear in the Mental Health Act 1992 (MHA). Psychosurgery is not equivalent to brain surgery philologically. However, there is Section 61, (15) which gives a special provision relating to brain surgery, and has prescribed a stringent process before subjecting a patient to it. The Law has demanded written consent from the patient, and the Review Tribunal also has to be satisfied with this consent. In addition, two psychiatrists have to give their approval with two
other health professionals’ support. From Section 61, it appears that the legal environment today has made it legitimate to operate on the brain to treat psychiatric conditions. The same section also implies that brain surgery is a procedure of the deliberate destruction of any part of the brain or brain function. (15) It is important to highlight that DBS neither intends to destroy brain tissue nor its function. From this perspective, if the MHA has not disqualified the potential use of DBS in psychiatry, it has failed to define what brain surgery may involve. It is worth asking whether our law is outdated. If an exclusion of DBS was made by the law, psychiatric patients would lose the opportunity to benefit from this treatment. Ethically, it raises another question: “Is our justice system denying access to health care?” The writer draws a conclusion that the MHA is not in accord with new information and applicable techniques in the field of psychosurgery. The MHA does not offer protection for patients who would benefit from DBS. It is not a mere semantic question whether DBS is a form of psychosurgery. How DBS is defined in the MHA is closely associated with how it is translated into practice. Currently, the use of DBS cannot be justified under the intent of the MHA in NZ.

Evaluating DBS from a Perspective of Ethics for Psychiatry

Psychiatry is a branch of medicine recognized for its psychological and social leanings. Particularly, issues around consent, personal responsibility, safety to self and others, competency, legal liability and treatment compulsion are far more relevant in psychiatry than other branches of medicine. This departure from a strict biomedical model indicates that general bioethical principles of nonmaleficence, beneficence, truthfulness and justice, do not suffice when addressing ethical dilemmas in psychiatric practice. Radden (16) has identified that the uniqueness of ethics for psychiatry lies in features of the therapeutic relationship, of the characteristics of the psychiatric patient, and of psychotherapeutic intervention. To perform DBS in psychiatry can have implications on each feature, which warrant careful analysis.

A sound alliance between a psychiatrist and a patient has long been considered to take precedence over all other therapeutic interventions. Although psychiatry has employed varying psychodynamic, cognitive behavioural, family and socio-cultural approaches, the alliance is established fundamentally by mutual understanding and explanation. To the traditional psychodynamic school, a therapeutic relationship is considered as a treatment tool, an analogy to the surgeon’s scalpel. (16) In the contemporary
biopsychosocial model, the relationship remains a vital factor in determining the effectiveness of intervention. For instance, the psychiatric interview functions as the central tool to gather history, monitor symptomology, assess risk and negotiate management plans, as well as an opportunity to establish rapport, elicit and resolve conflicting emotions, conduct a brief intervention of a talking therapy mode, and constitute the basis for purposeful engagement in the future. Inventions of psychoactive drugs and electroconvulsive therapy have challenged the relationship between the treatment provider and the patient. The use of DBS could further dislodge the foundation of the alliance. DBS potentially replaces the unbodied entity of the therapeutic relationship with tangible electrodes, wires and a battery box. It could vastly shift the practice of psychiatry into a biomedical or a surgical domain. If the disease process can be altered by physical manipulation, it proves a biological basis of psychiatry. Some people may argue that this shift favours the destigmatization of mental illness. (17) ‘There are limitations to this view. In psychiatry, it is acknowledged that the degree of confidentiality and boundaries of professionalism and patients’ vulnerability are determined in a context of power, societal stigma and questions of competency. (6) While building alliance inevitably imposes a special burden on the treatment provider, acting as the ‘instrument’ of intervention can be satisfying and though challenging experience. (16) Compared with the personal effort required in a delicate therapeutic engagement, offering DBS and dealing with the mechanics of DBS put less demand on the treatment provider inter- and intra-personally. A change of modality of psychiatric intervention to surgery may bury the essence of psychiatry.

The ethics of psychiatry is also determined by innate characteristics of patients. They are often deprived of their best defences against exploitation due to their reasoning and judgement being the first to suffer in matters concerning their long-term interest, self-care and safety. (16) Some identified difficulties of obtaining informed consent for DBS during MD candidate selection include emotive influence, unrealistic expectation, and underestimation of the level of commitment required of the patient during the procedure and follow-up. (10) Emotional state affects decision-making in all individuals. Achieving an informed consent from someone with an altered mental state can only be more challenging, especially to these vulnerable and desperate individuals suffering a refractory illness. Besides, the chronic nature of the
patient's psychiatric complaint may leave them impaired to such a degree that returning to previous function almost impossible, and stigma and alienation may have made holding psychosocial support taxing. (16) The procedure itself is immensely demanding. DBS at least involves two surgeries. The initial one usually lasts four to six hours, inserts intracerebral electrodes under local anaesthetic with the patient awake. The patient's head is attached to a stereotactic frame for the entire procedure. The subsequent surgery implants the pulse generator and connects up the wiring. The follow up will require each patient to be reviewed at the ACH six-monthly. At the four-year postoperative point the battery state would be checked in detail and the surveillance intensified with planning instituted to replace the batteries when they fail. (1) Without adequate psychosocial support, DBS is at high risk of being unsuccessful. (7) It is crucial to 'be cognizant of the fact that to abandon patients without social support would create additional disparities in the level of care for these patients, further disadvantaging them'. (10) As discussed above (in **DBS in Modern Psychiatry**), there has been no sound methodology to quantify the benefits and risks of this procedure. A considered selection of patients who should be offered DBS is an essential requirement for a successful intervention and a reduction of side-effects from a clinical as well as an ethical perspective.

Last but not least, the treatment objective in psychiatry has long been controversial. No different from other psychiatric interventions, such as psychoactive drugs, DBS should subject to an evaluation for its ethical consequence as a psychotherapeutic project. The debate whether DBS alters the sense of self or rescues the individual who suffers a mental illness is a philosophical one. (18) Clinically, the purpose of intervention may be as modest as to restore previous level of functioning and relieve debilitating signs and symptoms, or as ambitious as to reform the patient's whole self and character when person's long-term depositions, capabilities, and social and relational attributes are considered. The writer is more interested in the interactive nature of subjectivity. (19) In other words, if the sense of self is a reflection of being in the world with others, a reactive change of psychosocial environment is going to follow a changed mood, behaviour and thought. The writer has mentioned that DBS has high rates of cognitive, behavioural and psychiatric complications. It is true that the therapeutic value of psychiatric DBS is inserting positive influences on these parameters. But a so called successful DBS retains an uncertainty of how patients adjust psychologically and socially over the longer-term after surgery. (10) Therefore, a reduction of psychiatric
symptomology has a narrowed meaning in terms of the efficacy of DBS. An additional appraisal of a net benefit on an individual’s psychosocial adaptation is required, which seeks to appreciate the comprehensive effect on quality of life over time. It is an important aspect from an ethical point of view, but so far little is known. Moreover, the writer is fearful of the dangerous attraction of psychiatric DBS as it exacerbates the authentic desire to relieve some of the most malignant conditions known to afflict the human mind, and offers possibilities for gaining knowledge from investigating psychiatric conditions of the brain. (20) A purely scientific motive of curiosity and achievement is not a legitimate guide to the ethical management of patients. Such a dangerous and distorted treatment objective would not be in the patient’s best interest.

To summarize, the writer cannot conclude that DBS is ethically sound for psychiatry without careful and independent ethical review and surveillance. It is apparent that modern science does not justify the use of DBS in psychiatry, the history of lobotomy gives useful lessons, and the MHA does not reflect present knowledge of psychosurgery. Additionally, introducing DBS to psychiatry contests the unique ethics of psychiatry, and potentiates patients’ vulnerability to exploitation. Only preliminary groundwork is done here in an effort to encourage people who have the privilege to produce, assess and disseminate new knowledge to participate in the further discussion of the ethics of DBS use in psychiatry.

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